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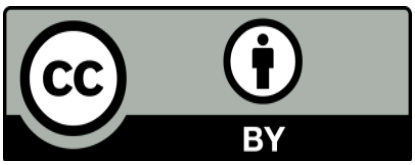

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Acknowledgments

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References

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Al-Kindy College Medical Journal (KCMJ)

Editorial

Xenotransplantation: Fact or Magic

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The knowledge of transferring body organs or tissues appears in ancient mythology of Roman, Greek, Indian, Chinese, and Egyptian civilizations. The stories of organ transplants performed by GODs and health care's using organs from cadaveric and after that transplantation change from lore to medical training (1). One of the obstacles that faced this brunch of medicine is shortage of organs donation and patients still waiting on the waiting list for long time to get the organ from brain death human on car accidents or any other diseases. The best example is kidney transplantation is used for treatment chronic renal failure and there is a limited numbers of organ donations. So, the best solution is xenogenic kidney transplantation that fill the gap of shortage in the graft donation (2). Many trails were done to transplant organs from animals known as xenotransplantation (3). There is an important number of fences to xeno-transplantation in human beings for example immunologic challenges like human leukocytes antigen (HLA) incompatibility that affect the survival rates of the graft (4). HLA is a group of antigens were coded from genes located on the short arm of chromosome number six and these were divided into three Classes (Class I, II, III) and the most important one is class II that coded HLA-DR and DP which is so important in transplantation that need either a fully compatible or limited degree of HLA mismatching with acceptable results in many cases (5). A prodigious deal of development and researches are needed in immunological strategies to make xeno-transplantation a clinical reality and truth. The greatest exciting view nowadays is the use of organs from pigs that used previously with a monkeys' by genetically eliminating the epitope that responsible for hyperacute and acute xenograft rejection and tolerance induction on cellular and chronic xenograft rejection (6). Now adays the newscast of three pig to human transplantation cases has roused public and community interest and attention. Team of surgeons at Alabama Transplant Institute have successfully achieved a pig kidney transplant to human using a genetically modified pig as the donor after several approaches. Two of porcine kidneys were transplanted into a brain-dead recipient after doing gene-editing to pig kidney graft that included species-specific antigen has been removed by genetic engineering by removing the galactose-alpha-1,3-galactose (alpha-gal) epitope by means of alpha-1,3-galactosyltransferase gene knockout (GTKO) with subcapsular autologous thymic tissue (7). Then, preoperative laboratory tests like

crossmatching between donor lymphocytes and patients' serum for detection any preformed antibodies through performing panel reactive antibodies (PRA) and screening for viral infection. The xenotransplantation kidney between pig and human had also some obstacles during surgery or evidence of hyperacute rejection during operation due to antibody mediated rejection. Genetically modified pigs kidney remained viable and functioning in brain-dead human recipients for 54 hours without hyperacute immune rejection (8). Unfortunately, the grafts did not work properly and decompensation of the patient. Even though, this study shed a light on new achievement in this research part and move xenotransplantation to the clinic. So, the use of successful immunosuppressive protocols of drugs like anti-CD154 antibody will be critical to maximize the success in the first trail in human (9). Improvements in this field are needed by recent clinical experimentation, and trails then general dissemination of organ xenotransplantation has begun to appear a possible near-term ambition.

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Review Article

Incorporation of Nurse Practitioners and Physician Assistants into patient care teams – Focus on infectious diseases

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ABSTRACT

There is a global shortage of health care providers needed to address all levels of primary and specialty care. The recent COVID-19 pandemic also highlights the importance and added value of health professionals with specialty training in infectious diseases. In the United States, advanced practice providers (APPs) are being engaged to meet the expanding demand for generalist and specialist patient care. The history and development of advanced practice registered nurses (APRNs) and physician assistants (PAs), are discussed as collaborative healthcare providers to promote better understanding of the ways they can be incorporated into a healthcare system. An example of how APPs are utilized to provide both inpatient and outpatient care of persons with infectious diseases is illustrated at our midwestern United States regional medical center. Especially relevant for regions of the world where both nurses and physicians are in short supply, this paper identifies ways that healthcare leaders can support, develop and strategically utilize APPs to provide critically necessary functions and achieve excellent outcomes. Challenges to future healthcare administration are articulated and compared with World Health Organization roadmap objectives for nursing that can be expanded to better utilize all APPs as valuable healthcare professionals.

Introduction

There is a global shortage of health care providers needed to address all levels of primary and specialty care in an effort to meet the Millennium Development Goals (1). The recent COVID-19 pandemic also highlighted the importance of health professional with subspecialty training in infectious diseases. The American Association of Medical Colleges reported in its sixth annual study entitled "The complexities of Physician Supply and Demand" that by the year 2033 the USA will face a physician shortfall in almost all areas, including primary care, surgical and medical specialties, totaling more than 100,000 providers (2). The World Health Organization (WHO) drafted a roadmap document in 2020 providing up to date evidence on the first "State of the Worlds Nursing Report: Investing in education, jobs and leadership" for consideration as a strategy to achieve Millennium Development goals for universal health care (3). Key elements of this roadmap document were developed using a wealth of data from 191 countries representing all WHO world regions, providing context and examples of: nursing in health priorities, the role of nursing in the 21st century, policy strategies to enable the workforce (4-5). The seventy second World

Health Assembly designated the year 2020 as "The International Year of the Nurse and Midwife" in recognition of their pivotal roles in healthcare and alluded to the capacity of these providers to further expand their roles in modern patient care (6). However, physician and nursing shortages are reported by virtually all countries around the world. Global maps indicating regions with the greatest shortages of physicians and nurses demonstrate almost complete overlap. Therefore, new approaches to growing and sustaining the healthcare workforce are needed (2,7).

A powerful but underutilized strategy to address healthcare provider shortages is the assimilation of physician assistants and advanced practice registered nurse practitioners (collectively referred to as APPs, or Advanced Practice Providers) within a healthcare system. Therefore, the purpose of this paper is threefold: (1) to review definitions and key elements in the history of APP evolution, (2) provide specific examples of how APPs are incorporated into patient care at our midwestern United States regional medical center, highlighting APPs in treatment of persons with infectious diseases, and (3) provide a framework to challenge healthcare administrations globally to better utilize APPs in new iterations of future healthcare delivery infrastructures.

General background and global workforce of APPs

Data in the Global Regulatory Atlas suggest there are at least 144 distinct titles of nurses around the world, ranging from 10 titles in the South-East Asia Region to over 30 in the Region of the Americas and Europe (8). The role of a nurse in one country may be different from the role of a nurse with the same title in another country and ambiguity in titles can contribute to misperceptions of the important skills and academic backgrounds for various APPs (9). In the USA, advanced practice registered nurses (APRNs) have both a bachelors degree as well as a master's or a doctorate degree that reflect specific skill sets and levels of academic achievement (10-14). There are over 270,000 APRNs in the United States alone, practicing in many settings and in multiple functional capacities (15). In mid 2020, it was estimated that the USA contained an estimated 120,000 physician assistants (PA), the largest census of physician assistants among eighteen countries surveyed globally. The country with the next largest PA census was the United Kingdom with 2,000. Only 53% of countries responding to the 2020 WHO survey reported having advanced practice roles for nurses, and fewer still had roles for PAs (16-17).

Assimilation of APPs into mainstream healthcare delivery systems is sometimes complicated by the fact that the regulation of nursing and physician assistant educational tracks is not harmonized broadly around the world. Nonetheless, the United Nations Sustainable Development Agenda for 2030 challenges all to achieve health and wellbeing for all, inclusive and equitable education, gender equality, and promoting sustainable economic growth (18-21). Therefore, our perspective is that WHO and United Nations supported strategies originally developed to solely advance nursing leadership priorities can at the same time support investment in continued medical education, harmonization of credentials and certification, jobs and capacity building throughout the full spectrum of APPs (3).

Physicians in the United States have benefited from working collaboratively with APPs over the last fifty plus years. APP professions exist in an evolving landscape of APP practice change and increasing scope of practice. Key changes in the USA for APPs include prescriptive authority and becoming national health insurance (Medicare) providers in 1998. Multiple studies demonstrate that in primary care as well as specialty care, patient outcomes of individuals cared for by APP are comparable to patient outcomes under the care of physicians and that patients, physicians, and APPs all benefit (22-29). One study, looking at utilization and costs for complex patients in care at a Veterans Affairs setting found that both were lower for patients managed by APPs when compared to their physician colleagues (22). This held true in both an ambulatory setting and inpatient setting for this study cohort. Another large study examined participants receiving care in federally qualified health care settings. This study analyzed five years of data representing approximately thirty million visits in the US to estimate the impact of receiving NP or PA care versus physician delivered care. Of the nine outcomes studied, seven outcomes showed no statistical differences between APP delivered care and physicians. In the remaining two outcomes, both showed that patients treated by APPs received more lifestyle and health related counseling than did those seen by physicians. One large cancer center in Texas described their inclusion of the PA role into the delivery of infectious disease care to cancer patients (23). They first utilized the PA in the inpatient setting subsequently adding additional PAs to expand to the outpatient setting, antimicrobial stewardship and finally to weekend coverage. Results reported an overall increase in departmental productivity, broadened patient care coverage, and ID physician satisfaction

Advanced practice nurses

The role of advanced practice nurses originally evolved in the United States of America at the time of the US Civil War (1861-1865) when nurses were called upon to administer simple anesthesia to soldiers (11). Nurses filled a need which eventually evolved, over many years, into the Certified Nurse Anesthetists practice that is seen today. Midwives, not all of whom are nurses, and clinical nurse specialists emerged and developed discrete practices to help address other patient care needs not fully addressed by the league of physicians available. In a similar way, nurse practitioners, who fulfill clinical roles within primary care and other subspecialties, emerged in response to patients who had little access to care by physicians.

Advanced practice registered nurses (APRN) in the USA are registered nurses educated at master's degree level or other post graduate level training in a specific role and patient population. Types of advanced practice nurses include certified nurse practitioners (CNP), clinical nurse specialists (CNS), certified registered nurse anesthetist (CRNA) and certified nurse-midwife (CNM). CNPs provide independent care and are accountable for health promotion, disease prevention, health education as well as the diagnosis and manage of acute or chronic disease. The settings in which they practice are usually in family practice, pediatrics, internal medicine, geriatrics and women's health. In addition, primary care

and acute care CNPs have distinct certifications and expanded practice environments. The scope of the clinical nurse specialist (CNS) differs slightly in that they are not direct patient care providers, but instead focus on improving nursing practice, healthcare organizations and systems. Certified registered nurse anesthetists (CRNAs) provide the full spectrum of anesthesia care for all levels of acute or chronic disease. Certified nurse-midwifes (CNM) provides primary health care services including gynecologic care, family planning services, pre-and post-partum care, childbirth and newborn care. While each advanced practice nurse education tract is slightly different, they generally require 2-4 years of post-graduate education, a standardized amount of direct patient care practicum hours, and require state licensure as well as nationally recognized board certification.

Seven core competencies have been described for APRNs to clarify the fundamentals of the discipline. These include direct clinical practice, guidance and coaching, consultation, evidence-based practice, leadership, collaboration, and ethical decision making (11). This helps differentiate the work of APRNs as compared to other registered nurses. Core competencies are utilized by nursing schools to complete the academic mission of preparing APRNs. From a patient perspective, APRNs may serve as the primary care provider for a panel of patients or as part of a team that provides acute and chronic disease management. Patients may encounter an APRN at every level of care, demonstrating that APRNs are prepared to provide this type of care based on their education, experience, and training (29,30).

Physician Assistants

The American Association of Physician Assistants (AAPA) defines the role of PA as medical professionals who diagnose illness, develop and manage treatment plans, prescribe medications, and often serve as a patient's principal healthcare provider (30). The AAPA was established in 1968 with its mission statement "to ensure the professional growth, personal excellence, and recognition of physician assistants, and to support their efforts to enable them to improve the quality, accessibility, and cost-effectiveness of patient-centered health care." In 1965 Dr. Eugene Stead founded the first 2-year PA program at Duke University Medical Center and the program curriculum was modeled on the fast-track training of doctors needed during World War II. The National Commission on Certification of Physician Assistants (NCCPA) was established in 1975. The PA profession experienced a very rapid growth and at present there are 123 accredited PA programs who have 47,180 PA graduates.

PAs are versatile and collaborative. PAs practice in every state in the USA and in every medical setting and specialty, improving healthcare access and quality. Presently there are more than 277 highly competitive PA programs in the USA, requiring a bachelor's degree and completion of classroom courses and more than 2,000 hours of clinical rotations over a three-year academic program. A bachelor's degree is required for acceptance into a PA program after which students receive a special master's degree. To obtain a license, PAs must graduate from an accredited PA program, pass a national certification exam. To maintain their certification, PAs must complete 100 hours of CME every two years and take a recertification exam every 10 years.

Some healthcare administrators and physician groups are concerned about the quality of patient care delivered by APPs compared to physicians. However, these theoretical concerns have not proven to be justified in a number of studies directly comparing physician and APP care. Data concluded that there were minimal differences in quality of care and patient satisfaction (23-29). Both groups of healthcare providers improved their performance with measurement and ongoing assessments and guidelines for their respective continuing medical education goals. However as stated earlier, data collected to address this specific question concludes that with proper education, training, and collaboration the outcomes for APPs and physicians are the same. Lastly, a financial advantage for those considering a career in healthcare as an APP, is that there are significantly lower educational expenses (and thus lower potential educational debt) to train as an APP vs as a physician.

Global perspectives

Globally, PAs can practice in Canada, UK, The Netherlands, Liberia, India, Ghana, South Africa, Australia, Saudi Arabia, Germany, New Zealand, Afghanistan, Israel, Bulgaria, Ireland, Kenya. Each country has its own unique training program, certification, prescription rights, and salary. In 2000, all 50 US states authorized PA practice. PAs work in a wide variety of healthcare settings: hospitals (38.3%), 45.5% outpatient/clinics (45%), Urgent Care (6%), University (2.5%) and other settings (7%). PAs in the USA can pursue specialized accreditation in surgical subspecialties, primary care, Internal medicine subspecialties, Emergency Medicine and pediatrics.

In the rapidly aging Japanese society, a program was established in 2014 that enabled nurses to independently operate community-based home care centers (31). In Australia, indigenous people have voiced their desire to increase care from peer indigenous practitioners, at any or all levels (32). In Thailand, the Program of Higher Nursing Education Development was established in 1994 (33). This program focuses on training master and doctoral level nurse educators qualified to teach in Thai nursing programs as well as in various programs across 10 other countries in East and Southeast Asia. Nursing capacity in Africa and the Middle East has been strengthened by incorporating advanced teaching methodologies and curriculum development in such a way to ensure Rwandan ownership and "cultural humility" (34,35).

APPs at the Wisconsin Regional Medical Center, Milwaukee, Wisconsin, USA.

At our regional medical center in Milwaukee, Wisconsin, USA, APPs are utilized in almost all service lines and areas of patient care, including outpatient, inpatient, critical care, operating room, and procedural areas with current numbers approaching 700 total APPs. There is a wide variety of work that is done and with various levels of autonomy and collaboration within this academic medical institution. In this medical center, there is frequent rotation of physicians in the inpatient setting due to outpatient demands, academic requirements for physicians in training, research, and teaching responsibilities. APPs are heavily relied upon for the continuity of care they provide as predictable and regular medical providers. In the outpatient setting, APPs are valuable to improve access to care and decrease wait times for outpatient clinics. Critical care settings have recognized the immense value of staffing APPs 24 hours per day, 7 days per week, in order to improve patient care as

patient populations become more complex and resident trainees work hours become more restricted per educational policies. Many consult services providing specialty care to these complex patients have also recognized the utility of expanding their provider workforce with APPs.

APPs in Infectious Diseases

The need for specialty care of patients with infectious diseases differs greatly around the world. Data in the USA clearly demonstrates the added value of specialists trained in infectious diseases. Metrics for patients hospitalized with serious infectious diseases show that input provided by infection specialists decrease the length of hospital stays and improve outcomes of patients, especially with those suffering from bacteremia and gram-negative sepsis (36-42). The stresses placed on all healthcare institutions by the COVID pandemic underscored the need for specialized training in the treatment or prevention of infectious diseases.

The orchestration of smoothly operating teams of infectious disease specialists is considered essential to quality medical care, patient and student clinical education, prevention of infectious diseases and patient satisfaction. Within the Infectious Diseases subspecialty, our current structure has APPs working in both outpatient and inpatient settings. Figure 1 summarizes how APPS in infectious diseases are strategically utilized at Froedtert and Medical College of Wisconsin Regional Medical Center in Milwaukee, Wisconsin, USA.

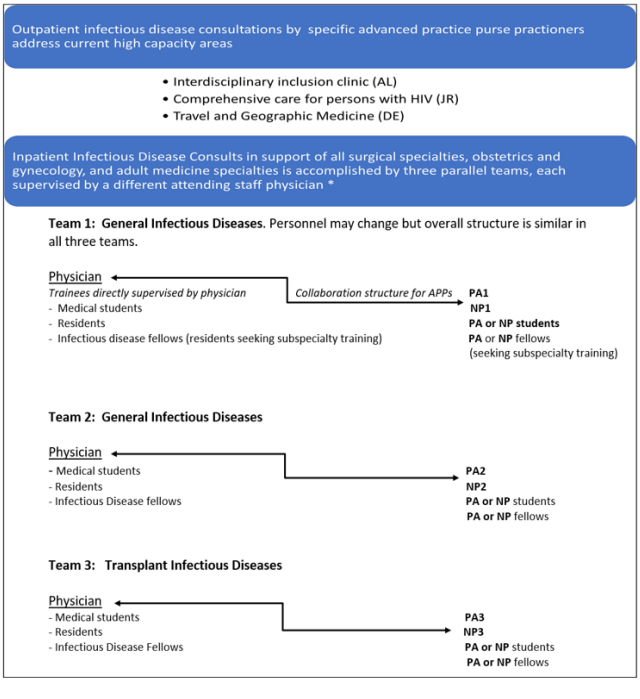

Figure 1. Infectious Disease team and collaboration structure*

* All pediatric infectious disease consoltations are made by separate pediatrics-infectious disease staff.

Inpatient infectious disease teams are comprised of physicians, medical students, resident trainees, infectious disease "fellows" (residents choosing to pursue additional training in infectious diseases), nurse practitioners and physician assistants, and corresponding NP/PA students and fellows. On the inpatient infectious disease consultative team, PAs and NPs work as peers without any functional difference in day-to day responsibilities or tasks despite having different titles and educational training backgrounds. This is the case in most healthcare institutions within the US, as there are more similarities than differences when it comes to utilization of APRNs and PAs.

Conclusion

The complexity of healthcare challenges all leaders and stakeholders to respond through innovative, patient-centered approaches. The theoretical concerns about quality of care provided by APPs vs physicians have not proven to be justified in a number of studies. As the healthcare landscape evolves, the role of multidisciplinary teams including APPs has become vital to sustainable models of care. Appropriate integration of APPs within the clinical culture must come from policy makers and top-level leaders who are able to influence large groups and organizations (Figure 2). Leaders and policy makers must acknowledge both the relevance and the importance of having APPs to contribute to patient care and coordinate care as they have been trained to do (10). Wisur-Hokkanen et al. (2015) found that leaders who were less familiar with the role of APRNs and what they could offer to the healthcare provision process were less likely to support the APRN role (8). Policy makers and other high-level leaders are called to empower APPs through structural, legal and regulatory support, specifically pertaining to licensing and clinical practice. Tailored to specific needs within a clinical practice, available resources and cultural expectations of patients, APPs can play a critically important role in providing excellent health outcomes and continuity of care.

Objective 1
Optimize APP performance structure, quality benchmarks, skill mix, retention incentives and remedy for inefficiencies along with unequal distribution of services to facilitate universal health coverage.

Objective 2
Invest in APP human resources aligned to population health, labor market dynamics, educational policies, provider shortages and unequal distribution of workforce. Use of Incentives to slow workforce migration, continuing education flexibility and retention incentives for underserved communities.

Objective 3
Build capacity of institutions for effective public policy management of APPs as essential members of healthcare workforce. Include APPs in governance structure to maximize roles in patient care.

Objective 4
Improved data collection for human resource management. Inclusion of APP stakeholders in governance. Data collection for monitoring and accountability to include engagement of intersectoral stakeholders (e.g. consumers) along with leaders and APP voices.

Figure 2. Proposed expansion of the WHO nursing roadmap global strategy on human resources for health to include all advanced practice providers (APPs.) Adapted from the WHO Roadmap for Nursing (6).

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Research Article

A Population based Study on Self Medication Practice in Pakistan

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Keywords: Self-medication, over the counter, Antibiotics, urban and rural.

ABSTRACT

***Background*:** The risk of antibiotics resistance (AR) increases due to excessive of antibiotics either by health care provider or by the patients.

***Objective*:** The assessment of the self-medication Practice of over the counter drugs and other prescription drugs and its associated risk factor.

Subjects and Methods: Study design: A descriptive study was conducted from "20th December 2019 to 08th January 2021". A pre validated and structured questionnaire in English and Urdu language was created to avoid language barrier including personal detail, reasons and source and knowledge about over the counter drugs and Antibiotics. Sample of the study was randomly selected. Data was analyzed by software SPSS version 22.

***Results*:** Out of n=3388 respondents, the prevalence of self -medication practice of over the counter (OTC) drugs and antibiotics as self – medication practice in all of the respondents is 88% and 85.9% respectively. Knowledge of the respondents about the use of the antibiotics as well as side effects of antibiotics was 40.7% and 15.3% respectively. Headache, fever, cough and stomach problem were the minor ailments for which majority of OTC drugs and antibiotics used respectively. The commonly used OTC drugs and OPDEA were Paracetamol and Omeprazole. The commonly used antibiotics were Metronidazole, Amoxicillin and Clavulanic acid and Ciprofloxacin.

***Conclusion*:** Government should make policies to train pharmacist in the community for antibiotics stewardship and standard treatment guidelines through educational workshops. Our future study will be on how to minimize antimicrobial resistance in the developing countries.

Introduction

The Self - medication is a taking of medicine (drug), herb or home remedies to treat self-evaluated recurrent symptoms or minor health problems without the prescription or instruction of a physician. The practice of self-medication (PSM) is worldwide challenge. Over the counter drugs are not harmful for minor ailments thus encourage the self - medication practice among people all over the world. The inappropriate use of antibiotics is one of the basic problems of health of public globally [1]. In Pakistan PSM is very common because the community and retail pharmacies provide easy accessibility of drugs to public without prescription. The frequency of self - medication in previous studies in Islamabad and Karachi was 76% and 42% respectively. There was no study on the practice of self - medication in rural population of Chahi Samahni District

Bhimber Azad Kashmir Pakistan previously. The prevalence of PSM depends mainly on the health care system policies and their implementation as well as awareness of public related to drugs indication, side effects and accurate dose. The common determinants of PSM are easy accessibility of drugs from pharmacies, media advertisements, previous experience of treating similar illness and symptoms, socioeconomic status, patient attitude, knowledge and education level, time saving, high fees of consultant, inadequate enforcement of regulatory policies [2]. On contrary, the inappropriate use of these medicines OTC and prescription drugs without seeking medical advice is becoming a very serious problem in developing countries exposes patients to dangers, adverse drug reaction, prolong suffering, drug interaction, morbidity, mortality, and treatment cost. Particularly in developing countries, antimicrobial resistance is an alarming problem worldwide where antibiotics can be obtained without any prescription. The common sources of self - medication are taking suggestion from families, friends, media, the pharmacist and previous prescription.

The aims of this paper are

'The assessment of the PSM of OTC and other Prescription drugs and its associated risk factors, common types of ailments in the society, reasons and causative factors of PSM and aware general public and health regulatory authority to resolve this health problem in students, rural and urban population of Pakistan.

Subjects and Methods

Study design: -

A descriptive cross-sectional study was conducted from "20th December 2019 to 08th January 2021". A pre validated and structured questionnaire in English and Urdu language was created to avoid language barrier. First section was demographics include gender, age, marital status, religion, country, city, occupation, education, family members, socio economic status. Second section focused on the disease, minor ailments, source of information related to medicines, causes and reasons of PSM of drugs. Third section consists of knowledge about the use and side effects of antibiotic. Sample was randomly selected from different universities, pharmaceutical industries as well as rural and urban areas of Pakistan.

Participants and Setting

The total participants were 3388 include 885 Peoples of rural area of Chahi Tehsil Samahni Bhimber Azad Kashmir Pakistan (CSB), 747 Peoples of urban area of Lahore Punjab Pakistan (LPP), 775 students (Pharmacy, Nursing and Doctor of Physiotherapy) University in Province Sindh Pakistan (USP), 620 National and 30 Foreigners Pharm D students of Punjab University Province Punjab Pakistan (PUCP), 208 employees of Pharmaceutical Industry Lahore (PIL) and 101 employees of Homeopathic Industry Lahore (HIL).

Consent to Participate

Universities have permitted the Researcher (KK, AZ, RK) to conduct the research study of PSM in their Institution. Participants were interviewed so taking oral consent before filling the questionnaire needed for the study.

Ethical approval

Ethics committee of University College of Pharmacy, University of the Punjab, Lahore, Pakistan (PUCP) has approved this study on self - medication practice.

Data analysis

Data of this research project was analyzed by the software SPSS version 22. Results were expressed by using descriptive statistics (frequencies and percentages). 30 Incompletely filled questionnaires and 200 pilot study questionnaires were excluded from the study.

Results

Out of n=3388 respondents, the prevalence of PSM of OTC drugs and antibiotics in all of the respondents (in December 2018-January 2020) is 88% and 85.9% respectively. The majority of PSM drugs and antibiotics in Peoples of rural area of CSB were 95% and 93% as compared to Peoples of urban area of LPP were 91.6% and 90.6% respectively. The majority of self - medication practice drugs and antibiotics in employees of Pharmaceutical Industry Lahore (PIL) were 98% and 95.7% as compared to employees of Homeopathic Industry Lahore (HIL) were 91.1% and 84.2% respectively. Whereas the majority of self - medication practice drugs and antibiotics in students (Pharmacy, Nursing and Doctor of Physiotherapy) University in Province Sindh Pakistan (USP)were 91.5% and 87% as compared to National Pharm D students of Punjab University Province Punjab Pakistan (PUCP) were 68.5% and 66%. The PSM of OTC drugs and antibiotics in Foreigners Pharm D students of PUCP were found to be 86.5% and 82.7% respectively (see table 1).

Table 1: Self-medication practice among general population as well as in all study groups

Variables	self - medication practice of over the counter drugs % (N)	self - medication practice of Antibiotics % (N)
General population	88% (2981)	85.9% (2910)
Rural people of CSB	95.7% (818)	93% (795)
Urban people of LPP	91.6% (684)	90.6% (676)
Students of USP	91.5% (709)	87% (674)
National Students of PUCP	68.5% (424)	66% (409)
Employees of PIL	98% (203)	95.7% (199)
Employees of HIL	91% (91)	88% (88)
Foreigner Students of PUCP	86.5% (25)	82.7% (24)

Demographic Detail

Of the total 3388 sample, (n=2193) 64.7% were females and (n=1195) 35.3% were males. There were (n=2573) 75.9% single and (n=815) 24.1% were married. The occupation of the participants were pre- medical students (n=173) 5.1%, arts students (n=601)

17.7%, employees (n=215) 6.3%, house wife (n=385) 11.4%, labors (n=299) 8.8%, Pharmacy students of Pharm D (n=620) 18.31%, DPT students of USP (n=486) 14.3%, Nursing students of USP (n=131) 3.9%, pharm D students of USP (n=158) 4.7%, Pharmaceutical employees (n=208) 6.1%, Homeopathic employees (n= 101) 3% retired (n= 2) 0.1% and others (n=9) 0.3%. The education level of total sample includes illiterate (n=600) 17.7%, Primary School (n=75)2.1%, High School (n=250) 7.3%, Intermediate (n=751) 22.1%, Graduation (n=1630) 48.1%, Master (n=78) 2.3% and PhD (n=4) 0.1%. The relationship between demographics of general population (GP) and self - medication as well as self - medication within the demographics (D) (see table 2). Illiterate were more self - medicated than literates. Females were more self - medicated as compared to males as well as married were more self - medicated as compared to single. House wife and labors were more self - medicated as compared to students in our study.

Table 2: Self-medication practice among general population as well as in all study groups

Demographic	Sample in total %(N)	self - medication practice over the counter and prescription drugs %(N)	self - medication practice of Antibiotics %(N)
Gender Male	35.3% (1195)	89.6% (1071)	86.8% (1038)
Female	64.7% (2193)	88.3% (1938)	85.3% (1872)
Marital status Single	75.9% (2573)	86.9% (2237)	84.1% (2165)
Married	24.1% (815)	94.7% (772)	91.4% (745)
Education Illiterate	17.7% (600)	99.3% (596)	96.1% (577)
Graduate	48.1% (1630)	82.5% (1346)	79.2% (1291)
Age 18-24 years	72.8% (2467)	86.5% (2136)	83.6% (2063)
25-30 years	12% (309)	93% (288)	92% (284)
31-40 years	9% (234)	96% (225)	94% (219)
41-60 years	5.4% (184)	95.1% (175)	93.4% (172)
61-80 years	2% (53)	90% (48)	80% (42)
Occupation House wife	11.3% (385)	98.4% (379)	96.8% (373)
Labors	8.8% (299)	97.6% (292)	94.9% (284)
PUCP students	18.2% (620)	68.3% (424)	66% (408)
Employees	6.3% (215)	91.6% (197)	86.9% (187)

Self - medication practice among urban and rural population

Majority of PSM of antibiotics used in the rural population of CSB for diarrhea (n=499) 56.4% and running nose (n=512) 57.9%, whereas in the urban population of LPP for sore throats (n=297) 39.8% and running nose (n=242) 32.4%. The common reasons for PSM in rural people of CSB was easy accessibility of drugs from pharmacies without prescription (n=404) 45.4% and doctor clinic far from home (n=369) 41.7% whereas in urban people of LPP was friends and family advice (n=213) 28.5% and easy accessibility of drugs from pharmacies without prescription (n=78) 10.4%. The common source of knowledge and information for PSM in rural people of CSB was friends (n=490) 55% whereas in urban people of LPP was advice of family member having similar problem (n=291) 39%. The Knowledge of the respondents of rural people of CSB about the use of antibiotics and side effects of antibiotics were (n=193) 21.8% and (n=107) 12.1% whereas in urban people of LPP were (n=219) 29.3% and (n=128) 17.1% respectively.

Self - medication practice among university students

The common source of knowledge and information for PSM in the students of USP was advice of family member having similar ailment/problem (n=449) 57.9% whereas in the students of PUCP was pharmacist (n=178) 28.7%. The Knowledge in the students of PUMHS about the use and side effects of antibiotics was (n=307) 39.6% and (n=89) 11.5% whereas in the students of PUCP was (n=607) 97.9% and (n=160) 25.8% respectively.

Self - medication practice among employees

The commonly used OTC and other prescription drugs in the employees of PIL were Paracetamol (n=196) 94.2% and Omeprazole (n=90) 43.5% whereas in the employees of HIL were Paracetamol (n=74) 73.3% and homeopathic medicine (n=68) 67.3% respectively.

Self - medication practice among general population

The easy accessibility from community and retail pharmacies and consultation of family member having same symptoms were common reasons for PSM and source of information for self - medication practice respectively. Knowledge of the respondents about the use of the antibiotics as well as side effects of antibiotics was 40.7% and 15.3% respectively.

Table 3: reasons for self-medication practice

Reason	Frequency % (N)	Reason	Frequency % (N)
Old prescriptions	25.2% (855)	Doctor clinic far from home	21.4% (726)
Easy accessibility	26.8 % (909)	High fees of Doctor	16.5% (558)
Save time	27.9% (944)	Doctor busy	10.4% (353)
Take from friends and family member with similar ailment	24.3% (822)	Others	5.9% (199)

Headache, fever, cough and stomach problem were the minor ailments for which majority of OTC and other prescription drugs used respectively. Sore throats, running nose and wounds were the minor ailments for which majority of Antibiotics used respectively. The commonly used OTC and other prescription drugs were Paracetamol and Omeprazole.
The commonly used antibiotics were Metronidazole, Amoxicillin and Clavulanic acid in combination with Ciprofloxacin.

Table 4: OTC drugs and OPDEA commonly used as self-medication

Over the counter Drugs and other prescription drug	Frequency N (%)	Over the counter Drugs and other prescription drug	Frequency N (%)
Paracetamol	2859 (77.5%)	Aspirin	935 (27.6%)
Multivitamin	1317 (38.9%)	Nutrition supplements	812 (24%)
Omeprazole	1233 (36.4%)	Homeopathic medicine	764 (22.6%)
herbal medicine	1158 (34.2%)	Antiemetic	577 (17%)
Ibuprofen	1158 (34.2%)	Synthetic glucocorticoids	492 (14.5%)
Methyl Salicylate	844 (24.9%)	Whitening creams	466 (13.8%)
Antitussive	808 (23.8%)	Antihypertensives	433 (12.8%)

Table 5: Antibiotics used as self medication

Antibiotics	Frequency N (%)	Antibiotics	Frequency N (%)
Metronidazole	2153 (63.5%)	Levofloxacin	617 (18.2%)
Amoxicillin + Clavulanic acid	1580 (46.6%)	Bacitracin + Polymyxin B	580 (17.1%)
Ciprofloxacin	1229 (36.3%)	Penicillin	530 (15.6%)

Discussion

The present study found high prevalence of self-medication of OTC and other prescription drugs in Pakistan. This is the first study of self - medication on the rural people of CSB. This study includes three geographical areas (3 states of Pakistan include Punjab, Sindh and Azad Kashmir). The prevalence of self -medication of OTC and other prescription drugs in our study was found to be 88% which is less than those studies conducted in Saudi Arabia 98.7% [4] Lahore 95% [5], Yemen 93% [6], Eritrea 93.7% [7] and higher then that Germany 27.7% [8], India Rajpur Punjab 80% [9], Turkey 19.1% [10], Cyprus 30.7% [11], Malaysia 80.9% [12], Cameroon 73.8% [13], Nepal 48.2% [14], Iraq 84.8% [15], Peshawar 64.8% [16], Vietnam 83.3% [17]. The commonly used OTC and other prescription drugs are Paracetamol 77.5%, Multivitamin 38.9% and Omeprazole 36.4%.
Majority of OTC and other prescription drugs used for headache (65.8%), fever (58.9%), cough (43.4%) and stomach problem (38.3%)
The prevalence of self - medication of antibiotics was found to be 85.9% which is higher than that in South India 81.6% [19], Kerala 66.2% [20], Iran 42.6% [21]. Majority of PSM of antibiotics were Metronidazole 63.5%, Amoxicillin + Clavulanic acid (46.6%) and Ciprofloxacin (36.3%) in the total sample. PSM of antibiotics used for sore throats (33.6%), running nose (31.7%), diarrhea 29.5% and wounds (20%) in our study.
Majority of antibiotics used in the rural population of CSB for diarrhea (n=499) 56.4% and running nose (n=512) 57.9% cause rising antimicrobial resistance (AMR) rates in Pakistan. Self-medication practice among people was due to misconception of the inappropriate use of antibiotics for runny nose and flu like symptoms of viral infection. In our study we observed that people mostly used broad spectrum antimicrobial agents like Amoxicillin + Clavulanic acid and fluoroquinolone for UTI which may increases risk of AMR of methicillin- resistant Stayphylococcus aureus. The common reasons for self - medication were Old prescriptions 25.2%, easy accessibility of drugs from community and retail pharmacies (27.2%). The most common source of information for self - medication was consult by family member having similar symptoms (38.8%). Knowledge of the respondents about the use and side effects of antibiotics was 40.7% and 15.3% respectively. Most of the respondents were unable to distinguish between OTC drugs and Antibiotics as well as bacterial and viral infections respectively.
Limitations of our study were recall and memory bias and the effect of social norms. Our findings cannot be generalized to the whole of Pakistan but these give common determinant of self – medication practice like reasons, cause, source, commonly used drugs, knowledge of the participants about use and adverse drug reaction and antimicrobial resistance.

Conclusion

In Pakistan, the prevalence of PSM is very high and an emerging challenge to health care providers as well as health regulatory authority. Our study indicates that government authorities should establish legislative framework as well as made changes in the policies and regulations for sale and dispensing of antibiotics. The common behaviors and attitude of the participants for self – medication practice was the incomplete course of antibiotics, low health literacy related to improper use of the antibiotics for supposed symptoms like infection caused by bacteria, adverse effects, dose and duration of therapy and AMR. Government health authority should enforce and implements laws and national guidelines on sale and dispensing of antibiotics strictly and also improves the healthcare infrastructure in rural areas. In rural areas of Pakistan, community pharmacist should provide patient awareness services on the inappropriate use of antibiotics for supposed bacterial symptoms and infections like cold and flu and resistance infections and counseling of the patients about the pros and cons of self - medication. Government should conduct intervention or seminars in the Universities and campaigns in society to aware students as well as the illiterate community to improve general public awareness

about the misuse of antibiotic and risks of antimicrobial resistance. Government should make policies to train pharmacist in the community for antibiotics stewardship and standard treatment guidelines through educational workshops. Our future study will be on how to minimize antimicrobial resistance in the developing countries.

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Author's contributions

KK and AZ are the Project leaders of this research project. They communicated and consulted with other authors RK and FKH of the project. They also collected, compiled, interpreted and analyzed the data of this project. The project was supervised by FKH. The paper was reviewed and approved by FKH.

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Ethics approval and consent to participate

Ethics committee of University College of Pharmacy, University of the Punjab, Lahore, Pakistan has approved this study on self - medication practice. Universities have permitted the Researcher (KK, AZ) to conduct the research study of Self Medication Practice in their Institution. Participants were interviewed so taking oral consent before filling the questionnaire needed for the study. The data was collected after the oral consent of each participant from students of different Universities, rural and urban peoples as well as employees of different Pharmaceuticals.

Competing Interest

No competing interests.

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Research Article

Antimicrobial Activity of Lepidium Sativum against multi-drug resistant and sensitive Pseudomonas aeruginosa: A microbiological study from Khartoum State, Sudan

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ABSTRACT

Background: L. sativum, are traditionally used for the treatment of various diseases and thought to have medicinal value. Isolates from many part of the world is now multidrug resistant. Therefore, there is an urgent need to look for and test an alternative herbal drug.
Objective: The present study aimed to evaluate the antibacterial activity of L. Sativum seed extract against multi drug resistant (MDR) and sensitive Pseudomonas aeruginosa clinical isolates.
Subjects and Methods: An ethanolic and aqueous stock extracts were prepared from L. sativum seed plant then serial dilutions were prepared and the obtained concentrations (50, 25, 12.5 and 6.2 mg/ml) were tested against 30 multidrug-resistant and 35 sensitive clinical isolates of Pseudomonas aeruginosa using wells diffusion method.
Results: It was found that L. sativum seed extracts had antimicrobial activity against MDR and sensitive isolates at different concentrations of 100, 50 and 25 according to the mean ± SD (standard deviation) of the maximum zones of inhibition. The total number of isolates that were sensitive to both extracts were 49/130 (37%) which represented 17/60 (28.3%) MDR and 32/70 (45.7%) sensitive isolates. The aqueous extract exhibited more inhibitory effect than ethanolic extract 43 (66%) vs. 6 (9%) against the examined isolates (n=65).
Conclusion: The study concluded that the L. sativum extracts had an antibacterial activity against the susceptible and MDR isolates which may enable it to be used an alternative treatment for medicinal purposes.

Introduction

Medicinal plants have been widely used in traditional medicine for the intention of health a long time ago for the deterrent and healing of many health-related ailments (1). Medicinal plants are considered the richest bio-resource of drugs for traditional systems of medicine and modern medicines as well as for nutraceuticals, food supplements, folk medicines, pharmaceutical intermediates and chemical entities of synthetic drugs (2-3). According to WHO (World Health Organization) about more than 80% of the world's total population, regularly, depends on traditional medicine and products for its healthcare needs especially in third world countries (4). Rural people adopt traditional treatment due to their proximity to

traditional healers and their firm belief that they know the nature of their diseases and often do not reach primary care centers to receive treatment (5-6-7). Therefore, there is a real need to investigate plants to better understand their properties, safety, and efficiency (8). Therefor. Thus Pharmaceutical companies have spent considerable time and money developing medication from plant extracts. The use of plant extracts and phytochemicals, both have antimicrobial properties, which give a greater significance treatment. In the last years, many studies have been conducted in different countries to prove such efficiency (9).

L. sativum famous as garden cress belongs to the family Brassicaceae (cruciferae). In Sudan it is known as 'Hab Alrashad (10-11-12). It is annual herb grows up to 50 cm height and its seeds contain volatile oils (13). The plant is native to Egypt and South west Asia. It's cultivated in India, North America and parts of Europe (14-15). L. sativum seeds possess varied medicinal properties like aperient, diuretic, expectorant, aphrodisiac, antibacterial, gastrointestinal stimulant, gastro protective, laxative (16-17-18). Cress seed is reported to exhibit anti-rheumatic bronchodilator potential. The paste of L. sativum seed is applied in rheumatic joints to relive the pain and swelling. It is also used for hiccup, diarrhea, dysentery, and disease of the skin caused by impurities of blood. Ethanolic extracts of cress seed were effective in treating inflammatory bowel disease (19).

Multi-drug resistant bacterial strains in hospitals and community consider a serious communal pathological state since the time of the invention of antimicrobial drugs, especially infections caused by Pseudomonas species and Ps. aeruginosa particularly (20). So, this study was undertaken to determine the antimicrobial activity of L. sativum against multi-drug resistant and Sensitive Ps. aeruginosa in Khartoum Sudan since very few studies were published regarding this works in our country.

Subjects and Methods

Plant Material:

The seeds of L. sativum used in this study were collected from the local market in Omdurman, Sudan in February 2021. The authentication or identification of the plant seeds was done by a botanist from the National Center of Research (NCR), Khartoum, Sudan.

Ps. aeruginosa clinical isolates:

The Clinical isolates of Ps. aeruginosa (n=30 MDR) that represented Multi drug resistant to different antibiotics (Gentamycin (10µg), Tobramycin (10µg), Amikacin (30 µg), Meropenem (10 µg), Imipenem (10 µg), Ceftazidime (30 µg), Cefpime (30 µg), Ciprofloxacin (5 µg) and Levofloxacin (5 µg), and sensitive isolates (n=35) that were sensitive to these mentioned antibiotics were included in this study. They were obtained from Fedail hospital during the period from February 2021 to August 2021 from different clinical specimens and from patients with different age and gender. The isolates were purified by sub culturing in sterile Nutrient agar media and incubated at 37 $\overset{o}{C}$ over night.

Preparation of the crude extract:

Ethanolic and aqueous extracts of L. sativum were prepared by using overnight maceration techniques according to the method described by Harbone (21) . A total of 50 ground material were macerated in 500 ml of each solvent (ethanol 70% and sterilized distilled water) for 3 days at room temperature. Occasional shaking for 24 h at room temperature was performed and, the supernatant was decanted. Thereafter, the supernatant was filtered under reduced pressure by rotary evaporation at 40°C. Each residue was weighed and the yields percentage were calculated and then stored at 4°C in tightly sealed glass vial ready for use. The remaining extract which not soluble was successively extracted using ethanol and sterilized distilled water with the described technique. The extract was kept in deep freezer for 48 hours until they were completely dried. The extract was kept and stored at 4 °C until required.

Determination of antimicrobial activity of plant extracts:

At the time of testing, 0.1 gram of ethanolic and aqueous extract L. sativum were measured using electronic balance and dissolved in 1 ml of dimethyl sulphoxide (DMSO 10%) and distal water respectively, to prepare stock solution concentration at 100 mg/mL, then (1:1) serial dilution with distal water was done to obtain concentrations at 50, 25, 12.5 and 6.2 mg/ml. Antibacterial activity was assessed by Agar well diffusion technique. Sterile dry surface Mueller Hinton agar was used to exam antimicrobial activity of L. sativum extract. For each isolate two to three of freshly 24 hours colonies were emulsified in sterile normal saline then they were adjusted to 0.5 McFarland standard turbidity with approximately 1 – 5 x 106 CFU/ml. Cotton swab was immersed in the suspension and inoculated on a plate of Mueller-Hinton agar. The inoculation was eventually distributed all over the plate surface. Then, holes with a diameter of 6 to 8 mm were punched aseptically with a sterile blue tip, and a volume (100 µL) of the extract solution at desired concentration were introduced into the wells with standard automatic pipette. Then the agar plates were incubated aerobically at 37 $\overset{o}{C}$ aerobically for 24 h. The antimicrobial agent diffuses in the agar medium and inhibits the growth of the microbial strain tested; the zone diameter around each well was manually measured by ruler and recorded (22).

Interpretation of results

The formation of clear inhibition zone around the wells of about >8mm diameters were taken as significant susceptibility measurement. The mean value and standard deviation value were used for analysis (23).

Statistical analysis

The collected data with the laboratory results were analyzed by the statistical package of social science (SPSS) soft program version 20, with reference p-value (0.05), P-value $\leq$.05 conceders as significant result. Frequencies and percent obtained in frequency tables, chi-square test for goodness of fit used to test these frequencies. The relations between variables tested using cross tables and chi-square (Fisher exact) test for independence.

Results

The collected clinical isolates (n=65) of Pseudomonas aeruginosa (35 Multi drug resistant MDR and 30 sensitive) had been collected from different clinical specimens, 17 (26%) from urine, 15 (23%) wound swabs, 11 (17%) sputum, 9 (14%) ear swabs, 2(3%)

body fluid, 3 (5%), tissue biopsy, 2(3%) blood culture and 6 (9%) from cerebrospinal fluid (CSF).

The antibacterial activity of ethanolic and aqueous seed extracts of L. sativum were tested against the clinical isolates at different concentrations (100, 50, 25, 12.5 and 6.2 mg/ml). It was found that L. sativum seed extracts have a potential antibacterial activity against the sensitive and M multi drug resistant isolates.

The ethanolic extract against the M multi drug resistant isolates showed maximum zone of inhibition (20 mm) at 100 mg/ml with a Mean±SD 2.4±6.3, followed by (16 mm) at 50mg/ml (Mean±SD 1.3±4.2) in comparison the aqueous extract at the same concentration showed the maximum zone of inhibition (20 mm) with a Mean±SD 5.1±7.5 followed by (15mm) (Mean±SD 4.4±6.4) as shown in Table (1).

Regarding the sensitive clinical isolates the maximum zone of inhibition with a Mean±SD which represented by methanolic extract at 100 and 50 mg/ml were (18 mm) Mean±SD 1.4±4.9, (15mm) Mean±SD 1.1±3.7 respectively while the aqueous extract represented (14 mm) Mean±SD 10.1±3.8, (12mm) Mean±SD 6.1±4.6 respectively at these concentrations as shown in Table (2).

The inhibitory action of each extact (ethanolic and aqueous) against the collective number of isolates (n=65) was calculated as in Table (3)

The frequency of antimicrobial effect of aqueous and ethanolic extract was compared against the Mmulti drug resistant Ps. aeruginosa (n=30) P. value =0.03 and the sensitive isolates (n=35) P. value= 0.7 as expressed in Table (4)

Table 1: Means of inhibition growth diameter of E ethanolic and Aaqueous extract of L. sativum against Mmulti drug resistant Ps. Aaeruginosa.

Ethanolic extract					
Concentration (mg/ml)	100	50	25	12.5	6.2
Minimum	0.00	0.00	0.00	0.00	0.00
Maximum	20.00	16.0	15.00	13.00	0.00
Mean±SD	2.4±6.3	1.3±4.2	0.9±2.3	0.43±2.3	0.00±0.00
Aqueous extract					
Minimum	0.00	0.00	0.00	0.00	0.00
Maximum	20.00	15.00	13.00	8.00	0.00
Mean±SD	5.1±7.5	4.4±6.4	2.4±4.5	0.26±1.46	0.00±0.00

Table 2: Means of inhibition growth diameter of Ethanolic and Aqueous extract of L. sativum against Ssensitive Ps. Aaeruginosa

Ethanolic extract					
Concentration (mg/ml)	100	50	25	12.5	6.2
Minimum	0.00	0.00	0.00	0.00	0.00
Maximum	18.00	15.00	10.00	0.00	0.00
Mean±SD	1.4±4.9	1.1±3.7	0.28±1.6	0.00±.00	0.00±.00
Aqueous extract					
Minimum	0.00	0.00	0.00	0.00	0.00
Maximum	14.00	12.00	11.00	0.00	0.00
Mean±SD	10.1±3.8	6.1±4.6	1.0±3.0	0.00±.00	0.00±.00

Table 3: Antimicrobial effect of L. Sativum against the total number of isolates (n=65)

	Aqueous	**Ethanolic**	**Total**	**P. value**
Sensitive	43 (66%)	6 (9%)	49 (37.7%)	
Resistant	22 (34%)	59 (91%)	81 (62.3%)	0.06
Total	65 (100%)	65 (100%)	130 (100%)	

The formation of clear inhibition zone around the wells of about >8 mm diameters were taken as significant susceptibility measurement (23).

Table 4: Frequency of Aantimicrobial effect of L. Sativum extracts against the Mmulti drug resistant and sensitive Ps. Aaeruginosa

	L. Sativum extracts against the M multi drug resistant Ps. aeruginosa (n=30)			
	Aqueous	**Ethanolic**	**Total**	**P. value**
Sensitive	12 (40%)	5 (17%)	17 (28.3%)	
Resistant	18 (60%)	25 (83%)	43 (71.7%)	0.03
Total	30 (100%)	30 (100%)	60 (100%)	
	L. Sativum extracts against the sensitive Ps. aeruginosa (n=35)			
	Aqueous	Ethanolic	Total	P. value
Sensitive	31 (88%)	1 (3%)	32 (45.7%)	
Resistant	4 (12%)	34 (97%)	38(54.3%)	0.7
Total	35(100%)	35 (100%)	70 (100%)	

Discussion

Antibiotic resistance toward commonly used medicinal drugs could also be a dangerously growing threat to our existence. Plants come with a variety of biomolecules and metabolites that have vital biological functions. In the fight against multidrug-resistant bacteria, these natural chemicals are a gold mine. Green synthesis could lead to the creation of plant-based antimicrobials as an alternative to commonly used pharmaceuticals. L. sativum, is a fast-growing herb found all over the world. The antimicrobial, antioxidant and anti-inflammatory properties of L. sativum seed are intriguing (24).

The Agar well diffusion method was used in this study to assess the antimicrobial activity of ethanolic and aqueous seed extracts of L. sativum against Ps. aeruginosa (MDR and sensitive isolates). According to Omenka and Osuoha (2000) (25), this method allows better diffusion of the extracts into the medium thus enhancing contact with the organisms.

The present study showed that L. sativum seed extracts had a potential antimicrobial activity against MDR and sensitive Ps. aeruginosa clinical isolates at different concentration 100, 50 and 25. Whereas the aqueous extract exhibited more inhibitory effect than ethanolic extract against Ps. aeruginosa (MDR and sensitive isolates) when comparing the mean values that it gave with that of ethanolic extract (Table 1 and 2) also when comparing the inhibited number among the total isolates (n=65), 43 (66%) Vs. 6 (9%) (Table 3). MDR isolates (40% vs. 17%) and sensitive isolates (88% vs. 3%) (Table 4). In contrast other study that carried out by Shama et al. (2011) (13) in Sudan to test the antimicrobial activity of the petroleum ether, methanol and water extracts of L. sativum seed extracts against six opportunistic pathogens including one Ps. aeruginosa. They found the petroleum ether extract in different concentrations (2.5-5-10%) were most active antimicrobials against all the tested microorganisms. Whereas Hero and Jwan, (2012) (23) found ethanolic extract was more inhibitory to Ps. aeruginosa than aqueous extract, other study done by Nafyad Ibrahim and Ameha kebede (2020) (26) in Ethiopia that found methanol extract of L.

sativum showed highest activity as compared to aqueous extract. These variations may be due to differences in geographical area, strains and sample size as these studies were worked on only one ATCC Ps. aeruginosa compared with Pseudomonas strains that in our this study.

All isolates (n= 65) were subjected to aqueous and ethanolic extracts. It was found the total number of isolates that were sensitive to both extracts were 49/130 (37%) as shown in (Table 3) and according to MDR and sensitive isolates, 17/60 (28.3%) and 32/70 (45.7%) were sensitive to both extracts respectively (Table 4). This finding demonstrated the potent effect of L. sativum seed extracts against Ps. aeruginosa clinical isolates used in the present study specially MDR which they were resistant to nine commonly used antibiotics (aminoglycosides, 3rd generation cephalosporine and carbapenem) that may lead this extracts to be an alternative treatment to infectious diseases caused by this organism. Similarly, different many studies were reported antimicrobial activity of L. sativum seed extracts against different microorganisms including Ps. aeruginosa, of these two studies that were done in Sudan by Shama et al. (2011) (13) and, Awdalla et al.(2020) (24) and other study conducted in Iraq by Hero and Jwan, (2012) (23) Therefore, L. sativum seed extract antibacterial activity may be related to their ability to inactivate cell envelope transport proteins, enzymes, microbial adhesions. and may be complex with polysaccharides (27).

Conclusion

The study concluded that L. sativum seed extracts revealed antibacterial activity against Ps. aeruginosa clinical isolated used in this study. Accordingly, the traditional plants may represent a new source of antimicrobials that can establish a scientific base for the use of plants in modern medicine. The ethanol and aqueous seed extracts showed variation in the degree of their efficiency against the studied bacteria; with increased affections of aqueous extract than ethanolic extract which it may reflects the differences in chemical constituents of L. sativum extract or the differences in the examined strains.

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Conflicts of interests

The authors declare that there are no conflicts of interest.

Ethical permission

Approval was taken from the Research Ethical Committee of Al-Neelain University and informed consent was obtained from the mentioned hospital.

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Research Article

Towards a Better Dacryocystorhinostomy, Evaluation of Multimodal Surgical Techniques in Nasolacrimal Duct Obstruction

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ABSTRACT

***Background*:** This study aimed to evaluate the outcome of long-term results of dacryocystorhinostomy (DCR) techniques in specialized eye care center in Iraq.

Subjects and Method: This is a prospective study of 650 patients from July 2014 to July 2019 with nasolacrimal duct obstruction in Ibn Al Haitham Eye Teaching Hospital. A preoperative questionnaire was done, then one month, three months, six months and one year postoperatively. The success of surgery defined as follow; Absence of epiphora completely, Resolve of dacryocele or mucocele or any new attack of daryocystitis, Appearance of fluorescein dye from nose in fluorescein disappearance test, Successful irrigation of nasolacrimal duct which is proofed endoscopically. The three types of surgery (External, Endoscopic and Transcanalicular Laser DCR) were discussed to the patient then preferred one is chosen. The results and complication were recorded.

Results: A total of 650 patients were included in this study, all were operated by same surgeon. The mean age of patients for external, endoscopic and Transcanalicular laser DCR (T-DCR) were 57, 44 and 51 years old respectively. The female patients were more than the male patients in all types of DCR surgeries and they represent 73.84% of total patients of external DCR (ext-DCR), 78.28% in endoscopic DCR (endo-DCR) and 55.15% in TCL-DCR. A satisfied patient to outcome according to surgery type was 91.20% with ext-DCR, 88.70% with endo-DCR and 51% with TCL-DCR.

Conclusion: The most satisfied techniques to patients with higher success rate are the ext-DCR and endo-DCR while the TCL-DCR is still evolving with limit indications and lower success rate.

Introduction

Obstruction of NLD is the cause of epiphora. This disorder of tear drainage is of three types; (1)

Anatomical obstruction; congenital or acquired disorders may occur at any part along the duct starting from the punctum till the valve of Hasner. The congenital cause is usually a membranous obstruction at valve of Hasner while the acquired cause is infectious, inflammatory, neoplastic, traumatic or mechanical.

Functional cause (lacrimal pump failure) during blinking, the contraction of deep heads of pretarsal and preseptal orbicularis oculi muscle lead to suction effect that draws the tear to the lacrimal apparatus e.g. facial palsy.

Secondary epiphora; caused by tear film instability and/or ocular surface disease e.g. dry eye, corneal irritation, conjunctivitis, etc. Antiglaucoma and chemotherapeutics also considered as a cause for secondary epiphora.

DCR is surgery of choice that resolves nasolacrimal duct (NLD) obstruction. Many methods reported, but the ext-DCR still the gold standard surgery. This type of surgery was introduced by Addeo Toti in 1904 who made access to lacrimal sac through the skin (2). In 1920 Dupuy-Dutemps and Bourguet made the basis of the modern technique by suturing the anterior and posterior flaps which is performed till nowadays. (3)

The second most common approach for surgery is the endoscopic type. Its principles were introduced by Caldwell in 1893 prior to external approach but its popularity and success grow only in recent time when the revolution of endoscopic surgery appeared. (4)

Mc Donogh and Meiring did their first study on endoscopic DCR on 1989 after that many surgeons upgrade their skills in that way (5). Many reasons encourage the endonasal approach; mainly:No skin scar of that with ext-DCR,No canthal region damage and cosmetic complication.

Very easy approach to abort nasal deviation and NLD obstruction in one step combined surgery,

Preserve pump mechanism that may impaired in external approach due to injury to orbicularis muscle,less bleeding,the success rate is near or equal to ext-DCR,useful with revision surgery.

The evolution of intranasal approach of DCR surgery started after 1980 when FESS surgery (functional endoscopic sinus surgery) developed in association with invention of new and advanced instruments. Massaro et al is the first who state the use of laser in lacrimal surgery (6) and after that different laser DCR surgeries were shared leading to the lastly and most commonly applied, the diode laser TC-DCR, by Eloy et al at 2000 due to the fact that the diode laser has a little collateral effect on surrounding tissue and its good osteotomy effect on nasal bone. (7).

Subjects and Methods

This is prospective cross-sectional comparative study of 650 patients who did DCR surgery with either ext-DCR, endo-DCR or TCL-DCR in Ibn Al Haitham Teaching Eye Hospital, Baghdad, Iraq for the period from July 2013 to July 2019.

The complain of all patients was epiphora. Other manifestation of acute or chronic dacryocystitis were recorded such as swelling, tenderness and redness over the sac region and almost all patient had hard stop of cannula (the cannula reach the medial sac wall namely the nasal bone) during syringing test.

Nasal assessment by portable nasal endoscope in order to design the type of surgery, if no significant nasal deviation, no polyp, no turbinate hypertrophy that interfere with endoscopic or laser work then either endo or TCL-DCR decided, otherwise ext-DCR were performed. Only one case had severed nasal deviation and refused ext-DCR because of nasal scar so she referred to otolaryngologist and combined septoplasty with DCR done and excluded from this study. All cases with abnormal mass or swelling unrelated to lacrimal system or any case with bloody discharge were send first for further checking by CT scan, consultation of maxillofacial or otolaryngologist. Anesthesiologist consultation for fitness to general or local anesthesia. Laboratory investigation including CBC, blood sugar, urea and serum creatinine in addition to bleeding and clotting time. In general, patients below 50 years old were preferred for GA, older patients preferred for LA with intravenous sedation.

All cases were had epiphora for more than 6 months and they did syringing with hard stop to exclude upper NLD obstruction (positive to the sac), reflux of saline from upper and/or lower punctum indicate distal obstruction. If the cannula was " positive to the sac " then the saline reach the nasal cavity " positive to the nose " then the NLD is intact or partially obstructed. here lacrimal pump failure should be excluded.

Dye disappearance test done and compare it to the other eye and by injecting saline to wash the sac we can differentiate between anatomic and functional obstruction.

Decision for the type of DCR taken by the surgeon after discussion with the patient regarding the success rate, possible complications, cosmetic scar and rehabilitation. Informed consent signed by the patient and all cases in this study were operated by one surgeon.

Nasal pack soaked in nasal decongestant and LA (XylometazolineR 0.1%) and adrenaline 1/100000 was inserted 15-20 minutes preoperatively for all patients.

External DCR (ext-DCR)

This is the gold standard type of DCR surgery suitable when other types failed or unreliable and when there is moderate to severe nasal deviation, traumatic or infectious dacryocystitis when the normal anatomy were changed, here the relative wide field of exposure of duct and its related structures.

Exclusion criteria for this type in this study were:

Patients on anticoagulant e.g. uremic patients on continuous wash, history of heart valve surgery, Patients who failed to get fitness for anesthesia, and functional secondary epiphora.

Surgical technique

Nasal packing soaked with xylometazoline 0.1% and adrenaline 1/200000 inserted to the nose trite of obstructed side (previously marked with surgical marker) for about 15 minute and removed prior to surgery.

Longitudinal or curvilinear incision of 10-15 mm length along the lacrimal crest region and 4mm from the medial can thus avoiding the angular vein (10mm from the medial canthus) then by curved forceps dissection of orbicularis muscle fibers till reaching the lacrimal bone, medial canthal ligament exposure is a landmark behind it lie the fundus of the sac. By Freer elevator, sac separation and exposure of lacrimal sac fossa then periosteum is separated from the anterior lacrimal crest posteriorly to the fossa. Ostium is created by piercing the thin bone of the post lacrimal fossa by Freer elevator then punching the bone by Rongeur Kerrison punch till the size of the ostium reach the size of fingertip, nasal mucosa now is exposed. Inflation of the sac by viscoat ophthalmic solution or BSS then H shaped incision done to create anterior and posterior flaps. Nasal mucosa is injected with 1/200000 adrenalin with xylocaine from the site of ostium in order to separate it from the underlining bone and to decrease the bleeding during anterior and posterior mucosal flap

creation. After the suturing the posterior flaps (mucosal and sac) together by 6/0 vecryl suture, Crowford stent is inserted from the punctum to the nasal cavity through the sac then suturing the anterior sac flap to the anterior mucosal flap by 6/0 vecryl suture. Suturing the orbicularis muscle fiber then the skin. From nostril, nine knots tying of Crowford stent done with the 1st two knots deeply situated to prevent postoperative stent extrusion, merocel nasal packing that removed on second postoperative day. Ceftriaxone vial bid was given at day of surgery then oral ciprofloxacin or co-amoxiclav tablets with acetaminophen 500mg tablets bid for seven days later. Nasal pack removed carefully on second day then daily nasal wash by nasal steroidal and sodium chloride spray for one week for the former and two weeks for the second, ofloxacine 0.3% eye drops qid for 7-10 day.

Follow up the patient in the 1st week, 1st month and in the 2nd month during which maintenance of ostium patency achieved by removing any crust endoscopically or by syringing. After 3-6 months the Crowford stent is removed by endoscopy.

Endoscopic DCR (endo-DCR)

Patients with chronic dacryocystitis or epiphora caused by lower NLD obstruction are candidate for this type of surgery. Patients who are unfit for endoscopic DCR are those with canalicular stenosis, secondary functional epiphora, children below 5 years old, sever nasal deviation or nasal pathology like polyps, active granuloma or malignancy.

All patients assessed for fitness for GA, although LA done for those who are old age or young but not tolerate GA due to respiratory difficulties, high risk for aspiration pneumonia or uncontrolled bleeding (limited cases).

Surgical technique: Under GA, with anti-Trendelenburg position, the patient's head is elevated higher than the feet by 15 -30o in supine position and head tilted posteriorly towards the surgeon head. Nasal pack soaked with 1/200000 adrenaline and xylometazoline hydrochloride is applied for about 15 minutes prior to surgery. With 4mm 0o rigid endoscope, maxillary line and middle turbinate were identified, injection of operative site of mucosa with 1/100000 adrenaline using dental syringe to achieve decongested area.

Mucosal flap creation by making incision starting 8 mm above the axilla of middle turbinate then extend it anteriorly 10 mm on the maxillary line making the flap just above the inferior turbinate. The incision extends superiorly to the agar nasi cells of ethmoid and inferiorly to the maxillary line avoiding the highly vascularized inferior turbinate border. Flap elevation with sharp Freer's elevator and bone exposure which punched by Kerrison punch starting from inferior and ascending superiorly till removing the frontal process of maxilla and expose the lacrimal sac behind. Probing the sac through the punctum and trying to tent it medially through the ostium to confirm the anatomy, incise the layers of lacrimal sac by sickle knife then evacuate and aspirate the sac contents of pus. Anterior and posterior flaps created; the latter is removed by sharp blacksely forceps. Crowford stent is intubated through the upper and lower puncta and tight it from the nasal cavity 3-4 mm below the level of the ostium. Merocil pack inserted into the nose.

Postoperative care of oral antibiotic (Augmentin) 625mg tid or ciprofloxacin 500mg bid prescribed, nasal pack is removed on second postoperative day with prescription of steroidal nasal spray for one week and saline nasal spray for two weeks. Stent removal usually after 6-12.

Transcanalicular Laser Assisted dacryocystorhinostomy (TCL-DCR)

This is a minimally invasive DCR technique that gains popularity with progressing outcome. In this incision free technique with less bleeding and shorter operating time, a diode laser ARC fox machine with wavelength of 810nm and CW mode of action and 400nm or 600nm fiber optic. The procedure performed under local anesthesia (LA) by injecting of xylocaine 2% with adrenaline 1/100000 given by 5ml syringe, G27 needle to the infraorbital foramen and lacrimal sac area to block the infraorbital and infratrochlear nerve respectively. External branch of anterior ethmoidal nerve block done by injecting the LA deeply to the side of nose to avoid swelling that obstruct the view to punctum, Figure 1.

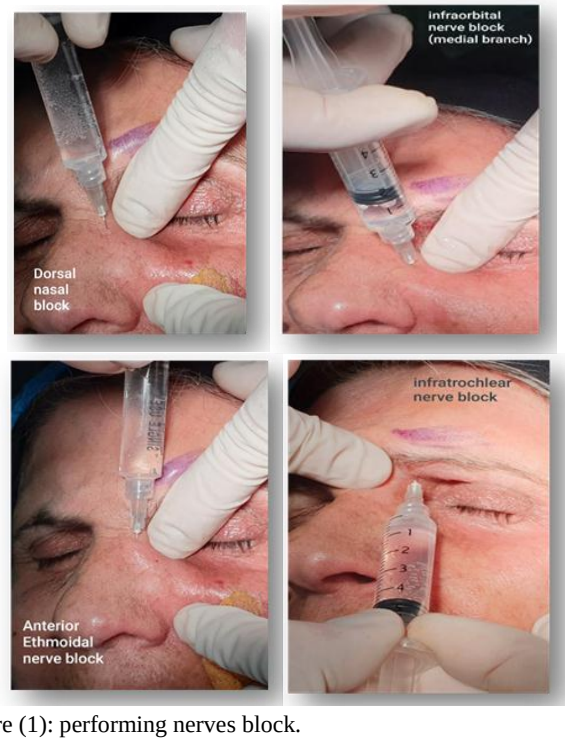


Figure (1): performing nerves block.

Nasal pack soaked with adrenaline 1/1000 and xylometazolin nasal spray inserted to the nasal cavity for 10 minute after xylocaine 10% nasal spray application. Nasal submucosal infiltration with xylocaine 2% and adrenaline 1/100000 is applied to the area anterior to maxillary line and to area of the middle turbinate to insure surgical dry field, Figure 2.

Figure (2): Otrivian nasal spray and adrenalin nasal pack.

Punctal dilatation and probing using Nettle ship dilator and Bowman's probe respectively then prepare the ARC fox laser machine probe by inserting the fiber optic inside and exposing it for 5-10mm to enhance its control inside the NLD and prevent canalicular break if it is too long exposed, Figure 3.

Figure (3): Punctal dilatation and probing

After removing the nasal pack, a rigid nasal (4mm*75mm-0o angle) endoscope is inserted through nasal cavity to identify the laser aiming beam transmucosal through the lacrimal bone. The laser parameters setting according to bone thickness and osteotomy response ranging between 8-12 Watt. Direct the laser probe downward through the NLD preventing the Sump syndrome which is a cause of surgery failure.

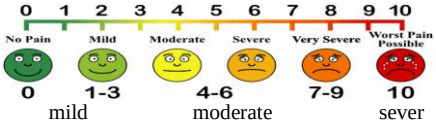
Anterior to the middle turbinate and in front of the maxillary line by 8-10 mm the osteotomy is performed under direct viewing of laser shots by endoscope. Crowford stent is inserted through upper and lower puncti and tied by 7-9 knots preferably up and just below the lacrimal sac to avoid tube dislodgement and not stick on sac to avoid ostium closure by the knot.

Postoperative care and medication in form of topical eye drops of antibiotics such as quinolone group (oflox 0.3%) qid for two weeks and steroid (dexamethasone) qid for 10 days. Steroidal nasal spray (Nasonex 50 microgram) started in the 2nd postoperative day and (after removal of merocil nasal pack) twice daily for 10 days. Nasal wash with physiologic isotonic saline applied for 2-3 weeks. Systemic antibiotic (amoxicillin/clavulanic acid 625mg, tid) for 7-10 days.

Inclusion criteria for TCL-DCR in this study were:
Nasal syringing with 'positive to the sac' result.
No significant nasal cavity pathologies such as sever septal deviation or pathological cavity obstruction.
Chronic epiphora in patient unsuitable for GA.
While exclusion criteria for this type of surgery in this study were:
Upper NLD obstruction proximal to the sac.
Significant obstructive nasal pathology such as sever septal deviation, polyp or tumor.
Significant eye lid pathology medial canthal cicatricial scar, ectropion or entropion.
Age below 4 years
Chronic dacryocystitis with lacrimal sac mucocele and mucopurulent discharge.

A set of printed questions with a choice of answers, devised for this study in order to assess the patients and chose the proper type of DCR surgery and for follow up them and determine the success rate of operation. The questionnaire includes the patients name, age, gender, occupation, Chief complaint and duration (Epiphora, Sticky eye, Dacryocystitis, Trauma, Previous NLD surgery, Side of pathology (right or left), table 1.

Table (1): Assessment tools and questions

Preoperative			
Lid exam	Laxity	ectropion	entropion blepharitis
Sac palpation	Not palpable	palpable	Tears reflux Pain, tender
Fluorescein dye test	Present after 10min		Disappear
Jones dye test I	+ve		-ve
Jones dye test II	+ve		-ve
Syringing test	Saline in nose		reflux
Probing test			
Rhinoscopy			
CT/MRI			
Operative			
Anasthesia	LA		GA
Type of DCR	Ext-DCR	Endo-DCR	TCL-DCR
Duration	<30min	30-60min	>60min
Post-operative Pain	0 2 4 6 8 10		
			
edema	mild	moderate	sever
complication			
Follow up			
1st week			
1st month			
3rd month			
6th month			
1 year			
Stent removal	< 3months	3-6 months	>6 months
Patient satisfaction	Not satisfied	Accept	Satisfied
Success surgery	Succeed	failed	

For all patients in the 1st post-operative day, pain assessment using Wong-Baker faces was applied.

Results

In this retrospective study, three types of DCR surgery were evaluated with a total number of 650 patients included (192 males and 458 females) from the period of July 2014 to July 2019 in Ibn Al Haitham Eye Teaching Hospital.

The Statistical Analysis System- SAS (2012) program was used to detect the effect of difference factors in study parameters. Chi-square test was used to significant compare between percentage. Least significant difference –LSD test (Analysis of Variation-ANOVA) was used to significant compare between means in this study.

A 235 (36%) of patients were operated with ext-DCR, 221 (34%) operated with endo-DCR and 194 (30%) with TCL-DCR, figure 4.

The female patients represent 75.7% of total patients of ext-DCR (n =178), 78.3% in endo-DCR (n = 173) and 55.2% in TCL-DCR (n =107); table 2.

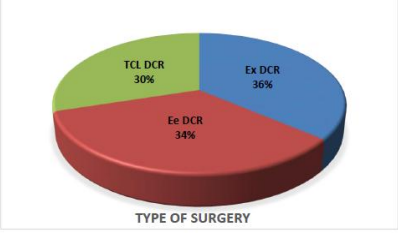


Figure (4) percentage of each DCR type

Table 2: Distribution of sample study according to sex

Type	Sex	No (%)	P-value
Ext-DCR	Male	57 (24.26%)	
(No= 235)	Female	178 (73.84%)	0.0001 **
Endo-DCR	Male	48 (21.72%)	
(No= 221)	Female	173 (78.28%)	0.0001 **
TC- DCR	Male	87 (44.85%)	
(No = 94)	Female	107 (55.15%)	0.0427 *

* (P<0.05), ** (P<0.01).

Mean age of patients for external, endoscopic and TCL-DCR were 57, 44 and 51 years old respectively, table 3.

Table 3: Mean and SE of age of patients according to type

Type	No	Mean ± SE of age (year)
Ext-DCR	235	57.00 ± 2.88 a
Endo-DCR	221	44.00 ± 1.74 b
TCL-DCR	194	51.00 ± 2.63 a
LSD value	---	5.042 **
P-value	---	0.0001

Means having with the different letters in same column differed significantly, ** (P<0.01).

Satisfied patients to outcome according to surgery type were 91.20% with ext-DCR, 88.70% with endo-DCR and 51% with T-DCR, table 4.

Table 4: Distribution of sample study according to outcome (satisfied patients)

Type	No	Percentage (%)
Ext- DCR	235	91.20
Endo-DCR	221	88.70
TCL-DCR	194	51.00
Chi-Square(χ2)	---	9.027 **
P-value	---	0.0001

** (P<0.01).

Discussion

In this study, the higher success rate is with the ext-DCR (91.2%). This result is comparable to previous studies namely; Cokkeser Y (89.8 %), Tarbet KJ (92%), Mekonnen W (93%) and Hartikainen J (91%) (8) (9) (10) (11) while Ozer S. study show higher rate (96%). (12)

A nearly similar result (88.7%) is achieved with endo-DCR and is also comparable to results achieved by previous studies; Cokkeser Y (88.2%), Hartikainen J (75%) and Plaza study (88%) (8) (9) (13), while Ozer S. study still show significant higher success rate (100%) (12).

Although endo-DCR show a little lower success rate than ext-DCR, it shows superior outcome related to cosmetic convenient, less bleeding and shorter operative time.

The success rate of TCL-DCR is (51%), compared to Koch KR study that state 78% success rate, Wali U who state 60.8% and Balikoglu-Yilmaz M (73.3%). (14-16)

The low success rate belongs to the TCL-DCR relative to the previous two procedures is attributed to the small ostium that may closed within months later, but still with this type of DCR getting the advantages of performing the surgery under local and regional anesthesia mainly in young patients and in olds who cannot tolerate the general anesthesia, add to that the fast healing rate, the perfect cosmetic result, less bleeding and the ease of procedure in presence of good facilities. We advise this procedure primarily for old patients who have the risk of general anesthesia and who doesn't have the signs of chronicity.

For those with chronic dacryocystitis; long history of epiphora, recurrent ocular infection and puffy lump near medial canthus who may not benefit from TCL-DCR and need bigger ostium, Endo-DCR or Ext-DCR are advisable.

Conclusion

The most satisfied techniques to patients with higher success rate are the ext-DCR and endo-DCR while the TCL-DCR is still evolving with limit indications and lower success rate.

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Conflict of Interest

No conflict of interest

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Research Article

A comparison of cross sections for Selenium -73 radioisotopes produced by accelerators and reactors

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ABSTRACT

***Background*:** Selenium-73 with half- life of 7.15 hour emits β^+ in nature and has six stable isotopes which are (^{74}Se,^{76}Se,^{77}Se,^{78}Se,^{80}Se and ^{82}Se). Selenium-73 has many applications in technology and radioselenium compounds of metallic have found various applications in medicine.

Objective: To make a comparison between different reactions that produced cross sections of Se-73 radioisotopes.

Subjects and methods: The feasibility of the production of Selenium -73 via various nuclear reactions was investigated. Excitation functions of ^{73}Se production by the reactions of ^{75}As (p,3n), ^{169}Tm(d,x), ^{74}Se, ^{nat}Se, ^{nat}Br (p,x) , ^{75}As (d,4n), ^{nat}Ge (^{3}He,x), ^{70}Ge (α, n), and ^{72}Ge (α, 3n) and neutron capture were calculated using the available data in the international libraries in accordance with SRIM code . Theoretical calculations of the thick target integral yields were deduced using the calculated cross sections by using Matlab program

Results: When proton induced reaction on ^{75}As, ^{74}Se, ^{nat}Se and ^{nat}Br to obtain ^{73}Se, the reaction ^{75}As(p,3n) with range of energy (22.5 to 45.5 MeV) and the maximum cross section is 315 mb at 36.5 MeV gives maximum yield ($2*10^6$ GBq/C).while for the reaction ^{75}As (d,4n) ^{73}Se with range of energy (25 to 56 MeV) , and maximum cross sections is 30 mb at 43MeV gives ($0.085*10^6$ GBq/C).

The three reactions ^{nat}Ge (^{3}He,x) , ^{70}Ge (α,n) and ^{72}Ge (α,3n) show that the best reaction to obtain ^{73}Se is ^{72}Ge (α,3n) within the range of energy (27 to 46 MeV) and maximum cross sections 494 mb at 42MeV give the maximum yield ($0.03*10^6$ GBq/C).

Conclusion: the use of proton as projectile is best compared with other particles in order to get maximum isotopes production yield of 73Se.

Introduction

Radioisotopes that related to radionuclide are medically uses in diagnoses or therapy, depending on their decay properties. Selenium 73 (half-life of 7.15 hour) and emits β^+ In nature, selenium has six stable isotopes, which are ^{74}Se (0.89 %), ^{76}Se (9.36 %), ^{77}Se(7.63 %), ^{78}Se(23.78 %), ^{80}Se(49.61 %) and ^{82}Se (8.73 %). Selenium has many applications in technology, because it has unique properties. The selenium is known to be major in physiology, selenium and the compounds of selenium are highly toxic in doses more than

concentrations of tracer. The radio selenium compounds of metallic have found various applications in medicine, i.e. studies PET by using radio selected (1). The radioactive nuclide ^{73}Se is very advantageous substitute for Sulphur in PET diagnostics and may replace the most established isotope ^{75}Se ($T_{1/2}$ = 120 day), due to it without gravity shorter half-life of 7.1 hour (2).

$$^{73}_{34}Se + {}^{0}_{-1}e \rightarrow {}^{73}_{33}As \quad \ldots\ldots\ldots (1)$$

Accelerators are produced radioisotopes by bombarded targets with beams of charged particles to obtain the required isotope (3). In this study, protons and deuterons are taken to induce nuclear reactions on thulium while alpha particles induced nuclear reactions on natural Erbium; theoretical excitation functions of Ytterbium 169 productions were calculated using different energies of charged particles. Production Yields were calculated theoretically by using SRIM code (Stopping Range of Ions in Matter) (4) for determining the suggested possible optimum reaction in Selenium 73 production.

Method

Nuclear data plays an important role in choosing of the radioisotopes for the medical purposes. In terms of the main criteria for selecting the appropriate decay of radionuclides for use in diagnosis and treatment (5), nuclear decay and structure data determine the appropriateness of radioactive isotopes in medical diagnosis, while nuclear reaction data study the extent to which the radioisotope can be optimally produced. (6).

The possibility of producing selenium-73 was verified through various nuclear reactions. Excitation functions of ^{73}Se production by the reactions of ^{75}As (p,3n), ^{169}Tm(d,x), ^{74}Se, ^{nat}Se, ^{nat}Br (p,x) , ^{75}As (d,4n), ^{nat}Ge (^{3}He,x), ^{70}Ge (α, n), and ^{72}Ge (α, 3n) were calculated using international data available in various libraries. By using the SRIM code (4), the thick target integrated yields were inferred using the calculated evaluated cross sections. The MATLAB programs (7.8 2009a) were calculated from the following equation (2) (7):

$$Y = \frac{N_L H}{M} I(1 - e^{-\lambda t}) \int_{E1}^{E2} \left(\frac{dE}{d(\rho x)}\right)^{-1} \sigma(E) dE \quad \ldots (2)$$

where Y is the activity (in Bq) of the product, H is the enrichment (or isotopic abundance) of the target nuclide, N_L is the Avogadro number, M is the mass number of the target element, I is the projectile current, σ(E) is the cross section at energy E, dE/d(ρx) is the stopping power, t the time of irradiation, λ is the decay constant. The integration limits give the energy range of the projectile effective in the target, and the yield is valid for that range of energy. The calculated yield value represents the maximum yield which can be expected from a given nuclear process. Such calculations are often done in radionuclide development programs. The assumptions made include: specific energy range, with irradiation time of 1 h, and beam current of 1 μA. Thus, the calculated yield is given in the units MBq/μA·h (7).

The production yield of isotopes using reactors can be calculated taking into account the radiation period and reactor flux using the equation (3)(8).

$$S = \frac{0.6\sigma\varphi}{A} I(1 - e^{-\lambda t}) \quad \ldots\ldots \quad (3)$$

σ: is the neutron activation cross-section leading to the production of radioisotope of interest in barn, φ: the flux in n/cm^2/s.

t: time of irradiation, λ: decay constant.

A: atomic weight of target element.

We first calculate the average value of nuclear cross section for the different libraries data by applied the following weighted mean formula (9).

$$W = \frac{\sum \omega_i y_i}{\sum \omega_i} \quad \ldots\ldots\ldots (4)$$

Where: $\omega_i = 1/\sigma_i^2$

σ_i= standard deviation of sample i , y_i=cross section value of sample i..

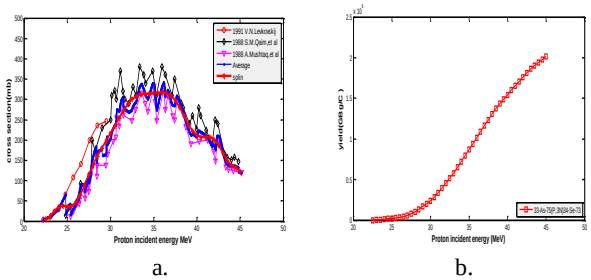
Results

A- Cyclotron production of ^{73}Se

1 -Production by protons incident

a. ^{75}As (p,3n) ^{73}Se reaction:

The excitation functions of the proton induced reaction on ^{75}As and the weighted average cross sections of all values were calculated using the relations (4) for several authors V. Levkovskij (10), S. M. Qaim, et al (11), and A. Mushtaq et al (12), in the energy range from 22.5 to 45 MeV. As shown in Fig. 1.a., the production yield of *^{73}Se* is determined by equation (2), and the stopping power values that calculated by using SRIM code (4), were shown in Fig. 1.b



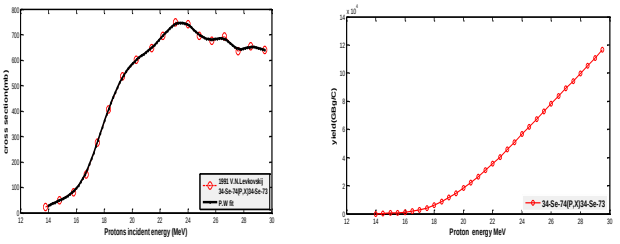
a. b.

Figure 1: a. Average cross sections of the reaction ^{75}As (p,3n) ^{73}Se. b. Isotopes production yield for the reaction ^{75}As (p,3n) ^{73}Se

b. 74Se, natSe, natBr (p,x) 73Se reactions

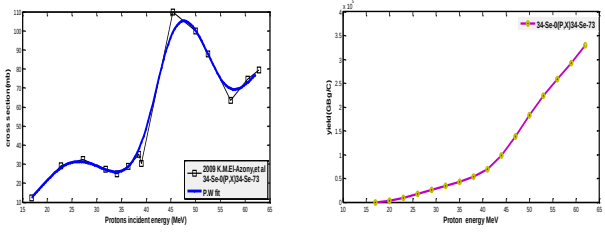
The production yield for proton induced reaction on ^{75}Se, ^{nat}Se, ^{nat}Br were determined by equation (2) and the calculated stopping power values by using SRIM code (4). Fig.2. ,fig.3. and fig.4. The evaluation of the results of the calculations showed that the ^{74}Se(p,x) ^{73}Se reaction with range of energy (14 to 29) MeV according to Levkovskij (10), the ^{nat}Se(p,x) ^{73}Se reaction with range of energy from (17 to 62) MeV according to K.M.El-Azony,et al (13), and the ^{nat}Br(p,x) ^{73}Se reaction with range of energy from (45 to 100) MeV according to M.Fassbender,et al (14).

The excitation functions for all results of the proton induced interactions Fig.5.a. Leading to the production yield of Selenium - 73 have been displayed in Fig.5.b.



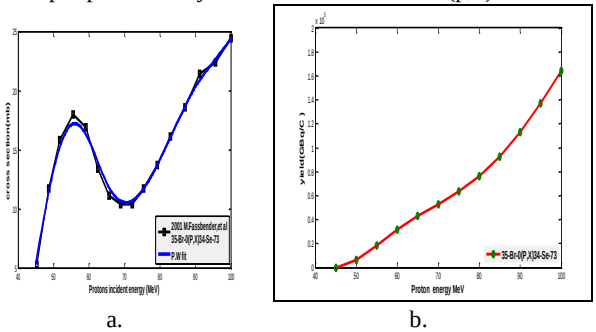
a. b.

Figure 2: a.Excitation function for the reaction ^{74}Se (p,x) ^{73}Se. b.Isotopes production yield for the reaction ^{74}Se (p,x) ^{73}Se.



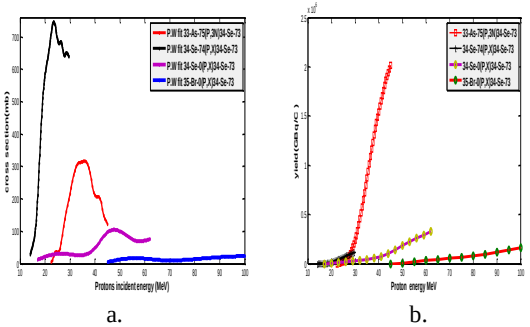
a. b.

Figure 3: a. Excitation function for the reaction ^{nat}Se(p,x)^{73}Se. b. Isotopes production yield for the reaction ^{nat}Se(p,x)^{73}Se



a. b.

Figure 4: a. Excitation function for the reaction ^{nat}Br(p,x)^{73}Se. b. Isotopes production yield for the reaction ^{nat}Br(p,x)^{73}Se.



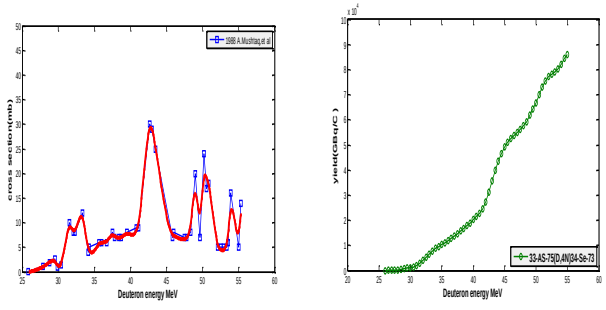
a. b.

Figure 5: a.Excitation function for production ^{73}Se for reactions ^{74}Se, ^{nat}Se , ^{nat}Br(p,x) ^{73}Se and ^{75}As(p,x) ^{73}Se. b. Isotopes production yield for the reactions ^{74}Se, ^{nat}Se , ^{nat}Br (p,x) ^{73}Se and ^{75}As(p,3n) ^{73}Se.

2 -Production by deuterons incident

The excitation functions of the reaction ^{75}As (d,4n) ^{73}Se, were determined by A. Mushtaq, S.M.Qaim, et al (11).for energy range (25 to 56) MeV as shown in Fig.6.a.

The isotopes production yield results were shown in Fig.6. b. was determined by equation (2) and the calculated stopping power values by using SRIM code (4).



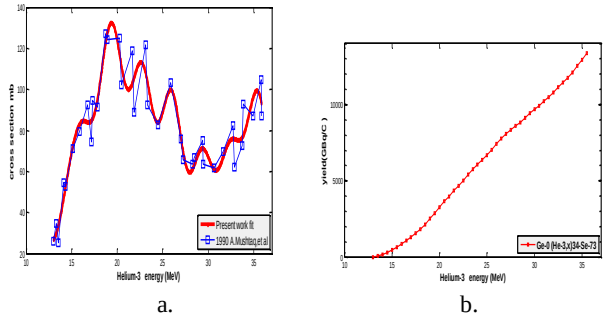
a. b.

Figure 6: a. Excitation function cross sections for the reaction ^{75}As (d,4n) ^{73}Se. b. Isotopes production yield for the reaction ^{75}As(d,4n)^{73}Se.

3 -Production by Helium-3 particles

The excitation functions of the reaction ^{nat}Ge (^{3}He,x)^{73}Se, were determined by A.Mushtaq, et al (15), for range of energy (12 to 36) MeV Fig.7.a.

The isotopes production yield results were shown in Fig.7.b, were determined by equation (2) and the calculated stopping power values by using SRIM code (4).



a. b.

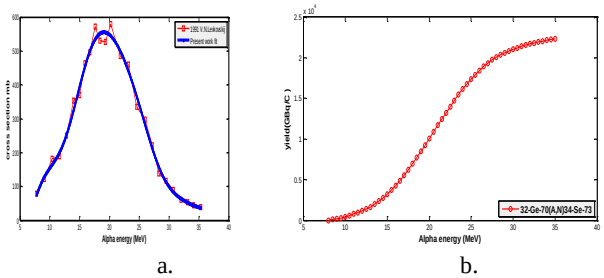
Figure 7: a. Excitation function for the reaction ^{nat}Ge (^{3}He,x)^{73}Se. b. Isotopes production yield for the reaction ^{nat}Ge (^{3}He,x)^{73}Se

4 -Production by alpha particles

a-70Ge (α, n)73Se

The Alpha particles induced reaction70Ge (α,n)73Se with range of energy (7 to 37) MeV Fig.8.a. According to V.N.Levkovskij (10).

The isotopes production yield results were shown in Fig.8. b. which was determined by equation (2) and the calculated stopping power values by using SRIM code (4)



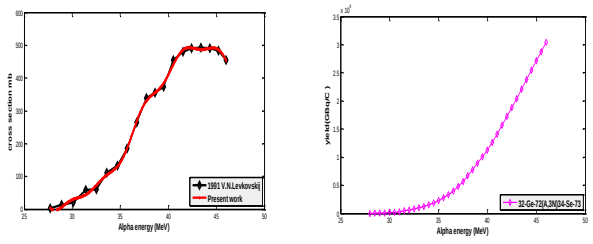
a. b.

Figure 8: a. Excitation function for the reaction ^{70}Ge (α,n)^{73}Se. b. Isotopes production yield for the reaction ^{70}Ge (α,n)^{73}Se

b-72Ge (α, 3n)73Se

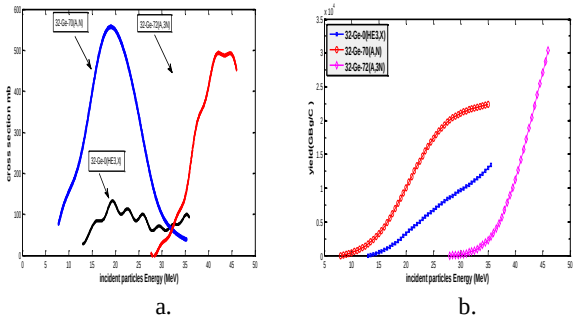
The alpha particles induced reaction ^{72}Ge (α,3n)^{73}Se with range of energies (27 to 46) MeV Fig.9. a. according to V.N.Levkovskij (10). The isotopes production yield results were shown in Fig.9. b. That determined by using equation (2) and the stopping power values were calculated by using SRIM code (57).

The excitation functions for each of Helium-3 and Alpha particles induced interactions Fig.10.a. leading to the production yield of Selenium -73, has been displayed in Fig.10.b.



a. b.

Figure 9: a. Excitation function for the reaction72Ge (α,3n)73Se. b. Isotopes production yield for the reaction 72Ge (α,3n)73Se



a. b.

Figure 10: a. Excitation function for production ^{73}Se for the reactions ^{nat}Ge (^{3}He,x) , ^{70}Ge (α,n) and ^{72}Ge (α,3n).b. Isotopes production yield for the reactions natGe (3He,x) , 70Ge (α,n) and 72Ge (α,3n)

All the nuclear data of ^{73} se that mentioned above for various nuclear reactions, can be summaries in table 1 below:

Table 1: Nuclear data of 73Se production by various nuclear reactions

Reaction	Energy Range (Mev)	Max. cs(mb)	Yield(GBq/C)	Yield(GBq/μAh)
^{75}As (p,3n)^{73}Se	22.5 - 45.5	315	$2*10^{6}$	7200
^{nat}Se (p,x) ^{73}Se	17 - 62	105	$0.32*10^{6}$	1152
^{nat}Br (p,x) ^{73}Se	45 - 100	24.5	$0.16*10^{6}$	576
^{74}Se (p,x) ^{73}Se	14 - 29	746.5	$0.11*10^{6}$	396
^{75}As (d,4n) ^{73}Se	25 to 56	30	$0.085*10^{6}$	306
^{nat}Ge	12 to 36	133	$0.03*10^{6}$	108
(^{3}He,x) ^{73}Se				
^{70}Ge (α,n) ^{73}Se	7 to 37	560	$0.02*10^{6}$	72
^{72}Ge (α,3n) ^{73}Se	27 to 46	494	$0.013*10^{6}$	46.8

B-Reactor production of ^{73}Se

^{74}Se (n, 2n) ^{73}Se reaction

The weighted average cross section for neutron induced reaction on ^{74}Se was calculated using equation (4) and shown in Fig.11 and table 2, According to M.Bormann,et al (16) , A.Abboud,et al (17) and M.Bormann,et al (18).

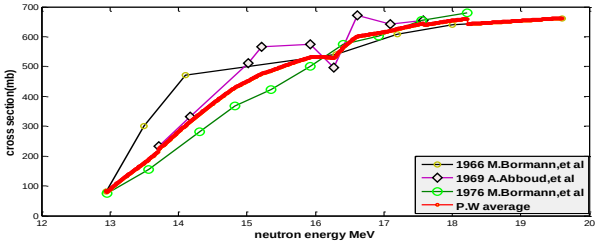


Figure.11. Excitation Function for Production ^{73}Se for the Reactions ^{74}Se (n, 2n)^{73}Se.

Table 2: Excitation Function for Production ^{73}Se for the Reactions ^{74}Se (n, 2n)^{73}Se

Neutron energy (Mev)	Cross-section (mb)	Neutron energy (Mev)	Cross-section (mb)
13	87.9274	16.5	581.4549
13.5	176.5097	17	615.2147
14	280.959	17.5	640.3161
14.5	375.0831	18	654.2727
15	449.6545	18.5	646.1875
15.5	498.3664	19	653.375
16	532.23	19.5	660.5625

.

Conclusion

1- Using cyclotrons and accelerators

a-Production by proton particles:

When proton induced reaction on ^{75}As, ^{74}Se, ^{nat}Se and ^{nat}Br to obtain ^{73}Se, the reaction ^{75}As(p,3n) with range of energy (22.5 to 45.5 MeV) and the maximum cross section is 315 mb at 36.5 MeV gives maximum yield ($2*10^{6}$ GBq/C).

^{nat}Se (p,x) with range of energies (17to 62MeV), the maximum cross sections is 105 mb at 48.5 MeV gives yield ($0.32*10^{6}$ GBq/C).

^{nat}Br(p,x) with range of energies (45 to 100MeV), the maximum cross sections is 24.5 mb at 100 MeV gives yield ($0.16*10^{6}$ GBq/C).

^{74}Se (p,x) with range of energies (14 to 29), the maximum cross sections is 746.5 mb at 24.5 MeV gives yield ($0.11*10^{6}$ GBq/C) as shown in Fig.5.a&b. and table (1).

b- Production by deuteron particles:

For the reaction ^{75}As (d,4n) ^{73}Se with range of energies (25 to 56 MeV), and the maximum cross sections is 30 mb at 43MeV, yield given is (0.085*10^{6} GBq/C) as shown in Fig.6. a.&b., and table (1) .

This result of isotopes production yield is considered low when compared with that produced by protons particles.

c- Production by Helium-3 and alpha particles:

Of the three reactions ^{nat}Ge (^{3}He,x) , ^{70}Ge (α,n) and ^{72}Ge (α,3n) show that the best reaction to obtain ^{73}Se is ^{72}Ge (α,3n) within the range of energies (27 to 46 MeV) and the maximum cross sections 494 mb at 42MeV gives the maximum yield (0.03*10^{6} GBq/C).

^{70}Ge (α,n) with range of energies (7 to 37 MeV), and maximum cross section is 560 mb at 19 MeV gives yield (0.02*10^{6} GBq/C).

^{nat}Ge (^{3}He,x) with range of energies (12 to 36 MeV), and maximum cross sections is 133 mb at 19 MeV gives yield (0.013*10^{6} GBq/C), that is very clear by observing Fig. 10.a.&b., and shown in table (1).

Through the above, we conclude that the use of proton as projectile are best compared with other particles in order to get maximum isotopes production yield of ^{73}Se .

2- Reactor production of ^{73}Se :

^{74}Se (n, 2n)^{73}Se reaction:

The *^{74}Se (n, 2n)^{73}Se* reactions with neutrons energies (13 to 19.5 MeV) have the maximum cross section 660.5 (mb) at 19.5 MeV as showen Fig.11, table (2).

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Al-Kindy College Medical Journal (KCMJ)

Research Article

Automated breast ultrasound: A comparison study with handheld ultrasound in detection and characterization of lesions in mammographically dense breast

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Keywords: automated breast ultrasound, handheld ultrasound, dense breast.

ABSTRACT

***Background*:** Although mammography is a powerful screening tool in detection of early breast cancer, it is imperfect, particularly for women with dense breast, which have a higher risk to develop cancer and decrease the sensitivity of mammogram, Automated breast ultrasound is a recently introduced ultrasonography technique, developed with the purpose to standardize breast ultrasonography and overcome some limitations of handheld ultrasound, this study aims to evaluate the diagnostic efficacy of Automated breast ultrasound and compare it with handheld ultrasound in the detection and characterization of breast lesions in women with dense breasts.

***Objectives*:** To evaluate the diagnostic efficacy of Automated breast ultrasound and compare it with hand held ultrasound in detection and characterization of breast lesions in women with dense breast.

Subjects and Methods: A prospective observational study conducted at Oncology Teaching Hospital during the period of ten months from 1st of February till 1st of December 2020. Included 62 women with dense breasts on diagnostic mammograms. All women underwent technician performed automated breast ultrasound and radiologist performed handheld ultrasound for both breasts. All suspicious lesions with selected probably benign lesions underwent biopsy, handheld ultrasound detected 48 masses (67.6%), 15 of them (21.1%) were cystic, automated breast ultrasound detected 54 masses (76.1%); 20 of them (28.2%) were cystic. The sensitivity of handheld ultrasound was=87.5%, Specificity=58.8%, the sensitivity of automated breast ultrasound was=93.8%, Specificity=70.6%.

***Conclusion*:** Automated breast ultrasound is an effective modality to detect occult breast lesion in women with dense breasts, automated breast ultrasound and handheld ultrasound have a reliable agreement in detection and characterization of breast lesions with higher accuracy of automated breast ultrasound in the evaluation of malignant lesions.

Introduction

The 3D (automated) breast ultrasound system is an invention that has been evolved to dissociate diagnosis from image acquiring and to undertake the limitations of handheld ultrasound. (1). Unlike HHUS, 3D-ABUS can be reproduced and barely depending on the operator during image acquiring. Additionally, the image acquiring can be separated from image reporting, by this mechanism the image is obtained by a well-trained technician then reported by authorized radiologist at a separate place or at a separate date. (1). ABUS also produce a three-dimensional delineation for the entire breast, with

their formatted coronal image has been shown to enhance the accuracy of the diagnosis (2).

Limitations of 3D-ABUS include: more false-positive outcome and call-back, more shadows artifacts, cannot be used as a guidance in biopsy, axillary region cannot be evaluated, non-availability of elastography and colour doppler studies, more expensive machine compare to hand held US machine. (3,4,5)

Artefacts of ABUS: Nipple shadowing and reverberation artefacts: appear as an aligned echogenic band with parallel orientation, arranged side by side with same distant from each other (6).

Skip artefact: manifest transversally as non-echoic band, it can be used as an indicator of underlying pathology. (7). Motion artefact: present as numerous wavy echogenic lines. (8). Contact artefact: occur due to in proper contact in between probe and chest wall produce hypoechoic non regular region (8). A specific descriptor for malignancies at ABUS is the retraction phenomenon, Result shown that retraction is usually evident in relatively slow growing malignancy with a poor proliferation rate (9).

Aim of study: To evaluate the diagnostic efficacy of Automated breast ultrasound and compare it with hand held ultrasound in detection and characterization of breast lesions in women with dense breast.

Subjects and Methods

Study design and data collection time A prospective observational study was conducted at Oncology Teaching Hospital in Baghdad Medical City during the period of ten months from 1st of February till 1st of December 2020

Study patients and sample size 62 women were diagnosed with dense breasts (ACR type C–D) on diagnostic mammograms and underwent bilateral whole breast ultrasound. Technician performed ABUS and radiologist performed HHUS for both breasts. All suspicious (breast imaging reporting and data system-BIRADS IV–V) and randomly selected lesions with BIRAD III findings detected on either modality had undergone U/S guided core needle biopsy with a 16 - 18G needle.

Inclusion criteria

women with dense breasts (ACR type C–D) on diagnostic mammograms.

Exclusion criteria

1.Womenwith category A and B breast density on mammography.

2.women who refuses ABUS examination and women.

3.women with recent breast intervention.

Equipment and techniques Hand-held ultrasound were performed by GE LOGIC S8 machine using a 4–15 MHz linear transducer (ML6-15). The expert radiologist (14 years' experience)performed it with woman lies in supine position after exposure of the region with ipsilateral arm bring up and the hand on the head, the entire time for the examination was approximately 20 min for both breasts, ABUS was performed by Acuson S2000 automated breast volumetric scan, Siemens Healthcare, carried out by a trained technician(2months training), the transducer wide-frequency bandwidth (5-14 MHz) catch about6 cm × 15.4 cm × 16.8 cm volume with a series of 320 high-resolution axial 2D images of 0.5 mm slice intervals , customized options were used to optimize frequency, depth and gain. The study had performed with the patient lying supine, a pillow is placed under the patient on the same side to be imaged; to maximize proximity between transducer and chest wall. With exposed breast of the breast, abundant quantity of lotion is applied on the breast with additional quantity on the region around the areolar and nipple to ensure optimal study with mild compression was applied by a transducer to avoid artefacts. With the nipple as a central mark, the anterior posterior (AP) orientation initially captured. Lateral orientation usually captured with the transducer angled from axillary region toward the sternal region and for the medial orientation with the transducer angled from the sternal region to the axillary region, the time for the acquisition of the image was approximately 15 min for both breasts,

Image analysis and interpretations both HHUS and ABUS are interpreted by expert radiologists in breast imaging. Interpretation done for: lesion detection, Characterization of lesion : Shape (Oval, round, or irregular), Orientation (parallel, not parallel), Margin (circumscribed, micro lobulated, angular, indistinct, spiculated), Echogenicity characteristic (non-echoic, hypo-echoic , iso-echoic, hyperechoic, heterogeneous, complex cyst and solid),Posterior characteristic (no features, shadowing ,enhancing, , combined pattern),Lesion location (clock-face and distance from the nipple in millimetres), and largest diameter (in millimetres),a BI-RADS finally reported for each lesion as one of these categories :Negative ,Benign, probably benign (2%risk of malignancy), suspicion (3–94% risk of malignancy), Highly suspicious of malignancy (95% or greater likelihood of malignancy). Breast lesions with BIRAD IV & V with randomly selected BIRAD III lesions, underwent histopathological diagnosis at the pathology department of the hospital following core biopsy using a 16-18guage needle or surgical excisional biopsy.

Ethical considerations and official approvals Verbal permission was taken from each woman preceding data collection, and the details was kept anonymous, administrative approvals were conceded from: The Council of Iraqi Board of Medical Specialization, Oncology Teaching Hospital in Baghdad Medical City.

Statistical analysis the data reanalysed Statistical Package of Social Sciences (SPSS) version 25, Cohen's Kappa Coefficient (K) measured inter-rater agreement for qualitative (categorical) items. A degree of P-value below 0.05 was regarded significance.

Results

The numbers of women included in the study was totally 62, age was ranging from 39 – 60 years (mean of 46.72 years) with 71 breast cases (nine patients with bilateral abnormality). They were evaluated by HHUS and ABUS, HHUS detected a mass in 48 cases (67.6%); 15 of them (21.1%) were cystic lesions; While ABUS detected a mass in 54 lesions in comparison, all lesions detected in HHUS were detected by ABUS with addition of 6 lesion (76.1%); 20 of them (28.2%) were cystic lesions .

Table 1: Comparison in mass detection between HHUS and ABUS.

Mass detection by HHUS	Mass detection by ABUS		Total	Kappa value	P-value
	Yes	No			
Yes	48	0	48		
No	6	17	23	0.793	0.001
Total	54	17	71		

Table 2: Comparison in mass shape between HHUS and ABUS

Mass shape by HHUS	Mass shape by ABUS			Total	Kappa value	P-value
	Oval	Round	Irregular			
Oval	11	0	1	12		
Round	0	2	0	2	0.936	0.001
Irregular	0	0	14	14		
Total	11	2	15	28		

By ABUS, the margin was circumscribed in 12 of them; all of them were confirmed by HHUS.

In conclusion, there was a substantial agreement between the margin by HHUS and ABUS, and this agreement was statistically significant (kappa= 0.634, P=0.001).

By ABUS, the echo pattern was hypoechoic in 23 lesions; 21 of them were confirmed by HHUS.

In conclusion, there was a moderate agreement between the echo pattern by HHUS and ABUS, and this agreement was statistically significant (kappa= 0.62, P=0.001).

By ABUS, the posterior feature was not detected in 16 lesions; all of them were confirmed by HHUS; there was a perfect agreement between the posterior feature by HHUS and ABUS, and this agreement was statistically significant (kappa= 0.85, P=0.001).

Table 3: Comparison in BIRAD between HHUS and ABUS.

BIRAD by HHUS	BIRAD by ABUS					Total	Kappa value	P-value
	I	II	III	IV	V			
I	7	4	2	0	0	13		
II	0	13	0	0	0	13		
III	0	5	15	1	0	17		
IV	0	3	0	20	0	23	0.719	0.001
V	0	0	0	0	1	1		
Total	7	25	17	21	1	71		

In this study, 33 lesions underwent histopathological examination; 16 of them were malignant (48.5%); table 4 shows the sensitivity, specificity, and accuracy of HHUS in diagnosing malignant lesions. The sensitivity of HHUS was = 87.5%, specificity = 58.8% and accuracy was 72.7%. +ve predictive value was 66.7%, while –ve predictive value was 83.3%.

Table 4: Sensitivity, specificity, and accuracy of HHUS in the diagnosis of malignant lesion

BIRAD by HHUS	Histopathological Finding		Total
	Malignant	Benign	
Suspicious (IV, V)	14	7	21
Probably Benign (III)	2	10	12
Total	16	17	33

Table 5 shows the sensitivity, specificity, and accuracy of ABUS in diagnosing malignant lesions.

The sensitivity of ABUS was = 93.8%, specificity = 70.6% and accuracy was 81.8%.

+ve predictive value was 75%, while –ve predictive value was 92.3%.).

Table 5: Sensitivity, specificity, and accuracy of ABUS in the diagnosis of malignant lesion

BIRAD by ABUS	Histopathological Finding		
	Malignant	Benign	Total
Suspicious (IV, V)	15	5	20
Probably Benign (III)	1	12	13
Total	16	17	33

By ABUS, 48 patients were detected positive; 30 of them confirmed by mammogram.In conclusion, there was no statistically significant agreement (P= 0.07) between patient detection by mammogram and ABUS. We noticed that from 35 detected lesions by mammogram, 20 were asymmetrical, and 15 were masses; from these 20 asymmetrical, 15 were positive, as shown in table(6).

Table 6: Comparison in lesions detection between mammogram and ABUS.

Patients by mammogram	Patients by ABUS		Total	Kappa value	P - value
	Positive	Negative			
Positive	30	5	35		
Negative	18	9	27	0.202	0.07
Total	48	14	62		

(HHUS: hand held ultra sound, ABUS: automated breast ultrasound, BIRAD: breast imaging reporting and data system)

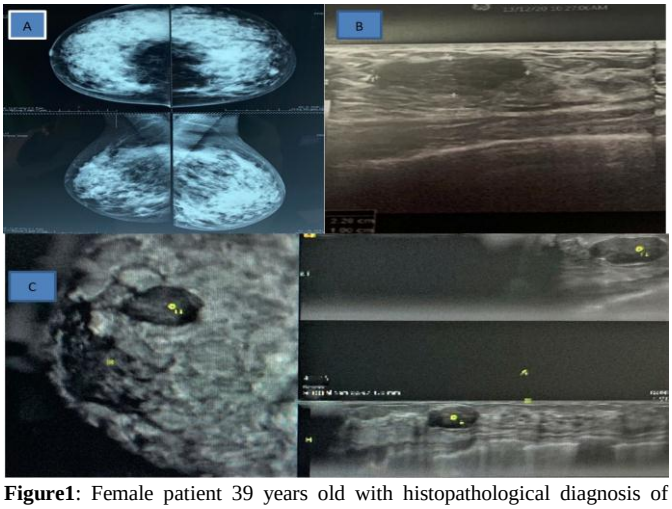

Figure1: Female patient 39 years old with histopathological diagnosis of fibroadenoma. A. Mammogram (cranio-caudal and Medio lateral oblique views of both breasts) showing dense breast (ACR D) with left sided equal density and obscured margin mass seen. B. HHUS image showing a parallel hypoechoic lesion in the upper outer quadrant of the left breast measuring 22*10mm. C. coronal, axial and sagittal reformatted ABUS image showing the well-defined hypoechoic lesion 25*11 mm which had a fine lobulated outline. The lesion was graded BI-RADS III.

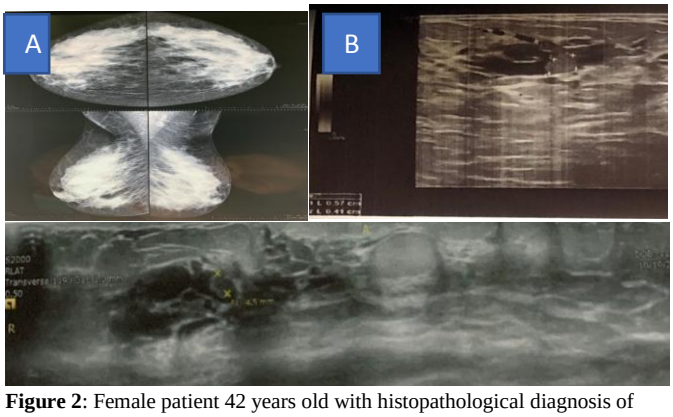

Figure 2: Female patient 42 years old with histopathological diagnosis of intra-cystic papilloma. A Mammogram (cranio-caudal and mediolateral oblique views of both breasts) showing dense breast (ACR D) with no obvious lesions or calcifications B. HHUS image show complex cystic lesion with 5.7 mm solid component. Axial reformatted ABUS image showing the complex cystic lesion with small solid component the lesion was graded BI-RADS IV on both imaging modality.

Discussion

Female with high fibro-glandular breast tissue dense breasts have a high risk for developing breast malignancy, and furtherly encountered less detection rate of breast pathology on mammogram due to obscuring effect of the hyper-dense parenchyma. As a result, other techniques needed for imaging

Like ultrasound, tomosyntheses or magnetic resonance imaging to enhance the evaluation for the female with high dense breast (10). ABUS can provide a three-dimensional delineation of the entire breasts, with the coronal orientation significantly increase the accuracy of the diagnosis. Automated breast ultrasound has superior than or similar achievement to hand held ultrasound(11).Regarding mass detection in this study, and by ABUS, mass was detected in 54 lesions; 48 of them were confirmed by HHUS, there was a substantial agreement between the mass detection of HHUS and ABUS, and this agreement was significant (kappa= 0.793, P=0.001). Kim and colleagues reported a different result in their study that was conducted in 2014, they found a moderate agreement on detection of mass observed by HHUS and ABUS in the assessment of breast lesion (κ=0.472) (12). This discrepancy can be explained by differences in sample size, operated dependency of HHU and ABUS reader has little experience with ABUS imaging (13). Concerning the mass shape in the current study and by ABUS, mass was irregular in 15 of them; 14 of them were confirmed by HHUS. As a result, there was a perfect agreement between the mass shape of HHUS and ABUS, and this agreement was statistically significant (kappa= 0.936, P=0.001). Different results were observed in Kim et al study in 2014, as observed a substantial agreement on the description of shape by HHUS and ABUS (κ=0.707) (12). In the same manner, Shin and colleagues in the study conducted in 2011, found a Substantial agreement between HHUS and ABUS for assessment of shape (κ=0.71). The agreement was more for irregular (K=0.76) shape and lower for rounded (κ = 0.25) shape (14). assessment of margin by ABUS in the present study showed that it was circumscribed in 12 of them; all of them were confirmed by HHUS. In conclusion, there was a substantial agreement between the margin by HHUS and ABUS, and this agreement was statistically significant (Kappa= 0.634, P=0.001). An agreement to the present work was noticed in Shin et al study in 2011, they observed a substantial agreement between HHUS and ABUS founded to assess the margin (κ = 0.61). there was about perfect agreement when classified margins into two groups: circumscribe margin or not circumscribed (κ = 0.808) (14),. Kim and colleagues reported a different result in their study that conducted in 2014, they found a moderate agreement on margin detection by HHUS and ABUS (κ= 0.438) (12), this can be explained by depended on proper orientation, angulation and compression of the probe which can affect the proper interpretation of the shape, also with proper machine setting (15)On the other hand, the Echo pattern assessment by ABUS in the present work was hypoechoic in 23 lesions; 21 of them were confirmed by HHUS. In conclusion, there was a moderate agreement between the echo pattern by HHUS and ABUS, and this agreement was statistically significant (Kappa= 0.62, P=0.001). In the same manner, Kim and colleagues found a similar result in a study conducted in 2014, they found a moderate agreement on echogenicity detected by HHUS and ABUS (κ= 0.524) (12), which also agreed to the study conducted in 2011, by Shin and colleagues. They found in the comparison between HHUS and ABUS that a moderate agreement was founded in the assessment of echogenicity in-between radiologist (K=0.45) (14)The posterior feature assessed by ABUS in this study revealed that it was not detected in 16 lesions; all of them were confirmed by HHUS. In conclusion, there was a perfect agreement between the posterior feature by HHUS and ABUS, and this agreement was statistically significant (Kappa=0.85, P=0.001). Kim and colleagues found a different result in a study conducted in 2014, they found a moderate agreement on posterior acoustic features detected by HHUS and ABUS (K=0.541) (12)which was by Shin et al study in 2011, as a moderate agreement was accomplished in the interpretation of posterior acoustic characteristics by HHUS and ABUS (K=0.42) (14),this may be affected by different in manipulation and gain of the machine setting which can significantly affect the posterior feature of the lesion. Finally, by ABUS in the current study, BIRAD was II in 25 lesions; 13 of them were confirmed by HHUS. In conclusion, there was a substantial agreement between the BIRAD by HHUS and ABUS, this agreement was statistically significant (kappa= 0.688, P=0.001). The current results agreed to that observed in Shin et al study in 2011, as noticed in terms of an agreement on BI-RADS features of breast masses comparison of the HHUS and ABUS, substantial agreement founded in the assessment finally (K= 0.64) (14).Different results were observed when compared to Kim et al study in 2014, as reported that BI-RADS final assessment yielded fair agreement (K=0.397) (12). Differently, a recent prospective study done by Vourtsis and others in 2018, involving 1,886 patients reported the excellent overall agreement (99.8%) between HHUS and ABUS, with a kappa value of 0.994. They concluded that ABUS could be successfully used in the visualization and characterization of breast lesions. Also, ABUS seemed to outperform HHUS in the detection of architectural distortion on the coronal plane and can supplement mammography in the detection of non-calcified carcinomas in those who had dense breasts (15) In the current study, the sensitivity of HHUS was=87.5%, specificity = 58.8% and accuracy was 72.7%, positive predictive value was 66.7%, while –ve predictive value was 83.3%. On the other hand, the sensitivity of ABUS was=93.8%, specificity=70.6% and accuracy were 81.8%. The positive predictive value was 75%, while the –ve predictive value was 92.3%. by compare with another studies, close outcome seen in Jia et al study in 2020, as noticed that female with high breast density on

mammogram, when 3D ultrasound was utilized as an adjacent study, the sensitivity reached about 99.10% and the specificity reached to 86.87% .The positive predictive value and negative predictive value were 69.97% ,99.68% respectively (16)Better results were observed in Lin et al study in 2012, in which both ABUS and HHUS detected 95 breast lesions. Compared with the pathological diagnosis in 35 lesions, both ABUS and HHUS exhibited high sensitivity (both 100%) and high specificity (95.0%, and 85.0%, respectively). On the other hand, Golatt and colleagues in a study done in 2015, concluded that ABUS might be a helpful new tool in breast imaging, especially in screening, as found a high NPV of 98 %, a high specificity of 85 % and a sensitivity of 74 % based on the cases with US-guided biopsy. Including the cases where the lesion was seen in a second-look ABUS the sensitivity improved to 84 % (NPV=99 %, Specificity=85 %) (87). Finally, ABUS was comparable to HHUS in Schmachtenberg et al study in 2017, in terms of sensitivity (93.3% vs. 100%), specificity (83.3% vs. 83.3%), accuracy (87.2% vs. 89.7%), positive predictive value (77.8% vs. 78.9%), and negative predictive value (95.2% vs. 100%) (17)The differences observed in the above studies can be explained by a different sample size of each study, the experience of the operator in performance of examination and radiologist in interpretation, and false-positive results with benign pathologies as focal fibrosis, fibroadenomas, inframammary lipoma, and fibrocystic changes, with and without inflammatory change, By ABUS in this study, 48 patients were detected positive(mass); 35 of them confirmed by mammogram (mass or asymmetry). In conclusion, there was no statistical significant agreement (P= 0.07) between patient detection by mammogram and ABUS, In comparison to other studies, a similar finding was observed in a study done by Abd Elkhalek and colleagues in 2019 that shows in all the results of the mammogram study, ABUS can detect it without significant change (P>0.05), They concluded that ABUS has advantages of better diagnostic accuracy of breast lesions in terms of early detection, better categorization, and accurate assessment. ABUS with mammography will add more value in the diagnostic field (18).

limitations of this study include:

- As it is a newly introducing modality, ABUS imaging still not very familiar to the technicians and radiologists.
- The technique itself is limited, as are other sonography techniques, in women with large or pendulous breasts.
- Patient cooperation is also necessary as motion beyond quiet breathing will degrade the examination.
- small sample size which mostly affected by the COVID 19 pandemic.

Funding

This research did not receive any specific fund.

Conflict of Interest

No conflict of interest

Conclusions

TcB In conclusion, ABUS is an effective modality to detect occult breast lesions in female with high density breast parenchyma on mammogram, automated breast(3D) ultrasound and handheld(2D) ultrasound have a reliable agreement in detection and characterization of breast lesions in women with dense breasts, with higher accuracy of ABUS in the evaluation of malignant lesions. High percentage of women with dense breast and the several benefits of automated breast ultrasound above handheld ultrasound, like reproducibility, operator-independent, less time-consuming, ABUS manifest considerable capability to be applied in breast Imaging.

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Al-Kindy College Medical Journal (KCMJ)

Research Article

Assessment of Awareness and Knowledge among Medical Students Regarding Radiation Exposure from Common Diagnostic Imaging Procedures

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ABSTRACT

***Objective*:** to assess the awareness and knowledge of our medical students regarding dose levels of imaging procedures and radiation safety issues, and to conclude how the curriculum of clinical radiology in the college medical program impacts such knowledge.

Subjects and methods: this is a cross-sectional study conducted among 150 medical students in Alkindy College of Medicine between January 2021 to July 2021, regardless of their age or gender. The study included six grades according to the year 2020-2021. A questionnaire consisting of 12 multiple-choice questions was conducted via an online survey using Google Forms. The questions were divided into two parts (awareness concerning issues of radiation protection, and information about dose levels of frequent radiological investigations).

***Results*:** Regarding their radiology knowledge, about one-third of all participants rated as average. Students who had not established training in radiology chose the inappropriate choice more often than individuals who had received training. Also, students without instruction/ teaching in diagnostic clinical radiology were more likely to connect MRI and ultrasound with an increased cancer possibility compared with those students receiving radiology teaching. About the desired educational method, 32% wanted a tutorial or workshops, 29% wanted a learning module, 25% chose a case study and 14% chose a lecture.

***Conclusion*:** With increasing years in medical school, the student's alertness demonstrates better performance regarding the radiation exposures in imaging diagnosis. The greater part of medical students has inadequate knowledge about different aspects of radiation sources, hazard, and their safety. We think that adding more theoretical and practical programs to the educational radiology curriculum will advance awareness of radiation safety and increase knowledge among medical students regarding the doses of radiological examinations.

Introduction

Currently, medical studies have recognized that increasing utilization of diagnostic imaging tools, principally computed tomography (CT), results in increasing patient radiation exposures (1). Furthermore, the number of referrals for pediatric CT examinations has augmented exponentially, raising considerable

issues concerning the risk of malignancy in this greatly radiosensitive population (2). Not unexpectedly, issues are rising regarding the risk linked with an elevated level of radiation exposure, mainly the probable amplified life span threat of cancerous diseases (3). The European Council Euratom directive of 1997 appreciated this subject and made numeral advice. The incorporation of radiation protection into the curriculum of medical schools was the most important recommendation issued by this directive (4). Hence, health professionals must be alert of the radiation exposures related to radiological diagnostic examinations, especially CT scans. In the last years, health workers from different specialties have been investigated by many studies regarding their familiarity with radiation dose and radiation hazard, and nearly all these studies' results were significantly unsatisfied (5-7). While many studies of medical students' knowledge of radiology have been achieved, the particular area of awareness among medical students regarding relative radiation doses associated with different diagnostic imaging investigations has so far been meticulously investigated (8-10). It is believed that students of medical colleges may not be aware of the radiation dosage and hazards related to frequently used diagnostic imaging procedures. Our work aims to evaluate the awareness and knowledge of our college students regarding radiation exposure, to compare between the stages to evaluate the efficacy and accuracy of the education in the late stage, to know the students' desire for the best way to study radiology, and to illustrate the importance of adding radiation protection education during the initial study years.

Subjects and Methods

We conducted a comparative cross-sectional study, to evaluate the knowledge concerning radiation exposure and its risks among medical students at Al-kindy College of Medicine. This study was conducted under the Declaration of Helsinki and was approved by the local thesis committee of the college (research project number;112/20). The personal information of all participants involved in the study was safeguarded .

A questionnaire with multi-choice was distributed to the participants of our study covered first to sixth-year students (n=150) at the end of the educational year (January 2021 to July 2021) in Al-kindy College of medicine. The questionnaire track a multi-choice arrangement of two main parts. The first part included demographic data of the student and a self-appraisal of awareness of radiology in comparison to other health topics, as well as prior contact to radiological training and teaching. The second part evaluated alertness and general awareness of radiation exposures linked to imaging investigations. Due to the corona pandemic, the questionnaire was in a Google form type.

For ethical considerations, there weren't questions asking about the participants' names, religions, or ID numbers. The questionnaire kept the participants' anonymity i.e. the participant was anonymous.

Statistical analysis

All patients' data were entered using the Statistical Package for Social Sciences software (IBM SPSS Statistics for Windows, version 21.0 Armonk, NY, USA). To evaluate the normal distribution of means, histograms tests of normality were applied. Microsoft Excel 2010 was used to analyze the data. The frequencies were stated first then the Chi-Square test and Fisher's exact test was used to investigate the association. A p-value less than 0.05 was considered significant.

Results

A hundred fifty (150) students participated in our study, accounting for a response rate of 61.9% male and 38.1% female. In the first, second, third, fourth, fifth, and sixth study years, the students were distributed (Table 1).

Table 1: Study population distribution

Stage	%
first	11.50
second	19.40
third	30.20
forth	10.10
fifth	15.10
sixth	13.70

About one-third of all students included (36.0%) reported their knowledge of radiology as an average. About 28.1% of the study population had been exposed to theoretical lectures in radiology, 10.8% exposed to tutorials/workshops, 19.4% exposed to a combination of lectures, tutorials, and workshops, Despite this, 41.7% of the study population were not exposed to any lessons or instruction centered on radiation safety. With the number of years completed effectively in medical school, the mean scores were improved (Table 2).

Table 2: Self-estimation of awareness of radiology in comparison to other health topics, and prior exposure to radiological training and education

	first	second	third	forth	fifth	sixth	p-value
Regarding ionizing radiation, have you any education in the form of lectures, tutorials, or training courses?							<0.001
Lectures	6.3%	59.3%	9.5%	14.3%	38.1%	42.1%	
Tutorials/workshops	0.0%	0.0%	16.7%	0.0%	19.0%	21.1%	
A combination of above	18.8%	7.4%	21.4%	7.1%	28.6%	31.6%	
None	75.0%	33.3%	52.4%	78.6%	14.3%	5.3%	
Compared with other medical topics, how does your knowledge of radiology?							<0.001
Excellent	0.0%	0.0%	2.4%	7.1%	19.0%	10.5%	
Good	0.0%	25.9%	16.7%	0.0%	33.3%	26.3%	
Average	18.8%	40.7%	38.1%	28.6%	33.3%	47.4%	
Poor	50.0%	25.9%	40.5%	28.6%	14.3%	5.3%	
No knowledge	31.3%	7.4%	2.4%	35.7%	0.0%	10.5%	

Additionally, the students who established education in clinical imaging and radiation safety achieved responses superior to those without education. Almost 26.6% of the participants thought that the dose of radiation exposure in a chest X-ray was less than one week of natural background radiation and 49% were not familiar with the response. About 23.8% of our study participants overvalued the total radiation of chest radiograph, with 10.1% selecting the choice that

the radiation exposure equal to a dose larger than 1 year of natural background radiation. Only 12.9% of students in our study properly responded that an abdominal X-ray implicated exposure with higher radiation than a chest X-ray, while 33.1% chose the chest x-ray, 9.4 % chose the ultrasound (Table 3).

Table 3: General awareness of radiation exposure related to diagnostic imaging examinations:

	first	second	third	forth	fifth	sixth	pvalue
The maximum patient's radiation exposure occurs in which of the following?							0.002
Abdominal Ultrasound	6.3%	14.8%	16.7%	0.0%	4.8%	0.0%	
Plain film of abdomen	0.0%	0.0%	16.7%	7.1%	33.3%	36.8%	
MRI of spine	18.8%	18.5%	31.0%	21.4%	14.3%	10.5%	
Chest x-ray	25.0%	48.1%	26.2%	35.7%	38.1%	26.3%	
Don't know	50.0%	18.5%	19.0%	35.7%	9.5%	26.3%	
In CXR, dose of radiation is equivalent to natural background radiation received in?							0.001
< One week	0.0%	14.8%	16.7%	14.3%	57.1%	63.2%	
One month	6.3%	3.7%	2.4%	7.1%	9.5%	10.5%	
Six months	6.3%	7.4%	9.5%	7.1%	9.5%	5.3%	
One year	0.0%	7.4%	11.9%	0.0%	4.8%	10.5%	
More than one year	0.0%	3.7%	2.4%	0.0%	9.5%	0.0%	
Don't know	87.5%	63.0%	57.1%	71.4%	9.5%	10.5%	
Which organ is least sensitive to radiation?							0.000
Thyroid	12.5%	3.7%	4.8%	0.0%	0.0%	5.3%	
Breast tissue	6.3%	3.7%	2.4%	0.0%	19.0%	5.3%	
Gonads	18.8%	11.1%	9.5%	7.1%	4.8%	5.3%	
Kidney	6.3%	63.0%	50.0%	28.6%	61.9%	63.2%	
Don't know	56.3%	18.5%	33.3%	64.3%	14.3%	21.1%	

The study group students had a piece of fair information regarding radiation dose associated with CT. Almost 21.6% of all study population mentioned that CT scan of the abdomen was equal to 300-1000 chest X-ray, while about 57.6% chose "I do not know". Students who established radiological education chose the right answer superior to those who were not educated. About 28.8% of the study population answered appropriately that CT is responsible for the greater part of the medical radiation exposure received by the population. The review of students' information regarding MRI and ultrasound principles give up the unsatisfactory outcome. Generally, students did not show good awareness regarding the method of MRI image production, with 33% of our study participants thoughts that MRI is responsible for about 15% of the population's receiving radiation dose. No students in the fifth and sixth stages thought that ultrasound was responsible for about 15% of the population's received radiation dose. In comparison to students not receiving radiological teaching, students who had received education/instruction in diagnostic radiology were unlikely to relate MRI or ultrasound with increased risk of cancerous diseases. About 28% of the medical students indicated that CT is associated with the most received radiation amongst the diagnostic imaging tools. (Table 4).

Table 4: General awareness of the study participants regarding the radiation exposure associated with diagnostic imaging examinations:

	first	second	third	fourth	fifth	sixth	P value
The radiation dose in abdominal CT is about equal to how many CXR?							**<0.001**
0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
20-50	6.3%	3.7%	0.0%	7.1%	0.0%	10.5%	
80-150	0.0%	22.2%	19.0%	0.0%	23.8%	10.5%	
300-1000	0.0%	3.7%	11.9%	14.3%	57.1%	52.6%	
10,000-20,000	0.0%	0.0%	2.4%	7.1%	0.0%	5.3%	
Don't know	93.8%	70.4%	66.7%	71.4%	19.0%	21.1%	
Clinical imaging accounts for about 15% of the population's received radiation dose. Which one of the following investigations is accountable for this dose?							**<0.001**
Ultrasound	0.0%	22.2%	11.9%	14.3%	0.0%	0.0%	
Chest x-ray	18.8%	37.0%	21.4%	21.4%	14.3%	15.8%	
CT	6.3%	7.4%	21.4%	21.4%	66.7%	57.9%	
MRI	25.0%	7.4%	11.9%	0.0%	4.8%	5.3%	
Lumbar spine x-ray	0.0%	3.7%	0.0%	7.1%	0.0%	0.0%	
Don't know	50.0%	22.2%	33.3%	35.7%	14.3%	21.1%	
How much radiation in mili Sieverts, mSv, is an individual exposed to, on average, each year, from natural background radiation?							**0.003**
0.24 msv	0.0%	14.8%	9.5%	7.1%	4.8%	5.3%	
2.4 msv	12.5%	22.2%	23.8%	21.4%	66.7%	36.8%	
24 msv	0.0%	7.4%	2.4%	0.0%	4.8%	10.5%	
30 msv	6.3%	0.0%	7.1%	0.0%	0.0%	0.0%	
Do not know	81.3%	55.6%	57.1%	71.4%	23.8%	47.4%	
In chest X-ray, what is the approximate radiation dose in mSv,?							**0.001**
0.02 msv	0.0%	0.0%	7.1%	7.1%	9.5%	15.8%	
0.2 msv	0.0%	14.8%	21.4%	7.1%	47.6%	47.4%	
2 msv	18.8%	18.5%	9.5%	7.1%	19.0%	0.0%	
20 msv	6.3%	3.7%	7.1%	7.1%	4.8%	0.0%	
Don't know	75.0%	63.0%	54.8%	71.4%	19.0%	36.8%	

When we asked which group is most sensitive to radiation, the majority of participants (48%), choose the right option which is children while 19% don't know the answer (Figure 1).

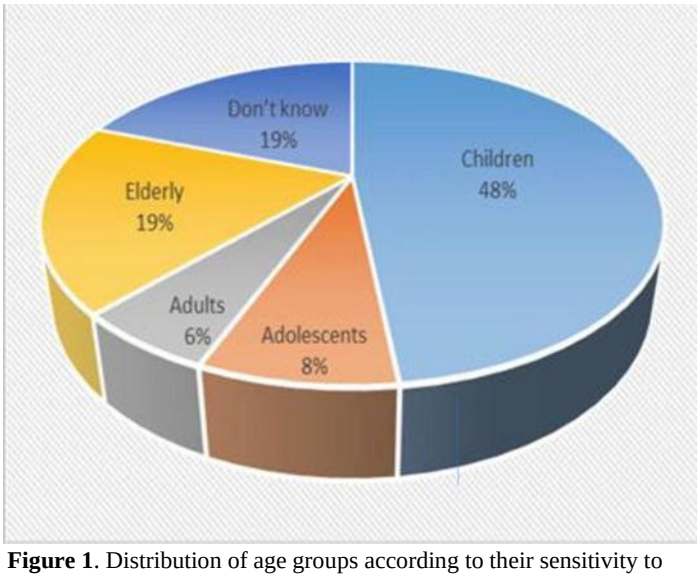

Figure 1. Distribution of age groups according to their sensitivity to radiation

Regarding the desired method of education, (32%) wanted a tutorial or workshops, (29%) learning module, (25%) case study, and only (14%) chose lecture (Figure 2).

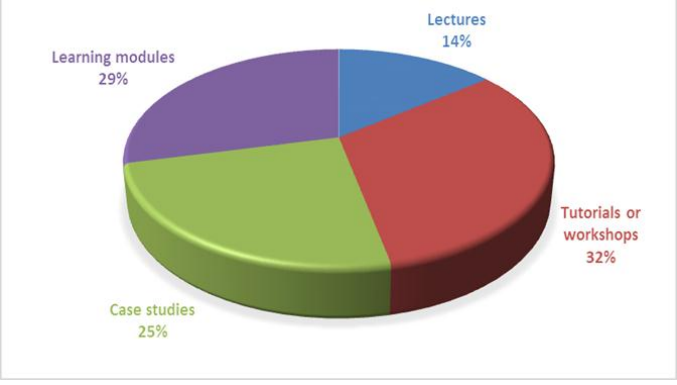

Figure 2. The desired method of education in radiology

Discussion

Everybody living in this world is being exposed to ionizing radiation. The European Council issued the Euratom instruction/directive in 1997 in an attempt to concentrate on radiation safety knowledge (4). This directive/instruction reported that medical radiation exposure must give way a good advantage to the patient and people in general. When clinical decisions are being made, the application of radiological tools using radiation to a lesser degree or if possible avoiding radiation should be considered. According to the directive, the medical students must learn what radiological tools use radiation and the estimated amount of radiation implicated so that they will be able to create suitable knowledgeable medical judgments. Our study revealed much significant deficiency in medical students' knowledge concerning vital points of radiation safety that must be appreciated when rising the medical college curriculum to meet great challenges in the future. Even though all medical students were exposed to a 6-year undergraduate integrated curriculum that included lessons in clinical radiology, their understanding, and knowledge of the fundamental ideas essential to radiation protection left much space for perfection. This may be to some extent clarified by the lack of a dedicated radiation safety module in the curriculum. Despite the lack of a formal radiation protection module, it was noted that students' awareness of radiation protection concerns enhanced year after year. Radiation safety training should be included as an essential part of a university's requirement. Proper knowledge about radiation dose and protective measures from ionizing medical investigations are vital constituents.

Our findings indicate that medical students near the end of their undergraduate careers tend to overestimate their knowledge of radiation protection. This is similar to other studies' findings (8,10,11). The majority of the population study demonstrates that the best way to raise their knowledge is through tutorials or workshops. This agrees with other studies (7,11-13). The study shows that the curriculum does not focus as much as necessary on radiation dose and related risks and protection. This issue is also mentioned in other studies (14-16).

Based on our results, we recommended that medical students (especially stages how do not receive enough education yet) need more teaching on radiation exposure and risk. The curriculum of medical college is the chief source for teaching the students regarding the safety measures of radiation. Hence, the incorporation of more radiation risk and protection education into the medical curriculum is an important concern. In addition, more instructive seminars, tutorials, or workshops may have impaction on the subject of radiation. Further studies are necessary to emphasize the importance of radiation harm and its protection. Awareness of the radiation hazards of radiological examinations can be raised among medical students.

Conclusion

This study concludes that the majority of medical students have insufficient information about radiation doses of common radiological tests, risks, and their protection. Misunderstanding about exposure risk was present among medical students that could potentially influence medical care judgments. Despite the newly increased sensitivity of the health society and radiology dealers towards building a stronger radiation protection background, more efforts are required to guarantee that radiation protection effectively becomes a crucial part of the professional skills of all healthcare contributors implicated. It is hoped that the conclusion and results from our study will aid give impulsion to enhanced referring medical students so that they may appropriately notify the patients and apply caution when requesting diagnostic radiological examinations. It is also anticipated that our study will encourage elevating awareness of the radiation risk among patients provided by the diagnostic radiology department so that they can be informed and play a vital responsibility in building judgments concerning their care.

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Conflict of Interest

No conflict of interest

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Al-Kindy College Medical Journal (KCMJ)

Research Article

Complications of Ponseti Technique in Treatment of Idiopathic Club Foot

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Keywords: Equinovarus, Clubfoot, Ponseti.

ABSTRACT

***Background*:** Clubfoot, or talipes equinovarus, is a congenital deformity that consist of; supination and adduction of the forefoot and midfoot; equinus of hindfoot and varus. It was found that more than 100,000 babies are born each year with congenital clubfoot

Objectives: The purpose of this study was to investigate the complications of ponseti method for treatment of children with idiopathic club foot.

***Subjects and Methods*:** 50 children with 74 clubfeet were managed by Ponseti method from May 2019 to July 2020 in Al-Wasity teaching hospital with primary correction of the deformity followed sometimes by elongation of Achilles tendon then the patients were followed up till June 2021 and the complications were calculated.

***Results*:** complications were 10.8% incomplete correction (mostly equinus) and it was corrected by surgery, 6.7% ulcer on the medial surface of head of 1st metatarsal, 9.4% cast falling and 18.9% relapse.

***Conclusions*:** Ponseti technique is a safe and effective method for correction of clubfoot and decreases the need for corrective surgery with minimal complications that can be easily managed.

Introduction

Clubfoot, or talipes equinovarus, is a congenital deformity that consist of supination and adduction of the forefoot and midfoot; equinus of hindfoot and varus. It was found that more than 100,000 babies are born each year with congenital clubfoot. most cases occur in developing countries. clubfoot causes crushing physical, social, psychological, and financial effects on the patients, their families, and the society. (1,2,3)

Club foot is an important cause of disability among congenital musculoskeletal defects. In developed countries, children with clubfoot frequently undergo extensive corrective surgery, with many failures and complications. Sometimes with one or more revision surgeries . Usually the foot looks better after surgery but it is stiff, weak, and often painful. In adolescence, pain usually increases and becomes crippling (3,4).

Clubfoot in can be corrected in 2 months or less with Ponseti tehnique of manipulations and plaster cast applications, with simple surgery. This was confirmed by the results of Dr. Ponseti 30-year follow-up study in 1995 and confirmed in many clinics around the world(5,6). At least 95% of club foot can be corrected without the need for extensive surgery if the treatment started soon after birth (7,8).

Subjects and Methods

During the period from May 2019 to July 2020, 50 patients with 74 club feet were enrolled in a prospective study, at orthopedic unit

in Al-wasity hospital using serial manipulation and casting guided by the ponseti principles. Patient age from 3 days to 1.5 years,(mean age 9.1 months) 36 patients were male and 14 were female. 23 patients were bilateral club foot, 28 patients were unilateral, 16 left, 12 right.

Inclusion Criteria: Patients with typical idiopathic congenital club foot with no other congenital abnormality.

Exclusion Criteria: All patients with other causes of club foot like spina bifida, arythrogryposis were excluded from the research.

The method: All babies were assessed clinically after explaining the method to the parents and taking their consent as following:

1. History: Pregnancy, Type of delivery and antenatal history, Neonatal history, Family history, Treatment to date, Address of the patient and phone no.
2. Examination: General examination .Orthopedic .. spine .. hips .. upper extremities - lower extremities
3. Scoring:The scoring system of pirani have been employed for all patients, each foot received a total score (TS), hind foot contracture score (HFCS) and mid foot contracture score (MFCS). This score was repeated weekly at each visit, helping us to :

asses the rate of progression of the correction .

guide us for further management e.g (if the child need tendoachilles tenotomy or need major postero-medial release).

4.Procedure: All components of the deformity were corrected in weekly step- wise as follows :

Midfoot cavus, results from pronation of the forefoot compared to the hind foot, corrected by supinating the forefoot in alignment with the hind foot; with the medial longitudinal arch well molded and the forefoot in some supination.

The foot was abducted gradually under the talus, which is prevented from rotation in the ankle by counter pressure with the thumb on the lateral aspect of the head of the talus; until the anterior part of the calcaneum is abducted from underneath the talus, heel varus will correct when the entire foot is fully abducted under the talus; the heel is never touched.

Finally, the equinus is corrected by dorsiflexing the foot; (15 -20 degree), any lack in proper dorsiflexion of the foot could be corrected by a percutaneous Ahilles tendon tenotomy under local or general anesthesia

Percutaneous Achilles tenotomy was done under general or local anesthesia (xylocaine infiltration) with systemic sedation (ketamin) in operative theatre, a small blade knife (gauge 11 or 12) was used to tenotomise the tendon, and the wound was so small that we didn't need to suture it.

For keeping the correction gained by manipulation or following Achilles tenotomy, a plaster cast is applied in 2 parts for one cast. The first part from the toes to just below the knee, and the second part from the knee to the thigh. The knee is placed at a right angle, with molding of the cast over bony prominences.

Correction of the foot is increased gradually with each manipulation and plaster cast application until hypercorrection to 70° of abduction is gained.

The period of casting ranged from (3-7) weeks prior to tenotomy if needed, then we need a further three weeks of casting before starting with the brace.

The one deformity that we failed to correct was equinus, so we used open elongation of Achilles tendon and posterior capsulotomy of ankle and subtalar joints to correct it.

None of our patients needed full posteromedial release. The number of casts needed to gain full correction of the deformity was used as an indicator for severity of the deformity.

When correction is obtained, a foot-abduction orthosis is used to keep the correction. This brace contains a bar with shoes attached at 70° of outward abduction on the affected side and 40° on the normal side. The distance between the heels should be equal to the width of the child's shoulders. The brace is worn for 23 hours for to 3 months and at night (12 hours) and during naptime (4 hours) till the time this thesis was prepared.

After that we start to follow the patients up as below;

2 weeks (for compliance issues), (noncompliance when the foot abduction orthosis was not worn for at least 10 hours a day).

2 months (to start the night and naps schedule).

Every 6 months till 13 months of age.

Results

During the period of treatment and follow-up our complications were:

Ulcer at the medial aspect of head of first metatarsal, 4 patient with 5 feet (6.7%), all above 6 months, (table 1) , (figure 1).

Table 1: (feet with and without ulcer)

	Number of feet	Percent
Feet with ulcer	5	6.7%
Feet without ulcer	69	93.3
Total	74	100%

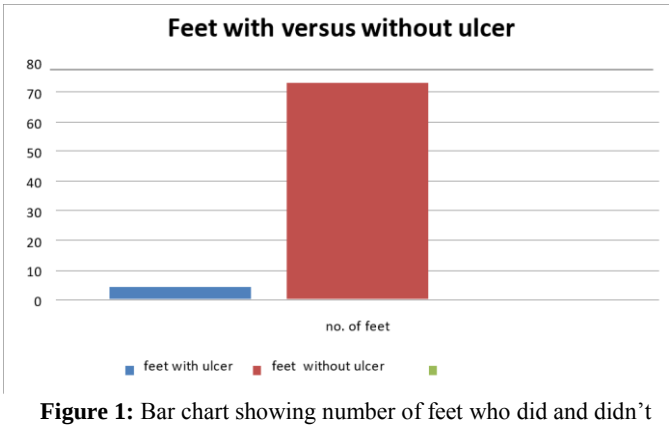

Figure 1: Bar chart showing number of feet who did and didn't develop ulcer

Cast falling4 patients with 7 feet (9.4%) , 2 cases with 3 feet were atypical club foot(short, stubby and stiff), (table 2) , (figure 2).

Table 2: (feet with and without cast falling)

	Number of feet	Percent
Feet with cast falling	7	9.4%
Feet without cast falling	67	90.6%
Total	74	100%

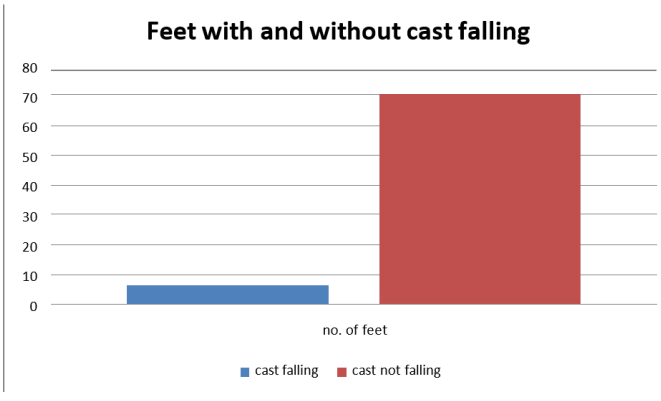

Figure 2: Bar chart showing number of feet with and without cast falling

Relapse Total of 10 patients with 14 feet (18.9%) had relapse , out of 6 noncompliant patients with 9 feet 5 patients with 6 feet (75%) had relapse, while of the other 44 compliant patients only 4patients with 6 feet (7.7%) had relapse , all above 3 months .

Relapse is defined as loss of abduction, dorsiflexion, recurrence of forefoot adduction or dynamic supination in toddlers any time after full correction which indicate poor compliance with the brace or muscle imbalance, (table 3), (figure 3).

Table 3: feet with and without relapse:

	Number of feet	Percent
Feet with relapse	14	18.9%
Feet without relapse	60	81.8%
Total	74	100%

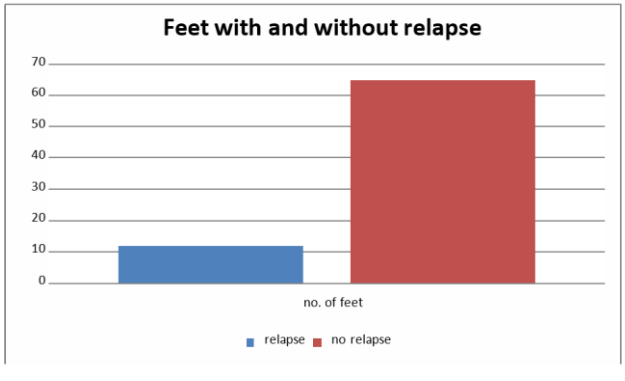

Figure 3: Bar chart showing number of feet with and without relapse

Incomplete correction were 5 patients with 8 feet (10.8%) (4 months – 1.5 years), incomplete correction is defined as inability to achieve 60-70 degrees abduction and 15-20 degrees dorsiflexion, (table 4).

Table 4: (feet with full and incomplete correction)

	Number of feet	Percent
Feet with full correction	66	89.2%
Feet with incomplete correction	8	10.8%
Total	74	100%

Discussion

Club foot is a serious cause of physical disability especially in developing nations , although treatable , many patients with this deformity undergo surgery ,leading to failures and complications , and may need for one or more revision surgeries , although the foot may look better after surgery , it is stiff , weak and painful from this observation Ponseti concluded that surgery is not the solution for children with club foot , so he started conducting his own method of serial manipulation and casting(9,10).

In this study we applied the Ponseti method for correction of idiopathic congenital club foot as it has not been used widely in our centers, we were careful in selecting patients with idiopathic congenital club foot and explained the whole program to the family before starting treatment.

The early results of this of this study demonstrate that with the use of the Ponseti method 91% of feet with idiopathic congenital club foot can be corrected with serial manipulation and casting .

Our result is a little bit lower than the result of Dr. Ponseti which was about 95%(11,12) , this may be due to our limited experience in the method , the level of education of the community which lead to less compliance of our patients with the method and less accurate follow up due the same reasons mentioned above.

The number of casts required to fully correct the deformity ranged from 3-7 casts, with the number of casts required increasing with older age and more severe stiffness of the foot, older patient have bigger, stiffer feet and more difficult to control during casting, younger patient with stiff feet also required more casts than patients of the same age which is comparable to the number of casts required by Ponseti (13,14).

We used Pirani score as a method of clinical assessment of the degree of the deformity, we found that it is a dependent measurement, it scores the amount of deformity and allows us document the progression of treatment (plotting), also it guides us to know when tenotomy is indicated (hindfoot score >1, midfoot score <1 and head of talus covered) and reassures the parents regarding progress (15).

Four of our patients (5 feet) developed ulcer on the medial aspect of head of first metatarsal due to pressure by the cast, all were above 6 months old, we think that in older patients the deformity is stiffer and more difficult to correct by casting, so lead to this pressure ulcer, all ulcers were treated easily by modification of technique (padding or opening a window in the cast).

We had 4 patients (7 feet) with the cast falling during the program, 2 of them (4 feet) had atypical club feet, they were managed by putting the cast in 120 degrees of knee flexion, and the other 2patients had cast falling due to poor hygiene by the mother.

We had 10 patients (14 feet) with relapse of the deformity, all above 3 months old, 6 had equinus and 4 equinovarus relapse, all were treated with serial manipulation and casting, then restarting the bracing protocol.

Our complications were comparable to those mentioned in the original paper published by Ponseti in 1995 (1,6,8,11) and to other recent publications.

The Ponseti method represents a complete protocol for the management of patients with club foot, including manipulation, casting, splintage, surgery and dealing with complications of treatment, so this method added greatly to other methods previously used.

Conclusion

Treatment of club foot still a challenge for many pediatric orthopedic surgeons, and knowing the pathology of the deformity is one the most important factors that can solve this problem.

The earlier the intervention of the deformity, the easier to correct it and the better the results.

We totally agree with those who dislike surgery as a primary treatment for idiopathic congenital club foot, because although surgery gives good anatomical correction (the shape of the foot), it has poor functional outcome (the foot is stiff and painful).

The Ponseti method is a safe and effective treatment for the correction of clubfoot that radically decreases the need for extensive corrective surgery, although the foot is not corrected as good as in surgery.

The minimal complications associated with Ponseti technique and the better functional results should encourage us to recommend this method as the standard in the primary treatment of congenital idiopathic clubfoot.

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Conflicts of interests

The authors declare that there are no conflicts of interest.

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Research Article

Cervical Pain Related to Position of the Neck during E-Learning

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Keywords: posture, Laptops, neck pain, smartphones.

ABSTRACT

***Background*:** During the pandemic, Corona virus forced many people, especially students, to spend more time than before on the computer and smartphone to study and communicate. The poor posture of the body may have worse effect on its body parts , most of which is the cervical spine (forward head posture).

***Objective*:** To assess the incidence of neck pain and the associated factors among undergraduate medical students related to position during E learning

***Subjects and Methods*:** Cross-sectional study was conducted among medical students in three Iraqi universities during 2021. The sample size was 152. Online questionnaire by Google forms sampling method were used to collect the data which was analysed using SPSS 25.

Results: The percentage of students who suffered cervical pain was (80.3%) of the 152 who participated in this study and the majority of those who suffered pain were complained from increase pain during the pandemic (72.1%). This study also showed the students recumbent on the floor 67 (44.1%) more than those who use the table and chair 62 (40.8%) during E-learning. The percentage of students who use the phone for more than 4 hours were (73.7%).

***Conclusion*:** there is a relationship between poor posture and cervical pain during E-learning in the pandemic. Most of students were suffering from neck pain with greatest percentage were in those who student in recumbent on the floor and when using chair and table.

Introduction

In 2020, the COVID19 cases arises in Iraq, which lead to the application of lockdown and social isolation has been imposed as one of the defensive actions to extent the coronavirus infection with economic burden in medical resources, quarantine measures, restriction of trade, disruption of production, loss of job, deteriorated finance, etc. (1)

The correct posture of the head occurs when the ears are located right above the shoulders with the chest open and shoulders back, thus stress on the neck is lessened since the head's weight is certainly well-adjusted on the cervical spine even the normal head weight about 10 to 13 pounds. (2) In poor position of the head, the lower cervical spine become hyperflexion with loss of the lordosis curvature of the spine and become flattening, this lead to hyperextension of the upper cervical and the lordosis becoming further obvious, this lead to more stress on the intervertebral discs, vertebrae, and facet joints. (2) Like sitting for prolonged periods of time in awkward positions in front of a computer for about 8 hours

per day in working office and additional 2-4 hours on their smartphones, (3) this poor neck posture can be associated with musculoskeletal disorders and physiologic dysfunction of the body.
Pain in the upper neck is typically arise from C2–3, and pain in the lower neck from C5– 6 and C6–7, resulting in somatic pain, dull, aching in nature pain, shooting pain (neurogenic origin) (4).
Global Burden of Disease (GBD) 2017 stated the musculoskeletal disorders is the second global debility illnesses (5). Neck pain can cause distress, debility, and decreased quality of life. (5,6) Undergraduate students represent a high incidence of neck and upper limbs pains up to 48-78%. (6,7)

Quick progress of communication, increasing custom of electronic devices like laptops, smartphones, tablets, have direct relation to severity of neck pain in general population especially in students. (7-9).

Pain is a main source of morbidity and debility in ordinary life and at work in several nations. It affects the person's physical, public, and emotional behavior with increase costs to society and businesses. (10-12) Neck pain also increase with aging especially in medium- and low-income countries. (13).

The cervical pain is the main musculoskeletal disorders in the adult account from 13.5% and 47%, with a complex etiology, like ergonomic factors (vigorous physical action, vibration, and poor position), individual factors (age, weight, and genome), behavioral factors (smoking), and psychosocial factors (occupation, stress, nervousness, and depression. (14-16).

There are a limited studies of the incidence of neck pain in medical students 12,13,14, and also in Iraq, which have focused on the musculoskeletal pain in undergraduate medical students.

Aim of this study is to assess the incidence of neck pain and the associated factors among undergraduate medical students related to position during E learning.

Subjects and Methods

This cross-sectional study was conducted among 152 medical students using an online questionnaire, focused on neck, shoulder pain in the past week and the past year during pandemic and depending on E-learning. Three universities were enrolled in this survey (University of Baghdad/AL-Kindy College of medicine, University of Almustansyria / College of medicine and University of Falluja/College of medicine). We included all medical students in these three medical colleges and excluded students with previous document cervical pain or surgery. The questionnaire including several parameters like demographics, site of pain. onset, character, radiation of the pain, associated symptoms, time /duration, any exacerbating and relieving factor, previous and the current neck pain symptoms, and potential risk factors (e.g., gender, age, study programs, electronic devices usage, study hours, sports participation, neck pain, stage of students, average use of mobile, using table, chair, etc., aggregated factor, consult doctor, smoking, and types of pillow use right, high or low).

Results

Regarding the sex , (52.63%) of students are females, while (47.37%) are males. (Fig. 1).

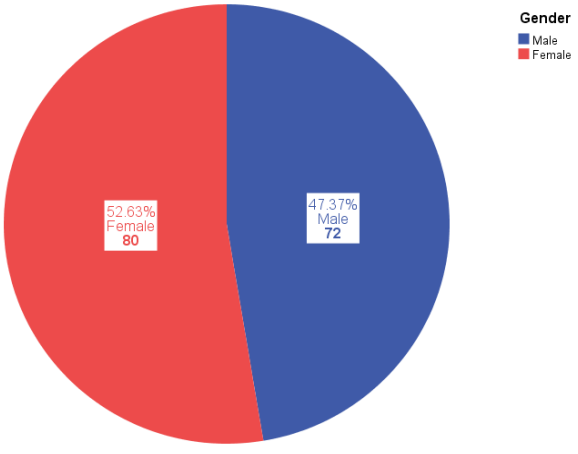

Figure (1): Gender distribution

The rate of recurrence of the pain among students of different stages, there were 77.8% of males suffering from neck pain, and 82.5% of females had a neck pain. (Tab 1)

Table (1): Show the frequency of pain among students of different stages

		Gender							
		Male 72 47.4%				Female 80 52.6%			
		Suffered from neck pain				Suffered from neck pain			
		Yes		No		Yes		No	
		56 77.8%		16 22.2%		66 82.5%		14 17.5%	
		No.	%	No.	%	No.	%	No.	%
Stage	First 9.2%	2	66.7%	1	33.3%	9	81.8%	2	18.2%
	Second 23.7%	15	100.0%	0	0.0%	15	71.4%	6	28.6%
	Third 34.2%	18	78.3%	5	21.7%	24	82.8%	5	17.2%
	Forth 16.4%	9	60.0%	6	40.0%	9	90.0%	1	10.0%
	Fifth 14.5%	10	71.4%	4	28.6%	8	100.0%	0	0.0%
	Sixth 2%	2	100.0%	0	0.0%	1	100.0%	0	0.0%
T.	152	72	47.4%			80.	52.6%		

Our result show that 75 of the students using pillow, more than half of them were suffering from neck pain only, other's pain was radiating to shoulders, either one or both of them. 53 of students are using low pillows, 21 of them has neck pain only, while 20 of them the pain was radiation to both shoulders. Who using high pillow were the least. (Tab. 2)

Table (2): Show the correlation between location of pain and pillow's heights

		Just right pillow 75 (49.3%)		**High pillow 24 (15.8%)**		**Low 53**	**Pillow (34.9%)**
		No.	%	No.	%	No.	%
The pain is	Neck only 77 (50.7%)	45	58.4	11	14.3	21	27.3
	Neck and radiate to one shoulder 31 (20.4%)	14	45.2	5	16.1	12	38.7
	Neck and radiate to both shoulders 44 (28.9%)	16	36.4	8	18.2	20	45.5

Table (3): Show the correlation between position of students during studying

				Neck pain			
				Yes 12280.3%		No 30 19.7%	
				No.	%	No.	%
Position during studying	Using chair and table 62 40.8%	Homework is	Just right	21	87.5%	3	12.5%
			Too much	24	82.8%	5	17.2%
			Not enough	8	88.9%	1	11.1%
	Walking 23 15.1%	Homework is	Just right	3	60.0%	2	40.0%
			Too much	10	71.4%	4	28.6%
			Not enough	4	100.0%	0	0.0%
	Lying on the floor 67 44.1%	Homework is	Just right	13	68.4%	6	31.6%
			Too much	34	85.0%	6	15.0%
			Not enough	5	62.5%	3	37.5%

The correlation between sitting position of students on chair/desk during studying and neck pain. We found that 62 of 152 were sitting on chair and table, 53 of them are suffering from neck pain and direct related to homework period time. 67 of the students were lying prone on the floor during study, 52 of them complaining from neck pain also. The students who were walking during studying were the least, also 12 students who using chair and table visit the doctor from neck pain, while 8 students visited the doctor who lying prone on the floor. (Tab. 3).

The correlation between the student's time during pandemic (habits) and neck pain summarize in (Tab. 4) , it obviously showed that 85 of students using mobile and 71 of them are suffering from pain in the neck ,and those who are reading were 48 student, 39 of them are having neck pain. The remains are the least.

Table (4): Show the correlation between position of students during studying

		Neck pain			
		Yes 122 80.3%		No 30 19.7%	
		No.	%	No.	%
During pandemic ,most of your time is	Reading 48 (31.6%)	39	81.3%	9	18.8%
	Using a mobile 85 (55.9%)	71	83.5%	14	16.5%
	Watching the TV 3 (2.0%)	3	100.0%	0	0.0%
	Other things 16 (10.5%)	9	56.3%	7	43.8%

The correlation between the daily average of using smart phone and neck pain summarized in (table 5). The students who using smart phone from 1 to 2 hours were 3.9% of total. From 2 to 4 hours were 34, about 75%of them were suffering from neck pain and the pain increase during pandemic, and those who using mobile more than 4 hours were the majority, 112 students, 65 of them were suffering from neck pain and pain increased during pandemic

Table (5): Show the correlation between the daily average of using smart phone and neck pain.

			Neck pain			
			Yes 80.3%		No 19.7%	
			Pain during E-learning		Pain increase during E-learning	
			Yes 88 72.1%	No 34 27.9%	Yes 11 36.7%	No 19 63.3%
Average daily of using smart phone	From 1 to 2 hours' daily 6 (3.9%)	No.	5	0	0	1
		%	100.0%	0.0%	0.0%	100.0%
	From 2 to 4 hours' daily 34 22.4%	No.	18	6	3	7
		%	75.0%	25.0%	30.0%	70.0%
	More 112 (73.7%)	No.	65	28	8	11
		%	69.9%	30.1%	42.1%	57.9%

The relation of neck pain and smoking, show that were 23 students have smokers, 15 of them, suffering from neck pain only, 4 in the neck and radiating to one shoulder, also 4 radiating to both shoulders. (tab.6).

Table (6): Show the correlation between neck pain and smoking

		Smoking				P value
		Yes 23	15.1%	No 129	84.9%	
		No.	%	No.	%	
The pain is	Only in the neck 50.7%	15	19.5%	62	80.5%	0.286
	Neck and radiating to one shoulder 20.4%	4	12.9%	27	87.1%	
	Neck and radiating to both shoulder 28.9%	4	9.1%	40	90.9%	

The associated symptoms with the neck pain, summarized in (Fig. 2). There are 98 student has a headache as result of neck pain, and 59 (39.6%) of students has a muscles weakness in the arm, 48 (32.2%) was suffered from stiffness of the neck

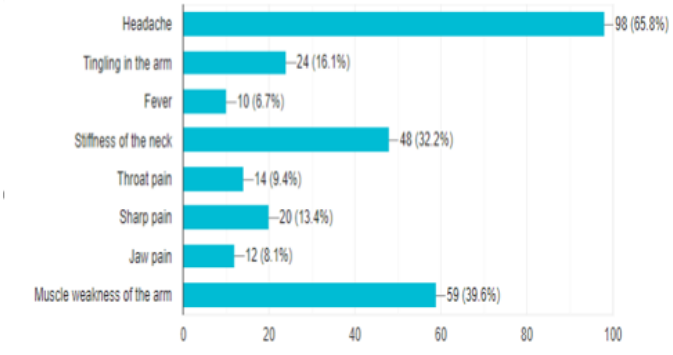

Figure (2): Show the associated symptoms with the neck pain

Discussion

Neck pain is a main source of morbidity and debility in ordinary, it affects the person's physical, public, and emotional behavior with increase costs to society and businesses, (10,11), Undergraduate students represent a high incidence of neck and upper limbs pains up to 17-28%. (7)

Regarding the gender (in table1), 72 males and 80 females, the result of asking about neck the result was as expected actually, 77.8% of males were suffering from neck pain, while in females was 82.5%. Our result is higher than the result done by T. T. W. Chiu et al 2002 (17), and same result by Laith Al-Ameri et al 2018. (18)

We also asked about the environment of student. So we started with sleep period; since humans spent third of their life's sleeping, everything affects sleeping will affect its life including the neck. (In table2), the questionnaire was about the heights of pillow, our results were unexpected, because 45 students suffering from neck pain without radiation to shoulders, with right (medium) height of pillow which may indicate harmful position during sleeping. The second majority were students who using low pillow, represented in 53 students with different location of pain, from neck to neck with both shoulders or one shoulder respectively. An approaching study was established, which results was an approach done by Gordon et al (2011), unsuitable cushion support has adverse effects on the cervical spine, leading to neck pain and headache, and disturbed sleeping. (19, 21)

The second environment after sleeping, is the position during studying. The results about this issue (in table3) show, that the majority of students lying on the floor (67) and using chair and table (62) for studying, most of them were suffering from neck pain with greatest percentage were in those who sitting on chair and table. Our result was similar to Faiza Sabeen et al. study 2013 (22) who state "Neck pain and computer users are direct relation due to prolong periods of sitting in a certain location with no disruptions to stretch the neck muscles because the neck bent onward, and thus shorting and tighten of the muscles in anterior aspect of the neck, while the muscles in the back of neck will grow longer and weaker. These changes will lead to development of neck pain", and also to study of Smith et al 2009 (23) who reported high prevalence of headaches and neck pain due to prolong sitting in fixed postures in front of computer or tables, and also done by Black et al 1996 (24), and Kang et al 2012 (25).

The free time of student during pandemic, since there is quarantine, there is more time being in the home and more and more of using smart phone or watching TV. The students that spent their time using smart phone was the great majority with 71 students ,83.5% of them were suffering from neck pain. This result was the same in above studies. Our result apposite to Bortuzzo et al study 2021. (26)

In (table 5), the great majority of student who suffering from pain and the pain increase was in those who using smart phone more than 2 hours, and thus a directed relationship between time of mobile usage and neck pain.

Table 6 show the correlation between smoking and the pain in the neck. The students who were smoking was only 23, 15 of them were suffering from pain, with 50:50 in those who's their pain was radiating to one shoulder and both. The smoking will damage blood vessels and thus affect the nourishment of the spinal discs, and from the microvasculature that line the endplates on either side of each disc and this may speed up the degenerative process. (27).

Last but not least, in figure2, the association factors which comes usually with neck pain, 98 students with a percentage of 65.8% in those who included in this research, was having a headache. This result corresponds to Bragatto et al 2019 (28).

Conclusions

Neck pain is not rare among undergraduate medical students. History of preceding neck pain during schooling makes a student prone for the current episode of pain. Academic stress, smartphone and laptop use tend to aggravate the pain in those who have neck pain.

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Al-Kindy College Medical Journal (KCMJ)

Research Article

Efficiency and Safety of Desferioxamine Chelation Therapy in Paediatric Patients with Transfusion-Dependent Anaemia: Experience of two Centers from Sudan

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Keywords: Transfusion dependent anemia, Iron chelation therapy, thalassemia, sickle cell anemia, Serum ferritin, desferoxamine.

ABSTRACT

***Background*:** Repeated blood transfusion is the main therapeutic option for transfusion-dependent anaemias with consequent iron overload and organ damage .Therefore iron chelating agents are important protective measures for these patients. The aim of this study was to investigate the efficiency and safety of Desferroxamine in paediatrics population subjected to iron overload as a consequence of repeated transfusion in a group of Sudanese children

***Subjects & Methods*:** This was a descriptive cross-sectional hospital based study. Conducted in two main paediatric reference hospitals in, Sudan. Within the period between November 2017 and April 2018 (6 months duration). The two centres were JaafarI bn- Oaf hospital and Albulk hospital. The study population included all patients of transfusion dependent anaemia who received desferrioxamine within the study period. Hundred patients were enrolled in the study. The study variables were demographic data, number of blood transfusions , serum ferritin pre and post blood transfusion and treatment of desferrioxamin

***Results*:** Sixty percent (60%) of the studied cases were males and 40% were females ,46% were thalassemic, 46% were sicklers, 5% aplastic anemia and 3% with red cell aplasia .The mean serum ferritin level before starting desferoxamine was 2.14 and after dessferoxamine was 2.48, P –value was highly significant. The most common side effect encountered was skin rash (36%)

***Conclusion*:** This study revealed some features of safety and efficiency of desferoxamine therapy in Sudanese paediatrics population affected by transfusion-dependent anemia. More studies are needed to describe this important health problem.

Introduction

Causes of transfusion dependent Anemias (TDAs) in paediatric population include thalassaemia , sickle cell anemia , aplastic anaemia and pure red cell aplasia (1). These entities pose global childcare challenges ,notably for thalassemia and sickle cell anemias , as both account for 3.4% of children death below the age of 5 years ((2) Repeated RBCs transfusion is the cornerstone for the management of TDAs , with the inevitable consequence of

iron over- load and the pathologic effect of iron deposition in different body organs inducing cardiac, hepatic damage and endocrinoapthies (1) . Therefore iron chelation therapy (ICT) is an essential component in the management of TDAs (2).

Most international guidelines on the management of TDAs indicated initiation of ICT after the transfusion of 10-20 Units of RBCs or when serum ferritin is greater than 1.000ng/ml (1)

Serum ferritin (SF) has been reported as the most important parameter in the diagnosis and follow-up of both iron deficiency and iron-overload disorders (3).

Serum ferritin measurement is well documented as a simple widely used index for assessing body iron status (4).

The overall goal for (ICT) in (TDAs) patients is to decrease the level of serum ferritin in order to protect against iron deposition induced organ damage (3).

The efficiency and safety of ICT in paediatric transfusion- dependent anemias (TDAs) has been well documented (5-9).

The aim of this study was to evaluate the efficiency and safety of desferroxamine therapy in Sudanese paediatric patients with TDAs and to explore the possible complications of iron overload.

Subjects and Methods

This was a descriptive cross-sectional hospital based study Conducted in two main paediatric reference hospitals in Sudan within the period between November 2017 and April 2018. The two centers were JaafarI bn- Oaf hospital and Albulk hospital.

The study population included all patients of transfusion dependent anaemia who received desferrioxamine within the study period and who were under the age 18 years old with complete medical records and whose guardians agreed to participate in the study .

One hundred patients were enrolled in the study using total coverage according to the inclusion criteria. The study variables included demographic data, number of blood transfusions , serum ferritin pre and post blood transfusion .

Statistical analysis was done by SPSS version 22. Descriptive data were displayed in tables . T- test, chi square test were used to compare between variables of the study. The P-value of 0.5 % or less is used to reject the null hypothesis .

Ethical approval was obtained from the ethical Committee board of the faculty of medicine ,Omdurman Islamic university Sudan . Written consent was obtained from the patients guardians.

Results

Twenty-eight 28% of the studied population were of 1-5 years old .42% between 6-10 and 30% between 11-18 years . 60% were males and 40% were females.

Forty –six 46% of the cases were thalassemics , 46% sticklers . Five (5%) were diagnosed with aplastic anaemia and 3% with red cell aplasia . Fifty-three(53%) of the patients were diagnosed before the age of one year ,44% diagnosed between 1-5 years old .3% diagnosed at 6-10 years old . Frequency of blood transfusion was shown in table (1)

Table 1: frequency of Blood transfusion in the population studied

Regular simple blood transfusion	69	69%
Regular exchange blood transfusion	0	0%
Both(regular simple and exchange)	19	19%
Not regular blood transfusion	12	12%
Total	**100**	**100%**

Distribution of patients according to serum ferritin before and after starting desferrioxamine therapy is show in tables (2&3)

Table 2: Serum ferritin levels before desferrioxamine chelation therapy

Sf level (ng/dl	No of cases	Percent
1000-2000	46%	46%
2000-3000	35	35%
3000-4000	6	6%
4000-5000	5	5%
5000- 6000	8	8%
Total	100	%100

Table 3: serum ferritin levels after desferrioxamine chelation therapy:

SF level (ng/dl)	No of cases	Percent
<500	9	9%
500- 1000	63	63%
1000-2000	15	15%
2000-3000	2	8%
3000-4000	8	8%
4000-5000	1	1%
5000-6000	2	2%
Total	100	100%

Fifty –nine (59%) of the cases started desferrioxamine therapy after the transfusion of 11-20 units of blood , 30% after 21-30 units ,10% of the studied cases started chelating therapy after being transfused 30 units ,less than 1% started desferioxamine after transfusion of less than 10 units of blood. Ninety-two(92%) of patients received 5 doses of desferrioxamine and 8% received less than 5doses . Ninety-one (91%) of the studied patients didn't report developing any side effects known to be related to desferioxamine therapy . Only 9% developed side effects shown in table (4).

Table 4:

Pattern of side effect due to desferrioxame chelation		
Skin rash	36	36%
GIT upset	14	14%
Red urine	14	14%
Tremor	22	22%
Injection site reaction	7	7%
Transient blurred vision	7	7%
Total	**100**	**100**

Eighty-six (86%) of the children care- givers reported awareness about the complications of iron overload, while 14% showed no awareness.

The mean difference of serum ferritin level before starting desferoxamine was 2.14 and after dessferoxamine became 2.48, P – value was highly significant, Shown in table (5).

Table 5: The mean difference of serum ferritin before and after starting desferrioxamine therapy

	Test Value = 0					
	t	df	Sig. 2 tailed	Mean differences	Confidence 95% Interval of the Difference	
					Lower	Upper
serum ferritin level before starting desferrioxame	14.289	99	0.000	2.14000	1.8428	2.4372
serum ferritin level after receiving desferrioxame	20.355	99	0.000	2.48000	2.2382	2.7218
P value 0.000 (highly significant)						

The relationship between serum ferritin before starting desferoxamine and age is shown in Table (6), p-value was significant.

Discussion

To the best of our knowledge, this is the first study to be conducted in Sudanese paediatrics population about the efficiency and safety of desferroxamine chelation therapy in patients with transfusion-dependent anemia.

We observed a significant difference of p value of 0.000 and 0.0347 respectively after and before starting chelation therapy.

Furthermore this study showed that only 9%of the studied group developed side effects of desferrioxamine, which were transient (skin rash, tremor, reddish urine color, gastrointestinal upset, and transient blurred vision)

These results were in agreement with Hassan MA et al, who evaluated iron chelation immunotherapy in transfusion-dependent beta-thalassemia major patients: a comparative study of deferasirox and deferoxamine (7&8).

As compared with a study reported by DeBaun et al which evaluated children with sickle cell anemia who receive regular blood transfusions (transfusion group) and standard care (observation group), and this showed the incidence of the primary end point in the transfusion and observation groups to be 2.0 and 4.8 events, respectively , per 100 years at risk, corresponding to an incidence rate ratio of 0.41 (95% confidence interval, 0.12 to 0.99; P=0.04),so regular blood transfusion therapy significantly reduced the incidence of recurrence of cerebral infarct in children with sickle cell anemia (10).

The study showed only 9%of patients developed side effects of desferrioxamine which were transient (skin rash, tremor, reddish urine color, gastrointestinal upset , and transient blurred vision) and most of the patients didn't report any side effects after receiving desferrioxamine, this indicate safety of the treatment, as compared with a study conducted by Sridharan K to compare the efficacy and safety of desferrioxamine (DFO), deferiprone (DFP), deferasirox (DFX) and Silymarin in patients with either thalassemia or sickle cell disorder through network meta-analysis and showed DFX/DFO was associated with better serum ferrintin levels compared to DFO, DFX, DFO/Silymarin and DFP/DFO. (11-12). as limitations to this study, study sample was small and the follow up duration was short.

Conclusion

This study revealed some features of safety and efficiency of desferoxamine therapy in Sudanese paediatrics population affected by transfusion-dependent anemias. Importantly, more studies including bigger sample reflecting the diversity of Sudanese population and investigating other aspects of the disease (e,g imaging, tissue biopsy and detailed blood indices) is needed to give a more detailed prospect about transfusion –dependent anaemia in Sudanese paediatrics patients.

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Conflicts of interests

The authors declare that there are no conflicts of interest.

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Research Article

Health-Related Quality of Life in Diabetic Women with Comparing Obese & Normal weight

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Keywords: Health Related Quality of Life, Diabetic women, Obese, Normal weight.

ABSTRACT

Background: The prevalence of both obesity & diabetes are increasing all over the world & more in women. They have a negative impact not only on morbidity & mortality but also on quality of life.

Objectives: To assess the HRQoL with a specific comparison between obese & normal weight among women with Type 2 Diabetes Mellitus.

Subjects and Methods: A cross sectional study was conducted among 814 diabetic women aged 18 to 45 years. Data collection was done by interview & SF36 questionnaire. A comparison for Physical Component Summary & Mental Component Summary scores were done on the base of their Body Mass Index.

Results: There was a significant difference score between obese & normal patients in PCS (p=0.001) & in MCS (p=0.009). The normal weight patients had significantly higher PCS mean (±SD), in strata of ; age (≤35,>35)=78.43(±8.80), 65.02(±17.9) /socioeconomic status (poor, fair) =69.96(±20.72), 67.50(±15.71) /marital status (single, married, divorced or widowed)=72.50(±14.81), 67.68(±17.44), 71.09(±16.79) /number of children (≤ 2 / >2) =68.66(±12.91), 69.64(±20.82) /smoking (smoker , nonsmoker) =72.50(±8.55), 68.44(±17.34) / duration of DM (5-10 year, >10 year) =67.68(±16.46), 70.27(±17.18)/complications of DM (one complication , > one complications) =71.12(±15.56), 77.91(±8.98)/treatment type (OHM, injection, both) =64.86(±18.87), 73.67(±14.49), 60.00 (±10.31)& regularity of visit (poor,fair,good) =66.25(±9.78), 60.31(±19.73), 72.63(±14.00). Also the same thing in MCS mean (±SD), in strata of; (SES) (poor) =72.11(±18.82), number of children (>2) =69.20(±19.66), smoking (smoker) =82.25(±11.50), duration of DM (>10 year) =67.55(±16.3), complications of DM (> one complications) =65.81(±10.17), & regularity of visit (poor) =59.86(±18.46).

Conclusions: Obese patients have a lower score as compared with normal weight patients in PCS & MCS.

Introduction

The worldwide obesity prevalence has increased to double since 1980 & tripled in developing countries last 20 years. In Arab Gulf countries, a significant increase in obesity among adult females with prevalence reaches up to 55% (1).

In Iraq, according to non-communicable disease (NCD) (NCD Risk Factors STEPS Survey, Iraq 2015), the prevalence of obesity among general women & men public was 42.6%, & 25.6% respectively (2). In 2016, the prevalence of obesity among adult (crude & age-standardized estimate) for female 33.8%, 37.0% & male 21%, 23.4% respectively, according to World Health Organization (WHO) (3).

At the same time, the number of diabetic adults has increased to fourfold all over the world since 1980 to 422 million, mostly living in developing countries (4). The Eastern Mediterranean Region Organization (EMRO) has the highest prevalence of diabetes in the world & there is 12% of the women with T2DM in the EMRO, which is the highest percentage of all WHO regions (5). Several studies were conducted in Iraq recently to estimate the prevalence of DM among population in general & women particularly, in 2015, a higher prevalence of DM (8.7%) was found among women as compared to (6.7%) among men (3) The International Diabetes Federation (IDF) reported that Iraq is considered as having a medium prevalence of DM in the Middle East (6) . The number of women at childbearing age are 1,874,123 million in Baghdad & 8,650,895 million in Iraq, according to annual statistic report of the ministry of health (7). The burden of obesity & DM on affected women health is unique & can be especially hard because they can affect mothers, their pregnancy, & child care as well as the risk of obesity & DM for the child in the future (8).

HRQoL is defined as an individual's subjective perception of both positive & negative aspects of life that are influenced by health status. It is a multidimensional concept that usually includes subjective evaluations of physical functioning, mental health, & social role functioning (9)

Any diabetic patient will consider the success of clinical care is meaningful only to the extent that they affect physical, emotional, & social well-being. Besides, healthcare providers realize that obesity & DM can affect the quality of life negatively. This perceived quality of life can strongly affect a patient's commitment to active DM self-management, which is the cornerstone of DM control (10).

In recent years, given the current overweight, obesity & DM epidemic, they are important to determine the impact of overweight & obesity on HRQoL of diabetic patients. HRQoL has been increasingly also recognized as an approach to health assessment , that if neglected, could lead to a lack of motivation for any effort required to improve optimal outcomes for all diabetic women & strengthen their capacity to prevent DM complications (11,12) .

Subjects and Methods

A cross sectional study with analytic components was conducted in the only two diabetic centers in Baghdad, the Specialized Center for Endocrinology and Diabetes in Al-Russafa side, and The National Center for Diabetes Research and Treatment in Al-Karkh side, Baghdad, Iraq, a convenient sample of diabetic women who met the criteria, from 1st November 2017 to 1st March 2018.Any woman between 18-45 years, (The participants in the study were obese and non-obese diabetic patients) diagnosed as T2DM and registered in the above two centers for at least one year with the complete data file & agree to participate in this study. Pregnant or lactating woman. Illiterate, woman with chronic diseases & receiving medications that interfere with body weight were be excluded

The sample size of this study was 814 diabetic women which was determined by using the following equation (13)

$$\text{Sample size } (n) = \frac{Z^2[P(1-P)]}{E^2}$$

- Z= 1.96
- P=Proportion = considered as 0.5 to increase sample size
- E= level of error= 0.05

The estimated sample size = 384. Final numbers were multiplied by 2 for valid comparison of both groups (obese and normal weight). 10% was added to the final number to address the problem of incomplete or insufficiently completed questionnaires.

Data was collected from each patient by direct interview, Patients' medical records & The SF-36 questionnaire (Arabic Version) of the health survey for quality of life measures were used (14-16). The validity & reliability of the Arabic version of the SF-36 questionnaire were assessed by several previous studies (17,18). This variable was measured after scoring SF-36 questionnaire items. It is a three steps process.

The first step, 36 items were labeled for 2, 3, 5 & 6 categorical answer which was scored (0-100), these numeric values are given to each answer for all items and recorded per the scoring given all items are scored. So that the lowest and highest possible scores are 0 and 100, respectively. A high score defines a more favorable health state. Scores represent the percentage of total possible score achieved

The second step, forming 8 domains from averaging items related to each domain after scoring items.

The third step calculation of PCS and MCS score.

HRQoL in (PCS) consists of four domains: Physical functioning, Role limitations due to physical health problems, Pain, General health. HRQoL in (MCS) also contains four domains: Energy, Social functioning, Role limitations due to emotional problems, Emotional wellbeing.

Domain scores represent the average for all items in the domain that the respondent answered (14,19,20).

The PCS & MCS were made & scored to achieve a number of advantage, in addition to reducing the SF36 from eight domains to two summary component without substantial loss of information. Each components summary scores were calculated by taking the mean for its related domains. Higher PCS & MCS scores indicate better health status.

Categorical classification of (PSC &MSC) into good, fair & poor was done as follow:

1- Good: patients with more than mean + 1 SD score.
2- Fair: patients with the mean ± 1SD score.
3- Poor: patients with less than mean - 1 SD score (21)

The analysis was done by:

Descriptive: Frequency & percentage. Mean & SD.

Analytic: Independent t-test for detecting the difference between the means of two independent groups.

ANOVA was used to detect the difference among the means of the three groups.

Binary logistic regression analysis was used. (95 % CI) was calculated by logistic regression to find the effect of each variable independently from others.

Bivariate analysis was used, to achieve the objectives of this study & compare the result of HRQoL in obese women with that of normal weight women,.

(To increase the validity of the results, & to overcome subjectivity of HRQoL measuring tool, variables with a highly significant (P value ≤0.01) difference / association were selected & considered as significant, & later on entered into the binary logistic equation.)

Results

Fig.1. shows that the prevalence of obesity, overweight & normal weight among those women were 52.6% (428 patients), 24.1% (196 patients) & 23.3% (190 patients) respectively,

Fair score was observed in 62% of PCS & 53% of MCS of patients

HRQoL (PCS, MCS) assessment among diabetic women

Regarding PCS, 62% of diabetic women have a fair score, good score constitute of 20%, and poor score constitute of 18%.

Regarding MCS, 53% of diabetic women have a fair score, good score constitute of 20%, and poor score constitute of 27%.

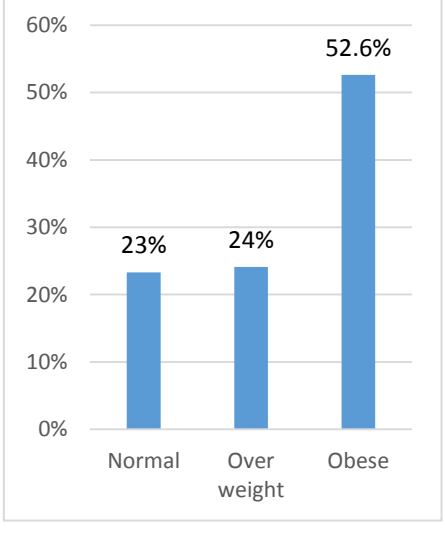

Figure1: Prevalence of obesity as compared to overweight

Tab.1. shows that, the obese patients had the lowest difference mean (±SD) significantly in comparison with the other two groups in the total study sample & Patients with; less than 35 years, good SES, less than 5 years duration of DM, no complications, good regularity of visit, single treatment either oral or injection had a higher score than their counterparts,

Table 1: The Physical Component Summary score of Health-related quality of life, Mean (±SD) scores according to variables classification of the study sample.

Variables		No	%	PCS scores M (±SD)	P-Value
Total		814		56.44 (±18.77)	
BMI	Normal weight	190	23.3	68.55 (±18.12)	0.001
	Overweight	196	24.1	55.92 (±18.93)	
	Obese	428	52.6	51.31 (±17.93)	
Age	≤35	116	14.3	69.02 (±19.34)	0.001
	>35	698	85.7	54.35 (±17.74)	
SES	Poor	370	45.5	54.19 (±17.33)	
	Faire	343	42.1	56.79 (±19.82)	0.001
	Good	101	12.4	63.50 (±19.79)	
Marital status	Single	42	5.2	64.34 (±19.30)	
	Married	688	84.5	56.02 (±18.84)	0.058
	Widow& divorced	84	10.3	55.98 (±16.25)	
Number of children	No children	94	11.5	59.35 (±19.69)	
	≤ 2 child	202	24.8	58.73 (±19.73)	0.054
	> 2 child	518	63.6	55.02 (±19.27)	
Smoking	Smoker	45	5.5	49.66 (±16.43)	0.045
	Nonsmoker	769	94.5	56.84 (±19.62)	
Duration of DM	<5years	292	35.9	60.07 (±19.21)	
	5-10years	351	43.1	54.17 (±19.80)	0.002
	>10years	171	21.0	54.90 (±19.98)	
Complications of DM	No complication	432	53.1	61.46 (±18.81)	
	One complication	275	33.8	52.93 (±18.67)	0.001
	More than one complications	107	13.1	45.21 (±18.53)	
Treatment type	OHM	421	51.7	58.53 (±18.17)	
	Injection	235	28.9	58.61 (±19.55)	0.001
	Both	158	19.4	47.65 (±19.62)	
Regularity of visit	Poor	101	12.4	53.16 (±18.32)	
	Faire	312	38.3	55.43 (±19.56)	0.002
	Good	401	49.3	59.11 (±18.96)	

Tab.2. shows that, the obese patients had the lowest difference mean (±SD) of MCS scores significantly in comparison with the other two groups in the total study sample. The comparison of MCS HRQoL scores according to study variables (age, SESI, marital status, number of children, smoking, duration of disease, complications, treatment type & regularity of visit) revealed a statistically significant difference with strata of complications of DM & regularity of visit. Patients with no complications of DM, or with a good regularity of visit had a higher score than their counterparts.

Table 2: The Mental Component Summary score of Health related quality of life Mean (±SD) scores according to variables classification of the study sample

Variables		No	%	MCS scores M (±SD)	P-Value
Total		814		61.28 (±19.06)	
BMI	Normal weight	190	23.3	65.57 (±19.62)	
	Over weight	196	24.1	61.85 (±18.11)	0.002
	Obese	428	52.6	60.47 (±17.99)	
Age	≤35	116	14.3	65.02 (±20.02)	0.06
	>35	698	85.7	60.66 (±18.44)	
SES	Poor	370	45.5	60.93 (±19.97)	0.37
	Faire	343	42.1	60.86 (±18.91)	
	Good	101	12.4	64.03 (±17.92)	
Marital status	Single	42	5.2	63.17 (±16.61)	0.74
	Married	688	84.5	61.31 (±19.52)	
	Widow& divorced	84	10.3	60.11 (±19.31)	
Number of children	No children	94	11.5	57.93 (±18.87)	0.22
	≤ 2 child	202	24.8	62.44 (±19.33)	

Variables		No	%	MCS scores	P-Value
	> 2 child	518	63.6	61.44 (±18.91)	
Smoking	Smoker	45	5.5	56.94 (±20.42)	0.15
	Nonsmoker	769	94.5	61.54 (±18.90)	
Duration of DM	<5years	292	35.9	62.67 (±20.21)	0.37
	5-10years	351	43.1	60.45 (±19.66)	
	>10years	171	21.0	60.62 (±16.95)	
Complications of DM	No complications	432	53.1	64.16 (±19.77)	
	One complications	275	33.8	59.25 (±19.54)	0.001
	More than one complications	107	13.1	54.89 (±18.09)	
Treatment type	OHM	421	51.7	62.69 (±18.82)	0.04
	Injection	235	28.9	61.27 (±19.51)	
	Both	158	19.4	57.57 (±18.71)	
Regularity of visit	Poor	101	12.4	58.33 (±16.50)	
	Faire	312	38.3	58.42 (±17.06)	0.001
	Good	401	49.3	64.01 (±19.82)	

In order to predict the effect of study variables on the HRQoL score (as an outcome), a binary logistic regression analysis was used. Only variables that appeared to have a highly statistical significant difference ($p = \leq 0.01$) in mean of PCS & MCS scores between different variables strata.

Tab. 3.shows that, the normal BMI (OR=0.365; P=0.001; 95% CI for OR=0.230-0.579), age with less than 35 years (OR=0.135; P=0.001; 95% CI for OR=0.047-0.388) & with no complications (OR=0.295; P=0.001; 95% CI for OR=0.157-0.553) were found to be protective factor against poor PCS of HRQoL. The patients with poor SES (OR=2.497; P=0.001; 95% CI for OR=1.423-4.382) & poor regularity of visit (OR=2.945; P=0.001; 95% CI for OR=1.476-5.873) were found to be positively associated with poor PCS of HRQoL. In this multivariate analysis, duration of DM (P=0.282) & treatment type (P=0.140) were not found to be a significant associated with the PCS of HRQoL, after adjustment of other variables.

Table 3: Binary logistic regression for Physical Component score with significant study variables

Variables	AOR	(95% C.I.)		P-Value
BMI	0.365	0.230	0.579	0.001
Age	0.135	0.047	0.388	0.001
Complications of DM	0.295	0.157	0.553	0.001
SES	2.497	1.423	4.382	0.001
Regularity of visit	2.945	1.476	5.873	0.002
Duration of DM	1.374	0.770	2.452	0.282
Treatment type	0.656	0.374	1.148	0.140

Tab.4. shows that, The patients with no complications (OR=0.502; P=0.001; 95% CI for OR=0.344-0.732), among diabetic women was found to be a protective factor against poor MCS of HRQoL.In this multivariate analysis, BMI (P=0.1) & regularity of visit (P=0.032) found to be not a significant associated with MCS of HRQoL after adjusting of the variables.

Table 4: Binary logistic regression for Mental Component score with significant study variables.

Variables	AOR	(95% C.I.)		P-Value
BMI	0.800	0.614	1.044	0.100
Complications of DM	0.502	0.344	0.732	0.001
Regularity of visit	1.655	1.04	2.453	0.032

Tab.5 shows that, after categorization of PCS scores to obese and normal weight values, (Bivariate analysis) there was a statistically significant difference, between normal weight & obese patients who had a higher score, in PCS the normal weight patients had statistical significantly higher PCS score in all variable's classification except in patients with; good SES, had no children, with less than 5 years of DM duration or had no complications.

Table 5: The difference between Physical Component Summary scores Mean (±SD) scores in obese and normal weight women according to study variables.

Variable		Normal weight		Obese		95% CI of difference		P-Value
		No	PCS M (±SD)	No	PCS M (±SD)	LL	UL	
Total no=618		190	68.55 (±19.12)	428	51.31 (±17.93)		0.001	
Age	≤35	50	78.43 (±8.80)	46	61.65 (±19.69)	10.46	23.09	0.001
	>35	140	65.02 (±17.9)	382	50.06 (±19.88)	11.24	18.67	0.001
SES	Poor	80	69.96 (±20.10)	198	46.96 (±20.72)	17.63	28.35	0.001
	Faire	75	67.50 (±15.71)	188	53.90 (±19.39)	8.77	18.40	0.001
	Good	35	67.58 (±12.04)	42	60.14 (±19.40)	-0.30	15.18	0.059
Marital status	Single	20	72.50 (±14.81)	18	53.33 (±16.99)	8.69	29.63	0.001
	Married	150	67.68 (±17.44)	368	51.70 (±19.20)	12.37	19.59	0.001
	Widow& divorced	20	71.09 (±16.79)	42	46.99 (±19.34)	13.22	34.97	0.001
Number of children	No children	40	66.17 (±15.47)	36	56.14 (±15.46)	-1.53	18.51	0.041
	≤ 2 child	70	68.66 (±12.91)	88	53.82 (±19.70)	9.34	20.33	0.001
	> 2 child	80	69.64 (±20.82)	304	50.01 (±17.98)	14.26	25.00	0.001
Smoking	Smoker	5	72.50 (±8.55)	28	47.67 (±19.14)	16.23	33.40	0.001
	Nonsmoker	185	68.44 (±17.34)	400	51.56 (±17.92)	13.57	20.18	0.001
Duration of DM	<5years	90	63.12 (±19.96)	146	52.40 (±17.16)	-1.23	22.67	0.078
	5-10years	85	67.68 (±16.46)	174	47.09 (±18.57)	15.81	25.36	0.001
	>10years	15	70.27 (±17.18)	108	55.53 (±18.42)	9.75	19.74	0.001
Complications Of DM	No complications	130	57.98 (±18.96)	198	52.29 (±19.00)	-1.44	12.81	0.11
	One complication	45	71.12 (±15.56)	156	54.94 (±18.62)	12.14	20.23	0.001
	More than one complications	15	77.91 (±8.98)	74	39.51 (±18.57)	32.01	44.79	0.001
Treatment	OHM	95	64.86	234	54.86	5.15	14.84	0.001

Variable		Normal weight		Obese		95% CI of difference		P-Value
type			(±18.87)		(±16.76)			
	Injection	85	73.67 (±14.49)	84	46.96 (±17.65)	21.28	32.14	0.001
	Both	10	60.00 (±10.31)	110	47.06 (±20.04)	8.315	17.54	0.001
Regularity of visit	Poor	25	66.25 (±9.78)	48	51.53 (±19.76)	7.08	22.34	0.001
	Faire	50	60.31 (±19.73)	172	50.52 (±18.99)	2.53	17.05	0.008
	Good	115	72.63 (±14.00)	208	51.91 (±16.90)	16.88	24.56	0.001

Tab.6. shows that, after categorization of PCS scores to obese and normal weight values, (Bivariate analysis)

There was a statistically significant difference, between normal weight & obese patients who had a higher score, in MCS

Poor SES, more than 2 children, smoker, more than10 years of DM duration, more than one complication and poor regularity of visit found to have statistically significant higher scores of MCS among normal weight than obese patients.

Table 6: The difference between Mental Component Summary scores Mean (±SD) scores in obese and normal weight women according to study variables

Variables		Normal weight		Obese		95% CI of difference		P-Value
		No	MCS M (±SD)	No	MCS M(±SD)	LL	UL	
Total No = 618		190	65.57 (±18.62)	428	60.77 (±18.99)		0.009	
Age	≤35	50	69.99 (±20.87)	46	61.50 (±16.13)	-0.90	17.88	0.07
	>35	140	63.98 (±18.72)	382	60.69 (±15.00)	-0.66	7.26	0.10
SES	Poor	80	72.11 (±18.82)	198	56.22 (±19.11)	10.54	21.22	0.001
	Faire	75	59.58 (±18.48)	188	63.94 (±18.64)	-9.89	1.18	0.12
	Good	35	63.43 (±19.02)	42	68.06 (±17.43)	-13.35	4.09	0.29
Marital status	Single	20	62.93 (±15.04)	18	62.23 (±19.91)	-10.83	12.24	0.90
	Married	150	65.97 (±19.21)	368	61.04 (±18.22)	-0.89	8.96	0.037
	Widow& divorced	20	65.15 (±19.60)	42	57.80 (±19.50)	-3.62	18.32	0.18
Number of children	No children	40	55.89 (±17.87)	36	62.82 (±17.41)	-15.68	1.81	0.11
	≤ 2 child	70	66.95 (±19.67)	88	62.98 (±18.18)	-2.62	10.56	0.23
	> 2 child	80	69.20 (±19.66)	304	59.89 (±17.28)	4.12	14.48	0.001
Smoking	Smoker	5	82.25 (±11.50)	28	51.78 (±20.22)	20.30	40.63	0.001
	Nonsmoker	185	65.11 (±18.71)	400	61.40 (±17.46)	-0.12	7.29	0.05
Duration of DM	<5years	90	66.42 (±20.43)	146	63.29 (±19.44)	-2.89	9.15	0.30
	5-10years	85	62.27 (±19.68)	174	49.16 (±18.22)	-23.76	12.45	0.036
	>10years	15	67.55 (±16.3)	108	57.73 (±17.24)	5.19	14.44	0.001
Complication of DM	No complication	130	68.24 (±20.68)	198	62.49 (±19.43)	-1.06	10.45	0.036
	One complication	45	57.75 (±19.34)	156	61.23 (±19.81)	-10.21	4.24	0.30
	More than one complication	15	65.81 (±10.17)	74	55.23 (±19.55)	3.26	17.90	0.006
Treatment type	OHM	95	66.89 (±19.29)	234	62.88 (±17.60)	-1.03	9.06	0.11
	Injection	85	64.46 (±17.98)	84	58.94 (±19.73)	-0.54	11.58	0.07
	Both	10	62.37 (±20.95)	110	57.69 (±18.91)	-14.11	23.47	0.59
Regularity of visit	Poor	25	59.86 (±18.46)	48	50.63 (±20.05)	8.92	11.54	0.001
	Faire	50	60.26 (±20.36)	172	60.29 (±18.09)	-8.14	8.45	0.99
	Good	115	69.50 (±17.98)	208	61.26 (±17.17)	-2.74	13.21	0.68

Discussion

HRQoL is an important outcome measure for chronic disease, burden & evaluation of efficacy intervention & has received increasing attention. T2DM is considered an important chronic disease. Obesity is one of the well-known adjustable risk factors, not only associated with about 80% of diabetics but also may modify HRQoL of patients (22).

Early onset of obesity in individuals had a higher risk of developing T2DM compared to older, (23). In our study showed that 52.6% & 24.1% of diabetic women were obese & overweight respectively, this means that 76.7% of the study sample had BMI ≥ 25 kg/m2.The above prevalence of obesity is higher than the prevalence of obesity among women in the general population in Iraq. According to NCD Risk Factors STEPS Survey, Iraq 2015, the prevalence of obesity among general women public was 42.6% (2). Several other studies, approximately agreed with this study. In Iran in 2016, (24) & Saudi Arabia in 2013 (25).This finding partially agreed with two national studies conducted on diabetic adults in Basra/Iraq, (26, 27).

HRQoL is an important patient-reported outcome in the DM study. Poor HRQoL is related to worse outcomes in diabetic patients, including poor response to treatment, disease progression and cardiovascular disease (28).The current study showed that the majority of diabetic women had a fair HRQoL score. Although there are many studies assessed the HRQoL of diabetic patients, most of these studies used different tools & methods. But the outcome of all these studies are a measurement of HRQoL among their studies sample, so the result of some studies might not directly match our result. In comparing with two national studies conducted in Iraq, the first one was done in Mosul & showed that the highest percentage of diabetic adults had a good score for a physical domain 42% & for a psychological domain 43% for total sample. But this national study showed that the highest percentage of diabetic women for the physical domain 42.6% was a poor score & for a psychological domain 36.6% was a fair score. The researcher concluded that quality of life of patients with T2DM was fair to good. T2DM, significantly affected the physical domain especially in females (29). The other study that was done in Hilla, found the same result of Mosul study (21). In a study done in Iran in 2016, among women with T2DM, the results showed that their HRQoL ranged from low to moderate level (24). A study was conducted in India in 2017 also found that most diabetic adults had a moderate quality of life score (28).

The discussion of this study´s variables was done based on the result of (logistic regression), in order to have an adjustment for the effect of these variables & have a valid conclusion about exposure and outcome. Only five variables (age, BMI, SES, complications, regularity of visit) were significantly associated with PCS & only one variable (complications of DM) was significantly associated with MCS. In the current study, there was a significant negative association between BMI & PCS, but not associated with MCS of HRQoL. This might explain to the effect BMI more on the musculoskeletal system of women, & at the same time, there was

psychological & social adjustment capacity in most patients, although, physical dysfunctional exists (30).This finding was supported by studies that were conducted on the general population as, in Beirut Arab University 2018, (31) & Iran 2013(32).

In DM patients, there was variation in studies around the world about the association of BMI with PCS & MCS. In German 2012, a cross-sectional study included T2DM patients with BMI≥25 kg/m2, found that BMI had negatively associated with both PCS & MCS (33).

While in studies conducted in Botswana 2018 (34), India 2017 (28) they found that there was no association of PCS & MCS or all domains of HRQoL with BMI among diabetic patients. Also, no association of BMI with HRQoL domains among diabetic women of all ages was found in a study in Iran conducted 2016. (24) This might be explained due to different methodology & sampling technique used in these studies or different socio cultural environments of these countries & includes both genders with different age or using different tools for measuring HRQoL. (34) While in Iranian study, might be explained due to a high prevalence of obesity & overweight among women may lead to disappearing effect of BMI.

Complications of DM are the most powerful variable influencing HRQoL. Diabetic patients, especially those with complications have a poor HRQoL & increased risk of mortality (28,35,36). The above result as, the presence of DM complications were associated with both PCS & MCS, agreed with a number of another studies that were conducted among diabetic patients, in Botswana 2018 (34), south India 2017 (28) & UAE 2011 (35). The explanation for this finding is that, as diabetic patients with time have more complications, this would lead to deteriorating their health by changing health behaviors, treatment commitment plans, & lowering patient's ability to self-care. And patients of multiple complications are more likely to receive multiple, but mostly ineffective care.(36).

Our study had been found that age was negatively associated with only PCS, but not MCS of HRQoL. This result agreed with several studies conducted among diabetic patients like, in Botswana 2018, (34) & Delhi in 2017 (28). Our finding disagreed with study Lithuania 2013, (37).

Obesity & T_2DM have increased in all socio-demographic categories (38). The current study found that SES was positively associated with only PCS. This might be explained by the vital role of SES in improving the quality of life of not only DM patients but in the general public. This result is in agreement with a study done in Egypt 2016. (39) Other two studies were conducted among diabetics in India and found that the total lower HRQoL score had a significant association with lower SES (40, 41).

The current study found that there was a significant positive association between regularity of visit with only PCS. This might be explained that patients with good regular visits have better glycemic control & hence, less risk of complications. Hu M. & his colleague found that frequent follow-up visit was associated with better quality of life & clinical indicators of T2DM patients (42). But this finding disagreed with two studies that were done in Iran 2016 & in Singapore 2011 (24,43).

In Comparison of HRQoL between Normal weight and Obese Diabetic Women, there was a significant difference in the mean score of PCS among most of variables´ strata. The obese patients had a significantly lower difference means as compared to normal weight in all variable's strata, except for good SES, had no children, less than 5 years duration, and had no DM complications. This might clearly high light the effect of obesity among most of the strata of variables on PCS. Good SES, means the availability of good conditions from all aspects as, education, occupation, own property, and lead to an improvement in HRQoL of patients. Having no children leads to decrease duties on woman & have more time for self-care. (44) DM duration of less than 5 years, and the patients have no complications, mean a good DM control (35,45) & hence, less impact on the physical component of HRQoL. These strata may have a positive impact on general health that reduces the effect of obesity on PCS of HRQoL.

On the contrary, there was no significant difference in the mean score of MCS of HRQoL among most of variables strata. This might high light that there is less effect of obesity on MCS not only among the variables but also among the different strata of that variables.The few significant strata of this study´s variables were poor SES, having more than 2 children, smoker, more than one complications & poor regularity of visit, found to have a significant difference between obese & the corresponding strata in normal-weight women.Poor strata in MCS were found to have more impact on MCS score. This might be explained to the association of poor SES with more challenges in different life aspects in providing the needs of life, which add further burden on the affected women (46).

The other significant strata with MCS further highlighted the impact of stress, workload & eventually difficulty to cope with a daily need. This may give additive effect with obesity that led to a decrease in the mean score of MCS HRQoL

Conclusion

The prevalence of obesity & overweight among diabetic women is high. PCS & MCS, of diabetic women have a fair score; Diabetic patient with no complications is a significant associated with increase MCS score of HRQoL. It is the only factor that affects both PCS & MCS of HRQoL. Obese diabetic women have significantly lower scores as compared to normal weight patients in both PCS & MCS.

Obese patients have a significantly lower difference means of PCS in all variables strata, except for good SES, had no children, less than 5 years duration, and had no DM complications.

There are no significant differences in the mean score of MCS among most of variables strata between obese & normal weight patients, except for poor SES, having more than 2 children, smoker, more than 10 years duration, more than one complications & poor regularity of visit.

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Conflict of Interest

No conflict of interest

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Al-Kindy College Medical Journal (KCMJ)

Research Article

Detection of Parvovirus B19 DNA in pregnant Sudanese women attending The Military hospital using Nested PCR technique

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Keywords: Human parvovirus B19, Nested PCR, erythema infectiousum, stillbirth, non-immune hydropsfetalis, haemoagglutination, TAE buffer.

ABSTRACT

***Background*:** Parvovirus B19 is a human pathogenic virus associated with a wide range of clinical conditions. During pregnancy congenital infection with parvovirus B19 can be associated with poor outcome, including miscarriage, fetal anemia and non-immune hydrops.
***Objective*:** The study aimed to determine the prevalenceof Parvovirus B19 DNA in pregnant women attending the Military hospital in Khartoum, demonstrating the association between the virus and poor pregnancy outcomes.
Subjects and methods: This study was a cross sectional study, testing pregnant Sudanese women whole blood samples (n= 97) for the presence of Parvovirus B19 DNA using nested PCR technique.
***Result*:** Two samples were found positive for Parvovirus B19 DNA out of the total number of samples screened.
***Conclusions*:** The prevalence of Parvovirus B19 DNA among pregnant women attending the Military hospital was 2.1%.

Introduction

Human parvovirus (B19V) was first described in 1975(1). The structural proteins determine many of the biological properties of the virus, including binding to cell receptor, haemoagglutination and induction of neutralizing responses (2). NS1 is an activating transcription factor for the single promoter of B19. In addition, NS1 nicks the replicative form of the viral genome at the origin of replication, allowing for replication of the viral DNA (3). Noscomial transmission has also been documented. The incubation period of the infection ranges from four to 14 days but can last as long as 21 days (4).

Although vaccine development has shown promising initial results, there is no currently vaccine available against parvovirus B19 (5).

Infection with parvovirus during pregnancy is not associated with increased risk of fetal malformation. However, infection during pregnancy is an important cause of intrauterine fetal death, stillbirth, and non-immune hydropsfetalis(6).

The fetus is particularly vulnerable to B19 infection because it has a rapidly expanding red-cell volume and relatively short red cell life span and because it may be unable to mount an effective immune response (7). The first association between parvovirus B19 infection in pregnancy and poor outcomes was reported in 1984, when hydropic fetuses were shown to have anti-B19 immunoglobulin M (IgM) (8). By increasing gestation age, the incidence of infection and fetal death decrease. If the mother has B19-specific antibodies, immunoglobulin G (IgG) against the virus, there will be no possibility of virus transition to the fetus (9).

In early studies, acute B19 infection was determined by demonstrating virus in serum by counter current immunoelectrophoresis (CIE) and immune electron microscope (IEM), tests that require serum specimens to be collected during the initial phase of infection when viral titer is high(10). In vitro the virus can be cultured in some erythromegakaryoblastoid cell lines, but replication is very inefficient (11).

Although B19 can be detected in serum by electron microscope (EM), B19 antigen enzyme linked immune sorbent assays (ELISA), and even hemoagglutination, B19 virus is usually detected by isolation of viral DNA by direct hybridization or Polymerase chain reaction (PCR) (12).The sensitivity of DNA hybridization tests can be increased by amplification of either target or the detector system. The most widely used method is amplification of the target by the polymerase chain reaction (13).

There is no much published data concerning the determination of the prevalence of parvovirus B19 among Sudanese pregnant women using nested PCR, in a study conducted by Adam. et al in Sudan (2015), which was based on serology and B19 DNA was not detected in any of the samples (14), another study conducted by Maksheed M. et al in Kuwait (1999) (15), which was also based on detecting B19 antibodies only. In addition to a study conducted by Barros De Freitas in Brazil (1999) which detected B19 DNA in only one mother(16), and B19 antibodies were also detected in pregnant women under different gestation trimesters by Mirambo MM. et al in Tanzania (2017) (17).

Subjects and methods

This study is across-sectional study conducted in the Military hospital, Khartoum state during the period from August 2020 – August 20221. According to the hospital's annual patient's records and the statistical equations, a sum of 97 samples was selected as a sample size. Probability sampling type and simple random sampling technique were applied. A minimum of 2ml venous whole blood samples were collected in EDTA containers from each of the pregnant women participating in the study.

DNA extraction:

DNA was extracted from whole blood samples using the chemical method, Guanidine Chloride Method using Roche High Pure kits.

Polymerase chain reaction:

To detect parvovirus B19 DNA, the virus B19 VPI coding gene was amplified using nested PCR employing two sets of outer and inner primers pair;

1.The outer primers pair were;(P1) 5'-CAAAAGCATGTGGAGTGAGG-3'(sense), (P2)5'-CTACTAACATGCATAGGCGC-3'(antisense).

2.The inner primers pair were;(P3) 5'-CCCAGAGCACCATTATAAGG-3'(sense), (P4) 5'-GTGCTGTCAGTAACCTGTAC-3'(antisense).

The amplification was performed as the following protocol: A- In the first round of amplification: outer primers (P1andP2) were used, 30 cycles were programmed in the thermocycler machine. Denaturation, annealing, and primers extension were set at 94C° for 1 minute, 55C° for 2 minutes and 72C° for 1 minute respectively, and then final extension was made for further five minutes. B: In the second round of amplification the inner primers (P3andP4) were used and cycling parameter of this round was the same as the first round (18, 19).

Data analysis:

The final data were analyzed using the computer programme, Statistical package for social sciences (SPSS), version 20. Chi square test was applied on the data to determine the association between the variables of interest, and p value of ≤ 0.05 was considered the borderline of significance.

Ethical consideration:

Ethical approval for this conduction was obtained from Sudan international university management. Informed consent was taken individually and orally from the eligible participants, information's including age, gestation period and number of miscarriages were gathered in a questionnaire and the final results were handed back to them. Permission for sample collection was obtained from the military hospital authorities.

The informed ethical consent form was designed and approved by the ethical committee of the Faculty of Medical Laboratory Research Board, National University-Sudan.

Results

A total of 97 whole blood samples were collected from pregnant women (of different trimesters). Out of them, 12 were in the first trimester (4-12) weeks, 26 in the second trimester (16-24) weeks, and the remaining 59 pregnant women were in the third trimester (28-36) weeks. There was no statistical significance difference between parvovirus B19 and gestation trimester (p value = 0.5).

The age of these pregnant women ranged from 20-40 years, and it was classified into 4 categories: 20-25 years, 26-30 years, 31-35 years and 36-40 years. The distribution of the participant pregnant women among these categories was: 31, 36, 18, and 12 respectively. Twenty-nine pregnant women had a history of previous miscarriage which was estimated to be 1-2 miscarriage, 5 had previous miscarriage of 2-3, 1 woman had more than 3 previous miscarriages, and the remaining 62 pregnant women had no previous miscarriages. There was a strong statistical non significance between B19 DNA and previous miscarriage (p value = 0.9).

Two cases from the evaluated 97 pregnant women samples were found to be positive (2.1%) for B19 DNA using nested PCR. There was a strong statistical non significance between PCR positive and negative samples (p value = 0.9).

Out of the 29 samples for pregnant women with 1-2 previous miscarriage, 1 revealed positivity (3.4%) for B19 DNA, and the other positive sample was for a pregnant woman with no history of previous miscarriages (1.6%), however both positive samples were for pregnant women in third trimester (3.4%) out of the 59 third trimester pregnant women.

Table 1: Frequency of PCR results

PCR result	Frequency	Percent
positive	2.0	02.1%
negative	95	97.9%
Total	97	100%

Table 2: Correlation between PCR results and age

Age		PCR results		Total	P.value
		positive	negative		
20-25	Count	0.1	30	31	0.5
	%	3.2%	96.8%	100.0%	
26-30	Count	0.0	36	36	
	%	0.0%	100.0%	100.0%	
31-35	Count	0.1	17	18	
	%	5.6%	94.4%	100.0%	
36-40	Count	0.0	12	12	
	%	0.0%	100.0%	100.0%	
Total	Count	0.2	95	97	
	%	02.1%	97.9%	100.0%	

Table 3: Correlation between PCR results and trimester

Trimester		PCR result		Total	P.value
		positive	negative		
1st	Count	0.0	12	12	0.5
	%	0.0%	100.0%	100.0%	
2nd	Count	0.0	26	26	
	%	0.0%	100.0%	100.0%	
3rd	Count	2.0	57	59	
	%	3.4%	96.6%	100.0%	
Total	Count	2.0	95	97	

Table 4: Correlation between PCR results and miscarriages

miscarriages		PCR result		Total	P.value
		positive	negative		
1-2	Count	1.0	28	29	0.9
	%	3.4%	96.6%	100.0%	
2-3	Count	0.0	5.0	5.0	
	%	0.0%	100.0%	100.0%	
>3	Count	0.0	1.0	1.0	
	%	0.0%	100.0%	100.0%	
no	Count	1.0	61	62	
	%	1.6%	98.4%	100.0%	
Total	Count	2.0	95	97	
	%	2.1%	97.9%	100.0%	

Out of the 2 B19 positive cases, 1 (3.2%) belonged to a pregnant female from the age group of 20-25 year, and the other 1 (5.6%) was for a pregnant women of an age group of 31-35 years.There was no statistical significance difference between age and B19 DNA (p value = 0.5).

Discussion

During pregnancy congenital infection with parvovirus B19 can be associated with poor outcome, including miscarriage, fetal anemia and non-immune hydrops (20).

This study revealed that the prevalence of B19 DNA among 97 pregnant women blood samples was 2.1%, which is agreed with the fact that parvovirus B19 prevalence in pregnancy is 1-5% , but in epidemic situation it receives to 10% (21).

Some studies results showed disagreement with this result, such as a study done by Adam. et al in Sudan (22), showed that the seroprevalence of B19 IgG among pregnant women (n =500) was 61.4% with one subject positive for IgM and B19 DNA was not detected using PCR. In addition another study done by Maksheed M. et al in Kuwait (23), aimed only to detect B19 IgG, and IgM using ELISA, and it was 53.3% and 2.2% for IgG and IgM respectively. This disagreement is probably due the relatively low specific methods of virus detection used by both researchers despite the large number of suspect involved.

In a study done by Barros De freitas. et al in Brazil (24), 42 B19 IgG and IgM negative and 5 IgG and IgM positive pregnant women samples which were previously screened by ELISA, were submitted to nested PCR and it was detected in one mother who seroconverted from IgG negative to IgG positive.From a comparison perspective, this low detection rate of B19 DNA is attributed to low number of samples screened knowing that a large portion of these samples were IgM negative (5samples).

In another study done by Mirambo. et al in Mwanza ,Tanzania (25), 258 pregnant women of a median age of 21 (19-25) years were tested for parvovirus B 19 IgM and IgG using ELISA.116 (44.96%) ,109 (42.25%), and 33 (12.79%) of these pregnant women were in the first, second and third trimester respectively.The prevalence of B19 IgM was 83 (32.8%) and IgG was 142 (55%).This study restricted the age range to a maximum of 25 years which is not corresponded with our age range that was relatively wide, and also the method used for screening the virus depended on serology only, however the researcher incorporated different gestation trimesters which is agreed with our study.

Conclusion

According to the study results parvovirus B19 DNA was screened, and positively detected in selected pregnant women with a percentage of 2.1%.

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Competing interests

The authors declare that they have no competing interests

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Research Article

A Comparative Study between Transcutaneous Bilirubinometry and Total Serum Bilirubin Measurement in Jaundiced Newborns

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Keywords: neonatal jaundice, total serum bilirubin, transcutaneous bilirubinometer.

ABSTRACT

***Background*:** Drawing blood to measure total serum bilirubin is painful & time consuming. Transcutaneous bilirubinometer working by multiwavelength spectral reflectance from the skin surface on forehead or upper sternum is a quick & painless technique.

Objectives: to compare the effectiveness of transcutaneous (over the upper sternum and forehead) and serum bilirubin measurement of neonate with jaundice.

***Subjects and Methods*:** This is a cross sectional prospective study. It enrolled 175 jaundiced neonates & excluded those exposed to phototherapy. It was conducted at Child Central Teaching Hospital in Baghdad, Iraq from the 1st of August to the 30th of October 2018. Transcutaneous bilirubin measurement on forehead and upper sternum was done by JM 103 Minolta Air shields bilirubinometer. Total serum bilirubin was measured by APEL BR 501 BILIRUBIN METER. Data entered & analyzed using SPSS 20 computer software. Means, frequencies, cutoff values, sensitivity & specificity were calculated.

***Results*:** The mean age, gestational age & birth weight were (6.3±4.3 days), (36.9±2.1 weeks) and (2.7±0.6 Kg) respectively. Mean total serum bilirubin, transcutaneous chest & forehead bilirubin levels were 12.6±4.2 mg/dl, 11.8±3.8 mg/dl & 11.2±3.9 mg/dl respectively. Mean total serum bilirubin was significantly higher than transcutaneous chest and forehead bilirubin. Cutoff values of transcutaneous chest & forehead bilirubin levels were [(9 mg/dl) with sensitivity (95.4%) & specificity (86.4%)] and [(8.2 mg/dl) with sensitivity (94.7%) & specificity (86.4%)] respectively.

***Conclusions*:** Transcutaneous bilirubin measurements on chest and forehead have an acceptable validity in predicting hyperbilirubinemia with less accuracy on forehead.

Introduction

Jaundice is a term taken from the French word 'jaune' which means 'yellow'. So, a jaundiced baby means a baby whose skin became yellow. Jaundice often happens few days after birth. The yellow color is the result of bilirubin which is formed after break down of old red blood cells (RBCs) (1).

Approximately 60% of term infants and 80% of preterm infants become jaundiced in the 1st week after birth. The yellow color is due to unconjugated (indirect) and conjugated (direct) bilirubin. The

unconjugated bilirubin is the lipid-soluble bilirubin that accumulates in the skin and it results from catabolism of hemeprotein by a series of enzymatic reactions by heme oxygenase (HO) and biliverdin reductase and nonenzymatic reducing agents in the reticuloendothelial cells. The conjugated bilirubin results from indirect, unconjugated bilirubin that has underwent conjugation in the liver by the enzyme uridine diphosphoglucuronic acid (UDP)–glucuronyl transferase to form the polar, water-soluble glucuronide of bilirubin. Bilirubin may act as an antioxidant; however, elevation of unconjugated bilirubin is potentially neurotoxic. The conjugated form is not neurotoxic; however, direct hyperbilirubinemia indicates a potentially serious hepatic disorders or a systemic illness (2).

The need for total serum bilirubin (TSB) testing can be estimated through Kramer's rule which depends on the progression of yellow discoloration of the skin from cepahlocaudal progression. It is based on a study performed in 1969 on full term infants. It found that bilirubin concentrations correlated to 5 specific 'dermal zones' which are head and neck, upper trunk, lower trunk and thighs, arms and legs below the knees, hands and feet. Lowest TSB levels were associated with yellow discoloration of the head and neck only & highest levels with the discoloration extension to the hands and feet (3). If jaundice reaches the midabdomen, or there are signs or symptoms, or high-risk factors that suggest nonphysiologic jaundice, or hemolysis; further evaluation is needed (2). However, recent studies showed a poor correlation between visual assessment of TSB and measured TSB (4). Drawing blood sample to measure TSB is commonly requested in the neonatal units. It is often done by heel prick approach which is painful and have potential long-term consequences (5). The neonate nervous system is immature & undergoing major developmental changes; therefore, exposure of neonate to painful stimuli can cause many neurodevelopmental changes, such as neurosensory, cognition, behavior, pain processing, and health outcomes that persist into childhood and even adulthood (6).

Risk factors for hyperbilirubinemia can be due to maternal and/or neonatal causes, Table 1 (7).

Table (1):

Risk Factors for Hyperbilirubinemia in Newborns

Maternal factors	Neonatal factors
Blood type ABO or Rh incompatibility	Birth trauma: cephalohematoma, cutaneous bruising, instrumented delivery
Breastfeeding	Drugs: sulfisoxazole acetyl with erythromycin ethylsuccinate (Pediazole), chloramphenicol (Chloromycetin)
Drugs: diazepam (Valium), oxytocin (Pitocin)	Excessive weight loss after birth
Ethnicity: Asian, Native American	Infections: TORCH
Maternal illness: gestational diabetes	Infrequent feedings
	Male gender
	Polycythemia
	Prematurity
	Previous sibling with hyperbilirubinemia

TORCH = toxoplasmosis, other viruses, rubella, cytomegalovirus, herpes (simplex) viruses.

Kernicterus refers to the neurologic outcomes caused by unconjugated bilirubin deposition in the brain with damage of the basal ganglia and brainstem nuclei (7). Bilirubin role in kernicterus is not fully understood. When the level of unconjugated bilirubin exceeds the binding capacity of albumin, it crosses the blood-brain barrier. Albumin-bound bilirubin may also cross the blood-brain barrier in certain conditions such as asphyxia, acidosis and hypoxia (7, 8). The exact bilirubin level associated with kernicterus in the healthy term infant is unpredictable. Some factors cause variation of toxicity levels such as maturation of infant and the presence of hemolytic disease (7). The risk of bilirubin toxicity in a healthy term new born without hemolysis is probably negligible (7); however, the precise threshold above which indirect-reacting bilirubin or free bilirubin will bring harm in an infant is unpredictable, but in a large series, it was >20mg/dl. Ninety percent of the infants with kernicterus were previously healthy, predominantly breastfed term and near-term. It is unknown what is the duration of exposure to high bilirubin levels that lead to harmful effects.

Early signs of kernicterus are nonspecific, typically appearing 3 to 4 days after birth. However, hyperbilirubinemia may lead to kernicterus at any time during the neonatal period (7). After the 1st week of life, the affected newborn begins to demonstrate late effects of bilirubin toxicity. If the infant survives the initial severe neurologic insult, chronic bilirubin encephalopathy (evident by three years of age) leads to developmental and motor delays, sensorineural deafness, and mild mental retardation, table 2 (7).

Table (2): (7)

Effects of Bilirubin Toxicity in Newborns

Early	Late	Chronic
Lethargy	Irritability	Athetoid cerebral palsy
Poor feeding	Opisthotonos	High-frequency hearing loss
High-pitched cry	Seizures	Paralysis of upward gaze
Hypotonia	Apnea	Dental dysplasia
	Oculogyric crisis	Mild mental retardation
	Hypertonia	
	Fever	

When TSB reaches 85 micromoles per deciliter (5 mg/dl), jaundice becomes clinically visible. Physiological jaundice increases in severity until day 4–5 then gradually decreases and disappears by day 10 and does not usually require any treatment. It is diagnosed by exclusion, i.e., careful evaluation needed to exclude pathological causes. If the jaundice appears on the first day of life even in preterm babies, it is considered pathological and require intervention. The same applies if it persists beyond the usual period (7). The presence of jaundice can be demonstrated by examining the infant in a room with good lights and blanching the skin with pressure applied by digits to reveal the color of the skin and subcutaneous tissue (7). The visual estimation of TSB when dermal icterus is confined to above the nipple line can be reliable. In this situation, TSB is invariably below 12 mg per dL. When jaundice extends below the middle of the chest, the correlation between physical signs and measured TSB becomes increasingly unreliable. Predicting the TSB based on caudal progression alone can get difficult due to racial differences, delays in deposition of rapidly rising bilirubin levels in the dermis, interobserver variability, and other factors (7). The different methods

to measure bilirubin levels are biochemical, bilimeter and transcutaneous bilirubinometer.

Biochemical method for the total and conjugated bilirubin assessment is the gold standard one for TSB estimation and it is based on the van den Bergh reaction (9). Bilimeter method is based on spectrophotometry and it assesses TSB (9).

Transcutaneous Bilirubinometer (TcB) measurement devices do not require blood sampling. They use multiwavelength spectral reflectance from the skin surface and they estimate total serum or plasma bilirubin. It is a 'Point of Care' test (bed-side test) that can be performed by physicians, nurses or any other health caregiver within hospital or in community (10). It is very useful because it is a noninvasive quick technique (11). It was introduced for the first time in 1980 (12). One randomized controlled trial in the Netherlands found a significant reduction in the number of blood sampling in TcB group compared with non-TcB group (13). It is an inexpensive test that can be performed over forehead or mediastinum, but measurement over mediastinum is better (14). The wavelengths used vary depending on the device (15). The results of these devices have been shown to correlate well with TSB levels in term and near-term infants (16). Common TcB available in the market includes the Airsheilds- Minolta, Bilitest, BiliCheck. These can be divided into 2 categories which are the two-wavelength (460nm, 540nm) spectral reflectance meter (Bili-test, Minolta which include JM 101, JM 102, JM 103 and JM 105) and the multi wavelength spectral reflectance meters (17). In our study we used JM 103 Minolta Air shields bilirubinometer (figure 1).

Figure (1): JM 103 Minolta Air Shields Transcutaneous Bilirubinometer

It measures the difference in the optical densities of light reflected by neonate skin. With this method, two optical paths are incorporated into a measuring probe that minimizes the interference caused by melanin or skin maturity. When the light returns to the fiber, it is scattered from shallow area of subcutaneous tissue and passes through the inner core (short optical path) of the fiber, whereas the light scattered from deep areas of subcutaneous tissue pass through the outer core (long optical path). The reflected light is then collected by photodiodes (18).

The use of TcB devices for jaundice evaluation in infants>35 weeks of gestation is recommended by the American Academy of Pediatrics (19). In addition, recently, the use of TcB in infants 28 to 35 weeks of gestation was shown to be reliable (13). Using TcB for estimating jaundice is a valid method and is used in increasing frequency; however, its use is still not widespread worldwide (13). In 2016, a review among most Dutch hospitals with neonatal wards, revealed that TcB was used in only 27% of these wards. This could be due to a low confidence in TcB, based on earlier studies using older non valid techniques (13). One reason of not using TcB may be the assumption that blood sampling is often done for other indications in sick neonates and TSB measurement is simultaneously done. Furthermore, in low-income countries, TcB is not widely applied, although this may be of great value due to feasibility of TcB in community settings with low resources (13).

Treatment of jaundice depends on the gestational age and the postnatal age. In preterm babies, treatment should start at a lower bilirubin level than term baby. Several factors determine the threshold for treatment like general well-being of the baby, severity of hemolysis, and presence of sepsis. The mainstay of treatment are phototherapy and exchange transfusion (19). Some drugs can be used in treatment of jaundice including Phenobarbital, Metalloporphyrins, Albumin and IV immunoglobulin.

Subjects and Methods

This is a cross sectional prospective study. It was conducted at the neonatal care unit at Child Central Teaching Hospital in Baghdad, Iraq over a period of 3 months from the 1st of August to the 30th of October 2018. It enrolled 175 neonates with jaundice. It excluded those above the 28 days and those exposed to phototherapy. Permission to enroll neonates in this study was taken from their parents. Data were collected about gender, gestational age in weeks, age in days, and birth weight. TcB measurement was performed in all jaundiced neonates whether they were outpatients' clinic visitors or admitted to the ward before starting phototherapy. TcB was done by using JM-103 Minolta air shields bilirubinometer. The fiber optic probe was placed against forehead and upper sternum of the neonate in supine position. The device displays a calculated average of three measurement for each bilirubin estimation, then blood samples for TSB measurement were collected by laboratory worker using the heel-prick technique, the blood collected by capillary tube then centrifuged for 5 minutes and the measurements were obtained by APEL BR-501 BILIRUBIN METER, in the lab of Child Central Teaching Hospital. Data were entered & analyzed using Statistical Package for Social Sciences SPSS 20 computer software. Means of Tcb (chest and forehead) and TSB were compared frequencies, cutoff values, sensitivity & specificity were calculated.

A study limitation was that it is a single center study.

Descriptive statistics presented as mean ± standard deviation, and frequencies as percentages. Multiple contingency tables conducted and appropriate statistical tests performed, one-way ANOVA analysis was used to compare more than two means (Post HOC test which is a part of ANOVA analysis was used to compare the mean of TcB and TSB). The Receiver operating characteristic (ROC) curve test was used to predict the better cutoff values of TcB on chest and forehead in comparison to TSB with calculation of their

validity (sensitivity & specificity). As sensitivity and specificity of test increase, the ROC curve moves towards the upper left-hand corner of the plot, with a correspondingly higher area under curve (AUC). AUC values of 0.5 lack any diagnostic ability whereas AUC values of 1.0 correspond to a perfect screening test. In all statistical analyses, level of significance (p value) set at ≤ 0.05 and the result presented as tables and/or graphs.

Results

Total number of neonates was 175; 114 were term (above 36 weeks of gestation) and 61 were preterm (30-35 weeks). Neonatal age was distributed according to the peak of jaundice appearing in 4-6 days so the age groups were 1-3 days, 4-6 days and ≥7 days. Mean neonatal age was 6.3±4.3 days; 25.1% of them were in the age group 1-3 days, 36% of them were 4-6 days and 38.9% of them were ≥7 days. Male to female ratio was 1.2:1. Mean gestational age was 36.9±2.1 weeks; 34.9% of them were preterm and 65.1% were term. Mean birth weight was 2.7±0.6 Kg; 3.4% of them had birth weight <1.5 Kg, 20% had birth weight of 1.5-2.4 Kg and 76.6% had birth weight of ≥2.5 Kg. All these variables are shown in table 3.

Table (3): Neonatal age, gender, gestational age and birth weight of jaundiced neonates

Variable	No.	%
Neonatal age mean±SD (6.3±4.3 days)		
1-3 days	44	25.1
4-6 days	63	36.0
≥7 days	68	38.9
Total	175	100.0
Neonatal gender		
Male	98	56.0
Female	77	44.0
Total	175	100.0
Gestational age mean±SD (36.9±2.1 weeks)		
Preterm	61	34.9
Term	114	65.1
Total	175	100.0
Birth weight mean±SD (2.7±0.6 Kg)		
<1.5 Kg	6	3.4
1.5-2.4 Kg	35	20.0
≥2.5 Kg	134	76.6
Total	175	100.0

Mean TSB of jaundiced neonates was 12.6±4.2 mg/dl; 50 (28.6%) neonates had normal TSB (bilirubin value ≤10 mg/dl was considered normal, while value >10 was considered high). Mean TcB on chest was 11.8±3.8 mg/dl; 58 (33.1%) neonates had normal TcB. Mean TcB on forehead was 11.3±3.9 mg/dl; 70 (40%) neonates had normal TcB. All these findings are shown in table 4.

There was a statistically significant difference between bilirubin levels measured by TcB on chest, TcB on forehead and TSB ($p<0.001$). Post HOC test revealed that mean TcB on chest was significantly higher than TcB on forehead ($p<0.001$), TcB on chest was significantly lower than TSB ($p<0.001$), and TcB on forehead was significantly lower than TSB ($p<0.001$). All these results are shown in table 5 and figure 2.

Table (4): Total serum and transcutaneous bilirubin of jaundiced neonates

Variable	No.	%
Total serum bilirubin mean±SD (12.6±4.2 mg/dl)		
Normal (≤10 mg/dl)	50	28.6%
High (>10 mg/dl)	125	71.4%
Total	175	100.0
Chest transcutaneous bilirubin mean±SD (11.8±3.8 mg/dl)		
Normal (≤10 mg/dl)	58	33.1%
High (>10 mg/dl)	117	66.9%
Total	175	100.0
Forehead transcutaneous bilirubin mean±SD (11.3±3.9 mg/dl)		
Normal (≤10 mg/dl)	70	40%
High (>10 mg/dl)	105	60%
Total	175	100.0

Table (5): Distribution of bilirubin level according to different techniques.

Variable	TcB. Chest Mean±SD (mg/dl)	TcB. Forehead Mean±SD (mg/dl)	TSB Mean±SD (mg/dl)	P
Bilirubin	11.84±3.79	11.29±3.88	12.57±4.22	<0.001
		Post HOC test		
TcB. Chest vs. TcB. Forehead	11.84±3.79	11.29±3.88		<0.001
TcB chest vs. TSB	11.84±3.79		12.57±4.22	<0.001
TcB Forehead vs. TSB		11.29±3.88	12.57±4.22	<0.001

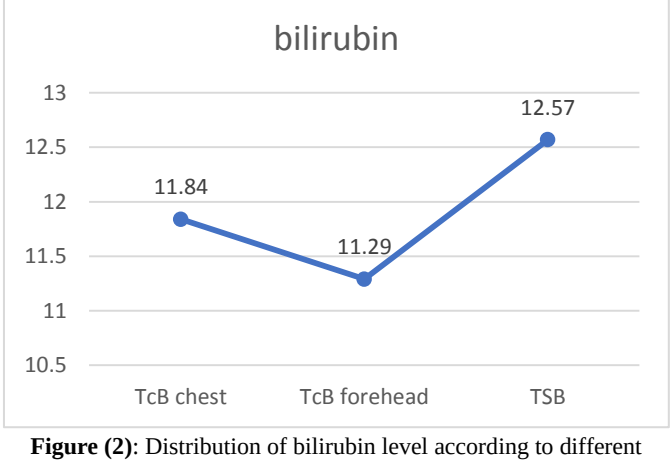

Figure (2): Distribution of bilirubin level according to different techniques

There was a significant positive correlation between TcB on chest, TcB on forehead and TSB as shown in table 6.

Table (6): correlation of bilirubin level among different techniques

	R (correlation coefficient)	P value
TcB. Chest vs. TcB. Forehead	0.973	<0.001

TcB chest vs. TSB	0.963	<0.001
TcB Forehead vs. TSB	0.946	<0.001

Table 7 demonstrates the distribution of bilirubin levels by technique for different age groups and gender. In all age groups, there was a significant difference between means of TcB on chest, TcB on forehead and TSB (p<0.001). TcB on chest was significantly higher than TcB on forehead in all age groups (p 0.006, p<0.001 and p<0.001 respectively), TcB on chest was significantly lower than TSB in the age groups 1-3 and ≥7 (P= 0.042 and P <0.001 respectively), while there was no significant difference in the age group 4-6 (P= 0.781). TcB on forehead was significantly lower than TSB in all age groups (p <0.001).

In both genders, there was a statistically significant difference between means of TcB on chest, TcB on forehead and TSB (p<0.001). TcB on chest was significantly higher than TcB on forehead in both genders (p<0.001), and was significantly lower than TSB in both genders (p<0.001), and TcB on forehead was significantly lower than TSB in both genders (p<0.001).

Table (7): Distribution of bilirubin levels according to technique for different age groups and gender

Variable	Tc. Chest	Tc. Forehead	TSB	P
	Mean±SD (mg/dl)	Mean±SD (mg/dl)	Mean±SD (mg/dl)	
1-3 days	10.70±3.56	10.28±3.84	11.13±3.90	<0.001
4-6 days	12.21±3.85	11.76±3.96	13.24±4.50	<0.001
≥7 days	12.24±3.78	11.53±3.79	12.89±4.00	<0.001
	TcB chest vs. TcB forehead	TcB chest vs. TSB	TcB forehead vs. TSB	
1-3 days	p 0.006	P 0.042	p <0.001	
4-6 days	P <0.001	P 0.781	P <0.001	
≥7 days	P <0.001	P <0.001	P <0.001	
Gender	Tc. Chest Mean±SD (mg/dl)	Tc. Forehead Mean±SD (mg/dl)	TSB Mean±SD (mg/dl)	P
Male	12.03±3.43	11.46±3.59	12.78±3.87	<0.001
Female	11.59±4.21	11.08±4.25	12.30±4.65	<0.001
	TcB chest vs. TcB forehead	TcB chest vs. TSB	TcB forehead vs. TSB	
Male	p<0.001	p<0.001	p<0.001	
Female	p<0.001	p<0.001	p<0.001	

Table 8 shows the distribution of bilirubin level according to technique for gestational age and birth weight. In both term and preterm neonates, there was a significant difference between means of TcB on chest, TcB on forehead and TSB (p<0.001). In both term and preterm neonates, TcB on chest was significantly higher than TcB on forehead and was significantly lower than TSB, while TcB on forehead was significantly lower than TSB (p<0.001).

In all birth weight groups, there was a statistically significant difference between means of TcB on chest, TcB on forehead and TSB (p 0.004, p <0.001 and p<0.001 respectively). TcB on chest was significantly higher than TcB on forehead in all age groups (p= 0.045, P 0.001 and p <0.001 respectively). TcB on chest was not significantly different from TSB in all weight groups except the group ≥2.5 Kg (P <0.001). TcB on forehead was significantly lower than TSB in all birth weight groups (p 0.003, p <0.001 and p <0.001 respectively).

Table (8): Distribution of bilirubin level according to technique for gestational age and birth weight

Variable	Tc. Chest	Tc. Forehead	TSB	P
	Mean±SD (mg/dl)	Mean±SD (mg/dl)	Mean±SD (mg/dl)	
Gestational age				
Preterm	11.36±4.06	10.74±4.11	12.02±4.37	<0.001
Term	12.10±3.63	11.59±3.75	12.87±4.14	<0.001
	TcB chest vs. TcB forehead	TcB chest vs. TSB	TcB forehead vs. TSB	
Preterm	p<0.001	p<0.001	p<0.001	
Term	p<0.001	p<0.001	p<0.001	
Birth weight				
<1.5 Kg	7.73±5.32	6.83±5.05	8.68±5.85	0.004
1.5-2.4 Kg	11.13± 3.59	10.57±3.59	11.58±3.66	<0.001
≥2.5 Kg	12.21± 3.66	11.68±3.79	13.01±4.18	<0.001
	TcB chest vs. TcB forehead	TcB chest vs. TSB	TcB forehead vs. TSB	
<1.5 Kg	p 0.045	p 0.146	p 0.003	
1.5-2.4 Kg	P 0.001	p 0.069	p <0.001	
≥2.5 Kg	p<0.001	P <0.001	p <0.001	

The appropriate cutoff points and the corresponding validity tests results (sensitivity & specificity) for TcB on chest in prediction of jaundice (TSB>10 mg/dl) were calculated by ROC test in SPSS which gives us ROC figure and two tables, first is area under the curve (AUC) table and second is coordinates of the curve table. ROC figure shows the cutoff values with relevant sensitivity and specificity in graphical way, while AUC table shows area under the curve value (the higher the AUC value, the higher the sensitivity and specificity), while coordinates of the curve table shows the individual values of TcB on chest with relevant sensitivity and specificity and by eye gaze we look at the individual values to choose a value that gives the highest possible sensitivity with the highest possible specificity. The value (9 mg/dl) met these conditions with acceptable validity results (96.2% sensitivity & 86.4% specificity). For the sake of briefing and space saving, we used figure 3 and included AUC value with its title, and we used table 9 showing only the chosen value (9 mg/dl) as a cutoff point and we omitted all other values.

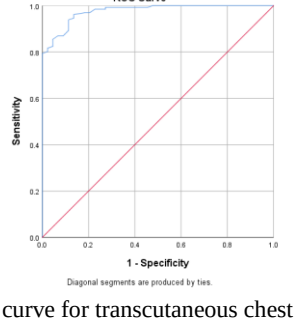

Figure (3): ROC curve for transcutaneous chest bilirubin values predicting TSB value >10mg/dl (area under the curve AUC=0.976)

Table (9): Coordinates of the Curve of transcutaneous chest bilirubin regarding jaundice.

Cutoff point	Sensitivity	Specificity
9 mg/dl	96.2 %	86.4%

The appropriate cut off points and the corresponding validity tests values (sensitivity & specificity) for TcB on forehead in prediction of jaundice (TSB>10 mg/dl) were calculated in the same way used to calculate the cutoff point of TcB on chest. Figure 4 and table 10 shows that AUC value was 0.973 and the cutoff TcB on forehead was 8 mg/dl and had acceptable validity results (96.2% sensitivity & 79.5% specificity).

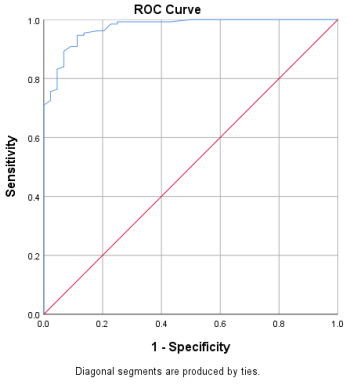

Figure (4): ROC curve for transcutaneous forehead bilirubin values predicting TSB value >10mg/dl (area under the curve AUC=0.973)

Table (10): Coordinates of the Curve of transcutaneous forehead bilirubin regarding jaundice.

Cutoff point	Sensitivity	Specificity
8 mg/dl	96.2%	79.5 %

Discussion

TcB measurement was introduced as a non-invasive method for measuring the bilirubin level of newborns and to minimize the blood loss from TSB measurement (21). In spite of the discrepancy between TcB measurement and TSB and between their different sites, the accuracy of bilirubin measurement has been proved (21).

The present study showed that the TSB of jaundiced neonates was significantly higher than TcB on chest and forehead ($p<0.001$) which is consistent with results of Taylor et al (11) study in USA which reviewed the medical records of newborns with jaundice comparing 8319 TcB measurements with matched 925 TSB measurements and found a significant difference in mean bilirubin measurement between TcB and TSB tests. In spite of this discrepancy, Taylor et al (11) stated that TcB measurement provided close estimates to TSB in newborns and this point is supported by the results of our study which revealed significant positive correlation of bilirubin level among TcB on chest, forehead and TSB. Another previous study in USA by Maisels et al (15) also detected difference in mean bilirubin measurement between TcB and TSB and this difference was affected by ethnicity. Our study revealed a significantly lower means of bilirubin assessed by TcB on chest in comparison to TSB ($p<0.001$). In contrast, Holland et al (22) documented overestimation of TcB on chest in comparison to TSB. However, in the present study, this underestimation did not affect the accuracy of TcB on chest as a screening device for referring neonates for further investigations including TSB. Present study showed also that mean TSB was significantly higher than TcB on forehead ($p<0.001$). This finding agrees with results of Şimşek et al (23) study in Turkey which compared the TcB (forehead & chest) with TSB for late term, preterm and term infants and found that TcB tended to be underestimated with increasing discrepancy from TSB for both forehead and chest. The current study revealed that TcB on chest was significantly higher than TcB on forehead ($p<0.001$) which is consistent with results of Conceição et al (24) study in Brazil that showed a significant correlation between TcB on chest and TSB but both of them significantly differ from TcB on forehead. The explanation of this difference between TcB on chest and forehead might be related to long period exposure to room light for forehead more than chest that was covered by clothes which in turn affect the readings of TcB (24). Many variable literatures found higher accuracy with strong correlation between TcB on chest and forehead and TSB (25-28).

Current study showed that accepted cutoff value in predicting TSB of >10 mg/dl using TcB on chest was 9 mg/dl with validity results of 96.2 % sensitivity & 86.4% specificity. These findings are close to results of Sarici et al (29) study in Turkey which reported cutoff value of TcB on chest for late preterm and term infants ranging from 9-11 mg/dl in predicting high TSB with sensitivity of 94% and specificity of 88%. The accepted cutoff value in predicting TSB of >10 mg/dl using TcB on forehead was 8 mg/dl with validity results of 96.2% sensitivity & 79.5% specificity. These findings are close to results of Mansouri et al (30) study in Iran which revealed that TcB on forehead of newborns was significantly correlated with TSB with validity results of TcB on forehead of 95.1% sensitivity and 68% specificity with cutoff value of 8 mg/dl. This lower cutoff value of TcB on forehead in comparison to TcB on chest is attributed to exposure of forehead to room light while the chest was covered by clothes leading to underestimation of TcB on forehead. This point is one of limitations for use of TcB (24).

In this study, the significant difference between TSB and both TcB on chest and forehead was more or less maintained in different neonatal age groups i.e. no changes in the significance of differences between techniques in different groups, except that in the age group 4-6 d. there was no significant difference between TcB on forehead and TSB. These findings are somewhat similar to results of El-Kabbany et al (31) study in Egypt which revealed that TcB is significantly correlated with TSB in different neonatal age groups but they reported that TcB on forehead for preterm newborns was less accurate than TcB on chest. Correlation between TcB (on chest or forehead) and TSB means that bilirubin values of all techniques tend to increase or decrease together in spite of the significant difference among them.

In this study, the significant difference between TSB and both TcB on chest and forehead was also maintained in in both genders ($p<0.001$). This finding agrees with results of Mandal et al (32) study in India which stated that there was an agreement between TcB and TSB with slight difference and this difference was not affected by neonatal age and gender. Regarding gestational age, the significant difference between TSB and both TcB on chest and forehead was also maintained in both preterm and term newborns and in all birth weight groups except that TcB on forehead was not significantly different from TSB in the birth weight groups 1.5-2.4 kg and ≥2.5 kg. This result is somewhat different from results of Maisels et al (33) study that found that mean difference between

TcB and TSB was significantly increased with decrease of gestational age or decrease of birth weight and this difference in the present study could be attributed to the fact that lower birth weight groups (<1.5 Kg and 1.5-2.4 kg) constitute 23.4 % of the sample i.e. it has a little impact on significance compared to the higher weight group (≥2.5 kg) which constitute the remaining 76.6 %. Maisels et al also recommended the use of TcB for newborns with gestational age of 28-35 weeks or less than 1.5 Kg birth weight before use of TSB.

Conclusions

TcB measurements in both chest and forehead have an acceptable validity (sensitivity and specificity) in predicting hyperbilirubinemia according to the device used in this study. TcB measurements are lower than TSB measurements. TcB on chest is more accurate than TcB on forehead.The difference between TSB total serum bilirubin and TcB is not much affected by neonatal age, gender, gestational age and weight.

Recommendations

TcB is a good choice for deciding which neonate needs referral for further TSB measurement. Rely on TcB on chest bilirubin measurement more than forehead site. Additionally, further national multi-center studies on TcB measurements are needed.

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Conflict of Interest

No conflict of interest

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Al-Kindy College Medical Journal (KCMJ)

Case Report

Acute Appendicitis and Multisystemic Inflammatory Syndrome due to COVID-19: a Case Report and Literature Review

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ABSTRACT

The prevalence of gastrointestinal symptoms of COVID-19 is variable with different types of presentations. Some of them many present with manifestations mimicking surgical emergencies. Yet, the pathophysiology of acute abdomen in the context of COVID-19 remains unclear. We present a case of a previously healthy child who presented with acute appendicitis with multisystemic inflammatory syndrome. We also highlight the necessity of considering the gastrointestinal symptoms of COVID-19 infection in pediatric patients in order to avoid misdiagnosis and further complications.

Introduction

Fever, dry cough, myalgia, tiredness, dyspnea, and anorexia are common symptoms of COVID-19 infection. However, a large number of individuals also reported gastrointestinal symptoms (1) . Gastrointestinal manifestations were the main elements in the clinical picture of about 92% of patients with multisystemic inflammatory syndrome (MIS) associated with COVID-19(2). Acute abdomen remains a rare presentation of COVID-19 but its association with the disease prognosis is still undetermined (1). In children with MIS, it is very often difficult to distinguish surgical etiologies of acute abdomen from nonsurgical etiologies and the use imaging tools remain necessary to guide further management (3). Blumfield et al. reported various abdominal imaging findings in COVID-19 patients, especially in pediatric patients with multisystem inflammatory and including ascites, bowel wall thickening, echogenic kidneys, hepatomegaly, splenomegaly, gallbladder wall thickening, bladder wall thickening, and mesenteric lymphadenopathy (4). We present the case of a 10 years child with no history of previous disease who developed acute appendicitis in the context of COVID-19 associated MIS.

Observation

A 10-year-old fully immunized male presented fever associated with chills, mild periumbilical abdominal pain radiating to the right

iliac fossa, myalgia and arthralgia. He we exposed to COVID-19 five weeks earlier. He was started in the clinic on antibiotics, Dexamethasone, and ibuprofen. When he arrived to our department, he had mild microcytic anemia, mild thrombocytopenia, lymphopenia and increased CRP Ferritin and D-dimer. He had negative COVID antigen test and PCR and positive Covid IgG antibody. Abdominal Ultrasound and CT scan showed multiple enlarged matted mesenteric lymph nodes clustered at the right iliac fossa associated with mild free fluid mainly in the right iliac fossa. Appendectomy was performed. Post-operatively, the patient was conscious and stable. Histology showed reactive lymph node and mild serositis in the resected appendix. Two days after the intervention, he became unstable with low oxygen saturation, tachycardia, tachypnea, dizziness, hypotension, lower limb edema, and myalgia and he was admitted to ICU. Chest X rays revealed bilateral infiltrates mainly on the right side, with left pleural effusion. The patient was treated with O2 nasal canula, antibiotics, methyl prednisone, aspirin, LMWH, and IVIG. The treatment was followed by resolution of the symptoms. He was afebrile with no significant findings upon systemic examination. Further, the patient developed sudden pain in his left leg, associated with tenderness, swelling, with no redness. The Doppler showed soft tissue edema. ECG showed signs of carditis and chest imaging revealed pleural effusion. The treatment by antibiotics and corticoids was continued. His status was improved and he was discharged on Prednisolone, Cefdinir, and Esomeprazol, figure 1.

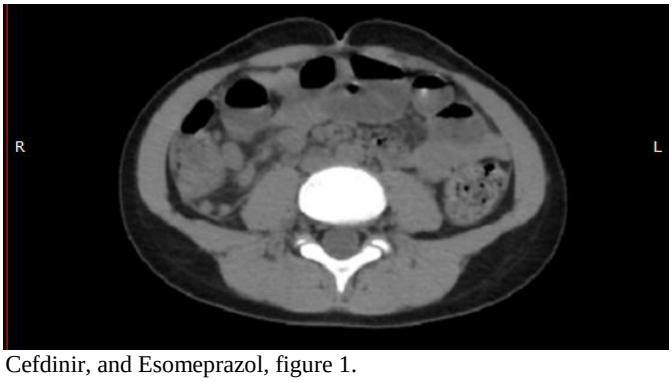

Figure (1): CT scan showing multiple enlarged matted mesenteric lymph nodes clustered at the right iliac fossa.

Discussion

The prevalence of gastrointestinal involvement of COVID-19 in pediatric patients varies is between 0 and 88% with a wide range of symptoms including vomiting, and abdominal pain, vomiting, diarrhea… Some atypical manifestations mimicking surgical emergencies may be also present, especially in the context of MIS(5). Various abdominal imaging findings have been reported in COVID-19 patients, especially in pediatric patients with MIS including ascites, bowel wall thickening, echogenic kidneys, hepatomegaly, splenomegaly, gallbladder wall thickening, bladder wall thickening, and mesenteric lymphadenopathy (4, 6).

Also, when the digestive symptoms are major, like in our case, MIS may be confused with other gastrointestinal diseases (7). Therefore, the diagnosis of MIS should be considered patients with a history of recent exposure to SARS-CoV-2 even in the absence of respiratory signs especially if inflammatory markers are high(6). The severity of abdominal pain may sometimes make it difficult to distinguish between surgical emergencies such as acute appendicitis and other conditions (3). In a recent report, acute abdomen was found in in 30.9% of MIS patients with gastrointestinal manifestations. Yet, the final diagnosis was not surgical in 76.4% of the cases. These non-surgical diagnoses included ileocolitis, mesenteric lymphadenitis; paralytic ileus, and ascites. Urgent laparotomy was found to be unnecessary in about 50% of the children while real emergencies including obstructive ileus and appendicitis were found in a small percentage of the patients(8). The management of these manifestations may led to a big dilemma since delaying acute abdomen treatment can have a serious impact on the prognosis while undergoing unnecessary surgical interventions in children with MIS may worsen the course of the infection and lead to high morbidity and mortality rates(2). The pathophysiology of appendicitis in the context of MIS is unclear. ACE2 which is the receptor of the SARS-CoV-2 virus is highly expressed in host enterocytes. Appendicitis may be caused by the inflammation caused by the viral invasion, by the resulted lymphoid hyperplasia or by the inflammation the appendicular artery (9). Moreover, the virus can interact with this receptor and infect gastrointestinal tract cells and lead to an excessive immunological response in these cells with the infiltration of host lymphocytes and plasma cells. This infiltration can induce interstitial edema and lead to the damage of the gut-blood barrier, causing a multisystem dysfunction because of the release of microbial metabolites, endotoxins and viral particles into the general circulation (5, 10).

Conclusion

We highlight the necessity of considering the gastrointestinal symptoms of the MIS caused by COVID-19 infection. Also, more deep studies should be done to identify the category of pediatric patients with COVID19 who should undergo urgent surgery for acute abdomen in order to avoid misdiagnosis and unnecessary interventions.

Ethical statement

A written consent signed by the parents was obtained to state their permission to publish the text and any images.

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Conflicts of interest

The authors declare no conflicts of interest.

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Al-Kindy College Medical Journal (KCMJ)

Case Report

Left Flank Pain and Hydronephrosis as the Initial Presentations of Advanced Gastric Cancer

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ABSTRACT

Ureteric obstruction is rarely noted in cases of gastric cancer. Its involvement by distant metastasis from gastric adenocarcinoma without direct invasion is an exceptionally unusual occurrence. This is the story of a 58-year-old man who arrived at the emergency department with acute flank pain and fever. He was initially diagnosed with obstructive pyelonephritis after the discovery of a new onset, complete ureteric obstruction on the left side. Subsequent investigations and follow-up revealed the presence of gastric adenocarcinoma with possible ureteric metastasis bilaterally, flank pain and hydronephrosis were the first and only presentations of gastric cancer. The rarity of the condition and the unusual presentation encouraged us to report the case.

Introduction

Malignant ureteral obstruction is not uncommon. However, Ureteral involvement by other metastatic malignant tumors is extraordinarily rare(1) , and its involvement in cases of advanced gastric cancer is a clinical finding that has been reported sporadically(2). It's extremely rare for gastric cancer to be presented only with symptoms related to the urinary system without other clinical or radiological manifestations. The diagnosis is usually confirmed histologically. However, negative urothelial ureteral biopsies dose not rule out the diagnosis of metastatic gastric cancer (1). We report a case of a 58-year-old male who was initially presented with symptoms related to the urinary system and finally diagnosed with gastric malignancy causing bilateral ureteric obstruction.

Case presentation

A 58-year-old man with a history of gastric lymphoma was treated with chemotherapy 10 years ago with a complete clinical response, and a history of low-grade transitional cell carcinoma of the urinary bladder was treated with transurethral resection a few years ago with no recurrences identified by follow-up. The patient complained of sudden onset left flank pain radiating to the groin and fever. Laboratory workup showed elevated serum white blood cells

and C-reactive protein, with normal kidney function tests and evidence of urinary tract infection on urine analysis. Triphasic urinary tract computed tomographic scan (CT) was done and showed an area of ureteric wall thickening and enhancement at the upper ureter (figure 1, a) associated with complete ureteric obstruction a few centimeters (cm) distal to the pelviureteric junction as appeared on delayed images at 15 minutes post contrast administration (figure 1,b).

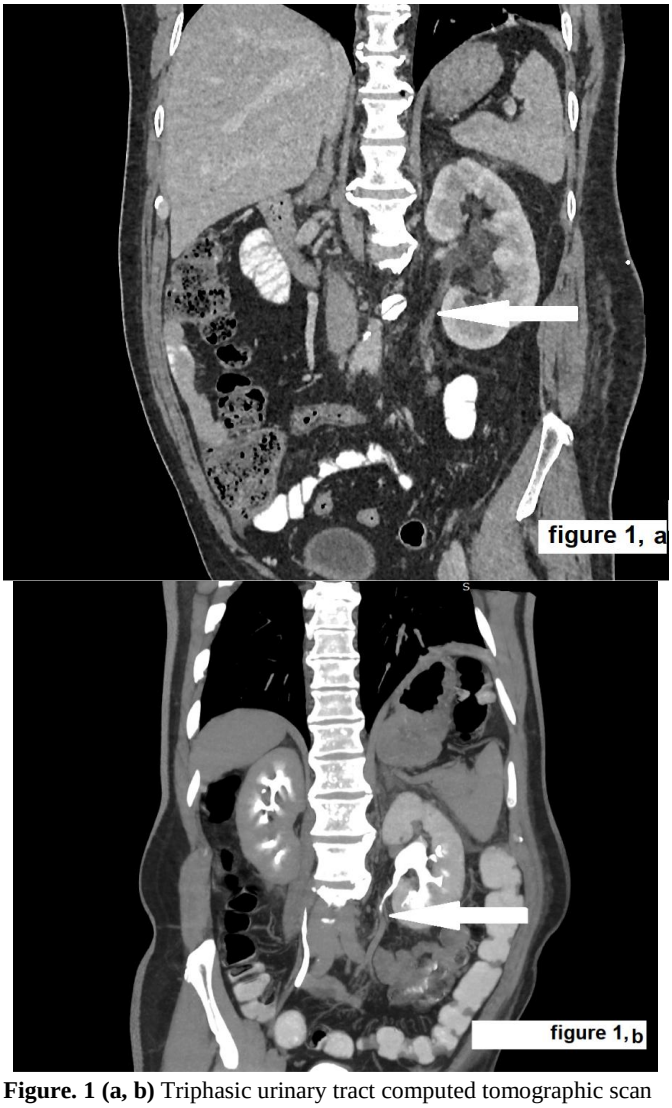

Figure. 1 (a, b) Triphasic urinary tract computed tomographic scan (CT) (a) An area of ureteric wall enhancement detected(arrowed) without evidence of adjacent masses or enlarged lymph nodes, (b) delayed images showed complete ureteral obstruction a few centimeters distal to the pelviureteric junction (arrowed)

There was no evidence of lymph node enlargement or compression from the outside. Additionally, a heterogeneous bone density with a suspected sclerotic lesion at the first vertebral body, measuring 1.7 cm in the axial plane, was noted. A routine follow-up CT scan of the abdomen and pelvis was normal 12 months prior to the presentation. Accordingly, the patient was diagnosed with obstructive pyelonephritis and underwent emergency ureteric stent insertion. An intraoperative retrograde pyelogram documented complete ureteric obstruction. After eradication of the infection, the patient was admitted for revaluation, and a follow-up CT scan was done 3 weeks later and documented the appearance of new enumerable sclerotic bone deposits.

The chest CT scan was negative as well. At that time, prostate specific antigen was done and was normal. Diagnostic cystoscopy was normal and ureteroscopy was done and revealed an area of obstruction at the upper ureter. Multiple mucosal biopsies were taken and the ureteric stent was reinserted. Histopathology (figure 2) revealed nonspecific mucosal ulcerations and inflammatory infiltrates with no evidence of malignancy.

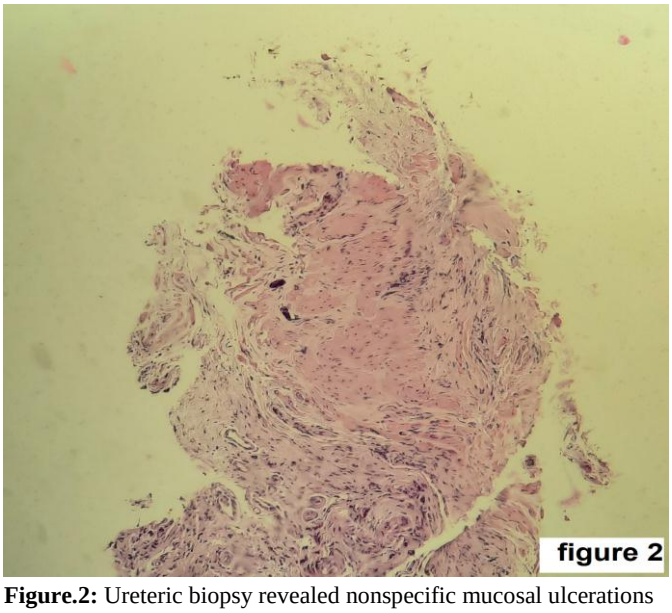

Figure.2: Ureteric biopsy revealed nonspecific mucosal ulcerations and inflammatory infiltrates with no evidence of malignancy

As the first trial of biopsy was not conclusive, a multidisciplinary (radiology, urology, and oncology) meeting was held and the decision to do a second look cystoscopy and multiple random bladder, ureteric, and prostate biopsies was taken. Which confirmed the absence of malignancy. As part of the evaluation, a positron emission tomography (PET) scan was done and showed an area of increased uptake in the stomach, in addition to the new appearance of a new onset right-side hydronephrosis.

Based on this observation, gastroscopy revealed an area of ulceration at the gastric antrum and biopsy showed poorly differentiated adenocarcinoma. He underwent right-side ureteric stent insertion and started on chemotherapy:

Discussion

Metastatic involvement of the ureter should be considered in patients with malignant diseases with initial symptoms consistent with ureteral obstruction, a few cases of gastric cancer have been reported to be initially presented with ureteric obstruction (2-4). Three scenarios have been described for ureteric involvement by metastatic diseases. The first is direct invasion of the ureter by a tumor in a neighboring organ. The second scenario involves

metastasis to lymph nodes around the ureter, resulting in external compression; the third situation, which has been documented sporadically, involves ureter involvement by distant metastases (5). In our case, the absence of radiological evidence of lymph node compression or masses around the area of obstruction necessitates taking a biopsy from the area of obstruction to rule out primary ureteric tumors.

Negative urothelial biopsy does not rule out metastatic ureteric tumors, as some tumors tend to occur in the muscular layer or even in the adventitia beneath the urothelial lining, which is sufficient to cause hydroureter and hydronephrosis (1), giving the mistaken impression that malignant illnesses are not a possible source of blockage. This may explain our patient's histopathological findings that are consistent with nonspecific inflammatory changes in the absence of malignant infiltration of the ureteric mucosa.

Synchronous bilateral ureteric involvement by metastatic gastric cancer has been reported (6), which may explain the appearance of contralateral hydronephrosis in our case. Ureteric involvement by metastatic tumors is a sign of bad prognosis and indicates an advanced disease. Treatment of ureteric involvement aims to provide relief of obstruction either by retrograde ureteric stenting or nephrostomy insertion, which are equally effective (1).

Conclusion

Metastatic ureteral tumors should be considered in the deferential diagnosis of ureteral obstruction in patients with known malignancies even in the absence of positive biopsy results, external compression, or direct invasion

Ethical considerations

Informed consent was taken from the patients, and they were informed that all the patient personal data will be disclosed from the public.

Author disclosure statement

The authors declare that they have no competing interests.

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Al-Kindy College Medical Journal (KCMJ)

Brief Report

A Spotlight on the Experience of E-learning as a Learning Method for the Undergraduate Pediatric Nursing Students in Iraq during the COVID-19 Pandemic

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Keywords: E-learning, nursing students, curriculum, COVID-19 pandemic.

ABSTRACT

The emergence of COVID-19 has resulted in an unprecedented escalation in different aspects of human activities, including medical education. Students and educators across academic institutions have confronted various challenges in following the guidelines of protection against the disease on one hand and accomplishing learning curricula on the other hand. In this short view, we presented our experience in implementing e-learning to the undergraduate nursing students during the present COVID-19 pandemic emphasizing the learning content, barriers, and feedback of students and educators. We hope that this brief view will trigger the preparedness of nursing faculties in Iraq to deal with this new modality of learning and improve it should the COVID-19 pandemic keep on or a new pandemic emerges.

Introduction

Coronavirus disease 2019 (COVID-19), related to the RNA virus family, is a highly contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Since its start in Wuhan, China in late December 2019, COVID-19 infection has affected many parts of the world inducing a state of governmental and public panic crisis. This has triggered the World Health Organization to declare a global pandemic and public health emergency on March 11, 2020 (1). Up to March 02, 2022, there have been 437,333,859 confirmed cases, including 5,960,972 deaths worldwide (2).

Apart from its detrimental effects on health as well as social, economic, and environmental aspects (3-6), COVID-19 has seriously hampered medical education. Worldwide, several challenges were faced. These included the following: social distancing influencing the delivery of medical knowledge, assessment, and interviewing; economic outcomes of the pandemic; the rise of patients compromising the core training; and the impact on the wellness and mental health of educators and students (7).

Nursing faculties across the world have responded to the challenges imposed by the COVID-19 pandemic in terms of closing educational institutions and setting electronic learning (e-learning).

Evaluation of this modality of learning has shown that e-learning during the COVID-19 period was as effective as traditional face-to-face learning for knowledge and practice (8,9) and virtual simulation has met students' clinical learning needs and outcomes (10). Moreover, it has offered students with the opportunity to set lifelong learning and continuing professional development in a practical and flexible manner (11).

In Iraq, little data are present on the evaluation of e-learning of undergraduate nursing students. Data are confined to the Kurdistan region and related mainly to the students' perspectives on that issue. Shehab and Khalifa reported that two-fifths of the students from two Colleges of Nursing had various grades of difficulties in handling e-learning and these difficulties differed from one college to another while only some of the students had preparedness and interest in e-learning (12). We attempted in this brief report to narrate our experience in implementing e-learning to the undergraduate nursing students during the COVID-19 pandemic in terms of the learning content, barriers, and feedback from students and educators.

The scope of e-learning for nursing students

For decades, traditional classroom learning and bedside teaching have been the usual methods of teaching/learning in Iraq. However, the rise in the number of COVID-19 cases in 2020 and measures taken by the health authorities in Iraq to limit the spread of the disease has forced the Ministry of Higher Education and Scientific Research to order changing teaching modalities in academic institutions. From the academic year 2020-2021onward, the department of pediatric nursing at College of Nursing, University of Baghdad, has responded timely to that order and introduced virtual reality technology in nursing learning curricula at the undergraduate level, and students' teaching was shifted from traditional learning to online alternative.

During the COVID-19 pandemic, educators at the faculty of pediatric nursing utilized a free learning platform (Google classroom) to continue the educational process. As the educators had no previous training on e-learning with the absence of related guidelines, the deanship of the college of nursing established quick and intensive workshops to teach educators how to use learning platforms. As a result, classrooms were set and students were asked to join these classes. The theoretical aspect of the learning curriculum was delivered to students in different ways, including PowerPoint templates that were introduced to the classroom homework (asynchronous learning), Google meet platform for live learning to guarantee effective interaction between students and educators (synchronous learning), and YouTube application to administer lectures on various topics in pediatric nursing. To make the learning sessions more useful, students were asked to actively participate in discussing the learning materials. They were also asked to prepare and administer seminars on certain topics to be openly discussed with students and educators. Considering the practical part of the curriculum, the educators presented short educational videos on various medical procedures in pediatric nursing supported by educators' voices to make these videos more explainable and understandable and their websites links were attached to the platform. Students were scored using various online formative and summative assessments such as short essays, single answer, multiple-choice questions, and true and false questions as well as oral examinations through the live Google meet platform. To define how the educational process flows, students' feedback was taken using a short online questionnaire.

Barriers facing e-learning implementation:

Implementing e-learning at our nursing faculty was not easy as it faced numerous barriers. Interrupted internet connectivity and electric power, impaired readiness of the faculty to deal with a new learning modality, unavailability of definite online learning guidelines set by the faculty, absence of technical expertise among a good number of educators and students, noticeable variation in the educational objectives, materials, and tools of delivery by educators, limited expertise of educators in delivering educational materials, particularly the clinical skills due to lack of formal training, limited interest and motivation of students to follow-up e-learning due to pessimistic impact of the pandemic, and the defective capability of a good number of the students to have updated communication tools such as mobiles, laptops, and internet flow to guarantee effective learning due to economic constraints.

Feedback from nursing students and educators on e-learning:

To have insight on the effectiveness of e-learning, feedback from students and educators was taken. On one hand, students and educators pointed out some positive aspects, namely the relatively helpful and informative e-learning option compared to traditional learning to continue the learning process during the pandemic, relatively effective involvement of educators in learning sessions, provocation of self‑directed learning, automated formative and summative students' assessments saving time and effort, and relative satisfaction in the learning process. On the other hand, students and educators stressed some negative aspects, notably implementing e-learning without prior adequate preparation, absence of active physical interaction with fellow students and educators, focusing the educational schedule on the theoretical aspect of learning at the expense of the practical aspect, lack of effective bedside teaching and manual skills acquisition on actual patients, inability to complete the learning schedule in due time, unavailability of highly qualified learning platforms due to high cost, breaking the assessment integrity with bias in assessing the actual students' performance and scores and easiness of utilizing unfair means in cheating in examinations and assignments, and improper infrastructures in terms of interrupted internet service and electricity power that have negatively affected delivering educational contents and assessment, increased the anxiety and tension in students and educators, and consequently impacted the compliance of students.

E-learning for nursing students in Iraq shared to some extent concerns similar to that reported in developing countries in terms of stressing students and educators, convenience and flexibility of e-learning, opportunities for professional and personal development, learning integrity, social isolation, acquisition of practical skills, and technical barriers (13-15).

Conclusion

E-learning has partially managed in enabling the continuity of learning through introducing medical knowledge, exploring practical skills, and fulfilling the learning objectives of nursing students despite the unprecedented obstacles met by the nursing faculty during the implementation of e-learning. Future large-scale studies across the country are needed to determine the real effectiveness, barriers, outcomes, and perspectives of e-learning and innovative, flexible learning modalities must be set should the COVID-19 pandemic keep on or a new pandemic erupts.

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