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Heparin Low Doses and Standard doses Effect on Transradial Catheterization

Gul Shan Ahmad[1], Muhammad Zafarullah[1], Safoora Anjum[2] & Samar Arfeen[1]

[1] Punjab Institute of Cardiology, Lahore-Pakistan.

[2]University of Lahore, Medical and Dental College, Lahore-Pakistan.

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Corresponding Author Email:
gulshan120@gmail.com

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Abstract

Background: Transradial artery is being utilized by an expanding number of interventional cardiologists to perform percutaneous interventions. Nevertheless, occlusion of radial artery (RAO) is prominent after transradial (TR) catheterization. The use of anticoagulant drugs is one way to prevent RAO. The use of high-dose heparin and standard-dose heparin is still debatable. The present study will analyze the non-randomized controlled trials of standard and high doses of heparin for the prevention of radial artery occlusion after transradial catheterization.

Methodology: A prospective double-blinded non-randomized controlled trial was carried out. Demographic data on socio-economic statuses, such as age, occupation, gender, and smoking habits, were collected. Grouping was done so that patients may either be placed in group 1, which will receive 2500UI or into group 2, which will get 5000UI of unfractionated heparin. RAO was the critical endpoint of our study. Major bleeding, hematomas, and radial artery spasms were secondary outcome measures.

Results: 471 patients were made part of this study. 235 patients were placed in group A which received 2500IU, and 236 were placed in group B, which received 5000IU. RAO was noted to be significantly higher in the group that received the standard dose of UFH as compared to the group that received a high dose of UFH (8 % vs. 3.3 %, p = 0.005). Female gender (OR: 2.951, 95% CI: 1.57-5.46, p = 0.002), hypertension (OR: 0.02, 95% CI: p = 0.005 and standard dose UFH (OR: 2.822, 95% CI: 1.343 – 5.911, p =. 0.007) were found to be the independent predictors of RAO.

Conclusion: Weight-adjusted higher dosage of UFH in TRA for diagnosis yielded remarkable results in reducing the rates of early RAO against the standard administered dosage.

Keywords

Heparin, Transradial, Catheterization, Doses, Radial Artery Occlusion.

Introduction

Cardiovascular disease (CVD) causes 80%-86% of deaths in countries with low and middle incomes and is considered a significant cause of fatalities worldwide[1-4]. Availability of non-invasive and invasive treatments alongside primary and secondary approaches related to the prevention of CVD has contributed to reducing the overall mortality in first world nations. In 1989, Campeau et al. introduced transradial coronary angiography to diagnose CVDs. While stenting and coronary angioplasty using TRA or transradial approach were first documented by Kiemeneij et al. in 1993. The most commonly implemented method for interventions and coronary angiography remains TFA or transfemoral approach. An expanding number of interventional cardiologists is utilizing radial artery to perform percutaneous interventions[5-7].

Moreover, numerous studies signify the benefits of TRA as its success rates are high in the general and overall satisfaction of the patients, and their comfort is also high. At the same time, there is relatively a lower potential of bleeding at the access site[8-11]. Despite unique advantages, the complications of trans-radial catheterization are still present, like. Radial arty occlusion, forearm hematoma formation, compartment syndrome, radial artery perforation, and pseudoaneurysm. Nevertheless, occlusion of radial artery (RAO) is prominent after transradial (TR) catheterization[12]. Following the interventions and coronary angiography, the associated rate of RAOs is still debated to vary between 0%-30.5%, considering some recent studies[13-15]. And rates were noted to be 0%-13.9%, particularly after coronary angiography[16-19]. Many other secondary complications arise after RAO, like the inability of the interventionist to reuse the artery vessel and shortage of grafts for coronary artery bypass surgery[20-21]. There are many possibilities to prevent radial artery occlusion RAO; the conservative method uses the gentle and skilled technique to avoid damage to the radial artery during the preoperative perforation process. Other prevention techniques are rational, such as using anticoagulant drugs, using non-obstructive hemostasis, reducing compression hemostasis time, preoperative injection of nitroglycerin, and moderate pain relief[15-22].

The selection of the dose of heparin in coronary angiography depends on the calculation of patients' weight and added to complete heparinization and is not determined yet[23]. The most commonly used doses of heparin are 2000IU -5000IU to prevent the complication of RAO for coronary angiography. The conventional dose is (2000IU-3000IU or 50IU/kg), and the high dose is (5000IU or 100IU/kg). Several studies establish an association linking RAO and the dosage of heparin. Nevertheless, the use of high-dose heparin and standard-dose heparin in transradial coronary angiography to efficiently prevent the incidence of RAO without increasing the risk of bleeding and other associated issues is still debatable. Furthermore, there is a lack of research comparing the clinical effects of these 2 doses of heparin in Pakistan. The present study will analyze the non-randomized controlled trials of standard and high doses of heparin for the prevention of radial artery occlusion after transradial catheterization.

Methodology

Study Design, Duration, and Setting

The prospective double-blinded non-randomized controlled trial was carried out at the department of cardiology at Punjab Institute of Cardiology Lahore from April 2020 to May 2021 over a 1-year duration. To select the patients, we used the method of non-probability consecutive sampling. Patients over the age of 18 years had a negative Allen's test, were directed for coronary catheterization by radial access, and consent about their participation in our study was set as the criteria for inclusion in our study. Patients that were subjected to chronic renal failure referred to angiography or angioplasty on an urgent basis had a radial PCI before, had bleeding disorders, or had pathological Allen tests that were not made part of our study. Approval was acquired from the institutional ethics committee about the study alongside written consent from the subjects after they had been provided information.

Pre-procedural Protocol

All the patients in our study underwent clinical examination, and their medical history was obtained. Demographic data related to socio-economic statuses, such as their age, occupation, gender, and smoking habits, were collected by a physician from the treatment group. Medical records like acute coronary syndrome, risk factors associated with CVD such as diabetes, use of appropriate medications, and occurrence of peripheral vascular disease were acquired by the physician. Standard means were employed for the measurements of the weight and height of the patients. Calculating BMI was done by dividing the patients' weight by height squared (kg/m2). Through a mercury sphygmomanometer, a trained nurse took the blood pressure of the patients following a standard protocol[34] that is to take the reading when the patient is in a sitting position and to take it twice from the left and right arms, providing the rest of 5 minutes.

Transradial Catheterization Procedure

In sterile conditions, an injection of 2% lidocaine was administered to achieve anesthesia. A needle of 20-gauge was utilized to puncture the site of the radial artery, which is present 2-3 cm adjacent to the wrist's crease. When a pulsatile flow appeared, a wire measuring 0.025 inches proceeded into the radial artery lumen. After the removal of the needle, a hydrophilic sheath measuring 6-Fr short (7 cm) was inserted over the guidewire. After the insertion of the sheath, a vasodilator (5 mg of verapamil or 100 µg of nitroglycerin) was provided to the subjects, and heparin (2,500 or 5,000 U) which was diluted beforehand in a syringe measuring 10-ml, was given to the patients afterward in the injection form in their radial artery.

Grouping was done so that patients may either be placed in group 1, which will receive 2500UI or into group 2, which will get 5000UI of unfractionated heparin administered by another staff member who was unaware of the medical history of the patients.

As soon as the procedure ended, the radial sheath was removed immediately, and a radial compression device known as TR Band (Terumo, Tokyo, Japan) was used at the site of access and filled with 15ml of air. 2ml air was removed periodically every 15 mins from the balloon of the TR Band, followed by its removal after 1 hour.

The patients were discharged from the hospital within 3-4 hours after their cardiac catheterization. Before their discharge, all the patients were observed for local swelling, hematoma, pain, absence of pulse, and weakness. 7 days following their cardiac catheterization, all patients were subjected to reevaluation using Doppler ultrasonography and physical examinations.

Study Endpoints

After the removal of the TR Band and maintaining their hemostasis, discharge was given to all the patients. RAO was the critical endpoint of our study, and significant bleeding, hematomas, and radial artery spasms were secondary outcome measures.

The patients were clinically examined by radial pulse palpation. Radial artery occlusion (RAO) was considered the loss of radial pulse on palpation, validated by loss of audible blood flow across the radial artery examined through portable hand-held Doppler, and the Doppler ultrasonography was used to perform radiological examination.

Hematoma and hemorrhage were described as swelling at a localized region accompanied by bruising and active bleeding at the site where the sheath was inserted; five signs were noticed to define radial artery spasm: i) unceasing pain in the forearm, ii) painful response whenever catheter was manipulated, iii) painful response when the catheter is withdrawn, iv) difficulty in manipulation of introducer sheath or catheter after getting trapped by the radial artery v) substantial resistance felt when the introducer sheath was withdrawn. When at least 2 out of these five signs were present, we declared the presence of radial artery spasm. Major bleeding was defined as when a transfusion of more than two units of blood was required.

Statistical Analysis

SPSS version 20 was used to perform all the statistical analyses. The data were presented as percentages for the categorical variables, and for the continuous variable, means were presented with standard deviations. Non-normally distributed variables were expressed as median (IQR). To compare the continuous variables student's t-test was used. We used the Chi-square test to evaluate categorical variables. We used Multivariate logistic regression analysis to determine independent predictors of RAO. All the probabilities were by nature two-tailed, and p values of less than 0.05 were deemed significant statistically.

Results

471 patients were made part of this study. Out of those 471 patients, 65.2% were male, while the mean age was analyzed to be 58 years. 235 patients were placed in group A which received 2500IU, and 236 were placed in group B, which received 5000IU. Disease history along with laboratory features, clinical, demographical, and procedural characteristics of the study population are summed up in Table 1. No significant difference was noted regarding the baseline characteristics and comorbidities between the group with higher doses of unauctioned heparin (UFH) and the group receiving standard doses of UFH.

Table 1: Baseline demographic, clinical, and angiographic characteristics

Variable	Group 1 (n = 235)	Group 2 (n = 236)	p-value
Gender Female, n (%)	97 (41.2 %)	89 (37.7 %)	0.43
Age, years	58.1 ± 10.6	59.2 ± 10.7	0.18
BMI, kg/m^2	27.1 ± 3.5	26.9 ± 3.9	0.25
Diabetes mellitus	75 (31.9 %)	85 (36 %)	0.17
Hypertension	114 (48.5 %)	107 (45.3 %)	0.41
Smoking	90 (38.2 %)	101 (42.7 %)	0.36
Previous CAD	72 (30.6 %)	84 (35.5 %)	0.29
Number of catheters (mean ± SD)	1.11 ± 0.31	1.15 ± 0.38	0.27
Fluoroscopy time (min) (mean ± SD)	8.21 ± 0.71	8.22 ± 0.46	0.06
Heparin doses, median (IQR)	3760 (3400 – 4000)	7100 (6550 – 8000)	< 0.001
Triglycerides (mg/dL)	159 ± 69	159 ± 65	0.98
HDL- cholesterol (mg/dL)	41 ± 9.1	38 ± 9.1	0.10
LDL- cholesterol (mg/dL)	112 ± 33	77 ± 12	0.18

BMI: Body mass index, CAD: Coronary artery disease, HDL: High-density lipoprotein, LDL: Low-density lipoprotein, SD: Standard deviation

Periprocedural adverse events pertaining to the groups under study are listed in Table 2. Between the group receiving the higher dose of UFH and the group receiving the standard dose, hematoma yielded indifferent results, i.e. (4.6% vs. 3 %, p = 0.60). Only one of the patients in the group with high UFH reported major bleeding.

Table 2: Periprocedural complications of the participants

Variable	Group 1 (n = 235)	Group 2 (n = 236)	p-value
Radial artery occlusion, n (%)	19 (8 %)	8 (3.3 %)	0.005
Hematoma, n (%)	7 (3 %)	11 (4.6 %)	0.60
Major bleeding, n (%)	0 (0 %)	1 (0.4 %)	-
Radial artery spasm n (%)	20 (8.5 %)	24 (10 %)	0.51

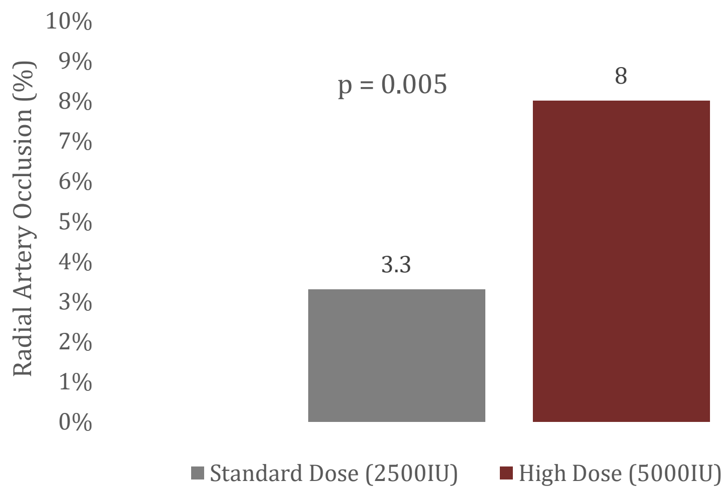

Figure 1: Comparison of RAO between standard and high dose groups

The rate of the RAS was similar in both the study groups as well, where RAS in the standard group was at 8.5%, while it was noted to be at 10% in the group with high dosage UFH, where p = 0.51. RAO was noted to be significantly higher in the group that received the standard dose of UFH as compared to the group that received a high dose of UFH (8 % vs. 3.3 %, p = 0.005, Figure 1).

Multivariate logistic regression analysis revealed the independent predictors of RAO (Table 3). Female gender (OR: 2.951, 95% CI: 1.57-5.46, p = 0.002), hypertension (OR: 0.02, 95% CI: p = 0.005 and standard dose UFH (OR: 2.822, 95% CI: 1.343 – 5.911, p = 0.007) were found to be the independent predictors of RAO.

Table 3: Independent predictors of RAO in multivariate analysis

Variable	Odds ratio	p-value	95% CI
Female Gender	2.951	0.002	1.57–5.46
Age	0.991	0.61	0.961–1.020
BMI	1.079	0.12	0.981–1.189
Hypertension	0.023	0.005	0.003–0.309
Standard heparin dose	2.822	0.007	1.343–5.911

Fluoroscopy time	0.989	0.08	0.991–1.002

Discussion

In our study, we investigated the link of RAO with high dose UFH in comparison with standard dose UFH and the incidence of RAO after radial access coronary angiography providing 2500 IU vs. 5000 IU injectable heparin. Occlusions of TRA access are often found to produce no symptoms and, as a result, remain underdiagnosed. Due to this, a logical approach seems to be to dealing with these events is to use anticoagulant therapy[24].

In the current study, we demonstrated that hypertension, a dose of heparin, and age are independent predictors of RAO. Lower rates of RAO were independently related to high dose UFH without elevating minor or major bleeding.

On a global scale, TRA is gaining popularity as the strategy of choice for cardiac catheterization crediting to its comfort level for patients, early discharge and mobilization for the patients, low bleeding at the site of access, and simple achievement of effective hemostasis. Modern guidelines accentuate TRA as the first approach for cardiac catheterization, linked with better clinical outcomes[25].

Nevertheless, challenges and complications do arise in TRA. TRA, in general, is considerably more technically tricky than the femoral approach as it requires the use of several specific catheters, problems during access, tortuosity of subclavian artery, RAS, abnormalities of anatomy related to radial and brachial artery, increased time to complete the procedure and severe pain additionally it takes up a longer duration to learn as well[26].

The most critical complication associated with TRA is RAO, as RAO shows no symptoms, and with techniques and time of evaluation of RAO showing such diversity in the literature, its rate of incidence is widely diversified, ranging from 0% and extending up to 30.5% with the average being 10%. RAO rates are reportedly higher right after the procedure but see a constant decline with the course of time, crediting to the spontaneous recanalization where the rate of incidence for the early RAO within a 24-hour period decrease from 7.7% to 5.5% in 1 month[27,28]. In addition to that, an absent radial artery pulse promotes underdiagnosis of RAO[27]. Thus, Doppler ultrasound provides in-depth, objective information related to RAO by determining blood flow using a color Doppler and providing structural imaging of the arteries[28]. Our study made use of Doppler ultrasound to diagnose RAO and found it to be present in 36 (5.7%) of the subjects on the 7th day of them after being subjected to cardiac catheterization. We found the ratio in our study to be in line with the data previously reported in literature[29].

Numerous parameters such as BMI, sex, co-morbid conditions such as diabetes mellitus and hypertension, including some periprocedural variables that include the ratio of the artery concerning the sheath, compression duration, and use of heparin have been investigated so that causes of RAO can be explained[29,30]. Many studies have been done on the optimal doses of heparin for the prevention of RAO, and they support the idea of administering at least 50IU/kg up to 5000 IU UFH through interatrial means[31]. In the current study, RAO was found to be significantly lower in the patients receiving a high dosage of UFH compared to the group that received a standard dosage. Besides that, we found a standard dose of heparin to be an independent factor for the increase in RAO by 2.8 folds. Furthermore, an increased dosage of heparin was correlated with a 65% reduction in the risk of RAO. The obtained results about the use of a high dosage of anticoagulation were in line with the results of prior studies, which outline the benefits of high-dose anticoagulation for the prevention of RAO in patients who are undergoing cardiac catheterization[32,33]. Thus it can be said that the use of a high dose of UFH in patients undergoing cardiac catheterization is a reasonable choice.

The risk of RAO in women after TRCAG is found to be higher, contributing to their short body stature[34]. In our study, we found women's risk for RAO to be significantly increased; the female gender was reported as an independent predictor of RAO. A study by Buturak et al. associates hypertension with radial artery patency following TRCAG[35]. Our findings that hypertension is another independent predictor of radial artery occlusion were following their findings. This may be attributed to the increased stiffness of the artery, which may prevent complete disruption of the flow in the artery during compression and provides better conditions for good patent hemostasis.

Our study has a number of limitations. First, our study was based on a single center, and the study sample size was small. Other than that, we did not account for the dimensions of the radial artery by ultrasonography prior to catheterization; thus, an estimation for the sheath to artery ratio could not be made. Examining the Impact of the diameter of the radial artery on the rate of RAO would contribute further to this study. The rate of RAO was calculated after 7 days of cardiac catheterization. Follow-up duration more extended than that of 7 days, i.e., the 1st month after the cardiac catheterization, could be better.

Conclusion

Weight-adjusted higher dosage of UFH in TRA for diagnosis yielded remarkable results in reducing the rates of early RAO against the standard administered dosage. The beneficial results produced by the usage of high-dose UFH were found to be without an increase in major bleeding. Considering that RAO affects almost 5.7% of the patients undergoing TRA, referring them to a higher dosage of UFH might be a sensible choice to prevent RAO.

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