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ORIGINAL RESEARCH

To study the paradigm shift demonstrating the feasibility of using the radial artery for primary angioplasty and the evaluation of high-risk subgroups

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Abstract

Aim: A paradigm shift demonstrating the feasibility of using the radial artery for primary angioplasty and the evaluation of high-risk subgroups.

Materials and methods: The nature of the research may be described as prospective, observational, and descriptive. Patients who presented with acute ST-segment elevation myocardial infarction (STEMI) and were treated with PCI via RA at the cardiology department of a tertiary care centre were included in the study. The interventionist was given complete autonomy in deciding whether to use a RA or FA strategy. Patients who had PCI performed through the femoral artery were not allowed to participate in this research. Patients were hospitalized and underwent evaluation for baseline features such clinical history, physical examination, and investigations such as electrocardiogram, two-dimensional echo, and normal laboratory investigation. After that, patients were separated into two groups for the subgroup analysis: HRG patients and non-HRG patients. Patients with unfavourable characteristics were included in the HRG. These characteristics included age (greater than 80 years), cardiogenic shock, severe left ventricular systolic dysfunction, high degree AV block, low body surface area (BSA), multi-vessel percutaneous coronary intervention (PCI), diabetes mellitus, and low body mass index (BMI). Patients who did not have these characteristics were included in the non-HRG.

Results: Males made up 83.33% of the total study population of 150 patients, with 24.67% of those patients being under the age of 50 and 6.67% of those patients being above the age of 80. The body mass index (BMI) was determined, and the results showed that 16.67% of people had a BMI of less than 19 kg/m2, whereas 30% had a BMI of more than 25 kg/m2. The majority of patients had one or more risk factors for Coronary Artery Disease (CAD), with diabetes mellitus in 33.33%, systemic hypertension in 30% and smoking in 16.67%. At presentation, patients average systolic BP was 141.8 ± 24.6 mmHg and diastolic BP was 84.4 ± 12.1 mmHg. Total is chaemic time was found to be 6.55 ± 2.69 hrs for the whole study group. ECG analysis revealed AWMI spectrum in fifty percent of patients, QRBBB pattern in five percent, IWMI spectrum in fifty percent of patients, and RVMI in five percent. According to the results of the echocardiogram, 20% of the patients had a good left ventricular function (LVEF >50%), 40% had mild LV systolic dysfunction (LVEF 40-50%), 20% had moderate LV systolic dysfunction (LVEF 30-40%), and 20% had severe LV systolic dysfunction (LVEF30%). Prior to intervention, coronary angiography revealed the presence of SVD in 40% of patients, DVD in 30%, TVD in 25%, and LMCA involvement in 5% of

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patients. To treat the other patients, thrombo-suction, bare metal stents (BMS), plain old balloon angioplasty (POBA), and drug-eluting stents (DES) were utilized respectively. Drug-eluting stents were used in the majority of patients (85%). After the operation, TIMI 3 flow was attained in 84.67 percent of cases, TIMI 2 flow in 13.33 percent of cases, and TIMI 1 flow in just 2 percent of cases. The majority of patients, or 89.33%, had fluoroscopy times that were less than 10 minutes during the surgery. The amount of contrast that was administered during the operation was less than 100 ml in 85.33 percent of patients, between 100 and 150 ml in 6 percent of patients, and more than 150 ml in the remaining patients.

Conclusion: The purpose of the trial was to investigate the viability of RA in primary angioplasty for patients who had one or more risk factors, the most prevalent of which were diabetes, hypertension, and smoking. Patients who were younger than 50 years had a higher incidence of having a family history of early CAD. When compared to NON-HRG, HRG had a significantly higher incidence of problems; however, this difference was not statistically significant (p value > 0.05).

Keywords: TIMI, angioplasty, LVEF

Introduction

Angioplasties have been performed in clinical practice using a variety of approaches, with widely variable degrees of effectiveness [1]. The many procedures that are available for angioplasty each have their own set of benefits and drawbacks, depending on the individual's level of experience [2-4]. Each access method is often up to the discretion of the operator. A transradial approach (RA), as opposed to a femoral artery (FA) approach, is becoming increasingly popular for percutaneous coronary intervention (PCI). This is due to the fact that there are fewer complications related to bleeding, increased patient comfort, early ambulation, and a shorter length of stay in the hospital [5-10]. This strategy has been used well in primary percutaneous coronary intervention for cases of acute myocardial infarction (MI). Recent years have seen a shift toward using radial artery access even in patients who are considered to be high risk [11,12]. The change in paradigm has allowed for the evaluation and comparison of RA for primary angioplasty in a large number of patients with a variety of risk factors and conditions. Therefore, the purpose of the clinical investigation was to analyze and contrast the convenience of access as well as any other relevant elements that contribute to the effective use of RA in any and all scenarios. The purpose of the research was to analyze and contrast the practicability of using RA on a regular basis in primary PCI, as well as in High Risk Group (HRG) and non-HRG subgroups. In addition to this, it sought to uncover the clinical and procedure-related factors that were linked with greater incidence of complications. The elements that were evaluated were the baseline characteristics, the complications, the procedure-related aspects such fluoroscopy duration, contrast volume, and angioplasty success rate, and the parameters that were taken into account (TIMI grade).

Materials and methods

The nature of the research may be described as prospective, observational, and descriptive. Patients who presented with acute ST-segment elevation myocardial infarction (STEMI) and were treated with PCI via RA at the cardiology department of a tertiary care centre were included in the study. The interventionist was given complete autonomy in deciding whether to use a RA or FA strategy. Patients who had PCI performed through the femoral artery were not allowed to participate in this research.

Patients were hospitalized and underwent evaluation for baseline features such clinical history, physical examination, and investigations such as electrocardiogram, two-dimensional echo, and normal laboratory investigation. After that, patients were separated into two groups for the subgroup analysis: HRG patients and non-HRG patients. Patients with unfavourable

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characteristics were included in the HRG. These characteristics included age (greater than 80 years), cardiogenic shock, severe left ventricular systolic dysfunction, high degree AV block, low body surface area (BSA), multi-vessel percutaneous coronary intervention (PCI), diabetes mellitus, and low body mass index (BMI). Patients who did not have these characteristics were included in the non-HRG. The descriptive analysis was used to conduct the evaluation, tabulation, and analysis of the results, as well as the procedural parameters and problems.

Methodology

In most cases, the interventionist would choose to do transradial PCI via the right radial artery. Following administration of local anaesthetic, the RA of the patients was perforated, and a sheath measuring 5 or 6 French (Fr) was introduced into the radial artery. After the sheath was put in place, 5000 units of heparin were injected into the patient. Following the completion of the diagnostic test, an extra bolus of 2500 units of heparin was injected shortly before to beginning the PCI procedure. In most cases, a Tigar catheter was used in order to try engagement of either the left coronary artery (LCA) or the right coronary artery (RCA) in order to perform diagnostic angiography. The guiding catheters EBU, JL, and JR were utilised in this procedure. After the PCI procedure, the sheaths used to access the arteries were withdrawn, and manual compression was used to stop the bleeding. Patients were allowed to begin walking about early provided their hemodynamics were stable and they did not have any problems. The information collected from every patient was analysed for both their baseline characteristics and the procedure parameters. Patients were prospectively followed up until the time when they were discharged, and in-hospital problems were recorded if they occurred.

Statistical analysis

The data were either represented by their mean, their standard deviation (SD), or their percentage (%). A comparison within the patients' own group was carried out to see how well they were using RA. In order to be declared statistically significant, the probability value needed to be lower than 0.05.

Results

Males made up 83.33% of the total study population of 150 patients, with 24.67% of those patients being under the age of 50 and 6.67% of those patients being above the age of 80. The body mass index (BMI) was determined, and the results showed that 16.67% of people had a BMI of less than 19 kg/m2, whereas 30% had a BMI of more than 25 kg/m2 (Table-1).

Table 1: Demographic profile in percentage

Variables		High Risk Group (N=50)	Non-High risk Group (N=100)	Total	
				N=150	Percentage
Gender	Male	40	85	125	83.33
	Female	10	15	25	16.67
Age	below 40	5	6	37	24.67
	40-50	6	20		
	50-60	15	38	103	68.67
	60-70	9	30		
	70-80	5	6		
	Above 80	10	0	10	6.67
BMI	Under weight (<19)	7	18	25	16.67

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	Normal (19-25)	30	50	80	53.33
	Over weight (>=25)	13	32	45	30

The majority of patients had one or more risk factors for Coronary Artery Disease (CAD), with diabetes mellitus in 33.33%, systemic hypertension in 30% and smoking in 16.67% (Table-2).

Table 2: Morbidity profile in percentage- exposed to one or more factors

Risk factors	High Risk Group (N=50)	Non-High risk Group (N=100)	Total (N=150)
DM	15	35	50(33.33)
HTN	15	30	45(30)
DLP	4	10	14(9.33)
H/O vascular disease	4	5	9(6)
F/H/O premature CAD in family	2	5	7(4.67)
Smoking	10	15	25(16.67)

At presentation, patients average systolic BP was 141.8 ± 24.6 mmHg and diastolic BP was 84.4 ± 12.1 mmHg. Total Ischaemic time was found to be 6.55 ± 2.69 hrs for the whole study group. ECG analysis revealed AWMI spectrum in fifty percent of patients, QRBBB pattern in five percent, IWMI spectrum in fifty percent of patients, and RVMI in five percent. According to the results of the echocardiogram, 20% of the patients had a good left ventricular function (LVEF >50%), 40% had mild LV systolic dysfunction (LVEF 40-50%), 20% had moderate LV systolic dysfunction (LVEF 30-40%), and 20% had severe LV systolic dysfunction (LVEF30%). Prior to intervention, coronary angiography revealed the presence of SVD in 40% of patients, DVD in 30%, TVD in 25%, and LMCA involvement in 5% of patients. To treat the other patients, thrombo-suction, bare metal stents (BMS), plain old balloon angioplasty (POBA), and drug-eluting stents (DES) were utilised respectively. Drug-eluting stents were used in the majority of patients (85%). After the operation, TIMI 3 flow was attained in 84.67 percent of cases, TIMI 2 flow in 13.33 percent of cases, and TIMI 1 flow in just 2 percent of cases. The majority of patients, or 89.33%, had fluoroscopy times that were less than 10 minutes during the surgery. The amount of contrast that was administered during the operation was less than 100 ml in 85.33 percent of patients, between 100 and 150 ml in 6 percent of patients, and more than 150 ml in the remaining patients. (Table 3)

Table 3: Comparison of Procedural parameters after randomization in both groups

Parameters		High Risk Group (N=50)	Non-High Risk Group (N=100)	Total (N=150)	P value
TIMI FLOW	Grade 1	2	1	3(2%)	0.21
	Grade 2	8	12	20(13.33%)	
	Grade 3	40	87	127(84.67%)	
FLUOROSCOPY TIME	**<10**	44	90	134(89.33%)	0.477
	>=10	6	10	16(10.67%)	
T-Test (Comparison of means of Fluoroscopy time among Risk groups)					
Mean ± SD		6.74±2.69	6.65± 2.74		0.63
	<=100	43	85	128(85.33%)	

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CONTRAST VOLUME (ML.)	100-150	3	10	13 (8.67%)	0.34
	>150	4	5	9(6%)	
T-Test (Comparison of means of contrast volume among Risk groups)					
Mean ± SD		111.37±20.55	113.74±21.63		0.41

Patients were monitored until they were discharged from the hospital, and in-hospital problems were recorded if they occurred. In eighty percent of individuals, there were no problems seen. Complications on the local level were uncommon, with just two patients exhibiting a minor haematoma. Twenty percent of individuals had difficulties across their systems. Among them, AKI accounts for sixty percent of all cases. The majority of cases of acute kidney injury were due to contrast-induced nephropathy, whereas 20% of patients had underlying chronic kidney disease. Every patient made a full recovery from the AKI, with the exception of one patient who required dialysis due to CKD. During their time in the hospital, two percent of patients had an acute stroke, and one patient experienced a transient ischemic attack. During the post-operative period, there were two patients who had to be brought back from cardiac arrest with primary VT/VF. Acute pulmonary edoema was seen in three of the patients.

Analyses of Different Groups

The research included a total of 150 individuals, and 50 of those patients had HRG. After doing a comparison with non-HRG, it was discovered that there was no statistically significant difference between the procedural factors (fluoroscopy duration, TIMI flow, and contrast volume) (Table 3) and the problems (p value >0.05). In HRG, problems such as acute pulmonary oedema and resuscitated cardiac arrest were seen more often than in other groups.

Discussion

Kiemeneij and Laarman [2] published the first ever report of an angioplasty operation using RA in the year 1993. Following percutaneous coronary intervention (PCI), the radial technique has been linked to less vascular access-related problems [12,13]. There was a reduction in mortality, the risk of bleeding, and the number of complications associated with STEMI therapy when primary angioplasty was done through the radial route [8,9,14]. These data confirmed the findings of our research as well. Patients who had PCI performed by RA were shown in a number of studies to have spent a shorter amount of time overall in the hospital and in the coronary care unit as a direct result of the lower incidence of complications [14-16]. These study findings do not match up with the observations that we made throughout our research. If there were no complications, the majority of our patients were released between three and five days after their procedures. In the current investigation, the feasibility of RA for primary angioplasty in patients with varying baseline characteristics was evaluated, and sub-groups analyses were performed to compare HRG and non-HRG patients. In spite of the rising body of information on this topic, there is still a significant amount of disagreement surrounding the regular use of RA. This criticism is predicated on the notion that this technique might impact the effectiveness of angioplasty and the reperfusion time in certain patient groups (i.e. high risk groups). In this particular research, there was not found to be a statistically significant difference between the HRG and the non-HRG in terms of the procedural factors or the complication rate. The high-risk group of patients (also known as cardiogenic shock) was left out of the RIVAL trial, but we decided to

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include them in our research. Despite this, the outcomes and the number of problems were similar to those seen in the RIVAL study [8]. A number of investigations, as well as a meta-analysis, have shown that FA is the most effective treatment for HRG [14]. Because of the steep learning curve that is associated with its usage, the use of RA is still seen as a challenging technique in the Indian context [13]. There have only been a handful of Indian studies that have been published that use RA for PCI, and none of them have taken into account the different HRG patients [11-15]. Our research was the only one that investigated and analysed HRG sub groups before successfully comparing them to non-HRG groups for a variety of metrics. The findings of a PPCI were given by Francisco J., et al., 2016; the sample size was 1029 patients, and more than 93 percent of the PPCI operations were performed utilising radiofrequency ablation (RA) [6]. On the other hand, in this particular research, each of our instances was handled with RA. The success rate of angioplasty was approximately 96% in that research, and crossover was necessary in just 3.0% of cases. In contrast, the success rate of angioplasty in our study was 98%. In that research, the use of RA did not change the success rate of angioplasty or the reperfusion period, but a greater crossover rate to FA was seen in less favourable subgroups. Despite this, the use of RA did not impact the success rate of reperfusion. However, the results of our research showed that the procedure success rate was the same whether HRG was used or not. When comparing HRG to non-HRG, the current research did not find any statistically significant variations in procedural parameters such as TIMI flow, fluoroscopy duration, or contrast volume. When comparing HRG patients to non-HRG patients, systemic problems were numerically more common in HRG patients, but there was no statistically significant difference detected between the two groups. Acute kidney damage (also known as AKI) was the systemic complication that occurred the most often. Systemic problems were more likely in patients older than 80 years of age as compared to those younger than 60 years of age. As was to be predicted, there were a greater number of complications in higher killip classes. The risk of complications was equivalent to that seen in previous significant trials on RA PCI [6,8,9]. The current research shown that primary PCI by RA may be performed safely on all patients, even those who have HRG. We searched the existing literature, but were unable to locate any substantial studies that compared HRG patients with non-HRG patients using RA. [14,17] None of the published research investigated and compared all of the indicators that were associated with the high risk groups. There is substantial data to suggest that patients who have bleeding during a procedure have a poor prognosis, marked by an increased risk of death and length of hospital stay. Several studies have shown that RA is associated with a lower risk of developing such complications than FA, with no detriment to reperfusion time [6-10, 14-17]. Even though these complications are generally uncommon, these studies have shown that RA is associated with a lower risk of developing such complications. The findings of this research demonstrated that primary PCI using RA is possible for regular usage in all patients, regardless of their baseline characteristics, and that it has the same level of effectiveness in HRG as it does in non-HRG patients.

Conclusion

The purpose of the trial was to investigate the viability of RA in primary angioplasty for patients who had one or more risk factors, the most prevalent of which were diabetes, hypertension, and smoking. Patients who were younger than 50 years had a higher incidence of having a family history of early CAD. When compared to NON-HRG, HRG had a significantly higher incidence of problems; however, this difference was not statistically significant (p value > 0.05). There was not a significant difference between the two groups in terms of the factors pertaining to the procedure. The findings of this research provide

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credence to the practise of routinely using RA in all possible sorts of patients, including those with high risk features.

References

1. Kiemeneij F, Laarman GJ, Odekerken D, Slagboom T, van der Wieken R. A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the access study. Journal of the American College of Cardiology. 1997 May;29(6):1269-75.
2. Kiemeneij F, Jan Laarman G. Percutaneous transradial artery approach for coronary stent implantation. Catheterization and cardiovascular diagnosis. 1993;30(2):173-178.
3. Kiemeneij F, Laarman GJ. Percutaneous transradial artery approach for coronary Palmaz-Schatz stent implantation. American heart journal. 1994 Jul 1;128(1):167-74.
4. Kiemeneij F, Laarman GJ, de Melker E. Transradial artery coronary angioplasty. American heart journal. 1995 Jan 1;129(1):1-7.
5. Wu, Chiung-Jen, Morgan Fu, Kean-Wah Lau, and Jui-Sung Hung. "Transradial coronary angiography and angioplasty in Chinese patients." Catheterization and cardiovascular diagnosis. 1997; 40(2):159-163.
6. Hernández-Pérez FJ, Blasco-Lobo A, Goicolea L, Muñiz- Lozano A, Fernandez-Díaz JA, Domínguez JR, Goicolea- Ruigómez J. Use of the radial approach in primary angioplasty: results in 1029 consecutive patients and analyses in unfavorable subgroups. Revista Española de Cardiología (English Edition). 2014 Jan 1;67(1):45-51.
7. Stone G W , Witzenbichler B, Guagliumi G, Peruga J Z, brodie B R, Dudek D, et al. "RA in patients with ST-segment elevation myocardial infarction undergoing primary angioplasty in acute myocardial infarction: the HORIZONS-AMI trial". Euro Intervention. 7 (2011):905-916.
8. Jolly SS,Lewis BS, Avezum A. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. The Lancet. 2011 ;377(9775):1409-20.
9. Chase AJ, Fretz EB, Warburton WP, Klinke WP, Carere RG, Pi D, Berry B, Hilton JD. Association of the arterial access site at angioplasty with transfusion and mortality: the MORTAL study (Mortality benefit Of Reduced Transfusion after percutaneous coronary intervention via the Arm or Leg). Heart. 2008 Aug 1;94(8):1019-25.
10. Romagnoli E, Biondi-Zoccai G, Sciahbasi A, Politi L, Rigattieri S, Pendenza G, Summaria F, Patrizi R, Borghi A, Di Russo C, Moretti C. Radial versus femoral randomized investigation in ST-segment elevation acute coronary syndrome: the RIFLE-STEACS (Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome) study. Journal of the American College of Cardiology. 2012 ;60(24):2481-9.
11. Vora AN, Rao SV. Same day discharge following transradial PCI in India: Creating value for patients and providers. Indian heart journal. 2015 Mar;67(2):90.
12. Goel PK, Jatain S, Khanna R, Pandey CM. Left main PCI: an observational analysis from large single-centre experience. Indian heart journal. 2016 ;68(1):36-42.
13. Chugh SK. Trans-radial interventions–From 'Bandwagon'to 'Movement': Where we were; where we are and where do we go from here. Indian heart journal. 2015 Nov;67(6):627.
14. Basu D, Singh PM, Tiwari A, Goudra B. Meta-analysis comparing radial versus femoral approach in patients 75 years and older undergoing percutaneous coronary procedures. Indian heart journal. 2017;69(5):580-8.

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 08, 2022

15. Gokhroo RK, Kaushik SK, Padmanabhan D, Bisht D, Gupta S. A single center multioperator initial experience of 4195 patients at a primary radial intervention program in a tertiary level center. indian heart journal. 2014 Mar 1;66(2):169-75.
16. Valgimigli M, Gagnor A, Calabró P, Frigoli E, Leonardi S, Zaro T, Limbruno U. Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomised multicentre trial. The Lancet. 2015;385(9986):2465- 76.
17. Bernat I, Horak D, Stasek J, Mates M, Pesek J, Ostadal P, Hrabos V, Dusek J, Koza J, Sembera Z, Brtko M. ST-segment elevation myocardial infarction treated by radial or femoral approach in a multicenter randomized clinical trial: the STEMI- RADIAL trial. Journal of the American College of Cardiology. 2014;63(10):964-72