OUTCOME ANALYSIS FOLLOWING TIBIAL ANGIOPLASTY IN PATIENTS WITH CRITICAL LIMB ISCHEMIA - A SINGLE CENTRE EXPERIENCE.

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Introduction:

Peripheral arterial disease affects a major portion of our elderly population. Presentation vary from claudication pain, rest pain to major or minor tissue loss. Main aim of intervention is to restore blood flow to the affected limb, thereby promoting wound healing and relief of rest pain. Sites of arterial involvement can be focal or multisegmental. Surgical intervention include open revascularisation or endovascular approach depending on the site of lesion and also taking into consideration patients co morbidities. As a major proportion of the elderly population have other associated risk factors like diabetes, hypertension, coronary artery disease, etc, endovascular approach has played a major role in reducing the morbidity and mortality rates.

Keywords:-
Critical limb ischemia, infra popliteal, angioplasty
Materials and methods:-
This was a single centre retrospective observational study which analysed 29 patients with PAD involving the infrapopliteal segment, between January 2016- Jan 2018. A total number of 29 patients (21 men and 8 females; mean age 62 years, range 38–84) with CLI (class 4 to 6 according to Rutherford) were included. All the patients underwent tibial angioplasty targeted at single vessel or double vessel. The primary study endpoints were wound healing, relief of rest pain, avoiding major amputation of the target limb at 6 months and occurrence of local and systemic complications specifically related to use of endovascular treatment.

| Characteristic                      | n (%)        |
|------------------------------------|--------------|
| Males                              | 21 (72%)     |
| Females                            | 8 (27%)      |
| Average age of presentation(years) | 62 years     |
| **Presentation**                   |              |
| Rest pain                          | 20 (68%)     |
| Major tissue loss                  | 16 (55%)     |
| Minor tissue loss                  | 5 (17%)      |
| Non healing stump                  | 4 (13%)      |
| Type2 diabetes                     | 18 (62%)     |
| Smoking/ tobacco consumer          | 21 (72%)     |
| **Revascularisation**              |              |
| Single vessel                      | 25 (86%)     |
| Double vessel                      | 4 (13%)      |
| All three vessels                  | Nil          |
| **Complication**                   |              |
| Puncture related(hematoma)         | 2 (6%)       |
| Dissection                         | 3 (10%)      |
| Perforation                        | 0            |
| Recoil                             | 6 (20%)      |
| **Outcomes**                       |              |
| Pulpable pulse/ABI improvement     | 18 (62%)     |
| Wound healing/ relieved of rest pain| 21 (72%)    |
| Conversion to open bypass          | 3 (10%)      |
| Amputation free survival at 6 months| 22 (75%)   |
| Major amputation                   | 3 (10%)      |
| Minor amputation                   | 4 (13%)      |
| **Primary patency rates:**         |              |
| 1 month                            | 21 (72%)     |
| 6month                             | 14 (48%)     |

Results:-
29 patients with infrapopliteal arterial involvement were evaluated. 72% of patients were male (21-male, 8-female, M/F: 2.6/1). The mean age was 62 years at the time of diagnosis. About 62 % of the patients were diabetics. The sex wise distribution and percentage of diabetics are given in figure 1and 2 respectively.
**Figure 1:** Sex distribution of patients

| Sex   | Count |
|-------|-------|
| Male  | 21    |
| Female| 8     |

**Figure 2:** Percentage of diabetic patients mostly presented with rest pain (68%) and tissue loss - major tissue loss (55%), minor tissue loss (17%) non healing stump (13%)

| Condition             | Count |
|-----------------------|-------|
| Diabetic              | 18    |
| Non-diabetic          | 11    |
Figure 3: Outcome was mainly evaluated by assessing the pulse status, rate of wound healing, conversion to open bypass procedure and amputation rates.

Figure 4: Complications included puncture site hematoma in 2 patients (6.9%), dissection was seen in 3 patients (10%), recoil of the target vessel seen in 6 patients (20%).
Figure 4: Complication Patients were regularly followed in OPD and patency was assessed with doppler ultrasound. Primary patency rate at 1 month was 72% and at 6 months 48%.

Discussion:
The prevalence of lower extremity peripheral arterial disease varies with population, but is approximately 10 percent of adults above the age of 55 years. The clinical presentation is varied from asymptomatic to intermittent claudication to limb threatening ischemia. Management include medical interventions such as smoking cessation, antithrombotic and lipid lowering therapy, diabetic and hypertension control. For those with significant or disabling symptoms not responding to pharmacologic therapy and lifestyle adjustment intervention (percutaneous, surgical) is advised.
The long-term effectiveness of percutaneous intervention is based upon the length and site of the lesion. Short, focal stenosis present with mild-to-moderate symptoms and respond well with interventional therapies. Percutaneous intervention is also preferred in poor surgical candidates with more extensive PAD, or for limb salvage before performing distal surgical bypass. Lesions with unfavorable anatomy such as long segment stenosis or occlusion, multifocal stenoses and eccentric calcified stenosis are associated with severe symptoms and will mostly require surgical intervention.

Revascularisation options for symptomatic tibial artery disease include angioplasty alone, angioplasty with adjunctive stenting, or primary stenting. Primary stenting is preferred for calcific or long segment lesions. Long term patency rate of percutaneous angioplasty for popliteal and tibial vessels are lower than PTA for aortoiliac disease. Smaller vessel diameter is the commonest cause for restenosis in the popliteal and infrapopliteal vessels. Other factors which negatively affect the long term patency include arterial occlusion, multiple vessel atherosclerotic disease, long or eccentric segment calcified lesion, poor distal run off and high Rutherford category. Below knee area is also prone to higher rates of restenosis, thrombosis and amputation in comparison to other vascular territories (2,3).

Multiple studies have evaluated the outcomes of endovascular revascularisation of infrapopliteal arterial occlusive disease and has found it comparable to bypass in terms of high limb preservation rates and lower rates of complications (4). A study by Mohapatra et al. compared bypass vs endovascular approach for tibial artery disease in patients with ischemic foot ulcers. It was found that at 6 months and 1 year follow up, the primary patency in the endovascular group was found to be lower than the bypass group (53.1% vs 38.2%) but the secondary patency was similar and the wound healing was better in the endovascular group (29%) compared to the bypass group (22.4%). In hospital complications including myocardial infarction and longer hospital stay was found to be significantly more with the bypass group. It was thus concluded that endovascular approach for tibial artery disease was a lower risk alternative to bypass with similar outcomes (5). Similar study by Kaichung et al. compared outcomes of endovascular revascularisation versus venous bypass for tibioperoneal arterial occlusion and found that the amputation free survival for ER was similar to bypass but was associated with lower patency rate and higher rates of reintervention (6). Primary stenting is also an evolving option for infrapopliteal disease. It was found to reduce the risk of reintervention and amputation, better wound healing, compared with plain balloon angioplasty with no negative impact on the mortality rates and Rutherford class (7,8). But issues of cost effectiveness, stent design, bare metal vs drug eluting stent are areas of debate and hence requires further randomised control trials.

Conclusion:
Our study showed that endovascular treatment of infrapopliteal disease is an effective and safe treatment in patients experiencing CLI, provides high limb preservation and lower complication rates. Study outcomes support endovascular treatment as a primary option for patients experiencing CLI due to infrapopliteal occlusive disease.

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