Initial experience in trans-radial percuteneous coronary intervention

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ABSTRACT

Background: Transradial compared to classic transfemoral coronary intervention has been shown to have similar efficacy rates, while being more cost-effective and most importantly safer due to fewer access site complications. Furthermore, patient comfort is increased and outpatient treatment may be feasible..

Objectives: To start trans-radial intervention program and the initial learning curve for fellows and the catheterization -laboratory nursing staff. To test how could it be applicable and comfortable for our patients

Methods: This prospective study was performed in Ibn-Albitar hospital for cardiac surgery over a period of 6 months from the 1st of August 2012 till the 1st of February 2013. Every patient referred for percutenuos coronary intervention whether on scheduled or on an emergency basis was considered initially for trans-radial approach for intervention unless they are excluded. Allen test was required ensuring adequate ullnar collateral supply. Sledinger technique was used for radial artery puncture and a special radial sheath was introduced. Intervention was performed through the same catheter and equipments that are used for femoral approach.. medication given according to center protocol, the relevant data collected and patients immediately ambulated unless they receive sedation.

Results: A total of 126 patients were referred for intervention during the study period, 20 cases were excluded for various reasons , 6caese were crossed over to femoral approach and the other 100 cases the procedure completed transradially. The mean age of the patients was 57 ± 8 years. Of these 72% were males ,with different risk factors . Most cases presented with chronic stable angiana (87%). Access site was right radial artery in 87% of patients while left radial approach used in 13% of patients. In 72% of cases single guiding catheter was used, in 21% of cases 2 guiding catheter were used and more than 2 types of guiding catheter were used in 7% of cases. In most session of intervention single artery was treated (78%) , 2 vessel intervention in 21%, 3 vessel in one case..Lesions treated were different types 26%,36%,38% A,B and C respectively. The success in obtaining radial access was 97.7% ,while angiographic procedural success rate was 96%. Mean total procedure time was (43+/-23min), mean fluoroscopy time (13+/-8 min)and the average amount of contrast used was (178+/-80ml). with no major complication apart from 3% small heamatom and 6% radial loss. Around 80% of patients preferred TRI approach.

Conclusion: Radial artery approach for percutenuos coronary interventions has high procedural success rate and associated with low risk of access site complications and no significant increase of procedural and fluoroscopy time. It is comfortable approach for most patients especially female and obese. Early ambulation with no risk of bleeding and reduction of the duration of hospital stay are in favor of TRI approach.

Key words: Tran-radial,Transfemoral , Percuteneous coronary intervention

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Percutaneous coronary intervention (PCI) is an integral part of treatment for ischemic heart disease. Coupled with evidence-based pharmacological strategies, the use of PCI in appropriate patients reduces morbidity and mortality across the spectrum of risk . Continual evolution of antithrombotic therapy and device technology has resulted in the application of PCI to a wider population of patients . Procedural success rates are high and ischemic complications relatively rare ; thus, attention has turned to periprocedural bleeding complications. Considerable evidence suggests that post-PCI bleeding is associated with an adverse prognosis . Clinical trials evaluating new pharmacological strategies have focused on reducing this risk ; however, absolute reductions in bleeding risk have been modest across most studies. A growing body of evidence suggests that a procedural strategy using the transradial rather than the transfemoral approach for PCI is associated with comparatively larger reductions in bleeding complications than those achieved with any anticoagulant strategy.

Although the transfemoral approach to cardiac catheterization has dominated the explosive growth of invasive cardiology in past decades, transradial access appeared early in the development of cardiac catheterization techniques.

In 1948, Radner published one of the first descriptions of transradial central arterial catheterization and attempts at coronary artery imaging using radial artery cut-down and 8-to10-F catheters. Despite early enthusiasm for the transradial approach, limitations of contemporary equipment resulted in a shift to larger vessels such as the brachial ,carotid, and femoral systems for most catheter-based procedures, and the radial artery was relegated to use as a site for monitoring arterial pressure.

In the late 1970s, percutaneous coronary angioplasty was introduced using predominantly 9-F guiding catheters(4). Building on reports of successful transradial angiography from Canada in 1989 , Kiemeneij and Laarman first reported on the transradial approach for coronary stenting in 1993. Given observed reductions in periprocedural bleeding and reported improvements in patient comfort with this approach, a few enthusiastic early adopters emerged, but the transradial approach generally remained a niche technique.

As experience with the transradial approach grew, the lack of severe access-site complications when compared with the transfemoral approach was repeatedly demonstrated in small observational studies. A "learning curve" for developing proficiency in transradial procedures was noted ,cost-effectiveness was demonstrated , and small single-center or limited multicenter randomized comparisons to femoral (with or without vascular closure devices) and brachial approaches showed the superiority of transradial procedures with respect to vascular access site complications, speed of post-procedural recovery, and patient preference. The safety of transradial PCI in patients therapeutically anticoagulated with warfarin and the potential for same-day coronary revascularization were described . In addition, transradial techniques have been expanded to peripheral arterial interventions, including carotid superficial femoral , mesenteric and renal arteries, as well as for pediatric percutaneous procedures [1].

The radial artery was previously viewed as a site for placement of monitoring lines in the coronary care unit, rather than an access route for cardiac catheterization.

The transradial approach is particularly advantageous for patients with peripheral vascular disease or morbid obesity. Access site bleeding complications are exceedingly rare, and hospital length of stay is significantly shortened, offering better outcomes at lower cost [5,6]. Transradial access is preferred by most patients because of reduced periprocedural discomfort, faster time to ambulation, and improved postprocedural quality of life. In comparison with femoral and brachial artery approaches, transradial access has a number of advantages. The radial artery is superficial, is easily compressible, and there are no major nerves or veins in its vicinity, reducing the risk of neuropathies or arteriovenous fistulae. Significant atherosclerosis of the radial artery is rare [7].

Limitations of transradial access include significant operator learning curve and smaller artery size, sometimes restricting interventional device options. The availability of hydrophilically coated sheaths and large-bore 6F and 7F guiding catheters, however, provides virtually complete device flexibility for complex procedures involving, for example, bifurcation treatment, vascular brachytherapy, rotational atherectomy, embolic protection, or rheolytic thrombectomy[8,9,10]. Because postprocedural occlusion of the radial artery occurs in 3% to 9% of transradial procedures , assessment of palmar arch patency must be addressed prior to the procedure. Most operators use the Allen test. This test measures the amount of time to achieve maximal palmar blush after compression release of the ulnar artery with continuing occlusive pressure of the radial artery. Patients with hand blushing in 8 seconds or less are candidates for TRA[11,12].

To maximize blushing, the hand is forcefully closed in a fist before arterial compression and opened before release of the ulnar artery compression. This test is subjective at best and should be performed by a physician as shown in figure 1.

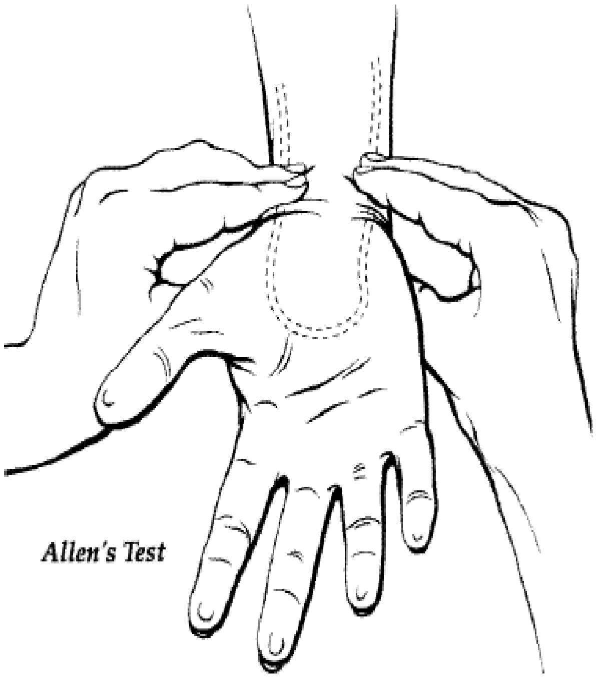


Figure 1: Allen test technique.

Most physician now use the modified Allen test. This approach simply places a pulse oximeter probe on the thumb while compressing the radial and ulnar arteries. The presence of an arterial waveform (even if with reduced amplitude or delayed appearance) and hemoglobin saturation >90% confirms the adequacy of palmar arch blood flow[13].

Although more challenging than routine transfemoral access, success rates for achieving transradial access are typically above 95% [14].

The right arm is preferred owing to several considerations. First, cardiothoracic surgeons prefer to harvest the left radial artery as a conduit for CABG, and conduit arteries should be avoided because routine catheterization is associated with intimal thickening by intravascular ultrasound [15]. Second, access via the left arm requires marked adduction of the arm to retain routine room setup and allow positioning of the operator and cath lab team to the right of the patient. Additionally, the following special considerations may dictate arm selection: (1) The arm with an arteriovenous fistula for hemodialysis should not be used for transradial catheterization; (2) Selective angiography of the left internal mammary artery is most easily accomplished via the left radial artery; and (3) An arm with an abnormal modified Allen's test result should be avoided .

Inability to access the radial artery is the most common cause of failure for the transradial catheterization procedure. Although experienced operators often cannulate the radial artery with the arm in an adducted position, it is recommended that operators in the learning phase place the arm in an abducted position with hyperextension of the wrist. After successful cannulation, the arm is adducted to the patient's side to permit operator positioning and laboratory setup similar to the femoral approach[16] as shown in figure 2.

Figure 2: Position of the hand in TRI.

Specialized kits for percutaneous transradial cannulation are available from several vendors and typically include a micropuncture needle (21 gauge, 4-5 cm in length), a 0.018-inch guidewire, and a 5- or 6-F hydrophilic-coated sheath (23-25 cm in length) with a tapered tissue dilator. The radial artery tapers to a smaller caliber near the radial styloid, where it gives origin to the palmar carpal and superficial palmar branches.

The pulse is palpated at the intended puncture site to create a mental map for the course of the radial artery. The preferred radial artery cannulation site is approximately 1 to 2 cm proximal to the radial styloid. Access of the radial artery over the flexor retinaculum should be avoided. Local anesthesia with Xylocaine is used sparingly (skin infiltration only) to minimize radial artery manipulation and spasm.

The guidewire should be advanced with great care. Resistance to passage is associated with subintimal passage or radial artery tortuosity, and further advancement can lead to dissection or perforation. Once the guidewire is fully advanced, a small skin nick is made with a scalpel at the point of needle entry to accommodate sheath insertion. Great care is needed to avoid incision of the artery[17,18].

Once fully advanced, this guidewire allows for the placement of a short (15 cm) or long (23 cm), 5F or 6F hydrophilic sheath with a tapered introducer.Anticoagulation (typically 2,500 to 5,000 U heparin intravenously) is administered immediately after sheath insertion, and many operators also administer a cocktail of vasodilators (nitroglycerine 100 to 200µg, verapamil 1.25 to 2.5 mg) via the sheath to reduce radial artery spasm [19,20]. The use of hydrophilic sheaths, however, has resulted in a dramatic reduction in radial artery spasm that can in turn lead to significant discomfort during catheter manipulation or sheath removal

Coronary intervention via transradial access requires only minor modifications relative to the femoral approach, but guiding catheter selection and lack of support are frequent sources of frustration during the learning phase. Intervention with 5F and 6F guiding catheters requires periodic deep catheter engagement for stent deployment. In larger male patients, it may be possible to use 7F or 8F guiding catheters, a long (23-cm) sheath should be used in these cases, but they should be introduced gradually and delicately.

With the use of larger sheaths, the risk of radial artery occlusion increases. In an effort to maintain a smaller profile, several operators have described the use of the "sheathless" guide technique. Once radial access is achieved and a 0.035-inch wire is advanced into the ascending aorta, a 7-F guide can then be advanced over a 5-F, 125-cm diagnostic catheter (such as a multipurpose shape) that acts as a dilator. Once in the ascending aorta, the guide can be advanced over the inner dilator catheter and into the coronary artery. This technique allows for larger guide diameter with less radial trauma. For instance, a 7-F guide catheter has the same outer diameter as a 5-F sheath[21].

Left Coronary Intervention: Common catheter shapes, such as the Judkins, XB (Cordis Corporation, Bridgewater, NJ), and EBU (Medtronic, Inc., Minneapolis, MN), provide significantly more backup when used from a femoral approach. Despite this, the common femoral shapes are still the most widely used guide catheters, with XB/EBU and JL being most common for the left coronary. Downsizing slightly to the JL 3.5 has been shown to increase backup support. The Ikari guide (Terumo Interventional Systems), Barbeau (Cordis Corporation, Johnson and Johnson, USA), and Kimny (Boston Scientific Corp, USA), guides were specifically designed to provide improved backup support from the right radial approach.

Right Coronary Intervention: For the right coronary, the JR is again the most frequently used guide catheter, with the Amplatz right a distant second choice. Unfortunately, lack of backup support remains an issue, particularly with the JR catheter, which does not contact the contralateral aortic wall at all. Some operators favor "deep-seating" the guide, especially when using a smaller 5-F guide, but there is some risk of dissection with this technique. When additional backup support is needed, a smaller AL 0.75 is useful, and the technique used for engagement is similar to the approach from the femoral artery.

Bypass graft intervention: IMA interventions are generally performed using an IMA guide from the ipsilateral radial artery. If the lesion to be treated is in the distal IMA or in the native artery beyond the anastomosis , consideration should be given to using a 90-cm guide to ensure that the usable length of balloon and stent catheters will be sufficient to reach the lesion. Guide support for SVG intervention can be especially difficult due to the location of the grafts and the proximity to the innominate or left subclavian artery.

When approached from the right radial, a significant portion of the catheter's curve is located in the innominate artery and does not provide support along the wall of the aorta. For SVGs to left coronary artery vessels, a JR guide can be considered but often will not have a long enough tip to engage the graft and will not provide backup support from the contra lateral aortic wall. An AL guide from the left radial provides the best support, but a coaxial position can be difficult to achieve.

For SVG interventions to RCA branches, a JR 4 guide can be considered but has similar limitations as when used for left-sided grafts. The preference is to use a multipurpose guide, particularly for grafts with an inferior takeoff[22].

MANAGEMENT POSTPROCEDURE RADIAL ARTERIOTOMY

Since the artery is superficial, haemostasis is simple and easy to control. After removing the catheter over a 0.035", the sheath is gently pulled back. Forceful pulling back of the sheath may result in avulsion of the RA. Although a compressive bandage (simple gauze and elastic bandage) is an option used in developing countries, the insertion of a compression device (TR Band, Hemoband, Radistop, Easy radial, Radstat) is recommended. The "airbag"-based bracelet (TR-Band, Terumo) with progressive deflation is the most commonly used dedicated radial compression device. The amount of air inflated in the TR-band usually varies between 13 to 18 ml. To reduce Occlusions, compression time should ideally be limited to 3 hours with progressive release (figure 3).

Figure 7: The Sheath Is Withdrawn After Inflation of the TR Band

Figure 8: The TR Band Deployed and the Patient Ready to Ambulate

Complications associated with transradial access and available management options

Vagal Reactions

During sheath insertion, procedural hypotension requiring treatment with atropine occurs infrequently. Vagal reaction may be exacerbated by verapamil, often administered to counteract spasm. Although these reactions are usually mild and short-lived, it was recently encountered few patients who became profoundly bradycardic and hypertensive, requiring brief isotropic support before completion of the case.

Appropriate preprocedural sedation, analgesia, and adequate local infiltration anesthesia can aid in decreasing pain, anxiety, and associated vagal output.

Radial Artery Spasm : The radial artery is a muscular artery, richly supplied by alpha-1 adrenoceptors, Stimulation of these receptors by circulating catecholamines leads to vasoconstriction, thereby mediating radial artery spasm. In addition, the relatively small size of the radial artery in relation to the arterial sheath predisposes to spasm, increasing frictional forces and potentially injuring the endothelium. Spasm is a frequent complication of radial access; an angiographic study indicated that a majority of patients have severe and diffuse radial artery spasm during the procedure. However, most vasospasms are temporary and resolve spontaneously. Routinely used hydrophilic sheaths have been shown to aid in sheath insertion and withdrawal and reduce patient discomfort. Intra-arterial antispasmotics are administered immediately after sheath insertion. The use of nitrates may result in a 16% enlargement of the diameter of the radial artery. Intra-arterial verapamil is preferred because the duration of action is longer.

Reducing patient anxiety and discomfort, using smaller catheters, and restricting catheter maneuvers and exchanges can often avoid spasm encountered during the procedure. A sheath entrapped by arterial spasm should never be forcibly removed because traumatic avulsion of the radial artery may result. Repeat intra-arterial vasodilators, additional patient sedation and/or analgesia, and reinsertion of the introducer and guidewire may be necessary. In extreme and refractory cases, axillary nerve blocks or general anesthesia may be required for catheter removal .

Radial artery occlusion: It has been reported to occur in 3% to 10% of patients. Occlusion may be related to prolonged cannulation, small diameter of the radial artery, ratio of the radial artery diameter to the sheath outer diameter, and anticoagulation during arterial cannulation. The sheath should be removed immediately after the procedure, while patients are still under the effects of anticoagulation. Without heparin anticoagulation, the rate of radial occlusion after angiography is in excess of 70%; this incidence decreases to less than 7% with doses ≥ 5,000 units and is currently closer to 1%.

Bleeding, Iatrogenic Perforation: The incidence of severe bleeding complications is significantly lower than femoral and brachial approaches.. Usually it is result from overzealous advancement of a wire when resistance is encountered, it is more readily avoided than treated. Hydrophilic wires, while useful in overcoming tortuous segments or radial loops, increase the risk of perforation. Wires should never be advanced against resistance; gentle injection of dilute contrast through the end of the sheath or catheter often reveals the obstacle (eg, an anomalous artery, a loop, tortuosity, or spasm). In the event of an obstruction, necessary measures can then be taken, such as selection of a smaller catheter, utilizing the contralateral radial artery, or adopting a femoral approach. When extravasation is diagnosed after a procedure, treatment options include reversal of anticoagulation, compression, and close observation. Compression can be achieved manually by using an adhesive pressure dressing or a blood pressure cuff at the arm or forearm level. The patient must be closely monitored for hand ischemia or compartment syndrome. Such conservative management is usually all that is needed . Bertrand et al have classified forearm bleeding into a useful and practical spectrum; they categorize five possible grades, ranging from a local superficial hematoma (grade I) and extending to ischemic threat from compartment syndrome (grade V). Grades I and II are directly related to the puncture site and are best managed with analgesia, ice, and compression. Grades III and IV result from intramuscular bleeding, require more aggressive compression methods, and may portend compartment syndrome. Any symptoms or signs suggesting compartment syndrome should result in early surgical consultation for limb-saving fasciotomy .

Compartment Syndrome

The incidence of compartment syndrome after interventions via the transradial approach seems to be very low ; an incidence of 0.4% is suggested . Possible etiologies include unrecognized perforation at a distance from the puncture site, unsuccessful compression at the puncture site, or radial artery laceration induced at sheath insertion or removal because of severe spasm just distal to the distal end of the introducer sheath.

Pseudoaneurysm: This rare complication, encountered more frequently in the femoral location, presents with painful swelling at the wrist, forearm, or cubital fossa. Usually the result of inadvertent perforation of an anomalous radial artery, it may not be recognized for days to weeks after the procedure. Occasionally, it has been observed in the days after the procedure at the puncture site, especially in patients receiving prolonged systemic anticoagulation. Diagnosis is usually by ultrasound. If identified soon after the procedure, firm local pressure is indicated. Other measures, including thrombin injection, ultrasound-guided compression, and surgical correction have been described .

Sheath and Hemostasis Device-Related Complications

Sterile abscesses: rarely occur with the use of hydrophilic-coated sheaths. They usually appear within 2 to 3 weeks after the procedure and are associated with subcutaneous remnants of silicone. In rare cases, abscess drainage is required. Compression devices used for hemostasis should selectively deliver pressure without obstructing venous return. The major complication with these devices is arterial occlusion .

Chronic Pain: prolonged, aggressive hemostatic compression at the access site may lead to vascular and/or neurologic complications, including persistent pain. Rarely, chronic regional pain syndrome (reflex sympathetic dystrophy) may occur. Sympathetic blockade, analgesics, and physical therapy are potential management options. Fortunately, chronic pain is exceedingly rare [23].

EXPERTISE REQUIREMENTS

OPERATOR AND VOLUME CENTRE ACTIVITY

The radial approach is a demanding technique, requiring expertise in both the operator and his/her team. Inability to puncture or cannulate the radial artery, inability to select the coronary artery and insufficient support to perform PCI is minimized by experience. An operator's annual procedure volume of more than 80 transradial cases (including diagnostic and interventional procedures) correlates with a significant reduction in access failure, sheath insertion time and procedure time .

FEMORAL EXPERTISE

All radial-proficient teams should aim to maintain optimal proficiency in femoral procedures as well. Some low-risk patients for femoral access site complications and procedures requiring femoral access (IABP, radial access failure or if guiding catheters ≥8 Fr are required) should provide a volume of cases to maintain adequate training in femoral artery puncture.

MANAGEMENT OF THE LEARNING CURVE

To start with, it is suggested that one use 5 Fr sheaths and catheters for diagnostic procedures and then move to 5 or 6 Fr for easy angioplasties. After the first 50 cases, the feasibility of radial and femoral access procedures should equalize. At this stage, if no absolute contraindications exist, it is important to perform radial access in consecutive patients, at least for diagnostic procedures. Gradually, more complex procedures can be performed and, in selected patients, 7 Fr sheaths and catheters can be used. A stepwise approach to learning is proposed according to clinical characteristics, presentation and coronary stenosis characteristics. The highest level of competency is obtained when patients requiring complex clinical management can be managed with timely and technically proficient control of coronary interventions, irrespective of vascular access anatomy .

DAY-CASE ANGIOPLASTY

Stable patients with an optimal PCI result, optimal pharmacological treatment according to ESC guidelines and no cardiac or vascular complications during the procedure or up to 4-6 hours afterwards can be considered for outpatient treatment if performed at high-volume centres by experienced interventionalists. Close follow-up and immediate readmission should be possible for delayed complications.

ANATOMIC VARIATIONS AND VASCULATURE NAVIGATION VIA THE RADIAL APPROACH

Challenging anatomy must be avoided to minimize the risk of complications and shorten the duration of both the procedure and radiation exposure. For this reason, a systematic preliminary angiogram of the arteries of the forearm through the introducer inserted into the radial artery for two to three cm has been suggested by some authors.

Different classifications of anatomical variation have been proposed, however, three major anatomical variations, high radial artery bifurcation, loops, and tortuosities, generate most procedural failures. High radial artery take-off or bifurcation is frequent. With traditional, type 3 high radial take-off , a remnant radial or slender hypoplastic radial artery exists such that the radial artery diameter may be too small even for 4 Fr catheters as shown in figure 4.

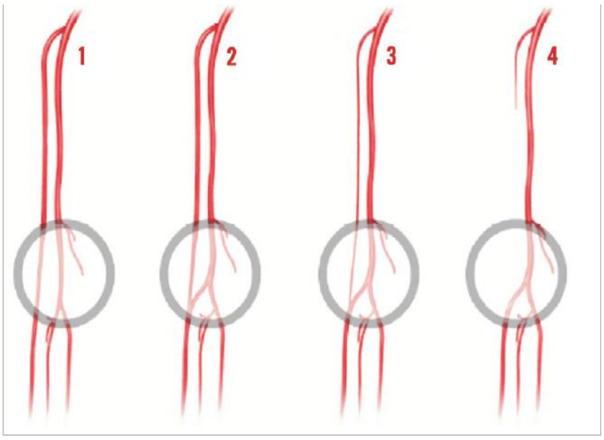


Figure 4: showing Anatomical variation of radial take off

An alternative approach is preferable in this extreme case, because progressing otherwise is painful and associated with spasm and an increased risk of perforation. Contralateral radial access is always a possibility to be considered in this setting, because forearm vasculature tends to be asymmetrical. Alternatively, conventional femoral access can be used. Angiographic assessment of the radio-ulnar anastomosis at the elbow is mandatory in these cases, because an angiographically-negotiable anastomosis between the radial and ulnar arteries often exists (figure 5); crossing this anastomosis allows the operator to reach the brachial artery directly .

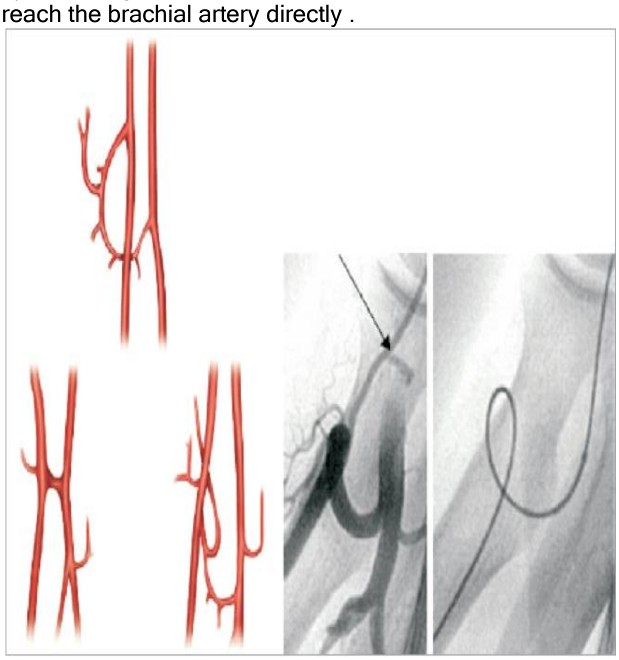


Figure 5: showing radioulnar arterial loop.

Resistance to wire progression can be caused by tortuosities at different levels: the radial artery, the brachial artery before the subclavian artery and the brachiocephalic trunk. These tortuosities are more common in older patients and in patients with a long history of hypertension, and plastic polymer-coated wires or PCI wires can be useful.

A special note of caution is appropriate, especially when the right transradial approach is used, due to the risk of stroke. Systematic fluoroscopy is required for crossing the subclavian artery and the brachiocephalic trunk to avoid penetration of the right carotid, vertebral arteries or a distal taking off mammary artery. During attempts to reach the ascending aorta, the patient should take and hold a deep breath, thereby facilitating the correct orientation and placement of the catheter in the ascending aorta.

Finally, a retro-oesophageal right subclavian artery (arteria lusoria, taking off at the distal part of horizontal aorta or directly connected to the descending aorta) is rare (0.25%) and, although technically negotiable for both diagnostic studies and PCI, it invariably requires unnecessary longer radiation exposures. Therefore a rapid diagnosis and conversion to an alternative arterial approach are strongly advised.

Operators should expect anatomical variations and have a plan to overcome them. In the vast majority of cases, caution advancing wires and catheters, angiographic assessment and using specific wires will yield a successful transradial intervention. In cases of high take-off of the radial artery associated with a remnant or slender radial artery, an alternative approach, like femoral or contralateral radial access, is preferable to avoid unnecessary prolongation of the procedure.

Chronic Total Occlusion (CTO) and radial approach

Treatment of chronic total occlusions requires a bilateral injection in all patients with good collaterals from a contralateral artery (50- 60% of cases). A transradial approach is appealing to reduce the bleeding risk consequent to the double arterial instrumentation with prolonged deep anticoagulation. However, many CTO-specific techniques and dedicated devices are difficult to use via 6 Fr catheters. An over-the-wire approach is mandatory in CTO recanalisation and 6 Fr catheters only accept thin OTW micro catheters such as the Fine cross which can be inserted together with a second Monorail balloon (anchoring, trapping technique) or a second microcatheter (parallel wire technique). If OTW balloons or the Corsair microcatheter are used they can only be used in isolation via a 6 Fr guide. Stability of the guide catheter and positional changes due to patient movements and breathing in procedures that may last hours are other potential concerns, together with the greater risk of radial artery occlusion maintaining 6 or 7 Fr sheaths *in situ* for hours. Still, innovative operators have developed approaches based on active intra-arterial engagement as well as simplified materials and techniques that are successful in many cases, with relatively simple CTOs.

Experienced CTO operators should be familiar with transradial recanalisation also using complex approaches including retrograde for patients with difficult or unusable femoral routes [24].

Aims of the study

1- To start trans-radial intervention program and the initial learning curve for fellows and the catheterization –laboratory nursing staff.

2- To test how could it be applicable and comfortable for our patients .

Patients and Methods This is a prospective study done in Ibn Al-baitar center for cardiac surgery over a period of 6 months from the 1st of August 2012 till the 1st of February 2013. This is a prospective study done in Ibn

Al-baitar center for cardiac surgery over a period of 6 months from the 1st of August 2012 till the 1st of February 2013. Allen test as mentioned in the introduction was required ensuring adequate ulnar collateral supply. All patients were prescribed 100 mg Aspirin and loaded with Clopidogrel over three days according to the cardiac center protocol .

Following successful radial puncture using Seldinger technique an 11cm special radial sheath(AVANTEE,CORDIS CORPORATION MEXICO,USA) inserted followed by flushing with 5 ml heparinized saline and 200 microgram of glycerine trinitrate. Intravenous heparin 70 unit/kg was routinely administered after engagement of the target artery. Guiding catheters were similar to those used in femoral approach with half French size reduction in the left coronary catheter in most cases .

A Successful transradial procedure was defined as gaining radial access, engaging coronary artery and treating the target lesion without the need for cross-over to femoral approach. Transradial approach was considered failed when one of the following criteria were met:

Clinical variables	Percent(%)
Age	57(40-84)
Gender	male (72%)-female(28%)
Hypertension	68%
Diabetes	43%
Smoking	44%
Hyperlipidemia	28%
Obesity	19%
Family history	25%
Clinical indication	
Stable angina	85%
Acute coronary syndrome	15%

Table1: Clinical characteristics of patients.

1-Failure to obtain radial arterial access.

2-Radial artery accessed, but the intended coronary artery was not engaged .

3-Inability to complete the procedure through the radial approach due to lack of support or the need for larger sheaths.

Angiographic success was defined as successful PCI produces sufficient enlargement of the lumen at the target site to improve coronary artery blood flow, A minimum stenosis diameter of<20% for stent and reduction of a minimum stenosis diameter to <50% with balloon angioplasty with final TIMI flow grade 3 (visually assessed by angiography) (25).

Procedure time was defined from sheath insertion to radial artery till the last angiographic picture ,while fluoroscopy time defined from start of fluoroscopic imaging until last angiographic frame.

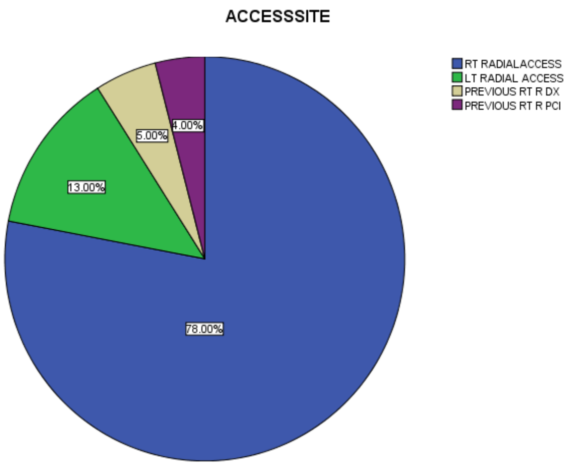
Throughout the procedure patients followed up closely clinically and by the hemodynamic data by specialist and trained nursing staff. Following successful PCI the arterial sheath was immediately removed and mechanical occlusive pressure device (TR-BAND TERUMO HATAGAYA, TOKYO,JAPAN) applied . Most patients were ambulated immediately after PCI provided no deep sedation was used and returned to the adjacent day-case word for observation then the TR- BAND was gradually removed (gradual deflation of 3 ml air every 15 minutes) with continuous monitoring of the puncture site for bleeding or hematoma until completely deflated, removed and replaced by conventional plaster dressing. Average time from TR -BAND applied till removal approximately 3 hours for most cases .

Results: During a study period of 6 months from August 1st 2012 to February 28th 2013 a total of 126 cases were referred for coronary intervention to the same team once weekly. Twenty cases were excluded (most of them during early time of the study due to initial experience) for different reasons as following: 6 cases were chronic total occlusions,4 cases with unstable hemodynamics, 3 cases with abnormal Allen test, 3 cases of SVG interventions and 4 cases of multivessel PCI.

Six cases were crossed-over to femoral approach 3 of them due to failure to gain radial access, one due to a radial loop that could not be straightened and one due to failure of engagement of the target artery and one due to total occlusion of right subclavian artery. This mounts to a success rate of 94.4% of the procedure by Transradial approach .the analysis involves these cases(100 cases).

A total of 100 patients were collected during the study period ,their age was 57 ± 8 years. Of these two third were male and with different risk factors as shown in table 1.The majority of patients were chronic stable angina.

Access site was right radial artery in 87% of patients ;5% of them had previous right radial diagnostic approach and 4% had previous right radial approach for percutenuos coronary intervention, while left radial approach used in 13% of patients as shown in figure 1.



RT- right, LT- left, RTR DX- trans right radial artery diagnosis, RTR PCI- trans right radial artery percutenuos intervention.
Figure 1: shows percent distribution of Right and Left radial access site.

In thirteen cases, the left radial artery was used most of them (8 cases) due to loss of radial pulse or the artery seemed to be weak from previous right diagnostic or interventional approach , three cases needed a good guiding support for PCI to either native RCA total occlusion or intervention on SVG to RCA and the other 2 due to inability to gain venous access in the Lt hand.

In 98% of cases we used 6F, 11cm length radial sheath and in only 2 cases we used 7F femoral sheath for TRI and those were male with large radial arteries .

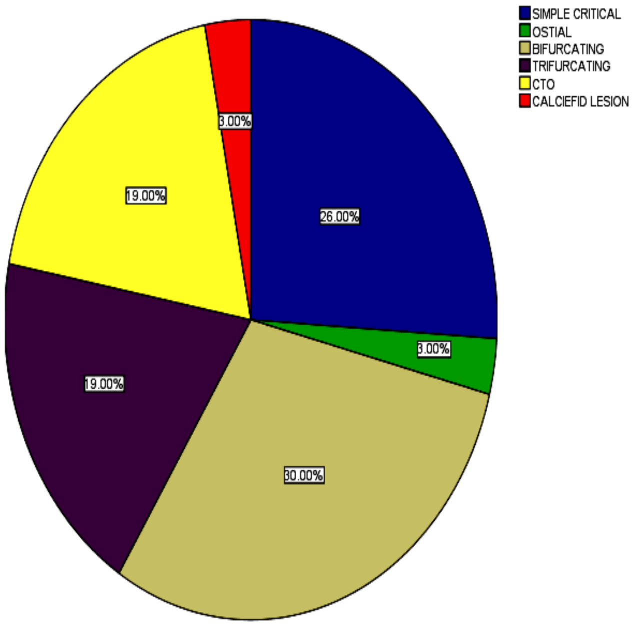
The most frequently used guiding catheter was JL 6/3.5 (66% of patients) this reflecting the dominancy of left coronary system intervention (table 3), JR 6 Fr was used in 20% of cases, other types of guiding catheter used less frequently(XB 6F ,AL 1, MP 6F , HOCKY STICK ,) ..

Table 2. Angiographic characteristics of vessels treated.

TARGET VESSELE	Number	PERCENTAGE%
LAD	65	52%
CX	18	14%
RCA	37	%30
DIAGONAL	4	3%
SVG	1	.8%
TOTAL	125	100%
NUMBER 0F GUIDING CHATHETER PER CASE		
SINGLE CATHETER	72	72%
TWO CHATHETER	21	21%
MORE THAN TWO	7	7%
NO OF VESSELES TREATED PER SESSION		
SINLE VESSELE	78	78%
TWO VESSELES	22	%22
MORE THAN TWO	1	1%
TOTAL	125	100%
LESION TYPES		
TYPE A	26	26%
TYPE B	36	36%
TYPE C	38	38%
NO OF STENTs PER CASE		
NO STENTS(failed)	4	4%
SINGLE STENT	42	42%
TWO STENTS	26	26%
MORE THAN TWO	28	28%
TOTAL	1OO%	100%

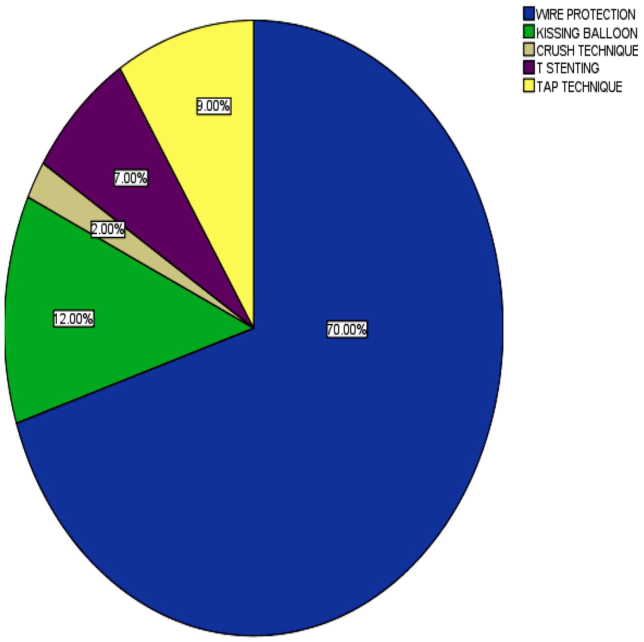
In most session of intervention single vessel was treated (78%).

Lesions treated were different types as shown in table 2,and these lesions were of different characteristics (figure 2)and Bifurcating lesions were treated in similar fashion to femoral approach using different techniques as shown in figure 3.



CTO-Chronic total occlusion

Figure 2: shows frequency distribution of lesion characters.



TAP –T and protrusion technique

Figure 3: shows frequency distribution of bifurcating techniques.

Total number of stents used was 194 stents , the average of total stent length per case was 40 mm (± 27 SD), the minimum length was 12 mm and the maximum was 96 mm .
FFR was done in 5% of patient and IVUS in 2% of patients .
The catheterization laboratory parameters recorded in this study are shown in table 3.

Table 3: Catheterization laboratory parameter.

Parameter	Minimum	Maximum	Average
Total procedure time	5 min	120 min	43± 23
Fluoroscopy time	2.5 min	41min	13± 8
Amount of contrast	40 ml	600 ml	178± 80

Regarding access site preference by patients, it is illustrated in figure 4; only 4 patients who had previous experience with femoral approach preferred it due to pain and spasm in the radial approach.

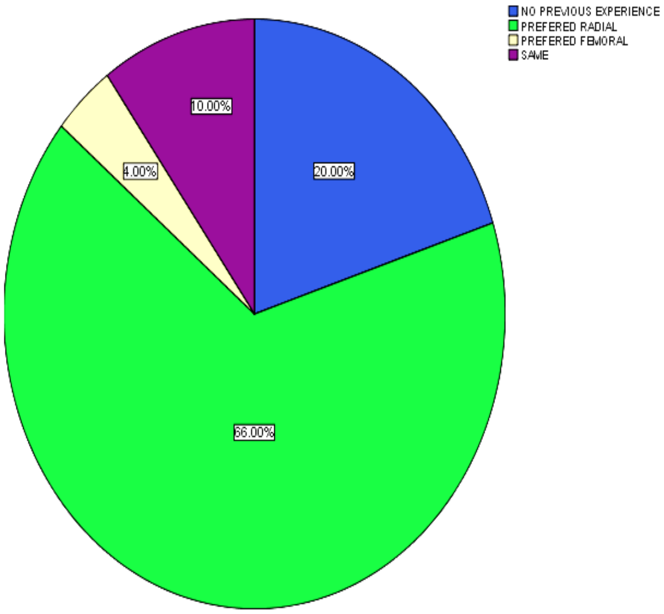


Figure 4: shows frequency distribution of patients' preference for TRI.

The average of local complications occurrence was 1.3 ± 1.7 SD and the percentage of these different types illustrated in figure 5, the three patients with hematomas were early in the study when the experience with TR - BAND deployment was limited.

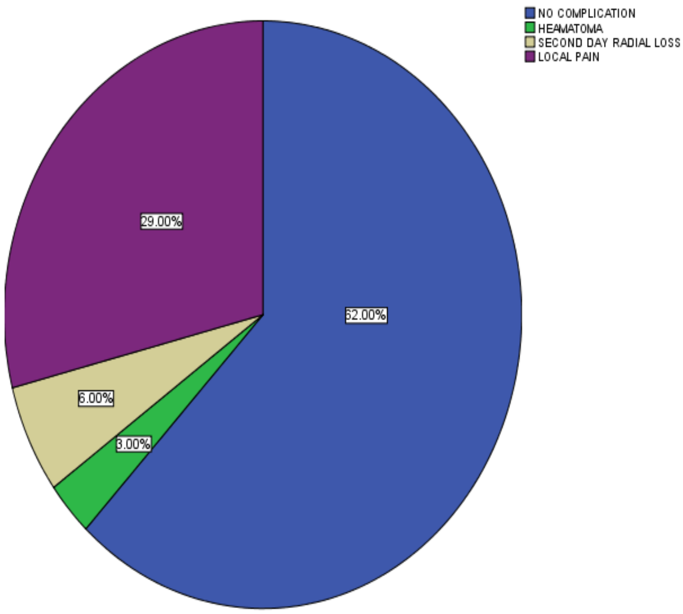


Figure 5: shows frequency distribution of local complication of TRI. The average hospital stay of patients was 24 hour.

Discussion

Transradial approach compared to classic transfemoral PCI has been shown to have similar efficacy rates, while being more cost-effective and most importantly safer due to fewer access site complications. Furthermore, patient comfort is increased and outpatient treatment may be feasible. However, the use of radial approach is heterogeneous worldwide.

This study represents a single center, single operator experience in trans radial coronary intervention . It showed a good success rate (97.2%) in obtaining vascular access (only three patients failed) comparable to José Carlos Brito (94%) [26]. .

There was small number of patients who crossed over to femoral access (6 patients) . During the initial period of the study several patients were excluded and with increasing experience similar patients were involved .The angiographic success rate was 96%.Those patients who failed were cases of chronic total occlusion where the operator did not believe that crossing to femoral approach would increase the chance of success .This success rate is similar to that reported in the literatures like Brueck et al who showed success rate of 97% [27].

Routinely, the right radial artery is used, which provides the same conditions of practical handling of the right brachial and femoral approach, in this study RRA access was dominant 87% vs 13% for LRA and it was accessible even in those with previous RRA approach whether diagnostic 5% or PCI 4% . The LRA approach used as default in 6% of cases and crossed over in the other 7% of patients .

The parameters of success in terms of mean total procedure time ,total fluoroscopy time and contrast volume are comparable and slightly less than other studies like STRIDE[28] study (43min, 13min, 178ml in our study versus 69 min, 16 min, 189 ml in STRIDE study respectively), Nevertheless, in comparison to the results of RIVAL trial[29] ,although we share approximately same median total procedure time (35 min) and total amount of contrast used (178 vs. 181 ml) , the median fluoroscopy time was slightly longer (11.7 vs 9.3 min) , as well as the ranges of these parameters was wider in our study. this difference in fluoroscopy time and wider ranges could be attributed to several factors. First it could truly reflects our initial experience with TRI approach, also we are a teaching center for interventional cardiology board students we go slowly for teaching purposes and for safety reasons , another factor that could explain this longer fluoroscopy time is the inclusion of stable angina patient with 23% underwent multivessel PCI, while the RIVAL trial was conducted for ACS patients where the intervention was intended for culprit lesion only.

Despite the recent manufacturing of specific material for the radial artery approach, we used traditional transfemoral guiding catheters, which again may contribute to our longer fluoroscopy time.

The characteristics and the frequency of material used in this study were similar to STRIDE study[28], 6 F and 7 F sheaths were used in a frequency of 98% and 2% respectively, and this entails that most of the coronary intervention techniques and different sizes hardware feasible through femoral approach could be used in radial approach.

Exchanging multiple guiding catheters across transfemoral approach approved to be feasible through radial approach, in this study the use of two or more catheters per case was 24% and this is comparable to that of RIVAL trial 20%, but the differences in sample size should be considered .

Like in RIVAL TRIAL and many other studies radial sheath were immediately removed and TR BAND applied in all cases.

The major advantages of using the radial approach is reduction in the incidence of local complications related to the access site, the incidence of access site complications in this study is consistent with that of RIVAL Trial and STRIDE study, in our study major bleeding , pseudo aneurysm, arterio-venous fistula, ischemic limb needing surgery and compartment syndrome were no seen and it is the same in the above mentioned studies ,but we have slightly higher incidence of hematomas which was 3% in our study while it was 1.2% and 2.4% in RIVAL TRIAL and SRIDE STUDY respectively, and actually reflect the initial experience with the use of TR-BAND by nursing staff.

These results again overlapped with the results of Kiemeneij et al. [30], which is a randomized study, compared the radial, femoral, and brachial approaches and observed a lower incidence in complications with the radial approach. Mann et al. [31], in a prospective study, compared the costs of coronary angioplasty performed through the radial and femoral approaches and observed a significant reduction in complications related to the vascular approach with significant cost reduction , in this study cost was not calculated but it is presumed to be less than transfemoral approach since most patients were discharged on the second day .

The increasing use of the GP IIb/ IIIa inhibitors in primary angioplasty or associated with a thrombolytic agent makes the radial approach attractive due to greater risks of hemorrhagic complications in these patients. In our study no complications related to the vascular access occurred in the patients with acute coronary syndrome despite the use of GP IIb/IIIa inhibitors in some patients.

Treating complex lesions appeared to be successful in many studies, for instance, Brito et al[26] were able to treat 80% complex lesion (type B and C) with success rate of 94%. This is in line with our study where we treated 70% out of 74% of complex lesions with success rate of 96%.

The major complications of this technique are the asymptomatic loss of the radial pulse (6%) of patients, even though patency of the radial
artery was assessed only by the palpation method, unlike a few studies that used ultrasound and this consistent with most radial trials which estimate the loss of radial pulse in the range of 4-10%. The use of 6F introducers and their withdrawal immediately after the procedure may have positively influenced the low rate of loss of the radial pulse observed in our and other studies .

Early hospital discharge with cost reduction is one of the major advantages of the radial approach. Other advantages are the reduction in nursing time and intensity with the access sites, in addition to the patient's sensation of comfort with early ambulation, in this study all of patients immediately ambulated.

In this study most of patients with previous femoral approach experience preferred the radial approach (66%) and even those without previous experience felt comfortable with radial approach .

Most of patient discharged on the second day of TRI provided no complication encountered.

The limitation of our study was the absence of a comparative femoral group.

Conclusion

Radial artery approach for percutenuos coronary interventions has high procedural success rate and associated with low risk of access site complications and no significant increase of procedural and fluoroscopy time. It is comfortable approach for most patients especially female and obese. Early ambulation with no risk of bleeding and reduction of the duration of hospital stay are in favor of TRI approach.

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