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ORIGINAL ARTICLE

Comparative Study Between Femoro-distal Bypass Graft and Tibial Arteries Angioplasty in the Treatment of Critical Lower Limb Ischemia

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Abstract

Background: **Patients with persistent limb-threatening ischemia now have two treatment options: open surgical bypass and percutaneous transluminal angioplasty with or without stenting (PTA/S) (CLTI).**

Aim: **For the treatment of patients with critical lower extremity ischemia, to assess the follow-up outcomes, benefits, drawbacks, complications, and patency rate of femorodistal bypass with percutaneous transluminal angioplasty of the tibial arteries.**

Subject and methods: **On 40 patients, this comparison study will be carried out in the vascular surgery department of the Al-Azhar University Hospitals.**

Results: **Regarding postoperative ABI, there is a substantial difference between the groups. Both groups experience a substantial postoperative rise in ABI. There is no statistically significant difference between the two study groups in terms of 30-day problems. When comparing the study groups' patency rates, the femorodistal bypass group's patency rate was much higher than the tibial arteries angioplasty group's.**

Conclusion: **Critical Lower Limb Ischemia can be treated safely and effectively with Femorodistal Bypass Graft and Tibial Arteries Angioplasty. Between the groups, there are no discernible differences in terms of complications. When comparing the study groups' patency rates, the femorodistal bypass group's patency rate was much higher than the tibial arteries angioplasty group's.**

Keywords: Femorodistal bypass graft, Limb ischemia, Tibial arteries angioplasty

1. Introduction

An ankle-brachial pressure index of less than 0.9 can be used to identify peripheral arterial disease (PAD), which is described as a slowly progressive, occlusive vascular disease of the extremities that is predominantly caused by atherosclerosis and can involve vasculitis and thrombosis. Intermittent claudication and critical limb ischemia may result from it as the condition worsens (CLI).[1]

Due to an overall rise in diabetes, obesity, and other cardiovascular diseases, PAD incidence is rising globally.[2]

Importantly, the prevalence of PAD will keep rising because it has historically been diagnosed in ageing populations, which are expanding globally. The most severe form of peripheral artery occlusive disease is critical limb ischemia (PAOD). The prognosis is terrible, with mortality after one year reaching 25% and amputation rates reaching 30%.[1]

Only one to four out of every five patients with PAOD will experience symptoms. Intermittent claudication is the clinical symptom of PAOD that occurs most frequently. It is described as ischemia pain that develops during physical activity and is swiftly eased by rest.[3]

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The following goals guided the comparison of femorodistal bypass versus percutaneous transluminal angioplasty (PTA) of the tibial arteries for patients with critical lower limb ischemia: follow-up results, advantages, disadvantages, difficulties, and the patency rate.

2. Patients and methods

The Al-Azhar University Hospitals' vascular surgery division was the site of this comparative investigation. A total of 40 individuals with critical lower limb ischemia will be included in the trial. Two groups of patients will be separated. Twenty patients receiving femorodistal bypass will be in Group A. While the remaining 20 patients (group B) will be treated by tibial arteries angioplasty.

Inclusion criteria: The study will include all patients who presented with critical lower limb ischemia that presented with any of the following: Disabling claudication, that significantly reducing life quality, persistent recurrent rest pain of more than two weeks duration, foot ulcers or tissue loss, gangrene of the toes or foot and patients with ankle systolic pressure <50 mm Hg.

Exclusion criteria: Patients with acute lower limb ischemia, patients undergoing previous endovascular or surgical intervention of the ipsilateral side, patients with abdominal/thoracic aortic aneurysms, patients with vasculitis and patients with inability or unwillingness to complete with the follow-up schedule.

2.1. Methods

All patients was with history taking, complete physical examination, and routine laboratory investigations as follows:

History: For every patient, a written medical history will be conducted and will include the following: Age, sex, the presence of hypertension, diabetes, smoking, and coronary artery disease, coronary artery bypass, and cerebrovascular disease. Site affected (unilateral or bilateral). Mode of onset (i.e. sudden, gradual), and any precipitating factors. Pain: Intermittent disabling claudication (duration, site, progressive or regressive, claudication distance, relief and rest pain. Color and trophic changes. The presence of ulceration or gangrene.

Examination: All patients will be examined according to the following scheme:

General Examination for: Pulse, blood pressure, constitutional disturbance: fever, tachycardia, associated diseases in the: heart, lungs, brain, and kidney and conditions of the blood vessels.

Local Examination of the Lower Extremities: Inspection: Color of the affected limb: Pallor, Cyanosis and mottled appearance. **Capillary circulation:** Normal, Sluggish and failed. **Manifestations of impending gangrene:** Thinning of the skin, loss of hair, atrophy of the muscles, brittleness and fissuring of nails and trophic ulceration.

Established gangrene: The site affected, type of gangrene: dry, moist, septic, or aseptic, the extent of gangrene, the line of demarcation: well defined or poorly marked and the limb above the gangrenous area: healthy, ischemic, congested, edematous, or acutely inflamed.

Palpation: Palpation of skin temperature: Reduced, No changes. Palpation of the peripheral pulses: Femoral, popliteal, posterior tibial, and dorsalis pedis pulses.

Ulceration: number, site, size, surface, shape, edge, floor, base, discharge, draining lymph nodes.

Examination of gangrenous area: Hard and shriveled i.e. dray gangrene, soft and edematous i.e. moist gangrene and tens and crepitant i.e. gas gangrene.

Routine Investigations: complete blood count, blood sugar for evidence of diabetes, and lipid profile, urine analysis, liver and kidney functions, prothrombin time and concentration and ECG, for associated coronary heart disease.

2.2. Statistical analysis

All data were collected, processed, and statistically evaluated using SPSS 22.0 for Windows (SPSS Inc., Chicago, IL, USA). Using the Shapiro Walk test, the distribution of the data was examined for normality. Qualitative data were expressed as frequencies and relative percentages. The chi-square test (2) and Fisher exact were used to determine the difference between the qualitative variables, as illustrated. Quantitative data were expressed using the mean and SD (standard deviation), respectively, for parametric and non-parametric data. The Independent *T* test and the Mann-Whitney test were used to determine the difference between quantitative variables in two groups for parametric and nonparametric variables, respectively. The paired *t*-test was used to compare non-normally distributed variables, whereas the Wilcoxon signed ranks test was employed to examine regularly distributed data.

3. Results

Table 1.

This table shows that the two groups were comparable in age, sex, and BMI without statistically significant difference between the groups Table 2.

Table 1. Demographic characteristics between the studied groups.

	Group A ($n = 20$)	Group B ($n = 20$)	t/χ^2	*P*
Age (years)				
Mean ± SD	53.75 ± 9.45	54.37 ± 10.46	0.196	0.845
Sex				
Female	9 (45%)	8 (40%)	0.102	0.749
Male	11 (55%)	12 (60%)		
BMI (kg/m^2)				
Mean ± SD	28.12 ± 3.57	27.74 ± 2.96	0.366	0.716

Table 2. Preoperative and postoperative Ankle brachial index (ABI) between the two studied groups.

	Group A ($n = 20$)	Group B ($n = 20$)	χ^2	*P*
Preoperative ABI				
Mean ± SD	0.393 ± 0.048	0.408 ± 0.052	1.75	0.088
Postoperative ABI				
Mean ± SD	0.825 ± 0.041	0772 ± 0.065	**3.1**	**0.004**
Paired *t*-test	**8.63**	**6.42**		
P	**<0.001**	**<0.001**		

Table 3. 30-day complications between the two studied groups.

	Group A ($n = 20$)	Group B ($n = 20$)	χ^2	*P*
Mortality	2 (10%)	1 (5%)	0.360	0.548
Myocardial infarction	2 (10%)	1 (5%)	0.360	0.548
Surgical site infection	5 (25%)	2 (10%)	1.56	0.212
Hematoma	2 (10%)	1 (5%)	0.360	0.548

Table 4. Patency rate between the studied groups.

	Group A ($n = 20$)	Group B ($n = 20$)	χ^2	*P*
At 1 month	18 (90%)	17 (85%)	1.38	0.026
At 3 months	17 (85%)	15 (75%)		
At 6 months	14 (70%)	12 (60%)		

There is a significant difference found between the groups regarding postoperative ABI. Moreover, there is a significant increase in ABI postoperatively in both groups Table 3.

There is no significant difference found between the groups regarding complications Table 4.

This table shows that patency rate was significantly higher in group A compared to group B Table 5.

Patency rate after 12-months was 72.4% in group A and 64.8% in group B with log rank test of 0.86.

Table 5. Patency-free survival.

	Mean	SE	95% CI	Log Rank test	Survival at 12-months
Group A	6.902	2.132	5.599–8.619	0.861	65%
Group B	5.724	1.145	3.833–7.615		55%

4. Discussion

For varying degrees of lower extremity limb ischemia, prior study compared bypass with PTA/S, although they did so with a number of methodological issues. Similar topics were covered in the published Randomized Bypass vs. Angioplasty in Severe Ischemia (BASIL) study, which found that, up to 2 years after the procedure, there was no difference between the bypass-first and angioplasty-first strategies, but that bypass was superior in terms of overall survival and amputation-free survival. The BASIL trial has drawn criticism for its strict eligibility requirements and for enrolling so few patients with infrapopliteal disease. Furthermore, the study's ability to provide guidance to those undergoing their first revascularization was constrained because the patients in their group included those who had previously undergone an intervention and experienced clinical failure (Adam et al., 2005).

This study compared femorodistal bypass and percutaneous transluminal angioplasty (PTA) of the tibial arteries for the treatment of patients with critical lower extremities ischemia in order to examine the follow-up outcomes, benefits, drawbacks, complications, and patency rates. The Al-Azhar University Hospitals' vascular surgery division was the site of this comparative investigation. 40 patients with critical lower limb ischemia participated in the trial. Two groups of patients were created. The remaining 20 patients (group B) had tibial artery angioplasty treatment whereas the 20 patients in group A underwent femorodistal bypass surgery. The trial lasted somewhere between six and twelve months.

As to socioeconomics of the dissected gatherings, there was no measurably tremendous distinction between the two gatherings regarding age, sex, or BMI. As opposed to our discoveries, Dear et al. study's 5 detailed that 1533 methodology were barred from the investigation of the 2869 lower furthest point revascularizations performed between January 2005 and October 2014: 663 mediations were performed on appendages with non-CLI side effects, 437 were re-intercessions, and 433 were appendages that had recently gone through an intercession. Eventually, 1',336 patients who were going through their most memorable detour a medical procedure or PTA/S activity (i.e., a first-time lower furthest points mediation for CLTI) matched our incorporation measures. Over the course of our ten-year analysis, the treatment type distribution evolved from surgery, angioplasty increasingly replaced it as the more popular

method, accounting for more than 75% of yearly CLTI revascularizations, to a much more even circulation.

Patients who first decided against having a surgical procedure were more likely to be male (62% versus 56%; $P = 0.02$), be younger (71 versus 72 years old; $P = 0.02$), and be white (82% versus 74%; P 0.001). In the study by Chong et al.,[4] patients with basic lower appendage ischemia were divided into 100 patients who underwent percutaneous transluminal angioplasty first and 364 subsequent patients who underwent infrainguinal sidestep surgery. The last option group consisted of older individuals (77 versus 74 years, $P = 0.014$). According to the Between Society Agreement for the Management of Fringe Blood vessel Sickness (TASC II), CLI is distinguished by the presence of ongoing ischemia pain at rest, ulceration, or gangrene that can be attributed to blood vessel occlusive disease. Typically, the restriction of peripheral blood flow is a long-term, recurrent cycle that occurs over months or years in correlation with ageing, predisposing factors and cardiovascular risk factors like smoking, diabetes, hypertension, and dyslipidemia., in progress excretory organ illness, hypercoagulable states and hyperhomocysteinemia.[5] In the concentrate in our grasp, as respect aspect, there's no vast distinction half-track down between the gatherings. Regarding arrangement between the 2 focused on gatherings; there's no tremendous distinction half-track down between the gatherings. Be that because it could, within the investigation of Sweetheart et al.,[6] Patients with pre-useable femoropopliteal TASC D sores (31% versus 13%; P 0.001) and pre-employable leg bone TASC D sores (37% versus 27%; P.001) went through sidestep initial medicines considerably a lot of often. Levels of obstructions comprised os, SFA, and limb in fifteen.9, 58.5, and 25.6%, severally, within the study by Ghoneim et al. ninety two of patients reported experiencing a series of diseases. Concerning 16 PF of all patients have aortoiliac sickness, whereas eighty-four have infrainguinal. Per the TASC II, there have been aortoiliac sores in an exceedingly, B, C, and D in thirty-three. 7, 12, 15.7, and 38.6% of cases, severally, and infrainguinal injuries in an exceedingly, B, C, and D in 3.7, 19, 35.4, and 68.3% of cases, severally.

The results of this study discovered a considerable distinction between the 2 analysed teams in terms of surgical articulatio talocruralis limb index (ABI) outcomes between the operative and surgical teams. Postoperatively, ABI considerably rises in each teams additionally. There's no statistically important distinction between the 2 study teams in terms of 30-day issues. Once scrutiny the study groups' patency rates, cluster A's patency rate was considerably larger than cluster B's. With a log-rank check of zero.86, the 12-month retention rates were seventy two.4% for A and sixty-four. 8% for blood type. Contrarily, Chong et al.6.'s study indicated that the bypass cluster had a larger operational morbidity (4% vs. 1%, $P = 0.03$) than the angioplasty-first cluster. Hospital mortality rates were similar (8% vs. 3%, $P = 0.15$). Compared to the angioplasty-first cluster, the bypass group's median hospital keep was longer (24 vs. 4 days, P0.001), and post-operatively, they additionally had the next median ankle-brachial index (0.92 vs. 0.70, P 0.001) and larger semipermanent patency.

Patients within the bypass cluster United Nations agency were yank Society of Anesthesiologists category four reported very high rates of surgical and inmate mortality (15% and thirty-first, respectively). The TransAtlantic InterSociety accord category of the treated lesion vie a job within the connective tissue transluminal angioplasty's semi-permanent patency.

At 3 years, limb salvage rates with surgical bypass and connective tissue transluminal surgical process were eighty-nine and seventy-eight, severally ($P = 0.046$). Semipermanent survival was reduced within the connective tissue transluminal angioplasty-first cluster (21% vs. fifty-one at five years, $P = 0.04$). Jones et al ninth's study also examined the negative consequences of subsequent re-vascularizations in patients with the peripheral vascular disease after intranasal treatment had failed. According to a comparison of 2350 patients undergoing a primary infrainguinal bypass with 1154 patients undergoing a secondary infrainguinal bypass (following an unsuccessful PTA/S or bypass), secondary bypass patients had worse 1-year outcomes, as well as major adverse limb event (MALE)-free survival and re-intervention- or amputation-free survival. Jones et al. suggest choosing the suitable patients instead of employing a 'endovascular first' strategy as a result of new analysis has incontestible that continual connective tissue treatments will have an effect on distal targets.[6]

In a different study, Engelhardt et al. evaluated the first care of 104 patients who had their first episode of CLTI in order to determine the patients' amputation-free survival rate. A total of 65% had revascularization of some kind, with PTA/S accounting for 45% of cases and surgical artery reconstruction accounting for 55%. 2.2% of limbs were first treated non-operatively, whereas 4.3% of patients passed away before conservative therapy could start. Following the initial revascularization therapy, six limbs (or 22%) needed additional

procedures, such as surgical reconstructions and subsequent amputations, in order to continue CLTI.

Furthermore, according to Ghoneim et al.,[7] 78.3% of patients received endovascular treatment in its entirety, compared to 16 PF WHO underwent surgery at once, 3.7% of endovascular cases that needed conversion to open surgery once endovascular treatment unsuccessful, and a couple of WHO received hybrid treatment. Lesions crossed the lumen intraluminally eighty seven.5% of the time and subintimally twelve.5% of the time. Though we have a tendency to were ready to with success revascularize ninety six.8% of all command line interface instances in our study, whether or not either surgery or endovascular operations, despite the fact that technically solely ninety-four of endovascular procedures were undefeated. At twenty-four months' follow-up, primary patency, secondary patency, and limb salvage following transdermic transluminal surgical process square measure, severally, 77.8, 84.7, and 90.7%. There are some notable limitations to the study. A retrospective, single-center review was first carried out, in which patients were given their treatments in accordance with the surgeons' preferences, which have changed over time. Due to the fact that this is a retrospective study, there are numerous patient details that are not reliably recorded during the course of the investigation, such as information about vein mapping in PTA/s-first patients, which may theoretically restrict the results that may be reached. Finally, only revascularization attempts are included in these data; the results of individuals who underwent initial amputation or medical care as a comparison are not included. However, this study continues to be one of the most comprehensive assessments of the first management of CLTI that compares surgical bypass versus PTA/S.

4.1. Conclusion

According to the results of our investigation, there is a substantial difference between the groups in terms of postoperative ABI. Both groups experience a substantial postoperative rise in ABI. Regarding 30-day difficulties, there is no statistically significant difference between the two study groups. When comparing the study groups' patency rates, the femorodistal bypass group's patency rate was much higher than the tibial arteries angioplasty group's.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article.

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Conflicts of interest

There are no conflicts of interest.

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