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Original Article

Surgery Section

Outcomes of Aortoiliac Occlusive Disease Treated by Aorto-femoro-popliteal and Distal Bypass Surgeries: A Prospective Cohort Study

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ABSTRACT

Introduction: Aortoiliac occlusive disease can contribute to lower extremity ischaemic symptoms requiring intervention. Though proximal aorto-femoral bypass surgery has been the mainstay of intervention, the delayed healing in many patients necessitates exploration of other techniques, including sequential revascularisation.

Aim: To estimate the outcomes of aortoiliac occlusive disease treated by aorto-femoro-popliteal and distal bypass surgeries.

Materials and Methods: A prospective cohort study was conducted to determine the treatment outcomes of 25 patients with aortoiliac occlusive disease visiting a tertiary care centre of Government Stanley Medical College and Hospital, Chennai, Tamil Nadu, India from October 2012 to December 2014. Data regarding the aetiology of the disease, co-morbidities including substance use, degree of disease involvement, and treatment modalities were collected. Data was analysed by Statistical Package for Social Sciences (SPSS) software version 22.0. The Chi-square test was used to compare outcomes with different treatment modalities, and a p-value <0.05 was considered statistically significant.

Results: The mean age of the study participants was 58.3±2 years (range 40 to 70 years). The study noted that the most common aetiology for aortoiliac occlusive disease was atherosclerosis in 18 (72%) cases. The most common associated co-morbidity was smoking in 18 (72%) cases. Abnormal profunda patency was noted in 15 (60%) cases and synthetic Polytetrafluoroethylene (PTFE) was used in 80% of sequential bypass cases. A significantly higher proportion (86.7% vs 30%) of people treated by the sequential procedure achieved relief from claudication pain (p-value <0.05). The complication noted after the proximal bypass was pseudoaneurysm (20%), and the only complication noted after the sequential bypass was graft thrombosis (13.33%). The mean Ankle-brachial Index (ABI) score and ulcer healing time were also significantly higher in the sequential bypass procedure (p-value <0.05).

Conclusion: Sequential bypass offers better advantages than proximal bypass for treating aortoiliac occlusive disease. It was found to be a safe and effective method for successful limb salvage, ensuring successful limb revascularisation and sufficient outflow to maintain graft patency.

Keywords: Arterial occlusive disease, Arteriovenous shunt, Limb salvage, Vascular grafting

INTRODUCTION

Critical Limb Ischaemia (CLI) is a severe form of Peripheral Artery Disease (PAD) posing a crucial problem in vascular surgery associated with high mortality and morbidity. The predisposing factors of CLI include smoking, diabetes, hypertension, dyslipidemia, and chronic kidney disease [1]. CLI leads to peripheral complications such as ulceration, gangrene, and infection, with a high risk of lower limb amputation [2]. Therefore, several approaches are available to treat CLI, such as exercise, pain and ulcer management, and revascularisation [3].

Traditional aorto-femoral grafting is used as a first-line therapy for more complex patterns of the disease, or as a secondary or tertiary procedure in the case of recurrent disease. High levels of patient satisfaction and excellent long-term outcomes remain the hallmark of aortobifemoral surgical revascularisation [4].

The treatment of chronic CLI remains one of the most challenging problems in vascular surgery and is caused by multi-segmental disease of the arterial tree, involving both the aorto-femoral and infrainguinal vessels [1,5]. Relevantly, the impact of synchronous superficial femoral artery disease on the results of aortoiliac revascularisation remains undefined in the current literature. Some reports have indicated similar patency rates between patients with and without superficial femoral artery occlusion [6,7], whereas others have reported lower long-term patency rates [8].

If an atretic or prohibitively diseased profunda is present in addition to a severely diseased superficial femoral artery, infrainguinal bypass grafting is likely necessary to ensure sufficient outflow for graft patency and foot perfusion [9]. The optimal management of patients with multilevel occlusive disease is often difficult to determine. The treatment planning centre around whether the lesion should be approached with inflow and outflow procedures either stage-wise or at the same time [10].

The aim of present current study was to compare the results after simultaneous and two-stage surgery in select patients for sequential aorto-femoro-popliteal distal reconstruction.

MATERIALS AND METHODS

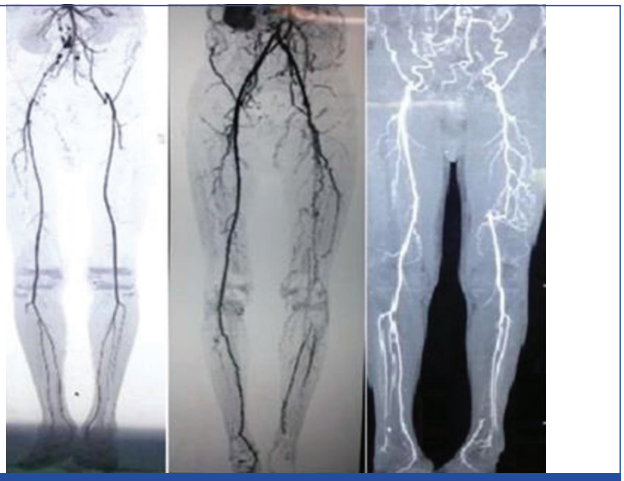
The present study was conducted at Govt. Stanley Medical College and Hospital, Chennai, Tamil Nadu, India from October 2012 to December 2014. A prospective cohort study was carried out on a total of 25 patients. Ethical clearance was obtained from the Institutional Ethical Committee at Study Institute Chennai (IEC/2013/9.7-SMC) before the study commenced. Written informed consent was obtained from all the participants before enrolment in the study.

Inclusion criteria: Patients visiting the Outpatient Department (OPD) of Vascular Surgery in tertiary care centre with CLI were selected for the study. All patients with CLI and vascular multilevel occlusive disease below the infrarenal aorta were included in the present study.

Exclusion criteria: Patients with vascular trauma, single-level occlusive disease, aortic aneurysm, subacute bacterial endocarditis, extra anatomical bypasses, undergoing malignancy treatment and combined interventional and surgical procedures were excluded from the study.

Study Procedure

The selected patients were admitted and evaluated with a proper clinical history followed by a thorough clinical examination. The multilevel occlusive disease was confirmed using a Computed Tomography (CT) angiogram [Table/Fig-1].



[Table/Fig-1]: CT angiograms showing multilevel occlusions.

In present study, aorto-femoro-popliteal distal reconstruction, consisting of proximal and sequential types, was performed. Based on the patency of the profunda in the angiogram and the profunda popliteal index [11], all the patients with patent vessels were treated with the aorto-femoro-popliteal distal reconstruction procedure, while those with complete blocks were treated with the sequential type.

During the aorto-femoro-popliteal distal reconstruction procedure [12], the femoral vessels were typically exposed first to reduce the time during which the abdomen was open and the viscera were exposed. The extent of exposure was dictated by the severity of the disease and the level of reconstruction planned at the Common Femoral Artery (CFA) and its bifurcation. The duodenum was mobilised to the right, allowing access to the infrarenal aorta. The retroperitoneal tissue overlying the aorta was dissected superiorly to the level of the left renal vein. Extensive dissection anterior to the aortic bifurcation and the proximal left iliac artery was avoided because the autonomic nerve plexus regulating erection and ejaculation in men sweeps over the aorta in this region.

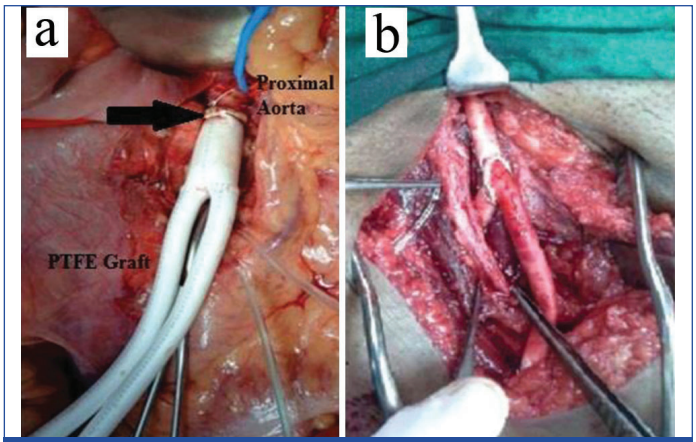
The tunnel for the graft was created by finger dissection on the anterior surface of the iliac arteries. On the left side, the tunnel was prepared to pass beneath the sigmoid mesentery and slightly more laterally to avoid disruption of the autonomic nerve plexus. Moist umbilical tapes or Penrose drains were passed with a smooth aortic clamp to mark the tunnels. Once the vessels were prepared and a tunnel was completed, systemic heparinisation was performed before vascular occlusion. Adequate hydration was ensured, and repetitive aortic cross-clamping and perioperative hypotension were avoided. Mannitol and furosemide were administered intravenously before aortic clamping to trigger diuresis.

The aorta was carefully palpated to identify the optimal sites for the application of the cross-clamps. Appropriate atraumatic vascular clamps were selected, and after sufficient time for the heparin to circulate, the aorta was clamped first, proximally below the renal arteries or distally above or below the inferior mesenteric artery at the site of least disease to avoid dislodgement and potential distal embolisation of plaque. PTFE grafts were used in present study. The graft was placed flatter in the retroperitoneum to enhance the ability to close the retroperitoneum over the graft, resulting in a lower rate of late graft infection and aortoenteric fistulae. The graft limbs were then passed through the retroperitoneal tunnels, and care was taken to match the graft size to the femoral artery diameter.

Arteriotomy limited to the distal CFA sometimes was sufficient. More commonly, an extension of the arteriotomy across the profundafemoris artery origin and profundaplasty was necessary. The distal anastomoses were completed in an end-to-end side fashion using flushing maneuvers before completing the anastomosis. When sequential declamping was done, the anaesthetic team was put on high alert to avoid a drop in blood pressure with reperfusion.

Once haemostasis was achieved, the abdomen was irrigated, and the retroperitoneum was closed. The groin wounds were copiously irrigated with an antibiotic solution, and the deeper tissue was closed in several layers using absorbable Vicryl sutures. Distal perfusion was confirmed, and the absence of distal embolisation was ensured.

The proximal procedure for both types of surgery was the same, and the sequential group received an additional distal procedure as described below. A severely diseased common femoral artery was treated with sequential aorto-femoro-popliteal distal reconstruction by facilitating proximal anastomoses for a femoro-popliteal bypass to the PTFE. Initially, an aorto-femoral bypass was performed using a PTFE graft. The distal limb of the aorto-femoral PTFE was exposed, and adequate control of the graft, common femoral artery, profunda femoris artery, and superficial femoral artery was obtained. The saphenous vein was dissected out in a routine fashion with a few extra centimeters. The patient was systemically heparinised, and the proximal femoral vessels were occluded. The saphenous vein was attached to the distal end of the common femoral artery. Soft clamps were placed on the vein bypass, and flow into the profunda femoris was restored, while distally proximal popliteal, posterior tibial artery, and anterior tibial artery were anastomosed [Table/Fig-2a,b].



[Table/Fig-2]: a) Proximal aorta to PTFE graft bypass. b) Showing sequential graft to graft bypass.

Data regarding the aetiology of the disease, co-morbidities including substance use, degree of the disease involvement, presence of claudication pain, treatment modalities including the artery involved in the bypass surgery, and complications of the management were all collected. Postoperatively, at three months, the patency of the vessel was monitored for all the patients through the Ankle-brachial Index (ABI) [13]. Wound healing was examined during monthly follow-up, and the patient was asked to come for review until the wound healed.

STATISTICAL ANALYSIS

Data was analysed by Statistical Package for Social Sciences (SPSS) software version 22.0. The Chi-square test was used to compare outcomes with different treatment modalities, and a p-value <0.05 was considered statistically significant.

RESULTS

In present study, all 25 patients happened to be male, with a mean age of 58.3±2 years (range 40 to 70 years). Among them, 7 (28%) were diagnosed with Thromboangitis Obliterans (TAO), Beurger's Disease, while the remaining 18 (72%) were found to have atherosclerosis. All patients had one or more co-morbidities, and the majority 18 (72%) were smokers. Additionally, a majority of pariticpants 10 (40%) exhibited abnormal profunda patency [Table/Fig-3].

Variables	Frequency (%)
Aetiology	
Thromboangitis Obliterans (TAO)	7 (28)
Atherosclerosis	18 (72)
Co-morbidities	
Smoking	18 (72)
Hypertension	3 (12)
Diabetes mellitus	4 (16)
Profunda patency	
Normal	10 (40)
Abnormal	15 (60)

[Table/Fig-3]: Characteristics of the patients with Aortoilliac occlusion (N=25).

Based on the profunda patency status in these 25 patients, proximal bypass was chosen for 10 (40%) CLI patients with normal profunda patency, while sequential bypass was chosen for 15 (60%) CLI patients with abnormal profunda patency [Table/Fig-3].

The age range of the patients in present study was 40-70 years. Out of the 25 patients, 10 underwent proximal bypass, and 15 underwent sequential bypass. A comparison of these groups yielded a non statistically significant p-value of 0.638. Among the 10 patients who underwent proximal bypass, four were between 40-50 years old and six were between 61-70 years old, whereas among those who underwent sequential bypass, six were between 61-70 years old [Table/Fig-4].

Numbers of patients/age	40-50 years	51-60 years	61-70 years	Total
Numbers of patients undergoing proximal bypass	04	02	04	10
Numbers of patients undergoing sequential bypass	05	04	06	15

[Table/Fig-4]: Age distribution among patients undergoing proximal bypass and sequential bypass.
*Chi-square test p-value=0.638

All 10 patients who received proximal bypass and all 15 patients who received sequential bypass were males. Among the 10 proximal bypasses, 4 (40%) were associated with TAO as the aetiology, and 6 (60%) were associated with atherosclerosis. Among the 15 sequential bypasses, 3 (20%) were associated with TAO, and 12 (80%) were associated with atherosclerosis as the aetiology. This comparison was not statistically significant, with a p-value of >0.05 [Table/Fig-5].

Bypass surgery	Total	TAO	Atherosclerosis	p-value*
Proximal	10	04 (40%)	06 (60%)	0.275
Sequential	15	03 (20%)	12 (80%)	

[Table/Fig-5]: Distribution of aetiology among patients undergoing proximal bypass and sequential bypass.
*Chi-square test

Out of the 15 patients undergoing sequential bypass, 12 (80%) received a synthetic PTFE graft, while three received a reversed greater saphenous vein graft. Within these 15 sequential bypass cases, 12 (80%) involved a proximal popliteal artery bypass, and 1 case each (6.66%) involved a distal popliteal artery bypass, a posterior tibial artery bypass, and an anterior tibial artery bypass [Table/Fig-6].

Bypass	Frequency	Percentage
Proximal popliteal artery	12	80%
Distal popliteal artery	01	6.66%
Anterior tibial artery	01	6.66%
Posterior tibial artery	01	6.66%
Total	15	100%

[Table/Fig-6]: Frequency of distribution of bypass used in sequential bypass.

Among the 10 patients treated with proximal bypass, claudication pain was relieved in three patients after surgery. Of the 15 patients treated with sequential bypass, claudication pain was relieved in 13 patients after surgery. In total, out of 25 patients treated with bypass, claudication pain was relieved in 16 patients, whereas claudication pain was not relieved in nine patients. This comparison showed a p-value of <0.004, thus it was highly statistically significant [Table/Fig-7].

Type of surgery	Claudication pain relieved n (%)		p-value*
	Yes	No	
Proximal bypass	03 (30)	07 (70)	<0.004*
Sequential bypass	13 (86.7)	02 (13.3)	
Total	16 (64)	09 (36)	

[Table/Fig-7]: Claudication pain relieved after proximal bypass and sequential bypass.
*Chi-square test

Among the 10 cases treated with proximal bypass, none of them displayed a palpable pulse after surgery, whereas of the 15 cases treated with sequential bypass, all of them displayed a palpable pulse after surgery.

Among the 10 patients who underwent proximal bypass, three patients developed complications of pseudoaneurysm and graft thrombosis, whereas among the 15 patients undergoing sequential bypass, two patients showed a graft thrombosis complication [Table/Fig-8].

Complications	Proximal bypass (n=10)	Sequential bypass (n=15)
Pseudoaneurysm	02 (20%)	00
Graft thrombosis	01 (10%)	02 (13.3%)
Graft infection	00	00
Lymphocele	00	00

[Table/Fig-8]: Complications encountered after proximal bypass and sequential bypass.

The ABI was recorded after bypass surgery, and it was noted that ABI improvement was seen in all 10 patients, with a mean ABI improvement of 0.510 in patients who underwent proximal bypass. ABI improvement was noted in all 15 patients who underwent sequential bypass, with a mean ABI improvement of 0.920. The p-value noted was <0.001, thus it was highly statistically significant [Table/Fig-9].

Variable	Bypass surgery	Mean	Std. Deviation	p-value*
ABI	Proximal	0.510	0.07	<0.001**
	Sequential	0.920	0.21	

[Table/Fig-9]: Comparison of Ankle-branchial Index (ABI) after proximal bypass and sequential bypass surgery (N=25).
*independent sample t-test: **p-value highly statistically significant

The average time taken for the healing of ulcers was five months in patients who underwent proximal bypass, whereas in sequential bypass, the average healing time taken was one month. This finding was highly statistically significant with a p-value of <0.001 [Table/Fig-10].

Bypass surgery	Ulcer healing time (months) (Mean±SD)
Proximal	5±1
Sequential	1±1

[Table/Fig-10]: Difference in ulcer healing between both the groups (N=25).

One patient in the sequential bypass group underwent major amputation (below-knee amputation), and there were no perioperative mortalities in both groups.

DISCUSSION

British anatomist and surgeon, Hunter J, first appreciated the implications of arterial occlusive disease of the aortic bifurcation in the late 1700s [14]. Surgical reconstruction for complex atherosclerotic occlusive disease began in 1947 with the successful endarterectomy of a heavily diseased common femoral artery by Portuguese surgeon dos Santos VP, and was extended to the aortoiliac level by Wylie et al., in 1951 in San Francisco [28,15].

Aortoiliac occlusive disease is a variant of PAD where there is atherosclerotic blockage of the distal abdominal aorta and the iliac arteries. The disease typically begins at the aortic terminus and common iliac artery origins and slowly progresses over time, both proximally and distally. The classic clinical presentation includes bilateral buttock claudication, decreased femoral pulses, and sexual dysfunction. The risk factors for AI are smoking, hypertension, diabetes, age, race, and sex [16].

The diagnosis of aortoilliac occlusive disease is made only after careful history and physical examination. Diagnosis of aortoilliac disease is straightforward in patients with claudication (mainly over the thigh and buttock), non palpable femoral artery pulsation, and the presence of multiple peripheral arterial risk factors. However, the diagnosis of aortoilliac is tricky when claudication is difficult to be distinguished from those of hip or nerve root irritation due to lumbar disk disease or spinal stenosis [12].

These clinical symptoms may also be seen in patients with diabetes, making it difficult to determine how much of the neuropathic change is caused by CLI alone. However, it is important to note that patients with diabetic foot ulcers may have inadequate blood flow for healing, even with perfusion levels that exceed the criteria for CLI. The common major manifestation of CLI is a burning sensation, uncomfortable coldness, or paresthesia of sufficient intensity to interfere with sleep; ischaemic ulcerations or gangrene of the forefoot and toes; and claudication of calf muscles alone or with involvement of the thigh, hip, or buttock. Palpable femoral and even pedal pulses may be detectable at rest, reflecting the presence of a robust collateral network. This clinical diagnosis is objectively confirmed by haemodynamic measurements, such as systolic ankle pressure <50 mm Hg, toe pressure <30 mm Hg, or ABI <0.40 [1].

Non invasive laboratory studies are sufficient for diagnosing AI occlusive disease in most patients. Non invasive studies, such as ABIs, segmental pressure measurement, and pulse volume recording, are the three most common modalities that help confirm the disease. ABI is generally the first screening test for the diagnosis of AI disease, as it is reliable, non invasive, and cost-effective [17].

Further disease localisation, severity, and assessment can be done by duplex sonography, Computed Tomography Angiography (CTA), or Magnetic Resonance Angiography (MRA) [18,19]. However, MRA might be accompanied by undue contrast burden to the patient and also overestimate the degree of stenosis [20].

Medical management is opted for non acute cases and poor surgical candidates. Primary measures, such as managing existing co-morbidities like diabetes mellitus, hypertension, hyperlipidemia, prothrombotic states, and tobacco use, are essential [17].

Antiplatelet therapy is the mainstay of cardiovascular risk reduction. Numerous studies have demonstrated that aspirin in doses ranging from 75 to 325 mg/day significantly lowers the risk of Myocardial Infarction (MI) and stroke in patients with symptomatic PAD [21]. However, the benefit of aspirin in asymptomatic PAD patients is less clear. Clopidogrel is a suitable alternative to aspirin for risk reduction in patients with symptomatic PAD. In very high-risk patients who are not considered at increased risk of bleeding, a combination of aspirin and clopidogrel may be beneficial. A statistically significant benefit, documented by a reduction in MI, stroke, or death, was noted in patients with symptomatic lower extremity ischaemia treated with aspirin and clopidogrel compared with those who received aspirin and placebo [22].

Surgical management is the primary treatment modality for AI occlusive diseases, and the goal of surgical management of AI occlusive disease is to re-establish the inflow to the lower extremities and pelvis, thereby preventing limb amputation. Open bypass surgeries are superior to endovascular intervention, but open bypass is expensive, requires longer hospitalisation, and has higher mortality and morbidity [23].

Aorto-femoral Bypass (AFB) has been the preferred surgical option for treating aortoiliac disease since the 1950s and is still considered the gold standard for long-term patency. It is associated with a high degree of vascularisation, with a five-year patency in 64-95% of patients, along with pain relief, especially when walking [4].

Obstructive lesions of the aortoiliac segment can be bypassed with a distal site of anastomosis to either the external iliac or common femoral arteries. Lesions found in the superficial femoral and popliteal segments are best treated using a saphenous vein bypass [24].

Favaloro RG et al., described the use of an autologous reversed Greater Saphenous Vein (GSV) graft as a bypass graft [25].

The sequential vein bypass graft technique is better than the single vein bypass technique as it offers advantages such as saving graft material, reducing the number of proximal anastomoses, and improving hemodynamics, thus yielding excellent long-term results [26]. However, the disadvantages include poor long-term patency and severe intimal hyperplasia, mainly due to the small caliber of the veins [27].

It was noted in present study that most of the patients were elderly men in the age range of 61-70 years. The present finding is similar to the findings of dos Santos VP et al., [28]. Aortoiliac occlusive disease affects multiple levels and is commonly encountered in the elderly. However, AI, when associated with smoking, is found to occur in a much younger age group.

In the majority of patients with AI in the present study, the noted aetiology was atherosclerosis, followed by TAO. The present finding was consistent with previous studies by Evans WE et al., who stated that atherosclerosis in patients over 50 years is more virulent than in patients under 50 years [29]. However, Valentine RJ et al., conversely stated that atherosclerosis is more virulent in elderly patients than in younger ones [30]. The most common comorbidity seen in the present study was smoking, followed by diabetes and hypertension. This finding in the present study was similar to the work of Kim TH et al., [31]. However, studies by Abelha FJ et al., showed that the most common comorbidity seen in patients undergoing bypass was hypertension [32].

Claudication pain was relieved in the majority of patients treated with bypass, which was similar to the work of Regensteiner JG et al., [33]. Authors further noted that claudication pain was not relieved in the majority of patients treated with proximal bypass, whereas sequential bypass was effective.

In present study, it was noted that the proximal popliteal artery was used for femoral artery bypass in the majority of cases, followed by the distal popliteal artery, anterior tibial artery, and posterior tibial artery, and this was found to be highly statistically significant. The present study was similar to the findings of Betz T et al., who found that femoral-popliteal bypass is safe and effective in the long-term [34].

The common complication noted after proximal bypass was pseudoaneurysm in most cases, followed by graft thrombosis. In sequential bypass, the only complication noted was graft thrombosis. Femoral artery aneurysm is an uncommon late complication after femoral bypass graft. They are usually not large in size and hence, not detected early, and their rupture leads to death [35].

Graft limb thrombosis is seen in 30% of patients undergoing AFB, and a higher incidence is noted in females, younger patients, and those who have not quit smoking. Graft thrombosis is thought to occur due to continuous intimal hyperplasia or outflow disease [36].

Though not encountered in the present study, other complications as per literature include cardiac ischaemia (50%), which leads to death in 1-2.5% of patients. Another common complication is renal insufficiency as a result of prolonged ischaemia due to clamping of the suprarenal artery or embolisation secondary to clamping, leading to hypoperfusion, hypovolemia, or intrinsic renal disease [37].

In the present study, it was noted that the mean improvement in ABI was greater in sequential bypass than in proximal bypass. In peripheral arterial disease, ABI is better at detecting proximal lesions than distal lesions and is also better at detecting stenosis >50% [38]. Improvement in ABI reflects the success of revascularisation; therefore, an increase in ABI is considered an independent factor, along with improvement in functional status. Lower ABI values are associated with the development of postoperative delirium after bypass surgery [39]. No single criterion mandates a combined procedure; however, the severity of distal ischaemia is probably the most important factor to be considered. When surgery is performed with several teams operating simultaneously, concurrent inflow and outflow revascularisation can be completed in a shorter time and a safer manner. Indeed, several reports found no significant differences in perioperative mortality or morbidity in patients undergoing multilevel reconstruction and those having the major inflow procedure alone. The presence of coronary artery and cerebrovascular disease must be assessed in all patients with manifestations of PAD as they are emerging as important risk factors [40]. PTFE grafts used in present study provide less turbulence, lower rates of proximal suture line pseudoaneurysm, and better long-term patency when end-to-end anastomosis is performed. Hence, the advantages in the suture material might also contribute to the good outcome of the procedure. The outcome of bypass surgery is poorer in females and is thought to be due to the smaller diameter of the artery, which may contribute to incomplete vascularisation and thus result in late adverse events [41].

Limitation(s)

The study was conducted on a cohort of patients with aortoiliac occlusion, and the treatment was determined based on disease severity. Due to ethical reasons, patients with complete occlusion could not be allocated to the proximal surgery group. One year postoperative vessel patency could not be established due to resource constraints.

CONCLUSION(S)

The current study data demonstrate that for patients with multilevel arterial occlusive disease, single-stage surgery is a safe and effective method for treating CLI. Features such as ulcer healing, improvement in claudication pain, palpable pulse, and ABI improvement were better in the sequential bypass group than in the proximal bypass group.

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