

ORIGINAL

Negative pressure therapy with closed incision in radical mastectomy for the prevention of complications at the surgical site

Terapia de presión negativa con incisión cerrada en mastectomía radical para la prevención de complicaciones en el sitio quirúrgico

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Cite as: Pedrique V, Casilli A, Moya J, Méndez MV. Negative pressure therapy with closed incision in radical mastectomy for the prevention of complications at the surgical site. South Health and Policy. 2025; 4:289. <https://doi.org/10.56294/shp2025289>


Submitted: 27-02-2025

Revised: 15-05-2025

Accepted: 25-08-2025

Published: 26-08-2025

Editor: Dr. Telmo Raúl Aveiro-Róbalo 

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ABSTRACT

Objective: to evaluate the efficacy of closed-incision negative pressure therapy in patients with radical mastectomy for the prevention of complications at the surgical site in the Autonomous Service of the Central Hospital of Maracay, Aragua State, Venezuela, during the 2023-2024 study period.

Method: a clinical-epidemiological study of experimental, prospective and longitudinal design was carried out. The population consisted of 40 patients undergoing radical mastectomy, from which a sample of 30 patients was selected, divided into two groups: Group A (vacuum therapy) with 15 patients and Group B (traditional treatment) with 15 patients. Variables such as age, sex, comorbidities, degree of risk of complication, side effects, and complications at the surgical site at 2, 7, and 14 days postoperatively were evaluated. Chi-square and Fisher Exact tests were used for categorical comparisons, with an alpha significance level <0,05.

Results: the mean age was 55,33 years in Group A and 60,67 years in Group B. All patients were women. There were no significant differences in comorbidities, except in the presence of cancer (60,00 % in Group A vs. 93,33 % in Group B, $p = 0,0400$) and low weight (20,00 % in Group A vs. 0,00 % in Group B, $p = 0,0238$). The degree of risk of complication was higher in Group B (100 % in grade III) compared to Group A (73,33 % in grade III). The incidence of wound dehiscence at 14 days was significantly lower in Group A (0,00 % vs. 26,67 %, $p = 0,0498$), as was the incidence of seroma (6,67 % in Group A vs. 46,67 % in Group B, $p = 0,0175$).

Conclusion: no significant differences were observed in hematoma and infection. Closed-incision negative pressure therapy is effective in reducing postoperative complications in patients undergoing radical mastectomy, especially in decreasing wound dehiscence and seroma. These findings suggest that this therapy may be a viable and beneficial option in clinical practice to improve postoperative outcomes and patients quality of life. Its implementation, staff training and additional studies are recommended to confirm these benefits and evaluate their cost-effectiveness.

Keywords: Negative Pressure Therapy; Radical Mastectomy; Breast Surgery; Negative Pressure Therapy for Closed Incision Wounds.

RESUMEN

Objetivo: evaluar la eficacia de la terapia de presión negativa con incisión cerrada en pacientes con mastectomía radical para la prevención de complicaciones en el sitio quirúrgico en el Servicio Autónomo del Hospital Central de Maracay, Estado Aragua, Venezuela, durante el periodo de estudio 2023-2024.

Método: se realizó un estudio clínico-epidemiológico de diseño experimental, prospectivo y longitudinal. La

población consistió en 40 pacientes sometidos a mastectomía radical, de los cuales se seleccionó una muestra de 30 pacientes, divididos en dos grupos: Grupo A (terapia de vacío) con 15 pacientes y Grupo B (tratamiento tradicional) con 15 pacientes. Se evaluaron variables como edad, sexo, comorbilidades, grado de riesgo de complicación, efectos secundarios y complicaciones en el sitio quirúrgico a los 2, 7 y 14 días postoperatorios. Se utilizaron pruebas de chi cuadrado y Fisher Exacta para las comparaciones categóricas, con un nivel de significancia alfa $<0,05$.

Resultados: no hubo diferencias significativas en comorbilidades, excepto en la presencia de cáncer (60,00 % en Grupo A vs. 93,33 % en Grupo B, $p = 0,0400$) y bajo peso (20,00 % en Grupo A vs. 0,00 % en Grupo B, $p = 0,0238$). El grado de riesgo de complicación fue mayor en el Grupo B (100 % en grado III) comparado con el Grupo A (73,33 % en grado III). La incidencia de dehiscencia de herida a los 14 días fue significativamente menor en el Grupo A (0,00 % vs. 26,67 %, $p = 0,0498$), al igual que la incidencia de seroma (6,67 % en Grupo A vs. 46,67 % en Grupo B, $p = 0,0175$). No se observaron diferencias significativas en hematoma e infección.

Conclusión: la terapia de presión negativa con incisión cerrada es efectiva para reducir las complicaciones postoperatorias en pacientes sometidos a mastectomía radical, especialmente en la disminución de la dehiscencia de herida y el seroma. Estos hallazgos sugieren que esta terapia puede ser una opción viable y beneficiosa en la práctica clínica para mejorar los resultados postoperatorios y la calidad de vida de los pacientes. Se recomienda su implementación, capacitación del personal y estudios adicionales para confirmar estos beneficios y evaluar su costo-efectividad.

Palabras Clave: Terapia de Presión Negativa; Mastectomía Radical; Cirugía Mamaria; Terapia de Presión Negativa para Heridas con Incisión Cerrada.

INTRODUCTION

Breast cancer is one of the main health problems in most Western countries, as it is one of the most common forms of cancer in women and one of the leading causes of death. It is the most common malignant tumor in women, with more than 2,2 million cases in 2020 (WHO figures). In 2022, 670,000 people died from breast cancer worldwide, making it the most common cancer among women in 157 of the 185 countries considered in 2022.^(1,2)

The number of cancer cases in the Americas was estimated at 4 million in 2020. By October 2023, the Venezuelan Anti-Cancer Society estimated a total of 8,691 cases. It is the leading cause of cancer death in Venezuelan women, with death occurring before the age of 64. Breast cancer can spread to different areas through blood vessels and lymph vessels. When it spreads to other parts of the body, it is said to have metastasized.^(1,2)

The primary treatment objective is surgical control at the primary site, seeking to eradicate the neoplastic cells present in the tumor and adjacent tissues. However, multidisciplinary management with surgery (mastectomy), chemotherapy, hormone therapy, biological therapy, and radiation therapy is warranted.^(2,3) In Venezuela, the deterioration of health care facilities, the obsolescence of equipment and instruments, the lack of accumulated investment, and the forced migration of health care personnel in search of better conditions have led to a reduction in screening, diagnosis, and classification of tumors in public hospitals, resulting in late diagnoses and an increase in radical surgical procedures.⁽⁴⁾

Complications in breast surgery cause unpleasant problems for the patient and the health system, increasing costs and patient stays, prolonging the postoperative period, and delaying hospital discharge. In breast cancer surgery, the appearance of these complications delays the application of complementary cancer treatment and, in many cases, can alter the outcome of the operation. The figures are currently unknown.⁽⁵⁾ It is common for some type of complication to arise that can lead to surgical site infection, such as seroma, which is a typical fluctuating collection under the wound that appears clean, or hematomas, which can occur due to the rich vascularization of the gland and its action on areas where hemostasis is difficult. Although less common, complications associated with flap necrosis may arise, which in the case of large breast resection can affect wound closure and is associated with adequate skin irrigation and sutures being performed with the appropriate tension to allow good circulation.⁽⁵⁾

In traditional healing procedures, dressings are used passively, covering only the wound and therefore not modifying the environment, resulting in what is known as dry healing. Water accompanied by soap, antimicrobials, or antiseptics is usually used to clean the wound before applying the dressing. This is done at least daily.

It should be noted that negative pressure therapy is an advanced treatment used in the resolution of both acute and chronic wounds. It consists of applying controlled pressure below atmospheric pressure to a wound using an electric pump. This action can be intermittent or continuous. The aim is to help promote healing

that is not achieved as a first-line treatment. This is possible by removing gas molecules from the area of interest, increasing local blood perfusion, creating new blood vessels, and thus stimulating granulation tissue by removing exudate from the lesion, as well as interstitial fluid, which accelerates healing.^(7,8)

As it is a closed system, it prevents the entry of contaminants, while generating a moist environment. The mechanical stress of the suction itself on the cells alters their proliferation, increasing the levels of endothelial growth factors, as well as fibroblasts, reducing the action of metalloproteinases and also acting directly to promote the contraction of the lesion.^(7,8)

This wound therapy method can now be found in almost any hospital in the country and is recommended for the management of complex wounds and closed incisional wounds in patients at high risk of surgical site complications, reducing tension resistance between incisions, which are additional benefits to those traditionally obtained. It is contraindicated in osteomyelitis without antibiotic treatment, non-enteric fistulas, necrotic tissue with eschar present, over exposed blood vessels or organs, full-thickness burns, and in relation to pleural drainage.⁽⁸⁾

Complications of negative pressure therapy are few and are related to the handling and technical control of the pressure pump. The main complication is damage to the tissue adjacent to the wound due to exposure to foam and pressure, which can lead to maceration of the edges and destruction of the skin surrounding the lesion. Pain at the start of therapy is common. In these cases, the pressure is increased slowly and gradually, allowing the patient to get used to the feeling of negative pressure.^(8,9)

In 2022, research associated with the efficacy of prophylactic application of negative pressure wound therapy to stop wound problems at the surgical site for closed incisions in breast cancer surgery determined that prophylactic application of negative pressure reduces infection at the surgical site, as well as wound dehiscence and necrosis.⁽¹⁰⁾

Furthermore, several studies on negative pressure therapy with closed incisions versus standard dressings in breast surgery have concluded that this type of therapy has the potential to reduce postoperative wound complications in breast surgery by 8 % compared to 30 % with traditional healing and has a better cost-effectiveness ratio compared to standard dressings. In addition, there is the possibility of better cosmetic results compared to standard dressings.^(10,11)

The objective of this research was to evaluate the efficacy of closed incision negative pressure therapy in patients undergoing radical mastectomy for the prevention of surgical site complications in the autonomous service of the Central Hospital of Maracay, Venezuela, during the study period 2023-2024.

METHOD

This study was a descriptive, experimental, observational, prospective, and longitudinal clinical-epidemiological investigation. The population was taken from elective radical mastectomy surgeries performed by the Breast Pathology Service of the Autonomous Central Hospital of Maracay, and consisted of 40 patients who underwent modified Madden or Merota-Patey radical mastectomy, without distinction of age or gender, from which a simple sample of 30 patients was taken, which was divided into two groups. Group A, with 15 patients, was designated as the experimental group for negative pressure therapy with closed incision, and group B, with 15 patients, was designated as the control group for traditional daily wound care.

In the application of the therapy in group A, the negative pressure therapy system (Prevena®) was implemented, with no conflicts of interest declared. It was applied with sterile gloves during the immediate postoperative period, maintaining the system for 7 consecutive days. The system consists of a portable battery-powered suction device that exerts a pressure of 125 mmHg, connected by a hose to 35 cm long polyurethane foam with 0,019 % ionic silver, covered with a translucent adhesive. The traditional Group B wound care therapy included the use of sterile gloves, adhesive, sterile gauze, and 0,9 % solution.

To designate the degree of risk of complications, the patient classification system was used according to the factors associated with each patient, dividing them into Grade I, when the patient has no risk factors; Grade II, when there is one factor; and Grade III, when there are multiple factors.

To compare complications with the use of negative pressure therapy with closed incision in radical mastectomy and in a control group with traditional dressings, dichotomous qualitative data obtained from observation of the wound in the postoperative period, such as the presence of surgical site infection, seroma, hematomas, and wound dehiscence, were recorded.

This observation was made through reviews carried out on days 2, 7, and 14 postoperatively in the group receiving negative pressure therapy and the control group receiving traditional dressings. To determine the appearance of side effects from the dressing, signs of damage to the tissue adjacent to the wound (maceration and destruction of the skin surrounding the lesion) were sought.

Quantitative variables were analyzed using the corresponding statistical methods. Similarly, 95 % confidence intervals were constructed, and associations were made using the chi-square or Fischer's exact test when the values in the records were less than 5. A p-value of <0,05 was established as statistically significant.

RESULTS

Regarding the distribution by age groups, in Group A, 73,33 % of patients were under 65 years of age, while 26,67 % were over 65 years of age, with an average age of 55,33 years. In Group B, 46,67 % of patients were under 65 years of age and 53,33 % were over 65 years of age, with an average age of 60,67 years. The difference in age distribution between the two groups was not statistically significant ($p = 0,1317$).

All patients in both groups were women, representing 100 % of each group. There were no differences in the distribution by sex ($p = 1,0000$). Regarding associated comorbidities, 66,67 % of patients in Group A had comorbidities, compared to 40,00 % in Group B. The difference in the presence of comorbidities between the two groups was also not statistically significant ($p = 0,1361$). This means that there were no statistically significant differences between the two groups, making them comparable for treatment (table 1).

Table 1. Distribution by sex, age, and associated comorbidities in patients undergoing radical mastectomy at the autonomous service of the Central Hospital of Maracay, Venezuela, in the period 2023-2024.

Variable	Study groups (n=30)				p
	Group A Vacuum Therapy (n=15)		Group B Traditional (n=15)		
	Fr	(%)	Fr	(%)	
Age (years)					
(X±SD)		55,33		60,67 ± 9,98	
Median		50		70	
Age group					0,1317
< 65 years	11	73,3	7	46,67	
> 65 years old	4	26,67	8	53,33	
Female	15	100	15	100	1000
Associated comorbidity					
Yes	10	66,67	6	40	0,1361
No	5	33,33	9	6	
Note: *Using the chi-square test and Fisher's exact test, *for categorical comparisons Significance level with alpha value <0,05					

With regard to the factors associated with patients undergoing radical mastectomy in the autonomous service of the Central Hospital of Maracay. In the case of diabetes mellitus, it was evident in only 12,33 % of Group A and 20,00 % of Group B. The difference was not statistically significant ($p = 0,5000$). Systemic arterial hypertension was found in 60,00 % of patients in Group A and in 40,00 % in Group B. This difference was also not statistically significant ($p = 0,4652$).

Anemia was present in 33,33 % of Group A and 13,33 % of Group B. The difference was not significant ($p = 0,1943$). Of the patients diagnosed with breast cancer prior to surgery, 60,00 % of patients in Group A had cancer, compared to 93,33 % in Group B. This difference was statistically significant ($p = 0,0400$). Hypoalbuminemia was present in 6,67 % of patients in Group A, while none of the patients in Group B had this condition. The difference was not significant ($p = 0,5000$).

Likewise, when evaluating the Body Mass Index (BMI), it was found that in Group A, 20,00 % of patients had a low BMI, compared to none in Group B. This difference was statistically significant ($p = 0,0238$). The use of Portovac drains is common in mastectomy surgery; however, it was found that in Group A, 73,33 % of patients had intraoperative drains placed, contrasting with Group B, where 100,00 % used drains. The difference was not significant ($p = 0,0998$). In the case of preoperative radiotherapy in Group A, 6,67 % of patients had received it, compared to 13,33 % in Group B. The difference was not significant ($p = 0,5000$) (table 2).

When studying the results obtained in relation to the degree of risk of complications: In Group A, 13,33 % of patients presented a degree of risk I, while in Group B, none of the patients were at this level of risk. As for risk level II, 13,33 % of patients in Group A were at this level, however, in Group B, none of the patients presented this risk level.

Most patients in both groups were in risk grade III. In Group A, 73,33 % of patients presented this risk grade, and in Group B, 100,00 % of patients were in this level. The difference in the distribution of risk levels between the two groups was not statistically significant ($p = 0,0996$) (table 3).

Table 2. Factors associated with patients undergoing radical mastectomy at the Central Hospital of Maracay, Venezuela, in the period 2023-2024.

Variable	Study groups (n=30)				p
	Group A Vacuum Therapy (n=15)		Group B Traditional (n=15)		
	Fr	(%)	Fr	(%)	
Diabetes Mellitus	2	12,33	3	20	0,5
Systemic arterial hypertension	9	60	6	40	0,4652
Anemia	5	33,33	2	13,33	0,1943
Cancer	9	60,00	14	93,33	0,0400
Hypoproteinemia	1	6,67	0	0	0,5000
BMI Underweight	3	20	0	0	0,0238
Drainage	11	73,3	15	100,00	0,0998
Previous radiotherapy	1	6,67	2	13,33	0,50
Note: *Using the chi-square test and Fisher's exact test *for categorical comparisons Significance level with alpha value <0,05					

Table 3. Risk level of complications in patients undergoing radical mastectomy at the Central Hospital of Maracay, Venezuela, during the study period 2023-2024

Variable	Study groups (n=30)				p
	Group A Vacuum therapy (n=15)		Group B Traditional (n=15)		
	Fr	(%)	Fr	(%)	
Risk level					
I	2	13,3	0	0	0,0996
II	2	13,33	0	0,00	
III	11	73,33	15	100	
Note: *Using the chi-square test and Fisher's exact test, *for categorical comparisons Significance level with alpha value <0,05					

Regarding side effects associated with the use of the therapy. In both groups, none of the patients presented maceration. In both Group A and Group B, 100 % of patients did not experience this side effect. The difference was not statistically significant ($p = 0,0996$).

In Group A, 13,33 % of patients presented lesions on healthy skin, while in Group B, none of the patients had this side effect. In Group A, 86,67 % of patients did not present lesions on healthy skin. The difference in the incidence of lesions on healthy skin between the two groups was statistically significant ($p = 0,0000$). However, these adverse effects may only be significant in Group A, given that it is the only group that uses negative pressure as therapy (table 4).

Table 4. Side effects associated with the use of therapy in patients with radical mastectomy at the Central Hospital of Maracay, Venezuela, during the study period 2023-2024.

Variable	Study groups (n=30)				p
	Group A Vacuum Therapy (n=15)		Group B Traditional (n=15)		
	Fr	(%)	Fr	(%)	
Maceration					
No	15	100,00	15	100,00	0,0996
Healthy skin lesion					
Yes	2	13,3	0	0,00	0,00
No	13	86,67	0	0	
Note: *Using the chi-square test and Fisher's exact test, *for categorical comparisons Significance level with alpha value <0.05					

Regarding wound dehiscence, the findings showed that on day 2: None of the patients in either group presented wound dehiscence ($p = 1,0000$). After 7 days: In Group A, 6,67 % of patients presented wound dehiscence, while in Group B, 13,33 % had this complication. The difference was not statistically significant ($p = 0,5000$). On day 14: In Group A, none of the patients presented wound dehiscence, while in Group B, 26,67 % had this complication. The difference was statistically significant ($p = 0,0498$).

With regard to seroma formation, up to day 2: In Group A, none of the patients presented seroma, in contrast to Group B, where 6,67 % had this complication ($p = 0,5000$). By day 7: In Group A, none of the patients presented seroma, while in Group B, 26,67 % had this complication. The difference was statistically significant ($p = 0,0498$). On day 14: In Group A, 6,67 % of patients developed seroma, while in Group B, 46,67 % (7 out of 15) had this complication. The difference was statistically significant ($p = 0,0175$).

Regarding the appearance of hematomas, on day 2: In Group A, none of the patients presented hematoma, while in Group B, 6,67 % had this complication ($p = 0,5000$). Day 7: In Group A, none of the patients presented hematoma, while in Group B, 13,33 % had this complication. The difference was not statistically significant ($p = 0,2413$). Day 14: None of the patients in either group presented hematoma ($p = 1,0000$).

When infection was assessed on day 2: None of the patients in either group presented infection ($p = 1,0000$). Subsequently, on day 7: In Group A, none of the patients presented infection, in contrast to Group B, where 13,33 % presented this complication. The difference was not statistically significant ($p = 0,2413$). On day 14: In Group A, none of the patients presented infection, while in Group B, 13,33 % had this complication. The difference was not statistically significant ($p = 0,2413$).

DISCUSSION

Negative pressure therapy with closed incision showed a significant reduction in postoperative complications, such as wound dehiscence and seroma, compared to traditional techniques. These findings are consistent with studies taken as part of the background to the research.

One study reported a decrease in surgical site infection and wound dehiscence with negative pressure therapy. In that study, no significant differences were observed in the incidence of seroma and hematoma, which also coincides with this study. It is important to note that the researchers did not take into account the presence of comorbidities or age, so the risk of complications at the surgical site or possible adverse effects were not evaluated, aspects that differ from the present study.⁽¹⁰⁾

The available literature from 2022 showed results of negative pressure therapy with closed incisions versus standard dressings in breast surgery, including mastectomies and axillary dissections, covering multiple countries. A variety of closed incision negative pressure devices were used, including PREVENA™ (used in our study), with pressures ranging from -80 to -125 mmHg. These devices were only used for 3 days, unlike the current study, which used them for 7 consecutive days.⁽¹¹⁾ This study did not involve variables associated with sociodemographic factors such as age, sex, or the presence of comorbidities; nor did it consider the degree of risk or adverse effects from the use of closed incision negative pressure therapy in this review. Overall surgical site infection rates showed that only 1 % occurred in the experimental group, similar to the 0 % obtained during the observational phase of the present study. With regard to the non-experimental group, an infection rate of 21 % was observed with traditional therapy, in contrast to the 13,33 % obtained in our study.⁽¹¹⁾

In the study on the use of closed incision negative pressure therapy in reconstructive and oncoplastic breast surgery and its usefulness in reducing skin necrosis, the sample was obtained from a single health center, which is consistent with this research. With regard to sex distribution, it was female, consistent with these results. The age in the population for traditional healing was $51,65 \% \pm 10,51$, negative pressure therapy $51,83 \% \pm 9,19$, which is similar to the results presented by the authors, where an average age of 60,67 years and 55,33 years in the negative pressure therapy group was reported. These authors took into account factors such as the type of incision, previous chemotherapy, smoking, and type of reconstructive surgery, while these variables were not considered in the data collection for this study. Another variable studied, also found in this study, was previous radiotherapy, which occurred in 4,72 % of the negative pressure group, similar to Group A (6,67 %). In traditional dressing therapy, 3,1 % of patients developed complications, compared to 13,33 % in our Group B. As the only complication studied was necrosis, there is no point of discussion, since it does not belong to any of the variables in the present study.⁽¹²⁾

CONCLUSION

The results obtained conclude that negative pressure therapy is effective in reducing postoperative complications, such as wound dehiscence and seroma, compared to traditional healing techniques. In particular, a significant reduction in the incidence of wound dehiscence and seroma was observed at 14 days postoperatively in the group that received negative pressure therapy. The homogeneity in the distribution by sex and comorbidities between the groups allows for a fair comparison and reinforces the validity of the results.

The incidence of side effects such as maceration and healthy skin injury was low. This indicates that,

although negative pressure therapy is effective, it may be associated with a slight risk of healthy skin injury. The study suggests that negative pressure therapy can significantly reduce postoperative complications compared to traditional techniques.

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FUNDING

None.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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