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Endovascular Versus Open Versus Hybrid Revascularisation In Infra Inguinal Disease – 2 Years Prospective Study in A Tertiary Care Center in South India

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ABSTRACT

Our aim is to share the clinical experience of endovascular, open and combined hybrid revascularization in infra inguinal disease and compare the results. A prospective study of 150 patients undergoing infra inguinal procedures was done, a period ranging from October 2017 to June 2019 with 3 months follow up. A number of patients undergoing CT – Angiogram, Digital Subtraction Angiogram (DSA) were recorded. A number of cases undergoing Angioplasty, Catheter Directed Thrombolysis (CDT), Open Surgical Bypass were noted. Cases of acute limb ischemia were excluded and chronic cases included in our study, age 35-85 years, sex distribution male 134 (89.3%) and female 16 (10.7%) cases. Similarly, individual risk factors were stratified. Ct angiogram was done in 60 (40%) and DSA in 90 (60%) cases. Diagnostic variables : left fempop occlusion 42 (28%), right fempop occlusion 55 (36.7%), left tibial occlusion 18 (12%) and right tibial occlusion 35(23.3%). Treatment procedure variables : CDT and Angioplasty 1(0.7%), angioplasty 87(58%), angioplasty and bypass 8 (5.3%), bypass 35 (23.3%), CDT 15 (10%), CDT and bypass 4 (2.7%). The results of the analysis were compared and statistical significance P-value were calculated by chi-square tests, SPSS software. Statistic significance was seen for risk factors CAD (0.001), Smoking (0.008), Hypertension (0.000) on comparison to treatment procedures and for corresponding clinical diagnosis (0.002), investigation modality (0.000) and treatment procedures.

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INTRODUCTION

Chronic occlusive atherosclerosis of the infra inguinal vessel is the most prevalent manifestation of peripheral arterial disease (PAD) (Lyden and Smouse, 2009). The mainstay of treatment for infra inguinal PAD (Van Den Berg *et al.*, 2012) Has been arterial bypass surgery, but recent advanced endovascular interventions have challenged surgery as the first-line treatment. The transatlantic Inter-Society Consensus (TASC) classification suggests the choices for first-line therapy and predicts successful intervention, endovascular or open, or hybrid procedure based on lesion location and length. Infra inguinal PAD affects different levels, femora popliteal or tibial arteries especially in cases of critical limb ischemia (CLI) (Balaz *et al.*, 2012). The anatomic variables, combined with patient-specific comorbidities, making therapeutic decisions more complex. Nowadays endovascular interventions can be combined with open revascularization,

creating so-called hybrid procedures (Dosluoglu *et al.*, 2010). The common occurrence of different level infra inguinal occlusive disease has increased the need for hybrid procedures (Fernandez *et al.*, 2011). At this juncture, hybrid procedures are reported to consist of 5-21% of a total number of vascular reconstructions and many authors have demonstrated the efficacy of hybrid procedure for the treatment of severe lower extremity arterial disease. The disease burden steadily raises with age, diabetes, hypertension, dyslipidemia and smoking. Rapid advances in Catheter-based technology → a shift towards the endovascular approach.

Aim

To share our clinical experience of endovascular, open and combined hybrid revascularization procedures in infra inguinal disease and compare results.

MATERIALS AND METHODS

A non-randomized prospective study of 150 patients undergoing infra inguinal procedures were done. The study period ranges from October 2017 to June 2019, with 3 months follow up. A number of patients undergoing CT – Angiogram, Digital Subtraction Angiogram (DSA) were recorded. A number of patients undergoing Angioplasty, Catheter Directed Thrombolysis (CDT), Open surgical bypass were noted. Comparative analysis was done to stratify the uses of various modalities for an optimal outcome. Patients of acute limb ischemia and chronic limb ischemia included with symptoms being incapacitating claudication, rest pain, ulcer/ gangrene.

RESULTS

In our study, the patient's age range was between 35-85 years, Mean age 57 and Standard deviation 11.6. Gender distribution was male 134 (89.3%) and female 16 (10.7%). On risk factor comparison, diabetes was present in 54 (36%) and absent in 96 (64%) cases. Hypertension was present in 33(22%) and absent in 117 (78%). Smokers 76 (50.7%) and non-smokers 74 (49.3%). Dyslipidaemia was present in 75 (50%) cases. CAD was present in 48 (32%) and absent in 102 (68%). CKD was present only in 8(5.3%) and absent in 142 (94.7%). As diagnostic investigations, CT Angiogram was done in 60(40%) and DSA in 90 (60%) patients. Diagnostic variables were Right fempop occlusion 55 (36.7%), Left fempop occlusion 42 (28%), Right tibial occlusion 35(23.3%) and Left tibial occlusion 18 (12%). Treatment procedure variables – Angioplasty 87 (58%), Open surgical bypass 35 (23.3%), CDT 15 (10%), Angioplasty and Bypass 8 (5.3%), CDT and Bypass 4 (2.7%), CDT and Angioplasty 1 (0.7%) patients. Table 1, Figures 2, 3 and 4.

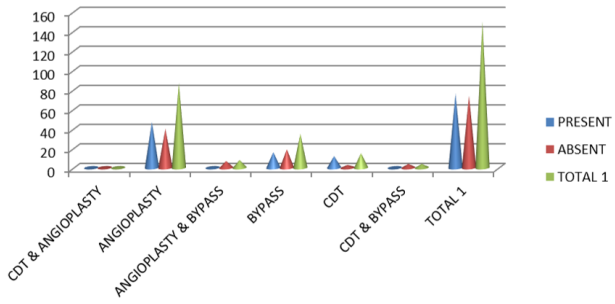

Figure 1: Smoking– significant P value

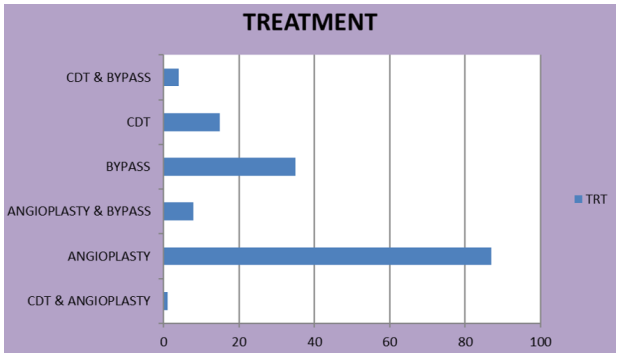

Figure 2: Distribution– treatment variables

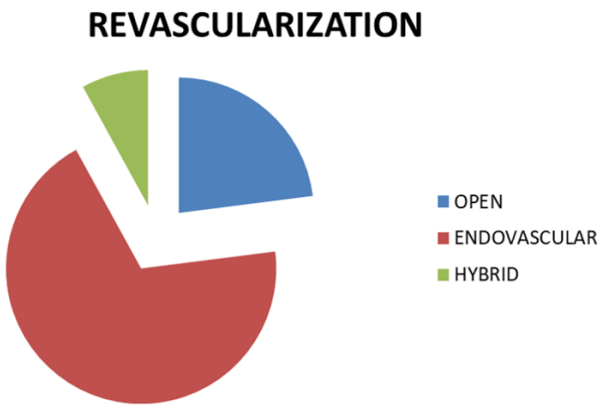

Figure 3: Distribution of procedures – nutshell

By Cross table analysis of procedure with diagnostic modality, CT Angiogram was done highest 23 (38.3%) for Open surgical bypass patients and none in CDT and Angioplasty patient. DSA skyrocket 67 (74.4%) for angioplasty patients and least 1 (1.1%) for CDT- Angioplasty and CDT – Bypass cases. Here, statistically significant P value 0.000($\leq$0.05) was seen, found using chi-square tests, SPSS software. Tables 2 and 3. On comparing clinical diagnosis with the investigation, CT Angiogram was done highest for 28 (46.7%) Right fempop patients and lowest in Left tibial occlusion 4 (6.7%) cases. DSA was done highest for 29 (32.2%) Right tibial occlusion cases and lowest for 14 (15.6%) Left- tibial occlu-

Table 1: Treatment Variables

		Frequency	Percent%	Valid Percent	Cumulative Percent
Valid	CDT & Angioplasty	1	.7	.7	.7
	Angioplasty	87	58.0	58.0	58.7
	Angioplasty & Bypass	8	5.3	5.3	64.0
	Bypass	35	23.3	23.3	87.3
	CDT	15	10.0	10.0	97.3
	CDT & Bypass	4	2.7	2.7	100.0
	Total	150	100.0	100.0	

Table 2: Treatment vs investigation analysis

			Investigation		
			CT	DSA	Total
TRT	CDT & Angioplasty	Count	0	1	1
		% within Investigation	.0%	1.1%	.7%
	Angioplasty	Count	20	67	87
		% within Investigation	33.3%	74.4%	58.0%
	Angioplasty & Bypass	Count	2	6	8
		% within Investigation	3.3%	6.7%	5.3%
	Bypass	Count	23	12	35
		% within Investigation	38.3%	13.3%	23.3%
	CDT	Count	12	3	15
		% within Investigation	20.0%	3.3%	10.0%
	CDT & Bypass	Count	3	1	4
		% within Investigation	5.0%	1.1%	2.7%
Total		Count	60	90	150
		% within Investigation	100.0%	100.0%	100.0%

Table 3: Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	33.592	5	.000
Likelihood Ratio	34.582	5	.000
N of Valid Cases	150		(significant P-value)

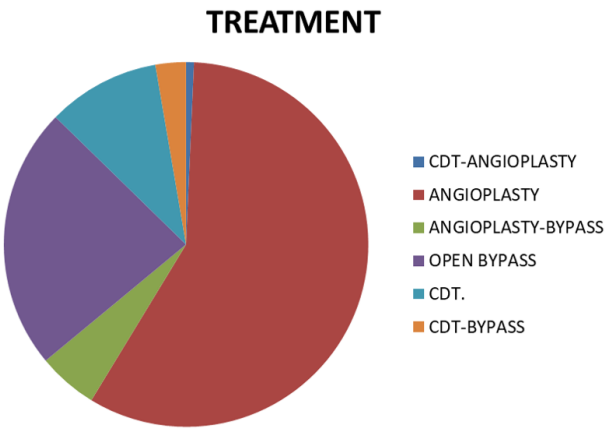

Figure 4: Elaborate distribution – procedures

sion cases. By the Chi-square test, here P value was 0.002 ($\leq$0.05) and significant. Among all treatment variables, Angioplasty was done highest for diabetics 31 (35.6%) and non-diabetics 56 (64.4%), the P-value was found to be 0.131 and not significant. All CKD cases 8 (8.9%) DSA was diagnostic modality and none for CT angiogram. By Chi-square test, P-value was 0.018 ($\leq$0.05) and significant. Among treatment procedures, Angioplasty was done highest in smokers 47(54%) and non-smokers 40(46%), the P-value was 0.008($\leq$0.05) and significant Figure 1. Similarly, Angioplasty was done highest for hypertensives 11(12.6%) and non – hypertensives 76(87.4%) cases, P-value 0.000($\leq$0.05) and significant. Among CAD cases, Angioplasty was done highest 22 (25.3%) and lowest only one underwent CDT and Angioplasty, P-value 0.001($\leq$0.05) and significant. Among dyslipidemic, Angioplasty was done highest 46 (52.9%), P-value 0.161 ($\geq$0.05) and not significant. Among CKD cases, Angioplasty was done highest 6 (6.9%) and P-value 0.848 ($\geq$0.05) and not significant. Of total 150 cases, Open surgical revascularization was done in 35 (23%), Endovascular in 103 (69%) and Combined Hybrid revascularization in 12 (8%) patients (Figure 3). Number of Amputations, below the knee – 5, above the knee – 4 and reported death in 3 cases.

DISCUSSION

The treatment of infra inguinal disease often requires complete revascularization of affected levels femoro popliteal/tibial, to renew blood flow to pedal circulation. Revascularization leads to relief from rest pain and healing of ulcer or gangrene. Conventional open surgical management of lesions require extensive revascularization and lengthy procedure, commonly associated with significant morbidity and mortality and typically reserved for physiologically younger patients. Endovascular interventions are preferred for elderly, high-risk cases, but in practice, we encountered situations where difficulty in proceeding with angioplasty alone because of simultaneous calcifications and stenosis of arteries. The hybrid procedures offer a solution for vascular lesions in which endovascular treatment may be used for in-flow or out-flow lesions and then open surgery if needed based on clinical response (Matsagkas *et al.*, 2011).

In our centre, we did endovascular interventions for simple lesions (TASC A or B). Having gained, experience, we included complex TASC C or D lesions, decreasing the frequency of open reconstruction. The important technical aspect of the endovascular procedure was the crossing of the occlusive lesion by a guidewire (Conrad *et al.*, 2011).

Our study population included 150 cases with significant comorbid risk factors, which predominantly presented with CLI (Critical Limb Ischemia). Dyslipidemia, Smoking, Diabetes, Hypertension, CAD (Coronary Artery Disease) and CKD (Chronic Kidney Disease) were risk factors studied. DSA scored over CT angiogram as diagnostic modality reason being lesser iodine contrast dye toxicity for CKD cases, affordability and one time combined diagnostic and therapeutic possibility in DSA & proceed. Similarly, DSA and Angioplasty was the most performed treatment procedure followed later by the open surgical bypass, CDT, Angioplasty and Bypass, CDT and Bypass and the least being CDT and Angioplasty, respectively.

Endovascular intervention for the treatment of limb ischemia has emerged as first-line therapy in many centers (Gargiulo and Connor, 2011). The rapid growth of endovascular modality has lead to a significant decline in open surgical revascularization. Minimally invasive nature of endovascular treatment and improved outcomes are reasons (Schrijver *et al.*, 2010). Multiple endovascular interventions to sustain long term patency possible as opposed to single surgical revascularization. Failed bypass grafts undergoing endovascular therapy has significant improvement in limb salvage (Scali *et al.*, 2011). TASC guidelines, Improvements in ABI and Rutherford grading were used to stratify and follow up on cases. The main limitations of our study were no long term follow up of cases and non-inclusion of patency rates.

CONCLUSION

With increasing technological advancements, the endovascular modality has emerged as a significant tool in reducing morbidity and mortality. Our future work aims to look into the patient's intrinsic factors

to gain insight into the impact of endovascular revascularization on the management of cases with infra inguinal disease.

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