The Egyptian Journal of Hospital Medicine (July 2023) Vol. 92, Page 5587- 5594

The Effectiveness of Ipsilateral Stenting VS Kissing Stenting in the Treatment of Unilateral Common Iliac Artery Ostial Lesion

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ABSTRACT

Background: Iliac arteries are commonly affected by occlusive atherosclerotic disease, leading to arterial insufficiency and lower extremity symptoms. Atherosclerosis in the iliac region often coexists with pathologies below the inguinal ligament.
Aims: This study aimed to compare the effectiveness of unilateral common iliac artery stenting versus bilateral kissing stents in terms of clinical and technical success for treating unilateral common iliac artery ostial lesions.
Method: A prospective study (October 2022-April 2023) that included 40 patients randomly assigned to two groups. Group A received bilateral kissing stents, while group B underwent unilateral common iliac artery stenting. Clinical evaluation, technical success, and complications were assessed over six months.
Results: Technical success rate was 100 % in groups A and B, six months primary patency rate in group A was 95% had patent stent with good inflow while 5% had claudication at 100 M, treated by a balloon expandable stent. While in group B, 85% had patent stent with good inflow while 5% had claudication at 100 M, treated by balloon expandable stent, 5% had renal failure, congested heart failure and died, and 5% neglected medication. DFI occurred, sepsis and AKA was done as a lifesaving.
Conclusion: Unilateral common iliac artery stenting demonstrated comparable clinical outcomes, technical success, and complication rates to bilateral kissing stents. It provides a safe and effective alternative for treating unilateral common iliac artery ostial lesions.
Keywords: Kissing stent, Unilateral stenting, Common iliac artery, Ostial lesion, Angioplasty.

INTRODUCTION

The iliac arteries are frequently affected by obstructive atherosclerosis, making them a common site for symptomatic peripheral artery disease, accounting for approximately one-third of cases [(1)]. Aortic bifurcation poses a significant challenge, accounting for approximately 10% of all iliac lesions. It predominantly involves the ostia of both common iliac arteries (CIA) and, in some cases, includes unilateral ostial disease, which leads to arterial insufficiency in the lower extremities with ischemic symptoms [(2)]. Atherosclerosis of the iliac artery can often be asymptomatic. It may be incidentally detected or present with acute ischemia, intermittent claudication, or critical limb ischemia (CLI) [(3)].Surgical intervention has been considered the gold standard treatment for aortoiliac lesions due to its effectiveness, with acceptable long-term patency rates of approximately 90-95% at 5 years and 82-87% at 10 years [(4)]. However, it carries significant complications and mortality risks, especially among high-risk patients, in addition to laparotomy-related complications such as incisional hernia and adhesions [(5)].

Endovascular intervention is now regarded as the preferred choice with the latest guidelines of the European Society for Vascular and Endovascular Surgery and demonstrated excellent 5-year patency rates ranging from 80-90%, with low rates of mortality and morbidity, as well as shorter hospitalization periods [(6)]. Various endovascular techniques are employed, with balloon angioplasty being the standard therapy for iliac arteries, particularly for short lesions (TASC A and B), providing acceptable long-term patency rates of 60-90% over 3-5 years. However, its use is limited by initial residual stenosis, late restenosis, and a high rate of distal embolization [(7, 8)]. Stents are frequently utilized, especially in lesions involving the distal aorta or the origin of the CIA [(9)].The concept of the kissing technique arose due to concerns about the risks of plaque shift and distal embolization to the contralateral iliac artery [(10)]. Unilateral ostial CIA disease has been treated using a single stent deployed only on the affected side, and it has been concluded that the technique is safe and demonstrated comparable mid-term outcomes to those achieved with kissing stents [(3)] , that need additional devices, bilateral femoral artery access, and the potential loss of future contralateral access options in the endovascular treatment of distant lesions.

This study aimed to assess the effectiveness of unilateral common iliac artery stenting compared to the use of kissing stents in terms of both clinical and technical success in the treatment of ostial lesions of the unilateral common iliac artery.

MATERIAL AND METHODS

This prospective study, conducted between October 2022 and April 2023 at Al Zahraa University Hospital, Cairo, Egypt, and Shark El Madina Hospital in Alexandria, Egypt. The study involved 40 patients with unilateral ostial occlusive disease of the common iliac artery (CIA). They were randomly assigned to two

Received: 01/05/2023
Accepted: 30/06/2023

treatment groups: Group A received bilateral kissing stents, and group B received a unilateral CIA stent. Clinical evaluations, technical success assessments, and complication monitoring were performed for 6 months.

Inclusion criteria: The study included individuals of all genders and ages meeting specific criteria: Unilateral ostial iliac artery lesion (TASC C & D) diagnosed through duplex ultrasound and computed tomography angiography, presence of claudication pain, tissue loss or gangrene, and peripheral artery disease severity (Rutherford classification 3 to 6).

Exclusion criteria: Limited life expectancy, previous unsuccessful endovascular procedures for the same lesion, contrast material hypersensitivity, end-stage renal disease, and aortic or iliac aneurysm.

All participants in the study underwent hospitalization. Comprehensive clinical assessments, including medical history, risk factor identification, physical examinations, diagnostic workup (duplex ultrasound and computed tomography angiography), and comprehensive laboratory investigations focusing on renal function and coagulation profile, were conducted for all patients.

Procedure details: Periprocedural medication involved dual antiplatelet administration: 300 mg of clopidogrel loading dose, 100 mg of salicylates, and a daily 75 mg maintenance dose. Postoperative therapy lasted ≥ 3 months. Access points varied based on lesion location. After sheath insertion, 70-100 U/kg of unfractionated heparin was intra-arterially injected.

In Group A, bilateral kissing stents were placed for 7 patients with left CIA lesions and 13 patients with right CIA lesions. Access approach varied: 14 patients had both ipsilateral and contralateral femoral access, while 6 patients had left brachial and contralateral femoral access. In cases of ipsilateral and contralateral access, bilateral retrograde CFA was employed. A 6 Fr sheath was inserted, Two 0.035 Terumo stiff-angled guide wire, and a 4 Fr vertebral catheter navigated through CFA, CIA, and the aorta to the bifurcation level. Pre-intervention angiography verified lesion characteristics, including length, stenosis or occlusion degree, contralateral CIA status, and distal run-off vessel condition. In cases of Lt brachial and contralateral access, A 0.035 Terumo stiff-angled guide wire and a 4 Fr vertebral catheter navigated through the aorta till its bifurcation, and towards the non-diseased CIA. A 6-Fr long sheath (90 cm, Cook Medical, Bloomington, Indiana, USA) was inserted through Lt brachial access, with its tip positioned above the aortic bifurcation.

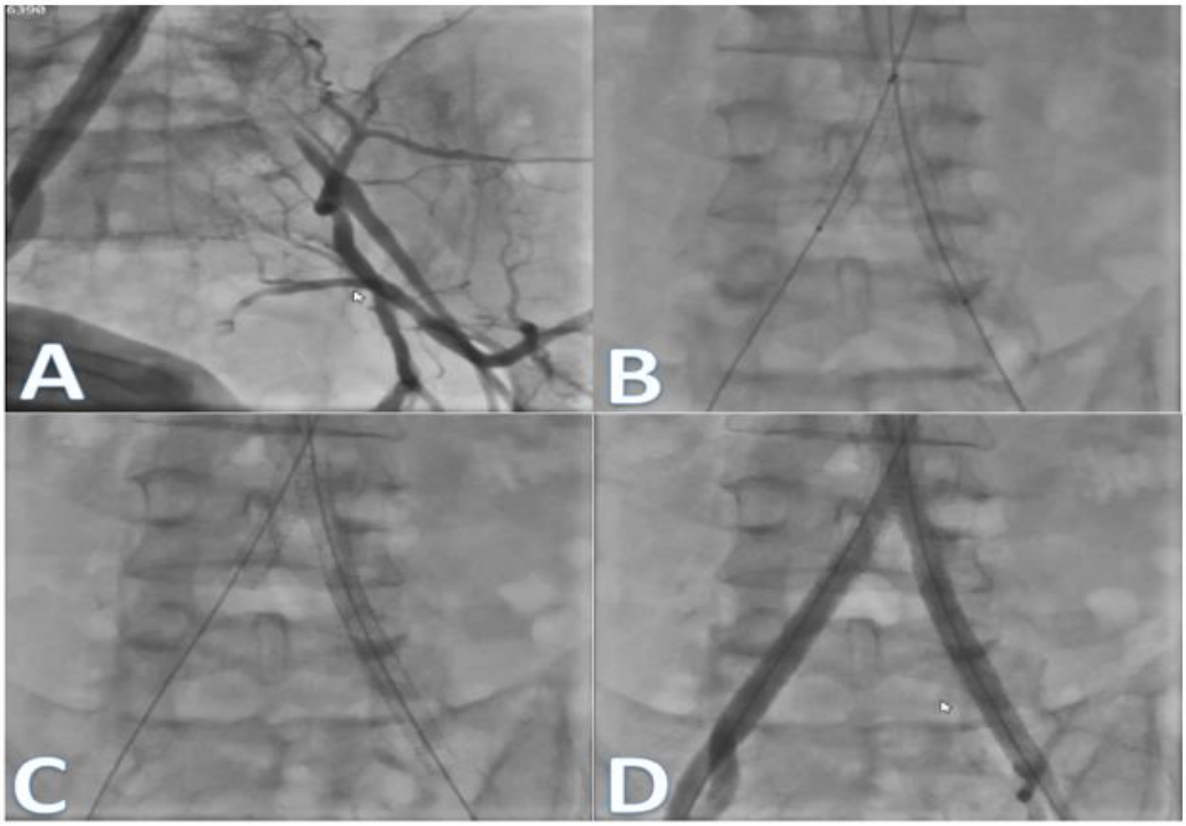

Fig 1. Representative patients with CIA ostial lesion. Bilateral Kissing-stents technique: (A) preprocedural angiography; (B) Simultaneous implantation of two balloon-expandable stents into the aortoiliac bifurcation (kissing stent procedure) (C) Additional Self-expandable stent and (D) Postintervention angiography.

The guide wire and vertebral catheter negotiated the CIA lesion, either intraluminally or subintimally, re-entering the proximal lumen of the common femoral artery. A contralateral 6-Fr femoral sheath was inserted, and another guide wire advanced toward the abdominal aorta. Angiographic reassessment was done before the procedure. A 5-6 mm low-profile standard balloon dilated the CIA lesion at nominal pressure for 1-2 minutes. Balloon-expandable stents were carefully inserted bilaterally, and positioned at the aortic bifurcation without crossing. The stent diameter matched the vessel diameter without oversizing. Lengthy lesions required additional self-expandable stents with 5-mm overlap to prevent fracture. Internal iliac artery ostium was covered only if necessary.

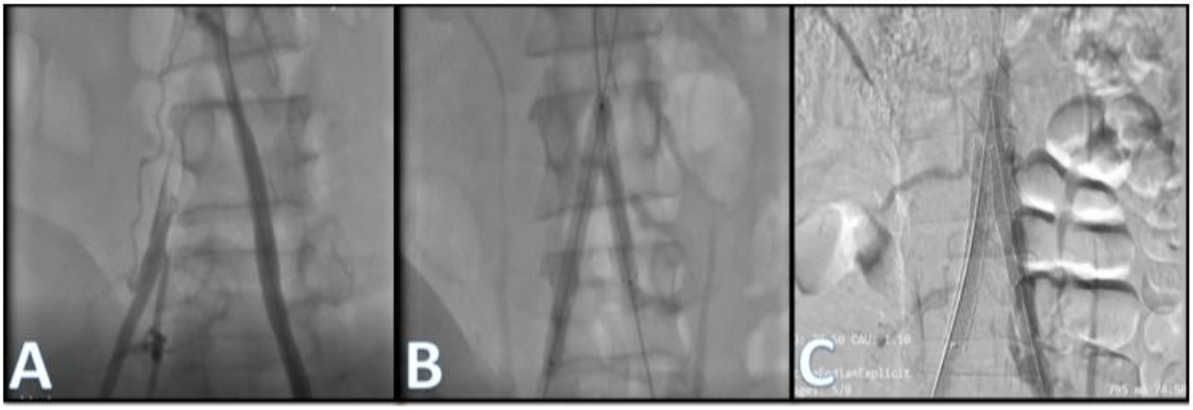

Fig 2. Representative patients with CIA ostial lesion. Bilateral Kissing-stents technique: (A) preprocedural angiography; (B) Simultaneous implantation of two balloon-expandable stents into the aortoiliac bifurcation (kissing stent procedure) (C) Postintervention angiography.

In Group B, unilateral common iliac artery stenting was performed. Left CIA lesions were observed in 9 patients, and right CIA lesions in 11 patients. Access was established using ipsilateral retrograde or contralateral cross-over through the common femoral artery, employing percutaneous methods. The antegrade approach via the left brachial artery was also considered.

In cases where ipsilateral CFA retrograde access was used, CFA access and 6 Fr sheath were inserted, and A 0.035 Terumo stiff-angled guide wire was used with 4 Fr vertebral catheter to navigate through SFA, CFA, CIA, and the aorta, For left brachial access cases, a 0.035 Terumo stiff-angled guide wire and a 4 Fr vertebral catheter navigated from the aorta to the aortic bifurcation and towards the diseased CIA. A 6-Fr long sheath (90 cm, Cook Medical, Bloomington, Indiana, USA) was inserted with its tip positioned slightly above the aortic bifurcation, For contralateral CFA retrograde access cases, CFA access and 9 Fr sheath were inserted and cross-over sheath to the opposite diseased side, A 0.035 Terumo stiff-angled guide wire were used with 4 Fr vertebral catheter to navigate through CFA, CIA and SFA.

Pre-intervention angiography assessed lesion characteristics: length, stenosis/occlusion degree, contralateral CIA status, and distal run-off vessel condition. The guide wire and vertebral catheter negotiated the CIA lesion intraluminally or subintimally, re-entering the proximal lumen of the common femoral artery.

Angiographic re-assessment was done before starting the technique. CIA lesion was predilated with a low-profile balloon. A balloon-expandable stent of the same size as the reference vessel diameter was positioned over the CIA ostium, extending a few millimeters into the distal aorta. Routine completion angiography evaluated the technical success and the presence of contralateral dissection or distal embolization. Angiography assessed below-knee run-off vessels, ensuring comprehensive treatment outcomes assessment and appropriate management of potential complications.

During hospitalization, daily follow-up was conducted, with subsequent outpatient visits at 3- and 6 months post-discharge. Patients with ischemic foot ulcers or gangrene received standard wound care, debridement, and potential amputation as part of their treatment. Follow-up visits included clinical assessments for pulse restoration, ankle-brachial index (ABI) measurement, relief from rest pain, and wound healing monitoring. Duplex ultrasound assessed target vessel patency. Upon discharge, all patients were prescribed dual antiplatelet therapy: 100 mg aspirin and 75 mg clopidogrel daily for at least 3 months.

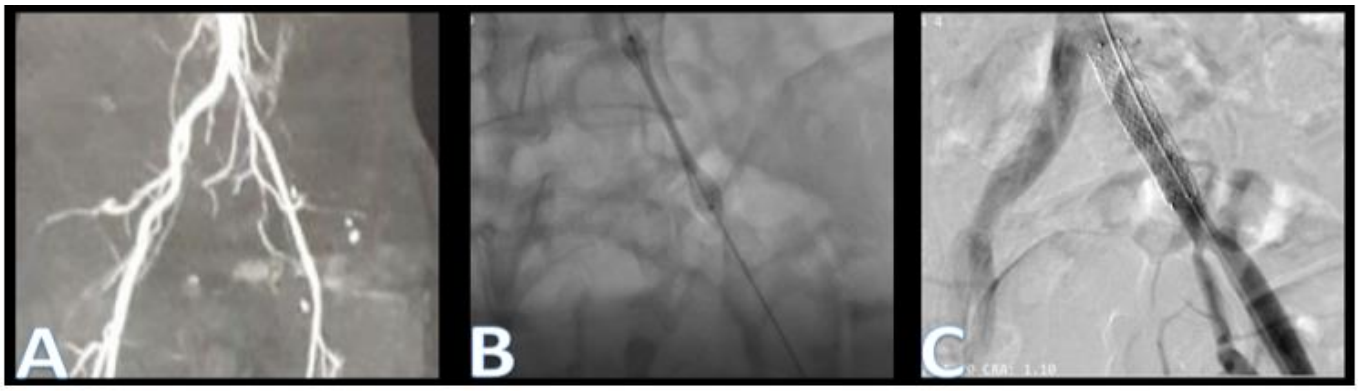

Fig 3. Representative patients with CIA ostial lesion. Single-stent technique: (A) preprocedural CTA with Lt CIA stenosis; (B) implantation of an Express 8-mm balloon-expandable stent; and (C) final angiography.

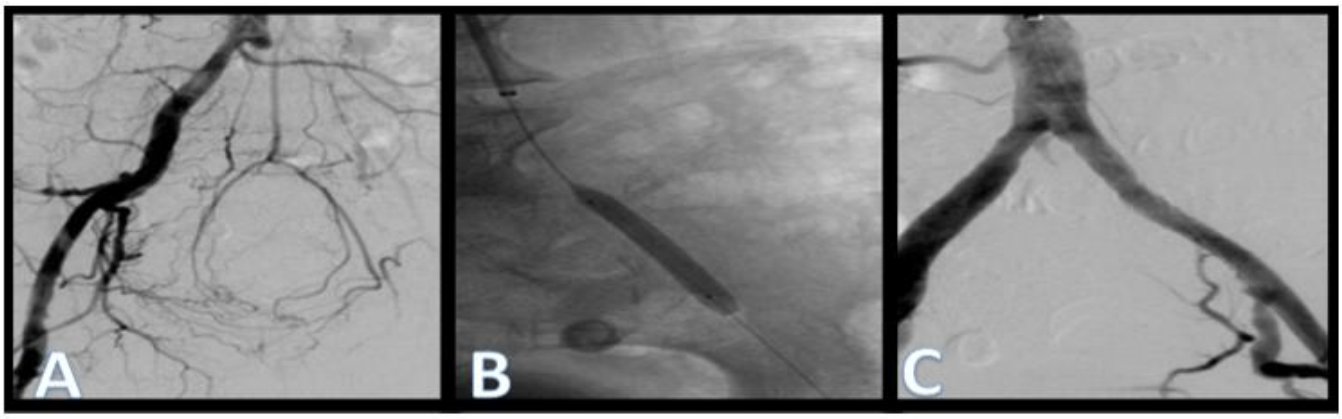

Fig 4. Representative patients with CIA ostial lesion. Single-stent technique: (A) preprocedural angiography with Lt CIA lesion; (B) implantation of an Express 8-mm balloon-expandable stent; and (C) final angiography.

Ethical approval:

The study was accepted by The Ethical Committee, Faculty of Medicine for Girls, Al-Azhar University (Reference: FMG- IRB. 1400) and enlightened written consent was taken from every patient in this study. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical analysis

Data were gathered, organized in tabular form, and analyzed using SPSS 26.0 for Windows. Qualitative data were presented as numbers and percentages, while quantitative data were summarized with range, mean, standard deviation, and median. Statistical comparisons were conducted as two-tailed tests, with a significance level of $P \leq 0.05$ indicating a significant difference.

A P-value of $p < 0.001$ indicated a highly significant difference, while a P-value > 0.05 suggested a non-significant difference. The chi-square (X^2) test assessed proportions between qualitative parameters, identifying significant differences or associations between categorical variables.

The independent t-test compared two independent groups with parametric quantitative data, revealing mean differences and potential significant variations in the measured variables.

RESULTS

A total of 40 patients with unilateral CIA ostial lesion disease, were enrolled in this study. Group A consisted of 20 patients (14 males and 6 females) with a mean age of 53.55 ± 2.87 years (range: 48-58 years) who underwent bilateral kissing stent treatment. Group B included 20 patients (13 males and 7 females) with a mean age of 52.79 ± 2.1 years (range: 48-58 years) who received a unilateral CIA stent on the affected side. Age, gender distribution, cardiovascular risk factors, and the presence of concomitant diseases were not significantly different between the two groups. Diabetes and smoking were the main reported risk factors among all patients (Table 1).

Table (1): Demographic data, risk factors, and lesion characteristics

	GroupA (Bilateral) **(N=20){n=%}**	GroupB (Unilateral) **(N=20){n=%}**
Age (years)	53.5 (48-58)	53 (48-58)
Male/Female	14(70%)/6(30)	13(65%)/7(35%)
Risk Factors		
Hypertension	19 (95%)	18 (90%)
Hyperlipidemia	9 (45%)	9 (45%)
Diabetes mellitus	18 (90%)	17 (85%)
Ischemic heart disease	4 (20%)	1 (5%)
Smokers	13 (65%)	15 (75%)
Rutherford classification		
Category 3	11 (55%)	7 (35%)
Category 4	5 (25%)	8 (40%)
Category 5	4 (20%)	5 (25%)
Length of lesion	44.2 ± 14.62	42.1 ± 9.3
Type of lesion		
Occlusion	8 (40%)	9 (45%)
Stenosis	12 (60%)	11 (55%)

Using: #Independent Sample t-test;▲: Chi-square test p-value >0.05 NS

Among the patients in group A, the mean lesion length was measured to be 38.5 ± 16.82 mm. In group B, the mean lesion length was measured to be 42.1 ± 9.3 mm. Based on the specific characteristics of the lesions, there was variation in both the vascular access methods and the number of stents required from one case to another. This table provides a comprehensive overview of the diverse access techniques and stent quantities utilized in the bilateral and unilateral groups (Table 2).

Table (2): Distribution according to vascular access and numbers of stents

Access	Bilateral group	Unilateral	Test	P - value
Ipsilateral and contralateral femoral access	14 (70%)	-	-	-
LT brachial and contralateral access	6 (30%)	-	-	-
Lt brachial A access	-	7 (35%)	-	-
Ipsilateral CFA retrograde	-	12(60%)	-	-
Contralateral lateral CFA access	-	1 (5%)	-	-
Numbers of stents				
1 stent	0	18 (90%)		
2 stents	15 (75%)	2 (10%)		
3 stents	5 (25%)	0	1.4	0.44

Using: #Independent Sample t-test;▲: Chi-square test p-value >0.05 NS

According to complications: Groin hematoma was observed in 5% in group A and in 10% in group B patients. Retroperitoneal hematoma was observed in 5% in group B patients, Spasm of brachia artery was observed in 5% in group A and in 10% in group B patients. Distal embolization was observed in 5% in group A and in 10% in group B. Perforation was observed in 5% in group B and CIN was observed in 5% in group A and in group B patients.

Table (3): Distribution according to the complications

	Bilateral group	Unilateral	Test	P - value
Groin Hematoma	1 (5%)	2 (10%)	0.4	0.19
Retroperitoneal Hematoma	0	1 (5%)	0.36	0.18
Spasm of Brachial A	1(5%)	2(10%)	0.4	0.19
Stent Mal Position	0	1 (5%)	0.36	0.18
Distal embolization	1 (5%)	2 (10%)	0.4	0.19
Acute Thrombosis	0	0	-	-
Dissection	0	0	-	-
Perforation or Rupture	0	1 (5%)	0.36	0.18
Infection of the stent	0	0	-	-
Contrast-induced nephropathy CIN	1 (5%)	1 (5%)	-	-

Using: #Independent Sample t-test; ▲: Chi-square test p-value >0.05 NS

According to the results for the bilateral and unilateral groups based on various parameters. After a 3-month follow-up, both groups demonstrated similar rates of patent stents with good inflow. However, there was a minor difference in the occurrence of claudication at 100 meters, with one case in the unilateral group.

After a 6-month follow-up, both groups maintained high rates of patent stents with good inflow, but the unilateral group showed a slightly lower percentage. Notably, one case in the unilateral group experienced heart failure, renal failure, and death, while one case in each group had claudication at 100 meters treated with a balloon-expandable stent. In addition, one case in the unilateral group experienced complications due to neglected medication, sepsis, and above-knee amputation (AKA). Further statistical analysis indicated that the differences observed between the two groups in terms of follow-up results and complications were not statistically significant (P > 0.05). These findings suggest comparable outcomes in terms of stent patency, inflow, and complication rates between the bilateral and unilateral groups (Table 4).

Table (4): Distribution according to follow up by duplex

	Bilateral group	Unilateral	Test	P value
Follow UP 3 Months			0.36	0.54
Patent Stent with Good Inflow	20 (100%)	19 (95%)		
Claudication at 100M, treated by drug coated balloon dilatation	0	1 (5%)		
Follow UP 6 Months				
Patent Stent with Good Inflow	19 (95%)	17 (85%)	0.42	0.44
Heart Failure and Renal Failure and Died	-	1 (5%)		
Claudication at 100M, treated by balloon expandable stent	1 (5%)	1 (5%)		
Neglected Medication, Sepsis, AKA	-	1 (5%)		

Using: #Independent Sample t-test;▲: Chi-square test p-value >0.05 NS

DISCUSSION

Traditionally, complex iliac artery occlusion has been treated surgically with aortofemoral bypass or revascularization techniques. However, these procedures pose risks of morbidity and mortality due to invasiveness, anesthesia complications, and longer recovery [(11)]. In accordance with European guidelines, endovascular intervention has been proposed as the primary therapeutic modality for aortoiliac lesions of TASC II types A, B, and C [(12)]. TASC II '15 update highlighted expertise & patient comorbidities in choosing treatment strategy. Many centers favor endovascular-first for iliac lesions, despite potential complications like distal embolization, arterial dissection, and iliac perforation [(13, 14)].

Lesion tackling offers multiple accesses: brachial, retrograde via the ipsilateral common femoral artery, and crossover via the contralateral common femoral artery. Antegrade negotiation reduces subintimal tracking risks near the aortic bifurcation and aortic dissection [(15)]. So, brachial access was important approach in crossing the ostial CIA lesion in this study. This concept agree with **Alvarez-Tostado *et al.* [(16)]** , where the brachial approach was reported to have superior push ability and fewer access-related complications. In contrast, the ipsilateral retrograde approach had drawbacks, such as challenges in femoral puncture distal to the occluded segment and navigating the guide wire through the occlusion, increasing the risk of extensive dissection. There is no one-size-fits-all solution for iliac lesions. Balloon-expandable stents treat focal and calcified lesions near the aortic bifurcation while self-expanding stents suit tortuous iliac vessels due to flexibility and conformity. Balloon-mounted stents offer advantages like straight design, high radial force, and precise deployment. However, they pose a risk of arterial rupture in severely calcified vessels [(17)].

Ensuring accurate placement of kissing stents is crucial and demands careful attention to prevent stent misalignment. The stents must be positioned side by side, at the same level, within the aorta [(18)], which helps minimize the displacement of atheroma or thrombotic material by the stent struts. **Saker *et al.*** [(19)] investigation of aortoiliac kissing stents demonstrated that variations in shear stress may increase neointimal hyperplasia. To avoid reduced blood flow, proximal stents should not extend more than 5 mm above the aortic bifurcation [(20)] . Pre-stent balloon dilatation is crucial for occluded, calcified lesions. Use a low-profile balloon smaller than the vessel diameter to minimize friction and prevent complications like plaque disruption, perforation, or thrombus migration [(21).]

Iliac revascularization outcomes are affected by lesion length, eccentricity, calcification, occlusion, and stenosis. Stenosis revascularization exhibits higher patency rates compared to occlusion revascularization. Occlusion predicts reduced patency rates due to increased atherosclerotic and thrombotic burden [(22)]. Additionally, revascularization of iliac artery occlusion exhibited a higher incidence of distal embolization compared to iliac stenosis. Managing iliac occlusions with PTA alone might pose a higher risk of limb loss, Balloon angioplasty was an effective and low-risk method for recanalizing iliac artery stenosis, with 95% technical success and 80-90% 5-year patency rates. Treatment of total occlusion presents several challenges, including safe guide wire advancement through the lesion, which is better achieved through antegrade recanalization. Another challenge is maintaining vessel patency after successful recanalization through stent deployment to prevent restenosis [(8, 17)].

Balloon angioplasty at the CIA ostium can displace plaque or cause embolization. The kissing balloons technique addresses this by inflating balloons at both iliac artery ostia simultaneously. It has been successful, but 9% of patients experience complications [(23)]. Due to these drawbacks, balloon angioplasty of common iliac lesions is not recommended [(24)].

Recently, the use of covered stents has become more common for aortoiliac stenting, replacing bare metal stents (BMS). Covered stents are seen as a valid alternative to surgery and have shown improved outcomes. It is distinguished by its cast encapsulation technology, where the stainless-steel component is enveloped by a thin outer and inner PTFE coating. This coating serves as a mechanical barrier, separating the intima from the lumen [(10)]. This coating reduces the

restenosis rate by preventing migration and proliferation through the stent struts and subsequent intimal hyperplasia [25]. In addition, covered stents offer improved thrombus entrapment between the stent graft and the wall of the vessel, resulting in a reduced incidence of distal embolization [26].

Technical success, which is defined as the successful restoration of aortic bifurcation without any instances of contralateral plaque shift or dissection, was achieved in all 40 patients, resulting in a 100% success rate in both groups A and B. Similar findings are reported by **Allam *et al.*** [27] and **Said *et al.*** [3]

In 3 month follow-up, the patency rate was 100% and 95% in groups A and B, only one patient in group B had significant stent stenosis and claudication at 100 M treated by drug-coated balloon dilatation. While in 6 months, primary patency rate was 95% and 85% in groups A and B, respectively. It was comparable between study groups without significant difference (P=0.44). Significant stent stenosis rate was 5% in group A and B (one patient in each group) that was claudicant at 100 M and significant stenosis occurred and was treated by balloon expandable stent. All cases of stent stenosis occurred in the same side of previously diseased CIA. Stent stenosis or occlusion can be treated by intervention or surgery.

In group B, one patient had renal failure and congestive heart failure, resulting in death. Another patient neglected medication and wound care, leading to diabetic foot infection, sepsis, and AKA. Distal embolization occurred in 3 patients, it is considered a common complication during the management of ostial CIA lesions [6]. Distal embolization occurred in one patient (Group A) and two patients (Group B). The patients presented with blue toe syndrome were successfully managed with subcutaneous anticoagulant and improved within two weeks.

This series demonstrated that the unilateral stent technique achieves similar CIA ostial occlusive disease patency as the kissing stent, preserves contralateral access, and allows future interventions. However, this approach carries a higher risk of plaque shift, iliac dissection, and distal embolization that should be considered during treatment planning.

CONCLUSION

The single-stent strategy demonstrated comparable safety and effectiveness to the kissing-stents strategy when treating unilateral common iliac artery ostial lesions. This was observed in terms of advantages such as using fewer stents, decreased need for vascular access, and achieving both technical and clinical success, leading to patient improvement.

- **Conflict of interest:** The authors declared no conflict of interest.
- **Sources of funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.
- **Author contribution:** Authors contributed equally to the study.

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