JCS Journal of Chest Surgery
https://doi.org/10.5090/jcs.23.012
pISSN: 2765-1606 eISSN: 2765-1614
J Chest Surg. 2023;56(4):264-271

Clinical Research

Comparison between Kissing Stents and Direct Surgical Bypass for Aortoiliac Occlusive Disease

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ARTICLE INFO
Received January 11, 2023
Revised March 2, 2023
Accepted March 9, 2023

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[†]This study was presented at the 54th Annual Meeting of the Korean Society for Thoracic and Cardiovascular Surgery in 2022.

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Background: The optimal management strategy for aortoiliac occlusive disease (AIOD) remains debatable. This study compared early and late outcomes between direct surgical bypass and kissing stents for AIOD treatment.
Methods: We retrospectively reviewed data, including age, sex, risk factors, comorbidities, symptoms, TransAtlantic Inter-Society Consensus (TASC) II classification, operation time, perioperative complications, in-hospital mortality, and length of hospital stay, from a cohort of 46 patients treated for AIOD (24 with kissing stents and 22 with direct surgical bypass) at Pusan National University Hostpital from January 2007 to December 2016. The primary, assisted primary, and secondary patency rates in both groups were compared.
Results: The hospital stay (direct surgical bypass vs. kissing stents: 16.36±5.19 days vs. 9.08±10.88 days, p=0.007) and operation time (direct surgical bypass vs. kissing stents: 316.09±141.78 minutes vs. 99.54±37.95 minutes, p<0.001) were significantly shorter for kissing stents. Kaplan-Meier analysis revealed that the primary, assisted primary, and secondary patency rates in the direct surgical bypass group were 95.5%, 95.5%, and 95.5%, respectively, at 1 year; 86.4%, 86.4%, and 95.5% at 3 years; and 77.3%, 77.3%, and 95.5% at 5 years. The primary, assisted primary, and secondary patency rates in the kissing stent group were 100.0%, 100.0%, and 100.0%, respectively, at 1 year; 95.8%, 95.8%, and 100.0% at 3 years; and 95.8%, 95.8%, and 100.0% at 5 years.
Conclusion: Except for special cases wherein endovascular revascularization is difficult, kissing stents are more advantageous for TASC II C and D lesions.

Keywords: Kissing stents, Direct surgical bypass, Aortoiliac occlusive disease

Introduction

Aortoiliac occlusive disease (AIOD) is a chronic, atherosclerotic, and occlusive disease of the aorta and iliac arteries, resulting in disabling claudication and critical limb ischemia. The traditional treatment for AIOD is direct surgical bypass. Specifically, the procedure of choice for local lesions that do not extend throughout the common iliac artery is aortoiliac bypass, while more diffuse lesions are traditionally treated with aortobifemoral bypass [1]. The durability of these procedures is particularly excellent in cases of claudication (85%–90% at 5 years) [1-3].

However, endovascular reperfusion has recently become increasingly popular among surgeons as an alternative to conventional surgery, yielding favorable clinical results [2,4,5]. In particular, the kissing stent technique has been proposed to treat complex aortic lesions. This technique is particularly attractive for high-risk patients, as complications and mortality from direct surgical bypass are relevant [6-9].

The optimal management of AIOD remains a matter of debate. Although direct surgical bypass is documented to produce lasting results, the kissing stent procedure has shown similar results, with fewer postoperative complications and better durability. Furthermore, open surgery remains an option if the kissing stent fails.

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The purpose of this study was to retrospectively compare the early and late outcomes of direct surgical bypass to those of kissing stents for the treatment of AIOD. This manuscript was written following the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) checklist.

Methods

This retrospective cohort study reviewed data from patients treated for AIOD at Pusan National University Hospital over 10 years (January 2007 to December 2016). Of the 46 patients, 24 were treated with kissing stents and 22 with direct surgical bypass. The preoperative diagnostic assessment consisted of ankle-brachial index (ABI) measurement and computed tomography (CT) angiography of the aorta and iliac-femoral axis. The data collected included age, sex, risk factors, comorbidities, symptoms, Trans-Atlantic Inter-Society Consensus (TASC) II classification, operation time, perioperative complications, in-hospital mortality, and length of hospital stay according to electronic medical records and picture archiving and communication systems. The symptoms of AIOD were graded using the Rutherford classification. AIOD was defined as an aortoiliac artery with severe stenosis (>70%) or complete occlusion. Primary patency was defined as a patent stent without any reintervention; primary assisted patency was defined as a patent stent after endovascular reintervention but without occlusion at any time; and secondary patency was defined as a patent stent after occlusion, with patency ending with an untreated or surgically treated occlusion [10].

Kissing stents were preferentially considered for patients with a TASC II classification of C or D. The anatomical indications for direct surgical bypass were lesions immediately below the origin of the renal artery, severe and diffuse calcification of the aorta and iliac arteries, and previous failed endovascular attempts. Patients' general condition and degree of comorbidities were also taken into account, and direct surgical bypass was considered for patients with a life expectancy of greater than 2 years.

Kissing stents were deployed by a single interventional radiologist, and direct surgical bypass was performed by 2 cardiovascular surgeons. Direct surgical bypass was performed in the operating room under general anesthesia using a transperitoneal approach. In all cases, bifurcated Dacron grafts were used. For proximal anastomoses, end-to-end anastomosis was performed. For distal anastomoses, end-to-end anastomosis was performed in the iliac artery, and end-to-side anastomosis was performed in the common femoral artery. Kissing stents were deployed using an angiogram under local anesthesia. In all cases, the bilateral common femoral arteries were accessed using the Seldinger technique. The standard kissing stent technique was performed, with the placement of the proximal stent ends at a higher level than the aortic bifurcation or the proximal extension of the lesion (power inflation index score >7). During the procedure, 5,000 units of unfractionated heparin were administered intravenously. Single antiplatelet therapy was also administered to all patients. Aspirin (100 mg/day) was administered, and no antiplatelet agent was added if clopidogrel was prescribed for patients with cardiovascular or cerebrovascular disease.

After intervention, follow-up was performed at an outpatient clinic once every 3 months, and CT angiography was performed if symptoms were present during follow-up. In patients with no symptoms, CT angiography or ABI testing was performed every 12 months, and CT angiography was performed among patients who had ABI abnormalities.

Before all procedures, the potential risks and benefits were explained in detail to the patients, and informed written consent was obtained. The principles of the Helsinki Declaration were strictly followed for the study's entire duration. This study was approved by the appropriate Institutional Review Board of Pusan National University Hospital (IRB approval no., 2204-022-114). The requirement for informed consent from individual patients was omitted because of the retrospective design of this study.

Statistical analyses were performed using IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA). Data are presented as mean±standard deviation for continuous variables and proportions for categorical variables. The Mann-Whitney U test for continuous variables and the chi-square test or Fisher exact test for categorical variables were performed to compare surgical bypass and kissing stents. Statistical significance was defined as $p<0.05$. Kaplan-Meier survival curves were used for the number of patients at risk and standard error at different follow-up times for the outcomes of primary patency, assisted primary patency, and secondary patency.

Results

Patients' demographic comparisons are described in Table 1. Age was significantly higher in the kissing stent group ($p<0.001$), with no statistically significant differences for the other demographics. In TASC II classification C, there were 19 patients in the kissing stent group and 3 patients in

https://doi.org/10.5090/jcs.23.012

Table 1. Patient demographics

Characteristic	Total (n=46)	Direct surgical bypass (n=22)	Kissing stents (n=24)	p-value
Age (yr)	69.93±9.93	64.05±8.81	74.29±8.34	<0.001
Female sex	4 (8.7)	1 (4.5)	3 (12.5)	0.745
Body mass index (kg/m^2)	22.61±2.46	22.07±2.25	23.11±2.57	0.338
Smoking	29 (63.0)	17 (77.3)	12 (50.0)	0.053
Antiplatelet	45 (97.8)	22 (100.0)	23 (95.8)	0.522
Diabetes mellitus	17 (37.0)	7 (31.8)	10 (41.7)	0.351
Hypertension	22 (47.8)	8 (36.4)	14 (58.3)	0.116
Coronary artery occlusive disease	10 (21.7)	5 (22.7)	11 (20.8)	0.578
Cerebrovascular accident	1 (2.2)	1 (4.5)	0	0.478
Hyperlipidemia	-	-	-	-
Iliac occlusion	25 (54.3)	14 (63.6)	11 (45.8)	0.18
Chronic kidney disease	2 (4.3)	0	2 (8.3)	0.267

Values are presented as mean±standard deviation or number (%). A p-value <0.05 is considered statistically significant.

Table 2. Patients' clinical characteristics

Variable	Total (n=46)	Direct surgical bypass (n=22)	Kissing stents (n=24)	p-value
TASC II class				<0.001
A	-	-	-	
B	-	-	-	
C	22 (47.8)	3 (13.6)	19 (79.2)	
D	24 (52.2)	19 (86.4)	5 (20.8)	
Rutherford class				0.151
0	-	-	-	
1	5 (10.9)	1 (4.5)	4 (16.7)	
2	10 (21.7)	3 (13.6)	7 (29.2)	
3	17 (37.0)	8 (36.4)	9 (37.5)	
4	10 (21.7)	7 (31.8)	3 (12.5)	
5	4 (8.7)	3 (13.6)	1 (4.2)	

Values are presented as number (%).
TASC, TransAtlantic Inter-Society Consensus.

the direct open bypass group. In TASC II classification D, there were 5 patients in the kissing stent group and 19 patients in the direct open bypass group (p<0.001). Within the Rutherford classification, 14 patients (30.4%) were graded as category 4 or 5, requiring emergency surgery. There was no significant difference between the 2 Rutherford classification groups (Table 2).

Clinical outcomes are presented in Table 3. Hospital stay (16.36±5.19 days for direct surgical bypass versus 9.08±10.88 days for kissing stents, p=0.007) and operation time (316.09±141.78 minutes for direct surgical bypass versus 99.54±37.95 minutes for kissing stents, p<0.001) were significantly shorter among patients who were treated with a kissing stent than those with direct surgical bypass. The follow-up duration (90.73±49.94 months for direct surgical bypass versus 60.88±42.21 months for kissing stents, p=0.033) was significantly longer among patients treated with direct surgical bypass than among those treated with a kissing stent.

No significant difference was observed in reinterventions between the direct surgical bypass (n=5, 22.7%) and kissing stents (n=2, 8.3%) groups (p=0.175). Furthermore, there was no difference in reintervention related to femoropopliteal lesions with severe stenosis (>70%) or complete occlusion between the 2 groups (direct surgical bypass [n=2, 9.1%] versus kissing stents [n=1, 4.2%]) (p=0.449). In the direct surgical bypass group, 5 patients had femoropopliteal lesions with severe stenosis (>70%) or complete occlusion. Of those 5 patients, only 1 underwent aortobifemoral bypass with popliteal artery occlusion, and a vein bypass from the femoral to anterior tibial artery was performed simultaneously. In the remaining 4 patients, no treatment was performed for femoropopliteal lesions during or immediately after surgery. Two of the 4 patients with multifocal severe stenosis in the superficial femoral artery did not require additional intervention after surgery. One patient

Table 3. Clinical outcomes

Variable	Total (n=46)	Direct surgical bypass (n=22)	Kissing stents (n=24)	p-value
Hospital stay (day)	12.04±6.88	16.36±5.19	9.08±10.88	0.007
Follow-up duration (mo)	60.88±45.79	90.73±49.94	60.88±42.21	0.033
Operation time (min)	206.22±84.47	316.09±141.78	99.54±37.95	<0.001
Freedom from reintervention (mo)	104.76±58.19	104.76±58.19	106.96±37.84	0.881
30-Day mortality	-	-	-	-
Technical failure	-	-	-	-
Early occlusion (<30 days)	-	-	-	-
Reintervention	7 (15.2)	5 (22.7)	2 (8.3)	0.175
Reintervention associated with FP	3 (6.5)	2 (9.1)	1 (4.2)	0.449
Amputation	1 (2.2)	1 (4.5)	-	0.478
Respiratory	-	-	-	-
Cardiac	-	-	-	-
Acute kidney injury	1 (2.2)	1 (4.5)	-	0.478

Values are presented as mean±standard deviation or number (%). A p-value <0.05 is considered statistically significant.
FP, femoropopliteal lesion with severe stenosis (>70%) or complete occlusion.

Table 4. Relationships between TASC II class and clinical outcomes

Variable	TASC II class					
	C (n=22)			D (n=24)		
	Direct surgical bypass (n=3)	Kissing stents (n=19)	p-value	Direct surgical bypass (n=19)	Kissing stents (n=5)	p-value
Hospital stay (day)	15.33±3.79	9.63±12.00	0.432	16.53±5.44	7.00±5.10	0.002
Follow-up duration (mo)	79.33±17.62	57.84±38.58	0.361	92.53±53.38	72.40±57.77	0.468
Operation time (min)	313.33±140.56	96.37±39.58	0.114	316.53±145.79	111.60±31.66	0.006
Freedom from reintervention (mo)	104.64±37.51	102.47±37.32	0.926	104.78±61.60	126.32±150.39	0.518
30-Day mortality	-	-	-	-	-	-
Operation failure	-	-	-	-	-	-
Early occlusion (<30 days)	-	-	-	-	-	-
Amputation	-	-	-	1 (5.3)	0	0.792
Respiratory	-	-	-	-	-	-
Cardiac	-	-	-	-	-	-
Acute kidney injury	-	-	-	1 (5.3)	0	0.792

Values are presented as mean±standard deviation or number (%). A p-value <0.05 is considered statistically significant.
TASC, TransAtlantic Inter-Society Consensus.

with occlusion in the superficial femoral artery required thrombectomy with femoropopliteal bypass 2 years and 6 months after aortobiiliac bypass. The patient with popliteal artery occlusion required additional intervention 4 years and 7 months after the aortobiiliac bypass. Five of the 22 patients required additional surgery after direct surgical bypass within 5 years, of whom 2 had femoropopliteal lesions with severe stenosis (>70%) or complete occlusion. In the kissing stent group, 5 patients had femoropopliteal lesions with severe stenosis (>70%) or complete occlusion. All 5 of those patients underwent combined treatment with kissing stents for these femoropopliteal lesions, with percutaneous transluminal angioplasty performed in 3 patients and femoropopliteal bypass performed in 2 patients. Only 1 patient required additional intervention 6 years and 4 months after kissing stent placement.

One patient in the direct surgical bypass group (4.5%) underwent amputation of the first toe before surgery due to necrosis. Acute kidney injury (AKI) occurred in 1 patient in the direct surgical bypass group (2.2%); on postoperative day 3, the patient's glomerular filtration rate decreased to 16.6 mL/min, and oliguria developed. Continuous renal replacement therapy was performed in the intensive care unit. On postoperative day 7, urine output recovered, and continuous renal replacement therapy was discontinued. Additional dialysis was not required.

The clinical outcomes of direct surgical bypass and kissing stents were analyzed by dividing patients into TASC II

https://doi.org/10.5090/jcs.23.012

classifications C and D (Table 4). No significant difference was found between the 2 groups in TASC II classification C; however, the kissing stent group had significantly shorter hospital stays (16.53±5.44 days for direct surgical bypass versus 7.00±5.10 days for kissing stents, p=0.002) and operation times (316.53±145.79 minutes for direct surgical bypass versus 111.60±31.66 minutes for kissing stents, p=0.006) in TASC II classification D. Amputation (1, 5.3%) and AKI (1, 5.3%) also occurred in the TASC II classification D group.

The clinical outcomes of direct surgical bypass and kissing stents were analyzed by dividing the Rutherford classification group into categories 4 and 5 (emergency) requiring emergency surgery and categories 0, 1, 2, and 3 (elective) (Table 5). In the elective group, patients with kissing stents had shorter hospital stays (14.17±2.37 days for direct surgical bypass versus 7.70±6.32 days for kissing stents, p=0.002), follow-up durations (95.67±49.85 months for direct surgical bypass versus 60.88±42.21 months for kissing stents, p=0.018), and operation times (284.83±78.18 minutes for direct surgical bypass versus 95.70±38.68 minutes for kissing stents, p<0.001) than those with direct surgical bypass. In the emergency group, patients with kissing stents had shorter operation times (353.60±191.23 minutes for direct surgical bypass versus 118.75±35.19 minutes for kissing stents, p=0.034) than those with direct surgical bypass. Amputation (n=1, 10%) and AKI (n=1, 10%) occurred in the emergency group.

According to the Kaplan-Meier analysis (Fig. 1), the primary, assisted primary, and secondary patency rates in the direct surgical bypass group were 95.5%, 95.5%, and 95.5%, respectively, at 1 year; 86.4%, 86.4%, and 95.5% at 3 years; and 77.3%, 77.3%, and 95.5% at 5 years. The primary, assisted primary, and secondary patency rates in the kissing stent group were 100.0%, 100.0%, and 100.0%, respectively, at 1 year; 95.8%, 95.8%, and 100.0% at 3 years; and 95.8%, 95.8%, and 100.0% at 5 years. A total of 5 patients in the direct surgical bypass group (22 patients) needed additional surgery within 5 years, and all of them belonged to TASC II classification D. In the kissing stent group (24 patients), 1 patient who belonged to TASC II classification C required additional surgery within 5 years.

Discussion

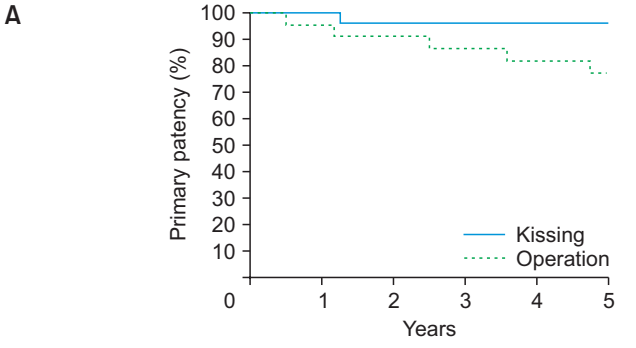
This study showed that kissing stents are preferable for TASC II C and D lesions. Significant technological improvements have been made in endovascular technology since the publication of the TASC II guidelines in 2007. These guidelines recommended open surgical revascularization of TASC C and D AIOD lesions [11]. Endovascular interventions are developing rapidly, along with surgical techniques and perioperative management. New guidelines and additional randomized trials for TASC II C and D lesions are required to verify best practices.

A growing number of TASC C and D AIOD lesions are treated with endovascular techniques [12]. Dorigo et al. [13] compared aortobifemoral bypass grafting in 82 cases and kissing stents in 128 cases (of TASC II classification C and D AIOD lesions. The primary, assisted primary, and secondary patency rates were similar between the 2 groups, and the reintervention rate was 6% in the aortobifemoral by-

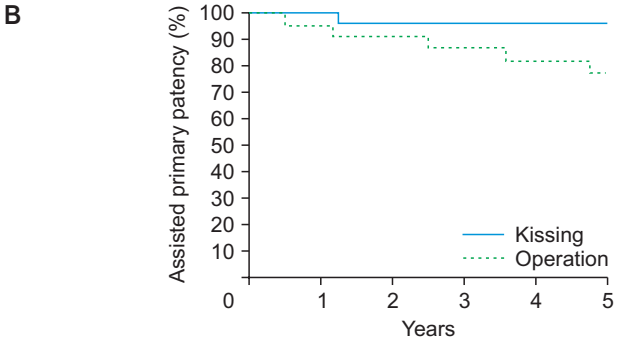
Table 5. Relationship between the Rutherford class and clinical outcomes

Variable	Rutherford class					
	0, 1, 2, 3 (Elective, n=32)			4, 5 (Emergency, n=14)		
	Direct surgical bypass (n=12)	Kissing stents (n=20)	p-value	Direct surgical bypass (n=10)	Kissing stents (n=4)	p-value
Hospital stay (day)	14.17±2.37	7.70±6.32	0.002	19.00±6.46	16.00±24.04	0.821
Follow-up duration (mo)	95.67±49.85	54.80±41.34	0.018	84.80±52.06	91.25±36.85	0.827
Operation time (min)	284.83±78.18	95.70±38.68	<0.001	353.60±191.23	118.75±35.19	0.034
Freedom from reintervention (mo)	105.50±52.66	103.45±37.12	0.898	103.88±67.17	124.50±41.97	0.583
30-Day mortality	-	-	-	-	-	-
Operation failure	-	-	-	-	-	-
Early occlusion (<30 days)	-	-	-	-	-	-
Amputation	-	-	-	1 (10.0)	0	0.714
Respiratory	-	-	-	-	-	-
Cardiac	-	-	-	-	-	-
Acute kidney injury	-	-	-	1 (10.0)	0	0.714

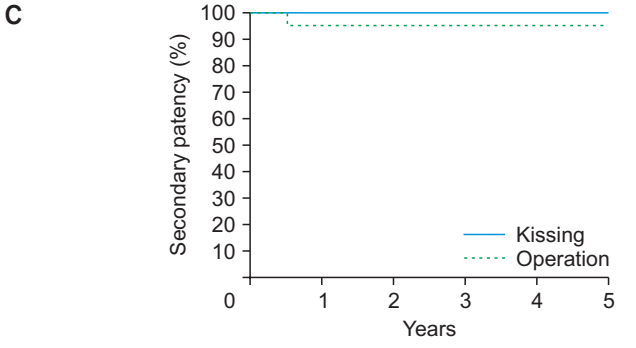
Values are presented as mean±standard deviation or number (%). A p-value <0.05 is considered statistically significant.



Kissing	No. at risk	24	24	23	23	23	23
	SE	-	-	0.04	0.04	0.04	0.04
Operation	No. at risk	22	21	20	19	18	18
	SE	-	0.04	0.06	0.07	0.09	0.09



Kissing	No. at risk	24	24	23	23	23	23
	SE	-	-	0.04	0.04	0.04	0.04
Operation	No. at risk	22	21	20	19	18	18
	SE	-	0.04	0.06	0.07	0.09	0.09



Kissing	No. at risk	24	24	24	24	24	24
	SE	-	-	-	-	-	-
Operation	No. at risk	22	21	21	21	21	21
	SE	-	0.04	0.04	0.04	0.04	0.04

Fig. 1. Kaplan-Meier curves with the number of patients at risk and standard error (SE) at different follow-up times for primary patency (A), assisted primary patency (B), and secondary patency (C). Log-rank test and chi-square test were used. (A) p=0.066, log-rank=3.38. (B) p=0.066, log-rank=3.38. (C) p=0.296, log-rank=1.09.

pass grafting. In this study, kissing stents showed satisfactory early and late results, similar to those of open surgery. Additionally, the recently developed covered endovascular reconstruction of aortic bifurcation (CERAB) technology has further improved the outcomes [14]. The CERAB configuration uses a third stent to form a funnel around the proximal end of the kissing stent to eliminate the area of inconsistency and improve localized flow at the proximal inflow of the kissing stent. A recently published study of CERAB showed promising results with 1- and 2-year primary patency rates of 87.3% and 82.3%, respectively, with mainly (85.4%) TASC D lesions treated [15].

Direct surgical bypass has been reported to have a 30-day mortality rate of 3.3%–4.3% [2]. Moreover, direct surgical procedures such as aortic-bifemoral/iliac bypass reportedly have a 5-year patency rate of up to 90% [16]. According to a recent study published by Quan et al. [17], among patients diagnosed with AIOD who underwent direct surgical bypass, the in-hospital mortality rate was 0% and the perioperative complication rate was 14.3%. The primary patency rate at 3 years was 82.6%, the primary assisted patency rate was 82.6%, and the secondary patency rate was 93.8%. In the present study, the primary patency rate at 3 years was 86.4% in the direct surgical bypass group, the primary assisted patency rate was 86.4%, and the secondary patency rate was 95.5%. The 30-day mortality rate was 0%, and the perioperative complication rate was 9.1% (2 of 22); thus, compared with previous studies, mortality and perioperative complications for direct surgical bypass had decreased. A recently published meta-analysis compared direct surgical versus endovascular revascularization for AIOD. In moderate-quality studies, patients who underwent direct surgical revascularization showed significantly better primary patency than those who underwent endovascular revascularization for AIOD, although the patients who underwent direct surgical revascularization were younger and may have differed from one another in other confounding parameters. Both techniques

had similar limb rescue rates [12].

This study had some limitations. First, this was a single-institution, retrospective study with a small sample size. Second, bias may have occurred because the treatment method was decided with consideration of patients' age, comorbidities, and level of calcification of the aorta and iliac arteries, as opposed to being designed as a randomized trial. In addition, since we performed additional interventions more aggressively in the kissing stent group than in the direct surgical bypass group for femoropopliteal lesions with severe stenosis (>70%) or complete occlusion, bias may have consequently occurred. However, since the TASC II classification has gone unrevised for many years, we believe that this study will help determine the treatment for TASC II C and D lesions.

The primary patency, assisted primary patency, and secondary patency rates over 5 years were similar for kissing stents and direct surgical bypass in TASC II C and D lesions. However, the kissing stent group showed significantly shorter hospital stays and operation times.

Therefore, it is advantageous to consider kissing stents preferentially for TASC II C and D lesions. However, direct surgical bypass should be considered in cases where the lesion lies just below the origin of the renal artery, there is severe and diffuse calcification of the aorta and iliac arteries, or in which previous endovascular attempts have failed, as these cases are challenging to treat successfully using kissing stents.

In conclusion, except for special cases wherein endovascular revascularization is difficult, kissing stents are more advantageous for TASC II C and D lesions.

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Conflict of interest

No potential conflict of interest relevant to this article was reported.

Funding

This work was supported by a clinical research grant from Pusan National University Hospital in 2022.

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