Safety and Effectiveness of a New Valvulotome: Insights from the LIMBSAVE Registry (Treatment of Critical Limb Ischemia with Infragenicular Bypass Adopting In situ Saphenous Vein Technique)

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Introduction

In the endovascular era peripheral bypass surgery still plays a key role. In situ saphenous vein bypass is a standardized technique. The main limitation of this procedure is the vein diameter. A new hydrophylic valvulotome (HYDRO LeMaitre® Valvulotome; LeMaitre Vascular, Burlington, MA, USA) allows even to disrupt the valves in smaller veins. The aim of this study is to analyze the intraprocedural and technical successes of this new valvulotome.

Materials and methods

In January 2018 in Italy a national, multicenter, observational, prospective registry based on the examination of treatment of critical Limb Ischemia with infragenicular Bypass adopting in situ Saphenous Vein technique (LIMBSAVE registry) begins the enrollment. Until June 2019 345 patients have been enrolled in the registry. All data concerning the procedures were prospectively collected in a dedicated database. The information included demographics, preoperative risk factors, clinical and diagnostic preoperative assessments, intraoperative features, and discharge outcomes, including the safety and effectiveness of the valvulotome during the surgical procedure.
Results
Patients were predominantly male (267, 77.4%) with a mean age of 73.3 years (range 42-95). The mean diameter of the great saphenous vein is 3.9 mm (range 1.7-8) in the proximal part of the thigh, 3.6 mm (range 1.6-7) in the distal part of the thigh, and 3.1 mm in the proximal part of the leg (range 1.6-7.3). The technical success was obtained in all cases (the bypass pulsed after the utilization of the valvulotome). The valvulotome was able to reach the proximal anastomosis in all cases. The mean number of utilisations is 2.5 (range 1-5). No vein perforation has been detected. In 7 cases (2%) a vein lesion occurred. In one case (0.3%) the replacement of the injured vein segment was necessary.

Conclusions
Preliminary intraprocedural outcomes of LIMBSAVE registry show that HYDRO LeMaitre® Valvulotome is safe and effective in disrupting the valves and obtaining the pulsatility of the saphenous vein. The rate of complications related to the utilization of the valvulotome is low. Further examinations are needed to evaluate the long-term outcomes of the bypass in terms of patency, reinterventions, and limb salvage.

Key-words: critical limb ischemia, limb salvage, in situ saphenous vein, peripheral bypass.

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