Hybrid Repair Combining Common Femoral Endarterectomy and Iliac Stenting for Iliofemoral Arterial Occlusive Disease

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ABSTRACT

Introduction: *Iliac and common femoral artery occlusive disease (IFOD) can often manifest in a debilitating condition for patients and be challenging to manage. Endarterectomy with patch angioplasty is the standard for treatment of isolated common femoral artery (CFA) occlusive disease. However, the management of disease that extends proximally into the iliac arteries is a more challenging problem. In the endovascular era, endoluminal treatment has been shown in certain situations to be a comparable option for iliac occlusive disease. However, it is not a suitable stand-alone therapy in the presence of significant CFA disease. In the presence of severe IFOD, hybrid repair (HR) combining endovascular iliac stenting and common femoral endarterectomy, may represent an alternative to open aortoiliofemoral surgical reconstruction. The main advantage of hybrid procedures is the ability to treat more complex anatomy by less invasive procedures in patients considered at high medical risk.* ***Aim:*** *The purpose of this study was to review our contemporary experience in treating severe chronic iliofemoral occlusive disease (IFOD) with hybrid repair (HR). Particular attention was given to periprocedural safety, technical outcomes, and procedural durability.* ***Patients and methods:*** *Between July 2010, and July 2014, 32 Common Femoral endarterectomies (CFEs) were performed on 32 symptomatic patients with iliofemoral occlusive disease (IFOD). These cases were performed as a hybrid procedure where concurrent endovascular treatment for their iliac disease was performed at the same session with common femoral artery endarterectomy.*
Results: *Data was obtained for 32 patients (32 limbs) who underwent hybrid procedures during the study period. Technical success was achieved in 100% (32 patients). Clinical success, according to the American Heart Association (AHA) classification at 1 month showed, 12.5% (4 patients) had grade 3 improvement, 56.3% (18 patients) had grade 2 improvement, and 25% (8 patients) had grade 1 improvement, while 6.3% (2 patients) worsened. During the follow-up period which was 12 months, there were 6 major adverse cardiovascular events (MACE). All our surviving patients except for five patients remained free of symptoms, without need for any other interventions at the time of the last follow-up. Our primary patency rate of the target treatment segment (common femoral and iliac axis) was 93.75% at 12 months. Our secondary patency rate of the target treatment segment was 100% at 12 months, while the freedom from reintervention rate to the treated limb was 84.15% at 12 months.* ***Conclusion:*** *Hybrid approach combining common femoral artery endarterectomy and iliac angioplasty for iliofemoral occlusive disease (IFOD) seems an attractive option for those patients, who are unfit for extensive bypass surgery, especially those with extensive multilevel disease where hybrid procedures can be performed safely, and with good durability.*

Keywords: *Hybrid; iliofemoral; endarterectomy; stenting*

INTRODUCTION

Patients with critical limb ischemia (CLI) are at increased risk for limb loss with amputation rates as high as 50% if left untreated.[1] Iliac and common femoral artery (CFA) occlusive disease (IFOD) can often manifest in a debilitating condition for patients and be challenging to manage.[2] Surgical endarterectomy has been the standard treatment for occlusive disease of the common femoral artery (CFA) for over 50 years.[3] Endarterectomy with patch angioplasty is the standard for treatment of isolated common femoral artery occlusive disease.[4] However, the management of disease that extends proximally into the iliac arteries is a more challenging problem. Standard open surgical therapies for iliac disease, include iliofemoral endarterectomy or femoral-femoral bypass for unilateral disease and aortofemoral bypass or axillobifemoral

bypass for bilateral disease. Although durable, these options are associated with increased perioperative morbidity.[5]

In the endovascular era, endoluminal treatment has been shown in certain situations to be a comparable option for iliac occlusive disease.[5] However, it is not a suitable stand-alone therapy in the presence of significant CFA disease.[6] There is scant data to shift the focus of CFA disease treatment away from an open surgical approach. Early studies examining the efficacy of CFA percutaneous transluminal angioplasty (PTA) demonstrate variable results.[7] Recently, there have been reports of successful stent placements for disease in the CFA.[8] Most surgeons believe, however, that the potential problems of placing a stent in the CFA, including risk of stent fracture and intimal hyperplasia,[9] possible need to sacrifice collaterals provided by the profunda, and potential compromise in future surgical options in patients who often present with multilevel disease, outweigh the presumed advantages of an endovascular approach.[3]

In the presence of severe IFOD, hybrid repair (HR) combining endovascular iliac stenting and common femoral endarterectomy (CFE), may represent an alternative to open aortoiliofemoral surgical reconstruction, with shorter length of hospitalization and less resources utilization.[10] The combined use of endovascular and open (hybrid) techniques in the same surgical setting has been reported since the mid 1990s[11] and has gained popularity over time as vascular surgeons have acquired increasing experience with endovascular interventions.[12] The main advantage of hybrid procedures is the ability to treat more complex anatomy by less invasive procedures in patients considered at high medical risk.[13]

The purpose of this study was to review our contemporary experience in treating severe chronic iliofemoral occlusive disease (IFOD) with hybrid repair (HR). Particular attention was given to periprocedural safety, technical outcomes, and procedural durability.

PATIENTS AND METHODS

Between July 2010, and July 2014, 32 Common Femoral endarterectomies (CFEs) were performed on 32 symptomatic patients with iliofemoral occlusive disease IFOD at Ain Shams University Hospitals and Nasr City Health Insurance Hospital. These cases were performed as a hybrid procedure where concurrent endovascular treatment for the iliac disease was performed at the same session with common femoral artery endarterectomy in the same limb.

Inclusion criteria: All patients presenting with critical limb ischemia due to focal or extensive iliac lesions only if concomitant common femoral artery endarterectomy is performed. Patients who needed any further additional infrainguinal intervention for revascularization were also included in this cohort.

Exclusion criteria: Patients presenting with thrombosis due to iatrogenic common femoral and iliac arteries injury or patients with iliac artery aneurysmal degenerative disease associated with the occlusive disease or patients with previous surgery involving the common femoral artery.

All patients underwent preoperative peripheral vascular evaluation including physical examination, and ankle-brachial indices (ABIs). Clinical category at the time of presentation was determined according to the Rutherford classification as specified by the Society for Vascular Surgery/American Association for Vascular Surgery reporting standards. Computed tomography angiography (CTA) was done to assess iliac and CFA disease burden. Patients with significant CFA occlusive disease with proximal extension into the external or common iliac artery were considered for the procedure. The presence of significant CFA disease was defined by more than 50% diameter reduction on CTA.

All procedures were performed by a vascular surgeon in an operating room suite with vascular imaging. CFE was performed using standard technique. External control of SFA and profunda femoris artery (PFA) was routine. A longitudinal arteriotomy was made extending from the proximal CFA onto the proximal SFA, or directly onto the PFA when SFA was occluded. Patch angioplasty was then performed using saphenous vein patch, or polytetrafluoroethylene patch.

Common femoral endarterectomy was performed prior to the endovascular component in all cases. Following CFE, access was obtained through the patch under direct vision in the ipsilateral limb, or through a contralateral or transbrachial access according to the angiographic feasibility. Hydrophilic guidewires were used under fluoroscopic control to ensure true lumen

entry. The use of angioplasty balloons and stents was tailored according to the patient's angiographic anatomy with the size and length determined according to the discretion of the operator with the preference of using self-expanding stents except for common iliac artery ostial lesions where balloon expandable stents were preferably used for accurate ostial deployment.

Intraoperative angiography was performed to confirm satisfactory revascularization at the conclusion of each case. Technical success was defined as residual stenosis <30% on biplanar intraoperative arteriography. **(illustrated technique, figure 1)**

Postoperative follow up was done immediately post procedure and at 1,3,6,9, and 12 months thereafter. Clinical success was defined according to the American Heart Association (AHA) classification.[15] **(Table I)**.

In our study, patency refers to the status of our target treatment area which is both the CFA endarterectomy and the endovascular intervention proximal to it. Primary patency was defined as patency of the reconstructed target treatment area without evidence of restenosis. Secondary patency was defined as an occluded target treatment area that required at least one intervention to restore patency. However, freedom from reintervention was defined as freedom from reintervention to the treated limb at any level.

The decision for repeated intervention was based on the recurrence of symptoms or signs of CLI or the rise of peak systolic velocity of more than 2.5 times on arterial duplex scan or the presence of a recurrent stenosis >50% on CTA.

Major amputations included above-knee and below-knee amputations, while minor amputations included transmetatarsal amputations and toe amputations.

Primary endpoints were primary and secondary patency of the target treatment area (common femoral and iliac axis) and freedom from reintervention to the treated limb at any level, which was performed using Kaplan Meier survival curves. Secondary endpoints were the occurrence of procedural complications and major adverse cardiovascular events (MACE).

Table I. American Heart Association guidelines for clinical improvement

Grade	*Clinical description*
3	Markedly improved; ABI > 0.9 and no ischemic symptoms
2	Moderately improved; ABI increase > 0.1 but not normal, and increase by one category
1	Minimally improved; ABI increase 0.1 but not normal, or increase by one category
0	No change
−1	Mildly worse; no category decrease or ABI increase < 0.1
−2	Moderately worse; one category worse or unexpected minor amputation
−3	Markedly worse; more than one category worse or unexpected major amputation

ABI, Ankle-brachial index.

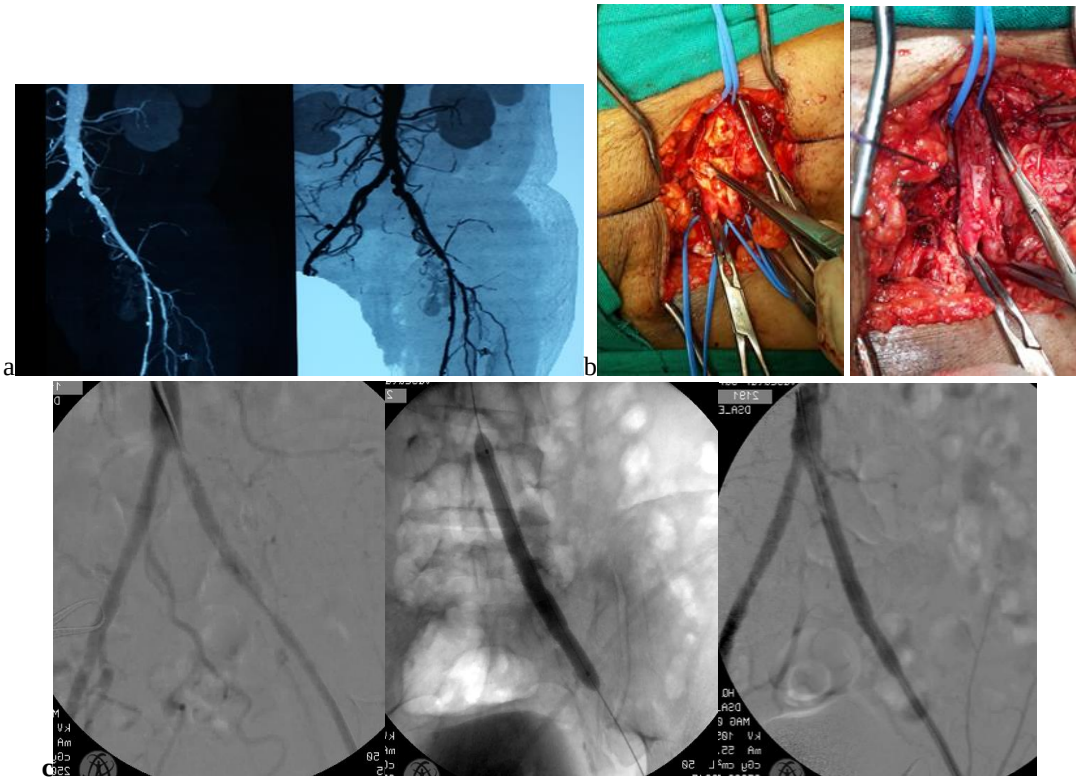


Fig. (1): Illustrated technique of CFA endarterectomy and iliac angioplasty. Preoperative angiogram (A); CFA endarterectomy and patching (B); Iliac angioplasty (C)

RESULTS

Data was obtained for 32 patients (32 limbs) who underwent hybrid procedures for patients presenting with iliofemoral occlusive disease (IFOD) during the study period. Demographic and clinical features of the study group are shown in Table 2. The group consisted of 19 (60%) males and 13 (40%) females with a mean age of 65.4 years (range: 53-74) and a high incidence of associated ischemic heart disease of forty percent (13 out of 32 patients). Seventy eight percent of patients had diabetes (25 out of 32 patients), Sixty nine percent of patients were under treatment for hypertension (22 out of 32 patients), fifty percent of patients were smokers (16 out of 32 patients), whereas 3 (9.4%) suffered from chronic kidney disease.

According to Rutherford classification, 15 (46.8%) limbs were treated for rest pain (Rutherford category 4), 11 (34.4%) suffered from minor tissue loss (Rutherford category 5), and 6 (18.8%) were treated for major tissue loss (Rutherford category 6), as shown in Table 3. Five of 32 patients were treated under general anesthesia, Seventeen patients were treated under regional anesthesia, whereas the remaining ten patients received groin local infiltration anesthesia.

In addition to the target treatment area, associated femoropopliteal lesions were present in 11 patients, combined femoropopliteal and infragenicular lesions were present in another 3 patients, while associated infragenicular lesions were present in 18 patients as shown in Table 4.

The common femoral endarterectomy (CFE) was extended as high proximal to the level of the inguinal ligament. This was to allow stenting of the external iliac artery to stop at the level of the inguinal ligament without crossing it. Tacking sutures (two or three posterior sutures) were taken in a vertical fashion to fix the distal intimal flap at the ostium of the superficial femoral artery (SFA) or the profunda femoris artery (PFA) when needed. The common femoral artery arteriotomy and patching was tailored in a vertical fashion

over the common femoral artery (CFA) extending to the ostium of the SFA in all cases except for five cases were the arteriotomy and patching was curved at its lower end to reach the ostium of the PFA. These were the five cases where there were associated femoropopliteal lesions in the form of total SFA occlusions and the clinical decision was not to tackle this SFA segment based on the patient's clinical presentation.

All 32 iliac lesions were treated with primary stenting. CFA endarterectomy was combined with femoropopliteal balloon angioplasty in 8 patients, of whom five patients needed stenting. Combined both femoropopliteal and infragenicular endoluminal procedure was done in 1 patient, while combined infragenicular balloon angioplasty was done in 9 patients as shown in Table 5. All combined procedures were done at the same session together with the target treatment area of the common femoral and iliac axis.

Immediate technical success was achieved in 100% (32 patients). In twenty two patients, crossing the iliac lesion was attempted in an antegrade fashion, seventeen of them via a transbrachial route and five via a contralateral route. In the remaining ten patients, crossing the iliac lesion was gained via a retrograde CFA access through puncturing the CFA patch. Our preferred lesion crossing strategy was to cross long occlusive iliac segments in an antegrade fashion from the brachial or the contralateral approach, and to cross stenotic iliac lesions and short occlusions in a retrograde fashion through the CFA patch.

Clinical success, according to the AHA classification, at 1 month showed 12.5% (4 patients) had grade 3 improvement, 56.3% (18 patients) had grade 2 improvement, and 25% (8 patients) had grade 1 improvement, while 6.3% (2 patients) worsened. These 2 patients are the ones who had early thrombosis of the target treatment segment within 30 days. The AHA clinical improvement table showed furthermore 3 patients with deterioration of clinical condition at 3, and 6 months but this was due to SFA restenosis and not related to restenosis in the target treatment iliac and CFA area as shown by shaded cells in Table 6.

During the follow-up period which was 12 months, there were 6 major adverse cardiovascular events (MACE) that resulted in myocardial infarction in 4 patients which occurred more than three months after the procedure and cerebrovascular stroke in another 2 patients, which occurred at 6 and 12 months after the procedure and were not considered to be directly related to the procedure as shown in Table 7.

We had 2 deaths, those were the 2 patients who had stroke at 6, and 12 months, and another 3 patients lost for follow up at 6,9, and 12 months of follow up. All our surviving patients except for five patients remained free of symptoms, without need for any other interventions at the time of the last follow-up. Those five patients who developed recurrent symptoms were as follows; two patients developed early acute thrombosis in the target treatment area of the iliac and CFA segment in less than one month and were treated by gentle (over the wire) Fogarty catheter mechanical thrombectomy followed by completion angiography and iliac stenting for skipped lesion in the iliac artery. This is shown in the AHA clinical improvement (Table 6 shaded cells) by the 2 patients who worsened clinically at 1 month.

Three other patients needed reintervention at 3, and 6 months for recurrent stenosis of the SFA but not to the target treatment area in the iliac or CFA, and were managed by reintervention to the SFA segment by balloon angioplasty and stenting. This again is shown in the AHA clinical improvement (Table 6 shaded cells) by the 3 patients who worsened clinically at 3, and 6 months.

There were only 4 minor complications in the form of groin infection which resolved by daily dressings and antibiotics according to culture and sensitivity tests. Fifteen patients of our cohort were treated for rest pain which resolved after the procedure and did not need any further surgical procedures, while the remaining 17 patients needed minor amputation and debridement for necrotic or gangrenous tissue after the intervention as shown in Table 7.

Our primary patency rate of the target treatment segment (common femoral and iliac axis) was 93.75% at 12 months **(Figure 2)**. Our secondary patency rate of the target treatment segment was 100% at 12 months **(Figure 3)**, while freedom from reintervention to the treated limb was 84.15% at 12 months **(Figure 4)**.

Table 2: Demographic data

Characteristics	**N (%)**
Age	Mean 65.4 (53-74)
Gender Male Female	 19 (60%) 13(40%)
Diabetes	25(78%)
Ischemic Heart disease	13(40%)
Hypertension	22(69%)
Smoking	16(50%)
Renal impairment	3(9.4%)

Table 3: Clinical presentation according to Rutherford classification

Rutherford category	**N (%)**
Ischemic rest pain (category 4)	15(46.8%)
Minor tissue loss (category 5)	11(34.4%)
Major tissue loss (category 6)	6(18.8%)

Table 4: Associated lesions in the femoropopliteal or infragenicular teritory

Associated lesions	**N (%)**
Associated femoropopliteal lesions only	11(34.3%)
Associated femoropopliteal and infragenicular lesions	3(9.4%)
Associated infragenicular lesions only	18(56.3%)

Table 5: Adjunctive procedures performed

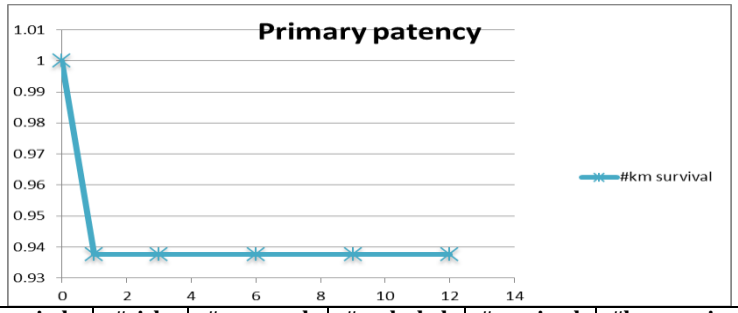
Adjunctive procedure	**N (%)**
Femoropopliteal PTA	3(9.4%)
Femoropopliteal PTA and stenting	5(15.5%)
Infragenicular PTA	9(28.1%)
Both femoropopliteal and infragenicular PTA	1(3.1%)

Table 6: AHA clinical improvement after intervention

AHA clinical improvement	**1 month n**	**3 months n**	**6 months n**	**9 months n**	**12 months n**
+3 points	4	4	4	3	3
+2 points	18	18	16	16	15
+1 point	8	9	8	10	9
No improvement	0	0	0	0	0
Worse (-1 point)	0	1	2	0	0
Worse (-2 points)	0	0	0	0	0
Worse (-3 points)	2	0	0	0	0
Number of patients died or lost for follow up	0	0	2	1	2
Total number of patients followed	32	32	30	29	27

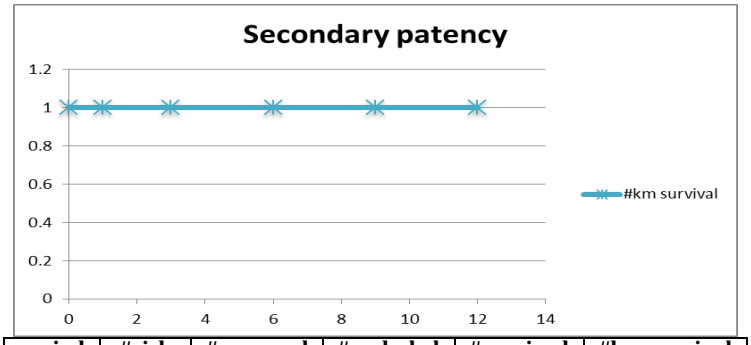
Table 7: Immediate technical success and complications

	N (%)
Immediate technical success	32(100%)
Major complications	0
Minor complications	4(12.5%)
MACE Myocardial infarction Stroke	4(12.5%) 2(6.25%)
Death	2(6.25%)



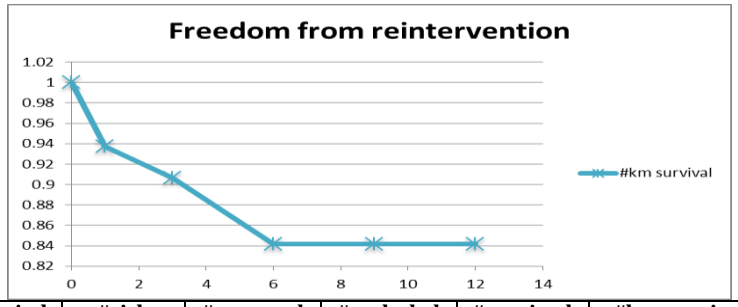
period	#risk	#censored	#occluded	#survived	#km survival
0	32	0	0	32	1
1	32	0	2	30	0.9375
3	30	0	0	30	0.9375
6	29	1	0	29	0.9375
9	28	1	0	28	0.9375
12	27	1	0	27	0.9375

Fig. (2): Kaplan Meier curve for primary patency



period	#risk	#censored	#occluded	#survived	#km survival
0	32	0	0	32	1
1	32	0	0	32	1
3	32	0	0	32	1
6	31	1	0	31	1
9	30	1	0	30	1
12	29	1	0	29	1

Fig. (3): Kaplan Meier curve for secondary patency



period	#risk	#censored	#occluded	#survived	#km survival
0	32	0	0	32	1
1	32	0	2	30	0.9375
3	30	0	1	29	0.90625
6	28	1	2	26	0.841517857
9	25	1	0	25	0.841517857
12	24	1	0	24	0.841517857

Fig (4): Kaplan Meier curve for Freedom from reintervention

DISCUSSION

There are 2 edges for the spectrum of treating Iliofemoral occlusive disease (IFOD) which is either totally surgical or totally endovascular. In our study we tried to elaborate that a hybrid approach for treating IFOD might be a more appealing approach especially if we can benefit from the advantages and avoid the disadvantages of both edges of the treatment spectrum as regards safety, efficacy, and durability.

The first issue that needs to be addressed in this discussion is that our cohort included patients with multilevel disease. It is well known that patients with CLI typically have multilevel arterial occlusive disease and significant comorbidities that increase their perioperative risk.[13] In a study by Jeanwan et al. they pointed out that treatment of inflow lesions alone resulted in both symptomatic and haemodynamic improvement, and that freedom from reintervention in the ipsilateral limb was the same for those with or without residual femoropopliteal lesions. They stated that "In the presence of patent profunda and adequate collateralization, treating any existing inflow lesions, including those in the CFA, may be a reasonable first step in treating patients with multilevel occlusive disease."[3] Similarly, Michele et al. in their study stated that "Additional profundoplasty to the CFE in a patient with femorolpopliteal disease could allow sufficient clinical improvement and critical outflow to the lower extremity."[2] In another study, Kang et al. followed 25 limbs with known femoropopliteal lesions that were not treated at the time of CFA endarterectomy. The authors reported that in the absence of major tissue loss (Rutherford Class 6), freedom from reintervention was equal for the limbs with residual lesions compared with the ones without residual lesions.[16] From the fore mentioned data we were justified in our study to involve patients with multilevel disease in addition to our target area of interest which is the iliofemoral occlusive disease (IFOD).

The second issue that needs to be highlighted in this discussion is the advantages and disadvantages of the totally surgical and the totally endovascular approaches in treating IFOD and how the results of our adopted hybrid approach compares to them and to other studies adopting this hybrid approach. Regarding the total surgical approach, a large body of literature has published outcomes after aortobifemoral bypass (AFB); however, most of the studies were performed in the 1970s and 1980s, before endovascular therapy gained popularity and widespread use. The most extensive review was done by de Vries and Hunink[17] in 1997. Their meta-analysis of 25 articles demonstrated that the overall 5-year patency rate was 91% for patients with claudication and 87% for patients with critical limb ischemia. In another study Kashyap et al.[18] reported an overall primary patency for ABF bypass of 93% at 3 years and secondary patency of 97%. Regarding morbidity and mortality, de Vries and Hunink in their meta-analysis, reported an aggregate operative mortality of 3.3% and postoperative morbidity of 8.3% for aortobifemoral bypass.[17] These results are comparable with the results in our study which showed a primary patency and secondary patency of 93.75%, and 100% respectively at 1 year with zero percent operative related mortality and 12.5% operative morbidity with the hybrid approach. Moreover the decreased hospital and intensive care unit stay together with the avoidance of an abdominal incision and the potential of male erectile dysfunction are factors that should be considered in favor of the hybrid approach.

Regarding the total endovascular approach for IFOD involving the common femoral artery, the endovascular management of symptomatic CFA stenosis has been attempted in small studies with variable success and is therefore not used routinely. A prospective study by Johnston et al. showed that midterm results of CFA balloon angioplasty are suboptimal, with clinical success rates decreasing from 78% in 1 month to 58% and 36% at 1 and 3 years, respectively.[19] Stricker and Jacomella[20] followed 33 limbs after stenting of the CFA bifurcation, reporting 1 and 3-year primary patencies of 87% and 83% respectively. Although reports of successful stenting of the CFA bifurcation do exist,[20,21] its efficacy and long-term results remain controversial. Balloon angioplasty of CFA often fails because the atherosclerotic lesions in this area tend to be heavily calcified and bulky, not allowing an optimal vessel dilation, and may have a persistent elastic recoil. These lesions also carry a substantial risk of dissection with subsequent occlusion of the profunda femoris artery (PFA) orifice. Most surgeons avoid placing CFA stents

because even when structural integrity is maintained, deployment across a high mobility joint appears to have a greater failure as a result of a more intensive neointimal hyperplasia response.[22] CFA stenting could jeopardize PFA patency and may compromise the feasibility of future surgical options.[16] From the fore mentioned data we conclude that endarterectomy with patch angioplasty therefore remains the standard of care for CFA occlusive disease, with proven efficacy and durability.[16,23] It has also the additional advantage that the PFA perfusion can be restored or improved simultaneously, thus maintaining an important collateral pathway.[13]

Regarding the adopted strategy of hybrid repair (HR) in our study, with combined common femoral endarterectomy and iliac artery stenting rather than traditional operative repair (OR) with aortofemoral or iliofemoral bypass for the treatment of severe iliac and CFA occlusive disease, our study was constructed to investigate whether HR can be performed with equivalent safety, efficacy, and durability as OR. The treatment of IFOD with HR has obvious appeal. Among the factors that have helped to popularize HR are decreased hospital and intensive care length of stay, less surgical morbidity by eliminating the invasiveness and physiologic stress that result from aortic cross-clamping, and patient preference dictating a minimally invasive approach. Consequently, HR could be a valid alternative to OR for high-risk patients.[2]

The efficacy of the hybrid approach has been previously documented. Nelson et al.[24] reported short-term results after combined CFA endarterectomy and iliac stenting with primary patency rate of 84% at 1 year which improved to 97% with secondary interventions. Cotroneo et al.[25] followed 44 patients (24 with claudication and 20 with CLI) after hybrid revascularization procedures and reported 2-year primary and secondary patency rates of 79.1% and 86.1%, respectively. Chang et al.[10] reported 5-year primary, primary assisted, and secondary patencies of 60%, 97%, and 98%, respectively.

Our results come to an agreement with the fore mentioned studies, regarding the efficacy of a hybrid strategy in these high-risk surgical candidates as it relates to patency, morbidity, and mortality, which showed a primary patency and secondary patency of 93.75%, and 100% respectively at 1 year with zero percent operative related mortality and 12.5% operative morbidity with the hybrid approach. Furthermore, most CFEs can be performed under regional or local infiltration anesthesia rather than general anesthesia. The low morbidity associated with CFE likely negates any presumed advantage of endovascular therapy over surgical endarterectomy.

In conclusion, this study is not intended to compare the hybrid approach with the gold standard open surgical repair, it rather points out that a hybrid approach combining common femoral artery endarterectomy and iliac angioplasty for iliofemoral occlusive disease (IFOD) seems an attractive option for those patients who are unfit for extensive bypass surgery, especially those with extensive multilevel disease where hybrid procedures can be performed safely, and with good durability.

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