Quality Improvement Guidelines for Mesenteric Angioplasty and Stent Placement for the Treatment of Chronic Mesenteric Ischemia

Anil K. Pillai, MD, Sanjeeva P. Kalva, MD, Steven L. Hsu, MD, MBA, T. Gregory Walker, MD, James E. Silberzweig, MD, Ganesan Annamalai, MD, Mark O. Baerlocher, MD, Jason W. Mitchell, MD, MPH, MBA, Mehran Midia, MD, FRCPC, Boris Nikolic, MD, MBA, and Sean R. Dariushnia, MD, for the Society of Interventional Radiology Standards of Practice Committee

ABBREVIATIONS

BMS = bare metal stent, CA = celiac artery, CMI = chronic mesenteric ischemia, SMA = superior mesenteric artery

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from the private and academic sectors of medicine. Generally, Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds (**Fig E1** and **Table E1**, available online at *www.jvir.org*).

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members using a modified Delphi consensus method (**Appendix A**). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions are made to create the finished standards document. Prior to its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION

Chronic mesenteric ischemia (CMI) is an entity that typically occurs as a result of mesenteric arterial stenosis or occlusion. The most common cause of mesenteric arterial steno-occlusive disease is atherosclerosis, which accounts for 35%–75% of cases (1). Nonatherosclerotic causes include vasculitis, fibromuscular dysplasia, segmental arterial mediolysis, and median arcuate ligament syndrome. The true incidence of mesenteric arterial disease is unknown. A population-based survey using duplex ultrasound (US) imaging in asymptomatic patients found that 17.5% of persons over 65 years of age had a critical stenosis of at least one mesenteric vessel (2). Because of the extensive mesenteric arterial collateral network, CMI

From the Department of Diagnostic and Interventional Imaging (A.K.P.), University of Texas Health Science Center, Houston, Texas; Division of Interventional Radiology, Department of Radiology (S.P.K., S.L.H.), University of Texas Southwestern Medical Center, Dallas, Texas; Division of Interventional Radiology (T.G.W.), Massachusetts General Hospital, Boston, Massachusetts; Department of Radiology (J.E.S.), Beth Israel Medical Center, New York, New York; Department of Medical Imaging (G.A.), University of Toronto, Mt. Sinai Hospital & University Health Network, Toronto, Ontario, Canada; Department of Radiology (M.O.B.), Royal Victoria Hospital, Barrie, Ontario, Canada; Department of Radiology and Imaging Sciences, Division of Interventional Radiology and Image-Guided Medicine (J.W.M., S.R.D.), Emory University, Atlanta, Georgia; Department of Diagnostic Imaging (M.M.), McMaster University, Hamilton, Ontario, Canada; and Department of Radiology (B.N.), Stratton Medical Center, Albany, New York. Received September 27, 2017; final revision received November 15, 2017; accepted November 19, 2017. Address correspondence to S.R.D., c/o SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033; E-mail: dariushnia1@yahoo.com

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Table E1 and Figure E1 are available online at *www.jvir.org*.

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usually occurs only when there is a fixed stenosis or occlusion of at least two of the three visceral arteries. However, isolated occlusion or stenosis of the superior mesenteric artery (SMA) can also present with CMI if collateral connections have been interrupted by prior abdominal or aortic surgery (3,4).

Mesenteric angioplasty and stent placement are endovascular therapies that are primarily used in the management of patients who have CMI. This document was written to address the factors that may affect the outcomes of endovascular therapy for CMI, including patient selection, imaging modalities used for the diagnosis of CMI, and postprocedure follow-up, and to provide an overview of the current literature of CMI endovascular treatment.

CMI generally occurs in the elderly population, with a threefold predilection for women. Most patients with mesenteric stenosis or occlusion are asymptomatic (5). Symptomatic patients may present with nonspecific abdominal pain and weight loss. Postprandial epigastric abdominal pain occurring 30 minutes after a meal and lasting for 1–3 hours is classic for CMI. Atypical presenting symptoms including nausea, vomiting, and diarrhea can be associated with ischemic gastropathy and suggest a poor prognosis. Physical examination is usually unremarkable except for weight loss and occasional audible bruit over the epigastrium. Results of laboratory tests including blood chemistry and hematologic parameters are often normal (5).

Screening for suspected mesenteric artery disease is usually performed with duplex ultrasound (US). The reported sensitivity and specificity of duplex imaging in identifying a significant stenosis ($\geq$ 70%) of the celiac artery (CA) approach 80% and 90%, respectively, and, for the SMA, these values are 90% and 92%, respectively (6–9). Computed tomographic (CT) angiography with three-dimensional reconstructions has a sensitivity and specificity of 96% and 94%, respectively, for detecting mesenteric arterial stenosis (10). CT angiography can also exclude other causes of chronic abdominal pain and can be used to plan percutaneous interventions. Magnetic resonance angiography has a sensitivity and specificity of 100% and 95%, respectively, for diagnosing CMI caused by CA and SMA stenosis/occlusion (11). Catheter angiography, however, remains the gold standard for diagnosis of mesenteric arterial stenosis/occlusion.

Although surgery has traditionally been the mainstay of treatment for CMI, angioplasty and stent placement have more recently become the first line of therapy at many centers as a result of improved technical efficacy and lower morbidity and mortality rates (12–17). Open revascularization is usually reserved for patients who are relatively young (age $<$ 50 y) and who are otherwise fit for surgical repair or in cases of early and late failure of endovascular repair (13,18–20). The decision to perform endovascular versus surgical repair should be made based on anatomic considerations, nutritional status, and presence of comorbidities. If the lesion is anatomically challenging for endovascular repair or if the patient is young and well nourished, surgical rather than endovascular treatment may be considered. Conversely, endovascular repair may be considered if the patient is a high-risk candidate for surgery or anesthesia with poor nutritional status.

These guidelines are written to be used in quality-improvement programs to assess mesenteric angioplasty and stent placement procedures. The most important aspects of care that affect quality of the intervention are (i) patient selection, (ii) performance of the procedure, and (iii) follow-up care of the patient.

DEFINITIONS

For the purpose of this guideline, the following definitions apply:

CMI: Chronic episodic or continuous intestinal hypoperfusion resulting from stenosis/occlusion of the mesenteric arteries and causing symptoms of postprandial pain, weight loss, or anorexia (21).

Postprandial abdominal pain: Dull abdominal pain starting a few minutes after food intake and lasting for 1–4 hours (1).

Significant weight loss: Unintentional weight loss of more than 5% body weight over a period of 6 months (22).

Significant stenosis: Narrowing of the mesenteric arterial lumen by 70% or greater, expressed in this document as a percentage of the diameter of an adjacent normal segment of the mesenteric artery, or a greater than 20-mm Hg systolic pressure gradient across the lesion (23). The authors recognize that a stenosis of less than 70% may be clinically significant in the presence of symptoms.

Mesenteric revascularization: Any procedure that restores stenotic or occluded flow to the intestines.

Technically successful mesenteric revascularization: Less than 30% residual stenosis measured at the narrowest point of the vascular lumen and restoration of the systolic pressure gradient to less than 10 mm Hg without pharmacologic intervention (23,24).

Clinical success: Complete or partial resolution of preprocedure clinical symptoms of mesenteric ischemia.

Primary patency: Uninterrupted vessel patency after initial intervention without repeat intervention (25).

Primary assisted patency: Successful restoration of vessel patency by endovascular treatment (eg, balloon angioplasty and/or stent placement) of restenosis or a newly occurring arterial stenosis of the previously treated lesion. Primary assisted patency ends with vessel occlusion (25).

INDICATIONS

Indications for mesenteric angioplasty and/or stent placement for CMI are as follows (4,26–40):

1. Symptomatic patients with the following clinical triad:
   a. Unintentional weight loss;
   b. Postprandial abdominal pain and/or food aversion; and
   c. Two-vessel disease on imaging.
2. Symptomatic patients with aortic dissection or spontaneous mesenteric artery dissection causing compromised mesenteric perfusion as a result of involvement of at least two of the three visceral arteries;
3. As a part of a fenestration/snorkel (ie, chimney) procedure in a patient undergoing endovascular repair of an abdominal aortic aneurysm or injury.

The threshold for these indications is 95%. When fewer than 95% of procedures are for these indications, the department will review the process of patient selection.

CONTRAINDICATIONS

There are no absolute contraindications to mesenteric angioplasty and/or stent placement. However, relative contraindications may exist. The following conditions may result in lower technical success rates and/or increased procedural complications (19,41–43):

1. Highly tortuous aortoiliac arteries
2. Long-segment occlusion
3. Small-diameter distal vessels
4. Heavily calcified stenosis/occlusion
5. Extrinsic compression (eg, arcuate ligament compression of the CA)

QUALITY IMPROVEMENT

Indicator thresholds are utilized to assess the effectiveness of ongoing quality-improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that, when exceeded or fallen below, should prompt a review. “Procedure thresholds” or “overall thresholds” refer to a group of indicators for a procedure such as success and complications rates. When indicators such as procedural success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, reviews should be performed to elucidate causes for crossing thresholds and to aid in implementation of process improvements. For example, if a procedural complication such as the occurrence of symptomatic embolization is evaluated as one measure of the quality of a mesenteric angioplasty and/or stent placement program, values in excess of a defined threshold should trigger a review of

Table 1. Technical Success Rates and Thresholds for Mesenteric Angioplasty and Stent Placement (15,20,23,24,43,56–59)

Procedure	Reported Success Rate (%)	Threshold (%)
Angioplasty alone	79	65
Stent placement	94	85

policies and procedures within the department to determine the causations of symptomatic embolization and to effect changes to reduce the rate of this complication. Thresholds may vary from those listed here, particularly when considering patient referral patterns and selection factors that are different across institutions. Thus, establishing universal thresholds is difficult, and thresholds should be adjusted to higher or lower values based on an institution's quality-improvement program needs.

SUCCESS RATES

Traditionally, mesenteric arterial steno-occlusive disease has been treated by surgical revascularization. Surgical repair has an excellent track record for long-term patency and clinical success. Primary graft patency rates can be as high as 80%–90% at 3–5 years, and clinical success rates have been reported at 80% and 60% at 5 and 10 years, respectively (44–49).

Angioplasty and stent placement have become the primary treatment in many patients who have suitable lesions, independent of their surgical risk. In a large retrospective study of the Nationwide Inpatient Sample, endovascular revascularization was shown to have a lower in-hospital mortality rate (3.7%) compared with surgical intervention (13%), even in patients at high risk (17). Moreover, compared with surgical revascularization, endovascular repair has been associated with shorter hospital stay (19,27). These factors have led to a tremendous increase in the use of endovascular procedures for the management of mesenteric ischemia over the past two decades (15,17,18,50–53), and, currently, > 70% of patients with CMI are treated with this modality (43).

Endovascular intervention to treat celiac and/or SMA steno-occlusive disease primarily utilizes stent placement for revascularization, as most of the lesions are ostial in location and thus have a tendency for elastic recoil after angioplasty (54,55). The reported overall technical success rates for endovascular stent placement range from 85% to 100%, whereas success rates for mesenteric arterial occlusions and lesions treated with balloon angioplasty alone are lower (**Table 1**) (15,20,23,24,43,56–59).

Older surgical series have suggested that recanalization of only the SMA is needed for symptom improvement (43,60,61), although dual mesenteric revascularization may provide a protective mechanism in the event of occlusion of one of the recanalized arteries (57). The most commonly treated splanchnic vessels are the SMA and CA. Stent placement within the inferior mesenteric artery can be performed when the SMA/CA cannot be recanalized, although data on endovascular revascularization of the inferior mesenteric artery are limited (62). The patency rates of SMA versus CA stents have been studied, but outcome data on this comparison are unclear. Whereas some studies have shown longer patency and lower restenosis rates for SMA stents compared with CA stents (63), others have shown no significant difference (23,64). Additionally, there are limited data on balloon-expandable versus self-expanding stents and their application within visceral artery stenoses/occlusions. Balloon-expandable stents are preferred when treating calcified lesions, as they demonstrate enhanced radial strength and can be more precisely placed (65), whereas self-expanding stents are used for distal lesions, where the vessel is more tortuous, and if stent extensions are required.

Several studies have reported primary patency rates following endovascular revascularization of the mesenteric/celiac arteries with bare metal stents (BMSs), which range from 58% to 88% and 30% to 81% at 1 year and 3 years, respectively (15,19,20,23,24,42,59,66,67). The 3-year primary assisted patency rates range from 54% to 100% (23,67). The 5-year primary patency and primary assisted patency rates of endovascular repair are reported to be approximately 45%–52% and 69%–79%, respectively, compared with 74%–90% and 96%–98% with surgical bypass (18,50,68,69). Fewer studies have addressed the use of covered stents within the mesenteric arteries (66,70). The largest study to date comparing the use of covered stents versus BMS placement demonstrated higher primary patency rates in the covered stent group (92% ± 6 for covered stents vs 52% ± 5 for BMSs) at 3 years (66).

Independent predictors of stent stenosis/occlusion recurrence include diabetes, female sex, and small-diameter (< 6 mm) arteries (43,50). There is no consensus regarding optimal follow-up intervals. Biannual Doppler imaging in the first year followed by an annual Doppler evaluation thereafter is a reasonable follow-up protocol (49). In-stent stenosis may occur in 28%–36% of patients within 2 years (20,51,59,71,72). There is no consensus on US threshold values for the diagnosis of in-stent stenosis. However, for in-stent stenosis of ≥ 70%, peak systolic velocities of ≥ 412–445 cm/s for the SMA and ≥ 289–363 cm/s for the CA have been described in different series (73,74). Dual antiplatelet therapy with aspirin and clopidogrel therapy for 3–12 months may confer additional benefit to prevent restenosis after mesenteric revascularization (14,41).

Table 2. Complication Rates and Thresholds (17,18,24,27,41,50,54,59,76)

Complication	Average Reported Rate (%)	Threshold (%)
Symptomatic embolization	2.5	5
Thrombotic mesenteric arterial occlusion	1	3
Iatrogenic dissection	2	5
Stent dislodgment	2	5
Access-site complication*	9	15

*Includes pooled femoral and brachial artery access data.

COMPLICATION RATES AND THRESHOLDS

The overall mortality rate for endovascular repair is between 0% and 19%, and the morbidity rate is between 0% and 31% (17,18,27,41,59). Specific major complications are listed in **Table 2**. Access-site complications occur in 4%–38% of cases, and incidences are especially high with brachial artery access, which is performed in as many as one third of cases (24,41,58). These complications may be attributable to the larger sheaths used in small arteries, which can cause hematoma, dissection, thrombosis, and distal thromboembolization. Transradial access is well established in coronary artery interventions, with fewer major access-site complications observed compared with transfemoral or transbrachial access (75). However, the efficacy and feasibility of transradial interventions for CMI has not yet been established. Other complications include distal embolization (0%–11%) and dissection of the mesenteric vessels (0%–6%) (19,41,54,59,76). Distal embolization leading to acute bowel ischemia and need for emergent bowel resection occurs in 2%–4% of patients (41,50). Factors associated with higher rates of distal embolization include mesenteric occlusion, severe calcification, and lesion length > 30 mm. The role of embolic protection devices during mesenteric revascularization is currently unclear (41,58).

Complications are stratified on the basis of outcome (**Appendix B**). Major complications are those that result in admission to a hospital for therapy (for an outpatient procedure), unplanned increase in the level of care, permanent adverse sequelae, or death. Minor complications result in no sequelae or require nominal therapy or a short hospital stay for observation (**Table 2**) (17,18,24,27,41,50,54,59,76).

APPENDIX A: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

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APPENDIX B: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. Require no therapy, no consequence; or

B. Require nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (< 48 h);

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h);

E. Have permanent adverse sequelae; or

F. Result in death.

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