Hypothesis of a corporate protocol for the use of Negative Pressure Therapy in Orthopedics and Traumatology.

Abstract

Even for the most superficial wounds, treatment is often difficult with poor healing responses and high rates of complications. Although several advanced technologies have been developed to improve the treatment of the complicated wounds, outcomes have been lacklustre and many technologies have been no more beneficial than basic care consisting of appropriate debridement and pressure offloading. The Orthopedic and Trauma’s wounds are often large and deep with exposed bone and tendons, and in people with compromised healing capacity. The negative pressure wound therapy (TPN) has emerged as a treatment for these complex wounds. Design a corporate protocol for the use of Negative Pressure Therapy in Orthopedics and Traumatology is essential to adopt this technique in the best way to treat wounds and major injuries of the musculoskeletal apparatus.

Keywords: Negative pressure therapy, trauma wound, open fractures, difficult wounds, vac protocol, nursing assistance, hypothesis.

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Introduction:

Tpn: appropriateness of the guidelines in its management and consistency of the company's protocols in the various health facilities.

The Negative Pressure Therapy offers healthcare an important therapeutic option for advanced management of many types of wounds. It was estimated that at least 1% of the population is suffering from acute or chronic wounds. More precisely, 15% of diabetic patients presenting later in life leg ulcers and 12-24% of these may have requested following an amputation. 1-5% of patients undergoing stereotomy presents a wound from healing and, finally, 10% of hospitalized patients presenting pressure ulcers and that proportion increases when one considers the lungodegenze. When, proved effective and safe, the use of specific technologies for the treatment of wounds from healing are of great interest for the positive impact it could have on the health system, the organization of services, patients and their families.

Before starting treatment with Negative Pressure Therapy it is necessary to define the intentions and objectives, as well as clinical endpoints. In some circumstances, the aim will be to avoid further complications and control the symptoms rather than affect the time required for healing. The aim of this protocol is to develop guidelines on the use of the Company to Negative Pressure Therapy in order to greater appropriateness of use and consistency of behavior in the different corporate structures. The contact persons are selected from the following specialists: general surgeon, vascular surgeon, orthopedic, thoracic surgeon, dialectologist, neurologist and nurses with training under the Wound Care or specifically trained in the use of Negative Pressure Therapy.

The goal of nursing is to:

- UNIFORM care interventions for prevention and treatment of wounds difficult with the base on the basis of scientific evidence and the compliance of the patient.
- Ensure CONTINUITY ‘ASSISTANCE hospital and periospedaliera
- OPTIMIZE the use of aids and devices medication provided by the
- Create through a protocol INSTRUMENT working PRACTICAL, EFFECTIVE and ACCESSIBLE nursing staff and support.

General recommendations

The prescription of therapy in Negative Pressure must be carried out by the referring clinical business.

The training of health professionals is necessary and must be specific.

Dressing changes, (according to the cases producers is to be carried out every 48-72 hours) the monitoring of the lesion, the management of the critical issues relating to medication, education and psychological preparation of the patient are the tasks of the nurse practitioner.

To ensure appropriate treatment and maximum benefit, it is vital to optimize patient welfare in all aspects physical, nutritional and psychosocial.

Therapy to the patient should be adequately illustrated through appropriate disclosure in writing.

It should follow the development of the lesion photographing and measuring it in order to update the status and assess the suspension, all through informative and written consent of the patient.

The treatment, unless otherwise specified, shall not exceed three weeks, checking the actual improvement in the tenth day of the injury in order to identify the indication to the suspension.

Treatment should be discontinued in the event of a worsening of the injury and if the patient has intolerance to treatment..

criteria and recommendations for use

In order for a correct reading of the Protocol, by all health care providers, it specifies:

- with uppercase letter A the recommendations for the use of the therapy mainly based on evidence derived from clinical studies;
- with the uppercase letter B recommendations based on expert opinion;
- with the upper case letter C contraindications to the use of the therapy.

Surgical wounds that repair by first intention (C)

There is no evidence that the use of negative pressure therapy is effective in the prevention phase, the application in this field should be limited only within controlled experimental studies.
Locations skin graft or flap (B)
There are exceptional conditions of use characterized by:
• the need to improve the consistency of the interface between graft and receiving surface when this is uneven;
• congestion of the flap.
For the remaining cases confirmed no indication

Traumatic wounds with loss of substance and deep burns (A)
Using the Negative Pressure Therapy it can be expected as a first-line treatment in combination to surgical drainage in case of injury:
• extensive (> 30cm²);
• and / or composite which provide for an interest of most tissues (eg. Exposure muscle, tendon and bone).

Partial thickness burns and traumatic injuries surface (C)
There is no evidence from well-conducted studies that support the use of Negative Pressure Therapy in patients with partial-thickness burns.
Confirmed no indication.

Open abdomen (A)
The use of TPN is dependent on the etiology of the open abdomen: in the case of anasarca can be considered a treatment of choice in order to obtain a decompression. In case of overt infection of the deep tissues and viscera of exposure to prosthetic materials abdominal (networks and biological membranes) is recommended to evaluate the use case and, in any case, after determining the clinical / laboratory investigations and / or instrumental microbial.
In general, the use can be continued for up to 7-10 days.

Necrotizing fasciitis (B)
Using the Negative Pressure Therapy should be carefully considered on a case by case basis and must include the complementarity of repeated cleaning treatment involving so large loss of substance.

Diabetic foot (C)
The treatment of diabetic foot should include first of all the definition of the etiology of the trophic lesion. If the etiology is mainly neuropathy, the gold standard of treatment is represented from the proper discharge of foot, in such cases is not confirmed the indication for the use of Negative Pressure Therapy.

Diabetic foot (A)
The treatment of diabetic foot should include first of all the definition of the etiology of the trophic lesion. If the etiology is mainly the arterial occlusive disease, the gold standard is the revascularization of the limb and / or trophic lesion.
Using the Negative Pressure Therapy represents a treatment that can be expected only after revascularization and for cases of healing by secondary intention.

Amputation stump with open surgical cleaning (A)
It can be considered the use of Negative Pressure Therapy.

Osteomyelitis (C)
Contraindicated the use of Negative Pressure Therapy.

Venous vascular lesions (C)
It is not indicated for use in Negative Pressure Therapy.

Arterial vascular lesions (B)
Using the Negative Pressure Therapy is a treatment that can be expected only after revascularization.
The use can be considered in case of trophic lesions of great extent, with dimensions greater than 30 cm² and in particular with exposure osteo-tendinous, needing healing by second intention.

Pressure sores (A)
It can be considered the use in pressure lesions of III ° and IV ° stage which do not eschar and / or devitalized tissue and overt infection.
Dehiscences of stereotomie (A)
It can be considered the use of Negative Pressure Therapy.

Dehiscence of surgical wounds are not infected (B)
Generally the use of Negative Pressure Therapy is not indicated except in the case of very extensive and deep lesions (> 30 cm²) with forecasted repair by secondary intention and that is not infected prosthetic below (eg. Prosthesis vascular, orthopedic, networks and surgical membranes, synthetic means) provided the absolute contraindication to direct application of vessels and nerves.

Wound infection (C)
Use of Negative Pressure Therapy is contraindicated in infected wounds that are deep infections for which the gold standard of treatment is surgical cleaning.
Using the Negative Pressure Therapy it can be considered as a treatment following the surgical cleaning and ongoing antibiotic therapy.

Use in pediatric (C)
Use of Negative Pressure Therapy is not recommended for children.
If deemed appropriate use, this must be done in conditions closely monitored and upon notice and request for authorization of the Coordinator Clinical Management. The timing of application of the device is equivalent to what foreseen in the recommendations for the suspension.

Limitations of Use

The FDA (2011) has published a report about the reports of adverse events related to the use of the therapy in Negative Pressure: 2007 to 2011 were reported 12 cases of deaths and 174 cases of adverse events.

Most of the accidents occurred in the setting of home care, for this reason it is recommended particular caution for patients who use the device in this specific area, also considering that most of the studies of the effectiveness of therapy in Negative Pressure are It was conducted in inpatient settings.

The leading cause of death involved events of acute massive hemorrhage, while most of the 174 adverse events known to cause the development of infections in many cases due to the lack of dressing changes and / or the non-operation of debridement in the presence of necrotic tissue (Peinemann 2011).0 days.
The report identifies patients and situations at risk of adverse events:
Patients at high risk of bleeding or hemorrhage.
or patients taking anticoagulants or antiplatelet drugs.
Patients with:
Fragility or infection or vessel.
or vascular anastomosis.
or infected wounds.
or Osteomyelitis.
or exposure of organs, vessels, nerves, tendons and ligaments (when the Therapy Negative Pressure is applied in direct contact).
or spinal injuries (stimulation of the sympathetic nervous system).
or enteric fistulas.
Patients who require:
or Hyperbaric chamber.
or defibrillation.
or MRI.
Use near the vagus nerve (bradycardia).
Application circumferential of the dressing.
How to use the therapy (intermittent vs continuous).

In all these cases the use of TPN must take place only if strictly necessary and providing a continuous monitoring of the wound and the patient.

Contraindications

The use of TPN is contraindicated in these types of injuries and / or conditions (FDA 2011):
presence of necrotic tissue with eschar; untreated osteomyelitis; Non-enteric fistula and not explored; neoplastic lesions; exposure of vessels; exposure of nerves; exposure of anastomosis; exposure of organs.

Indications for treatment discontinuation

If after 10 days of treatment with Negative Pressure Therapy at no observed clinical improvements expected, the treatment should be withdrawn. Treatment with Negative Pressure Therapy, unless otherwise specified, shall not exceed three weeks, checking the actual improvement in the tenth day of the injury in order to identify the indication to the suspension.

Indications for treatment discontinuation

The negative pressure therapy must be stopped immediately if you experience the following adverse events: bleeding; infection; Pain is not covered by adequate systemic therapy; cracks; fistulae; reduced quality of life; allergy to the components of the devices of medication used for the interface.

Informed consent

INFORMED CONSENT TO NEGATIVE PRESSURE THERAPY

The undersigned / a ______________________________ born / a il ______________________ resident a ______________________________ in street/square _____________________ No ___

I declare that I have been / to informed / a comprehensively by Dr. ______________________________ that for my disease ______________________________ it is advisable to apply the therapy to treatment with Negative Pressure supplied at this Hospital.

This treatment involves the application to the skin lesion of a negative pressure type and fluids, which has the effect of accelerating the healing process of wounds, dramatically increasing the blood supply tissue and significantly increasing the fibroblast proliferation.

To this end, we propose the application of Negative Pressure Therapy of Medical Company __________________________ for the approximate duration in ________ days.

Information sheet treatment Negative Pressure Therapy

1. The purpose of therapy: the application of such a treatment is used to determine a rapid appearance of the elements characterizing the start of a process of ulcer healing skin by reducing the bacterial load and favoring the formation of the neo-angiogenesis (formation of blood vessels for a better blood supply of the wound bed), obtaining as a result a valid granulation tissue and then a faster tissue repair.

2. Indications: the treatment is suitable for all skin lesions chronic / acute lower limb / upper. In the case of lesions that exhibit little tendency to healing for the presence of a strong exudative component or a bacterial contamination. In this sense, it fits into the context of advanced dressings, by which is integrated in order to cleanse the wound bed and thus speed up the healing process.

3. Contraindications: treatment is contraindicated in case of dry eschar; untreated osteomyelitis; neoplastic lesion, if not palliative intent to improve the quality of life; Non-enteric fistula and not explored; arteries; veins, organs, or nerves; anatomical sites.

4. Precautions: treatment requires the implementation of certain precautions (frequent monitoring) in some clinical situations: patients on anticoagulant or antiplatelet therapy, patients with difficult hemostasis, patients receiving corticosteroids in massive doses, or in the presence of malnutrition infected wounds.

5. Warning: You can not use the equipment in environments where you perform diagnostic MRI or CT scan for incompatibility between devices. Do not use in pediatric patients. Can not be used in units of hyperbaric oxygen therapy.
and in an environment with the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide. While showering or bathing, the patient must be disconnected from the device. The equipment should not be placed at a temperature below zero degrees Celsius.

6. Methodology used: will be framed the type of lesion to be treated and the ability to manage the negative pressure at your location, planning the necessary access outpatient monitoring. In this case the equipment supplied will continue therapy at home and will be agreed when and how to use the equipment and personnel to which you can refer for any clarification on the treatment.

7. Possible complications of treatment:
   Early complications: during and after the procedure individual may experience redness of the skin peri-lesional; hematoma by suction; local sensitization to components of the dressing used; pain.
   Late complications: maceration of the surrounding skin (even after the procedure).

Therefore, consciously, I declare that you understand all the information received about the type of treatment to be followed, the possible risks and complications inherent in the proposed procedure, on the possible therapeutic alternatives, the potential clinical consequences in case of refusal, having been able to have clarification from the end of a conscious choice.

I declare that I have been / to informed / a of goals, modalities of treatment which must be submitted / a.

Having read what was written in this statement and after having a wide-ranging interview with the doctor, Having been clarified the reasons of treatment, risks, alternatives, and the clinical implications in the event of refusal so to me understandable enough.

I, the undersigned / a _______________________________________

AGREE to voluntarily undergo / a treatment with Negative Pressure Therapy
Refusal to undergo / a treatment with Negative Pressure Therapy

Data____________________                      Doctor's signature (legible) Signature of patient
__________________________ __________________

INFORMED CONSENT AND AUTHORIZATION TO CONDUCT AND MATERIAL SEAL ICONOGRAPHIC

The / undersigned / a ____________________________ born / a when___________________
resident a________________________________________ in street/square ____________________________
I declare that I have been / informed / a comprehensively by Dr. _____________________ that for my disease____________________________________________________________ it is advisable to apply the therapy to treatment with Negative Pressure supplied at this Hospital. It should follow the development of the lesion photographing to update the status and assess the suspension.

Information sheet iconographic material
1. The holder of the exclusive rights of image and author of the photo is the signatory of patient consent.
2. What reasons are not fulfilled and / or obligations to third parties or claims of the latter for whatever reason, reason or cause in order to image rights or the author of the photos transferred.
3. Indemnity as of now responsible for the processing of the iconographic material from any and all claims made by third parties for any reason, reason or cause related to the object of this agreement, in particular consideration of the above points.

It is also understood that the protection of privacy in accordance with Legislative Decree no. 196/2003:
Will not be processed, published or broadcast personal information or sensitive person.
From the pictures you can not trace the identity, religious belief, political or racial origin of the person.
The iconographic material will be used for the following purposes:
measuring and updating the status of the lesion;
educational, or research;
publication in medical journals, websites, textbooks.

The iconographic material will be used only for the purposes expressly indicated and in compliance with Italian Legislative Decree no. 196/2003.

The person responsible for the material is the Clinical Coordinator, Coordinator Hospital’s Phone __________________________ email ________________

The updated list of data can be obtained by calling num__________.

The treatment of iconographic material is still carried out with the observance of all the precautionary measures of data security provided by law.

Investors are also warned that Article 7 Italian Legislative Decree no. 196/2003 grants the exercise of certain rights,
including the right to obtain the updating, rectification, integration as well as the cancellation of the data, making it specific request to the above mentioned Data Processor.

Having read what was written in this statement and after having a wide-ranging interview with the physician / clinician referent company Having been clarified why the iconographic treatment, alternatives, and the clinical implications in the event of refusal so to me and understandable enough.

I, the undersigned / a ______________________________________________________

AGREE to voluntarily undergo / a iconographic treatment while using Negative Pressure Therapy

Refusal to undergo / a treatment to treatment iconographic while using Negative Pressure Therapy

Data
Signature of medical / clinical referent company Signature of patient ______________________ ______________________

Modulo Request

APPLICATION FORM NEGATIVE PRESSURE THERAPY

To be sent to: Medical Direction
Pharmacy Service

SECTION A (by the doctor proponent)

CHARACTERISTICS OF THE PATIENT
Initial patient (name)
Sex M F
Date of birth (dd / mm / yy)

Collaborating YES NO
Use of anticoagulant drugs YES NO
Antidecubitus YES NO
Diabetes YES NO
Existing therapy Cortisonici

Antibiotics

Antineoplastic

Altro_______________________________________________________________

____________________________

TYPE OF INJURY
Etiology post traumatic surgical dehiscence
surgical dehiscence after sternotomy
venous ulcer diabetic foot
pressure ulcers
alto

Lesion site sacred buttock

leg abdomen
chest arms
foot hip
knee

Infection YES NO
Fistulas YES NO
Tunneling YES NO

Lesion length (cm) _______________ width (cm) _______________

No slight amount exudate

moderate abundant

Granulation tissue type of epithelial lesion
sluogh (fibrin) necrotic

Dressings previous
no alginate
antiseptic transparent films
non-adherent gauze hydrocolloids
antiseptic gauze hydrofibres
hydrogel polyurethane foams
absorbent granules grafts / skin flaps
altro

SECTION B (by the referent clinical enterprise)

OBJECTIVES OF THE TREATMENT
reduction in lesion volume increase% granulation tissue
reduction of bacterial exudate management
preparing the wound bed for plastic surgery
altro

Appliance model _________________________________

Medical Company _______________________________________________________

Type dressing gauze foam PU foam PVA
altro _____________________________________________

Date of treatment (dd / mm / yy)

Days alleged treatment

Date __________________
Doctor proponent (legible signature and stamp)

Date __________________
Referent clinical enterprise (legible signature and stamp)

RESERVED TO THE VALIDATION OF REQUEST

DATA__________________________________________
FIRMA________________________________________
NOTE________________________________________________________________________________

Form follow-up

FORM FOR FOLLOW-UP THERAPY NEGATIVE PRESSURE
This form must be sent to: Contact Clinical company
Pharmacy Service

Initial paziente_____________ date nascita______________
Folder clinica_____________ opening date terapia______________
N. days terapia______________

Events reported
Pain YES NO YES NO Bleeding
YES NO YES NO infection Fistolizzazioni
YES NO tunneling Altro______________________________
Intervention resulting in adverse event
Temporary suspension Suspension final
Debridement bottom lesion Use systemic antibiotics / local
Altro________________________________________________________________

Treatment outcomes
Achieved Partially achieved
Not achieved Altro____________________________________________________

Note:___________________________________________________________________________________________
________________________________________________________________________________________________
______________________________________________________________

Data________________
Doctor proponent (legible signature and stamp)

CONCLUSIONS

The negative pressure therapy must be considered as other treatments for wound care, must be chosen that is, if it provides the most effective method from the point of view both clinical and economic to achieve certain therapeutic objectives, therefore the use of a corporate protocol It allows a proper use of the equipment, to be able to contain costs and to be able to evaluate the results.

References


croniche. Servizio Sanitario Regione Emilia Romagna.