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Randomized Clinical Trial

Comparison of four surgical approaches for rectal prolapse: multicentre randomized clinical trial

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Preliminary data from this trial were presented as a poster at the European Society of Coloproctology Annual Meeting in Nice, 26–28 September 2018.

Abstract

Background: Several different procedures have been described for surgical treatment of rectal prolapse and consensus on the optimal approach has not been reached. The Swedish Rectal Prolapse Trial was performed with the aim to compare the outcomes after the most common surgical approaches to rectal prolapse.

Method: A multicentre randomized trial was conducted from 2000 to 2009. Patients were randomized between a perineal or an abdominal approach for correction of rectal prolapse (randomization A) if eligible for any procedures. Patients considered unsuitable for random allocation were only included in randomizations B or C. Patients in randomization B (perineal group) were randomized to Delorme's or Altemeier's procedures and those in randomization C (abdominal group) to suture rectopexy or resection rectopexy. Primary outcomes were bowel function and quality of life, measured using Wexner incontinence score and RAND-36, and secondary outcomes were complications and recurrence at 3 years.

Results: During the study period, 134 patients were randomized: 18 in randomization A group, 80 in randomization B group and 54 in randomization C group; of these, 122 patients underwent surgery. Mean follow-up was 2.6 years. Improvements in Wexner and RAND-36 scores were seen but with no significant difference between the groups. Health change scores were significantly improved from baseline up to 1 year after surgery ($P < 0.001$). At 3 years, recurrence rates were two of seven patients for abdominal *versus* five of eight patients for perineal approach ($P = 0.315$), 18 of 31 patients (58 per cent) for Delorme's *versus* 15 of 30 patients (50 per cent) for Altemeier's ($P = 0.611$) and four of 19 patients (21 per cent) for suture rectopexy *versus* two of 21 patients (10 per cent) for resection rectopexy ($P = 0.398$). There were no significant differences regarding postoperative complications.

Conclusion: For all procedures, significant improvements from baseline in health change scores were noted after surgery. Recurrence rates were higher than previously reported.

Registration number: NCT04893642 (http://www.clinicaltrials.gov).

Introduction

Full-thickness rectal prolapse, or procidentia, is a benign but distressing condition. It is defined as the circumferential protrusion of all layers of the rectal wall through the anal sphincters[1]. The annual incidence is 2.5 per 100 000, predominantly in the elderly, and male : female ratio is about 1 : 9[2]. Besides symptoms of a mass prolapsing through the anus, patients with prolapse may suffer from incontinence, constipation, rectal bleeding, pain, sensation of incomplete evacuation, urgency and tenesmus. The underlying cause is not completely understood, although there are some known anatomical defects associated with the condition: deep pouch of Douglas, muscular weakness in the pelvic floor and anal canal, atrophy of internal and external sphincters, often with pudendal nerve neuropathy, and lack of normal fixation of rectum with a mobile mesorectum[1,3,4].

Many different procedures have been described for surgical treatment of rectal prolapse and consensus has not yet been reached. Traditionally, perineal procedures have been reserved for older patients who are not fit for an abdominal operation[5]. The two most common perineal procedures are Delorme's operation, which is mucosectomy and rectal plication[6], and perineal rectosigmoidectomy, also known as Altemeier's operation, which is a full-thickness excision of the rectum[7]. Abdominal procedures have been practised for many years and usually involve a rectopexy with a mesh or with posterior sutures to the presacral fascia. The procedure can be done with or without a resection of the sigmoid colon[8]. A Cochrane review in 2000 included only eight randomized studies (264 patients) with the conclusion that it could not provide enough evidence to judge whether any form of surgical intervention was more effective or safe than another type of management[9]. So far, there is no significant evidence of superiority between perineal and abdominal approach or between resection or no resection in either approach[10–12].

The Swedish Rectal Prolapse Trial aimed to investigate the bowel function, quality of life (QoL), recurrence rate and complications after these different surgical approaches.

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Methods

Study design and randomization

This was a multicentre randomized trial conducted in 13 sites in Sweden between March 2000 and May 2009. Inclusion criteria were: full-thickness rectal prolapse; capable of participating in follow-up visits and answering questionnaires; informed consent; and the surgeon agreed that surgery was needed for the condition with no definite preference for any of the surgical options. Exclusion criteria were: irreducible or strangulated prolapse; patient below 18 years of age; and ongoing pregnancy. At inclusion, patients signed an informed consent form and the attending surgeon contacted the trial office at Danderyd Hospital, Stockholm, Sweden. Randomization was performed with randomly assigned envelopes in blocks of four, stratified for each participating centre. The size of the blocks was unknown to the investigators. Patients suitable for receiving any kind of treatment were randomized between a perineal or an abdominal approach (randomization A). Patients who were considered unsuitable for random allocation to a perineal or an abdominal procedure were included only in randomizations B or C (*Fig. 1*). Patients in randomization B (perineal group) were randomized to Delorme's or Altemeier's procedures and those in randomization C (abdominal group) to suture rectopexy or resection rectopexy.

The most common reason to select patients for randomizations B or C was a belief that elderly and frail patients were better suited to a perineal approach and that younger and fit patients fared better with an abdominal approach.

Preoperative evaluation and procedures

All patients were clinically examined and diagnosed with full-thickness rectal prolapse. Further examinations with endoscopy, colon transit studies, anorectal manometry, defaecography, endoanal ultrasonography and pudendal nerve motor latency were optional and were performed as indicated at each surgeon's discretion. Operative procedures were described in the study protocol (*Appendix S1*). Abdominal procedures were performed laparoscopically or open, based on the surgeon's skill.

Outcome measures

Primary outcome measures were bowel function and QoL, and secondary outcomes were recurrence rate at 3 months, 1 year and 3 years and surgical complications within 30 days. A validated bowel function questionnaire, developed by the Swedish Society of Colorectal Surgeons, was used[13]. Information from the questionnaire was later converted to Wexner incontinence score and four questions regarding constipation and bowel function were selected for analysis: the highest/lowest number of bowel movements per 24 hours; time to evacuate the bowel (5 min or less, approximately 10 min, approximately 20 min, more than 20 minutes); sensation of incomplete evacuation (never, less than once a week, 1–6 times per week, every day/always); bowel function affecting overall wellbeing (not at all, a little, quite a bit, very much). All questions were answered with focus on symptoms during the past 2 weeks.

QoL was analysed with the Swedish version of Short Form (SF) 36 Health Survey 1.0 Quality of Life questionnaire, equivalent to the RAND-36 questionnaire. The questionnaire includes 36 items calculated to the eight-dimensional QoL measures and an additional item measuring the perceived change in health over the past year. All categories are measured on a 100-point scale: a higher score indicates a better health state. In this trial the RAND-36 calculator was used. RAND-36 has been validated in a Swedish population. Minor differences exist between RAND-36 and SF-36 in the algorithms for two of the eight measures but these differences are negligible at a group level, which allows comparisons of results[14,15].

At discharge from the hospital, postoperative complications, duration of hospital stay, duration of surgery and estimated blood loss were recorded. Complications were reported according to Clavien–Dindo, although this classification was not yet launched at the initiation of the study protocol[16]. Recurrence was defined as circumferential rectal mucosa visible outside the anus with rectal muscle palpable at follow-up visits.

Follow-up

The patients were followed up at 3 months, 1 year and 3 years after surgery and examined clinically for recurrence and complications. Bowel function and QoL were assessed with questionnaires at each follow-up visit. If a recurrence was diagnosed, the patient was scheduled for a second procedure at the discretion of the surgeon.

A long-term follow-up regarding recurrence was performed in 2018. Medical records of all patients included in the study who underwent the allocated surgery were scanned for recurrence and long-term complications.

Statistical analysis

The target sample size was originally calculated to 220 patients in randomization A to detect a difference in recurrence rate of 13 per cent with a 90 per cent power and a P value of <0.050. Differences in bowel function and QoL were also expected to be found with this sample size. The original target was 100 patients each in randomization B and C to detect significant differences.

Data were analysed with the SPSS© Statistics version 25/26 (IBM, Armonk, New York, USA) and Microsoft Excel (Microsoft, Redmond, Washington, USA). Descriptive data were presented as mean and standard deviation. Categorical variables were analysed using either Fisher's exact test or Pearson's chi-squared test, as appropriate, and t-test was used to analyse continuous variables. For QoL scores, mean changes from baseline were calculated for each group and also between-group differences relative to baseline. Repeated-measurement ANOVA was used to compare changes over all time points in QoL scores and incontinence scores. Friedman's test was used to compare overall incontinence scores. Changes over time in RAND-36 domains were visualized in spider charts. Kaplan–Meier plots were used to visualize recurrence rates and differences were analysed with the log rank test. Patients were censored at the date of last follow-up or death. Recurrence rates were calculated in proportion to those who completed follow-up at each given time. Multiple analyses were performed; to adjust for the increased risk of type I error, $P < 0.010$ was considered statistically significant. Patients not operated with the assigned procedure were not followed-up, therefore a per-protocol analysis was performed. The local Ethics Committee at the Karolinska Institutet and at participating hospitals approved the present study (99-364 and 2017/1903-32).

Results

Some 134 patients were randomized at 13 hospitals in Sweden from March 2000 to November 2005. Unfortunately, inclusion rate was lower than anticipated, particularly for the perineal *versus* abdominal randomization, and the study was closed prematurely before reaching the accrual to detect differences in randomization B and C.

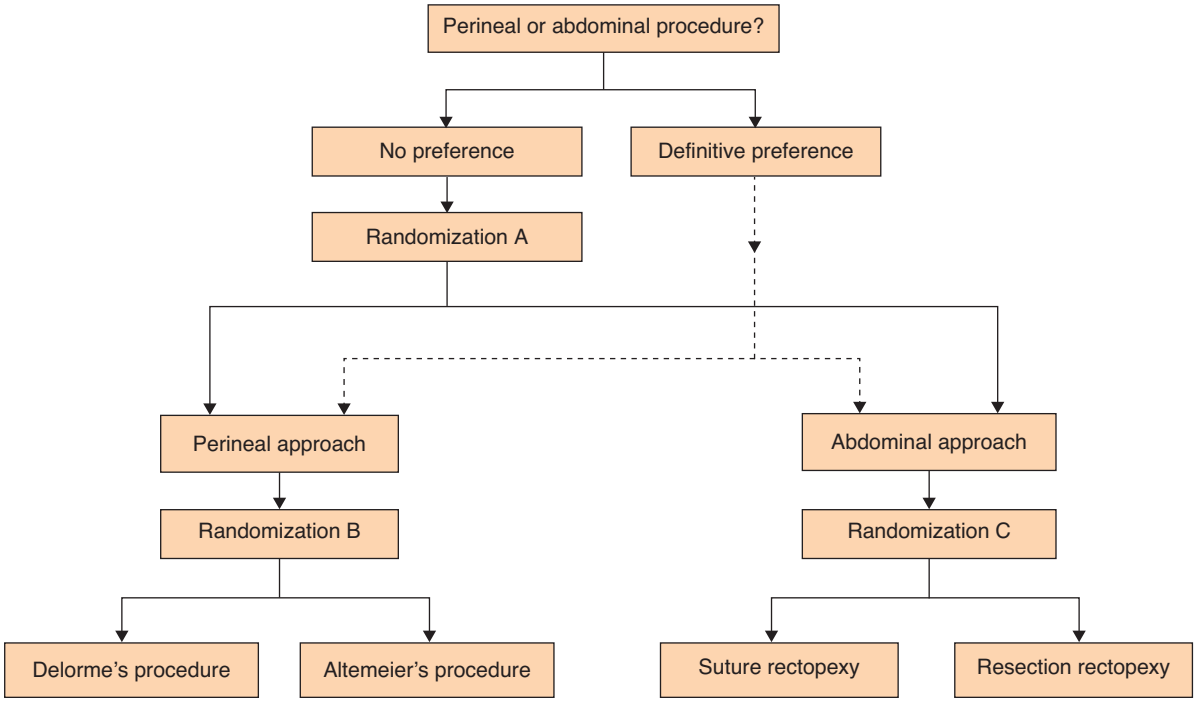


Fig. 1 Trial design

Table 1 Preoperative demographic and characteristics of the patients

	All patients ($n = 122$)	Randomization A		Randomization B		Randomization C	
		Abdominal approach ($n = 10$)	Perineal approach ($n = 8$)	Delorme's ($n = 36$)	Altemeier's ($n = 34$)	Suture rectopexy ($n = 27$)	Resection rectopexy ($n = 25$)
Age (years)*	71.3 (17.1)	76.4 (13.6)	69.4 (19.6)	78.7 (13.3)	79.4 (10.6)	62.7 (17.7)	57.9 (16.9)
Sex ratio (M : F)	7 : 115	1 : 9	0 : 8	2 : 34	0 : 34	2 : 25	3 : 22
ASA score							
I	35 (29)	3	2	4 (11)	5 (15)	11 (41)	15 (60)
II	65 (53)	6	6	21 (58)	21 (62)	15 (56)	8 (32)
III	22 (18)	1	0	11 (31)	8 (24)	1 (4)	2 (8)

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.).

Out of the total of 134 patients, 18 were randomized between perineal and abdominal approach and all patients were randomized between either Delorme's and Altemeier's (80 patients) or suture and resection rectopexy (54 patients). Twelve patients were excluded from the study, four did not receive their allocated treatment, four did not fulfil the inclusion criteria, two withdrew consent for the study and two patients were lost to follow-up. A majority of these patients were randomized to Altemeier's but were regarded as a random drop-out. In all, 122 patients underwent the randomized surgery. The mean(s.d.) age was 71.3(17.1) years. Mean(s.d.) age in the perineal randomization was 79.0(12.0) years and in the abdominal group 60.7(17.4) years. Ninety-four per cent of the patients were female (*Table 1*). Twelve of 27 suture rectopexies and ten of 25 resection rectopexies were done laparoscopically.

In all three randomizations, a total of 116 patients were followed up as planned for 3 years. Seven patients died before they completed follow-up, eight patients had no available details of a 3-year follow-up, five withdrew from the study or were too frail to attend and one left the study because of a Hartman procedure performed due to stenosis in the anastomosis (*Fig. 2*). Follow-up visits continued until May 2009, and the mean follow-up was 2.6 years.

Quality of life

RAND-36 scores at 3 months, 1 year and 3 years were not significantly different in any of the randomized comparisons. Health change scores were significantly improved from baseline for all patients having surgery, at 3 months and 1 year (*Table S1*). An improvement was observed at 3 years, although the score difference was not statistically significant. A presentation of changes over time in RAND-36 domains for each randomization is shown in spider charts (*Fig. 3*).

Bowel function

In the randomized comparisons there were no significant differences in improvement in Wexner incontinence score over time (*Table 2* and *Table S2*). The evaluation of changes over time was not performed for group A due to the small number of patients. At 1 year and 3 years there was a significant overall improvement in mean Wexner incontinence scores from baseline. Results of questions regarding constipation and bowel function are shown in *Table S3*. Due to drop-out over time statistical calculations were not possible.

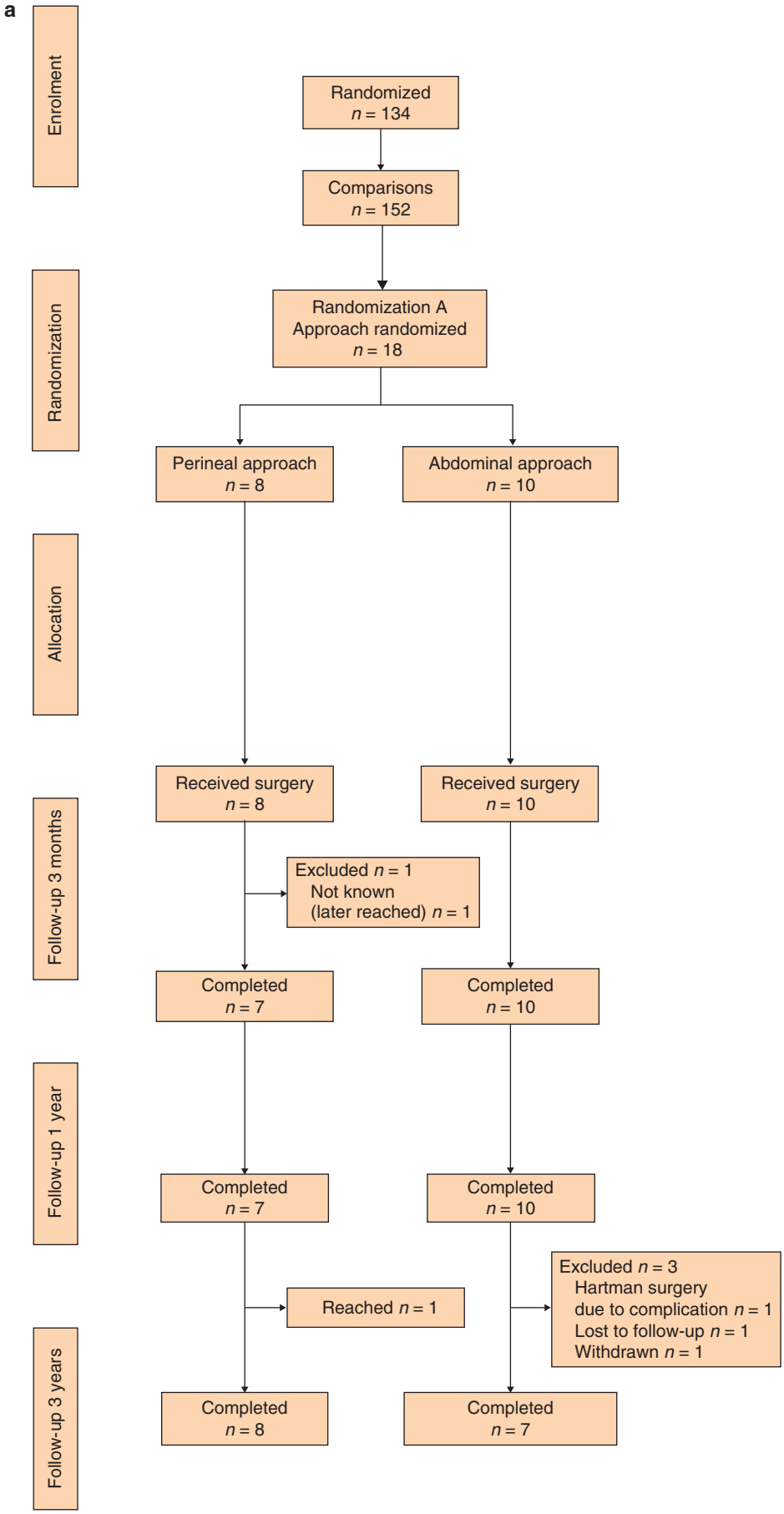
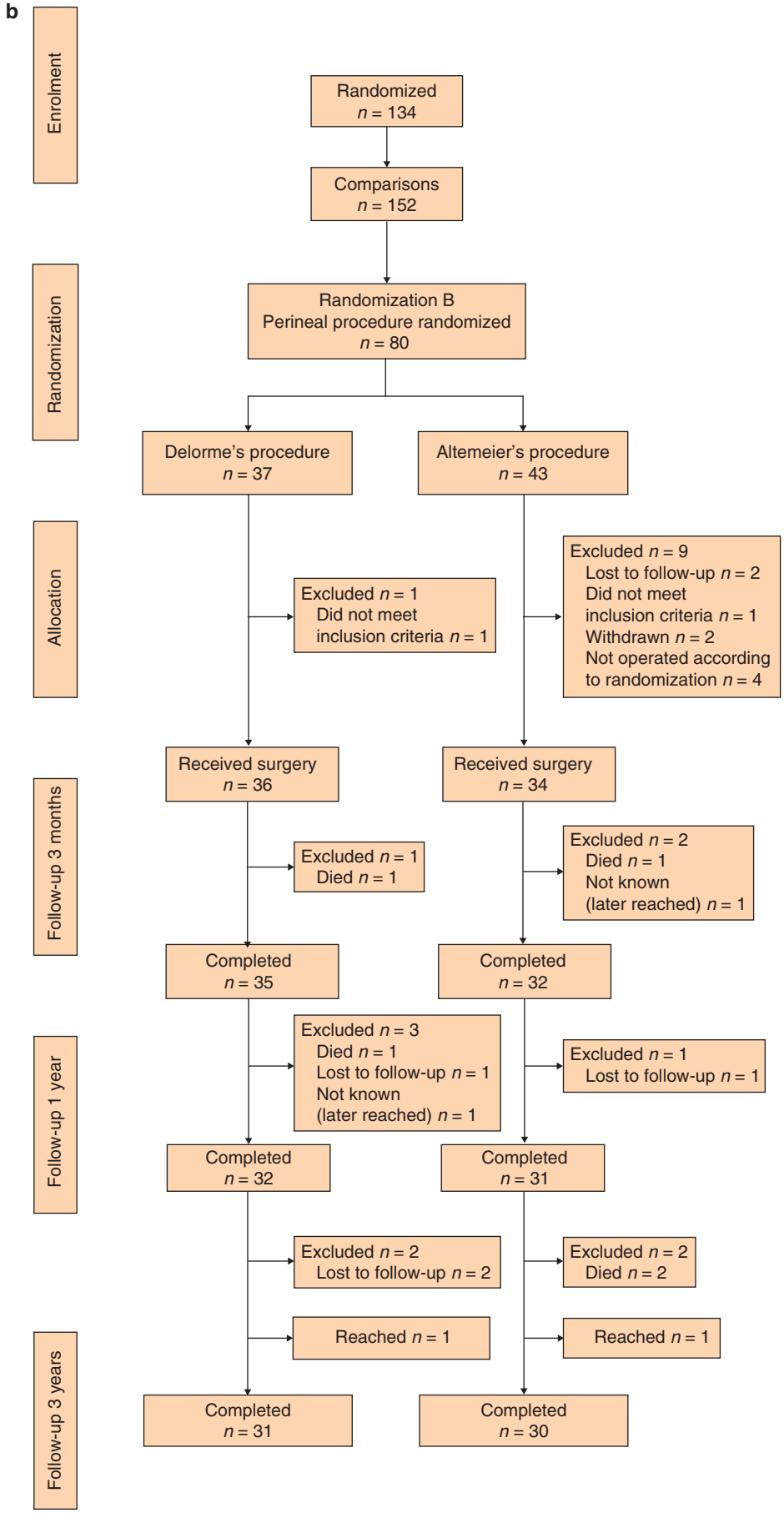


Fig. 2 a–c CONSORT diagram for each randomization arm



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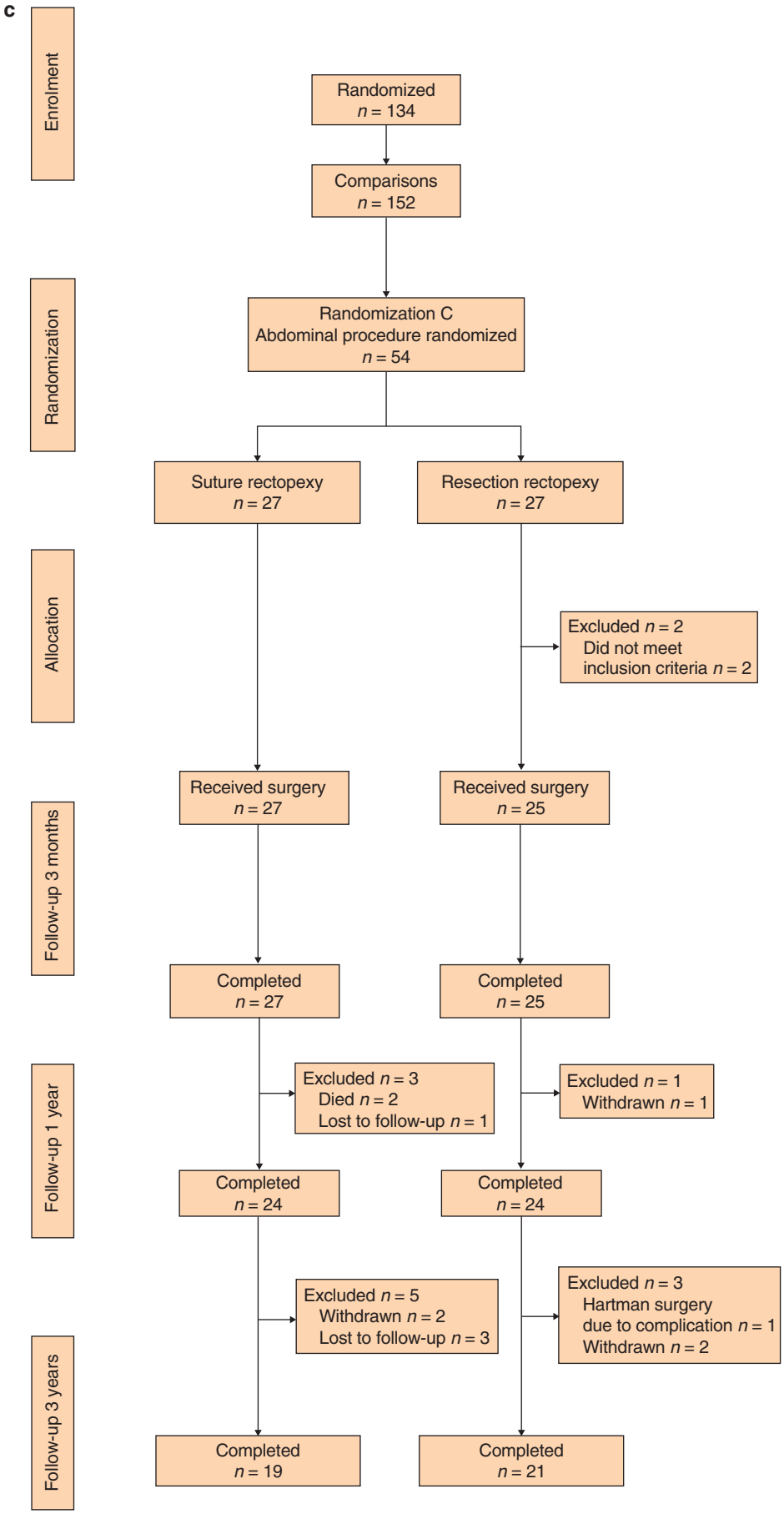

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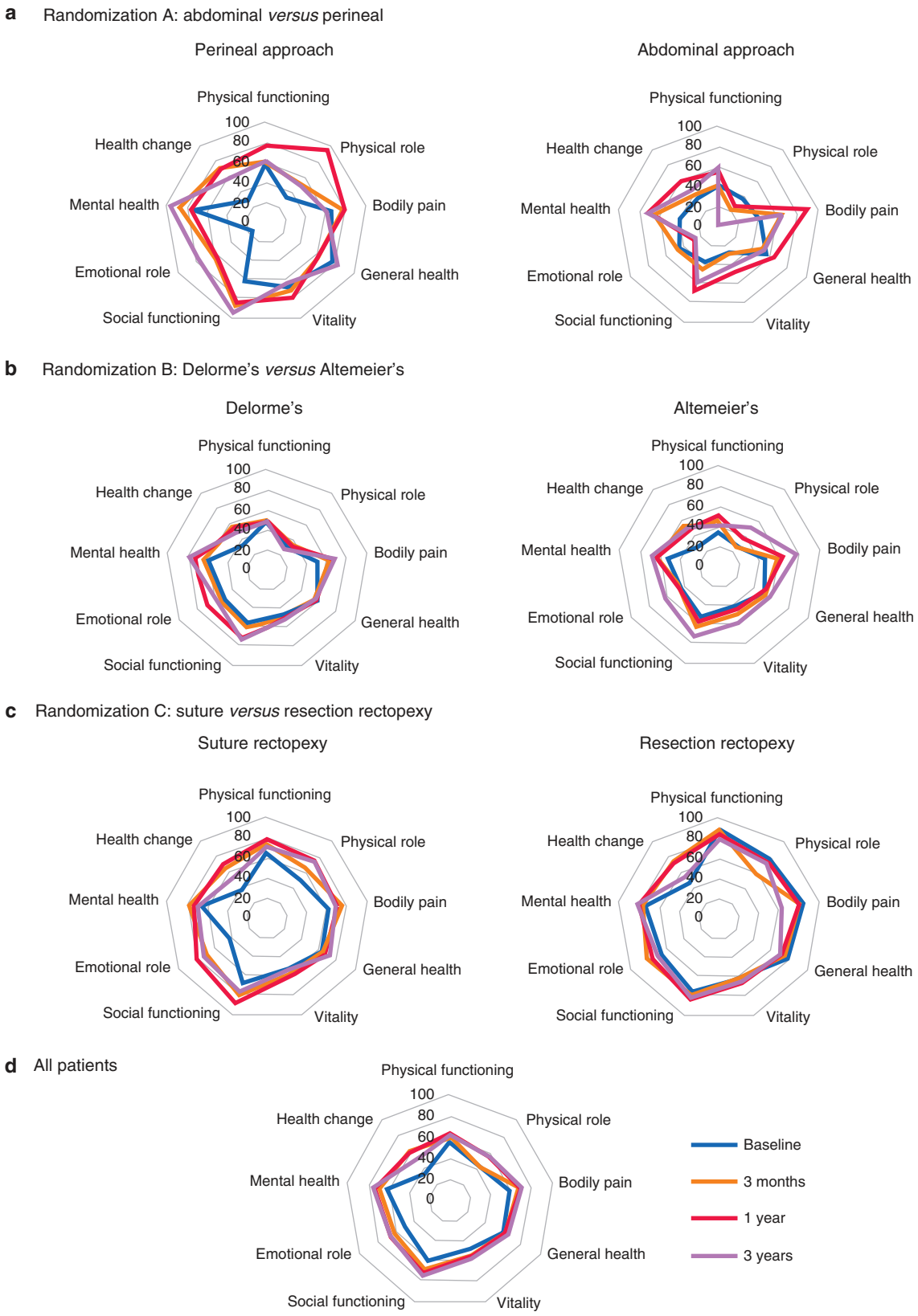


Fig. 3 Development of quality-of-life scores (RAND-36) over time

a Randomization A: abdominal *versus* perineal. **b** Randomization B: Delorme's *versus* Altemeier's. **c** Randomization C: suture *versus* resection rectopexy. **d** All patients.

Recurrence rates

The recurrence rate was higher for perineal than for abdominal approach, higher for Delorme's than Altemeier's and higher for suture rectopexy than resection rectopexy but none of the differences were statistically significant (*Table 3* and *Fig. 4*). At 3 years, recurrence rates were two of seven patients for abdominal

Table 2 Wexner incontinence score in the randomized comparisons

	Randomization A			Randomization B			Randomization C		
	Abdominal approach	Perineal approach	P*	Delorme's	Altemeier's	P*	Suture rectopexy	Resection rectopexy	P*
Baseline	11.6 (6.7)	15.5 (4.6)	0.253	14.9 (5)	10.7 (5.8)	0.005	13.2 (5.2)	10.7 (6.1)	0.142
3 months	12 (6.2)	15.6 (3.1)	0.291	11.8 (6)	11.7 (4.5)	0.960	10.9 (5.5)	7.8 (6.6)	0.139
1 year	7.5 (8.8)	16.7 (4)	0.133	11.2 (5.8)	9.9 (5.6)	0.518	9.3 (6.9)	7.5 (5.9)	0.405
3 years	9.5 (10.6)	12.7 (3)	0.746	8.6 (7)	8.6 (5.1)	0.995	9.3 (7.1)	7.2 (6.2)	0.461
Change over time			ND			0.617†			0.798†

Values are mean (s.d.). Wexner incontinence score, 0 = perfect continence, 20 = complete incontinence. *t-test, except †repeated-measurement ANOVA. ND, not done.

Table 3 Recurrence rates, complications and peri- and postoperative data in the randomized comparisons

	Randomization A			Randomization B			Randomization C		
	Abdominal approach	Perineal approach	P†	Delorme's	Altemeier's	P†	Suture rectopexy	Resection rectopexy	P†
Recurrence rate at:									
3 months	2 of 10	1 of 7	1.000‡	7 of 35 (20)	3 of 32 (9)	0.310‡	3 of 27 (11)	1 of 25 (4)	0.611‡
1 year	2 of 10	4 of 7	0.162‡	16 of 32 (50)	10 of 31 (32)	0.203‡	4 of 24 (17)	2 of 24 (8)	0.666‡
3 years	2 of 7	5 of 8	0.315‡	18 of 31 (58)	15 of 30 (50)	0.611‡	4 of 19 (21)	2 of 21 (10)	0.398‡
Long-term follow up	2 of 10	5 of 8	0.145‡	21 of 36 (58)	16 of 34 (47)	0.345‡	8 of 27 (30)	4 of 25 (16)	0.244‡
Clavien–Dindo classification			0.314§			0.331§			0.309§
Grade I	0	3		1	3		3	4	
Grade II	0	0		4	6		5	2	
Grade IIIa	0	0		0	0		0	0	
Grade IIIb	0	1		2	0		2	0	
Grade IV	0	0		0	0		0	0	
Grade V	0	0		0	1		0	0	
Operative time (min)*	139 (82)	76 (35)	0.061	92 (43)	77 (25)	0.068	104 (39)	143 (54)	0.006
Intraoperative bleeding (ml)*	106 (98)	50 (53)	0.166	109 (134)	89 (115)	0.537	108 (191)	126 (113)	0.703
Duration of hospital stay (days)*	8 (4)	5 (2)	0.022	4 (2)	6 (3)	0.004	6 (4)	6 (3)	0.564

*Values are mean(s.d.). †t-test, except ‡Fisher's exact test and §chi-squared test.

approach *versus* five of eight patients for perineal approach ($P = 0.315$), 18 of 31 patients (58 per cent) for Delorme's *versus* 15 of 30 patients (50 per cent) for Altemeier's ($P = 0.611$) and four of 19 patients (21 per cent) for suture rectopexy *versus* two of 21 patients (10 per cent) for resection rectopexy ($P = 0.398$). Within 3 years, 10 patients in the Delorme's group, 10 patients in the Altemeier's group, four patients in the suture rectopexy group and two patients in the resection rectopexy group had a reoperation because of a recurrence.

Complications

All complications within 30 days after surgery are shown in *Table 3*. There were no significant differences regarding postoperative complications in any of the randomized comparisons. One patient who underwent Altemeier's operation died of unknown cause 11 days after discharge from hospital. The cause of death was judged not to be treatment related. In all, four Clavien–Dindo grade IIIb complications were registered, two after Delorme's: one patient was severely constipated and needed manual evacuation under general anaesthesia and one had bleeding at the site of a suture, which demanded surgical intervention. Two patients suffered complications following suture rectopexy: one patient needed reoperation due to a haematoma in the mesocolon, which led to a resection of transverse colon, and one was operated because of intestinal obstruction due to a port-site incisional hernia.

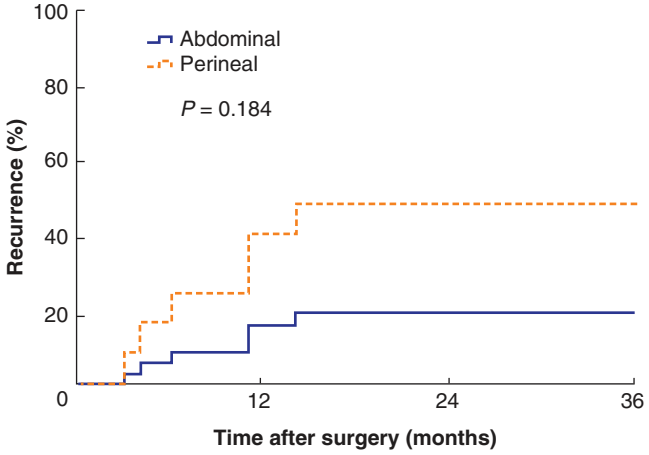
The duration of hospital stay was significantly shorter in the Delorme's group compared with Altemeier's. The operative time was significantly shorter for suture rectopexy compared with resection rectopexy (*Table 3*).

Long-term follow-up

In the long-term follow-up, ten additional recurrences were found; three after Delorme's (after 4, 8 and 9 years), one after Altemeier's (after 4 years), four after suture rectopexy (after 6, 9, 9 and 10 years) and two after resection rectopexy (after 6 and 12 years). In the randomized comparisons the long-term recurrence rate was two of ten *versus* five of eight patients comparing abdominal and perineal approach ($P = 0.145$), 21 of 36 *versus* 16 of 34 patients comparing Delorme's and Altemeier's ($P = 0.345$) and eight of 27 *versus* four of 25 patients comparing suture *versus* resection rectopexy ($P = 0.244$). After adjustment for deaths, the mean(s.d.) time of long-term follow-up was 10.1(4.3) years (not including patients who died or had a recurrence within 3 years). In total, 10 of 49 recurrences appeared later than 3 years after surgery, and 34 of 122 patients had a reoperation because of recurrence of rectal prolapse.

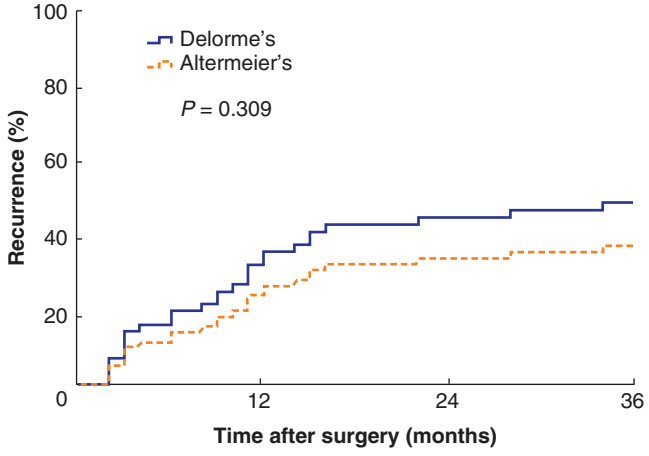
In the long-term follow-up, three patients operated with suture rectopexy were hospitalized for abdominal complications (one had surgery for intestinal obstruction and two had

a Randomization A: abdominal *versus* perineal



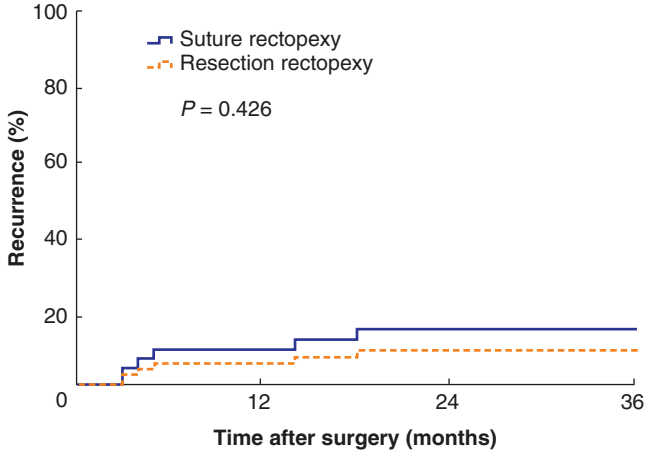
No. at risk				
Abdominal	10	7	6	6
Perineal	8	5	4	4

b Randomization B: Delorme's *versus* Altermeier's



No. at risk				
Delorme's	36	21	15	12
Altermeier's	34	23	20	16

c Randomization C: suture *versus* resection rectopexy



No. at risk				
Suture	27	21	16	16
Resection	25	22	19	18

Fig. 4 Time to recurrence of rectal prolapse

a Randomization A: abdominal *versus* perineal. $P^* = 0.184$. **b** Randomization B: Delorme's *versus* Altemeier's. $P^* = 0.309$. **c** Randomization C: suture *versus* resection rectopexy. $P^* = 0.426$. *log rank test.

constipation). One patient who had Altemeier's operation suffered from stenosis in the anastomosis and was later operated with sigmoidostomy. Eight patients were hospitalized due to faecal incontinence (one who had suture rectopexy, five who had Delorme's operation and two who had Altemeier's operation). Among those, one patient who had Delorme's operation was later operated with a sigmoidostomy.

Discussion

The results in present study showed an improved Wexner incontinence score after surgery for full-thickness rectal prolapse in all groups and the overall bowel function also seemed to improve after surgery. No significant differences regarding bowel function or QoL were seen in any of the randomized comparisons. A high rate of recurrence of rectal prolapse was found after all procedures but no significant differences were seen in the randomized comparisons. All methods appeared to be equally safe since no differences in complications were noticed.

The updated Cochrane review in 2015[1] included 43 patients enrolled in two trials comparing perineal and abdominal approach[12,17], three trials (115 patients) comparing rectopexy with and without sigmoid resection[10–12] and one trial (201 patients) comparing Delorme's and Altemeier's[12]. No significant differences in recurrence rates were found in the two trials comparing perineal and abdominal approach[12,17]. In 2016, a trial including 50 patients compared laparoscopic ventral mesh rectopexy with Delorme's operation, but no significant differences in recurrence or improvement of symptoms were observed[18]. Recurrence rates were much lower than in the present study, and 16 per cent of patients operated with Delorme's and 8 per cent of patients operated with laparoscopic ventral mesh rectopexy had a recurrent prolapse, although average age was much lower and more men were included. It seems like neither previous trials nor the present one had sufficient power to detect differences between abdominal and perineal procedures. Despite the absence of evidence there is a tendency to choose an abdominal approach for young and fit individuals and a perineal approach for frail and older people. This also seemed to be the case in the present trial where most surgeons chose not to include patients in randomization group A. A likely explanation is the perception of a higher recurrence rate for perineal procedures and a higher risk of complications after abdominal procedures. There was a major difference in average age when comparing the groups of patients included only in randomization groups B and C, where the surgeons chose to include younger patients in the abdominal randomization and older patients in the perineal randomization.

In all, three randomized trials have compared rectopexy with and without sigmoid resection[10–12]. The 2015 Cochrane review including those three trials found significantly less postoperative constipation after resection rectopexy[1]. Unfortunately, due to incomplete questionnaires and drop-outs, these results were not confirmed. One multicentre trial of 252 patients in 2011 compared rectal mobilization in combination with rectopexy with rectal mobilization only and found significantly lower recurrence rate after rectopexy. The patients in the rectopexy arm had a 5-year recurrence rate of only 1.5 per cent, which is remarkably lower than the findings in the present study[19].

It remains unclear if there is any superiority between Delorme's and Altemeier's. The PROSPER trial with 201 patients[12] and the present trial are the only randomized comparisons so far. Neither trial showed any significant differences between the methods.

When comparing recurrence rates, it is important to take into consideration that the rates have been calculated in different ways. In the PROSPER trial[12], which was similar in design and run during the same time period, the number of known recurrences was calculated in proportion to those who had surgery, which gives conservative numbers, while in the present trial the same calculation was done in proportion to those who attended follow-ups, which naturally resulted in higher numbers. However, even if recurrence rates were calculated at 3 years for the perineal procedures in proportion to the total number of patients who had surgery, assuming that none of the patients who died or were lost to follow-up would have a recurrence, the recurrence rates for perineal procedures were still higher. Comparing recurrence rates for abdominal procedures with the PROSPER trial, the rates were lower in the present trial than in the PROSPER trial, no matter how the rates are calculated, in proportion to all patients who had surgery or those who were followed up at 3 years. Another major difference comparing the two trials is the frequency of completed follow-up at 3 years. In the PROSPER trial 148 of 268 patients who had surgery (55.2 per cent) were followed up for 3 years, while 101 of 122 patients (82.8 per cent) completed follow-up at 3 years in the present trial. One fifth of the patients who were operated in the PROSPER trial died within 3 years while 6 per cent died in the present study. Most patients who died in the PROSPER trial were in the perineal arm. This difference is surprising since the average age was lower in the PROSPER trial and the ASA scores were comparable.

At least 20 per cent of the recurrences appeared later than 3 years after surgery. The fact that the long-term follow-up depends on the patients' own capacity of making contact with the hospital in case of a recurrence and also the limitation of only scanning the medical records at the hospitals where the patients were operated, can contribute to a false low recurrence rate.

This trial has some other limitations. The per protocol analysis can be regarded as a weakness and there is a potential for selection bias even though drop-outs were regarded as random and not connected to the operative procedure. Older patients may have problems with completing questionnaires during follow-up, which also could contribute to a selection bias. Another limitation is that over the years since this trial was executed, methods of rectal prolapse surgery have developed, especially the abdominal procedures. They are nowadays to a greater extent performed laparoscopically and new methods using mesh have been developed. Still, the procedures in this trial are widely used. A randomized trial of 75 patients compared functional outcome after posterior sutured rectopexy with ventral mesh rectopexy and found no significant differences[20], indicating that suture rectopexy can still be an acceptable choice. Ventral mesh rectopexy has become a standard procedure in many centres based on low recurrence rates, limited complications and good functional results[21] but it is possible that this procedure might soon be outdated. The use of mesh has been debated and the recurrence rates for ventral mesh rectopexy seems to be higher than originally thought[22]. It is therefore possible that surgeons will go back to established techniques, such as the ones in the present study.

Unfortunately, the present study lacked the power to detect differences in the randomized comparisons due to difficulties in recruiting. As proved before, recruitment to surgical trials for rectal prolapse is difficult, especially in randomized comparisons between abdominal and perineal approach[12]. Enrolment in surgical trials in general is known to be difficult and the most commonly reported patient-related reasons for non-entry of eligible patients into surgical RCTs are preference for one form of treatment,

dislike of the idea of randomization and the potential for increased demands on the patient. It has been shown that common non-patient-related reasons for failing to enrol are related to informed consent, clinician's loss of motivation attributable to lack of recognition or financial rewards, the complexity of study protocols, or a change in the attitude towards research in general[23]. The slow recruitment in this trial could be a combination of factors such as the ones listed above and also the fact that the incidence of rectal prolapse is relatively low.

The present study shows that recurrence rates are higher than anticipated when surgery is performed in a multicentre setting and an extended follow-up is applied. The operations were performed by a large number of surgeons with different volume of rectal prolapse surgery. This reflects the setting in many centres where rectal prolapse surgery is executed and the results are applicable on everyday surgery performed at both smaller and larger units.

This is, however, one of the largest randomized trials on surgical treatment for rectal prolapse so far. Together with the PROSPER trial, it stands out in its focus on QoL after surgery for rectal prolapse. The frequency of follow-up was high, with few patients lost to follow-up. The long-term follow-up is unique and the longest that has been published so far. The substantial number of late recurrences emphasize the importance of an extended follow-up to detect long-term recurrences after surgery for rectal prolapse.

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Supplementary material

Supplementary material is available at *BJS* Open online.

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