

Interventions for patients with post-sternotomy mediastinitis: an integrative literature review

Intervenções a pacientes com mediastinite pós-esternotomia: revisão integrativa da literatura

Intervenciones para pacientes con mediastinitis post-esternotomía: una revisión bibliográfica integradora

ABSTRACT

Objective: To analyze information available in the literature on interventions for patients with mediastinitis after a cardiac surgery. **Method:** An integrative review of primary studies in the databases LILACS, MEDLINE (via PUBMED), CINAHL and BDNF, published in English, Portuguese, and Spanish. **Results:** Most of the eight analyzed articles show that the most used intervention was negative pressure therapy, whether or not associated with antibiotic therapy and reconstructive surgery. **Conclusion:** The scientific evidence analyzed supports decision-making processes regarding interventions for patients with mediastinitis after cardiac surgery. It also allows the identification of knowledge gaps to conduct new research and implement nursing interventions for these patients.

Descriptors: Thoracic Surgery; Mediastinitis; Therapeutics; Review.

RESUMO

Objetivo: Analisar as evidências disponíveis na literatura sobre as intervenções a pacientes com mediastinite pós-esternotomia. **Método:** Revisão integrativa com busca dos estudos primários nas bases de dados LILACS, MEDLINE (via PUBMED), CINAHL e BDNF, publicados em inglês, português e espanhol. **Resultados:** Os oito artigos analisados mostram que, na maioria deles, a intervenção mais utilizada foi terapia por pressão negativa, associada ou não a antibioticoterapia e cirurgia reconstrutora. **Conclusão:** As evidências científicas geradas fornecem subsídios para a tomada de decisão quanto às intervenções para pacientes pós-cirurgia cardíaca com mediastinite, bem como a identificação de lacunas do conhecimento, para a condução de novas pesquisas com o propósito de implementar intervenções de enfermagem a esses pacientes.


Descritores: Cirurgia Torácica; Mediastinite; Terapêutica; Literatura de Revisão.

RESUMEN


Objetivo: Analizar las evidencias disponibles en la literatura sobre intervenciones en pacientes con mediastinitis después de la cirugía cardíaca. **Método:** Revisión integradora con búsqueda de estudios primarios en las bases de datos LILACS, MEDLINE (vía PUBMED), CINAHL y BDNF, publicados en inglés, portugués y español. **Resultados:** Los ocho artículos analizados muestran que en la mayoría de ellos la intervención más utilizada fue la terapia de presión negativa, asociada o no con la terapia con antibióticos y la cirugía reconstructiva. **Conclusión:** La evidencia científica generada respalda la toma de decisiones con respecto a las intervenciones en pacientes después de una cirugía cardíaca con mediastinitis, así como la identificación de lagunas de conocimiento para realizar nuevas investigaciones con el propósito de implementar intervenciones de enfermería para estos pacientes.

Descriptores: Cirugía Torácica; Mediastinitis; Terapêutica; Revisión.

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How to cite this article:

Cruz CLS, Mattia AL, Barbosa JAG, et al. Interventions for patients with post-sternotomy mediastinitis: an integrative literature review. Revista de enfermagem do Centro-Oeste Mineiro. 2021;10:e3873. [Access _____]; Available in: _____. DOI: <http://doi.org/10.19175/recom.v10i0.3873>

INTRODUCTION

Cardiovascular diseases in Brazil and worldwide are the main causes of death in women and men. Furthermore, they are responsible for the loss of the family's workforce and income ⁽¹⁾.

We have several therapeutic alternatives available for the treatment of heart disease. However, conservative clinical approaches are often insufficient for the management of patients with cardiac comorbidity and surgical interventions are necessary. We can highlight three types of cardiac surgery: corrective - the closing of the ductus arteriosus, atrial and ventricular septum; reconstructive - myocardial revascularization, aortic, mitral or tricuspid valve repair and substitutes - valve changes and transplants. Myocardial revascularization surgery (MRVS) is the most common type of reconstructive surgery. However, all cardiac surgeries are highly complex ⁽²⁾.

Hematoma, seroma, infections, and dehiscence are among surgical complications. Surgical infection is characterized by an inflammatory process with drainage of purulent secretion, whether or not it has a positive culture, with or without the involvement of tissues adjacent to the wound ⁽³⁾. Other variables also contribute to surgical site infection (SSI) in cardiac surgery such as a male patient, orotracheal intubation time greater than 24 hours, and postoperative reintubation ⁽⁴⁾.

In particular, the infection of the sternum wound after cardiac surgery is a very serious complication. A study showed that its incidence ranges from 0.9% to 20%, with coagulase-negative *Staphylococcus* and *Staphylococcus aureus* as the most common pathogens, in addition to others related to sternal infection and mediastinitis, such as *Acinetobacter*, *Enterobacter cloacae*, *Escherichia coli*, and *Klebsiella* ⁽⁵⁾.

We proposed an integrative review when considering the incidence of infection of the sternum wound, its severity, and the scarcity of studies on interventions for these patients. Thus, considering that the theme interventions to patients with post-sternotomy mediastinitis are poorly investigated, and the need to prepare health professionals for intensive and complex care, we justified the interest in conducting the integrative review. The results may generate evidence to support the care provided. Thus, this review aimed to analyze the evidence available in

the literature about interventions for patients with post-sternotomy mediastinitis.

METHOD

The integrative review (IR) was the method of synthesis of knowledge used. When carrying out this method, we follow five steps: the elaboration of the research question (identification of the problem), the search in the literature of primary studies, the evaluation of primary studies, the data analysis, and the presentation of the review ⁽⁶⁾.

To guide the IR based on the PICOT strategy (an acronym for the patient, exposure, comparison, outcomes, and time), we asked the following question: What is the available evidence in the literature on the treatment of surgical wounds for patients with post-operative mediastinitis? The first element (P = patient or problem) consists of patients undergoing cardiac surgery with median sternotomy who evolved with dehiscence and mediastinitis in the postoperative period. The second element (E = exposure or intervention) in the treatment with conventional dressing, vacuum dressing system, surgical debridement, and antiseptic irrigation. The third element (O = outcomes or results) in the healing process and (T = time) postoperative period.

We performed an online search for primary studies in four databases in the health area: Latino Americana e do Caribe em Ciências da Saúde (LILACS), Medical Literature Analysis and Retrieval System Online (MEDLINE via PUBMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Banco de Dados em Enfermagem (BDENF).

We established the descriptors and keywords according to each selected database, to ensure a rigorous and broad search of primary studies on the topic of interest, associated with the acronym PICOT delimited for the search strategy (Figure 1). To search for publications in each database, the descriptors and keywords were crossed with each other, through tactical operations, using the Boolean operators AND and OR.

Figure 1 – Descriptors and keywords selected in each base according to the PICOT acronym.

| Descriptors and keywords | | | |
|----------------------------|--------------------------------|-----------------|-------------------|
| LILACS | MEDLINE | CINAHL | BDENF |
| Cirurgia cardíaca | Thoracic surgery/complications | Cardiac surgery | Cirurgia cardíaca |
| Cirurgia do coração | Surgery, Thoracic | Mediastinitis | Mediastinite |
| Cirurgia torácica | Surgery | | |
| Mediastinite | Cardiac Surgery | | |
| Mediastinite-complicações | Heart Surgery | | |
| Deiscência | Cardiac Surgery | | |
| Infecção | Bandage | | |
| Curativo | Mediastinitis | | |
| Curativo-reabilitador | | | |
| Curativo-recuperativo | | | |
| Curativos de hidrogel | | | |
| Terapêutica | | | |
| Tratamento | | | |
| Ação terapêutica | | | |
| Medida terapêutica | | | |
| Procedimentos terapêuticos | | | |

Source: the authors.

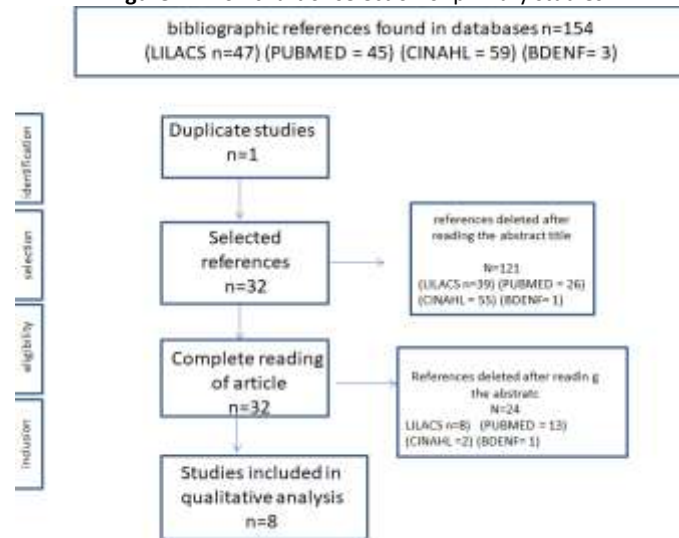
The search strategies were built by a librarian and the researchers to make the search more sensitive. Thus, the strategies were different for each database, using controlled and uncontrolled descriptors present in the vocabulary of Health Sciences Descriptors (DECS) of the Virtual Health Library. The strategy for the LILACS database was ("CIRURGIA CARDIACA") or "CIRURGIA DO CORACAO") or "CIRURGIA TORACICA" [Words] and (("MEDIASTINITE" or "MEDIASTINITE-COMPLICACOES") or "DEISCENCIA" or "INFECCAO") or "DEISCENCIA" [Palavras] and (((("CURATIVO" or "CURATIVO-REABILITADOR" or "CURATIVO-RECUPERATIVO" or "CURATIVOS DE HIDROGEIS") or "TERAPEUTICA") or "TRATAMENTO") or "ACAO TERAPEUTICA") or "MEDIDA TERAPEUTICA") or "PROCEDIMENTOS TERAPEUTICOS" [Words] that retrieved 47 studies. The strategy for MEDLINE was (((("thoracic surgery/complications" or Surgery, Thoracic or Surgery or Cardiac Surgery or Heart Surgery or Cardiac Surgery)))) AND Bandage AND Mediastinitis, with a total of 45 studies. The strategy for the BDENF and CINAHL databases was Cirurgia Cardíaca e Mediastinite and their respective descriptor in English (Cardiac surgery and Mediastinites), which retrieved 3 and 59 studies, respectively.

For the selection of studies in this review, we adopted the following inclusion criteria:

studies with a primary methodological design that investigated interventions for patients with post-sternotomy mediastinitis; research published in English, Portuguese, and Spanish and in the last 10 years. The delimitation of the period was established to ensure an adequate amount of research, and a large number of primary studies could hinder the integrative review or introduce bias in the following steps of the method. The exclusion criteria were studies with children.

From the results of the search strategies used in the databases selected for conducting the review, we imported a file into the reference manager EndNote, version X5. For the management of references, we created folders for each database and we carried out filtering for duplicate studies, books, dissertations, theses, and other non-scientific texts, in non-delimited languages and with the publication period out of the established. The pre-selection of primary studies by reading the titles and abstracts was carried out and, finally, we read the texts in full for the final selection of the research.

Figure 2 shows the flowchart for selecting primary studies. We used an instrument developed by a national researcher to extract data from primary studies, which contains a set of items that enable the identification of research, methodological characteristics, main results, and conclusions⁽⁷⁾.

Figure 2 - Flowchart of selection of primary studies.

Source: the authors.

We used the classification of evidence hierarchies according to the type of clinical question in the studies. The clinical question may be (a) meaning (with five levels of evidence, the strongest is level I, with evidence obtained from meta-synthesis of qualitative studies, and the lowest is level V, with evidence from the expert opinion), (b) prognosis, prediction or etiology (with five levels of evidence, the strongest is level I with evidence obtained from synthesis of cohort or case-control studies, and the lowest is level V, with evidence of expert opinion) and (c) intervention, treatment or diagnostic/diagnostic test (with seven levels of evidence, the strongest is level I, with evidence obtained from systematic review or meta-analysis, and the lowest is level VII, with expert opinion evidence)⁽⁶⁾. The review results were synthesized descriptively. Thus, the eight primary studies were included in the review sample.

Most of the studies that met the inclusion criteria were carried out in European countries, all of which were published in English. However, one of the studies was published in an Asian journal. The period of publication of the studies included in this review was from 2003 to 2014.

RESULTS AND DISCUSSION

We could identify studies with a short and long period of patient recruitment, which brought samples with very varied sizes and different types of interventions. Regarding the database, we identified eight primary studies.

Most studies had more than five authors, and the maximum number of authors was eight. Four studies showed the frequency of interventions, according to the gender of the patients. In these samples, we could identify that the male patients were more frequent.

Some explanatory variables were collected from the studies and described in Chart 1. Some studies do not describe the characteristics of the participants regarding the type of surgical procedure performed, and the presence of comorbidity of their patients. The most frequent surgical procedure was myocardial revascularization and the comorbidity was DM. Different types of interventions were proposed to patients for the control of mediastinitis, and the use of the vacuum closure system was the most used for the evaluation of treatment efficacy compared to other conventional treatment modalities.

Chart 1 - Characterization of studies, according to objectives, interventions, and level of evidence. Belo Horizonte, 2017.

| Author (s) | Objective | Interventions | LE* |
|---|---|--|-----|
| 1. Simek, M. et al. ⁽⁸⁾ | To verify that the vacuum dressing is a safe system and a reliable option in the treatment of infected sternum wounds in cardiac surgery. | The vacuum dressing is a safe and reliable option in the treatment of sternal wound infection in cardiac surgery. It is considered an effective complement to conventional treatment for the extensive and potentially fatal infections after cardiac surgery, particularly in the presence of risk factors. | IV |
| 2. Grauhan, O. et al. ⁽⁹⁾ | To verify if the management of surgical incision using negative pressure on closed surgical incisions for six to seven days reduces wound infections in a population of patients with total sternotomy. | The application of surgical incision management in clean and closed incisions in the first six to seven days after surgery reduced the likelihood of postoperative wound infection after median sternotomy not only in high-risk patients but also in many patients. | IIB |
| 3. Vos, Roemer J. et al. ⁽¹⁰⁾ | To analyze the clinical outcomes of vacuum dressing compared to open packing and estimate the risk factors for mortality. | Vacuum dressing therapy is superior to open dressing and results in a shorter length of stay in intensive care and improved survival. | IV |
| 4. Feo, M. et al. ⁽¹¹⁾ | To evaluate the 30-year experience in the treatment of deep sternal wound infection after cardiac surgery. | Early surgical debridement and the application of a vacuum dressing, followed by reconstruction by plastic surgery provided a satisfactory cure rate and a good survival rate. | IIC |
| 5. Zeitani, J. et al. ⁽¹²⁾ | To compare conventional treatment with surgical debridement and direct closure. | Sternotomy is a safe and valid treatment. The infected wound is not a contraindication for surgical treatment. Primary closure can contribute to reducing the risk of further infection and reducing healing time, patient discomfort, hospital costs, and health team workload. | IIC |
| 6. Domkowski, P.W. et al. ⁽¹³⁾ | To verify the effectiveness of the vacuum dressing system as an adjunct to conventional therapy or as a single therapy for patients with surgical mediastinitis heart disease. | Vacuum-assisted drainage is an effective therapy for mediastinitis, after debridement or before placing a flap of vascularized tissue. | IV |
| 7. Bapat, V et al. ⁽¹⁴⁾ | To verify the use of vacuum-assisted closure therapy in the treatment of post-sternotomy wound infection with an emphasis on recurrent wound-related problems after the use of a vacuum dressing and its treatment. | Vacuum therapy is a safe and reliable option in the treatment of sternal wound infection. However, the prolonged use of the vacuum system as a substitute for surgical closure of the sternal wound appears to be associated with recurrent sternal wound problems. The strategy of using a vacuum dressing for a short period followed by early surgical closure seems favorable. | IV |
| 8. Karaca, S; Kalangos ⁽¹⁵⁾ | To describe the treatment of M. hominis mediastinitis, after cardiac surgery with vacuum-assisted aspiration, combined with diluted antiseptic irrigation therapy for bacterial eradication. | The proper use of bactericidal agents in the infected tissue can be difficult, especially in mediastinitis with Mycoplasma species. Continuous closed irrigation has the advantage of washing bacteria, necrotic tissue, fibrin, and clots. Effective eradication of M. hominis is associated with intravenous antibiotic therapy and prepares the wound bed. | IV |

*LE: Level of evidence

Source: The authors.

This review enabled to identification and analysis of interventions performed for patients with severe complications in the postoperative period of sternotomy, after cardiac surgery.

Postoperative mediastinitis was defined in these studies, considering classifications established by the North American Central Disease Control (CDC). Mediastinitis has been reported as a rare complication; however, it is a risk factor for increased morbidity time, length of hospital stay, increased costs, and also for increased postoperative mortality⁽⁸⁻¹⁵⁾.

Post-median sternotomy mediastinitis, also called sternal wound infection, is a serious complication for the diagnosis to be closed and must follow one of the following criteria: an organism isolated from mediastinal tissue culture or fluid, evidence of mediastinitis observed during operation, signs of infection such as sternal chest pain, instability or fever, associated with the exit of purulent exudate from the mediastinum or surgical wound⁽⁸⁻¹⁵⁾.

Only one study subdivided mediastinitis wounds, using the severity classifications from

type I to type V. In this study, there was a higher frequency of subtypes II and III ⁽¹³⁾.

Its pathogenesis is extremely complex and is associated with multifactorial issues. The reviewed literature shows the following factors as predictive of risk: cardiovascular disease, obesity, DM, chronic obstructive pulmonary disease, and heart failure, and the presence of one of these diagnoses or risk factors increases the risk of the patient evolving with mediastinitis ⁽⁸⁻¹⁵⁾.

Most of the studies of this integrative review had $n = 7$ (87.5%) the therapy with vacuum closing system, also known in the literature for negative pressure therapy (NPT) ^(8-11, 13-15).

Thus, we will highlight the use of VAC in this discussion. To this end, we brought the discussion into two categories: VAC treatment (subdivided into 4 items) and exclusive surgical treatment:

1) VAC treatment

Indication and use of the vacuum assisted closing system (VAC)

The studies used VAC for superficial and deep infected sternal wounds after cardiac surgery ⁽⁸⁾. Other studies have not described the characteristics of the depth of the sternal wounds ^(9,11-13). Study 8 characterized the sternal wound as deep.

The patients received antibiotic therapy, according to the isolated microorganisms and their use was discontinued due to the absence of signs and symptoms of infection, negative culture, and granulation tissue formation ⁽⁸⁾.

VAC therapy was discontinued when C-reactive protein levels decreased by less than 50mg/l. For patients with deep wounds, the surgical procedure for their closure was performed as early as possible ^(8,10). In another study, besides these criteria, the patient's treatment was discontinued when the fever stops ⁽¹¹⁾. Also, another study mentioned that the vacuum application time was 6-7 days without explaining other criteria ⁽⁹⁾.

The negative pressure was less than 125mmHg ^(8,9,11). One of the studies described that the pressure used was 75 to 125 mmHg and the vacuum system was changed twice a week. The other studies did not describe the pressure used ⁽¹⁰⁾.

VAC pre-use interventions

Some studies have reported interventions performed before the administration of VAC therapy.

Among the precautions for administering VAC, any possibility of contact with the heart was prohibited in patients with deep exposure ^(8,11,15). In study 4, the protection was silicone. The debridement procedure of the necrotic tissue and intense irrigation with physiological saline solution preceded the use of vacuum ⁽⁸⁾.

One of the studies described that the wound was covered with transparent polyurethane film with a thickness between 400 to 600 μm ⁽⁸⁾.

The technique of using the VAC[®] involved the assembly of a cut piece of polyurethane foam in the sternum ⁽¹¹⁾.

The instillation line was for the 2% Polihexanid B fluid antiseptic, optimally distributed over the wound bed in 20 seconds. The distal tubing was connected to the VAC packaging. The antiseptic fluid remained in the mediastinal cavity for 10 minutes ⁽¹¹⁾.

Effectiveness of VAC Therapy and its consequences

The studies measured different perspectives on the outcomes of using VAC. They highlighted the hospitalization time, mortality, and wound closure time.

In one study, all patients underwent vacuum therapy, that is, there was no control group. The mean time to resolution of the infection was 9.2 days (range, 6 to 21 days) ⁽⁸⁾.

Patients undergoing treatment with VAC (Prevena[®] Therapy) obtained a favorable response for the control of mediastinitis with a statistically significant difference when compared to patients treated with conventional coverage. Their conventional coverage was not described. ($p < 0.05$; Odds ratio 2.74) ⁽⁹⁾.

Mortality was lower in patients undergoing gauze pads (procedure performed daily) when compared with vacuum therapy. Hospital mortality was statistically significantly lower in patients who underwent vacuum therapy ($p = 0.0032$). These data were collected for 10 years, between 2000 and 2010 ⁽¹⁰⁾.

The use of negative pressure therapy, known internationally by the acronym VAC (Vacuum Assisted Closure[®]) in a referral center in cardiac surgery for three decades, proved to be

more effective than other therapies. During this period, 22,366 patients underwent cardiac surgery by complete sternotomy. The infection rate was 0.89% (200 patients). Among these patients with surgical site infection, progressing to mediastinitis, the mean hospital stay was statistically significant in the group of patients treated with antibiotic therapy (group 1) and also in those undergoing surgical debridement (if failure - irrigation by 10 days and sugar coverage and hyperbaric treatment) (group 2) with those undergoing debridement and VAC and pectoral muscle reconstruction. Also, the time to stop the fever was shorter in group 3 than in groups 2 and 1. Also, the C-reactive protein count, in 7 days and the leukocyte count in 7 days, was statistically significantly lower in group 3. Hospital mortality in group 1 was higher, with a statistically significant difference than in groups 2 and 3. There was no statistical difference between groups 2 and 3 for mortality. (study 4) ⁽¹¹⁾.

The vacuum associated with debridement and associated with the surgical procedure with muscle reconstruction (omental or pectoral) beneficial in reducing infection (study 6) ⁽¹⁴⁾.

The antibiotic therapy report was described in a case report for a patient who underwent aortic replacement surgery. They empirically used imipenem and vancomycin. The patient was later diagnosed with *M. hominis*. and antibiotic therapy was exchanged. VAC-Instill[®] was used (instillation of Prontosan solution, 0.02% Polihexanid) ⁽¹⁵⁾.

The vacuum therapy, when compared to conventional coverage therapy, irrigation of the sternal wound with hydrogen peroxide, physiological saline solution and povidine-iodine solution, covered with silver, was more effective.

Adverse events

The studies poorly described the reporting of adverse events from negative pressure therapy.

Continuous pressure greater than 125 mmHg caused discomfort; however, we did not find complications related to the use of VAC ⁽⁸⁾.

VAC was well tolerated in all patients ⁽⁹⁾. The prolonged use of VAC therapy (period greater than 21 days) brought signs of causing bone necrosis and bone infection, requiring debridement of the tissue ⁽¹⁴⁾.

2) Surgical treatment

Between 1999 and 2002, 2400 patients underwent median sternotomy. Of these, 0.125%

(n = 3) had mediastinitis and 2.75% (n = 66) had profound dehiscence and 5.75% (n = 138) had superficial dehiscence ⁽¹²⁾.

All patients who underwent sternotomy surgery received antibiotic prophylaxis with 2g of ceftizoxime and skin antiseptics with povidine iodine ⁽¹²⁾.

There was an impressive difference in the treatment period between the two methods such as the number of drugs needed, with the surgical method proving to be more effective. Direct primary closure of superficial wound dehiscence after median sternotomy appears to be a safe and effective treatment ⁽¹²⁾.

A positive culture of open wounds does not seem to be a contraindication to primary closure and can reduce the risk of spreading the infection. When compared to secondary healing, healing time, patient discomfort, hospital costs, and hospital staff involvement, they are significantly reduced. The treatment period was 29.7 days (range 2 to 144 days) for group 1 (debridement) and 12.2 days (range 2 to 37 days), including the day of direct surgical closure and removal of sutures for group 2 (surgical treatment with complete suture) (p = 0.0001). The average number of medical treatments was 9.4 per patient in group 1 and 3.7 per patient in group 2 (p = 0.0001) ⁽¹²⁾.

The literature describes that negative pressure therapy is a type of active treatment of the wound that promotes its healing since it keeps the environment moist through controlled and locally applied subatmospheric pressure ⁽¹⁶⁾.

In the Brazilian scenario, currently, the most used intervention for the management of the sternal wound after cardiac surgery is the use of conventional coverings that keep the tissue moist to provide tissue granulation. However, studies have reported the use of negative pressure therapy (NPT), also known as vacuum closing system (VAC) or negative pressure therapy ⁽¹⁷⁾.

A Brazilian study compared the effectiveness of this international system with one patented at the University of São Paulo (USP). The national system uses products already known on the market (folded gauze pad, sterile sponge removed from the hand-wiping brush used pre-surgical procedure, urethral catheter, and vacuum system with pressure regulator and disposable collector). The researcher found no statistically significant difference in effectiveness between the international system and the one patented in Brazil, which demonstrates that the Brazilian

product can be used. However, the cost of the Brazilian product per patient is R\$ 47.89, and North American is R\$ 2,757.40⁽¹⁸⁾.

CONCLUSION

The use of the closure system due to negative pressure therapy was more effective than conventional coverings with daily changes and irrigation with different solutions (hydrogen peroxide, povidine iodine, and saline). Another evidence is that the surgical treatment for closing the dehiscence is more effective than closing the sternal wound, by the second intention.

Patients have some comorbidities, such as DM, chronic kidney disease, systemic arterial hypertension, and are mostly male and over 50 years old. However, these variables were not shown to be statistically significant for the appearance of mediastinitis in these studies.

As for the evidence for clinical practice, there is still no basis for establishing safe protocols, since the design of the studies lacks methodological rigor, with little information about statistical methods and allocation of patients in the intervention groups.

Through evaluation of the researches, we highlight that most of the studies have methodological designs considered weak for a recommendation of interventions that can be present in the Integrative Literature Review. Another limitation of the Integrative Review is that the chosen descriptors retrieve a sample of the scientific publication from the databases, which may not portray the completeness of the evidence.

In this review, we contributed to synthesize and update the existing knowledge for the treatment of mediastinitis in patients undergoing sternotomy for cardiac surgery. The patient will need qualified nursing to care for those who are in severe postoperative complications. Therefore, these results may subsidize nursing care based on scientific evidence, demonstrating the techniques used, and their effectiveness.

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Nota: This article is the product of the monograph by Carolina Letícia dos Santos Cruz in the Specialization Course in Stomatherapy at the Nursing School of the Federal University of Minas Gerais.

Recebido em: 25/06/2020

Aprovado em: 08/10/2020