

# Drug-Coated Balloons: The Future Ahead

Experts weigh in on the ongoing trial data supporting the use of drug-coated balloons.

**What is the significance of these investigational device exemption trials, and what does this mean for your future treatment algorithms for drug-coated balloons (DCBs)?**



**J.A. MUSTAPHA, MD**  
PI, LUTONIX BTK TRIAL

“Critical limb ischemia (CLI) has many associated comorbidities, which can make it extremely difficult to treat. Today, many of us struggle with what is the best therapy for our CLI patients. This type of below-the-knee (BTK) landmark trial will shed light on future therapeutic options for these patients while setting the stage and strengthening the foundation of additional studies and research.”



**PATRICK J. GERAGHTY, MD**  
PI, LUTONIX BTK TRIAL

“We know that treatment of CLI requires popliteal and/or tibial intervention in the majority of patients. Our current failure mode isn’t so much found in the restoration of patency to these vessels—we’re already quite good at that—but in our inability to maintain that newly restored lumen. Biologic modification of the injury response is critical to achieving durable success in this challenging territory, and the LUTONIX BTK trial is the first United States IDE to rigorously examine the ability of paclitaxel-coated angioplasty balloons to achieve that outcome. I’m excited that this trial will provide clinicians with superb data for clinical decision-making in CLI. That’s been a rarity in the past, but going forward, savvy clinicians are going to demand that competing technologies provide a similar level of evidence for their treatment. Data-driven CLI therapy—the LUTONIX BTK trial gets us a big step closer to that goal.”



**CARLOS MENA, MD**  
**PI, LUTONIX ISR TRIAL**

"In-stent restenosis (ISR) is one of the most complex clinical issues we have, as the superficial femoral/popliteal arteries are subjected to multiple forces that result in restenosis. In addition to this, patients often have issues getting their risks factors for peripheral artery disease (PAD) under control. Over the last few years, there has been an increased usage of endovascular (i.e., stenting) procedures, and because of this, many patients will experience ISR. Currently, there are no randomized clinical trials that would help us to determine the role, if any, of the DCB technology in this specific clinical setting. There are few other options that have been explored. From the endovascular point of view, if we are able to determine the role of DCB technology in this vexing clinical problem, it will be a step forward in the treatment of patients with PAD.

This trial will clearly determine if there is a role for this technology in this clinical scenario. If positive, this trial will result in DCBs becoming the default strategy for patients with ISR. Given the ease of use, the additional reimbursement (at least in the United States), and the low risk of complications, physicians all over the world would likely endorse this approach. Patients themselves would also favor this approach."



**SCOTT TREROTOLA, MD**  
**PI, LUTONIX AV TRIAL**

"Because of its large size and multicenter nature, this arteriovenous (AV) trial should determine the value of DCBs in hemodialysis fistulas. If a benefit of DCBs is shown over conventional percutaneous transluminal angioplasty, DCBs will become another key tool in our armamentarium against restenosis.

Further, by not leaving anything behind, as one does when placing a stent or stent graft, late concerns about stent integrity will be eliminated. Matching the natural longevity of fistulas with a means of recharging that longevity without a permanent footprint would be a major win for patients with hemodialysis fistulas."