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ORIGINAL ARTICLE

NEW TECHNIQUE FOR CLOSURE OF RECTOVAGINAL FISTULA USING COMPOSITE POLYPROPYLENE POLYGALACTINE (VYPRO™) MESH
RUNNING HEAD: MESH CLOSURE OF RECTOVAGINAL FISTULA

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Abstract

Background: The use of composite polyglactin polyprolene (Vypro) mesh might carry the hope of strengthen the rectovaginal septum with minimal erosion rate.

Purpose: To evaluate repair of traumatic rectovaginal fistula by Vypro mesh regarding erosion rate, recurrence and its effect on sexual function.

Methods: The study was conducted on twenty female patients. Pre operative data collected from patients included: patients' demographics, and a questionnaire for the presenting symptoms. Vypro mesh was inserted between the rectum and vagina through transperineal incision after excision of the fistula. The Cleveland Global Quality of Life (CGQL) score, and CCF continence score, were recorded. Patients were followed up after two weeks, 3months and one year.

Results: Mean operative (OR) time was 41.9 ± 19.1 minutes. No postoperative mortalities. Postoperative complications occurred in 7 patients in the form of: urinary tract infection in 2 patients, upper respiratory tract infection in 1 patient and wound infection in 4 patients, all of them started between the 3rd and 6th day postoperative.
After 2 weeks 16 patients (80%) showed improvement of symptoms while 4 patients who got wound infection didn't show symptom improvement. After 3 months 18 patients showed symptom improvement while the other 2 patients remained without improvement. 2 patients had mesh erosion.

Conclusions: Excision of rectovaginal fistula with reinforcement of rectovaginal septum using Vypro mesh is safe and reliable. Postoperative erosions and recurrences are possible serious inevitable complications in a considerable % of patients.

Keywords: Obstetric trauma, Perineal tear, Closure.

INTRODUCTION

A rectovaginal fistula (RVF) is an abnormal direct communication between the two epithelial-lined surfaces of the rectum and vagina that accounts for less than 5% of all anorectal fistulas. It presents a distressing problem for the patient and a challenge for the treating physician.(1)

The most common etiology for rectovaginal fistulas (RVF) is obstetric injury. Obstetric injury might result from pressure necrosis due to prolonged obstructed labor, failure of primary repair of a third or fourth degree laceration, unrecognized injury at the time of vaginal delivery, and from episiotomy infection with formation of a fistulous tract.[2-4]

Primary repair of these fistulas is associated with a success rate of 70 to 97 percent, while in recurrent cases, the reported outcome is worse, (40% to 85%).[5,6]

The choice of procedure for repair of a fistula depends upon whether it is simple or complex, and presence of sphincter damage. Previous attempts at surgical correction are critically important in the decision making process. Options for the surgical approach are transvaginal, transrectal, transperineal or transabdominal (by laparotomy or laparoscopy).[7,8]

Transvaginal repair methods include conversion of the fistula to a complete fourth degree laceration followed by excision of the fistulous tract and a layered closure. In the case of a fistula that is not accompanied by anal sphincter disruption, this entails damaging an intact sphincter lead to poor continence results at long-term follow-up.[9] Transrectal repairs generally involve the development of rectal mucosal flaps, mobilized to cover the excised fistula tract. Instrumentation and anal dilatation associated with this approach affect the anal sphincter so may affect the continence.[10,11] The transperineal approach starts with a curved incision on the perineum, through which the vagina and rectum are separated. The fistula is then divided and both the vaginal and rectal sides of the fistula are closed in layers in opposing directions so that the lines of the repair do not directly overlie one another. In addition this approach allow repair of associated sphencteric defect.[12]

Pye, et al[13] reported that Surgisis mesh placement can safely corrects recurrent RVFs. Theoretically, use of mesh will avoid an additional fascial harvesting procedure and provide a stronger materials than the patient's own fascial tissue.

Previous studies showed that placement of polypropylene mesh alone in the rectovaginal septum results in RVF. However, the use of the composite polyglactin polyprolene mesh in repair of rectocele showed that it is superior to absorbable mesh, with less erosion rate compared to non absorbable polypropylene mesh.[14] The use of composite polyglactin polyprolene mesh in repair of RVFs was not studied before but it might carry the hope of strengthen the rectovaginal septum with minimal erosion rate.

Specific Aim: The aim of this study was to evaluate repair of traumatic rectovaginal fistula by composite polyglactin polyprolene mesh regarding erosion rate, recurrence and its effect on sexual function.

PATIENTS AND METHODS

The study was conducted on twenty female patients admitted to Alexandria university hospitals suffering from obstetric rectovaginal fistula in the period from June 2007 to December 2008.

Inclusion criteria included patients with RVF due to obstetric trauma that persisted for more than 6 months. Exclusion criteria comprised inflammatory bowel disease, colorectal or vaginal neoplasms, severe anal stenosis and diabetes mellitus.

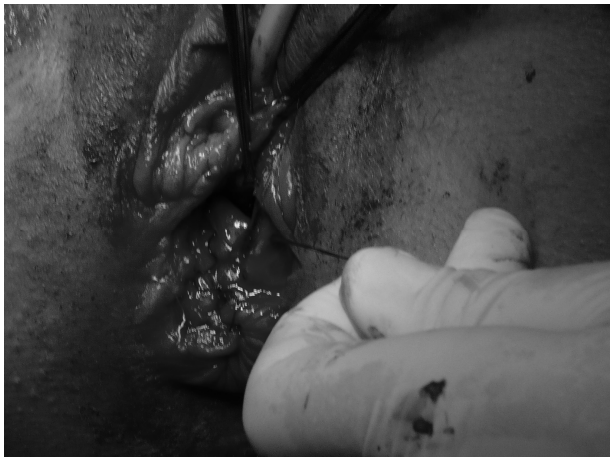
The Ethics Committees of Alexandria University approved the study protocol. All patients participating in the study gave preoperative written informed consent.

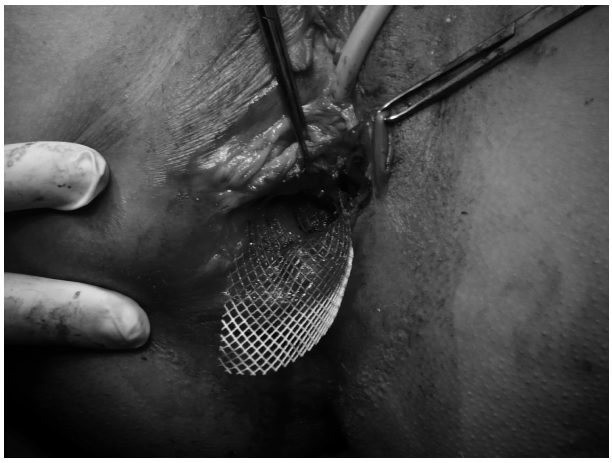
Pre operative data collected from patients included: patients' demographics, a questionnaire for the presenting symptoms, bleeding per rectum, pregnancies, delivery episiotomy, and previous pelvic or anal surgeries. Clinical examination of the perineum, rectum, and vagina to diagnose any associated abnormalities. Proctoscopy was performed for all patients to evaluate size and location of the rectovaginal fistula, state of the anal sphincter, any concomitant anorectal disease and colonoscopy was done if inflammatory bowel disease or malignancy was suspected. Vaginography with water soluble contrast medium was done for each patient for localization and delineation of the fistulous tract.

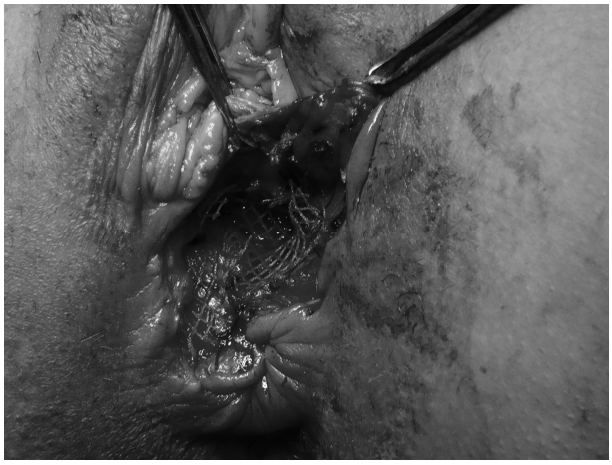
Anal manometry was performed for all patients using perfusion catheter systems (Synectics, Stockholm, Sweden) to measure resting anal pressure, maximum squeeze pressure and functional anal canal length.

The validated Cleveland Global Quality of Life (CGQL) score,[15] and CCF continence score,[16] were recorded.

Operative Technique[13]: Preoperative mechanical bowel preparation was done for all patients. With the patient placed in a lithotomy position transverse perineal skin incision is made just in front the anal verge. Dissection proceeds in the plane separating the vagina anterioly and anal canal, rectum posterioly till reach the fistulous tract. The vagina then dissected from the rectum approximately 2 cm above the fistula site. The rectal component of the repair is performed with a double layer of interrupted polygalactin 2/0 suture (Vicryl™, Ethicon Endo-Surgery, Inc.) folding the rectal mucosa over the fistulous tract. Composite Polyprolene polygalactin mesh was cut to size, approximately 5 cm × 5cm, placed in the rectovaginal space, and held with five 3/0 polygalactin suture (Vicryl™, Ethicon Endo-Surgery, Inc.) at each corner of the mesh and in the middle.The vaginal mucosa is closed over the mesh using a continuous 1/0 polyglactin suture. Sphincter repair was performed if sphincter injury was present using 2/0 polypropylene sutures (Prolene™, Ethicon Endo-Surgery, Inc.). (Figs. 1-3).







Figs. 1-3. Vypro mesh repair of rectovaginal fistula.

Operative data collected included, operative (OR) time, estimated operative blood loss (EBL) and bleeding from the suture line.

Immediate postoperative data collected included wound infection, hematoma or seroma collections, pain score using visual analogue scale (VAS) and length of stay (LOS).

Patients received one dose of IV ciprofloxacin intra-operative and every 12 hours for 5 days together with oral ketorolac 10 mg/8 hours.

Patients started oral soft diet on the day of surgery and regular diet with stool softeners from the 2nd day postoperative and discharge was determined by the surgeon decision. Patients were not allowed to have sexual relation expect after 1 month.

Patients were followed up after two weeks, 3months and one year. During the follow up visits, digital rectal examination was performed to evaluate anal sphincter tone. Complication such as wound infection, none healing, mesh erosion, dysparonia and recurrence were recorded.

Anal manometry was performed ofter one year postoperative while continence score and GQOL were measured after 3 months and one year.

Statistical analysis: Quantitative variables were expressed as mean ± standard deviation. Qualitative variables were expressed as frequency and percent. Comparison between preoperative and postoperative manometric data, continence scores and GQOL score were done using Wilcoxon's rank-sum test for paired data. Statistical significance was established at $p < 0.05$.

RESULTS

The study included 20 female patients. All of them were multiparous (mean number of deliveries 3.2 ± 1.91) and all had at least one vaginal delivery with episiotomy. Patients' mean age was 26.6 ±7.07 years (range: 20-40).

15 patients had failed repair of fourth degree perineal tear, 3 had infected episiotomy wounds and 2 had unrecognized rectal injuries during labor.

15 patients (75%) reported passage of flatus and/or fluid stools per vagina and 3 patients had solid stools passing per vagina. Only 1 patients (5%) had only vaginal discharge with fetid odor and 1 patient (5%) had resistant chronic vaginitis. All patients had incontinence, to gases and liquids, and only 4 patients (20%) were incontinent to solids. No single patient suffered from bleeding or mucus per rectum, 2 patients had dysparonia due to vaginitis and the rest were not having sexual relations. Table 1

Preoperative anal manometry revealed mean RAP of 38.3 ± 20.5 mm Hg , MSP of 59.9 ± 20.5 mm Hg while FACL ranged from 0-2 cm with the mean of 1.1 cm.

Preoperative continence score ranged from 6 to 20 with the mean of 14.6± 5.4 while CCF GQOL score ranged from 10 to 25 with the mean of 14.3 ± 7.8

Operative data: Mean operative (OR) time was 41.9 ± 19.1 minutes and estimated operative blood loss was less than 200 cc/ patient in all cases (range 100-180).

Postoperative data: No postoperative mortalities. Postoperative complications occurred in 7 patients in the form of: urinary tract infection in 2 patients, upper respiratory tract infection in 1 patient and wound infection in 4 patients, all of them started between the 3rd and 6th day postoperative. Wound infections were treated by drainage and antibiotics according to culture and sensitivity, 2 patients responded but with delayed wound healing up to 3 weeks and the other 2 patients remained with recurrent discharging sinuses. No incidence of postoperative bleeding. After two week, all patients had minimal postoperative pain (VAS: 1-2). Table 2.

Follow up: Patients were followed up for one year. After 2 weeks 16 patients (80%) of them showed improvement of symptoms while 4 patients who got wound infection didn't show symptom improvement.

After 3 months 18 patients (including 2 of the wound infected patients with good response to conservative measures) showed symptom improvement while the other 2 patients remained without improvement. 2 patients had mesh erosion in the vaginal side that was managed by surgical excision of the eroding mesh with recurrence of the RVF and appearance of newly developed dysparonia.

Other patients were all having regular sexual relations with neither dysparonia nor the smell of bad odor.

Anal manometry showed significant increase in both RAP, MSP and FACL. Mean continence score improved significantly to the mean of 2.1± 1.7 ($p<0.001$) while the GQOL score improved significantly to the mean of 23.9±2.3 ($p< 0.01$) Table 3.

After 1 year, no more improvement of continence, manometric measures or GQOL scores compared to the 3 month's visit. No improved patients showed delayed deterioration.

Table 1. Preoperative clinical presentation.

	Number of patients
Flatus and/or fluid stools per vagina	15
Solid stools passing per vagina	3
Vaginal discharge with fetid odor	1
Chronic resistant vaginitis	1
Continence disorders	20
Dysparonea	2
Bleeding per rectum	0

Table 2. Post operative complication.

	Number	%
Urinary tract infection	**2**	**10%**
Chest infection	**1**	**10%**
Wound infection	**4**	**20%**
Mesh Erosion	**2**	**10%**
Delayed healing	**2**	**10%**
Newly developed dysparonea	**2**	**10%**
Recurrence	**2**	**10%**

Table 3. Manometric and QOL changes after surgery.

	Preoperative	3 months postoperative	P value
RAP mmHg	38.3 ± 20.5	63.1± 20.9	P=0.003*
MSP mmHg	59.9 ± 20.5	140.4± 56.7	P<0.001*
FACL cm	1.1± 0.8	3.5 ± 1.1	P<0.01*
CS	14.6± 5.4	2.1± 1.7	P<0.001*
GQOL	14.3 ± 7.8	23.9±2.3	P<0.01*

*= significant result
RAP= Resting anal pressure
MSP= Maximum squeeze pressure
FACL= functional anal canal length
CS= Continence score
GQOL= Cleveland Clinic Global Quality of Life Score

DISCUSSION

Rectovaginal fistula (RVF) is one of the distressing surgical conditions that women can experience. Women with this condition are usually rejected by partners, as a result of malodorous feculent vaginal discharge.

RVF are usually classified as low, middle, and high positions relating to the level at which the rectovaginal septum is involved. High fistulas are involving the proximal vagina, which is covered with peritoneum. Fistulas entering the middle zone only involve the rectovaginal septum, whereas low fistulas are located at, or just above, the dentate line.[17] High RVF often can be approached trans-abdominally, whereas any of the other approaches may be suitable for low/middle fistulas.[18]

Patients with RVF are usually symptomatic. Only a small proportion of females are asymptomatic. The clinical manifestation largely depends on the size, location, and etiology of the fistula. Discharge of intestinal waste from the vagina is the predominant symptom and malodorous vaginal discharge may be accompanied with recurrence episodes of vaginitis. In our patients, the most common symptom was the passage of flatus or liquid through, vagina, which is similar to those described in the literature.[19]

Repair of recto-vaginal fistula is always challenging due to relatively limited blood supply to this area, high luminal pressure in the distal rectum, and the presence of chronically inflamed tissues.[20] The appropriate surgical approach is dependent on location, size of the defect, sphinteric function and the underlying cause.[21] There's a controversy regarding the best surgical approach as no surgical approach can fit all patients.

In a trial to prevent fistula recurrence, surgical repair with mesh insertion was designed. This is because friction between the two opposing suture lines (vaginal and rectal) after fistulous tract excision and defect repair may lead to failure of the reconstructive procedure so placing surgical mesh between these two layers prevent any suture contact and raises the chance of success.

Surgisis™ is a biocompatible mesh manufactured from porcine small intestinal submucosa that was used successfully in treatment of recto-vaginal fistula.[13] Its sterile, acellular properties enable it to be used without the complication of rejection. There is significant reduction in fibrosis during the healing process, because the mesh supports the patients' own connective tissue and smooth muscle growth. The alternative mesh products formed by synthetic materials (Polypropylene meshes) do not have these qualities, and although they are less expensive initially (Surgisis™ is three times the cost of Polypropylene mesh), yet the mesh erosion complication is really serious.[22]

In the current study we have tried to evaluate the short-term outcome of a new trans-perineal technique in the form of excision of the fistula, reinforcement of rectovaginal septum using Vipro ™ mesh with or without sphincter repair according to the patient's condition. Vypro II mesh is a composite polypropylene (35%) polyglactin 910, mono/multifilament, absorbable/nonabsorbable mesh. Vypro II has a reduced weight compared to Polypropylene (50 vs 92 g/m2) and induces less inflammatory response[23] when implanted in the body. Moreover, vascularization is more pronounced with Vypro mesh compared to Polypropylene.[23] These factors resuls in improved healing and less incidence of mesh erosion

In the current study the mean OR time was 42 minutes which was comparable to that obtained in mesh repair by Schwandner in 2009 (38 minutes)(24). we didn't have incidence of dysparonea except in recuurent cases due to vaginitis (10%) compared to 17% with rectovaginal fistulas repaired with Maritus grafts.[25]

This might be due to the fact that Vypro induced scar formation only around the filaments and did not include the whole mesh in the scar plate which leads to reinforcement of recto-vaginal septum without loss of vaginal elasticity.

Failure rate in this study was 10% due to mesh erosion versus 29% recurrences reported by Schwandner[24] and recurrences from 5- 36% following the rectal advancement flap repair.[21,26,27] The low incidence of recurrence might be due to the fact that Surgisis mesh used in the latter study supports the patients' own connective tissue and smooth muscle growth without enough fibrosis while Vypro mesh induces fibrosis that might strengthen the rectovaginal septum thus decreasing the risk of recurrence. Timing of repair is also of importance. The chances of success are increased if the surrounding tissue is in optimal condition, i.e. not inflamed or infected. So rest period of three to six months before starting repair was suggested by some authors,[28] in this study we followed this role in all cases.

Early Erosion reported in this study is possibly due to defective healing of the wound as erosion is usually found on the incision line. Inflammatory response to the implantation of a foreign body may cause impaired healing over the mesh. No erosion was reported with surgisis in repair of rectovaginal fistula[24,29] or with Dexon in rectovaginal septal repair.[30] Surgisis is gradually replaced as the host cells rebuild and remodel weakened tissue so no rosion is expected, while dexon is absorbable within 6 months and no previous published successful trials in cases of rectovaginal fistulas.

As expected there was significant postoperative increase of the RAP, MSP and FACL in patients who had preoperative sphincteric injury that was repaired during surgery. The improvement of the continence score was significant and it was maintained till the end of the follow-up. We think that the short time of follow-up contributed in these results. Long term results after

sphincteric repair are not that promising (from 13- 60% continence disorders in different series).[31,32]

Reports of success rates for rectovaginal fistula repair were largely limited to the success of closure of the fistula with little description of quality of life changes or functional outcome, in this study Cleveland clinic foundation quality of life score used as over all monitor to estimate the effect of rectovaginal fistula repair, on the quality of life of patients. Significant improvement in the GQOL after surgery, however, with mesh erosion, recurrence and dysparonea GQOL immediately drops significantly.

This study is limited by the small number of patients and short time of follow up, so a prospective randomized trail comparing different types of meshes with long follow-up is needed to format an evidence based conclusion

In conclusion, the current data suggests that excision of rectovaginal fistula with reinforcement of rectovaginal septum using Vypro mesh is safe and reliable. Postoperative erosions and recurrences are possible serious inevitable complications in a considerable % of patients. Randomized trial comparing different types of mesh repair of RVF is still needed.

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