Long-term results of extensive aortoiliac occlusive disease (EAIOD) treated by endovascular therapy and risk factors for loss of primary patency

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Abstract

Background: Although endovascular therapy has been widely used for focal aortoiliac occlusive disease (AIOD), its performance for extensive AIOD (EAIOD) is not fully evaluated. We aimed to demonstrate the long-term results of EAIOD treated by endovascular therapy and to identify the potential risk factors for the loss of primary patency.

Methods: Between January 2008 and June 2018, patients with a clinical diagnosis of the 2007 TransAtlantic Inter-Society Consensus II (TASC II) C and D AIOD lesions who underwent endovascular treatment in our institution were enrolled. Demographic, diagnosis, procedure characteristics, and follow-up information were reviewed. Univariate analysis was used to identify the correlation between the variables and the primary patency. A multivariate logistic regression model was used to identify the independent risk factors associated with primary patency. Five- and 10-year primary and secondary patency, as well as survival rates, were calculated by Kaplan-Meier analysis.

Results: A total of 148 patients underwent endovascular treatment in our center. Of these, 39.2% were classified as having TASC II C lesions and 60.8% as having TASC II D lesions. The technical success rate was 88.5%. The mean follow-up time was 79.2 ± 29.2 months. Primary and secondary patency was 82.1% and 89.4% at 5 years, and 74.8% and 83.1% at 10 years, respectively. The 5-year survival rate was 84.2%. Compared with patients without loss of primary patency, patients with this condition showed significant differences in age, TASC II classification, infrainguinal lesions, critical limb ischemia (CLI), and smoking. Multivariate logistic regression analysis showed age <61 years (adjusted odds ratio [aOR]: 6.47; 95% CI: 1.47–28.36; P = 0.01), CLI (aOR: 7.81; 95% CI: 1.92–31.89; P = 0.04), and smoking (aOR: 10.15; 95% CI: 2.79–36.90; P < 0.01) were independent risk factors for the loss of primary patency.

Conclusions: Endovascular therapy was an effective treatment for EAIOD with encouraging patency and survival rate. Age <61 years, CLI, and smoking were independent risk factors for the loss of primary patency.

Keywords: Critical limb ischemia; Endovascular therapy; Extensive aortoiliac occlusive disease; Mortality; Primary patency; Risk factors

Introduction

Aortoiliac occlusive disease (AIOD) has historically been treated by aortobifemoral (ABF) bypass because of its satisfactory primary patency rates at 5 and 10 years, ranging between 85–90% and 75–85%, respectively.^[1-3] However, perioperative mortality and morbidity is substantial, up to 17–32% and 12.2–32.0%, respectively.^[4-7] With the improvement of devices and increased experience of vascular surgeons, endovascular techniques have been developed as a minimal invasive alternative treatment for AIOD with reduced mortality and morbidity compared with ABF bypass. Although endovascular

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therapy currently has been firmly established as the firstline treatment for focal AIOD, its performance for extensive and complex AIOD, TransAtlantic Inter-Society Consensus II (TASC II) C and D lesions, remains controversial.^[8] Although there are many articles describing the outcomes of endovascular treatment for AIOD, the majority are confined to a small sample size, and risk factors associated with loss of primary patency after stenting have not been fully evaluated. This retrospective cohort study aimed to investigate the long-term outcomes of extensive aortoiliac occlusive disease (EAIOD), defined as TASC II C and D lesions, treated by endovascular therapy and to explore the potential independent risk factors for the loss of primary patency.

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Methods

Ethical approval

The study was approved by the Ethics Committee of Zhongshan Hospital, Fudan University and the study complied with the *Declaration of Helsinki* guidelines (No. Y2019–099). Given the retrospective nature of the study, the requirement of written informed consent was waived.

Patients and data collation

Between January 2008 and June 2018, patients who underwent endovascular treatment for AIOD classified as TASC II C and D lesions in our center were reviewed. All eligible patients and their medical records were reviewed for demographic, diagnosis, procedure characteristics and follow-up information. Preoperative diagnosis and TASC II classifications were mainly based on preoperative imaging modalities and intraoperative angiography. Segment, length, and characteristics of the lesions were evaluated by duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), and angiography. Local anesthesia of the inguinal region was performed in most patients. The transfemoral approach was the most commonly used. The transbrachial approach could be used to perform flush abdominal aortography to reveal the condition of the occluded segment without touching the lesions, and it is easy to engage both iliac arteries via this route. If the wire failed to pass through the lesion or could not reenter the true lumen owing to substantial dissection, retrograde transfemoral access was performed. The antegrade-retrograde kissing technique for reconstruction of the segment lesion was preferred in most cases. If the common femoral artery (CFA) was completely occluded, the hybrid procedure, including femoral endarterectomy (FEA) with possible thrombectomy, would be performed.

The kissing technique was performed in settings with: (1) short or no stump at the common iliac artery (CIA), leaving no reliable proximal landing zone; (2) an abdominal aortic bifurcation being involved. Self-expanding bare stents were preferred for long lesions, and balloon-expendable bare stents for focal, ostial, and severely calcified lesions. Covered stents were selected for lesions with a high probability of rupture or residual thrombus. Catheter-directed thrombolysis (CDT) was reserved only for patients complicated with acute limb ischemia or lesions close to the renal artery so as to create a proximal landing zone and leave the stent as distant from the renal artery as possible.

The femoral-femoral crossover reconstruction was employed if the iliac artery was patent or endovascularly reconstructed on one side and the contralateral side failed to be recanalized. Most patients with EAIOD had concurrent infrainguinal lesions. The majority did not need to be treated at one stage except for the presence of large ulcers or tissue loss. Stent placement was preferred for the treatment of infrainguinal lesions, and if the patient was not suitable for stenting then a femoral-popliteal bypass was performed. This study excluded patients with iliac stenoses undergoing balloon angioplasty or stenting. Patients with iliac dissection, an associated abdominal artery aneurysm (AAA), or iliac therapy during AAA endograft placement were also excluded. Dual antiplatelet therapy (aspirin 100 mg/d and clopidogrel 75 mg/d) was administrated for 6 months, and only aspirin thereafter for life-long use.

Variables and definitions

Variables included gender, age (<61 years, 61–70 years, >70 years), ongoing smoking (defined as active smoking before surgery and continued smoking after surgery), CLI (defined in accordance with TASC II guidelines^[8]), TASC II types (defined in accordance with TASC II guidelines^[8]), hypertension (defined as systolic pressure >140 mmHg and/or diastolic pressure >90 mmHg), diabetes mellitus, chronic obstructive pulmonary disease (COPD; defined as presence of symptoms or history diagnosed as COPD before), chronic kidney disease (CKD; defined as elevated serum creatinine concentration >1.5 mg/dL and dialysisdependent status), coronary artery disease (CAD; defined as the presence of symptoms or history of being diagnosed with CAD or having coronary artery balloon angioplasty or stenting), kissing technique, infrainguinal lesions, subintimal access (defined as the guide wire passing the lesion from under the intima), occluded level (lesion involving renal artery or not), and CDT.

Technical success was defined as the residual stenosis <30% determined by intraoperative angiography. Ankle-brachial index (ABI) and Doppler ultrasound or CTA were performed at 3, 6, 9, and 12 months, and yearly afterwards. Significant restenosis was defined as >2.4 peak systolic velocity ratio on duplex,^[9] >50% stenosis on angiography or CTA or a 0.2 decrease from the resting ABI.^[10] The loss of primary patency was defined as an ABI decrease associated with evidence of significant restenosis/occlusion, requiring reintervention for the target vessel to maintain arterial patency, or thrombosis of the treated lesions.

Statistical analysis

Data were collected using Microsoft Excel (Microsoft, Redmond, WA, USA) and analyzed by SPSS version 20.0 for Windows (IBM Co., Armonk, NY, USA). Continuous variables were presented as mean \pm standard deviation (SD) with range values or as the medians with the interquartile ranges (IQRs), and categorical variables were presented as frequencies and percentages. Univariate analysis and multivariate logistic analysis were used to identify potential independent risk factors for the loss of primary patency. For univariate analysis, the Student's ttest and Pearson χ^2 test were applied to test the differences between two groups (with and without loss of primary patency) for continuous variables and categorical variables, respectively. For categorical variables, if the cell with an expected value <5 exceeded 20%, Fisher exact test was used. In the multivariate logistic model, the variables included all variables that exhibited significant difference at the level of *P* value < 0.05 in the univariate analysis. The adjusted odds ratio (aOR) and 95% confidence interval (CI) were presented for each independent risk factor for the loss of primary patency at the level of P value < 0.05. Primary and secondary patency at 5 and 10 years, as well as survival rates, were calculated by Kaplan-Meier

analysis. All *P* values were two-tailed, and a *P* value < 0.05 was defined as statistically significant.

Results

From January 2008 to June 2018, a total of 148 patients with 173 limbs were diagnosed with AIOD and treated by endovascular surgery in our center. The technical success rate was 88.5%. The mean age of the patients was 68.6 ± 10.8 years (range, 27–90 years). The ratio of women to men was 1 to 11. Seventy-nine (53.4%) patients presented buttocks, hip, or thigh pain, while 58 (39.2%) presented claudication, 56 (37.8%) presented rest pain, and 34 (23.0%) had tissue loss (ulceration or gangrene). All the patients' conditions were diagnosed by at least one imaging modality. CTA was the most commonly used modality in 135 (91.2%) patients, while duplex ultrasound was performed in 55 (37.2%) patients and MRA in 31 (20.9%) patients. TASC II classifications were mainly based on intraoperative angiography. Fifty-eight (39.2%) and 90 (60.8%) patients were classified as TASC II C and D lesions, respectively. Transfemoral access was most commonly used. The transbrachial approach was performed in 38 (25.7%) patients, and 34 (89.5%) of them were TASC II D lesions. All of these patients were punctured at the left brachial artery, except one who had an arteriovenous fistula on the left arm. Local anesthesia was employed in 128 (86.5%) patients. Among 90 (60.8%) patients with concurrent infrainguinal lesions, FEA was performed in 20 (13.5%) patients, superficial femoral artery (SFA) stenting in 17 (11.5%) patients, femoral-popliteal bypass in 5 (3.4%) patients, and femoral-femoral crossover reconstruction in 17 (11.5%) patients. The median established blood loss (EBL) was

15.0 mL (IQR: 10.0–20.0 mL), and the median hospital stay was 8.0 days (IQR: 6.0–14.8 days). Eight (5.4%) patients died within 1 month after surgery. The causes of death were acute myocardial infarction in 2 (1.4%), acute aortic saddle embolism in 1 (0.7%), stroke in 1 (0.7%), respiratory failure in 1 (0.7%) and unrelated causes in 3 (2.0%) patients.

The mean follow-up time was 79.2 ± 29.2 months (range, 12-140 months). Perioperative complications occurred in 23 (15.8%) patients. The majority of the complications could be treated percutaneously or conservatively. Arterial dissection was the most common complication, which occurred in 8 (5.4%) patients, and all of them were treated by covered stent. Femoral pseudoaneurysm developed in 4 (3.0%) patients and was treated with surgical repair within 1 month of the endovascular procedure. Perforation of the iliac artery occurred in 2 (1.4%) patients, and one of them developed retroperitoneal hematoma. Both of them underwent covered stents placement. Stent graft infection occurred in 2 (1.4%) patients. One of them underwent removal of the endograft and femoral-femoral crossover reconstruction. The other died of multiple organ dysfunction syndrome (MODS). Two (1.4%) patients had distal embolism, and both recovered within 1 week after anticoagulation and vasodilation therapy. Postoperative kidney failure and myocardial infarction occurred in 4 (3.0%) and 5 (3.4%) patients, respectively. Access site hematoma occurred in $\overline{4}$ (3.0%) patients, and access site infection was the rarest complication and occurred in 1 (0.7%) patient. The primary and secondary patency rates at 5 years were 82.1% and 89.4%, respectively, and those at 10 years were 74.8% and 83.1%, respectively [Figure 1A]. The differences between primary and second patency were



Figure 1: (A) Kaplan-Meier plot of stent patency. Primary and secondary patency were 82.1% and 89.4% at 5 years, and 74.8% and 83.1% at 10 years, respectively, with a confidence interval of 95%. (B) Kaplan-Meier plot of long-term survival during the 144-month follow-up.

not significant (P = 0.08). Thirty-day mortality was 5.4%, and the 5-year survival rate was 84.2% [Figure 1B].

Compared with patients with patent stent, patients losing primary patency demonstrated statistically significant differences in age (P = 0.046), TASC II classification (P = 0.046), infrainguinal lesions (P = 0.049), CLI (P = 0.001), and smoking (P = 0.001) [Table 1]. The multivariate logistic analysis showed that age <61 years (aOR: 6.47; 95% CI: 1.47–28.36; P = 0.01), CLI (aOR: 7.81; 95% CI: 1.92–31.89; P = 0.04), and smoking (aOR: 10.15; 95% CI: 2.79–36.90; P < 0.01) were independent risk factors for the loss of primary patency [Table 2]. The Homser-Lemeshow test revealed a good fit ($\chi^2 = 3.52$, P = 0.90).

Discussion

Current guidelines recommend endovascular therapy for less complex lesions and ABF bypass for patients with TASC II C and D lesions. Unfortunately, these guidelines do not take patients' comorbidities and perioperative risks into account, but only the morphology of the lesion.^[11] Graft infection, acute graft thrombosis, and aortoenteric fistula could be potentially fatal complications.^[12] Other disadvantages include alternation of the normal anatomy, loss of collateral circulation, and loss of sexual function in males owing to pelvic autonomic nerve damage during surgery. All these have encouraged physicians to extend endovascular treatment to more EAIOD. Jongkind *et al*^[13] performed a systematic review including 1711 patients and found that more than 1000 patients diagnosed with EAIOD had been successfully treated by endovascular therapy, whereas according to TASC II guidelines, surgical revascularization should have been the preferred treatment. The present study, based on our experience in endovascular treatment for TASC II C and D lesions during the past decade, also demonstrated satisfactory mid- to long-term outcomes.

Evans *et al*^[14] determined that the atherosclerotic process in patients under 50 years old did not appear more virulent than that in patients over 50 years old. The majority of studies found arterial occlusive disease was preserved as a rare disease in young adults with a poor prognosis because of multiple vascular bed involvement and the accelerated nature of the disease progress.^[15] Atherosclerosis in most elderly patients is often characterized by a slow progress and a relatively benign course.^[16] In contrast, premature atherosclerosis has been described as "virulent" with severe symptoms and an aggressive course, producing early disability and death. Valentine $et \ al^{[17]}$ also noted that patients aged 40 years and younger required secondary procedures to relieve recurrent symptoms caused by rapid progression of the disease and recommended an aggressive interventional approach in the evaluation and treatment of young patients, and they also concluded that these patients were at significant risk of developing premature coronary occlusive disease and should be monitored closely. The SFA was most commonly affected in older patients with peripheral arterial disease (PAD); nevertheless, the aortoiliac artery was the most common location in young patients.^[14,17,18] Previous studies have found that the systematic evaluation of patients with early-onset PAD revealed a high prevalence of other arterial beds in 50% to 71%, especially in the coronary and cerebral arteries.^[19-21] Jensen *et al*^[22] noted that young patients exhibited an early manifestation of arteriosclerosis that eventually progressed. Patients younger than 61 years accounted for 24.3% in this study. In the multivariate analysis model, we validated that an age < 61 years was an independent risk factor for the loss of primary patency, which was consistent with others.^[6] And 30.6% (11/36) of patients aged under 61 years needed further interventions to maintain long-term patency after stenting, which was significantly higher than that in the older patients (P = 0.046). Reed *et al*^[6] also demonstrated that young patients accounted for 41.7% of all emergency admissions, which was significantly higher than that of older patients. Therefore, it could be inferred that atherosclerosis in young patients progressed more virulently and needed to be dealt with more aggressively.

Smoking has been proven to impact all phrases of atherosclerosis from endothelial dysfunction to acute clinical events by affecting vasomotor dysfunction, inflam-mation and the modification of lipids.^[23,24] Evans *et al*^[14] demonstrated that smoking was the most significant risk factor in patients under 50 years with atherosclerotic peripheral vascular disease. Studies have also noted that smoking was the most prevalent risk factor of PAD.^[18,25,26] In the current study, smoking was also identified as one of the independent risk factors for the loss of primary patency. Nearly half (48.9%) of the cohort were ongoing smokers before surgery. Furthermore, despite repeated notifications of vascular damage caused by smoking, none of the patients succeeded in quitting smoking after surgery. Among the patients losing the primary patency, 20 (76.9%) patients were active smokers, which was significantly higher than among the patients without loss of primary patency (P = 0.001).

Previous studies have shown that symptoms in patients with AIOD are not directly related to the severity of the disease due to the development of collateral arterial flow.^[27] The majority of patients may be asymptomatic for a long time, and the most common clinical manifestations are intermittent claudication and CLI.^[8] In this study, TASC II classifications were not significantly associated with the patients' clinical presentations (Rutherford classifications; P = 0.663). Meanwhile, 60.8% of the patients presented CLI, defined as rest pain and tissue loss (ulceration and gangrene). On the other hand, as a known marker of poorer results, CLI accounted for 60.8% among all patients in the present study and was identified as one of the independent risk factors for the loss of primary patency, implicating a more severe atherosclerosis burden in patients with CLI.^[8,28] The proportion of concomitant infrainguinal arterial lesions among CLI patients was higher than that among claudicants (67.8% vs. 53.4%), even though the difference was not statistically significant (P = 0.057). Moreover, most CLI patients had poorer collateral circulation or outflow and needed simultaneous distal revascularization, such as bypass, FEA or thrombectomy, indicating a more virulent and extensive atherosclerotic process. In this study, 20 (76.9%) of the patients with loss of primary patency presented coexisting infrainguinal lesions, which was significantly

Table 1:: Univariate analysis of the risk factors for patients with decreasing primary patency.

Variables			Loss of primary patency			
	Total	No	Yes	Statistic value	Р	
Gender				NA	0.443*	
Male	136 (91.9)	113 (83.1)	23 (16.9)			
Female	12 (8.1)	9 (9/12)	3 (3/12)			
Age	· · · ·		(, , , , , , , , , , , , , , , , , , ,	6.153	0.046^{+}	
<61 years	36 (24.3)	25 (69.4)	11 (30.6)			
61–70 years	49 (33.1)	44 (89.8)	5 (10.2)			
>70 years	63 (42.6)	53 (84.1)	10 (15.9)			
Cigarette smoking	· · · ·	· ,	· · ·	NA	0.001^{*}	
Yes	71 (48.0)	51 (71.8)	20 (28.2)			
No	77 (52.0)	71 (92.2)	6 (7.8)			
TASC II classification			(),	NA	0.046*	
С	58 (39.2)	43 (74.1)	15 (25.9)			
D	90 (60.8)	79 (87.8)	11 (12.2)			
CAD				NA	0.595^{*}	
Yes	29 (19.6)	23 (79.3)	6 (20.7)			
No	119 (80.4)	99 (83.2)	20 (16.8)			
DM			, ,	NA	0.485^{*}	
Yes	43 (29.1)	34 (79.1)	9 (20.9)			
No	105 (70.9)	88 (83.8)	17 (16.2)			
CKD				NA	0.591^{*}	
Yes	6 (4.1)	6 (6/6)	0 (0)			
No	142 (95.9)	116 (81.7)	26 (18.3)			
Hypertension			, ,	NA	0.604*	
Yes	115 (77.7)	96 (83.5)	19 (16.5)			
No	33 (22.3)	26 (78.8)	7 (21.2)			
Stroke				NA	0.131*	
Yes	23 (15.5)	16 (69.6)	7 (30.4)			
No	125 (84.5)	106 (84.8)	19 (15.2)			
COPD				NA	0.607^{*}	
Yes	7 (4.9)	5 (5/7)	2 (2/7)			
No	141 (95.3)	117 (83.0)	24 (17.0)			
CDT	· · · ·	· ,	· · ·	NA	0.370^{*}	
Yes	23 (15.5)	21 (91.3)	2 (8.7)			
No	125 (84.5)	101 (80.8)	24 (19.2)			
Renal artery involved	· · · ·	· ,	· · ·	NA	0.361^{*}	
Yes	9 (6.1)	9 (9/9)	0 (0)			
No	139 (93.9)	113 (81.3)	26 (18.7)			
Subintimal access	· · · ·	· ,	· · ·	NA	0.160^{*}	
Yes	16 (10.8)	11 (11/16)	5 (5/16)			
No	132 (89.2)	111 (84.2)	21 (15.9)			
Infrainguinal lesion				NA	0.049^{*}	
Yes	90 (60.8)	70 (77.8)	20 (22.2)			
No	58 (39.2)	52 (89.7)	6 (10.3)			
Kissing technique				NA	0.808^{*}	
Yes	40 (27.0)	34 (85.0)	6 (15.0)			
No	108 (73.0)	88 (81.5)	20 (18.5)			
CLI				NA	0.001^{*}	
Yes	90 (60.8)	67 (74.4)	23 (25.6)			
No	58 (39.2)	55 (94.8)	3 (5.2)			
Number of stents implanted	1.6 ± 0.5	1.6 ± 0.6	1.7 ± 0.5	0.354	0.321 [‡]	
Length of the lesions (cm)	9.7 ± 5.3	9.5 ± 5.1	10.5 ± 4.3	0.452	0.342‡	

The data are presented as n (%) or mean \pm standard deviation. * Pearson χ^2 test. [†]Fisher exact test. [‡] Student's *t* test. TASC: TransAtlantic Inter-Society Consensus; CAD: Coronary artery disease; DM: Diabetes mellitus; CKD: Chronic kidney disease; COPD: Chronic obstructive pulmonary disease; CDT: Catheter directed thrombolysis; CLI: Critical limb ischemia

more than patients without loss of primary patency (P = 0.049). This indicated that infrainguinal diseases negatively affected the stent patency, which was compara-

ble with other studies.^[29] However, in the multivariate analysis, infrainguinal disease was not the independent risk factor for loss of primary patency.

Table 2: Multivariate analysis of the risk factors for loss of primary	y
patency.	

Variables	Exp (B)	95% CI	Р
CLI	7.81	1.92-31.89	0.04
TASC II classification	0.55	0.19-1.63	0.28
Infrainguinal lesion	3.34	0.87-12.76	0.78
Age <61 years (reference: >70)	6.47	1.47-28.36	0.01
Cigarette	10.15	2.79-36.90	0

CI: Confidence interval; CLI: Critical limb ischemia; TASC: TransAtlantic Inter-Society Consensus.

Upchurch et al^[30] showed that between 1996 and 2000, stenting and angioplasty for AIOD increased by 8.5-fold and there was a concurrent 16% decrease in the incidence of open surgery to treat AIOD. According to the current study, the endovascular procedure could be the first-line therapy for EAIOD, with a satisfactory technical success rate and long-term outcomes. Its primary and secondary patency rates were 82.1% and 89.4% at 5 years, respectively, and 74.8% and 83.1% at 10 years, respectively, comparable to the conventional ABF procedure.^[13,31-33] On the other hand, its overall perioperative morbidity rate (15.8%) was lower than that reported after open surgery.^[6] Moreover, it was determined that patients might still be suitable for referral for conventional surgical therapy without much negative impact, even if the endovascular therapy failed. Danczyk *et al*^[34] determined that patients who underwent open surgery after failed endovascular therapy for AIOD did not require amputation and failed endovascular therapy did not lead to worse outcomes after surgical conversion. Even for patients with TASC II D lesions in this series, endovascular therapy was also regarded as the first choice with transbrachial access. Even if only one side of the iliac lesion was passed successfully, the femoral-femoral crossover reconstruction worked effectively as the alternative for contralateral reconstruction. Such a strategy succeeded in 17 (11.5%) patients, and only 1 (5.9%) patient suffered from postoperative renal failure.

There are several limitations in this study. First, this is a retrospective, nonrandomized study that complies with its own nature. Second, the evaluation of restenosis was not performed by angiography, but by ultrasound, CTA and ABI. Third, endovascular therapy was performed by several different surgeons during one decade, which may lead to selection bias concerning decision-making. However, this study does provide practical and useful information for the management of EAIOD.

In conclusion, endovascular therapy for EAIOD showed satisfactory early and late results. Age <61 years, CLI, and smoking were independent risk factors for the loss of primary patency.

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Conflicts of interest

None.

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