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# A randomized multicenter trial to compare functional outcome and complications of surgical procedures for low rectal cancers

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**Background.** The outcomes after different low rectal resection types applied for rectal cancer treatment are still uncertain. The aim of the investigation was to evaluate long-term functional results, the rate of complications and post-operative lethality after rectum low resection operations (connection with J-pouch group: coloplasty – group 2 and "straight" anastomosis – group 3).

**Patients and methods.** In 2003, a randomized study was started and completed on December 2007. The study included 82 patients (38 females and 44 males). The patients were randomized into three groups. They were suffering from cancer stage I–III.

**Results.** There were no postoperative deaths after 82 resections with total mesorectal excision (TME) and low connection. The overall rate of postoperative complications was 28%, and the rate of anastomosis suture leakage was 11%. The rate of post-operative complications was 20.7% (6 patients) in group 1, 28.6% (6 patients) in group 2, 34.3% (11 patients) in group 3. The rate of complications was substantially higher in groups 2 and 3; however, this difference was statistically not significant (p = 0.2636). The functional results after 3, 6, 9, 12 and 24 months showed no statistical difference among the groups; moreover functional results after 24 months in all groups were similar (p = 0.046). Anastomosis with or without pouch does not influence postoperative lethality. The incidence of complications and suture leakage is higher in cases of straight anastomosis; however, this finding is not statistically significant. Necrosis was observed only in patients for whom anastomosis with pouches was performed.

**Conclusion.** Comparison of functional results after 3, 6, 9, 12 and 24 months showed no statistically significant differences among the groups.The necrosis of pulled-down bowel was observed only in the pouch groups.

**Key words:** rectal cancer, anastomosis, J-pouch, coloplasty, functional results

## INTRODUCTION

The progress of surgical techniques has resulted in the decrease of both postoperative lethality and the incidence of complications after rectum resections with low anastomosis; therefore, more attention is being paid to functional results. In order to improve postoperative function, various pouches are being used. J-pouch and coloplasty for these purposes are performed most often. Results of surgical treatment of rectal cancer (RC) had dramatically improved with the implementation of stapling technique and the total excision of mesorectum (TME). However, the problem of complications and a high incidence of post-operative lethality when low connections after rectal resections are formed still remain a challenge.

The objective of our study was to evaluate whether pouch formation has an influence on the rate of com-

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plications and function after low anastomosis with or without pouch. A permission of the Lithuanian Bioethics Committee was obtained for this study. There were neither private conflict of interests nor interests of companies manufacturing medical equipment.

## PATIENTS AND METHODS

In 2003, a randomized prospective study was started in order to analyze the rate of complications, postoperative lethality and functional results after rectum resections with TME and low anastomosis. The study was completed on December 2007.

Patients were randomized into three groups: for patients of group 1, anastomosis with J-pouch were performed; patients of group 2 underwent anastomosis by means of coloplasty, and patients of group 3 underwent "straight" anastomosis. Written informed consent of all patients was obtained. The study included 82 patients (38 females and 44 males). Their age ranged from 30 to 70 years (mean, 62.8 years). The patients were suffering from cancer stage I–III according to UICC classification (6th edition). Carcinosis was diagnosed for one patient during the operation, and this patient was excluded from the study. Inclusion and exclusion criteria are listed in Table 1.

## RANDOMIZATION

The patients (n = 81) were blindly randomized into three groups: groups 1, 2 and 3 included 29, 21 and 31 patients, respectively.

Operative treatment: all the patients underwent resection of the rectum with TME and anastomosis formation using a CEE-31mechanical suture device; J-pouch and transversal coloplasty were performed using manual suture.

All patients suffering from T3 tumors underwent preoperative radiotherapy using large 5 × 5 Gy fractions.

The postoperative lethality rate was evaluated up to 30 days after the operation; the overall rate of postoperative complications and the rate of these complications in each group were evaluated.

Functional results were assessed using a questionnaire for the evaluation of anal function, modified by Nowacki (Table 2) (1); its assessment scores are listed in Table 3.

A decrease of patient sample in each group was observed during the follow-up of functional results, because 1 and 2 patients had developed necrosis of the pouch in group 1 and 2, respectively, and it was necessary to remove the pulled-down bowel and perform terminal colostomas in these patients. Furthermore, 1, 3 and 2 patients were lost for follow-up in groups 1, 2 and 3, respectively;

Table 1. **Inclusion and exclusion criteria**

| Inclusion criteria: | Exclusion criteria: |
|---|---|
| Rectal cancer, confirmed histologically | Local recurrence |
| Distance from anal ring ≤10 cm | Remote metastases |
| ECOG ≤2 | Urgent operation |
| Open operation follow | Potentially problematic postoperative follow-up of the patient |
| Age ≥ 18 ≤70 years | Prior surgery of minor pelvis or operations on any side of colon |
| Signed patient's informed consent | Tumours allowing trans-anal removal |
| | Distance from tumour to anal ring ≥10 cm |

Table 2. **Postoperative evaluation of rectal function**

| | Never | Sometimes | Often | Very often |
|---|---|---|---|---|
| Did the problems with defecation and releasing flatus cause restrictions in your work or other daily activities? | | | | |
| Did you have to use medications to reduce the number of stools? | | | | |
| Was there a need for enemas? | | | | |
| Did you have incontinence of flatus? | | | | |
| Did you have incontinence of liquid stool? | | | | |
| Did you notice soiling? | | | | |
| Were you forced to wear a pad? | | | | |
| Did you have incontinence of solid stool? | | | | |
| Did you have a feeling of uncompleted defecation? | | | | |
| Were you forced to return to the toilet within one hour after defecation? | | | | |
| Were you unable to defer the defecation >10 min? | | | | |
| Did you refrain from leaving home because of toilet dependency? | | | | |
| Did you have problems in discriminating between flatus and stool? | | | | |
| Assessment score scale (points): | 1 | 2 | 3 | 4 |

Table 3. **Assessment scores**

| Function | Points |
|---|---|
| Excellent | <13 |
| Good | 17–26 |
| Satisfactory | 27–39 |
| Poor | 40–52 |

Functional results were evaluated after 3, 6, 9, 12, 18 and 24 months.

therefore, functional results were assessed in 27 patients of group 1, 16 patients of group 2 and 29 patients of group 3. The follow-up duration was 9–24 months. The results of 12-month follow-up were evaluated in 25, 15 and 24 patients of groups 1, 2 and 3, respectively.

The results of 24-month follow-up were evaluated in 24, 15 and 16 patients of groups 1, 2 and 3, respectively.

Statistical processing was performed using SPSS 17.0 software, and survival was assessed using the Kaplan–Meyer method.

## RESULTS

There were no postoperative deaths after 82 resections with TME and low connection. The overall rate of postoperative complications and the rate of anastomosis suture leakage were 28 and 11%, respectively.

The rates of postoperative complications observed in group 1 (J-pouch), group 2 (coloplasty) and group 3 (“straight”) were 20.7% (6 patients), 28.6% (6 patients) and 34.4% (11 patients), respectively. The rate of postoperative complications was slightly higher in groups 2 and 3; however, this difference was not statistically significant (p = 0.263 6). The postoperative complications are presented in Table 4.

The rates of anastomosis leakage are compared in Table 5; it should be noted that there were three cases of pouch necrosis (in 1 patient after J-pouch and in 2 patients after coloplasty). In all cases, suture leakage was treated conservatively, preserving the anastomosis.

Assessment of functional results showed that the anal function after 3 and 6 months in the majority of patients was good or satisfactory, and only in 2 patients (in groups 1 and 2) the function was poor; however, there were no patients with a bad anal function after 9 months.

Functional results are presented in Tables 6–10.

Evaluation of functional changes showed that the function in all groups was similar. Our study demonstrated that pouch formation did not improve the anal function. The rate of complications and the incidence of suture leakage were slightly higher in the “straight” group; however, these differences were not statistically reliable.

After one year, no cases of local recurrence were diagnosed; after 2 years, recurrence was diagnosed in three patients (recurrence rate 3.7%), and after 3 years of the follow-up one more case of recurrence was diagnosed (recurrence rate 4.9%). Three cases of local relapse recurrence were diagnosed in the “straight” group and one in the J-pouch group.

The survival was followed up for 19–74 months after operation. The mean overall survival duration was 41.9 months (47.3, 44.0 and 35.4 months in J-pouch, coloplasty

Table 4. **Postoperative complications observed in three surgery groups**

| Anastomosis complications | J-pouch | Coloplasty | “Straight” |
|---|---|---|---|
| Total necrosis of the pouch | 1 | 2 | – |
| Anastomosis leakage | 2 | 2 | 5 |
| Urinary retention | 1 | – | – |
| Wound suppuration | 1 | – | 3 |
| Thrombophlebitis | 1 | – | – |
| Pelvic abscess | – | 1 | – |
| Presacral haematoma | – | – | 1 |
| Small bowel obstruction without re-operation | – | 1 | – |
| Pancytopenia | – | – | 1 |
| Dermatitis | – | – | 1 |
| Total | 6 | 6 | 11 |

Table 5. **Comparison of suture leakage rate in three surgery groups**

| Type of anastomosis | Cases | Rate, % | Rate ratio vs. total (95% CI) | p |
|---|---|---|---|---|
| J-pouch | 2 of 29 | 6.9 | 0.63 (0.07–3.04) | 0.2979 |
| Coloplasty | 2 of 21 | 9.5 | 0.87 (0.09–4.19) | 0.4576 |
| “Straight” anastomosis | 5 of 32 | 15.6 | 1.42 (0.37–4.73) | 0.2633 |
| Complications, total | 9 of 81 | 11 | 1.0 | – |

Table 6. **Anal function after 3 months in three surgery groups**

| Function | J-pouch (n = 27) | Coloplasty (n = 16) | "Straight" (n = 29) | p |
|---|---|---|---|---|
| Excellent | – | – | – | |
| Good | 19 (70.4%) | 11 (68.7%) | 17 (58.6%) | 0.487 |
| Satisfactory | 7 (25.9%) | 4 (25%) | 12 (41.4%) | |
| Poor | 1 (3.7%) | 1 (6.3%) | – | |

Table 7. **Anal function after 6 months in three surgery groups**

| Function | J-pouch (n = 26) | Coloplasty (n = 16) | "Straight" (n = 29) | p |
|---|---|---|---|---|
| Excellent | – | – | – | |
| Good | 20 (76.9%) | 13 (81.25%) | 22 (75.9%) | |
| Satisfactory | 6 (23.1%) | 2 (12.5%) | 7 (24.1%) | 0.6 |
| Poor | – | 1 (6.25%) | – | |

Table 8. **Anal function after 9 months in three surgery groups**

| Function | J-pouch (n = 25) | Coloplasty (n = 15) | "Straight" (n = 29) | p |
|---|---|---|---|---|
| Excellent | – | – | – | |
| Good | 21 (84%) | 13 (86.7%) | | 22 |
| Satisfactory | 4 (16%) | 2 (13.3%) | 7 (24.1%) | 0.6 |
| Poor | – | – | – | |

Table 9. **Anal function after 12 months in three surgery groups**

| Function | J-pouch (n = 25) | Coloplasty (n = 15) | "Straight" (n = 24) | p |
|---|---|---|---|---|
| Excellent | – | – | – | 0.046 |
| Good | 21 (84%) | 13 (86.7%) | | 21 |
| Satisfactory | 4 (16%) | 2 (13.3%) | 3 (12.5%) | |
| Poor | – | – | – | |

Table 10. **Anal function after 24 months in three surgery groups**

| Function | J-pouch (n = 25) | Coloplasty (n = 16) | "Straight" (n = 16) | p |
|---|---|---|---|---|
| Excellent | – | – | – | |
| Good | 21 (87.5%) | 14 (93.3%) | | |
| | 14 (87.5%) | | | 0.083 |
| Satisfactory | 3 (12.5%) | 1 (6.7%) | 2 (12.5%) | 2 (12.5%) |
| Poor | 1 (3.7%) | 1 (6.3%) | – | |

and "straight" anastomosis groups, respectively). The differences between the groups were statistically not reliable (p = 0.0069). The three-year survival of patients who had participated in the study was 79%.

## DISCUSSION

The improvement of surgical techniques and introduction of mechanical suture devices resulted in a decrease of postoperative complications and lethality after rectum resections. Therefore, low rectal anastomoses are being performed more often, and the problem of anal function becomes increasingly important. Bowel pouches (most often J-pouch or transversal coloplasty) are being performed in order to improve the function. Usually, two methods are compared to evaluate the rates of complications and functional results, i. e. J-pouch vs. "straight" anastomosis, coloplasty vs. "straight" anastomosis, coloplasty vs. J-pouch (2–5). We have compared all these three groups in our study.

On the basis of analysis of reviews presented in bibliographic databases (Medline, Cancerlit, Embase, Cochrane Databases) we have concluded that J-pouch is functionally

superior to "straight" anastomosis for the first 18 months after operations restoring the continuity of the intestine. Similar results were obtained when comparing coloplasty and J-pouch (6).

Data of meta-analysis of randomized trials (J-pouch vs. "straight" anastomosis) made many authors to conclude that the function after "straight" anastomosis became worse because of more requent defecation, a higher rate of fecal incontinence and of strictures. On the other hand, it is difficult to evaluate the long-term benefits of J-pouch as the number of large randomized studies is insufficient (7). Upon comparing coloplasty and J-pouch function vs. "straight" anastomosis function, it was concluded that formation of a pouch resulted in a less frequent nocturnal defecation, and also in the day-time patients defecated less frequently (8). Fazio et al. compared functional results and the profile of complications after J-pouch, coloplasty and "straight" anastomosis; they concluded that only J-pouch had functional benefits (2).

Lazorthes et al. (9) analyzed 40 cases (20 anastomoses with J-pouch vs. 20 "straight" anastomoses) and found no differences regarding the incidence of post-operative complications. Ommer et al. (10) formed J-pouch–anal anastomosis for 110 patients and preventive stomas were formed for 48.3% of patients. The frequency of suture leakage reached 6.9%; for three patients, laparotomy was performed due to this complication. The overall frequency of anastomosis complications reached 16.4% (those were J-pouch–vaginal fistula and ischiorectal abscess; for six patients, suture leakage was diagnosed after radiological examination without clinical symptoms).

Hallbook et al. (11) compared complication rates between anastomosis with J-pouch and "straight" anastomosis. In total, 100 patients were randomized; symptomatic suture leakage was less frequent in anastomosis with J-pouch (2% vs. 15%, p = 0.03).

Several authors have compared the incidence of complications and functional results between coloplasty and J-pouch anastomoses; e. g., Pimentel (12) states that the frequency of local complications in the event of these two anastomoses was similar and reached 20%; more cases of anastomotic suture leakage were observed when anastomosis with coloplasty was performed (13.2% vs. 6.6%), but the difference was statistically insignificant.

According to data of Cavaliere et al. (13), the frequency of post-operative complications after low rectal anastomosis with J-pouch or "straight" anastomosis is as high as 62%. Among them, suture leakage rate was 18%.

Jespersen et al. (14) have analyzed the incidence of complications after J-anastomosis formation. Thirty-two cases were studied. For two patients (6%), a clinic of suture leakage emerged and for two recto-vaginal fistulas developed.

Ulrich et al. (15) from Heidelberg University have analyzed the frequency of early postoperative complications after coloanal anastomosis with coloplasty formation. The authors state that the main problem of J-pouch is evacuation difficulties. An operation of resection type was performed for 201 patients, for 82 of them coloplasty. The overall rate of postoperative complications was 28%, including suture leakage (8.5%). Re-laparotomies were performed for 8.5% patients. Lethality was 3.6%. Authors concluded that coloplasty in rectal cancer treatment was a rather safe anastomosis.

The overall rate of post-operative complications in our study was 28%, the rate of anastomosis leakage being 11%. The rate of complications was slightly higher in groups 2 and 3; however, this difference was not statistically significant.

In conclusion, our study shows that the postoperative results after low anastomosis either with or without pouch are similar. The rates of complications and suture leakage are higher in the "straight" anastomosis group; however, this difference is not statistically significant. Necrosis was observed only in patients where an anastomosis with a pouch was formed.

## CONCLUSIONS

Comparison of functional results after 3, 6, 9, 12 and 24 months showed no statistically significant differences among the groups; furthermore, assessment of the function after 12 months revealed that the results were statistically significantly similar (p = 0.046). The complication rate, including leakage of anastomosis suture, was slightly higher in group 3; however, this difference was not statistically significant. The necrosis of the pulled-down bowel was observed only in the pouch groups (groups 1 and 2).

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## RANDOMIZUOTAS TYRIMAS: TIESI JUNGTIS, J FORMOS REZERVUARAS IR KOLOPLASTIKA PO TIESIOSIOS ŽARNOS REZEKCIJŲ DĖL VĖŽIO

*Santrauka*

**Įvadas.** 2003 m. pradėtas randomizuotas tyrimas siekiant įvertinti atokius funkcinius rezultatus, komplikacijų dažnį ir pooperacinį mirtingumą po žemai atliktų tiesiosios žarnos rezekcinio pobūdžio operacijų, kurių metu buvo suformuotos trys skirtingos anastomozės (jungtys): su J rezervuaru (pirma grupė), koloplastika (antra grupė) bei tiesia jungtimi (trečia grupė).

**Medžiaga ir metodai.** Randomizuotas tyrimas baigtas 2007 metais. Tyrime dalyvavę 82 pacientai – 38 moterys ir 44 vyrai, sergantys I–III stadijos vėžiu, buvo suskirstyti į tris grupes.

**Rezultatai.** Atlikus 82 operacijas, pooperaciniu periodu mirčių nebuvo. Bendras pooperacinių komplikacijų dažnis – 28 %, anastomozės siūlių nelaikymo dažnis sudarė 11 %. Pooperacinių komplikacijų dažnis siekė 20,7 % (6 ligoniai pirmoje grupėje), 28,6 % (6 ligoniai antroje grupėje) bei 34,3 % (11 ligonių trečioje grupėje). Komplikacijos buvo dažnesnės koloplastikos bei tiesios jungties anastomozių grupėje, tačiau tai statistiškai nepatikima (p = 0,2636). Palyginus funkcinius rezultatus, praėjus 3, 6, 9, 12, 24 mėnesiams po operacijų, skirtumų tarp visų anastomozių tipų nepastebėta, funkciniai rezultatai, praėjus 24 mėnesiams po operacijų, buvo panašūs (p = 0,046). Anastomozės pobūdis (lyginant anastomozę su rezervuaru ar be jo) neturėjo poveikio pooperaciniam mirtingumui. Bendras komplikacijų dažnis bei siūlių nelaikymas buvo didesnis atlikus tiesią jungtį, tačiau tai statistiškai nepatikima.

**Išvados.** Retai pasitaikanti komplikacija – žarnos nekrozė – nustatyta tik ligoniams, kuriems anastomozė suformuota panaudojant rezervuarą. Lyginant funkcinius rezultatus praėjus 3, 6, 9, 12, 25 mėnesiams po operacijos, jokio statistiškai patikimo skirtumo nepastebėta.

**Raktažodžiai:** tiesiosios žarnos vėžys, anastomozė, J rezervuaras, koloplastika, funkciniai rezultatai