Use of Covered Stents to Treat Occlusive Mesenteric Artery Disease

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Abstract: The number of mesenteric revascularizations has increased tenfold in the United States in the last decade. In most centers, angioplasty with stenting surpassed open bypass as the first treatment option for patients with chronic mesenteric ischemia (CMI); however, endovascular therapy using bare metal stents (BMS) has been plagued by high rates of restenosis and reinterventions affecting as much as 20% to 66% of patients treated for CMI. Studies have shown that covered stents (CS) can effectively decrease rates of restenosis and reintervention when applied to treat iliac occlusive disease and chronic mesenteric lesions, yielding results comparable to open surgical bypasses. This review describes the use of CS in endovascular treatment of chronic mesenteric ischemia, including indications, techniques, and results.

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Mesenteric ischemia is not a common disease; however, early diagnosis in patients with undifferentiated abdominal pain is paramount so that rapid mesenteric revascularization can be achieved to prevent disastrous bowel infarction. The number of mesenteric revascularizations has increased tenfold in the United States in the last decade, largely because of improved diagnosis and decreased morbidity and mortality of endovascular therapy. In most centers, including ours, angioplasty with stenting surpassed open bypass as the first treatment option and is currently used in more than 70% to 80% of the patients treated for chronic mesenteric ischemia (CMI). Currently, open surgery is relegated to a minority of patients (5% to 10%) who have failed or are not considered suitable candidates for an endovascular approach.

Despite the widespread acceptance of angioplasty and stenting and short-term advantages over open bypass, mesenteric revascularizations using bare metal stents (BMS) are plagued by high rates of restenosis and reinterventions affecting as much as 20% to 66% of patients treated for CMI, not matching the excellent patency rates reported for open surgical reconstructions. Unlike BMS, a covered stent for peripheral use is encapsulated with expanded polytetrafluoroethylene.
(ePTFE) film, which is designed to serve as a barrier to retard intimal hyperplasia and has been confirmed in animal models of restenosis. Covered stents have been associated with decreased rates of restenosis when applied to treat failing arteriovenous fistulas, for iliac occlusive disease, and for realignment of renal arteries during fenestrated endovascular repair of aortic aneurysms. In the mesenteric arteries, Schoch et al reported no restenosis or reinterventions after a mean follow-up of 7 months in 14 patients treated by covered stent. Our previous study also showed that covered stents outperformed BMS in terms of restenosis, symptom recurrence, and re-intervention, and currently our practice has shifted to endovascular treatment for CMI using covered stents.

SELECTING COVERED STENTS

Three types of covered stents are currently commercially available for peripheral use in the United States, with other options also used in the non-US market: (1) balloon-expandable iCAST/Advanta V12 (Atrium Macquet Medical Corporation), (2) self-expanding covered stent Fluency stent-graft (Bard Peripheral Vascular), and (3) self-expandable Viabahn stent-graft (W. L. Gore & Associates). For treatment of occlusive mesenteric lesions, we have preferred to use balloon-expandable covered stents because of precise deployment, excellent radial force, prevention of embolism by entrapment of debris, the ability to over-expand the stent to the desired diameter with minimal stent foreshortening, and less risk of arterial disruption. Stents are sized to match the reference vessel diameter, which typically ranges from 5 mm to 8 mm in the mesenteric territory. The most commonly used stent is 6 mm or 7 mm by 22 mm or 38 mm. Currently a second-generation 0.035” platform (6 Fr or 7 Fr) is available in the United States, whereas the non-US market also has access to a 0.018” platform that can be introduced via a 6 Fr sheath. Recent improvements to the device include flexibility and better adhesion to the balloon, avoiding the issue of stent dislodgement.

INDICATION

Endovascular therapy of mesenteric ischemia is indicated in anatomically eligible patients with symptoms of acute, subacute, or chronic mesenteric ischemia. Most patients (>95%) have ostial atherosclerotic mesenteric vascular disease in the proximal third of the mesenteric arteries. Patients with asymptomatic stenosis are not considered for prophylactic treatment because of the benign natural history, with the exception of select patients with severe three-vessel high-grade stenosis or occlusion. Stenting of arcuate ligament compression of the celiac axis is contraindicated, unless this has been surgically released by laparoscopy or open surgery. The ideal lesion for endovascular therapy is a short, focal stenosis or occlusion without significant calcification or thrombus. However, longer lesions, calcified lesions, and occlusions can also be treated by endovascular therapy with satisfactory results, but likely restenosis rates are higher on long-term follow-up. Because most lesions are proximal and ostial, a short balloon-expandable stent is often the only selected stent. Longer lesions may require a self-expandable stent or a balloon-expandable stent (proximally) coupled with a distal self-expandable stent in tortuous segments of the superior mesenteric artery (SMA). The use of covered stents is avoided across jejunal
branches and is used only in the proximal SMA.\(^2,3\)

**PATIENT SELECTION AND APPROACH**

The goal of endovascular revascularization is to restore antegrade flow into at least 1 of the 3 mesenteric arteries, preferentially the SMA. We found no benefit with 2-vessel stenting, and a celiac artery (CA) stent alone carries a high risk of recurrence.\(^15\) Review of preprocedure imaging studies including CTA, magnetic resonance angiography (MRA), or conventional angiography is the key to selecting the ideal approach based on the angle of origin of the mesenteric vessels in relation to the aorta, the amount of calcium and thrombus load, and the presence of important collaterals or unusual anatomy in proximity to the target lesion. The SMA is the primary target for revascularization, and as such the anatomy of the SMA is the most important determinant.\(^2,3\) The endovascular technique using covered stents is identical to BMS. We generally target the SMA first and consider CA stenting only if stenting the SMA is not feasible or if we obtained a suboptimal result (dissection or residual stenosis).

**ACCESS**

The ideal approach remains controversial. A brachial artery approach is preferred for patients with a sharp angulated origin of the SMA and for patients with long occlusions, particularly flush occlusions. Brachial access offers excellent support with small-profile systems and precise stent deployment in patients with an acute SMA angle, and may reduce the rate of severe mesenteric artery complications including dissections, vessel perforations and embolization. A radial approach may also be used. Our preference is to use the left brachial artery access with a small 1 cm to 2 cm incision to surgically expose the artery under local anesthesia using a 7 Fr sheath. Brachial access is established by a 0.018” micropuncture set, after which the system is exchanged for a 0.035” guidewire system.\(^2\) The author acknowledges that percutaneous access can also be used, but undoubtedly puncture-related complications are higher in the brachial artery and the morbidity of a small incision is close to none. A femoral access is also a reasonable option in patients with good SMA angle, but technical difficulties occur in some cases. A retrograde approach through the exposed SMA after laparotomy is useful in patients who have an indication for laparotomy because of bowel gangrene or perforation.\(^16-19\)

**TECHNIQUE**

Full systemic heparinization (80 mg/kg) is administered before catheter manipulations to achieve an activated clotting time above 250 seconds. A 7 Fr 90-cm hydrophilic sheath is positioned in the descending thoracic aorta above the celiac axis origin. A 5 Fr multipurpose catheter is ideal for selective catheterization of the mesenteric arteries through the brachial approach, whereas an SOS catheter (AngioDynamics) or VS1 catheter (Cook Medical) can be used from the femoral approach. The initial selective angiography should demonstrate the origin of the vessel from the aortic wall and the severity of the stenosis, and it should document the distal branches for comparison with post-intervention views. The target lesion is initially crossed with a 0.035” soft angled glidewire, which is exchanged for the interventional wire of choice after confirmation of true lumen access. Our preference is
to use a small-profile (0.014” or 0.018”) stiff guidewire for most interventions. The tip of the guidewire should be visualized and positioned within the main trunk of the SMA rather than within small jejunal branches, which are prone to perforation or dissection. Transluminal pressure gradient measurements are performed in selected patients, especially those who have undergone reintervention for restenosis. Embolic protection is used selectively in patients with occlusions, long lesions (>30 mm in length), severe calcification, thrombus, and acute or subacute symptoms. Our preference is to use a 320-cm working length 0.014” Spider RX filter wire (Covidien), the most frequently utilized filter device is a 7 mm filter basket positioned approximately 5 cm distal to the SMA origin, to avoid the major jejunal branches to be compromised. The two-wire technique is used by combining a 0.014” filter wire with a 0.018” “buddy wire.”

The covered stent is introduced via both wires for better support and to facilitate subsequent retrieval of the embolic protection device. The covered stent is positioned under protection of the sheath, covering slightly more than the entire length of the lesion. Positioning the covered stent so that it extends 1 mm to 2 mm into the aortic lumen is critical to avoid missing the proximal portion of the lesion. Ideally, the stent-graft should be flared gently into the aorta, which minimizes the potential to miss disease at the ostia and facilitates repeated catheterization if needed. After deployment and flaring of the stent, the embolic protection device is retrieved with careful attention to avoid entrapment into the stent. The basket is examined for debris.

A formal completion angiography should be performed, including a focal magnified view of the stent with the sheath into the aorta to demonstrate the vessel origin as well as a panoramic view of the entire SMA and its branches to rule out embolization or perforation. The stiff guidewire should be retracted, and nitroglycerin may be administered through the sheath to minimize spasm or kinks caused by the guidewire tip. In patients with residual stenosis, residual pressure gradient across the covered stent exceeding 10 mmHg will require that additional angioplasty and/or stenting be performed.2,3

In cases of mesenteric occlusions, the tip of the 5 Fr multipurpose catheter is used to engage the stump of the occluded SMA, and sufficient support is provided by the stiff support system combining a 7 Fr Rabee sheath (Cook Medical) and 7 Fr multipurpose guide catheter (Cook Medical). A 0.018” V-18 wire (Boston Scientific) can be used to cross the area of occlusion, followed by a 0.018” Quick-Cross catheter (Spectranetics). Alternately, a 0.035” soft or stiff glidewire and Quick-Cross catheter can be used. It is ideal to avoid the subintimal plane, which is best achieved by use of straight-tip guidewires. Once the lesion is crossed, access into the true lumen should be confirmed.2,3 Grilli et al preferred a femoral access in cases with chronic total occlusions, with the help of a Morph deflectable guiding sheath (Biocardia) to provide considerable resistance to catheters buckling into the supraceliac aorta.20

ADJUNCTIVE TECHNIQUES

An acute or subacute symptom presentation suggests fresh thrombus or complicated plaque. In these cases, local administration of tissue plasminogen activator
(tPA) into the diseased segment 15 minutes before stent placement may improve technical success.\textsuperscript{21}

**COMPLICATIONS**

Distal embolization, dissection, thrombus, or branch perforation occur in 5% to 10% of patients and remain a major source of morbidity and mortality if they are not immediately recognized.\textsuperscript{2}

**POSTPROCEDURAL MEDICATION**

Antiplatelet therapy is typically started before the intervention with acetylsalicylic acid and continued indefinitely thereafter. Clopidogrel is started the day of the intervention with a loading dose of 300 mg and continued for 6 weeks to 8 weeks as a dual antiplatelet agent, after which patients continue with acetylsalicylic acid alone.\textsuperscript{2,3}

**OUTCOMES**

Clinical data on the use of balloon-expandable covered stents in the treatment of mesenteric ischemia are scarce. The University of Tennessee group was the first to report favorable results in 14 patients treated by iCAST, with no reinterventions after 2-year follow-up.\textsuperscript{13} Our study showed that in 225 patients with CMI, of 147 vessels treated with BMS and 42 with covered stents, in the primary intervention group, rates of freedom from restenosis (92% vs 53%, $P=.003$), symptom recurrence (92% vs 50%, $P=.003$), and reintervention (91% vs 56%, $P=.005$) were higher in covered stents than in BMS at 3 years; similar results were obtained at 1 year in the reintervention group consisting of 15 BMS and 21 covered stents (89% vs 49%, 100% vs 64%, 100% vs 72%; $P<.05$).\textsuperscript{14}

In other vascular beds, the Australian prospective multicenter randomized controlled trial (RCT) Covered Versus Balloon Expandable Stent Trial (COBEST) studied 168 iliac arteries in 125 patients with severe peripheral arterial occlusive disease who were randomly assigned to a covered stent group (Atrium Advanta V12; Maquet) or a BMS group. TransAtlantic Inter-Society Consensus (TASC) classification was used to classify the lesions. Follow-up was carried out at 1, 6, 12, and 18 months, respectively. The COBEST demonstrated that covered stents had better outcomes for TASC C and D lesions than BMS in terms of long-term freedom from binary restenosis, which was defined as $\geq50\%$ reduction in lumen diameter (hazard ratio [HR], 0.14; 95% confidence interval [95% CI], 0.04–0.44; $P=.006$), and clinical outcome; nevertheless, this significance was not observed for TASC B lesions (HR, 0.75; 95% CI, 0.24–2.39).\textsuperscript{11}

By contrast, in the retrospective study that consisted of 254 common iliac arteries in 162 patients with symptomatic peripheral arterial occlusive disease, of 190 BMS and 64 covered stents (iCAST), rates of primary patency, primary assisted patency, and secondary patency were better in the BMS group: 89% vs 72%, 98% vs 90%, and 98% vs 92% respectively at 2 years. The authors pointed out that an RCT with long-term follow-up is required to determine the benefit of using covered stents in the iliac artery.\textsuperscript{22} Currently, an RCT, the Dutch Iliac Stent trial: COVERed balloon-expandable versus uncovered balloon-expandable stents (DISCOVER) in the common iliac artery, is being undertaken, which will compare the Advanta V12 stent and will include a total of 174 patients.\textsuperscript{23}

Although the cost of a covered stent is 3 to 5 times
that of a BMS, and late complications including the edge-stent stenosis, restenosis, acute stent thrombosis, and stent dislodgement are not well defined, there is a trend toward endovascular therapy using balloon-expandable covered stents in the treatment of mesenteric ischemia on the basis of single-center experiences\textsuperscript{13,14} and RCT related to iliac artery stenting.\textsuperscript{11} Careful preprocedural evaluation, including imaging studies, is the key to determine the patient eligibility. Randomized, controlled trials in endovascular mesenteric revascularization with longer follow-up are warranted to justify the benefit of covered stents.

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