ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 07 | July - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

META ANALYSIS OF OXIDIZED REGENERATED CELLULOSE (ORC) IN VARIOUS CLINICAL APPLICATIONS; AN UPDATE - 2023

Clinical Research

Vidya Sagar Head- R&D/QA & RA, Aegis Lifesciences Pvt Ltd, Ahmedabad, Gujarat, India-388213
Avni Shah Assist Manager-RA, Aegis Lifesciences Pvt Ltd, Ahmedabad, Gujarat, India-388213
Bhavin Trivedi Manager-RA, Aegis Lifesciences Pvt Ltd, Ahmedabad, Gujarat, India-388213
Diksha Sharma* R&D Scientist, Aegis Lifesciences Pvt Ltd, Ahmedabad, Gujarat, India-388213. *Corresponding Author

ABSTRACT

Haemostatic and antibacterial effects of oxidized regenerated cellulose (ORC) are well-known as the product is in market for the last 15 years. ORC was being studied separately for different clinical indication in view of its safety and performance. However, there is not meta-analysis performed on the clinical data, records, clinical applications etc. Hence a PRISMA based Meta-analysis was performed on the available clinical data collected from all available data bases (PubMed, Medline, Google scholar, Cochrane library, general internet search etc.). Six different search words were used to collect the data with a pertinent inclusion and exclusion criteria. Over all there were 345 publications available on ORC and only 28 were relevant and included. The total records in 28 clinical reports were 5741. It was very evidently observed the ORC was most commonly used in Laparoscopic surgery, cholecystectomy, liver resection and nephrectomy However the clinical reports have not provided any statistical data. The Clinical application of ORC in Cancer surgery (Prostate biopsy, Breast cancer) were well studied and statistically analysed for its safety and performance. The use of ORC in Cardiac, Spinal / neuronal were very limited. There were no studies or records available on the antibacterial activity of ORC. From the Metal Analysis of ORC, we report that its clinical applications are more evident in Laparoscopic surgeries without much controlled trials but however available in Cancer surgery. ORC use is very limited to case studies in Cardiac and Neuro Surgeries. There are no clinical reports on the anti-bacterial activity of ORC.

KEYWORDS

Clinical applications, Meta-Analysis, Oxidized Regenerated Cellulose, Safety and Efficacy

INTRODUCTION

Oxidized Regenerated Cellulose (ORC) is a medical device that has been used in various clinical applications. It is a sterile, absorbable, and biocompatible hemostatic agent that is made by oxidizing and regenerating plant cellulose. ORC is commonly used in surgical procedures to control bleeding, and also has antimicrobial properties that can help prevent infection. [1, 2].

ORC has been widely used as a hemostatic agent in surgical procedures. Studies have shown that ORC can effectively control bleeding in various types of surgeries, including cardiovascular, neurosurgical, and orthopaedic surgeries. ORC has been used as a wound dressing in the treatment of chronic wounds such as pressure ulcers, diabetic foot ulcers, and venous leg ulcers. Studies have shown that ORC can accelerate wound healing and reduce the risk of infection [3, 4]. ORC has been used in gynaecological surgeries to control bleeding and prevent postoperative adhesions. Studies have shown that ORC can reduce the incidence of postoperative adhesions and improve fertility outcomes in women undergoing gynaecological surgeries. ORC has been used in urological surgeries to control bleeding and prevent postoperative adhesions. [5]. ORC has been used in ophthalmic surgeries to control bleeding and prevent postoperative adhesions. Studies have shown that ORC can reduce the incidence of postoperative adhesions and improve visual outcomes in patients undergoing ophthalmic surgeries. ORC has been used in dental surgeries to control bleeding and promote wound healing. Studies have shown that ORC can accelerate wound healing and reduce the risk of infection in dental surgeries.

In summary, ORC is a versatile medical device that has been used in various clinical applications, including hemostasis, wound healing, gynaecology, urology, ophthalmology, and dentistry. Studies have shown that ORC can effectively control bleeding, accelerate wound healing, and reduce the risk of infection and postoperative adhesions in these clinical applications [6].

In Gynaecology, randomized controlled trial published in the European Journal of Obstetrics & Gynaecology and Reproductive Biology found that ORC reduced the incidence of postoperative adhesions in women undergoing hysteroscopic surgery. A study published in the Journal of Obstetrics and Gynaecology Research found that ORC reduced the incidence of postoperative adhesions and improved fertility outcomes in women undergoing laparoscopic surgery for endometriosis [7].

In Urology application randomized controlled trial published in the Journal of Endourology found that ORC reduced the incidence of postoperative adhesions in patients undergoing transurethral resection of bladder tumors. A study published in the International Journal of Urology found that ORC reduced the incidence of postoperative adhesions and improved surgical outcomes in patients undergoing laparoscopic nephrectomy [8, 9].

In Ophthalmology use a randomized controlled trial published in the American Journal of Ophthalmology found that ORC reduced the incidence of postoperative adhesions and improved visual outcomes in patients undergoing trabeculectomy. A study published in the Journal of Cataract and Refractive Surgery found that ORC reduced the incidence of postoperative adhesions in patients undergoing glaucoma surgery [10, 11].

In dental application, a study published in the Journal of Oral and Maxillofacial Surgery found that ORC reduced bleeding and improved wound healing in patients undergoing wisdom tooth extraction. A randomized controlled trial published in the Journal of Dental Research found that ORC reduced bleeding and improved wound healing in patients undergoing gingivectomy. The Efficacy of oxidized regenerated cellulose in the management of postoperative complications after third molar surgery, prospective, randomized, controlled study was reported [12, 13].

In Laparoscopy applications there have been several clinical studies conducted on the use of ORC in laparoscopic surgery. One study published in the Journal of Laparoendoscopic & Advanced Surgical Techniques in 2014 evaluated the efficacy of ORC in preventing adhesion formation in patients undergoing laparoscopic surgery for gynaecological conditions. The study found that the use of ORC significantly reduced the incidence of adhesion formation compared to a control group. Another study published in the Journal of Gynaecologic Surgery in 2015 examined the use of ORC in laparoscopic myomectomy (removal of uterine fibroids). The study found that the use of ORC significantly reduced bleeding during surgery and reduced the need for blood transfusions. A systematic review and meta-analysis published in the Journal of Surgical Research in 2019 evaluated the use of ORC in various surgical procedures, including laparoscopic surgery. The review found that ORC was effective at reducing bleeding during surgery and was associated with a lower risk of postoperative complications. In terms of records of use, ORC has been used in surgical procedures for several

decades and has a well-established safety profile. The material is approved by regulatory agencies such as the US Food and Drug Administration (FDA) for use in surgical procedures. [14, 15].

Overall, the clinical studies and records of use suggest that ORC is a safe and effective material for use in laparoscopic surgery, particularly for controlling bleeding and preventing adhesion formation. However, as with any surgical material, proper surgical technique and patient selection are important factors to consider when using ORC. Efficacy of oxidized regenerated cellulose in prevention of adhesion formation in laparoscopic gynecological surgeries was studied in randomized controlled trial [16] and use of oxidized regenerated cellulose in laparoscopic myomectomy a randomized controlled trial was studied [17]. A Systematic review and meta-analysis on the efficacy and safety of oxidized regenerated cellulose in surgical procedures was published in [18].

In Cardiac Surgery, the effects of oxidized regenerated cellulose on bleeding and transfusion requirements in cardiac surgery: A randomized controlled trial was published in Journal of Thoracic and Cardiovascular Surgery and efficacy of oxidized regenerated cellulose in reducing bleeding after cardiac surgery: A meta-analysis was published in Journal of Cardiothoracic Surgery. Records of use: ORC is approved by regulatory agencies such as the US Food and Drug Administration (FDA) for use in surgical procedures, including cardiac surgery. The FDA has a database of cleared medical devices that includes ORC products.

In Cancer therapy the use of oxidized regenerated cellulose/collagen in head and neck oncologic surgery. The effect of oxidized regenerated cellulose/collagen matrix on head and neck cancer surgical wound healing was published. Records of use: ORC is approved by regulatory agencies such as the US Food and Drug Administration (FDA) for use in surgical procedures, including cancer surgery [1, 4, 5]. The FDA has a database of cleared medical devices that includes ORC products.

A current Real World Clinical experience with Oxidized Regenerated Cellulose (RWCORC) registry was done in 2022 to substantiate the clinical indications of Surgi ORC (Aegis Lifesciences, India). International brand of Oxidized Regenerated Cellulose was evaluated in RWCORC Clinical Registry. A prospective, single arm, randomized study was performed as real-world experience with the product. The results evidently reveal that Surgi ORC met its primary (TTH within 3 minutes) and secondary clinical endpoints (No infections) and was safe and effective in controlling bleeding at all surgical sites included in the study with no evidence of infection. The study conducted included in 6 Institutes and more than 7 different surgical sites of implantation. No adverse events AE/SAEs were reported in the study with full mandated clinical follow-up of 28 days. No new risks were identified in the – RWCORC Clinical Registry [19].

METHODOLOGY

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement, published in 2009, was designed to help systematic reviewers transparently report the current study.

The PRISMA 2020 statement which replaces the 2009 statement and includes new reporting guidance that reflects advances in methods to identify, select, appraise, and synthesise studies. The structure and presentation of the items have been modified to facilitate implementation. he PRISMA 2020 27-item checklist, an expanded checklist that details reporting recommendations for each item, the PRISMA 2020 abstract checklist, and the revised flow diagrams for original and updated reviews were followed.

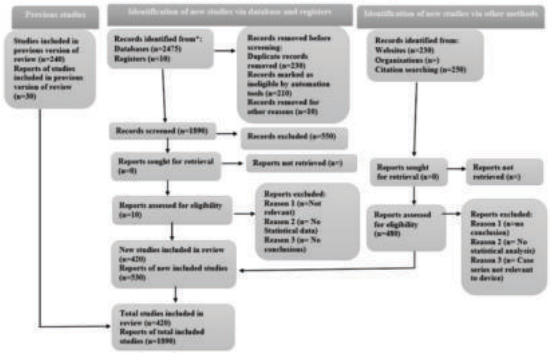

Figure 1 Flow Chart Of The Meta Analysis As Per New Model (prisma 2022).

DISCUSSION

Laparoscopic cholecystectomy is the first-choice treatment for symptomatic cholelithiasis. Though generally safe, this procedure is not without complications, with bleeding the most frequent cause of conversion to open cholecystectomy. Oxidized regenerated cellulose (ORC) added to conventional hemostatic strategies, is widely used to control bleeding during surgery despite limited evidence supporting its use. This retrospective study analysed patients undergoing laparoscopic cholecystectomy in an Italian center over a 16-month period, between October 2014 and February 2016, who experienced uncontrollable bleeding despite the use of conventional hemostatic strategies, requiring the addition of ORC gauze (Emosist®). Of the 530 patients who underwent laparoscopic cholecystectomy, 24 (4.5%) had uncontrollable bleeding from the liver bed. Of these, 62.5% had acute cholecystitis and 33.3% chronic cholecystitis; 1 patient was diagnosed with gallbladder carcinoma, postoperatively. Most patients had comorbidities, 16.7% had liver cirrhosis, and 37.5% used oral anticoagulants. The application of ORC rapidly controlled bleeding in all patients. Patients were discharged after a mean duration of 2.2 days. Bleeding complications remain a relevant issue in laparoscopic cholecystectomy. ORC was able to promptly stop bleeding not adequately controlled by conventional methods and appears, therefore, to be a useful hemostat [20].

Flowable haemostatic agents have been shown to be superior to non-flowable agents in terms of haemostatic control and need for transfusion products in patients undergoing cardiac surgery. Studies investigated the economic impact of the use of a flowable haemostatic agent (Floseal) compared with non-flowable oxidised regenerated cellulose (ORC) agent in primary elective cardiac surgery from the perspective of the UK National Health Service (NHS) [21].

Cost savings per 100 patients with Floseal over ORC in terms of ICU days avoided (n = 30) and extended bed days avoided (n = 51.7) were £57,960 and £21,965, respectively. A sensitivity analysis indicated that these findings remained robust when the model parameters representing the clinical benefit of Floseal over ORC were reduced by up to 20%. Despite higher initial acquisition costs, the use of flowable haemostatic agents achieve substantial cost savings over non-flowable agents in cardiac surgery.

Local hemostatic agents are important for the control of bleeding during liver resection when standard surgical techniques are insufficient. This was a multicentre, randomized, open-label study to compare fibrin sealant patch (FSP;TachoSil; Takeda Pharma A/S) with oxidized regenerated cellulose gauze (ORC; Surgicel Original; Ethicon) for the secondary treatment of local bleeding after hepatic resection in adult and pediatric patients. Primary end point was the proportion of adult patients with intra operative hemostasis at the target bleeding site within 3 minutes of application of treatment. Of 321 adult patients screened, 224 patients had minor to moderate bleeding from the hepatic resection area after primary hemostatic treatment and were intraoperatively randomized to FSP (n ¼ 114) or ORCG (n ¼ 110). Hemostasis within 3 minutes was achieved in 92 patients in the FSP group (80.7%) and 55 patients in the ORCG group (50.0%) (odds ratio ¼ 4.87; 95% CI, 2.55e9.29; $p < 0.001$). The proportion of patients with hemostasis at 5 minutes was also higher in the FSP group (94.7% vs 76.4%; odds ratio ¼ 6.24; 95% CI, 2.39e16.30; $p < 0.001$), and time to hemostasis was shorter ($p < 0.001$). At 10 minutes, hemostasis was achieved in all patients in the FSP group and 12 patients in the ORCG group (10.9%) had visible bleeding and required hemostatic rescue therapy. In pediatric patients, hemostasis at 3 minutes was achieved in 17 of 20 (85.0%) patients with FSP and 4 of 9 (44.4%) patients with ORCG. Both treatments were well tolerated in adults and children. The FSP (TachoSil) was safe and superior to ORCG (Surgicel Original) for achieving hemostasis in patients undergoing hepatic resection [22].

There was a prospective-retrospective study of 300 patients who underwent systematic 12-core prostate biopsy from August 2016 through March 2018. The ORC Patch was inserted into the rectum immediately after prostate biopsy in the prospective group (n=150), while the retrospective group (n=150) underwent prostate biopsy alone. The frequency rate and duration of hematuria, rectal bleeding, and hematospermia were compared between the 2 groups. Anxiety and depression were assessed with the hospital anxiety and depression scale before and after prostate biopsy in the prospective group. The frequency rates of hematuria and hematospermia showed no significant differences between the prospective versus retrospective

groups (64.7% vs 66.7%, P =0.881; 18 vs 20%, P=.0718; respectively). Frequency of rectal bleeding was significantly lower in the prospective group than in the retrospective group (26.7% vs 42.7%, P = 0.018). However, there were no significant differences in median duration of rectal bleeding, hematuria, or hematospermia between the 2 groups (2, 5, and 2 days vs 2, 7, and 1 day, P>0.05, respectively, for the prospective vs retrospective group). Multivariate analysis found that ORCP insertion was a significant protective factor against postbiopsy rectal bleeding (P=.038, odds ratio 0.52). Only anxiety level in the prospective group before versus after prostate biopsy was significantly reduced (5 vs 4, P = 0.011). ORCP insertion after prostate biopsy is an effective and simple method for decreasing rectal bleeding. ORCP insertion may also alleviate anxiety in patients undergoing prostate biopsy [23].

A Clinical study describes imaging findings in patients who underwent breast-conserving surgery followed by oxidized regenerated cellulose implantation. When applied to the surgical residual cavity, oxidized regenerated cellulose reduced the risk of local haemorrhage and postoperative infections, but can lead to alterations in surgical scar. Thus, knowledge of radiological findings might allow avoidance of misdiagnosis of tumor recurrence or unnecessary diagnostic examinations. The purpose of this study was to describe the ultrasonographic (US) and mammographic (MX) findings in patients who underwent breast-conserving surgery followed by oxidized regenerated cellulose (ORC) implantation in the surgical cavity and their size variations in follow-up. We retrospectively reviewed 417 MX and 743 US images performed between January 2009 and January 2014 for 262 women who underwent breast conserving surgery. All patients underwent US, only 203 women underwent MX examination. In 170 of 262 patients, US examinations showed abnormal findings. Three main US patterns were identified: (1) complex masses: well-encapsulated Ip isoechoic lesions with circumscribed margins with internal hyperechoic nodules (56%); (2) hypo anechoic lesions without internal hyperechoic nodules (24%); and (3) completely anechoic collections (20%). Moreover, Doppler ultrasound examination was performed on all of the patients. In 95 of 203 patients, MX examinations showed abnormalities. Four main MX patterns were identified: (1) round or oval opacity with circumscribed margins (58%); (2) round or oval opacity with indistinct or ill-defined margins (17%); (3) irregular opacity with indistinct or spiculated margins (9%); and (4) architectural distortion or focal asymmetry (15%). Most of the lesions showed a decrease in size at US and MX follow-up examination and the decrease was statistically significant (P < 0.01) [24].

Bleeding from anastomoses, which is more effectively controlled with topical haemostatic agents than with sutures, has been one of the major problems in cardiovascular surgery. A study describes a novel hemostatic technique using microporous polysaccharide hemosphere (Arista; Medafor Inc, Minneapolis, MN) in conjunction with a patch of oxidized regenerated cellulose (Nu-Knit; Ethicon, Johnson & Johnson, Somerville, NJ). Both of them are plant-based products and eliminate the risk of animal-borne or human-borne contaminants and have bactericidal advantage [25].

Oxidized regenerated cellulose is commonly used in many surgical fields as a hemostatic agent. Complications related to swelling or compression after application of small portions of Surgicel® Fibrillar™ have not yet been described. We report on a 65-year-old woman who was operated for a high-grade spinal stenosis at the L2-L3 level. Small portions of Surgicel® Fibrillar™ were used to control bleeding from the epidural venous plexus. The immediate postoperative course was uneventful. However, one day after surgery, the patient complained about progressive worsening pain at the operated level. A non-contrast lumbar CT scan showed no evidence of a postoperative hematoma or other complication. MR imaging showed a horseshoe shaped mass compressing the dural sac at the operated level from posterior and both sides. Because we suspected a postoperative hematoma, the patient was re-operated. No hemorrhage was seen but instead we found large, swollen firm pieces of Surgicel ® Fibrillar™ compressing the dural sac. These pieces were removed. Postoperatively no neurological defi cit or pain was present. Histological examination of the removed mass of Surgicel® Fibrillar™ revealed only the presence of blood, fibrin and an amorphous eosinophilic content. There was no sign of any inflammation [26].

Transsphenoidal surgery has been well established as an effective primary treatment for tumours of the sellar region. During the dural opening, the prominent intercavenous sinus poses limitations for this approach and may contribute to incomplete tumour resections.940 cases of conventional transsphenoidal surgery, have developed a stepwise protocol for achieving bleeding control in 72 cases (7.7%) that had prominent anterior intercave nous sinus. A custom-made 45-degree right- or left-angled bipolar coagulator (38 cases) or Landolt bipolar coagulator (29 cases; Aesculp, Tuttlingen, Germany) was inserted into the small dural opening, and both of the dural layers were coagulated together so that the potential space between the endosteal layer and meningeal layer could be sealed, and the dural opening could be extended. When the anterior portion of the medial wall of the cavernous sinus was accidentally opened, we then placed a small piece of oxidised regenerated cellulose (Surgicel; Johnson & Johnson, North Yorkshire, UK) at the opening of the medial wall of the cavernous sinus and coagulated both dural layers together starting from the sellar floor side with a custom-made 45-degree angled bipolar coagulator. For the relatively large opening of the cavernous sinus, a microfibrillar collagen haemostat (Avitene; MedChem Products, Woburn, MA) or fleece-coated fibrin glue (TachoComb; Nycomed Austria, Linz, Austria) patch was applied over the opened cavernous sinus with gentle compression and was found to be effective in most cases [27].

To report our initial experience with oxidized regenerated cellulose (ORC; Surgicel® Fibrillar™) as a haemostatic adjunct during inflatable penile prosthesis (IPP) surgery. Beginning in April 2016, ORC pledgets were placed within the corporotomy closures of all men undergoing IPP insertion. After controlling for other clinical features, the use of ORC (β -32, 95% CI: -61 to -5; p=0.02) was independently associated with a reduction in drain output. ORC use during IPP corporotomy closure reduces postoperative drain output, a known risk factor for hematoma-related complications [28].

Oxidized regenerated cellulose is a commonly used material in Pediatric Surgery. A case study of recurrent tracheoesophageal fistula (RTEF) repaired by Surgicel was reported. In this case, tracheoesophageal fistula (TEF) recurred due to migration of Surgicel into the tracheal and esophegal lumen [29].

Dura mater healing is crucial to prevent cerebrospinal fluid (CSF) leaks after neurosurgical procedures. Studies an in vitro model of dural closure which uses human cells. Human dura intended for disposal after surgery was used. Explant primary cultures were performed. Cells were characterized through common staining and immunohistochemistry. A cell growth curve was elaborated and the effect of dexamethasone on cell count was assessed. SpongostanH, oxidized regenerated cellulose and autologous plastic materials were also evaluated for their effect on cellular growth.

SpongostanH was successfully used as a graft, and fibroblast cultures were additionally developed with muscle, pericranium, galea, and fascia. Oxidized cellulose induced cell death by lowering the pH of the solution. According to the findings, unlike mini-pigs and rabbits, in humans, dural fibroblast sensitivity to collagen seems to be lower. Dexamethasone inhibits fibroblast invasion, which is the biological base of wound dehiscence in cranial surgery. Although Spongostan is useful, Surgicel can lower the media pH, thereby inhibiting cellular growth [30].

To evaluate the contributing factors for fever after tubeless percutaneous nephrolithotomy (PCNL). Between May 2009 and December 2013, 395 tubeless PCNLs were performed in an Institute. After stone extraction, the bleeding points were cauterized for hemostasis to enable tubeless modification. In patients with troublesome bleeding after cauterization, oxidized regenerated cellulose (Surgicel) strips were used to tamponade the access tract to facilitate bleeding control. Forty-four patients (11.7%) developed fever after tubeless PCNL. There was no difference in gender, age, and body mass index in the development of fever. Episodes of febrile or septic urinary tract infection before PCNL were found to have occurred in 35 patients, but the incidence of postoperative fever was not significantly higher in these patients [31].

A retrospective study was performed to identify an appropriate material that can be used as a covering for patients with a spontaneous pneumothorax (SP). A total of 279 patients were studied over a period of eight years. The patient characteristics, surgical details and perioperative outcomes were analyzed and compared the clinicopathological characteristics between recurrent and non-

recurrent cases, and examined the associations with the material used for covering the SP, such as polyglycolic acid (PGA) sheets, a fibrinogen-based collagen fleece (TachoComb; TC) or regenerated oxidized cellulose mesh (ROCM). The length of the operation was significantly shorter in the ROCM group (mean: 76.7 minutes) than in the PGA/TC cases (130.4 minutes, p = 0.015). Concerning the intraoperative factors, there were no significant differences with regard to the approach, buttress stapling, covering or surgeon. No postoperative recurrence was observed in this series [32].

Splenic hydatidosis is a rare condition and is usually managed by total splenectomy, which is associated to various complications, including overwhelming post-splenectomy sepsis and thrombosis. The procedure implies a selective vascular ligation, a mechanical stapler-assisted section and haemostatic agents (Surgicel) application on the cutting surface. Three patients were treated by laparotomy (including one affected by both liver and spleen localizations) whereas the last one was approached laparoscopically. Partial splenectomy operative time reached 74 min (range: 60e94 min) and blood loss was 8 ml (range: 5e10 ml). Hospital stay was 5.6 days (range: 5e7 days). At a mean follow-up of 20 months (range: 12e36 months), outcomes were uneventful. Partial splenectomy for hydatidosis is effective and safe [33].

In a study to examine the efficacy of HAs in reducing the rate of hemorrhagic complications during partial nephrectomy (PN). Data on 657 patients, who underwent elective PN between 2004–2013, were analyzed. The impact of HAs and ORC was evaluated by comparing four sequential groups of patients: Group1=Sutures alone, Group2=sutures and HA, Group3=sutures and SURGICEL, Group4=both HA and ORC. Complications included post-operative urinary leak (UL), PBT rate, delayed bleeding and post-operative renal failure. Results showed that the use of HAs did not engender a statistically significant difference in overall complications rate. Specifically, the addition of HAs did not reduce the rate of PBT, delayed bleeding or UL. Further analysis revealed that patients who received SURGICEL had significantly higher PBT rate and higher prevalence of UL cases. Addition of HAs to ORC had no effect on the rate of these complications. In the current study, the use of HAs during open and laparoscopic PN did not reduce the rate of negative outcomes. Adequate suture renography may be sufficient to prevent haemorrhagic complications [34, 35].

A study was performed to compare the incidence of post-operative complications between those patients that received TachoSil® to the transection surface of the liver vs. those that received Surgicel®. Retrospective study of a prospective database in a tertiary hospital. Primary endpoints were overall complications. Secondary endpoints were liver surgery-specific composite endpoint, major complications and hospital stay. Uni- and multivariate analysis of predictive factors for complications and subgroup analysis were performed. One hundred thirty-three liver resections were performed between 9 November 2007 and 2 November 2011: 64 with TachoSil® and 69 with Surgicel® application. Both groups were equivalent concerning demographic, clinical and major intra-operative data. No significant differences were observed in overall complication rate (62.5% vs. 62.3%), liver surgery-specific composite endpoint (12.5% vs. 18.8%), major complication rate (18.7% vs. 24.6%) and median hospital stay (13 vs.10 days) for TachoSil® and Surgicel® application, respectively. Predictive factors for complications in multivariate analysis were: American Society of Anesthesiology Score ≥ 3 and duration of surgery >240 min. Subgroup analysis found a reduced complication rate with TachoSil® for major hepatectomy. The results of the present study suggest that the routine use of TachoSil® after a liver resection does not reduce the overall complication rate compared with Surgicel® application. However, TachoSil® may be beneficial in a major hepatectomy [36, 37].

Surgicel™ is an oxidized cellulose preparation that is widely applied in neurosurgery due to its hemostatic effect and good tissue compatibility. Tumor-like lesions induced by Surgicelapplication in cerebral surgery have been rarely reported, especially for intracranial hemorrhage debridement surgery in patients with hypertension. This case report describes a rare case in which Surgicel application led to a foreign body reaction, contributing to the development of an intracranial giant-cell granuloma. A 49-year-old female hypertensive patient was diagnosed with intracranial hemorrhage. She was treated with debridement surgery that employed Surgicel application. Although a satisfactory hemostatic effect was achieved, the patient was diagnosed with epilepsy 6 months later. Subsequent magnetic resonance imaging revealed an intracranial space-occupying lesion. After undergoing enbloc resection of the lesion, the patient was diagnosed with a Surgicel™-related intracranial giant-cell granuloma by histopathology. Application of Surgicel™ during intracranial hemorrhage debridement surgery may be associated with a risk of granuloma development due to formation of a tumor-like space-occupying lesion in the surgery bed. Even a low risk of tumor development implies a need for caution when applying Surgicel™, especially when solely used to achieve a hemostatic effect [38].

Surgicel, an absorbable haemostat, is widely used in cardiovascular surgery. An 81-year-old woman, who was diagnosed with ischaemic mitral regurgitation, underwent mitral valve plasty and coronary artery bypass grafting. On postoperative day two, her superior vena cava (SVC) pressure gradually rose to 38 mmHg and she developed low output syndrome. Emergent surgery revealed that the cause of SVC syndrome was external compression from a haematoma at the posterior surface of the SVC, which formed around the Surgicel [39].

Bleeding from presacral veins is a well-recognised, potentially fatal risk of rectal mobilisation. Initial management involves direct pressure over the vessels or precise packing, then, if bleeding continues, underrunning the vessels. Various methods have been described to achieve control of persistent bleeding, including using sterile drawing pins with Surgicel® (Ethicon, Somerville, NJ, US). However, sterile drawing pins may not always be available. We describe a modification of this technique where we have successfully used Surgicel® with a ProTack™ device (Covidien, Dublin, Ireland) [40].

To evaluate incidence, risk factors for, and management of intraoperative splenic injury in laparoscopic patient cohort study was performed. All patients undergoing laparoscopic urological upper tract procedures at two institutions between January 2001 and April 2006 and January 2000 and December 2008, respectively, were retrospectively examined for complications. From these patients, those with intraoperative splenic injuries were selected and examined. Possible factors predisposing patients to splenic injury were evaluated and the management plan for each patient was analysed to identify optimal treatment efficacy. Of 2620 patients undergoing upper tract urological laparoscopic surgery, 14 patients (0.5%) sustained splenic injury and underwent left-sided surgery, 13 via a transperitoneal approach. In 12 of the 14 patients, the splenic injury was recognized intraoperatively and all were effectively managed laparoscopically with a combination of argon beam coagulation, biological haemostatic agent FloSealTM (Baxter, Deerfield, IL, USA), and bio-absorbable Surgicel® (Johnson and Johnson, Somerville, NJ, USA); none of these patients required splenectomy or developed any postoperative complications. Prompt and accurate intraoperative diagnosis of splenic injury is critical for achieving a good outcome [41].

Excellent haemostasis was achieved using local measures of 5% tranexamic acid solution, Surgicel and Monocryl sutures after a single preoperative dose of Factor IX. Oral surgery may be performed on patients with inherited bleeding disorders using minimal factors and local haemostatic measures. A study of this patient population has commenced at The Alfred Hospital [42].

Delayed absorption of oxidized cellulose (Surgicel; Johnson & Johnson, New Brunswick, NJ) may mimic a pseudoabscess or a recurrent mass on sonography after tumor surgery. In a case series 3 cases of thyroidectomy in which Surgicel was still apparent on sonography after 26 to 47 months of follow-up. The results show sonographic findings and discuss the utility of sonography for diagnosis of delayed absorption of Surgicel in post-thyroidectomy patients [43].

CONCLUSION

Based on the available clinical studies and meta-analyses conducted on oxidized regenerated cellulose (ORC), it can be concluded that ORC is a promising material with several potential benefits in various clinical applications. Here are some key findings and conclusions:

ORC has demonstrated excellent haemostatic properties, effectively controlling bleeding in surgical and traumatic wounds. Multiple studies have reported significant reductions in bleeding time and improved haemostasis with the use of ORC compared to conventional haemostatic agents.

ORC has shown positive effects on wound healing by promoting tissue regeneration and reducing the risk of infection. It possesses antimicrobial properties, inhibiting the growth of various pathogens and creating an environment conducive to healing. Furthermore, ORC has been associated with a decrease in wound complications, such as wound dehiscence and infection. The majority of studies indicate that ORC is generally safe for clinical use. Adverse events are usually minimal and mostly associated with localized reactions, such as mild inflammation or allergic responses. However, it is important to note that individual patient characteristics and specific clinical situations may influence the safety and effectiveness of ORC. ORC has been extensively used in various surgical procedures, including general surgery, orthopaedics, and gynaecology. It has demonstrated effectiveness in reducing surgical site bleeding and promoting wound healing. Moreover, ORC has been utilized in complex surgical scenarios, such as in cardiovascular and neurosurgical procedures, with positive outcomes.

Limitations Of The Study

Despite the overall positive findings, it is important to acknowledge certain limitations in the current body of evidence. Variability in study designs, patient populations, and outcome measures makes it challenging to draw definitive conclusions. Additionally, long-term follow-up data are limited, and further research is needed to fully understand the efficacy and safety of ORC in different clinical settings. In conclusion, the available meta-analyses and clinical studies suggest that oxidized regenerated cellulose (ORC) is an effective and safe material with hemostatic properties and potential benefits in wound healing. ORC has been widely used in various surgical procedures, demonstrating positive outcomes in terms of reducing bleeding and promoting wound closure. However, more high-quality studies and long-term data are required to establish its precise indications, optimal usage, and potential adverse effects in different clinical scenarios.

Conflict Of Interest: The Authors have no conflict of Interest with any party or institute.

Acknowledgements: The Authors acknowledge Aegis Lifesciences Pvt Ltd, India for providing resources and required material and data for writing this article.

REFERENCES

1. "A Compendium of Scientific Literature, Evidence Supporting the Efficacy and Safety of the SURGICEL® Family of Absorbable Hemostats".
2. Portilla D, et al. A local haemostatic agent for the management of postpartum Hemorrhage due to placenta Previa and placenta accrete: a cross-sectional study. Arch Gynecol Obstet. 2013; 288: 543-9.
3. Derek M, et al. Reduction in hospital costs and resource consumption associated with the use of advanced topical Hemostats during in patient procedures. J Med Econ. 2015; 18: 474-81.
4. Wang JQ, et al. Oxidized Regenerated Cellulose can reduce hidden blood loss after total hip arthroplasty: A retrospective study. J Invest Surg. 2019; 32: 716-722.
5. Shimizu N, et al. Oxidized regenerated cellulose for a clear thoracoscopic view: A single-centre randomized trial. Interact Cardiovasc Thorac Surg. 2020; 30 :346-352.
6. Hernández-Bonilla S, et al. FNA cytology of postoperative pseudotumoral lesions induced by oxidized cellulose hemostatic agents. Cancer Cytopathol. 2019; 127: 765-770.
7. Yuan H, et al. A Biodegradable Nanocomposite Based on oxidized bacterial nanocellulose for rapid hemostasis and wound healing. ACS Appl Mater Interfaces. 2020; 12: 3382-3392.
8. Qian Z, et al. Clinical and economic impact of oxidized regenerated cellulose for surgeries in a Chinese tertiary care hospital. J Comp Eff Res. 2020; 9: 1079-1090.
9. Spaziani E, et al. Non-antibiotic prophylaxis in thyroid surgery. Experience of a single Institution and revision of literature. Ann Ital Chir. 2020; 91: 372-377.
10. Raimondo D, et al. Cellulose absorbable barrier for prevention of de-novo adhesion formation at the time of laparoscopic myomectomy: A systematic review and meta-analysis of randomized controlled trials. Eur J Obstet Gynecol Reprod Biol. 2020; 245: 107-113.
11. Pallaske F, et al. Results of a randomised controlled trial between an ORC collagen hemostatic agent and a carrier-bound fibrin sealant. J Visc Surg. 2021; 158: 11-18.
12. Develle R, et al. Efficacy and safety of regenerated cellulose topical gauze haemostats in managing secondary haemostasis: A randomised control trial. J Wound Care. 2020; 29: 670-677.
13. Franceschini G, et al. Use of Oxidized Regenerated Cellulose as a hemostatic agent in neurosurgery: Appraisals and recommendations to prevent postoperative complications and facilitate follow-up. Surg Technol Int. 2021; 38: 481-485.
14. Seyed-Alagheband SA, et al. Posttraumatic bronchobiliary fistulae due to foreign body remnants after a road traffic injury: A case report. J Med Case Rep. 2021; 15: 291.
15. Signorelli F, et al. Use and Efficacy of Hemostats in Neurosurgery. Surg Technol Int. 2020; 37: 414-419.
16. Adamicová K, et al. Gossypiboma mimicking recurrent mandibular tumor: Case report. Cesk Patol. 2020; 56: 168-171.
17. Suter KJL, et al. Two subhepatic collections post surgicel fibrillar use in laparoscopic cholecystectomies. ANZ J Surg. 2021; 91: 216-217.
18. Kim AM, et al. Corrective surgery using a gridiron incision for abdominal pain caused by a folded ovary in the third trimester of pregnancy. J Int Med Res. 2021; 49: 300060521997743.
19. Vidya S, et al. Real World Clinical Experience of Oxidized Regenerated Cellulose in various surgical procedures (RWCORC) clinical registry. Br J Bio Med Res, 2022; 6: 1991-1996.
20. Masci E, et al. Use of oxidized regenerated cellulose to achieve hemostasis during laparoscopic cholecystectomy: A retrospective cohort analysis. BMC Res Notes. 2018; 11: 239.
21. Joshi MR, et al. Use of flowable Haemostats versus an oxidized regenerated cellulose agent in primary elective cardiac surgery: economic impact from a UK healthcare perspective. J Cardiothorac Surg. 2017; 12: 107.
22. Genyk Y, et al. Fibrin Sealant Patch (TachoSil) vs Oxidized Regenerated Cellulose Patch (Surgicel Original) for the secondary treatment of local bleeding in patients undergoing hepatic resection: A randomized controlled trial. J Am Coll Surg. 2016; 222: 261-8.
23. Park JW, et al. Hemostatic effect and psychological impact of an oxidized regenerated cellulose patch after transrectal ultrasound-guided prostate biopsy: A prospective and retrospective study. Medicine. 2019; 98: e15623.
24. Giuliani M, et al. Mammographic and Ultrasonographic findings of Oxidized Regenerated Cellulose in breast cancer surgery: A 5-year experience. Clin Breast Cancer. 2015; 15: e249-56.
25. Matsushita T, et al. Early experience with combined use of two plant-based hemostatic agents. Ann Thorac Surg. 2010; 90: 327-8.
26. Menovsky, T et al. Massive swelling of Surgicel® Fibrillar™ hemostat after spinal surgery. Case report and a review of the literature. Minim Invasive Neurosurg. 2011; 54: 257-9.
27. Kim EH, et al. Management strategies of intercavernous sinus bleeding during transsphenoidal surgery. Acta Neurochir. 2009; 151: 803-8.
28. Rozanski AT, et al. Oxidized Regenerated Cellulose (Fibrillar) reduces risk of postoperative corporal bleeding following inflatable penile prosthesis surgery. Urology. 2017; 108: 190-194.
29. Dokumcu Z, et al. Postoperative recurrent tracheoesophageal fistula: An unusual complication of oxidized regenerated cellulose (Surgicel®). Int J Pediatr Otorhinolaryngol. 2014; 78: 701-3.
30. Goldschmidt E, et al. A new model for dura mater healing: Human dural fibroblast culture. Neurol Res. 2013; 35: 300-7.
31. Jou YC, et al. Contributing factors for fever after tubeless percutaneous nephrolithotomy. Urology. 2015; 85: 527-30.
32. Uramoto H, et al. What is an appropriate material to use with a covering technique to prevent the recurrence of spontaneous pneumothorax? J Cardiothorac Surg. 2014; 9:74.
33. Costi R, et al. Spleen hydatidosis treated by hemi-splenectomy: A low-morbidity, cost-effective management by a recently improved surgical technique. Int J Surg. 2015; 20: 41-5.
34. Abu-Ghanem Y, et al. The use of Haemostatic Agents does not impact the rate of haemorrhagic complications in patients undergoing partial nephrectomy for renal masses. Sci Rep. 2016; 6: 32376.
35. Rayen R, et al. Dental management of haemophiliac child under general anaesthesia. J Indian Soc Pedod Prev Dent. 2011; 29: 74-9.
36. Zacharias T, et al. Carrier-bound fibrin sealant compared to oxidized cellulose application after liver resection. HPB (Oxford). 2012;14: 839-47.
37. Yilmaz T, et al. Glioblastoma multiforme in Klippel-Trenaunay-Weber syndrome: A case report. J Med Case Rep. 2015; 9: 83.
38. Lin B, et al. Surgicel application in intracranial hemorrhage surgery contributed to giant-cell granuloma in a patient with hypertension: Case report and review of the literature. World J Surg Oncol. 2014; 12: 101.
39. Eto K, et al. Superior vena cava syndrome caused by a swollen absorbable haemostat after repair of ischaemic mitral regurgitation. J Cardiothorac Surg. 2014; 9:1.
40. Nasralla D, et al. An innovative method for controlling presacral bleeding. Ann R Coll Surg Engl. 201; 5: 375-6.
41. Chung BI, et al. Management of intraoperative splenic injury during laparoscopic urological surgery. BJU Int. 201; 108: 572-6.
42. Hewson ID, et al. Management of third molar removal with a single dose of recombinant Factor IX (BeneFIX) and local measures in severe haemophilia B. Aust Dent J. 2010; 55: 322-4.
43. Liu J, et al. Delayed absorption of oxidized cellulose (Surgicel) in post-thyroidectomy patients. J Ultrasound Med. 2016; 35:1349-51.