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Comparative study of safety and efficacy of synthetic surgical glue for mesh fixation in ventral rectopexy

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Abstract
Background Ventral mesh rectopexy (VMR) is a surgical option to treat rectal prolapse with pelvic floor dysfunction (PFD). Using synthetic surgical glue to fix the mesh to the anterior rectal wall after ventral dissection could be advantageous in comparison with sutured or stapled fixation. This study aimed to evaluate the safety and efficacy of synthetic surgical glue for mesh fixation compared with suture mesh fixation in VMR.
Methods This observational cohort study is a retrospective analysis conducted in a University Hospital Pelvic Surgery Center. All consecutive female patients ($n=176$) who underwent laparoscopic or laparotomic VMR between January 2009 and December 2014 were included. Two groups were defined based on mesh fixation technique of the rectal wall: VMR with synthetic glue ($n=66$) and VMR with suture ($n=110$). The recurrence-free survival after VMR was determined by Kaplan–Meier method and multivariate analysis by Cox regression. Short-term postoperative complications, postoperative symptom improvement, the need for complementary treatment postoperatively, and procedure length were evaluated.
Results A total of 176 females patients (mean age, 58.6 ± 13.7 years) underwent VMR with synthetic mesh. Mean recurrence-free survivals after VMR were 17.16 (CI 95% 16.54–17.80) and 17.33 (CI 95% 16.89–17.77) months in the glue group and the suture group, respectively ($p>0.05$). Cox regression identified an independent effect on the recurrence risk of the external rectal prolapse, alone, or in combination with other anatomical abnormalities (HR = 0.37; CI 95% 0.14–0.93; $p=0.03$). There was no significant difference of short-term postoperative morbidity, procedure length, postoperative symptom improvement, or need for complementary treatment postoperatively between suture versus glue groups (all $p>0.05$).
Conclusions. Use of glue to fix the mesh in VMR was safe and had no impact on outcomes. External prolapse was the unique significant predictive factor for recurrence.

Keywords Surgical mesh · Cyanoacrylate glue · Surgical glue · Ventral mesh rectopexy · Pelvic floor dysfunction · Rectal prolapse

Pelvic floor dysfunction (PFD) prevalence is increasing with the aging of the female population. The exact prevalence of PFD related to rectal prolapse is unknown, because it can occur in isolation or in combination with other anatomical abnormalities, and is also diagnosed by radiology in patients without any symptoms. It is estimated that 25% of women will have at least one anatomical pelvic floor defect [1, 2]. Although PFD is not a life-threatening condition, the impact on quality of life can be devastating [3, 4].

Multiple surgical techniques have been described for the treatment of PFD [5–7]. The aim is to repair the anatomical rectal abnormalities and thereby treat the symptoms, which are usually related to obstructed defecation, fecal incontinence, and pelvic discomfort [3]. However, none of these surgical procedures seem to be ideal. Perineal approaches for external rectal prolapse (Altemeïer,

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Delorme procedures) are associated with a high rate of recurrence, and are therefore only advocated for older and high-risk patients who are not candidates for abdominal surgery [7, 8]. Laparoscopic surgery for rectal prolapse was introduced in 1992, and consisted of sutureless rectopexy with staples with or without resection [5–7]. The laparoscopic abdominal approach has gained popularity because of its lower recurrence rate and improved functional outcome compared with perineal surgery [7]. Its indications have been extended to symptomatic intra-anal rectal prolapse.

Laparoscopic ventral mesh rectopexy (VMR) as described by D'Hoore et al., has become the procedure of choice in many centers in Europe [9]. This technique has the advantages of correcting anatomical abnormalities of the middle and posterior pelvic compartments, reinforcing the rectovaginal septum. To avoid induced constipation, rectal mobilization is limited to rectal anterior wall in order to preserve the autonomic nerves. This is followed by fixation of the anterior rectal wall and the sacral promontory using a mesh. In theory, this limited dissection of the rectum should reduce new-onset of constipation [10]. However, complications related to the presence of the mesh have been reported, including mesh erosion, dyspareunia, fistulation, and stricture formation [11, 12].

In recent years, the application of synthetic glue for mesh fixation in abdominal hernia surgeries, especially in laparoscopic surgery, has become a well-established technique. Experimental and clinical studies have demonstrated the safety and efficacy of this adhesive fixation in comparison with penetrating fixation (suture, staples, and tackers) [13, 14]. The advantages of adhesive fixation include fast application, low infection rate, reduced postoperative pain, shorter hospital stay, and low recurrence rate [15].

Cyanoacrylate is a fast-acting adhesive resin that polymerizes exothermically in the presence of water, reaching the ideal fixation point in 60 s. The glue composition has good local tolerance and biocompatibility. After 360 days postoperatively, the mesh fixed with cyanoacrylate is usually covered with a mild formation of non-cellular fibrous connective tissue and a mild infiltration of inflammatory cells, including mononuclear cells and focal accumulation of multinuclear giant cells; these are exactly the same histologic characteristics found with sutured fixation [15]. The glue also has bacteriostatic effects, bonds to the tissue firmly and prevents folds, particularly in the more flexible meshes [13]. The use of surgical synthetic glue (cyanoacrylate) to fix the mesh to the rectal anterior wall after dissection may provide a good degree of stiffness, which enables proper positioning of the mesh and avoids folding.

This study aimed to evaluate the safety and efficacy of synthetic surgical glue for mesh fixation compared with suture mesh fixation in VMR.

Materials and methods

Study design

An observational cohort analysis of female patients who underwent laparoscopic or laparotomic VMR in a single center between January 2009 and December 2014 was performed. Two groups were defined and compared based on VMR technique: VMR with synthetic glue ($n=66$) and VMR with suture ($n=110$). Data were collected prospectively from the digital medical record database of a University Hospital Pelvic Surgery Center. Mesh fixation of the rectal wall in VMR was routinely done with suture during the first phase until November 2012; from November 2012 onwards, this procedure was replaced by VMR with synthetic glue (*n*-hexil cyanoacrylate). The primary analyzed outcome was symptom free from recurrence time after VMR. Secondary outcomes were short-term postoperative complications, postoperative symptom improvement, need for postoperative additional treatments, and procedure length. The primary and secondary outcomes were compared between synthetic glue group and suture group.

Patients and evaluation

In all cases, surgical decision was based on patients' reported severe symptoms of anal incontinence, obstructed defecation, pelvic discomfort, associated to rectal intra-anal or external prolapse. Roma III criterias were used to assess constipation. In addition to clinical examination, all patients had dynamic pelvic imaging by MRI or X-ray defecography. Anatomical pelvic findings indicating surgery when correlated to symptoms were external rectal prolapse, intra-anal rectal prolapse, rectocele, enterocele, isolated, or combined.

Patients were stratified, according to the type of prolapse, in two groups. The first included patients with external prolapse. The second group included the patients with internal intra-anal prolapse.

All patients were examined 4 weeks, 3 months, and 18 months after surgery, when the follow-up was concluded. Patients were instructed to return if symptoms of recurrence or complications occurred.

Age, body mass index, number of pregnancies, previous abdominal surgery, previous proctologic surgery, previous

PFD surgery, previous hysterectomy, and PFD recurrence were recorded.

The number of symptoms experienced by each patient was compared before and after the intervention. Patients reported postoperative outcomes were categorized as following: clinical improvement, no clinical improvement, and worsening symptoms. The symptoms evaluated were as follows: constipation, presence of lumpy and hard stools, need for manual maneuvers to facilitate defecation, sensation of incomplete evacuation, fecal incontinence, fecal urgency, pelvic pain, and pelvic discomfort.

Patients had mandatory full and clear information about the surgical procedure and the risk/benefit ratio. Since synthetic glue was already used in laparoscopic procedures, the study was ethically approved in our institution.

Surgical technique

Ventral rectopexy was performed as described by D'Hoore et al., by laparoscopy or laparotomy in case of previous abdominal surgery [9]. The procedure had been implemented in the colorectal unit since 2001. In all patients, after dissection of rectovaginal septum, a strip polyester mesh (Swing Technologies; Montpellier, France) of approximately 12×3 cm was fixed to the anterior rectal wall either with three non-absorbable sutures (suture group) or with 0.5 ml of n-hexil cyanoacrylate glue (glue group) (Ifabond®; Peters Surgical, Bobigny, France).

In the glue group, application was performed using a long disposable laparoscopic dedicated catheter. Glue was applied on the mesh on the anterior rectal wall, avoiding cranial tension on the mesh for 10 s until polymerization was obtained, allowing a proper fixation. Dissection of sacral promontory was minimal. It was limited to a small area of anterior vertebral ligament, laterally to the right hypogastric nerve and after clear identification of the right ureter. Fixation to the sacral promontory was done using non-absorbable suture after careful haemostasis of medial presacral veins. The Douglas pouch peritoneum was closed with continuous absorbable suture in both groups. No drain was used.

Statistical analysis

An independent statistician analyzed the data, using Statistical Package of the Social Sciences (SPSS) version 18.0 for Windows (SPSS Inc, Chicago, IL, USA). Pearson Chi-squared test was used for categorical variables, and the Student's *t*-test or the Mann–Whitney U test was used for continuous variables. The recurrence-free survival after VMR was determined by the Kaplan–Meier method. A multivariate Cox regression analysis was performed to identify predictive factors for recurrence. Estimates along with 95% pointwise confidence intervals were reported. The duration of recurrence-free survival was measured from date of surgery to the time of recurrence (complete) or the last follow-up (censored). Non-adjusted and adjusted odds ratios were calculated for secondary outcomes. To control for confounding factors, a binary logistic regression was performed, with variables with a p value >0.20 included in the model. Wald test was used to evaluate the significance of the post-adjustment associations. All p values <0.05 were considered statistically significant.

Results

Patients Characteristics and operative data

This study included 176 patients, of which 66 in the synthetic glue group, and 110 in the suture group.

Mean age was 58.6 ± 13.7 years. The group of anal internal prolapse alone or combined plus other anatomical abnormalities represented the majority of the patients (70%).

None of the parameters differed significantly between the two groups ($p > 0.05$), except that the rate of laparoscopy was significantly higher in the VMR with synthetic glue group than in the VMR with suture group ($p = 0.001$) (Table 1). In the laparoscopy group, one conversion to open surgery occurred due to extensive intra-abdominal adhesions.

Recurrence rates after VMR

A total of 19 patients developed recurrence, 7 patients in the synthetic glue group and 12 patients in the suture group (Table 2). The means of recurrence-free survival after VMR were 17.16 (CI 95% 16.54–17.80) and 17.33 (CI 95% 16.89–17.77) months in the synthetic glue group and the suture group, respectively ($p > 0.05$). The estimated recurrence-free percentages for the cohort according to the Kaplan–Meier method were 94% and 96% after 1 year for the glue group and the suture group, respectively (Fig. 1).

Nine patients developed recurrence in the external rectal prolapse group whereas nine in the second group of anal internal prolapse (Table 2). The means of recurrence-free survival after VMR were 16.73 (CI 95% 15.90–17.57) months in the patients with external rectal prolapse and 17.62 (CI 95% 17.40–17.83) in the patients with anal internal prolapse ($p = 0.03$). The estimated recurrence-free percentages for the cohort according to the Kaplan–Meier

Table 1 Ventral mesh rectopexy patient clinical characteristics and operative data

Variables	Total, $n=176$ (%)	Synthetic glue group, $n=66$ (%)	Suture group, $n=110$ (%)	p value[a]
Age in years (mean ± standard deviation)	58.6 ± 13.7	59.8 ± 15.2	57.8 ± 12.7	0.3642[b]
Diagnosis				
EP (alone or combined)[c]	52 (29.9)	15 (22.7)	37 (34.3)	0.107
AIP (alone or combined)[d] or other combinations[e]	122 (70.1)	51 (77.3)	71 (65.7)	
Weight (BMI ≥ 25 kg/m^2)	52 (33.1)	18 (31.6)	34 (34.0)	0.757
Three or more pregnancies	22 (28.2)	7 (21.9)	15 (32.6)	0.300
Abdominal surgical history	94 (62.7)	34 (57.6)	60 (65.9)	0.304
Previous hysterectomy	98 (62.8)	39 (63.9)	59 (62.1)	0.818
Proctologic surgical history	21 (13.5)	7 (11.7)	14 (14.7)	0.604
Previous pelvic floor disorder surgery	55 (35.0)	21 (34.4)	34 (35.4)	0.899
PFD recurrence	51 (33.1)	20 (32.3)	31 (33.7)	0.853
Surgical approach				
Laparoscopic	130 (75.1)	59 (89.4)	71 (66.4)	0.001
Laparotomy	43 (24.9)	7 (10.6)	36 (33.6)	
Procedure length in minutes (mean ± standard deviation)	94.67 ± 27.67	88.62 ± 22.32	98.36 ± 29.98	0.066 [f]

VMR ventral mesh rectopexy, *EP* external prolapse, *AIP* anal internal prolapse, *BMI* body mass index, *PFD* pelvic floor dysfunction

[a]Calculated by the Pearson's Chi-squared test unless otherwise specified

[b]Calculated by the Student's *t*-test

[c]EP+ enterocele or cystocele

[d]AIP+ enterocele or cystocele or rectocele

[e]Enterocele and/or cystocele and/or rectocele

[f]Mann–Whitney *U* test

method were 90 and 98% after 1 year for each group, respectively (Fig. 2).

Fifteen patients in the laparoscopic group and four patients in the laparotomic group developed recurrence (Table 2). The means of recurrence-free survival after VMR were 17.17 (CI 95% 16.35–17.99) and 17.29 (CI 95% 16.91–17.61) months in the laparotomy group and the laparoscopic group, respectively ($p>0.05$). The estimated 1-year recurrence-free survival for the laparotomy group and the laparoscopic group was 95 and 95%, respectively (Fig. 3).

When adjusting the confounding factors by Cox regression, external prolapse was the only predictive factor for recurrence. (HR = 0.37; CI 95%0.14–0.93; $p=0.03$) (Table 3).

Table 2 Recurrence according to the glue status

Recurrence	Total	Use of glue	
		Yes	No
Initial diagnosis[a]			
EP (alone or combined)[b]	9	3	6
AIP (alone or combined)[c] or other combinations[d]	9	4	5
Surgical approach			
Laparotomy	4	–	4
Laparoscopy	15	7	12
Total	19	7	12

EP external prolapse, *AIP* anal internal prolapse

[a]One case without information

[b]EP+ enterocele or cystocele

[c]IP+ enterocele or cystocele and/or rectocele

[d]Enterocele and/or cystocele and/or rectocele

Complications, functional outcomes, and complementary treatment

Clinical outcomes did not differ significantly between the two groups. There were no postoperative deaths. Global complication rates were similar in both groups. Non-mesh complications occurred in 8.13% of patients overall (7.8% in the synthetic glue group versus 8.7% in the suture group, $p>0.05$). Five patients had complications in the synthetic glue group: one had peritonitis due to an unseen peroperative ileal perforation, one had a wound hematoma, one had surgical site infection, and two had minor clinical complications of Clavien–Dindo type 1 [16]. Nine patients had complications in the suture group: five had wound hematoma, and the others

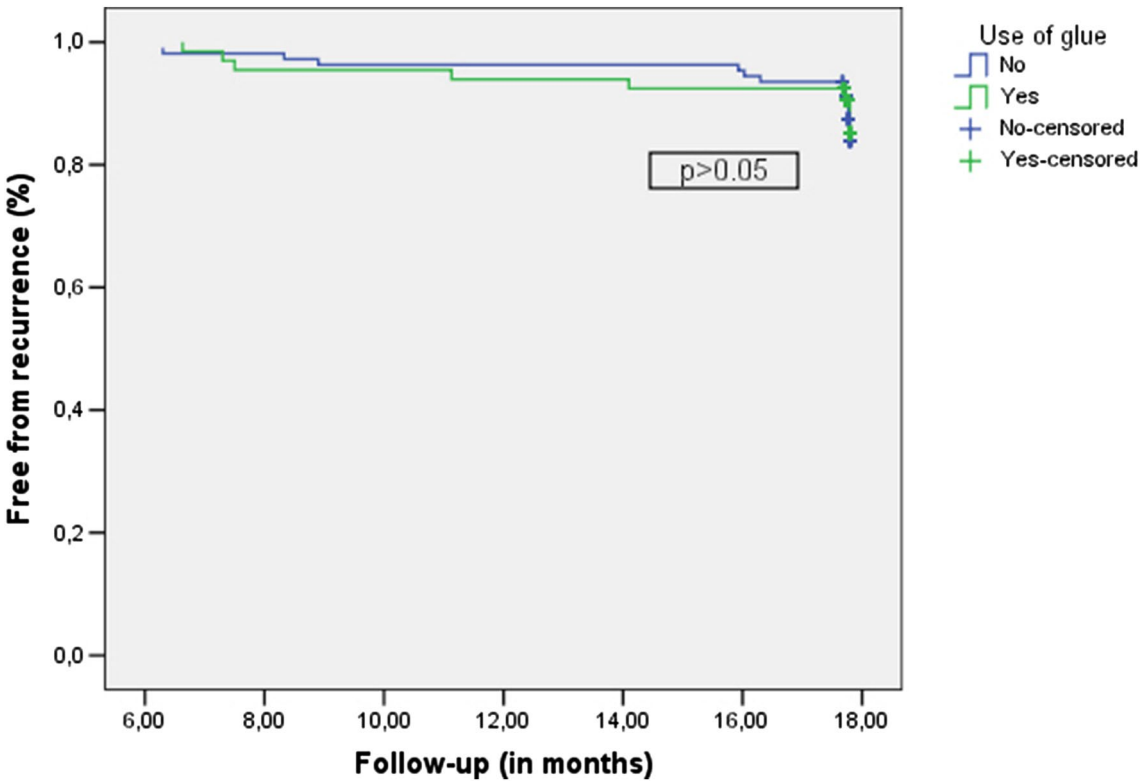

Fig. 1 Kaplan-Meïer probability for recurrence free survival according to the type of mesh fixation

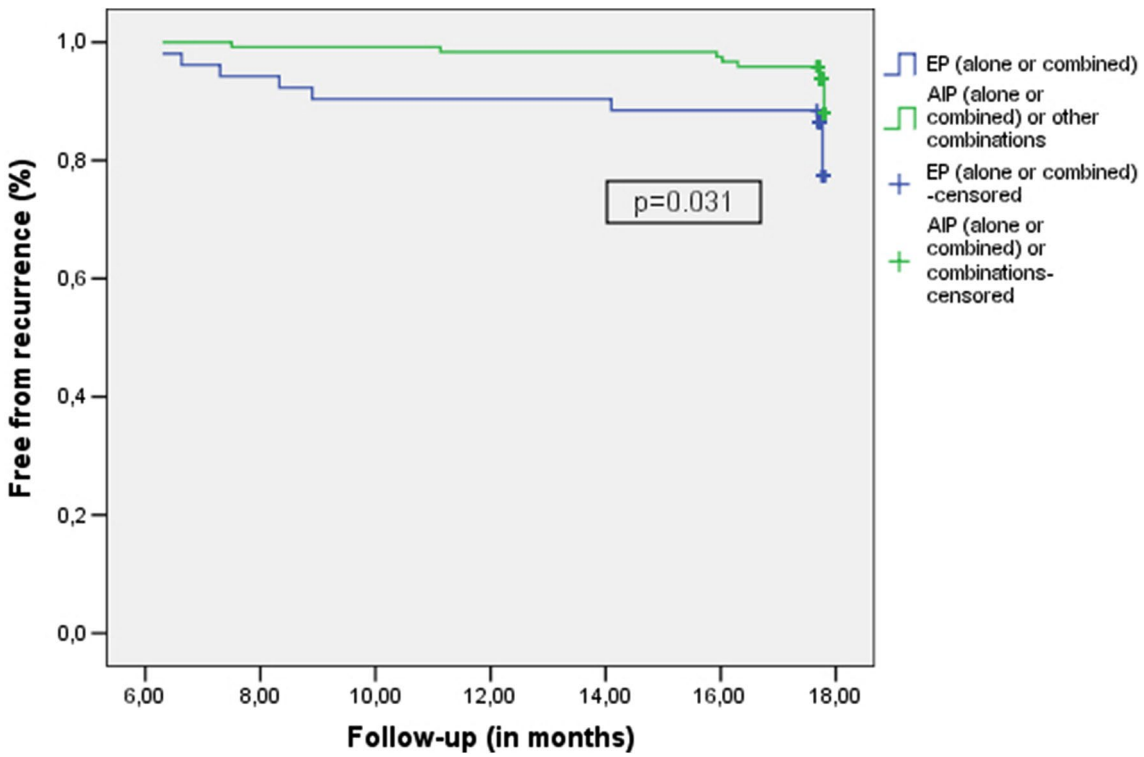

Fig. 2 Kaplan-Meïer probability for recurrence free survival according to the type of prolapse

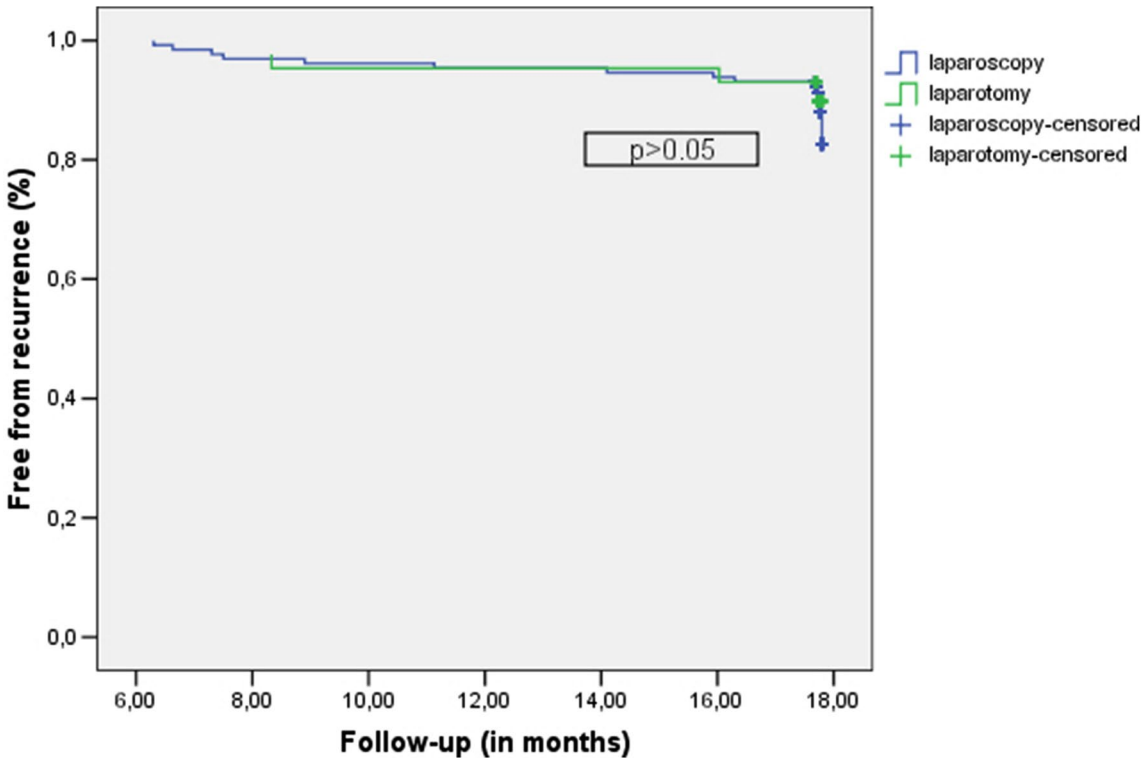

Fig. 3 Kaplan-Meïer probability for recurrence free survival according to the type of surgery

Table 3 Multivariate Cox regression model for recurrence after VMR

Variables	Non-adjusted HR (CI 95%)	*p* value	Adjusted HR (CI 95%)	*p* value
Without glue	1.04 (0.41–2.65)	>0.05	1.07 (0.40–2.84)	>0.05
EP(alone or combined)[a]	2,66 (1.05–6.70)	=0.038	0.37(0.14–0.93)	=0.03
Laparotomy	0.84 (0.28–2.53)	>0.05	1.69 (0.48–6.01)	>0.05

EP external prolapse

[a]EP+ enterocele or cystocele

had minor clinical complications of Clavien–Dindo type 1. The mesh had to be removed in one patient (0.53%) in the synthetic glue group because of mesh dislocation and recurrence, without vaginal or rectal exposure. Procedure length, need for tibial nerve transcutaneous electrical nerve stimulation were similar in both groups ($p > 0.05$, Table 4).

Discussion

Laparoscopic VMR has become the preferred treatment for rectal prolapse, especially in Europe, due to its superior outcome in terms of new-onset constipation postoperatively compared with previous abdominal techniques [10]. In VMR, the rectum has to be attached by a mesh that is sutured to the anterior wall of the rectum and the sacral promontory. This technique has the advantages of correcting supra-anal rectocele, reinforcing the rectovaginal septum, performing colpopexy, and avoiding damage to the autonomic nerves [9]. Symptomatic intra-anal prolapse has become a validated indication for VMR with fair functional outcomes which explain that most of cases in this series had internal prolapse [10].

Complications related to the mesh have been a matter of debate. Studies investigating mesh complications in laparoscopic VMR are scarce and have methodologic failures as they include different surgical techniques and different types of mesh in the same study. The reported mesh complication rates vary from 0 to 6.7%, and the reported mesh erosion rates ranges from 0 to 3.7% [17]. A multicenter collaboration study conducted to determine the morbidity of mesh complications in laparoscopic VMR showed only a 2% rate of mesh erosions, and lower rates were observed

Table 4 Clinical outcomes, postoperative morbidity, and complementary treatment after ventral mesh rectopexy

Variables	Total, $n=176$ (%)	VMR with synthetic glue group, $n=66$ (%)	VMR with suture group, $n=110$ (%)	OR non-adjusted (95% confidence interval)	p value[a]	OR adjusted (95% confidence interval)[b]	p value[c]
Postoperative morbidity							
Complications	14 (8.3)	5 (7.8)	9 (8.7)	0.90 (0.29–2.80)	0.848	–	–
Clinical outcomes[d]							
Clinical improvement	127 (72.2)	50 (75.8)	77 (70.0)	1.00			
No clinical improvement	32 (18.2)	12 (18.2)	20 (18.2)	0.92 (0.42–2.06)	0.846	–	–
Worsening symptoms	17 (9.7)	4 (6.1)	13 (11.8)	0.47 (0.15–1.54)	0.205		
Complementary treatment							
PTNS	32 (23.2)	16 (29.6)	16 (19.0)	1.79 (0.81–3.98)	0.151	1.47 (0.63–3.41)	0.372
Sacral neurostimulation	5 (3.5)	2 (3.4)	3 (3.5)	0.99 (0.16–6.11)	0.990	–	–
Procedure length > 90 minutes[e]	74 (42.5)	23 (34.8)	51 (47.2)	0.60 (0.32–1.12)	0.109	0.52 (0.27–1.02)	0.059

VMR ventral mesh rectopexy, *OR* odds ratio (with glue/with suture), *PTNS* tibial nerve transcutaneous electrical nerve stimulation

[a]Calculated by the Pearson's Chi-squared test

[b]Adjusted by type of surgical approach and diagnosis

[c]Calculated by the Wald test

[d]Based on postoperative global clinical improvement proportion compared with preoperative symptoms. The symptoms evaluated were constipation, presence of lumpy and hard stools, need for manual maneuvers to facilitate defecation, sensation of incomplete evacuation, fecal incontinence, fecal urgency, pelvic pain, and pelvic discomfort

[e]Median value

when a biologic mesh was used [17]. The laparoscopic approach seems to be safer than transvaginal pelvic organ prolapse surgery with mesh. There are other important risks factors associated with mesh complications that are related to the technical skill of the surgeon performing the mesh fixation to the rectum. The mesh size, method of fixation, and mesh positioning after fixation are related to the complications described above. In this study, complication rate was low, similar between the 2 groups, and mainly not related to the mesh. Only one patient had the mesh removed. Thus, glue fixation appears to be safe.

Recurrence rates after surgery increase over the time. Consten et al. reported a recurrence of 7% after 3 years, 10.7% after 5 years, and 14.3% after 10 years. These authors also found differences when comparing recurrences after VMR for external rectal prolapse and VMR for internal rectal prolapse [18]. In the present study, the association between diagnosis (external prolapse versus intra-anal prolapse) and recurrence was also significant, but with a 1-month difference which could not be clinically relevant. Mesh fixation with glue was not associated to increased recurrence risk after a follow-up of 18 months.

Surgical approach (laparotomy versus laparoscopy) could also be involved in the risk of recurrence. However, in the present cohort, this event was not significantly associated to recurrence after the proper treatment of the confounding factors. The surgical technique used was the same except for the use of synthetic glue.

The postoperative symptom improvement was similar in both groups, and the overall symptom improvement of 72.2% was similar to the literature [6, 9].

Mishra et al. demonstrated benefits of neuromodulation in symptom improvement and quality of life in patients with persistent fecal incontinence after rectopexy for internal rectal prolapse [19]. In this study, tibial nerve transcutaneous electrical nerve stimulation and sacral neurostimulation were used in patients with persistent fecal incontinence and constipation, but there was no significant difference between the two groups for the indication of these complementary treatments.

This study compared a new method of fixation of the anterior rectal wall with synthetic glue. Recurrence rates in published studies are questionable because of short follow-up, small samples, non-randomized studies, variations of surgical techniques, and other methodological flaws [6, 18]. The recurrence-free survivals observed in the present study were not significantly different between the synthetic glue group and the suture group. This study had methodological

limitations, mainly the lack of randomization, but surgical technique was reproducible and only differed by mesh fixation type. Confounding factors were included in a multivariate analysis that showed no influence of the fixation technique on recurrence rates.

Thus, fixation with synthetic glue could be a promising option. Synthetic surgical glue (cyanoacrylate composition) was initially used to fix the mesh in abdominal hernia operations. Koch et al. demonstrated the advantages of this adhesive fixation method in comparison to tack fixation; glue fixation significantly reduced the need for narcotic analgesia, hospital stay, and urinary retention in abdominal hernia surgery [20]. The glue is best suited to fatty tissues, and is less appropriate for bone surfaces [13], which makes it adequate to fix the rectal anterior wall. In terms of costs, the glue seems to be more attractive and less time-consuming, although this last advantage was not significant in our study. This can probably be explained by the learning curve (around 30 cases) of the procedure performed in most cases in this study by training surgeons under supervision [21]. Tacking or stapling devices are more expensive than glue, they can cause pain and perforation [14], and are not really adequate for closure of the peritoneum of the Douglas pouch. A recent study also demonstrated that the most common problems related to technical failures were insufficient ventral dissection, inefficient mesh fixation to the anterior wall, detachment of the mesh from the promontory, or inappropriate positioning of the staples to the promontory [17, 22]. In the present study, there was no significant difference between the synthetic glue group and the suture group concerning procedure length, complications, recurrence, symptoms after rectopexy, and indication for additional treatment (including bulking agents, laxatives, transcutaneous electrical nerve stimulation, sacral neurostimulation). At last, the glue technique is easy to perform, even for junior surgeons, compared to suturing technique in the narrow pelvis.

Conclusions

Mesh fixation using synthetic glue to perform VMR is safe, has low short-term complication rates, low recurrence rates, and similar clinical outcomes to suture fixation rectopexy. The good cost-benefit ratio associated with synthetic glue VMR could make this method the first option for mesh fixation in rectopexy.

Compliance with Ethical Standards

Disclosure Dr. Portier was consultant for Coloplast. Dr. Silveira Dr. Domingie, Dr. Kirzin, and Dr. Melo Filho have no conflicts interest or financial ties to disclose.

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