Randomized clinical trial

Randomized clinical trial of intracutaneously *versus* transcutaneously sutured ileostomy to prevent stoma-related complications (ISI trial)

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Background: **Ileostomy construction is a common procedure but can be associated with morbidity. The stoma is commonly secured to the skin using transcutaneous sutures. It is hypothesized that intracutaneous sutures result in a tighter adherence of the peristomal skin to the stoma plate to prevent faecal leakage. The study aimed to compare the effect of intracutaneous *versus* transcutaneous suturing of ileostomies on faecal leakage and quality of life.**

Methods: **This randomized trial was undertaken in 11 hospitals in the Netherlands. Patients scheduled to receive an ileostomy for any reason were randomized to intracutaneous or transcutaneous suturing (IC and TC groups respectively). The primary outcome was faecal leakage. Secondary outcomes were stoma-related quality of life and costs of stoma-related materials and reinterventions.**

Results: **Between April 2011 and February 2016, 339 patients were randomized to the IC (170) or TC (169) group. Leakage rates were higher in the IC than in the TC group (52·4 *versus* 41·4 per cent respectively; risk difference 11·0 (95 per cent c.i. 0·3 to 21·2) per cent). Skin irritation rates were high (78·2 *versus* 72·2 per cent), but did not differ significantly between the groups (risk difference 6·1 (95 per cent c.i. −3·2 to 15·10) per cent). There were no significant differences in quality of life or costs between the groups.**

Conclusion: **Intracutaneous suturing of an ileostomy is associated with more peristomal leakage than transcutaneous suturing. Overall stoma-related complications did not differ between the two techniques. Registration number: NTR2369 (http://www.trialregister.nl).**

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Introduction

Ileostomy construction is a common procedure, with an estimated 50 000 ileostomies formed annually in the USA, most commonly to divert a downstream low anastomosis[1]. The morbidity rate is high, ranging from 21 to 60 per cent[2]. This results in decreased quality of life (QoL), and disturbed physical and psychological well-being[3–10].

Peristomal dermatitis may occur in up to 65 per cent of patients with an ileostomy[11]. The most important factor contributing to peristomal dermatitis is leakage of faeces under the stoma plate. Causes of leakage include inappropriate stoma site, inappropriate use of stoma materials, stoma retraction, high BMI or a parastomal hernia. Leakage requires frequent changes of the stoma plate, which may result in further damage to the peristomal skin. In addition, ileostomies tend to produce frequent watery stool containing proteolytic enzymes with a high acid content, which can further damage the surrounding epidermal structure.

Although consensus exists on how to fashion an ileostomy, there is no standard method for suturing the stoma to the skin. This can be done transcutaneously, keeping the stitches exposed, or intracutaneously, burying the resorbable stitches below the skin surface. Most surgeons use a transcutaneous technique as it is technically

easier, but these sutures make puncture holes in the skin that might allow faeces to penetrate, resulting in skin irritation and early release of the stoma plate.

The hypothesis of this study was that intracutaneous suturing would result in tighter adherence of the peristomal skin to the stoma plate thus preventing faecal leakage. The primary aim was to compare faecal leakage rates between intracutaneously *versus* transcutaneously sutured ileostomies. Secondary aims were to compare skin irritation, QoL and costs between ileostomies formed by the two suturing methods over a 3-month follow-up period.

Methods

The ISI (Intracutaneously *versus* transcutaneously Sutured Ileostomy) trial was a multicentre, parallel-group RCT, performed in 11 centres in the Netherlands. The study was reported according to the CONSORT extended checklist for RCTs[12]. The trial was approved by the medical ethics review boards of the contributing hospitals and was registered before its inception as NTR2369.

Patients

All patients between the age of 18 and 80 years who received an end ileostomy or loop ileostomy for any reason, and who gave written informed consent, were eligible for inclusion. Patients were recruited at the outpatient department. Exclusion criteria were: life expectancy less than 1 year; BMI exceeding 35 or under 18 kg/m^2; emergency surgery; ASA fitness grade IV; and insufficient knowledge of the Dutch language or unable cognitively to complete Dutch questionnaires.

Randomization

Computerized randomization of participants to intracutaneous suturing (IC group) or transcutaneous suturing (TC group) was done 1:1 via the trial website (www.isitrial.nl). Randomization was either undertaken in the operating theatre just before suturing the stoma or at the preoperative visit by the stoma therapist, who put the allocation result in a sealed opaque envelope that was not to be opened until the end of the surgical procedure just before suturing the ileostomy.

Intervention

In this study, the surgical technique was standardized, as prescribed in the protocol (NTR2369; www.trialregister.nl) and discussed with the surgeons involved before the trial started. An instructional video was provided about creation of the ileostomy and how the stoma was to be sutured. Generally, in the Netherlands the sutures are placed at 3, 6, 9 and 12 o'clock, and another stitch in between, mostly with a 3/0 suture.

Before operation, all patients were seen by a stoma therapist, who marked the stoma site together with the patient. For intracutaneously sutured ileostomy, only multifilament suture materials were used, because these dissolve faster than monofilament sutures and were considered more suitable because of their greater pliability. For transcutaneously sutured ileostomy, surgeons were allowed to choose between multifilament and monofilament sutures. Transcutaneous sutures were removed by a stoma therapist after 10–14 days. The ileostomy was created in an open or laparoscopic procedure performed, or at least supervised, by an experienced gastrointestinal surgeon. In total, 22 surgeons participated in the trial.

Follow-up

Patients were followed for 3 months after surgery as complications occur mostly at this early postoperative stage[13]. Patients visited the stoma therapist 1 and 2 weeks, and 1, 2 and 3 months after surgery. The frequency and severity of any leakage were recorded by the patient in a diary and by the stoma therapist. Patients were also asked to keep a diary of how many stoma products they used each day, and the stoma therapist noted which brand of stoma bag was used. Data on the type and number of stoma materials used and any complications were recorded by stoma therapists in the online database, accessible via the trial website. Readmissions and reinterventions were also documented. The stoma therapists took a faecal culture, and measured the pH of the stool after 2 weeks and 2 months, using pH indicator strips (pH 4·0–7·0; Merck, Darmstadt, Germany), with a specific indicator for bleeding.

Patients were asked to complete QoL questionnaires, which were sent to their home address with a prepaid return envelope at 1 and 3 months after surgery.

Outcomes

Primary outcome

The primary outcome was the occurrence of faecal leakage under the stoma plate. The severity of leakage was categorized as minimal, mild, moderate or severe, according to a set of photographs provided on the trial website (*Fig. 1*). This set of images was based on the Ostomy Skin Tool, which was tested in the ISI trial study group before the start of the trial[14]. The stoma therapists in all participating centres were trained to judge the severity of leakage with the

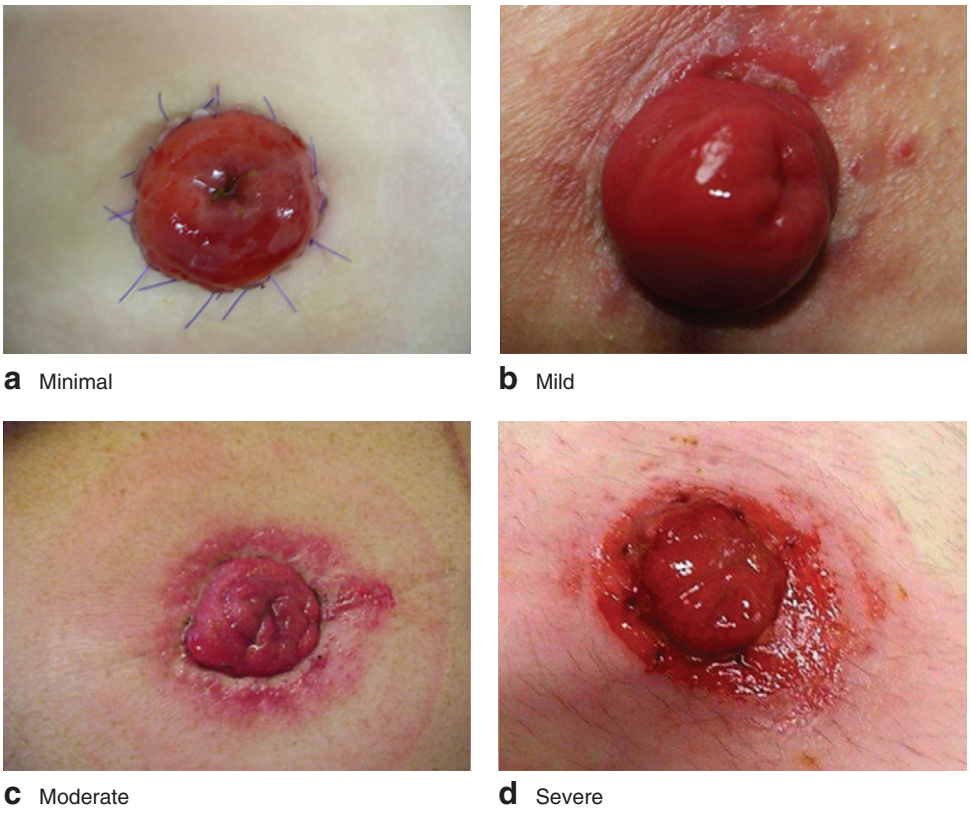


Fig. 1 Severity of faecal leakage: **a** minimal, **b** mild, **c** moderate or **d** severe

aid of these pictures before the start of the study to achieve uniformity in scoring.

Secondary outcomes

QoL was measured by means of the Stoma-QOL questionnaire[15]. This is a condition-specific instrument designed to measure aspects of QoL among patients with a stoma. Each of the 20 items of the Stoma-QOL is scored on a four-point scale. The scores are summed to obtain a total score that ranges from 20 to 80. For comparability with other questionnaire scales, the Stoma-QOL score was converted to a scale from 0 to 100, where 0 indicates the worst and 100 the best QoL outcome.

Stoma-related morbidity in the 3-month follow-up period was recorded: peristomal dermatitis, necrosis, fistula, prolapse, retraction, granulomas, high-output stoma (more than 1500 ml per 24 h) and parastomal hernia. These complications were diagnosed according to standard predefined criteria and were based on those occurring most frequently[2,4,16–22]. General postoperative complications were recorded, including surgical-site infection, abdominal abscess, ileus, abdominal fascia dehiscence, anastomotic leakage, pneumonia, urinary tract infection and a miscellaneous (other) group.

A cost analysis was undertaken, which included stoma materials, readmissions, stoma revisions and reinterventions during the first 3 months after ileostomy creation. Costs were calculated by counting resource use as recorded in the diaries and questionnaires, and were multiplied by unit costs. Standard unit costs were used when available, complemented by results from cost calculations where needed. Cumulative costs were calculated for the 3-month trial period and for each cost category.

Other secondary outcomes were faecal pH and faecal cultures at 2 weeks and 2 months to determine a possible reason for dermatitis.

Sample size calculation

Because of the lack of pre-existing data on this topic, it was postulated that a 15 per cent reduction in leakage rate (from an estimated 30 per cent to 15 per cent) would be clinically relevant. With a 5 per cent two-sided significance level and a power of 80 per cent, it was calculated that a

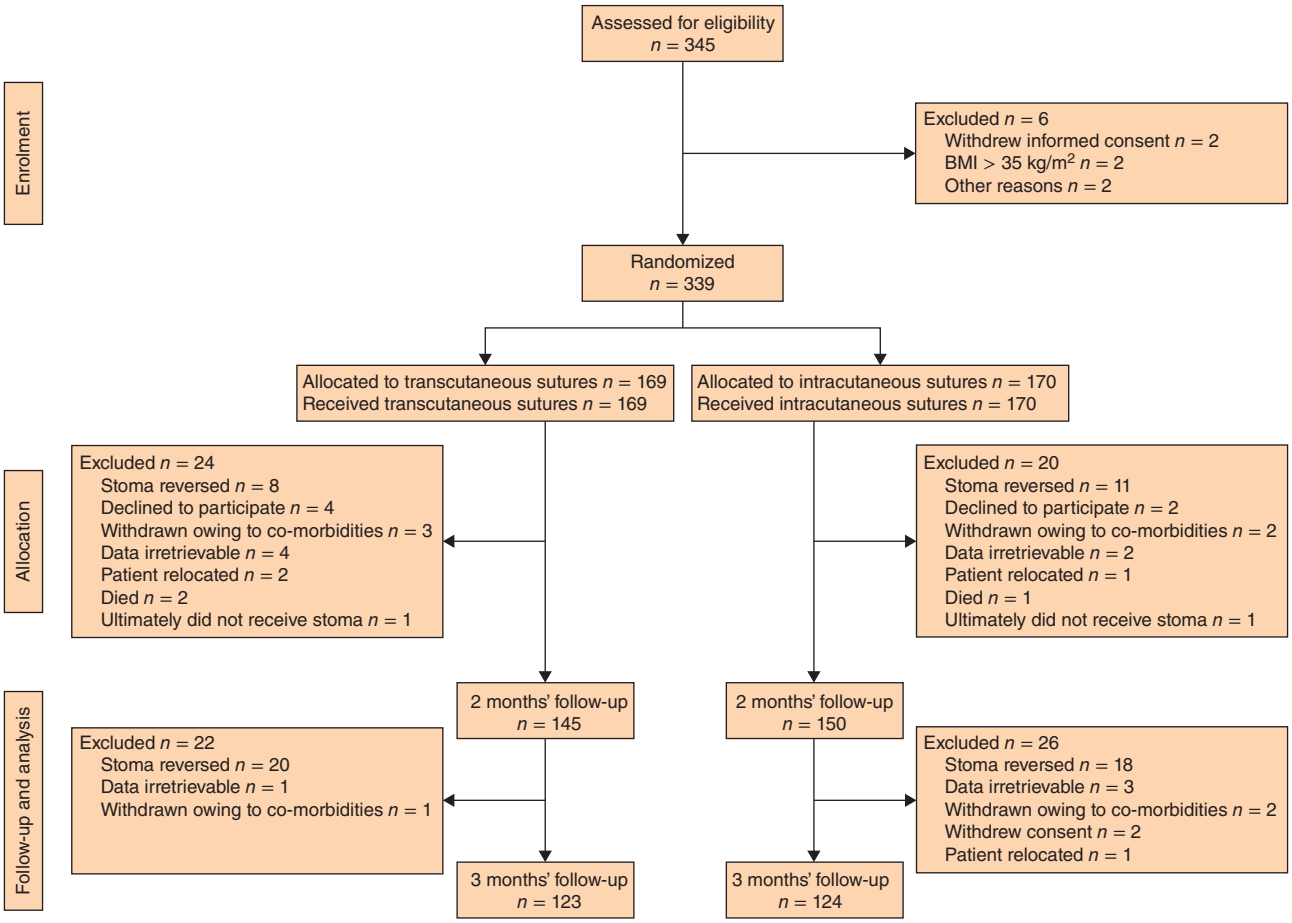


Fig. 2 Study flow chart

sample size of 134 patients per treatment arm would be required. Anticipating a dropout rate of up to 20 per cent, the study aimed to recruit 334 patients. With this sample size it was also possible to show a difference of 15 (s.d. 40) points on a 100-point scale in QoL, as well as a cost difference of €2 (s.d. €5) per day.

Statistical analysis

Surgical data in the two groups were compared using the χ^2 test. Patient outcomes were analysed using risk differences (RDs) with 95 per cent confidence intervals. Time to occurrence of leakage was assessed using Kaplan–Meier curves, with comparison between groups by log rank analysis. For QoL outcomes, the non-parametric Wilcoxon test was used to analyse within-group changes over time and the Mann–Whitney *U* test for between-group differences, as these outcomes were unlikely to have a normal distribution. Analyses were performed according to the intention-to-treat principle. Any baseline differences between the groups were accounted for by stepwise multivariable logistic regression analysis with the occurrence of leakage as the dependent variable. Data analysis was carried out using SPSS® version 23 (IBM, Armonk, New York, USA).

Results

Between April 2011 and February 2016, 345 patients were screened for inclusion, of whom 339 were recruited. There were 170 patients in the IC group and 169 in the TC group (*Fig. 2*). All patients received the suturing technique to which they were allocated. In general, no substantial differences were observed between the groups at baseline (*Table 1*). More patients in the IC group underwent short-course radiotherapy (RD 9·0 (95 per cent c.i. 2·2 to 15·4) per cent).

There was no difference between the groups in surgical procedures and types of stoma (*Table 2*). Some patients had surgery because of an obstructive tumour, or before

Table 1 Baseline patient characteristics

	Intracutaneous sutures ($n = 170$)	Transcutaneous sutures ($n = 169$)
Age (years)*	60·1(13·9)	60·0(14·0)
Sex ratio (M : F)	108 : 62	101 : 68
BMI (kg/m^2)*	25·7(3·7)	25·5(4·0)
ASA fitness grade		
I	62 (36·5)	61 (36·1)
II	95 (55·9)	92 (54·4)
III	13 (7·6)	16 (9·5)
Cigarette smoking		
Never smoked	120 (70·6)	112 (66·3)
Past smoker	31 (18·2)	35 (20·7)
Current smoker	19 (11·2)	22 (13·0)
Co-morbidity†		
None	62 (36·5)	67 (39·6)
1	27 (15·9)	31 (18·3)
> 1	35 (20·6)	36 (21·3)
Neoadjuvant therapy		
None	70 (41·2)	76 (45·0)
Short-course radiotherapy	53 (31·2)	37 (21·9)
Long-course radiotherapy	5 (2·9)	8 (4·7)
Chemoradiation	42 (24·7)	48 (28·4)
Indication for stoma		
Malignancy	135 (79·4)	120 (71·0)
Ulcerative colitis	9 (5·3)	13 (7·7)
Crohn's disease	9 (5·3)	7 (4·1)
Diverticulitis	6 (3·5)	7 (4·1)
Anal disorders	0 (0)	3 (1·8)
Other	11 (6·5)	19 (11·2)

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). †Cardiovascular disease, pulmonary disease, abdominal surgery, gynaecological surgery, oncological disease and neurological disease.

Table 2 Characteristics of surgical procedures

	Intracutaneous sutures ($n = 170$)	Transcutaneous sutures ($n = 169$)	P*
Surgical procedure			
Low anterior resection	128 (75·3)	116 (68·6)	0·439
Subtotal colectomy	11 (6·5)	18 (10·7)	0·194
Abdominoperineal resection	1 (0·6)	0 (0)	0·564
Right hemicolectomy	1 (0·6)	1 (0·6)	1·000
Left hemicolectomy	3 (1·8)	1 (0·6)	0·317
For anal disorders	1 (0·6)	1 (0·6)	1·000
Other	25 (14·7)	32 (18·9)	0·423
Stoma site			
Right lower abdomen	139 (81·8)	130 (76·9)	0·580
Right upper abdomen	24 (14·1)	28 (16·6)	0·674
Left lower abdomen	7 (4·1)	10 (5·9)	0·467
Left upper abdomen	0 (0)	1 (0·6)	0·496
Stoma type			
Loop ileostomy	146 (85·9)	143 (84·6)	0·859
End ileostomy	20 (11·8)	25 (14·8)	0·546
Split ileostomy	4 (2·4)	1 (0·6)	0·180
Suture material			
Monofilament	1 (0·6)	104 (61·5)	< 0·001
Multifilament	169 (99·4)	65 (38·5)	< 0·001
Antibiotic prophylaxis	167 (98·2)	161 (95·3)	0·120
Corticosteroid use	18 (10·6)	15 (8·9)	0·607
Procedure performed by			
Surgeon	125 (73·5)	134 (79·3)	0·617
Resident	45 (26·5)	35 (20·7)	0·258

Values in parentheses are percentages. *χ^2 test.

Table 3 Extent of leakage of faeces underneath the stoma plate

	Intracutaneous sutures ($n = 170$)	Transcutaneous sutures ($n = 169$)	Risk difference (%)*
Leakage	89 (52·4)	70 (41·4)	11·0 (0·3, 21·2)
Minimal	11 (12)	12 (17)	−5 (−17, 6)
Mild	47 (53)	38 (54)	−2 (−17, 14)
Moderate	23 (26)	15 (21)	4 (−9, 17)
Severe	8 (9)	5 (7)	2 (−8, 11)

Values in parentheses are percentages unless indicated otherwise; *values in parentheses are 95 per cent confidence intervals.

(chemo)radiation preceding rectal resection; these procedures were included in the subgroup 'other'. Surgeons constructed 259 of the ileostomies (76·4 per cent) and residents 80 (23·6 per cent).

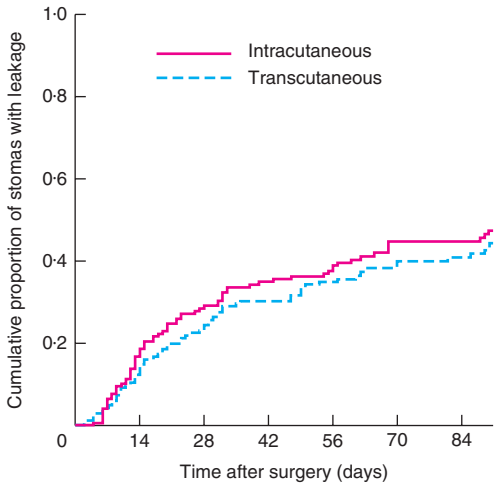
Primary outcome

Leakage of any severity occurred more frequently than expected in the IC and TC groups (52·4 and 41·4 per cent respectively) (*Table 3*). The overall leakage rate was significantly higher with use of intracutaneous sutures (RD 11·0 (95 per cent c.i. 0·3 to 21·2) per cent; number needed to treat 9, 95 per cent c.i. 5 to 316). The leakage rate was not significantly different between the suture types in the minimal, mild, moderate and severe subgroups. Data were missing with respect to the primary outcome in eight of 339 patients.

A regression analysis was carried out including sex, BMI, ASA grade, smoking status, neoadjuvant therapy, indication for stoma, surgical procedure, stoma type, high output, suture material, and whether the procedure was performed by a surgeon or resident. None of these parameters was found to be a significant independent predictor of leakage. Time to first occurrence of leakage is shown in a Kaplan–Meier plot (*Fig. 3*). Leakage occurred mostly between 14 and 31 days after operation.

Secondary outcomes

There was no difference in stoma-specific QoL between the two groups after 1 and 3 months. At 1 month, the



No. at risk

Intracutaneous	170	157	143	129	115	101	87
Transcutaneous	169	153	139	125	111	97	83

Fig. 3 Kaplan–Meier plot showing time to occurrence of faecal leakage after intracutaneously *versus* transcutaneously sutured ileostomy

mean(s.d.) QoL score was 72·9(13·4) for the IC group *versus* 71·3(13·5) for the TC group.

No differences were found between groups in other stoma-related complications (*Table 4*). Mild-to-severe skin irritation occurred in 78·2 and 72·2 per cent of patients in the IC and TC groups respectively. The occurrence of skin irritation around the stitches or owing to leakage of faeces did not differ between the two groups (*Table 4*). There was a relatively high incidence of high output from the ileostomy (more than 1500 ml per 24 h) and stoma retraction in both groups.

Rates of general complications were similar in the two groups (*Table 4*). In the IC group, there were 12 readmissions owing to leakage (6 patients) and skin irritation (6 patients); in the TC group there were nine readmissions because of leakage (3 patients) and skin irritation (6 patients) (RD 1·7 (95 per cent c.i. −7·2 to 3·7) per cent). Five patients were reoperated owing to severe leakage and/or skin irritation (sometimes due to dehiscence or retraction) in the IC group compared with six in the TC group (RD 0·7 (−5·0 to 3·6) per cent).

Mean total material costs during the first 3 months were €648·90 (s.d. €332·40) for intracutaneously sutured ileostomies and €622·20 (s.d. €301·20) for transcutaneously sutured ileostomies; this difference was not significant.

There were no differences in pH of the faecal matter between the IC and TC groups after 2 weeks (mean(s.d.) 6·36(0·52) *versus* 6·45(0·52) respectively) and 2 months (6·46(0·44) *versus* 6·42(0·47)). The majority of faecal cultures were sterile (89·7 per cent in the IC group and 94·9 per cent in the TC group); the positive ones did not show any differences in bacterial cultures between the randomization groups (mostly *Staphylococcus aureus*). No correlation was found between positive cultures and skin irritation.

Table 4 Complications

	Intracutaneous sutures ($n = 170$)*	Transcutaneous sutures ($n = 169$)*	Risk difference (%)†
Stoma-related			
Skin irritation	133 (78·2)	122 (72·2)	6·1 (−3·2, 15·1)
Necrosis	3 (1·8)	6 (3·6)	−1·5 (−6·0, 2·8)
Fistula	0 (0)	2 (1·2)	−1·4 (−4·9, 1·3)
Prolapse	1 (0·6)	3 (1·8)	−1·4 (−5·3, 1·9)
Retraction	18 (10·6)	13 (7·7)	3·1 (−3·7, 9·9)
Granulomas	2 (1·2)	1 (0·6)	0·6 (−2·6, 4·1)
High output	27 (15·9)	23 (13·6)	2·2 (−6·0, 10·4)
Parastomal hernia	3 (1·8)	9 (5·3)	−3·5 (−8·7, 1·1)
General			
Surgical-site infection	14 (8·2)	13 (7·7)	0·4 (−6·0, 6·8)
Abdominal abscess	8 (4·7)	13 (7·7)	−2·9 (−8·9, 2·8)
Ileus	26 (15·3)	31 (18·3)	−3·3 (−11·9, 5·3)
Abdominal dehiscence	2 (1·2)	0 (0)	1·3 (−1·4, 4·7)
Anastomotic leakage	9 (5·3)	6 (3·6)	1·9 (−3·2, 7·1)
Pneumonia	5 (2·9)	6 (3·6)	−0·8 (−5·4, 3·7)
Urinary tract infection	5 (2·9)	13 (7·7)	−4·9 (−10·6, 0·3)
Other	35 (20·6)	25 (14·8)	6·2 (−2·6, 14·8)

Values in parentheses are *percentages and †95 per cent confidence intervals.

Discussion

In this RCT, intracutaneous suturing of the ileostomy was not found to be superior to transcutaneous suturing with regard to peristomal leakage of faeces. In fact, the overall leakage rate was significantly higher in the IC group, which is the opposite of the authors' hypothesis that transcutaneous suturing would foster leakage.

The incidence of stoma-related complications was high in this study. About three-quarters of all patients developed a complication up to 3 months after creation of the stoma, mainly due to leakage and skin irritation. These complications may seem trivial, but have a substantial influence on patients' QoL and social functioning. The incidence of stoma-related morbidity is in agreement with published rates of 21–60 per cent[2]. This is likely to be due to the high output of ileostomies compared with colostomies. Another explanation might be the trial setting, in which stoma therapists regularly and scrupulously checked for the presence of complications, whereas in other studies the opinion of the treating surgeon was considered. From a medical point of view, the majority of these complications were mild to moderate. Because of the high rate of faecal leakage, the RD of 11·0 per cent noted after 3 months reached statistical significance, although the study was powered to detect a 15 per cent risk difference.

The occurrence of skin irritation in this trial surpasses the leakage rate reported in the literature. Skin irritation can be due to the stoma plate or actual leakage. In addition, the observed difference between leakage and skin irritation rates could be explained by varying perceptions of the assessors. However, the authors tried to minimize subjective differences in the present study by providing photographs showing ileostomies with complications of different degrees of severity on the trial website, for use as a uniform scoring tool.

Published data on the optimal suturing technique for ileostomies are lacking. Recently, Uchino and colleagues[23] compared interrupted *versus* subcutaneous suturing in a group of patients with ulcerative colitis who had an end ileostomy. Use of interrupted sutures was associated with significantly more dehiscence, but leakage was not mentioned. The authors concluded that removal of the sutures was an unnecessary manipulation and probably caused more dehiscence. Other endpoints in that study showed no significant differences.

Although the costs of stoma materials used and surgical reinterventions in both groups were considerable, these costs did not differ between the groups in the present study. Perhaps, and whenever possible, earlier reversal of an ileostomy could reduce these costs[24]. The pH values recorded were not notably different from physiological values and there were only a few positive cultures. It is therefore unlikely that these characteristics had any influence on the high incidence of skin irritation. Stoma-specific QoL did not differ significantly between groups. This is to be expected taken the lack of differences in complication rates, which have a proven adverse effect on QoL.

The follow-up time of 3 months was relatively short. However, most complications, in particular peristomal leakage, commonly occur within this time frame and a substantial number of ileostomies are usually reversed after this interval. In addition, the complication rate was high, possibly owing to the trial setting as stoma therapists made regular thorough checks for the presence of complications.

Collaborators

Other members of the ISI trial study group are: M. U. van Grevenstein (University Medical Centre Utrecht, Utrecht); S. C. Veltkamp (Amstelland Hospital, Amstelveen); P. L. Tolenaar (Bovenij Hospital, Amsterdam); A. W. J. M. van de Laar (Slotervaart Hospital, Amsterdam); G. D. Slooter (Maxima Medical Centre, Veldhoven); D. J. A. Sonneveld (Westfriesgasthuis, Hoorn).

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