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## DRESSINGS INDICATED IN THE TREATMENT OF MEDIASTINITIS AFTER CARDIAC SURGERY: INTEGRATIVE REVIEW

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#### **ABSTRACT**

**Objective:** identify and describe which dressings are recommended in the treatment of mediastinitis after cardiac surgery in adult patients.

**Method:** integrative review held in the databases MEDLINE/PubMed, LILACS, CINAHL, Web of Science, Cochrane, SCOPUS and manual search, between December 2017 and January 2018. It was selected studies on dressings used in the treatment of mediastinitis after cardiac surgery.

**Results:** eight articles were included: three addressed the treatment of negative pressure wounds and reported that most of the patients analyzed were successful in treatment, reducing the need for other interventions; four compared the previous therapy with conventional dressings and concluded that the rates of sternal reinfection and hospital mortality were lower in the first group; and one compared vacuum assisted therapy with a closed drainage system and lower rates of sternal reinfection were seen in the group undergoing vacuum treatment. **Conclusion:** the evidence indicates that the use of vacuum therapy to treat mediastinitis after cardiac surgery was effective. However, despite the positive outcome, clinical trials with strict methodological description and significant samples are suggested to minimize the risk of bias and to evaluate the impact of dressings in the treatment of mediastinitis.

**DESCRIPTORS:** Nursing. Mediastinitis. Thoracic surgery. Review. Treatment.

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#### CURATIVOS INDICADOS NO TRATAMENTO DE MEDIASTINITE APÓS CIRURGIA CARDÍACA: REVISÃO INTEGRATIVA

#### **RESUMO**

**Objetivo:** identificar e descrever quais curativos são recomendados no tratamento de mediastinite após cirurgia cardíaca em pacientes adultos.

**Método:** revisão integrativa realizada nas bases de dados MEDLINE/PubMed, LILACS, CINAHL, *Web of Science*, Cochrane, SCOPUS e busca manual, entre dezembro de 2017 e janeiro de 2018. Selecionaram-se estudos sobre curativos utilizados no tratamento de mediastinite após cirurgia cardíaca.

**Resultados:** incluíram-se oito artigos: três abordaram a terapia de feridas por pressão negativa e referiram que grande parte dos pacientes analisados obteve sucesso no tratamento, com redução necessidade de outras intervenções; quatro compararam a terapia anterior com curativos convencionais e concluíram que as taxas de reinfecção esternal e de mortalidade hospitalar foram menores no primeiro grupo; e um comparou a terapia assistida a vácuo com sistema de drenagem fechado e foi verificado taxas inferiores de reinfecção esternal no grupo submetido ao tratamento com vácuo.

**Conclusão:** as evidências indicam que o uso da terapia a vácuo para tratamento de mediastinite após cirurgia cardíaca foi efetivo. No entanto, apesar do desfecho positivo, sugere-se a realização de ensaios clínicos com rigorosa descrição metodológica e amostras significativas para minimizar o risco de viés e avaliar o impacto dos curativos no tratamento de mediastinite.

**DESCRITORES:** Enfermagem. Mediastinite. Cirurgia torácica. Revisão. Tratamento.

### CURACIONES INDICADAS EN EL TRATAMIENTO DE MEDIASTINITIS LUEGO DE UNA CIRUGÍA CARDÍACA: REVISIÓN INTEGRADORA

#### **RESUMEN**

**Objetivo:** identificar y describir cuáles son las curaciones recomendadas en el tratamiento de mediastinitis luego de una cirugía cardíaca en pacientes adultos.

**Método:** revisión integradora realizada en las bases de datos MEDLINE/PubMed, LILACS, CINAHL, *Web of Science*, Cochrane, SCOPUS y búsqueda manual, entre diciembre de 2017 y enero de 2018. Se seleccionaron estudios sobre curaciones utilizadas en el tratamiento de la mediastinitis luego de una cirugía cardíaca.

**Resultados:** se incluyen ocho artículos: tres abordaron la terapia de heridas por presión negativa e indican que gran parte de los pacientes analizados obtuvo éxito en el tratamiento, disminuyendo así la necesidad de otras intervenciones; cuatro compararon la terapia anterior con curaciones convencionales, en que se llegó a la conclusión de que las tasas de reinfección esternal y de mortalidad hospitalaria eran menores en el primer grupo; y uno comparó la terapia asistida por vacío con sistema de drenaje cerrado, donde se pudo comprobar las tasas inferiores de reinfección esternal en el grupo, bajo tratamiento por vacío.

**Conclusión:** las evidencias indican que el uso de terapia por vacío para el tratamiento de mediastinitis, luego de la cirugía cardíaca, fue efectiva. Sin embargo, a pesar del desenlace positivo, se sugieren realizar ensayos clínicos con una rigurosa descripción metodológica y muestras significativas para minimizar el riesgo de reincidencia y evaluar el impacto de las curaciones en el tratamiento de la mediastinitis.

**DESCRIPTORES:** Enfermería. Mediastinitis. Cirugía torácica. Revisión. Tratamiento.

#### INTRODUCTION

Health Care-Related Infections (IRAS) pose problems to patient safety. Based on this assumption, in 2009, the Pan American Health Organization, in conjunction with the National Sanitary Surveillance Agency and the Ministry of Health, launched the manual "Safe Surgeries Saves Lives", aiming to raise quality standards in health services. One of the items that constitute the manual concerns the prevention of Surgical Site Infections (ISC).<sup>1</sup>

The above infections are characterized by complications resulting from operative management, being classified according to the degree of involvement: superficial incision (skin and subcutaneous tissue), deep incision (fascia and muscle), and organ/space (sites inferior to the muscular layer).<sup>2</sup>

It is estimated that in the United States the SSI is responsible for 8,205 cases of annual deaths.<sup>2</sup> On the other hand, the Brazilian panorama brings surgical site infection as third place in the IRAS ranking, accounting for approximately 14% to 16% of hospitalized patients. In addition to the physical and psychosocial damages, the patient affected by SSI may have a prolonged hospitalization on average of seven to 11 days, increasing treatment costs.<sup>2</sup>

There are several factors that contribute to the onset of SSI, which are usually related to the patient, such as malnutrition, obesity, diabetes mellitus, chronic obstructive pulmonary disease (COPD), prolonged corticosteroid therapy, and long intensive care (ICU).<sup>3</sup>

In the case of cardiac surgery, the infection that affects organ/space is defined as mediastinitis, being considered a serious complication of the postoperative period, and its prevalence varies in the literature from 0.2% to 5%.4

Sternal wound infections can be divided into superficial and deep. The superficial ones reach the dermis and the subcutaneous tissue, and the deep ones reach the sternum and the anterior mediastinum. The *Staphylococcus aureus* is the most common microorganism, causing up to 80% of cases of post-surgical mediastinitis.<sup>5</sup>

The treatment for such complication varies between surgical and clinical methods and more and more dressings are being proposed for the management of sternal wound infection. A series of specific coatings can be used with the aim of favoring tissue granulation and reepithelization, accelerating the healing process through occlusion and maintenance of the moist environment.<sup>6</sup>

Based on the observation of the increase in the rates of mediastinitis in the postoperative period of cardiac surgery and great difficulties in indicating the type of dressing to be used, it was decided to seek evidence in the literature for the restlessness of the practice. In this way, the present study aims to: identify and describe which dressings are recommended in the treatment of mediastinitis after cardiac surgery in adult patients.

#### **METHOD**

It is an integrative review of the literature, a method that allows us to gather and synthesize results of studies on a given theme, through different methodologies, with the purpose of contributing to the incorporation of evidence in professional practice.<sup>7</sup>

This integrative review followed the following steps:<sup>8</sup> to establish the hypothesis or the question of the review, to select the sample to be reviewed, to categorize the studies, to evaluate the studies, to interpret the results and to present the review or synthesis of knowledge.

The PICO process was used to construct the guiding question in which: P – population and problem; I – intervention; C – Comparation and O – outcome (English term for outcome). It was considered: P, hospitalized patient in the postoperative period of cardiac surgery; I, use of dressing for treatment of infection in surgical wound; C, any comparison between dressings used; O, mediastinitis.

Based on this strategy the following question was asked: what is the recommended dressing for the treatment of mediastinitis in adult hospitalized patients after cardiac surgery?

The literature search occurred from December 2017 to January 2018 in the following databases: Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library, The National Library of Medicine (NLM) in MEDLINE/PubMed, Latin American and Caribbean Health Sciences Literature (Literatura Latino-Americana e do Caribe em Ciências da Saúde) (LILACS), Cumulative Index to Nursing and Allied Health Literature (CinAHL), Web of Science and SCOPUS, with the combination of descriptors identified in the Medical Subject Headings (MeSH) and in the Descriptors in Health Sciences (Descritores em Ciências da Saúde) (DeCS), e key words. Manual searches were performed on the cited references.

The following descriptors were used in the search strategy: mediastinitis, wound dressing e treatment, and their synonyms and keywords combined with Boolean operators AND and OR. Figure 1 shows the search strategy adopted in the MEDLINE database via PubMed, which was adapted for the other bases analyzed.

The inclusion criteria were: articles in Portuguese, English or Spanish, full texts available online in full and published in the period from January 2007 to January 2018 that answered the question of the review. Exclusion criteria were: articles in which surgical treatment was the only therapy used, editorial publications, narrative or integrative review, dissertations, theses, abstract of congress proceedings, repeated articles, studies with children and newborns, as well as experimental research on animals.

Two reviewers selected the articles independently and analyzed the titles and abstracts of the identified publications applying the eligibility criteria, and in case of doubt or disagreement, a third reviewer was asked to give an opinion on the inclusion or not of the study. The Kappa statistic was used to assess the degree of agreement between the reviewers, and the index reached was 0.922. Kappa ranges from 1 (complete agreement) to -1 (complete disagreement).

For the phase of data collection and analysis, a form developed by the researchers was used, which includes the following items: identification of the article (authors, year of publication and periodical), title of the article, country of publication, methodological delineation, study, results and outcomes, and conclusions/recommendations presented.

The data were grouped and analyzed by type of intervention, in a descriptive way. There was no conflict of interest in the conduct of this review and any kind of financing for the study.

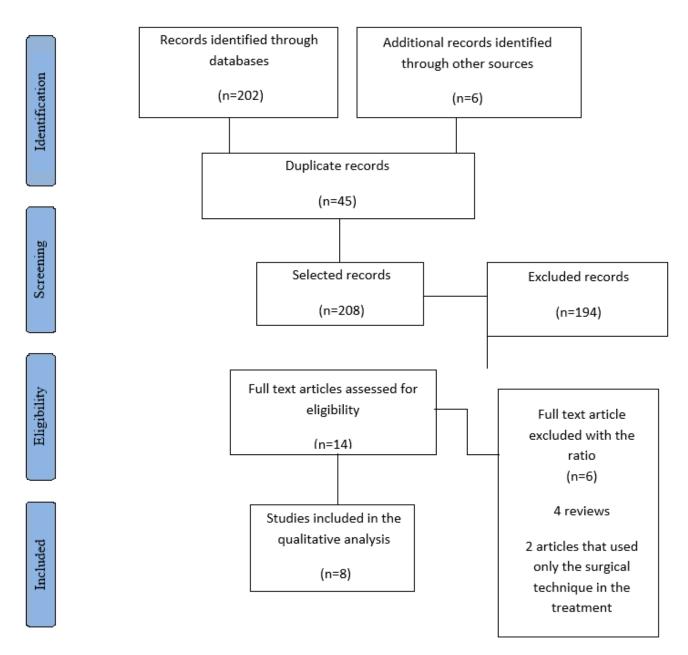
("mediastinitis"[MeSH OR "mediastinitis"[All Fields1) Terms] AND ("wounds and injuries"[MeSH Terms] OR ("wounds"[All Fields] AND "injuries"[All Fields]) OR "wounds and "wound"[All Fields]) AND injuries"[All Fields] OR ("bandages"[MeSH Terms] "bandages"[All Fields] OR "dressing"[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields1)

Figure 1 – Search strategy in the MEDLINE/PubMed database. Curitiba, PR, Brazil, 2017

#### **RESULTS**

A total of 208 studies were identified, of which 93 PubMed/MEDLINE, five CENTRAL,50 SCOPUS,44 Web of Science, six CINAHL, four LILACS and six in manual search. Of these, 45 were duplicates and 155 did not meet the inclusion criteria. Eight articles were included in the research, as shown in Figure 2.

Data regarding the identification of articles, such as year and language of publication, authors, methodological outline, therapies used and outcomes, are shown in chart 1.



**Figure 2** – Flowchart of identification, selection and inclusion of articles, meeting Prisma criteria. Curitiba, PR, Brazil 2017

All articles were developed by physicians of cardiothoracic surgery departments, and the participation of nurses was not clear. The articles included were published between 2008 and 2015. The countries of publication were not repeated in the studies, being: Saudi Arabia, Netherlands, Australia, Germany, UK, Norway, Iceland and Turkey. Regarding the methodological delineations found, six (75%) were retrospective observational studies, and two (25%) cohort studies.<sup>10–17</sup>

Six articles have similar methodological characteristics, being A1, A2, A3, A4, A5, and A8 retrospective observational studies, and two (A6 and A7) retrospective cohort studies. The analysis of the results showed three therapies used in the treatment of mediastinitis after cardiac surgery, being: Negative Pressure Wound Therapy (NPWT), also known as vacuum assisted therapy; conventional treatment; and drainage by closed system.<sup>10–17</sup>

Chart 1 - Identification of the included articles, title, country/year, design, intervention, outcomes. Curitiba, PR, Brazil, 2017

*	Title	Country/ Year	Designing	Intervention	Outcomes
A110	Vacuum-assisted closure system in treatment of postoperative mediastinitis	Saudi Arabia, 2013	Retrospective observational	Vacuum Assisted Therapy (AntiV.A.C.)	Wound closure: 21 patients (61.76%) had a direct surgical wound closure and 13 (41.16%) required a new fixation.
A211	Vacuum-assisted closure of post-sternotomy mediastinitis as compared to open packing	Netherlands, 2012	Retrospective observational	Vacuum Assisted Therapy (-75 to -125 mmHg) <i>versus</i> conventional dressings	Wound closure: Of the 89 patients undergoing vacuum therapy, 62 (69.66%) required new sternal fixation, and in 27 (30.33%) the wounds were closed for second intention. Mortality: In-hospital mortality was lower in the vacuum treated group (12.4% p =0.0032).
A312	Managing deep sternal wound infections with Vacuum-assisted closure	Australia, 2008	Retrospective observational	Vacuum Assisted Therapy (-125 mmHg) versus Vacuum Assisted Therapy with Sternal Reconstruction	Mortality: Of the 17 (65.38%) patients who only used vacuum therapy, six (35.29%) died due to infection. Sternal reconstruction: the remaining nine patients (34.61%) required sternal reconstruction.
A413	Negative pressure wound therapy for post-sternotomy mediastinitis reduces mortality rate and sternal re-infection rate compared to conventional treatment	Germany, 2010	Retrospective observational	Negative Pressure Wound Therapy set at -125 mmHg <i>versus</i> conventional treatment	Reinfection: two patients in the Negative Pressure Wound Therapy group compared to nine patients in the conventional group (p=0.008).  Mortality: Negative Pressure Wound Therapy reduced the mortality rate (p=0.005) and tended to decrease the duration of hospitalization (p=0.08).
A514	Assessment of Vacuum-assisted closure therapy on the wound healing process in cardiac surgery	United Kingdom, 2015	Retrospective observational	Vacuum Assisted Therapy (-125 mmHg)	Reintervention: of the 52 patients, 88.5% (n=46) treated exclusively with vacuum therapy were successful, and six (11.5%) required plastic interventions.  Mortality: no death related to complications of vacuum therapy.
A615	Mediastinitis after coronary artery bypass grafting: the effect of Vacuumassisted closure versus traditional closed drainage on survival and re-infection rate	Norway, 2012	Retrospective Cohort	Vacuum Assisted Therapy (-125 mmHg) <i>versus</i> conventional drainage	Reintervention: of the 66 patients treated with conventional drainage therapy, ten (15.1%) required a muscle graft to close the wound, and in the vacuum group, nine (14.1%) required a graft.  Mortality: there was no significant difference in the mortality rate after 30 days between the two groups.

# Chart 1 - Cont.

<u>*</u>	Title	Country/	Designing	Intervention	Outcomes
		rear	)		
A716	Negative-pressure wound therapy for deep sternal wound infections reduces the rate of surgical interventions for early reinfections	Iceland, 2012	Retrospective Cohort	Negative Pressure Wound Therapy (GranuFoam <sup>TM</sup> ) adjusted in -125 mmHg versus conventional dressing (chlorhexidine or paraffin).	Infection: in the conventional group, eight patients required surgical review for reinfections. In the vacuum therapy group, one patient reinfected (p=0.02). six patients in the conventional dressing group developed late chronic sternal infections (p=0.10).  Mortality: 30-day mortality was not significantly different between groups one and two (4% vs 0%, p>0.1).
A817	Treatment outcomes of postoperative mediastinitis in cardiac surgery; negative pressure wound therapy versus conventional treatment	Turkey, 2012	Retrospective observational	Negative Pressure Wound Therapy (-75 and -125 mmHg) <i>versus</i> conventional treatment.	Reintervention: all patients in the group undergoing NPWT (n=47) required only sternal fixation, and three patients in the conventional treatment group (n=43) required muscle grafting.  Mortality: the mortality rate after 90 days was significantly lower in the Negative Pressure Wound Therapy group.

\*ID: Identification.

#### **Negative pressure wound therapy**

The NPWT was mentioned in the eight articles included, and seven (A1, A2, A3, A5, A6, A7 and A8) cited the KCI Medical device as their choice, and one (A4) did not specify. Only Article A7 described the name of the material used as *GranuFoam*™.<sup>10–17</sup>

Three articles (37.5% of the sample), namely A1, A3 and A5, used Vacuum NPWT as the only choice in the treatment of mediastinitis, while five (62.5%) adopted the method of comparison between therapies (A2, A4, A6, A7 e A8).<sup>10–17</sup>

In A1, 34 patients diagnosed with mediastinitis and submitted to NPWT were analyzed. All were evaluated through clinical, laboratory and imaging tests. From this, the severity of the infection was classified (mean, moderate and severe), and 15 patients were classified as mean severity, 12 as moderate, and seven as severe.<sup>10</sup>

All of them received empirical antibiotic therapy until the results of the cultures, and afterwards the drug suitability was performed. The antibiotics mentioned in the study were: Vancomycin (29.41%), Cloxacillin (5.89%), Cephalexin (8.82%), Ciprofloxacin (23.52%), Gentamicin (11.76%), Imipenem and Cilastatin (11.76%), and Amoxicillin-clavulanate (8.82%). The pathogens identified were: *Staphylococcus epidermidis* (38.23%), *Staphylococcus aureus* (32.35%), *Staphylococcus aureus* resistant to methicillin (2.94%), *Klebsiella pneumoniae* (17.64%), and *Pseudomonas* (8.82%).<sup>10</sup>

Before the NPWT application, the 34 patients underwent debridement of the necrotic tissues and cleaning of the infected wound. The exchange of dressings happened every three days. No mention was made of the pressure graduation used during therapy, nor specified the adoption of measures to protect vital structures. A decrease in white blood cell count, negative cultures of the wound, reduction of drained content and no signs of fever indicating the end of treatment.<sup>10</sup>

Of the 34 patients observed, 21 (61.76%) benefited from vacuum therapy as an isolated measure, requiring only reinforcements in the steel strands that supported the sternum, while 13 (41.16%) were submitted to debridement of the sternum and a new fixation; 2 (6.33%) of the 13 patients required a muscle graft, and 1 (2.94%) developed chronic fistula four months after discharge. It was also found that one patient suffered a laceration of the right ventricle during the removal of the sponge, and the damage was surgically controlled.<sup>10</sup>

Vacuum therapy has been shown to be a safe, reliable and cost-effective modality treatment for postoperative mediastinitis, improving the outcome and may be combined with other conventional treatment modalities, especially in high-risk groups such as elderly or diabetic patients.<sup>10</sup>

The study A3 evaluated 31 cases of deep sternal wound infection. The diagnosis was made through tissue or bone biopsy. Of these, five patients (16.12%) did not receive vacuum therapy. The remaining 26 patients (83.87%) were submitted to sternal debridement and removal of non-viable tissues. After preparation of the insertion site, vacuum therapy was graded at -125 mmHg. The dressings were changed every two or three days, until the presence of granulation tissue was observed. The use of protective measures for vital structures has not been reported.<sup>12</sup>

Patients were treated with antibiotics that met the results of the cultures, however, they were not described in the study. The microorganisms found were: *Staphylococcus aureus* methicillinsensitive (39%), *Staphylococcus aureus* methicillin-resistant (23%), gram-negative bacilli (26%), and mixed (13%).<sup>12</sup>

Of the 26 patients, 17 (65.38%) only used vacuum therapy, of which six (35.29%) died due to infection. The other nine patients (34.61%) still needed sternal reconstruction, serving as prior therapy as a bridge to new approaches. It has been reported that one patient presented rupture of the right ventricle during the vacuum treatment, and it was necessary to intervene surgically.<sup>12</sup>

The average duration of therapy with vacuum application in this group was 13 to 10 days (3-32, median 12), and 17 who used vacuum therapy as an autonomous measure the duration was 21 to 18 days (2-57, median 15).<sup>12</sup>

Vacuum dressing presented satisfactory results when used in conjunction with other therapies, but as an isolated measure showed a high mortality rate as well as a longer duration of treatment.<sup>12</sup>

Study A5 considered 52 patients who underwent vacuum therapy, of which 46 (88.5%) were successful in treatment, and only 6 (11.5%) required additional plastic interventions. Vacuum therapy was graded at -125 mmHg. Of the 52 patients, 35 were male (67.03%) and 17 were female (32.07%), with an average age of 68.13 years, ranging from 47 to 82 years.<sup>14</sup>

The microbiology of sternal infections showed the following pathogens: *Staphylococcus* coagulase-negative (31.5%), Coliforms (27.4%), Coryneform (15.3%), *Serratia marcescens* (7.3%), non-hemolytic *Streptococcus* (7.3%), *Pseudomonas* spp. (6.5%), *Staphylococcus aureus* (4.8%), and Methicillin-resistant *Staphylococcus aureus* (0.8%). The study did not specify the use of antibiotic therapy.<sup>14</sup>

The follow-up was complete (average of 33.08 months) with an overall mortality rate of 26.09% (n=14), of which 50% of the patients (n=7) died in the hospital, two died of septicemia (28.66%) and five died (71.04%) of cardiac causes. None of the patients died of complications from vacuum therapy, although the study did not mention the adoption of preventive measures to avoid damage to the vital organs during the use of the dressing.<sup>14</sup>

Such therapy has been shown to be very effective and safe in the treatment of mediastinitis, but it is necessary to evaluate the risk factors before the indication of the vacuum.<sup>14</sup>

#### Vacuum Assisted Therapy versus Conventional Therapy

In A2 the authors analyzed 113 patients diagnosed with post-sternotomy mediastinitis. Of these, 89 (78.76%) were treated with Vacuum Assisted Therapy, and 24 (21.23%) with conventional therapy. All were submitted to surgical debridement and adequate antibiotic therapy.<sup>11</sup>

In the group in which conventional therapy was used, the wound irrigation was performed with hydrogen peroxide, saline and povidone-iodine (PVP-I), followed by sterile gauze coverage, and this procedure was repeated daily. In the group submitted to Vacuum Assisted Therapy, the dressings were changed twice a week, until the cultures of the wound were negative. Negative pressure was adjusted between -75 and -125 mmHg, and protective measures of vital organs were used in order to avoid damages. The criteria used to terminate therapy were: negative bacterial cultures, absence of fever, reduction of C-reactive protein (CRP) levels, and growth of viable granulation tissue in the wound.<sup>11</sup>

The presence of *Staphylococcus aureus* is similar in both groups, 62.9% in the group treated with vacuum therapy, and 62.5% in the conventional group. Other microorganisms were detected, such as: Coagulase-negative *Staphylococcus* (9.73%), *Staphylococcus epidermidis* (2.65%), *Escherichia coli* (1.76%), *Proteus mirabilis* (1.76%), *Serratia marcescens* (1.76%), *Klebsiella pneumoniae* (0.88%), and Methicillin-resistant *Staphylococcus aureus* (0.88%).<sup>11</sup>

Of the 89 patients who received vacuum therapy, 62 (69.66%) required additional procedure for closure or a new sternal fixation, while the remaining 27 (30.33%) had their wounds closed by second intention. There are no reports of intercurrences during dressing removal.<sup>11</sup>

The conventional dressing showed a disadvantage in relation to the length of ICU stay, as well as the in-hospital mortality rate related to mediastinitis. In-hospital mortality was significantly lower in the group treated with vacuum therapy (12.4%) compared to patients treated with conventional dressing (41.7% p=0.0032). The *odds ratio* (OR) for in-hospital mortality in the vacuum group was 0.20 (95% CI = 0.07-0.56).<sup>11</sup>

Assisted Vacuum Therapy has been shown to be superior to conventional dressings, since it reduces mortality, improves sternal instability, promotes patient comfort, and can be applied in an outpatient setting.<sup>11</sup>

The authors of study A4 performed a similar comparison to study A2, including in relation to the number of the sample. In this article, we studied 118 patients who developed post-sternotomy mediastinitis and were divided into two groups. The group that used NPWT contained 69 participants, whereas the conventional treatment group comprised 49 patients.<sup>11,13</sup>

The first group was submitted to debridement, removal of sternal wires and irrigation. The article mentions the use of sterile paraffin gauze on the right ventricle in order to protect it from intercurrences during manipulation. When installed, the device was set to -125 mmHg of negative pressure. The dressings were changed every two or four days, in a surgical room, with re-debridement and irrigation, if necessary. When the reduction of leukocytes and C-reactive protein in laboratory tests and absence of infectious signs were observed, NPWT was discontinued. The wound closure occurred by second intention with new sternal fixation. Muscle grafting was indicated in a few cases and was not specified in the study.<sup>13</sup>

The second group received conventional treatment, which consisted of surgical debridement, removal of sternal wires, drainage and irrigation (from three to four weeks), muscle grafting, when possible, and reestabilization of the sternum.<sup>13</sup>

More surgical interventions were required to complete treatment for mediastinitis in the group undergoing vacuum therapy than in the conventional treatment group. However, hospital mortality rates were significantly lower in the group submitted to vacuum therapy (5.8%) than in the conventional treatment group (24.5%). Still, sternal reinfection rates were lower in the first group (two patients) than in the second group (nine patients) (p=0.008 by the Fisher's exact test and 0.01 by the chi-square test).<sup>13</sup>

The difference in the period of hospitalization after surgery predisposed to the onset of mediastinitis tended to be shorter in the group treated with NPWT (NPWT group 42 days±15.4 and conventional therapy group 51 days±26.7, p=0.08 by the Mann-Whitney U test). There were no cases of damage to the right ventricle during vacuum handling.<sup>13</sup>

The NPWT has been shown to reduce mortality and sternal reinfection rates, as well as length of hospitalization, compared to conventional treatment.<sup>13</sup>

The A7 cohort study evaluated for 11 years the difference between the outcome of patients diagnosed with mediastinitis treated with conventional therapy or NPWT. A total of 43 patients were included in the study, divided into two groups: 23 (53.48%) submitted to conventional therapy, and 20 (46.51%) to NPWT. All patients received antibiotic therapy and surgical debridement to remove non-viable tissues, and in the vacuum treated group a layer of gauze was used to protect the right ventricle. The antibiotics used were not detailed in the study. The average age for the entire group of patients was 69 years and 74% were males.<sup>16</sup>

The pathogens identified in the study were: Coagulase-negative *Staphylococcus* (30% in group one, and 70% in group two), and *Staphylococcus aureus* (43% in the first group, and 20% in the second group).<sup>16</sup>

The dressings of the first group were performed twice a day, with sterile gauze and chlorhexidine, until it was possible to perform closure by first intention. The irrigation of 0.9% saline solution was necessary in only five cases (21.73%), and was followed by a closed system, with tubes inserted into the mediastinum, which were removed as soon as the wound was no longer considered infected.<sup>16</sup>

In the second group, dressings were changed every two or four days. The negative pressure applied was -125 mmHg. Therapy was discontinued when observed viable granulation tissue and absence of infectious signs.<sup>16</sup>

Of the 43 patients, 9 (21%) were diagnosed with a new sternal infection, 8 (35%) in the conventional group, and 1 (5%) in the NPWT group (p=0.02), being diagnosed *Pseudomonas aeruginosa*. In this case, the treatment was discontinued and replaced with another therapy.<sup>16</sup>

Surgical treatment for chronic sternal wound infection was required in one patient (5%) in the NPWT group, and in six (26.08%) of the conventional therapy group.<sup>16</sup>

There was no significant difference in the shorter residence time between the conventional therapy and NPWT groups:  $48\pm23$  days (median,43, interquartile range, 32-60) and  $47\pm17$  days (median,43, interquartile range, 34-60), respectively (p=0.84). The ICU stay was  $4.3\pm7.4$  days (median 1, interquartile range 0-5) when compared to  $3.7\pm7.6$  days (median 1, interquartile range 0-4) for the groups submitted to conventional therapy and NPWT, respectively (p=0.81). One patient in the conventional therapy group died during treatment due to rupture of the right ventricle. In the NPWT group, two patients presented bleeding from the heart during the treatment, however, none of them died.  $^{16}$ 

The study shows a significant decrease in rates of reinfection requiring surgical interventions in patients treated with negative pressure.<sup>16</sup>

Article A8 included 90 patients who developed postoperative mediastinitis, dividing them into two groups according to treatment modality: group one, initially submitted to NPWT (n=47); and group two, conventional treatment (n=43). The average age of the patients was  $62.86 \pm 11.6$ ; 57 (63.3%) were female and 33 (36.7%) were male.<sup>17</sup>

Both groups received prophylactic antibiotic therapy with 1.5g Cefuroxime. After confirmation of the mediastinitis, the exchange was performed for Vancomycin until new culture results were released. The microorganisms mentioned in the study were *Staphylococcus aureus*, and Methicillin-resistant *Staphylococcus aureus*.<sup>17</sup>

The treatment of the first group consisted of removal of the sternal wires and surgical review, with subsequent application of the vacuum dressing, adjusted to a negative pressure between -75 and -125 mmHg. The study does not report the application of preventive measures to the right ventricle. The dressing was changed every 48 or 72 hours, in a surgical center, for cavity review and debridement, if necessary.<sup>17</sup>

The second group had its treatment based on surgical review, removal of sternal wires, and debridement of non-viable tissues. The treatment was given in four ways: sternal reimplantation, open dressings, closed drainage system, or muscular graft with participation of plastic surgery.<sup>17</sup>

All the patients in the first group lacked new sternal fixation, and no other surgical interventions were necessary, while three patients (6.9%) of the second group underwent muscular grafting.<sup>17</sup>

The 90-day mortality rate was significantly lower in the NPWT group than in the conventionally treated group (8.5%, four patients *versus* 23.2%, ten patients, p<0.05). The cause of all deaths in each group was multiorgan failure due to severe sepsis. Treatment failure was observed in NPWT and in the conventional treatment group of 2.1% and 4.7%, respectively. There are no reports of complications during manipulation of the vacuum dressing.<sup>17</sup>

The NPWT is safe and effective, with excellent survival and decreased reinfection rates when compared to traditional treatment.<sup>17</sup>

#### Vacuum Assisted Therapy versus Closed Drainage System

The A6 cohort study sought to verify the effect of these treatments on mortality rate and sternal reinfection. In this direction, the article analyzed 130 patients, who were divided into two groups: NPWT (n = 64) and traditional drainage (n = 66).<sup>15</sup>

Patients treated with closed drainage therapy were first submitted to debridement, antibiotic irrigation until the drained contents had no infectious characteristics, and specific sternal fixation

technique. On the other hand, patients submitted to NPWT treatment had sternal wires removed and debridement performed. In order to protect the right ventricle, a layer of paraffin gauze was used between the sternum and the heart. The negative pressure was adjusted to -125 mmHg, and the exchanges occurred twice a week.<sup>15</sup>

Of the 66 patients treated with conventional drainage therapy, ten (15.1%) required a muscle graft to close the wound, while the remainder required only sternal fixation with specific technique. In the group submitted to Vacuum Assisted Therapy, nine (14.1%) needed a graft.<sup>15</sup>

The microbiology result of the evaluated tissues indicated bacterial growth in 79.4% of the sample (n=85). *Staphylococcus aureus* was predominant in the analysis, being present in 74 patients.<sup>15</sup>

The study did not portray differences between groups in the 30-day mortality rate. In the vacuum group, two patients died within 30 days: one of myocardial infarction and sepsis, 17 days after sternal reopening; and another due to rupture of the right ventricle during reopening of the sternum, 22 days after myocardial revascularization. Two other patients had rupture of the right ventricle, one week after starting treatment with vacuum. The laceration of the right ventricle was closed and both survived. In the traditional drainage group, there was no mortality in 30 days. The hospital stay had an average of 14 days in both treatment groups. The rate of sternal reinfection was lower in the NPWT group.<sup>15</sup>

#### DISCUSSION

The results pointed out that most of the studies are retrospective. However, considering that in the retrospective studies the analysis of the data occurs through previous information, it is necessary to reflect on the quality and reliability of the records collected for reduction of bias.<sup>9</sup>

Cohort studies seek to assess the exposure status (exposed and unexposed), as well as the risks and benefits of certain therapies, identifying the issues raised between the groups. It allows the evaluation of multiple outcomes and has the advantage, as long as correctly used, the reduction of confusion during the interpretation.<sup>9</sup>

Only study A4 did not cite the demographic data of the participants.<sup>13</sup> The other studies indicate that the average age of the patients was over 60 years, and that the vast majority of them were male. Only in A8 the female population was higher.<sup>17</sup> This study corroborates the increase in infection in males, and suggests the hypothesis that men may develop more infection due to a greater amount of hair follicles in the chest region, which predisposes the individual to the infection, since it increases the bacterial growth; therefore, more studies are needed to confirm this hypothesis.<sup>18</sup>

From the results listed by the present review, it was observed that dressings with vacuum application were more effective when related to wound closure, whether used alone or in combination with other therapies, when compared to the other treatment methods described.<sup>10–17</sup>

Regarding the mortality rate, only one study (A3)<sup>12</sup> reported a higher index in the NPWT group as an isolated measure; however, satisfactory results were observed when associated with other modalities. It is worth noting that the deaths identified were not related to the therapy used, but to the severity of the infection. Consistent with these data, a retrospective observational study<sup>19</sup> evaluated the vacuum treatment for mediastinitis, and concluded that mortality rates were lower when compared to conventional treatment, and that by associating the vacuum with the use of flaps, the results were even better.

In relation to wound closure, in A1<sup>11</sup> happened directly and in A2<sup>12</sup> indirectly by second intention. In a literature review of nine articles,<sup>20</sup> NPWT reduced the hospitalization time of the patients, as well as accelerated the process of wound healing.

The superiority of NPWT in sternal reinfection rates could also be evidenced when compared to conventional treatment in four articles (A4, A6, A7 and A8), the remaining four studies (A1, A2, A3 and A5) did not address such information.<sup>10–17</sup>

The mechanism of action of NPWT consists of cellular proliferation and angiogenesis, favoring the appearance of granulation tissue, reduction of the local inflammatory response, through the reduction of edema and exudate, and consequent contraction of the wound margins.<sup>21</sup>

Professionals of the European Association of Cardiothoracic Surgery published in 2016 a *guideline* on prevention and management of mediastinitis, in which treatment with negative pressure therapy is classified as grade of recommendation I, level of evidence B, that is, there is a general consensus that the procedure is safe and effective.<sup>5</sup>

However, it is important to emphasize that despite the benefits described, NPWT can also present complications and, therefore, safety measures should be adopted during treatment. In order to protect the right ventricle from damage that may occur, the *guideline* mentioned above recommends the application of multiple layers of gauze embedded in paraffin.<sup>5</sup>

Among the eight articles included in the review, only half of the sample (A2, A4, A6 and A7) explained the use of protective measures of vital structures, and yet there are reports of bleeding from the heart in two articles (A6 and A7). The remaining four articles (A1, A3, A5 and A8) did not specify the adoption of preventive measures, and of these, two (A1 and A3) reported problems arising from the procedure, such as rupture of the right ventricle.<sup>10–17</sup>

The success of NPWT also depends on the handling conditions of the system. As identified in the review, the *guideline* mentioned above supports the idea that the pressure setting should be between -75 and -125 mmHg. The volume of exudate to be drained the guiding parameter for adjusting the pressure of the device.<sup>5</sup>

There is also a consensus on the exchange of dressings, which should occur in a maximum of four days, since in longer periods the sponge saturation may reduce drainage capacity of the exudate, limiting the performance of therapy.<sup>21</sup> Among the eight studies analyzed in the review, only one (A5) did not report the dressing replacement period.<sup>14</sup> However, in the seven remaining articles (A1, A2, A3, A4, A6, A7 and A8), it was observed that the exchange pattern did not exceed four days.<sup>10–13,15–17</sup>

From the data collected with the review, it was also observed that the pathogens present in the mediastinal exudates are compatible with those pointed out in the literature, being predominant the *Staphylococcus aureus*. Because it is a microorganism present in the microbiota itself, it is suggested to adopt prophylactic measures already in the preoperative period. Therefore, the *Centers for Disease Control and Prevention* recommended for the prevention of surgical site infection bath with antiseptic at night before surgery (category 1B – strong recommendation, acceptable practice maintenance of glycemic levels with values lower than 200 mg/dl for all patients, regardless of whether they are diabetic (category 1A – strong recommendation), and care about normothermia (category 1A – strong recommendation).<sup>22</sup>

It was found as a limitation the difference between the methodological delineations of the articles included to carry out an effective comparison between the proposed therapies. Moreover, the lack of randomized clinical studies with a greater number of samples may be considered a complicating factor of the recommended dressings for the treatment of mediastinitis.

#### CONCLUSION

Considering the data obtained from the review, the included studies show that the use of NPWT in the cases of mediastinitis after cardiac surgeries assists in the closure of the wound, presents a low rate of reinfection, as well as mortality and reintervention. Such resource is effective and safe for the patient, in addition to contributing to the reduction of hospital costs through reduced hospitalization time.

However, in spite of the positive outcome, clinical trials with strict methodological description, numbers of more expressive samples, description of the pressure value used in the vacuum therapy, dressing change time, clear description of the participants, to reduce the risk of bias and to evaluate

the effectiveness of vacuum dressings for the treatment of mediastinitis. The development of studies with methodological quality is essential to establish the best evidence of the use of negative pressure therapy dressings, aiming at patient safety, and to develop and implement protocols for the treatment of mediastinitis.

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#### **NOTES**

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#### **CONFLICT OF INTERESTS**

There is no conflict of interest.

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