

## A Polymer-Free Paclitaxel-Eluting Stent Versus a Bare-Metal Stent for De Novo Femoropopliteal Lesions: The BATTLE Trial.

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### Résumé:

The primary objective of the BATTLE (Bare Metal Stent vs. Paclitaxel Eluting Stent in the Setting of Primary Stenting of Intermediate-Length Femoropopliteal Lesions) trial is to demonstrate the clinical superiority of the Zilver PTX stent over the Misago stent in the treatment of femoropopliteal lesions. No randomized studies have compared self-expanding paclitaxel-eluting stents with bare-metal stents in the treatment of femoropopliteal lesions. BATTLE is a multicenter randomized controlled trial in patients with symptomatic (Rutherford category 2 to 5) de novo lesions of the superficial femoral or proximal popliteal artery. The primary endpoint is freedom from in-stent restenosis (ISR) at 1 year, with restenosis defined as a peak systolic velocity index  $>2.4$  at the target lesion. The Kaplan-Meier method was used to evaluate time-to-event data for freedom from ISR over the 2-year follow-up period. Between March 2014 and August 2016, 186 patients were enrolled; 91 were assigned to the Misago arm and 90 to the Zilver PTX arm. Kaplan-Meier 1-year estimates of freedom from ISR were 88.6% for Misago and 91% for Zilver PTX (hazard ratio [HR]: 1.2; 95% confidence interval [CI]: 0.6 to 2.4;  $p = 0.64$ ). Comparing Misago with Zilver PTX, 2-year estimates were 6.4% and 1.2% (HR: 7.3; 95% CI: 0.9 to 59.3;  $p = 0.0632$ ) for mortality, 74.6% and 78.8% (HR: 1.2; 95% CI: 0.6 to 2.1;  $p = 0.62$ ) for patency, and 14.4% and 12.4% (HR: 1.2; 95% CI: 0.5 to 2.8;  $p = 0.69$ ) for target lesion revascularization. In the treatment of symptomatic femoropopliteal lesions, the Zilver PTX stent failed to show superiority over the Misago stent in freedom from ISR at 1 year.

**MeSH:** Aged|Aged, 80 and over|Cardiovascular Agents/administration & dosage/adverse effects|Drug-Eluting Stents|Endovascular Procedures/adverse effects/instrumentation/mortality|Female|Femoral Artery/diagnostic imaging/physiopathology|France|Humans|Male|Metals|Middle Aged|Paclitaxel/administration & dosage/adverse effects|Peripheral Arterial Disease/diagnostic

imaging/mortality/physiopathology/therapy|Popliteal Artery/diagnostic  
imaging/physiopathology|Prospective Studies|Prosthesis Design|Recurrence|Risk  
Factors|Stents|Time Factors|Treatment Outcome|Vascular Patency

**Mots clés auteurs:**

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