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Research Article

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StypCel Surgical Patch Versus Conventional Hemostatic Fleece Material for Control of Bleeding in on Pump Coronary Artery Bypass Graft Surgery: A Single Center Exprerience

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ABSTRACT

Prolonged bleeding during heart surgery increases both the risk of patient morbidity and mortality and the cost of surgery itself.

The current study was conducted to assess the efficacy and safety of StypCel compared with Tabotamp haemostatic fleece for the control of bleeding in patients undergoing cardiovascular surgical procedures.

A retrospective single center study was conducted at Caserta Hospital involving a total of 102 patients. The population was made ad adult patients (age >18 years) with planned elective coronary artery bypass graft on pump and were eligible if a surgical bleeding from the heart muscle, pericardium, a major vessel or a vascular bed was present after primary haemostatic treatment.

The results of this study indicate that StypCel is as safe and effective as conventional standard haemostatic fleece material for the control of local bleeding during cardiovascular surgical procedures.

Introduction

Bleeding is a common complication in cardiovascular surgery and it is associated with increased morbidity and mortality, surgical duration and cost and prolonged post-operative hospital stay [1-2].

It is estimated that 60-70% of all transfused red blood cells are used in the surgical setting [3-4]. In addition to infectious complications, transfusion is associated with a number of non-infectious side effects and is accompanied by substantial costs to the healthcare system. Surgical site bleeding leads not only to transfusion, but can require reoperation and is associated with other complications including coagulopathy and hematoma formation.

Extracorporeal circulation, heparinization and high blood pressure are all factors that predispose to bleeding. Reoperation caused by bleeding occurs in 2-6% of patients undergoing heart surgery and it is generally related to a worse prognosis [5]. Bleeding during cardiac surgery can be controlled both with the use of topical hemostatic agents and common surgical methods (compression, ligation, clipping and electrocautery). There are different topical hemostatic agents used in cardiac surgery: oxidized cellulose fleece, liquid fibrin sealants, synthetic glues [6].

This study aims to assess the efficacy and safety of topical hemostat using StypCel compared to the results obtained with the widely used Tabotamp haemostatic fleece.

Stypcel is a non-woven fabric which is based on absorbable material prepared by the oxidation of regenerated cellulose. This non-woven hemostat consists of multilayer of oxidized

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regenerated cellulose fiber, appearing white or slight yellow. It offers more convenience than the knitted fabric, because it allows the surgeon to grasp with any amount of StypCel that the bleeding site needs. A slight discoloration may occur over time, but it does not impact the performance. The oxidized regenerated cellulose is widely used as hemostat in clinic for decades, and it degrades or disappears within a period of about 7-14 days judged by visual inspection. The current study was conducted to assess the efficacy and safety of StypCell compared with Tabotamp haemostatic fleece for the control of bleeding in patients undergoing cardiovascular surgical procedure of CABG on pump.

Materials and Methods

Between June 2023 and February 2024, a retrospective single center study was conducted at Caserta Hospital involving a total of 102 patients. The population was made ad adult patients (age >18 years) with planned elective coronary artery bypass graft on pump and were eligible if a surgical bleeding from the heart muscle, pericardium, a major vessel or a vascular bed was present after primary haemostatic treatment. The area of most prominent haemorrhage had to be identifiable, and it had to be possible to apply the trial treatment by compression for a minimum of 3 min. Exclusion criteria were: patients with known coagulopathy. Primary haemostatic treatment could include compression, suturing, clipping or electrocoagulation based on the surgeon's discretion.

The bleeding target area was identified (aorta, left or right ventricle, left or right atrium, or other), and the site (vessels or heart tissue), type (arterial or venous) and severity of bleeding (mild oozing, moderate or severe) were assessed.

Patients requiring further haemostatic treatment with the intra-operative eligibility criteria were randomised to StypCel or Tabotamp.

StypCel Absorbable Hemostat was provided as 10.0 cm x 10.0 cm patches and was applied after the target area had been cleaned of surgical debris. Patches were placed so to extend 1-2 cm beyond the wound margins. StypCel or Tabotamp were only applied after protamine infusion.

The main endpoint was the proportion of patients achieving a proper haemostasis assessed with the median pre and post operative Hb values, the number of blood transfusion received, the necessity to go back to the OR due to post operative bleeding and the quantity of blood drained with the chest tubes in the first hour, 6 hours, 12 hours and 24 hours after the surgical procedure.

Statistical Analysis

102 patients (54 for Stypcel and 48 for control group) were screened to show a difference between the treatments at a power of 95% (T-Test). The endpoints (no bleeding requiring return in the OR, low transfusion rate, low Hb values loss and low quantity of blood drained with the chest tubes in the 24 hours after the surgical procedure) were analysed using the T-test.

Statistical Analysis

To compare the performance of the two treatments on surgical bleeding, a statistical analysis has been carried out. Two samples of N_A and N_B patients were screened, receiving the StypCel and the Tabotamp treatments respectively. Ranges of values, mean (μ), median (m) and standard deviation (σ) of the patients' age and IBM of the two samples are reported in Table 1. To demonstrate that the two samples *A* are *B* statistically comparable, an unpaired t-test is performed, as the samples can be assumed to be independent. In general, a t-test between two samples and returns a test decision for the null hypothesis (H_0) that the data in vectors *A* and *B* come from independent random samples from normal distributions with equal means and equal, but unknown, variances. The alternative hypothesis (H_1) is that the data in *A* and *B* come from populations with unequal means. The result of the test is 1 if the test rejects the null hypothesis at a significance level α (set equal to 5%), and 0 otherwise.

Once the samples have been demonstrated to be statistically comparable (i.e., the null hypothesis is confirmed for age and IBM distributions), an unpaired t-test is performed over the distributions of the following parameters: PostOp-PreOp Hb difference, drainage at 1 h, 6 h, 12 h and 24 h after completing the surgical procedure, and blood transfusion rate. In this work, the most relevant parameter to claim that the effect of the two treatments is the same has been the drainage at 1 h after the surgical procedure.

Results

Patients

A total of 102 patients (i.e., N_A equal to 54 and N_B equal to 48) were screened between May 2023 and February 2024. No patient required going back in the operating room for bleeding in both treatment and control groups; there was no exitus. Ranges of values, mean, medians and standard deviations of patients' age and IBS are reported in Table 1. Table 2 reports the percentage of Antiplatelet Agents (Aspirin 100mg) usage. In particular, 59 % of patients of the first sample and 71% of the second have received the Antiplatelet Agents. The null hypothesis for both age and IBM has been confirmed, i.e., the two samples are statistically comparable and the baseline characteristics are can be considered similar.

Table 1: Age and IBM statistics of the considered samples

Parameter	Range		Mean		Median		Standard deviation	
	A	B	A	B	A	B	A	B
Age	38 - 83	58 - 79	66.4	69.1	65.5	69.0	8.9	5.2
IBM	21.1 - 30.4	21.3 - 34.3	26.1	26.7	26.1	26.3	1.7	2.5

Table 2: Rate of antiplatelet chronical usage for the considered samples

Rate of antiplatelet chronical usage	
A	B
59 %	71 %

Procedure

Surgical procedures were all elective Coronary Artery Bypass Graft surgery (CABG) on Cardiopulmunary Bypass. Bleeding was mainly vascular rather than from tissue, arterial and mild to moderate in severity. There were no major differences between

bleedings in the two treatment groups. Suturing was the primary hemostatic treatment in both treatment groups. The use of systemic tranexamic acid was similar in both groups.

Chest drains were always under suction, and they were removed when drain output was less than 5ml/h at least 24 h after the surgery. Ranges of values, mean, median and standard deviation of PostOp-PreOp Hb difference, drainage at 1 h, 6 h, 12 h and 24 h after completing the surgical procedure, and blood transfusion rate are reported in Table 3. Figure 1 shows the boxplots of the drainage values at 1 h after completing the surgical procedure. On each box, the central mark (i.e., the red line) indicates the median of the statistics parameter (i.e., drainage value), the bottom and top edges of the box indicate the 25th and 75th percentiles, respectively. The difference between the 75th and 25th percentiles (i.e., the height of the box) is called interquartile range (IQR). The whiskers extend to a value equal to 1.5·IQR above the 75th percentile and 1.5·IQR below the 25th percentile. Outliers are the values beyond the whiskers and are plotted individually using the '+' symbol.

It can be noted that, except for the drainage at 6 h and 12 h after completing the surgical procedure, the null hypothesis has been confirmed for all the test parameters. Therefore, it can be stated that, at a significance level of 5%, the effects of the two treatments are statistically equal.

Re-operation was required in 0 patients. 42 patients (77.7%) in the StypCel group had postoperative blood transfusions and 46 patients (95.8%) in the standard treatment group. All transfusions consisted of packed red blood cell (RBC) transfusions (Mean of 1.59 transfusions in the StypCel group and 1.71 in the standard treatment group).

Table 3: Statistics and results of the hypothesis test. Green boxes correspond to confirmed null hypothesis; red boxes correspond to rejected null hypothesis.

Parameter	Mean		Median		Standard deviation		T-test
	A	B	A	B	A	B	
PostOp-PreOp Hb difference	1.74	2.30	1.45	2.35	1.07	0.94	
1H	93.7	84.8	90.0	86.5	27.1	17.6	
6H	244.2	129.2	240.0	122.5	74.7	31.0	
12H	479.1	304.2	490.0	305.0	115.2	22.8	
24H	972.2	1013.5	970.0	1010.0	217.4	82.6	
Trasfusions number	1.59	1.71	2.0	2.0	1.07	0.80	

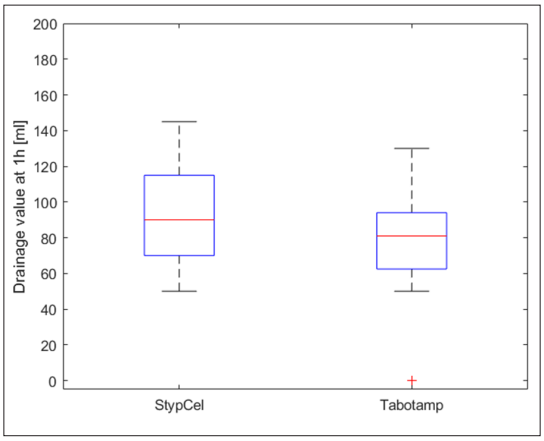

Figure 1: Comparison of drainage values at 1h after completing the surgical procedure.

Discussion

This study shows that StypCel is effective and safe in controlling mild-to-moderate surgical bleeding in adults undergoing cardiothoracic procedures. Although the optimal choice of a topical hemostat is primarily dependent on the surgical scenario, type of bleeding, and the agent's mechanism of action, bleeding intensity critically determines time to hemostasis. However, the difference in hemostatic success between mild and moderate bleeding sites declined over time, with both reaching more than 80% at 10 min. This is consistent with findings in preclinical models of liver punch biopsy or liver abrasion [7].

In patients undergoing cardiovascular surgery heparinisation and extracorporeal circulation compromise the coagulation capacity of the blood, while high arterial pressures predispose to bleeding. As such, the coagulation system of patients during cardiopulmonary bypass is significantly impaired [8].

This is the first controlled study of StypCel in patients undergoing cardiovascular surgery.

In this study there was no significant differences between Stypcel and Tabotamp haemostatic fleece material in achieving effective and fast intra-operative local haemostasis.

The results of the present trial are comparable with the previous randomised studies assessing topical haemostatic agents in non cardiac surgery [9-10].

Three-quarters of bleedings occurred from a vessel, with one fourth from the other tissues. All patients with vessel bleeding, both treated with Stypcel ot Tabotamp, achieved effective haemostasis through the use of oxidized cellulose fleece. Most of the times the cellulose fleece was uses was then left inside the thoracic cavity and no side effect or compression on adjacent structures was assessed.

StypCel was overall safe and well tolerated, with no AEs related to the use of the hemostatic fleece in the two treatment groups.

However, no significant differences were observed between treatments in term of pre and post operative Hb values, number

of blood transfusion received, necessity to go back to the OR due to post operative bleeding and the quantity of blood drained with the chest tubes in the 24 hours after the surgical procedure.

Conclusion

In conclusion, the results of this study indicate that StypCel is as safe and effective as conventional standard haemostatic fleece material for the control of local bleeding during cardiovascular surgical procedures. The research conducted has limitations to be considered, including a single institution study and an insufficent number of examined patients, which doesn't make an important statistical value possible to reach. Furthermore, only a type of surgery was taken into account. In conclusion, it would be interesting in future to correlate our data with ones collected by other medical centers in order to expand the study with a greater number of patients and with stronger statistical validity.

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