RESEARCH ARTICLE

Nitinol stent implantation in chronic limb ischemia secondary to iliac artery narrowing

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Background: Lower-extremity peripheral arterial disease is an important manifestation of systemic atherosclerosis that is associated with markedly increased rates of cardiovascular ischemic events and death. To offer a true therapeutic choice, we will need knowledge from clinical trials that define the potential risks and benefits of each treatment. Combinations of exercise, medication, and revascularization therapies have rarely been evaluated in populations of patients with peripheral arterial disease. The most common site of lower-extremity atherosclerosis is the superficial femoral artery, although the biologic basis for this fact is not clear. Narrowing of the iliac artery is a common presentation of systemic atherosclerosis. Nitinol, an alloy of nickel and titanium, is more flexible and more able to recover from being crushed than stainless steel. The recognition that standards of care for patients with peripheral arterial disease could be improved has led to the creation of new care guidelines. Until the completion of such large clinical trials specific to peripheral arterial disease, many fewer data are available for patients with peripheral arterial disease than for patients with coronary artery disease.

Objectives: The aim of the study was to find out the durability of primary implantation of a self-expanding nitinol stent for the treatment of lesions of the iliac artery in patients with chronic limb ischemia.

Patients and methods: This study was a prospective registry that was conducted on patients with peripheral arterial disease underwent percutaneous trans luminal angioplasty. The study assessed the influence of varying outcome criteria on the success rate at 12 months after percutaneous intervention for peripheral arterial disease and suggested a reporting method that can be used in studies that report results of interventions as measured by parameters of daily clinical practice. Comparison and interpretation of results associated with endovascular revascularization for peripheral arterial disease have been hampered by the different outcome criteria that are applied to classify outcomes as successes or failures. The Peripheral Intervention Registry was established for the quality assessment and improvement of current practice by monitoring the outcomes of percutaneous vascular interventions for peripheral arterial disease affecting the lower extremities. Twenty-five patients with chronic limb ischemia were included in the study referred for percutaneous trans luminal angioplasty constituted the population of the study. All patients included in the study were subjected to history taking, examination, complete general and local examination examination and investigations including 12 leads resting ECG, routine laboratory investigations and Duplex-ultrasonography.

Results: Our results showed that 96% of studied group was males while 4% was females with mean of ages 62.6 years. There was highly statistically significant difference between base line data and six months follows up regarding grade of ischemia and duplex. There was highly statistically significant difference between grade of ischemia after six months follows and risk factors.

Conclusion: For patients with claudication, supervised exercise provides a superior improvement in treadmill walking performance compared to both primary aortoiliac stenting and optimal medical care (home walking and cilostazol) over six months. This benefit is associated with an improvement in self-reported walking distance, an increase in HDL and decrease of fibrinogen. Secondary measures of treatment efficacy favored primary stenting, with greater improvements in self-reported physical function.

Keywords: Nitinol stent; iliac artery stenosis; lower limb ischemia

INTRODUCTION

Lower-extremity peripheral arterial disease is an important manifestation of systemic atherosclerosis that is associated with markedly increased rates of cardiovascular ischemic events and death [1].

Although most patients with peripheral arterial disease are asymptomatic, many have claudication, chronic critical limb ischemia, or acute limb ischemia. As a result, peripheral arterial disease considerably impairs functional status and the quality of life, and it is the most important cause of limb amputation. These effects are magnified by the high prevalence of peripheral arterial disease and the lack of provision of timely care [2].

To offer a true therapeutic choice, we will need knowledge from clinical trials that define the potential risks and benefits of each treatment. Combinations of exercise, medication, and revascularization therapies have rarely been evaluated in populations of patients with peripheral arterial disease. The Claudication: Exercise versus Endoluminal Revascularization (CLEVER) trial-sponsored by the National Heart, Lung, and Blood Institute and currently under way - is a prospective, multicenter clinical investigation that will compare the safety and efficacy of supervised exercise, endovascular stenting, and optimal pharmacotherapy for patients with aortoiliac peripheral arterial disease [3].

The most common site of lower-extremity atherosclerosis is the superficial femoral artery, although the biologic basis for this fact is not clear. However, angioplasty and stent placement in the superficial femoral artery have, to date, been less successful than percutaneous coronary-artery intervention. Furthermore, primary stent placement in the superficial femoral artery has not been shown to be reliably superior to balloon angioplasty alone [4-7].

In contrast to their performance in the coronary setting, sirolimus-eluting stents have not yet been shown to be superior to bare-metal stents for peripheral arterial disease [8,9].

Narrowing of the iliac artery is a common presentation of systemic atherosclerosis. With the recent development of invasive techniques, angioplasty and stenting offer excellent results for fixing limb ischemia of aorto-iliac arteries. However, despite novel interventional approaches and constantly increasing experience, complications such as distal embolization, stent migration, acute or subacute iliac artery occlusion,

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dissection, and perforations are still challenging. Early restenosis and/or reocclusion of peripheral artery stents is uncommon [10]. So, percutaneous recanalization of chronic iliac occlusions provides acceptable long-term results with lower mortality and morbidity [11].

Nitinol, an alloy of nickel and titanium, is more flexible and more able to recover from being crushed than stainless steel [12].

The recognition that standards of care for patients with peripheral arterial disease could be improved has led to the creation of new care guidelines [13,14]. In addition, a better-informed public will demand therapeutic interventions for the disease [15]. Thus, it is anticipated that both medical and endovascular techniques will be used increasingly to treat lower-extremity peripheral arterial disease.

Until the completion of such large clinical trials specific to peripheral arterial disease, many fewer data are available for patients with peripheral arterial disease than for patients with coronary artery disease. A larger investment is needed in designing and performing prospective, adequately powered clinical investigations of peripheral arterial disease and in evaluating the results. Because traditional standards for the clinical investigation of peripheral arterial disease may not be adequate, a higher standard should be used.

The aim of the study is to find out the durability of primary implantation of a self-expanding nitinol stent for the treatment of lesions of the iliac artery in patients with chronic limb ischemia.

PATIENTS AND METHODS

This study was conducted on 25 patients with peripheral arterial disease underwent percutaneous trans luminal angioplasty.

The study assessed the influence of varying outcome criteria on the success rate at 12 months after percutaneous intervention for peripheral arterial disease and suggested a reporting method that can be used in studies that report results of interventions as measured by parameters of daily clinical practice.

Comparison and interpretation of results associated with endovascular revascularization for peripheral arterial disease have been hampered by the different outcome criteria that are applied to classify outcomes as successes or failures.

The peripheral Intervention Registry was established for the quality assessment and improvement of current practice by monitoring the outcomes of percutaneous vascular interventions for peripheral arterial disease affecting the lower extremities.

Inclusion criteria

- Patients referred for endovascular treatment of the iliac artery owing to intermittent claudication or chronic critical limbischemia will be screened for enrollment in this randomized, single-institution trial.
- Before potential candidates for percutaneous intervention enrolled, their cases will be discussed by vascular surgeons and interventional cardiologists
- Symptomatic peripheral-artery disease with severe intermittent claudication (Rutherford stage3).
- Chronic critical limb ischemia with pain while the patient was at rest (Rutherford stage 4).
- Chronic critical limb ischemia with ischemic ulcers (Rutherford stage 5).
- The anatomical inclusion criteria, based on biplane digital subtraction angiography (DSA)performed at the time of intervention, will be stenosis of more than 50 percent or occlusion of the ipsilateral iliac artery, a target-lesion length of more than 30 mm, and at least one patent (less than 50 percent stenosed) tibioperoneal runoff vessel.

Exclusion criteria

- Acute critical limbischemia.
- Previous bypass surgery of the iliac artery
- Untreated inflow disease of the ipsilateralpelvic arteries (more than 50 percent stenosis or occlusion)
- Known intolerance to study medications or contrast agents.

Methods

All patients included in the study will be subjected to the following:

History taking

Full history taking with special emphasis on the history of claudication, coldness, loss of hair and risk factors (e.g. hypertension, DM, positive family history).

Examination

Complete general and local examination of the heart and blood vessels, the patients will be classified according to RUTHERFORD CLASSIFICATION [16].

Investigation

- Twelve leads resting ECG.
- Routine laboratory investigations including fasting blood sugar, liver and kidney function tests, complete blood picture, Lipid profile and coagulation profile.
- Duplex – ultra sonography to determine the site of arterial stenosis.

Percutaneous intervention of the iliac artery:

- Interventions will be performed percutaneously by an antegradeor anretrograde over-the-bifurcation approach with the use of 6-Frenchsheaths.
- Biplane DSA will be performed in two views at least 30 degrees apart to evaluate the structure of the lesion, in flow disease (obstruction or stenosis of the iliac artery), and runoff (the number of patent tibioperoneal vessels).
- To document the precise location of the lesion and the site of intervention, a ruler will be fixed on the patient's thigh with the distal end exactly overlapping the upper edge of the patella.
- After the guide wire had passed through the target lesion, patients were assigned to undergo primary stent implantation.
- Patients will be stratified according to the reason for revascularization (claudication vs. critical limb ischemia which refer to chronic rest pain, ulcers, or gangrene) and the length of the target lesion (≤60 mm vs. >60 mm).
- The stents will be implanted to extend 10 mm proximally and distally from the margins of the target lesion.
- When multiple stents are required, the margins of the stents overlapped 10 mm.
- Dilation after stenting will be performed strictly within the stented segment, with up to 10percent oversizing of the postdilation balloon.
- In patients undergoing angioplasty, each balloon was inflatedat 10 to 12 atm for at least two minutes.
- After dilation of the entire target segment, biplane angiograms will be obtained.
- In cases with a suboptimal primary result, which is defined as a residual stenosis of more than 30 percent or the presence of a flow-limiting dissection in the worst angiographic view, a second prolonged (more than two minutes) balloon dilation of the target segment will performed.
- In patients with a persistently suboptimal result after the second balloon dilation, secondary stenting will be performed.
- Self-expanding nitinol stents (Dynalink or Absolute, Guidant) with a nominal diameter of 6 mm will be used.
- Biplane angiography was performed after the intervention, with the use of the same angles and magnifications used in the baseline angiogramsto detect;

- Site of lesion.
- TASC class.
- Lesion Characteristics.
- Angioplasty balloons data:
- (Size, No. of inflations and inflated Pressure, State: new/used, Brand).
- Stents data:
- (Size, Type, Brand).
- Post deployment balloons:
- (Size, No. of inflations and inflated Pressure, State: new/used, Brand).

- Immediate outcome
  - Procedure success

Clinical success

Immediate improvement by at least on clinical category, sustained improvement by at least one clinical category and pulse distal to the lesion is well felt.

Technical failure

was defined as failing to enter the vessel, cross the lesion, or improve blood flow.

a. Access site complication: (Hematoma, Hemorrhage. Dissection. A-V fistula, Infection).

b. Limb amputation.

c. Strokes.

d. Renal failure.

e. Urgent surgical intervention.

Procedure details

- Vascular access:

(Contra-lateral, Ipsi-lateral retrograde, Ipsi-lateral antegrade, others).

(Size, Brand).

Pre-medication (Aspirin, Clopidogrel)

6 months follow up

Data regarding 6 months follow-up after the procedure were collected and entered in the Vascular Intervention Registry.

- **Patient state:** Alive or dead.
- If the patient is dead the causes were mentioned with all available details.
- **Recurrence of LL ischemia**.
- **causes of the recurrence of LL symptoms:**
- (Target lesion, Target vessel or other vessel).
- **Type of ischemia:**
- (Claudication, critical limb ischemia or acute ischemia).
- **Absent peripheral pulsations**
- **Presence of ischemic ulcer, infection, gangrene or rest pain**
- **Methods of objective assessment:**
  - The important criteria of follow up were: patient continued symptomatic improvement.
  - Clinical examination was performed to assess the clinical situation of the patient [claudication vs. critical ischemia (defined as ulceration, gangrene, or pain at rest, stages III and IV of the Fontaine classification)].
  - In all patients the information obtained by duplex scanning. Peak systolic velocity ratios greater than 2.5 or sonography stenosis of 50% or more was defined as recurrence of the stenosis.
  - Angiography: Angiographic stenosis of 50% or more was defined as procedural restenosis.
  - Multi-slice CT.
  - MRA.

Management

Statistical analysis

Data were entered checked and analyzed using Epi-Info version 6 and SPP for Windows version 8.

Data were summarized using: the arithmetic mean, the standard deviation, chi-squared test.

For all above mentioned statistical tests done, the threshold of significance is fixed at 5% level (p-value).

The result was considered:

- Significant when the probability of error is less than 5% ($p<0.05$).
- Non-significant when the probability of error is more than 5% ($p>0.05$).
- Highly significant when the probability of error is less than 0.1% ($p<0.001$).
- The smaller the p-value obtained, the more significant are the results.

RESULTS

Table 1 shows that 96% of studied group was males while 4% was females with mean of ages 62.6 years.

Table 2 shows that moderate ischemia was common among studied cases .it represented 68% of studied group while no mild cases present.

Table 1 Demographic characteristics of the studied group.

Age (years)	Range	52-70
	Mean ± SD	62.6 ± 4.7
Sex	Male	24(96%)
	Female	1(4%)

Table 2 Distribution of cases according to grade of ischemia.

	No.	**%**
Mild	0	0
Moderate	17	68
Sever	7	28
Critical	1	4
Total	25	100

Table 3 shows that 52% of studied group had normal ECG, 32% had LVH while, 16% had old MI. Table 4 shows that 96% of cases had DD, the mean LVDd was 55.8, LVSD was 36.5 and EF was 58.3.

Table 3 Distribution of cases according to ECG.

	No.	%
Normal	13	52
LVH	8	32
Old MI	4	16
Total	25	100

Table 4 Distribution of cases according to Echocardiography.

	Number=25	
	Mean ± SD	Range
DD (Number & %)	24	96%
LVDd	55.8 ± 4.5	50-69
LVSD	36.5 ± 6	30-55
EF	58.3 ± 6.7	40-68

Table 5 shows that 40% of cases had lesion in Rt. CIA and 52% TASC (B).the mean size of balloon was (5.6/34.8), mean number of inflation was 2.2, stent size was (9.8/67.2) and 92% had Post deployment balloon.

Table 5 Distribution of cases according to Angiography and angioplasty.

	No.	%
A-Lesion		
1-Site		
Rt.CIA	10	40
Lt CIA	6	24
Rt–ext IA	6	24
Lt–ext IA	3	12
2-TASC		
B	13	52
C	12	48
B-Balloon	**Mean ± SD**	**Range**
1-size		
Diameter	5.6 ± 3.3	0-8
Length	34.8 ± 21.4	0-70
2-No. of inflation	2.2 ± 1.4	0-4
3-Stent size		
Diameter	9.8 ± 0.7	12-Aug
Length	67.2 ± 12.4	40-90
4- Post deployment balloon		
Yes	23	92
No	2	8
Total	25	100

Table 6 shows that 100% of studied cases had procedural success and clinical success.

Table 7 shows that 12% of cases had Access site complication and haematoma.

Table 8 shows that 68% of cases used contralateral antegrade vascular access and the mean sheath size was 7.

Table 9 shows that result of 6 months follow up in which 96% of patients were alive, 92% of them had no recurrence of limb ischemia, 92% of them had no ischemia, 96% had intact peripheral pulsation and 96% normal douplex and 4% angiographic stenosis.

Table 6 Distribution of cases according to immediate outcome.

	No.	%
procedural success	25	100
Clinical success	25	100
Total	25	100

Table 7 Distribution of cases according to complications.

	No.	%
Access site complication	3	12
Infection	0	0
haematoma	3	12
haemorrhage	0	0
dissection	0	0
A V fistula	0	0
Limb amputation	0	0
Stroke	0	0
Renal failure	0	0
Total	25	100

Table 8 Distribution of cases according to procedural details.

	No.	%
A-vascular access		
Contralateral antegrade	17	68
Ipsilateral retrograde	18	32
B-sheath size		
Mean ±SD	7 ± 0.4	Range 6-8
Total	25	100

Table 9 Distribution of cases according to Six months follows.

	No.	%
A-patient state		
Alive	24	96
Dead	1	4
B-recurrence of limb ischemia		
Yes	2	8
No	23	92
C-grade of ischemia		
No	23	92
Mild	1	4
Moderate	1	4
Severe	0	0
Critical	0	0
D-peripheral pulsation		

Intact	24	96
Absent	1	4
E – duplex follow up		
Normal	24	96
Restenosis	1	4
F-angiographic stenosis		
Yes	1	4
No	24	96
Total	25	100

Table 10 shows that there was highly statistically significant difference between base line data and six months follows up regarding grade of ischemia and duplex as p value <0.001.

Table 11 shows that there was highly statistically significant difference between grade of ischemia after six months follows and risk factors as p value <0.001.

Table 10 Comparison between base line data and six months follows up regarding grade of ischemia and duplex.

	Number=25				**p value**
	Pre		**Post**		
	No.	**%**	**No.**	**%**	
Grade of ischemia					
No	0	0	23	92	
Mild	0	0	1	4	<0.001*
Moderate	17	68	1	4	
Severe	7	28	0	0	
Critical	1	4	0	0	
Duplex					
Normal	0	0	24	96	<0.001*
Abnormal	25	100	1	4	

Table 11 Association between grade of ischemia after six months follows and risk factors.

Risk factors	**Grade of ischemia**				X^2	
	Number		**Mild/moderate**			**p value**
	Number=23		**Number=2**			
	No.	**%**	**No.**	**%**		
DM	21	91.3	2	100		
HTN	17	73.9	1	50	80.8	<0.001*
Family history	2	8.7	0	0		
Dyslipidemia	9	39.1	2	100		
Smoking	21	91.3	1	50		

DISCUSSION

The estimated prevalence of PAD in people older than 70 years is between 14% and 29%. Intermittent claudication, the classical PAD symptom, is present in only 10% of patients. Approximately 50% of patients with PAD have atypical lower-extremity symptoms; another 40% are asymptomatic. Peripheral arterial disease is a strong predictor of systemic atherosclerosis and is considered a coronary artery disease (CAD) risk equivalent [17].

To offer a true therapeutic choice, we will need knowledge from clinical trials that define the potential risks and benefits of each treatment. Combinations of exercise, medication, and revascularization therapies have rarely been evaluated in populations of patients with peripheral arterial disease. The Claudication: Exercise versus Endoluminal Revascularization (CLEVER) trial - sponsored by the National Heart, Lung, and Blood Institute and currently under way - is a prospective, multicenter clinical investigation that will compare the safety and efficacy of supervised exercise, endovascular stenting, and optimal pharmacotherapy for patients with aortoiliac peripheral arterial disease [17].

The most common site of lower-extremity atherosclerosis is the superficial femoral artery, although the biologic basis for this fact is not clear. However, angioplasty and stent placement in the superficial femoral artery have, to date, been less successful than percutaneous coronary-artery intervention. Furthermore, primary stent placement in the superficial femoral artery has not been shown to be reliably superior to balloon angioplasty alone. In contrast to their performance in the coronary setting, sirolimus-eluting stents have not yet been shown to be superior to bare-metal stents for peripheral arterial disease [18].

Narrowing of the iliac artery is a common presentation of systemic atherosclerosis. With the recent development of invasive techniques, angioplasty and stenting offer excellent results for fixing limb ischemia of aorto-iliac arteries. However, despite novel interventional approaches and constantly increasing experience, complications such as distal embolization, stent migration, acute or subacute iliac artery occlusion, dissection, and perforations are still challenging. Early restenosis and/or reocclusion of peripheral artery stents is uncommon. So, percutaneous recanalization of chronic iliac occlusions provides acceptable long-term results with lower mortality and morbidity [18].

Nitinol, an alloy of nickel and titanium, is more flexible and more able to recover from being crushed than stainless steel. The recognition that standards of care for patients with peripheral arterial disease could be improved has led to the creation of new care guidelines. In addition, a better-informed public will demand therapeutic interventions for the disease. Thus, it is anticipated that both medical and endovascular techniques will be used increasingly to treat lower-extremity peripheral arterial disease [19].

In this study, we found out the durability of primary implantation of a self-expanding nitinol stent for the treatment of lesions of the iliac artery in patients with chronic limb ischemia in twenty-five patients with chronic limb ischemia.

All patients included in the study will be subjected to history taking, complete general and local examination of the heart and blood vessels, 12 leads resting ECG, routine laboratory investigations (including fasting blood sugar, liver and kidney function tests, complete blood picture, Lipid profile and coagulation profile), Duplex ultrasonography and percutaneous intervention of the iliac artery.

All patients received aspirin (100mg daily) indefinitely and clopidogrel (75 mg daily) for three months after the intervention. Most patients started taking clopidogrel at least two days before the intervention; for those who did not, a loading dose of 300mg of clopidogrel will be given during the intervention.

Our study showed that 96 of studied group was males while 4% was females with mean of ages 62.6 years. The most common risk factors were DM (92%), followed by smoking (88%) and hypertension (72%) and the least risk factors was among House wife (4%) and positive family history (8%).

TASC II Working Group [20] had elucidated the risk factors for lower extremity atherosclerotic occlusive arterial disease. Tobacco smoking is closely linked to PAD. The severity of PAD is directly proportional to the

number of cigarettes smoked. On average, the diagnosis of PAD is made 10 years earlier in smokers than nonsmokers. Overall, PAD is three times more prevalent in smokers.

The degree of hypertension is also closely linked to the development of PAD [21]. In our study, moderate ischemia was common among studied cases. It represented 68% of studied group while no mild cases present.

Our study showed that that 52% of studied group had normal ECG, 32% had LVH while, 16% had old MI. Our study showed also that 96% of cases had DD.the mean LVDd was 55.8, LVSD was 36.5 and EF was 58.3.

Our results found that 40% of cases had lesion in Rt. CIA and 52% TASC (B). The mean size of balloon was (5.6/34.8), mean number of inflation was 2.2, stent size was (9.8/67.2) and 92% had Post deployment balloon.

In the third National Health and Nutrition Examination Survey [22], PAD prevalence was significantly greater with tobacco use, African American ethnicity , glomerular filtration rate (GFR) of less than 60 mL /min, diabetes mellitus (DM), and hypercholesterolemia. The risk of PAD progressing to critical limb ischemia (CLI) is increased with DM, tobacco use, ABI less than 0.5, age greater than 65 years, and hypercholesterolemia. The extent to which the PAD prevalence increases depends on the number of risk factors present at diagnosis of peripheral arterial disease. Compared to patients with no risk factors at diagnosis, presence of one or more risk factors increases the likeness of PAD, and risk increase for increasing numbers of risk factors, compared to no risk factor.

In our study, this table shows that 100% of studied cases had procedural success and clinical success. Our study showed also that 12% of cases had Access site complication and haematoma. Our results found that 68% of cases used contralateral antegrade vascular access and the mean sheath size was 7.

Results of 6 months follow up in which 96% of patients were alive, 92% of them had no recurrence of limb ischemia, 92% of them had no ischemia, 96% had intact peripheral pulsation and 96% normal douplex and 4% angiographic stenosis. There was highly statistically significant difference between base line data and six months follows up regarding grade of ischemia and duplex. There was highly statistically significant difference between grade of ischemia after six months follows and risk factors.

Endovascular intervention for CLI as reported by Kandzari et al. [23] had a procedural success rate of 99% with a 1% major adverse event rate and no unplanned amputations. Heparin-coated, small-diameter, balloon-expandable stents were used for the treatment of tibial disease by Feiring et al. [24] with good results.

Bosch and Hunink [25] have established the high technical success of PTA for aorto-iliac occlusive disease, with a combined immediate technical success for stenoses and occlusions of 91 percent. Long-term success rates of PTA vary from 53 to 70 percent at five years, depending on the severity of disease and which diseased blood vessel was treated.

In 347 patients who underwent endovascular treatment for claudication in 481 limbs, Davies et al. [26] noted that vessels with compromised and poor runoff had significantly lower freedom from recurrent symptoms and from restenosis at 5 years' follow-up.

Whatling et al. [27] determined whether the perceived ease of stenting and shorter hospital stay is reflected in the long-term costs of the procedure. They suggested that stenting of occluded iliac arteries should be reserved for those patients with limited life expectancy. Patients who are younger and fitter should be offered femorofemoral crossover grafting as a primary procedure until research enables identification of those patients who are most likely to maintain long-term patency after stenting.

Ponec et al. [28] evaluated, with an equivalence design, the performance of the shape memory alloy recoverable technology (SMART) nitinol self-expanding stent and the stainless steel Wallstent for treating iliac artery disease after suboptimal percutaneous transluminal angioplasty (PTA). They concluded that the performance of the SMART stent was equivalent to that of the Wallstent for treating iliac artery stenosis. The design characteristics of the SMART stent may contribute to greater procedural success and more accurate stent deployment.

Ansel et al. [29] evaluated the effect of glycoprotein IIb/IIIa inhibition during nitinol stenting, of superficial femoral occlusive disease. They concluded that nitinol stenting of the superficial femoral artery was associated with favorable functional outcomes at 9 months. Adjunctive abciximab did not appear to demonstrate any identifiable effect.

Vorwerk et al. [30] demonstrated follow-up results of stent placement in aortic and iliac stenoses. They concluded that placement of self-expanding stents in iliac stenoses is technically safe and offers sufficient follow-up patency.

Mwipatayi et al. [31] determined if covered stents offer a patency advantage over bare-metal stents in the treatment of aortoiliac arterial occlusive disease. They concluded that patients with complex aortoiliac lesions, including chronic iliac artery occlusions and occlusion of the aortoiliac bifurcation, can be treated safely and effectively with a covered stent. For patients with severe aortoiliac arterial occlusive disease, there is an increased freedom from restenosis and occlusion with covered stents compared with BMSs at 12 and 18 months.

Murphy et al. [32] compared the benefits of optimal medical therapy, structured exercise, and stent revascularization on both walking outcomes and measures of QOL in patients with claudication due to aortoiliac PAD. They concluded that supervised exercise treatment results in superior treadmill walking performance than stent placement, even for those with aortoiliac PAD.

Our study is limited by its relatively small number of patients, but excellent overall follow up was achieved. Also, operator bias in treating patients might have influenced the target lesion revascularization rate in the absence of pre-defined prospective criteria for re-intervention.

Furthermore, there were no set criteria for lesion revascularization in this study. The presence of claudication or limb ischemia, however, was the driving factor to retreat these patients, as asymptomatic patient were not treated in this cohort. The procedure success did not influence the patient state one year after the intervention as the patients with procedural failure may had other endovascular or surgical interventions.

CONCLUSION

Dramatic shifts in the management of peripheral vascular disease have occurred toward endovascular intervention together with an overall decline in mortality and morbidity. There seems to be a significant mortality and morbidity advantages for endovascular as compared with traditional surgery. The increasing safety of vascular interventions should be considered when deciding which patients to treat with the caveat that independent factors of outcomes should be respected.

A global strategy to achieve optimal outcome with percutaneous peripheral interventions is offered:

- Obtain excellent acute angiographic results with less dissection and recoil.
- Protect the distal tibial vascular bed.
- Reduce smooth muscle cell proliferation with pharmacological intervention.

We demonstrated that for patients with claudication, supervised exercise provides a superior improvement in treadmill walking performance compared to both primary aortoiliac stenting and optimal medical care (home walking and cilostazol) over six months. This benefit is associated with an improvement in self-reported walking distance, an increase in HDL and decrease of fibrinogen. Secondary measures of treatment efficacy favored primary stenting, with greater improvements in self-reported physical function.

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