

The Experience of Merit Wrapsody® Covered Stent for Aortoiliac Occlusive Disease: A Case Series Report

Pedro Henrique Miguel Nunes ¹, Paulo César Guimarães Câmara ¹, Fábio Henrique Ribeiro de Souza ¹, Rafael de Athayde Soares ^{2*}

¹Instituto de Angiologia de Goiânia

²Hospital do Servidor Público Estadual de São Paulo, IAMSPE

***Corresponding Author:** Rafael de Athayde Soare, Hospital do Servidor Público Estadual de São Paulo, Iamspe.

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Abstract

In this paper, we aimed to report the experience of Merit Wrapsody® use for aortoiliac occlusive disease. We describe a case series of reports of 8 patients submitted to endovascular repair with Merit Wrapsody® for aortoiliac disease. Merit Wrapsody® a flexible self-expanding Cell-Impermeable endoprosthesis indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous (AV) fistula or AV graft, consisting of Nitinol, ePTFE, PTFE structure. In a case series communication, we aimed to describe the feasibility of a PTFE-lined stent for percutaneous treatment of conditions other than AV fistula obstruction. We report the successful use of Wrapsody to percutaneously treat aortoiliac occlusive disease, including covered Endovascular Reconstruction of the Aortic Bifurcation or CERAB technique and kissing iliac stenting, successfully recanalization of post-EVAR limb occlusion and a recanalization of aorta and renal occlusive disease. This case series illustrates the feasibility of the "off-label" use of self-expanded Wrapsody endoprosthesis to percutaneously treat arterial pathology conditions, especially aortoiliac occlusive disease territory with satisfactory and excellent results.

Keywords: atheroembolism; iliac lesion; endovascular treatment

1.Introduction

Endovascular treatment for aortoiliac occlusive disease (AIOD) is well-established worldwide. Occlusive disease of the aorta and iliac arteries often leads to incapacitant claudication and critical limb ischemia.[1] Indications for intervention include life-limiting claudication, rest pain, and tissue loss. Less commonly, atheroembolism caused by an aortic or iliac lesion, most often presenting with acute limb ischemia or "blue toe syndrome," is another indication for endovascular treatment. Approximately 45%-65% of patients present with claudication of the buttocks and thighs, which can drastically reduce quality of life.[2]

Covered stents formerly have been reserved for arteriovenous fistulas, iliac aneurysms, or iatrogenic perforations and ruptures. However, recent studies have provided encouraging results of covered stents compared with bare metal stents for aortoiliac occlusive disease. Several covered stents have been used with technical success for aortoiliac occlusive disease. Most of these stents are made of stainless steel (Atrium Advanta V12, Gore Viabahn VBX, Bard LifeStream) whereas others are made of cobalt chromium (Bentley BeGraft Aortic, Hechingen, Germany). The design of these stents differs significantly and the way the covering material is applied differs from polytetrafluoroethylene on both sides of the stent (Advanta, VBX, LifeStream) or an external layer only (BeGraft).[3]

Merit Wrapsody is a flexible self-expanding endoprosthesis indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous (AV) fistula or AV graft,

consisting of Nitinol, ePTFE, PTFE structure. Several papers showed encouraging results regarding the target lesion primary patency at 30 days of 100% (45/45 patients had reached 30 days of follow-up). The target lesion primary patency for the patients who had completed 12 months of follow-up was 84.6% (33 of 39). [4,5] Indeed, despite the massive use of Wrapsody in venous obstructions, there is a case report published showing satisfactory results of the use of Wrapsody in popliteal artery aneurysms, with 1-year follow-up.[6]

In this study, we aimed to report the use of Merit Wrapsody® for aortoiliac occlusive disease in a case series (8 patients).

Case Presentations

Case 1

A female patient, 84 years old, with arterial hypertension, dyslipidemia, and a previous surgical history of aortobifemoral bypass due to critical limb ischemia was admitted with proximal aorta anastomosis severe stenosis and right limb critical limb ischemia. The patient was submitted to endovascular treatment with the proximal aortic implant of endoprosthesis Wrapsody 16x80mm, followed by a post-dilatation catheter balloon. (Figure 1). The patient was discharged from the hospital on the first day post-operative and 1-year follow-up showed endoprosthesis patency with no endoleaks/stenosis.

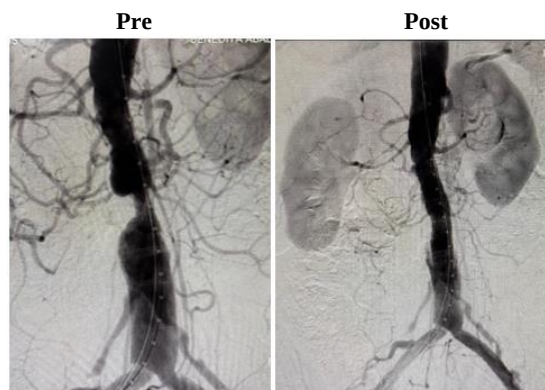


Figure 1: Proximal aortic implant of endoprosthesis Wrapsody 16x80mm, followed by post-dilatation catheter balloon.

Case 2

A female patient, 75 years old, with arterial hypertension, dyslipidemia, and former smoking was admitted with severe bilateral critical limb ischemia. Due to this important symptom, the patient was scheduled to undergo endovascular surgery with covered endovascular reconstruction of aortic

bifurcation (CERAB) technique, using Wrapsody 16x50mm implanted at distal aorta, Begraft 10x40mm implanted at distal aorta and left common iliac artery associated to Begraft 8x57 mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon. The patient was discharged from the hospital on the first day post-operative and 2 2-year follow-up showed endoprosthesis patency and no endoleaks with complete resolution of the previous disabling symptoms.

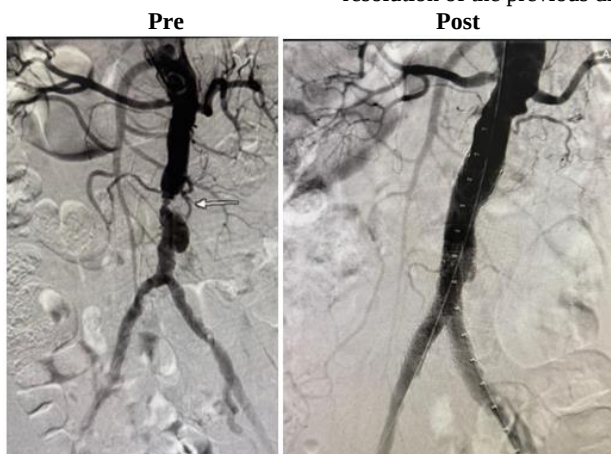


Figure 2: CERAB technique, using Wrapsody 16x50mm implanted at distal aorta, Begraft 10x40mm implanted at distal aorta and left common iliac artery associated to Begraft 8x57 mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon.

Case 3

A female patient, 73 years old, with arterial hypertension, dyslipidemia, and diabetes, was admitted with right inferior limb rest pain and ulcer. The patient was submitted to right common femoral artery endarterectomy with profundoplasty, associated with covered endovascular reconstruction of

aortic bifurcation (CERAB) technique, using Wrapsody 16x80mm implanted at distal aorta, Begraft 7x57mm implanted at distal aorta and left common iliac artery associated to Begraft 9x57 mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon. (Figure 3). The patient was discharged from the hospital on the first day post-operative and 1-year follow-up showed endoprosthesis patency with complete resolution of the previous symptoms.

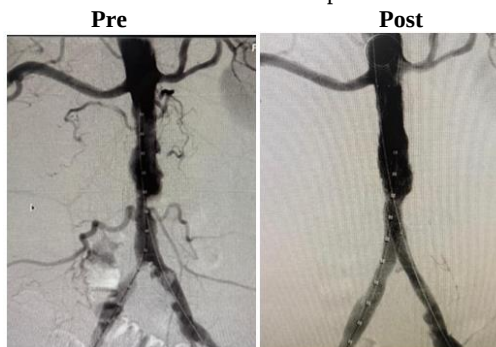


Figure 3. CERAB technique, using Wrapsody 16x80mm implanted at distal aorta, Begraft 7x57mm implanted at distal aorta and left common iliac artery associated to Begraft 9x57 mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon.

Case 4

A female patient, 72 years, active smoker, with arterial hypertension, diabetes, and a previous surgical history of endovascular repair of aortic aneurysm (EVAR) was admitted with endoprosthesis thrombosis. The patient was submitted to endovascular surgery with mechanical thrombectomy using Rotarex followed by an aortic implant of Wrapsody

10x125mm and an iliac kissing stent and implant of Wrapsody 10x125mm at the right iliac common artery and Wrapsody 10x125mm at the left common iliac artery, followed by post-dilatation with a catheter balloon. (Figure 4) The patient was discharged from the hospital the first day post-operative and the 6-month follow-up showed endoprosthesis patency with complete resolution of the previous symptoms.

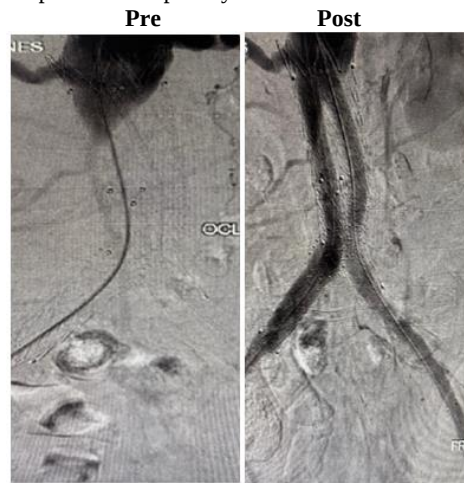


Figure 4: Mechanical thrombectomy using Rotarex followed by an aortic implant of Wrapsody 10x125mm and an iliac kissing stent and implant of Wrapsody 10x125mm at the right iliac common artery and Wrapsody 10x125mm at the left common iliac artery, followed by post-dilatation with a catheter balloon.

Case 5

A male patient, 77 years old, active smoker, with arterial hypertension and dyslipidemia, was admitted with a right inferior limb ulcer and rest pain. The patient was scheduled to undergo endovascular surgery with covered endovascular reconstruction of aortic bifurcation (CERAB) technique, using

Wrapsody 16x80mm implanted at distal aorta, Begraft 9x57mm implanted at distal aorta and left common iliac artery associated to Begraft 9x57mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon (figure 5). The patient was discharged from the hospital the first day post-operative and a 2-year follow-up showed endoprosthesis patency with complete resolution of the previous symptoms and complete ulcer healing.

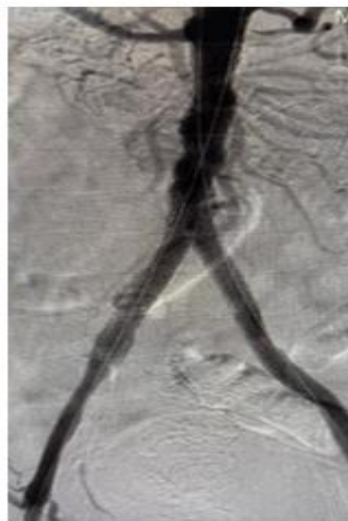


Figure 5: I CERAB technique, using Wrapsody 16x80mm implanted at distal aorta, Begraft 9x57mm implanted at distal aorta and left common iliac artery associated to Begraft 9x57mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon

Case 6

A male patient, 49 years old, with arterial hypertension and dyslipidemia was admitted with right inferior limb ischemia, rest pain, and cyanosis. The patient was submitted to an implant of a Wrapsody 16x60mm at the infra-

renal aorta, followed by post-dilatation (Figure 6). The patient was discharged from the hospital second day post-operative and the 6-months follow-up showed endoprosthesis patency with complete resolution of the previous symptoms.



Figure 6: Implant of a Wrapsody 16x60mm at infra-renal aorta, followed by post-dilatation

Case 7

A male patient, 74 years old, active smoker, with arterial hypertension and dyslipidemia, was admitted with critical limb ischemia at the left inferior limb, associated with rest pain and ulcer. Moreover, the patient had renal artery occlusive disease associated with infra-renal aortic severe stenosis.

The patient was submitted to an implant of ICOVER stent 6x27 at the right renal artery and ICOVER 6x37 left renal artery, followed by an implant of WRAPSODY 16x80mm at the infra-renal aorta and ICOVER stent at the left common iliac artery. (figure 7). The patient was discharged from the hospital on the first day post-operative and a 6-month follow-up showed endoprosthesis patency with complete resolution of the previous symptoms.

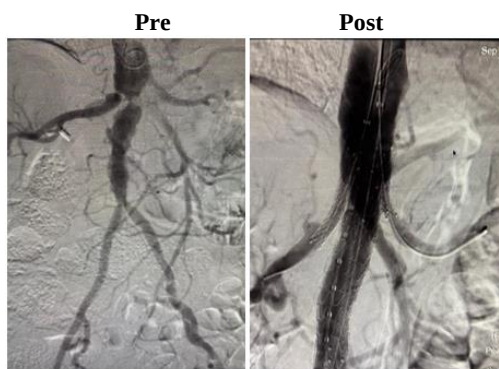


Figure 7: Implant of ICOVER stent 6x27 at right renal artery and ICOVER 6x37 left renal artery, followed by an implant of WRAPSODY 16x80mm at infra-renal aorta and ICOVER stent at left common iliac artery.

Case 8

A male patient, 76 years old, active smoker, with arterial hypertension and dyslipidemia, was admitted with critical limb ischemia at the right inferior limb, associated with rest pain and ulcer. The patient was scheduled to undergo endovascular surgery with covered endovascular reconstruction of aortic bifurcation (CERAB) technique, using Wrapsody 16x80mm

implanted at the distal aorta, ICOVER stent 10x57mm implanted at distal aorta and left common iliac artery associated to ICOVER stent 10x57mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon (Figure 8). The patient was discharged from the hospital the first day post-operative and a 2-months follow-up showed endoprosthesis patency with complete resolution of the previous symptoms.

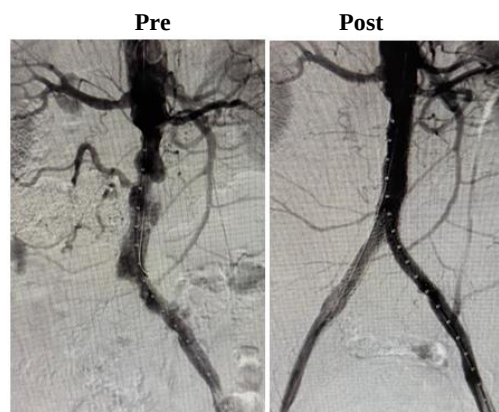


Figure 8: CERAB technique, using Wrapsody 16x80mm implanted at distal aorta, ICOVER stent 10x57mm implanted at distal aorta and left common iliac artery associated to ICOVER stent 10x57mm at distal aorta and right common iliac artery, followed by post-dilatation with catheter balloon

Discussion

This paper presents a challenging case series report of patients with aortoiliac disease, including aortoiliac occlusive disease, aortoiliac occlusive disease associated with renal arteries occlusive disease treated with a new device-

covered stent Wrapsody. The past decades have witnessed a paradigm shift to endovascular strategies as the preferred treatment for mild-to-moderate aortoiliac occlusive disease (AIOD).[7] reports are showing the primary patency, secondary patency, limb salvage, and survival rates at 1200 days of 88%, 95.3%, 86.3%, and 69.9%, respectively.[8] Recently, Covered stents

demonstrated to be optimal for complex lesions, particularly those involving aortic bifurcation, due to the high risk of rupture related especially to heavily calcified arteries.

Currently, available covered stents for the iliac arteries include both self-expanding and balloon-expandable platforms. Recently, a prospective evaluation of the Viabahn stent in 61 iliac arteries provided primary patency rates for the iliac arteries of 98% at 6 months and 91% at 12 months. The mean lesion length was 6.9 cm. Primary technical success, with correct placement and antegrade flow through the prosthesis, was achieved in all patients. Embolization to distal arteries was observed after stent graft placement in two out of five cases where an iliac artery occlusion was treated. No device- or procedure-related deaths were reported.[9]

The Covered Versus Balloon-Expandable Stent Trial (COBEST) was a prospective, multicenter, randomized controlled trial that included 125 patients (168 iliac arteries) with severe iliac occlusive disease who were randomized to receive either the V12-covered balloon-expandable stent (which is similar to the current iCAST stent) or a bare-metal stent (BMS). Lesions treated with a covered stent were significantly more likely to remain free from binary restenosis compared to those treated with a BMS (hazard ratio [HR]: 0.35; 95% confidence interval [CI]: 0.15–0.82). Freedom from occlusion was not statistically different (HR: 0.28; 95% CI: 0.07–1.09). Subgroup analyses demonstrated a significant improvement in freedom from binary restenosis for covered stents in TASC C and D lesions (HR: 0.14; 95% CI: 0.04–0.44). There was also a lower rate of repeat revascularization in the covered stent group compared with the BMS group (odds ratio [OR]: 0.21; 95% CI: 0.07–0.64). Most of the reinterventions were performed between 12 months and 18 months. The amputation rate was similar and low between the two groups.[10]

The Merit Wrapsody® is a self-expandable covered stent consisting of Nitinol, ePTFE, and PTFE structure. Self-expanding stents are better suited for tortuous vessels, especially in areas of permanent external forces such as the external iliac artery. These stents guarantee precise placement only on the end that is deployed first, but newer-generation nitinol self-expanding stents exhibit minimal foreshortening at human body temperature and have a more predictable length once deployed in the body. As a rule, the leading end of the device is always maneuvered just past the planned landing zone, allowing for fine adjustments and retraction during its deployment.[11] Given the PTFE lining, covered stents may overcome some limitations of standard stent designs by introducing a mechanical barrier between intimal hyperplasia and the arterial lumen. This covering potentially also prevents the migration of macrophages in the vascular wall, which are attracted by proinflammatory mediators secreted by the damaged vessel wall. These macrophages release further cytokines, metalloproteinases, and growth factors that contribute to the initiation of the restenotic process.[12]

There were 4 cases in this present paper where we used the CERAB technique to perform an endovascular treatment of the aortoiliac occlusive disease. Indeed, this technique involves the placement of a PTFE-covered stent expanded in the distal aorta with two additional kissing-covered balloon-expandable stents extending from the distal aorta into the common iliac arteries, endovascularly reconstructing the aortoiliac bifurcation.[12] Grimme et al[13] described a 95.1% technical success rate with primary patency rates of 87 and 82% at 1 and 2 years, respectively, and secondary patency rates of 95% through 2 years of follow-up. In a later retrospective multicenter analysis by Saratzis et al[14] in 2021 which included 116 TASC D lesions treated with CERAB, the authors found primary patency, assisted primary patency, and secondary patency rates of 88, 94, and 98%, respectively. These studies demonstrate the effectiveness of CERAB as a potential initial intervention for aortoiliac disease, especially in patients with high associated surgical risk.

This case report series has some limitations since it is a case series report, with a limited number of patients with mild-term follow-up. Larger studies should be performed to evaluate the safety and efficacy of endovascular treatment with Merit Wrapsody® for aortoiliac occlusive disease.

Conclusion

Endovascular treatment with Merit Wrapsody® covered stents for aortoiliac occlusive disease seems to be a safe and effective alternative for patients with chronic limb-threatening ischemia. Further and more robust studies are needed to validate these preliminary results.

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The Authors declare that there is no conflict of interest regarding this paper.

Informed consent has been obtained from the patient for publication of the case report and accompanying images.

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