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Long-Term Patency of Stent Angioplasty for Aortoiliac Occlusive Disease: A Literature Review

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Abstract

Introduction. Surgical revascularization remains a definitive therapy for aortoiliac occlusive disease. Revascularization could be achieved via endovascular treatment using angioplasty or open surgery. A limited number of studies currently assess the long-term patency of stent angioplasty of aortiliac occlusive disease. This study aims to evaluate or find recent evidence regarding the evaluation of the long-term patency of stent angioplasty for the treatment of aortoiliac occlusive disease.

Method. Literature searching was conducted through several online databases, including Cochrane, PubMed, and EBSCOHost. Several cohort and randomized controlled studies assessing long-term patency of stent angioplasty ranging from bare metal stent to balloon angioplasty published from 2010 to 2022 were included. Critical appraisal was conducted using the Oxford Centre of Evidence-Based Medicine checklist.

Results. Initial database searching yielded 26 published titles, of which 21 were excluded based on our inclusion-exclusion criteria and being a duplicate. Five studies, consisting of five cohort studies and one systematic review, were included. Long-term primary, assisted-primary, and secondary patency data were acquired in each study. **Conclusion**. We found heterogeneous data regarding long-term patency in each study. We found that 60-month primary patency ranges from 74.7% - 83.9%, assisted primary patency ranges from 83.7% - 95.8%, and secondary patency ranges from 92.8% - 99%. Overall, endovascular therapy by angioplasty has proven satisfactory long-term patency over five years.

Keywords: Angioplasty, stents, vascular patency, patency, long-term, primary, secondary, assisted-primary, aortoiliac occlusive disease

Introduction

Aortoiliac occlusive disease is a peripheral artery disease in the infrarenal aorta and iliac artery, along with its primary branches.¹ The general prevalence of aortoiliac disease is hard to determine due to a high number of asymptomatic patients. The estimates for aortoiliac occlusive disease were around 3.56% to 14% of the general population.^{2,3} This prevalence increases in the elderly to 14-20% in groups of patients older than 70 to as high as 23% in patients over 80. Like any other peripheral artery disease, aortoiliac occlusive disease was often caused by atherosclerosis plaque buildup. Plaque causes blockage of blood flow to distal organs, leading to lumen stenosis.¹ Occlusion often starts from the terminal aorta or common iliac artery, spreading to the proximal and distal iliac branches.⁴ Obstructive lesions can end in the infrarenal aorta, common iliac artery, internal iliac artery, and external iliac artery.¹

Definitive treatment of aortoiliac occlusive disease is revascularization and surgery.¹ The main principle in managing this disease is improving blood flow to the distal extremities and hips through recanalizing the occluded artery. Many modalities are available to achieve this purpose, include which aortoiliac bypass, aortofemoral bypass, thromboendartectomy, and angioplasty with or without stent placement.⁵ The endovascular approach is the first line of treatment for this patient, while the open surgical approach was reserved for patients with more extensive occlusion or failed treatment by endovascular.⁴ Transluminal percutaneous angioplasty is an endovascular treatment done by inserting a catheter with a balloon to the lesion location in the affected artery. This balloon will be dilated to open, increase the artery luminal diameter, and press the plaque to the arterial wall. This procedure is usually followed with stent placement to maintain the dilation after the procedure.^{1,6}

Patency is one of the outcomes concerns after endovascular therapy. Clinically, patency, defined as blood vessels, remains patent-proven by imaging techniques showing blood flow in the treated artery.⁷ Patency in the context of stent angioplasty is one of the indicators in determining treatment success. This review discusses long-term patency as a stent angioplasty success indicator in treating aortoiliac occlusive disease. Long-term patency was defined as stent patency up to five years after receiving the treatment. Three types of patency are discussed in this review: primary patency assisted primary patency, and secondary patency. This review proceeded due to the scarcity of studies assessing the long-term patency of stent angioplasty in patients with aortoiliac occlusive disease. Therefore, this study aims to contribute to giving evidence regarding this topic.

Method

This study reviewed the long-term outcome of angioplasty patency in patients with aortoiliac occlusion disease. Literature searching was conducted on several online databases, including Cochrane, PubMed, and EBSCOHost. Keywords used for database searching were angioplasty, stent, vascular patency, aortoiliac occlusive disease, and its derivatives. Several inclusion and exclusion criteria were applied. Inclusion criteria include 1) Meta-analysis, Systematic review, Randomized Controlled Trial (RCT), Cohort, and Case-control studies; 2) clinical studies conducted in human patients; 3) full-text available; 4) Studies in aortoiliac occlusive disease across all degrees of severity based on TASC. Exclusion criteria applied in this study were 1) Study without long-term patency as an outcome, 2) patency not due to restenosis, and 3) case series, case report, editorial, and commentary studies. Critical appraisal for studies included in this study was conducted based on a checklist from the Oxford Centre of Evidence-Based Medicine (CEBM) for systematic review and prognosis studies.

Results

Literature searching using the specified keywords resulted in 26 titles acquired (figure 1). Screening of title and abstract using the inclusion

and exclusion criteria resulted in 18 titles being excluded. After duplicates were removed, six titles were acquired that met the inclusion-exclusion criteria.



Figure 1. Study flowchart

One systematic review and five cohort studies were acquired based on inclusion-exclusion criteria. A critical appraisal assessing each study's validity was conducted based on the CEBM checklist for cohort studies and the checklist for systematic review studies. All the studies met the valid and reliable study criteria based on the appraisal. Cohort Studies details are presented in Table 1, including data such as author, year of publication, study sample's characteristics, treatment, and outcome summary. Table 2 presents some information acquired from the systematic review study included in this review.

Discussion

Angioplasty is the first line of treatment for aortoiliac occlusive disease. This procedure is usually followed by stent placement, which can maintain the dilated, previously occluded artery and maintain blood flow for a more extended period. Patency is one outcome in angioplasty treatment, defined as restenosis, that is less than 50%, as viewed using CT angiography or duplex ultrasound.⁸⁹ Database searching conducted in the literature review resulted in six studies assessing patency in aortoiliac occlusive disease patients who underwent stent angioplasty. All the studies used the exact definition of patency, divided into primary, assisted primary, and secondary patency. This review includes four retrospective Cohort, one prospective Cohort, and one systematic review.

The patency reported by these studies varies widely. Some studies report patency over 60 months or five years, while others only report over one or two years after treatment. Primary patency is reported by all six studies, with an overall 60-month patency ranging from 74.7% to 83.9%. Pulli et al.'s study was conducted in 2011 with 225 samples, and the reported primary patency ranged from 77.7% to 82.4%.¹⁰ Mwipatayi et al. reported 74.7% primary patency in 60 months using the same stent type.¹¹ Vertes et al. reported primary patency in three timeframes, 12, 24, and 60 months, with primary patency of 93.2%, 86.5%, and 76.9%, respectively. The stent used in the Vertes et al. study was not specified.¹² Higher primary patency rates are reported by Squizzato et al., with 86.9% primary patency in 60 months. This study used self-expanding covered stent (SECS) for stent angioplasty.¹³ Studies from Liang et al. with smaller samples of 15 patients reported primary patency in 12, 36, and 60 months of 92,3%, 83,9%, and 83,9%, respectively.¹⁴ Systematic review by Mwipatayi et al. reported primary patency in 12 months ranges from 83.6% to 92.0% based on real-world data acquired through non-randomized controlled settings, which reflected daily practices better than controlled studies.^{15,16} Generally, data gathered to report primary patency are gathered retrospectively through medical records with minimal intervention controls.

Assisted primary patency was generally higher than primary patency. Pulli et al. reported an assisted primary patency in 60 months of 85.5% to 90.6% for patients treated by balloon stent.¹⁰ Mwipatayi et al. reported 60 months of assisted primary patency of 84.7%. Meanwhile, the study by Vertes et al. reports a higher assisted primary patency rate of 95.8% in 60 months.¹² Some studies, which include a study by Squizzato et al., Liang et al, and systematic review by Mwipatayi et al., do not report assisted primary patency.¹³⁻¹⁵ Assisted primary patency is defined as a patency rate after an additional endovascular or surgical treatment given before the next restenosis happened which definitely, as shown in this review, gives higher patency rate than primary patency which does not get additional treatment.

Secondary patency is the rate after secondary endovascular or surgical treatment after the second restenosis.^{5,7} Secondary patency rates are generally higher than primary and assisted primary patency rates. Pulli et al. report secondary patency for 60 months of 92.8% of patients treated using balloon-covered stent angioplasty.¹⁰ Using the same stent, Mwipatayi et al. report a secondary patency rate in 60 months of 96.3%.¹¹ Vertes et al., using the unspecified stent, reported secondary patency in 12,24 and 60 months of 99% in all timeframes.¹² Squizzato et al., using SEC's stent, report a 95.8% secondary patency rate in 60 months.¹³ Liang et al., with 15 patients, reported a 100% secondary patency rate in 12, 36, and 60 months.¹⁴ Systematic review by Mwipatayi et al. reports 12 months secondary patency rate ranges from 95.0% to 100%.¹⁵

Besides patency rates, studies included in this review also compare some other variables and see their effect on patency rates. One such study is a study by Mwipatayi et al. in a trial named COBEST, which compared the patency rate between two different stent types: ballooncovered expendable (BCE) stent and bare metal stent (BMS). In this study, it was found that primary patency, assisted primary patency, and secondary patency were significantly higher in the BCE group than in the BMS group. Patient stratification based on TASC degree showed that this higher patency rate in the BCE group only applied to patients with TASC C and D, while no significantly higher patency rate in the BCE group was reported in TASC B patients.¹¹ Similar results were found in studies assessing these two stents in different occlusion diseases. In patients with chronic atherosclerosis in the mesenteric artery, it was found that 36 months of primary patency was significantly higher in patients treated by BCE stent when compared to patients treated using BMS stent (92% \pm 6% vs. 52% \pm 5%; p <0.003).¹⁷ This higher patency rate in covered stent achieved from the antiproliferative agent used as a coating covering the covered stent, which inhibits hyperplasia of intima cells and prevents macrophage migration through endothel and, therefore, inhibits the inflammatory process that causes restenosis. Bare metal stent, however, lacks this antiproliferative agent and thus has a higher risk for restenosis.¹⁸

One of the considerations for using angioplasty as a treatment for aortoiliac occlusive disease is the type of lesion in the patients usually classified into TASC categories. This classification starts at TASC A, which encompasses simple and focal stenosis, all the way to TASC D, which includes more complex and diffuse lesions.¹⁹ This classification was made to assist in choosing the appropriate treatment modalities between endovascular or open surgery. In the context of patency, the Pulli et al. study compares the patency of angioplasty using covered stents in two different patient groups: the TASC A/B group and the TASC C/D groups. This study showed that no significant patency rates were found between these two groups, indicating the same long-term efficacy of angioplasty in different lesion categories.10 When comparing angioplasty and open surgical treatment, Squizzato et al. studies. It was found that in TASC C/D patients, no significant primary and secondary patency in 60 months was observed for patients receiving angioplasty compared to patients receiving open aortofemoral bypass surgery.¹³ This study shows that in the long term, angioplasty shows comparable patency with open surgery in patients with complex lesions, highlighting the superiority of the endovascular approach in patients with complex lesions. However, more data are needed to confirm this result.

A systematic review by Mwipatayi et al. presented data on the comparison of patency rates between different stent types and stent brands. In this systematic review, Advanta12 was shown to be the most studied stent brand, with a primary patency rate varying between 72% to 92% and a secondary patency rate ranging from 92% to 100%. Other stent brands are also reported in this review; however, a comparison was only possible due to the high heterogenicity of the studies included in the systematic review.¹⁵

This literature review has several limitations. The first limitation is the high heterogenicity found in studies included in this review, with each study having a different sample characteristic than the other. For example, in a study by Pulli et al., the patients were equally divided into two groups based on TASC classification, while in another study, for example by Mwipatayi et al., no details of the sample TASC classification were given. Each study also used different stent types, such as balloon-expendable stent, self-covered stent, and even bare metal stent. This high heterogenicity between studies means that the patency rate found in each study cannot be directly compared to the others.

Conclusions

The patency rate of angioplasty varies widely from one study to another. Generally, 60 months of primary patency was reported to be around 74.7% to 83.9%, with assisted primary patency ranging from 83.7% to 95.8% and secondary patency ranging from 92.8% to 100%. The high heterogenicity between each study makes patency rates highly varied and cannot be compared between studies.

Disclosure

The authors declare no conflict of interest.

Role of authors

Conceptualization IHS AJU, Data curation IHS, Formal analysis IHS, Funding acquisition HIS AJU, Investigation HIS AJU, Methodology HIS AJU, Project administration HIS AJU, Resources HIS AJU, Software HIS AJU, Supervision AJU, Validation AJU, Visualization HIS AJU, Writing original draft preparation HIS AJU, Writing review and editing HIS AJU.

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