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 femop occlusion 42 (28%), right femop 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.

**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 infrainguinal PAD (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. Infrainguinal PAD affects different levels, femoral 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 infrainguinal 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 infrainguinal disease and compare results.

MATERIALS AND METHODS
A non-randomized prospective study of 150 patients undergoing infrainguinal 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 incapaciting 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(≤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.
### Table 1: Treatment Variables

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

### Table 3: Chi-Square Tests

| Test                | 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

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 treat 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.

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).
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 infrainguinal disease.

REFERENCES

Balaz, P., Rokosny, S., Bafrecn, J., Björck, M. 2012. The Role of Hybrid Procedures in the Management of Peripheral Vascular Disease. Scandinavian Journal of Surgery, 101(4):232–237.

Berg, J. V. D., Waser, S., Trelle, S., Diehm, N., Baumgartner, I. 2012. Lesion characteristics of patients with chronic critical limb ischemia that determine the choice of treatment modality. The Journal of Cardiovascular Surgery, 53(1):45–52.

Conrad, M. F., Crawford, R. S., Hackney, L. A., Paruchuri, V., Abularrage, C. J., Patel, V. I., Cambria, R. P. 2011. Endovascular management of patients with critical limb ischemia. Journal of Vascular Surgery, 53(4):1020–1025.

Dosluoglu, H. H., Lall, P., Cherr, G. S., Harris, L. M., Dryjski, M. L. 2010. Role of simple and complex hybrid revascularization procedures for symptomatic lower extremity occlusive disease. Journal of Vascular Surgery, 51(6):1425–1435.

Fernandez, N., Mcenaney, R., Marone, L. K. 2011. Multilevel versus isolated endovascular tibial interventions for critical limb ischemia. Journal of Vascular Surgery, 54(3):722–729.

Gargiulo, N. J., Connor, D. J. 2011. The proportion of patients with critical limb ischemia who require an open surgical procedure in a center favoring endovascular treatment. American Surgeon, 77(3):315–321.

Lyden, S. P., Smouse, H. B. 2009. TASC II and the endovascular management of infrainguinal disease. Journal of Endovascular Therapy: An Official Journal of the International Society of Endovascular Specialists, 16(2):15–18.

Matsagkas, M., Kouvelos, G., Arnaoutoglou, E., Papa, N., Labropoulos, N., Tassiopoulos, A. 2011. Hybrid Procedures for Patients With Critical Limb Ischemia and Severe Common Femoral Artery Atherosclerosis. Annals of Vascular Surgery, 25(8):1063–1069.

Scali, S. T., Rzucidlo, E. M., Bjerke, A. A., Stone, D. H., Walsh, D. B., Goodney, P. P., Powell, R. J. 2011. Long-term results of open and endovascular revas-