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- Time-Trend Analysis of Bladder Cancer and its Association with Bilharziasis in Egypt
- Safety profile of immediate post-partum intrauterine device insertion during caesarean delivery – a clinical trial with three years of follow up
- A serology conundrum – HIV infection in acute babesiosis infection could merely be a false positive result



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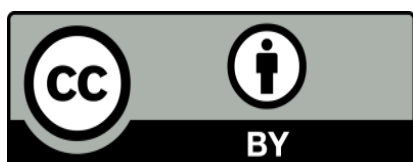
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- ✓ Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data (in particular, distinguish between clinical and statistical significance, and avoid making statements on economic benefits and costs unless the manuscript includes the appropriate economic data and analysis).
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✓ Whenever warranted, state new suggestions and recommendations, but make them as simple and clear as possible.

Acknowledgments

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5- Comprise in a logical sequence all the tests performed as part of the management.

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Editorial

Surrogates Markers of Insulin Resistance

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Insulin resistance (IR) is a fundamental feature of obesity, diabetes, and cardiovascular diseases and contributes to many of the metabolic syndrome's abnormalities. It is defined as a subnormal reaction to normal insulin concentrations or a situation where greater than normal insulin concentrations are necessary for a normal response. Turner RC et al. discovered that insulin resistance was linked to diabetes mellitus as early as 1979. They discovered that the severity of hyperglycemia in diabetes corresponded to the severity of insulin resistance (1).

Identifying patients with IR is critical for developing therapies and prevention measures for Insulin resistance-related chronic disorders, including obesity and type 2 diabetes, which are extremely common. Early detection of IR is critical for predicting the onset of cardiovascular disease, fatty liver disease, and metabolic illnesses (2).

Insulin resistance can be evaluated in a variety of ways. The standard gold test is the hyperinsulinemic-euglycemic clamp (HIEC). Still, it is difficult and time-consuming and necessitates insulin infusion and periodic blood samples, limiting its clinical screening uses. The homeostasis model for IR (HOMA-IR) was developed in 1985 and is widely used to estimate IR. It uses fasting blood glucose levels and insulin concentration as variables. The lack of a standard test for measuring fasting insulin levels makes it difficult to compare absolute results of plasma insulin concentrations between laboratories (3).

The development of novel surrogate indicators of insulin resistance that are more relevant for clinical screening and large population-based studies is urgently needed. As a result, a variety of surrogate indices have been used to make the determination of insulin resistance easier and more accurate. Triglyceride and glucose index (TyG index), Lipid accumulation product (LAP), Visceral adiposity Index (VAI), among others, are examples of novel surrogate markers of insulin resistance (4-7).

The TyG index has been linked to diabetes, hypertension, nonalcoholic fatty liver disease, and cardiovascular events. It is a non-insulin-based marker derived mathematically from a single determination of fasting blood glucose and triglycerides. Glucotoxicity and lipotoxicity have been shown to be important contributors in IR modulation. Because of its connection to lipotoxicity and glucotoxicity, the triglyceride-glucose (TyG) index has been proposed as an alternative measure of IR. TyG index showed a good correlation with the standard gold method of IR determination. Both

glucose and lipid levels are routinely checked in almost every care setting and are less expensive than insulin-based indicators (4,5).

The LAP, is a model based on fasting Triglyceride level and waist circumference, it is a promising marker of central lipid accumulation and insulin resistance. And a reliable and independent predictor of all-cause and cardiovascular mortality, as well as metabolic syndrome, type 2 diabetes, and cardiovascular disease. (6).

Visceral Adiposity Index (VAI) is a model calculated by both anthropometric parameters (body mass index and waist circumference) and laboratory parameters (triglycerides and high-density lipoprotein cholesterol). It is a simple marker of adipose tissue dysfunction that can be used to predict cardiometabolic risk before it manifests as metabolic syndrome and/or cardiovascular problems. The VAI is inversely associated to adiponectin levels, insulin sensitivity, and insulin secretion, as well as being separately linked to GH levels. The VAI has been considered a marker of Cardiometabolic risk, altered adipose function, insulin resistance, non-alcoholic fatty liver diseases, and non-alcoholic steatohepatitis (7,8).

The clinical usefulness of new lipid indices in detecting IR in the general population is supported by many researches (9). Lipid indices can be effective markers of IR risk assessments in clinical settings since they can be easily determined with normal laboratory procedures. These surrogate markers for assessing insulin resistance could thus help to maximize the utilization of medicinal resources while reducing expenses and undesirable side effects (10).

Because these markers may be easily measured using standard laboratory protocols, they might be useful markers for IR risk evaluations in clinical settings. These surrogate markers may thus help to maximize the use of medical resources while lowering costs and negative effects.

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Al-Kindy College Medical Journal (KCMJ)

Editorial

Two Decades in the Journey of Al-Kindy College Medical Journal: Key Barriers, Achievements, and Prospects

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Apart from graduating five-star doctors, a particular medical college has the mission to motivate and offer researchers the opportunity to publish high-quality researches on various health problems and disseminate updated medical knowledge to a wide range of local and international readers. This could be accomplished by establishing a medical journal and releasing issues regularly. Though Al-Kindy College of Medicine (AKCM), University of Baghdad was established in 1998, the planning to formulate a medical journal was delayed till 2002 when the first preliminary issue of the Al-Kindy College Medical Journal (KCMJ) was published to be followed by irregularly publishing few issues. The reasons behind the irregular release of issues are generally attributed to the poor logistic support from the newly established AKCM and the limited expertise of the antecedent assigned editorial boards of the journal. Moreover, the US-led invasion in 2003 and associated corruption, violence, and poor administration have tremendously ruined the integrity and infrastructure of the various institutions, including those related to the Ministry of Higher Education and Scientific Research. The KCMJ has started to be regularly issued in 2004.

With the release of the current issue of the KCMJ, two decades have elapsed since the release of the first preliminary issue of the journal in 2002. Although we feel happy that we have successfully maintained to some extent the regular release of the journal, we simultaneously feel sad that we have not yet fulfilled our ambition to make the journal regionally and globally recognized.

It is worthy to mention that world literature recruits thousands of scholastic journals. Only journals that are indexed in the major journals' database, namely Scopus and Clarivate Analytics, and attained higher visibility through wider access, and larger citation scores are ranked high impact, top scholastic journals. In an attempt to make KCMJ a unique journal and encourage researchers and postgraduates to publish their manuscripts in the journal, dynamic steps were to be set and followed during the antecedent two decades. With tremendous respect and appreciation to the preceding editorial boards of the journal, the journey of the journal was regrettably slow and swinging during the past decade and the major part of the second decade. However, it was more sustainable and productive over the last two years with the establishment of a new editorial board. The progress achieved was multifaceted and it involved the following aspects: changes in the scope (medicine and medical sciences), design

(reshaping the journal's architecture and introducing new sections), submission guidelines, reviewing process, processing and publication fees, and publication schedule of the journal; indexing of the journal in the Iraqi academic scientific journals (IASJ), Google scholar citation, CrossRef, Researchgate, directory of open access journals (DOAJ), digital object identifier (DOI) system, open access scholarly publishers association (OASPA); promoting the scientific integrity of the journal content using Turnitin software for plagiarism detection and prevention; issuing the journal three times annually; release of the journal in print and electronic formats; adding to the editorial board a group of guest editors of reputable academicians and researchers from esteemed medical colleges and distinguished hospitals; distribution of the journal free of cost to medical colleges and research centers inside the country; attaining the interest of the readers and researchers across the country and to a lesser extent abroad; and finally increasing the number of the online access and citation of the articles published in the journal. Despite accomplishing the above-mentioned inspiring achievements, we still believe that the AKCMJ is still in its infancy as the journal is not yet indexed in the biggest abstract and citation database of peer-reviewed world literature. Efforts are directed to fulfill the requirements essential in indexing the journal in the Scopus database and we are optimistic that we could achieve that goal in 2023. Fulfillment of that goal is expected to positively inspire us and facilitate our endeavors to index the journal in Clarivate Analytics.

On looking forward to receiving continuous support from the deanship of the AKCM and ongoing contributions from the internal and external researchers, the KCMJ could steadily and strenuously make a forward advance marching ahead into the silver anniversary of the journal release with the objectives of indexing the journal in the world database of scholastic journals, fulfilling wider visibility and higher citation, and publishing four issues per year.

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Review Article

Time-Trend Analysis of Bladder Cancer and its Association with Bilharziasis in Egypt

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ABSTRACT

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Background: Both bladder cancer and schistosomiasis are endemic in Egypt. The former has a unique epidemiological pattern, which has been linked to bladder infestation by *Schistosoma*. The last decades have witnessed a great reduction in the infection rate of schistosomiasis and a decline in the incidence and changes in the patterns of bladder cancer. Whether these changes are linked to each other or a co-incidence is a subject of investigations.

Subjects and Methods: Literature on epidemiological data of bladder cancer and *Schistosoma* in Egypt was searched for in Medline, Scopus, PubMed, and Google Scholar. Furthermore, a hand search for literature and reports released by the Egyptian government and involved agencies was performed.

Results: Studies describe an overall reduction in *Schistosoma* infection rate from 80% in 1920s to 1.2% in 2006. Studies on bladder cancer epidemiology, on the other hand, agree on a decline in incidence and changes in the pattern, but differ in figures describing the magnitude of these changes. Many studies tried to link the changes in *Schistosoma* and bladder cancer patterns. The evidence for this link, however, seems to be insufficient for a cause-and-effect relationship.

Conclusion: The relationship between the reduction in schistosomiasis infection rate and the changes in bladder-cancer epidemiological pattern in Egypt cannot be overlooked, but needs to be proved by more reliable evidence like prospective studies that include local health facilities and tertiary cancer centers.

Objective: explore the possible cause-and-effect relationship between the changes in *Schistosoma* infection rates and incidence and patterns of bladder cancer in Egypt.

Introduction

Bladder cancer

Although bladder cancer is considered the ninth most common cancer all over the world, its incidence differs greatly across different countries in the world. It is generally more prevalent in the developed compared to developing countries, however, some areas are considered exceptions (1). The Middle East, Egypt, Iraq, and southern parts of Saudi Arabia, have relatively high incidence rates

(2, 3). Bladder cancer is considered the most common solid tumor in Egyptian men and second only to breast cancer in Egyptian women (4), and has been well known for years to be the most common cause of death of young men in Egypt (5). While the overall incidence of bladder cancer is comparable between the United States and Egypt (13.1 and 11.6 per 100,000 persons respectively) (6), its mortality rate is 4 times greater in Egyptians than Americans (16.3% and 3.7% respectively) (7). This is considered the highest bladder cancer mortality rate in the world (8, 9).

Transitional cell carcinoma (TCC) and squamous cell carcinoma (SCC) are the most common histopathological types of bladder cancer. The risk factors linked to each type are different. Historically, Ferguson was the first to connect bladder infestation with *Schistosoma* to SCC (10). His work formed the basis of most investigations that took place over the proceeding century and focused on finding the exact mechanism of carcinogenesis or a cause-and-effect relationship. The major risk factors reported for TCC are smoking and occupational/environmental exposure to some toxins and heavy metals (11).

Bilharziasis

Schistosoma, the parasite infests humans causing the triad of hematuria, dysuria, and anemia, was first described by a German physician named Theodor Bilharz in 1850. Hence, the names Schistosomiasis and Bilharziasis are interchangeable.

Having the freshwater snail (*Bulinus* species) as an intermediate host essential for their life cycle, these worms predominate in watershed lands and farms irrigated from rivers (Nile in Egypt). Changes affecting rivers whether natural as floods or man-made like building dams or irrigation channels will affect the snail population and eventually the prevalence of schistosomiasis. Many studies showed that building the Aswan High Dam in Egypt (1960-1970) has resulted in a dramatic increase in the snail population and incidence of the disease peaked by 10-fold (2).

Schistosomal bladder-cancer

Bilharzia-associated bladder cancer has a unique epidemiologic pattern in terms of age at diagnosis, gender distribution, histopathological type, stage of the disease at j programs have succeeded to reduce the prevalence of Schistosomiasis from 70-80% in early the 1920s to as low as 1.2% in 2006 (2). This reduction in the rate of Schistosomal infestation was paralleled by an increase in the exposure to TCC risk factors, specifically smoking and occupational toxins (12).

Reports on bladder cancer in Egypt show an obvious change in its epidemiologic pattern over the last decades and most of these reports attribute that change to the good control of Schistosomiasis achieved (1, 2, 4, 7, 13, 14). The aim of this literature review is to explore the changes in bladder-cancer epidemiological patterns and their relationship to the changes in *Schistosoma* infestation rates. Furthermore, the possible scientific clarification for these changes and associations will be discussed.

Subjects and Methods

A literature search using “bladder cancer”, “epidemiology”, “schistosomiasis”, and “bilharziasis” subject headings was conducted. PubMed, Medline, Scopus, and Google Scholar databases were searched. The search was limited to “Egypt” and “English” language. Due to limited resources found, the search was then expanded using the references and bibliographies of the useful literature found in the first search. A general internet search was made looking for reports and literature related to the epidemiology and control of bilharzia released or published by the Egyptian government and national and international non-governmental

organizations and agencies. A specific search was made for the world health organization (WHO) and World Bank (WB) reports on bilharzia in Egypt. The results were then filtered to include only the studies that investigated the epidemiological aspects of bladder cancer and bilharzia. The literature was later grouped according to following factors: the time period covered, the number of patients’ records analyzed, the place of the study, and the epidemiological parameters studied. Results of the selected studies were then summarized and analyzed.

Results

Schistosomiasis:

The disease control efforts made by the Egyptian government and the international agencies were directed into three parallel lines: snail control, chemical Schistosomal control, and public education. However, the incidence of Bilharziasis in the rural areas was as high as 50% by the middle of the last century (15). The main breakthrough in the disease control history was the availability of praziquantel, a chemical agent with more than 90% effectiveness against the worms and negligible side effects (16). In conclusion, the local and international programs to control the disease were highly successful, with a reduction in its prevalence from around 40% in 1980 to barely above 1% in 2006 (17).

Bladder cancer:

The incidence of bladder cancer over the world has changed greatly during the last few decades. According to the International Agency for Research on Cancer 2012 figures, Belgium has the highest rate of bladder cancer (17.5/100,00 persons) followed by Lebanon and Malta, while Egypt ranked 10th with incidence rate of 13.1/100,000 persons (6). Egypt, however, continued to have the highest bladder cancer mortality rate in the world (8, 9, 18). Indeed, the incidence and mortality rates are not the only differences between bladder cancer in Egypt and other parts of the world. It has been well established many decades ago that bladder cancer in Egypt has a unique epidemiologic pattern(19). In comparison with the western countries, bladder-cancer patients in Egypt are younger (mean age is 47 years compared to 72.9 in USA), and with more profound male predominance (male to female ration of 7.8:1 compared to 3.5:1 in USA)(2, 5, 20). Pathologically, the SCC type (76.6%) dominates bladder cancer in Egypt. It is of a higher stage at presentation and poorer prognosis (5, 20, 21). *Schistosoma* has been thought to be the cause for both the high incidence of bladder cancer in Egypt as well as its unique pattern (19). Physical (chronic irritation), chemical (production of carcinogens such as N-nitrosamines) and microbiological (associated bacterial infection) mechanisms for schistosoma-induced bladder cancer have been hypothesized and investigated thoroughly (10, 22-25).

There are many other proved and potential risk factors for bladder carcinoma; these include smoking (tobacco, water pipe, and shisha), occupational toxins and chemicals (aromatic amines), environmental exposure to heavy metals (arsenic in drinking water), use of artificial sweeteners (saccharin and cyclamates), and medications like cyclophosphamide and chlornaphazine(11, 12). These risk factors, however, have been linked mainly to TCC (11, 26).

Changing epidemiological trends:

The changes in bladder-cancer epidemiology, and their hypothesized relationship to similar changes in the epidemiology of

schistosomiasis, have been addressed in several studies. Most of the literature found during the search for this review were retrospective studies and relied on data obtained mainly from the national cancer institute in Cairo (NCI). All the studies reviewed in this work agree on the changes in the major epidemiologic parameters of bladder cancer in Egypt. They showed a significant decline in the relative frequency of bladder cancer in Egypt. This was also evident in the 2012 world cancer incidence and mortality report (6). It clearly indicated a rise in the mean age of patients, a reduction in the male to female ratio, an obvious domination of TCC over SCC in the last years, and a significant drop in the number of patients with bilharzial-egg positivity (1, 4, 5, 7, 12-14, 27). The longest time period covered and the largest number of patients' records included were found in the study conducted by Gouda et al. in 2007 (4). They analyzed the records of 9843 patients diagnosed and treated over 38 years (1970 through 2007) in NCI. The next study in the time length and patient's number is that of Zaghoul et al. who were able to cover the period from 1988 to 2004, and collected 5071 records (14). The NCI records were their main data source as well. The main drawback of this study, however, was its limitation to patients treated with cystectomy. The characteristics of the four major studies are summarized in table 1.

Table 1: The four major studies tracing bladder carcinoma and schistosoma trends

Study	Patients number	Time covered	Value of epidemiologic parameters at start and end of the study period					
			RF %	Age (yr)	M:F	SCC %	TCC %	BEP% (Belharizi Egg Positive)
Gouda et al. (2007*)	9843	1970-2007	27.6 to 11.7	47.4 to 60.5	5.4:1 to 3.3:1	75.9 to 28.4	16 to 65.8	82.4 to 55.2
			Zaghoul et al. (2008*)	5071	1988-2004	51 to 57.2	3.2:1 to 3.6:1	56.9 to 43.6
Felix et al. (2008**)	2778	1980-2005	46.5 to 60	3.3:1 to 4.2:1	78 to 6.5:1	21 to 27	72.7 to 72.7	49.6 to 46.6
			Salem et al. (2011*)	1932	2001-2010	18 to 13	41 to 52	6.5:1 to 4.2:1

*National Cancer Institute (NCI)only

** cystectomy patients form NCI only

¥ data from NCI, Gharbia cancer center in the north, and Minia cancer center in the south

π Kasr Al-Aini hospital/cairo

El-Bolkainly et al. (1981) and Koraitim et al. (1995) tried in their studies to find the epidemiological differences between bilharzial-egg positive (BEP) and negative (BEN) bladder cancer patients (5, 27). El-Bolkainy and his group studied 1095 cystectomy patients records from NCI and Al-Mansoura center in the period from 1976

to 1978. Koraitim, on the other hand, compared patients from two different time periods (1962-1967, and 1987-1992) in a different location (Alexandria). Despite these differences, the two groups reached similar conclusions. They found that the BEP patients had a significantly lower mean age, a more domination of males over females, and were more likely to have SCC.

Fedewa et al. (2009) failed to show any significant change in the epidemiological parameters in their study, which included 1209 patients from the Gharbia region during 1999 through 2002(1). Less attention was paid to the pathological stage and grade of bladder cancer in the studies addressing the epidemiology of the disease despite its important clinical implications. Although no significant association was found between the BEP status and tumor stage, grade, and lymph node involvement status, a shift from solid nodular tumors towards papillary tumors was noticed, with higher grades tending to be found in BEN cases (1, 5).

Regarding the prevalence of schistosomiasis, the early efforts to control the disease using antimony compounds and molluscicides had a very limited success. There was a reduction in its prevalence from around 80% in 1920 to a slightly more than 50% in 1980. The adoption of Schistosoma Research Project (SRP) by the National Schistosoma Control Program and the mass treatment with praziquantel, however, has succeeded to drop the prevalence to 6.6% by 1993 and 1.2% by 2006 (Fig.1)(17). In addition to schistosoma eradication programs, many factors dramatically affected the incidence and prevalence of schistosoma in the Egyptian population. Two important factors to mention here are the changes that the introduction of an irrigation system triggered after the completion of the Aswan High Dam in the mid-1900s, and climate changes, specifically the recorded rise in temperature and its effect on the schistosomal intermediate host (the Bullinus snail) (28).

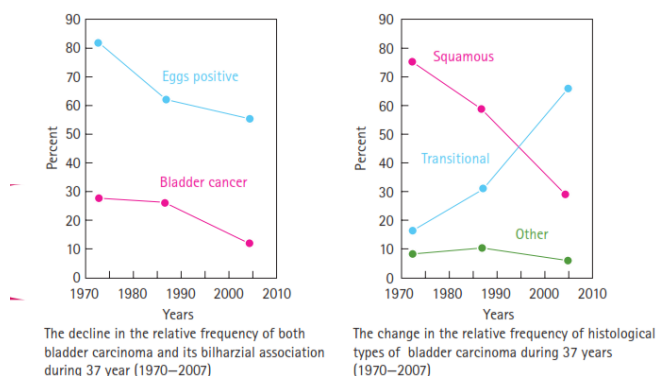


Figure 1: Relative frequency of bladder cancer and bilharziasis in Egypt over a 37 years period. Courtesy of the Journal of the National Cancer Institute (17).

Discussion

A change in the epidemiological pattern of bladder cancer in Egypt is clear and obvious. This change appears to be linked to the successful control of schistosomiasis. Epidemiologic data form the basis for this conclusion. These epidemiologic studies were successful in covering almost all parts of the country and including a large number of records. Epidemiologic data alone, however, are not sufficient for a cause-and-effect relationship. Some of these epidemiological changes have been noticed also in many other

countries, for example the overall reduction in bladder cancer relative frequency and relative risk, as well as the increased mean age of the patients (6). There is great reduction in the relative frequency of bladder cancer in Egypt over the past few decades. The decrease from more than 45% to around 13% cannot be considered parallel to the magnitude of reduction in the prevalence of schistosomal infestation from 80% to 1.2%, which was achieved as early as 2006. The increased exposure to other risk factors for bladder carcinoma should not be overlooked. Smoking habit is increasing among the Egyptian population, in particular the non-classical types of smoking like water-pipe smoking (shisha).

Moreover, all the studies that were included in this search were conducted in the NCI or one of the major cancer institutes of Egypt. Therefore, these studies are analyzing the same data set. An important point to take in account is that bladder-cancer patients are usually managed at the local health-facility level and transferred to a tertiary center only after failure of early conservative therapeutic modules and a need for more invasive treatment emerges. In addition, some studies analyzed only records of patients who underwent cystectomy.

The degree of bilharzial infestation needs to be taken in consideration. The carcinogenic effect of schistosoma is related to the degree of irritation of the bladder mucosa, thus mildly infested and non-infested bladders may react similarly when exposed to another risk factor like smoking.

In such patients, TCC would be the expected histopathological type since it develops in the normal transitional mucosa of the bladder. For SCC to develop, it requires severe irritation of the bladder mucosa causing a squamous metaplasia, which is followed later by dysplastic changes. Another weakness in the present studies is that they overlooked the pathological stage and grade of the tumor and their time trends. SCC is known to be locally advanced but rarely metastasizes because of the severe fibrosis of the perivesical lymphatic channels caused by schistosomal infestation and irritation. Based on the above, and to uncover the exact magnitude of the epidemiological changes of bladder cancer in Egypt and its relationship to the control of schistosomiasis, a more systematic and nationwide study is required that includes the local health facilities in addition to the tertiary and referral centers. A prospective study would be more likely to reflect the reality, but more difficult to conduct.

Conclusion

This review has demonstrated that there is some evidence supporting the hypothesis linking the changes in the epidemiological pattern of bladder cancer in Egypt to similar and parallel changes in the epidemiology of schistosomiasis. However, this evidence alone is not sufficient to infer a solid conclusion on a cause-and-effect relationship between the reduction in the incidence of schistosomiasis and the pattern changes of bladder cancer.

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Review Article

Potential Influence of Parasitic Diseases as Protective Agents from Infection with Pandemic COVID-19

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ABSTRACT

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Parasitic diseases can affect infection with COVID-19 obviously, as protective agents, or by reducing severity of this viral infection. This current review mentions the common symptoms between human parasites and symptoms of COVID-19, and explains the mechanism actions of parasites, which may prevent or reduce severity of this viral infection. Pre-existing parasitic infections provide prohibition against pathogenicity of COVID-19, by altering the balance of gut microbiota that can vary the immune response to this virus infection.

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which cause coronavirus disease 2019 (COVID-19), was recorded as the first time in China, in Wuhan City 2019 (1, 2). This viral infection was stated by WHO as a pandemic, because of its globally spread. The fast transmission of this infection, and the absence of screening instruments, made researchers depending on other criteria, included clinical features, and rapid effective measures in order to decrease the number of COVID-19 deaths (3). Primarily this infection spreads by respiratory droplets, and the most common clinical manifestations are cough, fever, rhinorrhea, diarrhea, chest pain, dyspnea, and myalgia (4), while in critical cases, it may cause multiorgan inability, then dying (5). Regarding to the laboratory

examinations, the infection is confirmed by making screening with RT-PCR(6), elevation of liver enzymes concentrations, ferritin lactate dehydrogenase, elevation in the levels of D-dimer, and C-reactive protein may be indicators of disease severity (7), sometimes blood tests may showing leucopenia, thrombocytopenia, and lymphocytopenia (8).

Parasites infect nearly 2 billion people annually (9), it have the same mechanisms of causing disease with different microorganisms, similar processes of inflammation, and inducing of immune or allergic reactions. Clinical manifestations of parasitic infections could be characterized by fever, dyspnea, and cough, so it can't be distinguished easily from other diseases of respiratory system, and most commonly influenza (10). Parasitic infections effect the immune system, and damage tissue, in spite of that

immunomodulation results from parasites could also keep from damaging tissue by inflammatory processes reduction (11).

Similarity of symptoms between parasitic infections and COVID-19

COVID-19 symptoms could be similar to other diseases caused by parasites (Figure 1) (12), such as parasitic pneumonia result from migration of parasitic larva through the lung (13), other symptoms like fever, cough, dyspnea, fast breathing, and Löffler's syndrome in severe cases. Another similarity to this viral infection, those parasites of GIT can make GIT disorders, like abdominal pain, diarrhea, vomiting, and nausea. Metazoan parasites such *Ancylostoma*, *Ascaris*, *Enterobius*, *Trichuris*, and *Schistosoma*, also protozoal parasites like *Giardia*, *Entamoeba*, *Cryptosporidium*, and *Toxoplasma*, are considered the major pathogens which cause global intestinal parasitic disease (14, 9).

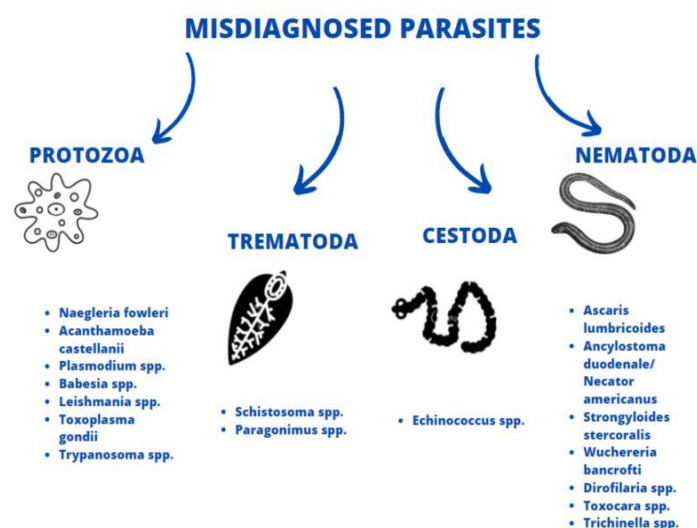


Figure 1. Parasites with similar symptoms to COVID-19 (12)

Potential role of parasitic infections in protection against COVID-19 or decrease its severity

Persistent or chronic parasitic infections, make direct modulation of immune responses of the host, and were confirmed to change clinical manifestations of other infections (15, 16), and these parasitic infections could change immune response of human to this viral infection. The virulence of severe COVID-19 is connected with activation of immunity (17), and the absence of parasitic infection may increase hazard of COVID-19 riskiness (18).

Therefore parasites may have potential role to decrease severity of COVID-19 (19), through modulation response of systemic immunity. Old parasitic infections are connected with activation of macrophages, T helper-2 (TH2), and type 2 innate lymphoid cells (ILC2), all of their activities are accompanied with inducing

cytokines like interleukins 4,5,13 and improve responses of eosinophils, beside IgE (20). During parasitic infections TH2 immune responses accompanied with activation response of regulatory T cells (Tregs) that considered very important to keep parasitic persistence, that in turn affect the response to other infections (15, 16, 19). While severe COVID-19 is linked with increasing hyper inflammation (20).

So, persistent parasite control Treg response and TH2 response, and may counterbalance overactive TH1 responses, that was founded in severe COVID-19, as well as, parasite control changes of gut microbiota, and may modulate immune response of the host (18). Thus, infections of the parasites can affect pathogenicity by immediate modification in the immune system, and through balancing microbiota (15, 16, 18). Another study has shown that GIT metazoan can acts as protectors versus viral infections of the lungs by action together with microbiota through inducing of type I interferon signaling (21), and several studies have been recorded the antagonistic relation of infection with COVID-19 and between parasitic infection (22, 23, 24). Influence of parasitic infections on COVID-19 especially those related with helminths, may decrease occurrence and death-rate of COVID-19 (25, 26), while co-parasitic infection with intestinal parasites could reduce severity of this virus (27). (Figure 2) (28).

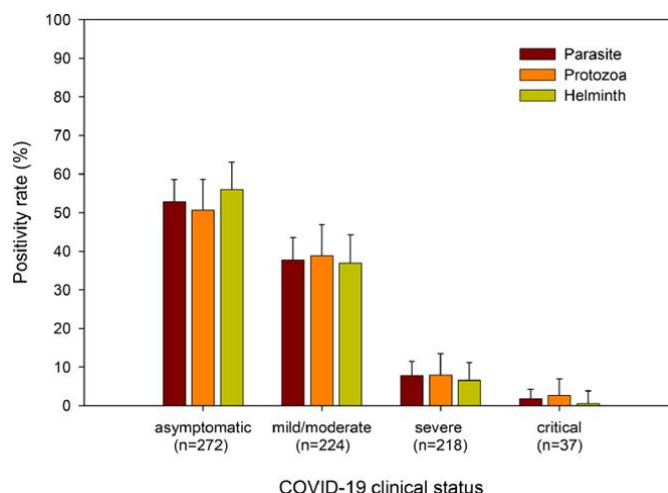


Figure 2. Relation between co-parasitic infection and severity of COVID-19 (28).

Conclusion

It is obvious there is a considerable counteractive relation between parasitic incidence and COVID19 severity, suggesting that parasitic infection, with protozoa and/or helminths, may play a potential role as protective agents versus COVID-19, or reducing severity progression of this viral infection.

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Original Article

Impact of Tobacco Use in the Etiology of Chronic Renal Failure among Sudanese Patients

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ABSTRACT

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Keywords: Chronic renal failure, tobacco, Sudan, educational level.



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Background: Chronic renal failure (CRF) is a clinical syndrome that occurs when there is gradual decline in renal operation overtime.

Objective: This study aims to investigate the prevalence of depression among medical students at university of Baghdad, college of medicine in Iraq and the association between some variables and depression.

Aim: This study aimed to identify the impact of tobacco use in the etiology of chronic renal failure among Sudanese patients in Omdurman Military Hospital and Omdurman Kidney Dialysis Center

Materials and methods: This descriptive community-based study was conducted in Khartoum State. A random sample of 100 cases with chronic renal failure and 100 control subjects were selected. Demographic, socioeconomic characteristics, prevalence of tobacco use among the respondents and incidence of acute and chronic illnesses associated with renal failure were statically tested to find its correlation to renal failure

Results: Findings showed that there was no significant statistical association between educational level and occupational status, to chronic renal failure (P-value > 0.05). Use of tobacco including cigarettes, snuff and water pipe, indicated significant association (P-value ≤ 0.05).

Conclusion: From the above findings the followings could be concluded that educational level showed significant statistical correlation to chronic renal failure. Use of tobacco (smoking, snuff and water pipe) is one of the most important remediable renal risk factors. Further studies focusing on controlled information on the success of a modern smoking cessation strategy in renal patients is highly recommended.

Introduction

The first stage Chronic renal failure (CRF) is marked by a period of silent deterioration in renal status, kidney function decrease, but blood urea nitrogen (BUN) and creatinine values stay within normal limits. The second stage is characterized by development of a slight renal insufficiency. A 50% reduction in normal functioning is necessary before BUN and creatinine values are reflect the pathologic changes by increasing above reference ranges. The third stage is typified by impending renal failure. Anemia begins to develop (due to the constant deficient in erythropoietin production) and systemic acidosis commences (due to the faulty clearance of endogenous metabolic acids). The fourth and the last stage commences with the onset of the classic symptoms of the uremic syndrome. The conditions that can participate in ARF also may lead to CRF. Several factors were identified as causative agents for CRF (1).

A study conducted by Abboud et al, (2) showed that in 20 patients with CRF in Soba University Hospital, etiology was not determined because of late presentation to hospital, accordingly they concluded that etiology of CRF in Sudan greatly differ from that of developing countries. The main differences were in the renal calculi, which, although being the second commonest cause of CRF in the Sudan, were rare in European countries. Also Aboud et al, (2) reported that diabetes mellitus was the much commoner cause of CRF in Sudan than Europe, while other etiological factors were similar.

The renal failure is one of the most common problems in Sudan among both males and females. It is fatal disease so that this study runs to find out the negative impacts of tobacco use on renal function, by study the effect of this bad habit in patients with chronic renal failure.

This study aimed to identify the impact of tobacco use in the etiology of chronic renal failure among Sudanese patients.

Materials and Methods

Study area: -

Omdurman Military Hospital and Omdurman Center for Kidney Dialysis.

Study design:

This was descriptive cross-sectional study.

Ethical consideration:

The aims of this study were fully explained to the respondents and their consent to participate in this study was obtained verbally. The results showed and discussed with the respondents.

An official letter was taken from Ahfad University to approach the directors of both Omdurman Military Hospital and Omdurman Center for Kidney Dialysis for permission to conduct this study.

Study population:

The study population consisted of the test group and control group of Sudanese males and females.

Sample size

Questionnaires were filled with two hundred (200) participants, divided equally among control and test group. The control group consisted of hundred (100) healthy Sudanese males and females with

no signs and symptoms of renal failure, while the test group consisted of hundred (100) Sudanese patients diagnosed with renal failure.

Data collection methods

Primary data were collected using questionnaires. Secondary data were obtained from relevant topics in both published and unpublished works including books, reports, previous studies, periodicals and Internet.

Questionnaire

A structured questionnaire designed to obtain personal information, usage of tobacco by respondents, causes of renal failure, was administered to all the respondents.

Data Management and Analysis

The primary data from questionnaires were analyzed using Statistical Packages for Social Sciences (SPSS). Risk factors data were compared between test and control groups by using chi square test. Frequency distributions were used to present the data of the two groups. Data will be presented in tables and figures.

Results

Table 1: Distribution of occupation of respondents

Group	Occupation	Frequency	Percent
Control	Student	30	30.0
	Labor	18	18.0
	Policeman	10	10.0
	Employee	9	9.0
	Farmer	1	1.0
	Businessman	12	12.0
	Housewives	2	2.0
	Teacher	5	5.0
	Doctor	1	1.0
	Technician	4	4.0
	Labor	1	1.0
	Driver	5	5.0
	Without work	1	1.0
	Lawyer	1	1.0
	Total	100	100.0
Case	Student	26	26.0
	Labor	18	18.0
	Policeman	2	2.0
	Employee	8	8.0
	Farmer	1	1.0
	Businessman	15	15.0
	Housewives	3	3.0
	Teacher	3	3.0
	Doctor	2	2.0
	Technician	6	6.0
Driver	2	2.0	
Lawyer	6	6.0	
Without work	8	8.0	
Total	100	100.0	

Occupational status as shown in table (1) showed no clear differences among cases and control, where the highest parentage of both control (30%) and cases (26%) were students, and labors scored the same percentage (18%) among both of the studied groups. Other

occupation showed low parentages ranged between 1-15 % with no clear variations between cases and control subjects.

Statistical test for association between occupation and chronic renal failure among the respondents indicated no significant association ($P \geq 0.05$, at 95% confidence).

Table 2: Level of education of respondents

Group	Level of education	Frequency	Percent
Control	Basic	15	15.0
	Secondary	33	33.0
	University	45	45.0
	Post graduate	4	4.0
	Illiterate	3	3.0
	Total	100	100.0
Case	Basic	15	15.0
	Secondary	27	27.0
	University	48	48.0
	Post graduate	4	4.0
	Illiterate	6	6.0
	Total	100	100.0

The commoner educational level among both control and case subjects was university level (45%) for control and (48%) for cases, followed by secondary level which was mentioned by 33% of the control in contrast to 27% of the cases, 15% of both control and cases have basic level of education, 3% of control were illiterate in contrast to 6% of cases.

No significant statistical association between chronic renal failure and educational level of the respondents ($P \geq 0.05$, at 95% confidence).

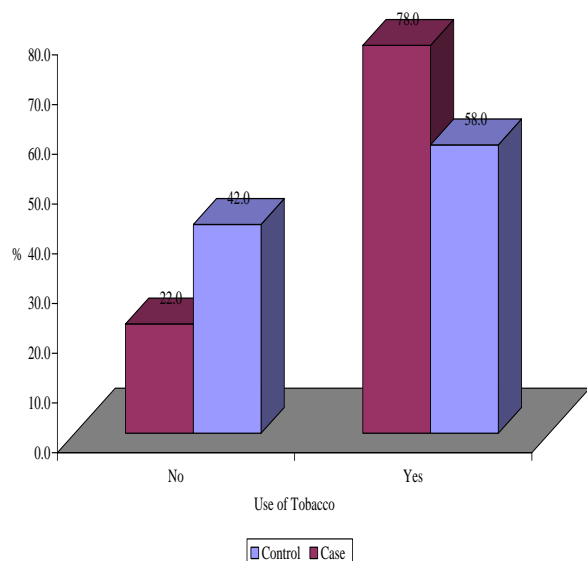


Figure.1: Use of tobacco by respondents

According to the above figure, use of tobacco was more common among the cases (78%) than control subjects (58%). This showed significant statistical association between use of tobacco and chronic renal failure among the respondents ($P \leq 0.05$, at 95% confidence).

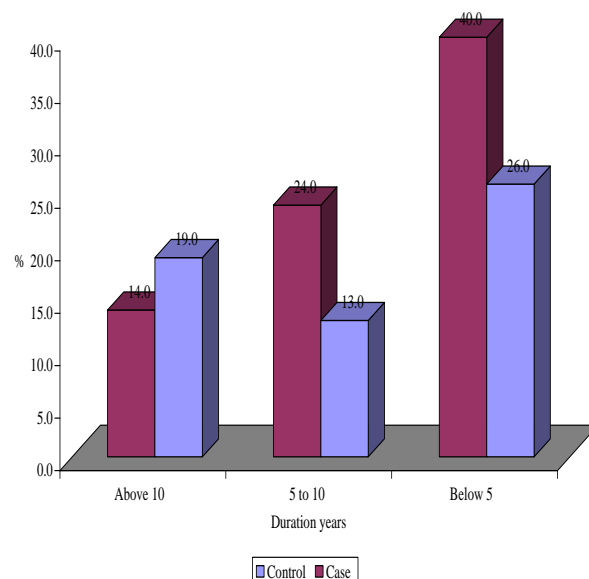


Figure. 2: Duration of tobacco used by respondents

As shown in Figure (2) duration of using tobacco among the respondents showed significant statistical association with renal failure ($P \leq 0.05$, at 95% confidence), where the cases who use tobacco for 5 – 10 years (24%) were more than control who used tobacco for the same duration.

Table 3: Type of tobacco used by respondents

Group	Type of tobacco used	Frequency	Percent
Control	Cigarette	22	22.0
	Snuff	2	2.0
	Water pipe(shisha)	9	9.0
	Cigarette and snuff	8	8.0
	Cigarette and water pipe(shisha)	12	12.0
	Snuff and water pipe(shisha)	1	1.0
	All types	4	4.0
	Total	58	58.0
Case	Cigarette	33	33.0
	Snuff	2	2.0
	Water pipe(shisha)	15	15.0
	Cigarette and snuff	8	8.0
	Cigarette and water pipe(shisha)	7	7.0
	All types	13	13.0
	Total	78	78.0

The frequency of depressed participants is 238 (73.7%) while that of the non-depressed (minimal depression) participants is 85 (26.3%). The prevalence of depression among males was $68/108 = 0.629$ (62.9%) while that of females was $170/215 = 0.79$ (79%). The prevalence of non-depressed among males was $40/108 = 0.37$ (37%) while that of females was $45/215 = 0.209$ (20.9%).

Distribution of the respondents according to type of tobacco used as indicated in table (3) showed clear variations among case and control subjects. Use of cigarette was more common among cases (33%) than among control (22%), also the use of water pipe (shisha) was found among (15%) of cases versus (9%) of control. Use of all types of tobacco was clearly varied among both groups, where (13%) of cases used all types of tobacco in contrast to only (4%) of the control.

Statistical test showed significant association between the type of tobacco used and chronic renal failure ($P \leq 0.05$, at 95% confidence).

Table 4: Health problems complained by the respondents due to tobacco use and its association with renal failure

Group	Disadvantages of tobacco use	Frequency	Percent
Control	Hypertension	5	5.0
	Kidney stones	10	10.0
	Diabetes	3	3.0
	Heart diseases	2	2.0
	Urinary tract infections	11	11.0
	None	69	69.0
	Total	100	100.0
Case	Hypertension	40	40.0
	Kidney stones	20	20.0
	Diabetes	18	18.0
	Heart diseases	12	12.0
	Urinary tract infections	10	10.0
	Total	100	100.0

The above table indicated clear variation among control and cases with regard to certain chronic diseases associated with renal failure and use of tobacco, while (40%) of the cases were hypertensive, only (5%) of the control group in the same category, kidney stones was common among (20%) of cases versus (10%) of the control, diabetic cases were (18%) of cases compared to (3%) of the control subjects, and the other complications showed the same ratios. There was significant statistical association between prevalence of certain chronic diseases and chronic renal failure among the respondents ($P \leq 0.05$ at 95% confidence).

Discussion

Demographic and socioeconomic characteristics of the respondents were statistically tested and correlated to case and control subjects.

Occupational status showed no clear differences among cases and control, where the highest parentage of both control (30%) and cases (26%) were students, and labors scored the same percentage (18%) among both of the studied groups. Other occupation showed low parentages ranged between 1-15 % with no clear variations between cases and control subjects. Statistical test for association between occupation and chronic renal failure among the respondents indicated no significant association (P - value ≥ 0.05 , at 95% confidence).

Educational level showed no significant statistical association with chronic renal failure (P -value ≥ 0.05). Murthy and Matthew, (3)

said that (Low economic status is recognized as a risk factor of many health problems, particularly in low resource settings, people with low socioeconomic status often have limited income, restricted access to health care services, poor nutrition, and a low level of awareness about health issues and preventive behavior. All of these factors can make them more vulnerable to illness and preventable diseases). Results agreed with Kabbalo, et al., (4).

Smoking and other types of tobacco use among the respondents were investigated. The findings showed that, use of tobacco was more common among the cases (78%) than control subjects (58%), in addition the average use rate of tobacco per day was found to be more common among the case subjects than control, for a period ranged between 5 – 10 years for different types of tobacco including cigarettes, snuff and water pipe, which indicates significant association between use of tobacco and chronic renal failure among the respondents (P - value ≤ 0.05), findings supported by reports of Janssen et al., (5), Pinto et al., (6) and Whelton et al., (7)

Incidence of chronic diseases associated with chronic renal failure were tested among both, the case and control subjects. Findings indicated clear variation among control and cases with regard to certain chronic diseases associated with renal failure and use of tobacco, while (40%) of the cases were hypertensive, only (5%) of the control in the same category, kidney stones was common among (20%) of cases versus (10%) of the control, diabetic cases were (18%) compared to (3%) of the control subjects, and the other complications showed the same ratios. There was a significant statistical association between prevalence of certain chronic diseases and chronic renal failure among the respondents (P -value ≤ 0.05).

Studies showed clear evidence of association between renal failure and certain chronic diseases, such as reports of Wachtell et al, (8) and Stengel et al., (9).

A previous study by Lee et al., concluded that findings suggest potentially harmful effects of the degree of exposure to smoking on the progression of chronic kidney disease (10).

Boggia et al., reported that smoking cessation slows the progression of kidney disease in smokers should drive our effort to help our patients quit smoking. Smoking prevention at the population level and particularly in those at risk of chronic kidney disease or with established chronic kidney disease should be part of health policies and regulations all around the world (11).

Smoking is associated with a greater risk of end-stage kidney disease; the risk increases with an increase in the smoking duration, number of cigarettes smoked daily, and pack-years (12).

Smoking significantly increased the risk for new-onset of chronic kidney disease based on proteinuria development in population without chronic kidney disease, and the association was more predominant in the younger population (13).

Conclusion

From the above findings the followings could be concluded that educational level showed significant statistical correlation to chronic renal failure. Use of tobacco (smoking, snuff and water pipe) is one of the most important remediable renal risk factors. It has a negative impact on renal function even in subjects without apparent renal disease, which presumably may have dramatic socioeconomic consequences.

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Original Article

Assessment of Nurses' Knowledge, Attitude, and Practices on Antibiotic Use and Resistance in Baghdad: A single-hospital study

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ABSTRACT

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Keywords: Knowledge Attitude Practice; Antibiotic Resistance; Antibiotic Usage; nursing staff..



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Background: There are so many evidences that there was antimicrobial resistance, and there were many strains that emerged which were difficult to treat. We are living in a situation that the dissemination of multiple drug resistant bacteria can lead us to the situation, in which no treatment could be offered for bacterial infection in future.

Aim of study: Assessment of nurses' knowledge, attitude, and practices on antibiotic use and resistance in Fatima Al Zahra hospital in Baghdad.

Subjects and Methods: A cross-sectional study. The study was carried on from 1st of February to 31st of March 2021. A questionnaire was constructed by the research team based on literature review and was adapted to assess the nurses' knowledge, attitude, and practices on antibiotic use and resistance in Fatima Al Zahra hospital. The adopted questions were mainly based on previous studies carried out in Lebanon, and Ethiopia. It was piloted among 10 nurses. The questionnaire was further revised by the research team. The final questionnaire contained 26 questions on the following: Demographics characteristics (5 questions), Knowledge of antibiotics (7 questions), Attitude towards antibiotic use (7 questions); and practice with regards to antibiotic use (7 questions). Analysis plan: IBM SPSS (Statistical Package for the Social Sciences) Statistics version 21 Multilingual and Microsoft Excel 2010 were used to analyze the data. The frequencies were stated first then Chi-Square test and Fisher's exact test were used to investigate the association. The p-value less than 0.05 were considered significant.

Results: One hundred and eight nurses participated in this study, of whom 101 (93.5%) were female, 31(28.7%) of participants at the age group of (18-27) years, 33(30.6%) were at the age group of (28-37) years, with mean age 26 ± 0.54 SD. Regarding the highest qualification, 41(38%) graduated from the high school of nursing, 35(32.4%) graduated from the midwife school. About 46(42.6%) of the participants were working in pediatric words, and 23(21.3%) were working in gynecology and obstetrics (Gyn & Obs) words. There was gap in the knowledge especially in nurses who had lowest qualification: 44(40%), of them believe that using antibiotic in cold can speed recovery and 41 (38%) believe that antibiotic can cure viral infections, and 42(38.9%), of them consider that newer and more costly antibiotics affect better.

Conclusion: There was a gap in nurse's knowledge, and practice, towards the antibiotic use and antibiotic resistance, the Current work place was the most effective factor in this gap.

Introduction

High numbers of infections are untreatable due to antimicrobial resistance (AMR). About 214 thousand newborns die every year from sepsis caused by bacteria resistant to current antibiotics. (1)

One of the major causes of women's death following abortion and childbirth is, caused by bacteria resistant to current antibiotics. Antibiotic resistance may also be a serious problem when women have sexually transmitted infections (STI), especially gonorrhea, which may lead to pelvic inflammatory disease, causing chronic pain and discomfort, infertility, and ectopic pregnancies, and newborn blindness. "An estimated 3 million treatment failures due to resistant gonorrhea occur each year in the world and will lead to an additional cost of US\$ 500 million". (2)

World health organization (WHO) leads the response to AMR over the past 20 years and its actions led to the development of the Global Action Plan on Antimicrobial Resistance (GAP-AMR) by the Sixty-eighth World Health Assembly in May 2015. (3)

In 2019, the WHO announced AMR as one of the top 10 global public health threats facing humanity in 2019. (4)

The cost of AMR to the economy is significant, in addition to death and disability, prolonged illness results in longer hospital stays, this lead for more expensive medicines and financial loads for those effected. (5)

The WHO reported that antibiotics contribute to, 17% of the substandard or falsified medicines consumed globally, and this will contributed to drug resistance. (6)

There are so many evidences that there was antimicrobial resistance, and there were many strains that emerged which were difficult to treat. (7-12)

Many studies demonstrated that, the most common cause of developing antimicrobial resistance is unscientific prescription and antibiotics misuse which leads to the failure of drug therapy, and prolonged the duration of therapy and leads multi-drug resistance bacteria. (13-17)

To deal with this threat doctors and all the medical staff should assess the problem and try to prevent the dissemination of multi resistant strains of bacteria, by the rational use of antibiotic and infection control methods. (18)

The control of AMR requires change in the antimicrobial prescribing behavior of health workers. Changes in antimicrobial prescribing patterns will need changes in physicians' behavior towards the magnitude of AMR problem. Nurses in hospitals play important role in prevention of transmissions of resistant bacteria and promoting awareness on AMR for patients and communities. Thus, information on physicians' and nurses' knowledge and belief on AMR will permit the development of more effective interventions on containment of AMR. (19)

Nurses are eager to participate in antibiotic surveillance. Efforts to engage nurses should address knowledge needs and consider the roles in which nurse-driven antibiotic surveillance occurs. (20)

In order to assess the future antimicrobial resistance outcome, it is very important; to assess the knowledge, attitude, and practice (KAP) of young nursing staffs as it was found very few studies which evaluate KAP on antimicrobial resistance among Nursing Staffs, this study was carried out to assess nurses' knowledge,

attitude, and practice on antibiotic use and resistance in Fatima AL Zahra hospital.

Subjects and Method

A cross-sectional study was conducted from 1st of February to 31st of March 2021, by using a questionnaire that was structured by the research team based on literature review and was adapted to assess the nurses' knowledge, attitude, and practices on antibiotic use and resistance in Fatima Al Zahra hospital. The adopted questions were mainly based on previous studies carried out in Lebanon, and Ethiopia. (17, 21)

It was piloted among 10 nurses. The questionnaire was further revised by the research team. The final questionnaire contained 26 questions on the following: Demographics characteristics (5 questions), Knowledge of antibiotics (7 questions), attitude (7) and practice (7).

Regarding knowledge questions it contained 7 questions, assessed using correct, wrong and unsure responses, 3 scores was given for each correct answer and 2 scores for each unsure and 1 score for the wrong answer, the good Knowledge score was (15-21), for average Knowledge score (8-14) and for poor Knowledge score (1-7).

Attitude towards antibiotic use (7 questions), assessed using agree, disagree, and neutral responses, 3 scores was given for each correct answer and 2 scores for each neutral and 1 score for the wrong answer, so the positive score of attitude was 14-21, and for negative attitude score was 1-7, and for neutral score was 8-13. Practice with regards to antibiotic use (7 questions), Scoring and analysis of responses to the practice subscale assessed using strongly agree, agree, neutral, disagree and strongly disagree responses, score for strongly agree 5, for agree 4, for neutral 3, for disagree 2, and for strongly disagree 1 if the answer was correct. The score for good practice was 24-35, for neutral score was 12-23, and (1-11) for bad practice. (22)

The knowledge questions and it's correct answers were:

- K1: (Yes) I heard of antibiotic resistance.
- K2: (no) antibiotic can cure viral infections.
- K3: (no) using antibiotic in cold can speed recovery.
- K4: (Yes) antibiotics can cure bacterial infection.
- K5: (Yes) newer and more costly antibiotics have no better affect.
- K6: (no) antibiotics are effective in obstructed nose and headache.
- K7: (Yes) Antibiotics effective in treating urinary tract infections.

The attitude question and it's correct answer was:

- A1: measures are needed to minimize antibiotic resistance (agree).
- A2: there is a risk with irrational use of antibiotics at present (agree).
- A3: antibiotic resistance can result from inappropriate use of antibiotics (agree).
- A4: sensitivity test is a good option for assessing antibiotics resistance (agree).
- A5: antibiotic isn't safe drug and can't be commonly used (agree).
- A6: the more antibiotics we use in society, the higher is the risk that resistance develops and spreads (agree).
- A7: I can take antibiotics without seeing doctor (disagree).

The practice question and it's correct answer was:

P1: I ask physician about sensitivity test for assessing antibiotic resistance before I use antibiotic (strongly agree).

P2: I don't use antibiotic in lower than recommended dose because this can lead to antibiotic resistance (strongly agree).

P3: I use hand washing & vaccination, as important steps in prevention of AMR (strongly agree).

P4: I don't buy the same antibiotics, if I am sick and they helped me get better when I had the same symptoms before (strongly agree).

P5: I consult a pharmacist about taking antibiotics (strongly agree).

P6: I believe that skipping one or two doses of antibiotics contribute to the development of antibiotic resistance (strongly agree).

P7: I don't ask the doctor to prescribe antibiotic for the common cold (strongly agree).

The final questionnaire was translated to Arabic in order to facilitate the task to read and answer the questionnaire.

Sampling method: the hospital has 152 nurses at the morning shift, of these nurses 124 only who fulfilled the inclusion criteria, distributed in the various wards; pediatrics wards 46 nurses, Gyn & Obs ward 23, operation theater 16, outpatient 21 nurses, delivery room 18 nurse. Those who completed the questionnaire were only 108.

The study team used a convenient sampling methodology to recruit participants for the KAP survey due to limitations of the resource. The sampling framework was subsequently stratified among the five groups, gynecology and obstetrics and pediatrics, operation theater, delivery room, and outpatient department.

All study participants were assured for privacy and informed that their names will not appear in the questionnaire. Participants were only identified by age, gender, marital status, and place of current work and participant names only used in the consent forms.

Inclusion criteria: all nursing staff who was working on morning shift at any department of the Fatima Al Zahra hospital who agree to participate in the study.

Exclusion criteria: the nursing staff on night shift.

Statistical analysis: The statistical analysis was performed using statistical package for social science (SPSS-21). The Chi-square and fisher's exact probability tests were used. A P value of ≤ 0.05 was considered significance and a 95% confidence interval was calculated for all odds ratio calculations.

Ethical approval was obtained from Al-Rusafa Health Directorate Scientific and Ethical Review Committee, Ministry of Health, Iraq.

Results

One hundred and eight nurses participated in this study, of whom 101 (93.5%) were female, 31(28.7%) of participants at the age group of (18-27) years, 33(30.6%) were at the age group of (28-37) years, with mean age 26 ± 0.54 SD. Regarding the highest qualification, 41(38%) graduated from the high school of nursing, 35(32.4%) graduated from the midwife school. About 46(42.6%) of the

participants were working in pediatric words, and 23(21.3%) were working in gynecology and obstetrics (Gyn & Obs) words. Thirty-three participants (30.6%) had 1-5 years of Work experience. Regarding the Marital status of the participants 68(63%) of them were married. table 1.

Table 1: Demographics Characteristics of the participants

		Frequency	Percent
Age group(years)	18-27	31	28.7
	28-37	33	30.6
	38-47	25	23.1
	> 47	19	17.6
Gender	Male	7	6.5
	Female	101	93.5
Highest qualification	High school of nursing	41	38.0
	High school of midwife	35	32.4
	High institute of health	25	23.1
	College of nursing	7	6.5
	Pediatric	46	42.6
Current work place	Obs. & Gyn.	23	21.3
	Outpatient	13	12.0
	Delivery ward	19	17.6
Work experience (years)	Operation room	7	6.5
	1-5	33	30.6
	6-10	31	28.7
	11-15	16	14.8
Marital status	>15	28	25.9
	Married	68	63.0
	Unmarried	30	27.8
	Widow	6	5.6
	Divorced	4	3.7
Total		108	100.0

Regarding the knowledge questions the responses were as following:

Most of participants 98(90.7%), heard of antibiotics resistance, and 92(85.1%) of them consider antibiotics can cure bacterial infection, and 94(87%) know that antibiotics effective in treating urinary tract infections, but there was a gap in the knowledge especially in nurses who had lowest qualification: 44(40%), of them believe that using antibiotic in cold can speed recovery, and 41 (38%) believe that antibiotic can cure viral infections, and 42(38.9%),of them consider that newer and more costly antibiotics affect better. Table 2.

The attitude questions responses were:

The nursing staff attitude towards antibiotic use and resistance, it was positive attitude since most of them agree that there is a misuse of antibiotics at present, and 66.7% of the participants agree that they should ask a doctor before using antibiotics. Most of the participants agree that the more antibiotics we use in society, the higher is the risk that resistance develops and spreads, and that antibiotic isn't safe drug and can't be commonly used. Table 2.

Table 2: frequency and percentages of participant`s responses to the knowledge, attitude, and practice questions

Answer	Knowledge(k) , attitude(A) and practice(P) question													
	K1		K2		K3		K4		K5		K6		K7	
yes	98	90.7	57	52.8	62	57.4	92	85.2	54	50	25	23.1	94	87
no	4	3.7	41	38	44	40.7	9	8.3	42	38.9	72	66.7	11	10.2
do not know	6	5.6	10	9.3	2	1.9	7	6.5	12	11.1	11	10.2	3	2.8
Disagree	A1		A2		A3		A4		A5		A6		A7	
	NO.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
	11	10.2	9	8.3	7	6.5	14	13	24	22.2	25	23.1	72	66.7
	18	16.7	14	13	20	18.5	15	13.9	9	8.3	12	11.1	14	13
Agree	79	73.1	85	78.7	81	75	79	73.1	75	69.4	71	65.7	22	20.4
Strongly disagree	P1		P2		P3		P4		P5		P6		P7	
	NO.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
	2	1.9	2	1.9	1	.9	2	1.9	2	1.9	2	1.9	2	1.9
	17	15.7	30	27.8	2	1.9	28	25.9	29	26.9	31	28.7	53	49.1
disagree	11	10.2	24	22.2	2	1.9	3	2.8	3	2.8	22	20.4	7	6.5
Neutral	74	68.5	48	44.4	95	88	71	65.7	70	64.8	49	45.4	42	38.9
agree	4	3.7	4	3.7	8	7.4	4	3.7	4	3.7	4	3.7	4	3.7
Strongly agree														

The practice questions responses:

Regarding Practice the current study found that 30(27.8%) of the participants agree that antibiotic use in lower than recommended can't cause antibiotic resistance and 31(28.7%), of them believe that skipping one or two doses of antibiotics can't contribute to the development of antibiotic resistance and 22(20.4%) were unsure about the answer. Table 2.

Table 3: the association of knowledge score to some sociodemographic characteristics

		Level knowledge						P value
		Good		Average		Poor		
		Count	%	Count	%	Count	%	
Age group(years)	18-27	11	35.5	14	45.2	6	19.4	.763
	28-37	10	30.3	14	42.4	9	27.3	
	38-47	7	28	10	40	8	32.0	
	>47	3	15.8	11	57.9	5	26.3	
Gender	Male	3	42.9	4	57.1	0	0	.313
	Female	28	27.7	45	44.6	28	27.7	
	high school of nursing	9	22	20	48.8	12	29.3	
	high school of midwife	11	31.4	12	34.3	12	34.3	
highest qualification	high institute of health	8	32.0	15	60	2	8	.160
	college of nursing	3	42.9	2	28.6	2	28.6	
	pediatric	16	34.8	23	50.0	7	15.2	
	obs & gyn	0	0	12	52.2	11	47.8	
current work place	outpatient	6	46.2	4	30.8	3	23.1	.001
	delivery ward	4	21.1	9	47.4	6	31.6	
	operation room	5	71.4	1	14.3	1	14.3	
	1-5	13	39.4	14	42.4	6	18.2	
work experience year	6-10	8	25.8	16	51.6	7	22.6	.640
	11-15	4	25	7	43.8	5	31.3	
	>15	6	21.4	12	42.9	10	35.7	
	married	19	27.9	31	45.6	18	26.5	
marital status	unmarried	9	30.0	15	50.0	6	20	.891
	widow	2	33.3	2	33.3	2	33.3	
	divorced	1	25	1	25.0	2	50.0	

The current study found that current work place has significant statistical association to knowledge of the nursing staff, but there

were no significant statistical association between knowledge and nurse's gender, age, qualification, experience or the Marital status. Table3.

It was shown that participants' attitude towards antibiotic use was not statistically associated with gender, age, qualification, current work, experience nor the Marital status. Table 4.

Table 4: the association of attitude scores to some sociodemographic characteristics

demographic variables	Negative attitude, count		Positive attitude, count		P value	
	count	%	count	%		
Age group(years)	18-27	3	9.7	28	90.3	1.000
	28-37	3	9.1	30	90.9	
	38-47	3	12.0	22	88.0	
	> 47	2	10.5	17	89.5	
Gender	Male	0	0.0%	7	100	0.356
	Female	11	10.9%	90	89.1	
	high school of nursing	5	12.2	36	87.8	
	high school of midwife	5	14.3	30	85.7	
highest qualification	high institute of health	1	4.0	24	96.0	.559
	college of nursing	0	0.0	7	100	
	pediatric	4	8.7	42	91.3	
	obs & gyn	2	8.7	21	91.3	
current work place	outpatient	0	0.0	13	100.0	.282
	delivery ward	3	15.8	16	84.2	
	operation room	2	28.6	5	71.4	
	1-5	1	3.0	32	97.0	
work experience (years)	6-10	5	16.1	26	83.9	.313
	11-15	2	12.5	14	87.5	
	>15	3	10.7	25	89.3	
	married	6	8.8	62	91.2	
marital status	unmarried	4	13.3	26	86.7	.649
	widow	1	16.7	5	83.3	
	divorced	0	0.	4	100	

Current study shows that participants' practice towards antibiotic use was not statistically associated with gender, age, qualification, experience or the marital status, but current work place has significant statistical association to practice of the nursing staff. Table (5).

Table 5: the association of attitude scores to some sociodemographic characteristics

demographic variables	Good practice		Bad practice		P value	
	Count	%	Count	%		
Age group (years)	18-27	14	45.2	17	54.8	.533
	28-37	10	30.3	23	69.7	
	38-47	11	44.0	14	56.0	
	> 47	6	31.6	13	68.4	
Gender	Male	3	42.9	4	57.1	1.000
	Female	38	37.6	63	62.4	
	high school of nursing	13	31.7	28	68.3	
	high school of midwife	13	37.1	22	62.9	
highest qualification	high institute of health	13	52.0	12	48.0	.395

demographic variables		Good practice		Bad practice		
current work place	college of nursing	2	28.6	5	71.4	
	pediatric	18	39.1	28	60.9	
	obs & gyn	3	13.0	20	87.0	.032
	outpatient	6	46.2	7	53.8	
	delivery ward	11	57.9	8	42.1	
work experience (years)	operation room	3	42.9	4	57.1	
	1-5	12	36.4	21	63.6	
	6-10	14	45.2	17	54.8	.792
	11-15	6	37.5	10	62.5	
	>15	9	32.1	19	67.9	
marital status	married	25	36.8	43	63.2	
	unmarried	13	43.3	17	56.7	.618
	widow	1	16.7	5	83.3	
	divorced	2	50.0	2	50.0	

Discussion

There are so many evidences that there was antimicrobial resistance, and there were many strains that emerged which were difficult to treat. We are living in a situation that the dissemination of multiple drug resistant bacteria can lead us to the situation, in which no treatment could be offered for bacterial infection in future. The overuse of antibiotics in the outpatient sectors and during hospitalization is expected to increase the bacterial antibiotic resistance.

The study surveyed nursing staffs in Fatima Al Zahra hospital, to assess their knowledge, attitude, and practice towards antibiotic use in the form of questionnaires.

More than one third of studied hospital nursing staffs believed that antibiotics can speed up recovery of common cold & cough, and 37.9% of them believed that antibiotics can cure illnesses caused by viral infections. This may lead to miss prescription of antibiotic for treating common cold and other viral disease like diarrhea due to Rota virus. Our results are harmonious with other studies when Huang Y, et al, found that 43.4% of nurse student think that antibiotics can cure illnesses caused by viral infections & 23.3% of them believe that antibiotics can speed up recovery of common cold & cough. (11-13)

Half of the participants may use antibiotic in low dose and they think it can't cause antibiotic resistance, also they agree that skipping one or two doses of antibiotics doesn't contribute to the development of antibiotic resistance, these two mistakes can cause bacterial antibiotic resistance, (1,23), these results were also reached by other studies, when Kulkarni P, et al, found that about 40% of the participants (among interns in a teaching tertiary care hospital)were either agree or unsure that skipping one or two doses of antibiotics doesn't contribute to the development of antibiotic resistance, and when Bharti RK, et al, found that 36.2% of the nurses agree that Skipping one or two doses does not contribute to the development of antibiotic resistance, (12, 24).

The current study found that more than three quarter of the participants know that antibiotics can cure bacterial infection, which is comparable to 88% in a study conducted by Marzan M, et al, in Bangladesh , (25), and higher than the proportion (73%) reported in Qatar (26).

Most of participants 98(90.7%), heard of antibiotics resistance, this result was reached by other studies, Jayaweerasingham M, (27), but it was higher than result found by other when Dönmez S, et al, found

that 66.5% of participants have previously heard of antibiotic resistance; in Turkey. (28)

In the current study it was found that more than two thirds of the participants asked the doctors and do antibiotic sensitivity test before use of antibiotic which was higher than the result of another study when, Jayaweerasingham M, et al, found that (58.3%) among a group of trainee nurses in Sri Lanka stated that "they always consult a doctor before starting antibiotics". (27)

Half of the participants in the current study, think that newer and more costly antibiotics have no better affect; this was lower than results of when Huang Y, et al, found that 72.4% of the nurses think that the "efficacy is not better if the antibiotics are newer and more costly".(11)

The current study shows that more than half of participants ask the doctor to prescribe antibiotic for the common cold this result was higher than other study when they found that one third of the participants "Ask doctor to prescribe antibiotics for common cold".(13)

This study found that more than two thirds of participants don't use antibiotic to treat headache, this was also inconsistent with other study when they found that two thirds of participants will "Use antibiotics for obstructed nose with headache). (13).

Conclusion

There was a gap in nurse's knowledge, and practice, towards the antibiotic use and antibiotic resistance, the Current work place was the most effective factor in this gap.

Recommendations

1. Establishment of a course on rational use of antibiotics at the nursing and midwife schools.
2. There should be a focus on the antibiotic usage and prescription practice introduction of nursing staff in their curriculum, and on the antibiotic knowledge education for nursing staff.

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Original Article

Awareness Regarding Diabetes Risk Factors, Prevention and Management among Community Members in Diyala/ Baqubah

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ABSTRACT

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Background: Background: Diabetes mellitus is a life-threatening disease. Global prevalence of diabetes mellitus is increasing rapidly providing a worrying indication and major threat to global health unless interventions are created through community awareness and knowledge regarding different aspect of DM.

Aims: To assess the level of awareness regarding diabetes risk factors, prevention and management among community members in Baqubah city and to identify any association between awareness level and some variables.

Subject and Methods: Across sectional study was carried out from the 1st of January - 30th of November 2019 in all primary health care centers (six centers) in center of Baqubah city. A convenient sample of 400 participants who attended the health centers during the study period and eligible to inclusion criteria were included. Data were collected via direct interview with a structural questionnaire that include personal data, questions regarding knowledge, regard diabetes definition, prevention, risk factor, management and control.

Results: Good diabetes awareness were reported among 50% of studied. A significant statistical association were found between good awareness and age of 20-30years, more than secondary school education, high family income and positive family history of diabetes with the following (52, 34, 35 & 68) % respectively.

Conclusion: Good diabetes awareness was dominant and was significantly associated with middle age group, higher education and positive family history of diabetes. an educational health programs that tackles area of weakness about awareness of diabetes mellitus need to be implemented on the governmental level.

Introduction

Diabetes mellitus (D.M) is one of the most common non-communicable diseases worldwide. In the Eastern Mediterranean Region there has been a fast increase in the incidence of diabetes

mellitus and it is now the fourth principal cause of death. The emergence of diabetes complications considered as important cause of early morbidity and mortality. (1)

The World Health Organization (WHO) in 2007 report shows that at least 171 million people of the world are suffering from diabetes. (2,3) International Diabetes Federation in a recent station in 2017 reported that 415 million people aged 20-79 years have had diabetes in 2015, this number is predictable to reach 552 million by 2030 and 642 million by 2040. (4) According to Ministry of Health (MOH) in Iraq the prevalence of diabetes in Iraq increased from 5% in 1978 to 13,9% in 2015. (5)

Diabetes is a major contributor to illness and death and generates large direct as well as indirect cost. (6-8) . high blood glucose levels can lead to serious diseases affecting the heart and blood vessels, eyes, kidneys, nerves and teeth. In addition, people with diabetes also have a higher risk of developing anaemia and infections.(9,10)

The risk factors for type I diabetes are still being investigated however having family member with type I diabetes slightly increase the risk of developing the disease. ((11) Environmental influences and exposed to some viral infections may linked to increase risk of developing type I diabetes. (12)

Type 2 diabetes may be associated with numerous risk factors like family history of diabetes, physical inactivity, increase age, overweight, unhealthy diet, , high blood pressure, impair glucose tolerance, history of gestational diabetes and poor nutrition during pregnancy. (11,12)

Following life-style changes, global prevalence of diabetes mellitus is increasing quickly providing a worrying indication and major threat to global health. This consumes the nation's health care inexpensive. Unless interventions are made through community awareness; Diabetes mellitus is predicted to be the world's main disablers and killers of the working age groups in the next 20 years. (11,13)

The focus on diabetes mellitus was growing; studies showed that a number of adults having diabetes will be more than double between 2000 and 2030. (14)

The general community remains unaware that raised levels of blood glucose are consorted with long-term damage to the organic structure and the failure of different organs and tissues. (15)

Diabetes mellitus is a preventable and controllable disease by raising the awareness of the public by its progression, for example Knowledge of the prevention and risk factors of ocular complications is essential to prevent vision loss among DM patients. (16)

Diabetes like other no communicable disease gets lower attention than it deserves, despite its social, human and economic costs. Fewer countries including Iraq have national programmers and basic facilities that are appropriate for the prevention and control of the disease in all areas of interventions at the primary, secondary and tertiary health care levels. (17)

Patient education is an important component of diabetes treatment, projected not merely to transfer information but also to attain behavioral alteration as well. (18) Diabetes education should be considered not only for diabetics, but also for the social surroundings of diabetics and indeed the population as a whole. This enables the patient and their social surroundings to learn as much as possible about the disease so that the patient can share the obligation for

glucose regulation and complication prevention with the health-care team. (18-20).

health literacy of people strongly influences the prevention and management of chronic illnesses (21). Performed studies indicate that the level of health literacy affects people's decisions and actions as well as their ability to embrace a healthy lifestyle and access the most appropriate form of health care (22,23). Studies indicate that poor health literacy is among the important factors influencing health outcomes in diabetic patients (24, 25)

Thus, Greater literacy amongst the population about understanding diabetes symptoms may improve the use of health care and, ultimately, positively affect community health outcomes. ((26)

Aims of the study

Primary outcome: To assess awareness regarding diabetes risk factors, prevention and management among community members in Baqubah city at 2019.

Secondary outcome: To determine any association between patient awareness and some socio-demographic and other studied factors.

Subjects and Methods

Study design: -

Across sectional study.

Study setting:

the study was carried out in all six primary health care centers of Baqubah city from where the study sample were collected.

These six primary health care centers include the following:

- 1.Al.Saray primary health care center.
- 2.Al.Mustafa Primary health care center.
- 3.Al.Takia primary health care center.
- 4.Buhriz primary health care center.
- 5.Al.Tahrer primary health care center.
- 6.Al.Yarmuk primary health care center.

Study duration:

The study was conducted from 1st of January till the 30th of November 2019,working 4 hours per day in two days per week.

Target population: A convenient sample of 400 participants who visited the mentioned primery health care center and willing to participate were included in this study.

Inclusion criteria:

- Any subject visited the primary health care center whether are patient or relative or companion of the patients.
- Any subjects age 20 years and above.
- Both genders.
- Whether diabetic or non-diabetic.

Study tools and data collection: A convenient sample was collected from the target population during the expected period of data collection (11 months), as one and a half to two month for each primary health care center included in the study with average of 65-66 participants from each center, the total number of sample were 400 subjects.

Data was obtained by a questionnaire prepared by the researcher with supervisor after extensive literature review to collect relevant data, it includes the following information:

Part 1 the participants sociodemographic factors and other related factors:

Part 2: This part includes 24 knowledge questions that covering key area in awareness about diabetes mellitus including "definition, risk factors, prevention, control, management, complication, hypoglycemic symptoms identifications, plasma glucose level awareness.

A scoring system was developed for each question, each correct answer was given score of (1), and each incorrect or don't know answer was given a score (0) the total score ranged from (0-24) transfer to 100% questionnaire.

Three categories were defined on basis of the score obtained by each participant:

- Poor awareness (if awareness score < 40% of the total score).
- Acceptable awareness (if awareness score 42- 60 % of the total score).
- Good awareness (if awareness score > 60% of the total score).

Ethical approval:

The study protocol is reviewed and approval is obtained from scientific council of family medicine to conduct the study. Also, approval and official letter is obtained from Diyala health directorate (including approval by ethics review committees) which is handed to the manager of each selected primary health care centers accordingly.

Verbal consent of each interviewed person was approved after full explanation of the aim of the study and ensuring the confidentiality of collected data which was not be used but for the research purpose.

Statistical analysis:

Data collected were entered into Microsoft excel and loaded into the statistical package for social science (SPSS) software "version 23". Data were analyzed via descriptive statistics, the results showed in tables and figures. Frequencies and percentage were used to summarize dichotomous data and categorical data. Chi square test" were used to compute the association between studied variables. Significant association is considered at level of ≤ 0.05 (p-value).

Results

Table (1) shows the socio-demographic characteristics of the study population, 52% of the participants where 30-50 years of age, 54% were female, 34% o completed more than secondary level of education.

Distribution of the study sample according to their level of diabetes awareness:

Figure (1) shows that the majority of the study population 200 (50%) had a good diabetes awareness, 40% of them showed acceptable awareness and only 10% had poor awareness.

The association between the level of diabetes awareness and studied factors:

Table (2) shows significant association between the level of diabetes awareness and age, 52% of good awareness were among (30-40) years old. Significance association also found with the highest educational level and high monthly income with 34%, 35% respectively

Table 1: Distribution of the study sample according to some sociodemographic characteristics

Category	No. (400)	%
Age (years) :		
20-29	104	26
30-39	208	52
≥40	88	22
Gender :		
Male	176	46
Female	224	54
Marital status :		
Married	328	82
single	48	12
Other	24	6
Educational level:		
Less than primary	72	18
Primary	96	24
Secondary	128	32
More than secondary	104	26
Monthly income of family:		
Low < 500,000ID	104	26
Intermediate 500- 1000,000ID	224	56
High > 1000,000 ID	72	18
Diabetes status:		
Diabetic	200	50
Non-diabetic	200	50
Family history of diabetes		
Positive	264	66
Negative	136	34
Total	400	100

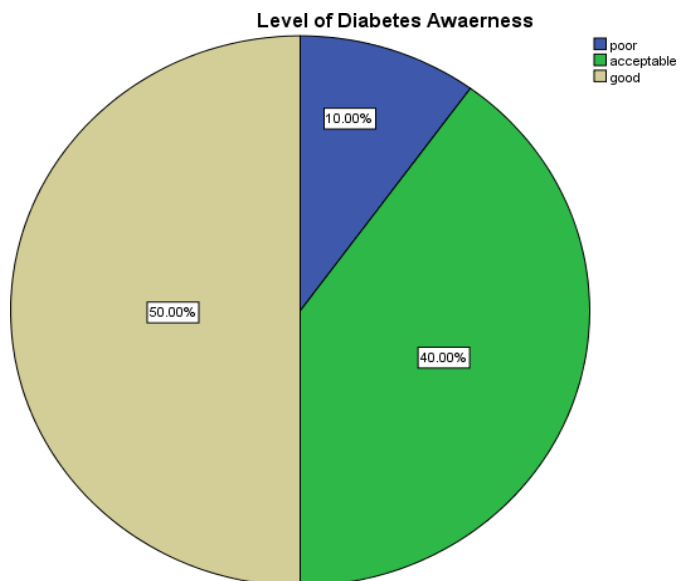


Figure. 1: Distribution of the study sample according to the level of diabetes awareness

Table 2: The association between the level of diabetes awareness and some socio-demographic factors among study group

variables	Diabetes level of awareness								P-value
	Poor (40)		Acceptable (160)		Good (200)		Total (400)		
	No.	%	No.	%	No.	%	No.	%	
Age (years)									
20-29	18	45	38	24	48	24	104	26	0.01
30 -39	12	25	92	59	104	52	208	52	
>40	10	30	30	17	48	24	88	22	
Gender									
Male	16	40	72	45	96	48	184	46	0.617
Female	24	60	88	55	104	52	216	54	
Educational Level									
Less than primary	16	40	42	26	14	7	72	18	0.004**
Primary	8	20	30	19	58	29	96	24	
Secondary	10	25	58	36	60	30	128	32	
More than secondary	6	15	30	19	68	34	104	26	
Monthly income									
Low	23	57.5	18	11	63	31.5	104	26	0.05**
Intermediate	16	40	141	88	67	33.5	224	56	
High	1	2.5	1	1	70	35	72	18	

Table (3) shows the association between the level of diabetic awareness and family history and diabetic status, these two factors are significantly associated with the highest percentage of good awareness are among those with positive family history and those who are diabetic with (68,60)% respectively.

Table 3: The association between the level of diabetes awareness and family history and diabetes state:

variables	Diabetes level of awareness								P-value
	Poor (40)		Acceptable (160)		Good (200)		Total (400)		
	No.	%	No.	%	No.	%	No.	%	
Family history of diabetes									
Positive	16	40	112	70	136	68	264	66	0.001**
Negative	24	60	48	30	64	32	136	34	
Diabetic status									
Diabetic	16	40	64	40	120	60	200	50	0.001**
Not Diabetic	24	60	96	60	80	40	200	50	

Discussion

Global prevalence of diabetes mellitus is increasing rapidly providing a worrying indication and major threat to global health unless interventions are created through community awareness and knowledge regarding different aspect of DM. This study was undertaken to evaluate the awareness regarding diabetes mellitus risk factors and preventive measures among general population in Baqubah city.

In this study sample of 400 attendants to all primary health care centers in Baqubah city were surveyed, regarding the level of diabetes awareness, about half participants had a good level of awareness, and less than one quarter had a poor awareness, The relatively large proportion of respondents with high university level of education may be contributed factor to the high average score.

Similar finding was reported in a study by Kassahun C.W. et al (2017) in Ethiopia among community members showed that 52.5% participants had good general knowledge about diabetes mellitus of people were with good level of awareness. (27) Approximately 56.02% good knowledge reported by Shiferaw et al in Debra Bethan town, northeast Ethiopia (2020). (28)

The current study results are disagree with a survey reported by Brown RL (2017) which showed that about most of participants (23.3 %) had good awareness. (29)

Based upon results of a survey by Maina W.K. et al (2010) it was reported that about 27.2 % had good diabetes awareness and 72, 8% had poor awareness. (30)

This disagreement with the current study may be due to difference in the study design, scoring system and difference in the socio cultural characteristic between the study populations.

Concerning the association between diabetes mellitus awareness and age, the current study showed positive association between diabetes awareness and age, the percentage of good awareness improve with increasing age.

This finding is in consist with a study done by Maina A. et al (2016) (30) which showed that good awareness is highest in age group 30-40 years (16.05%). While disagree with study done by Islam M. et al (2014) (31) which showed that good awareness was highest (43.3%) at age group below 30 years. They found that age was important predictor for diabetes awareness and that level of awareness increased with deceased age.

The present study revealed that the educational status was significantly associated with diabetes, more than third of respondents with good awareness had more than secondary school level of education, this could be explained by the fact that low education level can limit information access, due to possible limiting abilities of reading and learning , on the other hand person with higher education would have more chance to get different information, such as leaflets and manuals, helping them more be aware about diabetes. Furthermore, this more highly educated group tend to have better communication skills that allow them to communicate more easily with health care workers concerning questions or worries.(32)

This finding is consistent with a study of Maina W.K. et al (2010) which reported that 52%of good awareness in those completed more than secondary education compared to 25% in those completed secondary education. (30)

The current study observed that attendants belonging to poor socioeconomic state were of less diabetes awareness than those belonging of the higher class, while highest level of good awareness reported among participants with high income.

Limited family income which usually associated with limited education may be the predictor of awareness deficits.

This finding was consistent with Kassahun C.W. (2017) et al survey which showed that 68.6% of subjects with high income level was significantly associated with high level of good awareness regarding diabetes mellitus. (27)

The results of the present showed that two third of participants with positive family history of diabetes associated with good diabetes awareness.

Individual with positive family history of diabetes may develop a personal experience with diabetic relative and increase their learning interest regarding diabetes, this finding was in agreement with the surveys of Maina A. et al in (2016) who reported that awareness in population with positive family history was 60% compared with those with negative family history 14.31%.(30) which is similar to findings in a semi-urban Omani population.(32)

Another study agree with this result done by Alanzi. et al (2017) which showed that awareness level is higher among those with positive family history of diabetic than those with negative family history and the percentage was 60%, 40%.(32)

Another study held by Salem et al (2017) in al-Riyadh showed that good awareness was higher (69.2%) among participants with positive family history compared to 31.8% with negative family history. (33) Which is similar to findings in a semi-urban Omani population (32)

On the other hand, in the present study, those who had diabetes were almost two times more aware about diabetes than those who did not have diabetes. this result suggest that the awareness of diabetic individual may be accumulate over the span of their illness, and those patients have probably learnt from their own experiences, and as they in contact with their own physician or health care professionals who may play a role in disseminating health information about diabetes to their own patients. This finding is consistent with a study conducted by Mohan D. et al (2005) in India which showed that the awareness score by diabetic subjects are 53.5 % compared to those who non-diabetic subjects 47.5 %. (34) And the finding also supported by the study done in Bangladesh (31) and Bale zone (27).

Conclusion

This community-based cross-sectional study showed that the overall awareness about DM was good. Middle age group, educational status, family history of DM and exposure to diabetes had significant associations with the diabetes awareness of the study participants. Therefore, an educational health programs that tackles area of weakness about awareness of diabetes mellitus and its complications and management need to be implemented on the governmental level. Health care professionals, different kind media, health policy makers, teachers of different level may play a significant role in increasing risk perception of people about diabetes mellitus for effective prevention, control and management of this globally affected issue.

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Original Article

Assessment of Lipid Profile among Sudanese patients with Type 2 Diabetes Mellitus

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ABSTRACT

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Keywords: Cardiovascular Disease (CVD), Dyslipidemia, Type 2 Diabetes Mellitus (DM), Lipid Profiles



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Background: Diabetes mellitus is a major health issue that is one of the leading causes of cardiovascular disease. Recent studies have found a link between uncontrolled diabetes and cardiovascular disease, with dyslipidaemia predicting glycated-hemoglobin (HbA1c), which could be a major contributor to type 2 diabetes complications and etiology.

Objectives: The objective of present study was estimate lipid profiles among control and uncontrolled type 2 diabetic patients.

Subjects and Methods: Analytical case control based study, One hundred twenty participate were included in study, 70 patients with DM as case group refer to Abuagala Center and difference follow up diabetic center and 50 non diabetic subjects taken as control group males and females their age between 20 to 80 years. Fasting blood glucose (FBG), blood HbA1c, and serum lipid parameters were measured by CobseC311 from Roche instrument. Data was analyzed using SPSS version 22, which expressed as (mean±SD) with p.value.

Result: Among 120 participant the levels of fasting blood glucose, blood HbA1c, and Triglyceridewere increased significantly in T2DM (161.7±72.5mg/dl), (8.88±3.9 %), (121±61.9 mg/dl) when compare with control group (91.28±13.9), (5.7±0.50), (80±11.7) with P.value (0.000), while total Cholesterol, High Density Lipoprotein, and Low Density Lipoprotein were not significant different in T2DM when compared with control group. There was weak positive correlation between HbA1c with FBG, CHOL, LDL, and HDL (r = 0.207, P =0.089, r = 0.186, P =0.124, r = 0.167, P =0.168, r = 0.308, P =0.01) respectively, while TG had weak negative correlation (r = - 0.146, P =0.228).

Conclusion: The results indicated to considerable increase in the lipid profile levels in type two diabetic patients when compared with healthy controls group which may lead to increase in coronary risk factors.

Introduction

Diabetes mellitus type two is a metabolic disorder that is characterized by hyperglycemia in the context of insulin resistance and relative lack of insulin (1). The gradual increasing in diabetes mellitus prevalence worldwide and is reaching epidemic proportions. The prevalence of diabetes in adults globally is estimated to be

6.4%, affecting 285 million people in 2010 and may be expected to increase until 7.7% affecting about 439 million people in 2030. Lipid abnormalities associated with diabetes are called dyslipidemias instead of hyperlipidemias a result of the changes may be in both quantity and types of the lipoproteins. Diabetes mellitus (DM) is a one of common secondary cause of increase lipid in blood,

especially, if glycaemic control is poor, which in-turn is an important risk factor for atherosclerosis and coronary heart disease (2). The rise in diabetes prevalence worldwide can be associated with an inescapable increase in the long-term complications. Diabetes menaces to increase morbidity and mortality as a consequences of its complications which include macrovascular and microvascular (3). Diabetic dyslipidemia (DD) is one of common diabetes mellitus macrovascular complications (4). DM is considered as a major health which is one of the most important risk factors for cardiovascular disease (CVD) in both developed as well as developing countries (5). Dyslipidemias frequent more than 75% among patients with type 2 DM (T2DM) exclusively mixed dyslipidemia. Due to insulin resistance, the components of DD is characterized by quantitative and type of lipids which contributing to CVD risk (6). Lipids level in controlled diabetic patients is normal level as normal individual (Non-diabetic patients); but some studies concluded to abnormalities in lipid levels include uncontrolled diabetic patients (7). The risk factors for atherosclerosis include increase cholesterol, triglyceride and LDL, also decrease HDL which all this aspect of dyslipidemia are found in poor glycemic control in T2DM (8). As a result of increase LDL particles in parallel with increase VLDL and IDL, which that mean high apolipoprotein B levels. In other hand, the high levels of postprandial serum triglycerides are illustrated the increase probability to cardiovascular disorders. The high lipids level in blood lead to accumulated in body tissues and causes obesity and consequence of insulin resistance which term as metabolic syndrome. The obesity is the most criteria obvious in patients with T2DM, which is mean, T2DM patients had high blood glucose because insulin resistant, as result of it increase lipogenesis especially cholesterol and LDL and decrease HDL according to diabetic control status (9).

Subjects and Methods

Study population: -

The analytical case control study conducted in Abuagla center for diabetic patients, Wad Madani, Gezira state, Sudan during the period 2018 to 2021 for followup. One hundred twenty individuals were included in this study, 70 patients with T2DM as case group and 50 healthy non diabetic subjects taken as control group with their match age and sex, age ranged between 20 to 80 years.

Sample collection:

About 1.5 ml to 3 ml of venous blood was obtained as a part of the required investigation for these children. The blood samples were placed in a sterile plain tube, allowed for clotting at room temperature for 30 minutes and then centrifuged at 1500 rpm for 5 minutes. All sera were stored at -20°C pending testing. Samples were tested for CMV-specific IgM antibodies by commercially available IgM capture ELISA kits (Bioactiva, Germany). CMV negative samples were also tested for CMV-specific IgG antibodies. The manufacturer's instructions were strictly adhered to in the performance and interpretations of the tests and results.

Sample collection:

Five ml of blood were collected from each patient and healthy individual (control group) and divided as follows: Two ml of blood in EDTA tubes for HbA1c, one ml of blood was withdrawn into

fluoride tube for measuring fasting blood glucose and two ml of blood were withdrawn in heparin tube for analyzed lipid profiles. Lipid profiles, FBG and HbA1c were analyzed using Cobas C311 (Roche diagnostics, Germany) clinical chemistry analysis.

Principle of glucose estimation test:

Glucose was estimated by enzymatic reference method with hexokinase. Hexokinase catalyzes the phosphorylation of glucose to glucose-6-phosphate by Adenosine triphosphate (ATP). Glucose-6-phosphate dehydrogenase oxidizes glucose-6-phosphate in the presence of Nicotinamide Adenine Dinucleotide Phosphate to gluconate-6-phosphate.

Principle of glucose estimation test:

Glucose was estimated by enzymatic reference method with hexokinase. Hexokinase catalyzes the phosphorylation of glucose to glucose-6-phosphate by Adenosine triphosphate (ATP). Glucose-6-phosphate dehydrogenase oxidizes glucose-6-phosphate in the presence of Nicotinamide Adenine Dinucleotide Phosphate to gluconate-6-phosphate.

Principle of HbA1c test:

The blood sample is diluted and mixed with tris(hydroxyl methyl)aminomethane buffer to release hemoglobin from the erythrocytes. A fraction of the sample is conveyed into a reaction chamber where it is mixed with sodium lauryl sulfate (SLS). SLS is used to form the SLS-hemoglobin complex. The concentration of total hemoglobin is calculated by measuring SLS-hemoglobin complex with a wavelength of 525 nm. Hemoglobin A1c (HbA1c) in another fraction of the sample is first denatured by potassium ferricyanide and sucrose laurate. Denatured HbA1c was bonds with HbA1c antibody on the latex particle. Latex agglutination inhibition reaction then occurs by reacting of the agglutinator that has synthetic antigen which can bond with HbA1c antibody. The concentration of HbA1c is calculated by measuring the latex agglutination inhibition reaction with a wavelength of 625 nm. % HbA1c value is measured using a ratio of concentrations of HbA1c to total hemoglobin.

Principle of serum Cholesterol:

Cholesterol esters are cleaved by the action of cholesterol esterase to yield free cholesterol and fatty acids. Cholesterol oxidase then catalyzes the oxidation of cholesterol to cholest-4-en-3-one and hydrogen peroxide. In the presence of peroxidase, the hydrogen peroxide formed effects the oxidative coupling of phenol and 4-aminophenazone to form a red quinone-imine dye.

Principle of serum HDL Cholesterol:

Homogeneous enzymatic colorimetric assay In the presence of magnesium ions and dextran sulphate, water-soluble complexes with LDL, VLDL, and chylomicrons are formed which are resistant to Polyethylene glycol (PEG)-modified enzymes. The cholesterol concentration of HDL cholesterol is determined enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG to the amino groups.

Principle of serum LDL Cholesterol:

Homogeneous enzymatic colorimetric assay Cholesterol esters and free cholesterol in LDL are measured on the basis of a cholesterol enzymatic method using cholesterol esterase and cholesterol oxidase in the presence of surfactants which selectively

solubilize only LDL. The enzyme reactions to the lipoproteins other than LDL are inhibited by surfactants and a sugar compound.

Principle of serum Triglycerides:

Triglycerides are hydrolyzed by lipoprotein lipase (LPL) to glycerol and fatty acids. Glycerol is phosphorylated to glycerol-3-phosphate by ATP in a reaction catalyzed by glycerol kinase (GK). The oxidation of glycerol-3-phosphate is catalyzed by glycerol phosphate oxidase (GPO) to form dihydroxyacetone phosphate and hydrogen peroxide (H₂O₂). In the presence of peroxidase (POD), hydrogen peroxide affects the oxidative coupling of 4-chlorophenol and 4-aminophenazone to form a red-colored dye.

Ethical consideration

Ethical approval was obtained from health ministry Gezira State, when the ethical permission was obtained from faculty of medical laboratories sciences, university of Gezira and informed consent was collected from diabetic patients under privacy and was used only for this study.

Data Collection and Data Analysis

The data was collected by structural a questionnaire and then analyzed using statistical package for social science (SPSS) computer version (22). The blood sample is diluted and mixed with tris(hydroxyl methyl)aminomethane buffer to release hemoglobin from the erythrocytes. A fraction of the sample is conveyed into a reaction chamber where it is mixed with sodium lauryl sulfate (SLS). SLS is used to form the SLS-hemoglobin complex. The concentration of total hemoglobin is calculated by measuring SLS-hemoglobin complex with a wavelength of 525 nm. Hemoglobin A1c (HbA1c) in another fraction of the sample is first denatured by potassium ferricyanide and sucrose laurate. Denatured HbA1c bonds with HbA1c antibody on the latex particle. Latex agglutination inhibition reaction then occurs by reacting of the agglutinator that has synthetic antigen which can bond with HbA1c antibody. The concentration of HbA1c is calculated by measuring the latex agglutination inhibition reaction with a wavelength of 625 nm. % HbA1c value is measured using a ratio of concentrations of HbA1c to total hemoglobin.

Principle of serum Cholesterol:

Cholesterol esters are cleaved by the action of cholesterol esterase to yield free cholesterol and fatty acids. Cholesterol oxidase then catalyzes the oxidation of cholesterol to cholest-4-en-3-one and hydrogen peroxide. In the presence of peroxidase, the hydrogen peroxide formed effects the oxidative coupling of phenol and 4-aminophenazone to form a red quinone-imine dye.

Principle of serum HDL Cholesterol:

Homogeneous enzymatic colorimetric assay In the presence of magnesium ions and dextran sulphate, water-soluble complexes with LDL, VLDL, and chylomicrons are formed which are resistant to Polyethylene glycol (PEG)-modified enzymes. The cholesterol concentration of HDL cholesterol is determined enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG to the amino groups.

Principle of serum LDL Cholesterol:

Homogeneous enzymatic colorimetric assay Cholesterol esters and free cholesterol in LDL are measured on the basis of a cholesterol enzymatic method using cholesterol esterase and

cholesterol oxidase in the presence of surfactants which selectively solubilize only LDL. The enzyme reactions to the lipoproteins other than LDL are inhibited by surfactants and a sugar compound.

Principle of serum Triglycerides:

Triglycerides are hydrolyzed by lipoprotein lipase (LPL) to glycerol and fatty acids. Glycerol is phosphorylated to glycerol-3-phosphate by ATP in a reaction catalyzed by glycerol kinase (GK). The oxidation of glycerol-3-phosphate is catalyzed by glycerol phosphate oxidase (GPO) to form dihydroxyacetone phosphate and hydrogen peroxide (H₂O₂). In the presence of peroxidase (POD), hydrogen peroxide affects the oxidative coupling of 4-chlorophenol and 4-aminophenazone to form a red-colored dye.

Ethical consideration

Ethical approval was obtained from health ministry Gezira State, when the ethical permission was obtained from faculty of medical laboratories sciences, university of Gezira and informed consent was collected from diabetic patients under privacy and was used only for this study.

Data Collection and Data Analysis

The data was collected by structural a questionnaire and then analyzed using statistical package for social science (SPSS) computer version (22).

Results

A total of 120 patients with T2DM (Case; 70 - Control; 50) were included in this study. The mean ± SD of FBG in case and control was 161.7 ± 72.5 mg/dl, 91.28 ± 13.9 mg/dl, HbA1c was 8.9 ± 1.9 %, 5.8 ± 0.5 %, CHOL was 171.8 ± 37.3 mg/dl, 169.7 ± 20.8 mg/dl, Triglyceride was 121.9 ± 62.0 mg/dl, 80.2 ± 11.78 mg/dl, HDL-C was 37.9 ± 13.8 mg/dl, 40.4 ± 4.58 mg/dl, and LDL-C was 113.2 ± 34.8 mg/dl, 121.7 ± 24.6 mg/dl respectively in cases then control group, with significant differences in FBG, HbA1c and TG (P. value 0.000). The mean ± SD of FBG, HbA1c, CHOL and TG were higher in cases than controls and the mean ± SD of HDL and LDL were lower in case than controls (Table 1)

Table 1: FBG, HbA1c and Lipid Profiles in cases and controls

	Cases				
	Control	N	Mean	S. D	P.value
FBG	Case	70	161.739	72.5483	0.000
	Control	50	91.280	13.9869	
HbA1c	Case	70	8.889	1.8800	0.000
	Control	50	5.778	.5024	
CHOL	Case	70	171.771	37.2536	0.704
	Control	50	169.740	20.8393	
TG	Case	70	121.871	61.9682	0.000
	Control	50	80.160	11.7861	
HDL	Case	70	37.887	13.7605	0.155
	Control	50	40.420	4.5807	
LDL	Case	70	113.229	34.8334	0.123
	Control	50	121.660	24.6176	

FBG: Fasting Blood glucose HbA1c: Glycated hemoglobin CHOL: Total cholesterol TG: Triglycerides HDL: High density lipoprotein LDL: Low density lipoprotein

The mean value of CHOL and HDL were slightly higher and significant differences in female compared with male patients (P-value 0.013 and 0.030) respectively, while FBG, TG and LDL were slightly higher in female compared with male patients and insignificant differences with P-value (0.80, 0.091 and 0.232) as shown in Table 2.

Table 2: FBG and Lipid profile with T2DM

	Sex	N	Mean	SD	P. value
FBG	Female	4	163.488	79.9597	0.801
	Male	2	159.179	61.4185	
CHOL	Female	4	181.095	32.6615	0.013
	Male	2	157.786	39.8584	
TG	Female	4	131.429	68.7495	0.091
	Male	2	107.536	47.7598	
HDL	Female	4	40.410	16.5651	0.030
	Male	2	34.104	6.5166	
LDL	Female	4	117.548	30.6556	0.232
	Male	2	106.750	40.0154	

Among diabetic patients group hypercholesterolemia, hypertriglyceridemia and Abnormal LDL-C levels were found in 16 (23%), 14 (20%), 44 (63%) respectively on the other hand HDL-C was less than 40 mg/dl in 48 (69%) of them. (Table 3)

Table 3: Comparison of FBG and Lipid profile in cases according to normal rang.

Parameters	Normal		Abnormal	
	Number	Percent %	Number	Percent %
FBG	28	41	41	59
CHOL	54	77	16	23
TG	56	80	14	20
HDL	22	31	48	69
LDL	26	37	44	63

Patients were divided into two groups according to their glycemic index (HbA1c); the first group consisted of control patients with HbA1c values less than 7.0% and the second group consisted of uncontrolled patients with HbA1c values more than 7.0%. Uncontrolled patients had increase values of FBG, CHOL, HDL and LDL while TG was increased among controlled. The FBG of patients did not show any significant differences according to HbA1c control (p = 0.86). There was non-significant differences in CHOL (p = 0.43), while demonstrated a significant differences with TG (p = 0.006). The differences in HDL was statistically non-significant (p = 0.23). Furthermore, it was found non-significant differences in LDL (p = 0.09) (Table 4)

Table 4: FBG and Lipid profiles in diabetic patients according to glycemic control

	Control	N	Mean	SD	P. Value
FBG	Control	7	157.3	85.7	0.86
	Un-Control	62	162.2	71.7	
CHOL	Control	7	161.1	50.8	0.43
	Un-Control	63	173.0	35.8	
TG	Control	7	181.4	103.3	0.006
	Un-Control	63	115.3	52.9	
HDL	Control	7	32.0	9.5	0.23
	Un-Control	63	38.5	14.1	
LDL	Control	7	92.1	33.7	0.09
	Un-Control	63	115.6	34.4	

There was positive insignificant correlation between HbA1c with FBG, CHOL and LDL (r = 0.207, P = 0.089, r = 0.186, P = 0.124, r = 0.167, P = 0.168) respectively while HDL had positive significant correlation (r = 0.308, P = 0.01). Moreover, TG was negative insignificant correlation (r = -0.146, P = 0.228). (Table 5).

Table 5: The correlation between HbA1c with FBS and Lipid profiles

	FBG	CHOL	TG	HDL	LDL
Pearson correlation	0.207	0.168	-0.146	0.308**	0.167
Sig(2 tailed)	0.089	0.124	0.228	0.01	0.168
N	69	70	70	70	70

** Correlation is significant at the 0.01 level (2-tailed).

Discussion

Diabetes mellitus especially poor glycaemic control is a common secondary causative agent of hyperlipidaemia, which is major risk factor for atherosclerosis and lead to coronary heart disease (3). Most of previous studies associated between the importance of attaining optimal glycemic control and reducing the risk of CVD (10). One present reduction in HbA1c reduces the possibility of myocardial infarction by about 14%, risk of microvascular complications by about 37%, emphasizing to maintaining of HbA1c goals less than 7% for diabetic adults patients. Indeed, high level of blood glucose is regarded to be a promoting factor of high blood LDL and other pathology lead to atherosclerosis (11). The finding of this study is emphasizing the predictive role of lipid level for glycemic control status in DM2 patients. There was increased in FBG, HbA1c and TG levels in case group when compared with control group with highly significant differences (P .value 0.000), the mean of CHOL levels is higher in cases than controls and showed non-significant differences with P. value 0.70 despite this there was decreased in HDL and LDL levels in cases group via control group, this finding agree with study done by Artha and others in 2019 (12) and also agree with study done by Sabahelkhier, K.M and others in 2016 (13). According to the gender classification the data showed that there was no significant difference between males and females (p > 0.05) in glycemic parameters as well as lipid profile except CHOL and HDL which were increased in female than male, this study was disagree with Muhammad Adnan and others from Pakistan reported that the Gender was significantly associated with HDL Cholesterol (p-value

0.000); and triglycerides (p-value 0.001) Furthermore, a study from Italy done by Giuseppina Russo and others showed that significant decrease levels of CHOL, HDL and LDL while TG showed increase level and other study carried out in Sudan done by Amar Babikir and others showed no significant difference between males and females. Hyperlipidemia in females may be due to the effects of sex hormones on body fat distribution, which leads to differences in lipoproteins(14) except in HDL values which are significantly higher in females. In diabetic patients group about 8% of participants showed dyslipidaemia, all of them had history of diabetes mellitus and some of them were female, age above 60 year and had low physical activity. Dyslipidemia is highly prevalent among women. Women undergo a number of hormonal changes throughout their lives that have significant effects on lipoprotein metabolism(15). This study shows that the diabetic patients group had hypercholesterolemia, hypertriglyceridemia and decrease HDL levels which are major risk factors for cardiovascular diseases. Insulin impacts the liver Apo lipoprotein production which regulates the enzymatic activity of lipoprotein lipase and Cholesterol ester transport protein. Also insulin deficiency reduces the activity of hepatic lipase. These are main causes of dyslipidemia in Diabetes mellitus(16). In this study the T2D patients with an HbA1c value $\geq 7.0\%$ had significant increase in the levels of FBG, CHOL, HDL and LDL-C without significant differences (P. Value ≥ 0.05) while the level of TG had significant differences with (P. Value 0.006). Awadalla .H and others from Sudan reported there was no significant difference in TG, CHOL, LDL, and HDL between the glycemic control group and the uncontrolled group(17). Shahwan and others from United Arab Emirates reported there was significant difference in CHOL and LDL-C without significant changes in TRI and HDL-C compared with the uncontrolled group(18). Meen .J and others from India showed that HbA1c was associated with FBG, CHOL, HDL, and LDL(16). These results may be due to different in life style of population included in studies and other causes the HbA1c levels are stable over a period of time, whereas lipids levels and blood glucose levels are dynamically changing, this led to different results (19).

Conclusion

The study concluded that there was significant difference between the level FBG, HbA1c and TG in diabetic patients' group when compared with healthy individual (control group). There was no statistically significant difference between males and females diabetic patients in FBG, glycemic parameters as well as lipid profile except CHOL and HDL which were increased in female than male. Also there was significant difference between triglycerides concentration and HbA1c in diabetic patients. Dyslipidemia was found in majority of patients with Type-2 DM especially patients with poor or uncontrolled blood glucose level.

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Conflict of Interest

No conflict of interest

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Original Article

Prevalence of Cytomegalovirus Infection among Suspected Infants in Baghdad

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ABSTRACT

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Keywords: Cytomegalovirus, Infants, intrauterine infections



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Background: Cytomegalovirus (CMV) virus is a recognized important cause of congenital CMV infection which carries a significant risk for symptomatic disease and developmental defects in newborns. Its prevalence varies from place to other and time to time. This study is conducted to estimate its prevalence in Baghdad among infants suspected of having a congenital infection and to study the associated findings.

Subjects and Methods: The study was carried out in Al-Alwiyia pediatrics teaching hospital. Data were collected, and blood samples were taken for infants suspected to have intrauterine infections over a period of one year, from 1 October 2019 to 1 October 2020. Immunoglobulin M (IgM) tests for CMV were conducted for all collected samples. CMV-immunoglobulin G (IgG) was a further analysis if negative results were obtained for CMV-IgM testing. Samples were tested by Eliza method.

Results: The overall positivity for CMV-specific antibodies among suspected infants was 16.7% for IgM and 66 % for IgG. Males constitute 55% of CMV-IgM positive results. These results are statistically significant concerning age groups. 1-3-month age group was the largest (40 % of IgM positive infants) with a p-value of 0.000. This indicates delayed presentation of CMV-affected infants. With the same p-value, 74% of infants less than one month of age were IgG positive reflecting the maternal prevalence of CMV- IgG in an equivalent percentage.

Convulsion followed by delayed milestones was the most common presenting symptoms in congenital CMV infection with statistically significant associations.

Conclusions: The study indicates that infection with CMV constitutes a significant portion of suspected infants. The study recommends special attention to take steps concerning early management.

Introduction

Human cytomegalovirus (HCMV) is the type species of the virus genus Cytomegalovirus (CMV), a member of a family known as Herpesviridae or herpesviruses (1,2). HCMV is also called cytomegalovirus (CMV), although there are eight types of species are included in the genus CMV, and HCM is one type of these (2,3). The human cytomegalovirus (CMV) virus is recognized as an important cause of congenital infection leading to birth defects and

developmental disabilities (4). Congenital CMV infection is one of the TORCH infections which include: toxoplasmosis, syphilis, rubella, CMV, and HSV. These infections carry a risk of significant symptomatic disease and developmental defects in newborns.

Congenital CMV infection is the most common congenital infection worldwide, with an incidence ranging from 0.2% to 2.5% of all live births worldwide (5). Its incidence in developed countries ranges from 0.6 to 0.7% of all live births (6).

Not every maternal CMV infections lead to a congenital CMV since transmission to the fetus occurs in only 40% of primary maternal infections, which results in the delivery of 10-15% symptomatic and 85-90% asymptomatic congenitally-infected newborns (7). Asymptomatic disease in infants is not entirely benign as 10 to 15% go on to develop long-term morbidities (8). Seroconversion of CMV immunoglobulin M (IgM) happens in both primary and reactive forms of CMV, while seroconversion for immunoglobulin G (IgG) happens in primary infection.

For non-primary infections, the transmission rate is significantly low at 1.1–1.7% of infected mothers (6,9).

The seroprevalence rates of CMV among pregnant women in developed countries were lower than those of developing countries, which is estimated to be between 1 and 5% of all live births (6, 10).

Infection earlier in life is typical in developing countries, whereas up to 50% of young adults are seronegative in many developed nations (11). In general, estimated CMV IgG antibodies was (40-80%) in developed countries and (90 - 100%) in developing countries (12,13,14).

CMV is considered to be the second leading cause of mental retardation in the United States and is currently the leading cause of sensorineural deafness.

Congenitally infected infants are often divided into two groups: those with findings that are apparent in the neonatal period and those with signs of CNS damage that become apparent later in childhood. In addition to intrauterine growth restriction, over 70% have evidence of CNS involvement (15). The clinical manifestations of congenital cytomegalic inclusion disease include jaundice, splenomegaly, petechiae, intrauterine growth retardation, microcephaly, and retinitis, lethargy, hypotonia, optic atrophy, decreased hearing, and intracranial calcifications (11). Furthermore, they may have seizures or retinitis. Some babies with signs of congenital CMV infection at birth may have long-term health problems, such as developmental and motor delay, vision loss, seizures, and late-onset hearing loss even if normal at birth or passed the newborn hearing test (11,15,16).

Of infants who are asymptomatic at birth, 10 to 20% eventually will have CNS involvement (17).

CMV excretion is common in children with congenital infection and may represent a reservoir for infection in other children and daycare workers (11).

The IgM level is elevated in patients with recent CMV infection, or there is a 4-fold increase in IgG titers. CMV- IgM antibodies may be found as early as 4-7 weeks after initial acquired infection and may persist as long as 16-20 weeks (11).

The drug of choice for the treatment of CMV disease is intravenous ganciclovir, although valganciclovir may be used for non-severe CMV treatment in selected cases (11). CMV immune globulin can be used in combination with ganciclovir to treat CMV pneumonia.

The purpose of this study is to shed light on the prevalence of congenital CMV among suspected infants living in Baghdad and to study some associated characteristics.

Subjects and Method

Ethical Approval: -

This study was approved by the research ethical committee/ research unit in the Baghdad Al-Risafa Health Directorate as part of the 2020 research plan. This plan was also approved by the training and planning directorate / MOH-Iraq.

As far as patients involved in this study, parent/s approval was taken for every infant involved in this study. The procedures and information taken during this study are part of the routine work in the hospital.

A cross-sectional study design was conducted from 1 October 2019 to 1 October 2020. All children who were suspected of having congenital infection consulting al-Elwya pediatric teaching hospital were enrolled in the study. Criteria for inclusion included the presence of any of the following: neonatal or persistent hepatosplenomegaly, jaundice, rash, congenital malformations, various CNS manifestations like convulsions or delayed milestones, and hearing or ophthalmological abnormalities.

Samples of blood were taken from all infants and sent to the virology laboratory as a part of routine diagnostic services as well as for research purposes.

Sample collection:

About 1.5 ml to 3 ml of venous blood was obtained as a part of the required investigation for these children. The blood samples were placed in a sterile plain tube, allowed for clotting at room temperature for 30 minutes and then centrifuged at 1500 rpm for 5 minutes. All sera were stored at -20°C pending testing. Samples were tested for CMV-specific IgM antibodies by commercially available IgM capture ELISA kits (Bioactiva, Germany). CMV negative samples were also tested for CMV-specific IgG antibodies. The manufacturer's instructions were strictly adhered to in the performance and interpretations of the tests and results.

Statistical Analysis:

The following statistical data analysis approaches were used to analyze and assess the study's results under the application of the statistical package (SPSS) ver. (22.0): 1) descriptive data analysis. 2) inferential data analysis to accept or reject the statistical hypotheses, which included the contingency coefficients (C.C.) test for estimating correlations.

Results

Figure. (1) Prevalence of CMV IgM and IgG seropositivity:

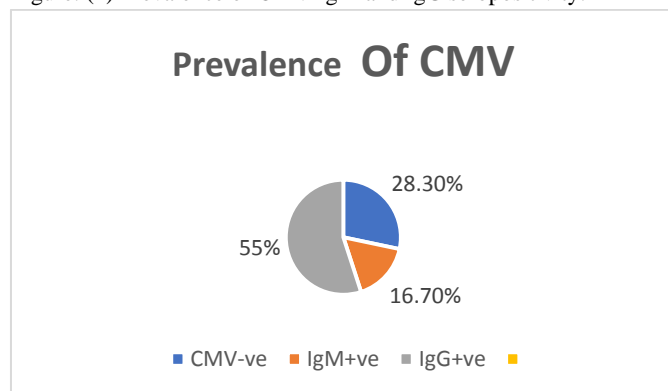


Figure.1 shows that CMV IgM and IgG seropositivity were 16.7% and 55% respectively among the studied sample.

Table 1: Gender distribution of the sample distributed according to seropositivity and seronegativity with comparison significance

Gender	No. & %	Outcomes			Total	C.S. (*) P-value
		IgG +ve	IgM +ve	-ve test		
Male	No.	36	11	18	65	C.C. = 0.016 P=0.985 NS
	%	55.4%	16.9% (55%)	27.7%	100%	
Female	No.	30	9	16	55	
	%	54.5%	16.4% (45%)	29.1%	100%	
Total	No.	66	20	34	120	
	%	55%	16.7% (100%)	28.3%	100%	

(*) NS: Non Sig. at P>0.05

Table 1 shows that the constructed contingency's coefficient had reported a weak relationship with no significant difference at p>0.05 for the studied CMV results (IgG +ve, IgM +ve, and -ve results). Furthermore, Table 1 shows that 55 % and 45% of patients were males and females, respectively had CMV-specific IgM results (Figure 2).

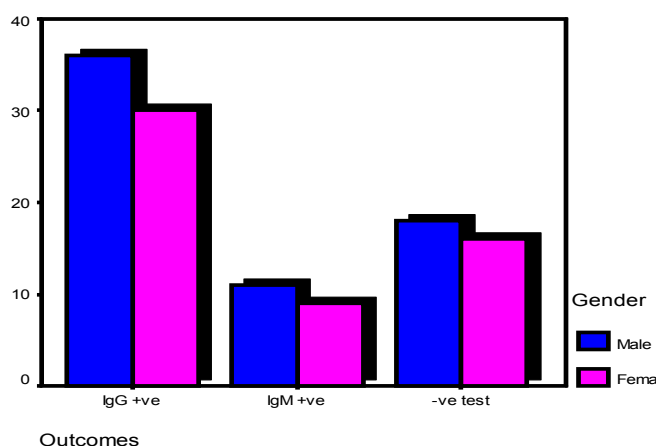


Figure. 2: Gender distribution of the sample

Table 2: Age distribution of the sample distributed with comparison significance

Age Groups	No. & %	Outcomes			Total	C.S. (*) P-value
		IgG +ve	IgM +ve	-ve test		
Neonatal period	No.	20	3	4	27	C.C. = 0.524 P=0.0 HS
	%	74.1%	11.1% (15%)	14.8%	100%	
1-3 M	No.	24	8	3	35	
	%	68.6%	22.9% (40%)	8.6%	100%	
4-6 M	No.	18	3	4	25	

Age Groups	No. & %	Outcomes	Total	C.S.		
7-9 M	No.	1	3 (15%)	12	100%	
	%	6.3%	18.8%	75.0%		
10-12 M	No.	3	3	11		
	%	17.6%	17.6% (15%)	64.7%		
Total	No.	66	20	34		120
	%	55%	17% (100%)	28%		100%

(*) HS: Highly Sig. at P<0.01

The results show that the constructed contingency coefficient reports a strong relationship with a highly significant (a value p-value =0.000) association of the age groups with (IgG +ve, IgM +ve and -ve results). There was a constraint association since 74% of neonates were IgG +ve and to some extent the IgM +ve marker at 1-3 months of life constituted 40 % of IgM positive infants. The maximum seronegative percentage was in the 7-9-month age group constituting 75% of seronegative infants (Table 2, Figure 3)

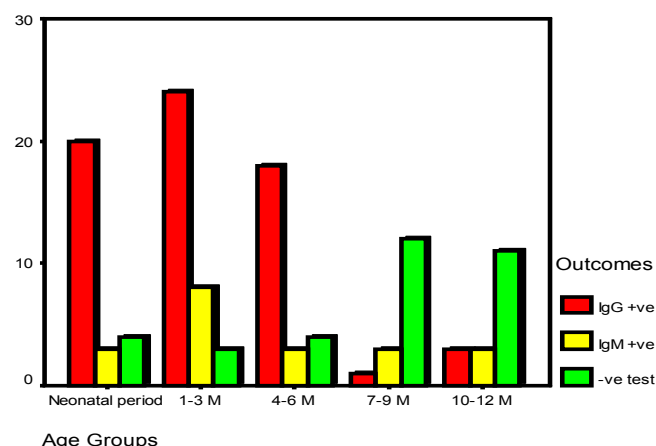


Figure.3: Age distribution of the sample

Table 3: Distribution according to maternal age with comparison significance.

Maternal Age Groups	No. & %	Infant test results			Total	C.S. (*) P-value
		IgG +ve	IgM +ve	-ve test		
Less than 20 yrs.	No.	8	3	4	15	C.C. = 0.120 P=0.9 40
	%	53.3%	20.0%	26.7%	100%	
20 - 30 yrs.	No.	38	13	19	70	
	%	54.3%	18.6%	27.1%	100%	

	No.	%	%	%	%	NS
31 - 40 yrs.	18	60.0	10.0	30.0	100	
> 40 yrs.	2	40.0	20.0	40.0	100	
Total	66	55.0	16.7	28.3	100	

(*) NS: Non Sig. at P>0.0

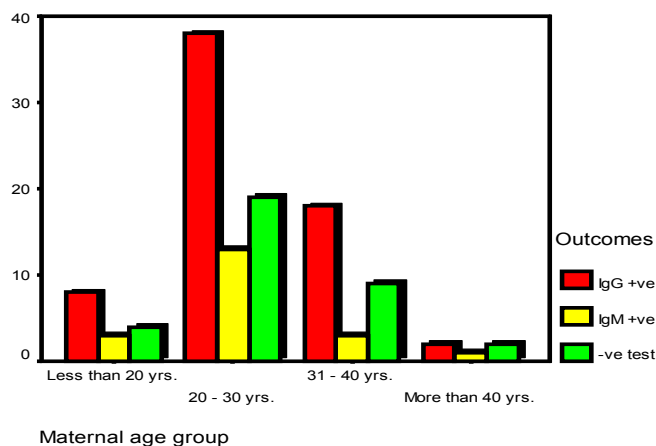


Figure.1: Distribution according to maternal age.

The results in Table 3 show that the constructed contingency coefficient reported a weak relationship with no significance at $p>0.05$ for the studied CMV results (IgG +ve, IgM +ve, and -ve tests) according to the mother's age groups variable. The maximum seroprevalence of infant CMV specific IgM was high in infants whose mother were within < 20-year age group (20%). The maximum CMV-specific IgG was high in infants whose mothers were within the 31-40 year age group (60%) (Table 3 and Figure 4):

Table 4: Distribution of presenting complaints across studied infants CMV immunoglobulins results (IgG +ve, IgM +ve and -ve) with comparison significance

Complaint	Res p.	No. & %	Outcomes	Total	C.S. (*)	P-value	C.C. =
Hypotonia/lethargy	Absent	No. 47 % 71.2	16 80%	31 91.2%	94 78.3%	0.206	
	Present	No. 19 % 28.8	4 20.0%	3 8.8%	26 21.7%	NS	
Abnormal features	Absent	No. 49 % 74.2	17 85.0%	32 94.1%	98 81.7%	0.220	
	Present	No. 17 % 25.8	3 15%	2 5.9%	22 18.3%	NS	
Poor feeding	Absent	No. 52 % 78.8	17 85.0%	31 91.2%	103 83.3%	0.283	
	Present	No. 14 % 21.2	3 15%	3 8.8%	20 16.7%	NS	
Delayed mile stones	Absent	No. 52 % 78.8	14 70%	34 100%	103 83.3%	0.282	
	Present	No. 14 % 21.2	6 30%	0 0.0%	20 16.7%	NS	
Jaundice	Absent	No. 50 % 75.8	18 90%	32 94.1%	111 83.3%	0.222	
	Present	No. 16 % 24.2	2 10%	2 5.9%	20 16.7%	NS	
Microcephaly	Absent	No. 62 % 93.9	17 85.0%	32 94.1%	115 92.5%	0.378	
	Present	No. 4 % 6.1	3 15%	2 5.9%	9 7.5%	NS	

Complaint	Res p.	No. & %	Outcomes	Total	C.S. (*)	P-value	C.C. =
Convulsion	Absent	No. 47 % 71.2	9 45.0%	31 91.2%	87 72.5%	0.319	
	Present	No. 19 % 28.8	11 55%	3 8.8%	33 27.5%	NS	

Complaint	Res p.	No. & %	Outcomes	Total	C.S. (*)	P-value
Hydrocephaly	Absent	No. 61 % 92.4	20	33	114	95.0%
	Present	No. 5 % 7.6	0	1	6	2.9%
Failure to thrive	Absent	No. 64 % 97.0	18	33	115	95.8%
	Present	No. 2 % 3.0	2	1	5	4.2%
Skin rash petechial	Absent	No. 63 % 95.5	19	34	116	96.7%
	Present	No. 3 % 4.50	1	0	4	3.3%
Hearing impairment	Absent	No. 63 % 95.5	20	34	117	97.5%
	Present	No. 3 % 4.50	0	0	3	2.5%
Visual impairment +/- glaucoma	Absent	No. 64 % 97.0	20	33	117	97.5%
	Present	No. 2 % 3.0	0	1	3	2.5%
Trauma	Absent	No. 65 % 98.5	20	34	119	99.2%
	Present	No. 1 % 1.5	0	0	1	0.8%

(*): HS: Highly Sig. at P<0.01; NS: Non Sig. at P>0.05; testing based on the contingency coefficient.

In order of frequency the clinical findings were (Table 4):1) Convulsion accounted for 11/20 (55 %) of patients with CMV-specific IgM making it a major presenting symptom (HS). 2) DMS accounted for 6 /20 (30%) of patients with CMV specific IgM making it the second most common presenting symptom in our sample (HS). 3)Hypotonia and lethargy accounted as 4/20 (20%) making them at the third order (NS) (p- value 0.07) 4) Three CMV-infected infants (3/20 ;15%) of CMV infected infants were accounted for each of abnormal features , microcephaly, and poor feeding (NS) 5) Failure to thrive (FTT) (NS) and jaundice (S) were accounted for 2/20 (10 %). 6) Skin rash accounted for 1/20 (5%) (NS).

Table 4: Distribution according to associated conditions or finding with comparison significance

Associated Conditions or Finding	Res p.	No. & %	Outcomes			Total	C.S. P-value
			IgG +ve	IgM +ve	-ve test		
Hepatomegaly +/- Splenomegaly	Absent	No. 66 % 100	18	30	114	95.0%	
	Present	No. 0 % 0.0	2	4	6	5.0%	
CHD	Absent	No. 64 % 97.0	18	31	113	94.7%	
	Present	No. 2 % 3.0	2	3	7	6.1%	
Low birth weight	Absent	No. 66 % 100	20	33	119	99.2%	
	Present	No. 0 % 0.0	0	1	1	0.8%	
Prematurity	Absent	No. 66 % 100	20	33	119	99.2%	
	Present	No. 0 % 0.0	0	1	1	0.8%	
Laryngomalacia	Absent	No. 66 % 100	20	33	119	99.2%	
	Present	No. 0 % 0.0	0	1	1	0.8%	
PKU	Absent	No. 66 % 100	20	33	119	99.2%	
	Present	No. 0 % 0.0	0	1	1	0.8%	
Galactosemia	Absent	No. 66	20	33	119	C.C. =	

Associated	Res	No.	Outcomes	To	C.S.		
CHT	ent			9	0.144		
		%	100	97.	99.	P=0.27	
			%	1%	2%	9	
	Pre	No.	0	0	1	1	NS
	sent	%	0.0	0.0	2.9	0.8	
			%	%	%	%	
	Abs	No.	65	20	34	11	C.C. =
	ent	%	98.5	100	100	99.	0.083
			%	%	%	2%	P=0.66
	Pre	No.	1	0	0	1	2
	sent	%	1.5	0.0	0.0	0.8	NS
			%	%	%	%	

(*) HS: Highly Sig. at P<0.01; NS: Non Sig. at P>0.05; testing based on the contingency coefficient.

Table shows that constructed contingency's coefficient reports a significant relation in the studied (IgG +ve, IgM +ve, and -ve) findings concerning to (hepatomegaly +/- splenomegaly) meanwhile , CHD had weak relationship (not significant at p>0.05).

Discussion

Some of positive CMV IgM infants could be due to postnatal infection. 13.3% of the infants at the age of one month were seroconverted to anti-CMV IgM at one study in china (18). Therefore, it is important to explore other possible causes regarding infant complaints.

CMV IgM seropositivity was 16.7% among the studied sample (Figure 1), comparable to 12.5%-20% of suspected children with congenital infection in different studies from India (7,19,20).

CMV-specific IgG was 66% in this study (Figure 1). The finding of these antibodies (Abs) among infants largely represents the transplacental passage of maternal Abs (as far as there is no evidence of recent infection). Maternal Abs can last for 9 months. Just 3 out of 120 cases (2.5 %) showed these Abs above 9 months of age, representing the most probable previous postnatal acquired infection. Seroprevalence of CMV-specific IgG varies greatly from country to country.

The highest seroprevalence was seen in the World Health Organization (WHO) Eastern Mediterranean region (90%) and the lowest in WHO European region (66%) (21).

In Ghana, the estimated IgG seroprevalence lies between 76 and 96% among the general population (22).

Maternal IgG passes through the placenta and its presence in newborn infants reflects maternal CMV antibodies. These anti CMV Abs protect infants up to 8-9 months from CMV infection (18,23,24).

In general the prevalence of CMV IgG antibodies in pregnant mothers in developed countries is 40-80% and 90 - 100% in developing countries (12, 13). The reported figures vary between 80 and 90% in India (25), 98.9% in Turkey(5), 93-98 in China (18,26,27) ,and 95.6%. in Ghana (28). In conclusion, these immunoglobulins are found in newborn infants and last for several months as exogenous transplacental passive immunity. Compatible with this, we found (with HS association) that the seroprevalence of anti-CMV IgG was much higher in young infants (<6 months old) as compared to older infants denoting waned maternally acquired antibodies (table 2).

CMV-specific IgGs were present among 74.1% of infants of less than one month of age in this study; we suggest that maternal anti-

CMV IgG prevalence among childbearing mothers would be around 74 %. In one previous study in Thi-Qar / Iraq, it was 60%(29) while a seroprevalence of 85.9% in pregnant women was found in Duhok / Iraq (30).

Our results are statistically significant concerning age groups with a p-value of 0.000. 1-3 months' age group constitutes 40 % of IgM-positive infants. This indicates delayed presentation of CMV-affected infants beyond the neonatal period.

We recommend testing maternal IgG and IgM-CMV status during antenatal care and to take further measures after any observed seroconversion.

There was no significant difference between the gender of participants and IgM results in this study (males constituted 55% as shown in Table 1) which is compatible with a previous study in Iraq (31).

In this study, the seroprevalence of infant CMV, specific IgM, was more common in infants of the < 20-year maternal age group, decreasing with increases in maternal age (Table 3). Contrarily, IgG prevalence increased with an increase in maternal age, which reflects an increase in the prevalence of maternally-acquired CMV-IgG Abs, as seen in the infant CMV-IgG prevalence distribution (Table 3). A previous study in Iraq also showed an increasing prevalence of IgG with maternal age (30). Further studies abroad were in concordance with this as well (13,32,33). Maternal IgG seropositivity lessens the fetal risk for congenital infection since identifying maternal CMV IgG status for pregnant women is an important predictor of congenital CMV infection. Symptomatic CMV congenital disease is less likely with mothers with pre-existing immune responses to CMV than in CMV-naïve individuals (34). Annual seroconversion rates for pregnant women ranged from 1-7% (34).

In contrast to our findings, the most common clinical findings at birth for congenital CMV infection reported in literature included petechiae (71%), jaundice (67%), microcephaly (53%), and small size for gestational age (50%)(11). While in this study in order of frequency: Convulsion accounted as (55 %) of patients with CMV positive IgM (HS) followed by DMS (30%) (HS), Hypotonia and lethargy (20%) (S); abnormal features, microcephaly, and poor feeding (15% of each) (NS), failure to thrive (10 %) (NS), jaundice (10 %) (S) and hepatomegaly +/- splenomegaly (10%)(S), congenital heart disease (10%)(N S) and skin rash 1/20 (5%). (NS).

In contrast to our findings, the most common clinical findings at birth for congenital CMV infection reported in the literature included petechiae (71%), jaundice (67%), microcephaly (53%), and small size for gestational age (50%) (11).

The variances are attributed to the small size of the sample and the quality of our sample with delayed presentation.

Hearing impairment was not a presenting symptom in this study because Iraq has not yet implemented a universal neonatal hearing screening program.

Hearing loss can occur later on at any point during childhood, even those with normal hearing at birth, and accounts for 20% of sensorineural hearing loss in children (15,35,36,37).

A frequent hearing assessment is advised for our patients during initial presentation and follow-up visits.

One of the study's limitations is that diagnosis depends on an IGM assay rather than PCR. The gold standard for diagnosing CMV infection in early life is to detect the virus in urine or saliva by viral culture and/or PCR. Another limitation is the difficulty in ascertaining (to 100%) whether some infants were infected during

intrauterine life. Furthermore, this study involved symptomatic infants whose parents were looking for treatment and never involved asymptomatic infants who could develop certain squally at a later age.

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Conflict of Interest

No conflict of interest

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Original Article

Safety profile of immediate post-partum intrauterine device insertion during caesarean delivery – a clinical trial with three years of follow up

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ABSTRACT

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Keywords: immediate post-partum intrauterine device, immediate long-acting reversible contraception, cesarean delivery, complications of immediate intrauterine device insertion, expulsion rate of intrauterine device.



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Background: Many countries recommend the use of long-acting reversible contraceptive intrauterine device immediately after cesarean delivery. The cesarean delivery rate in Iraqi public hospitals is 32.2% and may reach 85.8% in private hospitals. Immediate post-partum intrauterine device insertion at cesarean is rarely done in Iraq.

Objectives: To assess the safety and practicality of immediate post-partum intrauterine device insertion during cesarean delivery for family planning and pregnancy spacing in Iraqi women.

Subjects and Methods: A single arm clinical trial included 150 eligible women who attended Al-Elwiyah Maternity Teaching Hospital or Al Hayat Rahibat Hospital for term delivery. A copper intrauterine device was placed in the uterine cavity immediately after delivery of the placenta during cesarean delivery. The intrauterine device was fixed in place at the fundus using an absorbable suture. Patients were followed up at six weeks, then annually for three years.

Results: Expulsion of the intrauterine device was not reported by any of the participants. The most-reported complaints in the first twelve months of intrauterine device placement were abdominal pain, abnormal vaginal discharge, and heavy menstrual blood loss, however, none were statically significant ($P=0.256$). After the first year, there was a significant reduction in the frequency of complaints ($P=0.002$). Only 7.33% (95% CI: 6.92–7.75%) of the patient requested intrauterine device removal within the three years. The main reason was to plan a new pregnancy followed by recurrent infection associated with uncontrolled diabetes mellitus. Diabetes was a significant predictor for immediate post-partum intrauterine device removal, $P=0.049$.

Conclusion: The intrauterine device placement during cesarean delivery with suture fixation is a safe procedure with a zero-expulsion rate and is an effective reversible long-term contraceptive method.

Introduction

In the developing countries, around 885 million women in reproductive age would like to avoid pregnancy, nonetheless, 25%

experienced an unmet need for modern contraception. This is particularly true in the low- and middle-income countries. (1)

Pregnancy in the first year following birth can be as high as 10%–44%, too early pregnancy may associate with many adverse outcomes as fetal losses, premature labor, postpartum hemorrhage

and maternal deaths. Women are more likely to accept family planning advice soon after giving birth. Offering immediate postpartum contraception has a proven high impact practice in family planning since it encourages pregnancy spacing and reduce the likelihood of pregnancy in the first year postpartum. (2, 3)

Long-acting reversible contraception methods (LARC) have been used more widely in spacing pregnancies. Copper intrauterine device (IUD) can be an attractive option for postpartum women as it can be inserted immediately after delivery of the baby and the placenta, offering a one-stop approach service especially in countries where the institutional deliveries are considerably high. Immediate post-partum intrauterine device (IPPIUD) insertion is particularly important for women who want to space their pregnancies but have low opportunity to access family planning services in the postpartum period because of various socioeconomic factors. (4, 5) While IPPIUD is effective for family planning after both vaginal and cesarean delivery (CD), another benefit for women who deliver surgically is that it reduces the chance of aberrant placentation if an unexpected pregnancy occurs during the first 18 months. (6)

Zerzavy on 1967 had published the first study on the immediate placement of IUD after placental delivery whether during vaginal or CD using Birn berg Bow size 5 or 7 and sutured them during CD. Since then, sporadic studies have been published in the same context, till 1990s, when the fear from using this contraceptive approach was subside and at a later time in 2013 FIGO had started their project of IPPIUD in six countries where this practice became more popular. (7, 8) On August 2016, The American College of Obstetricians and Gynecologists recommended offering immediate LARC, following proper counselling. (9)

In a Cochrane review, researchers stated that an IPPIUD is not only safe and effective contraceptive method, but it can bend maternal and child mortality by more than 30% and 10%, respectively. The World Health Organization (WHO) had considered the IPPIUD as a category 1 rating in its medical eligibility criteria, which may avert the discomfort that had been linked to interval insertion. (10, 11) The higher expulsion rate that had been occasionally identified with the IPPIUD, compared to interval insertion, could be balanced with the high rate of non-insertion in the delayed postpartum period. As 40-75% of women who wanted to insert an IUD after puerperium, are not able to do that. (12, 13)

The number of CD is increased worldwide and in Iraq, with a CD rate of 32.2 % in public and may reach 85.8% in private hospitals. Repeated caesareans contribute much to increase maternal morbidity owing to the increase incidence of placenta previa, placenta accrete, postpartum hemorrhage and caesarean hysterectomy, which were much higher than what was encountered previously. Elevated number of early marriage in Iraq, high fertility rate and up to 96.9% institutional deliveries, (14) are all reasons made IPPIUD, especially during CD, an attractive option for pregnancy spacing and to prevent early repeated CDs.

This study is aiming to investigate the safety of IPPIUD during CD and its acceptability and feasibility in spacing of pregnancy in Iraqi women.

Subjects and Methods

This a single arm clinical trial that was carried out at Al-Elwiyah Maternity Teaching Public Hospital and Al Hayat Rahibat Private Hospital from September 2015 to June 2019. A total of 150 women who completed 36 weeks of pregnancy and were undergoing CD have been recruited after giving an informed written consent including a full description of the procedure, advantages and the frequency of occurrence of any possible complications. Women who were planned for elective CD approached in the antenatal period and women with emergency caesarean were counselled when they before entering the labour theatre.

Exclusion criteria included women who tested positive for sexually transmitted diseases in this pregnancy, uterine anomalies and pathologies, intrapartum fever, a history of ruptured membranes for more than 24 hours before delivery, diagnosed chorioamnionitis, placenta previa or accrete, anaemia during pregnancy (Hb < 10 g/dl), or intrapartum haemorrhage.

Primary outcomes measured were the expulsion rate and the percentage of immediate and late complications of IPPIUD, namely heavy menstrual blood loss, abdominal pain, abnormal vaginal discharge, absent threads, perforation. *Secondary outcomes* were to determine IUD removal predictors, how frequent the involved women would recommend this method of contraception for others, and the feasibility of IPPIUD insertion concerning the extra cost and time that will be added.

Interventions

The copper IUD (Cu-T 380A) was prepared and removed from the applicator tube and left on the sterile field, after delivery of the placenta (within 10 minutes), ensuring haemostasis and starting the uterine incision closure, an absorbable suture: vicryl 0 is introduce through the fundus to the uterine cavity, cutting the needle and wrapped the suture around the IUD arm, pulling the thread out to place the IUD at the fundus and make a knob outside the fundus to keep the IUD in place. The IUD threads were placed in the lower uterine segment, and then proceeds with completing the closure of the uterine incision, ensuring not to incorporate the IUD threads with uterine suture. All IUDs were inserted by the same investigators, one consultant obstetrician, and two specialists in obstetrics, who received training about the procedure. The extra cost for the copper IUD (Cu-T 380A) was \$2.5 / per case, and the average extra time of the procedure for the insertion of the device was 3.5 min.

Follow-up

Women were assessed before hospital discharge and were provided with a mobile number for follow-up. subsequent visit was at six weeks postpartum, where speculum examination was performed to check IUD threads, when seen, it was trimmed at two cm from external cervical os. when not seen, a pelvic ultrasonography was performed to ensure accurate location of IUD. Then, women

were reassessed at yearly intervals for three years, looking for the occurrence of the concerned complications

McNemar test was used to assess the change in complaint frequency at each time period (paired data). The odd ratio and its 95% confidence interval (CI) were calculated using the binary logistic analysis. To categorise the parameters, affect, the Wald test was used for this purpose (Wald basically is t^2 which is Chi-Square distributed with $df = 1$). GraphPad Prism version 8.3.0 was used to produce the statistical analysis, and the p-value was considered when appropriate to be significant if less than 0.05.

The study was approved by the Scientific Affairs Unit and Medical Ethics committee at Al Kindy College of Medicine (reference:123/June 29th, 2015) and the hospitals administrative boards. The trial was registered at clinicaltrials.gov (NCT04136613) under the name of Utility of Immediate Post Placental Insertion of Intrauterine Device During Cesarean Delivery. It was conducted according to Good Clinical Trial practice and the principles of the Declaration of Helsinki.

Results

Recruitment was started at September 2015. The participant's flowchart is demonstrated in Figure 1. Approximately 72% of invited women were eligible for the study, 63 women were further excluded; 40 of them became ineligible at the time of CD, and 23 women delivered in other health facilities. After three years of follow-up, only 150 women continued from the initial sample, while 13 women (7.8 %) didn't attend their follow up visits and could not be reached through mobile calls.

The mean age (SD) of participants was 32.7 ± 4.3 years, ranged between 23–42 years. The majority of them were from urban residency and have intermediate education levels, only 29.7% were working. 67.3% of the women were offered the procedure in public health services. Both abdominal pain and heavy menstruation were reported by few participants and were not significant over the period of follow up. Abnormal vaginal discharge reported in 10.7% of the participants at 12-month visit, however, this was significantly reduced at 3rd year visit ($P=0.004$). The thread of the IUD was absent in 32% of the patients at the 6th week visit and this was significantly reduced in 1st and 3rd year visits. Patients' minor complaints were reported in the 6th week and 12-month visits, but the IUD was well tolerated at the 3rd year visit with only 5% complaint as illustrated in Table 1 and Figure 2.

IUD removal predictors:

IUD removal was requested by 7.33% within the three years (95% CI: 6.92–7.75) and the most frequent reason was the intention to conceive (4.0%) as illustrated in Table 2 and Figure 3. Overall, participants were satisfied with IPPIUD and 97.3% recommended the procedure to a friend or relative.

Diabetes Mellitus was the only significant predictor of IUD removal, and its presence increased the risk of IUD removal by 5.956 folds. Other parameters such as not working, elective CD and numerous

CD showed lower likelihood to get their IUD removed, yet statistically were not significant as illustrated in Table 3.

Discussion

To our knowledge, this is the first Iraqi study evaluating the IPPIUD as a method of contraception during CD. We were able to recruit 163 women who fulfilled the inclusion criteria, and 150 completed three years follow up. The main outcome was zero expulsion rate and the overall complaints from IPPIUD were rather low. Uterine perforation rate was zero, since the IUD was inserted under direct vision during CD.

One of the major advantages of IPPIUD insertion, is lower discomfort than an interval insertion, it also does not interfere with breast feeding.(15) Interestingly, patient received IPPIUD did not report an increase of postpartum bleeding, infection, or uterine subinvolution consistent with other studies.(16) By contrast, our participants had reported a decrease in blood loss in the first postpartum days in comparison with their previous deliveries, however, this was an incidental finding and has not been assessed statistically.

The main early problems with any immediate IPPIUD insertion are; first is the expulsion rate which could be linked to personal operative experiences. Previous studies reported around (5%–17%) expulsion rate when the IUD is inserted during caesarean within the first six weeks.(17, 18) Şevki Çelen et al in their study that include 245 women shown that IPPIUD insertion can give reasonable protection against pregnancy, however, greater than 25% have discontinued IUD use because of spontaneous expulsion or some other reasons. (17) A Cochrane Database showed higher expulsion rates with immediate insertion of IUDs than later insertion even when modifications as putting a stitch had been practiced, but other studies later showed reasonable justification for using fixation suture in various countries such as Egypt, China, Mexico and others.(10, 19) Several other studies have optimizing other anchoring procedures that can bring the expulsion rate close to zero.(7) Taking all these studies in consideration, and to reduce the expulsion rate to minimum we used absorbable suture (vicryl 0) to stabilize the IUD in place at the uterine fundus. This type of suture holds its tensile strength for approximately two to three weeks in tissue then it will be absorbed completely by the time when the uterine involution process will be completed. This fixation approach had a minimum negligible impact on the procedure time and required only simple extra training. The second important early finding with IPPIUD was absent threads, which was the most prominent finding in our study when the women were reexamined at the sixth week. It was observed in 32% of participants which was resolved significantly (6.7%) by the third years. Missing thread is higher after IPPIUD insertion during Caesarean delivery 44%–79% versus 5% after vaginal delivery.(12) Similar results were described by Sunita et.al who reported string visibility in 61.87% at the first visit versus 84.62% at 12 months.(18)

The IPPIUD did add very little extra time to the CD procedure, which was only 3.5 minutes and a small extra cost which was only

\$2.5 per case. In a study evaluated the cost–benefit of IUD programme in the immediate postpartum period in Oregon between 2001 and 2006, results showed that for every dollar spent in the programme, \$2.94 was saved. Similarly, Washington CI et. al found that there was a cost savings of \$282,540 with a gain of 10 quality adjusted life year for each 1,000 women who desired IPPIUD.(20, 21) Further studies are needed to examine the cost effectiveness of this intervention in our hospitals.

While the frequency of IUD removal within the three years was 7.33%, Diabetes Mellitus was the only significant predictor of IUD removal. This is expected as diabetes associates with increased risk for persistent infection therefore, removal of the IUD was requested in two of the cases, one of which was as early as six weeks. The most common cause of IUD removal was the will to conceive (4.0%). Three of the removed IUD were due to heavy menstrual blood loss which was not responding to medical treatment. Otherwise all other participants were happy to continue with their IUD and 97.3% did recommended the procedure to other women which indicate reasonable satisfaction. Singal et al, had same removal rate of 7%, although they were for different reasons as psychological causes, menstrual irregularity and pelvic pain.(18)

Counselling of the participants for immediate IPPIUD insertion whether antenatally or at the time of admission had no significant contribution to the IUD removal, so absent antenatal counselling for IPPIUD was not a barrier for providing this services immediately at the time of delivery, this was also described by Alberto Moreno Zaconeta et al.(22) That will add to the advantage of this contraception services type especially in a country like Iraq where contraception counselling is not usually offered during the antenatal period.

Taking in consideration that by the sixth week postpartum, most women will be sexually active; the immediate postpartum period would be an ideal time to begin contraception. It is the time when the women will be much motivated to delay their pregnancies.(15, 16, 23) Leaving the hospital with an effective long method of contraception would be an appropriate choice to a country with socioeconomic and demographic factors like Iraq particularly when knowing that 63% of our participants were having less than one-year interpregnancy interval before their last pregnancy and considerable numbers of them having three previous CD scars which make them at risk of further complications.

Conclusion

This work showed that IPPIUD placement during CD is safe, feasible; contribute to a negligible prolongation in the operation time and add no extra cost if compared with cost and complication of unplanned pregnancy. Using fixation suture is a safe and efficient method to prevent the IUD expulsion. These results can be taken further to implement the FIGO project that started in 2013 in other countries in order to institutionalise the provision of IPPIUD services into the daily maternity care.

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Conflict of Interest

No conflict of interest

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Original Article

The Anxiety and Fear of COVID-19 Pandemic at the First Year in Dentists Working in Specialist Dental Centers

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ABSTRACT

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Background: COVID-19 pandemic has influenced all life aspects; Dental staff, like other healthcare providers, may be exposed to COVID-19 as part of their work and its psychological impacts on healthcare workers should not be ignored

Objectives: To assess the anxiety, and fear from COVID-19 pandemic in dentists working in specialist dental centers: sample the Al-Resafa health directorate, and its relation between the anxiety, and COVID-19 fear with some of their demographic variables

Subjects and Methods: A cross-sectional study was conducted on 2nd Jan. to 14th Feb. 2021, by an electronic version of questionnaire through Google-form; the questionnaire was formed based on Mental-Health-American-Organization (MHAO) for anxiety test & the English-Version of the Fear of COVID-19 Scale. Analysis of data by using SPSS, Frequencies, percentages chi-square test had calculated; P-value considered significant if it's ≤ 0.05 .

Results: The response rate was 90.43%, most of them aged less than 30 years old, female 356(60.8%), married status 295(50.3%), Rotator 297(50.7%). The study revealed that moderate anxiety 115(19.6%), moderate and mild fear of COVID-19 in 275(46.9%), severe in 120(20.5%) of them. there is a significant relation between gender & anxiety, marital status & No. of children with COVID-19 Fear.

Conclusion: One-fifth of dentists had moderate anxiety, and half of them had a mild fear of COVID-19 & one-fifth had a severe fear of COVID-19.

Introduction

Severe illness outbreaks have been identified throughout history, but the arrival of disease 2019 coronavirus disease (COVID-19) has been deadly and devastating, posing a threat to researchers and healthcare systems. Dental care professionals and students have been

identified as having a high risk of exposure by the occupational Safety and Health Administration. (1)

COVID-19 may be transmitted from person to person by tiny droplets from the nose or mouth, so dental workers, like other healthcare professionals, may be at risk.

In dental practice, COVID-19 can be transmitted via airborne aerosols generated during dental procedures, contact spread, and contaminated surfaces spread are all possible routes of transmission, dental practice. Furthermore, dental employees may be stretched among their professional roles as health care workers and their personal roles as family members (e.g., husbands). (2)

SARS-CoV-2 infection isn't the only source of psychological distress during the COVID-19 pandemic. It could also be attributed to social, cultural, and environmental factors, all of which could exacerbate the conflict. (3)

However, it is important not to overlook the psychological impact on healthcare employees. There is no question that healthcare professionals on the frontlines who offer care and treatment to patients face a tremendous psychological toll. More attention and knowledge of the outbreak's psychological implications should be provided. (4)

Every aspect of life has been affected by the novel coronavirus (COVID-19) pandemic. Many people changed their lifestyles as a result of the disease's extremely infectious existence and fatal outcomes. The (COVID-19) pandemic poses a particular threat to dental professionals. They are also more likely to experience anxiety and fear as a result of the increased risk of infection during dental care, particularly during pandemics. Social distancing, avoiding public spaces, hand washing more often, and wearing face masks in public was among the lifestyle changes. These shifts were often linked to stressors including temporary unemployment, working from home, homeschooling children, lack of physical interaction with other family members, friends, and coworkers, and fears that loved ones and significant others could be contaminated. (5)

Dentists who previously treated patients without gloves, masks, or eye protection were confronted with new situations. COVID-19 increases the awareness of dental aerosols and pushes dentists to review safety standards and to innovate ways to safely deliver care for patients. (6)

Generalized Anxiety Disorder was used to measure the psychological impact of COVID-19. Nearly 85% of dentists reported being concerned about developing the infection during a clinical operation. According to the findings, 9% of respondents had serious anxiety. To summarize, the COVID-19 emergency is having a significant negative impact on dentists' practice. (7)

Psycho-physiological symptoms, on the other hand, occurred later and lasted longer, resulting in drastic and profound impacts. (8)

During the extreme acute respiratory syndrome (SARS) outbreak, the tension between altruism and professional responsibility, on the one hand, and apprehension and guilt for potentially endangering their relatives to a highly infectious agent, on the other hand, was a huge burden for many medical staff members, according to Maunder et al. (2).

this study done to assess anxiety, and fear from COVID-19 pandemic in dentists working in specialist dental centers- sample the Al-Resafa health directorate, and to find the relation between the presents of anxiety & fear from the COVID-19 pandemic in them with some of their demographic variables.

Subjects and Methods

A cross-sectional study was conducted on 2nd Jan. to 14th Feb. 2021, by an electronic version of questionnaire through Google-form, with facilitating order delivered to all the specialist dental centers of Al-Resafa health directorate, and with the questionnaire link.

Included criteria: Any dentists working in specialist dental centers of Al-Resafa health directorate, and accept to participate in this study can be enrolled in this study once in spite whether had COVID-19 infection or not; and without excluded criteria.

The study protocol has been approved by the research committee of Al-Resafa health by using the code of ethics of the Ministry of Health in Iraq. The objectives of the study were explained to all the participants and that data will be confidential, by consent message at the beginning of the electronic questionnaire.

Researcher's mission facilitating order delivered to all the specialist dental centers of Al-Resafa health directorate, mention the electronic questionnaire link.

Questionnaire:

The questionnaire was formed based on: anxiety test from Mental Health American Organization (MHAO) (9), and Fear of COVID adapted from the English Version of the Fear of COVID-19 Scale (FCV-19S) (10)

The questionnaire consists of four parts: the first demographic features consist of seven questions (age, gender, job, and years of experience, marital status, children number, & presence of chronic diseases or not).

The second part was diagnosis with COVID-19 consist of three questions (the participant and /or their family diagnostic procedure of COVID-19, the rank of their diagnosis with COVID-19 with their family members, is there any Psychological support, Social support, and financial support and from whom)

The third part consists of the anxiety test consist of seven questions (Feeling nervous, anxious, or on edge, Not being able to stop or control worrying, Worrying too much about different things, Trouble relaxing, Being so restless that it is hard to sit still, Becoming easily annoyed or irritable, Feeling afraid, as if something awful might happen).

The fourth part fear from Coronavirus-19 consists of seven questions (I am most afraid of coronavirus-19, It makes me uncomfortable to think about coronavirus-19, My hands become clammy when I think about coronavirus-19, I am afraid of losing my life because of coronavirus-19, Coronavirus-19 watching news & stories on social media make me nervous or anxious, I cannot sleep because I am worried about getting coronavirus-19, and My heart races or palpitates when I think about getting coronavirus-19.)

Coding

Anxiety: 7 questions answered as (Never= 1, rarely=2, sometimes=3, mostly=4, always=5) so it's coded as" No anxiety (7-13), Mild anxiety (14-20), Moderate anxiety (21-27), Severe anxiety (28-35)"

COVID-19 FEAR: 7 questions answered as (Yes =2, no=1) so it's coded as "No fear (all 7 is no), mild fear (8-10), severe fear (11-14)"

Data collection procedure:

Data were collected by an electronic version of the questionnaire through the Google-form site on

<https://forms.gle/Vjwsdd4PpKKypJ7N6>.

The researcher had sent the questionnaire to all dentists working in specialist dental centers of the Al-Resafa health directorate, through facilitate-letter through the human resources and training department, also through the oral-dental division, and the response rate as appeared in the figure (1).

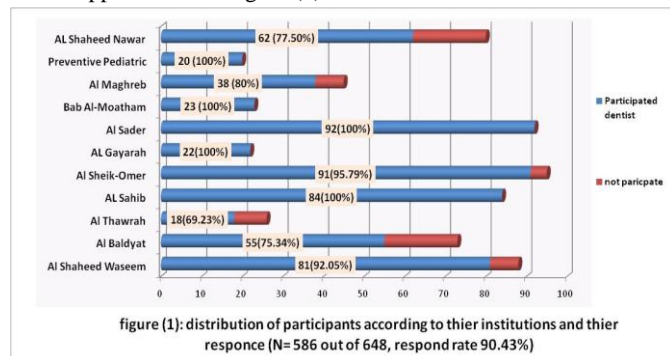


figure (1): distribution of participants according to their institutions and their response (N= 586 out of 648, respond rate 90.43%)

Statistical analysis Outcomes and procedures:

The answers were downloaded from the electronic form of the Questionnaire (Google-form) to the computer as an excel file and imported to SPSS ver. 23 to be analyzed. Analysis of data by using SPSS, Frequencies, percentages ANOVA test had calculated; P-value considered significant if it's ≤0.05.

Results

A total of 11 specialist dental centers of the Al-Resafa health directorate represent 586 dentists enrolled in this study with a response rate of 90.43%, most of them aged less than 30 years old, female 356(60.8%), married status (295)(50.3%), Rotator 297(50.7%), with less than five years of experience 357(60.9%), one-three children 219(37.4%), most of them free from chronic disease, the highest percentage chronic disease present is osteoporosis&/or Vit D deficiency 158(27.0%), orthopedic Disease 101(17.2%), while psychological disease present in only 21(3.6%). (Table 1)

Table 1: Distribution of participants according to their age, Gender, Job, Years of experience, marital status, and Children number:

	Frequency	Percentage
	N=586	%
Age		
<30 yr	363	61.9
30-39 yr	134	22.9
40-49	63	10.8
≥50 yr	26	4.4
Gender		
female	356	60.8
male	230	39.2
Job		
Rotator	297	50.7

	Frequency	Percentage
	N=586	%
Training dentist	40	6.8
Certificated dentist	65	11.1
Permanent dentist	27	4.6
GP dentist	14	2.4
Master dentist	77	13.1
Senior dentist	66	11.3
Years (yr) of experience		
≤5 year	357	60.9
6-10 yr	83	14.2
11-15 yr	56	9.6
16-20	36	6.1
21-25	25	4.3
≥25 yr	29	4.9
Marital status		
single	282	48.1
married	295	50.3
Previous married	9	1.5
not married so no children	283	48.3
Children number		
married but no child yet	63	10.8
one-three children	219	37.4
four and above	21	3.6
Osteoporosis/ vitamin D deficiency	158	27.0%
Ortho disease	101	17.2%
Asthma/ Chronic obstructive pulmonary disease	55	9.4%
chronic diseases presence		
Hypertension	44	7.5%
Psychological disease	21	3.6%
Heart disease	16	2.7%
Diabetes Miletus	9	1.5
Cancer	4	0.70%
Other (thyroid, skin, neurological, est.)	31	5.3%

Most of the participated dentist (infected or not) did not receive psychological support 314 (53.6%) or social support 329(56.1%) and mostly no financial support 545(93.0%), while most who received support was from their family, relatives, and friends {154 (26.3%), 206(35.2 %), 32 (5.5%) consequently}. (Table 2).

Table 2: Distribution of participants according to from who gete Psychological support, Social support, and financial support

	F	%
Psychological support		
No psychological support	314	53.6
family, relative, Neighbors	154	26.3
mixed without governmental	73	12.5
friends /social media friends	26	4.4
mixed with governmental	9	1.5
governmental	8	1.4
Psychiatrist	2	0.3
Social support		
No social support	329	56.1
Family, relative, neighbors	206	35.2
Friends and social media friends	23	3.9
Mixed with governmental	14	2.4

	F	%
Governmental	7	1.2
*NGO & Religious groups	5	0.9
Mixed without governmental	2	0.3
Financial support		
No Financial support	545	93.0
family, relative, neighbors	32	5.5
governmental	6	1.0
friends and social media	3	0.5
friends		
Total	586	100.0

*NGO= nongovernmental organizations

The study revealed that 268(45.73%) had been diagnosed with covid-19 by nasal swab for polymerase chain reaction (PCR test), 187 of them have confirmed it with rapid test also, and 141 of them additional confirm by computed tomography scan (CT scan) for lung for follow-up. (Figure 2)

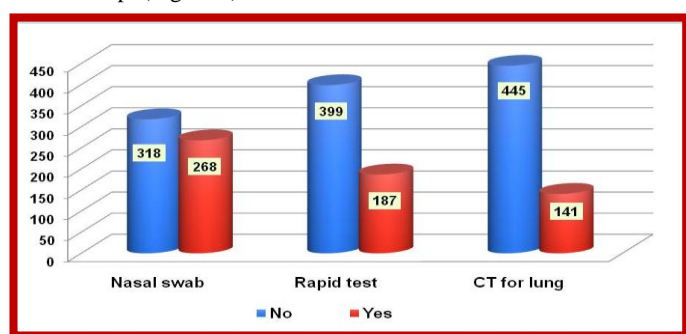


Figure:2 Distribution of participants according to them &/or their family diagnostic procedure of COVID-19

A hundred dentists (37.31%) announced that they were not the first covid infection in their families, and 98(36.57%) had infected at the same time with their family, and only 70(26.12%) they were the first covid -19 infection in their family. (Figure 3)

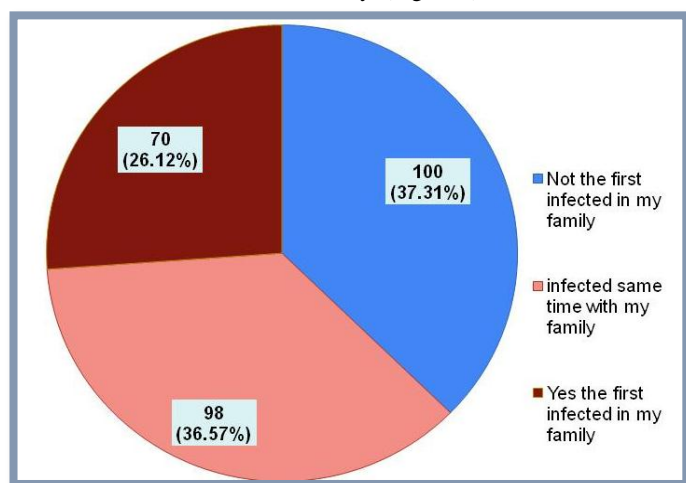


Figure:3 Distribution of participants according to the rank of their diagnosis with COVID-19 with their family members (N=268)

Most participants answered with (never) in question about anxiety, "Being so restless", "Becoming easily annoyed or irritable", "Feeling afraid", and "Avoid activities or situations because they

remind you of a stressful experience from the past?" (189, 329, 207, 206 correspondingly), while most of them answer with sometimes about "Not being able to stop or control worrying"235, Worrying too much about different things"213, and Trouble relaxing 199, as it's appeared in the table (3).

Table 3: Distribution of participants according to anxiety and post-traumatic stress syndrome

Anxiety questions	Frequency	Percent	
Feeling nervous, anxious, or on edge	never	189	32.3
	rarely	131	22.4
	sometimes	177	30.2
	mostly	60	10.2
	always	29	4.9
Not being able to stop or control worrying	never	114	19.5
	rarely	81	13.8
	sometimes	235	40.1
	mostly	105	17.9
	always	51	8.7
Worrying too much about different things	never	156	26.6
	rarely	106	18.1
	sometimes	213	36.3
	mostly	76	13.0
	always	35	6.0
Trouble relaxing	never	169	28.8
	rarely	128	21.8
	sometimes	199	34.0
	mostly	60	10.2
	always	30	5.1
Being so restless that it is hard to sit still	never	329	56.1
	rarely	114	19.5
	sometimes	108	18.4
	mostly	18	3.1
	always	17	2.9
Becoming easily annoyed or irritable	never	207	35.3
	rarely	118	20.1
	sometimes	160	27.3
	mostly	71	12.1
	always	30	5.1
Feeling afraid, as if something awful might happen	never	261	44.5
	rarely	91	15.5
	sometimes	144	24.6
	mostly	56	9.6
	always	34	5.8

In concern of fear from COVID-19, mostly answered with "no" (456, 549, 404, 538, and 463) only question about "It makes me uncomfortable to think about COVID -19" 302(51.5%), and "COVID-19 watching news & stories on social media make me nervous or anxious" were answered with "yes" 294(50.20%). (Table 4).

Table 4: Distribution of participants according to fear of COVID-19 question:

	no	%	yes	%
I am most afraid of COVID19.	456	77.8	130	22.2
My hands become clammy when I think about COVID 19	549	93.7	37	6.3
I am afraid of losing my life because of COVID -19.	404	68.9	182	31.1
I cannot sleep because I am worried about getting COVID19.	538	91.8	48	8.2
My heart races or palpitates when I think about getting COVID -19.	463	79.0	123	21.0
It makes me uncomfortable to think about COVID -19.	284	48.5	302	51.5
COVID -19 watching news & stories on social media makes me nervous or anxious.	292	49.8	294	50.2

The study revealed that only 45(7.7%) of the participant dentists had moderated depression, and only one with severe depression, while moderate anxiety present in 115(19.6%), moderate PTSD 111(18.9%), and 26(4.4%) had severe anxiety and severe PTSD, and at last, the fear of COVID 19 was mild in 275(46.9%) of dentists and severe in 120(20.5%) of them. (Figure 4 & 5).

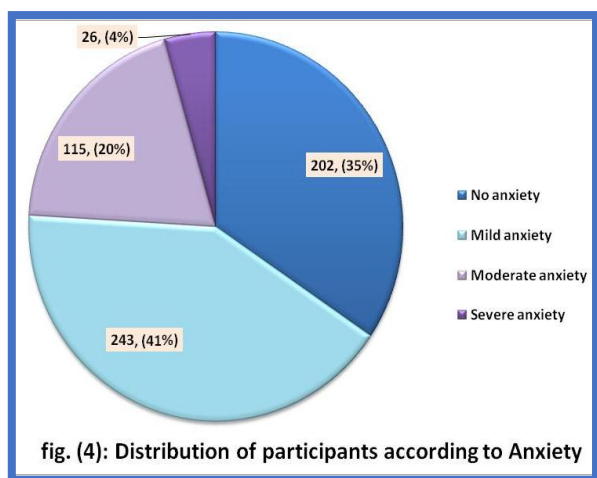


fig. (4): Distribution of participants according to Anxiety

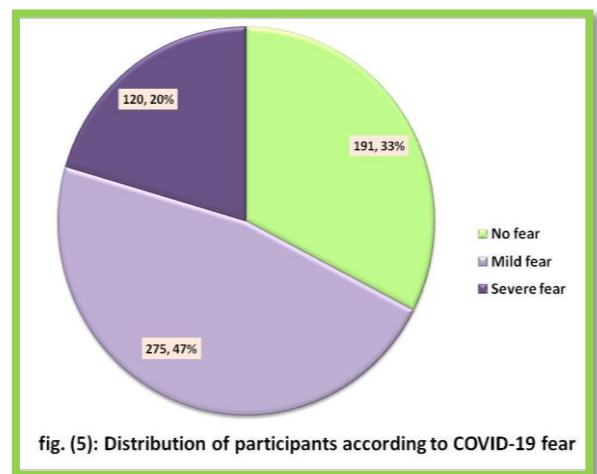


fig. (5): Distribution of participants according to COVID-19 fear

Through the chi-square test; the study found there is a significant relationship between gender and anxiety. Also, there is a significant relation between COVID-19 FEAR and marital status, No. of children. All other (Table 5 & table 6).

Table 5: Relation between participants' demographic variables and anxiety

		anxiety				Total	P value		
		no anxiety	mild	moderate	sever				
age	<30 yr	131	139	73	20	363	0.523		
	30-39 yr	42	61	28	3	134			
	40-49	22	28	11	2	63			
	≥50 yr	7	15	3	1	26			
gender	female	110	150	72	24	356	0.002		
	male	92	93	43	2	230			
job	rotator	112	113	53	19	297	0.158		
	training dentist	13	17	8	2	40			
	certificated dentist	18	32	14	1	65			
	permanent dentist	9	7	11	0	27			
	GP dentist	3	6	5	0	14			
	master dentist	25	39	11	2	77			
	senior dentist	22	29	13	2	66			
	Marital status	single	115	104	51	12		282	0.082
		married	83	136	62	14		295	
		Previous married	4	3	2	0		9	
No ofnot children	so no children	116	104	51	12	283	0.083		
	one-three children	65	97	46	11	219			
	four and above	4	14	3	0	21			
	married but no children yet	17	28	15	3	63			
Total		202	243	115	26	586			

Table 6: Relation between participants' demographic variables and anxiety

		COVID-19 FEAR			Total	P Value
		No fear	mild	sever		
age	<30 yr	127	161	75	363	0.307
	30-39 yr	40	72	22	134	
	40-49	19	29	15	63	
	≥50 yr	5	13	8	26	
gender	female	104	177	75	356	0.089
	male	87	98	45	230	

		COVID-19 FEAR			Total	P Value
job	rotator	99	135	63	297	0.356
	training dentist	16	14	10	40	
	certificated dentist	14	38	13	65	
	permanent dentist	14	10	3	27	
	GP dentist	3	8	3	14	
	master dentist	26	37	14	77	
	senior dentist	19	33	14	66	
Marital status	single	104	134	44	282	0.013
	married	82	138	75	295	
	Previous married	5	3	1	9	
No children	ofnot married so no children	105	134	44	283	0.016
	one-three children	55	107	57	219	
	four and above	7	11	3	21	
	married but no children yet	24	23	16	63	
		191	275	120	586	

Discussion

With a response rate of 90.43%; 586 dentists enrolled in this study, which considers a good response.

In the current study, at least one in four dentists report symptoms of moderated to severe anxiety; which is expected due to the major stressful condition with the COVID-19 crises, this is mostly reactionary due to their work closely to the source of infection (mouth and nose) and due to social distancing or quarantine, which they occurred at the pre- and during the study time.

COVID-19 pandemic has the potential to have a serious impact on the mental health of healthcare workers (HCWs), who stand in the frontline of the epidemic. Monitoring rates of mood, sleep, and other mental health conditions to understand mediating factors and inform targeted approaches. (11, 12, & 4) and that agreed with a study was done in Spain which found 21.6% of the sample has anxiety. (13) Another study done in Iraq by Karim, et al. 2020, found during the COVID-19 pandemic, nearly half of the respondents have anxiety. Also, being female, younger ages, holding an academic degree, or being a college student are associated with more prominent degrees of anxiety. (14)

The COVID-19 advent and implications have sparked suspicions, concern, and anxiety among people all over the world. (14) The present study used the English Version Fear of COVID-19 Scale (FCV-19S) (10); to supplements clinical efforts in preventing the spread and treating of COVID-19 cases. The current study has shown no afraid of coronavirus and shown that the negative impacts of psychological reactions and that agree with Fincher and Thornhill, 2020. (15)

Meanwhile, health care practitioners play a critical role in crisis management. Nurses, as the largest group of health care staff, spend more time than any other healthcare professionals and play a critical role in disease prevention, management, and treatment. During an outbreak of emerging diseases, all social institutions, including the patients' family members, are distanced from him/her, and it is the duty of the medical staff to take care of the patient despite the potential health risks. (16)

The present study showed that (psychological support) the higher answer "no any psychological support" in more than half, and that agree with Lai et al., 2020, (17) also in a study done by Puradollah, 2020, he found due to the increasing prevalence of the virus and also the increasing number of deaths of nurses, which can be a stressor for other nurses, it is necessary to pay attention to the mental health of nurses. (18) Stress and mental disorders can, like a vicious cycle, weaken the immune system and lead to coronavirus infection, especially where health workers with a history of mental disorders are more concerned. Health workers' mental disorders can also significantly reduce their quality of care. (19, 20)

Current study found a statistically significant relationship between gender and anxiety. Also, there is a significant relation between COVID-19 FEAR and marital status, No. of children. This is agreed with a study done at Washington State University. (21).

Limitations

Most of participants hesitated at the beginning to enroll in this study, because they were thinking it's for other than research purpose, until communication accrued with the managers of the centers and the researchers answered all the questions of the dentists, (beginning of online surveys in Iraq).

Conclusion

One-fifth of the participants dentists had moderate anxiety, and half of them had a mild fear of COVID-19 & one-fifth had a severe fear of COVID-19 with a significant relation between gender and anxiety, but not with the Fear COVID-19, Also, there is a significant relation between marital status, No. of children with the COVID-19 FEAR. So Psychological supporting courses for the dentist must be planning to be done soon and further assessment involves other health workers to find if there is a need for psychotherapy or support.

Conflicting Interests:

The authors declare that they have no competing interests.

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Original Article

Correlation between Body Mass Index and nonalcoholic fatty liver disease

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ABSTRACT

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Introduction

Non-alcoholic fatty liver disease is the most common liver disorder globally. The prevalence is 25% worldwide but is widely distributed across different populations and regions. The highest rates are reported in the Middle East (32%) (1). Due to modern lifestyles and diets, there has been a persistent increase in the

Background: Non-alcoholic fatty liver disease (NAFLD) is the most common liver disorder globally. The prevalence is 25% worldwide, distributed widely in different populations and regions. The highest rates are reported for the Middle East (32%). Due to modern lifestyles and diet, there has been a persistent increase in the number of NAFLD patients. This increase occurred at the same time where there were also increases in the number of people considered being obese all over the world. By analyzing fatty liver risk factors, studies found that body mass index, one of the most classical epidemiological indexes assessing obesity, was associated with the risk of fatty liver.

Objectives: To assess age, sex, and body mass index (BMI) as risk factors in NAFLD.

Subjects and Methods: It is a case-control cross-sectional study from September 2020 till June 2021 which included all obese patients consulted the obesity research and therapy unit during the period of the study. Age and sex were recorded, body mass indices were calculated for all patients and categorized into normal with BMI < 25kg/m², overweight with BMI 25-30 kg/m², and obese with BMI > 30 kg/m², ultrasonography was done to them to diagnose fatty liver changes which were categorized into three grades; mild, moderate and severe

Results: 192 patients were enrolled in the study with an age range from 18-55 years with a mean of 38.09, males were 48 and females were 144. Sever NAFLD is present in 2.8% of obese females and 5.5% of obese male with 0% in normal and overweight individuals.

Conclusion: NAFLD was more prevalent with increasing BMI and age in all sexes.

number of NAFLD patients. This increase occurred at the same time that there were also increases in the number of people considered being obese all over the world (2,3). By analyzing fatty liver risk factors, studies found that body mass index (BMI), one of the most classical epidemiological indexes assessing obesity, was associated with the risk of fatty liver (4-13). NAFLD represents a spectrum of progressive liver disease occurring in the absence of excessive

alcohol consumption. The clinical spectrum ranges from isolated intrahepatic triglyceride accumulation to necroinflammation of hepatocytes. A certain proportion of the patients ultimately progress to fibrosis/cirrhosis and potentially hepatocellular carcinoma (HCC). NAFLD has a low fatality for liver diseases. Although a high proportion of the population has NAFLD, only a minority progresses to advanced liver disease or liver-related death (14,15). It's commonly associated with related metabolic diseases, leading to cardiovascular events as its leading cause of death. The metabolic disorders include abdominal obesity, hypertension, dyslipidemia, and insulin resistance (IR) with further increased risk of cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM), and chronic kidney disease (CKD)(16). There is a close link between NAFLD and metabolic syndrome (17). Individuals with metabolic syndrome-related disorders have a higher risk of developing NAFLD, whilst NAFLD confers an increased risk of developing metabolic syndrome-related disorders (18,19).

Subjects and Methods

It is a case-control cross-sectional study done in the obesity research and therapy unit in Alkindy college of medicine/University of Baghdad from September 2020 till June 2021 , which included all obese patients consulted the obesity research unit during the period of the study. Age and sex were recorded, body mass indices were calculated for all patients and categorized into normal with BMI < 25kg/m2, overweight with BMI 25-30 kg/m2, and obese with BMI > 30 kg/m2, ultrasonography was done to them to diagnose fatty liver changes which were categorized into three grades; mild, moderate and severe according to Ultrasound B mode imaging where grade 0 has normal liver echotexture, grade 1 slight diffused increased echogenicity with normal liver visualization of the diaphragm and portal vein wall, grade 2 moderate increase in liver echogenicity with slightly impaired appearance of portal vein wall and diaphragm and grade 3 in case of a marked increase in liver echogenicity with poor or no visualization of the portal vein wall , diaphragm and posterior part of the right liver lobe.

A control group was set in the study of 70 individuals with normal BMI and no alcohol consumption

Exclusion criteria were patients with a diagnosis or history of chronic diseases and patients with a history of alcohol consumption.

Ethical approval and permission

Ethical permission was approved by the scientific committee in Alkindy college of medicine

Statistical analysis

Statistical analysis was performed by use of IBM SPSS 23.0.

Results

A total of 192 patients were enrolled in the study with an age range from 18-55 years with a mean of 38.09, males were 48 and females were 144 as shown in figure 1:

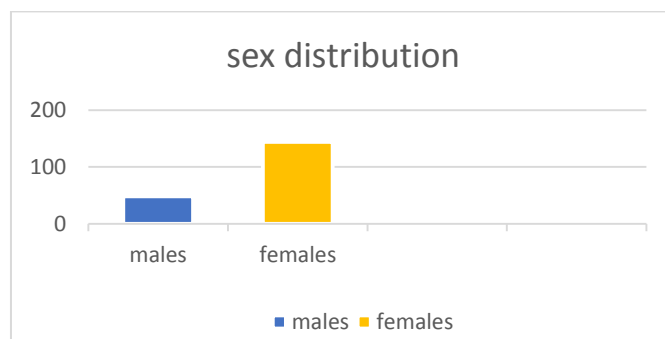


Figure.1: sex distribution in the study sample.

One hundred and ten patients (57%) out of 192 were obese and 82(42%) were overweight

The severity of NAFLD was shown in table 1, 36 obese males and 109 obese females, severe NAFLD present in 2.8% of obese females and 5.5% of obese males. With 0% in normal and overweight individuals. The incidence of NAFLD in obese and overweight was increasing with age in both sexes table 2,3,4 and 5.

Table 1: NAFLD in relation to BMI and sex

The severity of fatty liver disease	Obese male	Obese females	Overweight males	Overweight females	Normal males (%)	Normal females (%)
Severe (grade III)	2 (5.5%)	3 (2.8%)	0	0	0	0
Moderate (grade II)	4(11.1%)	14(12.8%)	1(8.3%)	1(2.8%)	1(2.9%)	0(0%)
Mild (Grade I)	17(47%)	45(41.3%)	3(25%)	11(31.4%)	3(8.5%)	4(11.4%)
Normal	13(36%)	47(43.1%)	8(66.7%)	23(65.7%)	31(88.6%)	31(88.6%)
Total	36	109	12	35	35	35

Table 2: Incidence of NAFLD in relation to age in obese females.

The severity of fatty liver disease	18-30 years	30-40 years	40-55 years	Total
Severe (grade III)	0(0%)	1 (34%)	2 (66%)	3
Moderate (grade II)	4 (28%)	4 (28%)	6 (42%)	14
Mild (Grade I)	10(22.22%)	13(28.88%)	22(48.9%)	45
Total	14	18	30	62

Table 3: Incidence of NAFLD in relation to age in obese males.

The severity of fatty liver disease	18-30 years	30-40 years	40-55 years	Total
Severe (grade III)	0	0	2 (100%)	2
Moderate (grade II)	0	2 (50%)	2(50%)	4
Mild (Grade I)	1(5.9%)	4(23.5%)	12(70.6%)	17
Total	1	6	16	23

Table 4: Incidence of NAFLD in relation to age in overweight females

Severity of fatty liver disease	18-30 years females	30-40 years females	40-55 years females
Severe (grade III)	0	0	0
Moderate (grade II)	0	0	1
Mild (Grade I)	1	4	6
Total	1	4	7

Table 5: Incidence of NAFLD in relation to age in overweight males

Severity of fatty liver disease	18-30 years males	30-40 years males	40-55 years males
Severe (grade III)	0	0	0
Moderate (grade II)	0	0	1
Mild (Grade I)	0	1	2
Total	0	1	3

Discussion

In this study, there was more prevalence of NAFLD in females than in males in all age groups and more prevalence with increasing age as shown in tables 2,3,4 and 5 this finding compared to Jee-FuHuangabc et al.(20) where There was an increasing trend of NAFLD according to the increasing age, ranging from 25.8% of those aged <30 years to 54.4% of those aged 50–70 years while contrasting it in the prevalence of NAFLD among the males was (49.3%) , which was numerically higher than the females (42.5%). There was no gender difference in the prevalence of NAFLD across each age group(20).

A Vusirikala et al. (21) showed that individuals who were overweight were at significantly greater risk of incidence of NAFLD(21) compared to this study, as shown in table 1

A Katrina Loomes et al. (22) showed the risk of recorded NAFLD increased linearly with BMI and was approximately 5-fold higher in Humedica (HR = 4.78; 95% confidence interval, 4.17–5.47) and 9-fold higher in THIN (HR = 8.93; 7.11–11.23) at a BMI of 30–32.5 kg/m² rising to around 10-fold higher in Humedica (HR = 9.80; 8.49–11.32) and 14-fold higher in THIN (HR = 14.32; 11.04–18.57) in the 37.5- to 40-kg/m² BMI category. The risk of NAFLD/NASH was approximately 50% higher in men . This is comparable to this study, which showed an increased incidence of NAFLD with increasing BMI (obese vs overweight as in table 1).

Conclusion

NAFLD is more prevalent with increasing BMI and age.

Funding

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Conflict of Interest

No conflict of interest

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Original Article

Possible role of Spironolactone in a sample of Iraqi patients with acute central serous chorioretinopathy

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ABSTRACT

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Background: Central serous chorioretinopathy (CSCR) is an idiopathic condition aggravated by exogenous or endogenous glucocorticoids. Vascular deregulation in the choroid is a new hypothesis regarding central serous chorioretinopathy occurrence. The inhibition of choroidal mineralocorticoid receptors has a great role in shortening the duration of CSCR by inhibiting choroidal vasodilatation and leak.

Objective: To assess the effect of oral spironolactone on subretinal fluid, central macular thickness and visual acuity in patients with acute CSCR compared to observation.

Subjects and Methods: a hospital based, randomized clinical trial carried out at outpatient clinic in Ibn-Alhaitham Teaching Eye Hospital/ Baghdad, enrolling 60 patients with acute unilateral CSCR, allocated randomly (every other patient) to either receiving spironolactone 25 mg orally, twice daily for 2 months (30 patients) or observation only (30 patients). The follow-up included visual acuity measurement, central macular thickness and subretinal fluid height examinations by ocular coherence tomography (OCT) at one- and two-months post enrollment for all patients.

Results: Complete absorption of subretinal fluid was observed in 21(70%) of the eyes in the treatment group and in 6(20%) in the control group at two-months. Visual acuity and mean macular thickness improved significantly in both groups at the one- and two- months, mean changes was larger in treatment group compared to control group at the two-month-follow up endpoint.

Conclusion: Oral spironolactone imparted greater improvement in central macular thickness and faster resolution of sub retinal fluid in patients with acute central serous chorioretinopathy versus observation.

Introduction

Central serous chorioretinopathy (CSCR), is detachment of the sensory retina from retinal pigmented epithelia frequently seen in the macular area. It is the fourth most common nonsurgical maculopathy

after diabetic retinopathy, choroidal neovascularization, and branch retinal vein occlusion. (1)

It typically affects middle- aged men, it can be seen from 20 to 64 years with annual incidence of 9.9 per 100,000 men and

1.7/100,000 women in a population-based study in United States. (2) Poorer visual acuity, diffuse retinal pigment epitheliopathy changes, and secondary choroidal neovascularization membrane occur frequently in elder patients. (3) Generally, CSCR is a self-limiting disorder, bulk of patients with acute state achieve natural resolution within three months, (4) 30% of patients sub retinal fluid (SRF) resolves in 8 weeks during the usual course of the disease, so observation is the first-line of management. (5)

To increase the chance of spontaneous resolution risk factors should be addressed, life style modification for patients with type A personality disorders and discontinuing intake of exogenous corticosteroids. (6) Various treatment modalities, including; systemic carbonic anhydrase inhibitors, conventional and subthreshold laser photocoagulation, anticorticosteroids (ketoconazole, mifepristone, rifampin), beta blockers, acetylsalicylic acid, intravitreal bevacizumab or ranibizumab, have been investigated as potential therapeutic options for chronic CSCR. (7)

Photodynamic therapy (PDT) with verteporfin has been the most promising treatment in this regard, with a success rate approaching 90%. (8) Lack of response, cost, and adverse effects are disadvantages associated with these treatment modalities. (9) Recently, unfortunate activation of mineralocorticoid receptors (MRs) situated in the choroidal vessels has been identified as a potential pathological pathway underlying the vascular choroidopathy in CSCR, this finding suggests that therapeutic blockade of the MRs could reverse choroidal vasculopathy. (10)

Activation MRs pathways by aldosterone or glucocorticoid increase vasodilator potassium channels KCa2.3 leading to the hyperpolarization of endothelial cells and underlying smooth muscles leading to vasodilatation of choroidal vessels. (11) Spironolactone, a synthetic 17-lactone steroid, acts as a non-selective mineralocorticoid receptor antagonist (MRa) with moderate affinity for both progesterone and androgen receptors. (12).

Subjects and methods

Study design: -

This study is a hospital based, randomized clinical trial conducted from April 2018 and last patient's response documented in February 2019.

Subjects:

In this study sixty patients with age range from 28-45 years, who attended the outpatient ophthalmic clinic at Ibn Al-Haitham Teaching Eye Hospital in Baghdad, were diagnosed with acute, first attack of unilateral CSCR with duration of symptoms \leq 12 weeks enrolled in this study. Thirty patients were treated with (spironolactone 25 mg per oral, two times every day) for 8 weeks, and in the other group thirty patients subjected to observation only.

Randomization:

The patients were allocated into one of the two groups randomly during the study period as follows: the first patient was allocated into the treatment group and the next was allocated into the control group (every other patient) until reaching the targeted sample size of 60 patients.

Exclusion criteria:

1. Chronic CSCR (>12 weeks) or with history of recurrence.
2. Patient with other retinal diseases like diabetic retinopathy.
3. Previous treatment with laser photocoagulation, photodynamic therapy (PDT) or intra vitreal injection of (anti-VEGF).
4. Pregnancy.
5. Previous use of corticosteroid drugs or systemic diseases e.g endogenous hypercortisolism.
6. General illness for which spironolactone contraindicated like impaired renal, cardiac or hepatic function or standard serum potassium level >5.5 mmol/L.

Measurements:

At baseline, all patient included in the study underwent ophthalmic examination in form of distant best corrected visual acuity (BCVA) on Snellen charts (logMAR), intraocular pressure measurement, slit lamp biomicroscopy, spectral domain optical coherence tomography (OCT) (Heidelberg Engineering GmbH 69121 Heidelberg, Germany) for measurement of central macular thickness (CMT) and subretinal fluid height (SRFH) which manually measured from the retinal outer segment line to the pigment epithelia level at the center of macula and fundus fluorescein angiography (FFA). Patients then monitored at one- and two- months post-enrollment with visual acuity, slit lamp examination, OCT for CMT and SRFH measurement.

Statistical analysis:

Were carried out by using IBM® Statistical Package for Social Sciences (SPSS) ® version 20. Descriptive statistics included means \pm standard deviations for quantitative data, and as frequency and percentages for categorical data. Chi-square test was utilized to investigate the statistical association between categorical data. Evaluations of age, duration of symptoms, BCVA, CMT, and SRFH in both groups were performed using the student independent samples T-test. Assessments of differences in BCVA, CMT and SRFH at baseline and at the two study-endpoints was done through analysis of variances (ANOVA) with least significant differences (LSD). A value of $P < 0.05$ was considered statistically significant.

Ethical issues:

The study design and data collection were done after getting approval of Iraqi committee for medical specialization. All patients were informed about methodology and purpose of study and written consents of patients were obtained.

Results

In treatment group the mean age was 34.56 ± 1.68 years, males signified (80%) while the females (20%), duration of symptoms was 2.44 ± 0.21 weeks, number of patients with leakage point in FFA was 16 (53.33%) in both groups. In the control group the mean age was 33.1 ± 1.41 years, 83.33% were males, and the symptoms' duration was 2.49 ± 0.19 weeks. The male-to-female ratio between the two groups revealed no significant difference ($p=0.739$). Baseline BCVA (log MAR), CMT and SRFH were not significantly different between the two groups ($p = 0.052$, $p=0.771$ and $p=0.094$ respectively). In addition, no statistically significant differences had

been found between both groups, in all demographic variables and in all comparisons (p. value > 0.05).

Table 1: Baseline demographic features in both groups

Demographic character	Groups		P Value
	Treatment group N= 30	Control group N = 30	
gender			
male	24(80.0)	25(83.33)	0.739(NS)
female	6(20.0)	5(16.66)	
Age (years) mean± SD	34.56±1.68	33.1±1.41	0.507(NS)
Duration of symptoms (weeks) mean± SD	2.44 ±0.21	2.49 ± 0.19	0.871(NS)
BCVA(logMAR) mean± SD	0.26±0.21	0.35±0.21	0.052(NS)
CMT (µm) mean± SD	442.4±93.06	450.1±110.26	0.771(NS)
SRFH (µm) mean± SD	216.96±102.37	262.86±106.36	0.094(NS)
Patients with leakage point			
Yes	16(53.33)	16(53.33)	1(NS)
No	14(46.66)	14(46.66)	

SD: standard deviation, S: significant difference (P<0.05), NS: Non-significant difference (P>0.05), BCVA: best corrected visual acuity, CMT: central macular thickness, MRa: mineralocorticoid receptor antagonist, SRFH: sub retinal fluid height.

Table-2 shows the mean BCVA at baseline, 1 month and 2 months in both groups, in spironolactone group, mean BCVA was 0.26±0.21 at baseline, 0.13±0.08 at 1 month and 0.09±0.12 at 2 months. The BCVA considerably improved related to base line in spironolactone group. In control group, the mean BCVA at baseline was 0.35±0.21, 0.25±0.14 at 1 month and 0.21±0.18 at 2 months. However, the mean difference in the BCVA was obvious in both groups relatively larger in spironolactone group.

Table 2: Distribution of participants according to PHQ questions

Check point	Treatment group	Control group	P.value between groups
	Mean BCVA (Log MAR)	Mean BCVA (Log MAR)	
Baseline	0.26±0.21	0.35±0.21	0.052
1 month	0.13±0.08	0.25±0.14	0.015
2 month	0.09 ± 0.12	0.21±0.18	0.017
P. value within group	0.032	0.042	-

Table-3 shows; mean changes in the CMT. In spironolactone group, the mean macular thickness declined considerably from 442.4±93.06 µm at baseline to 276.1±44.72 µm at 2 months. Regarding the control group the mean CMT was 450.1±110.26 µm at baseline, decreased to 371.26±70.34 µm at 1 month and to 339.6±81.80 µm at 2 months. There was a greater difference in the mean macular thickness between the two groups along the study period.

Table 3: Alterations in CMT (µm)

Check point	Treatment group	Control group	P.value between groups
	Mean CMT (µm)	Mean CMT (µm)	
Baseline	442.4 ± 93.06	450.1 ± 110.26	0.771(NS)
1 month	328.46 ± 74.39	371.26 ± 70.34	0.026(S)
2 month	276.1 ± 44.72	339.6 ± 81.80	0.001(S)
LSD	37.94 (S)	45.99 (S)	

LSD: Least significant differences.

Complete resolution of SRF was achieved in 70 % (21/30) of the eyes in the treatment group and 20 % (6/30) in the control group at 2 months. SRFH diminished significantly by mean of 216.96±102.37 µm at baseline to 104.06±60.65 µm after 4 weeks of treatment drop to 58.7±33.30 µm at 8 weeks. Regarding control group a significant decline from 262.86±106.36 µm at baseline to 179.36±62.50 µm at 1 month then to 134.86±82.05 µm at 2 months.

Table 4: alterations in SRFH (µm)

Check point	Treatment group	Control group	P.value between groups
	Mean SRFH (µm)	Mean SRFH (µm)	
Baseline	216.96±102.37	262.86±106.36	0.094(NS)
1 month	104.06±60.65	179.36±62.50	0.002(S)
2 month	58.7±33.30	134.86±82.05	0.003(S)
LSD	47.740(S)	51.962(S)	-

Discussion

Central serous chorioretinopathy is still an enigmatic condition in large part due to a natural progression of spontaneous improvement in a high proportion of patients and also to the fact that no single treatment has provided overwhelming evidence of efficacy in published randomized control trial (13) Previous studies have shown a promising effectiveness of MRa in the treatment of chronic and recurrent CSCR, from this point other ophthalmic researchers studied the effect of oral spironolactone in patients with acute CSCR. (14)

The baseline characteristics of the patients revealed higher proportion of males among the studied groups and a mean age of 34.6 and 33.1 years in MRa and control groups respectively, indicated that the majority of the study participants were within their middle age, these findings came in line with the clinical picture of acute CSCR, where it more frequently affects middle aged males. (15-17)

The present study found that although the BCVA improved significantly in both study groups, the improvement was greater in treatment group as patients improved by five letters logMAR at one- and two-month endpoints compared to control group which indicated better and quicker improvement in treatment group. Improvement in the BCVA was similarly reported in previous studies, in term of BCVA, Pichi et al. reported in 2017 that treatment with spironolactone was effective in improvement of BCVA from the first month and concluded that spironolactone is better than eplerenone in refining visual acuity in patients with persistent CSCR. (18)

The present study found that CMT at 1 and 2 months decreased significantly in both groups. Despite the reduction in CMT was found in both groups, the change was larger in the MRa group and the difference between both groups was significant at one and two months, ($P < 0.05$). These findings agreed with the previous study of Sun et al. from China where the researchers treat patients with acute serous retinopathy with MRa drug, approving a positive impact in most cases. (14)

Findings of the present study supported those reported in previous studies which documented similar changes and improvement, like in the study of Sun et al. who reported that complete resolution of SRF was reported in more than half, 55.6%, of the treatment group who received spironolactone for 2 months, compared to 8.3% in control group, and the mean BCVA improved with time compared to its baseline levels, in both groups. (14)

Zucchiatti et al. in 2018 showed the effect of eplerenone on patients with acute CSCR and compared the result with observation. The BCVA and CMT improved in eplerenone group at 3 months. Complete disappearance of subretinal fluid was observed in 80% of subjects in the treatment group, versus 25% in the control group. (4)

Kapoor and Wagner, in United States concluded in their case control study in 2017 that using MRa in patients with CSCR accelerated the resolution and improvement and there were improved visual acuity gain and reduction in the subretinal fluid at 1, 2 and 3 months compared to baseline, furthermore, they documented a significant improvement in the resolution of sub-retinal fluid and two-line visual acuity gain by month 2 in the treatment group compared to the observation group. (19)

Chin et al. used oral glucocorticoid antagonists for refractory cases of central serous retinopathy and concluded that MRa treatment had a positive treatment effect in half of the patients in the study. The decrease in CMT and macular volume was much less in the recalcitrant group compared to the group of no previous treatment for CSCR. (20)

Findings of the present study were comparable to the cure rates reported with other modalities which indicated that using spironolactone it is not inferior to other treatment modalities and could be a promising mode of treatment for CSCR.

Limitations

The main limiting factor in this study included a small sample size, that might be related to the limited duration of conducting research in the program of the Iraqi Board of Ophthalmology. Another limiting factor could be patients' compliance to treatment, which could affect the results as the disease could resolve spontaneously.

Conclusion

- Oral spironolactone achieved greater improvement in central macular thickness and faster resolution of sub retinal fluid in patients affected by acute CSCR compared to observation.
- This study endured the effectiveness of this treatment in Iraqi patients in which about 70% of the patients got complete absorption of the sub retinal fluid in a short period without any side effects.

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Conflict of Interest

No conflict of interest

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Original Article

Evaluation of podophyllin and Trichloroacetic acid for the treatment of genital warts in Iraqi female patients

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ABSTRACT

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Background: human papillomavirus infections (genital warts) are the most frequent sexually transmitted viral infections. a wide range of treatment options is available with different efficacy.

Objective: To evaluate the efficacy of podophyllin, trichloroacetic acid (TCA) in the treatment of genital warts and side effects of them.

Subjects and methods: a total of sixty patients with genital warts were randomly selected, 30 in each group, in the Department of Dermatology, medical city for a Duration of 11 months from January 2009 to December 2009 treated with 35 % podophyllin in the tincture of benzoin or 50% TCA).Forty-eight patients were followed up for three months.

Results: warts cleared in 63% and 70% of the patients after treatment with podophyllin and TCA respectively within 3 months. Soreness happened in 6 patients with podophyllin and in 9 patients with TCA. small ulcers happened in 1 patient by podophyllin and 2 patients with TCA. pain was in 5 patients treated by podophyllin and in 6 patients treated by TCA. erythema was noticed in 10 patients treated by podophyllin and in 11 patients treated by TCA.

Conclusion: there was a higher clearance rate with TCA and earlier response. The occurrence of adverse reactions is little more with TCA.

Introduction

Anogenital warts (AGWs) are benign lesions on the epithelium of the genitalia, anus or perineum, due to human papillomavirus, Condylomata acuminata are the most common sexually transmitted viral diseases. These lesions are caused by infection with mucosal human papillomaviruses (HPVs). However, there is limited information on HPV strain distribution involved in the molecular pathogenesis of these lesions, (1) The overall (females and males) reported annual incidence of any AGWs (new and recurrent) ranged from 160 to 289 per 100,000, with a median of 194.5 per 100,000.

New AGW incidence rates among males ranged from 103 to 168 per 100,000 and among females from 76 to 191 per 100,000, with a median of 120.5 per 100,000 per annum. The reported incidence of recurrent AGWs was as high as 110 per 100,000 among females and 163 per 100,000 among males. Incidence peaked before 24 years of age in females and between 25 and 29 years of age among males. The overall prevalence of AGWs based on retrospective administrative databases or medical chart reviews or prospectively collected physician reports ranged from 0.13% to 0.56%, whereas it ranged from 0.2% to 5.1% based on genital examinations.(2)

Anogenital warts may have negative effects on patients' quality of life, (3) because of their cosmetic appearance, association with a sexually transmitted disease, symptoms, no cure, and social stigma. (4)

Various treatment like topical podophyllin, imiquimod, sinecatechins ointment and 5-fluorouracil and ablative modalities like trichloroacetic acid application, cryotherapy, electrosurgery, scissor excision, Co2 laser and systemic therapy like are used but clearance of lesions and recurrence is still a challenge. (5)

Podophyllin is an alcoholic plant extract from dried rhizomes of plants (6) and trichloroacetic acid is a topical destructive agent and causes coagulation of cellular proteins causing cell death. It is effective in treating any warts in the concentrations of 70%–80%. (7-9)

The incubation period between incident genital HPV infection and the appearance of warts is highly variable but has been found to be shorter in women (median 2.9 months) than men (median 11.0 months). (10,11)

The aim of this study to evaluate the efficacy of podophyllin, TCA in the treatment of genital warts and side effects of them.

Subjects and Methods

This is an interventional study for 60 female patients with genital warts attended the department of dermatology at Baghdad teaching hospital /medical city /Iraq from January 2014 to December 2014, who were chosen after examination and accepted participation in the study.

Inclusion criteria: all women with genital warts attending the department of dermatology were chosen, just 60 patients accept to participate in the study.

Exclusion criteria: Pregnant and nursing women, previous treatment for genital warts in the three months before their initial visit, and Patients who refuse to return for follow-up or with poor compliance. Randomly divided into two groups, 30 in each group, with 35% podophyllin in the tincture of benzoin or 50% trichloroacetic acid (TCA). Eight patients didn't return for follow-up. Fifty-two patients were followed up for three months.

patients were offered an appointment weekly. Patients were divided randomly into 2 groups of 30 for each group. The first group received podophyllin 35% and the second group received TCA 50%. The therapy was stopped when the lesions clear or the end of 12 weeks of treatment. The endpoint is 12 weeks after first application. All clinical notes and side effects were registered at each visit. podophyllin was used in a concentration of 35% in tincture of benzoin, TCA 50% in spirit. Both solutions were prepared by one pharmacy. Podophyllin or TCA was used by a cotton-tipped swab once per week. First, the area was cleaned with normal saline then leaved to dry. The clear skin is protected with Vaseline or powder then washed after four hours, repeated every week; any side effects were registered. Follow up for 12 weeks.

Assessment of clearance of warts was clinical, clearance means no wart.

The analysis was done using excel 2016 and spss 26.

Results

This study included 60 female patients with genital warts who attended the dermatology department. Informed consent, history and a medical examination were done. Eight patients did not return for follow-up.

The patients treated with podophyllin had clearance of (2)7% at 4 weeks while (3)10% in patients treated with TCA, (7)23 % of the patients treated with podophyllin had clearance at 8 weeks while (9) 30 % in patients treated with TCA and (19) 63 % of the patients treated with podophyllin had clearance at 12 weeks while (21) 70 % of the patients treated with TCA. table 1

Soreness happened in (6) 20% patients who were treated with podophyllin and in (9)30% patients by TCA. small ulcers happened in (1)3% patient by podophyllin and (2)7% patients with TCA. pain was in (5)17% patients treated by podophyllin and in (6)20% patients treated by TCA. erythema was noticed in (10)33% patients treated by podophyllin and in (11)37% patients treated by TCA. Table 2

Three patients discontinued the treatment due to side effects by podophyllin and TCA, which were mild to moderate.

No significant difference between the two groups by using t test and p value in spss 26:

Table 1: Results of using topical podophyllin versus TCA

Treatment	No Of patients	No defaulte d	No of clearance at 4 wk	%	No of clearance at 8 wk	%	No of clearance at 12 wk	%
Podophyllin 35%	30	3	2	7	7	23	19	63
TCA 50%	30	5	3	10	9	30	21	70

Table 2: side effects of podophyllin and TCA

	Soreness	Ulcers	Pain	Erythema
Podophyllin	6(20%)	1(3%)	5(17%)	10(33%)
TCA	9 (30 %)	2(7%)	6(20%)	11(37%)

Discussion

Genital warts are wide world problem with many modalities of treatment with different efficacy and failure rate.

In the present study, two topical therapies studied to see the difference, (2)7% of the patients treated with podophyllin had clearance at 4 weeks while (3)10% treated with TCA, (7)23 % of the patients treated with podophyllin had clearance at 8 weeks while (9) 30 % treated with TCA and (19) 63 % of the patients treated with podophyllin had clearance at 12 weeks while (21)70 % of the patients treated with TCA, which means earlier clearance and higher response with TCA, but higher side effects like Soreness in (6)20% patients with podophyllin and (9)30% patients by TCA, small ulcers in (1)3% patient by podophyllin and (2)7% patients with TCA, pain in (5)17% patients by podophyllin and in (6)20% patients by TCA and erythema was noticed in (10)33% patients by podophyllin and in (11)37% patients by TCA.

In Gurralla study: 16.7% of the patients treated with podophyllin had clearance at 4 weeks and 50% at 8 weeks despite the difference in podophyllin concentration between this study and their study which is 25% dissolved in tincture of benzoin and there is no

standard concentration globally because of different preparation of podophyllin. (8)

Studies using TCA had clearance rates of 70-81 percent after 6 applications and recurrence rates of 36 % ,11,12 which is near present result.

Three patients leave the program due to side effects of podophyllin and TCA, which were mild to moderate, which is acceptable small number and similar to other studies.

If the patients couldn't visit clinic continuously, dosing schedule closely affects treatment choice.

In the present study; results recommend TCA superior to podophyllin, the opinion of Tseng's study and Cohen's study mention that TCA did not have increased fetal morbidity or mortality, or birth defects. TCA have the best safety profile in treating warts during pregnancy. (9)

Selection of a treatment type depend on the number, size, pregnancy, and location of the warts. There is weak evidence that one approach is better than another, but costs differ. (10)

In Iraq cost is important factor in selecting the mode of treatment. Both podophyllotoxin preparations are also more cost-effective than podophyllin. Podophyllotoxin solution is used for penile lesions; cream or gel formulations are easier to use for vaginal and anal lesions. (11)

Podophyllin and TCA are well-known, suitable price and widely used drugs in Iraq.

Difference of results in studies using podophyllin may be due to unavailable standard preparation. (12)

The use of podophyllin should be limited to cases where side effects are discounted and that compliance and medication cost are important. (13). The most appropriate priced drug for genital warts is podophyllin. (14), (15).

Conclusion

In the present study; results recommend TCA superior to podophyllin especially in pregnant women, as the opinion of Tseng's study and Cohen's study because TCA did not have increased fetal morbidity or mortality, or birth defects.

TCA have the best safety profile in treating warts during pregnancy.

There was a higher clearance rate with TCA and earlier response. The occurrence of adverse reactions is little in both groups but more with TCA.

It is a doctor-applied outpatient method.

In this type also patient compliance plays an important role as they should come to the clinic every week. Advantages are simple and cost-effective method, so selection of mode variable according to each case.

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Conflict of Interest

No conflict of interest

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Original Article

The role of Strain Elastography in Evaluating Borderline Axillary Lymph nodes

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ABSTRACT

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Background: Axillary lymph node (ALN) enlargement with diffuse cortical thickening and conserved echogenic hilum may represent a diagnostic and therapeutic challenge. Sonographic strain elastography may help the characterization of borderline ALN.

Aim: To evaluate the strain elastography of borderline ALN and to calculate a cutoff value of strain ratio (SR) that can identify suspicious ALN with the highest sensitivity and specificity to reduce unnecessary invasive procedures.

Subjects and Methods: A prospective study included 45 patients who attended the Breast clinic in Oncology Teaching Hospital with borderline axillary lymphadenopathy (intact hilum and diffusely thickened cortex more than 3mm) who had normal ipsilateral breast, suspicious ipsilateral breast lesion, or who had ipsilateral mastectomy. B-mode sonography and elastography were performed for all participants. Four-point elasticity score (ES), and SR were obtained for the targeted lymph node followed by ultrasound-guided fine needle aspirate (FNA) biopsy.

Results: Malignant ALN constituted 20% of the cohort. B mode measurements were not able to differentiate between cytologically confirmed benign and malignant ALN in terms of axis ratio (mean \pm standard deviation, 0.46 ± 0.08 vs 0.50 ± 0.12) and cortical thickness (4.88 ± 1.93 vs 6.27 ± 2.46). The mean SR of all samples was 2.66 ± 2.25 . Metastatic ALN depicted significantly higher SR ($P < 0.0001$), with 88.9% exhibiting ES score 3 and 4. None of the metastatic ALN had ES score 1. ROC curve was used to investigate the utility of SR as a diagnostic tool. The area under the curve (AUC) was 0.906 with a 95% CI of 0.814-0.997, $P < 0.001$. SR cutoff of 2.1 was chosen with 100% sensitivity and 66.7% specificity.

Conclusion: High proportion of borderline ALNs are not malignant. Strain elasticity can improve the risk stratification of such cases and prevent unnecessary invasive procedures. We suggested an algorithm that could better tackle borderline ALN which will need further evaluation

Introduction

Unilateral axillary lymph node (ALN) enlargement may represent a diagnostic and therapeutic challenge. Several infectious and inflammatory conditions are associated with unilateral ALN adenopathy (1). Although primary breast carcinoma presented as ALN adenopathy is relatively uncommon with a range of 0.3-1% (2), exclusion of metastatic disease remains the primary target in the evaluation of ALN adenopathy. In ultrasonography, a benign ALN appears ovoid, with a thin hypoechoic cortex and hyperechoic hilum due to the presence of lymphatic tissue cords and medullary sinusoids within connective tissue trabeculae (3). Features that render an ALN suspicious are thickening of the cortex, compression or absence of the hilum, altered vascular pattern, and change of the shape. A completely hypoechoic ALN with absent fatty hilum is a specific alteration of metastatic disease that occurs usually in advanced disease warranting presurgical biopsy (4). The real challenge is when an ALN shows alteration in cortical thickness in the presence of the hilum which may associate with early metastasis (3). Several cortical thickness cutoff values have been proposed to predict suspicious LN by imaging ranging between 2.3-3mm with various sensitivity and specificity ranging between 59%-95% and 44%-100% respectively (3, 5).

Sonographic strain elastography is a noninvasive, relatively new technique that uses the color map to demonstrate stiffness and homogeneity (6). It has been used to early detect and evaluate malignant lesions in addition to its value in the assessment of response to treatment as in thermal ablation and chemotherapy (6). Several studies demonstrate the ability of US elastography to identify early circumscribed malignant infiltration in cervical, axillary, and inguinal lymph nodes by demonstrating stiffness of the cortex and medulla (7, 8).

Different qualitatively US elastogram classifications have been proposed. A 4-point (9), 5-point (10), 6-point, 7-point (7), or 8-point rating scale (11, 12). In the 4-point rating scale, the metastatic LNs were mostly evaluated to score 3-4. According to several studies, strain ratio (SR) >1.5 or hard composition over 50% has been suggested as an indicator of malignancy (11). Nonetheless, elastogram evaluation remains an operative-dependent technique and reproducibility can be affected by commercial system design and settings.

This study aimed to evaluate the strain elastography of borderline ALN in a sample of Iraqi patients and to calculate a cutoff value of strain ratio that can identify suspicious ALN with the highest sensitivity and specificity to reduce unnecessary invasive procedures.

Subjects and Methods

A total of 45 patients visiting the Referral Training Center for Early Detection of Breast Cancer, Oncology Teaching Hospital, Medical City in Baghdad during the period between October 2020 and September 2021 were prospectively recruited. The study protocol was approved by the Ethical committee of the Oncology Teaching Hospital. Informed consent was given by all participants.

Inclusion criteria were: borderline axillary lymphadenopathy with intact hilum and diffusely thickened cortex more than 3mm patients with normal ipsilateral breast, suspicious ipsilateral breast lesion, or patients with an ipsilateral mastectomy who completed medical treatment for more than one year and did not receive radiotherapy.

Exclusion criteria included highly suspicious ALN with lost hilum, ALN with cystic changes or calcific foci, patients with a history of ipsilateral radiotherapy of mastectomy site or as part of breast-

conserving therapy (BCT), and also breast cancer patients who received chemotherapy in the last 12 months.

In a supine position, with the arm of the examined side lifted above the head, proper breast or mastectomy site sonographic evaluation was done, then the patient turned to supine oblique position for proper evaluation of the ipsilateral axilla. B-mode sonography and sonographic elastography were performed for all participants using the linear transducer 9L-D (2-8 MHz with FOV 44 mm) of a GE healthcare sonographic machine (LOGIQ S8 XD clear 2.0) by two Board-certified radiologists with at least 6 years of experience. After identification of the borderline ALN on B-mode sonography, important measurements were taken (LN short-axis and long-axis diameters with maximal cortical thickness), long-to-short axis (L/S) ratios were subsequently calculated.

Real-time elastography images of the lymph node were obtained by starting strain elastography after pressing the "Elasto" button at the console of the machine. The size of the box was adjusted to place the concerned LN at the center along with part of surrounding normal tissue. Manual compression over the lymph node with an ultrasound transducer for at least 5 seconds was used to catch a quality graph with consistent high (nearly flat, plateau-like) peaks to freeze the image for color analysis and measurement of the strain ratio.

A four-point elasticity score was obtained based on the percentage of high elasticity. The elastography color bar refers to soft lesions as red and the blue color denotes stiff lesions. According to this system ALN in our cohort were classified to: score 1 when ALN was predominantly red color with <10% of the area colored as blue; score 2 when elastography was predominantly red and green, with 10%-50% of the area shown as blue; Score 3 when predominantly (50%-90%) was blue and green; while score 4 refers to a stiff nodule that is predominantly (>90%) blue (13, 14).

The strain ratio, a pseudo-quantitative measurement, was calculated for each ALN in the cohort by taking the E-Indexes of the first (reference tissue) and the second (the lesion of interest). The reference selected was fatty areas of the axilla at nearly the same level as the LN (14). A strain ratio >1 indicates that the target lesion is less compressible than the normal reference tissue, indicating lower strain and greater stiffness.

Ultrasound-guided fine needle aspirate (FNA) biopsy was performed for all the borderline ALN. Patients with cytology report positive for malignancy or granuloma were confirmed by histopathology. Patients with reactive cytology were followed up for 3-12 months within the period of the study, 16/26 retained the normal morphology while the rest did not show worsened morphology. Patients who were lost during the follow up were excluded from the study.

Statistical analysis

All statistical analyses were carried out using Statistical Package for Social Sciences (SPSS) software version 25 (IBM Corp., Armonk, N.Y., USA). Continuous variables were expressed as mean, standard deviation, and range. Mann Whitney and Chi-Square tests were used to compare groups as required. Sensitivity was measured as the proportion of malignancies that were correctly identified. Specificity was measured as the proportion of benign diseases that were correctly identified as such. The positive predictive value (PPV) was measured as the proportion of positive for malignancy tests that were truly positive. Negative predictive value (NPV) was measured as the proportion of negative for malignancy tests that were true negative. The overall test accuracy was measured as the proportion of all results that were true. Receiver operating characteristic (ROC) curve analysis was performed for the strain ratio. A *P* value of less than 0.05 was considered statistically significant.

Results

The mean age of the patient was 42.15 ± 11.5 -year ranging between 22-71 years, 91% of them were women. Symptomatic patients with palpable or tender axillary lumps represented 64.4% of the cohort, while the rest were on surveillance for benign or malignant breast lesions as shown in Table 1.

Table 1 Demographic characteristics and diagnostic impression of the study cohort

Parameter	Number	Rate
Age		
≤ 30	5	11.1
31-39	16	35.6
≥40	24	53.3
Gender		
Female	41	91.1
Male	4	8.9
Chief complaint		
Palpable axillary lump	11	24.4
Axillary tenderness	18	40
Follow up for benign breast lesion	5	11.1
Cancer patient surveillance	11	24.4
Radiological impression		
Axis ratio (short/wide axis)		
<0.5	27	60
> 0.5	18	40
Cortex thickness		
3-6mm	31	68.9
≥6mm	14	31.1
Cytological impression		
Reactive	29	64.4
Granulomatous	7	15.6
Malignant	9	20.0

The mean short/long axis ratio in all cases was 0.47 ± 0.09 , ranging between (0.32-0.8). The mean of long and short axes of cytologically confirmed metastatic ALN was greater than that of the reactive ALN, however, statistically, that was not significant as shown in Table 2. The mean cortical thickness of all cases was 5.16 ± 2.09 , ranging between (3-11) mm. Cortical thickness of 6mm and more was seen in 5/9 (55.6%) metastatic ALN compared to only 16% of the benign/ inflammatory ALN (P=0.077). The mean SR of all samples was 2.66 ± 2.25 ranging between (0.6-11.0). SR was significantly higher in metastatic ALN (P<0.0001), with 88.9% exhibited elasticity score (ES) 3 and 4. None of the metastatic ALN had ES 1 as shown in Table 2, Figure 1 shows examples of elasticity studies of malignant and benign ALN.

Table 2 B-mode and elastography features of the reactive and metastatic axillary lymph nodes.

Sonography Criteria	Reactive (n=36)	Malignant (n=9)	P-value
Long axis (Mean ± SD)	19.83 ± 8.13	21.00 ± 8.13	0.293
Short axis (Mean ± SD)	8.91 ± 3.02	10.11 ± 3.72	0.211

Axis ratio (short/ long axis) (Mean ± SD)	0.46 ±0.08 22 (61.2) 14 (38.9)	0.50 ±0.12 5 (55.6) 4 (44.4)	0.761
<0.5 No (%)			
≥0.5 No (%)			
Cortical thickness (Mean ± SD)	4.88 ±1.93 27 (75.0) 9 (25.0)	6.27 ±2.46 4 (44.4) 5 (55.6)	0.077
<6 No (%)			
≥6 No (%)			
Strain ratio (Mean ± SD)	2.01 ±1.35 24 (66.7) 12 (33.3)	5.46 ±3.36 0 (0) 9 (100)	<0.0001
<2.1 No (%)			
≥2.1 No (%)			
Elasticity score No (%)			<0.0001
1	9 (25)	0	
2	22 (61.1)	1 (11.1)	
3	3 (8.3)	2 (22)	
4	2 (5.6)	6 (66.7)	
Elasticity score No (%)			<0.0001
1 & 2	31 (86.1%)	1 (11.1%)	
3&4	5 (13.9%)	8 (88.9%)	

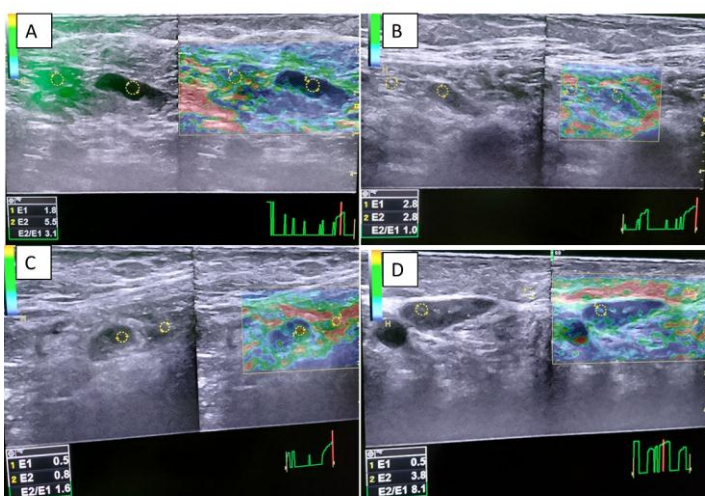


Figure 1 Elastography study of axillary lymph nodes. A) A patient with newly diagnosed breast cancer had enlarged ipsilateral axillary LN, elasticity score was 3, strain ratio was 3.1, FNA revealed malignancy that was proved after excisional biopsy. B) A patient complained of left axillary pain, the ultrasound revealed an infected sebaceous cyst with an ipsilateral enlarged axillary lymph node, elasticity score 2 and the strain ratio was 1, cytology impression was reactive, reduction in cortical thickness was noted at the follow up visit. C) A patient complained of a palpable lump at the left axilla after COVID 19 vaccination, the ultrasound revealed left axillary lymphadenopathy with an elasticity score of 2 and a strain ratio of 1.6, the cytology impression was reactive, reduction in cortical thickness was noted at the follow up visit. D) A patient complained of right axillary pain, ultrasound revealed right axillary lymphadenopathy with an elasticity score of 3 and the strain ratio of 8.1 with no ipsilateral breast abnormality. The radiological impression was suspicious, cytology revealed reactive lymphadenopathy confirmed by excisional biopsy (False positive).

ROC curve was used to investigate the utility of SR as a diagnostic tool. The area under the curve (AUC) was 0.906 with a 95% CI of 0.814-0.997, P<0.001, Figure 2. By reviewing the sensitivity and the specificity of the different cutoff values, we found that SR which

could efficiently identify the metastatic ALN was 2.6 with a sensitivity of 88.9% and specificity of 83.3%, however, in screening tests, the aim is to achieve the higher sensitivity, therefore, we considered an SR cutoff of 2.1 with 100% sensitivity but lower specificity of 66.7%. When predictive values and accuracy of the calculated SR cutoff (2.1) were compared to the literature suggested value of 1.5, the former had higher overall accuracy (73.3% vs 62.2%). Combined elasticity score and ratio improved individual test specificity to 88.9 and PPV and NPV to 66.7% and 97.7% respectively, as shown in Table 3.

Table 3 validity of elasticity score and ratio using the proposed cutoff value and literature proposed cutoff value

	Sensitivity	Specificity	PPV	NPV	Accuracy
ES 1&2 vs 3&4	88.9%	86.1%	61.5%	96.9%	86.7
SR >1.5 vs ≤ 1.5	100%	52.8%	34.6%	100%	62.2
SR ≥2.1 vs <2.1	100%	66.7%	42.9%	100%	73.3
SR > 2.6 vs ≤2.6	88.9%	83.3%	57.1%	96.8%	91.1
SR >1.5 and ES>2	88.9%	86.1%	61.5%	96.9%	86.7
SR ≥2.1 and ES>2	88.9%	88.9%	66.7%	97.0%	88.8
SR >2.6 and ES>2	88.9%	91.7%	72.7%	97.7%	91.1

Abbreviations: ES, elasticity score; SR, strain ratio; PPV, positive predictive value; NPV, negative predictive value.

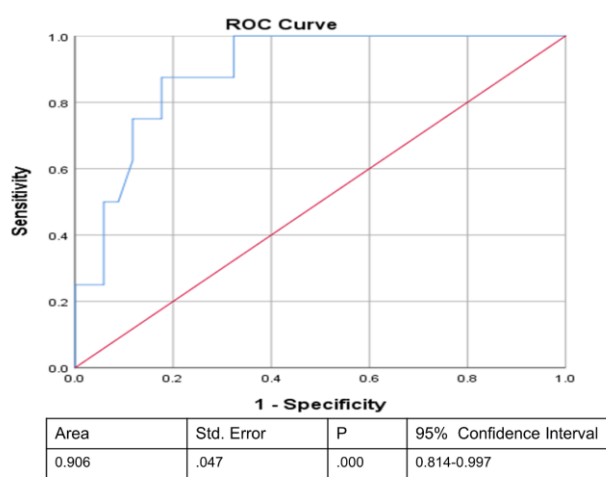


Figure 2 ROC curve of elasticity ratio

Discussion

Borderline ALN can be frequently seen during breast cancer patient surveillance as well as nonmalignant conditions. In the absence of radiological features such as lost echogenic hilum and focally thickened cortex, the suspicion level is reduced yet focal malignancy cannot be excluded mandating further invasive procedures (15). Sentinel ALN is recommended in such cases during the first

diagnosis of breast cancer while in the absence of malignant breast lesion adding further evaluating tools may reduce the need for unnecessary surgery. The utility of elastography in identifying focal malignant changes is established in many of the internal organs (16, 17). This study examined the benefit of incorporating strain elasticity to predict early malignant changes in borderline ALN.

The selection criteria of our cohort were strict, excluding all highly suspicious lymph nodes and focusing on relatively small ALN with a diffuse increase in cortical thickness and subtle shape change regardless of breast pathology. Among the 45 collected cases, cytology/histopathology diagnosed 80% as benign. B mode US evaluation showed no significant difference in these parameters in metastatic ALN compared to reactive/ inflammatory ALN. Cohort characteristics explain the disagreement with the results of Choi et al.(18) who concluded that cortical thickness, absent hilum and S/L access were significantly different in metastatic ALN, as he have included breast cancer patients with looser selection criteria, including highly suspicious ALN.

We adopted the four-tiered elasticity score which is easier to conduct and interpret with a good predictive value compared to the 5 and 6 tiered adopted by other studies (19, 20). Our results showed a significantly higher prevalence (88.9%) of metastatic ALN in elasticity scores 3 and 4 compared to (11.1%) score 2, whereas score 1 did not associate with any metastatic ALN. This was in agreement with Choe et al. 2011 who used a 4 tiered score modified from Alam’s5-tiered score (18, 19).

Strain elasticity ratio, in our cohort, was referenced to axillary fat as recommended by many studies (18, 21). Mean SR was significantly higher in metastatic ALN. In the literature, different cutoff values were suggested depending on the cohort characteristics, referenced tissue, and the targeted predictive value. To reduce unnecessary invasive procedures in borderline ALN, we were aiming for the highest sensitivity and compromising on specificity. Therefore we suggested a cutoff value of 2.1 with an NPV of 100% and a specificity of 66.7% which was higher than the specificity of cutoff value (1.5) proposed by Lyshchik et al. (20).

Based on our findings, we proposed an algorithm for borderline ALN management, figure 3, by stratifying the risk into, a low-risk group with an elasticity score of 1 or 2 and SR< 2.1 who could be followed up for 6 months. A high-risk group with an elasticity score of 3 or 4 and strain ratio ≥ 2.1 should undergo FNAC. The intermediate-risk group includes two categories when ES is 1 or 2 but the SR is 2.1 or higher or when the ES is 3 or 4 but the SR is lower than 2.1. In both situations, FNA is recommended if a suspicious breast lesion (BIRADS IV or V) was identified in the ipsilateral side, otherwise, the patient would be scheduled for following up. A prospective study with a calculated sample size, however, would be required to evaluate the validity of this algorithm.

The study limitations included small sample size and a small number of participants in some subgroups. For better differentiation of benign lymph nodes from one another such as granuloma for reactionary purposes more cases in subgroups would be required.

Conclusion

A high proportion of borderline ALN is not malignant. Strain elasticity can improve the risk stratification of such cases and prevent unnecessary invasive procedures. We suggested an algorithm that could better tackle borderline ALN which will need further evaluation.

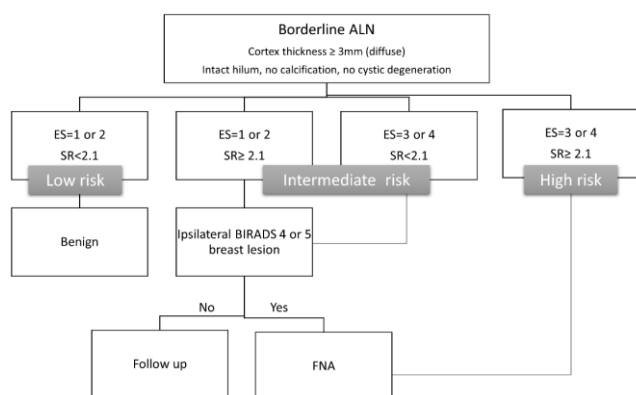


Figure 3. A flow chart illustrates a management algorithm for borderline axillary lymph nodes. Abbreviation, axillary lymph nodes (ALN), elasticity score (ES), strain ratio (SR).

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Conflict of Interest

No conflict of interest

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Original Article

Comparative Study on the Corneal Endothelial Cell Count between Type 2 Diabetic and Non-Diabetic Patients

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ABSTRACT

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Background: Diabetes mellitus is one of the commonest chronic disorders worldwide with a rapid rise in prevalence. In Iraq its prevalence is high especially in elderly age group. Patients with type 2 diabetes mellitus have higher vulnerability for complications, whether microvascular or macrovascular. Ocular complications are common in diabetes mellitus, and comprise diabetic retinopathy, diabetic papillopathy, cataract, glaucoma, dry eye disease and diabetic keratopathy. Diabetic keratopathy involves endothelial and epithelial tissues of the cornea, leading to persistent epithelial defect, corneal erosion, or corneal ulcers.

Aim of the Study: To compare the mean corneal endothelial cell count between patients with type 2 diabetes mellitus and non-diabetics.

Subjects and Methods: This is a case-control study conducted in Ibn Al Haitham Teaching Eye Hospital – Baghdad and included 249 participants, 125 cases with type 2 diabetes and 124 controls who had no diabetes. Endothelial cell count was measured for 1 eye of each participant using TOPCON® SP-3000P microscope. Patients who had diabetes for less than 5 years, and patients who had previous ocular surgery, injury or disorders were excluded.

Results: There was a significant difference in endothelial cell count between cases with type 2 diabetes mellitus and controls; $P = 0.001$. There was also a significant negative correlation between age and endothelial cell count, $R = -0.20$, $P = 0.002$. Similarly, there was a significant negative correlation between duration of diabetes mellitus and endothelial cell count, $R = -0.44$, $P < 0.001$.

Conclusions: Type 2 diabetes mellitus causes significant reduction in mean corneal endothelial cell count. There is also a negative correlation between corneal endothelial cell count and both age and duration of the disease.

Introduction

Diabetes mellitus (DM) is one of the commonest chronic metabolic disorders, leading to a global public health burden of disease. This rapid rise in prevalence is attributed to several factors

including aging, population growth, obesity and lack of physical activity.[1] Iraq, among the Middle-Eastern countries, has a high prevalence of DM among its population, especially in elderly age group, with a prevalence of 15% in people of age 50 years and older,

as estimated by the Iraqi Ministry of Health (MOH) in its report of Iraq Family Health Survey (IFHS) conducted on 2006 and 2007 in collaboration with the World Health Organization (WHO).[2]

Three types of DM have been described: Type 1 or insulin dependent DM (IDDM), type 2 or non-insulin dependent DM (NIDDM), and gestational DM (GDM).[3] Patients with type 2 DM have higher vulnerability for complications, both short-term and long-term, when compared to type 1 diabetics. This is partly related to the higher prevalence of this type of DM as well as its later recognition when compared to type 1 DM. [4] These complications, whether microvascular complications such as retinopathy and nephropathy, or macrovascular complications such as stroke and peripheral arterial diseases, make DM an important and challenging health issue of the 21st century.[5]

Ocular complications are common, involving various tissues of the eye and comprise diabetic retinopathy, diabetic papillopathy, cataract, glaucoma, dry eye disease and diabetic keratopathy. [6, 7]

The cornea is the transparent anterior structure of the eye that covers and protects the iris, pupil, and anterior chamber.[8] The corneal endothelium is a monolayer of cells lining the posterior surface of the cornea. This layer has an important role in hydration control of the stroma and maintaining stromal deturgescence by an active pump action that draws fluid from the stroma into the aqueous humor. [9, 10]

Endothelial cell density of human cornea varies throughout life, with an approximate 6000 cells/mm² at birth, declining to approximately 3500 cells/mm² at age of 5 years. This decline is attributed to both growth of the cornea and to the decrease in the number of endothelial cells.[10] It is estimated that the average rate at which the endothelial cell density declines annually is about 0.6% per year.[11] Correspondingly it was found that mean cell density declined from 3400 cells/mm² at age 15 years to about 2300 cells/mm² at age of 85 years.[10]

Diabetic keratopathy is a common ocular complication of DM involving endothelial and epithelial tissues of the cornea, leading to persistent epithelial defect, corneal erosion, or corneal ulcers.[12] Diabetic keratopathy causes alterations to these corneal tissues that lead to 3 main distinct types of tissue dysfunction: impaired wound healing of the corneal epithelium, sub-basal nerves abnormalities, and inadequate pump function of the corneal endothelium.[9] These changes result in thickening of the endothelium, decreased corneal sensitivity, and tear secretion abnormalities.[13]

The structure and function of the corneal endothelium can be assessed using non-contact specular microscopy, which is a non-invasive technique that provides morphological analysis of the corneal endothelial cell layer.[14].

Aim of the Study

To compare the mean corneal endothelial cell count between patients with type 2 diabetes mellitus and non-diabetics using specular microscope.

Subjects and Methods

This is a case-control study conducted in Ibn Al Haitham Teaching Eye Hospital - Baghdad from July 2017 through April 2018 and included a total of 249 participants, 125 cases with type 2

diabetes diagnosed by physician their age range 40-70 years (57.2 ± 8.5), and 124 control who had no diabetes according to fasting blood sugar their age range 40-70 years (56.1 ± 9.2).

Formal permission and approval were obtained from related offices to conduct this study. Verbal Informed consent was obtained from all participants after explaining the purpose of the study and type of data collected, and data was treated in anonymity and confidentiality.

Information obtained from participants included age, gender, history of diabetes and other chronic disorders, and detailed history of any previous ocular disorders or interventions. All study participant underwent specular microscopy for one eye to measure the endothelial cell count. This was done using TOPCON® SP-3000P (Japan) non-contact specular microscope by the same operator. Images undergoing analysis involved about 100 ± 20 endothelial cells from the center of the cornea. This procedure was repeated three times for each eye, and the median number of endothelial cell density was selected. Examinations for anterior and posterior segments were performed before specular microscopy by slit-lamp biomicroscopy including intraocular pressure measurement by Goldmann applanation tonometer and air puff tonometers.

Exclusion criteria were patients who had diabetes for less than 5 years from the date of diagnosis, patients with eye trauma or previous surgery to the eye, patients who wear contact lenses, uveitis or other ocular infections, and patients who had previously undergone corrective laser eye surgery, previous retinal photocoagulation, glaucoma, dry eye, pseudo-exfoliation, pigment dispersion syndrome, endothelial corneal dystrophy, topical medication and smoking.

Statistical Analysis

Statistical Package for Social Sciences (SPSS®) Software version 23.0 for Linux® has been used to perform statistical analysis in this study. Qualitative data are presented as number and percentage, while continuous numerical data are presented as mean \pm standard deviation. Comparison of study groups was carried out using Student's t-test for continuous data, and continuous variables were compared using Pearson's product-moment correlation coefficient, and plotted on scatter diagrams to further illustrate the relationship between the two variables. P-value of < 0.05 is considered statistically significant.

Results

The study included 249 participants, 125 cases of DM type 2 and 124 controls. No significant difference exists in age between cases and controls, as detailed in table (1), thus eliminating the effect of age as a confounder. Age groups of study participants were illustrated in figure (1).

Table 1: Age distribution of study participants

Age (years)	Cases (n=125)	Controls (n=124)
Range	40 – 70	40 – 70
Mean \pm SD	57.2 ± 8.5	56.1 ± 9.2

Age (years)	Cases (n=125)	Controls (n=124)
Student's t-test = 1.00, d.f.* = 247, P-value = 0.319		

* d.f. = degrees of freedom

To compare between studies groups regarding endothelial cell count; independent-samples t-test was used. There was a statistically significant difference in endothelial cell count between cases group and control group; $t(247) = -3.41$, $P = 0.001$, as detailed in table (2). Table (2)

Table 2: Comparison of endothelial cell count between cases and controls

Parameter	Cases (n=125)	Controls (n=124)
Mean	2543.65	2647.10
SD	256.51	220.27
Student's t = -3.41, d.f. = 247, P = 0.001		

A Pearson product-moment correlation coefficient was computed to assess the relationship between age and endothelial cell count. There was a significant negative correlation between the two variables, coefficient of correlation (R) = -0.20, coefficient of determination (R²) = 0.04, n = 249, P-value = 0.002. A scatterplot summarizes the results (Figure 1).

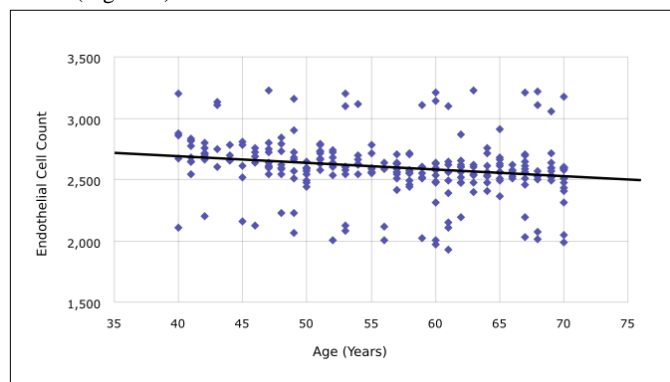


Figure.1: Scatterplot diagram showing correlation between endothelial cell count and age in years

Another comparison was performed between endothelial cell count and duration of DM using Pearson's product-moment correlation coefficient. There was also a highly significant negative correlation between the two variables, coefficient of correlation (R) = -0.44, coefficient of determination (R²) = 0.19, n = 249, $P < 0.001$, as illustrated in figure (2).

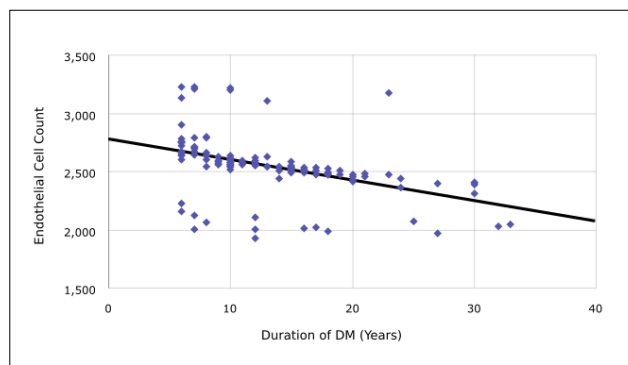


Figure.2: Scatterplot diagram showing correlation between endothelial cell count and duration of DM in years.

Linear regression was calculated between endothelial cell count and diabetes with adjustment to age and gender, to predict endothelial cell count based on presence of diabetes. A significant regression equation was found (P-value < 0.001), with a coefficient of determination (R²) of 0.08. Endothelial cell count is lower by an average of 98 cells in diabetic patients when compared with non-diabetics, regardless of age and gender (adjusted t-test=-3.27, P-value = 0.001).

Discussion

In this study, the study groups were first compared regarding difference in age and gender, and no significant difference was observed, therefore reducing the confounder effect of those two characteristics. Comparison of the study groups regarding endothelial cell count have shown a statistically significant reduction of 3.91% in mean endothelial cell count between cases and controls (P = 0.001). This finding is consistent with a similar study conducted in Japan by Inoue et al. which found a significant reduction of 4.08% in mean endothelial cell count (P = 0.016).[15] Another study conducted in Malaysia by Choo et al. have found a significant reduction of 4.5% in mean endothelial cell count.[16] Similarly, El-Agamy et al. found a reduction of 5.24% among Saudi Arabian patients who were enrolled in that study[17], and Lee et al. found a reduction of 4.54% in their Korean study.[18] A lower, yet still significant, reduction of 2.82% was observed by Ahuja et al. in their study done in India.[19] However, the results of the study in Denmark by Storr-Paulsen et al. have shown non-significant reduction of only 1.03% in mean endothelial count, which is not consistent with the findings in the present study.[20]

This marked change in the diabetic corneal tissue could be explained by the effect of DM on the activity of Na⁺-K⁺ ATPase enzyme, elevated glucose level reduces the activity of the aforementioned enzyme, changing the permeability and morphology of the cornea, which in turn leads to the destruction of the corneal cells. Diabetes also slows down Krebs cycle in the cornea, therefore the production of ATP is reduced. This reduction affects the endothelial pump function, further damaging the cornea. [16, 17]

Analysis of Pearson correlation between endothelial cell count and age have shown a significant correlation indicating that endothelial cell count decreases with increasing age. This reduction over time could be part of certain morphological changes that occur with aging process. Similar finding was reported by Busted et al.

[21] and Parekh et al. [22] However, Inoue et al. reported no significant correlation with age.[15]

This study demonstrated a significant negative correlation between duration of DM and endothelial cell count, meaning that increases in duration of DM were correlated to decreases in endothelial cell count. A similar significant correlation was reported by Parekh et al. [22] But El-Agamy et al. found no such correlation.[17]

A possible limitation of this study is the potential of presence of confounding factors that influence the association between variables under study, although adjustment to age and gender used in this study significantly reduced the confounding effect of those two variables.

The results and findings in this study concludes that mean corneal endothelial cell count is significantly lower in patients with type 2 diabetes mellitus when compared to non-diabetics.

The results also described that there is significant correlation between age and mean corneal endothelial cell count, suggesting that mean corneal endothelial cell count decreases with aging.

Another conclusion is the demonstration of the correlation between the duration of DM and the mean corneal endothelial cell count, showing that longer the duration of disease, lead to lower mean corneal endothelial cell count.

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Case Report

A serology conundrum – HIV infection in acute babesiosis infection could merely be a false positive result

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ABSTRACT

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Babesiosis is a tick-borne disease caused by *Babesia microti*. We present a case of false positive HIV in the setting of confirmed babesiosis infection. An understanding that patients with babesiosis can have a false positive HIV test result is important in management decisions.

Introduction

Babesiosis is a tick-borne disease caused by *Babesia microti*. We present a case of false positive HIV in the setting of confirmed babesiosis infection. An understanding that patients with babesiosis can have a false positive HIV test result is important in management decisions.

Case Presentation

A 46-year-old male presented with an acute febrile illness of 7 days duration manifesting as fever, headache, fatigue, and myalgia. The patient was recently diagnosed with acute sinusitis and started on amoxicillin by his Primary care physician, though had worsening of his systemic symptoms including fever. He was found to have

transaminitis and thrombocytopenia on presentation; therefore, he was admitted for further evaluation. A petechial rash was noted on his lower extremities concerning for Rocky Mountain spotted fever (RMFS). The patient was started on doxycycline empirically pending work-up initiated by the Infectious Disease team. Relevant laboratory results included a positive parasite smear for babesia with a 3% parasitemia load, positive mononucleosis screen, EBV and CMV IgM positive serologies, and positive HIV screen. With the low-likelihood that patient would have concurrent infection with EBV, CMV, and HIV and the fact that the patient reported being in a monogamous relationship with his wife for the past 10 years and denied HIV risk factors, made 3 concurrent viral infections less likely requiring further investigation. The patient was appropriately started on atovaquone/azithromycin and continued doxycycline

awaiting anaplasmosis, RMSF and Lyme studies which ultimately came back negative. As parasitemia persisted at 3%, regimen was changed to quinine/clindamycin with good response as parasitemia trended down. Transaminitis and thrombocytopenia improved on the new regimen as well; however, patient developed tinnitus, which is a known side effect of quinine, therefore the regimen was changed to atovaquone/azithromycin to complete a total of 10 days. In the interim, confirmatory HIV multispot came back positive, however HIV RNA was negative, excluding acute retroviral syndrome. It was thought that the concurrent positive serologies were false positive test results in the setting of babesiosis. These studies were repeated after the clearance of parasitemia was proven by negative parasite smear after treatment course completion; HIV Ab was non-reactive with undetected HIV RNA viral load and negative CMV IgG/IgM which confirmed our false positive theory.

Conclusion: HIV is a risk factor for babesiosis, and coinfection is common. However, there have been 3 reported cases of false positive HIV findings in patients with acute babesiosis-to the best of our knowledge. This case is unique in that our patient had confirmed babesiosis infection with three concurrent false-positive viral serologies. Further study is needed to investigate this association. For now, we suggest that affected patients should undergo repeat confirmatory testing once parasitemia has cleared prior to determine if further treatment is required.

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Case Report

Spinal Tuberculosis in Children

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Spinal tuberculosis is the result of infection with *Mycobacterium tuberculosis*. It is a secondary infection, the primary lesion of which is in the lungs, genitourinary system, or gastrointestinal tract and can be active or latent. Involvement of the vertebral segment is the result of hematogenous spread of infection along the arterial pathway or Batson's vein plexus, lymphatic spread, or direct invasion from adjacent internal organs.

Epidemiology

Tuberculosis continues to be the leading cause of morbidity and mortality, with an estimated annual incidence of 10.4 million worldwide.

It has been estimated that 10% of patients with extrapulmonary tuberculosis have musculoskeletal involvement, with the spine being the most common.

Spinal tuberculosis (TB) accounts for 50% of cases of musculoskeletal tuberculosis. (1)

Pathogenesis

Spinal tuberculosis is the result of infection with *Mycobacterium tuberculosis*. It is a secondary infection, the primary lesion of which is in the lungs, genitourinary system, or gastrointestinal tract and can be active or latent. Involvement of the vertebral segment is the result

of hematogenous spread of infection along the arterial pathway or Batson's vein plexus, lymphatic spread, or direct invasion from adjacent internal organs. There are three tuberculous lesions: paradiscal, central and anterior. Paradiscal pattern is the most common lesion and has a higher incidence in adults than in children. Paradiscal infection spreads through the epiphyseal arteries. The progression of the disease causes further destruction of the vertebral body, which leads to late deformity and neurological deficits. The central lesion extends along the Batson vein plexus and results in destruction of the vertebral body with disc involvement. Central lesions are more common in children. Anterior destruction of the vertebral body under the anterior longitudinal ligament occurs as a result of the tearing of the periosteum and the anterior longitudinal ligament in combination with a significant accumulation of abscess.

Involvement of the posterior elements is rare, but is associated with late diagnosis and neurological deficits. Computed tomography (CT) and magnetic resonance imaging (MRI) allow early detection of spinal lesions. (2), (3)

The most common part of spinal tuberculosis is the lumbosacral articulation and the adjacent segment with local kyphosis. Failure of more than one segment is not uncommon. Asymmetric destruction of bones contributes to scoliotic deformity, and with extended anterior destruction, dislocation of the facet joint can develop, which can lead to complete translocation of the spine and complex deformity (4).

Diagnosics

Computed tomography (CT) is better suited for assessing the extent of the lesion when contrast is used to enhance granulomatous tissues and abscesses, but exposes the patient to high radiation.(5) Magnetic resonance imaging (MRI) can detect changes that occur in the early stages of the disease. The destruction of bones in the vertebral bodies leads to a decrease in intensity on T1-weighted images and an increase in intensity on T2-weighted images, since the bone marrow is replaced by inflammatory cells.5 MRI scans are more sensitive than x-ray and more specific than computed tomography for diagnosing spinal tuberculosis. (5) Due to its superiority in soft tissue imaging, MRI is effective in detecting extension into bone anatomy and the spinal canal. It is also useful for differential diagnostics5,6. In tuberculosis, MRI provides the most information for the reasons stated above and should be the first line test if ST is suspected. When MRI is not available, computed tomography should be done. If computed tomography is unavailable, x-ray can be an alternative. Computed tomography is better for evaluating bone anatomy. X-ray is more common for initial diagnosis and often done in emergency department or family clinic. A definitive diagnosis of ST can only be confirmed by culture of a sample obtained by biopsy or aspiration. This method is recommended by the National Institute for the Advancement of Health and Medical Care (NICA) in the United Kingdom (7). Biopsy using computed tomography is the preferred method for obtaining a sample of the lesion. Laboratory methods that can aid in diagnosis include detection of metabolic products such as interferon-G and M. tuberculosis polymerase chain reaction, which detects bacterial DNA if present in a serum sample (6), (8).

WHO has suggested that any extrapulmonary tuberculosis should require sputum examination and chest x-ray, as there is a high risk of pulmonary infection (9).

Thus, computed tomography (CT) and magnetic resonance imaging (MRI) are the main modalities for detecting tuberculous spondylitis.

Patient and Observation

2 years old male, with lower paraparesis (muscle strength 2-3 grade) and inability to walk. The child stopped walking on his own 3 months before coming to our clinic. Received drug therapy from an orthopedist, without a positive effect. After neurosurgeons consultation, whole spine MRI was done. MRI found kyphotic deformity of the thoracic spine, compression of the spinal cord by a huge vertebral mass, Th3-Th4 vertebral bodies destroyed by the

mass. CT reveals absence of bone signals from the VTh3 body and 1/3 of the VTh4 body (Figure 1)

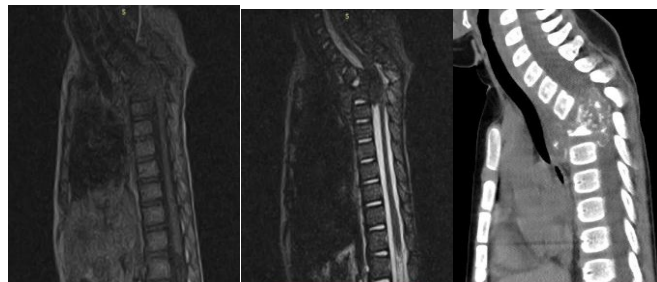


Figure 1. Preoperative MRI and CT images (spinal cord compression).

Surgery: Under general anesthesia in the position of the child lying on the left side, a linear 10 cm long incision was made between the anterior and posterior axillary lines in 3-4 intercostal space. Access to the tumor of VTh3 and VTh4 bodies was made. Branches of Azygos vein that penetrate the tumor were ligated. The tumor was completely removed with an ultrasonic destructor and microsurgical instrumentation. In some parts it has clear boundaries and a capsule, in other parts it grows into the surrounding soft tissues. Tumor grew into the spinal canal at the level VTh2 and VTh5. VTh3 and VTh4 bodies were replaced by tumor mass. The tumor is separated from the dura, a weak pulsation of the spinal cord has appeared. Fragments of the mass were taken for pathohistological examination. An interbody titanium cylindrical implant 0.8 cm in diameter and 2.5 cm in length was placed between the VTh2 and VTh5 bodies. A lateral plate was fixed with screws 2 cm long into the VTh2 and VTh6 bodies. The wound was sutured hermetically. An active drainage left in the pleural space. Cosmetic intradermal suture on the skin. Aseptic dressing.

Post-op: The postoperative period was uneventful. Received 4 courses of rehabilitation. Complete regression of paresis of the lower extremities 2 months after surgery. The child began to walk on his own 3 months after the surgery.

Postoperative CT images show the restoration of physiological kyphosis of the cervicothoracic spine. No mass compressing the spinal cord (Figure. 2).



Figure 2. CT images and 3D reconstruction of the spine after surgery

Post-op CT image: the screw has passed through the spinal body into the spinal canal, which does not compress the spinal cord and is acceptable for this patient (10) (Figure. 3).

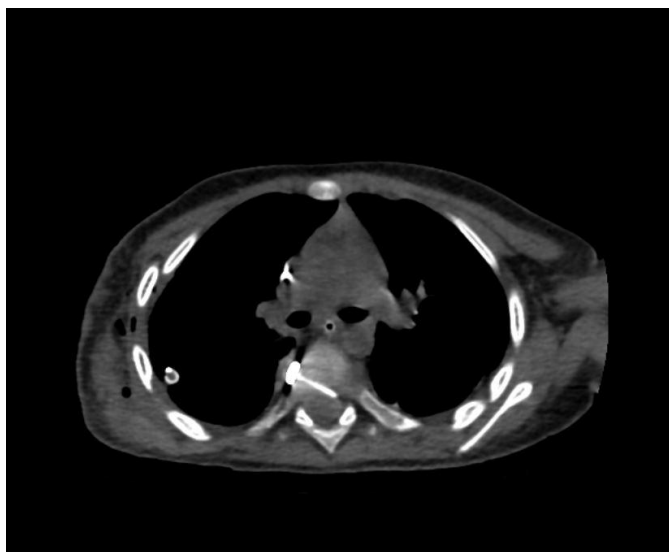


Figure 3. The image shows the intracanal screw

Pathohistological examination of the tumor cells revealed a malignant giant cell tumor. Neither on MRI, nor on CT, as well as macroscopically, the lesion did not have similar features for this type of tumor. Therefore, the revision of the histological material was done. The revision of the pathological cells gave a picture of tuberculous spondylitis. To exclude an active tuberculous process, follow up CT and sputum examination were performed. The results were negative. The patient received a course of adjuvant anti-tuberculosis therapy.

Discussion

Tuberculous spondylitis in childhood is relatively rare, but it is a very important cause of spinal column deformity and neurological deficits (11).

ST can be difficult to diagnose, evaluate, and treat. Its widespread and non-specific manifestation can lead to a delay in diagnosis, increasing the risk of disability and mortality. A favorable prognosis can be ensured through early diagnosis and treatment. MRI provides the most information for ST diagnosing, however CT and x-ray can be used in resource-limited regions. These techniques are not as sensitive as MRI for early diagnosis of ST.

Medical therapy and surgery is the most effective approach for tuberculous spondylitis. Surgical treatment is indicated for patients who do not respond to drug therapy or who have progression of the disease or neurological deficits. Eradication of tuberculosis is the only method to prevent TB, which requires the development of a more effective vaccine than BCG(1).

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