Prospective, Randomized, Comparative, Non-Inferiority Clinical Evaluation of the Safety and Efficacy of PerClot in Achieving Hemostasis in Splenectomy for Portal Hypertension

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Objective: The purpose of this prospective, randomized, comparative, non-inferiority clinical evaluation was to evaluate and compare the safety and efficacy of PerClot™ with absorbable gelatin sponge and Arista™ in achieving hemostasis in actively bleeding wounds in splenectomy for portal hypertension.

Methods: Forty-five patients undergoing splenectomy for portal hypertension were randomized to receive PerClot, absorbable gelatin sponge, or Arista (n=15 each). All patients were evaluated at 24 hours postoperatively, 3 days postoperatively or at discharge (whichever was earlier), and at 30 days postoperatively.

The primary efficacy endpoint was hemostasis of the first treated wound within 5 minutes of hemostat application. The primary safety endpoint was the occurrence of serious device-related adverse events within 30 days postoperatively. Secondary objectives consisted of the time to hemostasis, the number of applications of hemostat required to achieve hemostasis within 5 minutes, and all adverse events.

Results: The severity of bleeding did not vary significantly among the three treatment groups. No significant difference in the primary efficacy endpoint, hemostasis within 5 minutes, was found between the PerClot and Arista groups (86.7% versus 80.0%, respectively). The 5 minute hemostatic success rate for the gelatin sponge group (40.0%) was significantly lower than the hemostatic success rates of the PerClot and Arista groups ($p<0.05$).

The mean times to hemostasis were 2.25±0.93 minutes, 2.38±1.19 minutes, and 4.17±0.98 minutes for the PerClot, Arista, and absorbable gelatin sponge groups, respectively. One application of PerClot per wound was required to achieve hemostasis within 5 minutes.

No clinically significant adverse reactions occurred in any of the three treatment groups.

Conclusion: There were no clinically significant differences between PerClot and Arista in achieving hemostasis. PerClot yielded a significantly greater success rate for achieving hemostasis than absorbable gelatin sponge. No clinically significant adverse reactions or complications were observed in any treatment group. PerClot can be used as an adjunct therapy for controlling bleeding in splenectomy for portal hypertension.

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