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K. B. Meyer, MD

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Contact individual: Klemens B. Meyer, MD

Address: Division of Nephrology, New England Medical Center, 750 Washington Street, NEMC#391, Boston MA 02111

UNITED STATES (USA)

Phone: 617-636-5869 Fax: 617-636-8329 E-mail: Klemens.meyer@es.nemc.org

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Control of Post Dialysis Bleeding in Patients on Chronic Oral Anticoagulation Therapy K. B. Meyer, MD, <sup>1</sup> C. S. Jenuleson, MS, <sup>1\*</sup> A. Vital, <sup>1\*</sup> C. H. Schmid, PhD, <sup>2\*</sup> A. B. Whitson, MS, <sup>3\*</sup> S. Finkielsztein <sup>3\*</sup>. <sup>1</sup> Nephrology, Dialysis Clinic Inc., New England Medical Center, Boston, MA. <sup>2</sup>Biostatistics Research Center, NEMC, Boston, MA. <sup>3</sup> Marine Polymer Technologies, Danvers, MA.

When hemodialysis access needles are removed, many patients require prolonged compression of the puncture sites to stop bleeding. An average of 16.0 +/-6.9 minutes compression time was documented among 66 patients at our facility. Extensive compression to stop the bleeding after dialysis results in costly operational inefficiencies, exposes other patients and facility staff to blood borne pathogens and has been acknowledged as a contributory variable to vascular access damage. The purpose of this study was to test the SyvekPatch® (Marine Polymer Technologies, Inc., Danvers, MA) as an agent to promote rapid control of bleeding in hemodialysis patients. The study was conducted in 50 hemodialysis patients in two separate tracks. Each patient served as his/her own control (standard of care was compression with gauze, using either digital pressure or clamps). The order of treatment was randomly assigned. Track 1 evaluated the safety and effectiveness of the product in the general patient population. Track 2 evaluated the product in a high risk patient population (patients who routinely require 15 minutes or more of manual compression with gauze to stop bleeding). The demographics of the two Tracks were very similar. (60% / 40%: Fistula/Graft; 56% male, 44% female; 48% with Diabetes or Hypertension; 50% on concurrent daily prophylactic anticoagulation therapy). During the trial there were no complications in either the control or the treatment group. In the general patient population (Track 1) SyvekPatch® was more effective than the gauze control in 86% of the patients tested. SyvekPatch® stopped bleeding within 5 minutes in 72% (18 of 25) of the patients. Standard care (gauze) stopped bleeding within 5 minutes in 16% (4 of 25) of the patients. In the high risk patient population (Track 2), the Syvek Patch® proved superior in all cases. In Track 2, average compression time with standard care was 18.1+/- 5.5 (mean +/- S.D.) minutes. With the SyvekPatch® the average compression time was 6.4 +/- 2.7 minutes. The SyvekPatch® was found to be a safe and effective method to rapidly control bleeding in hemodialysis patients. There were no cases of re-bleeding when using the SyvekPatch®. The SyvekPatch® was found to be especially useful with hypertensive patients and patients taking concomitant anticoagulation.

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