Assessment of Vascular Complications of Repeated Transradial Access for Cardiac Catheterization

OSAMA A. AMIN, M.D.; HESHAM BOSHRA, M.D. and HUSSEIN M. HUSSEIN, M.D.
The Department of Cardiology, Faculty of Medicine, Beni-Suef University Hospital

Abstract

Background: Transradial catheterization has the potential to reduce procedural costs. Additionally, less staffing is needed to care for patients following transradial catheterization. Although repeated transradial procedures have undoubtedly been performed frequently at centers favoring this technique for arterial access, the utility of this approach has never been reported.

Objectives: The study was designed to evaluate vascular complications and success rate in repeated ipsilateral transradial access for cardiac catheterization in comparison to the initial transradial procedure done in Beni-Suef University Hospital Cardiology Department.

Methods: The study included: Group (A) including 138 patients who underwent diagnostic cardiac catheterization using initial transradial approach of the right arm. Then a subgroup of 90 patients (Group B) who had PCI by repeated ipsilateral transradial access. The ultrasonic examinations of the radial artery were performed on the same day before discharge after the initial and the repeated transradial procedure. The study was performed by an experienced cardiologist who had no knowledge of his group assignment or catheterization procedure. Follow-up assessment for vascular complications by ultrasonic examination was done within two weeks in patients with repeated ipsilateral transradial access.

Results: In this study there was no statistically significant difference between group (A) and group (B) in procedure success as procedure success rate in the initial procedure was (97.83%) compared to (93.33%) in the repeated procedure with p-value of (0.326). Crossover occurred in 3 patients in the initial procedure (2.17%) due to inability to introduce the wire in the radial artery while in the repeated transradial procedure crossover occurred in 6 patients (6.67%); 4 patients due to failure of radial artery cannulation, and 2 patients due to occurrence of radial artery spasm that wasn’t resolved by verapamil 10mg and nitroglycerin 100 µg inside the sheath.

Conclusion: The repeated use of the same radial artery is demonstrated to be safe and effective.

Key Words: Vascular complications – Repeated transradial approach.

Introduction

CARDIAC catheterization via the radial artery has increased drastically due to reduced vascular complications compared to access via the femoral or humeral route [1-4].

Up to 80% of all major bleeding events associated with PCI may be access-site related, and both major and minor bleeding with PCI are significant predictors of mortality and morbidity [3-8]. Patient groups who derive an increased benefit from transradial cardiac catheterization include elderly persons [6], those with acute coronary syndrome, and those receiving IIb/IIIa inhibitors [21].

In the RIVAL trial, 90% of patients who were randomized to undergo the transradial approach reported preference for the same approach if a repeat procedure was needed; as opposed to 49% in the transfemoral arm [8]. Other studies have reported improved quality of life measures with transradial versus transfemoral cardiac catheterization [2].

Transradial catheterization also has the potential to reduce procedural costs [9,10]; fewer complications equate to shorter hospital stays [2]. Additionally, less staffing is needed to care for patients following transradial catheterization. Furthermore, same-day discharge is feasible after coronary intervention, which shortens stays and significantly reduces costs [11,12].

Radial artery occlusion (RAO) is a complication of transradial catheterization that can lead to permanent occlusion of the radial artery. Estimated to occur in 1-10% of cases it has been described as the “Achilles’ heel” of the transradial technique. Once the artery is occluded, it cannot be used as an access site for future catheterization or as an arterial conduit for bypass surgery [13].
Although repeated transradial procedures have undoubtedly been performed frequently at centers favouring this technique for arterial access, the utility of this approach has never been reported. As the transradial approach to catheterization is often selected for patients likely to require multiple percutaneous diagnostic and therapeutic procedures throughout their lifetime, so establishing the safety and efficacy of repeated radial artery access for cardiac catheterization is important [14].

**Aim of the study:**

The study aimed at the assessment of vascular complications and success rate in repeated ipsilateral transradial access for cardiac catheterization in comparison to the initial transradial procedure.

**Material and Methods**

The study, from December 2011 through August 2014, included group (A) 138 patients who underwent diagnostic cardiac catheterization using initial transradial approach of the right arm in Beni-Suef University Hospital Cardiology Department. Then a subgroup (Group B) of 90 patients who underwent PCI by repeated ipsilateral transradial access.

**Inclusion criteria:**

Patients with good pulsating radial artery and adequate collateral connection with the ulnar artery as demonstrated by modified Allen’s test [1].

**Exclusion criteria:**

1- Patients who had evidence of an abnormal modified Allen’s test or abnormal reverse Allen test for patients selected to repeat radial artery access.
2- Patients with Buerger’s disease, severe Reynaud’s or other forms of upper extremity peripheral vascular disease.
3- Patients in whom the radial artery was considered as conduit for coronary artery bypass grafting.
4- Chronic renal failure patients with arteriovenous fistula.
5- Failed previous trial of transradial coronary angiography or angioplasty.

**Assessment and clinical examination:**

- Informed consent.
- For each patient, a detailed history for coronary artery disease, upper extremity vascular disease, and vascular risk factors.
- Complete clinical examination.
- Routine laboratory investigations.

- Modified Allen’s test was documented in every patient.
- The ultrasonic examination of the radial artery was performed on the same day, after the initial and the repeated transradial procedure. The study was performed by an experienced cardiologist who had no knowledge of his group assignment or catheterization procedure.
- Follow-up assessment for vascular complications by ultrasonic examination was done within two weeks in patients with repeated ipsilateral transradial access.

**Reverse allen’s test:** This was performed in patients who had a second procedure through the same radial site. Patients with abnormal reverse Allen’s test didn’t undergo the repeated procedure via the same site.

**Local anesthesia:** In our study was done using 1% Lidocaine injection at the site of puncture.

The radial artery was punctured with a 20 gauge open needle to obtain a pulsatile blood flow. The artery is cannulated with a 45cm 0.018 straight wire. A short (15 cm) 6 French sheath is then inserted.

A cocktail of 100 µg glyceryl trinitrate and verapamil 5-10mg was injected after sheath insertion followed by 5000 international units heparin inside the sheath for diagnostic angiography and 10,000 international units for angioplasty. The arterial access sheath was removed immediately after trans-radial procedure, and homeostasis was achieved by radial compression with tourniquet for 2 hours. The need to puncture a second access site due to any procedural failure was defined as a “crossover”.

The American College of Cardiology (ACC) database definitions for vascular complications were used to define the complications as minor or major. Minor vascular complications were defined as any of the following: Hematoma <10cm, arteriovenous fistulae, or pseudo aneurysm. Major vascular complications were defined as death caused by vascular complications, vascular repair, major vascular bleeding (>3g hemoglobin decrease because of access site or retroperitoneal bleeding or requiring administration of blood transfusions or vascular repair, alone or in combination), vessel occlusion, or loss of pulse [15,16].

In our study we defined local access site bleeding according to The Global Use of Strategies to Open Occluded Arteries (GUSTO) definition of bleeding [17].
Statistical analysis:

Data were analyzed using Statistical Program for Social Science (SPSS) version 18.0. Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

- Independent-samples t-test of significance was used when comparing two means.
- Chi-square ($X^2$) test of significance was used in order to compare proportions between two qualitative parameters.
- Probability ($p$-value): A $p$-value < 0.05 was considered significant.

Results

This prospective study included group (A) 138 patients who underwent diagnostic cardiac catheterization using initial transradial approach with the right arm. Then a subgroup (group B) of 90 patients who underwent PCI by repeated ipsilateral transradial access. The mean time interval was 45±20 days between the initial and the repeated procedure.

The mean age in group (A) was (58.87±8.38) years and in group (B) was (59.43±8.68) years. There was no statistically significant difference between group (A) and group (B) with regard to age with $p$-value of (0.52).

In the initial transradial approach (group A), there were 75 male (54.35%) and 63 female patients (45.65%). In the repeated transradial approach (group B) there were 54 male patients (60%), and 36 female patients (40%). There was no statistically significant difference between group (A) and group (B) with regard to gender with $p$-value of (0.627).

In this study there were 93 hypertensive patients in the initial approach (67.39%) to 60 patients with hypertension in the repeated approach (66.67%) with $p$-value of (0.948) with no statistically significant difference between group (A) and group (B).

There were 63 diabetic patients (45.65%) in group A versus 39 patients (43.33%) in group (B) with $p$-value of (0.842). With no statistically significant difference between group (A) and group (B) with regard to DM.

In the initial transradial approach there were 99 patients (71.74%) with dyslipidemia in comparison to 63 patients (70%) in repeated transradial group with $p$-value of (0.870). No statistically significant difference between group (A) and group (B) with regard to dyslipidemia.

57 smoker patients in group A (41.30%) to 36 patients (40%) in group B with $p$-value of (0.910) and no statistically significant difference between group (A) and group (B) with regard to smoking.

Procedure success (cross over):

In this study there was no statistically significant difference between group (A) and (B) in procedure success ;as procedure success rate in the initial procedure was (97.83%) compared to (93.33%) in the repeated procedure with $p$-value of (0.326). Table (1).

Table (1): Procedure success and failure in the studied groups.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Success</th>
<th>Failure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Group (A)</td>
<td>135</td>
<td>97.83%</td>
<td>84</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group (B)</td>
<td>84</td>
<td>93.33%</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>219</td>
<td>96.05%</td>
<td>9</td>
</tr>
</tbody>
</table>

Crossover occurred in 3 patients in the initial procedure (2.17%) due to inability to introduce the wire in looped segment in the radial artery, while in the repeated ipsilateral transradial procedure crossover occurred in 6 patients in (6.67%): 4 patients due to failure of radial artery cannulation and 2 patients due to occurrence of radial artery spasm that wasn’t resolved by injecting verapamil 10mg and nitroglycerin 100 $\mu$g inside the sheath.

Vascular access time:

The mean vascular access time in the initial transradial approach (group A) was (2.83±2.02 min.) in comparison to the repeated ipsilateral transradial approach (group B) was (2.96±2.13 min.) with $p$-value of (0.465) that appears to be more prolonged vascular access time in group B but with no statistically significant difference. Table (2).

Vascular complications:

In group (A), 15 patients (16.66%) had vascular complications after the procedure in the form of: 9 patients with absent radial pulse clinically and with duplex results diagnosed as acute radial artery occlusion (RAO) (10.00%), 3 patients (3.33%) had a minor hematoma, that didn’t require surgical interference, and the other 6 patients (6.67%) had a severe radial artery spasm (RAS).
Table (2): Comparison between group (A) and group (B) with regard to vascular access time (min).

<table>
<thead>
<tr>
<th>Groups</th>
<th>Vascular access time (min)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td></td>
</tr>
<tr>
<td>Group (A)</td>
<td>2.83 ± 2.02</td>
<td>0.465</td>
</tr>
<tr>
<td>Group (B)</td>
<td>2.96 ± 2.13</td>
<td></td>
</tr>
</tbody>
</table>

In group (B) 18 patients (13.04%) had vascular complications in the form of: 3 Patients (2.17%) had an absent pulsation and diagnosed as radial artery occlusion (RAO), 12 patients (8.7%) had radial artery spasm (RAS) (with 3 of them developed a minor hematoma) from totally 6 patients who had minor hematoma at site of sheath insertion (4.35%). No statistically significant difference between group (A) and group (B) with regard to vascular complications (p=0.517). Table (3).

Table (3): Comparing the vascular complications rate in groups (A&B).

<table>
<thead>
<tr>
<th>Vascular complication</th>
<th>Group (A)</th>
<th>Group (B)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>RAS</td>
<td>12 (8.70)</td>
<td>6 (6.67)</td>
<td>18 (7.89)</td>
</tr>
<tr>
<td>RAO</td>
<td>3 (2.17)</td>
<td>9 (10.00)</td>
<td>12 (5.26)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>6 (4.35)</td>
<td>3 (3.33)</td>
<td>9 (3.95)</td>
</tr>
<tr>
<td>Negative</td>
<td>120 (86.95)</td>
<td>75 (83.33)</td>
<td>195 (85.52)</td>
</tr>
<tr>
<td>Total</td>
<td>138 (100.00)</td>
<td>90 (100.00)</td>
<td>228 (100.00)</td>
</tr>
<tr>
<td>p-value</td>
<td></td>
<td></td>
<td>0.517</td>
</tr>
</tbody>
</table>

Post procedure vascular duplex:

To determine the prevalence of post-procedural RAO as confirmed by absence of antegrade flow in vascular high resolution ultrasound and other local access site complications (bleeding events, pseudoaneurysm, and arteriovenous fistula), respectively.

There was 3 patients with radial artery occlusion in (group A) in comparable to 9 patients in repeated approach (group B) with p-value 0.333. Table (4).

Table (4): Comparing duplex results in group (A) & group (B).

<table>
<thead>
<tr>
<th>RAO</th>
<th>Group A (n=138)</th>
<th>Group B (n=90)</th>
<th>Follow-up group B (98.3%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post procedural duplex (radial artery occlusion)</td>
<td>3</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Post procedural duplex (Normal)</td>
<td>135</td>
<td>81</td>
<td>81</td>
</tr>
<tr>
<td>p-value</td>
<td>0.333</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No cases of dissection, massive bleeding events, pseudo aneurysm, and arteriovenous fistula were reported.

Discussion

The mean time interval was 45 ±20 days between the initial and the repeated procedure which was considered a short time interval compared with other related studies because the patients in the repeated transradial procedure group had a significant coronary artery disease shown in the previous diagnostic transradial cardiac catheterization and were in need for coronary revascularization as soon as possible.

In most related studies the mean time intervals were longer than our study time. Byung-Su Yoo, et al., [18] included 117 cases of repeated use of the same radial artery (more than once) compared to 1771 patients in the initial procedure from May 1997 to April 2000 and the mean time interval between initial and repeat radial procedures was 4.5 ± 4.1 months.

Procedure success:

In our study success rate in the repeated transradial approach was high as in the initial procedure. It was (93.3%) in the repeated approach compared to (97.8%) in the initial approach. First reason for crossover was inability to puncture successfully the radial artery. Second, the artery was cannulated, but failed to proceed because of persistent radial artery spasm in spite of using nitroglycerin & verapamil. The most related studies confirmed the high success rates and conclude that repeated transradial approach can be done safely and feasible. In a study by H. Sakai et al., [19] the success rate of transradial approach performed in the same arm was calculated for men and women. Transradial approach was performed in the same arm up to three times in 90% of the men and 80% of the women. In study by Marinos Charalambous et al., [20] the procedural success rate was 98% in performing the same artery repeated transradial catheterization. In study by Byung-Su Yoo et al., [18] the repeated use of the radial artery is feasible in most patients with a high procedural success rate (97.4%) in the initial procedure compared to (98.3%) in the repeated procedure. In Ronald P. Caputo et al., [14] The rate of procedure success was similar for patients in group I the repeated transradial compared with group II the initial transradial approach (100% vs. 98%; p-value NS).
Vascular access time:

In our study there were no statistically significant differences in vascular access time between the initial and the repeated transradial procedure. The mean vascular access time in the initial procedure was (2.83±0.20min.) to (2.96±2.13min.) with p-value of (0.46). In study by Byung-Su Yoo et al., [18] There was no statistically significant difference in vascular access time (2.9±3.1min.) at the initial procedure and (3.3±3.6min.) at the repeated procedure (p=0.08).

In study by Orazio Valsecchi et al., [21] vascular access time was (1.9±2.1min.) at the initial procedure and (2.2±3.1min.) at the repeated one with no significant difference in vascular access time.

Vascular complications:

In our study there were no major vascular complications (arterio-venous fistula, perforation, dissection and pseudoaneurysm).

In study by marinos Charalambus et al., [20] No major access vascular complications were noted.

In study by Byung-Su Yoo et al., [18] No other vascular access site complications were noted in repeated approach. However, the incidence of radial arterial occlusion was higher for repeated procedures (2.6% vs. 0%; p 0.01). In Ronald P. Caputo et al., [14] there was no occurrence of major post procedural bleeding, hematoma, loss of palpable radial pulse, or neurologic deficit after any procedure.

Radial artery occlusion:

Radial artery occlusion (RAO) appears to be a significant problem after radial artery catheterization; it has been reported at rates ranging from 2% to 18% in several studies [91]. So Still the radial artery occlusion (RAO) is the most common and most important vascular complication occurred after transradial approach and limits its use for frequent times. In our study the incidence of RAO raised from (2.17%) in the initial transradial approach to (10%) in the repeated transradial approach.

As limited numbers of cases in our study had radial artery occlusion we could not detect actually what were the risks related to increased incidence of radial artery occlusion after transradial procedure. But in study by Abdullah Tuncez et al., [25] they observed risk factors for RAO are; no anticoagulant use, prolonged high-pressure compression of the radial artery, and small radial artery to sheath ratio, smoking, and recurring procedures.

Thrombus formation appears to be involved in the pathophysiology of early RAO [9].

Orazio Valsecchi et al., [21] revealed that RAO is the common complication of transradial approach as reported to occur after 6 F catheters in 2% to 6% of patients clinically. In study by H. Sakai et al., [19] radial artery occlusion has been reported to occur after the use of a 6 Fr catheter in 2%-6% of patients examined clinically and 5%-9% of patients examined by Doppler ultrasound. Yokoyama et al., [23] and Nagai et al., [24] have reported three factors related to radial artery occlusion: The diameter of the radial artery prior to the procedure, the ratio of the radial artery diameter to the sheath outer diameter, and diabetes. Accordingly, the occlusion rate should be low in patients with a large diameter radial artery and in patients in whom a small diameter sheath is used. However, the effects of such factors could not be confirmed in our study due to the fact that pre-and post-procedure diameters were not measured.

Follow-up for vascular complications (RAO):

Previous studies observed that radial artery occlusion may appear early or late after the procedure so recommended follow-up to radial pulse clinically and by duplex should be done but still Studies regarding long-term results following tranradial catheterization are limited.

In our study, patients with repeated transradial approach planned for a limited short term follow-up within two weeks by duplex study and show no more incidences in vascular complications or RAO.

Patients with radial artery occlusion still have radial artery occlusion without symptoms and without signs of recanalization in spite of giving a low molecular weight heparin for one week.

In the study done by Byung-Su Yoo et al., [18] radial artery occlusion was checked by palpation and ultrasonography assessment for 6 weeks follow-up and RAO observed in 2.6% of cases in repeated transradial procedure and late recanalization not observed after 12 weeks follow-up. In study by Orazio Valsecchi et al., [21] loss of radial artery pulse occurred in 1.6% in 30 day follow-up. H. Sakai et al., [19] reported that radial artery occlusion was recanalized in long terms follow-up.

Conclusion:

The repeated use of the same radial artery is demonstrated to be safe and effective, considering its high procedural success and low vascular complication rates in the majority of patients with
careful technique in the hands of experienced operators.

The most common vascular complication of transradial approach is RAO, in the range of 2-10%. Further research is needed on additional preventive strategies and treatment of this condition.

References
15- American College of Cardiology. National Cardiovascular Data Registry Module Version 3.0.