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Original Article

Endarterectomy vs endovascular therapy for primary atheromatous CFA lesions

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Abstract

Aim: Advances in endovascular technology have challenged the gold standard of common femoral endarterectomy (CFE). Our study aims to assess technical success, primary patency rate and rate of morbidity and mortality following common femoral artery (CFA) endovascular therapy, using either paclitaxel-coated balloons or stenting using interwoven nitinol stents, as compared to CFE.

Material and Methods: This is a randomized controlled trial. Patients were randomized into two groups: CFE and CFA endovascular therapy. Patients were followed up after 1, 6 and 12 months. Inclusion criteria included primary atheromatous hemodynamically significant CFA lesions, and presentation with Rutherford stages 3,4,5,6. Exclusion criteria included recurrent disease, non-atheromatous lesions, indication of bypass associated with CFA revascularization, and pregnancy. The primary outcome tested was the rate of morbidity and mortality and primary patency rate.

Results: The study included 120 patients, 64 underwent CFE and 56 received endovascular therapy. Technical success was achieved in all cases. The rate of wound and access site complications was lower in the endovascular group (7.1% vs. 18.6%), however this difference was statistically insignificant ($p = 0.061$). One-year primary patency rate was better in surgery group (100% vs. 64.6%, $p < 0.001$), but the limb salvage rate was similar in both groups. One-year primary patency rate was better with stents as compared with drug-coated balloon (DCB) (80.0% compared to 57.6%, $p = 0.132$), however limb salvage rate was similar with stenting and DCB.

Conclusion: Although CFE remains the first option in treating CFA disease, endovascular therapy of the CFA provides good patency rates and a limb salvage rate comparable with that of surgery.

Keywords: Common femoral artery; endarterectomy; drug-coated balloon; interwoven stents

INTRODUCTION

The prevalence of peripheral arterial disease (PAD) has increased markedly over the past decades. It is estimated that 236 million people suffer from PAD worldwide [1]. One of the common sites of arterial affection in PAD is the common femoral artery (CFA). Traditionally, CFA lesions have been managed surgically via endarterectomy since the first femoral thromboendarterectomy by Dos Santos in 1946 [2]. It is a relatively straightforward procedure with excellent long-term patency rate [3], and can be done for either isolated CFA disease or as a step in bypass procedures or hybrid endovascular settings. The disadvantage of common femoral endarterectomy (CFE) is local wound complications, which are prone to happen in groin wounds due to extensive lymphatics.

CITATION
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Advances in endovascular technology have aroused interest in its possible use in CFA territory. The CFA has traditionally been considered a "no-stent zone", fearing stent fracture and thrombosis due to hip joint mobility [4]. However, several studies have demonstrated safe and effective endovascular therapy (including stenting) of the CFA [5-7], perhaps most noticeably the TECCO trial, a French randomized comparative study [8].

The aim of our study was to assess technical success, primary patency rate and rate of morbidity and mortality following CFA endovascular therapy, using either paclitaxel-coated balloons or stenting using interwoven nitinol stents, as compared to CFA endarterectomy.

MATERIAL AND METHODS

Study Design and Population

This study was a randomized controlled trial conducted at Kasr AlAiny Medical School, Cairo University, during the period from March 2023 to March 2025, on vascular surgery patients with peripheral vascular disease in the form of symptomatic primary atheromatous CFA lesions (Rutherford stages 3 to 6).

We conducted our study according to our Scientific and Ethical committee approval (MD-418-2022, of Kasr AlAiny School of Medicine, Cairo University) (Date: 09.03.2023) and complying with the terms of Helsinki Declaration.

Inclusion criteria included:

- Primary atheromatous common femoral artery lesions
- Symptomatic lesions (Rutherford stages 3, 4, 5 and 6)
- Haemodynamically significant lesions (occlusion or stenosis of 50% or more, diagnosed by arterial duplex or computed tomography (CT) angiography).

Exclusion criteria included:

- Restenosis
- Non-atheromatous lesions (dysplasia, post-traumatic, inflammatory, thromboembolic)
- Indication of aorto-femoral, ilio-femoral, femoral-popliteal or femoro-tibialis bypass to associate with the common femoral revascularization
- Inability to monitor during the test period
- Participation in another clinical trial
- Pregnancy

Methodology

Eligible patients were divided into two groups, a group that received CFA endarterectomy and another group that received CFA endovascular therapy. Written informed consent was obtained from all participants prior to randomization. Patients who met the inclusion criteria were randomized to receive either CFA endarterectomy (Group A), or CFA endovascular therapy (Group B).

Pre-operative investigations:

For all patients, pre-operative investigations included complete blood count (CBC), international normalized ratio (INR), a chemistry panel including serum creatinine level, as well as imaging in the form of lower limb arterial duplex or CT angiography. Classification of disease distribution was done according to the revised TASC II classification [9], and isolated CFA disease was further classified according to the classification proposed by Azema et al. in 2011 [6] as follows:

Type I: lesions in the external iliac artery extending to the CFA

Type II: lesions limited to the CFA

Type III: lesions involving CFA bifurcation

Type IV: lesions involving previous anastomosis in the CFA (excluded from this study).

Method of randomization:

Patients were assigned to each group using sealed numbered ordered envelopes numbered from 1 to 200. Had the number within the envelope been an even number, the patient was assigned to Group A (CFA endarterectomy). If the number within the envelope was an odd number, the patient was assigned to Group B (CFA endovascular therapy).

Endarterectomy:

For the group receiving CFA endarterectomy, the procedure was performed in the standard fashion, with or without profundoplasty depending on arterial lesion and patient presentation. Synthetic or vein patch was used according to vein availability and operator preference (Figure 1).

Endovascular therapy:

For the group receiving CFA endovascular therapy, arterial access was gained percutaneously using a 6Fr or 7Fr sheath, with the aid of local or general anesthesia, either via the contralateral femoral artery (retrograde, crossover) or via the left brachial artery, depending on arterial anatomy and operator's preference. If there was bilateral CFA disease, trans-brachial approach was used. A scouting (diagnostic) angiogram was obtained of the distal aorta and the entire arterial tree of the side to be treated, including both CFAs and their bifurcations in multiple projections. At this point, 80 IU/kg of heparin was infused through the arterial sheath to ensure adequate systemic heparinization. Type I and II lesions of the CFA were managed by plain only balloon angioplasty (POBA), while type III lesions

(involving femoral bifurcation) were also managed by POBA but using kissing balloons technique in which both the SFA and profunda femoris arteries were angioplastied simultaneously using two balloons. A post-angioplasty angiogram was obtained in all cases. If the angiogram showed residual stenosis or dissection flaps, stenting using Supera® (Abbott Vascular, Santa Clara, CA, USA) stent was performed. If required, the stent was extended beyond the bifurcation into the SFA and the profunda was jailed (Figure 2). On the other hand, if the angiogram following POBA showed no dissection or residual stenosis, the angioplastied segment was treated with Ranger® Drug-Coated Balloon (Boston Scientific, Marlborough, MA, USA). The drug-coated balloon (DCB) was inflated to its nominal diameter for 3 minutes as per the recommendations by the manufacturer. Diameters used in the CFA ranged from 5mm to 7mm. After deflation, we then performed a completion angiogram to confirm vessel patency (Figure 3). In all cases, the technical result of the procedure was assessed by biplane completion angiogram. Concomitant endovascular procedures to treat either inflow or outflow vessels were performed according to arterial disease distribution, the patient's clinical status, and operator's discretion. After the procedure was completed, the arterial sheath was removed and manual compression applied to ensure adequate hemostasis. Although some patients had bilateral CFA disease, none required simultaneous correction in the same setting. Previously asymptomatic limbs that required intervention in a second session were excluded from our study to avoid bias in selecting treatment modality as the choice of treatment in these patients was not randomized. Following stenting, postoperative medications included dual antiplatelet therapy (clopidogrel 75mg once per day and aspirin 75mg twice per day).

For both groups, follow-up was scheduled at 1, 6, and 12 months, using:

- Clinical improvement, in the form of walking distance improvement, rest pain improvement, wound healing and limb salvage rate.
- Ankle-brachial index.
- Bi-plane x-ray for the patients who received stents to detect stent fractures.
- Arterial duplex if clinically required (absent pulse, re-appearance of rest pain or claudication, wound resistant to healing).
- Arterial duplex was used to confirm patency of jailed profunda even if patient is asymptomatic.

All cases of in-stent stenosis underwent redo angioplasty using DCBs. On the other hand, restenosis following DCB in the initial treatment was managed according to clinical presentation, revascularization was clinically driven and asymptomatic cases were managed conservatively.

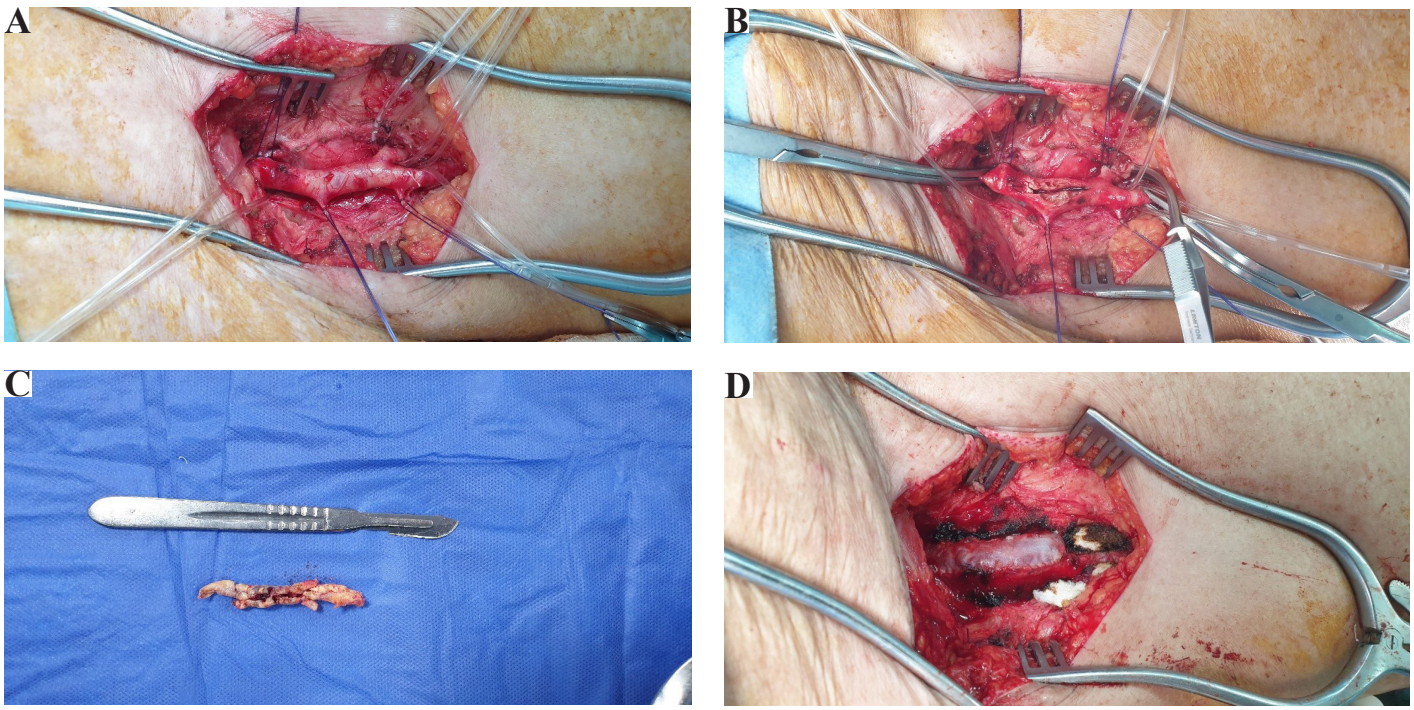


Figure 1. A 52 year old lady who presented with rest pain for which CFE was performed. Usual steps of CFE are shown: CFA exposure (**A**), arteriotomy revealing diseased CFA (**B**), excised atheromatous plaque from the vessel (**C**), closure of the artery using venous patch (**D**).

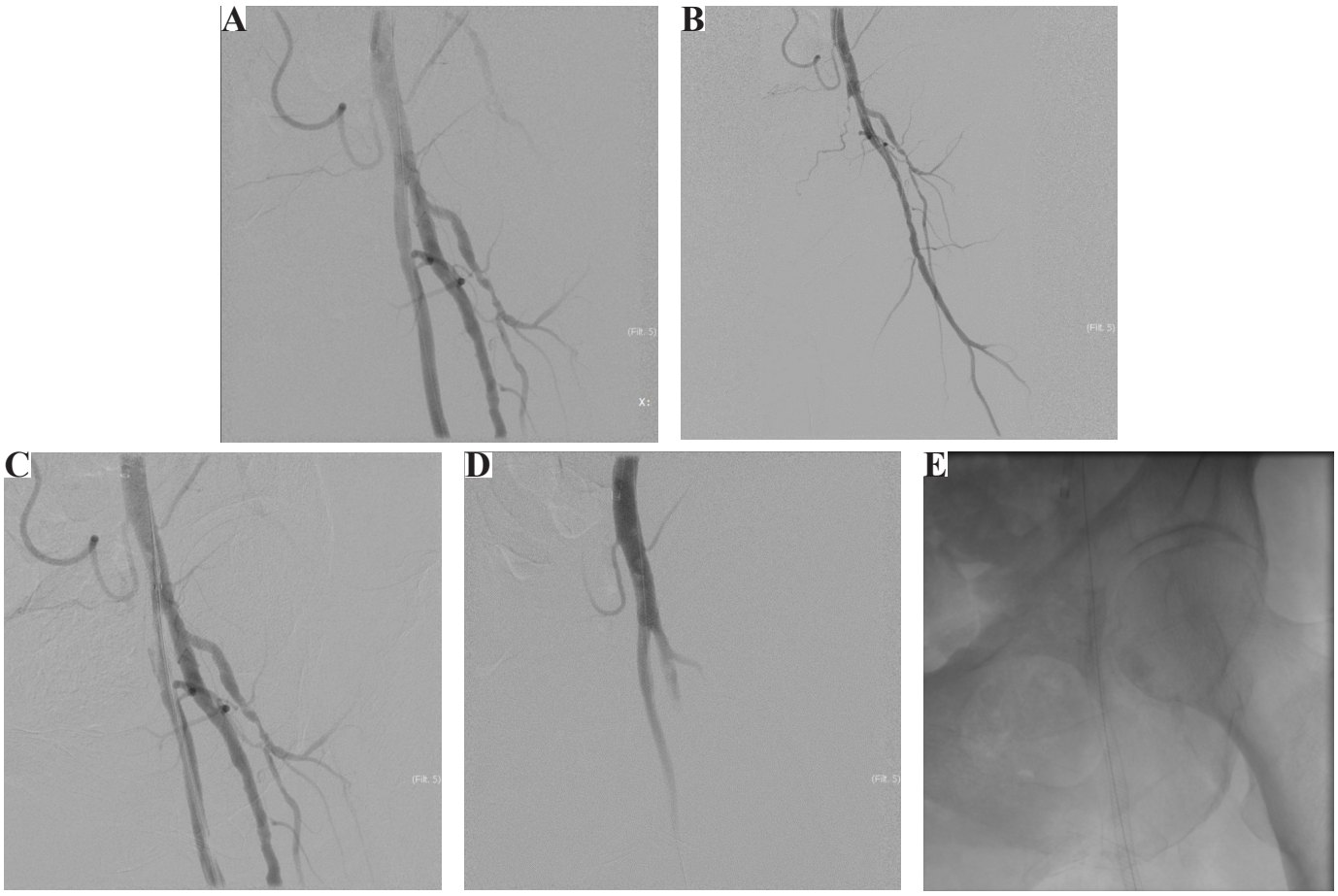


Figure 2. A 71 year old lady who presented with gangrenous tip of big toe, with CFA stenosis and SFA occlusion (**A**); CFA and SFA residual stenosis and dissection apparent after POBA (**B**); Using retrograde access via the posterior tibial artery, interwoven nitinol stent deployed across the femoral bifurcation in the diseased segments (**C**, **D**, and **E**), with normal filling and flow in the jailed profunda.

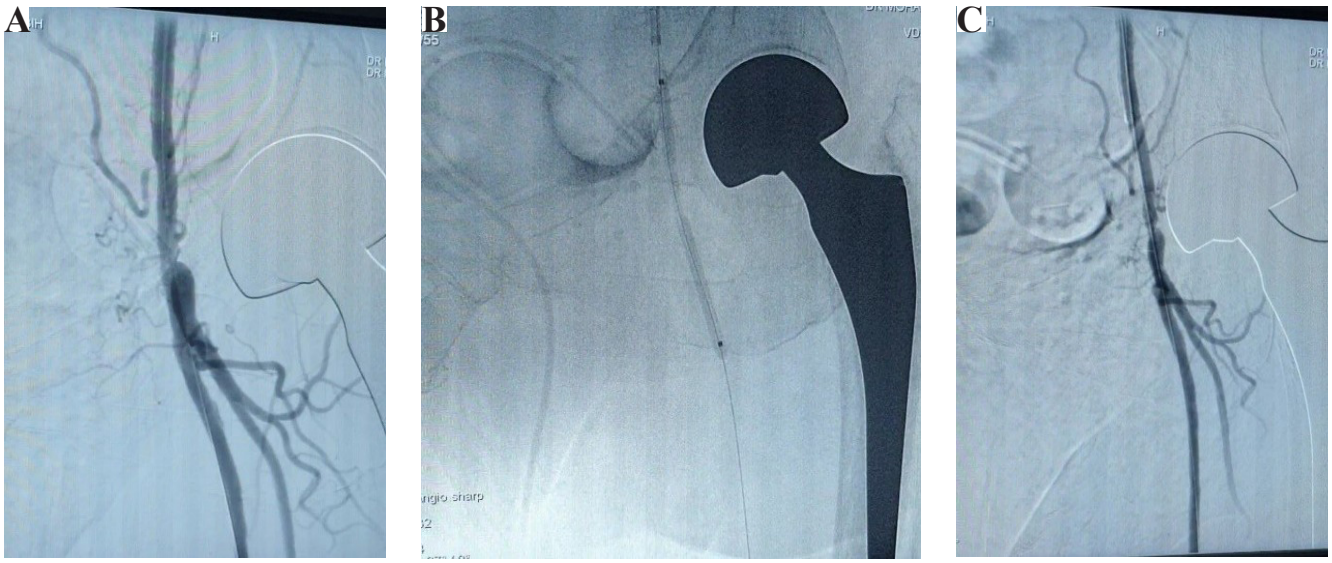


Figure 3. An 89 year old gentleman who presented with gangrenous tip of 2nd toe, for which CFA angioplasty using DCB was performed; Pre dilatation (**A**), angioplasty (**B**), post dilatation angiogram.

Study outcomes:

Primary outcomes:

1. **Technical success:** For CFE, technical success was defined as complete removal of occlusive material from the CFA with restored pulse distal to the arteriotomy. For endovascular therapy, technical success was defined as successfully traversing and treating the lesion with completion angiogram showing less than 20% residual stenosis with no dissection flaps.
2. **Morbidity and mortality rate at 30 days:** Morbidity was defined as in the form of either access site complications or systemic complications. Access site complications included hematoma, active bleeding, thrombosis, lymphorrhea, wound infection, delayed wound healing, false aneurysm and arteriovenous fistula. Systemic complications included myocardial infarction, stroke, or other major adverse clinical events that caused or prolonged hospitalization and/or re-intervention
3. Primary patency at 1, 6, and 12 months.

Secondary outcome parameters included:

1. Length of hospital stay
2. Primary assisted patency rate.
3. Secondary patency rate.
4. Limb salvage rate.
5. Target lesion revascularization.
6. In-stent restenosis.
7. Stent fracture.
8. Target extremity revascularization.

Sample size and statistical analysis:

Calculation of the sample size was carried out by ClinCalc. A sample size of 120 CFA interventions was sufficient to yield a study power of 0.8 with a significance level (alpha error) of 0.05.

Data were systematically coded and entered into the Statistical Package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Summary statistics were generated, including mean, standard deviation, minimum, and maximum values for quantitative variables, while frequencies (number of cases) and relative frequencies (percentages) were computed for categorical variables. Comparisons between different groups were executed using an unpaired t-test. For the assessment of categorical data, the $\chi 2$ test was employed, and Fisher's exact test was used when the expected frequency was less than 5. Statistical significance was defined as p values less than 0.05. Kaplan-Meier analysis was used to evaluate patency and limb salvage.

RESULTS

The study encompassed 120 patients that underwent intervention for symptomatic (Rutherford stages 3 to 6) CFA lesions at Kasr Alainy Medical School, Cairo between March 2023 and March 2025. Patients were randomized to receive either CFA endarterctomy (Group A, N = 64), or endovascular therapy in the form of CFA stenting or using DCB (Group B, N = 56).

Technical success was achieved in all patients in both groups.

Baseline demographics and clinical presentation exhibited uniformity in both study groups (Table 1). Also, disease distribution was similar in both groups, and the majority of patients had multilevel arterial disease rather than isolated CFA affection (Table 1).

Table 1. Baseline demographics, clinical characteristics, and disease distribution

Variable	Group A: Surgery (n = 64)	Group B: Endo (n = 56)	p value
Demographics & risk factors			
Age (years), mean ± SD (range)	65.8 ± 11.4 (44 – 89)	69.5 ± 12.6 (44 – 92)	0.168
Baseline ABI, mean ± SD (range)	0.37 ± 0.08 (0.30 – 0.60)	0.37 ± 0.06 (0.30 – 0.50)	0.780
Baseline CFA diameter, mean ± SD (range)	6.28 ± 0.44 (5.4 – 7.1)	6.44 ± 0.45 (5.3 – 7.2)	0.066
Female sex, No. (%)	20 (31.3)	19 (33.9)	0.755
Male sex, No. (%)	44 (68.7)	37 (66.1)	
Diabetes mellitus, No. (%)	45 (70.3)	41 (73.2)	0.725
Hypertension, No. (%)	59 (92.2)	53 (94.6)	0.722
Chronic kidney disease, No. (%)	17 (26.6)	22 (39.3)	0.138
Smoking, No. (%)	49 (76.6)	41 (73.2)	0.673
Type of lesion			
Isolated, No. (%)	4 (6.25)	3 (5.36)	0.963
TASC B, No. (%)	4 (6.25)	4 (7.14)	
TASC C, No. (%)	29 (45.31)	28 (50.00)	
TASC D, No. (%)	27 (42.19)	21 (37.50)	

Abbreviations: ABI, ankle brachial index; CFA, common femoral artery; TASC, transatlantic intersociety consensus.

Most patients required concomitant endovascular procedures to treat associated lesions other than the CFA. Concomitant endovascular procedures done were similar in both groups (Table 2). The majority of our patients presented with tissue loss (Rutherford grades 5 and 6), clinical presentation was similar in both groups (Table 2).

Table 2. Concomitant endovascular procedures and presentation

Variables	Surgery (n = 64), No. (%)	Endovascular (n = 56), No. (%)	p value
Procedure			
Iliac and SFA stenting	2 (3.1)	3 (5.4)	0.349
Iliac stenting	21 (32.8)	14 (25.0)	
Iliac stenting + SFA and tibial angioplasty	0 (0.0)	2 (3.6)	
Iliac stenting + SFA angioplasty	2 (3.1)	2 (3.6)	
SFA and tibial angioplasty	2 (3.1)	6 (10.7)	
SFA angioplasty	9 (14.1)	7 (12.5)	
SFA stenting	5 (7.8)	7 (12.5)	
SFA stenting + tibial angioplasty	5 (7.8)	3 (5.4)	
Tibial angioplasty	0 (0.0)	2 (3.6)	
None	18 (28.1)	10 (17.9)	
Presentation			
Rutherford grade 3	7 (10.9)	7 (12.5)	0.966
Rutherford grade 4	16 (25.0)	12 (21.4)	
Rutherford grade 5	17 (26.6)	16 (28.6)	
Rutherford grade 6	24 (37.5)	21 (37.5)	

Abbreviations: SFA, superficial femoral artery.

Perioperative amputation was performed in 8 patients (Table 3). In the surgery group, two patients required primary amputations (one above the knee and one below the knee) due to spreading gangrene beyond the ankle. Another patient required below knee amputation after one week due to spreading infection on the shin of tibia. In the endovascular group, one patient required primary below knee amputation due to unsalvageable heel wound, 2 patients required primary below knee amputation due to spreading infection and sepsis, while 2 patients required primary above knee amputations due to delayed presentation and gangrene beyond the distal leg.

For the endarterectomy group, patients received either regional (54.7%) or general (45.3%) anesthesia, while the majority of patients in the endovascular group received local anesthesia (73.2%). Regional anesthesia was avoided in the endovascular group to avoid the risk of neurogenic complications associated with the use of antiplatelet drugs prior or after endovascular procedures. This difference in the type of anesthesia used was found to be statistically significant ($p < 0.001$).

In the endarterectomy group, the choice of patch used for arteriotomy closure was made according to vein availability and operator's preference. Most patients received vein patches, with no statistically significant difference ($p = 0.78$) in the incidence of wound complications using either option.

The rate of access site complications was slightly lower in the endovascular group, however this difference did not reach statistical significance ($p = 0.061$). All access site complications following endarterectomy were managed conservatively and none required re-intervention, while a patient in the endovascular group required brachial thrombectomy. Also, the rate of systemic complications and duration of hospital stay were similar in both groups. There was no incidence of perioperative mortality in either group (Table 3). Contrast volume and procedure time were similar in both groups, while estimated intraoperative bleeding was more in the surgery group (Table 3). In either groups, there was no incidence of arterial or venous thrombosis or pulmonary embolism. 2 patients in the surgery group and one in the endovascular group suffered from myocardial infarction perioperatively (Table 3), all 3 received PCI and survived. There was no incidence of stroke in either groups. 2 patients in the surgery group and 3 in the endovascular group had elevated kidney functions postoperatively, however only one patient (from the endovascular group) required one hemodialysis session with no long-lasting renal impairment (Table 3). Duration of hospital stay was similar in both groups (Table 3).

Table 3. Complications and perioperative amputations

Outcome	Surgery (n = 64)	Endovascular (n = 56)	p value
Access site complications, No. (%)	12 (18.6)	4 (7.1)	0.061
Wound infection, No. (%)	7 (10.9)	–	N/A
Contrast volume, mean ± SD (range), ml	56.80 ± 46.98 (0 – 140)	67.59 ± 41.26 (15 – 165)	0.190
Procedural time, mean ± SD (range), hours	3.39 ± 0.98 (2 – 5)	3.16 ± 1.18 (1 – 6)	0.225
Perioperative systemic complications, No. (%)	4 (6.3)	4 (7.1)	1.000
Perioperative bleeding volume, mean ± SD (range), ml	136.1 ± 23.29 (90 – 210)	29.1 ± 9.87 (20 – 60)	< 0.001
Perioperative arterial thrombosis, No. (%)	0 (0)	0 (0)	N/A
Deep vein thrombosis, No. (%)	0 (0)	0 (0)	N/A
Pulmonary embolism, No. (%)	0 (0)	0 (0)	N/A
Myocardial infarction, No. (%)	2 (3.1)	1 (1.8)	1.000
Stroke, No. (%)	0 (0)	0 (0)	N/A
Acute renal failure, No. (%)	2 (3.1)	3 (5.4)	0.663
Acute need for hemodialysis, No. (%)	0 (0)	1 (1.8)	0.467
Hospital length of stay, mean ± SD (range), days	4.07 ± 2.10 (2 – 11)	3.79 ± 2.48 (2 – 13)	0.224
Perioperative amputations, No. (%)	3 (4.7)	5 (8.9)	0.471

At the 1-month and 6-months follow-up assessments, there were no statistically significant differences between the two groups in survival, patency and limb salvage rates. There were no incidences of stent fracture, and target extremity revascularization rates were similar in both groups.

At the 12-months follow-up assessment, there was no statistically significant difference between the two groups in survival, 9 patients were dead in the surgery group (2 due to stroke, 1 due to MI, 1 due to HCC, and 5 due to unknown causes) and 8 patients were dead in the endovascular group (3 due to MI and 5 due to unknown causes). However, all patients in the endarterectomy group retained their primary patency, while 17 patients in the endovascular group lost their primary patency. The difference in primary and assisted primary patency rates was found to be statistically significant ($p < 0.001$ and $p = 0.004$ respectively). Secondary patency rate was also better in the endarterectomy group, however the difference did not reach statistical significance ($p = 0.098$) (Table 4) (Figure 4). Limb salvage and target extremity revascularization rates were similar in both groups. There were no stent fractures.

A subgroup analysis was conducted on the patients in the endovascular group comparing patency and limb salvage between stenting and angioplasty using DCB. Patients who received stenting had a better patency rate, however this difference did not reach statistical significance ($p = 0.132$). Limb salvage rate was similar in both groups (Table 5) (Figure 5).

Table 4. Twelve-month patency and limb salvage (surgery vs endovascular)

Outcome	Surgery (n = 55), No. (%)	Endovascular (n = 48), No. (%)	p value
Primary patency	55 (100)	31 (64.6)	< 0.001
Primary assisted patency	55 (100)	41 (85.4)	0.004
Secondary patency	55 (100)	45 (93.8)	0.098
Limb salvage	40 (72.7)	36 (75.0)	0.794

Table 5. Twelve-month outcomes in stent vs drug-coated balloon groups

Outcome	Stent, No. (%)	DCB, No. (%)	p value
Primary patency	12 (80.0)	19 (57.6)	0.132
Limb salvage	11 (73.3)	25 (75.8)	1.000

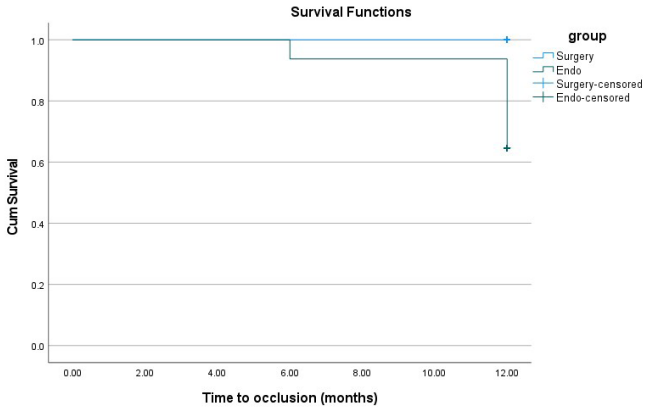


Figure 4. Kaplan-Meier curve comparing 1-year patency rates between both groups.

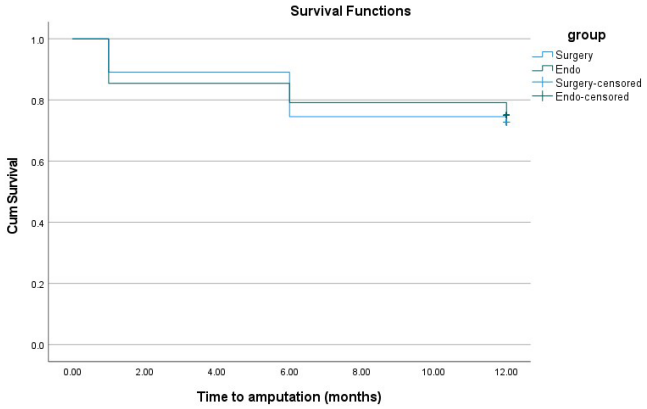


Figure 5. Kaplan-Meier curve comparing 1-year limb salvage rates in both groups.

DISCUSSION

CFA atherosclerotic lesions are currently considered one of the last remaining territories in which endovascular therapy is not considered the first option in management. However, recent advancements in stenting and endovascular technologies make this option more feasible and durable than before.

Several studies have been published regarding CFA endovascular therapy, most with promising results. Azema et al [6] have reported good patency rates comparable to CFE with few access site complications and stent fractures. Goueffic et al [8] also reported shorter duration of hospital stay. However, to our knowledge, all studies published so far regarding CFA endovascular therapy included mostly claudicant patients, with very few patients presenting with critical limb threatening ischemia (CLTI). And thus a comparison of limb salvage rates between CFE and CFA endovascular therapy in patients presenting with CLTI is not yet available. The majority of the patients included in our study (88.3%) presented with CLTI in the form of rest pain or tissue loss (Rutherford grades 4, 5 and 6).

A major advantage of endovascular therapy is its minimally invasive nature, making it possible to be performed under local anesthesia. To our knowledge, no study regarding CFE or CFA endovascular therapy has discussed the impact of type of anesthesia on the choice of treatment strategy. However, we assume given our results that frail patients, in which regional or general anesthesia would be risky, would particularly benefit from endovascular therapy, being less invasive and more feasibly done under local anesthesia.

Our findings show a lower incidence of access site complications with endovascular therapy compared to endarterectomy. Although this difference did not reach statistical significance, it is worth taking into consideration. Goueffic et al reported significantly lower rate of wound complications in the endarterectomy group compared to CFA stenting [8]. Also, in the study by Bonvini et al [10], they report procedure-related complication rate of 6.4%. On the other hand, several studies report rates of wound complications following CFA endarterectomy ranging from 6.6% to 8.6% [11-13], which is consistent with our findings.

In our study, there was no difference between both groups in the incidence of systemic complications, which is in line with other published studies [6,8,11-13].

In our study, there was no difference in the duration of hospital stay between both groups. We assume that this is because the duration of hospital stay depended mainly on the general condition of the patient and the condition of foot wounds following amputation or debridement. Most of the patients enrolled in our study presented with chronic limb threatening ischemia in the form of tissue loss, either due to gangrene or extensive infection or both. Most of these patients required close follow-up of their foot wounds following debridement post revascularization, requiring repeated dressings and usually multiple sessions of debridement. We believe that this process was the main factor in determining the duration of their hospital stay rather than the type of intervention used during revascularization. On the other hand, Goueffic et al reported significantly shorter duration of hospital stay in the stenting group [8]. It should be noted, however, that the majority of patients enrolled in the study by Goueffic et al were claudicants [8], in contrast to our study that included mainly patients presenting with CLTI.

Our study reports a significantly better 1-year primary patency rate following endarterectomy compared to endovascular therapy. This is in line with most published literature, which report excellent patency rates following CFA endarterectomy [11-14]. Azema et al report 80% 1-year primary patency rate following CFA stenting [6], while Bonvini et al report 72.4% primary patency rate at 10.3 ± 5.4 months in 360 CFA endovascular procedures [10].

Interestingly, in our study, the superiority in patency rate of surgery over endovascular therapy did not translate to an

improvement in limb salvage rate. The 12-months limb salvage rate was similar in both groups (72.7% in surgery group and 75.0% in endovascular group). We presume that this could be attributed to the fact that the majority of our patients in both groups (78 out of 120, 65%) presented to us with spreading gangrene or infection (Rutherford grade 5 and 6), some of which required major amputation either primarily or following multiple trials of debridement and prolonged periods of wound care, despite having patent CFA. Also, only a small fraction of our patients (7 out of 120) presented to us with isolated CFA disease. The majority of our patients required either inflow or outflow revascularization alongside the CFA procedure done, some of which re-occluded and required revascularization or led to limb loss despite having patent CFA. It should be noted that the majority of studies reporting results of CFA endovascular therapy have included mainly claudicant patients, and so reported no major amputations [6,8,10]. Kuma et al and Hashimoto et al reported similar limb salvage rates following endarterectomy as our study [13,14].

Although we were not able to perform calcium scoring prior to randomization, we were able to calculate the modified PACSS score in patients that underwent endovascular therapy by reviewing their angiograms retrospectively.

- **Grade 0:** no visible calcification
- **Grade 1:** unilateral calcification with length of calcification less than 5 cm
- **Grade 2:** unilateral calcification with length of calcification more than or equal to 5 cm
- **Grade 3:** bilateral calcification with length of calcification less than 5 cm
- **Grade 4:** bilateral calcification with length of calcification more than or equal to 5 cm

The modified PACSS score takes the circumferential calcification of the target vessel into account to give additional points, such as:

- **0 points:** calcification less than 25%
- **1 point:** calcification between 25-50%
- **2 points:** calcification more than 50%

These points are added to the original grade to give a total score between 0-6 [15].

Out of the 56 patients in the endovascular group, 3 had a score of 0, 5 had a score of 1, 7 had a score of 2, 7 had a score of 3, 10 had a score of 4, 16 had a score of 5, and 8 had a score of 6. The majority of our patients had a score of grade 4 or more (60.7%). However, it was noted that out of 11 patients that received stents, 10 had a score of 4 or more (90.9%), which may indicate that higher degree of calcification resulted in inferior outcome of angioplasty that necessitated stenting, especially in the absence of advanced vessel preparation techniques. Unfortunately, the small numbers and retrospective nature of this analysis does not allow useful statistical data to be drawn, however it does point to the importance of calcium scoring in decision making, and that perhaps highly calcified lesions are better managed surgically to avoid unnecessary stenting and to ensure the best technical results. More studies focused on this point are needed to draw specific recommendations.

Our study reported no stent fractures during 12-months follow up period, which is similar to what is reported in the literature [6,8,16]. While Azema et al and Goueffic et al used traditional bare metal stents in their studies, we used newer interwoven nitinol stents, the Supera® Peripheral Stent System (Abbott Vascular; Santa Clara, CA, USA), as did Tao et al in their study published in 2022 [16]. We chose the Supera stent because of its highly flexible interwoven design that makes it particularly suitable in highly mobile segments of the artery opposite to the hip joint and knee joint. This is supported by the excellent results of the Supera stent in the femoro-popliteal segment, with zero stent fractures and 1-year patency rate of 91% [17]. In our study, we jailed the profunda in 8 patients, all of which remained patent with triphasic flow at its ostium after 1 year. This is in line with other published literature, as Tao et al reported 4 jailed SFA or profunda, all of which were patent at 1 year [16].

The subgroup analysis in our study showed a non-significant improvement in patency rate using stents compared to DCB angioplasty. We used the Ranger® Drug-Coated Balloon (Boston Scientific, Marlborough, MA, USA) as it uses a lower concentration of paclitaxel while providing similar outcome as demonstrated in the COMPARE trial [18]. In our study, DCB angioplasty was used directly after POBA without advanced vessel preparation techniques such as rotational atherectomy or lithotripsy. This may account for the lower patency rate. Hata et al reported no difference in 1-year patency rate between POBA and DCB angioplasty [19]. Several studies have reported the results of using rotational atherectomy with DCB or compared the results of either modalities in the CFA [20-23]. Also, Stavroulakis et al reported 72% 12-months patency rate when combining DCB with lithotripsy in the CFA [24]. It is clear from published literature so far that the patency rate following DCB use is greatly enhanced if combined with the use of rotational atherectomy or lithotripsy rather than alone.

Despite the generally positive results of CFA stenting, some concerns still remain that limit its use more frequently. CFA stenting may complicate future open surgical procedures. Also, most clinicians believe that CFA stenting precludes further endovascular intervention at the puncture site, and this ipsilateral femoral approach is no longer available for future endovascular procedures. However, the CFA could be punctured under either fluoroscopic guidance or duplex scan just above or below the stent to prevent strut damage but increasing the risk of bleeding

or pseudo-aneurysms [6]. Although we did not attempt stent puncture in our study, Tao et al reported multiple stent re-punctures in the same patient with no adverse effects [16]. They also report successful entry and angioplasty of a jailed profunda vessel with good angiographic results [16]. These results are promising regarding the use of Supera Peripheral Stent System as compared to older bare metal stents, however further research involving more patients and a longer follow-up period is needed to ascertain these promising results and obtain reliable data and recommendations.

Study Limitations

Study limitations include the relatively small number of patients included in the study, especially those who underwent stenting, possibly leading to a type 2 statistical error. Only a small number of patients presented with isolated CFA disease (7 out of 120), which limited our ability to study the effect of disease distribution on CFA patency rate as compared to isolated disease. Duplex ultrasound was not used to provide an objective measure of technical success. Advanced vessel preparation techniques (such as atherectomy/lithotripsy) were not used during endovascular therapy. Calcium scoring was not used due to heterogeneous imaging modalities. Also, the cost-effectiveness of both treatment modalities was not studied, and a longer follow-up period is needed to draw long-term results in both groups.

CONCLUSION

CFA endarterectomy remains the procedure of choice when managing CFA atherosclerotic lesions, with excellent durability and few complications. However, endovascular therapy of the CFA has been shown to be a safe and viable option with good patency rate and minimal complications especially with the advent of highly flexible interwoven nitinol stents and novel endovascular technologies. The concept of the CFA being a "no-stent zone" is becoming more and more obsolete, and future endovascular advancements will further improve results in the CFA territory. More trials with long term follow-up periods are needed to obtain reliable recommendations.

Ethics Committee Approval: We conducted our study according to our Scientific and Ethical committee approval (MD-418-2022, of Kasr AlAiny School of Medicine, Cairo University) (Date: 09.03.2023) and complying with the terms of Helsinki Declaration.

Patient Consent for Publication: The research was entirely voluntary, and participants may withdraw from it whenever they want. All stages of data entry, gathering, and analysis were conducted in accordance with the Declaration of Helsinki in a very private and confidential way. Consent was obtained for publication provided no personal identifying details regarding any of the patients were included.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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