

Is Early Reversal of Defunctioning Ileostomy a Shorter, Easier and Less Expensive Operation?

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Abstract

Background A defunctioning loop ileostomy mitigates the consequences of anastomotic leak from low rectal anastomosis but it is associated with significant morbidity. In this study, the outcome of early reversal of defunctioning ileostomy during the same admission with the primary operation was assessed.

Methods This randomized study was carried out at York Teaching Hospital during the period 2003–2007. All patients with defunctioning ileostomy were considered for an early second operation if they had an uneventful recovery and were in good general condition. Patients on steroids, at high cardiorespiratory risk and those experiencing any postoperative complication were excluded. Eligible patients with satisfactory gastrografin enema on postoperative day 6 were randomized to early versus late reversal at 6–8 weeks. Outcome measures were ease of closure as assessed by a visual analog scale by the operating surgeon, all postoperative complications, duration of the operation, total length of hospital stay and associated costs.

Results Thirty-nine consecutive patients were assessed for eligibility and finally 26 were included in the study. Sixteen patients underwent early reversal. The median(interquartile range (IQR)) age was 62(22) years. Early reversal was significantly superior in terms of ease of abdominal wall closure, ease of reversal ($p < 0.01$ each), duration of the operation (median(IQR) 20(13) vs. 40(9) min, $p < 0.01$) and costs of stoma care (median(IQR) 27(9) vs. 311(108) £, $p < 0.01$). There were no major (grade III/IV) complications in either group. Total length of hospital stay was similar between groups.

Conclusion In carefully selected patients, early reversal of defunctioning ileostomy is feasible, technically easier and has shorter operative time which can also lead to significant cost savings.

Introduction

Diverting ileostomy seems to mitigate the consequences of anastomotic leak from low rectal anastomosis. Gastrointestinal continuity is restored after a period of

6–12 weeks but it can be longer if the patient is on adjuvant chemotherapy or due to low priority given to this procedure [1]. This exposes up to one-third of the patients to significant morbidity having an impact on the quality of life and considerable economic costs. Earlier reversal of ileostomies a few days after primary anastomosis reduces the length of exposure to stoma-related morbidity and may improve quality of life, reduce stoma-related costs and still protect the distal anastomosis [2–4]. Herein, we aimed to assess the results of early closure of defunctioning ileostomy following satisfactory gastrografin enema.

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Methods

Approval was obtained from the local ethics committee. Between Jan 2004 and Aug 2007, all consecutive patients under a single colorectal consultant, having a defunctioning ileostomy during a low rectal or anal anastomosis, were considered eligible and offered to participate in the trial. Patients currently on steroids, at high cardiorespiratory risk and those experiencing any postoperative complication were excluded. High cardiorespiratory risk was defined as anaerobic threshold value $<11 \text{ ml min}^{-1} \text{ kg}^{-1}$. Informed written consent was obtained from the patients. On day 6 after the operation, a water-soluble gastrografin enema was performed to check the integrity of the anastomosis. Patients who showed a radiological leak were excluded from the study. The remaining patients were randomized into early and late reversal groups using sealed envelopes. The early reversal group had the stomata reversed the following day. The late reversal group were discharged home and brought back after an interval of 8 weeks for reversal. All procedures were performed by the same senior surgeon. Height of anastomosis was always below 10 cm and always below the level of sacral promontory. Closure of wound was done with linear interrupted sutures. The duration of the operation was noted and the ease of reversal of stoma and closure of abdominal wall were assessed on a scale of 0–100 (0 = difficult, 100 = easy) by the operating surgeon. Postoperative complications were recorded in concordance with the definitions of Dindo et al. [5]. Costs associated with stoma care (consumables and nurse visits) were calculated. Of thirty-nine consecutive patients who had a defunctioning ileostomy during the study period, 26 patients were eligible for a second early operation. Reasons of exclusion are presented in the CONSORT diagram (Fig. 1). Twenty-six patients were randomly assigned to undergo early closure of their defunctioning stomas ($n = 16$) or conventional closure ($n = 10$). Baseline and preoperative characteristics of the patients are presented in Table 1. There were no consent withdrawals or other patients' exclusions. Indications of primary operation were benign disease ($n = 14$) and rectal cancer ($n = 12$). Six patients received preoperative chemoradiation. Data were analysed using SPSS[®] for Windows[®] version 13.0 (SPSS[®], Chicago, Illinois, USA).

Results

Median(interquartile range) time from primary anastomosis to stoma closure was 8(2) days in the early group versus 57(38) days in the late group (Table 1). There was no major complication related to the stoma reversal in either

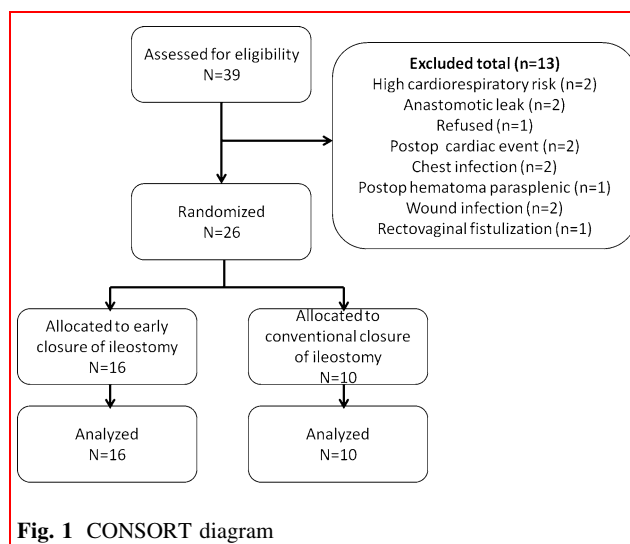


Table 1 Preoperative and perioperative characteristics of early versus late defunctioning ileostomy

	Early closure ($n = 16$)	Late closure ($n = 10$)
Male:female	10:6	5:5
Age	63(24)	61(24)
Indication of pelvic surgery		
Benign disease	9	5
Cancer	7	5
Preoperative treatment		
Chemoradiotherapy	4	2
None	12	8
Type of anastomosis		
Colorectal	12	9
Ileal pouch anal	4	1
Delay until stoma closure (days)	8(2)	57(38)
Postoperative complications		
No	12	9
Yes	4	1
Duration of operation (min)	20(13)	40(9)*
Ease of abdominal wall closure**	80(14)	38(32)*
Ease of closure**	83(22)	35(23)*
Total length of hospital stay (days)	14(3)	14.5(4)*
Cost of stoma care (£)	27(9)	311(108)*

Brackets next to numbers represent median(interquartile range) values

* Mann–Whitney *U* test two-tailed significance <0.01

** Ease of closure assessed by visual analog scale 0–100 (0 = difficult, 100 = easy)

group. In the early reversal group, two patients developed wound infection, one urinary retention and one ileus. In the late group, one patient developed postoperative ileus. All complications were treated conservatively. Median

duration of the operation was significantly shorter in the early group ($p < 0.01$). Closure of the abdominal wall and ease of ileostomy reversal were significantly easier in the early group ($p < 0.05$). There was no significant difference in the median total length of stay between the two groups.

Discussion

This is the first study to report on the ease of early closure of ileostomy. In all cases, closure was straight forward without the need of sharp dissection to mobilize the bowel from the stoma site. Minor oedema of the bowel wall due to recent surgery did not seem to compromise closure with the use of staplers in any patient. This may not only decrease the risk of inadvertent injury to the bowel but may also decrease the operating time significantly. Indeed, operative time was half in early versus delayed closure which may have cost implications and may also facilitate patient's recovery from general anaesthesia. Interestingly, in the randomized study of Alves et al. no difference in the duration of the operation was observed [2]. The mean operative time in this trial was double the one reported here even in the delayed closure group reaching 90 min. One possible explanation may be that in our study all operations were done by the same experienced consultant surgeon.

Prospective and retrospective studies show that stoma-related complications increase from around 5 % to more than 30 % from the 10-day follow-up to the 3-month follow-up [6, 7]. Peristomal dermatitis, dehydration, electrolyte abnormalities, parastomal hernia and bowel obstruction not only delay or disrupt adjuvant treatments but also put patients' lives in danger. Stoma-related problems such as low sexuality, body image concerns (difficulty with clothing, feeling unattractive) and practical concerns related to the stoma itself, such as finding privacy to empty the bag and problems with leakage, have a negative impact on the overall quality of life [8]. There is only one prospective randomized trial comparing early (8 days) versus late (8 weeks) reversal of defunctioning ileostomy [2]. This study has shown no significant difference in the frequency of complications between groups, but there were significant differences in the type of complications. Early closure group had significantly higher wound complication rates and late group had more cases of small bowel obstruction and stoma-related complications. These results are difficult to interpret because in this study antegrade contrast studies failed to show anastomotic leak in all the patients who needed reoperation with this indication. It is difficult to predict how this could have affected the main outcomes of the study but most would agree that engaging to early reversal of ileostomy without confidence about the integrity of anastomosis has tremendous implications for

patients' safety. There are no studies evaluating imaging methods to detect anastomotic leak in asymptomatic patients. In patients with clinically apparent leak, water-soluble contrast enema and CT with rectal contrast are recognized as diagnostic methods of choice in a recent systematic review [9]. In this study, we used water-soluble contrast enema and experienced no incident of leakage after ileostomy reversal. Similar results were reported from small prospective and retrospective studies [1, 7, 10].

We recommend routine early reversal of defunctioning ileostomies in selected patients who experience an uncomplicated postoperative recovery after their primary pelvic surgery, and they do not show any evidence of anastomotic leak when gastrografin enema was administered on the 6th to 7th postoperative day. We do not recommend early reversal for patients on steroids who might be at higher risk even for late anastomotic leak and for patients with any postoperative complication, particularly the septic ones as it is the case with every elective procedure. Patients at high cardiorespiratory risk at cardiopulmonary exercise test were excluded from the study under the consideration that they might not tolerate the stress of a second early procedure while they are still recovering from the first one. However, this notion has not been substantiated in more recent studies, so we do not consider any more high cardiorespiratory risk as an absolute contraindication for early reversal [1, 2, 11]. Careful selection of the patients is crucial to maintain low overall postoperative morbidity which is the aim of early reversal. In our study, one-third of the patients with loop ileostomy were not deemed appropriate for early reversal. Selection rates in other prospective and retrospective studies which apply similar eligibility criteria range between 38 and 66 % [3, 4, 10].

Cost savings resulting from early versus late ileostomy reversal have been recently reported in a study involving 103 patients. Direct hospital costs were compared and early closure reduced about 25 % healthcare costs despite higher wound infection rates. This resulted from lower rate of ileostomy complications, fewer hospital readmissions and operative costs [12]. In the present study, cost savings due to stoma care reached 300£ per patient.

Nevertheless, our results should be interpreted cautiously due to several sources of bias. First of all, the number of patients and the number of recorded complications were small. With larger samples, differences in the complication rates may become apparent between groups. Small number of patients and chance resulting from simple randomization explains the disparity in the size of two groups (16 vs. 10). Very short operative times may result from the fact that this is a single centre study and all the operations have been performed by the same experienced surgeon. Assessment of ease of closure was subjective and

could not be blinded to the operating surgeon. Therefore, ease of closure scores may have favoured the early group. However, significantly shorter operative time in the early closure group supports further the notion that closure was easier in the early group. Another area of weakness of the study is the significant delay in the publication of the results since the patients have been included before 2007. This might limit theoretically the applicability of our findings to current patient cohorts even though there have not been any significant advancements in the management of defunctioning ileostomy during these years. The main reason for the delay was low prioritization and loss of interest of the contemporary research team because of the slow recruitment rate. However, the results of this study were sufficient to change safely the practice in our department regarding ileostomy reversal and, in the lack of robust data on the subject until now it was felt it would be useful to add our evidence to the existing body of literature.

So, many questions remain unanswered and many appropriately designed studies overcoming the aforementioned limitations are necessary. As such, the EASY trial (NCT01287637) of the Scandinavian Surgical Outcomes Research Group has already finished recruitment of 200 patients from Sweden and Denmark and first results are awaited in the beginning of 2016 [11].

In conclusion, in this study early closure of defunctioning ileostomy in carefully selected patients was feasible, easier and was associated with shorter operative time and therefore significant cost savings.

Compliance with ethical standards

Conflict of interest Authors declare no conflict of interest.

References

1. Omundsen M, Hayes J, Collinson R et al (2012) Early ileostomy closure: is there a downside? *ANZ J Surg* 82:352–354
2. Alves A, Panis Y, Lelong B et al (2008) Randomized clinical trial of early versus delayed temporary stoma closure after proctectomy. *Br J Surg* 95:693–698
3. Bakx R, Busch OR, van Geldere D et al (2003) Feasibility of early closure of loop ileostomies: a pilot study. *Dis Colon Rectum* 46:1680–1684
4. Menegaux F, Jordi-Galais P, Turrin N et al (2002) Closure of small bowel stomas on postoperative day 10. *Eur J Surg* 168:713–715
5. Dindo D, Demartines N, Clavien PA (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 240:205–213
6. Robertson I, Leung E, Hughes D et al (2005) Prospective analysis of stoma-related complications. *Colorectal Dis* 7:279–285
7. Bakx R, Busch OR, Bemelman WA et al (2004) Morbidity of temporary loop ileostomies. *Dig Surg* 21:277–281
8. Neuman HB, Patil S, Fuzesi S et al (2011) Impact of a temporary stoma on the quality of life of rectal cancer patients undergoing treatment. *Ann Surg Oncol* 18:1397–1403
9. Hirst NA, Tiernan JP, Millner PA et al (2014) Systematic review of methods to predict and detect anastomotic leakage in colorectal surgery. *Colorectal Dis* 16:95–109
10. Jordi-Galais P, Turrin N, Tresallet C et al (2003) Early closure of temporary stoma of the small bowel. *Gastroenterol Clin Biol* 27:697–699
11. Danielsen AK, Correa-Marinez A, Angenete E et al (2011) Early closure of temporary ileostomy—the EASY trial: protocol for a randomised controlled trial. *BMJ Open* 1:e000162
12. Robertson J, Linkhorn H, Vather R et al (2015) Cost analysis of early versus delayed loop ileostomy closure: a case-matched study. *Dig Surg* 32:166–172