



A Successful Nine-Step Concept to Reduce the Risk of Perineal Infections after Abdominoperineal Resection of the Rectum

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Abstract

Objective: Infections and wound healing problems after abdominoperineal resection of the rectum (APR) are common. In 2013, a retrospective review of consecutive APRs in 2010-2012 was performed at Skaraborg Hospital, Skövde, Sweden. The review showed that 66 % (27 out of 41) of the patients, who were operated on in the prone jack-knife position, had a perineal infection and wound healing problems. Because of these alarming results, we scrutinized every step of the perioperative care process and created a nine-step concept. The aim of this study was to determine whether the introduction of this intervention had resulted in a decrease in postoperative perineal infections and the length of perineal wound healing in patients undergoing APR.

Methods: A prospective study during 2013-2014 included 41 consecutive patients who had undergone APR. The diagnoses were rectal cancer (n=36), Crohn's disease (n=2), ulcerative colitis (n=2), and familial polyposis (n=1). A comparison was made with the consecutive historical controls from 2010-2012. Time to wound healing was recorded and the severity of the infection was classified according to a modified Clavien Classification of Surgical Complications. Clinical data were collected from the Swedish ColoRectal Cancer Registry.

Results: After the introduction of the nine-step concept the infection rate was reduced from 66 % to 10 % (p< 0.001).

Conclusion: The nine-step concept significantly reduced the perineal infections after APR. Fewer infections mean less suffering for the patient and substantially reduced use of health care resources.

Keywords: Perineal infections; Abdominoperineal; Anaesthesia

Introduction

Abdominoperineal (APR) resection of the rectum is frequently associated with perineal wound healing problems and infections, especially after neoadjuvant radio chemotherapy, where wound problems have been reported in up to 50% of patients [1,2]. Postoperative complications may delay the initiation of postoperative chemotherapy [3]. In addition to the direct suffering of the affected patients, the cost implications for the health care system are substantial, as patients with perineal infections require prolonged hospital stays, hospital readmissions, home-nursing wound care after discharge and multiple outpatient visits [4]. Delayed perineal wound healing may also involve a risk of persistent symptoms such as pain, paraesthesia, sitting disability, tension, tingling and cramps [5].

To perform the perineal part of the procedure in the jack-knife position (JKP) has gradually become the standard approach in Sweden. At Skaraborg Hospital, Skövde, we introduced the JKP in 2010. After this change we noticed an increased rate of perineal infections. To identify the true incidence of infections and wound healing problems, a retrospective review was performed using consecutive data from 82 medical records from 2007-2012, including 41 patients operated in the lithotomy position (2007-2009), versus 41 patients in the JKP (2010-2012). Wound healing took significantly longer and infections were more common in patients operated in the JKP, 66%, compared with the earlier lithotomy position, with 28% (p< 0.001). These results have been presented, in part, at the National Swedish Congress for Surgeons, 2013. Thus, perineal complications after APR are a clinical problem, regardless of patient positioning [2,6].

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Table 1: Data comparing the retrospective group operated on in the JKP before the intervention and the patients in the present, prospective study (T test, Mann-Whitney U test).

	JKP before intervention n = 41 (24 men and 17 women)	JKP after intervention n= 39 (25 men and 14 women)	p value
Age (median)			
Men	70	71	0.624
Women	75	76	0.544
Diagnosis (count)			
Cancer	37	34	0.657
Ulcerative colitis	3	2	
Crohn's disease	1	2	
Familial polyposis	0	1	
Preoperative radiotherapy			
Yes	30 (81%)	26 (67%)	0.154
No	7 (19%)	13 (33%)	
Laparoscopic surgery	17 (43%)	25 (64%)	0.043
Open surgery	24 (57%)	14 (36%)	
Perioperative bleeding (mean, SD)	393 (372)	353 (349)	0.563
CRM mm (median)	4	6	0.162
pT stadium	36 (1 missing)	32 (2 missing)	
pT stadium 0	0	1 (3%)	0.144
pT stadium 1	3 (8%)	2 (6%)	
pT stadium 2	10 (28%)	16 (50%)	
pT stadium 3	20 (56%)	13 (41%)	
pT stadium 4	3 (8%)	0	
Bowel perforation (count)	3	4	0.483
Diabetes	4 (10%)	5 (13%)	0.665
Steroids	3 (7%)	6 (15%)	0.254

Ten of the patients in the retrospective review who had postoperative infections were interviewed. They described a substantial impact on quality of life, with problems of pain, leakage, abscesses, smell, social isolation and loss of integrity, and extended periods of hospitalization [7].

Following these alarming data, we scrutinized each step of the perioperative care process, and a new nine-step concept was created in order to improve the situation for these patients.

The aim of this study was to explore whether the new concept would decrease the incidence of postoperative perineal infections in patients undergoing APR.

Methods

As a quality improvement project, a prospective study was performed during 2013-2014, including 41 consecutive patients who underwent APR in the prone position (JKP) and were treated according to the new nine-step concept. This prospective group was compared, with regard to postoperative perineal infection, with a retrospective group of 41 consecutive patients, who had undergone APR in the JKP just prior to the introduction of the new nine-step concept, as historical controls. All patients were operated on according to the TME method. No extralevator abdominoperineal excisions were performed. cT4 tumours were referred to the regional university hospital and are thus not included in this series. The indications for surgery were similar in the two groups (Table 1). Two different methods were used to measure wound healing: 1) Time

to perineal wound healing, assessed by the stoma therapists at the outpatient clinic; a completely healed wound within one month was considered normal, and 2) Classification of the severity of the wound complications, by a modified Clavien-Dindo Classification of Surgical Complications [8] (Table 2). Clinical data were also collected from the Swedish ColoRectal Cancer Registry. The study was approved by the regional Ethical Committee in Gothenburg (Reg. no: T941-13).

Statistical analysis

The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS version 22-0). The T test and the Mann-Whitney U test were applied to a univariate analysis of the data. There was no difference between the group before and the group after the intervention with respect to the variables in (Table 1). To control for possible confounders, we applied a multivariate logistic regression model with infections as outcome and surgical approach, TNM stage and preoperative radiotherapy as covariates.

The new concept

The new concept was created after a consensus meeting in a group including the colorectal surgeons, stoma therapists, and nurses from the surgical ward, anaesthesia department and the outpatient clinic. The changes to the perioperative routines are referred to as "the nine-step concept". Apart from this new, nine-step concept, nothing else was changed in the perioperative care.

The Nine Step - Concept

1) A small enema (120 ml), for mechanical bowel preparation, is

Table 2: Classification of wound healing and postoperative infections.

	Classification of time to perineal wound healing	Classification of the severity of postoperative infections
0)	Wound heals > 0 - ≤ 1 month	Normal wound healing, i.e., completely healed without any problems within a month.
1)	Wound heals > 1 - ≤ 3 months	Deviates from the norm but does not require major action (tape gap, the wound not quite healed, some yellow and sticky debris)
2)	Wound heals > 3 - ≤ 5 months	Unhealed wounds that require wound dressing and/or flushing, or antibiotics
3)	Wound heals > 5 - ≤ 7 months	Unhealed wounds that require surgical treatment (revision/drainage)
4)	Wound heals > 7 - 10 ≤ months	Unhealed wounds requiring surgery (anaesthesia/VAC)
5)	Wound heals > 10 months	Life-threatening complications (ICU/sepsis, organ failure)

administered in the evening before surgery and in the morning on the day of surgery to minimize the risk of faecal leakage to the operation site (responsible: surgical ward).

2) The operation starts with a perineal antibacterial wash with Descutan[®], after which the anus is closed with double rows of sutures to minimize the risk of faecal leakage to the operation site. This step is completed with a repeated antibacterial wash. Thereafter the abdominal part of the operation is performed and completed (responsible: operating team).

3) The patient is placed in the prone position/JKP: According to our guidelines for antibiotic prophylaxis, one dose of Cefuroxime (1.5g) and one dose of Metronidazole (1g) are administered preoperatively. In the new concept, an additional dose of 1.5g Cefuroxime is given before the perineal part of the operation starts. This is occasioned by the short duration of cefuroxime, with a T_{1/2} of 70 minutes, and the start of the perineal phase is often more than three hours after the start of the operation (responsible nurse anaesthetist).

4) The levators are divided only as far laterally as oncologically needed, according to the preoperative MRI results, to minimize tissue loss and tissue tension (responsible: surgeon).

5) The levators are closed with antibacterial sutures, 2-0 PDS Plus[®] (polydioxanone with triclosan) [9] (responsible surgeon).

6) Septocoll[®] or Collatamp[®] (gentamicin-impregnated collagen fleece), 5 x 10 cm, is inserted immediately above the levators before they are closed, for a local antibiotics deposit [10] (responsible surgeon).

7) Active Univac Ch10 drainage is placed beneath the levators via a separate incision to avoid pooling of wound secretion (responsible surgeon). The drainage is usually removed on day 2 postoperatively.

8) Subcutaneous tissues are sutured with antibacterial suture 2-0 Monocryl Plus[®] (with triclosan) [9] (responsible surgeon).

9) Postoperatively, a seat ring is mandatory to reduce compression of the wound (responsible: surgical ward).

Results

A comparison of the data for the retrospective group operated in the JKP before the introduction of the nine-step concept and the consecutive patients in this prospective study showed no significant difference in background data between the two groups, except for laparoscopic vs. open surgery ($p < 0.043$) (Table 1).

Perineal infections were registered for a total of 10% of the patients in the prospective group, compared with 66% in the retrospective group ($p < 0.001$). The infection rate remained significantly reduced after intervention (OR=0.05; 95%CI 0.01-0.3) also when we applied a multiple model including TNM stage (OR=7.04; 95%CI 1.8-

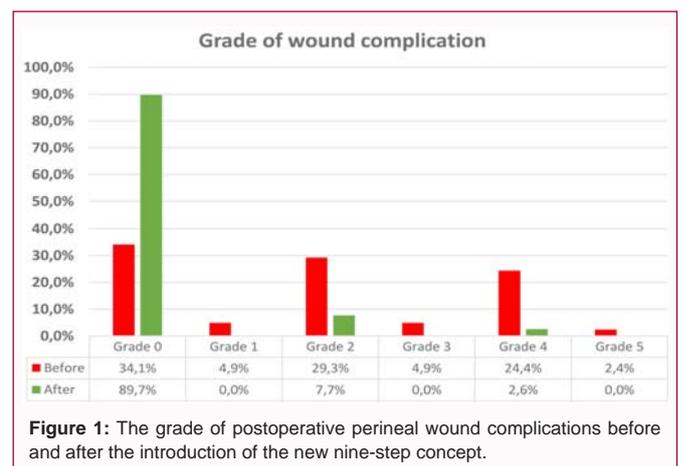


Figure 1: The grade of postoperative perineal wound complications before and after the introduction of the new nine-step concept.

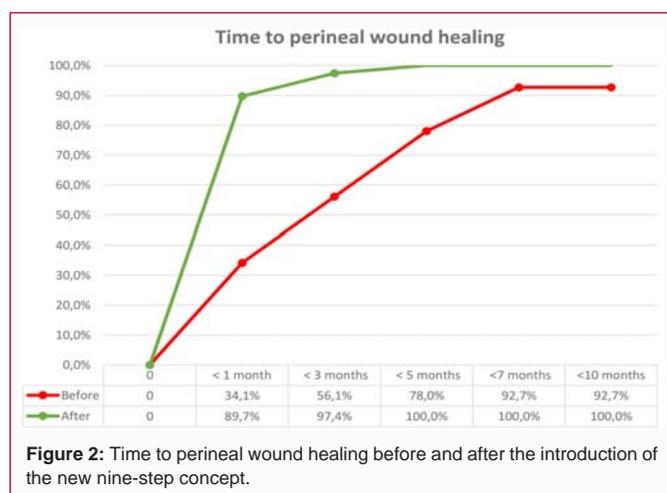
27.7), preoperative radiotherapy (OR=1.52; 95% CI 0.20-11.6) and surgical approach (open surgery OR=1.65; 95% CI 0.34-8.11). The postoperative infections were also less severe in the prospective group (Figure 1). The time to perineal wound healing was shorter in the prospective group compared with the retrospective group (Figure 2). Four patients in the prospective group developed a postoperative infection. Three patients had a superficial infection, which healed within three months. One patient had a severe infection that required surgery. This patient died after four months, still having a perineal infection, and is included in the analysis.

Two patients died within 30 days after surgery (one of stroke and one of circulatory collapse), and were excluded from the analysis.

No differences in the oncological results were seen in our study.

Discussion

This study showed that this new concept of preoperative enema, dual anal suturing and disinfection, additional prophylactic antibiotics, moderate levator excision, antibacterial sutures, antibiotic-impregnated collagen, perineal drainage and postoperative seat ring use is effective. To be able to assess wound healing and postoperative infections we modified the Clavien-Dindo classification of surgical complications [8], to make it more suitable for different grades of postoperative perineal problems. Small infections also affect patients and increase the costs for society, for example, in terms of change of dressings, extra visits to district nurses and outpatient clinics, need for longer sick leave, etc. For those reasons we decided to identify and report every deviation from "the normal" as a problem. The extreme infection rate noted after introducing the JKP, and before introduction of the new concept, is high when compared with other studies [2,6]. One explanation could be that we recorded all disturbances in terms of perineal postoperative infections and wound healing. Minor problems are often not accounted for in the literature. In the Swedish



ColoRectal Cancer Registry (SCRCR), the recording of complications (such as infections) starts with Clavien-Dindo II and ends 30 days postoperatively. In this study, we discovered, as in other studies [11], that a number of perineal infections occurred later than 30 days after the index operation (Table 2). In a validation of the SCRCR, it was shown that 22% of surgical complications were missed [12]. This is in accordance with our findings, where a comparison showed that 20% of the perineal complications would have been missed if only the registry had been used. The same Clavien-Dindo scale has been used in all three cohorts of patients (before JKP retrospectively, after JKP retrospectively, and in this prospective study), but in the first two historical cohorts, we classified the patients retrospectively from case records and the registry. Some minor infections may therefore have been missed in the retrospective groups, but in this prospective study group, all wound problems have been accounted for.

The strength of this study is the design with consecutive patients without dropouts. The two study groups are comparable with respect to gender, age, preoperative diagnosis, diabetes, steroid medication, and perioperative bleeding and bowel perforation (Table 1). The study was performed in one department, with the same staff, and with the same surgeons performing the surgery throughout the whole study period.

There are some limitations to the study, as it is not randomized and the controls are historical. However, since we had an unacceptably high infection rate and long wound healing time, we felt that it would be unethical to perform a randomized study. The sample size is small, but patients are consecutive APR cases before and after the intervention. There are some differences between the groups, such as a tendency towards less preoperative radiotherapy and lower tumour stages in the intervention group. Both these differences could contribute to fewer infections. However, these differences are not statistically significant. The only statistical difference between the two groups is that the abdominal part of the operation was performed by laparoscopy in more patients in the intervention group (64% vs. 43%, $p < 0.043$). This fact should not influence the perineal part of the operation, but it has been suggested that the immunological response is less affected after laparoscopy compared with open surgery [13], which may also influence the infection rates.

Which of the nine steps in the concept are the key factors? Two main differences can be recognized, for instance, the early closure of the anus with a double row of sutures and the extra dose of antibiotics (Cefuroxime). The early closure of the anus resembles what we did

in the supine position and could prevent leakage of fluid and stools contaminating the perineal skin. Before the concept was introduced, this closure was postponed until after the patient was turned to the JKP.

Our choice of prophylactic antibiotics includes Cefuroxime with a short half-life. An extra dose was therefore given just before the start of the perineal part of the operation, to ensure good MIC values in the operating area. The perineal dissection starts approximately 3-4 hours after the first administration of the antibiotic. The roles of perineal drainage, local antibiotics [10] and antibacterial sutures [9] are more difficult to assess. Hence, since the total concept works, we have not excluded any of the steps so far. The combined concept involves all perioperative steps of the patient care process and the whole team is aware of the process, as well as of their role in implementing the concept.

A further consideration, which could affect the outcome, might be the learning curve for the surgeons. We altered our positioning of the patient according to the JKP in the retrospective group from 2010. This means that the surgeons were more accustomed to the JKP in the prospective group in 2013-2014. However, the infections were evenly distributed in the retrospective group without any observed learning curve effect.

Postoperative wound complications are expensive. The costs include prolonged hospital stays, readmissions, surgery, home nursing care, repeated wound dressing, materials costs and outpatient visits. It is difficult to estimate the costs, but our hospital economist estimated the extra costs to at least €8800 per patient with complications. The results have huge implications for many patients. Prevention of an infection means less suffering for the patient and reduced health care expenditure.

This study highlights the importance of how team collaboration can improve results by introducing a multi-modal approach and a check-list to address a defined problem (such as the SSI rate). The alarm signal of an increasing number of postoperative problems came from the stoma therapists and the retrospective analysis confirmed their suspicions. The team discussed the situation and all steps of the perioperative care process were evaluated. We contemplated returning to the lithotomy position; however, the presumptive advantages of the JKP, such as better ergonomics, view and assistance, and potentially better oncological surgery with increased circumferential margins and fewer bowel perforations [14,15], convinced us to continue with the JKP.

Conclusion and Clinical Implications

In summary, after introducing a new concept, including nine perioperative steps during APR, we found a substantial reduction in the rate of postoperative perineal infections. The effect is promising, does not involve any expensive investments or special equipment, and is easy to implement in clinical practice. Fewer infections mean less suffering for the patient and substantially reduced use of health care resources.

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