

Omentoplasty versus tachosil in preventing leakage after colonic anastomosis

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Context

Leak from an intestinal anastomosis is the complication most feared by colorectal surgeons. The role of omentoplasty in securing colorectal anastomoses is controversial. Collagen-bound fibrin sealant sheets have recently been used in many aspects of surgery and many experimental animal studies have proven its efficacy in securing gastrointestinal anastomoses. The safety and feasibility of a collagen-bound fibrin sealant has been proven. Its application in sealing colonic anastomosis is a new field and needs to be evaluated.

Aim

The aim of this study was to evaluate and compare the efficacy of omentoplasty versus TachoSil in decreasing the rate of anastomotic leakage in colorectal anastomoses.

Settings and design

This is a prospective randomized trial.

Materials and methods

Ninety-seven patients with colonic anastomosis were divided into two groups; 48 were subjected to omentoplasty and 49 to TachoSil for prevention of leakage. The patients were followed up for symptoms and signs of leakage postoperatively.

Statistical analysis

Continuous variables were expressed as means and SD. Categorical variables were expressed as frequencies and percentage.

Results

The rate of clinical leakage in the omentoplasty group was 8.3% and that in the TachoSil group was 2%, which was within the reported range of 1.5–16%. Three out of four leakages in the omentoplasty group were severe (>500 ml/day) and the only case in the TachoSil group was less severe (<500 ml/day). The average hospital stay in the omentoplasty group was 9.3 days and that in the TachoSil group was 7.2 days ($P<0.05$).

Conclusion

The study proved that TachoSil is more effective than omentoplasty in preventing anastomotic leakage. The use of the collagen-bound fibrin sealant TachoSil appears to be beneficial, being better than omentoplasty with respect to the length of hospital stay and severity of leakage, if leakage is inevitable.

Keywords:

omentoplasty, prevention of colonic leakage, tachosil

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Introduction

A leak from an intestinal anastomosis is the most feared complication by colorectal surgeons. Reported colonic anastomosis leak rates range from 1.5 to 16%, with mortality rates typically quoted between 10 and 20% [1].

Many factors have been proven to affect the rate of anastomotic leakage, preoperative, intraoperative, and postoperative: for example, age, sex, general fitness of the patient, anastomotic tension, resection in an emergency setting, tumor stage, fecal contamination, increased blood loss during surgery, low preoperative serum albumin level, steroid use, and increased duration of surgery [2–6].

To decrease the rate and severity of anastomotic leakage and infective complications, several methods have been proposed, such as antibiotic prophylaxis, colonic preparation with antiseptic enema, fecal diversion for protecting high-risk anastomoses, biofragmentable anastomosis ring, and pelvic irrigation [7]. External coating of anastomoses with various materials has been proposed as a means of reducing the leakage rate [8].

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The omentum has long been used in gastro intestinal, cardiothoracic, neurological, gynecological, orthopedic, vascular, urological, plastic, and reconstructive surgeries [9].

The role of omentoplasty in securing anastomoses after esophageal resections is well established [10]. Its role in securing colorectal anastomoses shows some controversy, being recommended by some authors [11–13], considered equivocal to others [7], and not recommended by a third group of authors [14].

Performing an omentoplasty is not without risks. Although uncommon, complications such as hemorrhages, necrosis of the omentum, and internal herniation have been described [14].

Even though technical modifications have decreased the rate of leakage in colonic anastomosis, the high mortality and severe morbidity in patients suffering from anastomotic leakage justify the necessity for evaluation of additional methods for decreasing the rate of anastomotic failure in these operations [15].

Collagen-bound fibrin sealant sheets have recently been used in many aspects of surgery: for example: hernia [16], gastrointestinal [17,18], ophthalmic [19], gynecologic and obstetric [20], renal [21], vascular [22] and cardiac [23,24] surgeries; and many experimental animal studies have proved its efficacy in securing gastrointestinal anastomoses [25–27].

In 2010, Huh and colleagues performed a prospective study involving 223 patients with rectal cancer who underwent laparoscopic resection. One group underwent surgery followed by application of fibrin sealant over the stapled anastomosis, whereas the other group underwent surgery alone. The clinical leakage rate was 5.8% for the fibrin group and 10.9% for the other group [28].

De Stefano *et al.* [29] conducted a study on 63 open resective colorectal surgeries and concluded that ‘Our initial experience with TachoSil has confirmed the safety of this patch and we can therefore suggest a possible positive effect on anastomotic healing’.

In 2012, Parker *et al.* [17] concluded that the application of TachoSil to reinforce the anastomotic line in colorectal resections appears to be feasible and well tolerated in most circumstances.

The aim of the present study was to compare the role of omentoplasty versus that of TachoSil in preventing the

leakage after colonic anastomosis and the difference between them regarding the severity of leakage if inevitable and the length of hospital stay.

Patients and methods

The study was prospective in nature and carried out between May 2011 and April 2015. Consecutive patients were alternately allocated to omentoplasty or TachoSil (Facebook, Takeda UK Ltd) patch to externally wrap the completed anastomosis. The study was approved by the ethical committee in the Faculty of Medicine, Ain Shams University. The colon was chemically and mechanically prepared; thus, patients undergoing emergency surgery were not included.

Surgical technique

The surgical technique for resection anastomosis was standardized according to The ASCRS Manual of Colon and Rectal Surgery [30]. Drainage of the abdominal cavity was left to the choice of each surgeon.

In this study we included only the clinically evident anastomotic leakage; thus, the investigation for leakage started clinically – that is, if the patient was suffering from abdominal pain, tenderness, fever, and/or leukocytosis. The occurrence of anastomotic leakage was evidenced by the presence of fecal discharge through the pelvic drain left intraoperatively or inserted after radiological evidence of leakage. Gastrograffin enema for detection of preclinical leakage was not performed on a routine basis.

All operations were carried out by using either a hand-sewn or a stapled technique without a protective stoma. After completing the anastomosis and testing for air tightness [31], the patient was assigned to either an omentoplasty or a TachoSil patch for covering the anastomosis.

Omentoplasty is defined as ‘a surgical procedure in which a portion of the greater omentum is used to cover or fill a defect, augment arterial or portal venous circulation, absorb effusions, or increase lymphatic drainage’ [32].

We followed standard surgical techniques while performing omentoplasty, making sure that the vascular pedicle is intact, taking into consideration the guidelines of Topor *et al.* [12].

TachoSil is a registered trademark of Nycomed Pharma AS. It is a sterile, ready to-use, absorbable

surgical patch consisting of an equine collagen sponge coated with human fibrinogen and human thrombin measuring 9.5×4.8×0.5 cm. This new carrier-bound fibrin sealant was approved by the FDA (<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm207486.htm>), the Scottish Medicines Consortium (http://www.scottishmedicines.org.uk/files/TachoSil_medicated_sponge__344-07_.pdf), and the European Medicines Agency – Committee for Medicinal Products for Human Use (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000505/WC500032410.pdf).

The TachoSil patch was pressed gently over the anastomotic line for 1–3 min, making sure that the sheet covered and adhered to at least 1 cm on each side of the anastomosis.

In each patient, we recorded the following data (among others) [33]: age, sex, American Society of Anesthesiologists score, BMI, smoking, alcoholism, steroids, neoadjuvant therapy, site of anastomosis, intraoperative blood loss, postoperative blood transfusion, duration of surgery, use of drain, clinical leakage, severity of leakage, hospital stay, postoperative complication, postoperative mortality, whether anastomosis was done manually or mechanically, time of evidence of gastrointestinal tract movement.

Each of these factors was compared between the two groups to test for homogeneity in the demographic data between the two groups, as well as to compare the outcomes. Patients were followed up for 45 days postoperatively for evidence of leakage and other surgery-related complications. The average cost of the TachoSil patch per patient was calculated.

Results

Ninety-seven patients were included in this study. We excluded one patient from the study who was found to have an atrophied omentum.

When the omentum was mobilized, it was most often based on the left gastroepiploic artery and was wrapped loosely around the suture line and fixed to the colonic segments proximally and distally with separate sutures. The average cost of TachoSil patches per patient was \$210. The mean postoperative stay in the TachoSil group was 7.2 days and that in the omentoplasty group was 9.3 days ($P<0.05$).

Discussion

Uncomplicated healing of an intestinal anastomosis even after carefully executed surgery by an experienced surgeon is still a challenge because the healing process is dependent on multiple physiological, biochemical, and morphological factors [34].

Anastomotic leaks are detected anywhere from 3 to 45 days postoperatively, and the diagnosis is mostly made between days 6 and 9. However, it stands to reason that the processes that lead to failure start much earlier, probably in the immediate postoperative period when the wound strength is believed to be low [27].

In our study, omentoplasty proved to be simple to perform and not time-consuming, as evidenced by comparing the operative time between the two groups, wherein no statistically proven difference was noticed ($P>0.05$). No complication was noted due to the use of omentoplasty in our study during the follow-up period. One limitation for the use of omentoplasty is atrophy of the omentum, which may be congenital or acquired [35].

Anastomotic leakage after colectomy is one of the most serious complications in colorectal surgery. Best defined as 'leak of luminal contents from a surgical join between two hollow viscera', its incidence ranges from 2 to 4% for proximal anastomosis, to 6–12% for distal extraperitoneal anastomosis, and is associated with mortality rates of 10–30% [3].

When comparing the two groups (Table 1), there was no statistically significant difference found ($P>0.05$), except in the severity of leakage and hospital stay (where $P<0.05$).

The overall incidence of anastomotic leakage in this study was 5.15% (5/97), which trends towards the lowest rate reported in other studies [1]; this may be attributed to the patient selection criteria, as we excluded from this study all emergency colectomies. Emergency colectomy is well documented to be associated with a higher incidence of anastomotic leakage [34].

We excluded emergency colectomies from this study because of a previous work by Chmelnik *et al.* [36]. Their experimental study in rats showed severe preanastomotic dilatation in additionally sealed small-diameter anastomoses when using a fibrin-coated collagen patch. They attributed this finding to increased inflammation as a result of bacterial

Table 1 Results of the study

Item	Omentoplasty (N=48 patients)	TachoSil (N=49 patients)	P value
Age (years)	48.87±6.43	51.51±9.68	0.11
Sex			
Male	30/48	27/49	0.45
Female	18/48	22/49	
ASA score			
I	5/48	6/49	0.74
II	20/48	25/49	
III	18/48	14/49	
IV	5/48	4/49	
BMI			
≥30	3/48	4/49	0.71
Loss of >5 kg in 6 months	11/48	14/49	0.52
Smoking			
Yes	22/48	17/49	0.26
No	26/48	32/49	
Alcoholism			
Yes	3/48	2/49	0.62
No	45/48	47/49	
Steroids			
Yes	1/48	1/49	0.98
No	47/48	48/49	
Neoadjuvant therapy			
Radiotherapy	1/48	0/49	0.29
Chemoradiation	10/48	6/49	
No	37/48	43/49	
Site of anastomosis			
Right colon	9/48	9/49	0.84
Left colon	11/48	9/49	
Rectum	28/48	31/49	
Intraoperative blood loss			
<500	8/48	5/49	0.46
500–1000	22/48	28/49	
>1000	18/48	16/49	
Postoperative blood transfusion			
Yes	11/48	6/49	0.16
No	37/48	43/49	
Duration of surgery (h)			
<2	9/48	7/49	0.75
2–4	28/48	32/49	
>4	11/48	10/49	
Use of drain			
Yes	22	17	0.26
No	26	32	
Clinical leakage			
Yes	4/48	1/49	0.16
No	44/48	48/49	
Severity of leakage			
<500	1/4	1/1	0.17
>500	3/4	0/4	
Hospital stay (days)			
<7	6/48	11/49	0.19
7–14	22/48	24/49	0.35
>14	20/48	14/49	0.04
Postoperative complication			
Wound complication	6/48	7/49	0.79
Chest and urinary tract infections	13/48	14/49	0.87
DVT	3/48	7/49	0.19

(Continued)

Table 1 (Continued)

Item	Omentoplasty (N=48 patients)	TachoSil (N=49 patients)	P value
Postoperative mortality	1/48	0/49	0.31
Anastomosis technique			
Manual	14/48	20/49	0.22
Mechanical	34/48	29/49	
Time of evidence of GIT movement (days)	6.5±1.52	4.8±1.15	<0.05

A comparison between the two groups was done, taking the significance level to be at $P \leq 0.05$. ASA, American Society of Anesthesiologists; DVT, deep vein thrombosis; GIT, gastrointestinal tract.

contamination and a disproportion between bowel wall and patch thickness. They reported: 'As a result of our findings, the application of TachoSil in small-diameter intestinal anastomoses cannot be recommended. Whether TachoSil generally can be safely used in bacterially contaminated tissues needs to be investigated in future studies'. Thus, we excluded emergency colectomies to avoid applying TachoSil in heavily contaminated tissue.

Most of the recently published studies [37,38] suggest that mechanical bowel preparation is of no value in anastomotic integrity – a point that is in favor of omentoplasty and against TachoSil. As already mentioned, it is better to avoid using TachoSil in the presence of heavy bacterial contamination [36], while such recommendation is not applicable with omentoplasty. Colon preparation with antibiotics has recently been proved beneficial [39].

The rate of leakage in the TachoSil group was 2% (1/49), whereas in the omentoplasty group it was 8.3% (4/48), which implies no beneficial effect of omentoplasty in preventing anastomotic leakage. This is in accordance with the most recent publication in this field [40].

When comparing the two groups, we found no statistically significant difference between the incidence of leakage after omentoplasty and that after application of collagen-bound fibrin sealant ($P > 0.05$). However, the study showed that there is a trend of the collagen-bound fibrin sealant to be more effective than omentoplasty, because the rate was four cases in the omentoplasty group and one case in the TachoSil group. Failure to demonstrate a statistically significant difference may be due to the relatively small number of cases included in this study.

Another finding of our study is that leakage, if it occurs, tends to be less severe in the TachoSil group compared with the omentoplasty group. Three out of four leakages in the omentoplasty group were severe leakages (>500 ml/day), whereas the single case of leakage in the TachoSil group was less severe

(<500 ml/day). This can be attributed to the difference in the mechanism of action between omentoplasty and TachoSil in sealing the anastomosis.

Omentoplasty works to protect the anastomosis in many ways: when placed in contact with an anastomotic gap, an entirely viable omentum forms an effective bridge over anastomotic defects and responds with an outgrowth of richly vascular tissue, which acts as the major vascular source to the wound. Omentoplasty provides an adherent sleeve that plugs or locally contains early anastomotic leakages during the dangerous period before revascularization occurs. The stimulated neoangiogenesis and the richly vascularized tissue also could act as protective factors, lowering the incidence of anastomotic stricture [13].

The mechanism of action of TachoSil follows the principles of physiological fibrin clot formation. Upon contact with a bleeding or leaking wound surface, or triggered by the presence of physiological saline, the coating of the collagen sponge dissolves and the subsequent thrombin–fibrinogen reaction initiates the last step of the coagulation cascade: fibrinogen is converted by the action of thrombin into fibrin monomers, which spontaneously polymerize to a fibrin clot. Thrombin can also activate endogenous factor XIII, which covalently cross-links the fibrin to create a firm and stable fibrin network (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000505/WC500032410.pdf).

This stable fibrin clot leads to sealing of the anastomosis in many ways: the physical barrier created by the fibrin clot, the facilitation of tissue approximation, the promotion of tissue healing by the components, and the creation of adhesion with surrounding tissues [28].

These mechanisms of action of TachoSil are reflected in our study: both the rate and the severity of leakage are lower in the TachoSil group than in the omentoplasty group.

In the postoperative period, the bowel anastomosis should be able to withstand forces from different directions. The bursting pressure, which reflects the capacity of the anastomosis to resist intraluminal forces, is a good marker to test anastomotic strength [41]. Many researchers examined the effect of fibrin sealant on the bursting pressure following anastomoses and demonstrated a beneficial effect [42,43].

It is known that colonic anastomoses are most fragile on days 3 and 4 because of low collagen content mediated by high activity of colonic collagenase induced by injury to the bowel wall during the healing phase of the anastomosis, and on day 7 after anastomosis collagenolytic activity reverts to normal [15].

We should stress that collagen-bound fibrin sealants are different from earlier fibrin glues. Early studies on the use of fibrin glue to seal colon anastomoses were disappointing, with evidence that the glue inhibited wound healing and decreased anastomotic strength, burst strength, and collagen deposition at the treated wound sites. Fibrin glue may also inhibit macrophage migration and neutrophil function [25,27].

In our study, when we compared both groups with respect to the timing of regain of gastrointestinal movement, we found a statistically significant result proving that omentoplasty, in some way, delays the recovery of gastrointestinal movement. This result was reported in a previous study [14]. In this aforementioned study, the authors explained that the mechanisms involved are the presence of a pedicled omentum in the abdominal cavity causing a relative mechanical obstruction and the devascularization of the greater curvature of the stomach, thus delaying gastric functioning.

The safety of TachoSil in sealing gastrointestinal anastomoses with a collagen patch coated with fibrin components has been proven before in a study by Nordentoft *et al.* [26]. Their study revealed equal healing strength and complication rate after sealing with a collagen patch coated with fibrin glue components compared with unsealed anastomoses. Further, they found no difference in stenosis of the anastomoses. Another reported benefit of fibrin sealants is that it decreases intra-abdominal adhesions [44]. Furthermore, one study proved that TachoSil has no negative physiological or histological side effects [26]. The feasibility of the application of TachoSil for sealing colorectal anastomosis was proven in another study [17].

A shorter mean postoperative stay of 7.2 days was observed for patients in whom TachoSil was applied compared with 9.3 days for patients with no TachoSil application. This difference was mainly related to anastomotic insufficiencies recorded in the no-TachoSil group. This was in accordance with a recent study from Italy [29].

Another argument against TachoSil is the possibility of transmission of blood-borne diseases. There is a potential risk of transmission of microorganisms from the blood samples that are used to produce TachoSil, even if, according to the manufacturer, blood comes only from selected donors and all active measures against enveloped viruses are used [45].

In a comprehensive review of external coating of colonic anastomoses, Pommergaard *et al.* [8] concluded that the beneficial effects of using fibrin sealants could be achieved only with TachoSil.

In our study, the average cost per patient in the TachoSil group was \$210, which could be an argument against its use. This extra cost could be compensated for, at least in part, by the shorter hospital stay. In our study, the TachoSil group patients stayed for a shorter time in the hospital and the difference from the omentoplasty group was statistically significant ($P < 0.05$). This finding was reported before [46].

One more argument against TachoSil is that it is a source of fibrin. Thus, it may lead to an increase in the incidence of thrombotic complications postoperatively. In our study, there is a slight increase in the incidence of DVT (diagnosed by duplex) in the TachoSil group compared with the omentoplasty group, but it was not statistically significant ($P < 0.05$). The main effect of TachoSil is the local activation of the coagulation cascade leading to the local (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000505/WC500032410.pdf) deposition of stable fibrin network. Whether or not this activation of the coagulation cascade can reach the systemic circulation needs further study.

Conclusion

Within the limitation of the patient number included in this study, we conclude that omentoplasty has no beneficial effect in sealing colonic anastomoses. TachoSil is proving to be more effective than omentoplasty in preventing anastomotic leakage. The use of the collagen-bound fibrin sealant TachoSil

appears to be beneficial, being better than omentoplasty with respect to the length of hospital stay and the severity of leakage, if leakage is inevitable. Despite years of research, the ideal tissue adhesive is yet to be found; however, the benefits of using adhesives are becoming more apparent'.

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Conflicts of interest

There are no conflicts of interest.

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