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Mahsoub Mourad Amin
Department of Vascular Surgery, Faculty of Medicine for boys, Al-Azhar University, Assuit, Egypt

Mohammed Alsagher Alhewy
Department of Vascular Surgery, Faculty of Medicine for boys, Al-Azhar University, Assuit, Egypt

Ahmed Abbas Neaz
Department of Vascular Surgery, Faculty of Medicine for boys, Al-Azhar University, Assuit, Egypt,
dr.ahmadabass@gmail.com

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ORIGINAL ARTICLE

Self-expanding Versus Balloon-expandable Stents for Treatment of Iliac Artery Occlusive Disease

Mahsoub Mourad Amin, Mohammed Alsagher Alhewy, Ahmed Abbas Neaz*

Department of Vascular Surgery, Faculty of Medicine for Boys, Al-Azhar University, Assuit, Egypt

Abstract

Background: **An ankle-brachial index is used to identify peripheral artery occlusive disease (PAOD), which is characterized by diminished arterial blood flow to the lower extremities as a result of atherosclerotic arterial lesions.**

Aim and objectives: **The goal of this research was to compare and contrast the use of self-expanding vs balloon-expandable stents in the management of iliac artery occlusive diseases.**

Patients and methods: **In the time starting at February 2020, this randomized controlled clinical research was carried out in the vascular surgery department at Al-Azhar University Hospitals. The study includes 30 patients (15 patients for Self-Expanding stents and 15 patients for Balloon-Expandable Stents) suffering from Iliac artery occlusive disease.**

Result: **We achieved a limb salvage rate of 70% (21 patients). With 10 patients (66.6%) in group A and 11 patients (73.3%) for group B and a major amputation rate of 26.7% (13 patients) over 1-year follow-up period.**

Conclusion: **We conclude that in the presence of CLI, balloon-expandable stents are a safe and efficient therapeutic option for iliac artery occlusive disease. Stent patency rates, limb salvage, and postoperative mortality are all improving. Correcting merely the proximal lesions is not sufficient, particularly in patients who have tissue loss, since this is often accompanied by poor patency rates and low total limb salvage rates.**

Keywords: Balloon-expandable stents, Iliac artery treatment, Occlusive disease, Self-expanding

1. Introduction

An ankle-brachial index of less than 0.9 indicates the presence of peripheral artery occlusive disease (PAOD), which is characterized by decreased arterial blood flow to the lower extremities as a result of atherosclerotic arterial lesions. It might result in critical limb ischemia (CLI) or intermittent claudication (IC), depending on how the condition develops.[1]

Only one to four out of every five people with PAOD will have symptoms. IC is the clinical symptom of PAOD that occurs most often. It is described as ischemia discomfort that develops after physical activity and is immediately eased by rest.

CLI, which is characterized by ischemic rest discomfort or ischemic skin lesions, such as ulcers or gangrene, is a more severe form of PAOD. Age, cigarette usage, and diabetes mellitus are the three main risk factors for developing the advanced type of PAOD.

Over the age of 65, the frequency of PAOD increases to 13.4% of the general population, and over the age of 75, it increases to 21.6%. According to the German Get ABI research, the prevalence was 19.8% for males and 16.8% for women over 65.

Anatomically, the iliac arteries host around 30% of the arterial lesions in PAOD.[2]

IC and CLI may be brought on by iliac artery atherosclerotic disease. Serious side effects including infection, amputation, and even death may result from it.

Revascularization reduces symptoms and shields against these problems. It required open surgery, either an endarterectomy or a bypass.

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* Corresponding author at: Department of Vascular Surgery, Faculty of Medicine for boys, Al-Azhar University, Assuit, Egypt.
E-mail address: dr.ahmadabass@gmail.com (A.A. Neaz).

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Endovascular repair has emerged as the first-line therapy for iliac arterial occlusive diseases during the last ten years.

However, primary stenting with a balloon-expandable stent in the common iliac artery is most strongly recommended in cases of more severe illness, such as lengthy or multiple stenosis or occlusions.[3]

A self-expanding stent for the iliac artery has recently been developed. It has been shown to lower rates of restenosis.[2]

Our hypothesis is to compare result of self-expanding stents with balloon-expandable stents.

The objective of this research was to compare and contrast the use of balloon-expandable vs self-expanding stents in the management of iliac artery occlusive disease.

2. Patients and methods

In the time starting at February 2020, this randomized controlled clinical research was carried out in the vascular surgery department at Al-Azhar University Hospitals. The trial involves 30 patients with Iliac artery occlusive disease (15 patients for balloon-expandable stents, and 15 patients for self-expanding stents).

Patients over the age of 18 with symptoms of advanced common iliac artery atherosclerosis, defined as stenosis longer than 3 cm and occlusions, were included in the research.

The common iliac artery was endovascularly dilated for the first group, and one or more balloon-expandable stents were then implanted. The identical procedures were used on the other group, but one or more self-expanding stents were inserted.

Inclusion criteria: Age over 18, symptomatic common iliac artery atherosclerosis, hemodynamically severe stenosis measuring more than 3 cm in length, or blockage, and informed permission given.

Exclusion criteria: Patients with a serum creatinine level greater than 1.7 mg/dl, those who have a known allergy to iodinated contrast agents, those who are pregnant or nursing, those who have a stenosis with a length of less than 3 cm, those who have undergone endovascular or surgical treating of the common iliac artery on the affected side, those who cannot or do not want to follow the follow-up schedule, those who have CLI and occlusion or Aneurysm of the abdominal aorta.

2.1. Methods

Patient evaluation: After Informed written consent, patients were subjected to the following: Clinical evaluation, duplex US, and CT angiography.

2.2. Clinical data for every patient was recorded in a printed vascular sheet

History: Complaint, Present history, Analysis of complaint: onset: …. course: …. duration, **Past history and family history:**

Examination: general assessment, local assessment: Arterial survey: Ankle/brachial index were measured in all our patients using a hand-held Doppler and it was used for both diagnosis and postoperative follow-up.

Investigation: Laboratory (Coagulation profile, lipid profile, CBC, blood sugar level, kidney and liver functions, and hepatitis indicators), Radiological: plain X-ray foot: if there is foot ulceration or gangrene, to detect osteomyelitis. Duplex ultrasound: with assessment of (PSV) was initially done as a less invasive technique to evaluate the arterial system before CT angiography. Computed tomography angiography (CTA): was done for all patients to detect: Patency of the Aorta, multi-segment arterial stenosis or occlusion and distal runoff.

Technique: We randomly divided patients into two groups. Group A (15 patients for Self-Expanding stents) and Group B (15 patients for Balloon-Expandable Stents) suffering from Iliac artery occlusive disease.

Procedure details for angioplasty: Patients were admitted at the day of the procedure where a loading dose of clopidogrel (300 mg) was to be given. Under local anesthetic (lidocaine 2%: 3–5 mg/kg), three sites of arterial access were used depending on the operator's preference Fig. 1.

All patients received 5000 IU intra-arterial heparin immediately following sheath insertion, and a

Fig. 1. Duplex guided needle puncture.

Fig. 2. Bilateral CIA stenting for bilat. CIA occlusion.

second dose of 5000 IU intra-arterial heparin was given if the procedure time exceeds 2 h. To determine the location(s) of the sick segment, the length and severity of stenosis or occlusion, and the amount of distal run-off, a first digital subtraction angiography was conducted Fig. 2.

Following percutaneous transluminal angioplasty (PTA) with stenting, final angiogram was obtained, and procedure outcome was recorded. In case of arterial spasm, 0.1-mg nitroglycerine was given as an intra-arterial bolus. The arterial access sheath was removed when appropriate, and hemostasis achieved by manual compression.

After obtaining instructions on risk factors to manage and treatments such aspirin 81 mg/day for life, clopidogrel 75 mg/day for at least 3 months, and regularly administered atorvastatin, the majority of patients were released on the second day after the surgery (40 mg for 2 weeks and then 20 mg for 6 months).

3. Results

Fig. 3.

Their age ranged between 40 years and 80 years with a mean age of 60.7 ± 12.35 Table 1.

The associated comorbidities were IHD and C.V.S. The associated risk factors were D.M., smoking, hypertension and dyslipidemia Figs. 4 and 5.

Symptoms and signs of patients included in this study included Rest pain, Ischemic Ulcers,

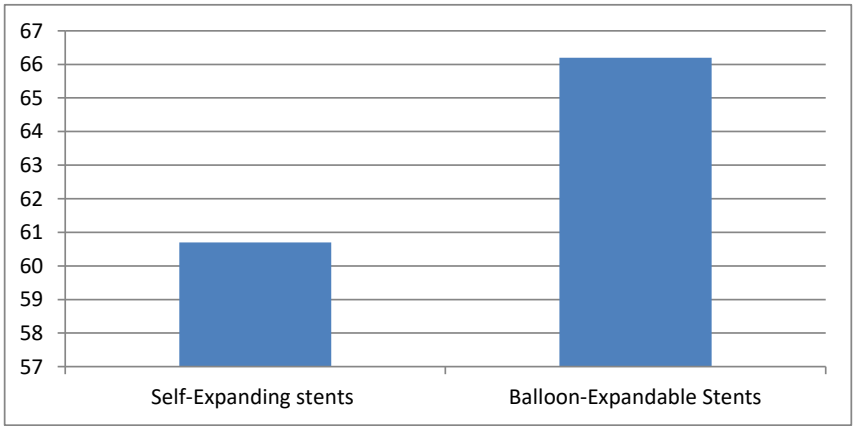

Fig. 3. Distribution of the studied patients regarding their age.

Table 1. The associated diseases and risk factors in the patients.

	Group A	Group B
IHD	3	4
C.V.S.	2	2
D.M.	10	11
Smoking	9	10
Hypertension	11	8
Dyslipidemia	12	11

Gangrene of Toe, Heel or Forefoot as shown below Table 2.

A total number of 30 were done for 30 patients for treatment of CLI due to iliac Artery Occlusive Disease. Antegrade approach by ipsilateral femoral access used in all patients Fig. 6.

Mean operation time was calculated for each procedure and exact numbers are shown in Figure below Table 3.

Table 2. Success rate.

Self-expanding stents		Balloon-expandable stents	
Success *N* (%)	Failed *N* (%)	Success *N* (%)	Failed *N* (%)
13 (86.6)	2 (13.4)	14 (93.3)	1 (6.7)

We achieved a limb salvage rate of 70% (21 patients). With 10 patients (66.6%) in group A and 11 patients (73.3%) for group B and a major amputation rate of 26.7% (13 patients) over 1-year follow-up period Fig. 7.

After one year, the main patency percentage in Group A was 53.3% while in Group B it was 60% Fig. 8.

Vessel perforation occurred in 2 patients and was managed by prolonged balloon inflation. We had registered 13 cases of stent thrombosis (Six in group

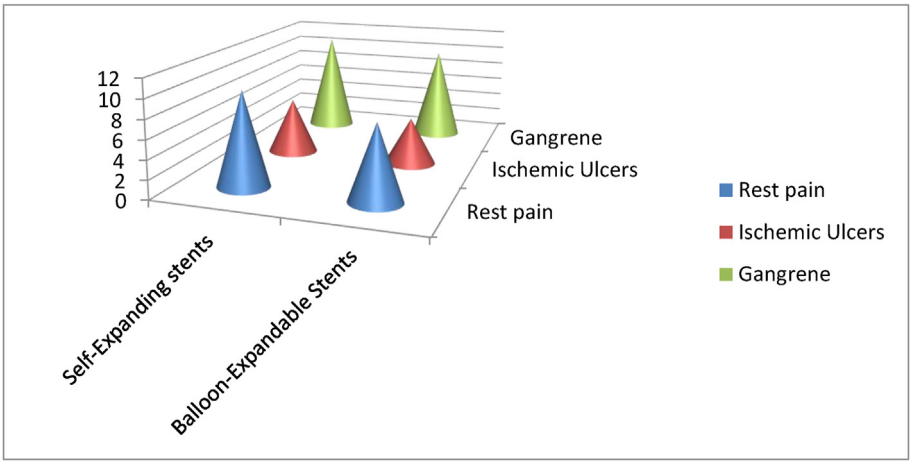

Fig. 4. Symptoms and signs of patients included in this study.

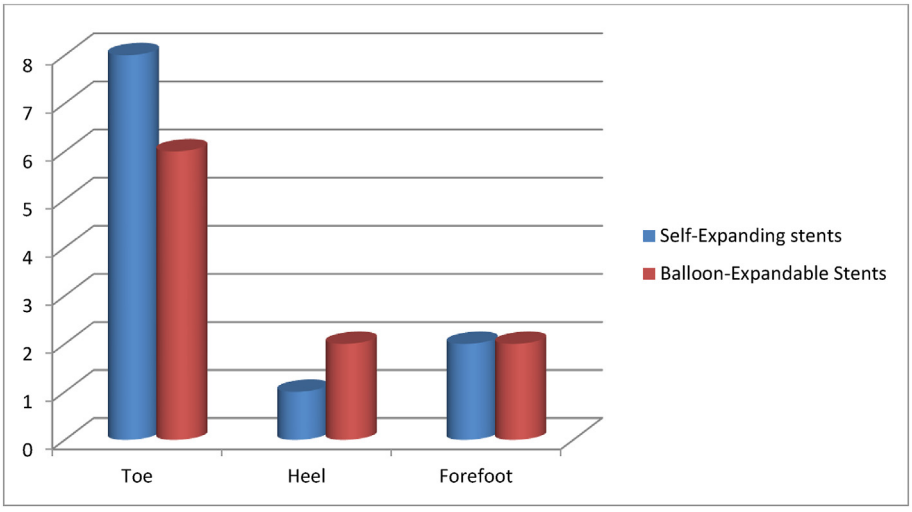

Fig. 5. Distribution of gangrene among the cases.

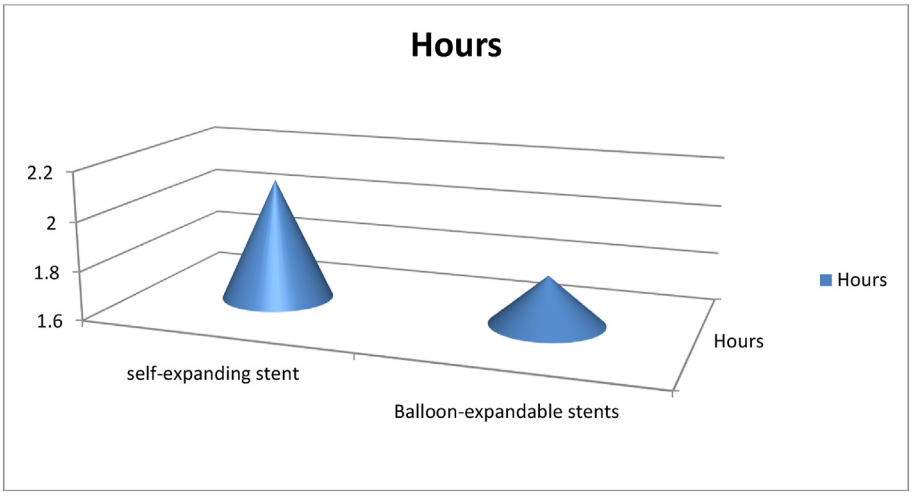

Fig. 6. Procedure duration (hours).

Table 3. Limb salvage.

Period (months)	Group A		Group B	
	Number of limp lost	Salvage	Number of limp lost	Salvage
1	1	14	1	14
3	2	12	0	14
6	1	11	2	12
12	1	10	1	11
Total N.	5	10	4	11

B and seven in group A). Above-knee amputation was done for 9 (20%) patients in our study. Group A showed higher amputation rate but nonsignificantly different with group B.

4. Discussion

The most common reason for death and morbidity in people with diabetes is diabetic vasculopathy, which also contributes to the high frequency of vascular disorders including stroke, myocardial infarction, and peripheral vascular diseases.

Many writers, like Baker et al. and Flanigan et al., highlight the significance of the degree of illness in the deep femoral artery, which constitutes the primary collateral network in the existence of superficial femoral artery obstruction, in cases of CLI. One of the most significant reasons to undertake multisegmental repair is the occlusion of diffusely damaged profunda artery.[4]

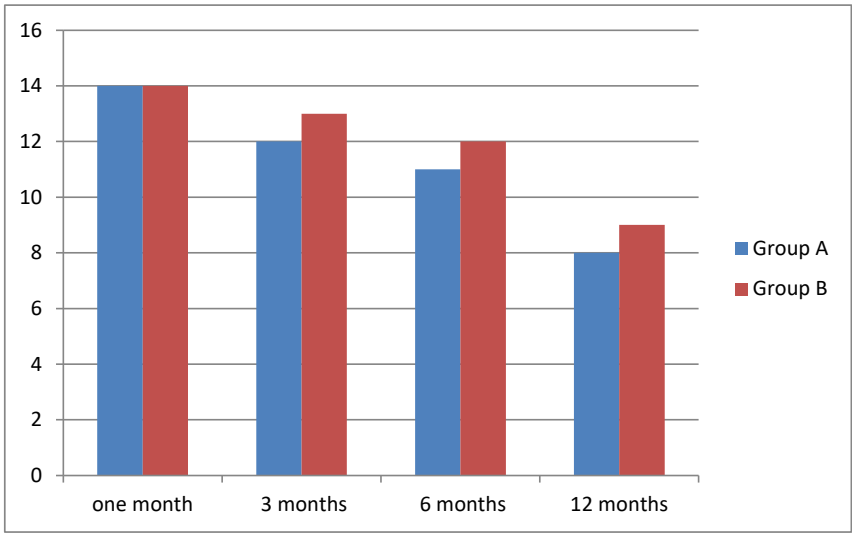

Fig. 7. Primary patency rate.

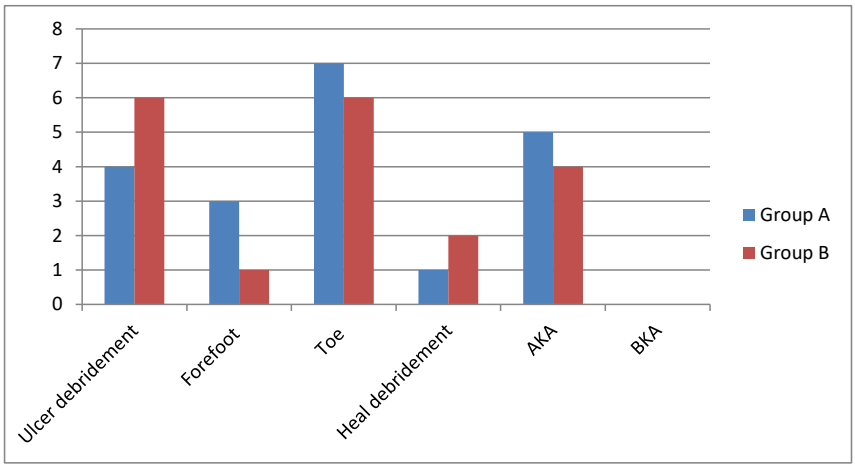

Fig. 8. Debridement and limb loss in both groups.

We attempted to choose the reconstruction criteria based on the most straightforward, widely applied, and affordable clinical vascular laboratory and angiographic data.

Our study included 30 patients divided into two groups matched in age and sex suffering from iliac Artery Occlusive Disease.

The common iliac artery will be endovascularly dilated in the first group, and one or more balloon-expandable stents will then be implanted. The identical therapy will be given to the other group, but they may have had one or more self-expanding stents implanted.

All patients enrolled in our study had related conditions and dangers (e.g. Diabetes, hypertension, ischemic heart disease, smoking, renal impairment, stroke, or chest disease), which were presented in the study as numbers of comorbidities and risk factors for each patient.

Among our 30 patients with critical lower limb ischemia success rate after total revascularization (group A) reached 86.6% success rate.

The success rate after staged revascularization (group B) reached 65% success rate from inflow cases and 93.3% of the outflow repair.

We achieved a limb salvage rate of (66.6%) in group A and (73.3%) for group B and a major amputation rate of 30% over 1-year follow-up period.

Five limbs in total—or 33.3%—were lost throughout the observation period in Group A, whereas eight—or 26.6%—were lost in Group B. There was no statistical substantial variation between the groups.

At the 36-month follow-up, Dalman et al. reported a 90% limb salvage rate in their sample of 62 patients. It should be emphasized that 20% of the patients in this group had claudication surgery.[5]

Eidt et al. shows 153 individuals in his study good limb salvage rates. The only limbs lost throughout a five-year follow-up period were seven. However, in this group, patients were excluded if they had gangrene and were solely chosen for aorto-femoro-popliteal reconstruction in cases of ischemic rest discomfort. In this group, not a single femorotibial bypass procedure was carried out.[6]

We also found that increasing numbers of risk factors and comorbidities had drawback on the primary patency rate at 3-month and 12-month and on limb salvage rates with increase in the amputation rate.

Abularrage et al. reviewed that in 920 individuals who had 1075 PTA/stent surgeries, diabetes mellitus is an independent predictor of lower long-term primary patency, and long-term limb salvage is even worse in diabetic patients compared to nondiabetic patients due to a more serious clinical presentation and poor run-off. Miura et al.[7,8]

Sadek et al. in a study for the treatment of iliac lesions on 85 patients mentioned a limb salvage rate of 76.1% ($P = 0.05$).[9]

Wound healing was achieved in 75% in group A and 60% in group B with multilevel disease at 1 year ($P = 0.05$).

Guo et al. in a study including 53 patients with iliac lesions showed a Wound healing of 95% with mean follow-up period of 12.2 ± 6.1 months (5–38 months).

Above-knee amputation was done for 9 (30%) patients and no below-knee amputation was done in

our study. Group B showed lower amputation rate but nonsignificantly different with group A ($P = 0.5$).[10]

Improvement in ABI after surgery was considered to be an objective sign of better limb perfusion. ABI rose in Group A from 0.29% before the surgery to 0.89%, in Group B from 0.37% to 0.63% after inflow operations and to 0.85% following outflow procedures. $P = 0.047$ indicates that there was a statistically substantial variation between the groups.

4.1. Conclusion

We conclude that in the presence of CLI, balloon-expandable stents are a safe and efficient therapeutic option for iliac artery occlusive disease. Stent patency rates, limb salvage, and postoperative mortality are all improving. Particularly in patients who arrive with tissue loss, correction of the proximal lesions alone cannot be deemed adequate since it is often linked with poor patency rates and total limb salvage rates.

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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