https://doi.org/10.33878/2073-7556-2024-23-3-59-68

Evagination method for rectovaginal fistulas

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ABSTRACT *AIM: to assess early and late results of the evagination method for the treatment of rectovaginal fistulas (RVF) in patients with anal incontinence due to muscle defect in the anterior semicircle.*
PATIENTS AND METHODS: the study included 45 patients. The prevailing etiology of RVF was delivery lesion in 19/45 (42.2%). The median follow-up was 6 (4; 8.5) months. On day 30 after surgery, the outcome was assessed clinically. Late outcomes were assessed in all patients 3–12 months including clinical control, transanal ultrasound and sphincterometry.
RESULTS: recurrence occurred in 9/45 (20%) patients. The significant improvement of continence was revealed: in mean pressure in rest ($p = 0.004$), in maximum contraction pressure ($p < 0.0001$), in Wexner incontinence score ($p < 0.0001$). With a fistula opening less than 16 mm, the recurrence risk increases ($p = 0.0003$).
CONCLUSIONS: the evagination method is effective option in extent septal defects and correcting additional anal sphincter insufficiency.

KEYWORDS: *rectovaginal fistula, evagination, evagination method, defect of rectovaginal septum, anal sphincter insufficiency*

CONFLICT OF INTEREST: *the authors declare no conflict of interest*

FOR CITATION: Serebriy A.B., Titov A.Yu., Kostarev I.V., Anosov I.S., Kiselev D.O., Ivanova A.S., Ignatenko M.A., Khryukin R.Yu., Mudrov A.A. Evagination method for rectovaginal fistulas. *Koloproktologia*. 2024;23(3):59–68. (in Russ.). https://doi.org/10.33878/2073-7556-2024-23-3-59-68

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Received — 06.05.2024 *Revised — 26.06.2024* *Accepted for publication — 01.08.2024*

INTRODUCTION

The possible etiology of rectovaginal fistulas (RVF) is extremely diverse (purulent-inflammatory diseases of the perineum, perianal manifestations of Crohn's disease, congenital fistulas, trauma, a radiation complications). However, the most common cause of RVF is complicated childbirth. Thus, rectovaginal fistulas develop in 0.05% of patients after episiotomy, in 1% — after ruptures III-IV grades [1]. In addition, the severity of the condition is associated not only with a lesion in the rectovaginal septum, but also with the presence of the anal incontinence (AI) due to its lesion along the anterior semicircle [2]. In the Russia grade III-IV injuries range from 0.15 to 1.78 per 1000 births [3].

Usually, bright clinical manifestations of RVF (the release of gases and/or intestinal contents through the vagina), patients do not focus the attention on the presence of AI. Only after successful elimination of the fistula, they may experience AI. At the same time, a complete clinical and instrumental examination of patients with RVF in the preoperative period, including pathophysiological methods and transrectal ultrasound (TRUS), allows us to identify signs of a lesion in the anal sphincter along the anterior semicircle and determine indications for surgical correction not only of RVF, but also of AI [4]. Despite more than 100 proposed operative methods for RVF, there are no correct methods for simultaneous elimination of lesions in the rectovaginal septum and anal sphincter. First of all, this is due to the

difficulty of adequate disposition of suture lines in the low rectum and on the anal sphincter during simultaneous surgery aimed at both eliminating RVF and correcting AI and, accordingly, the risk of surgical site infection.

All this was the reason for the development of an evagination method for RVF [5]. This method is aimed not only at the elimination of extended lesions of the rectovaginal septum, but also at the simultaneous correction of the anal sphincter incontinence.

PATIENTS AND METHODS

Hypothesis: the use of the evagination method will simultaneously eliminate extended lesions of the rectovaginal septum and improve the occlusive function of the anal sphincter in patients with RVF and AI caused by a muscle lesion of anal canal anterior semicircle.

Primary points of the study:

- the rate of RVF healing;
- the degree of AI according to sphincterometry after surgery.

Secondary points:

- the rate and structure of postoperative morbidity;
- the length of hospital-stay.

Inclusion criteria:

- women aged ⩾ 18 years;
- confirmed lesion of the rectovaginal septum according to the TRUS data;
- confirmed AI according to sphincterometry.

Non-inclusion criteria:

- a severe inflammation in the rectovaginal septum;
- post-radiation fistula;
- inflammatory bowel diseases (IBD) in the acute stage;
- decompensation of comorbiditiers;
- pregnancy and lactation.

Exclusion criteria:

- violation of the study protocol;
- the patient's refusal to participate further.

Study Design

From July 2019 to February 2024, the evagination method was used in 45 women with lesions of the rectovaginal septum of various lengths and concomitant AI caused by a lesion of the anal sphincter along the anterior semicircle (Fig. 1).

The follow-up period for patients after surgery was 3–12 months, Me = 6 (4; 8.5).The group was dominated by young females (Me = 35). It should also be noted that in 55.6% fistulas were recurrent (Table 1).

Taking into account the significant number of recurrent RVF (55.6%), we assessed in detail the number and volume of previous operations in all 25 patients (Tables 2,3).

Among the patients included in the study, the most common cause of RVF was lesions sustained during childbirth — 19 (42.2%) women, 10 (22.2%) patients noted peculiar symptoms after acute inflammatory diseases (Table 4).

35 patients included in the study had a history of childbirth: one delivery in 22 (63%) women; two — in 12 (34%) women; three — in 1 (3%) patient. In 13/35 (37%) cases, childbirth was uncomplicated, and in 22/35 (63%), some kind of trauma to the perineum and birth canal was present (Table 5).

The diagnosis of rectovaginal fistula in all patients was established clinically, verified by transrectal ultrasound. The study also made it possible to assess the presence of congestion along the fistula, the presence and extent of a lesion in the muscular structures of the anal sphincter (Table 6).

The functional status of the anal sphincter was assessed using sphincterometry, which makes it possible to determine a decrease in the mean

Figure 1. *The study design*

Table 1. *The clinical characteristics of RVF patients*

Parameter	Value
Age (years), Me (Q1; Q3), (min-max)	35 (30; 44), (20–66)
BMI (kg/m²), Me (Q1; Q3), (min-max)	22.6 (21.2; 27.9), (18.59–34.96)
Time of the disease (years), Me (Q1; Q3), (min-max)	1 (1; 3), (0.5–29)
Stoma, *n* (%)	9 (20)
Recurrent fistula, *n* (%)	25 (55.6)

Table 2. *Distribution of patients by the number of operations*

The number of previous surgeries	The number of female patients, %
1, *n* (%)	11 (44)
2, *n* (%)	6 (24)
3, *n* (%)	5 (20)
4, *n* (%)	3 (12)
Total, *n* (%)	25 (100)

Table 3. *Characteristics of previous operations for RVF*

Previous surgeries	Number, *n* (%)
Elimination of RVF with a split vaginal-rectal flap	14 (27)
Segmental proctoplasty	12 (23)
Excision of the fistula, ligature	11 (21)
Separate suturing of rectal and vaginal lesions	11 (21)
Flap surgery using a biological implant	3 (6)
The Martiusp rocedure	1 (2)
Total previous operations	52 (100)

*Note: *One patient could undergo 1 or more different operations, based on the total number of operations performed*

Table 4. *Etiology of rectovaginal fistulas*

Etiology		Number *n* (%)
Delivery		19 (42.2)
Acute inflammatory diseases	Perianal abscess	8 (17.8)
	Bartholinitis	2 (4.4)
Postoperative	Extrasphincter fistulectomy	3 (6.7)
	Coloprotectomy with ileal pouch	1 (2.2)
	Low anterior resection	1 (2.2)
	TEM*	1 (2.2)
IBD	Ulcerative colitis	1 (2.2)
	Crohn's disease	3 (6.7)
Other factors	Post-traumatic	4 (8.9)
	Congenital	2 (4.4)
Total		45 (100)

*Note: *TEM — transanal endomicrosurgical tumor removal*

Table 5. *Nature of perineal and birth canal trauma in RVF patients*

Peculiarities of childbirth	*n* (%)
Ruptures of 1st degree	1 (4.6)
Ruptures of 2nd degree	6 (27.3)
Ruptures of 3rd degree	8 (36.4)
Ruptures of 4th degree	1 (4.6)
Episiotomy	1 (4.6)
Episiotomy + ruptures	5 (22.7)
Total	22 (100)

Table 6. *Ultrasound in RVF patients*

Parameter	Value
Diameter of the fistula opening (mm), Me (Q1; Q3), (min-max)	20 (15; 25), (7–40)
The extent of the lesion of the anal sphincter along the anterior semicircle (hours), Me (Q1; Q3), (min-max)	2 (2;4), (1–8)
The presence of additional fistula tracks, n (%)	5 (12.2)

Table 7. *Distribution of patients by degrees of AI(according to sphincterometry)*

Parameter	Value
1 Degree, n (%)	22 (48.9)
2 Degree, n (%)	20 (44.4)
3 Degree, n (%)	3 (6.7)
Incontinence assessment as per Wexner's scale (n = 36), Me (Q1; Q3), (min-max)	11.5 (7; 14), (0–20)

pressure in rest and maximum pressure in the anal canal with volitional contraction, and to grade the degree of incontinence according to existing criteria [6]. In patients without intestinal stoma, a subjective assessment of the severity of AI phenomena was also performed on the Wexner scale (Cleveland Anal Incontinence Assessment Scale) (Table 7).

The Surgical Technique

Operation is performed under spinal anesthesia in a supine position with legs as close to the abdomen as possible. A revision of the operative area is carried out (Fig. 2). After injection the saline solution with the addition of adrenaline into rectovaginal septum, the location of the ends of the anal sphincter, muscle structures of levators with (Fig. 3), transvaginal incision around the lesion of the rectovaginal septum, circular dissection of the posterior vaginal wall and allocation of the fistula to the wall of the rectum are performed. It should be noted that the distance from the edge of the lesion to the incision of the vaginal wall is determined individually and is, on average, 3 mm (Fig. 4). For the complete removal of the fistula (evaginate) beyond the anal canal, an important stage of the procedure is the splitting of the rectovaginal septum in all directions from the edges of the lesion to a distance of up to 5 cm (Fig. 5). After adequate mobilization of the rectal wall on the anterior semicircle, the anterior portions of the levatorsand the ends of the external anal sphincter (distal in the direction almost to the perianal skin) (Fig. 6).

Next, filaments are applied to the edges of the lesion from the vaginal side (Fig. 7), which are

brought out through the fistula, the lumen of the rectum and through the anus, and then evagination ('inversion') of the fistula passage and the segment of the intestinal wall bearing the lesion beyond the anal canal (Fig. 8). Sphincterolevatoroplasty is performed with single sutures with mandatory capture of unaffected, proximal to the lesion, sections of the rectal wall into the line of sutures (Fig. 9). Sphincterolevatoplasty is extremely important not only for correcting the AI

Figure 2. *The rectovaginal septum defect*

Figure 3. *The rectovaginal septum hydropreparation*

Figure 4. *A circular incision of the vagina round the fistula*

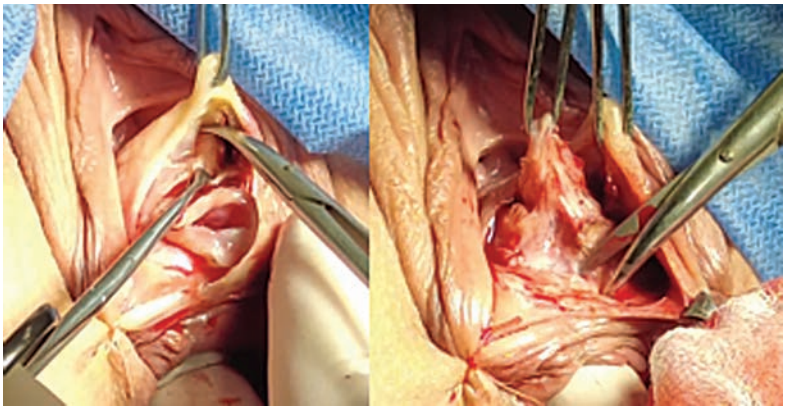

Figure 5. *Cleavage of the rectovaginal septum in the proximal and distal directions*

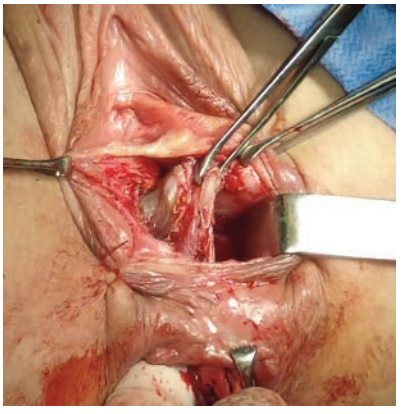

Figure 6. *Separated right levator*

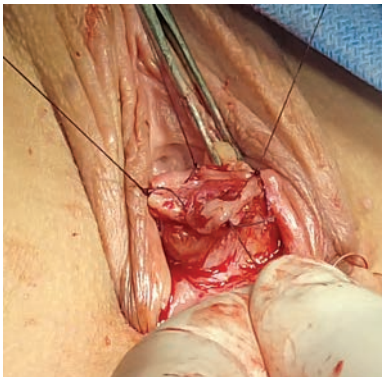

Figure 7. *The imposition of filaments-holders from the side of the vagina*

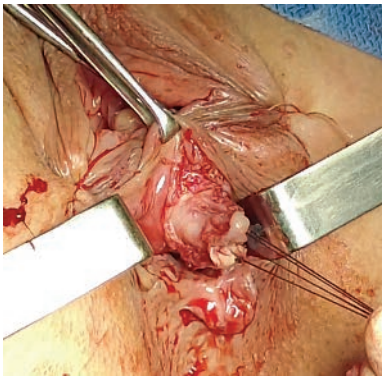

Figure 8. *Evagination of the fistula through the anus of a rectal segment containing a rectovaginal septal defect*

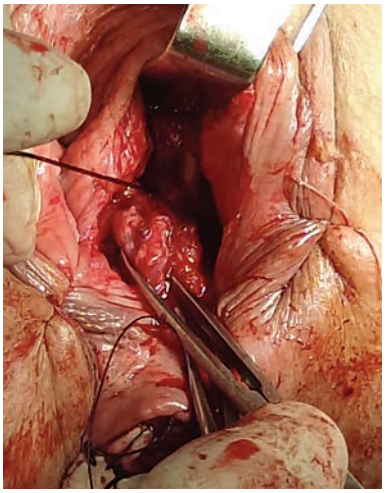

Figure 9. *Sphincterolevatoplasty*

Figure 10. *Evaginate removed outside the intestinal lumen*

Figure 11. *Suturing a vaginal wound*

and eliminating its lesion, but also allows you to additionally fix the evaginate outside the anal canal. In turn, the evaginate is not cut off (Fig. 10), and the wound in the vagina is sutured with single sutures (Fig. 11).

In the early postoperative period, the condition of the wound from the vaginal side is assessed, as well as the presence and condition of evaginate in the perianal region. The first digital examination of the rectum was performed on all patients during a control on the 30th day after surgery and allowed them to suspect the presence of a recurrence of the disease already at this time. For the final assessment of the treatment result in 3–12 months after the surgery, in addition to the clinical study, the patients underwent control ultrasound and sphincterometry. We considered a recurrence to be the return of complaints about the discharge of intestinal contents through the vagina after surgery and/or the presence of a message according to the control TRUS.

Statistical analysis

Patient data was entered into a Microsoft Excel 2019 for Windows spreadsheet. Statistical data analysis was performed in the Statistica 13.3 program (TIBCO Software Inc., USA). Quantitative data are represented by the median (Me) and quartiles (Q1; Q3), (min-max). When comparing sphincterometry parameters before and after surgery, the Wilcoxon criterion was applied for related samples. The significance level of the differences is at $p < 0.05$. To identify risk factors for recurrence, a univariate analysis of clinical and anamnestic parameters was performed using the logistic regression method, the results obtained are presented by the odds ratio (OR) and the coincidence interval (95% CI). The ROC analysis was performed in the GraphPad Prism program.

RESULTS

The surgery duration ranged from 25 to 106 minutes (Me = 60 (50;85). In 2/45 (4.4%) cases, the overlying wall of the rectum was injured intraoperatively during the mobilization of the fistula, which was associated with a pronounced fibrous cicatricial process in the rectovaginal septum due to previous surgeries. In 14 (31.1%) women, a hematoma of the perianal region was detected on day 3–4. However, in no case did this complication require any surgical manipulations (Table 8). The median number of days spent by patients in the hospital was 14 (10; 17).

According to the clinical and instrumental examination, recurrence of the disease was diagnosed in 9/45 (20.0%) patients. It should be noted that in all patients, regardless of the presence or absence of a recurrence of the disease, during the control, we noted statistically significant improvements in retention function (Table 9).

Table 8. *Complications*

Complication	Number of female patients, *n* (%)
Perforation of the overlying wall of the rectum	2 (4.4)
Hematoma of the perianal area	14 (31.1)
Total	16 (35.5)

Table 9. *Functional outcomes*

Indicator, unit of measurement	Before surgery	After surgery	*p*
Pressure in rest (mm Hg), Me (Q1; Q3), (min–max)	36 (32; 38), (26–51)	38 (36; 39), (28–69)	0.004
Maximum contraction pressure (mm Hg), Me (Q1; Q3), (min–max)	104 (82; 132), (51–226)	114 (99; 146), (70–227)	< 0.0001
Incontinence scale by Wexner (points), Me (Q1; Q3), (min–max)	11.5 (7; 14), (0–20)	3.5 (1; 8), (0–13)	< 0.0001

Table 10. *Risk factors*

Factor	OR	*p*
Age (years)	1.03 (0.96; 1.11)	0.35
BMI (kg/m²)	1.17 (0.99; 1.37)	0.053
Disease time (years)	1.02 (0.93;1.12)	0.73
Number of deliveries	2.38 (0.83; 6.81)	0.1
Number of previous operations	1.29 (0.77; 2.17)	0.33
Diameter of the fistula opening (mm)	0.46 (0.26; 0.82)	0.008
Length of the fistula passage (mm)	0.95 (0.84; 1.08)	0.46
Comorbidities	0.72 (0.12; 4.38)	0.73
Stoma	1.38 (0.23; 8.36)	0.73
Presence of additional tracks	5.33 (0.86; 32.9)	0.07

In order to find factors affecting the risk of developing a recurrence of the disease, clinical and anamnestic parameters were analyzed. At first glance, such significant factors as: the presence of an intestinal stoma; age; the number of previous operations; the length of the fistula; the presence of purulent congestion did not affect the recurrence rate of RVF. When assessing BMI values, there was only a slight trend to have an association with the disease recurrence rate (p = 0.053) (Table 10).

The only factor we identified that increased the risk of RVF recurrence was the diameter of the fistula opening. Moreover, paradoxical is the fact that the risk of recurrence increased with a smaller in the size of the fistula opening in the intestinal wall. When constructing the ROC curve, it was revealed that with a diameter of the fistula opening less than 16 mm, the probability of recurrence increases (OR = 85.3 (95% CI 7.8; 933.2), p = 0.0003), (Fig. 12).

Of the 9 patients with recurrent RVF after the use of the evagination method, seven were re-operated in the following 3–7 months. Two patients, due to the absence of pronounced clinical picture, refused to undergo re-operation. Three more patients managed to eliminate the external fistula opening in the vagina and transfer the fistula to an anterior incomplete extrasphincteric, in connection with which they underwent surgery of eliminating the internal fistula opening with a lateral rectal flap. Four patients were re-examined and operated on by the method of elimination of RVF with a split vaginal-rectal flap (SVRF). After SVRF, a recurrence developed in one patient, in order to eliminate which, she underwent repeated surgery using a lateral split rectal flap. At the moment, there is no data for recurrence (Fig. 13).

DISCUSSION

Recently, due to changes in the tactics and strategy of treatment of RVF, the introduction of new

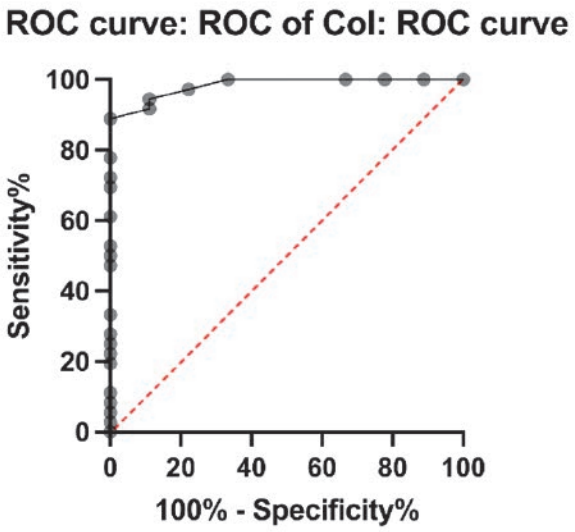

Figure 12. *ROC is the curve of RVF recurrence versus fistula diameter. AUC = 0.983 ± 0.015 (95% CI: 0.953–1.0), p < 0.01, cut-off point corresponds to 16 mm. TPR = 100% (95% CI 66.3–100%). FPR = 88.9% (95% CI 73.9–96.9%). PPV (positive predictive value) = 69.2% (95% CI: 38.6–90.9%). NPV (negative predictive value) = 100% (95% CI: 89.1–10%)*

surgical methods, it has been possible to eliminate the pathological junction between the rectum and the vagina in more than 90% of patients. However, the issue of the treatment of patients with extensive lesions of the rectovaginal septum remains relevant, since with a diameter of the fistula opening of more than 16–20 mm, the method of choice is the method of separate suturing of the rectum wall and vagina. No less significant and relevant, given the characteristics of patients with RVF, is the problem of the presence of AIin this category of patients with a 'vivid' manifestation of its clinical symptoms in the case of successful elimination of the fistula. The evagination method allows us to try to solve both problems in one step. Moreover, the entire segment of the rectal wall with its lesion is removed from the intestinal lumen, which allows not only to eliminate RVF, but also to minimize the risk of infection of the muscle plasty zone, which is extremely high in the case of other methods due to the presence of a suture line in

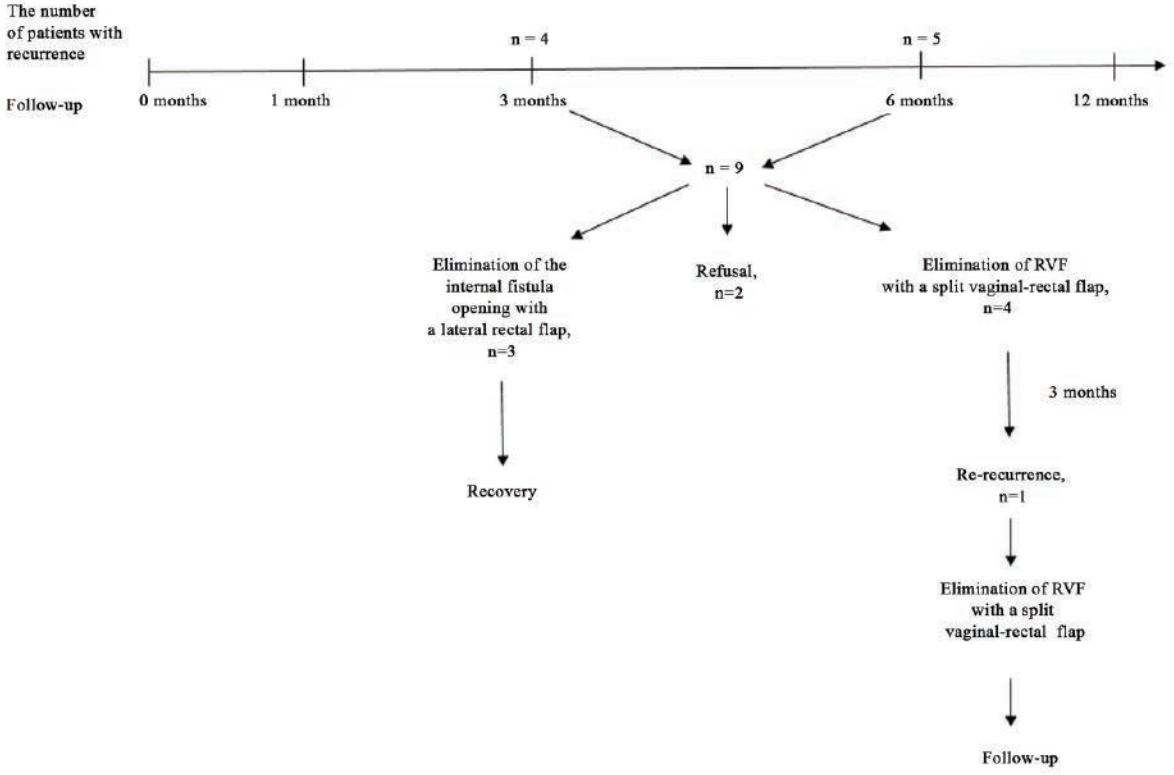

Figure 13. *Approach to RVF recurrence after the use of the evagination method*

the lower ampullary part of the rectum. It should also be noted that performing sphincterolevatoroplasty when using this method is an obligatory stage of the operation, aimed not only at eliminating the lesion of muscle structures, but mainly at additional fixation of the proximal sections of the rectal wall, which prevents the retraction of evaginate.

The paradoxical effect of the size of the rectal wall lesion on the results of the evagination method can only be explained by the fact that with a smaller diameter of the fistula opening, patients have more preserved structures of the perineum, including the anal sphincter, which may make it difficult to mobilize the rectal wall in the distal direction.

CONCLUSION

The invagination method has shown its high efficiency (80%) in eliminating extended lesions (more than 16 mm) of the rectovaginal septum. Also, this method allows you to simultaneously perform a plastic step aimed at correcting the anal sphincter incontinence.

Taking into account previous studies, the most significant parameters for choosing a surgical method for correcting lesions of the rectovaginal septum are such parameters as the diameter of the fistula and its localization in relation to the surgical anal canal. Thus, the evagination method can justifiably occupy its 'niche' in the tactical 'line' of methods: up to 5 mm, the use of a split vaginal-rectal flap is effective [7]; from 5 to 16 mm, the invagination method [8]; and with a diameter of more than 16 mm, it is advisable to use the evagination method.

AUTHORS CONTRIBUTION

Concept and design of the study: *Andrei A. Mudrov, Alena B. Serebriy*

Collection and processing of the material: *Andrei A. Mudrov, Ivan S. Anosov, Alena B. Serebriy, Dmitry O. Kiselev*

Statistical processing: *Roman Yu. Khryukin, Mariya A. Ignatenko, Anastasiya S. Ivanova*

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