REVIEW ARTICLE

REVISTA ENFERMAGEM ATUAL IN DERME

INFLUENCE OF NEGATIVE PRESSURE THERAPY ON THE OUTCOME OF FOURNIER SYNDROME: INTEGRATIVE REVIEW

INFLUENCIA DE LA TERAPIA DE PRESIÓN NEGATIVA EN EL RESULTADO DEL SÍNDROME DE FOURNIER: REVISIÓN INTEGRATIVA

INFLUÊNCIA DA TERAPIA POR PRESSÃO NEGATIVA NO DESFECHO DA SÍNDROME DE FOURNIER: REVISÃO INTEGRATIVA

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ABSTRACT

Aim: to describe the evidence about the effects of Negative Pressure Therapy on the clinical outcome of Fournier Syndrome. **Method:** this is an integrative literature review, carried out between March and June 2023, by two researchers independently, with a search in the Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science (WoS) and Latin American and Caribbean Literature on Health Sciences (LILACS), using cross-controlled descriptors with the Boolean operators AND and OR. Rayann software and the PRISMA method were used for data selection and presentation, respectively. **Results:** Through the search and after the process of selection and data extraction, 2 studies with retrospective analysis were included that recommend the use of therapy with subatmospheric pressure because it is a therapy that promotes neoangiogenesis, exudate control, reduces the need for surgical events, in addition to preventing further complications such as infections, resulting in effective and faster healing. **Conclusion:** there is still no robust evidence that can provide safety in its indication and implementation, making it necessary to continue the development of new studies with better methodological quality.

Keywords: Negative Pressure Wound Management; Necrotizing Fasciitis; Healing; Stomatherapy.

RESUMEN

Objetivo: describir la evidencia sobre los efectos de la Terapia de Presión Negativa en el resultado clínico del Síndrome de Fournier. **Método:** se trata de una revisión integrativa de la literatura, realizada entre marzo y junio de 2023, por dos investigadores de forma independiente, con búsqueda en el Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science (WoS) y Literatura Latinoamericana y del Caribe en Ciencias de la Salud (LILACS), utilizando descriptores cruzados con los operadores booleanos AND y OR. Se utilizó el software Rayann y el método PRISMA para la selección y presentación de datos, respectivamente. **Resultados:** através de la búsqueda y posterior al proceso de selección y extracción de datos, se incluyeron 2 estudios con análisis retrospectivo que recomiendan el uso de terapia con presión subatmosférica por ser una terapia que favorece la neoangiogénesis, el control del exudado, reduce la necesidad de eventos quirúrgicos, además a la prevención de complicaciones posteriores, como infecciones, lo que da como resultado una curación más rápida y efectiva. **Conclusión:** sin embargo, aún no existe evidencia robusta que pueda brindar seguridad en su indicación e implementación, por lo que es necesario continuar con el desarrollo de nuevos estudios con mejor calidad metodológica.

Palabras clave: Manejo de Heridas por Presión Negativa; La fascitis necrotizante; Cicatrización; Estomaterapia.

RESUMO

Objetivo: descrever as evidências acerca dos efeitos da Terapia por Pressão Negativa no desfecho clínico da Síndrome de Fournier. **Método:** trata-se de uma revisão integrativa da literatura, realizada entre os meses de março a junho de 2023, por dois pesquisadores de forma independente, com busca nas bases de dados *Medical Literature Analysis and Retrieval System Online* (MEDLINE), *Cumulative Index to Nursing and Allied Health Literature* (CINAHL), *Web of Science* (WoS) e Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS), utilizando descritores controlados cruzados entre si com os operadores *booleanos AND* e *OR*. Utilizou-se do *software Rayann* e do método PRISMA para seleção e apresentação de dados, respectivamente. **Resultados:** através da busca e após o processo de seleção e extração de dados, foram inclusos 2 estudos com análise retrospectiva que recomendam o uso da terapia com pressão subatmosférica por se tratar de uma terapêutica que promove neoangiogênese, controle do exsudato, reduz a necessidade de eventos cirúrgicos, além de prevenir maiores complicações como infecções, resultando em uma cicatrização eficaz e mais rápida. **Conclusão:** ainda não há evidências robustas que possam proporcionar segurança na sua indicação e implementação, tornando-se necessária a continuidade no desenvolvimento de novos estudos com melhor qualidade metodológica.

Palavras-chave: Tratamento de Ferimentos com Pressão Negativa; Fasciite Necrosante; Cicatrização; Estomaterapia.

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INTRODUCTION

Fournier Syndrome (FS) or Fournier Gangrene (GF) is a bacterial dermohypodermitis of the perineum, perianal region and external genital organs[1,2,3]. It was first described in 1883 by Jean-Alfred Fournier, and is characterized as a rare disease, with an incidence of 1.6/100,000 individuals per year, which affects people of any age, mainly men, and progresses rapidly, with high rates of mortality[4,5].

The etiological cause of SF is infection by polymicrobial organisms, such as Escherichia coli, Streptococcus pyogenes, Pseudomonas aeruginosa, Klebsiella pneumoniae, Enterococci spp, Bacteroides fragilis and anaerobic streptococci, which cause a final thrombosis of the subcutaneous vessel and lead to tissue necrosis[6].

The agent is identified in the majority of cases, generally in the progression of anorectal, urogenital or cutaneous infections of the genital region[5]. The infection is commonly associated with immunosuppression, with risk factors for diseases such as Diabetes Mellitus (DM), chronic alcoholism, smoking, senility, obesity, urological anomalies, colorectal diseases, local trauma, Human Immunodeficiency Virus (HIV) infection and other immunosuppressive states[6,7].

After infection, the individual presents clinically with pain in the infected region, edema, erythema and blisters, associated with fever, chills and tachycardia[8].

Early diagnosis and multidisciplinary emergency intervention are mandatory in cases of FS due to rapid fascial necrosis and seeking to avoid complications[4]. The classic approach to treatment consists of removing necrotic tissue through emergency surgical debridement, interruption of polybacterial action, attenuation of systemic effects and preparation of the wound bed[7].

The post-surgical approach, with preparation of the wound bed with dressings, is essential, as the wound remains open for a long period. Furthermore, due to the degree of exudate, an adequate dressing is essential for controlling exudative discharge and reducing bacterial load[5]. From this perspective, the use of biological dressings and Negative Pressure Therapy (NPT) become alternatives for the effective management of SF[6].

TPN has been used to treat complex wounds as it physiologically favors the wound healing process, reducing edema, removing infectious material and exudates and increasing blood supply[6], however, little is done in practice based on robust evidence that ensures the efficiency of this therapeutic technique.

In this context, the present study seeks to delve deeper into the literature regarding scientific knowledge of the evidence-based effects of NPT on the clinical outcome of FS.

METHODS

Type of study

The study carried out is of the Integrative Review (IR) type. The steps followed were: identification of the guiding question (step 1), establishment of inclusion and exclusion criteria

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(step 2), data sources and search strategy (step 2), search and selection procedures (step 2), procedures for extraction, organization and summarization of data (step 3), evaluation of included studies (step 4), analysis/interpretation of results (step 5), presentation of the review (step 6)[9].

Identification of the guiding question (step 1)

The question to be answered by the review was: what scientific evidence is available in the literature on the use of negative pressure therapy and its impact on the clinical outcome of Fournier Syndrome? To prepare this question, the acronym that includes Population, Intervention, Comparator and Outcome (PICO) was adopted, with P = patient with Fournier Syndrome; I= Negative Pressure Therapy; C= standard treatment (conventional dressings); O= healing. Table 1 describes the possibilities for adopting the PICO acronym.

Table 1 – Description of the PICO acronym adopted to prepare the research question for this study. Crato, CE, Brazil, 2023.

POPULATION	**Adult** **Fasciitis, Necrotizing** • Fournier syndrome • Fournier's grangrene
INTERVENTION	**Negative-Pressure Wound Therapy** • Vacuum dressing • Subatmospheric pressure therapy
COMPARATOR	**Conservative treatment** • Conservative Therapy • Conservative Monitoring • Conservative Conduct
OUTCOME	**Wound Healing** • Wound Healing • Wound Healing

Establishment of inclusion and exclusion criteria (step 2)

The eligibility criteria for the development of this IR were: primary studies whose authors investigated the use of TPN in patients with FS, aged ≥ 18 years; published in English, Portuguese, Spanish between May 2018 and May 2023. In view of the above, editorial, response letter, secondary studies (for example,

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systematic review), experience report or expert opinion were excluded from the review sample.

The time frame was established to ensure an adequate number of primary studies, since the inclusion of a high volume of research may make it unfeasible to conduct an integrative review or introduce biases in the following stages of the method. Furthermore, it was decided to search for studies current ones, since NPT has been better discussed and studied recently, especially in the last 5 years.

Data sources and search strategy (step 2)

Among the databases, four were selected to search for primary studies, all relevant to the area of health and nursing, namely: Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science (WoS) and Latin American and Caribbean Literature in Health Sciences (LILACS). The study was carried out from March to June 2023.

The three described components of the PICO acronym were used in different combinations of controlled descriptors, keywords and Boolean operators AND and OR (search strategies for publications in the databases). In two databases (MEDLINE and WoS), the controlled descriptors were delimited from the Medical Subject Headings (MeSH). The search strategies adopted can be seen in Table 2.

Table 2 – Search strategies adopted to carry out this integrative review. Crato, CE, Brazil, 2023.

DATABASE	SEARCH STRATEGY
MEDLINE=6	(*Negative-Pressure Wound Therapy AND Adult AND Fasciitis, Necrotizing AND Wound Healing)*
Web of Science=2	*(Negative-Pressure Wound Therapy AND Adult AND Fasciitis, Necrotizing AND Wound Healing)*
CINAHL=14	*(Negative-Pressure Wound Therapy AND Adult AND Fasciitis, Necrotizing AND Wound Healing)*
LILACS =1	*(Negative-Pressure Wound Therapy AND Adult AND Fasciitis, Necrotizing AND Wound Healing)*

Search and selection procedures (step 2)

In the CINAHL and LILACS databases, the search strategies adopted were similar, but with the use of the base vocabulary (controlled descriptors), that is, CINAHL Headings and Health Sciences Descriptors (DeCS), respectively. Still in the databases, the final search strategies for publications were implemented on May 10, 2023.

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The Rayyan platform was used to select primary studies among reviewers[10]. Thus, this selection was carried out by reading the titles and abstracts of the publications, having as their axis the IR question and the eligibility criteria. This step was carried out by two reviewers independently and masked. The blinding of the Rayyan database was open and, in consensus meetings, the reviewers selected the primary studies for full reading; It should be noted that in these meetings a third reviewer assisted in the discussions.

The search and eligibility process for the materials found and included was presented in a flow diagram. This is a guideline recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 Statement – PRISMA[11].

The reading of the selected primary studies (n=2) in full was also carried out by two reviewers independently. If there were disagreements, a third reviewer would be consulted to resolve the questions and to assist in the final selection of research included in the IR sample.

Procedures for extracting, organizing and summarizing data (step 3)

To collect data from the studies included in the review, a script was constructed with the following items: authors, study title, year of publication, name of the journal, objective, details of the sample and method, statistical analysis, data on the occurrence/ incidence, main results and conclusion. This stage was carried out in May 2023, by two reviewers, independently, and differences were discussed until consensus was reached through meetings.

Assessment of included studies (step 4)

The type of study was identified according to the name assigned by the authors of the research included in the review. The methodological quality of primary studies was assessed using tools developed by the Joanna Briggs Institute (JBI). This international organization provides free tools for each type of study, that is, randomized clinical trial, quasi-experimental study, cohort study, cross-sectional study, among others. Such tools are made up of questions, for each one the reviewer answers yes, no, uncertain or not applicable. Through the questions, the internal validity and risk of bias of the study are assessed (selection of participants, method adopted and analysis of results)[12].

The tool entitled JBI Critical Appraisal Checklist for Case Series [13] was used to evaluate case series studies. The assessment of methodological quality was carried out in June 2023, by two reviewers, independently, and differences were discussed in meetings until consensus was reached.

In order to qualify the scientific quality and determine the level of evidence of the study, the evidence pyramid was used as a parameter as a simple, practical and widely used strategy among health studies. In this, at the top are meta-analyses as studies with the highest level of evidence and consequent recommendation. On the other hand, the base contains case reports

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and, therefore, has a lower level of recommendation.

Analysis/Interpretation of results (step 5)

Data analysis and synthesis were carried out descriptively.

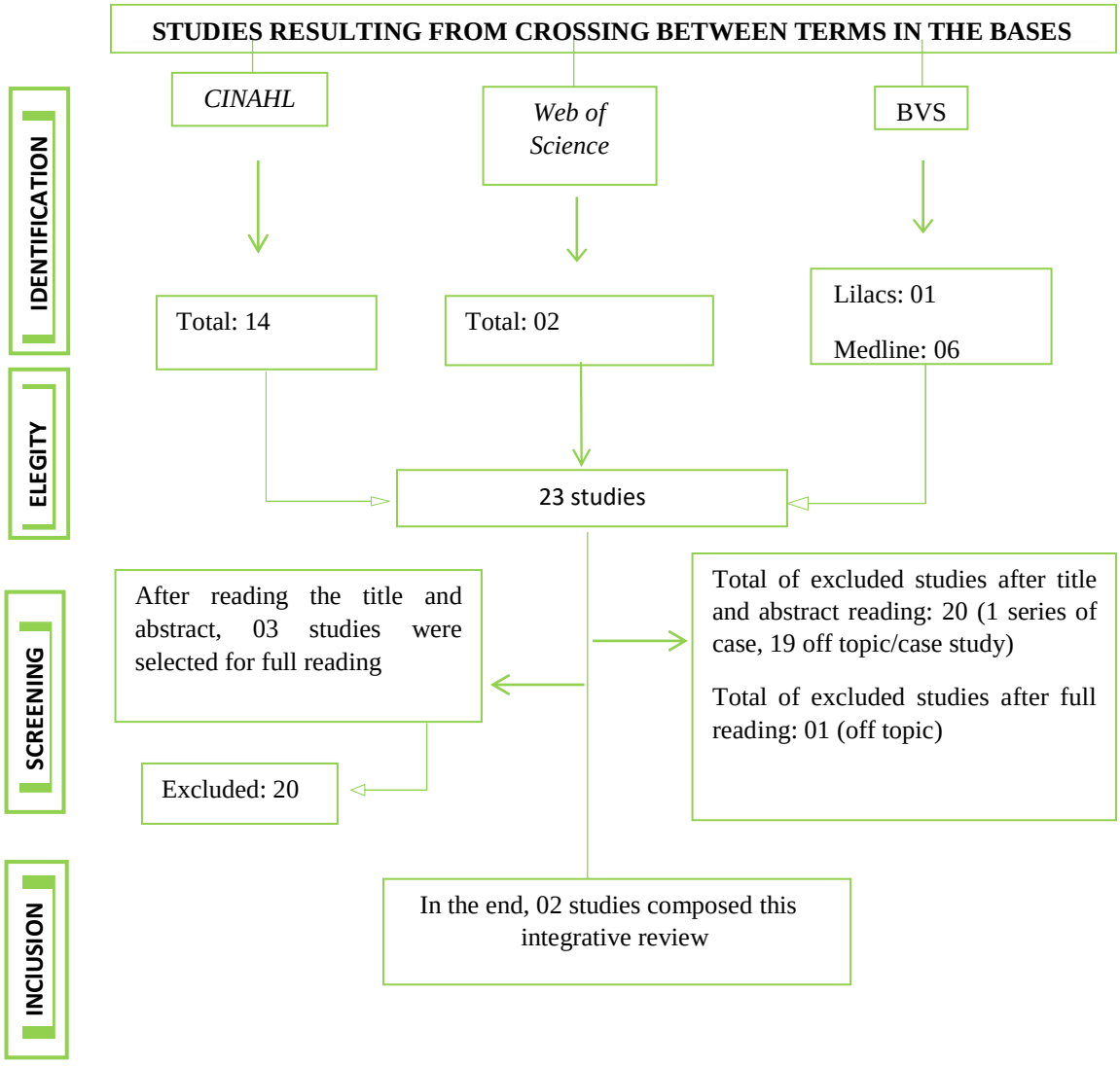
Presentation of the review (step 6)

The last step included the presentation of the review with the synthesis of the knowledge constructed. It should be noted that compliance with ethical aspects was ensured, respecting the copyright of the citations.

RESULTS

To present the steps leading to the selection of primary studies included in this IR, the PRISMA flowchart was used as can be seen in Figure 1.

Figure 1 - Selection process for primary studies included in the review, presentation based on the PRISMA method. Crato, Ceará, Brazil, 2023.



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Thus, of the 23 publications identified in the databases (registries), after applying the eligibility criteria, 03 primary studies were selected for full reading and at the end 02 studies comprised the review sample. Data relating to those included can be viewed in Table 3.

Table 3 – Descriptive summary of the primary studies included in the integrative review. Crato, Ceará, Brazil, 2023.

#	Title	Authors / Journal / Year of publication / Country / Level of evidence	Study design	Aim	Total adult participants ≥ (aged 18 or over) (N) Gender	Main results
01	*Outcomes in Fournier's Gangrene Using Skin and Soft Tissue Sparing Flap Preservation Surgery for Wound Closure: An Alternative Approach to Wide Radical Debridement*	Perry et al. [14]/ Wounds/ 2018/ United States / V	Retrospective analysis that sought to report the clinical outcomes of patients with Fournier syndrome treated with tissue-sparing debridement associated with TPN and delayed primary closure	To report the clinical outcome of patients with Fournier's gangrene using a surrogate approach of skin and soft tissue debridement, negative pressure therapy, and delayed primary closure.	17 pacients of both genders	In patients treated with the skin and soft tissue preservation triad with debridement, TPN with antibiotic irrigation and delayed primary closure, sparing them from an immediate surgical procedure, safely sparing the skin and soft tissues for possibly necessary future reconstructions. In this study, the average healing time using the triad was 24.3 days. DM was the main predisposing disease. 6 cases developed complications, such as sepsis (n=3), pneumonia (n=2), renal failure (n=1) and heart failure (n=1). Bacteria cultured from the wound included Escherichia coli (n=5), Enterococcus faecium (n=4), Staphylococcus aureus (n=2), Pseudomonas aeruginosa (n=2), Acinetobacter (n=1)

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						and methicillin-resistant Staphylococcus aureus (n=1). 10 cases had their wounds treated with TPN with maintenance every 3-7 days, however, it is still unclear.
02	*A retrospective case series of Fournier's gangrene: necrotizing fasciitis in perineum and perianal region*	Zhang et al. [15]/BMC Surgery/ 2020/ China/ V	Retrospective analysis of the profile of SF cases among patients hospitalized between June 2016 and June 2019.	Describe clinical manifestations, diagnosis, treatment and outcomes for patients hospitalized with Fournier gangrene	12 patients with a mean age of 60 years, both sexes (male predominance 6:1).	

Also considering the importance of evaluating the methodological quality of the included studies in order to make it possible to produce a reliable study, this step was carried out using the analysis tool proposed by the JBI Critical Appraisal Checklist for Case Series, as explained in Table 4.

Table 4 – Assessment of the methodological quality of primary studies using the JBI Critical Appraisal Checklist for Case Series tool. Crato, Ceará, Brazil, 2023.

Author, year	**Q****	**Q2**$**	**Q3**+**	**Q4**§**	**Q5**‖**	**Q6**¶**	**Q7*******	**Q8**$$**	**Q9**++**	**Q10**§§**	**Total (Yes)**
Perry *e* 2018	Y*	Y*	Y*	Y*	Y*	Y*	Y*	Y*	Y*	†N	9/10
Zhang *e* 2020	†N	Y*	Y*	Y*	Y*	Y*	Y*	Y*	Y*	Y*	9/10

Source: Questions taken from Munn et al. [13].
Q1= Were there clear criteria for inclusion in the case series?; $Q2 = Was the condition measured in a standard and reliable way for all participants included in the case series?; +Q3 = Were valid methods used to identify the condition for all participants included in the case series?; Q4§= Did the case series include consecutive participants?; ‖Q5 = Did the case series have complete inclusion of participants?; ¶Q6 = Was there clear reporting of the demographic data of the study participants?;*Q7= Was there a clear reporting of the clinical information of the participants?; $$Q8 = Were case follow-up outcomes or outcomes clearly reported?; ++Q9= Was there clear reporting of the demographic information of the presenting site(s)/clinic(s)?; §§Q10 = Was the statistical analysis appropriate?; *Y= Yes; †N= No.

DISCUSSION

TPN is a therapeutic approach that has been used in a variety of conditions, including the treatment of FS. This pathology is a necrotizing infection of the soft tissues of the perineum and genital region that can lead to a rapid decline in the patient's health and, in severe cases, death[14]. In turn, the therapy involves

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applying subatmospheric pressure to a wound through a controlled suction system. The main objective of this therapy is to promote wound healing, removing excess fluids and reducing edema, improving local vascularization and stimulating the growth of granulation tissue [15].

When applied to SF, TPN can have several beneficial effects. Negative pressure considerably reduces the patient's recovery time and may even, in some modalities, be a positive strategy in helping to remove necrotic tissue. In short, it is a therapeutic strategy that contributes to microbial control and wound exudate, thus reducing the risk of infection and promoting cleaning of the affected area. Furthermore, it improves local blood circulation, which can help bring nutrients and defense cells, aiding the healing process[16].

The patient with extensive lesions, and in the meantime, affected by FS, will have their indication for TPN evaluated individually by a trained professional, preferably a stoma therapy nurse. Generally, TPN is indicated when the wound has extensive dimensions with high exudate production, presenting difficulty in healing with conventional dressings or, even, if there is a need for rapid healing[16,17,18].

Through this IR, it was possible to present, through two studies[19,20] that explored the use of TPN in SF, that this is a therapeutic modality capable of providing positive results. These studies demonstrated a significant reduction in healing time, decreased need for surgical debridement, reduced risk of complications and improved quality of life for patients. An important effect was also observed in reducing local edema, as when applied to the wound, TPN helps to remove excess fluids, which improves tissue oxygenation and promotes neoangiogenesis.

The SF must be carefully prepared before applying TPN, this involves removing any necrotic tissue through surgical debridement or conservative instruments, and resolving any infectious condition when present. There are currently several TPN systems available on the market, the choice will depend on the characteristics of the wound or the professional's preference[21]. Therefore, when applied, the wound must be regularly monitored to assess the response to treatment and the need to change the system, which will depend on the amount of exudate produced, the presence of bacteria and the patient's response to treatment[15].

The use of this therapy can also help prepare the wound for future debridement interventions in difficult-to-handle injuries, stimulating the formation of granulation tissue and subsequent epithelialization, thus facilitating the effective healing process in less time[15,17,18].

However, there is still an important lack of information in the scientific literature, which may make evidence-based practice unfeasible. It was not possible to verify in this study the association of NPT in individuals with comorbidities, whether or not this occurrence could contraindicate therapy. It is worth mentioning that DM is one of the main predisposing factors for FS, in addition to

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immunosuppression, malignancy and chronic steroid use[6,7].

A meta-analysis showed that mortality from SF is associated with the prevalence of DM in around 67% of patients[18], local intravenous administration of drugs may also be the predisposing factor in rare cases. It is believed that in diabetic patients with the disease, TPN can bring significant improvements in quality of life by reducing the need for invasive and prolonged surgical procedures, minimizing the associated discomfort and pain[22]. However, there is no robust evidence to support this practice.

Therefore, it is important to emphasize that TPN is not an isolated therapy for the treatment of FS, it must be used as part of a multifactorial approach that includes infection control with appropriate antibiotics, adequate fluid resuscitation, surgical debridement when necessary and nutritional support. Furthermore, TPN may not be appropriate for all patients, especially those with certain underlying health conditions[19].

Although studies have shown promising results, it is important to recognize that TPN is not without limitations. Prolonged application of the subatmospheric pressure system can lead to complications such as skin irritation, lesions of surrounding skin, pain and discomfort. Furthermore, in some cases of FS, extensive debridement or even resection of affected tissues is mandatory, in order to avoid further complications. In these cases, when daily monitoring is not necessary to complete the cleaning process and/or infectious control, TPN can be used as a complement to surgery, helping to prepare the wound for closure or grafting[14,15,22].

In the meantime, it is necessary to continue developing scientific studies, with high methodological rigor, with the aim of presenting robust evidence that ensures the indication and safe use of TPN with a positive effect on the clinical outcome of FS.

CONCLUSION

This research sought to describe, through an integrative literature review, the main scientific evidence on the indication of TPN in the clinical management of FS. In this way, it was possible to observe that treatment with TPN can help preserve the skin and soft tissues of patients for possibly necessary future reconstructions, however, the results must be evaluated with caution, since treatment with TPN does not yet present evidence robust findings about its superiority over conventional dressing therapies with daily changes.

During the construction of this study, there were limitations related to the scarcity of articles related to the topic. But despite the impasse, the studies were very thorough, which allowed a compilation of essential elements to be drawn up to outline a vision of the topic addressed.

Therefore, carrying out new research on this topic is important to strengthen information and bring other results, evidence and

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perspectives to qualify TPN in the clinical outcome of FS.

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