




## ORIGINAL ARTICLE

# Perineal healing following salvage surgery for anal cancer

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## Abstract

**Aim:** Approximately 25% of anal cancer patients undergo abdominoperineal excision or more extensive surgery. Following surgery, a high perineal complication rate has been reported. Enhanced recovery after surgery (ERAS) is an evidence-based multimodal interventional programme introduced to mitigate the risk of complications. This study aims to describe perineal healing in relation to ERAS compliance, type of resection and method of perineal reconstruction in patients with anal cancer after salvage surgery.

**Method:** This is a retrospective cohort study including all patients undergoing abdominal surgery for squamous cell anal cancer in Stockholm between January 2005 and December 2015. Data collection was from registers supplemented by chart review. All patients were followed until death or 1 year after surgery. The associations between ERAS compliance, patient and treatment characteristics and perineal wound healing were evaluated using logistic regression.

**Results:** In total, 101 patients (67 women) were included, of whom 72 were ERAS compliant. Of patients alive, healing after surgery occurred in 61/98 and 84/89 at 3 months and 1 year, respectively. Perineal healing at 3 months was statistically significantly associated with younger age and type of perineal reconstruction (in favour of vertical rectus abdominis myocutaneous flap). No associations were observed at 1 year but almost all wounds were healed.

**Conclusion:** Age and type of perineal reconstruction appear to be significantly associated with improved healing at 3 months whereas compliance to an ERAS protocol and type of resection do not. Nearly all patients had a fully healed perineal wound 1 year after surgery for anal cancer.

## INTRODUCTION

Squamous cell anal carcinoma (SCCA) is an uncommon disease primarily treated non-surgically [1]. However, in patients with a poor response to chemoradiation with either residual or recurrent tumour, surgery (often called 'salvage surgery') can be necessary.

In recent randomized trials approximately 20%–30% of patients eventually underwent surgery [2–4]. Anal cancer patients requiring surgery generally need at least an abdominoperineal excision (APE) but significant numbers require a posterior pelvic exenteration (PPE) or a total pelvic exenteration (TPE) to obtain clear margins [1].

High rates of perineal complications in anal cancer surgery have previously been reported [5,6] with improved results after the

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introduction of perineal reconstruction using musculocutaneous flaps [7,8]. Various flaps have been used but consensus on the optimal flap is lacking [9–11].

Enhanced recovery after surgery (ERAS) is an evidence-based multimodal perioperative interventional protocol introduced to decrease perioperative physiological stress [12]. ERAS has been shown to improve postoperative recovery and reduce complication rates, and adherence to an ERAS protocol has improved clinical and survival outcomes following colorectal surgery [13]. However, studies regarding any association between anal cancer surgery and ERAS and in particular perineal healing are lacking.

The aim of this study was to assess perineal healing rates in a consecutive cohort of anal cancer patients treated with salvage surgery in an ERAS setting.

## PATIENTS AND METHODS

A retrospective observational cohort study including all patients who underwent APE, PPE or TPE for SCCA in Stockholm, Sweden, between January 2005 and December 2015 was undertaken. Ethical approval for this study was obtained from the regional Swedish Ethical Review Authority (Dnr: 2017/1894-31/1). The study is reported in accordance with STROBE guidelines.

In the Stockholm-Gotland healthcare region in Sweden (population 2.4 million) all surgery with curative intent for SCCA is performed at either Ersta Hospital or Karolinska University Hospital. A regionally maintained register on all patients with SCCA was used to identify them. In-house registers of performed operations at the two hospitals were scrutinized for completion and detection of patients referred from other Swedish regions for surgery. Characteristics for each patient were collected retrospectively from (a) patient charts including operative notes, histopathology reports and reports from imaging and (b) data from the prospective international ERAS Interactive Audit System (erassociety.org). All patients were followed until 1 year from date of surgery or death, if sooner.

Data extracted from patient charts were age, gender, initial tumour stage according to TNM, fractionation and dose of radiotherapy, date of detection of tumour growth after conclusion of radiotherapy, operative details including type of resection (APE, PPE or TPE) and type of perineal reconstruction, complications (graded according to Clavien–Dindo), resection margins and perineal healing status at 3 months and 1 year. Patients in whom a tumour was detected within 6 months of conclusion of radiotherapy were categorized as having a residual tumour and patients with tumours detected later were classified as recurrent SCCA. Patients who had previously undergone APE and presented with a recurrence were classified as having a re-recurrence.

Perineal complications were graded as ‘minor’ if no intervention under general anaesthesia was necessary or ‘major’ if a procedure under general anaesthesia was performed. The perineal wound was defined as healed when patient charts revealed no signs of infection

### What does this paper add to the literature?

Compliance with an ERAS programme appears to be of limited value regarding perineal healing in anal cancer surgery. The magnitude of surgical intervention appears not to influence perineal healing but a vertical rectus abdominis musculocutaneous flap for perineal reconstruction is associated with improved healing 3 months after surgery.

or inflammation and the incision was fully epithelialized or covered by scar.

For all patients, the type of surgery was defined as APE, PPE (including an APE and removal of internal female genital organs with or without vaginal resection) or TPE (including APE and removal of the urinary bladder and female internal genital organs when present). The procedure performed was decided following preoperative imaging at a multidisciplinary team conference. During the study period, minimally invasive approaches were not used.

After completion of the abdominal procedure, patients were placed in the prone jack-knife position for the perineal resection and reconstruction. The perineal resection was performed according to extra-levator APE principles, although the levator muscles were not completely removed in all patients [14]. The type of perineal reconstruction was divided into three groups: (a) primary closure (with or without a mesh), (b) flap reconstruction using a gluteal myocutaneous flap or (c) flap reconstruction using a vertical rectus abdominis flap. The choice of perineal reconstruction was made by the attending colorectal surgeon and, where applicable, the reconstructive plastic surgeon.

All included patients were submitted to the institutional ERAS perioperative protocol. Data on ERAS compliance were extracted from the ERAS register, and missing data were collected from patient charts. Compliance with the ERAS protocol was defined as compliance with at least seven of the following eight ERAS items: preadmission counselling, no mechanical bowel preparation, preoperative carbohydrate drinks, no long-acting sedative premedication, epidural analgesia, intra-operative warming (e.g., Bairhugger™), antibiotic prophylaxis and thrombosis prophylaxis.

### Statistical methods

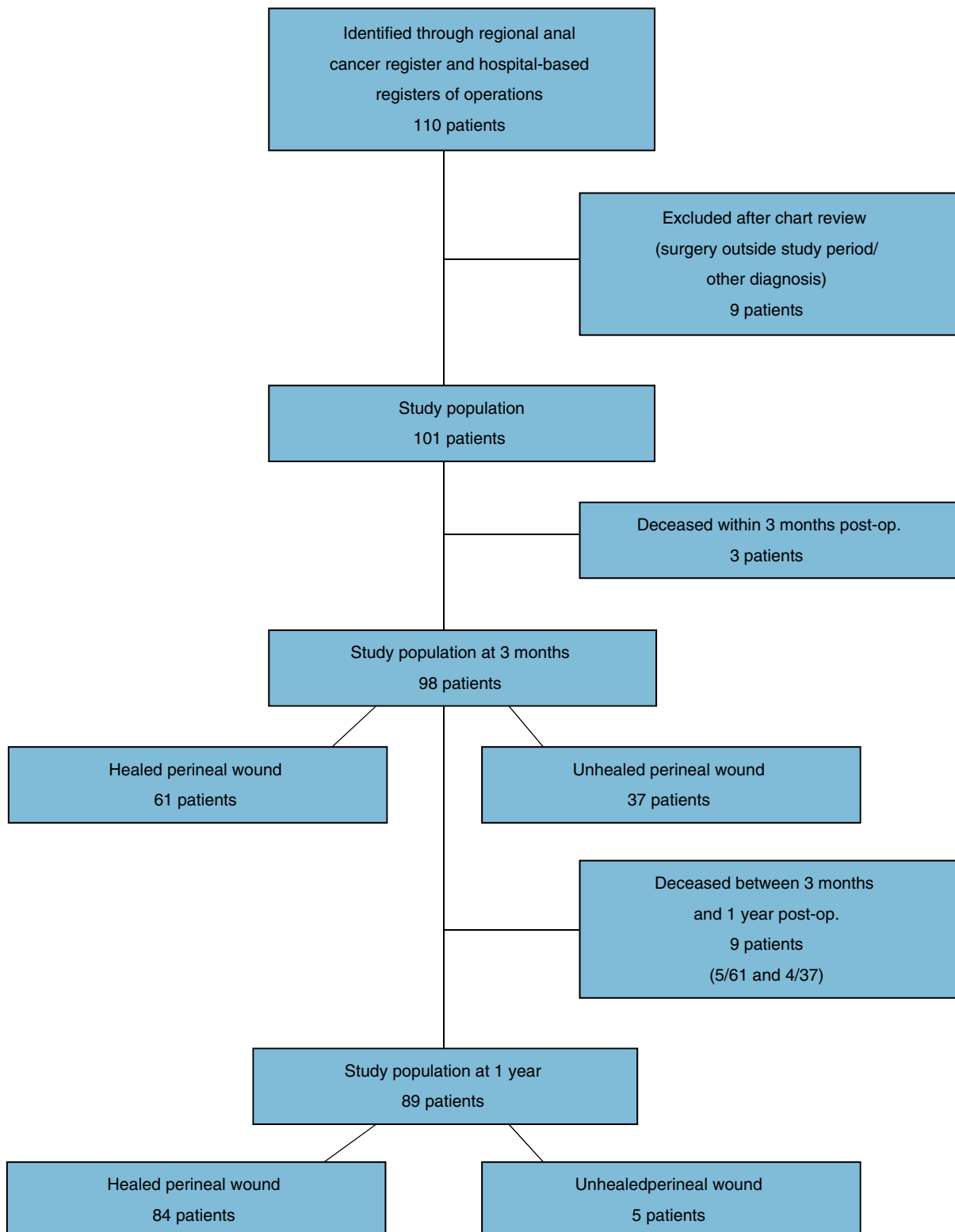
Differences between healing status (unhealed/healed) at 3 months and clinical characteristics were tested using the *t* test for continuous variables and Pearson's chi-squared test for categorical variables.

The effect of clinical variables on healing status was modelled using logistic regression. Results from these models are presented as odds ratios together with 95% confidence interval. *P* values from these models refer to Wald tests. All reported *P* values are two-sided.

## RESULTS

During the study period, 101 consecutive patients with anal cancer underwent salvage surgery (Figure 1). Seventy-six patients

were operated at Ersta Hospital and 25 at Karolinska University Hospital. Patient, tumour and treatment characteristics are presented in Table 1. All patients who underwent TPE were operated at Karolinska University Hospital. During follow-up, three patients died



**FIGURE 1** Flowchart of the study population

**TABLE 1** Patient, tumour and treatment characteristics of all patients (*n* = 101)

	All patients	ERAS+	ERAS-
Age (years), median (range)	64 (34–89)	63 (34–89)	61 (41–85)
Gender (male:female)	34:67	21:51	13:16
BMI, median (range)	23 (15–37)	24 (15–35)	21 (15–37)
HIV (positive:negative)	3:98	1:71	2:27
Smoker (yes:no)	23:78	14:58	9:20
ASA classification			
1	10	8	2
2	51	40	11
3	29	17	12
4	0	0	0
Missing	11	8	3
Tumour location (anal margin:anal canal)	6:95	4:68	2:27
Initial T stage			
T1–T2	48	33	15
T3	23	19	4
T4	27	18	9
Missing	3	1	2
Initial treatment			
RT ≤46 Gy ± chemotherapy	58	43	15
RT >46 Gy ≤64 Gy ± chemotherapy	37	26	11
Previous RT	3	1	2
No RT	3	2	1
Indication for surgery			
Residual tumour	78	54	24
Recurrent tumour	17	16	1
Re-recurrent tumour	3	2	1
Primary surgery	3	1	2
Type of surgery			
APE (male)	58 (34)	43 (21)	15 (13)
PPE (male)	32 (0)	20 (0)	12 (0)
TPE (male)	11 (7)	9 (6)	2 (1)
Type of perineal reconstruction			
Primary closure <sup>a</sup>	39	30	9
Gluteal flap	31	19	12
VRAM flap	31	23	8
Margin status			
R0	95	67	28
R1	6	5	1

Abbreviations: APE, abdominoperineal excision; ASA, American Society of Anesthesiologists; BMI, body mass index; ERAS-, non-compliant to ERAS; ERAS+, compliant to ERAS; HIV, human immunodeficiency virus; PPE, posterior pelvic exenteration; RT, radiotherapy; TPE, total pelvic exenteration; VRAM, vertical rectus abdominis myocutaneous flap.

<sup>a</sup>Including three patients with biological mesh.

within 3 months and an additional nine within 1 year after surgery. None of these deaths could be attributed to complications relating to a perineal flap. Thus, at 3 months perineal healing was assessed in 98 patients and at 1 year in 89 patients.

On the basis of the aforementioned criteria, ERAS compliance was seen in 72 patients. The ERAS items most commonly adhered to were antibiotic and thrombosis prophylaxis whereas the interventions most commonly omitted were carbohydrate loading and pre-admission counselling.

Minor perineal complications were found in 17 patients and major, necessitating intervention under general anaesthesia, occurred in 16 patients. In total, 61 of 98 patients had a healed perineal wound at 3 months. One year after surgery complete perineal healing was seen in 84 of 89 patients.

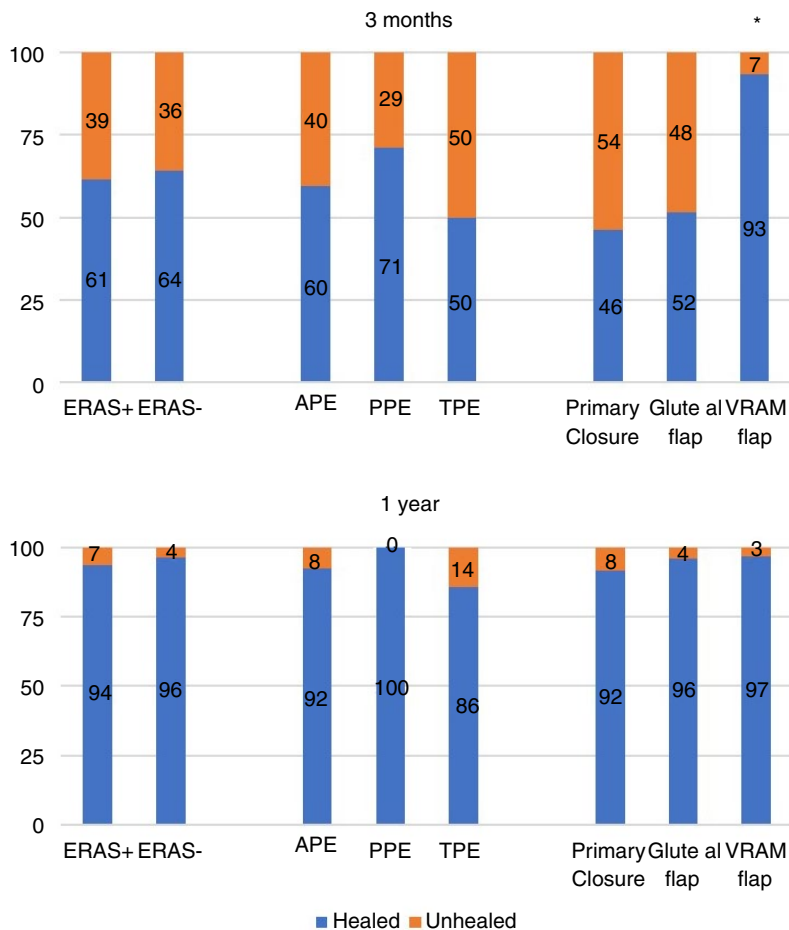
Complications unrelated to the perineal wound were detected in 16/101 patients. Complications of Clavien–Dindo Grade 3b or more occurred in 10 patients. No patient died within 30 days of surgery.

In Figure 2, the proportions of healed and unhealed perineal wounds in relation to ERAS compliance, type of surgery and type of perineal reconstruction at 3 months and 1 year are presented. There was no difference in perineal healing at 3 months in the ERAS compliant and non-compliant patients, 61% and 64% respectively (Figure 2, Table 2). Furthermore, ERAS compliance was not associated with perineal healing at 3 months in the multivariable regression model (OR 0.69, 95% CI 0.23–2.05, Table 2). Perineal healing at 3 months was associated with a younger age (healed vs. unhealed; median age 61.0 vs. 67.1 years, *P* = 0.010) (Table 3). Perineal healing at 3 months occurred less commonly among patients aged 65 years or more (45% vs. 75%, OR 3.25, 95% CI 1.21–8.74). In patients who had a perineal reconstruction by a vertical rectus abdominis flap almost all had a healed perineal wound at 3 months, which contrasts with those who had a gluteal flap or primary closure (93% vs. 52% vs. 46%, *P* < 0.001) (Table 2). There were no statistically significant differences in healing associated with gender, dose of radiotherapy or R0/R1 resection (Table 3). At 1 year, nearly all patients had fully healed perineal wounds and no statistically significant associations between perineal healing and the variables analysed at 3 months could be detected in the univariable or multivariable analyses (results not shown).

## DISCUSSION

This report on 101 consecutive anal cancer patients requiring surgery indicates that perineal healing at 3 months is not associated with ERAS compliance but is associated with a younger age and the type of perineal reconstruction. Almost all perineal wounds heal within a year after surgery. Since younger patients could be indicative of a higher resilience to surgical trauma and less comorbidity, the finding of improved healing at 3 months among patients under the age of 65 years is not unexpected.

An unhealed perineal wound can cause pain, odour and severe discomfort for the patient. Furthermore, it is associated with



**FIGURE 2** Proportions of healed and unhealed perineal wounds in relation to ERAS compliance, type of surgery and type of perineal reconstruction (numbers in bars: %). An asterisk indicates significance. APE, abdominoperineal excision; ERAS-, non-compliant; ERAS+, compliant; PPE, posterior pelvic exenteration; TPE, total pelvic exenteration; VRAM, vertical rectus abdominis myocutaneous flap

	Univariable OR (95% CI)	P value	Multivariable OR (95% CI)	P value
<b>Age (years)</b>				
<65	1.0 (Ref)		1.0 (Ref)	
≥65	3.63 (1.54-88.56)	0.003	3.25 (1.21-8.74)	0.020
<b>Gender</b>				
Female	1.0 (Ref)		1.0 (Ref)	
Male	1.45 (0.61-33.45)	0.395	1.74 (0.56-5.48)	0.341
<b>ERAS</b>				
Compliant	1.0 (Ref)		1.0 (Ref)	
Non-compliant	1.13 (0.45-2.81)	0.792	0.69 (0.23-2.05)	0.505
<b>Type of surgery</b>				
APE	1.0 (Ref)		1.0 (Ref)	
PPE	0.60 (0.24-1.55)		1.44 (0.38-5.37)	
TPE	1.48 (0.38-5.69)	0.411	1.36 (0.29-6.41)	0.837
<b>Type of perineal reconstruction</b>				
Primary closure <sup>a</sup>	1.0 (Ref)		1.0 (Ref)	
Gluteal flap	0.80 (0.31-2.10)		0.55 (0.17-1.73)	
VRAM	0.06 (0.01-0.29)	0.002	0.06 (0.01-0.31)	0.004

**TABLE 2** Logistic regression analysis on perineal healing at 3 months

Note: OR corresponds to non-healing.

Abbreviations: APE, abdominoperineal excision; ERAS, enhanced recovery after surgery; PPE, posterior pelvic exenteration; TPE, total pelvic exenteration; VRAM, vertical rectus abdominis myocutaneous flap.

<sup>a</sup>Including three patients with biological mesh.

**TABLE 3** Healing rates at 3 months (*n* = 98)

	Healed	Unhealed	P value
Total ( <i>n</i> )	61	37	
Age, median (SD)	61.0 (9.9)	67.1 (12.8)	0.010
Age (%)			0.003
<65 years	42 (75)	14 (25)	
≥65 years	19 (45)	23 (55)	
Gender (%)			0.39
Female	43 (65)	23 (35)	
Male	18 (56)	14 (44)	
Radiotherapy dose (%)			0.59
≤46 Gy	35 (59)	24 (41)	
>46 Gy	24 (65)	13 (35)	
Resection margin (%)			0.92
R0	58 (62)	35 (38)	
R1	3 (60)	2 (40)	
ERAS compliance (%)			0.79
Yes	43 (61)	27 (39)	
No	18 (64)	10 (36)	
Type of operation (%)			0.41
APE	34 (60)	23 (40)	
PPE	22 (71)	9 (29)	
TPE	5 (50)	5 (50)	
Type of reconstruction (%)			<0.001
Primary closure	18 (46)	21 (54)	
Gluteal flap	15 (52)	14 (48)	
VRAM flap	28 (93)	2 (7)	

Abbreviations: APE, abdominoperineal excision; ERAS, enhanced recovery after surgery; PPE, posterior pelvic exenteration; TPE, total pelvic exenteration; VRAM, vertical rectus abdominis myocutaneous flap.

increased resource utilization and cost for healthcare providers and for these reasons early healing is desirable. The results reported here indicate that there may be both non-adjustable and adjustable factors that can influence the healing time. Although ERAS compliance did not significantly influence healing rates in this series, compliance with ERAS was defined as adherence to at least seven of eight registered ERAS measures. Although the ERAS concept is often perceived as the impact of a bundle of measures, it is likely that some interventions are more important than others with regard to perineal healing. Thus, results on ERAS compliance should be interpreted with caution and it should not be assumed that ERAS interventions have no value for anal cancer patients. It is likely that some other ERAS interventions could have an impact on healing. For instance, a pre-habilitation programme, an intervention that may impact on complications and healing rates, was not deployed during the study period. Interestingly, this report did not reveal an increase in healing problems with an increased magnitude of surgery. Another comforting observation is that nearly all wounds eventually heal.

To date, no randomized studies on different flaps for perineal reconstruction following APE for anal cancer have been published.

In published reviews on perineal reconstruction [15–18], most studies have significant limitations such as inclusion of different cancers, limited sample size, no direct comparisons between matched groups with respect to type of perineal reconstruction and no stratification according to type of surgery. Also, some conflicting results were reported in these systematic reviews. There is therefore insufficient evidence to recommend one particular method of perineal reconstruction over another. However, despite these uncertainties, the position statement from the Association of Coloproctology of Great Britain and Ireland on perineal closure favours a myocutaneous flap when concern for perineal healing exists after APE in irradiated anorectal tumours [19]. Also, in the European anal cancer guidelines from 2014, perineal reconstruction with a myocutaneous flap is recommended in salvage surgery, albeit without specifying which flap is preferable [1].

The favourable results of perineal healing in this cohort contrast sharply with reports in which perineal flap reconstruction was not used [5,6] but are in line with those reported from more recent series [7,8], strengthening the notion that flap reconstruction is beneficial.

The vertical rectus abdominis flap has the advantage of adding volume into the pelvis, and also for being reliable and being harvested from a non-irradiated area. Good results have been reported with the vertical rectus abdominis flap in a series of 100 TPE patients [20]. However, the vertical rectus abdominis flap generally necessitates assistance of a reconstructive plastic surgeon and adds complexity and operating time to the procedure. In addition, this flap is associated with abdominal wall morbidity [20] and, when TPE is performed, problems with respect to placement of two stomas may occur. In the era of minimally invasive surgery it seems counterintuitive to make large abdominal incisions. The gluteal flap, although yielding poorer results in this series, leaves the abdominal wall untouched but is harvested from the irradiated perineal area and provides less bulk to fill the pelvis. Other flaps such as the gracilis, V-Y fasciocutaneous and lotus petal fatty cutaneous flaps, all with advantages and disadvantages, can also be used for perineal reconstruction [11]. However, as recommended in the European guidelines and supported by the current results, primary closure of the perineal wound should only be used selectively in anal cancer patients [1].

This study has several limitations. Data reported were not randomized and mostly were collected retrospectively. There may be data relevant for healing outcomes that were not collected and could have been overlooked. Also, healing was assessed indirectly through chart review. However, patient data on ERAS compliance were collected prospectively, patients were operated on consecutively and the study is recent. Taking the rarity of anal cancer into consideration this is a large cohort. All eligible patients during the study period were included, with complete follow-up.

## CONCLUSION

Perineal healing disturbances following salvage surgery for anal cancer remain a significant clinical problem. Age under 65 years and

perineal reconstruction with vertical rectus abdominis flap appear to be significantly associated with improved healing at 3 months. Nearly all patients, irrespective of the method of perineal reconstruction, had a fully healed perineal wound 1 year after surgery.

### CONFLICT OF INTEREST

None.

### ETHICAL APPROVAL

Ethical approval was obtained from the regional Swedish Ethical Review Authority (EPN) (Dnr: 2017/1894-31/1).

### DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions.

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