Femoro Popliteal Bypass Vs Angioplasty in TASC D Lesion in Endovascular ERA. Is It Time to Change the TASC Recommendations?

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ABSTRACT

Background: *The incidence of CLI is estimated at 1% of the population aged 50 years and older and at approximately double that rate in the over-70 age group. These frequencies are expected to increase significantly with the aging population and the expected increase in diabetes. Within 1 year of being diagnosed with CLI, 40% to 50% of diabetics will experience an amputation, and 20% to 25% will die.* ***Aim of the Work:*** *Is to discuss whether patients with CLI due to TASC D lesion will still best managed with femoropopliteal bypass or can be managed by balloon angioplasty that much decreases postoperative morbidities especially with appearance of new advances in endovascular techniques.* ***Patients and Methods:*** *This was a prospective randomized comparative study, including 30 patients that attended outpatient clinic in Ain Shams University Hospital and Nasser Institute Hospital. The patients were divided into two groups: Group "**A**" include 15 patients (from1 to 15) underwent bypass **surgery** and Group "**B**" include 15 patients (from 16 to 30) underwent balloon **angioplasty**.* ***Results:*** *The ages of patients ranged from 60:70 years old with mean age 65+ 5 Years.* ***In group (A)*** *ABI of the 15 patients increased more than 0.3 postoperative while* ***in group (B)*** *ABI of 9 patients increased more than 0.3 while ABI of 3 patients showed minimal increase less than 0.3 (and they clinically failed) after exclusion of technical failure group.* *As regard to poatency* ***in group (A)****, primary and secondary patency at 3rd and 6th month was 100% while* ***in group (B)****, our three and six months primary patency results were 66.6% and 62.6% respectively while secondary patency was 88.8% and 87.5% at 3rd and 6th month respectively.* ***In group (A),*** *No patients underwent major amputation until the 3rd month while* ***in group (B),*** *one patient underwent below knee amputation at the 3rd month.* ***Conclusion:*** *The overall recommendation is that severe limb ischemia patients with long life expectancy and useable great saphenous vein, should usually have bypass surgery first. This is because that saphenous vein bypass surgery has long-term patency results and associates with significant improved amputation free survival. The rate of balloon angioplasty failure is high, and results of bypass surgery after failed balloon angioplasty are significantly worse than for primary bypass surgery. However, patients with short life expectancy (as those who are old aged with multiple comorbidities such as cardiovascular diseases) and those without a useable vein, should usually have balloon angioplasty first because they will not survive to reap the longer-term benefits of surgery.*

Keywords: *Femoro Popliteal Bypass – Angioplasty - Trans Atlantic Inter Society Consensus*

INTRODUCTION

The incidence of CLI is estimated at 1% of the population aged 50 years and older and at approximately double that rate in the over-70 age group. These frequencies are expected to increase significantly with the aging population and the expected increase in diabetes. Within 1 year of being diagnosed with CLI, 40% to 50% of diabetics will experience an amputation, and 20% to 25% will die **(1)**.

Atherosclerotic stenosis and occlusion of the superficial femoral artery (SFA) are common patterns of arterial disease both in patients with claudication and in those with limb-threatening ischemia **(2)**.

Current Trans Atlantic Inter Society Consensus Document on Management of Peripheral Arterial Disease (TASC II) recommendations advocates traditional surgical therapy for the treatment of more complex TASC D lesions **(3)**.

However, advances in endovascular techniques including the utilization of the subintimal technique and advances in technology, specifically, the development of re-entry devices making it possible to treat even the most complex

occlusive lesion with minimally invasive techniques [4].

Aim of the Work

Is to discuss whether patients with CLI due to TASC D lesion will still best managed with femoropopliteal bypass or can be managed by balloon angioplasty that much decreases postoperative morbidities especially with appearance of new advances in endovascular techniques.

PATIENTS AND METHODS

Patients:

This was a prospective randomized comparative study, including 30 patients that attended outpatient clinic in Ain Shams University Hospital and Nasser Institute Hospital.

Inclusion criteria:

1. Male or female patients more than >60 years.
2. High risk group patients (including diabetic patients and cardiac patients).
3. Critical limb ischemia with either rest pain or tissue loss.
4. Salvageable limb.
5. TASC D lesion in pre-intervention angiogram including chronic total occlusion of SFA (> 20 cm).

Exclusion criteria:

1. Claudication.
2. Arteritis.
3. Unsalvageable limb.
4. No distal runoff.
5. Patients with short life expectancy < six months.
6. Patients with malignancy.
7. Renal failure.
8. Patients having significant iliac, popliteal or tibial lesion that needs intervention.
9. Redo cases
10. Acute on top of chronic ischemia.

Methods:

- This was a prospective randomized comparative study that included 30 patients who attended at outpatient clinic in Ain Shams University Hospital and Nasser Institute Hospital.
- All patients provided a written formed consent.
- Every patient was given a number from 1:30 according to time of his admission.
- The patients were divided into two groups:

a. Group "A" include 15 patients (from1 to 15) underwent bypass surgery.

b. Group "B" include 15 patients (from 16 to 30) underwent balloon angioplasty.(Using different new devices such as long balloon, drug eluting balloon and covered stent).

- **History Taking:**

1. Age.
2. Gender.
3. Comorbidity:
   - Diabetes mellitus.
   - Hypertension.
   - Ischemic heart disease.
   - Renal impairment.
   - Previous CVS event
   - Other comorbidity.
4. History of smoking.
5. Previous angioplasty or bypass surgery.
6. Previous amputation.
7. Presenting symptom (rest pain or tissue loss).

- **The following investigations were done for all patients**

1. CBC
2. Liver & renal functions tests.
3. Electrocardiography
4. C.T.A arterial system of affected limb.
5. Duplex study.

The responsible consultant vascular surgeons were permitted to use their preferred techniques, equipment and graft material as for their normal practice.

In group (A) surgical bypass

- **Preoperative Assessment**

Perioperative blood pressure control, antianginal regimens, and treatment for congestive heart failure are optimized. Postponement of infrainguinal bypass is recommended in CLTI patients to allow further cardiac evaluation only in the presence of frequent or unstable angina, recent myocardial infarction, poorly controlled congestive heart failure, critical aortic stenosis, or symptomatic arrhythmia.

- **Anesthesia**

General epidural or spinal epidural

- **Femoral and popliteal exposure:** as described before
- **Bypass surgery:** as described before using the ipsilateral G.S.V which was suitable in all cases (soft- compressible - ≥3mm in diameter)
- **Postoperative care:** as described before
- ***The endpoint in this procedure is presence of pulse distal to anastomosis of the conduit to popliteal artery postoperative.***

In group (B) endovascular intervention

- **Preprocedural medications:**

Patients received 300mg of clopidogrel (4 tablets 75 mg), 300 mg of acetylcysteine, and hydration with normal saline at rate of 80-100 ml /h (the night before the procedure).

- **Technique:**

- All patients were admitted one day before or on the day of the procedure.
- Position: supine position
- Preparation: both groins were prepared using antiseptic solution povidone iodine.
- Anesthesia: under local anesthesia.
- Equipment: all procedures were done in an angiosuite, C-arm image intensifier with road mapping capability was used.
- Arterial access:
  The SFA was accessed through contralateral femoral puncture and performing a crossover technique.

- **Angiography:**

After gaining access a 6F sheath is inserted and free arterial flow is allowed to confirm the right position of the sheath. Angiography is done to confirm data obtained by preoperative investigations using nonionic low osmolar dye diluted to 50% with normal saline.

We defined TASC D lesion in as chronic total occlusion of SFA > 20 cm in pre-intervention angiogram.

Systemic anticoagulation with heparin infusion (80-100 IU/kg).

- **Crossing the Lesion:**

Crossing the lesion was done by different techniques and equipment individualized to each case but the standard tools for recanalization of stenosis and occlusions consist of a 0.035 hydrophilic guidewire and an angled-tip catheter, (4F Berenstein or vertebral).

Once the lesion has been crossed, the catheter should be advanced beyond the lesion, the wire removed and contrast injected to ensure that the catheter is within the lumen.

- **Deploying the Balloon/Stent:**

1) Angioplasty:

- A balloon catheter, selected for appropriate diameter and length, is advanced over the wire to the distal extent of the lesion.
- The balloon is inflated until any waist on the balloon has been abolished. The inflation time is not standardized. Inflation times vary from 30 seconds to 3 minutes.
- Prior to inflation of the balloon, the patient should be warned that they may experience pain, although this should not be excessive.
- As the balloon inflates, assessment of the roadmap image should confirm that the balloon catheter is appropriately sized.
- After balloon deflation, the balloon catheter is withdrawn slightly and the balloon catheter should be re-inflated with overlaps until the whole lesion has been covered.
- The balloon catheter is withdrawn completely, while keeping the guidewire in place across the lesion so that re-insertion of the balloon catheter or a stent delivery system could be performed if required.
- Angiography to assess the result is performed by injecting contrast medium through the side arm of the sheath.
- There should be rapid forward flow through the treated segment with no residual stenosis greater than 30%.
- Dissections in the wall of the artery are expected and do not imply a poor result unless they are flow limiting.
- If there are residual stenosis, the balloon catheter should be re-inserted and re-inflated at the site of stenosis.

2) Stent Insertion:

Indications for stenting:

a. Elastic recoil (If the balloon inflates fully, but the stenosis persists).

b. flow-limiting dissection, (prolonged balloon inflation can be performed to (tack down) the flap. If this fails, a stent is indicated.

- A self-expanding stent was used. The stent should not be oversized relative to the diameter of the SFA. The stent should be long enough to cover the lesion with 5–10mm coverage of the normal artery on either side of the lesion.
- The wire is left across the lesion for access and an intra-arterial nitroglycerin (100-200ug) is given, a check angiogram is performed and redilatation was done whenever required.
- ***The endpoint in this procedure is unrestricted forward flow of contrast with no evidence of significant (>30%) residual stenosis.***
- When the procedure was completed, the arterial access sheath was removed immediately.

- Hemostasis achieved by manual compression. Digital compression was held proximal to the skin puncture site for 15-20 minutes and mobilization was delayed for 6-12 hours.
- **Post procedure care:**
  Most patients were discharged on the second day following the procedure after receiving instructions on risk factors control and treatment including:
- Acety salislic acid (Aspirin) 150 mg /day for life.
- Clopidogrel (Plavix) 75 mg /day for at least one month.
- Atorvastatin (Ator) 4o mg /day.

The patients received foot care consisting of wound dressing, minor debridement, limited amputations (up to transmetatarsal amputation), infection control, and appropriate footwear before discharge.

Definitions

Technical success:

Was defined as continuous arterial patency to the popliteal artery without any obvious flow-limiting lesions (absence of a stenosis > 30%, flow limiting dissection) or major extravasation.

Runoff vessels:

Were defined as the number of patent crural vessels after the procedure in continuation with the treated femoro-popliteal segment.

Clinical success:

Was defined as resolution of rest pain, healing of ulcer or minor amputation site.

Limb salvage:

- Was defined as no amputation proximal to the metatarsus (Any above-the-ankle amputation was considered as major amputation).

Primary outcomes were:

- Limb salvage
- Healing of ulcers (complete or decreasing size).
- Improvement of ABI.
- Regain of distal pulse.

Secondary outcome:

- Was follow-up of patency in 6 months postoperative by duplex ultrasound.

Follow up:

- Clinical follow-up consisted of pulse examination and evaluation of the ulcer or amputation site healing or resolution of infection.
- Clinical outcomes, primary patency, secondary patency and complications following the procedure were reported.
- All patients were re-examined after one week to check for access site complications and to confirm patency.
- All patients were followed for 6 months with regular visits at 1,3 and 6 months or when new complaints arise.
- Follow up consisted of clinical examination ± imaging study (duplex US, angiography) if needed in cases of absent or diminished pulse or recurrence of symptoms.

Data collection and statistical analysis:

- Data were statistically described in terms of mean ± standard deviation (SD), median and range, or frequencies (number of cases) and percentages when appropriate.
- All statistical calculations were done using computer programs SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

RESULTS

I. Demographic data in both groups,

1) Age:

The ages of patients ranged from 60:70 years old with mean age 65+ 5 Years

Table (1) Age in study population

	Group A	Group B
Age	Mean 65± 5	Mean 65± 5

2) Gender:

a. In group (A) All patients were male.

b. In group (B) 11 patients were male & 4 patients were female.

Table (2) Gender in study population

Gender	Group A	Group B	P Value
Male	15	11	
Female	-	4	0.100

Fisher`s exact test

II. Risk factors and comorbidities

1. Smoking:

a. In group (A) 11 patients were smoker, 4 patients were nonsmoker.

b. In group (B) 8 patients were smoker, 7 patients were nonsmoker.

Table (3) Smoking in study population

Smoking	Group A	Group B	P Value
Yes	11	8	0.256
No	4	7	

Chi-square test

2. Comorbidities:

a. In group (A) 9 patients were diabetic and 6 patients were not diabetic and 9 patients were hypertensive and 6 patients were not hypertensive and 9 patient suffered from cardiac problems with EF <52% and 6 patients had no cardiac problems with EF > 52%.

b. In group (B) 11 patients were diabetic and 4 patients were not diabetic and 6 patients were hypertensive and 9 patients weren't hypertensive and 6 patients suffered from cardiac problems with EF EF<52% and 9 patients had no cardiac problems with EF > 52%.

Table (4) Comorbidities in study population

Comorbidities		Group A	Group B	P Value
D.M	**Yes**	9	11	0.439
	No	6	4	
Hypertensive	**Yes**	9	6	1.000
	No	6	9	
I.H.D	**EF>52 %**	6	9	1.000
	EF<52 %	9	6	

Chi-square test

III. Indications for intervention (presentation):

a. In group (A) 6 patients were presented by ischemic rest pain (Rutherford category 4), 5 patients were presented by dry gangrene or minor tissue loss (Rutherford category 5), 4 patients were presented by major ulcer (Rutherford category 6).

b. In group (B) 7 patients were presented with ischemic rest pain (Rutherford category 4), 3 patients were presented with dry gangrene or minor tissue loss (Rutherford category 5), 5 patients were presented with major tissue loss (Rutherford category 6).

Table (5) Presenting Complain in study population

Presenting Complain	Group A	Group B	P Value
Rest pain	6	7	0.805
Minor Tissue loss	5	3	
Major Tissue loss	4	5	

Fisher`s exact test

IV. ABI (before intervention)

a. In group (A) 9 patients had ABI < 0.3 and 6 patients had ABI between 0.3 and 0.6.

b. In group (B) 9 patients had ABI < 0.3 and 6 patients had ABI from 0.3 and 0.6

Table (6) ABI in study population

ABI	Group A	Group B	P Value
<0.3	9	9	0.464
0.3: 0.6	6	6	

Chi-square test

V. Number of distal runoff vessels in preprocedural CT angiography

a. In group (A)4 patients had (one) runoff vessel, 5patients had (two) run off vessel and 6 patient had (three) runoff vessels.

b. In group (B)5 patients had (one) runoff vessel, 5patients had (two) runoff vessel and 5 patient had (three) runoff vessels.

Table (7) Number of distal runoff vessels in study population

Number of distal runoff vessels	Group A	Group B	P Value
1	4	5	1.000
2	5	5	
3	6	5	

Fisher`s exact test

VI. Procedure outcome

1) Technical success:

a. In group (A), Technical success defined as presence of pulse distal to anastomosis of the bypass conduit to popliteal artery and that achieved in the 15 patients.

b. In group (B), Technical success defined as angiographic patency without residual stenosis >30% in completion angiography and that achieved in 12 patient while technical failure occurred in 3 patients. 3 of the technical success group had below knee amputation due to spreading of infection despite presence of

popliteal pulse post procedure decreasing clinical success to 9 patients. In the technical failure group[the 3 patients] thrombosis of distal runoff vessels occurred during procedure in one case who underwent above knee amputation while the other 2 cases underwent femoro-popliteal bypass.

Table (8 a) Technical success in study population

Technical success	Group A	Group B	P Value
Succeeded	15	12	0.224
Failed	0	3	

Fisher`s exact test

2) Clinical success:

Defined as relief of rest pain, healing of ulcer or no amputation proximal to ankle level postoperative.

In group (B) 3 cases among the 12 cases who technically succeeded underwent below knee amputation due to spread of infection decreasing clinical success to 9 cases (these the 3 cases that also showed minimal increase in A.B.I < 0.3)

Table (8 b) Clinical success in study population

clinical success	Group A	Group B	P Value
Succeeded	15	9	0.075
Failed	0	3	

3) Improvement of ABI:

We considered that any increase in ABI 0.3 or more had an impact on clinical success.

a. In group (A) ABI of the 15 patients increased more than 0.3 postoperative.

b. In group (B) ABI of 9 patients increased more than 0.3 while ABI of 3 patients showed minimal increase less than 0.3 (and they clinically failed) after exclusion of technical failure group.

Table (8 c) Improvement of ABI in study population

Improvement of ABI	Group A	Group B	P Value
Increase more than 0.3	15	9	0.075
Increase less than 0.3	0	3	

Fisher`s exact test

4) Technical failure:

a. In group (A), No cases were reported.

b. In group (B),Technical failure occurred in 3 cases due to different causes including:

1. Failure of reentry after subintimal passage of the wire.
2. Failure to cross the lesion intraluminally or to create a subintimal plane.
3. Acute thrombosis after angioplasty.

The first two cases underwent femoropopliteal bypass while the 3rd case underwent above knee amputation.

5) Procedural post procedural complication:

a. In group (A), Complication occurred in 2 patients (1 case had groin wound infection and the other had infection at the wounds of saphenous harvesting and managed with conservative treatment).

b. In group (B), Complication occurred in 3 cases (groin hematoma reported in two case and pseudo aneurysm in one case) and managed with conservative treatment.

Table (8d) Complications in study population

Complication	Group A	Group B	P Value
Wound infection	2	0	0.200
Groin hematoma	0	2	
Pseudo aneurysm	0	1	

Table (8e) Incidence of complications in study population

Presence of complication	Group A	Group B	P Value
Yes	2	3	0.628
No	13	9	

Fisher`s exact test

VII. Clinical success correlations

1) Relation of clinical success to number of distal runoff vessels.

a. In group (A), Clinical success occurred in all patients either with 1 or 2 or 3 distal runoff vessels.

b. In group (B), Clinical failure was higher in cases having one distal runoff vessels (2 cases) compared with cases having 2 distal runoff vessels (1 case) and with cases having 3 distal runoff vessels (no cases).

Table (9a) Relation of clinical outcome to number of distal runoff vessls in study population

Clinical outcome	No of distal runoff Vs	Group A	Group B	P Value
Failure	1	0 of 4	2 of 3	-
	2	0 of 5	1of 4	
	3	0 of 6	0 of 5	
Success	1	4 of 4	1of 3	
	2	5 of 5	3of 4	
	3	6 of 6	5 of 5	

Table (9b) Relation of clinical outcome to number of distal runoff vessls in group (B)

Clinical outcome	No or distal runoff Vs	Failure	Success	P Value
Group B	1	2	0	0.045*
	2	1	4	
	3	0	5	

Fisher`s exact test
***Statistically significant at p- value < 0.05**

2) Relation of clinical success and limb salvage to presenting symptom.

a. In group (A), No patients underwent major amputation until the 3rd month.

b. In group (B), Major amputation was higher in patients presented with tissue loss than those presented with rest pain as one patient presented with gangrene among the 9 patients that had clinically succeeded underwent below knee amputation at the 3rd month.

Table (9c) Relation of limb salvage to presenting complain in study population

Number of patients underwent major amputation among the clinically succeeded group	Rest Pain		Tissue Loss	
	A	B	A	B
At 3rd mg	0	0	0	1
At 6th month	0	0	1	2

VIII. Follow-up

1. Mortality during follow-up period

a. Group (A) Mortality occurred in 1 caseat the 4thmonth postoperative due to myocardial infarction which necessitated admission to urgent PCI and patient died during the procedure.

b. Group (B) No mortality reported cases of

Table (10 a) Mortality in study population

Mortality	Group A	Group B	P Value
Yes	1	0	1.000
No	14	15	

2. Patency rates

a. In group (A) Primary patency at the third month postoperative was100% (from 15) and the 6th month postoperative was 92.9%.(from 14)

b. Limb salvage at 3rd month was 100% and at the 4th month one case underwent below knee amputation due to spread of infection decreasing limb salvage to 93.3%.

c. In group (B) After exclusion of the initial technical failure group (3 cases) and clinical failure group (other 3 cases that underwent below knee amputation after technically succeeded due to spread of infection at 1 month post-operative) 9 cases are followed- up for 6 months, primary and secondary patency rates and limb salvage rates were defined at 3rd and 6th month post procedure.

- Primary patency was 66.6 (of 9 cases) and 62.5 (of 8 cases) at 3rd and 6th month respectively
- Secondary patency was 88.8 (of 9 cases) and 87.5 (of 8 cases) at 3rd and 6th month respectively
- Limb savage was 88.8 (of 9 cases) and 87.5 (of 8 cases) at 3rd and 6th month respectively
- Between 2nd and 3rd month 3 patients presented with restenosis or re occlusion recurrent rest pain in two cases and recurrent tissue loss in 3rd case (new tissue loss or failure of healing).
- Re- intervention was attempted in the 3 patients and succeeded in 2 patients presented with recurrent rest pain as the painrelieved post procedure but failed in the 3rd case that was presented with recurrent tissue loss and underwent below knee amputation.
- Secondary procedures increased the patency and limb salvage at 3rd month from 66.6% to 88.8%.
- Between 5th and 6th month 3 patients presented with re-occlusion or restenosis(recurrent rest pain in two cases and recurrent tissue loss in the 3rd case).

- Re-intervention was attempted in the 3 cases and succeeded in two cases after stent placement, re-vascularization occurred and rest pain relieved, but failed in the 3rd case that was presented by recurrent tissue loss and underwent above knee amputation.
- Secondary procedures increased patency and limb salvage at 6th month from 62.5% to 87.5%.

Table (10 b) 1ry patency, 2 ry patency & limb salvage in study population

Time	**1ry patency**		**2 ry patency**		**Limb salvage**	
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**
3rd month	100%	66.6%	100%	88.8%	100%	88.8%
6th month	100%	62.5%	100%	87.5%	93.3%	87.5%

Table (10 c) 1ry patency at 3rd month in study population

1ry patency at 3rd month	**Group A**		**Group B**		**P value**
	N	**%**	**N**	**%**	
Remain patent	15	100	6	66.7	**0.045***
Others	0	0	3	33.3	

Fisher`s exact test

***Statistically significant at p- value < 0.05**

Table (10 d) 2ry patency at 3rd month in study population

2ry patency at 3rd month	**Group A**		**Group B**		**P value**
	N	**%**	**N**	**%**	
Patent after secondary procedure	15	100	8	88.9	**0.375**
Others	0	0	1	11.1	

Fisher`s exact test

Table (10 e) Limb Salvage at 3rd month in study population

Limb salvage at 3rd month	**Group A**		**Group B**		**P value**
	N	**%**	**N**	**%**	
No major amputation	15	100	8	88.9	**0.375**
Others	0	0	1	11.1	

Fisher`s exact test

Table (10 f) 1ry patency at 6th month in study population

1ry patency at 6th month	**Group A**		**Group B**		**P value**
	N	**%**	**N**	**%**	
Remain patent	13	92.9	5	62.5	**0.117**
Others	1	7.1	3	37.5	

Fisher`s exact test

Table (10 g) 2ry patency at 6th month in study population

2ry patency at 6th month	**Group A**		**Group B**		**P value**
	N	**%**	**N**	**%**	
Patent after secondary procedure	13	92.9	7	87.5	**1.000**
Others	1	7.1	1	12.5	

Fisher`s exact test

Table (10 h) Limb Salvage at 6th month in study population

Limb salvage at 6th month	**Group A**		**Group B**		**P value**
	N	**%**	**N**	**%**	
No major amputation	13	92.9	7	87.5	**1.000**
Others	1	7.1	1	12.5	

Fisher`s exact test

DISCUSSION

Regarding patients characteristics, in our study the majority of cases were male (86.6%) with mean age of 65 years old.

A look at the patient characteristics in the retrospective study done by ***Baril et al.*** [5] in 79 TASC D limbs in 74 patients; revealed that the average of male gender was 53% and the mean age of all patients included in the study was 76 years old.

So, the percent of male gender in our study was higher in comparison to other studies on patients with symptomatic chronic occlusive lower limb ischemia. On the other hand, we had lower mean age. This could be explained by the fact that we are a developing country with low health care standards in comparison to the developed countries and that leads to low life expectancy in the general population.

Regarding risk factors, in our study; 19 patients were smokers (63.3%), hypertension was present in 15 patients (50%), and diabetes mellitus in 20 patients (66.6%).

In ***Baril et al.*** [5]***,*** the average of the percentages were 52% for smoking, 82% for hypertension, and 38% for diabetes mellitus.

In comparison to ***Baril et al.*** [5]***,*** we had more diabetic and this may be related to the fact that 70.9% of the patient group in ***Baril et al.*** study had critical limb ischemia and we had all patients in both group suffering from critical limb ischemia. More over the incidence of diabetes is very high in our country.

Analysis of co-morbidities shows that in our study 18 patients (60%) were cardiac. In ***Baril et al.*** [5]***,*** the averages of the percentages were 63% for cardiac patients. **In BASL trial**, > 40% of patients were diabetic, > 33% were smoker and most had a significant cardiovascular medical history.

Indications of intervention in our study are minor tissue loss in 8 patients (26.6 %); Rutherford class V, major tissue loss in 9 patients (30%); Rutherford class (VI) and rest pain in 13 patients (43.3%); Rutherford class IV.

In BASL trail indication was rest pain in 25.6% of patients and tissue loss (minor or major) in 74.4% of patients.

Clark et al. [6] state that poor tibial runoff is most predictive of lower long-term patency rates, and that is compatible with results in our study especially in endovascular group as clinical failure was higher in cases of one distal run off vessels (2 cases among 3 that had clinically failed "66.6%").

The treatment of these TASC D lesions relies on particular techniques as well as equipment to optimize technical success. In particular, these lesions, by definition are often quite long, which may require the use of stiff wires to optimize the ability to push across these lesions. In addition to crossing ability, TASC D lesions are more complex in that re-entry may be difficult secondary to calcification.

In our study we did not face much difficulty in re-entering the true lumen expect in one case; we did not use any re-entry devices due to lack of availability.

Different techniques and new devices have been reported to facilitate re-entry into the true lumen. Two devices are currently available that facilitate true-lumen reentry [The OutBack LTD reentry catheter (Cordis) and the Pioneer catheter (Medtronic)]. We strongly recommend using these devices if available as they achieve high success rate in safe re-entery to the true lumen, and may reduce the chance of vessel perforation and procedure times.

Our overall technical success in group B was 80%, and this was not dissimilar from other studies which have looked at combined outcomes of endovascular treatment of TASC C and D lesions ***Donald et al.***[7] reviewed 74 patients with 79 limbs TASC II D lesions who were treated with subintimal angioplasty and selective use of a re-entry device and reported a technical success rate of 89%.

However, ***Setacci et al.*** [8] reviewed 145 patients with TASC II C and D lesions who were treated with subintimal angioplasty and selective use of a re-entry device and reported a technical success rate of 83.5% with a 16.5% usage rate of a re-entry device. ***Rabellino et al.*** [9] reviewed 234 limbs, 52% of which were TASC II D lesions and reported initial technical success of 97%.

In surgical group in our study, Technical success was 100%.

As regard procedural and post procedural complications, unlike bypass, endovascular intervention may be performed with minimal physiologic impact on these often critically ill patient population. In our current series, there was no systemic complication directly related to the procedure with local complications in 3 cases in the form of pseudoaneurysm and groin hematoma all managed successfully. In surgical group in our study, Wound infection occurred in 2 cases among 15 (13%).

In a recent review of data obtained through the National Surgical Quality Improvement Program (NSQIP) on patients undergoing infrainguinal bypass, major complications occurred in 18.7% patients, including a 9.4% rate of wound infections and systemic complications occurred in 5.9% of patients [10].

Clearly, an endovascular approach obviates the need for incisions, which often create new wound issues in these compromised extremities [7].

During the follow up period in our study (6 months) mortality occurred in one patients within the surgical group due to MI following femoropopliteal bypass highlighting the fact that endovascular intervention may be more suitable in treating patients with critical limb ischemia who are usually older with multiple comorbidities.

The 2-year survival for patients enrolled in **BASIL** was 70%, quite comparable with the 1-year mortality of 15% observed in the **Project of Ex-Vivo Vein Graft Engineering via Transfection (PREVENT) III trial.**

In surgical group in our study primary and secondary patency at 3rd and 6th month was 100%.

Thus we achieved superior results compared with other studies as in Pereira et al recent meta-analysis of 75 studies who reported that primary patency rates of above-knee femoropopliteal bypasses with the saphenous vein was to be upward of (70.0% –75.6%) at 5 years. However, the primary patency rate of bypasses with synthetic graft is lower: 63% at 2 years and as low as 37% at 5 years [11]

In endovascular group in our study, our three and six months primary patency results were 66.6% and 62.6% respectively while secondary patency was 88.8% and 87.5% at 3rd and 6th month respectively.

In a recent review of 506 infra-inguinal arterial occlusions, Scott et al. reported primary patency of 45% and 25% at 6 and 12 months respectively, while secondary patency was 76% and 50% at the same time intervals [12].

The overall limb salvage in our study in endovascular group was 87.5 %. The reason beneath the fact that the limb salvage may be higher than patency rates is that all of the cases had critical limb ischemia and endovascular intervention may provide sufficient blood supply needed for healing then by the time the vessels is occluded, the demand of blood supply is decreased and the collaterals developed are enough for the tissue viability.

In endovascular group in our study 2 patients required surgical intervention (femoropopliteal bypass) after failed endovascular procedure and success rate was 100%. It stresses that angioplasty and open surgery are not "either/or" therapies, but are complementary. It highlights the importance of having surgeons who possess both open and endovascular skills and can provide a full range of therapeutic options to the patients with lower extremity ischemia.

This crossover treatment after initial therapy (surgery after angioplasty and vice versa) was evident in the BASIL study with more than half of the angioplasty arm and more than third of the surgery arm required further intervention [13].

In our study, limb salvage was selected to be the primary end point and it was in surgical group 100% at 3rd month and 93.3% at 6th month while in **BASIL** trial, limb salvage was 88% at first year and in the **project of Ex-Vivo Vein Graft Engineering via Transfection (PREVENT) III trial** was 90% at first year.

In endovascular group, in our study, limb salvage was 88.8% at 3rd month and was 87.5% at 6th month while in BASIL trial, limb salvage was 86% after first year and in ***Laird et al. and***

Giles et al. trials, it was 93% and 84% respectively after the first year.

We have limitation in the study:

It is to be noted that our follow up period was relatively short compared to other studies. The follow up period in the study of ***Baril et al.*** [5] was 2 years and at the study of ***Min-yi et al.*** [14] was 4 years.

We have few number of patients included in this study; only 30 patients compared to 74 patients with 79 TASC D limbs in the study of ***Baril et al.*** [5]**.**

In our study we just used the simplest endovascular tools, however evolving endovascular strategies embrace new technologies in an attempt to improve the safety and efficacy of revascularization procedures for lower extremity arterial occlusive disease as drug-eluting stents and drug coated balloons, and the use of stent grafts.

CONCLUSION

The overall recommendation is that severe limb ischemia patients with long life expectancy and useable great saphenous vein, should usually have bypass surgery first. This is because that saphenous vein bypass surgery has long-term patency results and associates with significant improved amputation free survival. The rate of balloon angioplasty failure is high, and results of bypass surgery after failed balloon angioplasty are significantly worse than for primary bypass surgery. However, patients with short life expectancy (as those who are old aged with multiple comorbidities such as cardiovascular diseases) and those without a useable vein, should usually have balloon angioplasty first because they will not survive to reap the longer-term benefits of surgery.

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