

Received: 2012.07.09
Accepted: 2012.08.20

Assessment of effectiveness of endovascular treatment of common and external iliac artery stenosis/occlusion using self-expanding Jaguar SM stents

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Summary

The goal of this work was to assess the effectiveness of endovascular treatment of common and external iliac artery stenosis/occlusion classified according to TASC using a self-expanding stent Jaguar SM. The study group included 95 patients (61 men and 34 women) who underwent treatment for stenosis or occlusion of lower limb arteries at the Department of Radiology of the University Hospital in Białystok and the Diagnostic Radiology Department of the Central Clinical Hospital of the Ministry of Interior (MSWiA) in Warsaw between 2005 and 2007. All arterial lesions were of atherosclerotic etiology. The shortest stenotic fragment was 10 mm long and the longest occluded arterial fragment did not exceed 90 mm. Morphological classification of iliac artery lesions in treated patients was performed according to TASC II classification and included 10 patients with type A, 39 cases of type B, 36 with type C and 10 patients with type D lesions. Endovascular procedure failed to restore flow in five patients with TASC type D lesions, who were later referred for surgery. One patient suffered a complication – vessel perforation during predilatation, and had a stentgraft implanted. In 95% of patients stents were expanded using a balloon after implantation. Good results were achieved in practically all patients who underwent stent implantation. Patients were subjected to follow-up clinical and imaging evaluation during next 1–24 months. Success rate of the performed procedures as well as in a 30-day observation period was 100% in case of stenosis and 80% in case of vessel occlusion. A follow-up after 12 and 24 months showed patency of treated vessels in 84% and 76% of patients, respectively.

Key words: angioplasty • PTA • iliac arteries • self-expanding Jaguar SM stent

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Background

Cardiovascular diseases due to atherosclerosis pose some of the most important problems of contemporary medicine [1–3]. Despite unquestionable progress in pharmacotherapy and surgery in this field, they remain to be the causes of over 50% of all deaths. Nearly 95% of all cases of stenosis and peripheral artery occlusion are caused by atherosclerosis [4–6]. Frequency of limb ischemia due to atherosclerosis is constantly rising. Development of atherosclerotic lesions

may be asymptomatic. As the disease progresses, initially isolated stenotic lesions and vessel occlusions may assume a multi-level character. Development of collateral circulation is sometimes insufficient and often does not keep abreast of the disease progression. Cessation of smoking, physical exercise and pharmacotherapy as well as widely understood prophylaxis do not abolish the need for more aggressive treatment [7,8]. Methods of treatment of lower limb occlusion using patients' own veins or artificial prostheses have been known for decades.

The beginnings of endovascular surgery go as far back as 1964, when Dotter and Judkins performed the first percutaneous angioplasty in an 82-year-old woman with advanced lower limb atherosclerosis and shin ulceration [9]. Treatment consisted of coaxial introduction of catheters of increasing diameters into the lumen of femoral artery. Pain subsided and ulceration healed after the procedure. In the following years this treatment method underwent numerous modifications involving use of tapered teflon catheters. A breakthrough in endovascular treatment came in 1974 when Grüntzing introduced a double-lumen balloon catheter for transcatheter angioplasty [10]. Currently, Grüntzing balloon catheters are widely used in percutaneous transluminal angioplasty (PTA). Introduction of stents stabilizing the effects of angioplasty was another milestone. Julio Palmaz was the first one to use stents in humans in 1985 [11]. Effectiveness of endovascular procedures is limited by restenosis and in-stent thrombosis [12]. Antiplatelet drugs are commonly used in order to reduce the risk of their occurrence. There are also attempts at using new endovascular technologies: endovascular brachytherapy, kriotherapy, biodegradable stents, stents coated with antimitotic substances and peripheral stent-grafts [13].

The most prevalent method of endovascular therapy is PTA [14–17]. Percutaneous angioplasty is effective when primary restenosis does not exceed 20%, no *elastic recoil* phenomenon is observed, there was no dissection disrupting blood flow and intravascular pressure gradient through the stenosis is less than 10–15 mmHg [18]. The outcome of treatment depends primarily on the type of lesion (stenosis, occlusion), its length and outflow to the vessels of the shin [19,20]. Short fragments of stenosis accompanied by good outflow into the shin ensure high patency rates in even long-term observation. Contemporarily, increasingly more often stents are implanted following angioplasty. Common indications for stent implantation include ineffective

Table 1. Patient characteristics and risk factors.

Parameters	Number of patients (n=95)
Average age	61
Age range	44–79
Sex (m/f)	61/34
Risk factors	
Smoking	71
Hypertension	66
Hyperlipidemia	42
Diabetes	6

Table 2. Standards of endovascular treatment of lower extremity atherosclerosis (iliac, femoral, popliteal and tibial arteries).

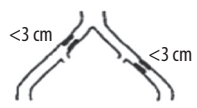

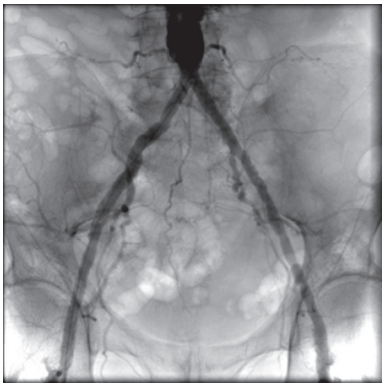
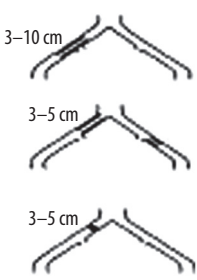

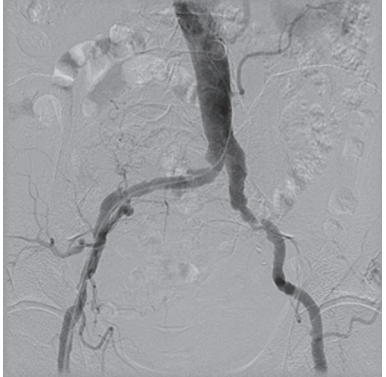
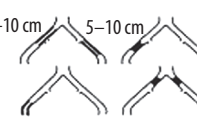
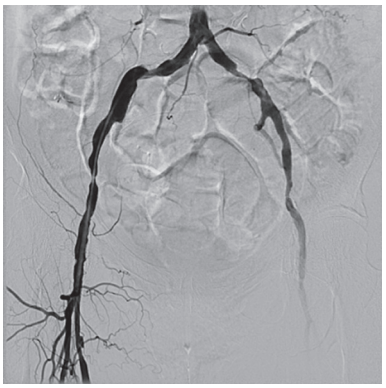
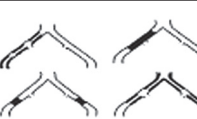
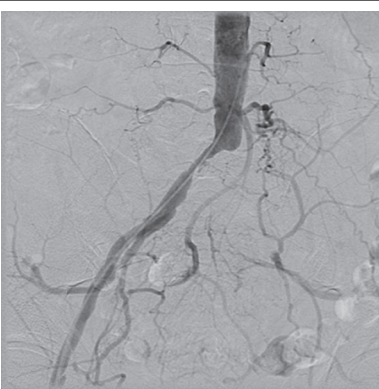

Clinical indications
• Intermittent claudication with a walking distance less than 200 m
• Limb pain at rest – ulcerations or tissue necrosis (fingers, foot)

angioplasty presenting with detachment of atherosclerotic plaque causing occlusion of the vessel lumen or blood flow disruption, recurrent stenosis associated with the elastic recoil of the vessel wall, pressure gradient of over 10–15 mmHg. Other indications for stent implantation are also the following: restenosis following earlier angioplasty and chronic occlusion. Primary stent implantation is performed more often in such cases, as there is a belief that it improves long-term outcomes [19,21]. This point of view is supported by numerous publications especially with regard to extensive or multi-level occlusion [19,20,22,23].

Table 3. Classification of iliac lesion morphology according to TASC.

Type A iliac lesions according to TASC classification
1. Single stenosis <3 cm in length within the common or external iliac arteries (uni- or bilateral)
Type B lesions of iliac arteries according to TASC classification
2. Single stenosis 3–10 in length, not extending into the common iliac artery
3. Two stenotic lesions <5 cm in length involving common iliac artery and/or external iliac artery not extending into the common iliac artery
4. Unilateral common iliac artery occlusion
Type C iliac lesions according to TASC classification
5. Bilateral stenoses 5–10 cm long of the common iliac artery and/or external iliac artery not extending into common iliac artery
6. Unilateral external iliac artery occlusion not extending into common iliac artery
7. Unilateral external iliac artery stenosis involving common iliac artery
8. Bilateral common iliac artery occlusions
Type D iliac lesions according to TASC classification
9. Diffuse, multi-level, unilateral stenoses of common iliac, external iliac and common femoral artery (usually >10 cm in length)
10. Unilateral common iliac and external iliac artery occlusion
11. Bilateral external iliac artery occlusion
12. Diffuse lesions involving aorta and both iliac arteries
13. Stenoses involving iliac arteries in a patient with abdominal aortic aneurysm or other lesions requiring open aortic or iliac surgery

Table 4. Preferred methods of invasive treatment of iliac disease depending on a type of lesion.

TASC I			
TASC II			
TASC III			
TASC IV			

Material and Methods

The goal of this work was to prospectively analyze the effectiveness of endovascular treatment of common and external iliac artery stenosis/occlusion classified according to TASC II (A, B, C, D) using a self-expanding Jaguar SM stent [1,20,24].

The study group consisted of 95 patients treated with self-expanding Jaguar SM stents due to stenosis/occlusion of lower limb arteries between 2005 and 2007 at the Department of Radiology of the University Hospital in Białystok and the Diagnostics Radiology Department of MSWiA Central Clinical Hospital in Warsaw. There were 61 men and 34 women aged 44–79 years (average age 61 years) included in the study. Smokers comprised 74.7% of patients, while 69.5% were treated for hypertension, 44.2% for hyperlipidemia and 6.3% suffered from diabetes (Table 1). Atherosclerosis was a causative factor of all arterial lesions. The shortest stenotic fragment was 10 mm long and the longest arterial occlusion did not exceed 90mm. All patients complained of lower limb weakness, pain and numbness of the sural region on walking. Gluteal claudication was present in patients with common iliac artery occlusion while some patients with external iliac artery occlusion complained of pain at rest (Table 2).

Morphological classification of iliac lesions in treated patients was conducted on the basis of TASC II classification and encompassed 10 type A lesions, 39 cases of type B, 36 cases of type C and 10 cases of type D morphology (Table 3).

According to TASC guidelines and their further modifications on the basis of 2005 *Charing Cross* Conference in London, endovascular treatment is the method of choice in case of TASC A and B type lesions. Attempts at endovascular treatment of type C lesions should be undertaken only if the operator is experienced at performing such procedures (Table 4) [6,25]. Effectiveness of endovascular angioplasty in a patient with intermittent claudication depends on the presence of peripheral outflow. Endovascular procedures will be ineffective if there is insufficient outflow.

Upon finishing the diagnostics, a team consisting of an experienced interventional radiologist and a vascular surgeon made a decision with regard to endovascular therapy, conventional vascular surgery or disqualification from invasive treatment.

All patients referred for stenting of lower extremity arteries were prepared for the procedure according to the guidelines of the Polish Angiological Society, i.e. the following tests were performed:

- Laboratory tests: complete blood count, coagulation, electrolytes, creatinine, glucose, blood group,
- ECG,
- Doppler ultrasound examination of lower limb arteries,
- angiography or angio-CT examination of lower extremities,
- consultation of a specialist in internal diseases or cardiology if comorbidities are present,

- saturating the patient with antiplatelet drugs for at least 2 days before planned procedure (150–325 mg of acetylsalicylic acid and 500 mg of ticlopidine or 75 mg of clopidogrel per day).

Stenting of lower limb arteries using self-expanding Jaguar SM stent was performed in a catheterization lab that contained a stationary angiograph and met the sterility criteria of an operating room. Arterial access was established by puncturing the common femoral artery. An intra-arterial injection of 2500–5000 units of heparin was given followed by a preliminary angiography and angioplasty with implantation of a self-expanding Jaguar SM stent. Common femoral artery was exposed if the pulse could not be palpated in the inguinal region, patient was obese or puncture of a contralateral artery was unsuccessful. After anesthetizing the groin with 1% lignocaine solution, incising the skin and dissecting the artery, stenting procedure was continued. Following stent implantation, in 95% of patients stents required post-deployment balloon dilatation. Five patients with TASC type D lesions, in whom recanalization was not possible, were referred for surgery. Control angiography was performed following stent deployment.

Patients were observed for 24 hours after the procedure in a vascular surgery ward. Upon returning to the ward they received 1000–1500 ml of fluids in order to stimulate diuresis and accelerate contrast excretion. Several hours after the procedure patients received low-molecular-weight heparin subcutaneously for 3 days at a dose of 11400 U per day. Antiplatelet drugs – acetylsalicylic acid (500 mg/day) and ticlopidine (500 mg/day) were re-commenced on the following day. Patients with contraindications for salicylates continued to receive low-molecular-weight heparin injections, but no more than for 7 days. Patients received ticlopidine (500 mg/day) for 30 days and acetylsalicylic acid (75 mg/day) for 3–6 months. Further treatment was continued under care of a vascular surgery outpatient clinic. Patients were scheduled for follow-up visits after 3, 6, 12 and 24 months, which included clinical examination, assessment of pulse on the affected limb and ABI (ankle-brachial index) examination. Periodic Doppler ultrasound examination was performed 12 and 24 months after the procedure or in case of abnormalities detected in clinical examination.

Results

Good technical outcome of the procedure was achieved in all patients with implanted stents (n=89) (Figures 1–3). One patient suffered from a complication – the vessel was perforated during predilatation – and required stentgraft implantation (Figure 4A, B). Five patients with TASC type D lesions that could not be reanalyzed were referred for open surgery.

Patients underwent follow-up clinical examination and imaging in a period of next 1–24 months. Success rate of performed procedures and at 30-day follow-up was 100% in case of stenosis and 80% in case of artery occlusion. Follow-up after 12 and 24 months (87 cases, 2 patients did not report for an appointment) showed patency of treated vessels respectively in 84% and 76% of all cases (Table 5).

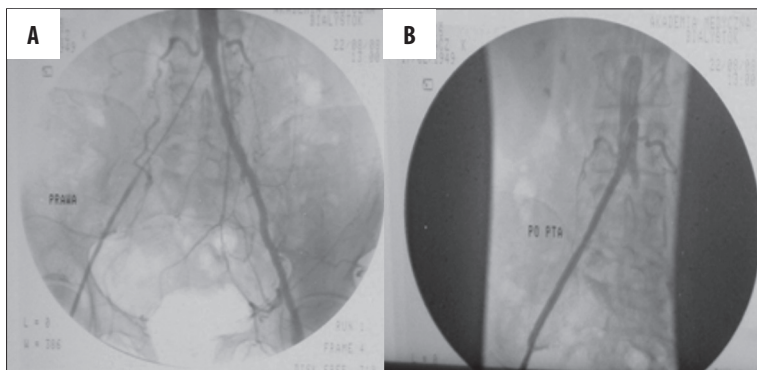


Figure 1. (A) Long right iliac artery occlusion – post balloon predilatation state. (B) State following stent implantation – proper patency of the vessel.

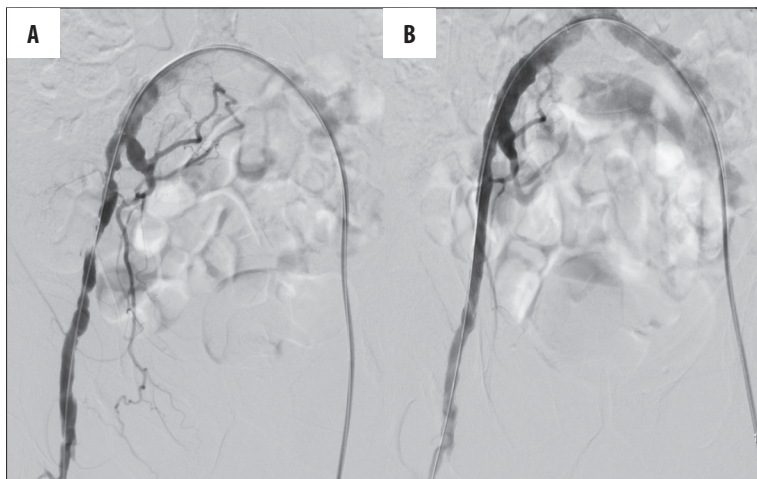


Figure 2. (A) Segmental right iliac artery stenosis. (B) State following stent implantation using the cross-over technique.

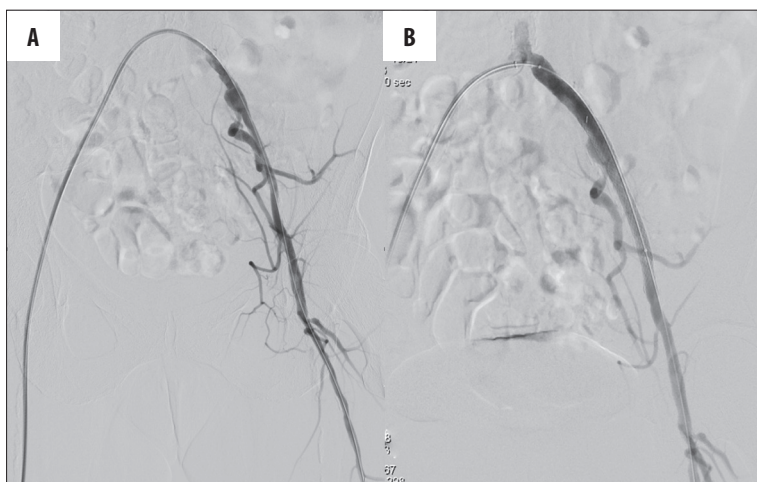


Figure 3. (A) Left common and external iliac artery stenosis. (B) State following stent implantation – proper blood flow through the vessel.

Discussion

Aortic bifemoral bypass is an established method of treatment of iliac artery stenosis [20,26,27]. Long-term outcomes of this treatment modality are well documented, with 90% of grafts patent after 5 years and 75% after 10 years following surgery [26,28]. However, surgical treatment is burdened with a higher proportion of perioperative complications (5% to 10% of early complications) and higher mortality than endovascular treatment.

In a group of younger male patients, sexual dysfunction is an important complication of surgery. Endovascular

treatment ensures lower complication rate, eliminates the need for general anesthesia and shortens the hospitalization time.

Angioplasty with stent implantation is currently the standard endovascular treatment with an average proportion of patent stents amounting to 70–80% after a 5-year follow-up period [29–31].

Currently, the nitinol self-expanding stents made of metal alloys with thermal shape memory are recommended in case of tortuous and long artery occlusions. They assume a programmed diameter at a temperature of human body.

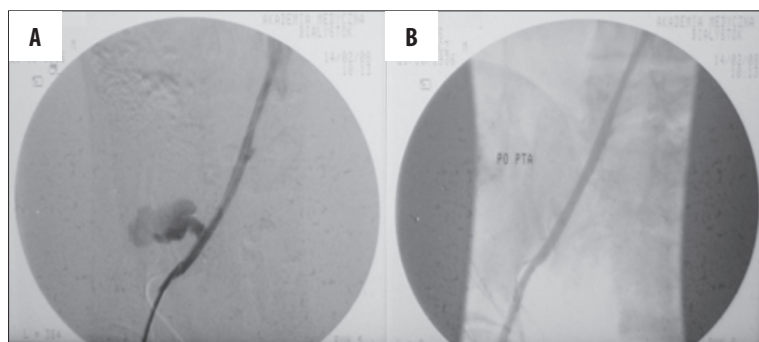


Figure 4. (A) Complication – vessel wall perforation during PTA. (B) State following stentgraft implantation.

Table 5. Effects of endovascular treatment in a 12- and 24-month observation period.

TASC classification	n – number of patients (95 – study group)	Effect of treatment at 30-day follow-up (n-89)	Effect of treatment 1 year after the procedure (n-87)	Effect of treatment 2 years after the procedure (n-87)
Type A	10	1	9*	9
Type B	39	39	38*	36
Type C	36	35	34	32
Type D	10	4	2	1

TASC classification	Effect of treatment up to 30 days following the procedure	Effect of treatment year after the procedure	Effect of treatment 2 years after the procedure
Type A	100%	100%	100%
Type B	100%	100%	95%
Type C	100%	97%	92%
Type D	80%	40%	20%

* Two patients did not report for a follow-up appointment 1 year after the procedure: 1 patient from type A group, 1 patient from type B group.

They are characterized by a relatively large radial force, easily adapt to the natural course of the vessels, while their disadvantage is related to the tendency for shortening during deployment.

Complications during stent implantation are well known and include arterial dissection, distal occlusion, thrombosis of stent branch, pseudoaneurysm or hematoma formation and infection at the puncture site. A significant drawback of nitinol stents, which has been noted in publications, is a risk of fracture, especially in case of long stents (10–12 mm), which may lead to vessel perforation, pseudoaneurysm formation and stent thrombosis. The risk of fracture concerns primarily the stents that are laser-cut out of a nitinol tube.

Stent deployment is not traumatic to the vessel wall [32]. However, predilatation performed before stent implantation or stent expansion using balloon inflation is damaging to the vessel and may release minute particles of embolic material [33,34]. However, proper preparation (anti-aggregation therapy, heparinization) and careful execution of the procedure decrease the risk of thrombotic complications [13,35].

Restenosis, which reduces the effectiveness of endovascular treatment, is the greatest problem among late complications of therapy [12,36].

Self-expanding Jaguar SM stent is made of nitinol wire (nickel and titanium alloy). It is intended for percutaneous intravascular implantation in patients with atherosclerotic, post-radiation and post-traumatic lesions. Stent is placed at the end of a delivery system. As it is deployed from the delivery system, it expands and assumes a cylindrical shape. High radial force exerted by the self-expanding stents causes them to gradually increase their nominal diameter even after the end of the procedure.

A delivery system consists of two units – a stationary and movable one. Stent is deployed into the position by sliding the movable part of the system against the stationary unit. Delivery system comes in two diameters – 6F and 7F. The latter is used for the greatest diameters of 10–12-mm stents. A guide wire is inserted through the central canal and it is used to introduce the system. The second, external canal comprises a space separating the stationary unit containing the stent from the mobile one, enabling stent deployment.

As nitinol is poorly visible under fluoroscopy, platinum markers were placed at both ends of the stent, allowing for easier localization during the procedure. Markers placed at the ends of the stent also make it possible to assess the degree of stent shortening during implantation.

Delivery system is flexible, facilitating implantation even in tortuous vessels, and allows for using the "cross over" approach. Small diameter of delivery systems is another feature of self-expanding stents. Its flexibility and diameter allows for implantation of a stent from the axillary artery access. The rounded and soft tip of delivery system is atraumatic toward the arterial wall. Jaguar SM adapts to the arterial lumen and does not migrate. A rare feature of the Jaguar SM stent is that it can be repositioned during the procedure. There is also a possibility of folding it and re-expanding before final deployment.

Stents are available in many lengths – up to 15 cm – allowing for restoration of the patency of a stenotic or occluded vessel using just one stent. Shorter duration and lower cost of the procedure are advantages of this method.

Vessel predilatation using balloon catheter enables easier stent placement. However, balloon plasty is not obligatory before stent implantation. There are literature reports regarding better long-term outcomes of stenting without prior predilatation [36]. Predilatation is necessary in case of vessel occlusion or high-grade stenosis. In the remaining cases it is recommended that stent deployment should be performed without prior predilatation as it decreases the rates of restenosis caused by proliferation of intima media initiated by high-pressure trauma.

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In our material we achieved technical success in all cases. One patient was treated successfully with stentgraft implantation for a complication – vessel perforation, which occurred during predilatation. In 5 cases TASC type D lesions (occlusion) precluded endovascular therapy.

Assessment of treatment effectiveness is based on clinical examination and ultrasound studies with Doppler flow imaging. Patients included in the study group were subjected to periodic control assessments during the 24 months of follow-up.

Early follow-up examinations showed a 100% effectiveness of stenting in case of stenosis and 80% success rate in case of vessel occlusion. Control studies performed 12 months after the procedure revealed patency of treated vessels in 84% of patients. After 24 months proper stent patency was seen in 76% of cases. Recurrence of symptoms was most often associated with the progress of atherosclerotic lesions. Control imaging examinations often revealed a patent stent and presence of significant stenoses in other parts of lower extremity arteries.

Conclusions

- Endovascular treatment should be the first-choice therapy in case of focal stenoses or short-segment occlusions.
- Application of self-expanding Jaguar SM stents is an effective and safe method characterized by high success rate and associated with low complication risk.

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