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Original Article

Morbidity associated with the immediate vertical rectus abdominus myocutaneous (VRAM) flap reconstruction after radical pelvic surgery

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What does this paper add to the literature?

This paper adds to the literature a large series (over 150 patients) from two high volume colorectal centres having major pelvic surgery with immediate reconstruction using Vertical Rectus Abdominis Myocutaneous (VRAM) flap. It outlines the complication profiles encountered and shows that careful selection of patients can achieve good results.

Abstract

Background; Patients who undergo radical pelvic surgery, often have problems with perineal wound healing and pelvic collections. While there is recognition of the perineal morbidity, there also remains uncertainty around the benefit of VRAM flaps due to the balance between primary healing and the complications associated with this form of reconstruction.

Aim: This study aimed to evaluate factors associated with significant flap and donor site related complications following VRAM flap reconstruction for radical pelvic surgery.

Method: A retrospective analyses of VRAM flap-related complications was undertaken from the prospectively maintained databases for all patients undergoing radical pelvic surgery (2001- 2017), in two cancer centres.

Results: 154 patients were identified (median age 62 yrs (range 26-89yrs), 80 (52%) male). 33 (21%) patients experienced significant donor or flap-related complications. Major complications (Clavien-Dindo ≥ 3) related to the abdominal donor site occurred in 9 (6%) patients, while those related to the flap or perineal site occurred in 28 (18%) patients. Only

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smoking (p=0.003) and neoadjuvant radiotherapy (p=0.047) were associated with the development of significant flap-related complications on univariate analysis. Flap related complications resulted in a significantly longer hospital stay (p<0.001).

Conclusion: Careful patient selection is required to balance the risks versus the benefits of VRAM flap reconstruction. Immediate VRAM reconstruction in patients undergoing radical pelvic surgery can achieve early healing and stable perineal closure, it has a low but significant morbidity. Major flap-related complications are significantly associated with smoking status, neoadjuvant radiotherapy and result in a prolonged length of hospital stay.

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Introduction

Clear surgical margins (R0) are associated with improved survival in patients with primary and recurrent pelvic malignancy.[1-6] In order to achieve an R0 resection, surrounding structures may have to be removed en-bloc, most commonly in locally advanced primary or recurrent anorectal and associated pelvic malignancy. In selected patients, there has therefore been a paradigm shift to increasingly radical surgical resection in the form of extralevator abdominoperineal excision or extended pelvic exenteration.[5,7,8]

This increasing radical local excision however often comes at a cost, that of a larger perineal wound, and it is in such patients that perineal wound healing is often problematic and can at times be a significant management challenge. The presence of a large pelvic dead space is a major cause of morbidity as it predisposes to fluid collections, and subsequent infective collections, which can adversely affect perineal wound healing.[9,10] The reported incidence of complications such as dehiscence, chronic abscesses, fistulae and delayed healing in patients who undergo direct closure of the perineal wound has been high as 67% of cases, with even higher rates noted in diabetic and smoking patients which is compounded in those who have received preoperative radiotherapy.[11-14] In an attempt to reduce these complications, the use of vertical rectus abdominus myocutaneous (VRAM) flap to reconstruct the dead space, and introduce well-vascularised healthy tissue, has been advocated.[12,15-18]

While there is a reduction of perineal morbidity with the use of VRAM flaps in patients undergoing abdominoperineal resection and pelvic exenteration [19], it remains of uncertain

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overall benefit due to the specific morbidity associated with the VRAM flap technique of reconstruction. This study aimed to evaluate factors associated with significant flap and donor site related complications following VRAM flap reconstruction for radical pelvic surgery.

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Materials and methods

Study design

This study was conducted across two high volume tertiary referral centres for advanced pelvic malignancy and recurrent rectal cancer. Prospectively maintained databases for all patients undergoing radical pelvic surgery were searched for those having VRAM flap reconstruction between 2001 and 2017 from two tertiary referral centres in Australia and New Zealand: (1) Christchurch Hospital, Christchurch, New Zealand 2001-2017 and (2) Peter MacCallum Cancer Centre, Melbourne, Australia. 2001-2015. All patients included were counselled preoperatively by a consultant plastic surgeon. This included discussion surrounding the risks and benefits of VRAM flap. In those who were not suitable, other options such as inferior gluteal artery perforator (IGAP) or Gracilis flaps were considered.

Patient demographics including age and sex were included. Comorbid factors that may be associated with reduced tissue healing including smoking status, diabetes, vascular disease as well as the American Society of Anaesthesiologists (ASA) grade, a marker for general poor health, were included. Intraoperative factors, including the extent of resection, surgical clearance and the presence of a skin paddle, were also examined. Perioperative factors, including preoperative chemoradiotherapy, the requirement for postoperative blood transfusion and length of stay were also studied. The primary endpoint were the development of postoperative complications, and the modified Clavien-Dindo classification was used to assess this.[20]

Patients with either type I or type II diabetes were classified as diabetic. Smokers were grouped as current smokers or non-smokers depending on their status at the time of preassessment. Patients were regarded as having vascular disease if they had a history of peripheral vascular disease, cerebrovascular disease or cardiovascular disease. American

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Society of Anaesthesiologists (ASA) grade I to IV were included. Grading system as follows; I. Healthy; II Mild systemic disease; III Severe systemic disease; IV Severe systemic disease that is a constant threat to life . These were grouped into low (I, II) and high risk (III, IV) for analysis. Body mass index (BMI) was only available in the Christchurch cohort and calculated in the usual fashion.[21] This data was not available in the Melbourne cohort. Blood transfusion, in units, included intra and postoperative transfusion requirements. Neoadjuvant radiotherapy and chemotherapy were administered to selected patients based on multidisciplinary team decisions and depended on patient comorbidity, and any previous courses of radiotherapy received. Operations were classified as radical or extended radical resections.[22] Radical resections were defined as a bowel resection alone (abdominoperineal resection, anterior resection or panproctocolectomy). Extended radical resections were defined as en-bloc resection of adjacent pelvic organs and structures. Of those patients with malignancy, histological margins of the surgical specimens were recorded with the residual tumour classification; R0 corresponding to complete resection; R1 to a microscopic residual tumour within <1mm of the resection margin; R2 to a macroscopic tumour at the resection edge.[18,23]

The surgical technique for creation of a VRAM flap in patients undergoing pelvic exenterative surgery has been described previously by our group with flaps being muscle only or skin and muscle.[18] Two consultant plastic surgeons in Christchurch and two consultant plastic surgeons from Melbourne perform VRAM flaps included in this study. At least one consultant plastic surgeon was present and scrubbed for all flaps.

Complications occurring within 30 days of surgery were graded according to the modified Clavien-Dindo classification.[20] The system classifies complications into five grades of increasing severity. For patients experiencing more than one complication, or a complication that progressed through more than one grade, only the highest grade of complication was recorded for that patient. Flap complication includes flap breakdown, flap dehiscence, flap necrosis (partial or complete), perineal wound infection, perineal wound discharge, perineal collection. Donor site complications include abdominal wound dehiscence, abdominal wound infection. Only significant VRAM flap specific complications, occurring at either the donor site or related to perineal healing, were considered (Clavien-Dindo score of 3 or more) as these were felt to have the potential to affect the long-term patient outcome. Moreover, Clavien-Dindo scores of <3 are less significant complications that do not require intervention

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with local or general anaesthetic. These are generally minor and normally only result in short term issues. They are also historically poorly captured due to the subjective nature of their classification and recording. They have therefore not been included.

Abdominal collections and other unrelated complications were excluded from analysis. Those that died within 30 days were excluded. The minimum follow-up was 30 days or until both donor site, and VRAM flap had healed.

Statistics

The relationship between continuous variables, including age, BMI, blood transfusion (units) and length of stay with VRAM flap specific complications were examined using Kruskal-Wallis test for comparing medians (Table 1). The relationship between categorical variables including sex, diabetes, smoking status, ASA high versus low risk, neoadjuvant chemotherapy and radiotherapy, standard versus extended radical resection, residual tumour classification with VRAM flap specific complications were examined using Pearson's X^2 test (linear by linear) (Table 1). A p-value of < 0.05 was considered statistically significant. Analyses were performed using SPSS (IBM, SPSS, IL, USA).

No formal ethics approval was required as this was a retrospective audit study that did not require patient contact. This was confirmed in New Zealand at the national level (https://neac.health.govt.nz) and in Melbourne at a state level.

Results

154 patients were identified as having undergone radical pelvic surgery with immediate VRAM flap reconstruction. The median age was 62yrs (range 26-89 yrs), and the majority of patients were male (52%). Ninety-eight cases (64%) were undertaken at Christchurch Hospital while 56 (36%) were undertaken at Peter MacCallum. Two deaths were excluded.

The majority of patients underwent neoadjuvant therapy with 121 (79%) patients receiving chemotherapy and 123 (80%) patients radiotherapy.

The outcomes following VRAM flap reconstruction in 154 patients studied are demonstrated in Figure 1. Significant complications (Clavien-Dindo ≥ 3) related to the abdominal donor site occurred in 9 (6%) patients. Six patients had wound dehiscence, and 3 had significant

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wound infection, of which 5 patients returned to theatre for dehiscence and 1 for infection. Significant complications (Clavien-Dindo ≥ 3) related to the flap or perineal site occurred in 28 (18%) patients. Twenty-six patients had an element of flap dehiscence or necrosis, and 2 had significant wound infection, of which 24 patients returned to theatre for resuturing or debridement and 1 for drainage of infection (16% return to theatre rate). Two patients included in these figures had both a flap and donor site complication that required return to theatre. One patient has complete flap failure, due to venous congestion of the pedicle, that required a further reconstructive procedure. Overall, 33 (21%) patients experienced significant (Clavien-Dindo ≥3) donor or flap-related complications.

The association between patient factors, preoperative management, surgical resection and VRAM flap specific complications in 154 patients is shown in Table 1. Twenty three (15%) patients were diabetic, 30 (23%) were smokers, and 28 (20%) had vascular disease. The median BMI was 25 (range 13-65). Of those requiring blood transfusion (76%), a median of 3 units was transfused (range 0 to 30) per patient. Of these factors, only smoking status was associated with the development of a significant flap-related complication (p=0.003).

Radical resection was performed in 35 (23%) patients, and an extended radical resection was performed in 118 (77%) patients. Of the whole group, 48 (31%) patients required a sacrectomy. The definitive histology showed that 97 (66%) patients had clear radial histological margins, 36 (24%) had microscopic tumour within 1mm of the resection margin, and 14 (10%) had macroscopic tumour at the resection margin. The median length of hospital stay was eighteen days (range 6 – 151). Of these factors only neoadjuvant radiotherapy (p=0.047) was associated with the presence of a significant flap-related complication. Not surprisingly, flap-related complications were associated with a longer length of hospital stay (p<0.001).

Discussion

Radical pelvic surgery is associated with significant perineal wound morbidity with higher rates of major perineal wound complications associated with more extensive pelvic resections.[12,24-26] However, over the past decade, several studies have reported a reduction in perineal wound complications if immediate myocutaneous flap reconstruction is performed; however, they have focused on the total patient complications, not the reconstruction specific complications.[14,16,27]

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The postoperative incidence of major complications (for the purposes of comparison with other studies considered to be Grade III or above) related to the flap or donor site in our series was 18%, and the overall median length of stay was 18 days. These outcomes compare favourably to those reported for other recent VRAM series, particularly in view of the major indication for surgery being malignancy (98%) and the high proportion of patients receiving neoadjuvant radiotherapy (80%) and undergoing an extended radical resection (77%). [26] The in-hospital postoperative mortality rate in this series of patients was comparable to that reported by other studies of patients undergoing pelvic exenteration surgery.[28,29]

A recent "best evidence review" on the topic of "should the irradiated perineal wound following abdominoperineal resection (APR) be closed with primary repair or a myocutaneous flap", identified only eight quality papers. They report that the best evidence available was from a systematic review of cohort studies and case series and that although no meta-analysis was performed, overall wound healing was improved using flap closure with a low frequency of flap necrosis. Five papers compared vertical rectus abdominus muscle (VRAM) flap with primary closure, of which two demonstrated statistically significant improvement in complication rates with flap closure. All studies suffered from significant limitations, small sample size and no direct comparisons between matched groups with respect to the type of anatomical flap, wound size, tumour recurrence or radiation dose. Their conclusion, however, was that there is some limited evidence for recommending flap closure in abdominoperineal resection post radiotherapy as far as wound healing, though no specific analysis was undertaken looking at VRAM specific complications.

There is only one randomised controlled trial (RCT) of VRAM primary closure which reported on 60 patients undergoing APR for low rectal cancer at Cairo University over a period of 4 years from August 2008 to July 2012. [30]. They found a significantly lower rate of perineal wound complications in the VRAM group compared to the primary closure group (17% versus 46%; P = 0.015) with a similar rate of abdominal wound complications between the two groups.[30]

The Clavien-Dindo classification has been used to compare outcomes in a recent randomised controlled trial of collagen mesh for the prevention of abdominal incisional hernia in patients having a VRAM flap during surgery for advanced pelvic malignancy.[31] A Grade III or higher surgical complication occurred in 15/58 (26%) patients while 16/58 (28%) patients

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experienced no surgical complications and the median length of hospital stay was 15 days. They reported that there was no significant difference in the incisional hernia rates between the conventional closure and mesh-assisted closure groups at one year. Due to limited follow-up, long-term results of hernia formation at the flap or donor site are not included in the present results. However, other studies have reported that in patients undergoing APR the inclusion of VRAM flap reconstruction does not lead to an increased incidence of an abdominal wall incisional hernia[32-34] or abdominal wall complications.[12,25]

The strengths of our study include the fact that this is the largest single study on VRAM flap complications so far published. In fact, the recent systematic analysis on VRAM flaps which involved 36 trials only had a total of 300 VRAM flaps. Other strengths include the prospective entry of patient, treatment and outcome data into central databases; similar surgical techniques used in all the patients studied; and the use of a standardised, validated reporting system to describe complications and a relatively large number of patients. The weakness of this study is the retrospective assessment of outcomes. There is no control group as this study was focused on the flap-related complications, not the perineal wound healing rates, and therefore there is no comparison group as those who did not have a VRAM did not have any complications. We do however plan to carry out a comparison of flap and perineal healing rates in the future. It has also been recognised that some data fields that may be associated with poorer outcomes, such as BMI, were incomplete and therefore may not have fully demonstrated associations.

In conclusion, careful patient selection is required to balance the risks versus the benefits of VRAM flap reconstruction. While immediate VRAM reconstruction in patients undergoing radical pelvic surgery can achieve early healing and stable perineal closure it is associated with a low but significant morbidity. Major flap-related complications are significantly associated with smoking status, neoadjuvant radiotherapy and result in a prolonged length of hospital stay.

Table 1. The association between patient factors, preoperative management, surgical resection and VRAM flap specific complications (n=154).

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		n=154	Clavien-Dindo < 3 n (%)	Clavien-Dindo ≥ 3 n (%)	p-value
Age	Median (range)	154	62 (26-87)	57 (33-89)	0.493*
	Unknown	0			
Sex	Male	80	65 (81)	15 (19)	
	Female	73	55 (75)	18 (25)	0.401#
	Unknown	1			
Diabetic	No	128	102 (80)	26 (20)	
	Yes	23	17 (74)	6 (26)	0.352#
	Unknown	3			
Smoker	No	101	87 (86)	14 (14)	
	Yes	30	18 (60)	12 (40)	0.003#
	Unknown	23			
Vascular disease	No	115	92 (80)	23 (20)	
	Yes	28	20 (71)	8 (29)	0.228#
	Unknown	11			
BMI	Median (range)	63	25 (13-65)	24 (20-33)	0.964*
	Unknown	81			
ASA	Low risk (1,2)	94	79 (81)	18 (19)	
	High risk (3,4)	51	39 (76)	12 (24)	0.338#
	Unknown	9			
Blood transfusion (units)	Median (range)	115	2 (0-30)	3 (0-22)	0.458*
	Unknown	39			
Neoadjuvant Radiotherapy	No	22	13 (62)	8 (38)	
	Yes	123	101 (82)	23 (18)	0.047#
	Unknown	9			
Neoadjuvant Chemotherapy	No	32	26 (81)	6 (19)	
	Yes	121	94 (78)	27 (22)	0.434#
	Unknown	1			
Extent of Resection	Standard	35	28 (80)	7 (20)	
	Extended	118	92 (78)	26 (22)	0.501#
	Unknown	1			
Sacrectomy	No	106	82 (77)	24 (23)	
	Yes	48	39 (81)	9 (19)	0.375#
	Unkown	0			
Skin paddle included	No	35	31 (89)	4 (11)	
	Yes	119	90 (76)	29 (24)	0.102#
	Unknown	0			
Residual tumour classification	R0	96	76 (79)	20 (21)	
	R1	36	28 (78)	8 (22)	0.900#
	R2	14	11 (79)	3 (21)	
	Unknown/NA	8			
Length of Stay	Median (range)	115	15 (6-145)	30 (8-151)	<0.001*

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	Unknown	39			

* Kruskal-Wallis. #X^2 test for linear association

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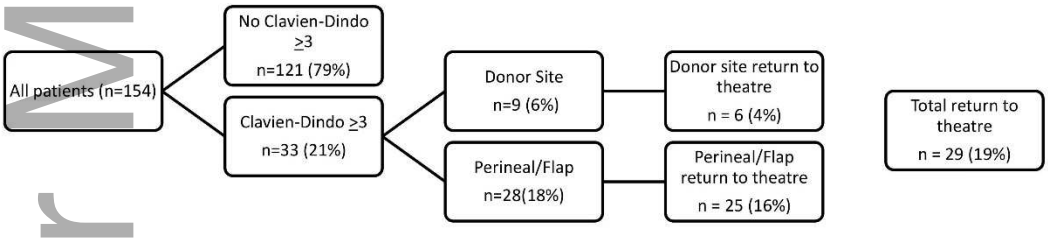

Figure 1. Patient outcomes following VRAM flap reconstruction (n=154).

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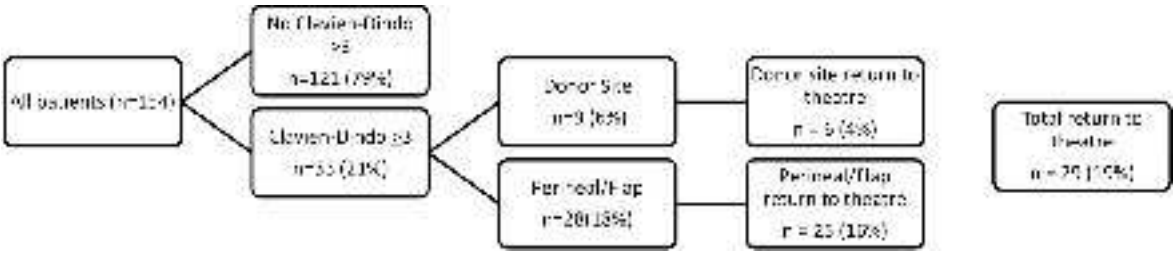

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