



Comparison of Modified Allen's Test with Measurement of Radial Artery Diameter by Doppler and its Suitability for Transradial Coronary Angiography - An Observational Study

Authors

Adeel Majeed Belim^{1*}, Sheikh Mohamad Tahir², Shubana Ashraf³, Rajiv Agarwal⁴

¹Consultant Cardiologist, Fortis Balaji Hospital, Jodhpur, India

²Consultant Cardiologist, Superspeciality Hospital, Government Medical College, Srinagar, J&K, India

³Consultant Neurologist, Superspeciality Hospital, Government Medical College, Srinagar, J&K, India

⁴Interventional Cardiologist, Saket City Hospital, New Delhi India

*Corresponding Author

Adeel Majeed Belim

Consultant Cardiologist, Fortis Balaji Hospital, Jodhpur, India

Abstract

Background: *The feasibility of using modified Allen's tests and Doppler ultrasonography to evaluate arterial circulation and diameters in the forearm arteries for transradial coronary angiography, and the correlation of these tests with the complications were examined.*

Material & Methods: *This was an observational study and the hand circulation of 70 patients scheduled for transradial coronary angiography was assessed by Modified Allen's test and Doppler ultrasonography. Findings of the positive modified Allen's test and diameter of the radial, ulnar arteries were recorded and compared for the various demographic, risk factors profile, vascular access complications and procedural outcomes.*

Results: *A total of 70 patients were evaluated and 16 had a positive modified Allen's test. The mean diameter of right and left radial artery was 2.5 ± 0.4 mm and 2.4 ± 0.4 mm respectively ($p=0.470$). The mean diameter of right and left ulnar artery was 2.7 ± 0.4 mm and 2.7 ± 0.4 mm respectively ($p=0.782$). Highly significant difference was found between the respondents ($p<0.001$) when forearm arteries was compared to each other. There was no relationship of the size of the radial and ulnar artery with age, body Mass Index (BMI) and various risk factors studied. However, the diameter of the forearm arteries showed good correlation with each other. Significant correlation was found between arterial spasm ($p<0.001$) and crossover ($p=0.010$) & modified Allen's test. Statistically significant correlation was found between Doppler measured right radial artery diameter and arterial spasm ($p=0.001$). The positive Modified Allen's test and Doppler measured Forearm artery diameters when correlated, then statistically significant difference was found suggestive of smaller diameters were found in patient with a positive Modified Allen's test.*

Conclusions: *Use of Modified Allen's test as a screening tool to assess the collateral circulation of hand correlates well with the occurrence of complication and there has been a significant correlation between the positive Modified Allen's test and Doppler measured radial artery diameter and the occurrence of complications in our study. A positive modified Allen's test completely obviates the need for Doppler assessment and provides no additional benefit rather we exercise caution and change the access site if possible.*

Keywords: *Allen's Test, Modified Allen's Test, Radial Artery Diameter, Transradial Coronary Angiography.*

Introduction

The first successful diagnostic transradial coronary catheterization was done by Campeau in 1989 and the first transradial percutaneous coronary intervention (PCI) was carried out by Kiemeneij in 1993. Since then the radial artery has been increasingly used as an access site for coronary procedures, because of lower rate of access site complications, shorter hospital stay, improved patient comfort, and safe hemostasis compared with transfemoral access. Nonetheless, radial access still accounts for only 10% of coronary catheterizations worldwide and for <2% of coronary procedures in the United States⁽¹⁾. Bleeding at the vascular access site is an important predictor for post-interventional morbidity and mortality as demonstrated in several studies. The recently published multicenter RIVAL (radial versus femoral access for coronary intervention) trial was conducted to compare radial with femoral access in the setting of acute coronary syndromes. The radial access was shown to reduce major vascular complications compared with the femoral access. Another interesting finding was the mortality reduction in favor of transradial access in patients with ST-segment elevation myocardial infarction⁽²⁾. Radial artery (RA) cannulation carries a risk of RA occlusion with an incidence of 4.8% to 19%. This is usually of no consequence, because the hand receives blood from both the radial and ulnar arteries with extensive collateral channels however, some patients have incomplete palmar arches and might not have adequate communications between the ulnar and radial arteries. In these patients, there is a potential risk of hand ischemia in the event of RA occlusion⁽³⁾. A simple bedside test to check for communications between the ulnar and radial arteries is the Modified Allen's test(AT). Despite these well recognized advantages, the radial approach has challenges that reduce procedural success. These challenges include failure of radial artery (RA) cannulation, the learning curve associated with this technique, small caliber of RA and existence of anatomical variations in

radial distribution and radial anomalies all of which lead to failure and crossover from radial to femoral access (FA). Spasm and injury to RA and often subsequent RA occlusion and patient discomfort are also a cause for apprehension. The importance of sheath-artery mismatch has been shown to correlate with RA spasm and subsequent occlusion. In small individuals and in some ethnic groups, RA size is small. Small artery are more difficult to puncture and because of the stretch even by the smallest available catheters which are >1:1 to the artery size, there is more spasm and discomfort to patients, often leading to procedure failure or crossover to femoral. It has been previously shown that pre-procedure RA sizing can be done using color Doppler to determine the feasibility of using large bore catheters. Not only can pre-procedure assessment of size of the access artery avoid such difficulties by excluding such small arteries beforehand, ultrasound can also be used to determine arterial patency as well as anatomical variations of RA, which may include tortuosity, hypoplasia, anomalous branching and radio-ulnar loops. In addition detection of such anatomical challenge scan identify patients for whom an ulnar artery or contra lateral RA access or even a femoral approach may be preferred. The reasons for this study are to correlate the results of Modified Allen's test with Doppler study to assess the suitability of radial artery for coronary angiography. The aim of the present study is to understand the utility of ultrasound Doppler in comparison to Modified Allen's test and occurrence of the complications after coronary angiography. Therefore the following objectives are studied; (a) To compare the advantages of ultrasound Doppler of forearm vessels over Modified Allen's test in patients undergoing transradial coronary angiography. (b) To observe the adverse outcomes of coronary angiography performed through radial artery.

Material and Methods

Study Design- This is a prospective observational study comparing two modalities for the suitability of radial artery for coronary angiography.

Setting- The present study was undertaken in the Department of Cardiology, Batra Hospital and Medical Research Centre, New Delhi.

Time Period- Over a period from 1st may 2013 to 31st may 2015.

Study Population- Patients undergoing Transradial coronary angiography at Batra Hospital and Medical Research Centre were screened with the Modified Allen's test and Color Doppler imaging. Patients were enrolled consecutively until we reached a pre-specified number of subjects. All patients were asked for informed consent. All patients were also followed during their hospital stay for assessment of complications and their correlations.

Inclusion Criteria- All Patients undergoing Transradial coronary angiography age over 18 years.

Exclusion Criteria- Symptomatic peripheral vascular disease, such as Raynaud's phenomenon, bleeding disorder, not taking antiplatelet therapy, pregnant and lactating female.

Sample Size- Based on the pilot study at the department of cardiology, Batra Hospital, New Delhi, the approximated 15% of reported cases undergone for angiography and type one error at 5%. Therefore, the minimum required sample size is worked out using this information with the absolute marginal error of 10%. The sample size (n) is calculated by using the following formula; where, p = prevalence of angiography = 15% q=100-p = 85% and l= absolute marginal error = 10% now, the minimum sample size calculated was 51 cases for this study. However, we have collected 70 cases to get the robust results.

Procedure- The modified Allen test was performed according to the following protocol. The examiner faces the patient, whose hand is supinated. The radial artery (RA) and ulnar artery (UA) were located by their pulses. The examiner places each thumb lightly over the RA and UA simultaneously, with the 4 fingers of each hand placed behind the patient's wrist, thus holding the wrist lightly between the thumb and fingers. The patient's hand is closed as tightly as possible for a period of 1 minute. The patient is

then asked to relax the hand and extend the fingers into a slightly flexed position while the examiner maintains pressure on the RA and UA. The hand at this point should appear blanched. The examiner then releases the pressure on the UA and continues applying pressure to the RA. The return of color to the hand and fingers was noted. The recovery time was recorded as the time taken (in seconds) for the hand to return to its normal color after the release of the UA. One experienced observer performed all of the tests. An abnormal modified Allen test result was defined as a recovery time of more than 10 seconds.

Color Doppler imaging- Measurement of radial and ulnar arteries diameter were done on both upper limbs at the wrist followed by pulse Doppler interrogation of waveform on both vessels to rule out collateral flow suggesting upstream occlusion. A linear transducer with the frequency 7.5 MHz was used for imaging (Philips Sono 7500). The optimal ultrasound depth setting for imaging of RA was 1-2cm, while that of UA was 3-5cm. The gain of the system was adjusted to ensure optimal imaging and was adjusted in 5% increments on most systems. The transducer were held initially perpendicular to the vessel wall to obtain transverse image. Maximum diameter of the radial artery was measured in transverse view, ideally at 1 cm proximal to the styloid process of the radius. After performing two dimensional imaging of the artery in the transverse view, a longitudinal view of the radial and ulnar artery was obtained to measure the diameter of the artery. The artery was scanned in the gray scale in the transverse and longitudinal plane from the styloid process of the radius to the brachial artery. Next, Color Doppler imaging were performed to assess the presence of flow and to distinguish the artery from surrounding structures. To evaluate for stenosis and occlusion, a pulsed Doppler was done on both radial and ulnar arteries bilaterally with the transducer oriented at an angle of intonation of 45° to 60°. Normal flow was represented by a bi-phasic or tri-phasic signal, while monophasic signal suggested collateral flow from an upstream block in the artery.

All patients enrolled were followed during the hospital stay for the assessment of various complications and correlations. The following events or complications were recorded:- Hematoma, Recurrent bleed after compression, others – persistent pain/swelling/inflammation/ Compartment syndrome. A case record form was filled up detailing patient demographics, clinical status, procedure done and outcome. An attempt was made to correlate complications with abnormal Modified Allen's test and radial artery diameter.

Statistical Analysis: The suitable master chart was prepared using MS Excel 2007 for data analysis. Data contained both continuous and categorical variables. Therefore, mean with SD and frequency with proportions were used for presentation of continuous and categorical variables respectively. The appropriate pie diagram, bar diagram and mean charts were used to depict data graphically. The correlations between the quantitative variables were assessed by scatter plots first and then Pearson's correlation coefficients were calculated. Student -t test or Mann-Whitney "U" for quantitative variables with two independent groups. Chi-square/Fisher's test was used for statistical significance between qualitative variables. The cut-off values for various diameters were computed with sensitivity analysis with 95% confidence intervals. A „p" value less than 0.05 was considered as statistical significant. The Statistical software IBM PASW (Version 22.0) was used for entire analysis.

Ethical Issues: Investigator and supervisor were aware of the ethics in biomedical research policy and declaration of Helsinki revised in 2002. Keeping this in view, written informed consent of all participants was obtained before gathering any information. The study involved no ethical issues related to human or animal experimentation.

Results

Table 1: Majority of the respondents were tobacco abusers followed by 37.1% diabetic respondents and 24.3% respondents were suffering from the problem of hypertension. Out of total only 10.0% was found to be suffered from dyslipidemia.

Table 1: Demographic profile of studied patients

Variables	No. of patients (n)	Percentage (%)
Male	65	92.9
Female	5	7.2
Diabetes	26	37.1
Dyslipidemia	7	10.0
Hypertension	17	24.3
Tobacco abuse	34	48.6

Table 2: The mean age of respondents was found to be 57.4 ± 10.4 years and maximum age of respondents was found to be 78 years and minimum was 35 years of age. Maximum BMI of total respondents was found to be 34 and minimum to be 17. Thus mean BMI was found to be 23.1 ± 3.7 mm. Total 140 radial arteries of both the forearms were studied. The mean internal diameters of right and left radial arteries were 2.5 ± 0.4 mm and 2.4 ± 0.4 mm respectively. The mean diameter of all the radial arteries was 2.5 ± 0.4 mm. Total 140 ulnar arteries of both the forearms were studied. The mean internal diameters of right and left ulnar arteries were 2.7 ± 0.4 mm and 2.7 ± 0.4 mm respectively. The mean diameter of all the ulnar arteries was 2.7 ± 0.4 mm. None of our patients had significant atherosclerosis or stenosis of forearm arteries on Doppler.

Table 2: Descriptive statistics of the studied patients

Variables	Range	Mean \pm SD	95% C.I.
Age (years)	35 – 78	57.4 ± 10.4	54.9 – 59.9
BMI (wt./ht ²)	17 – 34	23.12 ± 3.7	22.3 – 24.1
LRAD	1.8 – 3.2	2.4 ± 0.4	2.3 – 2.5
RRAD	1.8 – 3.3	2.5 ± 0.4	2.3 – 2.6
LUAD	1.9 – 3.6	2.7 ± 0.4	2.5 – 2.8
RUAD	1.9 – 3.7	2.7 ± 0.4	2.5 – 2.8

Table 3: The scatter plots were made to assess the correlation between scale variables and there were no significant correlations between arteries inner

diameters, with Body mass index and Age. However, the diameter of the forearm arteries showed good correlation with each other.

Table 3: Correlation between Age, BMI and Doppler measured Arterial diameters among studied patients

Correlations	Age (years)	BMI	LRAD	RRAD	LUAD	RUAD
Age (years)	1					
BMI	0.165	1				
Left Radial artery diameter	-0.035	0.058	1			
Right Radial artery diameter	-0.038	0.065	.996**	1		
Left Ulnar artery diameter	-0.037	0.078	.944**	.951**	1	
Right Ulnar artery diameter	-0.028	0.097	.974**	.981**	.959**	1

Table 4: Mean LRAD in male and female was found to be 2.45±0.35mm and 2.24±0.32mm respectively in table 5. There were no significant different was found between male and female (p=0.203). Similarly, regarding to the mean RRAD in male and female was found to be 2.49±0.35mm and 2.29±0.35mm that difference was also not statistically significant (p = 0.216).

Mean LUAD in male and female was found to be 2.67±0.43mm and 2.41±0.36mm respectively which was not found to be significant (p=0.197) and also the same regarding mean RUAD in male and female was found to be 2.69±0.423mm and 2.45±0.38mm (p=0.231). Thus, there was a trend towards larger forearm arteries in males which was not statistically significant.

Table 4: Gender wise significance of Forearm artery diameter among the studied patients

Variable	Male (n=65)	Female (n=5)	t-value	p-value
	Mean± SD	Mean± SD		
LRAD	2.45 ± 0.35	2.24 ± 0.32	1.28	0.203
RRAD	2.49 ± 0.35	2.29 ± 0.35	1.25	0.216
LUAD	2.67 ± 0.43	2.41 ± 0.36	1.29	0.197
RUAD	2.69 ± 0.42	2.45 ± 0.38	1.21	0.231

Table 5: Correlation between complications and modified Allen’s test shows significant correlation was found between arterial spasm (p<0.001) and

cross over (p value=0.010) whereas insignificant correlation was found between Hematoma (p value=0.215) & modified Allen’s test.

Table 5: Percentage risk of complications with Modified Allen’s test Positive and Negative among the studied patients

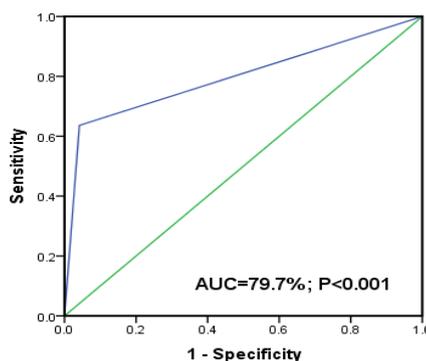
Variables	Modified Allen's test				Combined		P value
	Negative (n=54)		Positive (n=16)		(N=70)		
	n	%	n	%	n	%	
Arterial spasm							
No	46	85.2	2	12.5	48	68.6	p<0.001
Yes	8	14.8	14	87.5	22	31.4	
Crossover							
No	54	100	13	81.3	67	95.7	0.010
Yes	0	0	3	18.8	3	4.3	
Hematoma							
No	47	87	12	75	59	84.3	0.215
Yes	7	13	4	25	11	15.7	

Figure 1: The ROC analysis was used for classification of complications by modified Allen’s test. Arterial Spasm (AUC=79.7%; p<0.01) and Crossover (AUC=90.3%; p<0.05)

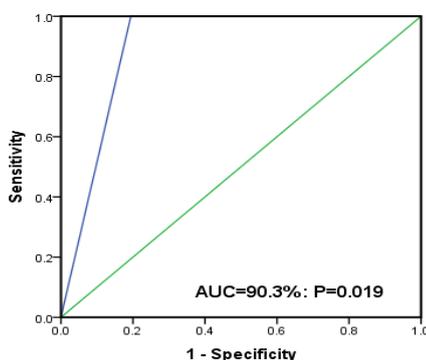
were well classified by the test however Hematoma (58%; p>0.05) was not found significant.

Figure 1: Prediction of complications by Modified Allen’s test using ROC analysis

(a) Arterial Spasm



(b) Crossover



(c) Hematoma

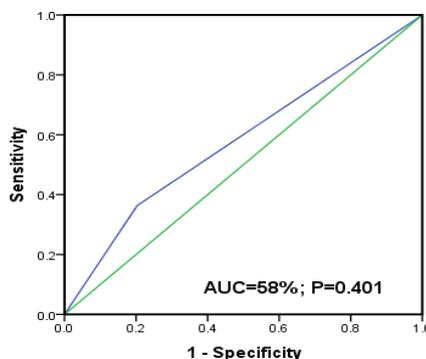


Table 6: Shows a positive modified Allen’s test appears most useful in predicting arterial spasm.

Table 6: Predictability of complications by Modified Allen’s test

Type of complications	Sensitivity 95% C.I.	Specificity 95% C.I.	PPV 95% C.I.	NPV 95% C.I.
Arterial Spasm	63.6 (40.8-82.0)	95.8 (84.6-99.3)	87.5 (60.4-97.8)	85.2 (72.3-92.9)
Crossover	100.0 (30.9-100.0)	80.6 (68.8-88.9)	18.8 (5.0-46.3)	100.0 (91.7-100.0)
Hematoma	36.4 (12.4-68.4)	79.7 (66.8-88.6)	25.0 (8.3-52.6)	87.0 (74.5-94.2)

Table 7: Further, correlation between modified Allen’s test and radial artery diameter is presented which shows statistically highly significant correlation between the positive Modified Allen’s

test and Doppler measured Forearm artery diameters stating smaller diameters were found in patient with a positive Modified Allen’s test.

Table 7: Correlation between the Doppler measured Arterial diameter and Modified Allen's Test

Variables	Modified Allen's test	N	Mean	SD	P value
Left radial artery diameter	Positive	16	2.01	0.11	p<0.001
	Negative	54	2.56	0.29	
Right radial artery diameter	Positive	16	2.05	0.12	p<0.001
	Negative	54	2.61	0.29	
Left Ulnar artery diameter	Positive	16	2.15	0.12	p<0.001
	Negative	54	2.80	0.37	
Right Ulnar artery diameter	Positive	16	2.17	0.11	p<0.001
	Negative	54	2.82	0.36	

Discussion

Coronary interventions have become an essential part in the management of patients with CAD. Percutaneous coronary procedures are usually performed via the transfemoral approach. Transradial access for coronary artery catheterization has several advantages in comparison with the transfemoral route. Bleeding complications at the femoral puncture site can result in increased morbidity and duration of hospitalization. Transradial approach reduces access site bleeding complications, allows earlier ambulation, and improves patient comfort. The near elimination of bleeding complications makes the radial artery a safe entry site for coronary procedures in patients with normal Allen test results.

Majority of the respondents 92.9% in our study were male, similar to a study by Choussat et al (2000) (90.3%)⁽⁴⁾. Nearly fifty percent (48.6%) of the respondents were tobacco abusers followed by 37.1% diabetic respondents was similarly reported by Yokoyama et al⁽⁵⁾ (2000) i.e., 36.5% and 24.3% respondents were suffering from the problem of hypertension in the present study whereas in a recent study by Pal et al (2014)⁽⁶⁾ quoted as 38.5%. This difference may be depending on the sample size and study duration. Out of the total, only 10.0% was found to be suffered from dyslipidemia which is low as found to be 34.18% in a study by Pal et al (2014)⁽⁶⁾. The mean age of respondents was found to be 57.4±10.4 years as compared to 51.9±9.8 and maximum age of respondents was found to be 78 years and minimum was 35 years of age which was also similar to be 75 & 32 years respectively by Ashraf et al (2010)⁽⁷⁾. Maximum BMI of total

respondents was found to be 34 and minimum to be 17. Thus mean BMI was found to be 23.12 ± 3.7. Maximum artery diameter in total respondents was found to be 3.7mm of Right Ulnar Artery diameter (RUAD) and minimum of 1.81mm of Left Radial Artery diameter (LRAD). Mean RUAD was found to be 2.7 ± 0.4mm and mean LRAD to be 2.4 ± 0.4mm in total respondents. Mean Right Radial Artery diameter (RRAD) was 2.5 ± 0.4mm and mean Left Ulnar Artery diameter (LUAD) was 2.7 ± 0.4mm. Insignificant difference was found in left (2.44±0.35mm) and right radial (2.48±0.35mm) artery diameter of respondents (p=0.470) and also insignificant difference was found in left (2.65±0.43mm) and right ulnar (2.67±0.42mm) artery diameter of respondents (p value = 0.782) which is same as found in Doscher and colleagues⁽⁸⁾.

The mean radial artery diameter in our study was 2.457±0.352 mm which is close to the measurement taken by Yee et al⁽⁹⁾ but is less than that of Japanese population i.e. 3.10±0.06mm in male and 2.80±0.60mm in females⁽¹⁰⁾. But if overall diameter of artery was compared then highly significant difference was found between radial and ulnar artery diameter of the respondents (p<0.001) which is similar to findings of Tariq Ashraf et al⁽⁷⁾. Insignificant difference was found in mean radial artery diameter of diabetic respondents 2.5 ± 0.4mm and non-diabetic respondents 2.5±0.3mm (p=0.748) and mean ulnar artery diameter in diabetic respondents 2.7±0.5mm and non-diabetic respondents 2.6 ±0.4mm (p=0.641) which is in contrast to the study of Yee et al⁽⁹⁾. Insignificant difference was found in mean radial artery diameter of hypertensive respondents 2.4±0.4mm and non-

hypertensive respondents 2.5 ± 0.4 mm ($p=0.721$) and mean ulnar artery diameter in hypertensive respondents 2.6 ± 0.4 mm and non-hypertensive respondents 2.7 ± 0.4 mm ($p=0.616$) in contrast to a study by Yee et al⁽⁹⁾, but similar to Ashraf et al⁽⁷⁾. Insignificant difference was found in mean radial artery diameter of dyslipidemia respondents 2.5 ± 0.4 mm and non-dyslipidemia respondents 2.4 ± 0.4 mm ($p=0.722$) and mean ulnar artery diameter in dyslipidemia respondents 2.7 ± 0.4 mm and non-dyslipidemia respondents 2.6 ± 0.4 mm ($p=0.804$) which is same as found in study a study by Pal et al⁽⁶⁾.

Significant correlation was found between arterial spasm ($p<0.001$) and cross over ($p=0.010$) which is similar to the study of Abdelaal et al⁽¹¹⁾, whereas insignificant correlation was found between hematoma ($p=0.252$) with Doppler measures radial artery diameter & modified Allen's test. Modified Allen's test was positive in 16 out of 70 patients in our study. Positive test had significant correlation with the arterial diameters measured by Doppler and were predictive of complications. In fact once the Modified Allen's test was factored in, the Doppler measurement of radial artery diameter yielded no further independent information regarding the likelihood of complications in our study.

In our set up, we are also presently not doing modified Allen's test or Doppler measurement of radial artery diameter routinely and there has been no published study in the literature of hand ischemia after transradial procedures or after surgical harvest related to the state of the Allen's test. This suggests that the hand circulation is very resilient and the sequelae of hand ischemia is at least rare. The radial artery approach has now been widespread for 15 years, and is used at hundreds of cardiac centres. Therefore, many thousands of patients have undergone transradial procedures either with a false positive Allen's test or with no assessment of palmar arch circulation at all. If one accepts that 5% of these patients will develop radial artery occlusion, without significant hand ischemia correspondence by Gilchrist⁽¹²⁾. There is no evidence that a normal

Modified Allen's test is required for the safe undertaking of a transradial procedure. It is important not to deny this access site to patients with an abnormal test, particularly those in whom a femoral procedure carries increased risks. Nevertheless a Modified Allen's is easy to perform and may alert the operator to the possibility of complications as in our study.

Conclusion

Use of Modified Allen's test as a screening tool to assess the collateral circulation of hand correlates well with the occurrence of complication and there has been a significant correlation between the positive Modified Allen's test and Doppler measured radial artery diameter and the occurrence of complications in our study. So performing the Modified Allen's test is recommended and if turned out to be positive, then there is no additional information obtained by Doppler study, rather we may exercise extreme caution or change the access site if the Modified Allen's is positive.

Limitations of the Study

Findings of our study should be considered in the light of certain limitations. The acceptability at large is limited due to small sample size, and a study with a larger sample size is required for further assessment and confirmation. Our study is based on single centre; therefore one should carry forward a study with multiple centres. The duration of the data collected for this study was small. One can consider longer duration to look at the complications.

Conflict of Interest: None

Source of funding: None

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