Comparison of the Renal Function Using Two Different Approaches for Primary Percutaneous Coronary Intervention: A Retrospective Cohort Study

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ABSTRACT

Background: Contrast-induced nephropathy (CIN) continues to be one of the most common major adverse side effects of cardiac catheterization, and is associated with short- and long-term morbidity and mortality. Since the trans-radial approach to coronary angiography was first reported in 1989, trans-radial access has been used for primary percutaneous coronary intervention (PCI) for approximately 20 years. There is a growing perception that, within the setting of intra-arterial procedures, there is a different risk factor for renal involvement when using radial or femoral access, with femoral access leading to the greatest risk because of its proximity to the high flow bed of the renal arteries. This study aimed to compare the degree of renal dysfunction by different indices in trans-radial and trans-femoral primary PCI.

Materials and Methods: This study had been conducted in the cardiology department; the National Heart Institute during the period from September 2018 to February 2020. The study included 90 patients admitted to the hospital with acute myocardial infarction and underwent primary PCI either through a femoral or radial approach with the Cystatin C and serum creatinine measured before and 72 hours of primary PCI.

Results: A statistical difference between both groups regarding CIN, with p-value=0.044 was found. There was no statistical difference between both groups after PCI regarding serum creatinine and cystatin C with p-value: 0.723 and 0.439, respectively. Concerning serum urea, there was statistical difference between both groups after PCI in the direction to be more in the radial group: it was 28.46 ± 13.89 mg/dl in femoral group and 30.06 ± 7.99 mg/dl in radial group (p=0.003). However, time to vascular access was easier with femoral group than with radial group with p-value < 0.001. Regarding complications, there were no statistical difference between two groups except for hematoma (p-value=0.026).

Conclusion: The study showed significant results according to developing CIN between the two groups which is more in femoral approach. The study showed that serum cystatin C did not add value to diagnosis of CIN.

Keywords
Primary PCI, Renal dysfunction, Cystatin C, Serum creatinine, Radial approach, Femoral approach, CIN, Dialysis.

Introduction
Traditionally; Contrast-induced nephropathy "CIN" is defined as either a greater than 25% increase of serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dl within 48-72 hours of intravenous contrast administration [1].

CIN is normally a transient process, with renal functions reverting to normal within 7-14 days of contrast administration. Less than one-third of patients develop some degree of residual renal impairment [2].
CIN continues to be one of the most common major adverse side effects of cardiac catheterization, and is associated with short- and long-term morbidity and mortality [3].

This is particularly true in the population presenting with acute ST-elevation myocardial infarction (STEMI) which was significantly higher compared with patients undergoing non-emergent catheterization [4].

Since the trans-radial approach to coronary angiography was first reported in 1989, trans-radial access has been used for primary percutaneous coronary intervention (PCI) for approximately 20 years. Many studies have confirmed the advantages of the trans-radial approach over the traditional trans-femoral approach including decreased incidence of access site complications, earlier ambulation, and improved patient comfort [5].

There is a growing perception that, within the setting of intra-arterial procedures, there is a different risk factor for renal involvement when using radial or femoral access, with femoral access leading to the greatest risk because of its proximity to the high flow bed of the renal arteries [6].

Serum levels of cystatin C are a more precise test of kidney function (as represented by the glomerular filtration rate, GFR) than serum creatinine levels [7]. This study aimed to compare the degree of renal dysfunction by different indices in trans-radial PCI and trans-femoral PCI.

Materials and Methods

Ninety patients presented to the National heart institute with acute coronary syndrome (ST-segment elevation myocardial infarction) planned for primary percutaneous coronary intervention. The patients received the standard anticoagulation and antiplatelet therapy in the form of heparin/enoxaparin, aspirin, and clopidogrel.

The route of access (whether radial or femoral) was at the discretion of the operator. We divided the patients into two groups:

Femoral group: patients underwent primary PCI through femoral approach (45 patients).
Radial group: patients underwent primary PCI through radial approach (45 patients).

Inclusion Criteria

I- Patients with good pulsating radial artery and adequate collateral connection as demonstrated by Allen’s test and pulse oximetry were included in our study.

- Allen’s test: The palm is rendered ischemic by clenching and opening the hand during compression of the radial and ulnar arteries; the test is positive (normal) if the palm coloration returns to normal within 10 seconds of the release of compression of the ulnar artery while radial artery compression is maintained. Pulse oximetry: A pulse oximeter was placed on the ipsilateral thumb and the morphology of the plethysmography tracing is noted. The examiner then occluded the radial artery, and any change in the tracing was noted. The examiner also noted whether the pulse oximeter still gave a constant reading (positive oximetry) or whether it couldn’t find a reading (negative oximetry). The response to this maneuver was categorized into 1 of 4 types. Patients with type A and type B responses had uninterrupted arterial filling during radial occlusion. The delayed appearance of a pulsatile tracing in patients with a type C and type D response (1.5% of patients) did not have good pulsatile collateral flow and are excluded from trans-radial catheterization [8].

2- Acute myocardial infarction was diagnosed in patients according to ESC/ACC (universal) definition of myocardial infarction: [9] Any of the following criteria satisfy diagnosis of an acute, evolving, or recent myocardial infarction: Typical rise and gradual fall (troponin) or rapid rise and fall (creatine Kinase MB) of biochemical markers of myocardial necrosis with at least one of the following:

A. Ischemic symptoms. Typical persistent myocardial ischemic pain, for at least 30 minutes.
B. Development of pathological Q waves on ECG.
C. ECG changes indicative of myocardial ischemia.
D. Coronary artery intervention (e.g., Coronary angiography in doubtful myocardial infarction).

Exclusion Criteria

I- Vascular status:
A. Absence of pulse in both femoral and radial arteries.
B. Abnormal Allen’s test results (for trans-radial approach).
C. Patients with cardiogenic shock.
D. The delayed appearance of a pulsatile tracing with pulse oximetry in patients with a type C and type D response.

II- Procedural characteristics: Use of 6 French incompatible devices.

III- Patients on regular dialysis

Each patient was subjected to the following
Full history and clinical examination

Electrocardiography: A 12-lead surface ECG was done for each patient on admission, repeated after receiving nitroglycerin. After PCI, another 12-lead ECG was done. ECG was recorded at a paper speed of 25 mm/s and amplification of 10 mm/mV.

All patients were given 600 mg clopidogrel, 300 mg aspirin, UFH/LMWH (low-dose unfractionated heparin, 50 U/kg (regardless of the use of glycoprotein IIb/IIIa inhibitors), while the standard dose of unfractionated heparin is 85 U/kg (60 U/kg with Gp IIb/IIIa inhibitors) [10] during the procedure and continued during hospital stay unless contraindicated, IIb/IIIa glycoprotein receptor blocker (Tirofiban) unless contraindicated, in addition to the conventional anti-ischemic and anti-anginal treatment as nitrates.

Laboratory investigations: the following investigations were done on admission: Serum creatinine, cystatin C, electrolytes, complete blood count, random blood sugar, creatine phosphokinase...
For left coronary artery:
The contrast penetrates around the site of complete occlusion, with the absence of contrast was a 135cm long catheter with a 0.040” diameter internal lumen French distal 35 cm monorail section and 4.6 Fr proximal section, the Export Aspiration Catheter (EAC). The EAC, with a 5.4 × 3.5 Wire Plus temporary occlusion wire with an inflation system and the Guard Wire Plus system consisted of two elements: the Guard Aspiration Catheter

For right coronary artery:
The distal monorail section could accommodate any commercial 0.014” coronary angioplasty guidewire. The catheter could be inserted through any 7 Fr coronary guiding catheter over a 0.014” guidewire in a monorail fashion into coronary arteries with a luminal diameter larger than 2 mm. The catheter was connected to a syringe for manual aspiration, and the aspirated material could be retained for further examination [13]. Rapid change balloon catheters were used in combination with 0.0014 –in floppy wire in most cases. Stents were deployed using the standard technique.

**Coronary angiography:** was performed as soon as possible, upon arrival of the on-call team. We started, by catheterization of the artery of the non-infarct region, followed by the culprit one. PCI stenting of the culprit lesion was done.

**Femoral artery cannulation:** The percutaneous transluminal technique was used for all patients. After the appearance of pulsatile blood from the arterial needle, a 0.035- guidewire was advanced then followed by insertion of a 6 Fr arterial sheath.

**Radial artery cannulation:** The wrist was shaved and wiped with iodine. The groin was shaved and wiped with iodine in case of radial artery puncture failure. The arm was supported by an extension of the catheterization table and abducted (45°). The wrist was hyperextended by placing a supporting role under the dorsum of the hand. Local anesthesia in the form of 1-2ml of xylacine 2% was given before the puncture [11].

**Puncture:** The radial artery was punctured using 19-gauge arterial needles 1 cm proximal from the styloid process, at 45° from lateral to medial.

**Sheath insertion:** A 0.021-inch guidewire was introduced through the needle without using force. A small skin incision was made by a number 11 surgical blade with rounded to prevent damage to the radial artery. A 6 French sheath was inserted in the radial artery to prevent spasms and to reduce discomfort during catheters exchange.

**Local medication:** To reduce discomfort and to prevent spasms in the radial artery, the intra-arterial cocktail was administrated locally consisting of 5000 IU unfractionated heparin (in spite that it is not a spasmolytic drug, 200 microgram Nitroglycerine [12].

**Coronary artery cannulation:** 6 French guiding catheters were used. A guiding catheter was selected with an appropriate curve to provide backup support during angioplasty.

- **For left coronary artery:** Judkins left and Amplatz left.
- **For right coronary artery:** Judkins right, Williams, and Amplatz right.

**Aspiration Catheter**
The Guard Wire Plus system consisted of two elements: the Guard Wire Plus temporary occlusion wire with an inflation system and the Export Aspiration Catheter (EAC). The EAC, with a 5.4 × 3.5 French distal 35 cm monorail section and 4.6 Fr proximal section, was a 135cm long catheter with a 0.040” diameter internal lumen that allowed for aspiration and removal of particulate debris. The distal monorail section could accommodate any commercial 0.014” coronary angioplasty guidewire. The catheter could be inserted through any 7 Fr coronary guiding catheter over a 0.014” guidewire in a monorail fashion into coronary arteries with a luminal diameter larger than 2 mm. The catheter was connected to a syringe for manual aspiration, and the aspirated material could be retained for further examination [13]. Rapid change balloon catheters were used in combination with 0.0014 –in floppy wire in most cases. Stents were deployed using the standard technique.

**Sheath Removal**
In the case of radial access, the sheath was removed immediately after the procedure. Some back bleeding was allowed to prevent distal embolization. Hemostasis of the radial puncture site was obtained by placing a rolled pile of gauze over the puncture site immediately after sheath removal. Two elastic straps were applied crosswise over the gauze. One tourniquet was applied over this pressure bandage. For the first 2 hours, the pressure of the tourniquet was gradually decreased. A careful follow-up to the hand and forearm was done to detect any local complications. Patients were advised to restrict movement of the wrist joint. After the femoral approach, patients had bed rest for 10 hours, the sheath was removed after APTT returned to normal value.

**Angiographic Analysis**
The procedure was considered successful with adequate struts expansion, less than 30 % residual stenosis, absence of edge dissection, and absence of in-stent thrombosis.

**Coronary Flow Assessment**
Coronary flow was graded according to the TIMI study criteria as by Gibson et al. [14].

- **TIMI grade 0:** complete occlusion, with the absence of contrast flow distal to the infract-related occlusion site.
- **TIMI grade 1:** The contrast penetrates around the site of obstruction but minimal distal antegrade perfusion is present.
- **TIMI grade 2:** Reduced rate of entry and clearance of the contrast into and from the distal coronary artery bed.
- **TIMI grade 3:** Normal entry and clearance rates of contrast to and from the distal coronary artery bed.

No reflow was diagnosed when there is a reduction of 1 or more in the TIMI grade or patients with TIMI 3 flow and low TIMI myocardial perfusion grade (0-1).

**Echocardiography and Doppler Imaging**
All patients underwent a conventional transthoracic two-dimensional and Doppler echocardiographic examination. The patients were examined in the supine or left lateral positions. This was done to obtain the left ventricular ejection fraction by 2-D Simpson’s method, diastolic function, valvular affection, and presence of wall motion abnormalities [15].

All through the previous procedures, the patients were subjected to close follow-up, and vital signs monitoring. Major adverse cardiac
and cerebral events (MACE) defined as re-infarction, death; target vessel revascularization, coronary artery bypass grafting will be monitored, in addition to cerebral hemorrhage, stroke, and severe bleeding necessitating blood transfusion.

The Efficacy endpoints were assessed as follows:
A. **Clinically:** time to resolving of chest pain, absence of signs of heart failure, or re-infarction.
B. **ECG:** resolution of the ST segment elevation 90 minutes after the PCI (≥ 70% = complete, 30-69% = partial, < 30% = none) [16].
C. **Angiography:** restoration of TIMI III flow, myocardial blushing, and absence of residual stenosis in the infarct-related artery.
D. **Echocardiography:** good global LV systolic function, good global and regional LV functions in the area supplied by the infarct-related artery. Good SWMA score in the area of the culprit artery [15].

The safety endpoints were assessed through the occurrence of puncture site complications as follows:
A. **Pseudo-aneurysm:** defined by a pulsating hematoma from disruption of a portion of the arterial wall. It was assessed and diagnosed by a Duplex study on the affected limb [17].
B. **Arterio-venous fistula:** resulting from accidental puncture of adjacent vein during arterial puncture with hematoma formation between the two holes. It may also result in association with venous catheterization and was assessed by stethoscope and Duplex study.
C. **Arterial dissection:** defined by the presence of arteriography evident intimal damage producing either an intraluminal filling defect or extravasation of contrast material [18].
D. **Subcutaneous hematoma:** It is the collection of blood within the soft tissue that causes a tender baseball size mass.
E. **Major hemorrhage:** defined as: uncontrolled bleeding, bleeding requiring transfusion, an expanding hematoma whose size threatened the viability of the overlying tissues.

**Statistical Analysis**
All data were collected, tabulated, and statistically analyzed using SPSS 20.0 for windows (SPSS Inc., Chicago, IL, USA). Quantitative data were expressed as the mean ± SD & median (range), and qualitative data were expressed as numbers and percentages. Continuous data were checked for normality by using the Shapiro Walk test. Independent Student t-test was used to compare two groups of normally distributed data. Mann-Whitney U test was used to compare two groups of non-normally distributed data. Wilcoxon signed ranks test was used to compare two dependent groups of non-normally distributed data. Categorical variables were compared using the Chi-squared test or Fisher's exact test when appropriate. Spearman's coefficient was calculated to assess the relationship between study parameters, (+) sign indicate direct correlation & (-) sign indicate inverse correlation, also values near to 1 indicate strong correlation & values near 0 indicate weak correlation. Receiver operating characteristic (ROC) curve analysis was used to identify optimal cut-off values of serum Cystatin C with maximum sensitivity and specificity for the prediction of CIN. Area under Curve (AUROC) was also calculated, criteria to qualify for AUC were as follows: 0.90 – 1 = excellent, 0.80-0.90 = good, 0.70-0.80 = fair; 0.60-0.70 = poor; and 0.50-0.6 = fail. The optimal cutoff point was established at the point of maximum accuracy. All tests were two-sided. p < 0.05 was considered statistically significant.

**Results**
There was no statistically significant difference regarding the demographic data i.e. sex, age and weight in our study between both groups (p=0.153, 0.277, 0.422 respectively) (Table 1).

There was no statistically difference between both groups regarding systolic blood pressure, diastolic blood pressure, smoking, hypertension or dyslipidemia (p=0.662, 0.844, 0.833, 0.673, 0.239 respectively) while there was statistically significant difference between both groups regarding diabetes mellitus and history of premature CAD in the radial group (p=0.011, 0.048 respectively) (Table 1).

There was statistically significant difference between both groups regarding Time to vascular access as the operator consumed 1.15 ± 0.42 minutes to get the vascular access in femoral group and 3.15 ± 1.38 minutes in radial group (p-value < 0.001) as mentioned in table 2 while there was no statistical difference regarding contrast volume used and radiation exposure time. (p=0.376, 0.663 respectively) (Table 2).

**About renal markers before and after PCI (Table 3): with serum creatinine and cystatin C:** There was statistical difference between both groups before PCI (p=0.018, 0.022 respectively) but there was no statistical difference between both groups after PCI (p=0.723, 0.439 respectively) while with serum urea, there was statistical difference between both groups regarding before and after PCI. Before PCI; It was 23.95 ± 5.84 mg/dl in-femoral group and 28.90 ± 7.64 mg/dl in-radial group (p=0.001). After PCI it was 28.46 ± 13.89 mg/dl in femoral group and 30.06 ± 7.99 mg/dl in radial group (p=0.003).

There was statistical difference between both groups in contrast-induced nephropathy. In femoral group, we had 8 patients (17.8%) developed CIN while in radial group, we had only 2 patients (4.4 %) who developed CIN (p=0.044). On the other hand, there was no statistical difference between both groups regarding the need for dialysis (p=1.000) (Tables 4 & 5).

There was no statistically significant difference between both groups regarding MACE, heart failure, atrial fibrillation, ventricular fibrillation, and cardiogenic shock (p=0.748, 1.000, 1.000, 1.000 respectively) while there was statistical difference between both groups regarding local vascular access hematoma, in femoral group we had 7 patients (15.6%) with hematomas while in radial group there was only 1 patient (2.2 %) developed hematoma (p =0.026). Finally, we did not have mortality in our study patients (Table 6).
Table 1: Comparison between Both Groups Regarding Demographic, Clinical Data, And Risk Factors.

| Variable                           | Femoral group (N=45) | Radial group (N=45) | p-value  |
|------------------------------------|----------------------|---------------------|----------|
| **Demographic data**               |                      |                     |          |
| **Sex**                            |                      |                     |          |
| Male                               | 30 (66.7%)           | 36 (80%)            | 0.153    |
| Female                             | 15 (33.3%)           | 9 (20%)             |          |
| **Age (years)**                    | 54.31 ± 10.62        | 56.64 ± 9.56        | 0.277    |
| **Weight (kg)**                    | 76.44 ± 9.46         | 74.88 ± 7.98        | 0.422    |
| **Blood Pressure**                 |                      |                     |          |
| SBP (mmHg)                         | 123.11 ± 17.94       | 124.77 ± 17.64      | 0.662    |
| DBP (mmHg)                         | 76.44 ± 8.83         | 77.22 ± 10.63       | 0.844    |
| **Risk factors**                   |                      |                     |          |
| Smoking                            | 21 (46.7%)           | 22 (48.9%)          | 0.833    |
| Diabetes mellitus                  | 28 (62.2%)           | 16 (35.6%)          | 0.011    |
| Hypertension                       | 22 (48.9%)           | 20 (44.4%)          | 0.673    |
| Premature coronary artery disease  | 11 (24.4%)           | 4 (8.9%)            | 0.048    |
| Dyslipidemia                       | 15 (33.3%)           | 10 (22.2%)          | 0.239    |

SBP: systolic blood pressure, DBP: diastolic blood pressure

Table 2: Comparison between the Studied Groups Regarding Technical Data of PCI.

| PCI parameters                  | Femoral group (N=45) | Radial group (N=45) | p-value |
|---------------------------------|----------------------|---------------------|---------|
| **Time to vascular access (mins)** | 1.15 ± 0.42          | 3.15 ± 1.38         | <0.001  |
| **Contrast volume (ml)**        | 208.44 ± 96.29       | 220.44 ± 86.57      | 0.376   |
| **Radiation exposure time (min)**| 48.33 ± 11.28        | 50.33 ± 13.45       | 0.663   |

Table 3: Comparison of Renal Function Parameters between the Studied Groups before and After PCI.

| Variable                       | Femoral group (N=45) | Radial group (N=45) | p-value |
|--------------------------------|----------------------|---------------------|---------|
| Serum creatinine (mg/dl) Before PCI | 0.97 ± 0.17          | 1.18 ± 0.38         | 0.018   |
| After PCI                       | 1.31 ± 1.04          | 1.24 ± 0.76         | 0.723   |
| Serum Urea (mg/dl) Before PCI   | 28.90 ± 7.64         | 23.95 ± 5.84        | 0.001   |
| After PCI                       | 28.46 ± 13.89        | 30.06 ± 7.99        | 0.003   |
| Serum Cystatin C (mg/L) Before PCI | 0.90 ± 0.14          | 1.05 ± 0.28         | 0.022   |
| After PCI                       | 1.21 ± 0.62          | 1.27 ± 0.66         | 0.439   |

Table 4: Comparison between the studied groups regarding contrast-induced nephropathy (CIN).

| Variable | Femoral group (N=45) | Radial group (N=45) | p-value |
|----------|----------------------|---------------------|---------|
| CIN      | 8 (17.8%)            | 2 (4.4%)            | 0.044   |

CIN: contrast-induced nephropathy.

Table 5: Comparison between the subgroups of patients developing CIN regarding the need for dialysis.

| Variable    | Femoral group (N=8) | Radial group (N=2) | p-value |
|-------------|---------------------|--------------------|---------|
| Need for dialysis | 2 (25%)            | 1 (50%)            | 1.000   |

Table 6: Comparison between the studied groups regarding outcomes.

| Outcome               | Femoral group (N=45) | Radial group (N=45) | p-value |
|-----------------------|----------------------|---------------------|---------|
| MACE                  | 6 (13.3%)            | 5 (11.1%)           | 0.748   |
| Heart Failure         | 3 (6.7%)             | 2 (4.4%)            | 1.000   |
| Atrial fibrillation   | 2 (4.4%)             | 1 (2.2%)            | 1.000   |
| Ventricular tachycardia | 1 (2.2%)           | 1 (2.2%)            | 1.000   |
| Shock                 | 0 (0%)               | 1 (2.2%)            | 1.000   |
| Hematoma              | 7 (15.6%)            | 1 (2.2%)            | 0.026   |
| Death                 | 0 (0%)               | 0 (0%)              | 1.000   |
SBP: systolic blood pressure, DBP: diastolic blood pressure, r: Spearman's correlation coefficient, p< 0.05 is significant.

Table 7: Correlation between renal markers before PCI and study variables.

| Variables          | Serum creatinine (mg/dl) before PCI | Serum urea (mg/dl) before PCI | Serum Cystatin C (mg/L) before PCI |
|--------------------|-------------------------------------|-------------------------------|-----------------------------------|
| Age (years)        | r =0.075 p-value = 0.483            | r =0.146 p-value = 0.169      | r =0.060 p-value = 0.571          |
| Weight (kg)        | r =0.147 p-value = 0.168            | r =0.195 p-value = 0.066      | r =0.195 p-value = 0.065          |
| SBP (mmHg)         | r =0.121 p-value = 0.256            | r =0.112 p-value = 0.294      | r =0.138 p-value = 0.193          |
| DBP (mmHg)         | r =0.141 p-value = 0.184            | r =0.052 p-value = 0.625      | r =0.006 p-value = 0.953          |

SBP: systolic blood pressure, DBP: diastolic blood pressure, PCI: percutaneous coronary intervention, min: minutes, r: Spearman's correlation coefficient.

Table 8: Correlation between renal markers after PCI and study variables.

| Variables          | Serum creatinine (mg/dl) after PCI | Serum urea (mg/dl) after PCI | Serum Cystatin C (mg/L) before PCI |
|--------------------|-------------------------------------|-------------------------------|-----------------------------------|
| Age (years)        | r =+0.327 p-value = 0.002           | r =+0.235 p-value = 0.026    | r =+0.182 p-value = 0.086         |
| Weight (kg)        | r =+0.295 p-value = 0.005           | r =+0.203 p-value = 0.055    | r =-0.007 p-value = 0.948         |
| SBP (mmHg)         | r =+0.140 p-value = 0.189           | r =+0.156 p-value = 0.142    | r =+0.169 p-value = 0.110         |
| DBP (mmHg)         | r =+0.091 p-value = 0.392           | r =+0.108 p-value = 0.311    | r =+0.052 p-value = 0.625         |
| Chest pain to PCI time (min) | r =-0.010 p-value = 0.927     | r =+0.202 p-value = 0.056    | r =+0.067 p-value = 0.532         |
| Contrast volume (ml) | r =+0.252 p-value = 0.016       | r =+0.220 p-value = 0.037    | r =+0.158 p-value = 0.137         |
| Radiation time (min) | r =+0.199 p-value = 0.061      | r =+0.105 p-value = 0.326    | r =+0.007 p-value = 0.944         |

There was no significant correlation between renal markers before PCI and other studied variables (Table 7) while there was statistically significant positive correlation of both serum creatinine (r=0.327, p =0.002) and serum urea (r=0.235, P=0.026) with age of the study cases. Also, there was statistically significant positive correlation of both serum creatinine (r=0.252, p=0.016) and serum urea (r=0.220, P=0.037) with contrast volume used in the study cases (Table 8).

Discussion

Coronary angioplasty and stenting are performed via the trans-femoral approach in the majority of Egyptian centers. In primary PCI, the suspected complex intervention is higher than elective interventions, so, the need for complex intervention tools is higher and so, easier through the femoral approach. Our study included 90 patients; 45 patients underwent primary PCI via femoral approach and 45 patients via radial approach.

In this study, no patient was shifted from radial approach to femoral approach, but 2 patients were shifted from femoral to radial approach, the first patient was due to highly aortic tortuosity and the second was due to old stable abdominal aortic aneurysm.

According to the difference between the two approaches on developing CIN, our results were concordant with Vuurmans et al. where there is a growing perception that, within the setting of intra-arterial procedures, there is a different risk factor for renal involvement when using radial or femoral access, with femoral access leading to the greatest risk because of its proximity to the high flow bed of the renal arteries [6].

The trans-radial approach might minimize the risk of cholesterol embolization to the kidney. Also, there was a reduction in episodes of hypotension because of hemodynamically significant bleeding or vasovagal responses in association with femoral sheath removal with a resultant component of ischemic renal injury [19].

Complicated cases of myocardial infarction may direct the operator to the femoral approach, which is easier, more accessible, less time consuming. Hypotension and shock are important complications associated with MI in which renal perfusion decreases helping in increasing the incidence of renal impairment. Complex lesions and difficult interventions need much more time and dye which increased the incidence of renal impairment regarding demographic, clinical data, and risk factors, the results of this study were concordant with Pancholy et al. in their study on 283 consecutive patients who underwent primary PCI, 177 by trans-radial approach and 106 by transfemoral approach [20].

Diabetes Mellitus and premature coronary artery disease were statistically significant risk factors between the two groups and these were against the results of Pancholy et al. [20].

The time taken for puncture and sheath insertion was longer in the radial group compared with the femoral group and this was concordant with Philippe et al. in their study on 119 patients who underwent primary angioplasty with abciximab either through transfemoral or trans-radial [21], while radiation exposure time showed non-significant results which were not consistent with Georges et al. in their multicenter study who reported that radial access was associated with lower radiation doses to patient than femoral access in high-radial-volume centers and stated that provided that radioprotection methods are employed, radial access could be associated with lower patient radiation exposure [22].
There were non-significant results according to MACE between the two groups as only 6 patients in the femoral group developed MACE versus 5 patients in the radial group. There was no mortality in our study and our results are concordant with TEMPUA Trial, follow-up results of survivors in both groups (six months follow-up) and the composite MACE-free survival showed no statistically significant differences in both groups [5]. Also, results of Philippe et al. study showed that uncomplicated clinical course occurred in 62 (97%) of patients in the radial group and 49 (89%) of patients in the femoral group were free of MACE (P=0.04). These results were statistically non-significant [21].

Only one patient (2.2%) from the radial group suffered from a minor puncture site complication which was (minor bleeding-small hematoma). In comparison, four patients (15.6%) from the femoral group suffered from statistically significant hematomas. Mathias et al. in their study reported that trans-radial angioplasty in acute myocardial infarction may be an attractive option in thrombolytic therapy patients (facilitated PCI) or those who require aggressive antiagulation and antiplatelet therapy. They included fourteen patients with acute STEMI who underwent trans-radial coronary angioplasty and stenting. Thirteen patients received a glycoprotein IIb/IIa inhibitor. There were no procedural or access site complications [23].

The radial artery is also superficial, and it may be easily compressed achieving adequate hemostasis without active manual compression, but only with a passive pressure device or bandage, reducing the workload of nursing and medical staff. Conversely, transfemoral procedures are constantly burdened by several local complications that even closure devices cannot completely avoid, despite the technological improvement in these devices and increasing experience regarding their use.

This was evident in the series of patients reported by Louvard et al. and the results of a non-randomized comparison of trans-radial and trans-femoral approaches for primary PCI. The study included 1214 patients treated in two European centers; 22% (n=277) of patients were treated via the trans-radial approach while 78% (n=947) of patients were treated via the trans-femoral approach with the use of a vascular closure system in 889 patients and manual compression in the remaining 58 patients. Overall, local bleeding complications only occurred in patients treated via the trans-femoral approach, whether or not the per close system was used; transfusion or surgery was required in 12 patients from the 947 patients of the femoral group (1.3%). However, in patients who received a per close system only two patients from 889 (0.02%) patients required blood transfusions and none needed surgical intervention whereas the rate was 10 patients from 58 (17.2%) for patients treated by manual compression [24].

Our study showed the relation between the urea, creatinine, and cystatin C among the two groups before the primary PCI which was significant for the urea, creatinine, and cystatin C. This was not consistent with Liu et al. who found that baseline serum creatinine was non-significant [25]. This was in disagreement with Shacham et al. who found that the baseline serum creatinine was highly significant among the studied groups [26].

The study showed the relation between the urea and the creatinine among the three groups after the primary PCI was significant for the serum urea and highly significant for the serum creatinine and Cystatin C. This was in agreement with Shacham et al. who found that there was an increase in the serum creatinine and serum urea after primary PCI [27].

Serum cystatin C is one of the most sensitive renal markers regarding CIN but it did not add value to serum creatinine level in our study, these results were concordant to Roos, et al. who found that the traditional serum creatinine follow up is fair enough for a diagnosis of CIN [7].

This study recommends using the radial approach in primary PCI as an alternative to the femoral approach due to low incidence of acute kidney injury and developing contrast-induced nephropathy and low local vascular complications. Limitations of our study were that the results were obtained from a single center (National heart institute) and different operators with variable skills; it is a non-randomized controlled trial with different possibilities of biases.

In conclusion, this study showed significant results according to developing CIN between the two groups, which is more in femoral approach. The study showed that serum cystatin C have not benefit to the diagnosis of CIN.

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