ORIGINAL ARTICLE

Evaluation of hemostatic efficacy and safety of oxidized regenerated cellulose (Pahacel®) in coronary bypass surgery

Evaluación de la eficacia hemostática y de la seguridad de la celulosa regenerada oxidada (Pahacel®) en cirugía de bypass coronario

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Abstract

Objective: *The aim of this study is to evaluate the efficacy and safety of oxidized regenerated cellulose (ORC) in patients who underwent coronary artery bypass grafting (CABG) surgery and to compare the results of patients in whom ORC was used or not used for control of bleeding.* **Method:** *Pre-, intra-, and post-operative demographic and medical parameters of the patients in whom ORC was used or not used were compared. Quantitative data were analyzed with mean and standard deviation. Group differences were assessed with the Mann–Whitney U test.* **Results:** *It was found that the duration of surgery, average numbers of erythrocyte and fresh frozen plasma (FFP) transfusions during surgery, average post-operative FFP transfusion count, duration of intensive care unit stay, and chest tube removal times were lower in the ORC group compared to the control group, and all these differences were statistically significant ($p < 0.05$ for all of these parameters).* **Conclusions:** *The study successfully demonstrated the effective and safe use of topical ORC in controlling bleeding and preventing oozing during CABG surgeries.*

Keywords: *Coronary artery bypass grafting. Oxidized regenerated cellulose. Complications. Hemostat. Hemostasis.*

Resumen

Objetivo: *Evaluar la eficacia y la seguridad de la celulosa regenerada oxidada (CRO) en pacientes sometidos a cirugía de injerto de derivación de arteria coronaria y comparar los resultados de los pacientes en los que se utilizó o no la CRO para el control del sangrado.* **Método:** *Se compararon los parámetros demográficos y médicos pre-, intra- y posoperatorios de los pacientes en los que se utilizó o no CRO. Los datos cuantitativos se analizaron con media y desviación estándar. Las diferencias grupales se evaluaron con la prueba U de Mann Whitney.* **Resultados:** *Se encontró que la duración de la cirugía, el número promedio de transfusiones de eritrocitos y de plasma fresco congelado durante la cirugía, el recuento promedio de transfusiones de plasma fresco congelado posoperatorias, la duración de la estadía en la unidad de cuidados intensivos y los tiempos hasta la extracción del tubo torácico fueron menores en el grupo de CRO en comparación con el grupo control, y todas estas diferencias fueron estadísticamente significativas ($p < 0.05$).* **Conclusiones:** *El estudio demostró con éxito el uso eficaz y seguro de la CRO tópica para controlar el sangrado y prevenir la supuración durante las cirugías de derivación de arteria coronaria.*

Palabras clave: *Cirugía de derivación de arteria coronaria. Celulosa regenerada oxidada. Complicaciones. Hemostático. Hemostasia.*

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Introduction

Bleeding is a common surgical complication which increases post-operative complications, unfavorable transfusion-related events, and the risk of infection, necessitating a longer hospital length of stay (LOS) and greater use of medical resources. When bleeding cannot be controlled during surgery using standard techniques, absorbable hemostatic agents (AHA) have been utilized as adjunctive therapy. When electrocoagulation, ligation, or other conventional techniques of bleeding control are ineffective or impractical, oxidized regenerated cellulose (ORC), a commonly used AHA, can be used in the control of small arterial, venous, and capillary hemorrhage[1]. ORC is a biodegradable, sterile, fibrous substance created by the oxidation of regenerated cellulose. Various forms of ORC are used in surgery for the control of bleeding as an absorbable hemostatic substance[2]. Despite the fact that ORC is widely used worldwide, research on issues relating to the safety and efficacy of this hemostat, as well as its effects on medical costs and surgical outcomes, has been ongoing for years. Many studies have examined its efficacy in numerous specialties, including urology, plastic surgery, obstetrics and gynecology, general surgery, neurology, and cardiovascular surgery[3-7]. Nevertheless, no studies other than two technical descriptions of the use of ORS in cardiac bypass procedures were found in the literature review[8,9]. Despite the fact that 345 coronary artery bypass grafting (CABG) surgeries used one of these techniques, the outcome factors assessed in that study were sparse and not provided in detail[9].

The objective of the present investigation was to conduct a retrospective assessment of the effectiveness and safety of ORC in individuals who underwent coronary bypass surgery, specifically focusing on cases where this hemostatic agent was employed for bleeding control. In addition, the study aimed to compare these outcomes with those of patients in whom the hemostatic agent was not utilized. Numerous hemostatic products are used in medical practice, and the data obtained from this study can serve as a reference for researchers to compare the outcomes of different studies involving various hemostats. Positive findings from this study have the potential to generate interest among surgeons who have not yet utilized ORC in coronary bypass surgeries, encouraging them to use this product and to compare the efficacy and safety of ORC with other hemostats.

Methods

This retrospective, cross-sectional, and observational research included patients who had undergone coronary bypass grafting surgery between September 2022 and March 2023 in the Cardiovascular Surgery Department of Health Sciences University Ankara Training and Research Hospital and in whom ORC was used or not used for control of bleeding. The study was approved by the Ethics Committee of Ankara Training and Research Hospital. The ORC product, used in this study was PAHACEL® standard absorbable hemostat, which is a Class III medical device, and manufactured by Altaylar Medikal, Ankara, Türkiye.

After pre-medication and induction of anesthesia, approximately 300-400 mL of blood was collected from all patients with hemoglobin levels above 12.0 for autotransfusion. All patients underwent the standard conventional cardiopulmonary bypass (CPB) technique. Autologous blood was intravenously administered to the patient after CPB. In the control group, conventional hemostasis was achieved and ORC was not applied. In patients in the ORC group, to ensure hemostasis, ORC product (PAHACEL®) was temporarily applied over the distal and proximal coronary bypass anastomoses, even if the bleeding was minimal, or there was oozing. Following the instructions in the product's user manual, the ORC product was removed once bleeding or leakage was controlled and was not left in the surgical area. After achieving hemostasis, three chest drainage tubes were inserted, one in the left hemithorax and two in the mediastinum. The sternum was approximated using four figure-of-eight wires, and the subcutaneous tissue was closed with PDS sutures, followed by skin closure using staples.

The evaluated parameters regarding the patients and the surgical procedures during the pre-operative, operative process, and post-operative hospital stay were age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score, smoking status, additional diseases (diabetes mellitus, hypertension, chronic obstructive pulmonary disease [COPD], etc.), pre-operative thrombocyte, hematocrit, prothrombin time (PT) and pre-, intra-, and post-operative anti-clotting time (ACT) values, operation time, the number of per- and/or post-operative red blood cell or fresh frozen plasma (FFP) transfusions, post-operative platelet transfusion or fibrinogen treatment, the duration of post-operative intensive care

stay, post-operative hospital stay, amount of drainage into the chest tube, the time of chest tube removal, main complications, morbidity, and mortality.

Following standardized protocols, all patients who underwent surgery at the Cardiovascular Surgery Clinic for coronary artery disease were scheduled for a follow-up visit at the outpatient clinic on the 15th day after the operation for examination and removal of sutures were performed. In addition to this regular procedure, patients were informed upon discharge that if they experienced any unexpected signs or symptoms such as severe pain, redness, or discharge at the surgical site, high fever, or difficulty in breathing, they should promptly return to the hospital for immediate evaluation and care.

In line with these principles, during the standard follow-up visit on post-operative day 15 or when patients seek medical attention due to unexpected issues, their current complaints were assessed through questioning, and physical examinations were conducted. If a wound infection was suspected, the wound was drained, and a sample was collected for culture and antibiotic sensitivity testing. In cases where complications were suspected, appropriate tests were carried out and carefully evaluated.

The early complications identified for this study were obtained from patient records during their hospital stay and within the 1st month after the surgery. These complications included seroma, superficial and/or deep wound infections, hematoma, bleeding, tamponade, and pleural effusion. Retrieving information for this retrospective study posed no difficulties since all the parameters evaluated were routine and mandatory data recorded in the hospital's registry system by the attending physician.

Patients with pre-existing chronic liver or kidney dysfunction and those with missing recorded data were excluded from this retrospective analysis. All of the patients had been receiving acetylsalicylic acid preoperatively. Although it had a significant antiaggregant effect, this medication was not stopped, and the patients continued to receive the acetylsalicylic acid treatment.

Results

The study compared a control group of 40 patients, aged 61.05 ± 9.12 (range, 33-78 years), with a group of 52 patients who underwent hemostasis using ORC (ORC group), with an average age of 62.56 ± 9.29 (range, 44-83 years). Table 1 presents the demographic, medical, and pre-operative hematological profiles of the patients. The groups were similar in terms of age, gender, BMI, ASA scores, smoking habits, and most comorbid diseases, except for COPD, as well as pre-operative PT, platelet count, hematocrit, and ACT values. The mean number of vascular grafts was comparable between the control and ORC groups (3.35 ± 1.07 and 3.25 ± 0.91, respectively, $p > 0.05$). All patients in both groups had an ASA III score.

Table 2 outlines the intraoperative parameters. There was a statistically significant difference in the average duration of the operation between the control group (289.17 ± 50.62 min) and the ORC group (265.13 ± 59.45 min) ($p < 0.05$). The ORC group had significantly fewer erythrocyte and FFP transfusions compared to the control group ($p < 0.05$). The mean duration of cardiopulmonary bypass and ACT values did not differ significantly between the groups ($p > 0.05$). LIMA was consistently used as a graft in both groups, with the most common number of grafts being three.

Post-operative parameters in table 3 revealed that in the ORC group, there were significantly fewer FFP transfusions, a shorter mean follow-up time in the intensive care unit, and a shorter mean chest tube removal time compared to the control group ($p < 0.05$). While there was no statistical difference in the total amount of drainage to the chest tube ($p > 0.05$), the mean total drainage was less in the ORC group (1067.31 ± 528.58 mL) than in the control group (1115.00 ± 465.36 mL). ACT, activated partial thromboplastin time, and the mean number of erythrocyte transfusions did not differ significantly between the groups ($p > 0.05$). Although the mean duration of post-operative hospital stay was shorter in the ORC group, there was no significant difference between the groups ($p > 0.05$). Only one patient in the ORC group required a platelet transfusion, and no patients in either group received fibrinogen supplementation.

In the ORC group, eight complications occurred in seven patients, including 3 cases of atrial fibrillation (7.3%), 3 cases of superficial wound infection (7.3%), and 2 cases of pleural effusion (4.9%). The control group experienced 2 sternal wound infections (5.0%) and 4 pleural effusions (10.0%). All complications were effectively addressed during the initial hospitalization period and none of the patients required readmission.

Two patients (3.8%) in ORC and 1 patient (2.5%) in control group required reoperation due to excessive bleeding, which was defined as bleeding exceeding

Table 1. The demographic and medical features and pre-operative hematological profile of the patients

Parameters	Control (n = 40)	ORC group (n = 52)
Age (years) (mean ± SD)	61.05 ± 9.12	62.56 ± 9.29
Gender (number/percentage)		
Male	31 (77.5%)	41 (78.8%)
Female	9 (22.5%)	11 (21.2%)
BMI (kg/m^2) (mean ± SD)	28.05 ± 4.19	28.16 ± 4.73
ASA scores (number/percentage)		
ASA 1	-	-
ASA 2	-	-
ASA 3	40 (100%)	52 (100%)
ASA 4	-	-
Smokers (number/percentage)	12 (30.0%)	13 (25.0%)
Comorbidities (number/percentage)		
HT	23 (57.5%)	32 (61.5%)
DM	24 (60.0%)	30 (57.7%)
COPD	1 (2.5%)	8 (15.4%)
Others	1 (2.5%)	3 (5.7%)
Prothrombin time (s) (mean ± SD)	12.79 ± 1.76	13.72 ± 1.08
Platelet count (×10^3/μL) (mean ± SD)	271.56 ± 56.62	263.96 ± 69.20
Hematocrit (%)	41.01 ± 5.74	40.59 ± 6.47
ACT (s)	135.29 ± 20.09	139.91 ± 20.08

No difference was found between the groups for all parameters ($p > 0.05$); ASA: American Society of Anesthesiologists; BMI: body mass index; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; HT: hypertension; ACT: activated clotting time; SD: standard deviation; ORC: oxidized regenerated cellulose.

Table 2. Pre-operative parameters of the patients

Parameters	Control (n = 40)	ORC group (n = 52)
Operation time (min) (mean ± SD)*	289.17 ± 50.62	265.13 ± 59.45
Duration of cardiopulmonary bypass (min)	51.20 ± 14.82	48.64 ± 18.50
Mean number of vascular grafts	3.35 ± 1.07	3.25 ± 0.91
Erythrocyte transfusions (mean ± SD)*	0.38 ± 0.16	0.02 ± 0.01
FFP transfusions* (mean ± SD)	0.40 ± 0.16	0.27 ± 0.12
ACT (s ± SD)	749.54 ± 157.57	709.77 ± 157.26

*Statistically different, $p < 0.05$. FFP: fresh frozen plasma; ACT: activated clotting time; s: seconds; SD: standard deviation; ORC: oxidized regenerated cellulose.

200 cc/h during the early post-operative period. Both patients experienced 200 cc/h bleeding over a period of 5 h, leading to the decision for emergent reoperation. Surgical intervention was performed to achieve local hemostasis since the patients had active surgical bleeding (not oozing) that could not be controlled using hemostatic agents. It was concluded that these two cases of hemorrhage requiring reoperation were not directly associated with the evaluation of ORC's efficacy and safety, which were the aim of the current study. Therefore, these reoperations were not considered in the "discussion" part.

No mortality was observed in the current study.

The Statistical Package for the Social Sciences (SPSS) version 25 (SPSS Inc., Chicago, USA) program was used for statistical analysis. For quantitative data such as age and length of hospital stay, the mean and standard deviation values were used to determine the measure of central trends. Frequency tables and charts were used to present estimated rates of

Table 3. Post-operative parameters of the patients

Parameters	Control (n = 40)	ORC group (n = 52)
Erythrocyte transfusions (mean ± SD)	1.90 ± 1.06	1.71 ± 1.05
FFP transfusions (mean ± SD)*	1.65 ± 1.12	1.23 ± 1.18
Platelet transfusion (number of patients/number of transfused platelet suspension)	0/0	1/1
Fibrinogen supplementation (number of patients/number of transfused fibrinogen suspension)	0/0	0/0
ACT (s ± SD)	119.19 ± 11.64	121.63 ± 13.64
aPTT (s ± SD)	30.50 ± 6.31	28.25 ± 2.73
Follow-up time in intensive care unit (h ± SD)*	102.15 ± 36.79	90.19 ± 45.67
Post-operative hospital stay (days ± SD)	12.54 ± 6.83	10.75 ± 6.86
Total amount of drainage to chest tube (mL ± SD)	1115.00 ± 465.36	1067.31 ± 528.58
Chest tube removal time (h ± SD)*	94.45 ± 37.88	52.29 ± 46.74
Post-operative early complications (number of patients)		
Atrial fibrillation	0 (0%)	3 (5.7%)
Superficial wound infection	0 (0%)	3 (5.7%)
Sternal wound infections	2 (5.0%)	0 (0%)
Reoperation for bleeding	1 (2.5%)	2 (3.8%)
Cardiac tamponade	0 (0%)	0 (0%)
Pleural effusion	4 (10.0%)	3 (5.7%)

*Statistically different, $p < 0.05$. FFP: fresh frozen plasma; ACT: activated clotting time; s: seconds; h: hours; SD: standard deviation; ORC: oxidized regenerated cellulose; aPTT: activated partial thromboplastin time.

qualitative data such as gender and rate of complications. To determine whether there was a difference between the experimental and control groups, it was examined whether the difference between the groups was significant. In this context, since parametric test assumptions were not met, this difference was examined with the Mann–Whitney U test, which is one of the non-parametric tests for the comparison of groups.

Discussion

The disproportion between the blood supply of the myocardium through coronary vessels and the oxygen need of the myocardium leads to ischemic heart disease[10]. Annually, more than 200,000 CABG procedures are carried out in the United States. CABG surgery is frequently regarded as a high-risk procedure with high 30-day morbidity (up to 14.0%) and mortality (up to 2.0%) rates[11]. In the current study, there were no instances of mortality (0%). The morbidity rates, at 15% for the control group and 15.4% for the ORC group, align with existing literature. While the recent adoption of early extubation and fast-track protocols has generally resulted in shorter hospital stays, averaging 5.4 days postoperatively[11], in the current research, longer post-operative LOS, with 12.54 ± 6.83 days for the control group and 10.75 ± 6.86 days for the ORC group, were found. Following CABG surgery, a large number of patients commonly require hospital readmissions (approximately 14%) and emergency department visits (additional 10%) within 30 days after discharge, frequently for complications or complaints linked to the surgery. In all, 7% of patients who have had CABG surgery will require more than one readmission or emergency department visit within 30 days following the procedure[11]. Every complication identified in the present study was successfully addressed during the initial hospitalization period, and there was no necessity for patients to be readmitted after discharge.

Several risk factors contribute to perioperative morbidity and mortality in CABG surgery. Post-operative bleeding is a common complication, impacting approximately 10% of patients and leading to adverse outcomes and higher costs. Definitions of “excessive” bleeding vary but are often based on chest tube drainage. Age, complex operations, pre-operative anemia, cardiac function, cardiopulmonary bypass time, male

sex, and lower BMI contribute to the risk of excessive bleeding, emphasizing the importance of careful management of post-operative bleeding due to its association with increased mortality risk. The risk of bleeding is also associated with surgeon-specific factors such as attention to hemostasis. Pre-operative dual antiplatelet medication (acetylsalicylic acid and clopidogrel, ticagrelor, or prasugrel) may have an approximately 15% risk of bleeding. Although guidelines advise to stop dual antiplatelet treatment 5 days before surgery, this is frequently impossible in emergent operations[12]. In the present study, although all of the patients had been receiving acetylsalicylic acid, which had a significant antiaggregant effect in the pre-operative period, only 2 patients (3.9%) in ORC group and 1 patient (2.5%) had reoperation for bleeding.

Post-operative bleeding, often linked to antiplatelet or anticoagulant use in CABG surgery, remains a constant concern for surgeons. Persistent bleeding from mediastinal drains can lead to sudden cardiopulmonary instability, particularly acute pericardial tamponade, resulting in death. While various sources contribute to bleeding after CABG, oozing from anastomotic suture lines is a primary cause, requiring prompt surgical exploration to prevent adverse outcomes[12].

Traditional surgical methods such as ligation and cauterization may sometimes fail to control bleeding, prompting the use of alternative approaches. Topical hemostatic agents, including ORC, offer a solution. ORC, composed of structured cellulose, stands out for its bioabsorption, biocompatibility, and ease of use. It activates the intrinsic coagulation pathway, forms a gel-like layer, and induces vasoconstriction. ORC's versatility makes it suitable for various surgical sites, ensuring quick adaptation and effective management of local bleeding[1,2,13]. Although ORC is widely used in many surgical fields worldwide, there are only two technical descriptions of the use of ORC in coronary artery bypass surgeries[8,9].

Di Lello et al.[8] employed ORC for sutureless fixation of long aortocoronary saphenous vein grafts (SVG), tailoring an appropriate-sized ORC sheet over the graft segment. While their aim differed from the current study, focusing on graft fixation rather than hemostasis, the technique showcased ORC's versatility.

Canver[9] introduced a method to reduce fatal complications in myocardial revascularization, covering the internal thoracic artery pedicle, distal anastomosis, and SVGs with ORC pieces. Liquid thrombin prevented dislodging, and the chest was closed while monitoring bleeding through flexible suction catheters. In 345 consecutive CABG procedures using this technique, only 0.57% required re-exploration for early post-operative bleeding. No instances of cardiopulmonary collapse or long-term complications were reported, suggesting ORC application might prevent post-operative bleeding and acute graft kinking effectively.

In my opinion, the main limitation of the previous study was the evaluation of a very limited number of outcome parameters, despite the inclusion of a large number of patients. In addition, no other research studies were found in the literature utilizing the same hemostasis technique, suggesting that the results of the study may not have been deemed satisfactory by other researchers. In contrast, the present study evaluated a significant number of outcome parameters. Another difference between the previous study and the current study is that while the previous study applied a liquid thrombin spray on ORC, such an application was not performed in the present study. The final and significant difference of the current study from the previous one is the presence of a control group in the current study.

Given the limited number of studies assessing the hemostatic effects of ORC in CABG surgery, the author conducted the current comparative retrospective analysis. The aim was to compare the pre-, intra-, and post-operative data of patients in whom ORC was used for enhanced hemostasis with those who did not receive any hemostatic agent during CABG surgeries. In summary, when considering various parameters between two groups that exhibited similarities in demographic and medical features, pre-operative hematological profiles, and the number of vascular grafts applied, it was found that the duration of surgery, average numbers of erythrocyte and FFP transfusions during surgery, average post-operative FFP transfusion count, duration of intensive care unit stay, and chest tube removal times were lower in the ORC group compared to the control group, and all these differences were statistically significant. On the other hand, although statistically significant differences were not found, it is noteworthy that the post-operative hospital stay and the total amount of drainage to the chest tube were lower in the ORC group compared to the control group. Given that all these parameters with different values between the groups could be directly or indirectly associated with the patient's hemostatic success and bleeding status, these differences were

interpreted as indicative of the positive contributions of ORC use to hemostasis.

Although some other hemostatic agents such as fibrin sealant[13] and tranexamic acid[14] were used successfully in patients undergoing CABG surgery, there was no studies comparing the effects of these hemostats with ORC in CABG surgeries.

While ORC is widely used and effective, there have been reported adverse effects. In a rare case, ORC residue caused a post-traumatic bronchobiliary fistula, attributed to ORC erosion and diaphragmatic migration[15]. Another case involved a child with pelvic neuroblastoma, where ORC, used for hemostasis, led to a mass mimicking tumor recurrence. Pathological evaluation revealed fibrotic tissue with giant cells, prompting caution about minimizing topical hemostat use and avoiding retention unless essential[16]. Despite ORC's biocompatibility, insufficient absorption can trigger foreign body reactions, mimicking various conditions such as tumor recurrence, granuloma, or abscess[2]. An adverse event occurred with oxidized cellulose (OC) combined with epsilon aminocaproic acid (EACA), leading to acute ischemia. *In vitro* experiments revealed OC's rigid structure in EACA, prompting a cautionary note against their combined use[17].

In addition to these undesirable effects, seroma, allergic skin reactions, or in some cases, abscess formations may develop with the use of ORC[2]. In addition to a case series[18] reporting subhepatic mass formation (five out of 83 patients) after laparoscopic cholecystectomy operations, there are also studies reporting that the use of ORC increases the risk of rehospitalization[19].

Conclusion

The findings of the current study, which utilized topical ORC to achieve hemostasis and prevent oozing at anastomotic sites in CABG surgeries, demonstrated the effective and safe use of ORC with low complication rates. A key aspect of this approach was the removal of ORC after achieving hemostasis, in accordance with the usage guidelines. Although some literature reports have highlighted potential adverse effects associated with ORC usage, none of these effects have been deemed significant enough to hinder the use of ORC. Moreover, the technique described in this manuscript can effectively mitigate most of these undesired adverse events. Conducting studies that compare the outcomes of patients undergoing CABG surgery with or without the use of ORC, along with studies involving a larger number of patients, would provide valuable guidance for surgeons regarding the safety and effectiveness of ORC in achieving hemostasis in these surgeries. In addition, studies comparing ORC with other hemostatic agents in terms of hemostatic success in CABG procedures would contribute to a better understanding of the efficacy and safety of these products.

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Conflicts of interest

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Ethical disclosures

Protection of human and animal subjects. The author declares that no experiments were performed on humans or animals for this study.

Confidentiality of data. The author declares that they he has followed the protocols of his work center on the publication of patient data.

Right to privacy and informed consent. The author has obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

Use of artificial intelligence for generating text. The author declares that he has not used any type of generative artificial intelligence for the writing of this manuscript nor for the creation of images, graphics, tables, or their corresponding captions.

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