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Sub.: Acceptance of Manuscript for Publication in the KMJ

Re: Manuscript No. KMJ-107/011

Dear Dr. Mohamed,

I am glad to inform you that your manuscript titled "**Pedicle Seromuscular Flap for Inforcement of High Risk Intestinal Anastomoses**", with co-author/s, Dr. Waleed Asker, Dr. Ashraf Abbas and Dr. Ibraheim Dawoud, has been accepted for publication in the Kuwait Medical Journal.

It will be published under the section '**Original Articles**' in one of the forthcoming issues of the KMJ.

We will send you a copy of the galley proof at the time of its publication, which has to be returned to us within two days with your final consent.

We thank you once again for your support to the KMJ and look forward to receive more contributions in future.

Sincerely yours,



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Original Article
KMJ-107/011

Pedicled Seromuscular Flap for Inforcement of High Risk Intestinal Anastomoses

Running title :High Risk Anastomoses

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ABSTRACT (220 Words)

Objective: To study the safety and feasibility of this type of autologous tissue as a protective layer in high risk intestinal anastomoses.

Design: A retrospective case matched study was conducted at Mansoura university hospital, dep. of surgery, Mansoura, Egypt.

Setting: Patients who presented at the emergency department in the period from April 2009 through June 2011 with peritonitis were included in this study, 30 patients of the 1st group were matched to a control group for age, gender, weight, diagnosis, method of anastomosis and comorbidity.

Subjects: The study included 60 patients who underwent intestinal resection and anastomosis for different reasons.

Interventions: Intestinal resection and anastomosis was done with seromuscular flap enforcement (1st group), or without (2nd group).

Main Outcome measures: The primary endpoints were to assess the incidence of anastomotic leak or fistula, the length of postoperative hospital stay, and mortality.

Results: The flap creation make the operative time slightly longer with **mean 25.3 minutes (P<0.006)**, however, the 1st group had significant less incidence of leak (P<0.008), and consequently less postoperative complications (P<0.002) e.g. wound infection, wound disruption, and shorter hospitalization time (P<0.001).

Conclusion: Seromuscular flap is safe, simple, and feasible technique, it may provide local support to the anastomosis until it reaches good tensile strength. We recommend this technique particularly in those patients at high risk for intestinal leak.

Keywords: Intestine; Anastomosis; Seromuscular flap; Leakage

INTRODUCTION

Intestinal anastomotic leak is a major postoperative morbidity, it prolongs the hospitalization time, increases the expense to the patients and the hospital and even causes death^[1]. Intestinal anastomosis in the emergency situation has been usually doomed to failure.

Most of these patients are malnourished, critically ill and have not been prepared well for operation as in elective surgery^[2], so the risk of anastomotic failure is high in those patients if primary anastomosis only was done. Few surgical procedures to reinforce the anastomotic site and reduce the risk of anastomotic leakage or fistula formation following intestinal surgery such as omental wrapping have been described previously^[3-5].

A new method of protecting high risk intestinal anastomoses that involves the use of a pedicled seromuscular flap was described by Miroura et al^[6], in Pubmed search there is only one paper conducted by Talwar et al 2005 who used such flap to assess its usefulness of this flap^[7]. We performed this case-matched control study to confirm the safety and efficacy of this flap in high risk intestinal anastomoses in emergency situation.

SUBJECTS AND METHODS

This study was conducted at Mansoura university hospital, dep. of surgery (unit 7), Mansoura, Egypt. Patients who presented at the emergency department in the period from April 2009 through June 2011 with peritonitis due to acute intestinal pathology that necessitate resection anastomosis were included in this study. Informed consent was obtained from all the patients or their relatives after explaining all details of the procedure.

Thirty patients underwent intestinal resection anastomosis with pedicled seromuscular flap inforcement (1st group) for their intestinal pathology during the study period was included in this study. During the same period indicated above, 67 patients underwent intestinal resection anastomosis by the same unit surgeons with intestinal resection with primary anastomosis without inforcement.

To compare outcomes with the same conditions, each patient of the 1st group was matched to a control patient of the 2nd group. To increase the accuracy of our study, patients were matched in terms of the following variables: gender; age; American Society of Anesthesiologists (ASA) score; diagnosis, type of anastomosis (single continuous extramucosal layer with polyglycolic suture was the method of anastomosis done), and associated comorbidity.

The 1st three authors performed the whole number of the 1st group surgery, and these patients were matched with the control 2nd group who underwent surgery by the same surgeons.

All patients were examined clinically and radiological investigation to confirm the diagnosis (done only in 19 patients), all patients were optimized preoperatively for a while by intravenous fluid(IVF), nasogastric decompression, adequate analgesia and IV antibiotic against Gram negative bacteria and anaerobes (cefotraxone 1gm and metronidazole infusion 500 mg three times daily preoperative and for 5 days postoperative), then abdominal surgery was done as soon as the patient was optimized and the operating room was available.

Surgical technique

All surgeries have been done under general anesthesia using the midline incision in all patients, identification of the pathology which necessitate intestinal resection, resection of the

diseased bowel segment was done, then single extramucosal continuous suture with 2/0 polyglycolic was the standard method used for anastomosis.

In the 1st group the same steps were fulfilled with only one difference, a segment of the intestine either the distal or the proximal, with appropriate length, sufficient to wrap the bowel, was separated as a pedicled flap (Fig. 1).

After finishing the anastomosis, the flap was prepared by slitting it at its antimesenteric border and holding its four corners by Alis forceps then injecting diluted adrenalized saline (1:200000) and removing the mucosa carefully using scissors leaving a thick exposed submucosal surface and controlling any significant bleeding points with diathermy using fine tipped forceps or haemostatic stitches (Fig 2). The flap with raw submucosal surface was wrapped around the anastomosis in such a manner that the flap is 90° perpendicular to the bowel lumen. The flap was sutured to the bowel wall by 3/0 polyglycolic sutures taking full thickness bites of the flap and seromuscular bites of the bowel wall (Fig 3).

Good peritoneal wash was done with warm saline and closing the abdomen with single continuous polyproline suture after inserting two tube drains, one in the pelvis and the other in the right paracolic gutter.

Postoperative Follow Up

The patients were monitored by clinical progress data (vital signs, drains amount and fluid character, urine output, chest and abdominal examination, the same preoperative antibiotic, deep vein thrombosis (DVT) prophylaxis using(enoxaparin sodium 40 mg subcutaneously daily). Nasogastric tube (NGT) was removed once the bowel activity return and daily amount was less than 200 ml, then patients started to have sips of oral fluid graduate to full oral as he/she tolerates. Patients were discharged if they were pain free, no vomiting, no drains and no NGT.

The primary endpoints were to assess the incidence of anastomotic leak or fistula, the length of postoperative hospital stay, and mortality. The second endpoints were the operative time, estimated blood loss, wound infection or dehiscence, and reoperation.

Follow up at our outpatients' clinic, 1st follow up was one week after discharge, to check the wound for infection and dehiscence, and to remove the stitches and ultrasonography (U/S) was done for all patients. Then they were scheduled for further follow up every month for clinical examination and doing abdominal U/S if needed, the mean follow up was 31±9.1 weeks.

Statistical analysis

The statistical analysis of the data in this study was performed using the SPSS version 10. Analysis of data was by intension-to-treat. For continuous variables, descriptive statistics were calculated and were reported as mean ± SD. Categorical variables were described using frequency distributions The Student's *t*-test for paired samples was used to detect differences in the means of numerical variables, Chi-square test was used for nominal variables and Fisher's exact test was used in cases with low expected frequencies. *P* values <0.05 were considered to be significant.

RESULTS

From April 2009 to June 2011, 30 consecutive patients of 1st group were involved in this study, they were matched with control group of the same number. Cases and controls were matched for age, sex, BMI, ASA, and operative diagnosis, the basic characteristics of the patients are summarized in (table 1).

Operative time was significantly longer in the 1st group, the flap increase the operative time with 25.3 (17-39.4) minutes, both groups were comparable in terms of blood loss, the 2nd group showed statistically high significant long hospital stay ($p < 0.001$). (table 2)

We have one case of anastomotic leak in the 1st group, he had a mesenteric venous thrombosis with venous gangrene of the terminal one meter of the intestine sparing 25 cm proximal to the ileocaecal valve and a leak was discovered on the 5th POD, he was reoperated and 10 cm gangrenous segment was found that was resected and end ileostomy brought out. He stayed in the hospital for 10 more days and discharged well and underwent ileostomy closure after 2 months. There was no mortality in the 1st group. (table 3)

In the 2nd group, we had 5 cases with intestinal leak, 2 of them had typhoid perforation and once leak happen they were reoperated and end entrostomy was done but they had chest infection and expired 10 and 14 days respectively after the second operation. The 3th patient had strangulated incisional hernia, leakage was noticed on the 4th POD and she was also managed surgically by end entrostomy and she had smooth postoperative course and 2 months later she underwent entrostomy closure. The 4th one had adhesive intestinal obstruction with strangulation, leak was noticed on the 4th POD and treated conservatively and discharged well 3 weeks later. The last one 75 years old female patient, she had strangulated femoral hernia, resection anastomosis was done, leak was noticed on the 5th POD she underwent re-exploration but unfortunately she can't withstand the 2nd time surgery and died intraoperatively.

wound infection was noticed in 3 cases in the 1st group versus 5 cases in the 2nd group but all of them were managed conservatively and infection was controlled in 5.2 ± 2.4 days and the window opened at the lower corner of the wound was left to heal by secondary intention in all cases. Wound dehiscence happened in 2 patients and 6 cases in 1st and 2nd groups respectively, 7 cases were managed conservatively because there was no evisceration of the intestine and 6 months later their incisional hernias were managed by mesh hernioplasty except for one case, she refused to undergo another operation for hernia repair, the last patient, he had wound dehiscence on the 2nd POD with his intestine came out so emergent reoperation and performed and wound was closed with tension stitches.

DISCUSSION

Anastomotic leaks are among the most dreaded complications after intestinal surgery especially in the emergency situations. The safety of small intestinal anastomosis depends upon the good blood supply and water tight approximation of the edges. in case of high risk

anastomoses, many autologous materials were tried to reinforce such anastomosis including greater omentum^[8], whoever this flap is not usually available due to previous resection, or not long enough due to massive adhesions that may make its use difficult, moreover, some assume that the omentum lacks strength so it produce less resistance to tension on an anastomosis^[6] and some claimed that it does not provide any real advantages to protect anastomoses^[9].

The seromuscular flap has been used by Moriura et al in patients with Behcet's disease^[1]. It is known that the submucosa has a rich vascular and lymphatic plexus and it is a collagen rich layer which promotes better healing^[10]. Moreover, it is assumed that this flap may reduce tension on the anastomosis caused by peristaltic movements^[11]. It may provide an additional support to the anastomosis until it reaches normal tensile strength and it may prevent the adverse effect of corticosteroids on intestinal anastomoses^[12].

Many studies support the use of seromuscular flaps to surgically challenging sites where there are factors threatening the healing like infection and irradiation such as repair of recurrent broncho-cutaneous fistulas, closure of the pancreatic stump, infected aortic stumps and repair of irradiation-induced rectovaginal and vesicovaginal fistulas^[13-16].

The major complications of intestinal surgery is the anastomotic leak, which vary from 5.2% to 21%^[2,17]. Our study documents that use of this pedicled flap significantly reduce the incidence of the anastomotic leak from 16.7% to 3.3% (P<0.008) and consequently less total postoperative complications (P<0.002) including less wound infection, wound disruption, shorter hospital stay (P<0.001), in spite that the flap made the operative time slightly significant longer with mean 25.3 minutes (P<0.006).

CONCLUSION

Reinforcement of the intestinal anastomosis with a seromuscular flap is a simple, feasible, and effective protective adjunctive maneuver that can minimize the risk of intestinal anastomotic leak. Our study supports the use of this pedicled flap technique especially in patients whose anastomoses carry high risk for disruption and leakage. Inforcement should be considered as an adjunct, not a substitute, to proper surgical principles in constructing a reliable intestinal anastomosis.

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Conflict of interest statement: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper

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Table 1 : Basic characteristics of patients.

Variables	1 st group(n=30)	2 nd group(n=30)	p value
Age(years)*	62.8(11.4)	63.2(9.3)	0.9
Sex(F:M)*	17:13	16:14	0.8
Weight (kg)*	67.1(5.7)	65(6.8)	0.2
Billrubin(mg/dl)*	1.7(0.4)	1.6(0.5)	0.4
Albumin(g/dl)*	3.3(0.5)	3.34(0.5)	0.7
Creatinine (mg/dl)*	1.4(0.5)	1.3(0.4)	0.6
ASA*	2.7 (0.8)	2.8(0.9)	0.7
Diabetes†	7(23.3)	6(20)	0.8
Cirrhosis†	12(40)	10(33.3)	0.2

(F:M)=female :male,*,*= standerd deviation,†= percentage

Table 2: operative data.

Variables	1 st group(n=30)	2 nd group(n=30)	P value
Operative diagnosis:			0.4
1- Perforated Crohn's†	1(3.3)	1 (3.3)	NS
2-Typhoid perforation†	3(10)	2(6.6)	NS
3- Strangulated SBO †	9(30)	10(33.3)	NS
4- MVT †	13(43)	12(40)	NS
5-Traumatic perforation.†	4(13.3)	5(16.7)	NS
Operative time(min)*	114.1(9.7)	108.8(10.2)	0.045
Blood loss*	237(51.7)	224(45.8)	0.3
Hospital stay*	6.1(2.1)	11.5(6.2)	0.001

MVT= mesenteric venous thrombosis,*,*= standerd deviation,†= percentage.

Table 3: postoperative outcomes.

Variable	1st group(n=30)	2nd group(n=30)	p value
P.O. Complications	6(20)	18(60)	0.002
Leaks†	1 (3.3)	5 (16.7)	0.008
Wound infection†	3(10)	5(16.7)	0.5
Wound dehiscence†	2(6.7)	6(20)	0.1
Pneumonia	0	2(6.7)	0.2
Reoperation†	3(10)	9 (30)	0.05
Total mortality †	0	3(10)	0.08

† represent percentage.

Figurelegends:

Fig.1: Segment of the intestine is preserved as a flap.

Fig.2: Slitting the flap at its antimesentric border, removal of the mucosa after injecting saline

Fig.3: Wrapping the flap around the anastomosis ,the mesentry is parallel to the bowel lumen.