

Comparative Study of Topical Haemostatic Agents in Surgical Practice: Oxidized Regenerated Cellulose, Gelatin-Based Sponge and Haemocoagulase versus Conventional Methods

Authors:

Udipt Shringi¹, Sudhir Kumar², Aarushi Vashist³

¹Assistant Professor, Ajay Sangal Medical College, Jhunjhuna, Shamli, Uttar Pradesh, India.

²Assistant Professor, Department of General Surgery, NC Medical College, Israna, Panipat, Haryana, India.

³Assistant Professor, Department of ENT, Kalpana Chawla Medical College, Karnal, Haryana, India.

Corresponding Author:

Dr. Udipt Shringi, Assistant Professor, Ajay Sangal Medical College, Jhunjhuna, Shamli, Uttar Pradesh, India. Email: udiptshringi@gmail.com

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ABSTRACT

Background: Topical haemostatic agents are widely used adjuncts to conventional mechanical and thermal techniques for achieving intraoperative haemostasis, particularly in high-risk or difficult-to-access surgical fields. Oxidized regenerated cellulose (ORC), gelatin-based sponge and haemocoagulase are among the agents commonly used, but comparative clinical data on their relative efficacy and safety remain limited. **Objectives:** To compare the effectiveness of ORC, gelatin-based sponge and haemocoagulase against conventional haemostatic methods, and to assess their relative cost-effectiveness in routine surgical practice. **Methods:** This prospective comparative study included 240 adult patients undergoing elective breast, kidney, liver, prostate, splenic or thyroid surgery at Hamidia Hospital, Bhopal, between July 2010 and August 2015. Patients were allocated to six surgery-based groups of 40 each, further divided into four subgroups of 10 according to the haemostatic method used (conventional, haemocoagulase, ORC, gelatin-based sponge). Outcomes assessed were time to haemostasis, nature and volume of postoperative drain collection over five days, postoperative blood transfusion requirement, wound infection and abdominal sepsis. Data were analysed using two-factor and one-factor ANOVA, chi-square test and unpaired t-test, with $p < 0.05$ considered significant. **Results:** ORC achieved haemostasis fastest (mean 75.5–92.4 minutes to a clear drain trend by day 3–5, and 1–2 minutes to primary haemostasis in all 60 patients), significantly faster than gelatin-based sponge, haemocoagulase and conventional methods (unpaired t-test, $p < 0.001$ for all comparisons). The proportion of patients with a clear (non-haemorrhagic) drain was consistently higher in the ORC group from day 1 onward and reached 56/60 (93%) by day 5, compared with 40/60 (67%), 38/60 (63%) and 17/60 (28%) in the gelatin, haemocoagulase and conventional groups respectively (χ^2 $p < 0.0001$ for days 2–5). Blood transfusion was required in 3/60 (5%) ORC patients versus 8/60 (13.3%), 10/60 (16.6%) and 14/60 (23.3%) in the gelatin, haemocoagulase and conventional groups ($\chi^2 = 8.40$, $p = 0.0385$). Wound infection occurred in 1/60 (1.6%) ORC patients versus 12/60 (20%), 10/60 (16.6%) and 14/60 (23.3%) respectively ($\chi^2 = 12.62$, $p = 0.0055$). Among patients undergoing splenectomy or liver-injury surgery, no patient in the ORC subgroup developed abdominal sepsis, compared with 2/20, 3/20 and 7/20 in the gelatin, haemocoagulase and conventional subgroups ($\chi^2 = 10.20$, $p = 0.017$). **Conclusion:** Oxidized regenerated cellulose provided faster and more effective haemostasis than gelatin-based sponge, haemocoagulase and conventional methods, with lower rates of postoperative drain collection, transfusion requirement, wound infection and abdominal sepsis. Although ORC costs more than the alternatives, its clinical benefits support its use as a preferred first-line topical haemostatic agent, particularly in high-risk solid-organ and vascular surgery, while cost remains a relevant consideration in resource-limited settings.

Keywords: haemostasis; oxidized regenerated cellulose; gelatin sponge; haemocoagulase; topical haemostatic agents; surgical bleeding

INTRODUCTION

Control of intraoperative bleeding is fundamental to safe surgical practice. Physiological haemostasis proceeds through primary platelet-plug formation followed by secondary, fibrin-based clot consolidation via the coagulation cascade, and is ultimately balanced by fibrinolysis.¹⁻⁴ During surgery, however, it is often neither practical nor safe to await unassisted physiological haemostasis, particularly in vascular, hepatic, splenic or renal procedures where bleeding may be diffuse or from a wide raw surface.⁵

Conventional mechanical techniques direct pressure, ligature and tourniquet and thermal techniques such as electrocautery remain the mainstay of intraoperative haemostasis, but are time-consuming, operator-dependent, and can be ineffective or even harmful (through tissue necrosis and impaired healing) in complex or inaccessible bleeding.⁶ Topical haemostatic agents have therefore assumed an increasing role as adjuncts, particularly for diffuse capillary or venous oozing that is not amenable to suture or cautery.⁷

A range of topical agents is currently available, acting either by augmenting primary haemostasis, providing a matrix for endogenous clot formation, or directly contributing procoagulant activity.⁷⁻⁹ Among these, oxidized regenerated cellulose (ORC), gelatin-based sponge and haemocoagulase are the agents most widely used in general surgical practice, including at our institution. The ideal topical haemostat should combine high efficacy, minimal tissue reactivity, biodegradability and acceptable cost, but no single agent fulfils all these criteria, and comparative clinical evidence to guide agent selection remains limited.¹⁰ Choice in practice is therefore often guided by surgeon preference, cost and local availability rather than by comparative outcome data.

This study was undertaken to prospectively compare the clinical effectiveness of ORC, gelatin-based sponge and haemocoagulase against conventional haemostatic methods across a range of common surgical procedures, and to evaluate their relative cost-effectiveness, with the aim of informing rational selection of topical haemostatic agents in routine surgical practice.

MATERIALS AND METHODS

Study design and setting

This was a prospective, comparative, observational study conducted in the Department of Surgery, Gandhi Medical College and associated Hamidia Hospital, Bhopal, over a five-year period from July 2010 to August 2015.

Participants

A total of 240 adult patients undergoing elective surgery were enrolled. Inclusion criteria were age ≥ 18 years and the need for an elective, primary or repeat surgical procedure. Patients with known intolerance to blood products, autoimmune or immunodeficiency disorders, a deranged coagulation profile, pregnancy, or an intraoperative finding precluding the use of a topical haemostat were excluded. Written informed consent was obtained from all patients after explaining the procedure, the haemostatic agents to be used, and their relative cost and effectiveness.

Grouping

Patients were stratified into six groups of 40 according to the type of surgery performed breast, kidney, liver, prostate, spleen and thyroid and each group was further divided into four subgroups of 10 patients according to the haemostatic method applied to the operative field: conventional methods, haemocoagulase, oxidized regenerated cellulose, or gelatin-based sponge.

Preoperative Assessment

All patients underwent routine preoperative investigations along with a coagulation profile (bleeding time, clotting time, platelet count, prothrombin time, activated partial thromboplastin time and international normalised ratio), recorded on a standardised proforma.

Outcome Measures

The following outcomes were assessed for each patient:

1. Time to cessation of bleeding, measured by stopwatch from application of the haemostatic agent to complete cessation, compared against a control side managed without additional haemostatic measures.
2. Postoperative pain and swelling.
3. Nature and volume of postoperative drain collection, recorded daily for the first five postoperative days and classified as clear, serohaemorrhagic or haemorrhagic.
4. Postoperative complications, including wound infection and (in splenectomy and liver-injury patients) abdominal sepsis.
5. Requirement for postoperative blood transfusion.

Statistical Analysis

Data were entered in Microsoft Excel 2007 and analysed using Microsoft Excel and Epi Info™ version 7. Two-factor ANOVA was used to assess the significance of differences in time to haemostasis according to type of surgery and type of haemostatic agent; one-factor ANOVA was used to assess differences in drain output by agent. The single-table chi-square test was used to compare the nature of drain fluid across groups on each postoperative day, and to compare transfusion, wound

infection and sepsis rates. The unpaired t-test was used for pairwise comparison of time to haemostasis between ORC and each of the other agents. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 240 patients (6 surgery-type groups × 4 haemostatic-agent subgroups × 10 patients) completed the study (Table 1).

Table 1. Distribution of study patients by type of surgery and haemostatic agent used

Type of surgery	Conventional	Haemocoagulase	ORC	Gelatin-based	Total
Breast	10	10	10	10	40
Kidney	10	10	10	10	40
Liver	10	10	10	10	40
Prostate	10	10	10	10	40
Spleen	10	10	10	10	40
Thyroid	10	10	10	10	40
Total	60	60	60	60	240

Time to haemostasis

Primary haemostasis was achieved within 1–2 minutes in all 60 patients receiving ORC. With gelatin-based sponge, haemostasis occurred within 1–2 minutes in 50/60 patients and within 2–3 minutes in the remaining 10. With haemocoagulase, haemostasis occurred within 1–2 minutes in 34/60 and within 2–3 minutes in 26/60. With conventional methods, no patient achieved haemostasis within 1–2 minutes; 25/60 required 2–3 minutes, 26/60 required 3–4 minutes, and 9/60 required more than 4 minutes.

Table 2. Mean time (minutes) to haemostasis by surgery type and haemostatic agent

Surgery type	Conventional (mean ± SD)	Haemocoagulase (mean ± SD)	ORC (mean ± SD)	Gelatin-based (mean ± SD)
Breast	184.0 ± 23.7	127.0 ± 14.9	92.4 ± 8.1	116.0 ± 9.7
Kidney	158.0 ± 16.9	98.0 ± 7.9	79.5 ± 7.2	92.0 ± 6.3
Liver	229.0 ± 37.3	130.0 ± 15.6	79.0 ± 12.0	107.5 ± 18.4
Prostate	175.0 ± 15.1	95.0 ± 8.5	82.0 ± 7.9	91.0 ± 7.4
Spleen	229.0 ± 37.3	130.0 ± 15.6	79.0 ± 12.0	107.5 ± 18.4
Thyroid	165.0 ± 15.8	92.0 ± 7.9	75.5 ± 9.6	91.0 ± 7.4

Two-factor ANOVA, $p=0.0001$ (conventional), $p=0.0001$ (haemocoagulase), $p=0.00615$ (ORC), $p=0.00002$ (gelatin-based).

Table 3. Pairwise comparison of time to haemostasis with ORC (unpaired t-test)

Groups compared	t statistic	P value	Inference
ORC vs Haemocoagulase	10.154	<0.001	Highly significant
ORC vs Gelatin-based	8.054	<0.0001	Highly significant
ORC vs Conventional	20.026	<0.001	Highly significant

Postoperative drain output

The proportion of patients with a clear (non-haemorrhagic) drain increased progressively over the first five postoperative days in all groups, but rose fastest and reached the highest proportion in the ORC group (Table 4). By postoperative day 5, 56/60 (93%) ORC patients had a clear drain, compared with 40/60 (67%) with gelatin-based sponge, 38/60 (63%) with haemocoagulase and 17/60 (28%) with conventional methods; the corresponding proportion with a haemorrhagic drain on day 1 was lowest with ORC (0/60) and highest with conventional methods (55/60).

Table 4. Nature of postoperative drain fluid by haemostatic agent, days 1–5 (n=60 per agent per day)

Day	Agent	Clear	Serohaemorrhagic	Haemorrhagic	χ^2 (df)	P value
1	Conventional	0	5	55	14.76 (6)	0.0222
	Haemocoagulase	0	12	48		
	ORC	3	16	41		
	Gelatin-based	0	10	50		
2	Conventional	0	40	20	36.69 (6)	0.0001
	Haemocoagulase	1	44	15		
	ORC	10	48	2		
	Gelatin-based	1	42	17		
3	Conventional	0	50	10	74.33 (9)	0.0001
	Haemocoagulase	6	50	4		
	ORC	26	34	0		
	Gelatin-based	8	50	2		
4	Conventional	5	50	5	83.18 (9)	0.0001
	Haemocoagulase	14	45	1		
	ORC	48	12	0		
	Gelatin-based	21	38	1		
5	Conventional	17	42	1	67.31 (9)	0.0001
	Haemocoagulase	38	22	0		
	ORC	56	4	0		
	Gelatin-based	40	20	0		

Blood transfusion, wound infection and abdominal sepsis

Postoperative blood transfusion was required least often in the ORC group (3/60, 5%) and most often with conventional methods (14/60, 23.3%); gelatin-based sponge and haemocoagulase were intermediate (8/60, 13.3% and 10/60, 16.6% respectively; $\chi^2=8.40$, $df=3$, $p=0.0385$) (Table 5). Wound infection likewise occurred least often with ORC (1/60, 1.6%) and most often with conventional methods (14/60, 23.3%), with gelatin-based sponge (12/60, 20%) and haemocoagulase (10/60, 16.6%) intermediate ($\chi^2=12.62$, $df=3$, $p=0.0055$) (Table 6). Among the subgroup of 80 patients undergoing splenectomy or surgery for liver laceration, no patient in the ORC subgroup developed abdominal sepsis, compared with 2/20 (10%) with gelatin-based sponge, 3/20 (15%) with haemocoagulase and 7/20 (35%) with conventional methods ($\chi^2=10.20$, $df=3$, $p=0.017$) (Table 7).

Table 5. Requirement for postoperative blood transfusion by haemostatic agent

Haemostatic agent	No transfusion	Transfusion required	Percentage (%)	Total
Conventional	46	14	23.3	60
Haemocoagulase	50	10	16.6	60
ORC	57	3	5.0	60
Gelatin-based	52	8	13.3	60
Total	205	35	—	240

$$\chi^2=8.3958, df=3, p=0.0385$$

Table 6. Wound infection by haemostatic agent

Haemostatic agent	No infection	Infection	Percentage (%)	Total
Conventional	46	14	23.33	60
Haemocoagulase	50	10	16.6	60
ORC	59	1	1.6	60
Gelatin-based	48	12	20.0	60
Total	203	37	—	240

$$\chi^2=12.6215, df=3, p=0.0055$$

Table 7. Abdominal sepsis by haemostatic agent (splenectomy and liver-laceration patients, n=80)

Haemostatic agent	No sepsis	Sepsis	Percentage (%)	Total
Conventional	13	7	35	20
Gelatin-based	18	2	10	20
Haemocoagulase	17	3	15	20
ORC	20	0	0	20
Total	68	12	—	80

$$\chi^2=10.1961, df=3, p=0.017$$

DISCUSSION

Topical haemostatic agents exert their effect through diverse mechanisms by augmenting primary platelet-mediated haemostasis, providing a scaffold for endogenous clot formation, or directly contributing procoagulant activity and the choice of agent in practice is typically guided by the type of procedure, severity of bleeding, cost and surgeon preference rather than by robust comparative evidence.⁷ In this prospective comparison of 240 patients across six surgical categories, ORC was consistently superior to gelatin-based sponge, haemocoagulase and conventional methods across every outcome assessed: time to haemostasis, resolution of drain output, transfusion requirement, wound infection and abdominal sepsis.

Time to haemostasis with ORC (1–2 minutes in all patients) was shorter than with gelatin-based sponge and haemocoagulase (2–3 minutes) and markedly shorter

than with conventional methods (3–>4 minutes), a difference that was highly significant on unpaired t-testing ($p<0.001$ for all pairwise comparisons). This is consistent with the experimental findings of Takács et al., who reported shorter time to haemostasis with ORC than with gelatin-based or haemocoagulase-type agents in a bovine model.¹¹

The pattern of postoperative drain resolution paralleled the time-to-haemostasis findings: the proportion of patients with a clear drain rose fastest in the ORC group, reaching 93% by day 5 compared with 67%, 63% and 28% in the gelatin-based, haemocoagulase and conventional groups respectively. This is in keeping with the findings of Briceño et al. in liver resection, where ORC use was associated with lower drainage volume, fewer transfusions, fewer moderate-to-severe complications and shorter hospital stay.¹² Zacharias and Ferreira, by contrast, reported broadly similar outcomes

between gelatin-based and ORC dressings after liver resection, with only a marginally longer hospital stay in the gelatin group,¹³ whereas the present study found a more pronounced advantage for ORC, which may reflect differences in the surgical procedures, patient populations or agent formulations studied.

Earlier resolution of drain collection with ORC is clinically relevant because it permits earlier drain removal and is associated with earlier recovery and shorter hospital stay, a benefit also reported by Kakaei et al.¹⁴ Conversely, the persistently haemorrhagic drain pattern observed with conventional methods in this study (55/60 patients haemorrhagic on day 1, falling only gradually thereafter) corresponded to a higher postoperative transfusion requirement, a finding also noted in the same series.¹⁴

Faster haemostasis with ORC in renal surgery in this study is consistent with previous reports in percutaneous and open renal procedures.^{15–19} A similarly favourable response was observed with ORC in thyroid surgery, in agreement with Testini et al.,²⁰ and in solid-organ injury (liver and spleen), where drain output fell rapidly by day 2–3 and no patient developed postoperative abdominal sepsis, consistent with previous series in hepatic and splenic trauma and surgery.^{21–23} Additional supportive evidence for ORC efficacy across gynaecological and other surgical applications has also been reported elsewhere.^{24–26}

Wound infection was least frequent with ORC (1.6%) in this study, in keeping with reports that the low pH and antimicrobial properties of oxidized cellulose may help limit bacterial proliferation at the operative site.²⁷ Gelatin-based sponge, in contrast, was associated with a higher rate of wound complications (20%), a finding attributed elsewhere to its bulkier, more porous structure acting as a nidus for microbial colonisation if retained in larger amounts,^{28,29} and with delayed drain clearance and consequently longer hospital stay compared with ORC.³⁰ Gelatin-based sponge nonetheless performed favourably in pyelolithotomy in other series, with earlier drain removal reported by some authors.

Cost remains an important practical consideration: ORC, while clinically superior in this study, is more expensive than gelatin-based sponge, which in turn was associated with a higher complication rate. Balancing efficacy against cost, our findings support ORC as the preferred agent where its additional expense is affordable and the clinical stakes of bleeding control are high, while acknowledging that further multicentre studies with larger and more homogeneous patient groups are needed to confirm these findings and to refine cost-effectiveness estimates across different surgical settings.

This study has limitations. It was a single-centre, non-randomised comparison with subgroup sizes of 10 patients per surgery-agent combination, which limits

statistical power for some subgroup comparisons and the ability to fully adjust for confounding related to surgeon, disease severity and intraoperative blood loss. Blinding of outcome assessment was not feasible given the visibly different physical characteristics of the agents. Randomised, adequately powered, multicentre trials are warranted to confirm these findings.

The strengths of this study include its prospective comparative design, inclusion of patients undergoing a range of commonly performed surgical procedures, and evaluation of multiple clinically relevant haemostatic outcomes. The study directly compared oxidized regenerated cellulose, gelatin-based sponge, haemocoagulase and conventional haemostatic methods using predefined outcome measures, including time to haemostasis, postoperative drain characteristics, blood transfusion requirement, wound infection and abdominal sepsis. The inclusion of patients from different surgical categories also provides a broader assessment of the practical performance of these haemostatic approaches across varied operative settings. In addition, the five-day postoperative assessment of drain characteristics allowed early postoperative haemostatic outcomes to be evaluated longitudinally.

CONCLUSION

In this comparative study of 240 patients, oxidized regenerated cellulose achieved faster haemostasis and was associated with earlier resolution of postoperative drain collection, lower transfusion requirement, fewer wound infections and no abdominal sepsis among high-risk solid-organ patients, when compared with gelatin-based sponge, haemocoagulase and conventional haemostatic methods. Despite its higher cost, the clinical benefits of ORC support its preferential use as a topical haemostatic agent in general surgical practice, particularly for high-risk vascular and solid-organ procedures, while agent selection in resource-constrained settings should continue to balance efficacy against cost and availability.

Declarations

Ethics Approval and Consent to Participate

This study was conducted after obtaining approval from the Institutional Ethics Committee of Gandhi Medical College, Bhopal. Written informed consent was obtained from all participants before enrolment. The study was conducted in accordance with the ethical principles applicable to research involving human participants.

Consent for Publication

Not applicable. No individual patient-identifiable information or images are included in this manuscript.

Competing Interests

The authors declare that they have no competing interests.

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Authors' Contributions

All authors contributed to the conception and design of the study, data collection, analysis and interpretation of the findings, and preparation and critical revision of the manuscript. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Data Availability

The data generated and/or analysed during the present study are available from the corresponding author on reasonable request, subject to appropriate ethical and institutional restrictions.

Use of Artificial Intelligence

The authors declare that no artificial intelligence tools were used to generate, analyze, or interpret the scientific data reported in this manuscript.

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