Covered Stents for Endovascular Treatment of Aortoiliac Occlusive Disease

A Systematic Review and Meta-Analysis

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Abstract

Purpose: The goal of the current study was to summarize available literature and to determine whether covered stents are superior to bare metal stents for the treatment of AIOD, in terms of both periprocedural and long-term outcomes.
Methods: A meta-analysis of 47 studies was conducted with the use of random effects modeling. The incidence of adverse events during follow up among the individual included studies was synthesized.
Results: The reported primary patency rates for the non-covered and covered stent group during an average follow up of 24.3 months among the individual studies, were 84% and 92% respectively, while surgical or endovascular re-intervention was required in 10% of non-covered stent cases and in 6% of covered stent cases. Combining TASC C/D lesions together 12 studies reported 92% (95%CI:89%-95%) primary patency in the covered stent group, while 7 studies reported 75% (95%CI: 60%-88%) primary patency for cases treated with non-covered stents.
Conclusion: This study demonstrated that covered stents are safe and effective when utilized for the treatment of AIOD. Covered stents were associated with statistically significant higher odds of primary patency in both the overall cohort and in more complex TASC C/D lesions. However, additional comparative analyses between covered vs bare metal stents are needed to determine the most optimal treatment modality for AIOD.

Introduction

Figure 1 - "GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. © 2019. Keith.
Please see Instructions for Use for complete device information, including approved indications and safety information.

Aortoiliac occlusive disease (AIOD) impacts the aortic bifurcation and iliac arteries. The diseased lesions are either stenotic or fully occlusive resulting in a triad of signs and symptoms including claudication, weak peripheral pulses, and/or impotence.[1] Historically, the treatment of AIOD was accomplished with open surgical techniques, which demonstrate good long-term patency rates but also high peri-operative mortality and morbidity rates.[2,3] For this reason, standard treatment for AIOD in the last couple decades has largely shifted to an endovascular approach.[4]

Bare metal stents (BMS), including balloon-expandable and self-expanding stents have shown favorable technical success and durable vessel patency.[4–7] Covered stent grafts, originally intended for aneurysms or arterial ruptures, are now commonly used for AIOD, as they offer a potential advantage in preventing in-stent restenosis and reduce the risk for distal embolization in complex disease.[4–7] The polytetrafluoroethylene (PTFE) covering of covered stents prevents the exposure of macrophages to atherosclerotic tissue, reducing cytokines and growth factor secretion and directly blocks smooth muscle cell migration and neointimal tissue growth, due to its design (i.e. stent struts).[8,9] Additionally, covered stents have been associated with improved flow patterns (i.e. laminar flow) compared to bare metal stents[10] and as such lower thrombosis risk, especially in "kissing-stent" procedures. [11,12]

However, clinical decision making regarding the most optimal stent type remains uncertain, due to the limited number of comparative studies and the lack of specific treatment protocols.[7,13,14] The goal of the current study was to evaluate the safety and efficacy of covered stents compared to BMS in AIOD.

Methods & Materials

This systematic review and meta-analysis was performed according to the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines.[15] See full paper for inclusion criteria.

Two groups were synthesized including cases treated with covered vs. non-covered stents. Odds ratios (OR) between covered vs non-covered stent group for primary and secondary outcomes were synthesized. In all tests, a random effects model was used to account for heterogeneity among studies.

Results

Patients and Lesion Characteristics

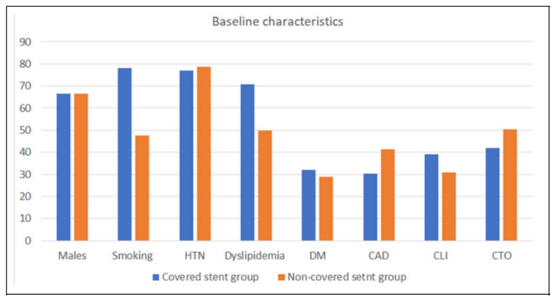

Figure 2 - Baseline Patient Characteristics.[16]

Periprocedural Outcomes

Procedural technical success was 99% and 100% in BMS and covered stent groups, respectively. Overall perioperative complications, including access site hematoma, iatrogenic perforation, pseudoaneurysm formation, acute stent thrombosis, and/or distal embolization were similar between groups, overall 8%.

Long-Term Outcomes

The reported primary patency rates for the non-covered and covered stent group during follow up were 84% (95% CI: 80%-87%) vs. 92% (95% CI: 89%-94%) respectively.

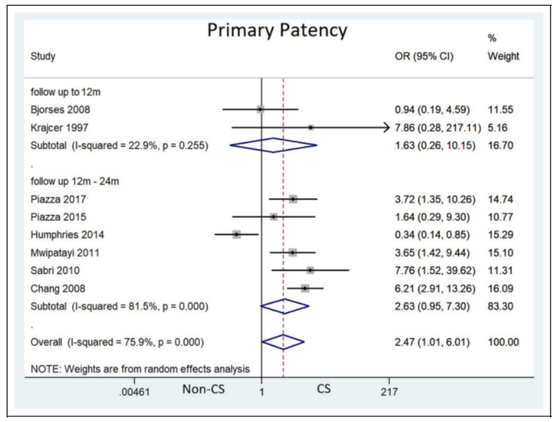

Figure 3 - An overall comparison of primary patency between groups.[16]

Long-Term Outcomes Stratified by TASC Classification

Long-term primary patency was also analyzed after only including TASC C or D lesions. We report a combined 92% (95% CI: 89%-95%) primary patency in the covered stent group and 75% (95% CI: 60%-88%) primary patency for cases treated with non-covered stents.

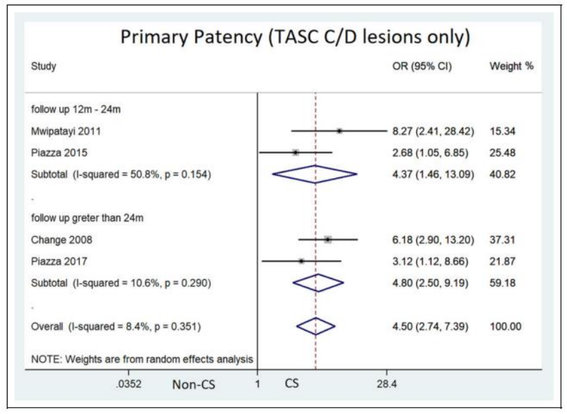

Figure 4 - A comparison of primary patency between groups for TASC C and D lesions only.[16]

Discussion

Conclusions

This study was a meta-analysis and systematic review of 47 studies. The covered stent group exhibited 92% primary patency rate, whereas the non-covered stent group primary patency was 84% during an average follow up of 24.3 months. Sensitivity analysis including the double arm studies showed statistically significant superior patency rates among the covered vs non-covered stents, even when including only TASC C/D lesions.

The benefits of covered stents are likely attributed to its design, which provides a seal for friable athero-sclerotic plaques and an impermeable barrier to neointimal formation, limiting the risk for distal embolization and in-stent restenosis respectively.[17]

Limitations

The results of the present study have several limitations to be considered. First, most of the data was provided by real-world studies and as such limited by potential selection bias. Second, due to the heterogeneity in reported outcomes, only limited direct comparisons could be made between covered vs non-covered stents. It should also be taken into account that most of the pooled estimates were unadjusted risk estimates, indicating that the patient, procedural, and study characteristics might have confounded the outcomes. Further prospective studies are warranted to estimate the annual risk of restenosis/occlusion for covered vs non-covered stents, providing direct comparisons to help identify the most optimal treatment modality for AIOD.

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