

Threatened Ventricular Assist Devices: Meta-analysis of Negative Pressure Therapy and Flap Reconstruction Outcomes

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Background: Infected Ventricular Assist Device (VAD)-associated wounds are common and associated with significant morbidity and mortality. The efficacy of hardware salvage utilizing flaps and negative pressure wound therapy (NPWT) remains understudied. We hypothesized that patients treated with flaps and/or NPWT would have higher hardware salvage rates compared with other surgical management strategies.

Methods: A meta-analysis study evaluating VAD-associated wounds was performed following PRISMA guidelines. Primary predictor variables were flap-reconstruction (FR), NPWT, no FR, and infection location (mediastinum versus driveline). Primary outcomes were hardware retention (salvage) versus explantation, infection recurrence, or death. Twenty-nine studies were included. Standard statistical methods included logistic regression analysis.

Results: Seventy-four subjects with nonsignificant demographic differences between cohorts were identified. Overall salvage was 59.5% in both driveline and mediastinum cohorts. Overall, NPWT significantly improved salvage compared with no NPWT [77.4% versus 46.5% respectively ($P = 0.009$)], and FR significantly improved salvage compared with no FR [68.6% versus 39.1% respectively ($P = 0.022$)]. Logistic regression analysis predicting odds of salvage by FR (area under curve = 0.631) was significantly three times higher (95% CI: 1.2–9.5) and predicting the odds for salvage by NPWT (area under curve = 0.656) was significantly four times higher (95% CI: 1.4–11.1) compared with other treatment.

Conclusions: NPWT or flap reconstruction for treatment of threatened VAD hardware was associated with a significantly improved device salvage compared with other surgical strategies. Further study should focus on subgroup analysis of flaps utilized and synergistic treatment benefits. (*Plast Reconstr Surg Glob Open* 2022;10:e4627; doi: 10.1097/GOX.0000000000004627; Published online 24 October 2022.)

INTRODUCTION

The Ventricular Assist Device (VAD) has emerged as a mainstay for patients with end-stage heart failure no

longer responsive to medical therapy.¹ Although originally designed as a bridge therapy for patients awaiting transplantation, evolution in device efficacy concomitant with increased prevalence of end-stage heart failure and stagnant availability of donor hearts has led to its regular utilization as a destination therapy. This has created a need for interdisciplinary partnership among industry, physicians, surgeons, and healthcare providers across a broad range of specialties to control comorbidities in a rapidly evolving special patient population.²

Due, in part, to immune compromise and poor health of unmanageable heart failure, post-operative chest wall and device-associated infections are common and may occur in more than 22% of patients.³ These have been associated with significantly increased morbidity and mortality⁴ and

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can be difficult to manage, requiring an interdisciplinary approach including reconstructive surgical management.⁵

VAD-associated infections can be further subdivided into driveline, pump pocket (mediastinal), and blood-stream infections. Severe mediastinal and driveline infections intractable to medical management require prompt surgical intervention. A range of surgical management strategies have been reported, including debridement and irrigation, antibiotic-impregnated beads, negative pressure wound therapy (NPWT), and flap coverage.⁶⁻⁹

Likely due to the relative novelty and complexity of the surgical management of VAD-associated wounds, few data are available regarding specific efficacies within this diverse group of surgical strategies. As of yet, no evidence-driven algorithm is available to guide the surgeon in the management of these high-risk patients.³ With a growing patient base in need of mechanical circulatory support, this problem of management will continue to become commonplace in plastic and reconstructive surgery.¹⁰

With flap utilization and NPWT on the forefront of reconstructive management of thoracoabdominal wounds,^{11,12} we hypothesized that these strategies would be associated with improved outcomes in the salvage of VAD-associated infections. Because of the commonplace use of omental transposition in flap reconstruction of these wounds and its demonstrated value in other procedures,¹³ we also became interested in its associated outcomes. We conducted this systematic meta-analysis to characterize the surgical treatments used in VAD-associated infections and demonstrate the efficacy of NPWT and flap reconstruction in this understudied patient population.

PATIENTS AND METHODS

A systematic review of the literature was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (Fig. 1). PubMed and MEDLINE databases were searched utilizing various combinations of terms associated with VAD, infection, wound, management, and reconstruction. Works cited in fully examined articles were also screened for inclusion. A total of 512 titles were found and subsequently screened by title and abstract by two independent reviewers without difference in inclusion, leaving 39 studies for full-text analysis. Inclusion criteria included English language, clinical study, article availability, VAD-associated wound, infection, and mention of surgical management. Exclusion criteria included review articles, repeat data, and articles without data on surgical management.

Full-text review left 33 articles for qualitative analysis and review.^{6-9,14-42} Due to aggregate, or inconsistent reporting of data, four articles were removed from quantitative analysis.^{6,30,31,38} This left 29 studies, including 16 case reports and 13 retrospective studies or case series. Data relating to seven patients were further removed due to criteria or inadequate reporting.

From 74 cases, data were collected regarding location of infection, whether surgical management included flap reconstruction (FR) or no flap reconstruction (NFR), whether FR included omental transposition ± any other flap, whether NPWT was utilized, and patient outcomes.

Takeaways

Question: Do negative pressure wound therapy (NPWT) and/or flap reconstruction (FR) improve salvage of ventricular assist devices (VADs) threatened by infection?

Findings: This systematic meta-analysis collates all available studies regarding surgical management of infected VAD-related wounds and analyzes rates of salvage versus explant, infection recurrence, or death when utilizing NPWT and/or FR versus other surgical management. Findings demonstrate benefit of NPWT with or without FR in salvage of infected VADs.

Meaning: Flap reconstruction and negative pressure wound therapy improve salvage in VAD-related wound infection, but further study is necessary to further elucidate specific flap value and synergy between the management strategies.

When available, age, sex, rationale for VAD therapy (destination therapy versus bridge-to-transplant), and time to infection were also collected.

For analysis, cases were divided into cohorts by location of infection (mediastinum versus driveline), the use of flap reconstruction (FR versus NFR), and the utilization of NPWT (NPWT versus no NPWT). Additionally, FR cases including omental transposition were compared with those not including omental transposition. Outcomes were divided into eradication of hardware-associated infection with hardware retention (salvage) versus hardware explant, infection recurrence, or death (ERD).

Comparison was made using an independent sample *t*-test for continuous variables with normal distribution or the Mann-Whitney U test in the case of non-normal distribution. Fisher exact test was used for all categorical variables. The Shapiro Wilk test was used to assess the normality of the continuous variables with a *P* value greater than 0.05 considered normal distribution. Logistic regression analysis was performed to predict the odds for salvage with flap reconstruction or negative pressure wound therapy as primary predictors. Statistical Analyses were performed with SPSS 27 software,⁴³ with a two-tailed *P* value less than 0.05 considered statistically significant. Figures were generated via a combination of Microsoft Excel, Microsoft PowerPoint, and Adobe Illustrator.⁴⁴⁻⁴⁶

RESULTS

In the studies quantitatively analyzed, nonreconstructive surgical management included multiple rounds of debridement and irrigation in nearly all cases. Other strategies included device relocation, silver impregnated dressings, and implantation of antibiotic impregnated beads. Sixteen studies^{7,9,14-16,18,19,25-27,32-34,39,41,42} reported utilization of NPWT, with one study²⁴ reporting success with the use of instillation NPWT.

Flap reconstruction included a range of tissue selections and methodologies. Most commonly reported flaps were omentum (49% of FR cases), rectus abdominis (37% of FR cases) and pectoralis major (18% of FR cases). Others (<10% of FR cases) included local tissue advancement, perforator flaps, latissimus dorsi, and anterior lateral

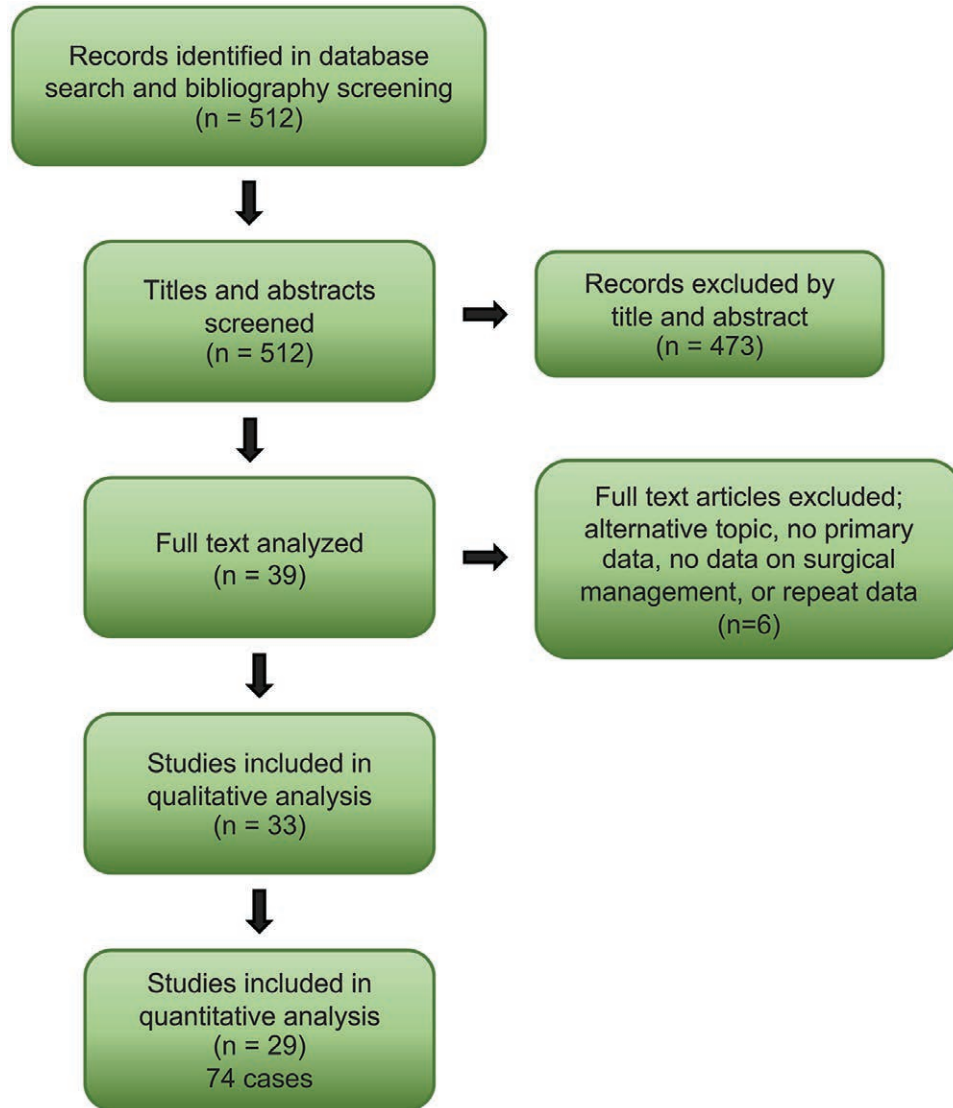


Fig. 1. Systematic literature search and analysis according to PRISMA guidelines.

thigh. Multiple flaps were often used in conjunction, and rationale for graft selection included immunologic properties, plasticity, location, and available blood supply.

Culture data were reported in 81% of cases. All cultures demonstrated known biofilm-forming organisms. This included mixed infection (23%), *Staphylococcus aureus* (18%), *Pseudomonas aeruginosa* (15%), MRSA (13%), Coagulase-negative *Staphylococcus* (13%), and other organisms (18%). There was no significant difference in outcomes when comparing these categories ($P = 0.062$).

Demographic Analysis

Quantitative analysis was performed with data from 74 cases that fit criteria and were adequately reported (Table 1). Flap reconstruction was performed in 69% of cases, whereas non-flap surgical management was performed in 31%. Utilization of NPWT was reported in 42% of cases and not reported in 68%.

Age was reported in 51 cases with a mean of 53.5 ± 15.8 years. Time from implantation to infection was reported

in 39 cases with a median of 64 days. Follow-up was reported in 93% of salvage cases with median follow-up of 6 months (2 mo/6 mo/10 mo) and 37% of ERD cases with median follow-up of 4 months (3 mo/4 mo/9 mo). Sex was reported in 59 cases, with 83% being men. Rationale for therapy was reported in 39 cases: 36% destination, and 64% bridge-to-transplant. Driveline-associated infection was reported in 27% of cases, whereas mediastinum-associated infection was reported in 73%.

Borderline statistical significance was noted in patient age between FR and NFR cohorts: 53.8 ± 16.1 versus 42.7 ± 16.9 respectively ($P = 0.049$). No other significant demographic differences were noted between cohorts. Described demographic parameters were found to be similar between studies analyzed qualitatively^{6,30,31,38} and those of this dataset.

Overall Hardware Salvage

In the overall cohort ($n = 74$), successful salvage was reported in 59.5% of cases, and ERD was reported in 40.5%. In the 20-subject driveline-associated infection

Table 1. Patient Demographics

Detail	n*	Mean ± SD or 25th/50th/75th or No. (% of Reported)			P	Mean ± SD or 25th/50th/75th or No. (% of Reported)		
		Total Cohort (n = 74)	Flap Reconstruction (n = 51)	No Flap Reconstruction (n = 23)		NPWT (n = 31)	No NPWT (n = 43)	P
Age (y)	55	50.6±16.3	53.8±16.1 (n = 44)	42.7±16.9 (n = 11)	0.049*	51.0±15.3 (n = 28)	52.2±18.4 (n = 27)	0.790
Time to infection (d)	42	34/62/261	25/60/304 (n = 32)	48/148/298 (n = 10)	0.314	38/62/361 (n = 22)	30/75/208 (n = 20)	0.520
Follow-up (mo)	52	2/6/9	3/6/9	2/8/11	0.839	3/6/13	2/5/9	0.165
Men	49	(83.1%)	38 (77.6%)	11 (22.4%)	0.688	23 (46.9%)	26 (53.1%)	0.999
Women	10	(16.9%)	7 (70.0%)	3 (30.0%)	—	5 (50.0%)	4 (50.0%)	—
Destination therapy	14	(35.9%)	11 (78.6%)	3 (21.4%)	0.999	5 (35.7%)	9 (64.3%)	0.740
Bridge therapy	25	(64.1%)	19 (76.0%)	6 (24.0%)	—	11 (44.0%)	14 (56.0%)	—
Driveline	20	(27.0%)	12 (60.0%)	8 (40.0%)	0.398	8 (40.0%)	12 (60.0%)	0.999
Mediastinitis	54	(73.0%)	39 (72.2%)	15 (27.8%)	—	23 (42.6%)	31 (57.4%)	—

*n: number of patients with data available, NPWT: negative pressure wound therapy. Significant difference was noted in age between flap reconstruction and no flap reconstruction cohorts. No Significant difference in analyzed demographic parameters between NPWT and no NPWT cohorts. Each statistics column demonstrates results of analysis comparing the two preceding cohorts.

*P < 0.050 was considered statistically significant.

cohort, salvage was reported in 60.0% of cases, and ERD was reported in 40.0%. In the 54-subject mediastinum-associated infection cohort, salvage was reported in 59.5% of cases and ERD was reported in 40.5%. No significant difference in outcome was noted between mediastinum and driveline cohorts (P = 0.999) (Fig. 2).

Negative Pressure Wound Therapy (NPWT)

Use of NPWT in wound management was reported in 31 cases. Overall, NPWT was significantly associated with improved outcome, yielding salvage in 77.4% of cases and ERD in 22.6%, whereas no NPWT yielded salvage in 46.5% of cases and ERD in 53.5% (P = 0.009).

There was no significant association between utilization of NPWT and outcome within the driveline-associated infection cohort (P = 0.373). Of the eight driveline cases reporting NPWT, salvage was achieved in 75% and ERD reported in 25%, whereas 12 cases not reporting NPWT yielded salvage in 50% and ERD in 50%.

Within the mediastinum-associated infection cohort, utilization of NPWT was associated with improved outcome (P = 0.024). Of the 23 cases reporting NPWT, salvage was achieved in 78.3% and ERD reported in 17.7%,

whereas 31 cases not reporting NPWT yielded salvage in 45.2% and ERD in 54.8% (Fig. 3A).

Logistic regression analysis was performed to predict the odds of salvage by NPWT (area under curve = 0.656). The odds of salvage compared with ERD were found to be significantly four times higher (95% CI: 1.4–11.1) for cases with NPWT compared with those with no NPWT (Fig. 3B).

Flap Reconstruction

Reconstructive wound management utilizing a tissue flap was overall associated with improved outcomes (P = 0.022). Of the 51 cases reporting FR, salvage was achieved in 68.6% and ERD was reported in 31.4%. Of the 23 cases in which FR was not reported, salvage was achieved in 39.1% while ERD was reported in 60.9%.

There was no significant association between management with FR and outcome in the driveline-associated infection cohort (P = 0.648). Of the 12 driveline cases in which FR was utilized, salvage was achieved in 66.7%, whereas ERD was reported in 33.3%. Of the eight cases that did not utilize FR, salvage was achieved in 50% whereas ERD was reported in 50%.

FR was associated with improved outcomes within the mediastinum-associated infection cohort (P = 0.029). Of the 39 cases which utilized a flap, 69.2% achieved salvage, whereas ERD was reported in 30.8%. Of the 15 cases that did not utilize a flap, 33.3% achieved salvage, whereas ERD was reported in 66.7% (Fig. 4A).

Logistic regression analysis was performed to predict the odds of salvage by FR (area under curve = 0.631). The odds of salvage compared with ERD were found to be significantly three times higher (95% CI: 1.2–9.5) for cases with FR compared with those with no FR (Fig. 4B).

Subset Analysis: Omental Transposition

Within the flap reconstruction cohort, 49% (25) reported omental transposition ± other tissue flap utilization. In cases reporting omental transposition, salvage was achieved in 60.0%, whereas ERD was reported in 40.0%. Of cases in which omentum was not used, 76.9% reported salvage and 23.1% reported ERD. This was not associated with significant difference in outcome (P = 0.237) (Fig. 5).

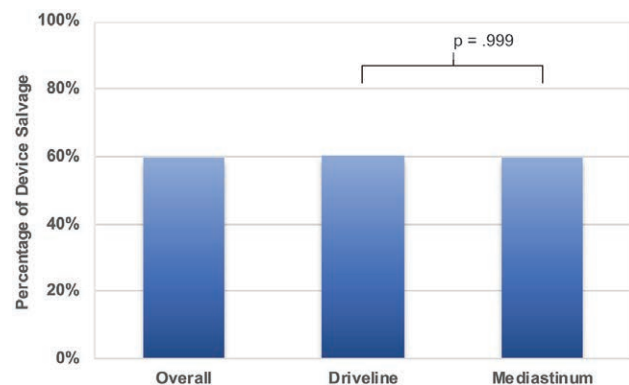


Fig. 2. Overall reported hardware salvage vs device explantation, infection recurrence, or death. Overall cohort had 74 cases with salvage reported in 59.5% (44). Driveline cohort had 20 cases with salvage reported in 60.0% (12). Mediastinum cohort had 54 cases with salvage reported in 59.5% (32).

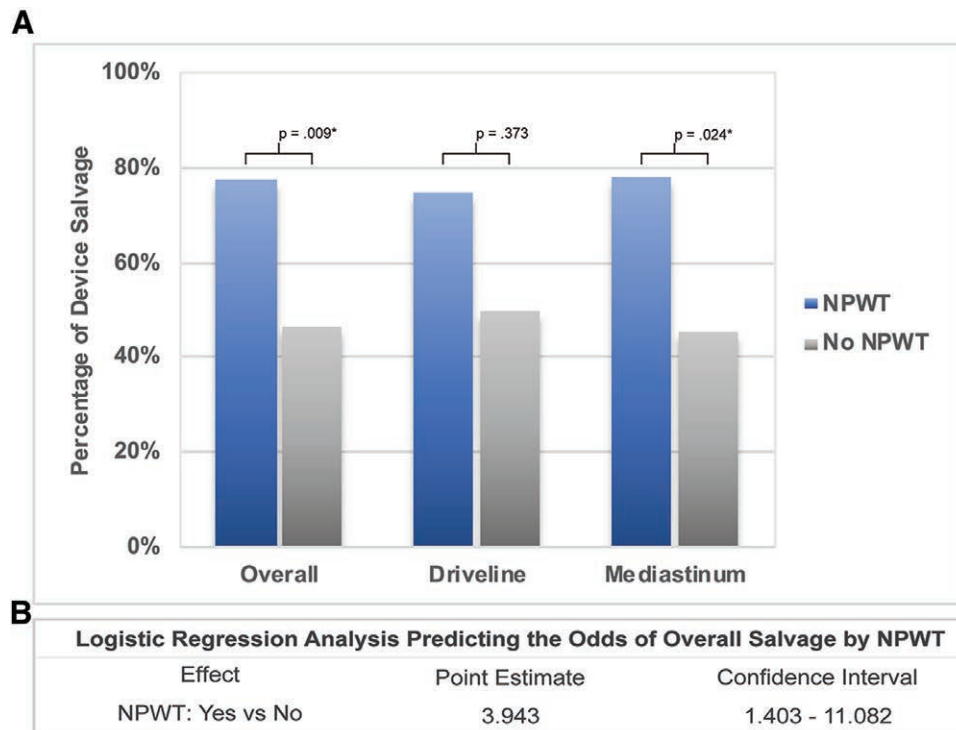


Fig. 3. Reported hardware salvage with and without reported used of negative pressure wound therapy (NPWT) in overall, driveline, and mediastinum cohorts. A, Overall, 31 cases reported NPWT with salvage in 77.4% (24) while 43 cases did not report NPWT with salvage in 46.5% (20). Overall, NPWT was significantly associated with improved outcomes. In the driveline cohort, eight cases reported NPWT with salvage in 75.0% (6), and 12 cases did not report NPWT with salvage in 50% (6). NPWT was not associated with significant difference. In the mediastinum cohort, 23 cases reported NPWT with salvage in 78.3% (18), while 31 cases did not report NPWT with salvage in 45.2% (14). NPWT was significantly associated with improved outcomes. B, Logistic regression analysis of NPWT predicting salvage was performed (area under curve = 0.656). The odds for salvage with NPWT compared with no NPWT were found to be significantly four times higher.

Subset Analysis: NPWT and Flap

Among the cohort of 43 cases not reporting the use of NPWT, 67.4% included FR and 32.6% did not. Within the (-)NPWT, (+)Flap cohort, salvage was achieved in 58.6% of cases and ERD was reported in 41.4%. Within the (-)NPWT, (-)Flap cohort, salvage was achieved in 21.4% of cases and ERD was reported in 78.6%. In the absence of NPWT, FR was associated with significantly improved outcomes ($P = 0.027$).

Among the cohort of 31 cases reporting NPWT use, 71.0% included FR and 29.0% did not. Within the (+)NPWT, (+)Flap cohort, salvage was achieved in 81.8% of cases while ERD was reported in 18.2%. Within the (+)NPWT, (-)Flap cohort, salvage was achieved in 66.7% of cases and ERD was reported in 43.3%. No significant association was noted between flap reconstruction and outcome in the presence NPWT ($P = 0.384$) (Fig. 6). Due to inadequate sample size, multivariable logistic regression analysis could not be performed to further characterize these relationships.

DISCUSSION

This review describes surgical management strategies for VAD-associated infections. Quantitative analysis of 74 cases from 29 systematically procured publications

reveals that, among these strategies, flap reconstruction and NPWT are beneficial in device salvage, thus improving patient outcomes.

This study has also demonstrated the perilous nature of these cases, which were shown to lead to an overall device explantation, infection recurrence, or mortality rate of 40% with similar ERD in driveline and mediastinum infection cohorts. Such high rates of morbidity and mortality suggest a tenuous patient population, but also indicate that development of a robust and evidence-driven algorithm is necessary to guide the surgeon in combating these complex wounds. This is in accordance with previous reviews, which call for increased research on the topic.^{3,5} Our analysis may provide evidence to assist the surgeon in management of these cases, but more study is necessary to further elucidate best-practice guidelines.

The use of antibiotic impregnated beads in wound management is a widely reported strategy,^{47,48} which remains understudied in VAD-associated wounds. Four studies in this systematically procured library reported bead utilization.^{6,18,22,40} The 2014 study by Kretlow et al, which was not included in this quantitative analysis, described efficacy with a salvage rate of 65% in a 26-patient cohort.⁶ This is in line with, and greater than, our demonstrated overall

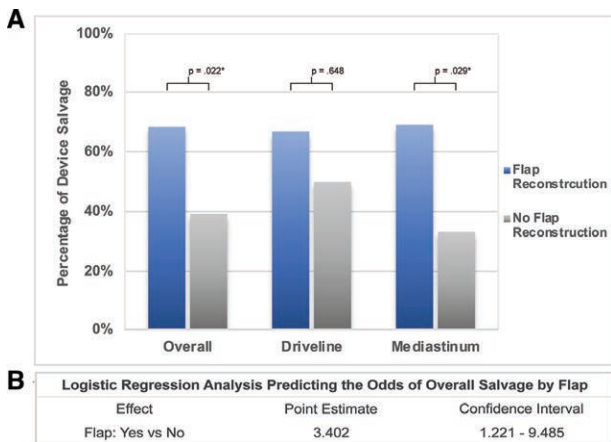


Fig. 4. Reported hardware salvage with and without use of flap reconstruction in overall, driveline, and mediastinum cohorts. A, Overall, 51 cases reported FR with salvage reported in 68.6% (35), whereas 23 cases did not report FR with salvage in 39.1% (9). Overall, FR was associated with improved outcomes. In the driveline cohort, FR was reported in 12 cases with salvage in 66.7% (8), and NFR was reported in eight cases with salvage in 50.0% (4). There was no significant association between FR and outcomes. In the mediastinum cohort, FR was reported in 39 cases with salvage in 69.2% (27), while NFR was reported in 15 cases with salvage in 33.3% (5). FR was associated with improved outcomes. B, Logistic regression analysis of FR predicting salvage was performed (area under curve = 0.631). The odds for salvage with FR compared with NFR were found to be significantly three times higher.

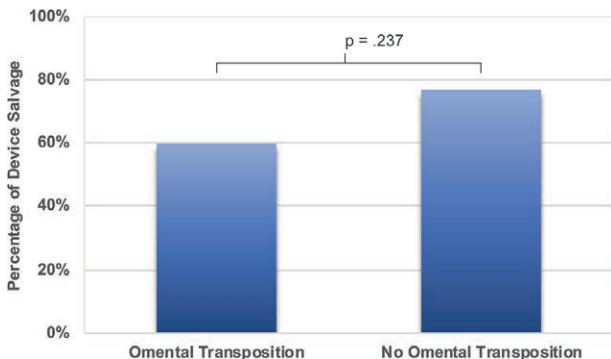


Fig. 5. Reported salvage in overall flap reconstruction cohort with and without omental transposition. Of the 25 FR cases which reported use of omentum, salvage was reported in 60.0% (15). Of the 26 FR cases which did not, salvage was reported in 76.9% (20). No significant association was found between outcomes and FR with and without omental transposition.

salvage rate of 60%. Although not a factor in our analysis, further study on the use of antibiotic beads in VAD-associated infections is warranted.

Demographic analysis of this 74-case cohort demonstrated similar patient populations within FR versus NFR and NPWT versus no NPWT divisions. Overall, mean patient age was 51 ± 16 , gender was 83% men, and median time from implant to infection was 62 days. These demographics are in line with reviews⁵ and qualitatively analyzed studies,^{6,30,31,38} thus indicating generalizability of this data set. Not all cases reported all demographic values of interest, limiting the analysis.

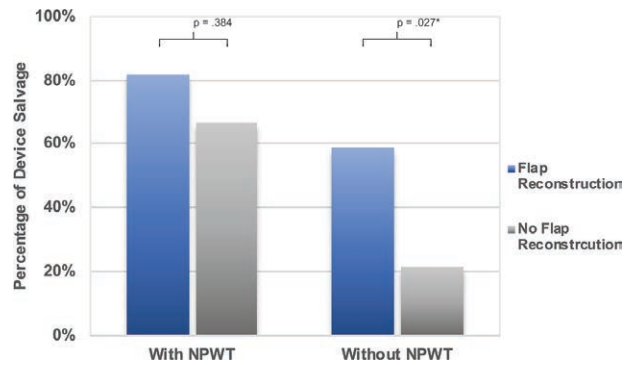


Fig. 6. Overall hardware salvage with and without flap reconstruction controlling for use of negative pressure wound therapy (NPWT). Within the NPWT cohort, FR was reported in 22 cases with salvage reported in 81.8% (18), whereas NFR was reported in nine cases with salvage in 66.7% (6). With use of NPWT, no significant difference was noted in outcomes between FR and NFR cohorts. Within the no NPWT cohort, FR was reported in 29 cases with salvage reported in 58.6% (27), whereas NFR was reported in 14 cases with salvage in 21.4% (3). Without use of NPWT, FR was significantly associated with improved outcomes.

Negative pressure wound therapy was shown to be valuable in the management of these wounds. Reported use of NPWT was associated with improved outcomes overall with a rate of salvage of 77% versus salvage of 47% in cases not reporting NPWT. This association held true amongst those with mediastinum-associated infections but was not significant in the driveline-associated infection cohort. The driveline cohort consisted of only 20 patients, limiting the power of statistical analysis. A larger sample may further elucidate the value of NPWT in driveline infections. Additionally, logistic regression of the overall cohort yielded an odds ratio of salvage four times higher with NPWT than without (CI: 1.4–11.1).

The demonstrated benefits of NPWT concur with the 2016 comprehensive review by Anghel et al describing 13 randomized controlled trials across a range of fields, which found NPWT to be associated with positive outcomes.¹²

Flap reconstruction was also associated with improved outcomes. Overall, salvage rate of 69% was reported with FR while that of 39% was reported without FR. This was a significant difference. Significance was maintained within the mediastinum-associated cohort. In the driveline cohort, the difference was not significant. Additionally, logistic regression of the overall cohort yielded an odds ratio of salvage three times higher with FR than without (CI: 1.2–9.5)

These results may be biased by patient selection factors. The use of a flap for closure could correlate with patients who are more stable, while such procedures may not be indicated in those with the most severe and life-threatening circumstances.

Reported indications for flap selection, including vascular supply, infection location, defect size, and immunologic properties, were diverse across publications and not considered in this analysis. With the current absence of evidence-based guidelines, flap selection is case-dependent and based on clinical findings and surgeon experience.

Omental transposition was commonly reported. The omental flap has been described as last-resort management of patients with intractable infections due to its vascularity and immunologic and angiogenic properties.¹³ The 2006 study by Sajjadian et al provides five cases demonstrating success with the omental flap and reasoning for its perceived value in management of this patient population.⁹

In comparison between flap reconstruction cases reporting omental transposition and those not, analysis did not show significant difference. Flap reconstruction, including omental transposition, yielded an overall salvage of 61% while that without yielded an overall salvage of 77%. This result may be biased by clinical utility of the omental flap. More data and further controlled studies may be necessary to examine its value in VAD-associated infection management.

Because of the significantly improved outcomes demonstrated in NPWT and flap reconstruction cohorts, it follows that a combination of the two management strategies may provide the best chance for successful device salvage. Without NPWT, flap reconstruction yielded significant improvement with salvage rate of 59% versus that of 21% without flap reconstruction. With NPWT, no significant difference was noted between FR and NFR groups. Although nonsignificant, these showed a similar trend with better overall outcomes; FR yielded salvage in 82% while no FR yielded salvage in 67%.

This study contains flaws, which impact data quality and analysis. Data reported were often variable and heterogeneous. Follow-up data were only available in 93% of salvage cases and, although not significantly different between cohorts, was not equivalent with a median of 6 months and IQR of 8 months thus limiting the accuracy of logistic regression analysis. Some of the largest studies that could have provided the least potential for bias could not be included due to aggregate reporting without cohesive description of relationships between predictor and outcome variables. Because this study mainly consisted of reports of small patient cohorts, publication bias may play a role in overall outcomes and correlation between outcome and management strategy.

Heterogeneity in data limited the granularity of the herein reported predictor and outcome variables. Many details, which would provide the reconstructive surgeon with valuable guidance, could not be adequately reported or accounted for. To optimize patient outcomes, granular information is needed regarding variables such as comorbidities, timelines, drain management, preoperative conservative management and antibiotics, number and type of operations, and duration of NPWT. It is clear that these cases are very complex and, with the binary information provided by this study, conclusions regarding the benefit of flap reconstruction or NPWT for any specific case are difficult.

Nonetheless, this publication provides a large body of evidence and a call for increased study on the surgical management of VAD-associated wounds. Further research should provide detailed reporting of cases, examine if synergistic benefit of NPWT with FR exists, and characterize FR outcomes based on flap utilized.

CONCLUSIONS

Overall, NPWT and flap reconstruction showed benefit in the surgical management of medically intractable VAD-associated infections. These results retained significance in mediastinum-associated infections, but conclusions cannot be made about their value in driveline-associated infections. The use of NPWT correlated with high rates of salvage and should be indicated in these patients. Although flap reconstruction did not show statistically significant benefit when employed in conjunction with NPWT, it was shown to be a valuable management strategy on its own. Further study may show the combination of the two to have the strongest correlation with device salvage. This study provides valuable evidence to assist in efforts to manage these life-threatening situations.

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