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In patients with post-sternotomy mediastinitis is vacuum-assisted closure superior to conventional therapy?

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Abstract

A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was whether vacuum-assisted closure therapy (VAC) is superior to conventional therapy for treating post-sternotomy mediastinitis. Altogether >261 papers were found using the reported search, of which 9 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. Several studies indicate that VAC therapy is associated with shorter lengths of intensive care and in-hospital stay as well as faster rates of wound healing and fewer dressing changes. It has also been shown that VAC therapy is correlated with a statistically significant reduction in reinfection rates, particularly those that occur in the early postoperative period (at the 1-week follow-up). Patients can be discharged with the dressing *in situ* and managed in the community with a view to delayed closure or reconstruction. However, the studies comparing VAC with conventional therapy are all retrospective in nature and reinforce the need for randomized controlled trials in order to more accurately establish differences in outcomes between VAC and conventional therapy. Additionally, owing to the variability of treatment protocols within the non-VAC arm, it is more challenging to draw definitive conclusions regarding the superiority of VAC therapy to every modality that is considered conventional treatment. We conclude that VAC therapy is a portable and an increasingly economical option for the treatment of post sternotomy mediastinitis. Although reductions in mortality rates were not reproduced in all studies, evidence suggests that VAC should still be considered as a first-line therapy for post-sternotomy mediastinitis and as a bridge therapy to musculocutaneous reconstruction or primary closure.

Keywords: Negative pressure wound therapy • Vacuum-assisted closure therapy • Deep sternal wound infection • Cardiac surgical procedures

INTRODUCTION

A best evidence topic was constructed according to a structured protocol. This is fully described in the *ICVTS* [1].

CLINICAL SCENARIO

You are currently attached to two consultants, each with a patient with culture-positive mediastinitis following coronary artery bypass grafting (CABG). You are asked by one of them to carry out surgical debridement, closed irrigation and reconstruction. However, the other consultant asks you to use vacuum-assisted closure therapy (VAC) therapy and delayed closure, as he believes it is superior to conventional therapy (CvT). You wonder what the evidence is for this statement and decide to carry out a literature search.

THREE-PART QUESTION

In [patients with post-sternotomy mediastinitis] is [vacuum-assisted closure therapy] or [conventional therapy] superior for achieving [shorter lengths of stay and better mortality and morbidity outcomes]?

SEARCH STRATEGY

Medline 1946 to November Week 3 2012 using OVID interface, EMBASE 1980–2012 week 51 [exp Sternotomy/OR exp Cardiac Surgical Procedures/OR exp Cardiopulmonary Bypass/OR CABG.mp OR valve replacement.mp.] AND [exp Surgical Wound Infection/OR Deep Sternal Wound Infection.mp. OR Mediastinitis.mp.] AND [exp Negative Pressure Wound Therapy/OR Vacuum-Assisted Closure Therapy.mp. OR VACmp. OR Topical Negative Pressure Therapy.mp.]

SEARCH OUTCOME

Two hundred and sixty-one papers were found using the reported search. From these, 9 papers were identified that provided the best evidence to answer the question. These are presented in Table 1.

Table 1: Best evidence papers

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments/weaknesses
Damiani *et al.* (2011), J Plast Reconstr Aesthet Surg, Italy [2] Meta-analysis of observational studies (level 3a)	A meta-analysis was performed to assess the impact of VAC compared with conventional therapy on length of stay and mortality in patients with infected sternal wounds 6 studies were identified that included 321 patients of which 169 underwent VAC therapy and 152 had conventional therapy. Conventional therapy included debridement, reconstruction with muscle flaps, closed or open drainage and continuous irrigation	Mortality Length of stay (days)	VAC therapy OR 0.61, [95% CI 0.29–1.27] better than conventional treatment No significant differences Mean difference; −7.18, [95% CI −10.82 to −3.54] in favour of VAC therapy	This meta-analysis showed that VAC therapy significantly reduced inpatient stay and tended to reduce mortality when compared with conventional treatment. The authors conclude that VAC is a valid alternative to conventional therapy because it reduces the duration of wound treatment and hospital stay without any significant impact on mortality rates Limitations: the included studies all employed different methods as their conventional treatment arm. Thus, the validity of drawing conclusions from such comparisons can be called into question
De Feo *et al*. (2011), Asian Cardiovasc Thorac Ann, Italy [3] Retrospective cohort (level 3b)	200 patients with deep sternal wound infections (DSWI) from 1979 to 2009 were included, Group A (n = 62; 1979–1994) was treated with conservative antibiotic therapy followed by surgery in case of failure. Group B (n = 83; 1995–2002) underwent wound debridement, closed irrigation and delayed plastic reconstruction. In case of failure, patients were managed with sugar and hyperbaric treatment. Group C (n = 55; 2002–2009), the treatment protocol included early surgical debridement, no <10 days of VAC therapy at a continuous pressure of −125 mmHg and reconstruction with a pectoralis muscle flap	In-hospital mortality Length of stay (days) Normal CRP within 7 days	A: 19 (30.6%) B: 2 (2.4%) C: 1 (1.8%) Not significantly different between VAC and conventional therapy A: mean 44 SD 9 B: mean 30.5 SD 3 C: mean 27.3 SD 9 Conventional therapy entailed significantly longer hospital stays (P < 0.05) A: 15(24.2%) B: 44 (53%) C: 39 (69%) Significantly faster rate of reduction in CRP in the VAC group when compared with conventional treatment (P < 0.05)	Those undergoing VAC therapy had significantly shorter in-hospital stay and C-reactive protein levels declined faster; however, there were no significant difference in mortality rates The authors recommend that 'the most reasonable management protocol is based on early surgical debridement of the wound, vacuum application, followed by plastic reconstruction with pectoralis muscle flap'
Steingrimsson *et al*. (2012), Interact CardioVasc Thorac Surg, Iceland [4] Retrospective population based cohort (level 3b)	43 patients with DSWI were included in the study. All patients were initially treated with intravenous antibiotics, surgical debridement and removal of sternal wires. 23 patients treated before July 2005 underwent CvT group, which involved surgical revision followed by twice daily open wound dressings with paraffin or chlorhexidine gauze with or without subsequent closed irrigation, until delayed primary closure can be achieved. In the other 20 patients negative pressure wound therapy (NPWT) was used as a first-line therapy (NPWT group). A paraffin gauze was placed at the bottom of the wound in order to protect the right ventricle and two layers of polyurethane foam (VAC GranuFoam, KCI Medical, San Antonio, TX, USA) was placed in the wound and a negative pressure of −125 mmHg was applied using the Vacuum Assisted Closure system (KCI Medical). The wound was reopened and dressings changed every 2–4 days. After granulation formation and clearance of infection delayed primary closure or secondary closure was performed	Length of stay in hospital (days) In-hospital mortality 1–year mortality Early reinfection Chronic infection	CvT: mean 48, SD 23 NPWT: mean 47, SD 17 P = 0.84 CvT: 1 (4%) NPWT: 0 (0%) P = 1 CvT: 4 (17%) NPPWT: 0 (0%) P = 0.07 CvT: 8 (35%) NPWT: 1 (5%) P = 0.02 CvT: 4 (17%) NPPWT: (0%) P = 0.07	This study showed that NPWT is associated with a significantly lower rate of early reinfections (persistent, Centres for Disease Control and Prevention (CDC) defined DSWI after at least one adequate treatment attempt) that required surgical revision as well as a trend towards lower 1-year mortality rates and fewer late chronic infections (infections diagnosed after discharge requiring surgical intervention that did not fulfill the CDC criteria for DSWI) The authors conclude that NPWT led to fewer surgical reinterventions and should be used as first-line therapy in most DWSI patients Limitations: the groups were both small and therapy was conducted over different time periods

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments/weaknesses
Vos *et al*. (2012), Interact CardioVasc Thorac Surg, Netherlands [5] Retrospective cohort (level 3b)	113 patients with post-sternotomy mediastinitis were treated either with VAC (n = 89) or open packing (n = 24). The team used a continuous negative pressure of 75–125 mmHg and treatment discontinuation was based on negative cultures	In-hospital mortality Intensive care stay (days) Length of stay (days)	VAC: 14 (12.4%) Open packing: 47 (41.7%) P = 0.0032 VAC: mean 6.8, SD 14.4 Open packing: mean 18.5, SD 21.0 P = 0.0081 VAC: mean 74, SD 61 Open packing: mean 69, SD 62 P = 0.9778	The VAC group had significantly lower in-hospital mortality rates and shorter durations of intensive care stay. Although overall hospitalization times were similar, a case can be made for using VAC as a cost saving method given the reduced time spent in intensive care However, despite the use of protective polyvinyl alcohol dressings, a patient suffered a right ventricular wall rupture secondary to the high negative pressures employed The authors conclude that 'VAC therapy is superior to open packing, resulting in shorter intensive care stay and improved survival' Limitations: retrospective, non-randomized analysis. Asymmetrical sample sizes with significantly younger patients included in the VAC group
De Feo *et al*. (2011), Tex Heart Inst J, Italy [6] Retrospective cohort (level 3b)	83 patients with post-cardiac surgery mediastinitis from 1995 through 2001, treated with CvT, underwent debridement, closed chest irrigation and final plastic reconstruction with pectoral muscle flap in the majority of cases. 74 mediastinitis patients underwent extensive wound debridement followed by NPWT from 2002 onwards. NPWT was instigated for no <10 days and a continuous pressure of −125 mmHg was applied in all trial participants	In-hospital mortality Length of stay (days) Rate of reinfection	NPWT: 1 (1.4%) Conventional: 3 (3.6%) P = 0.35 NPWT: mean 27.3, SD 9 Conventional: mean 30.5, SD 3 P = 0.02 NPWT: 1 (1.4%) Conventional: 14 (16.9%) P = 0.001	2 homogeneous groups in terms of demographics and operative procedures underwent conventional or VAC therapy. VAC therapy produced lower early mortality rates (P = 0.35), lower reinfection rates (0.001) and shorter hospital stays (P = 0.02) There the authors state that 'negative pressure wound therapy is advisable as first-choice therapy for deep sternal wound infection after cardiac surgery' Limitations: patients were treated non-concurrently and improvements in medical care since 1995 may positively affect the outcomes in the NPWT group
Assmann *et al*. (2010), Thorac Cardiovasc Surg, Germany [7] Retrospective cohort (level 3b)	A total of 192 patients with DSWI after median sternotomy were included in the study. 82 of these were placed on VAC therapy, while 38 patients were treated by intermittent open disinfectant irrigation and delayed secondary wiring. The CvT group had more beneficial baseline characteristics in terms of younger age, lower incidence of COPD and less complex cardiosurgical produces undertaken	Length of ICU stay (days) Length of stay in hospital (days) In-hospital mortality	VAC: mean 2.1 SD 1.2 Conventional: mean 3.9 SD 1.7 P < 0.05 VAC: mean 45.6 SD 18.5 Conventional: mean 55.2 SD 23.6 P < 0.05 VAC: 14.6% Conventional: 26.4% P < 0.05	Despite the VAC group having more disadvantageous baseline characteristics, the study reported lower mortality rates; shorter lengths of ICU and in-hospital stay as well as overall lower rates of postoperative complications (P < 0.05) including cardiovascular complications, sepsis and renal failure Thus they recommend: 'VAC is a non-invasive, easily applicable and effective means to treat DSWI. Particularly patients at high risk of wound infections should be primarily treated using vacuum-assisted wound closure instead of conventional regimens Limitations: this was a retrospective non-randomized study with subjects treated over different time periods, thus causal interpretations may be difficult

Continued

Table 1: (*Continued*)

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments/weaknesses
Petzina *et al.* (2010), Eur J Cardiothorac Surg, Germany [8] Retrospective cohort (level 3b)	In 118 patients with post-sternotomy mediastinitis, a group of 69 patients were treated with NPWT after debridement and irrigation. A continuous pressure of −125 mmHg was applied in all patients and the wound filler was changed every 2–4 days. NPWT discontinuation was guided by CRP and wound swabs. Another group of 49 were treated with CvT, which involved debridement, drainage and irrigation as well as transposition of the greater omentum and restabilization of the sternum There were no significant differences in preoperative demographics apart from a higher Body Mass Index (BMI) in the CvT group	In-hospital mortality Reinfection rate Length of stay in hospital (days)	NPWT: 4 (5.8%) Conventional: 12 (24.5%) $P = 0.005$ NPWT: 2 (2.9%) Conventional: 9 (18.3) $P = 0.008$ NPWT: mean 38 Range 19–87 Conventional: mean 41, range 28–150 $P = 0.08$	The in-hospital mortality and sternal reinfection rate were significantly lower in the VAC group. The in-hospital stay tended to be lower in the VAC group The authors conclude that NPWT should be the first-line treatment for deep sternal wound infections Limitations: retrospective cohort with patients treated over different time periods. Additionally, the patients in the VAC group required a mean of 5.5 (SD 1.6) operative procedures to complete the treatment whereas the conventional group only required one. On the one hand, this entailed more surgical trauma, but on the other it also meant more frequent debridement which is known to improve infection control
De Feo *et al.* (2010), Asian Cardiovasc Thorac Ann, Italy [9] Prospective cohort study (level 3a)	The study compared patients with post-cardiotomy staphylococcal deep sternal wound infection. A group of 39 patients treated with VAC therapy has been compared with 30 patients who received closed mediastinal irrigation and antibiotics. The VAC therapy was instigated for no <10 days and a continuous pressure of −125 mmHg was applied in all trial participants. Main outcomes investigated were hospital and wound healing	Hospital stay Healing time	VAC: mean 26.6 ± 8.4 Control group: mean 36.4 ± 3.2 VAC: mean 13.5 ± 3.2 Control: mean 21.2 ± 16.4	Using VAC technology shortened hospital stay and wound healing time in deep sternal wound infections, including methicillin−resistant cases Limitations: prospective cohort study without blinding, randomization and a small sample size
Segers *et al.* (2005), Interact CardioVasc Thorac Surg, Netherlands [10] Retrospective cohort (level 3b)	Retrospective data analysis identified 63 patients with post-sternotomy mediastinitis of which 29 were treated with topical negative pressure (TNP) and 34 with conventional closed drainage techniques. A continuous negative pressure of −125 mmHg was applied, as it was noted that intermittent pressure was associated with patient discomfort. Treatment withdraw was guided by CRP levels and cultures. Clinical outcomes were compared	Therapeutic failure rate (%)	TNP: 27.6% Conventional: 58.9% ($P = 0.01$)	Negative pressure treatment was shown to be an effective approach Limitations: it is a retrospective, non-blinded study with a small sample size

CvT: conventional therapy; OR: odds ratio; VAC: vacuum-assisted closure therapy.

RESULTS

Damiani *et al.* [2] performed a meta-analysis of six observational studies ($n = 321$) and evaluated the difference in lengths of hospital stay and mortality rates. They found that VAC therapy, when compared with other more conventional forms of treatment reduced in-patient stay by 7.18 days [95% CI: 3.54, 10.82] without a significant impact on mortality (odds ratio (OR) 0.61 [95% CI: 0.29, 1.27]). However, as previously pointed out by Bain *et al.* [11], the studies included in this meta-analysis employed various different methods in their conventional treatment arm. These include therapies such as debridement, closed irrigation and open packing and reconstruction with pectoral or omental flaps. These all vary in their treatment failure and mortality rates and may not be suitable as a single control variable.

De Feo *et al.* [3] also found no difference in mortality, but did find a reduction in length of hospital stay ($P < 0.05$) in their patients treated with VAC therapy compared with those treated with closed irrigation in addition to granulated sugar and hyperbaric therapy ($n = 200$). They also found that the rate of reduction in C-reactive protein was significantly faster in the VAC group ($P < 0.05$).

Steingrimsson *et al.* [4] showed that VAC therapy significantly reduced the early post-treatment recurrence of mediastinitis when compared with open packing and closed irrigation ($n = 43$). However, they found no significant differences in length of stay, early or late mortality rates. The authors believe that VAC led to

lower rates of chronic infections and necessitated fewer surgical reinterventions.

Vos *et al.* [5] compared patients ($n = 113$) who underwent open packing with those on VAC therapy and found that CvT was associated with a prolonged intensive care stay ($P = 0.0081$) and increased rates of early in-hospital mortality ($P < 0.05$). VAC therapy increased patient comfort and allowed for discharge and outpatient review while the dressing was still *in situ*. However, despite the use of polyvinyl alcohol dressing as protection there was still one incident of right ventricular rupture secondary to the high negative pressure (−125 mmHg) produced by the VAC system.

De Feo *et al* [6] studied 157 patients with post-sternotomy mediastinitis who had undergone VAC therapy after debridement or conventional treatment, which consisted of primary wound reopening, debridement, closed chest irrigation, topical application of granulated sugar and pectoralis musculocutaneous reconstruction. They found lower re-infection rates ($P < 0.05$) and shorter hospital stays ($P < 0.05$) but no significant differences in mortality rates.

Assmann *et al* [7] compared VAC therapy with primary rewiring and disinfectant irrigation and showed that rewiring was associated with a greater chance of treatment failure and led to a poorer outcome ($n = 192$). Despite having worse baseline characteristics, the VAC group had shorter lengths of intensive care unit and hospital stay ($P < 0.05$) and increased survival ($P < 0.05$), with lower rates of postoperative complications. This improvement in survival in the VAC group was found despite more frequent use of both internal thoracic arteries, which is normally associated with poorer outcomes.

Petzina *et al.* [8] also found a reduced mortality rate ($P < 0.05$), lower sternal reinfection rate ($P = 0.008$) as well as a tendency towards shorter lengths of hospital stay ($P = 0.08$) when comparing the VAC group with conventionally treated patients who had drainage and irrigation, omentoplasty (when appropriate) and stabilization of the sternum ($n = 118$). They postulated that the increased number of operative procedures required for the VAC treatment (mean 5.5) compared with the CvT (mean 1) offered optimal infection control due to repeated debridement and microbiological testing.

De Feo *et al.* [9], looked specifically at methicillin-resistant post-sternotomy mediastinitis ($n = 69$). They found that closed irrigation, and when necessary granulated sugar or musculocutaneous reconstruction, resulted in a longer hospital stay ($P < 0.05$), increased rates of reinfection and longer healing times ($P < 0.05$) than those treated with VAC therapy. Despite the small sample size, the authors showed a significant decrease in the time necessary for wound healing when VAC was used.

Segers *et al*. [10] also reported lower rates of recurring infection and therapeutic failure in their patients who had undergone VAC therapy compared with those who had closed drainage ($P < 0.05$) ($n = 63$). The small sample size and retrospective nature of the study encourage a careful interpretation of those results.

CLINICAL BOTTOM LINE

VAC therapy is a portable and an increasingly economical option for the treatment of post-sternotomy mediastinitis. VAC therapy removes wound exudate, oedema and cell debris and has been shown to increase the rate of granulation and wound healing [12]. This results in fewer dressing changes and improved patient comfort. Patients with VAC dressings may be managed in the community with a view to delayed closure or later reconstruction. Several studies indicate that VAC therapy is associated with shorter lengths of intensive care and in-hospital stay as well as faster rates of wound healing. Studies also show a statistically significant reduction in reinfection rates, particularly those that occur in the early postoperative period (at the 1-week follow-up). However, the studies comparing VAC with CvT were all retrospective in nature. The great variability in what the CvT was in the non-VAC arms of the studies must be taken into account when considering the evidence combined. This reinforces the need for randomized controlled trials in order to more accurately establish differences in outcomes between VAC and CvT. Although reductions in mortality rates were not reproduced in all studies, evidence suggests that VAC should still be considered as a first-line therapy for post-sternotomy mediastinitis and as a bridge therapy to reconstruction or primary closure.

Conflict of interest: none declared.

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eComment. Post-sternotomy mediastinitis management: negative pressure is the key

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I read with great interest the paper by Yu *et al.* in which they compare outcomes of vacuum-assisted closure (VAC) therapy with conventional management in patients with post-sternotomy mediastinitis (PSM) [1]. There is no general consensus concerning the appropriate surgical approach to PSM and multiple wound healing strategies have been proposed [2]. The treatment of PSM has changed radically with the advances made in VAC systems since the concept of negative wound pressure therapy was first described in the mid 1990s. VAC therapy was introduced to clinical practice in 1995 in North America and two years later it was available in Europe. Since the introduction of VAC techniques in the management of sternal wound infection, there has been a paradigm shift toward the use of this less invasive strategy as a first-line therapy in the management of PSM [2].

Although I recognize the efforts of Yu *et al.* in reviewing the literature to find the best strategy for patients with PSM, I would like to mention one important point that they failed to include in their report.

Closed drainage with Redon catheters is another alternative technique for PSM first used by Durandy *et al*. [3]. The high negative pressure (-700 mmHg) induced by the bottles fulfils exactly the role of VAC in a different fashion. Vos *et al*. [4] were the first to perform a prospective study comparing clinical outcomes of VAC with primary closure using Redon catheter in the setting of PSM. They included in their study 161 patients with PSM; there were 89 patients in the VAC group and 43 patients in the Redon group. Both groups were similar in risk factors and severity of mediastinitis. Hospital stay was significantly shorter in the Redon group (45 + /-38 days) compared with the VAC group (74 + /-61 days). The in-hospital mortality rate was similar in both groups, however re-infection rate was higher in the VAC group probably due to the increased risk of wound contamination during dressing changes. The authors of the present study concluded that this treatment modality using Redon drains provides sternal wound healing without repeat intervention while significantly reducing the hospital stay without compromising mortality.

By applying negative pressure to a sternal wound either by VAC or Redon drain connected to bottles several advantages are combined: removing exudate from the infected area and increasing blood flow into the wound. None of these studies is a randomized trial; therefore a prospective clinical trial is required to address this issue at a higher level of evidence.

Conflict of interest: none declared

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