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Clinical Investigation Paper

Performance of GELITA-SPON® RAPID³ during use in open vascular surgeries, as an alternative to traditional hemostatic agents.

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Abstract

Background: Achieving hemostasis in vascular surgery is often challenging. This single-center, retrospective review of 449 Patient data shows the excellent hemostatic effectiveness and biodegradation of a ready to use out of the package Gelatin-Sponge in several different Vascular Surgery procedures.

Methods: Only procedures, in which GELITA-SPON® RAPID³ has been used in place of other topical or active hemostats in vascular procedures at the RVH were considered in this evaluation.

Results: GELITA-SPON® RAPID³ has been observed to be an effective, economical and fast-acting hemostatic agent (hemostat) that is ready to use right out of the package. The hemostat began working immediately upon contact with blood and fluid, and was still easily handled when saturated. No complications have been observed in any of the studied cases.

Conclusion:

GELITA-SPON® RAPID³ confers advantages over other hemostatic agents in vascular surgery without any additional drawbacks, which is underscored by the absence of complications in over 449 vascular procedures.

Introduction

In vascular surgery, hemostasis is often challenging to achieve, because arterial and graft sutures and anastomoses must be meticulously performed, and the concerning patients are often treated with a high dose of antiplatelet medication for cardiovascular comorbidities.[1] Vascular wounds must be safely and effectively closed and bleeding controlled to ensure the success of surgical procedures. Failure to do so can result in serious or possibly life-threatening complications, including recurrence of bleeding, infection and occlusion of the prosthesis, stenosis and thrombosis of the artery, reoperation, wound infections and healing disorders. The form and shape of the hemostat and its tissue adhesion are important to enable proper handling, which is essential to control bleeding.[2] By using local hemostats, it is possible to improve the condition of the patient, reduce complications, and lower direct and indirect costs[2]. The hemostat improves blood conservation by reducing blood loss (anemia and bleeding are major sources of morbidity and mortality for a broad range of patients who have undergone a surgical procedure[3]), saving transfusion blood, avoiding the adverse effects of systemic hemostatic drugs, and shortening the time to hemostasis and time spent in the operating room.[2] Furthermore, the use of a local hemostat may reduce the requirements for post-operative care, i.e. meaning a shorter stay in the intensive care unit or hospital stay for the patient.

A significant concept in the use of hemostats is usability. A number of hemostats require a certain amount of "preparation" time and cannot be used directly from the packaging, this is less important in elective surgical procedures, but may well be critical in emergency procedures. Moreover, many hemostats require mixing or wetting prior to use.

To more effectively manage the bleeding in surgical procedures, GELITA MEDICAL GmbH has developed the hydrophilic GELITA-SPON® RAPID³ as a fast-acting sponge hemostat, made of 100% purified gelatin, which is characterized by a high pore density, increased lamellae, and a high nano scale roughness of the surface.

This novel hemostat is a real alternative to traditional hemostatic agents, as the name GELITA-SPON® RAPID³ refers to: the quick application of the product out of the packaging; how rapidly it absorbs blood and fluids upon application; and how fast it is reabsorbed by the body. Compared to other topical hemostats, which are slow to be absorbed within the body or require removal at a later date, GELITA-SPON® RAPID³ is readily biodegradable and decomposes within days with little risk of encapsulation.

The primary aim of this retrospective study was to characterize the patient population, and to evaluate the performance and safety of GELITA-SPON® RAPID³ in vascular surgery patients in a real world setting.

Patients and Methods

A retrospective evaluation of patient-records from a period of over two years was performed. In this timeframe GELITA-SPON® RAPID³ was used in over 449 vascular procedures, conducted by Dr. Sandy McDonald in the Royal Victoria Regional Health Center, Barrie, Ontario, Canada.

The data were extracted from the database at the Royal Victoria Regional Health Center in Canada. In accordance with the Canadian data protection regulation to protect patient confidentiality, the data were de-identified.

After extraction of the vascular surgical cases, real-world usage of the GELITA-SPON® RAPID³ was evaluated.

Patients included for analysis, were hospitalized for elective or emergent vascular surgeries, with surgical interventions conducted between December 2011 and December 2013. Patients underwent endarterectomies of the aorta, carotid, femoral and popliteal arteries, bypasses involving the aorta and bi-femoral and femoral and popliteal arteries, repair of stenotic arteries and aneurysms in the abdominal aorta or femoral artery, grafts, patches and angioplasties, and combinations of these interventions.

Study variables evaluated included: ASA classification according to the American Society of Anesthesiologists, type of intervention, medication, medication, co-morbidities, length of hospital stay, complications, and hemostat presence at 1 month after surgery. Descriptive analyses were conducted on these variables.

Results

The GELITA-SPON® RAPID³ was used in a total of 449 patients. The patient characteristics can be found in table[1]. The patients treated were between 20 and 90 years, with an average age of 71, and both genders are represented in this evaluation, with over 60% being male.

These patients in which the GELITA-SPON® RAPID³ was used underwent a wide range of procedures: Endarterectomies of the aorta, carotid, femoral and popliteal arteries in 228, bypasses involving the aorta and bi-femoral and femoral and popliteal arteries in 88, repair of stenotic arteries and aneurysms in predominantly the abdominal aorta or femoral artery in 74, grafts, patches and angioplasties in 31, and a combination of these in 28 cases. All of these procedures were performed under open conditions.

In addition these patients suffered from a multitude of co-morbidities, and the physical status, classified according to the "ASA" table, further underlines the diversity of this population. The majority of the patients were on antiplatelet drugs (>60%), and less than 5% received coumarin derivatives. No significant differences were noticed between men and women.

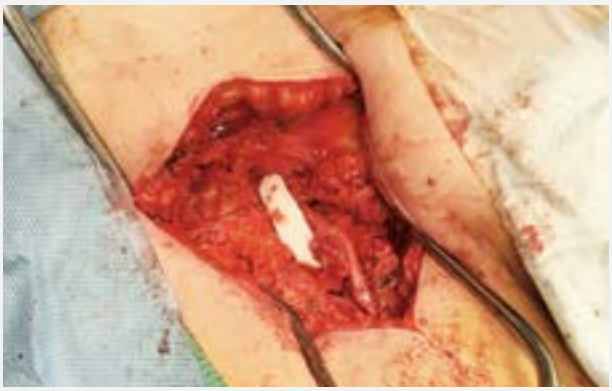
Table 1. Population characteristics

	men (n)	women (n)
Number of cases	**281**	**168**
Average (SD) age at surgery	**70 (10.2)**	**71 (11.1)**
ASA score		
0	0	0
1	0	1
2	11	1
3	162	95
4	100	68
5	1	0
unknown	7	3
Anticoagulants		
Coumarin derivatives	13	4
Thrombin inhibitors	11	2
Antiplatelet drugs	172	106
Admission type		
Elective	229	142
Emergency (%)	52	26
Procedures		
Endarterectomies of the aorta, carotid, femoral and popliteal arterectomies of the aorta	127	79
Bypasses involving the aorta and bi-femoral and femoral and popliteal arteries	8	4
Repair of stenotic arteries and aneurysms in the abdominal aorta (predominantly) or femoral artery	50	15
Grafts, patches and angioplasties	49	32
Combinations of above interventions	34	27
Other	13	11
Average number of days (SD) at the hospital	**2.9 (3.55)**	**3.8 (5.35)**

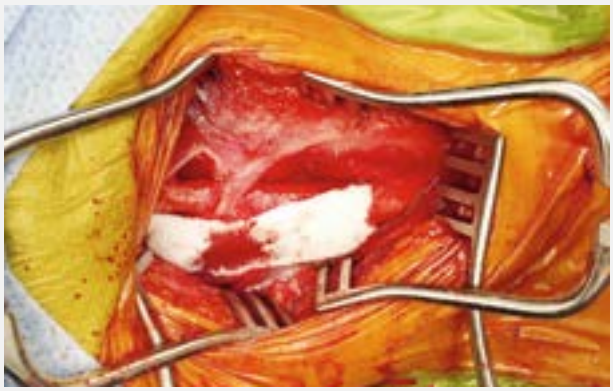
Interventions

GELITA-SPON® RAPID³ was used to quell bleeding and oozing of arterial anastomoses in 449 vascular surgery cases. The application of the novel hemostat was performed in the same manner as the previously used Fibrillar Oxidized regenerated cellulose hemostat.

Once the package was opened, the scrub nurse cut the hemostat in 3 or 4 strips which have been applied to the anastomosis using a forceps. The hydrophilic properties of GELITA-SPON® RAPID³ required that dry instrument have to be used to place the hemostat onto the anastomosis, as it would begin absorbing fluid immediately upon exposure to moisture on the surface of forceps and gloves. Care was taken to gently apply the hemostat to the repaired vessel with a soft tamponade for at least one minute. Sometimes a longer period, depending on the procedure and the amount of oozing or bleeding was necessary. Prior to closing the incision, protamine sulfate was administered to counteract the effect of heparin. The incision was then closed with the hemostatic agent left in situ.



GELITA-SPON® RAPID³ used in pericardial patch angioplasty, showing excellent conformability to the site of anastomosis.



GELITA-SPON® RAPID³ used in a carotid endarterectomy; absorbs blood immediately upon contact, and stops the bleeding within 2 minutes.

Due to the ability to use the hemostatic agent right out of the package, GELITA-SPON® RAPID³ showed excellent handling properties. It saves valuable time for the operating room staff, which is imperative for use in vascular surgeries, particularly those involving major arteries. The nurses responsible for cutting the gelatin-sponge into smaller portions reported no trouble doing so. The hemostatic agent was cut easily and cleanly without folding over the scissors.

The hemostatic agent was easily placed and showed excellent conformability and adherence to the site of anastomosis. GELITA-SPON® RAPID³ was grasped with a pair of forceps, and its semi-rigid dry state allowed a high degree of maneuverability during placement. Once placed, the sponge-hemostat was easily manipulated to conform to the contours of the vessel for optimal placement. Even after the absorption of blood and fluids, the sponge retained its strength and could easily be repositioned, allowing for optimal placement prior to closing the operative field.

GELITA-SPON® RAPID³ successfully induced hemostasis at the site of vascular anastomoses during a range of procedures involving major arteries. Upon application to the site of the anastomosis, RAPID³ was held for approximately one to two minutes to halt bleeding and oozing. Although it was held for that duration, it appeared to have induced hemostasis before application of pressure was ceased. It was observed to quickly absorb fluids from the site and held them within, improving visibility to the site of intervention and surrounding tissues. No device related complications were observed.

Post-Operative Follow-up

Interestingly, it seems that women stayed almost one day longer at the hospital post-surgery as compared to men, even though there is a tendency for men to undergo more severe interventions judged by the emergency hospital admittance rate, 15 and 19% respectively, and the aneurysm repair plus combined intervention rate, i.e. 25 and 30% respectively.

The next observation of the anastomotic site was 4 weeks post-surgery at the clinic in Barrie. The GELITA-SPON® RAPID³ had long been reabsorbed and was therefore not present in any of the ultrasound images.

Ultrasound also indicated no complications pertaining to the use of a hemostatic agent had occurred (e.g. bleeding, encapsulation, tumor mimicking, etc.). The infection and re-bleed rates remained low and thus were comparable to those seen with previous products.

Discussion

This retrospective analysis of vascular surgical patients where the GELITA-SPON® RAPID³ hemostat was used, indicates a good performance, safety, and handling profile in a wide range of vascular surgeries.

GELITA-SPON® RAPID³ is ready to use out of the package without preparation, thus resulting in easier and quicker handling for the surgeon, cost reduction (shortening OR time) and patient benefit, and the product appears to induce hemostasis faster than previously used hemostatic agents. These aspects of its performance made it especially appealing for use in vascular procedures.

Once exposed to blood or plasma, RAPID³ maintained its shape while wet, making it easier to reposition if needed. Product costs are an important consideration of any product used in any hospital, and in this regard, GELITA-SPON® RAPID³ offers economic benefits as it is less expensive than the hemostat previously used for vascular surgeries.

No devices related complications and only few infections and re-bleed comparable to those seen with previous products indicates a good safety profile.

Conclusion

GELITA-SPON® RAPID³ has excellent handling properties irrespective of the procedure for which it is used. The hemostat seems a cost effective hemostatic agent for use in vascular surgery, and its rapid re-absorption should decrease the likelihood of encapsulation and infection. It appears to be at least as effective as previously used oxidized regenerated cellulose hemostatic agents.

References

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[3] Shander, A. (2007): Financial and clinical outcomes associated with surgical bleeding complications. Surgery 2007 Oct; 142(4 Suppl): S20-5.