Covered stents in aortoiliac occlusive disease
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DOI:
10.1016/j.ejvs.2014.08.009
10.1016/j.jvir.2015.04.007

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Document Version
Publisher's PDF, also known as Version of record

Publication date:
2015

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):
DOI: 10.1016/j.ejvs.2014.08.009, 10.1016/j.jvir.2015.04.007

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CHAPTER 10.

Summary and discussion
SUMMARY AND DISCUSSION

It has been eight years since the TransAtlantic Inter-Society Consensus Group published the TASC-II guidelines which advises on treatment strategies in arterial occlusive disease, based on lesion morphology.\textsuperscript{1} Short, simple lesions (TASC A/B) are advised to be treated endovascularly, whereas more extensive, complex lesions (TASC C/D) should be surgically reconstructed.

As stated in Chapters 2 and 3, surgical treatment options consist mainly of aortoiliac and aortobifemoral bypass grafting, which are associated with outstanding patency rates, up to 86.3\% at five years.\textsuperscript{2} Unfortunately, these operations are related to an 8.3-12.2\% complication rate and a 3.3-4.4\% mortality rate, which has not decreased during the past decades.\textsuperscript{3} Late complications include incisional hernia (incidence of 9.8\%)\textsuperscript{4} and postsurgical adhesion formation, which are the most important causes of small bowel obstruction and inadvertent enterotomies.\textsuperscript{5} Endovascular treatment may reduce early and late complications, as well as the persistent mortality rate. This justifies the search for minimal invasive alternatives.

Many studies have been published regarding the use of stents in aortoiliac occlusive disease. Chapter 3 presents an overview which outlines the results of various strategies and materials used. Reported patency rates in cohort studies are better for covered balloon expandable stents (CBES) than bare metal stents (BMS). However, the studies published to date consist of primary and selective stent strategies, the use of self expandable or balloon expandable stents, bare metal stents, covered stents, different lesion morphologies and different definitions of patency. As a consequence, these studies are very difficult to compare.\textsuperscript{6}

In isolated occlusive lesions of the infrarenal aorta, possible disadvantages of endovascular therapy using bare metal stents are the risk of distal embolization (up to 16\%)\textsuperscript{7} and vessel rupture during intervention (especially in eccentric and heavily calcified lesions). The use of covered stents would treat any rupture instantly and captures thrombus between the vessel wall and stent fabric, thereby preventing distal embolization. In the cohort study presented in Chapter 4, no vessel wall rupture or distal embolization was observed. The overall 30 day complication rate was 6\%, which was low compared to other studies (0-28.5\%).\textsuperscript{7-15} In isolated aortic lesions, primary patency rate was 100\% up to two years. The use of CBES stents in the iliac artery was outlined in Chapter 5. With the use of a primary stenting strategy, CBES resulted in a primary patency rate of 88.7\% at one year and 71.5\% at four years. Freedom from target lesion revascularization (TLR) was 74.4\%
at four years. When CBES were placed after previous stent placement, primary patency rates were significantly (P=.03) lower, 53% at four years. This might be influenced by the fact that the patients treated repeatedly are those with more severe or progressive arterial disease.

In the Dutch Iliac Stent Trial trial, using BMS, patency rates were better with the use of a selective stent strategy, compared to primary stent placement. A meta-analysis showed that a primary stent strategy resulted in significantly higher patency rates for TASC C/D lesions.

In occlusive lesions located at the aortic bifurcation kissing stents have frequently been used. The reported one-year primary patency rate varies between 70-100% with a morbidity rate of 6% to 24%, and distal embolization was reported up to 8% (Chapter 3). The use of CBES in kissing configuration resulted in a one-year primary patency of 96.9% and four-year patency of 71.5%. Freedom from TLR was 76.5% at four years (Chapter 6). Patency rates were mainly effected by stent occlusions, possibly due to single antiplatelet therapy.

The positioning of kissing stents and the radial mismatch (the discrepancy between the stented lumen and the aortic lumen) in this stent configuration have been identified as possible factors that influence patency of kissing stents. It causes flow perturbations and thrombus formation which decrease stent patency (Chapter 7). The Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) technique was developed (Chapter 7) in order to reduce radial mismatch, to create a more anatomical and physiological reconstruction and to prevent distal embolization.

With the use of anatomic vessel phantoms and computer models we have assessed the geometry of CERAB compared to kissing stents (Chapter 8). As hypothesized, the CERAB configuration showed the lowest radial mismatch. Covered kissing stents led to the highest radial mismatch, and therefore, in theory, may have the highest risk of re-stenosis.

The first results of the CERAB technique have been described in Chapter 9. Calculated primary patency rate was 87.3% at one year and 82.3% at two years. Secondary patency rate was 95.0% at two years. Importantly, 30-day major complication rate was 1.9% and mortality rate was 0%. The CERAB technique shows promising results and appears to be safe. The one year primary patency rate of CERAB (87.3% [Chapter 9]) was lower than the primary patency rate of kissing CBES (96.9% [Chapter 6]). In the CERAB group however, 94% of the lesions were classified as TASC-II C/D and in the kissing CBES only 38%. This would make a comparison between the two studies unreliable.
Possible stent infections occurred twice in our studies (Chapters 4, 6). One aortic stent was proven to be infected and was removed surgically, the other patient died because of sepsis and a stent infection could not be ruled out. Although not proven in literature, covered stents may be more prone to infection than bare metal stents, since foreign material is implanted. Therefore the use of antibiotic prophylaxis seems mandatory.

**FUTURE PERSPECTIVES**

In five years the long term patency rates of the CERAB technique will be known. If these results are satisfactory, it may lead to an “endovascular first” approach in occlusive lesions of the aortic bifurcation. Surgical treatment modalities are still optional after failure of endovascular treatment.

One of the advantages of the current CBES is the ability of creating any shape without losing radial force. Computer models could calculate the ideal stent position to create a customized bifurcation, based on patients’ anatomy and calculated flow patterns. In theory decreased or stagnant blood flow results in lower shear stress, which is associated with increased neointimal thickening, hereby leading to stenosis. Flow studies are needed to show whether the CERAB geometry leads to laminar flow.

Frequently there are collateral arteries in aortoiliac occlusive disease, such as lumbar arteries and the inferior mesenteric artery. In the CERAB technique, these arteries could be occluded by the covered stent. In order to preserve the inferior mesenteric or renal arteries it is feasible to create chimneys alongside the CERAB, although results have to be awaited. However, a brachial access is needed for this technique, related to a risk on cerebral complications. Moreover, we did not observe any visceral or spinal cord ischemic events.

One of the critical issues of the use of CBES remains the cost-effectiveness. As showed by Indes et al. endovascular techniques are cost-effective on short term. The shorter in-hospital stay contributes to this reduction. On the long term however, reinterventions and patency rates will determine the cost-effectiveness compared to open reconstructions. A cost-analysis should be performed on the use of the CERAB technique.

Ideally, a randomized controlled trial should compare surgical bypass procedures to kissing stents or the CERAB technique to assess for morbidity, mortality and cost-effectiveness. However, these lesions have a low incidence in a group of patients with high morbidity. Therefore, the feasibility is low and the highest obtainable level of evidence may consist of the long term results of cohort studies.
In the search for less invasive techniques laparoscopy is used too. It may prevent late complications such as incisional hernia and adhesion formation. Drawback is the technical difficulty and learning curve, mainly based on the anastomosis of the prosthesis. A recent study by Segers et al. showed the results of a new technique (EVREST) in which the aorta is approached by laparoscopy and thereafter a stentgraft is positioned after puncture of the aorta. In twelve patients, the mean operative time was 265 minutes. Median duration of aorto-prosthetic connection was 60 seconds.20 The role of conservative treatment in aortoiliac occlusive disease by means of supervised walking exercise are currently investigated in the SUPER trial.21 For patients suffering from intermittent claudication there is a rationale to start with supervised walking exercise, while patients with critical limb ischemia obviously demand a more upfront approach.

GENERAL CONCLUSION
In this thesis we have outlined the current treatment strategies for aortoiliac occlusive disease as well as the results of the use of CBES and the CERAB technique. The short term results of CBES are promising. The CERAB technique appears to be a safe and effective alternative for open surgical reconstruction in patients with complex arterial occlusive disease of the aortic bifurcation.
REFERENCE LIST


