A Review of the Serranator Alto PTA Serration Balloon Catheter Background, Technique, and Efficacy

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Abstract

The purpose of this study was to understand the practice and benefits of serration technology in balloon angioplasty, to understand the function of the Serranator™ Alto PTA Serration Balloon Catheter, and to understand the current evidence demonstrating the effectiveness of the Serranator™ device. A literature search was conducted to identify all recent articles discussing the Serranator device, and relevant findings from the PRELUDE trial and others were extracted. The Serranator™ device has been found to be a safe and effective treatment in peripheral artery disease (PAD) and has demonstrated significant improvement over plain old balloon angioplasty (POBA) in final residual stenosis achieved, flow volume, inflation pressures, and bailout stent rate. Results are limited by small samples sizes but indicate that the Serranator™ device is a promising advancement in the treatment of femoropopliteal PAD.

Introduction

Balloon angioplasty has long been used as a technique in peripheral artery disease to manipulate vasculature and reopen critically stenotic vessels to improve and restore blood flow to regions of the body at risk for ischemia. Recent advances in vessel preparation techniques have been made to reduce barotrauma, improve penetration of drugs from drug-eluting stents, facilitate vessel expansion, and reduce the risk of dissection as the length and complexity of the lesion increases. One such technique involves scoring the intima of the vessel via serration. The Serranator™ Alto PTA Serration Balloon Catheter (Cagent Vascular, Wayne, PA) is a novel device that aims to improve the mechanical dilation effect of the balloon catheter. The device is an over-the-wire balloon dilation catheter with four embedded serrated strips placed on the longitudinal axis of the balloon. As the balloon inflates, the projections penetrate the intima and media to create linear, longitudinal serrations along the endoluminal surface. The aim of this study was to evaluate the practice and benefits of serration technology in balloon angioplasty for peripheral artery disease, understand the function of the Serranator catheter, and evaluate the current evidence demonstrating the effectiveness of the device.

Methods

A literature search was conducted using both PubMed and Scopus to identify articles discussing vessel scoring and/or the Serranator™ device. Search terms used included “Serranator”, and “serration angioplasty”. As the Serranator is a recent development, only seven articles appeared in searches for the term “Serranator”, with only four of the results discussing primary results of trials involving the device. Results describing final residual stenosis, mean lumen gain, flow volume, Rutherford Clinical Category, bailout stent rate, average inflating pressure, dissection rate, wound healing, and arterial recoil were extracted and compared between studies. Relevant results were then reported.

Results

Serration catheters work based on well-understood principles of physics. The small serrations on the blades of the catheter provide many small points of contact, which increases the applied pressure at each point. The incorporation of serrations made in the vessel plaque combined with inflation make the material much more responsive to directed energy and able to change its shape more predictably. This allows for lower pressures to achieve a full balloon effacement, reducing the risk of barotrauma and the consequences thereof.

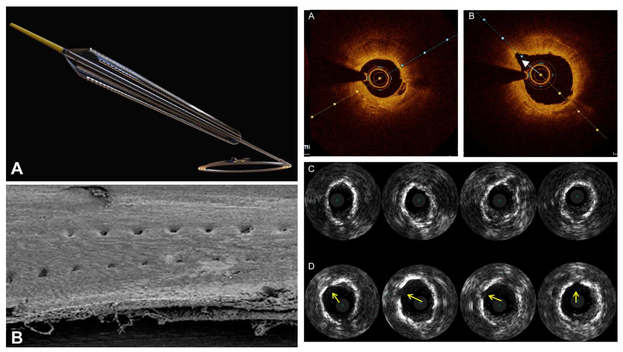

Figure 1: Left: Serranator Balloon Catheter (A) with high-resolution image of animal artery after angioplasty (B), taken from (1). Right: Pretreatment and post-treatment of Serranator-treated arteries by optical coherence tomography (A-pretreatment; B-post-treatment) and intravascular ultrasound (C-pretreatment; D-post-treatment). Taken from (3).

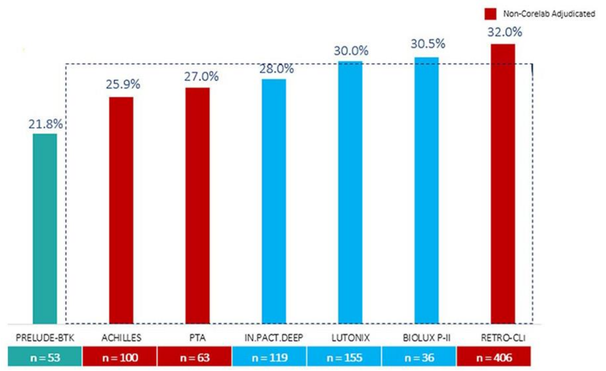

Figure 2: Final residual stenosis after Serranator scoring balloon angioplasty in the entire PRELUDE-BTK study population in comparison with available literature from BTK studies. Red column: non-core lab adjudicated; blue column: core laboratory adjudicated, green column: PRELUDE-BTK. Taken from (2).

Results Continued

Searches on PubMed and Scopus yielded a total of seven relevant articles presenting and/or discussing the results of the Serranator™ device. Three papers came from the primary trial evaluating the safety and efficacy of the device, known as the PRELUDE trial. Three articles were reviews, and the remaining work was an independent study examining vessel recoil with use of the device.

Results from the PRELUDE trial demonstrated that the Serranator™ device is safe and effective in the treatment of atherosclerotic lesions in both the superficial femoral and popliteal arteries. No adverse events related to use of the device were reported, and the bailout stent rate was very low, with a rate of 1.9% in below-the-knee (BTK) subjects. In a sub analysis of the PRELUDE trial, average residual stenosis was often reduced to 20% or less compared to nearly 34% in POBA comparison groups. Notably, use of the Serranator™ device allowed the use of lower operating pressures compared to POBA, with Serranator™ balloons only requiring an average of 5 atm of inflation pressure compared to 9 atm for the POBA group. Clinical improvement was also noted in patients treated with the Serranator™ device, with a majority of patients (70%) demonstrating significant improvements in Rutherford Clinical Category, wound healing, and ankle-brachial index.

The Serranator™ catheter also demonstrated improvement in flow volume compared to POBA treatments, independent of pre-treatment vessel radius. In another trial examining vessel recoil, the Serranator™ device was found to significantly reduce the presence of arterial recoil compared to POBA. Clinically relevant recoil was found to be present in 10% of Serranator™ patients compared to 53% of POBA patients.

It is important to note the limitations of these studies, which include small sample sizes of no more than 60 study lesions and evaluation of primarily short-term outcomes. Despite these limitations, these works demonstrate the exciting potential that serration angioplasty has for advancing the treatment of atherosclerotic lesions. However, randomized controlled trials comparing serration angioplasty with POBA and other revascularization methods are needed to verify these findings and examine patient outcomes.

Conclusions

Recent studies evaluating the Serranator™ balloon catheter are promising and demonstrate that the device may be a significant advancement in the treatment of femoropopliteal PAD in patients with chronic limb-threatening ischemia, with studies showing improvements in residual stenosis, lumen, flow volume, bailout stent rate, clinical status, and wound healing. The Serranator™ catheter appears to be clinically suitable as a primary therapy and may function as stand-alone therapy in PAD patients. Randomized controlled trials in larger patient populations are needed to verify these results.

Acknowledgements

I wish to thank Dr. Geogy Vatakencherry and Dr. John Gossen for their assistance in preparing this abstract and poster presentation.

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