

The Use of Porcine Intestinal Submucosa to Strengthen Stapling in Laparoscopic Rectosigmoidectomies

O Uso de Submucosa Intestinal Porcina no Reforço de Grampeamento em Retosigmoidectomias Videolaparoscópicas

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ABSTRACT

INTRODUCTION: Anastomotic complications (bleeding, dehiscence with abscess/peritonitis, or fistulas) are highly morbid intestinal surgeries and several alternative techniques are being developed and presented to the medical community. Among these alternatives are strengthening membranes that can be applied to the cartridges of staplers. **MATERIALS AND METHODS:** In 2008, we performed 42 laparoscopic rectosigmoidectomies for infiltrative endometriosis involving the rectosigmoid using a double stapling technique. In this observational study, patients were grouped according to the type of cartridges/trays used in the linear staplers: Group A (without the use of membranes, n = 28) and Group B (with the use of Surgisis®, a porcine intestinal submucosa membrane, n = 14). **RESULTS AND DISCUSSION:** One complication related to the anastomosis (rectovaginal fistula) was observed in the group which did not use Surgisis® (2.8%, 1/28). The use of these stapling reinforcements appears to be safe and appears to decrease the incidence of complications of mechanical stapling, both the immediate mechanical reinforcement of the sutures and the facilitation of cicatrization, as observed in animal studies and in clinical trials in bariatric surgery. Randomized controlled trials are needed for definitive evidence of such benefits.

Key words: Rectosigmoidectomy. Laparoscopy. Surgical complications. Anastomotic reinforcement. Porcine intestinal submucosa membrane. Surgisis®.

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INTRODUCTION

The evolution of laparoscopy in gastrointestinal surgery has only been possible with the development of mechanical endostaplers to suture the intestine. The use of these instruments permit speed in sectioning and anastomoses of the gastrointestinal tract. Their use is not immune to complications such as bleeding and the feared suture dehiscence, fistulae and intracavitary abscesses. Good surgical technique aims to prevent these complications. In addition, various technologies have been developed in order to reduce the incidence of complications.

Some of these technologies can be employed at the time of stapling, such as patches used in the stapler cartridge and anastomosis sealants.^{1,2,3} Among the membranes developed, one that stands out is the porcine **small intestine submucosa**, abbreviated **SIS**, and marketed as **Surgisis®** by Cook Medical Inc, (Bloomington, IN, USA),⁴ which is applied in the stapler cartridge, in order to reduce the incidence of complications related to stapling. This membrane works initially by strengthening the tissue to be stapled, minimizing tearing of the tissue. Once applied, the SIS interacts with the tissue allowing healing through this animal substrate, remodeling it, and promoting a strong and well vascularized scar tissue, which is more

resistant to infection. In this article we report our experience using Surgisis® in rectal sectioning with endostaplers during retosigmoidectomy using the double stapling technique in surgeries for the treatment of deep endometriosis.

MATERIALS AND METHODS

In the period from February to December 2008, we performed 42 laparoscopic rectosigmoidectomies for the treatment of infiltrative endometriosis (American Fertility Society classification of endometriosis stage IV) involving the rectosigmoid. The procedures were performed in private institutions in Rio de Janeiro by the same multidisciplinary team, which consisted of colorectal surgeons, general surgeons, gynecologists, and urologists.

All patients underwent bowel preparation with a residue-free liquid diet for 30 hours followed by a minimum of 8 hours of fasting prior to surgery. The evening before surgery patients ingested 60 g of sodium sulfate. Finally four tubes of osmotic laxative composed of sorbitol and sodium lauryl sulphate (Minilax®) were administered rectally.

In all 42 cases a written request for use of the Surgisis® was submitted to the patient's insurer payer. Authorizations were received for only 14 patients. This created two groups of patients and the conditions for a natural, albeit non-randomized experiment: 28 patients (labeled Group A) in which Surgisis® was not used and 14 patients (Group B) in which Surgisis® was used.

The laparoscopic technique used employs four ports: 10 mm transumbilical, 12 mm in the right iliac fossa (RIF), 5 mm in the left iliac fossa and flank. As per routine, a pneumoperitoneum with a maximum pressure of 12 mmHg is established by open technique and the patient is placed in a modified lithotomy position with moderate Trendelenburg.

The restoration of the pelvic anatomy is initiated by the gynecology and urology teams through the freeing of both ureters and the opening of the rectovaginal septum, after treatment of whatever adnexal alterations are encountered.

After identification and displacement of the left ureter and gonadal vessels, the intestinal phase of the procedure is then performed through a medial approach to the mesosigmoid, with the identification and sectioning of the inferior mesenteric artery.

The freeing of the sigmoid colon and the upper and middle thirds of the rectum is done posteriorly by the mesorectum with the preservation of the retroperitoneal autonomic innervation, including – whenever possible – the identification of the superior hypogastric nerves.

Once you are past the distal end of endometriotic lesion, all the fatty tissue surrounding the mesorectum is removed. At this point the distal cut is done with the endo-stapler loaded with 60mm gold or green cartridges through the 12 mm port in the right iliac fossa.

It is in this surgical step that the Surgisis® membrane, when available, is applied. The cartridges needed for complete sectioning of the rectum are then fired (in most cases only one or two cartridges are needed). After lateral release from the left parietocolic gutter – release of the splenic flexure is not routinely done because of the short segment to be resected – the specimen is externalized by the expansion of the right iliac fossa incision, or preferably through the vagina in those cases where an excision of a vaginal fragment has been made by the gynecologist as part of the treatment of endometriosis nodules.

With resection of the specimen completed, the ogive of the 33 or 34 mm circular stapler is placed in the proximal stump which is reintroduced into the abdominal cavity. The colorectal anastomosis is made with the circular stapler and the “tire mechanic” test is routinely done at the end. Pelvic drainage with a silicon drain and closed with soft suction (Blake drain) is done in cases of extraperitoneal anastomoses or in cases with more extensive raw surface areas.

Among our perioperative clinical care recommendations, we emphasize 1) not administering pharmacological DVT prophylaxis (conventionally Enoxaparin) until 12 hours after the use of the stapler, and instead encourage non-drug preventive measures, mainly effective analgesia so that the patient ambulates as soon as possible; 2) early replacement of electrolytes (Na, K, Mg and Ca), as prophylaxis against ileus secondary to dehydration and electrolytes disturbances and the use of hydration with Hydroxyethyl Starch 6% (Voluven®) a plasma volume expander during surgery (rather than just crystalloids) in order to avoid edema of the bowel, which could hamper the intestinal anastomosis.

A trial of an oral liquid diet (100 mL every two hours) is initiated on the first or second postoperative

day and advanced slowly. Discharge typically occurs around the fifth day with soft oral diet and only after bowel movements have resumed. During outpatient visits the first and second postoperative weeks, physicians look for signs and symptoms of intracavitary abscesses and rectovaginal fistulas.

RESULTS

In the cases reviewed in this period there was one case (2.8%) of rectovaginal fistula in Group A (which did not use Surgisis®), which was diagnosed in the ambulatory clinic on postoperative day (POD) 14. The patient reported flatulence and feces escaping from the vagina since POD 12. She was readmitted to the hospital and treated conservatively with elemental enteral nutrition administered via naso-enteral catheter and antibiotics (metronidazole and ciprofloxacin). The patient progressed satisfactorily, with a cessation of the vaginal discharge on the 10th day of therapy and was discharged from the hospital four days later.

In group B (with application of the Surgisis® membrane) no complications related to the intestinal anastomosis was observed.

There were no bleeding complications in either group.

Using the chi-square test the difference in complications between the groups was not statistically significant.

DISCUSSION

Anastomotic complications contribute to the significant increase in morbidity from intestinal surgery

and all technical efforts possible should be done by the surgical team in order to avoid such morbidity. The use of membranes or patches in the stapler cartridges is aimed at protecting the mechanical suture, both immediately by increasing the mechanical resistance of the tissue to the metal staples, and later by strengthening the scar tissue. Pinheiro and cols. demonstrated a significant (more than double) increase in the strength of the mechanical sutures with the application of Surgisis® in comparison with the mechanical sutures without this reinforcement in animal models.⁵ There are few studies in humans using Surgisis® in the mechanical suturing. The stand outs are studies of its use in lung resections,⁶ where bronchial fistulas constitute serious complications, and in bariatric surgery,⁷ where the anastomotic complications are potentially fatal.

In these 14 cases, the application of Surgisis® worked without difficulties or complications, other than creating one more step in the preparation of the mechanical suture, since the membrane does not come ready in the cartridge of the stapler and needs to be applied and fixed to it each shot. The use of biological glue would be an alternative, but in addition to its higher cost, it extends the operative time, because it implies another surgical step, after the anastomosis.⁷ The absence of complications was a desired outcome, but a causal relationship between the use of Surgisis® and this outcome cannot be asserted given the small number of patients and the lack of randomization. These preliminary results should encourage the use of these mechanisms of protecting the anastomosis in randomized clinical trials to prove their relative effectiveness.

RESUMO

INTRODUÇÃO: Complicações anastomóticas (sangramentos, deiscências com abscesso/peritonite ou fístulas) são altamente mórbidas em cirurgias intestinais e diversas alternativas técnicas são dia-a-dia desenvolvidas e apresentadas a comunidade médica. Entre essas alternativas figuram as membranas de reforço a serem aplicadas nas cargas dos grampeadores. **MATERIAL E MÉTODOS:** No ano de 2008, realizamos 42 retosigmoidectomias por videolaparoscopia pelo diagnóstico de endometriose infiltrativa com acometimento de retosigmóide pela técnica de duplo grampeamento. Neste estudo observacional, as pacientes foram agrupadas quanto aos tipos de cargas utilizadas pelos grampeadores lineares: Grupo A (sem o uso de membranas; n=28) e Grupo B (com o uso de membrana de submucosa intestinal porcina Surgisis®; n=14). **RESULTADOS E DISCUSSÃO:** Uma complicação relacionada à anastomose foi observada (fístula reto-vaginal) no grupo onde não foi utilizado o Surgisis® (2,8%, 1/28). O uso destes reforços de grampeamento parece ser seguro e parece diminuir a incidência de complicações da sutura mecânica, tanto pelo reforço mecânico imediato da sutura quanto pela facilitação da cicatrização - observada em estudos animais e ensaios clínicos em cirurgias bariátricas. Estudos clínicos randomizados são necessários para a definitiva comprovação destas vantagens.

Palavras chave: Retosigmoidectomia. Laparoscopia. Complicações cirúrgicas. Reforço da anastomose. Membrana de submucosa intestinal porcina. Surgisis®.

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