Comparative study of single-layer anastomosis in high-risk colonic anastomosis versus single layer reinforced using fibrin glue

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Introduction
Complications of bowel anastomosis may be a catastrophe and devastating to the patient's life. Reinforcing colonic wall anastomosis is of utmost importance to decrease leakage in risky colonic anastomosis.

Aim
The aim of this study was to consider the efficacy of reinforcing single-layer colonic anastomosis with fibrin glue in high-risk colonic anastomosis.

Patients and methods
A prospective study was conducted in Zagazig University Hospitals from December 2011 until May 2014 on 70 patients with high-risk colonic anastomosis, who were divided into two groups. Group I included 35 patients operated by means of single extramucosal bowel anastomosis and group II included 35 patients operated by means of single layer reinforced by adding fibrin glue.

Results
In our study, there were 28 male and seven female patients in group I and 10 male and 25 female patients in group II. We recorded seven (20%) cases with postoperative leak; of them, five complicated to fecal fistula in group I, whereas in group II there were only three (8.5%) patients with leakage and one patient with fistula. Postoperative abscesses were 8.5% in group I and 2.9% in group II.

Conclusion
Single-layer anastomosis is not enough in high-risk colonic anastomosis and needs reinforcement. Fibrin glue is widely accepted in gastrointestinal anastomosis and provides a good sealant.

Keywords:
colonic anastomosis, fibrin glue, reinforcing anastomosis

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Introduction

It is of utmost importance to consider the incidence and prevalence of anastomotic leakage following bowel resection and primary anastomosis in high-risk patients, which lead to prolonged hospital stay, increased mortality and morbidity, abscess formation, fistula, sepsis, and possible death. The prevalence of intraperitoneal anastomotic leak after handsewn anastomosis varies between 0.5 and 30% [1–3].

Single-layer anastomosis has the superiority in elective bowel anastomosis, but in high-risk patients it may be enough yet questionable not because of the technique rather the risk factors that predispose to leakage. Therefore, reinforcement of anastomosis decreases the risk of devastating complications [4,5].

Tissue adhesives, mainly fibrin sealant, were used to reinforce gastrointestinal anastomosis. The surgery is based on two concepts. First, to prevent leakage by making an anastomosis water and airtight by applying a seal around an anastomosis. Second, the adhesive acts as a mechanical support of wound margins instead of sutures, or as an extra support, thus decreasing an incidence of leakage [6,7]. In addition to serving as a seal for visceral leaks, it walls off infections [8]. Fibrin sealant became the first modern era material approved as a hemostat, sealant, and adhesive by the Food and Drug Administration (FDA) [9].

Patients and methods

Inclusion criteria

All adult patients requiring emergency laparotomy for symptoms and signs of intestinal obstruction or peritonitis, admitted to the Emergency Unit, Zagazig University, were considered eligible.

Exclusion criteria

Patients who had undergone small bowel resection anastomosis were excluded.

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Patients with risk for bowel anastomosis were defined as those with risk factors such as diabetes, steroids, anastomotic method, poor blood loss, marked bowel distension, debilitating diseases, presence or absence of peritonitis and nutritional factors, which are predictive of anastomotic failure.

All patients were subjected to full laboratory work.

Most patients signed a high-risk consent form and gave permission for stool diversion, if necessary. High-risk patients were admitted to the operation theater with no time for elective bowel preparation and only preoperative rapid colonic preparation was performed with bowel lavage on the table.

Technique

General endotracheal intubation and nasogastric tube and Foley's catheter insertion were mandatory. The abdomen was draped and prepped in an ordinary manner. All patients underwent midline exploratory incision, thorough exploration of the abdomen and the pelvis, and had pathology identified. Bowel lavage was performed on the table, with intestinal clamps applied proximal and distal to the pathology, and resection was performed.

The two bowel segments were approximated and prepared for anastomosis, either large bowel (left hemicolectomy) or enterocolic. Two transmural stitches were applied at the sides of the two bowel segments to act as a stay for colocolic or enterocolic anastomosis (Figs. 1 and 2).

All single-layer anastomoses were constructed using a continuous 3–0 vicryl round needle suture (Fig. 3), which began at the mesenteric border (Fig. 4). All layers of the bowel wall except the mucosa were incorporated. Each bite included 4–6 mm of the seromuscular wall; the larger bites were used at the mesenteric border to ensure an adequate seal. Each stitch was advanced ~5 mm. We rendered the anastomosis watertight. The time recorded for construction of the anastomosis began with the placement of the stay suture and first stitch and ended with tying the knot for the continuous suture.

The two transmural stay sutures at the sides were tied, and then the mesenteric window was closed.

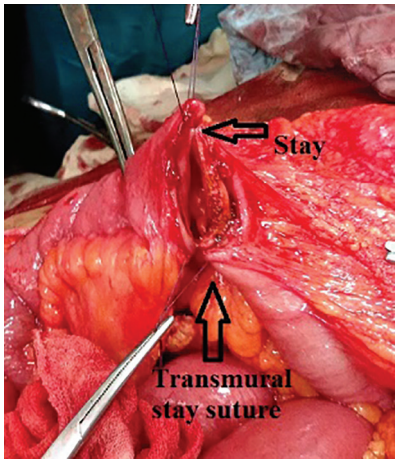
The same steps were carried out in group II, but with addition of fibrin glue. The commercial fibrin sealant includes two lyophilized pathogen inactivated components of 6.5 g/dl equal to 1000 IU/ml. Component I comprised a high concentration of human fibrinogen. Component II comprised human thrombin.

The package of the glue contained two syringes, each 3 ml, one vial of sterile water for injection, and one double barrel needle (Y-shaped delivery system).

The two component of the glue were prepared and diluted with the supplied sterile water, then applied to the Y-shaped delivery system or the two syringes approximated and injected simultaneously (Figs. 5 and 6) by dropping the glue all around the anastomosis. The glue was applied part by part as when applied on the anterior wall. We then waited for 1 min until the glue dried, and then applied on the sides, followed by the posterior wall. Any remaining drops of glue were applied to the mesenteric window.

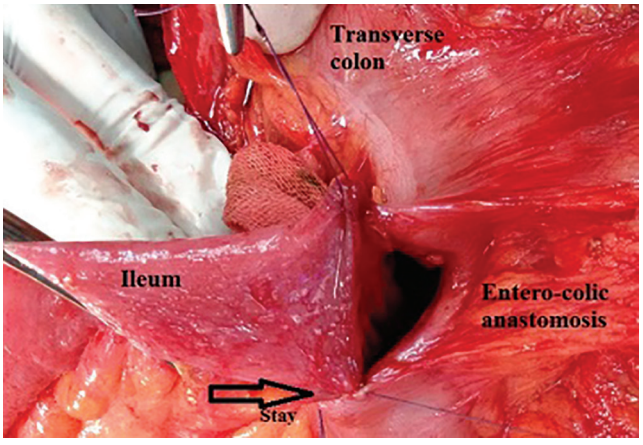
On mixing the two components, the concentrated fibrinogen in the solution is converted into a solid fibrin clot, imitating the final stage of the coagulation cascade. The velocity of the coagulation process

Figure 1



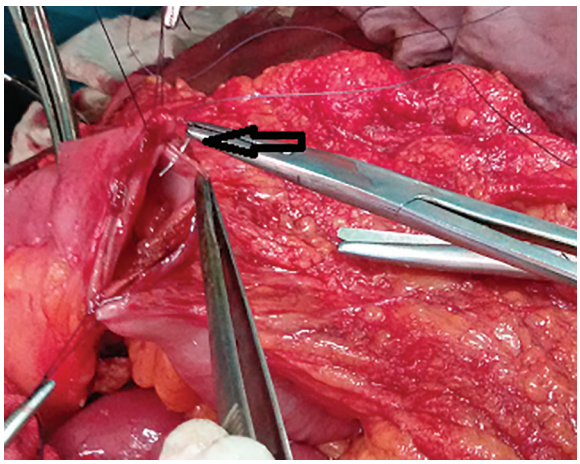
Transmural stitch.

Figure 2



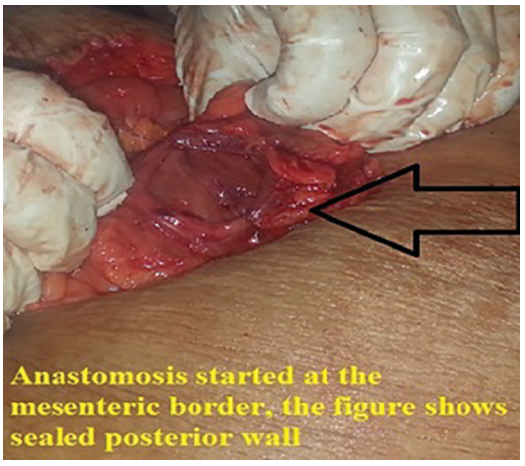
Transmural stitch for enterocolic anastomosis.

Figure 3



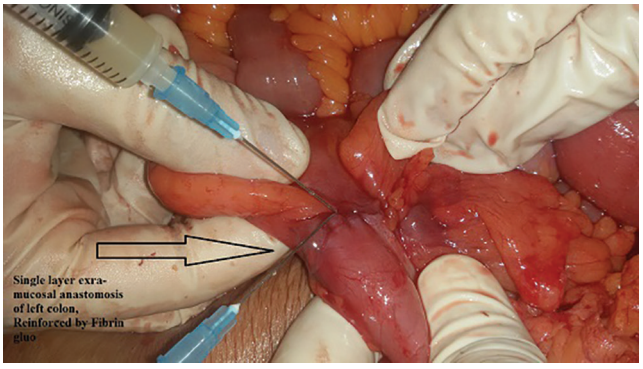
Single-layer anastomosis.

Figure 4



Anastomosis started at mesenteric border–posterior wall first.

Figure 5



Application of fibrin glue.

Figure 6

Simultaneous injection of the two syringes of glue.

depends on the concentration of the thrombin solution used. Although the sealant takes 30–60 s to set with a thrombin concentration of 4 IU/ml, this process takes only a few seconds when a higher thrombin concentration of 500 IU/ml is used. Generally, a higher thrombin concentration is used for hemostasis, whereas the lower concentration is used for sealing of tissues.

For both techniques, only one drain was inserted perianastomotically.

Data collection, parameter evaluation, and follow-up

Standardized data collection was performed by the attending resident and our surgeon team, and each patient was evaluated by the main surgeon twice per day for 3–5 days on the basis of hospital stay. The patients were then followed up at the hospital outpatient clinic monthly for 3 months.

During the hospital stay the patients were followed up for evaluating the following parameters:

(1) Vital signs that made high attention for high fever.
(2) Fluid therapy including maintenance and deficit depending on input and output.
(3) Antibiotic received, as all patients received broad spectrum antibiotics and metronidazole infusion.
(4) Drain output observed for the amount, color, and nature of contents.

Postoperatively, any complication related to the operation, including high fever, pain, distension, delayed peristalsis, abdominal distension, intestinal sounds, wound complication, and abnormal output from the drain were recorded and documented.

Patients started taking sips of water on the third postoperative day in group II and on the fourth postoperative day in group I and continued diet as tolerated. Drain was removed on the fourth postoperative day and patients were discharged from

the hospital if there was no serious infection, leakage, distension, or proved fecal fistula.

Anastomotic failure was defined as a fistula documented clinically or radiographically, or by the finding of (charcoal) draining from the wound after oral administration, or as a visible disruption of the suture line during re-exploration. The complication of abscess without fistula was also included in the analysis because it is potentially related to the anastomosis.

All patients were followed up for 9 months postoperatively. Thereafter, they were called again to continue the follow-up postoperatively every week for 4 weeks because of late infective complications known to occur occasionally after patients' discharge, followed by monthly visits.

Procedure-related complications and management

The complications in our study included early postoperative complications and late complications. Early complications included wound complications, intra-abdominal abscess, leakage, fecal fistula, and prolonged postoperative ileus. Late complications mainly attributed to postoperative adhesions and stricture.

Wound complications

Patients with wound complications responded to conservative measures such as dressing twice daily, chemical debridement for wound infection and antibiotic coverage. Cases of wound disruption were mainly partial. Such patients also responded to conservative measures and their wounds were left to heal by granulation tissue formation.

Postoperative leakage

Postoperative anastomotic leakage and fistulas were defined clinically, radiologically, and/or using the charcoal test. Most cases that presented with low output postoperative leak were managed conservatively in the form of postponing oral diet, continuous fluid therapy for maintenance and deficit, coverage with broad spectrum antibiotics, and ultrasound-guided drainage for localized collection and abscess. Patients with high output leakage were re-explored for fecal fistula.

Intra-abdominal abscess

Differentiating an 'anastomotic leak' from a postoperative abscess was difficult. In three cases in our study (two cases in group I and one case in group II), we were able to show that a postoperative abscess was caused by a small anastomotic leak and that the other patient presented with peritonism. The majority of patients with postoperative abscess were managed with ultrasonography-guided drainage, whereas other patients responded to medical treatment, which was sufficient.

Fecal fistula and peritonitis

Cases complicated by fecal fistula with high output leakage and peritonitis were re-explored, peritoneal toilet was performed, and disrupted anastomosis was found. In the left colonic disrupted anastomosis, resection of anastomosis was performed and converted to Hartman. Diversion alone without resection of the leaking anastomosis was not ideal because of persistent sepsis from the leaking anastomosis. In such cases, wide drainage of the anastomosis was performed. Repair of the anastomosis, either alone or in combination with a proximal stoma, was not feasible nor recommended because of the high risk of recurrent anastomotic failure and/or anastomotic stricture in the presence of intra-abdominal sepsis. In all cases, two drains were inserted, perianastomotic and pelvic, and patients kept nothing per oral (NPO) for another 4 days and then diet as tolerated was started.

Prolonged postoperative ileus

Some cases suffered from prolonged postoperative ileus, and it was attributed mainly to some sort of electrolyte imbalance and lack of education in this small cohort of patients. Correction of electrolyte and ambulation correct the ileus but persist for a while in some patients proved to have intra-abdominal abscess.

Late postoperative complications

Late complications were mainly due to adhesions discovered during the postoperative follow-up period between sixth and ninth month. These patients were readmitted to the hospital and they responded to conservative methods of treatment such as of nasogastric tube (NGT), intra-venous fluids (IVF), antibiotics, and enemas.

Statistical analysis

Categorical qualitative variables were expressed as absolute frequencies (number) and relative frequencies (%). Continuous data were checked for normality using the Kolmogorov–Smirnov test. Independent Student's *t*-test was used to compare two groups of normally distributed data. Percentage of categorical variables was compared using Pearson's χ^2-test. All tests were two-sided. A *P*-value of less than 0.05 was considered significant. All statistical analyses were performed using SPSS 22.0 (SPSS Inc., Chicago, Illinois, USA) for Windows and MedCalc 13 (MedCalc Software bvba, Ostend, Belgium) for Windows.

Results

We operated on 70 patients in the emergency unit over a period of 2.5 years. We operated on 35 patients with resection anastomosis using single-layer continuous anastomosis, and on 35 patients resection anastomosis performed using single layer reinforced with fibrin glue. In group I, the number of male patients was higher than the number of female patients (28/7). In group II, the number of female patients was higher: 25 female and 10 male patients. In group I, the ages of the patients ranged from 28 to 63 years, with a mean of 45 ± 8.5 years. In group II the ages of the patient ranged from 31 to 72 years, with a mean of 46.5 ± 9.5 years (Table 1).

The cause for exploration was mainly acute intestinal obstruction or peritonitis. In group I, there were 21 (60%) patients with malignant bowel intestinal obstruction (mainly in the left colon in 13 patients) and 14 (40%) patients with nonmalignant causes such as volvulus, perforated diverticulum, bands, and inflammatory bowel. In group II, there were 25 (71.5%) patients with malignant intestinal obstruction (mainly in the left colon in 14 patients) and 10 (28.5%) patients with nonmalignant causes such as inflammatory bowel with peritonitis, postoperative fecal fistula, and perforated sigmoid diverticulum (Table 2).

In both groups the pathology was confined to the large bowel. In group I, left-sided colonic resection anastomosis was performed for 21 cases, whereas in group II, only 16 patients underwent right hemicolectomy. Iliotransverse anastomosis was performed for 14 cases in group I and for 19 cases in group II (Table 2).

The duration of anastomosis was shorter in group I (about 20 min), whereas in group II it was 25 min. The difference is attributed to the time of fibrin glue preparation. Length of hospital stay was prolonged in group I than in group II, as they initiated diet later in group I compared with group II (Table 3).

The complications in our study included the following. In group I, the incidence of wound complications was high: there were four (11.4%) patients with seroma, three (8.5%) patients with wound infection, and two (5.7%) patients with wound disruption. However, in group II there were only two (5.7%) patients with seroma, one (2.9%) patient with wound infection, and one (2.9%) patient with wound disruption. In group I, seven (20%) patients suffered from postoperative leakage, five (14.2%) patients complicated with fecal fistula, and two patients were found to have an abscess. A total of three (8.5%) patients suffered from abscess and pelvic collection, two patients presented with leakage, and the other patient presented with peritonism not proceeded by leakage. In group II, three (8.5%) patients suffered from postoperative leakage, one (2.9%) patient complicated with fecal fistula, one (2.9%) patient suffered from abscess and pelvic collection, and one patient improved with conservative measures. Postoperative ileus was mainly found in group I in about 14.2% of patients, whereas in group II it was found in 2.9% of patients. Late postoperative adhesion was 5.7% in group I and 2.9% in group II (Table 4).

Discussion

The reliability and suitability of any technique for intestinal anastomosis is its ability to heal without leakage. Leakage and fistula have catastrophic

Table 1 Demographic data

Diagnosis and site of anastomosis	Single layer (N = 35)	Single layer with fibrin glue (N = 35)	P
Sex			
Male	28 (80)	25 (71.4)	0.577‡
Female	7 (20)	10 (28.6)	
Age			
Mean ± SD	45 ± 8.5	46.5 ± 9.5	0.488§
Range	28–63	31–72	

Values are represented n (%); ‡χ^2-Test; §Independent Student's t-test; $P < 0.05$ is significant.

Table 2 Diagnosis and site of anastomosis

Diagnosis and site of anastomosis	Single layer (N = 35)	Single layer with fibrin glue (N = 35)	P
Diagnosis			
Malignant	21 (60)	25 (71.4)	0.450‡
Nonmalignant	14 (40)	10 (28.6)	
Malignant IO			
Rt colon	8 (30.1)	11 (44)	0.916‡
Lt colon	13 (61.9)	14 (56)	
Nonmalignant IO			
Rt colon	6 (42.9)	8 (80)	0.161‡
Lt colon	8 (57.1)	2 (20)	
Site of anastomosis			
Colocolostomy	21 (60)	16 (45.7)	0.338‡
Enterocolic	14 (40)	19 (54.3)	

Values are represented as n (%); IO, intestinal obstruction; Lt, left; Rt, right; ‡χ^2-Test; $P < 0.05$ is significant.

Table 3 Diet initiation, time of anastomosis, and length of hospital stay

Time of anastomosis and postoperative period	Single layer (N = 35)	Single layer with fibrin glue (N = 35)	P
Initiation of diet	4 ± 0.9	3 ± 0.8	<0.001§
Time of anastomosis	20 ± 2.5	25 ± 3.5	<0.001§
Length of hospital stay	7 ± 2.3	5 ± 1.7	<0.001§

Values are represented as mean ± SD; §Independent Student's t-test; $P < 0.05$ is significant.

Table 4 Postoperative complications

Postoperative complications	Single layer (*N* = 35)	Single layer with fibrin glue (*N* = 35)	*P*
Wound seroma	4 (11.4)	2 (5.7)	0.669‡
Wound infection	3 (8.6)	1 (2.9)	0.606‡
Wound disruption	2 (5.7)	1 (2.9)	1.000‡
Intra-abdominal abscesses	3 (8.6)	1 (2.9)	0.606‡
Postoperative leaks	7 (20)	3 (8.6)	0.305‡
Postoperative fecal fistula	5 (14.3)	1 (2.9)	0.200‡
Postoperative ileus	5 (14.3)	1 (2.9)	0.200‡
Postoperative adhesions	2 (5.7)	1 (2.9)	1.000‡

Values are represented as *n* (%); ‡χ^2-Test; $P < 0.05$ is significant.

consequences on the patient's health as well as the cost of care. Ischemia, considerable tension on the anastomosis, and poor technique were added risks for anastomotic failure in critically ill patients. As high-risk bowel anastomosis carries a known incidence of anastomotic dehiscence, single-layer anastomosis was not enough and should be reinforced to decrease the incidence of early and late postoperative complications. In our study the complication rate was less, with less leakage, abscess, and fistula in reinforced anastomosis than in single layer alone, and this was comparable to the study conducted by Merad *et al*. [10], who reinforced the anastomosis but with omentoplasty, and they used more number of patients and included elective resection anastomosis in their study.

In our study, reinforcement of single layer was performed using fibrin sealant, which gained increasing acceptance among surgeons. This is in agreement with Lee and Jones [11], who frequently used fibrin sealant for reinforcing gastrointestinal anastomosis and for repairing perforated duodenal ulcers. This was similar to the method used by Truong *et al*.[12], who used fibrin sealant for endoscopic treatment of postoperative gastrointestinal fistulas and leaks.

As regards postoperative complications, we recorded an incidence of 20% for leakage and 14.2% for fistula development in the single layer group, but in the reinforcement anastomosis group, we recorded a less incidence of leakage (8.5%) and fistula (5.7%). This was comparable to that reported in another study [13], in which they used fibrin glue for the treatment of 18 cases with postappendectomy fecal fistula after failed ultrasound-guided drainage and was a successful approach. The failure and leakage accounted only for 7.8%, and they concluded that fibrin glue is safe to use in colonic anastomosis, especially in the right side.

Our approach to reinforcing single-layer colonic anastomosis and our incidence of complications were comparable to that reported by many authors [14–20], but they used the technique for reinforcing gastric wall after continuous single-layer closure.

Our study was not compatible with the study by Bülbüller *et al*. [21], who used reinforcement methods to reduce leakage complication. They found that 18 patients had Tisseel fibrin sealant applied throughout the staple line of gastric wall after greater curvature gastrectomy, According to their results, they demonstrated that good results can be obtained without any reinforcement. Reinforcement with tissue fibrin sealant increases the cost.

Conclusion

In summary, surgeons should be aware of risky colonic anastomosis and its high incidence of leakage. Proper surgical technique avoids this devastating complication. Single-layer anastomosis is not enough for this risky anastomosis and should be reinforced. Reinforcement with fibrin glue provides a watertight anastomosis.

Fibrin sealant has been used with increasing frequency in a variety of gastrointestinal surgical anastomosis for its adhesive abilities and hemostatic function. The process of adding fibrin glue mimics the last step of the coagulation cascade and takes place independent of the patient's coagulation status.

Acknowledgements

Conflicts of interest

None declared.

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