

MEDTRONIC SUMMARY: CLINICAL PAPER

Medtronic provides the following synopsis of clinical publications involving the Veriset™ haemostatic patch.

TITLE	“A Multicenter, Randomized Clinical Trial Comparing the Veriset™ Haemostatic Patch with Fibrin Sealant for the Management of Bleeding during Hepatic Surgery”
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JOURNAL	Published in HPB Dec 2012 DOI:10.1111/hpb.12009

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PURPOSE OF THE CLINICAL TRIAL

The authors prospectively evaluated the safety and effectiveness of the Veriset™ haemostatic patch in hepatic surgery compared to TachoSil™.

METHODS

- This study was a prospective, non-inferiority, multicenter, two arm, randomized, patient-blinded study to compare a haemostatic patch (Veriset™ haemostatic patch) with a fibrinogen and thrombin coated collagen patch (TachoSil™; control) in the management of bleeding during hepatic surgery.
- The study was conducted at six institutions in Europe.
- Patients included in the study were aged >18 years and had a target bleeding site of generalized minor or moderate bleeding that persisted on the cut surface of the liver, in which hemostasis was not achieved utilizing conventional methods and which necessitated the use of a topical hemostat.
- Subjects were randomized to either Veriset™ haemostatic patch or TachoSil™.
- Each treatment was applied in accordance with its respective instructions for use. In the control group, according to the manufacturer’s instructions, the product was left in situ for 3 min, at which point the first inspection was made; this was followed by inspections every 30 s until bleeding stopped. In the Veriset™ haemostatic patch group, the bleeding site was inspected every 30 s from application of the patch until bleeding stopped.

RESULTS

- A total of 101 patients consented to their potential participation in the study. Of these, 50 met the intraoperative criteria and were randomized to study treatment (32 to the Veriset™ group and 18 to the TachoSil™ control group). The most frequent reason for not enrolling a consented patient was lack of an appropriate target bleeding site.
- No significant differences were observed between treatment groups in any demographic, baseline or procedure characteristics.
- The most common types of resection performed were hemihepatectomies and wedge resections.
- The size of the target bleeding site dictated the number of devices applied; the majority of sites were treated with one or two devices.
- The Veriset™ haemostatic patch achieved haemostasis significantly more quickly than the control device (median time to haemostasis: 1.0 min versus 3.0 min; $P < 0.001$).
- For bleeding sites that were > 100 cm², the Veriset™ patch also achieved hemostasis more quickly than the control device (median time to hemostasis: 1.0 min versus 4.0 min; $P = 0.033$).
- No observed difference between the Veriset™ haemostatic patch and TachoSil™ groups with respect adverse events, serious adverse events, transfusions or other post-operative outcomes.

CONCLUSION

Regardless of bleeding severity or surface area, the Veriset™ haemostatic patch achieved haemostasis significantly faster than the control device in patients undergoing hepatic resection. It was safe and easy to handle in open hepatic surgery.

	% Patients Reaching Haemostasis		
	< 1 min	3 min	4 min
Veriset™ haemostatic patch	78.1%	94%	100%
TachoSil™	-	71%	71%

SAFETY AND EFFECTIVENESS OF A SYNTHETIC HEMOSTATIC PATCH FOR INTRAOPERATIVE SOFT TISSUE BLEEDING

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Medical Devices: Evidence and Research; 31 March 2015. 8 167-174.

INTRODUCTION

The effective control of intraoperative bleeding is challenging, and conventional hemostatic measures (e.g. sutures, clips, electrocautery) are often impractical. Topical hemostatic agents have been developed, but there is still a need for more effective products that are safe and easy to use. The Veriset™ hemostatic patch is a recently developed topical hemostat composed of absorbable oxidized cellulose and hydrogel components. It takes the form of a ready-to-use patch that should be applied polyethylene glycol-side down on to the bleeding site, where it works with physiological fluids to initiate hemostasis. It lacks any human- or animal- derived components and is therefore unlikely to transmit viruses or elicit an immune response.

PURPOSE OF THE STUDY

The purpose of this study was to provide evidence of the safety and effectiveness of the Veriset™ hemostatic patch when applied to soft tissue bleeding sites in a variety of surgical procedures.

METHODS

- A prospective, multicenter, single-arm, post-market study of the Veriset™ hemostatic patch to support its safety and effectiveness in causing hemostasis (N=30)
- During surgery, a target bleeding site (TBS) was identified and assigned a severity level of Type 2 (oozing/mild) or Type 3 (moderate).
- The Veriset™ hemostatic patch was applied, and the time to hemostasis was then assessed. It could be cut as necessary to cover the bleeding site with 1-2 cm margins.
- Patients were assessed after 24 hours (in-person), after 7 days (phone), after 30 days (in-person), and after 90 days (in-person) post-surgery.
- Primary effectiveness endpoint: Percentage of success in causing hemostasis within 5 minutes of applying the Veriset™ hemostatic patch
- Secondary effectiveness endpoints: Percentage of subjects achieving hemostasis within 1 minute; Median time required to achieve hemostasis

- Primary safety endpoint: Number of device-related serious adverse events (SAEs) per subject during the 30 days after surgery
- Secondary safety endpoint: Incidence of reoperation for device-related bleeding complications during the 5 days after surgery

RESULTS

- Of the 30 subjects included in the study, 28 completed the 90-day follow-up visit.
- One subject was lost to follow-up between the 30- and 90-day visits.
- One subject died before the 7-day assessment from embolic complications of a pre-existing atrial thrombus that was unrelated to the test device.
- The majority of the subjects had Type 2 bleeding severity (N=22) and the remaining subjects had Type 3 bleeding severity (N=8). In 86.7% (26/30) of subjects, conventional methods of obtaining hemostasis were attempted first but were deemed ineffective. In the remaining 4 subjects, the investigator determined that conventional methods were impractical.
- The median time to hemostasis was 1 minute. Hemostasis was obtained within 1 minute in 70% (N=21) of subjects and within 5 minutes in 96.7% (N=29) of subjects.
- There were a total of 20 SAEs in 36.7% (N=11) of the subjects during the 30 days after surgery, none of which were device-related.
- There was no incidences of reoperation for device-related bleeding complications during 5 days after surgery.

CONCLUSION

The Veriset™ hemostatic patch is effective in promoting hemostasis when applied to soft tissue, and does not elicit any safety concerns.

RESULTING IN TBS	PROCEDURES RESULTING IN TBS	SOURCE OF BLEED (% BY TYPE)	LAYERS OF GAUZE PENETRATED PRIOR TO APPLICATION	TIME TO HAEMOSTASIS (MINUTES)
Colectomy	3	100% Resection/Dissection	8.33±2.87	0.5±0.0
Low Anterior Resection (LAR)	1	100% Arterial	39.00±0.00	4.0±0.0
Lymphadenectomy	11	100% Resection/Dissection, 72.73% Venous	14.36±8.99	1.86±1.62
Esophagectomy	4	100% Resection/Dissection	7.25±2.38	1.13±0.22
Gastrectomy	1	100% Resection/Dissection	8.00±0.00	0.5±0.0
Pancreatic Bed	3	100% Resection/Dissection	7.00±1.63	0.5±0.0
Cholecystectomy	1	100% Resection/Dissection	8.00±0.00	1.5±0.0
Mastectomy	1	100% Resection/Dissection	4.00±0.00	0.5±0.0

A Prospective, Randomized, Single-Blind Study to Compare the Veriset™ Hemostatic Patch to TachoSil™* as an Adjunct to Hemostasis in Subjects Undergoing Cardiovascular Surgery

CSR NUMBER: COVEUCV0140-CSR
DATE OF REPORT: March 5th, 2014
PRODUCT DISCUSSED: Veriset™ Hemostatic Patch

INTRODUCTION

This study was designed to assess the safety and effectiveness of Veriset™ patch in cardiovascular procedures by comparing Veriset™ patch to TachoSil™* (control) in subjects undergoing cardiovascular surgery involving the aorta (e.g., aortic valve replacement (AVR), David procedure, Bentall procedure, abdominal aortic aneurysm repair), the surface of the heart (e.g., mitral valve repair, tricuspid valve repair), or CABG (coronary artery bypass graft).

OBJECTIVE

The primary objectives of this study were to determine the safety and effectiveness of Veriset™ hemostatic patch when used as an adjunct to hemostasis during cardiovascular procedures.

Data from 90 patients from 12 centers are included in this analysis.

EFFICACY RESULTS

Superiority of Veriset™ hemostatic patch over TachoSil™* was established based on both the Intent-to-Treat (ITT) and the Per-Protocol (PP) populations in the interim analysis. Results from this final analysis confirm the superiority of Veriset™ hemostatic patch over TachoSil™*.

For the PP population in this final analysis the median time to hemostasis in the Veriset™ patch group and TachoSil™* group was 1.5 mins and 3.00 mins, respectively. The number of subjects who achieved hemostasis at all treated bleeding sites within 3 minutes was similar among both groups, 36/41 (87.8%) Veriset™ hemostatic patch subjects and 41/45 (91.1%) TachoSil™* subjects.

SAFETY RESULTS

No subjects in either treatment group required a reoperation for bleeding complications up to 5 days post-surgery, or experienced device-related adverse events or unanticipated adverse device effects during the course of the study.

In the As-Treated (AT) population in this final analysis, 12/44 subjects and 10/45 subjects treated with Veriset™ hemostatic patch and TachoSil™*, respectively, exhibited at least one serious adverse event up to 30 days post-surgery. No subjects in either treatment group required a reoperation for bleeding complications up to 5 days post-surgery, or experienced device-related adverse events or unanticipated adverse device effects (UADEs) during the course of the study.

CONCLUSION

Veriset™ hemostatic patch is more effective than TachoSil™* at obtaining hemostasis in cardiovascular procedures, while exhibiting similar safety.

This concludes the clinical synopsis of this publication

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IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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