BEST PRACTICES FOR REPROCESSING HEALTH PRODUCTS

Melhores práticas de reprocessamento de produtos para saúde

Mejores prácticas para reprocesar productos sanitarios

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ABSTRACT: Objective: To know the scientific production on the practices for reprocessing hospital materials. **Method:** This is an integrative review, conducted in August and September 2019 in the following nursing databases: Latin American and Caribbean Health Sciences Literature, Cumulative Index to Nursing and Allied Health Literature, Medical Literature Analysis and Retrieval System Online, and Scientific Electronic Library Online. We used descriptors in Portuguese, Spanish, and English, with a five-year time frame. Results were presented in a table, and the corpus for analysis in categories, according to the deductive method. **Results:** We retrieved 1,207 articles and selected six of them based on the eligibility criteria. The most frequent designs were quantitative studies in Portuguese, and three thematic categories were identified: cleaning process of healthcare products; packaging and sterilization of healthcare products; storage of healthcare products. **Conclusions:** The main procedures performed at each stage of material reprocessing were determined and should be described in institutional protocols. We highlight the lack of research on the reprocessing of healthcare products with a higher level of evidence.
Keywords: Hospitals. Equipment and supplies, hospital. Sterilization.

RESUMO: Objetivo: Conhecer a produção científica sobre as práticas de reprocessamento de materiais hospitalares. **Método:** Revisão integrativa, realizada em agosto e setembro de 2019 nas bases de dados da enfermagem, Literatura Latino-americana e do Caribe em Ciências da Saúde, Cumulative Index to Nursing and Allied Health Literature, Medical Literature Analysis and Retrieval System Online e Scientific Electronic Library Online. Utilizaram-se descritores em português, espanhol e inglês, com recorte temporal de cinco anos. Os resultados foram apresentados em quadro, e o *corpus* de análise em categorias, conforme o método dedutivo. **Resultados:** Foram identificados 1.207 artigos e selecionados seis deles em conformidade com os critérios de elegibilidade. Os delineamentos mais frequentes eram estudos quantitativos, no idioma português, configurando três categorias temáticas: processo de limpeza dos produtos para saúde; acondicionamento e esterilização dos produtos para saúde; armazenamento dos produtos para saúde. **Conclusão:** Foram evidenciados os principais procedimentos realizados em cada etapa do reprocessamento de materiais, que deve ser descrita em protocolos institucionais. Destaca-se a lacuna de pesquisas com nível de evidência, voltadas para o reprocessamento de produtos para saúde.
Palavras-chave: Hospitais. Equipamentos e provisões hospitalares. Esterilização.

RESUMEN: Objetivo: Conocer la producción científica sobre las prácticas de reprocesamiento de materiales hospitalarios. **Método:** Revisión integrativa, realizada de agosto a septiembre de 2019, en bases de datos especializadas en Enfermería, Literatura Latinoamericana y Caribeña en Ciencias de la Salud, *Cumulative Index to Nursing and Allied*, *Medical Literature Analysis and Retrieval System Online* y *Scientific Electronic Library Online*. Se utilizaron descriptores en portugués, español e inglés, con un marco de tiempo de cinco años. Los resultados se presentaron en una tabla y el corpus de análisis en categorías, según el método deductivo. **Resultados:** Se identificaron 1.207 artículos y se seleccionaron seis de ellos, de acuerdo con los criterios de elegibilidad. Los diseños más frecuentes fueron estudios cuantitativos, en portugués, configurando tres categorías temáticas: proceso de limpieza de productos sanitarios; envasado y esterilización de productos sanitarios; almacenamiento de productos sanitarios. **Conclusión:** Se destacaron los principales procedimientos realizados en cada etapa del reprocesamiento del material, los cuales deben ser descritos en los protocolos institucionales. Se destaca la brecha en la investigación con nivel de evidencia, enfocada al reprocesamiento de productos sanitarios.
Palabras clave: Hospitales. Equipos y suministros de hospitales. Esterilización.

INTRODUCTION

The Sterile Processing Department (SPD) is responsible for processing healthcare products (HP), a complex and essential activity performed following sequential stages that require operational and technological capability[1]. SPD is an important sector of health facilities, associated with the quality of the services provided and patient safety[2], although, in many circumstances, its real value is not recognized.

Sterilization acts directly in the battle against healthcare-associated infections and therefore affects the quality of care and the safety of patients and professionals. Any failure during the reprocessing of HPs might compromise their sterility and lead to adverse events during and after hospitalization[2,3].

Thus, the reprocessing of HPs consists of a systematic and methodological set of actions taken to ensure these products are suitable for safe use. Reprocessing steps include: pre-cleaning, reception, cleaning, drying, evaluation of the integrity and functionality of the instrument, preparation/packaging, disinfection or sterilization, storage, and distribution to the consumer units[4,5].

To guarantee quality in all stages, the SPD must have a proper infrastructure in line with the current legislation and best scientific practices. Therefore, these steps must be strictly followed to ensure a contaminant-free HP[6].

In Brazil, the Collegiate Board Resolution No. 15/2012 established the requirements for best HP processing practices and highlighted the need for an operational quality management system to document and control the processes. In addition, it discusses the validation of each reprocessing step, demanding their description in the Standard Operating Procedures, manuals, and protocols since they classify, standardize, and validate the work processes[7].

From this perspective, the need to analyze and compile scientific production in this context becomes clear so that sterilization practices can be based on the best evidence, given the lack of a high level of evidence in this area.

OBJECTIVE

To know the scientific production on the practices for reprocessing hospital HPs.

METHOD

This is an integrative review developed in five stages: establishing the problem; selecting the sample and defining the inclusion criteria; characterizing the studies; analyzing the results; presenting and discussing the findings[8].

The guiding research question was structured based on the issue presented: What is the scientific evidence for best practices related to reprocessing hospital HPs in the SPD?

Searches were carried out in August and September 2019 in journals indexed in the electronic resources: Nursing Database (*Base de Dados em Enfermagem* — BDEnf), Latin American and Caribbean Health Sciences Literature (*Literatura Latino-Americana e do Caribe em Ciências da Saúde* — LILACS), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medical Literature Analysis and Retrieval System Online (PubMed/MEDLINE), and Scientific Electronic Library Online (SciELO), through search strategies structured specifically for each database, with the help of a librarian specialized in this type of research.

In order to define the search strategy, we used keywords in English, Portuguese, and Spanish: Equipment and Supplies, Hospital OR Equipment and Supplies, Hospital OR Hospital Equipment and Supplies OR Hospital Supplies OR Hospital Supply OR Hospital Equipment OR Materials Management, Hospital OR Materials Management, Hospital OR Hospital Material Management OR Storeroom OR Storerooms OR Materials AND Sterilization.

The inclusion criteria consisted of original articles in English, Spanish, and Portuguese. The exclusion criteria were editorials, dissertations, theses, opinion articles, experience reports, and comments. The filters used were: articles with their full text available for free; written in English, Spanish, and Portuguese; published in prior five years (between January 2014 and July 2019).

In the first step of the eligibility process, the references were retrieved with only their titles and abstracts. The second step involved reading the studies in full. The third consisted of a new reading and justification for the selection of the articles comprising the sample.

In the inclusion stage, one of the researchers compiled the articles in sequential order in a Microsoft Word document. The topics of interest recorded were: author, study title, database, year of publication, objective, methods, and results.

The investigation of the most frequent themes of the articles included in this review was based on the analysis of

deductive content, starting with predefined categories, in line with the steps of the HP reprocessing procedure.

We underline that copyright principles have been respected throughout the process.

RESULTS

A total of 1,207 articles were identified, of which 1,172 comprised the corpus of analysis after the removal of 35 duplicates. Six articles met the criteria for data selection, extraction, and summarization, comprising the study sample. Figure 1 shows the steps of the article selection process. Chart 1 summarizes the six articles selected for the corpus for analysis of this review.

Regarding language, four articles were published in Portuguese (Brazil), one in English (India), and one in Spanish (Spain). The year with the most publications was 2017, with three articles. The quantitative method was the most used (five studies).

With respect to the subjects of the studies, two articles addressed aspects related to cleaning; two investigated packaging and the sterilization process; two focused on HP storage.

DISCUSSION

Investigation of the most frequent themes of the articles included in this review was based on the structuring of three
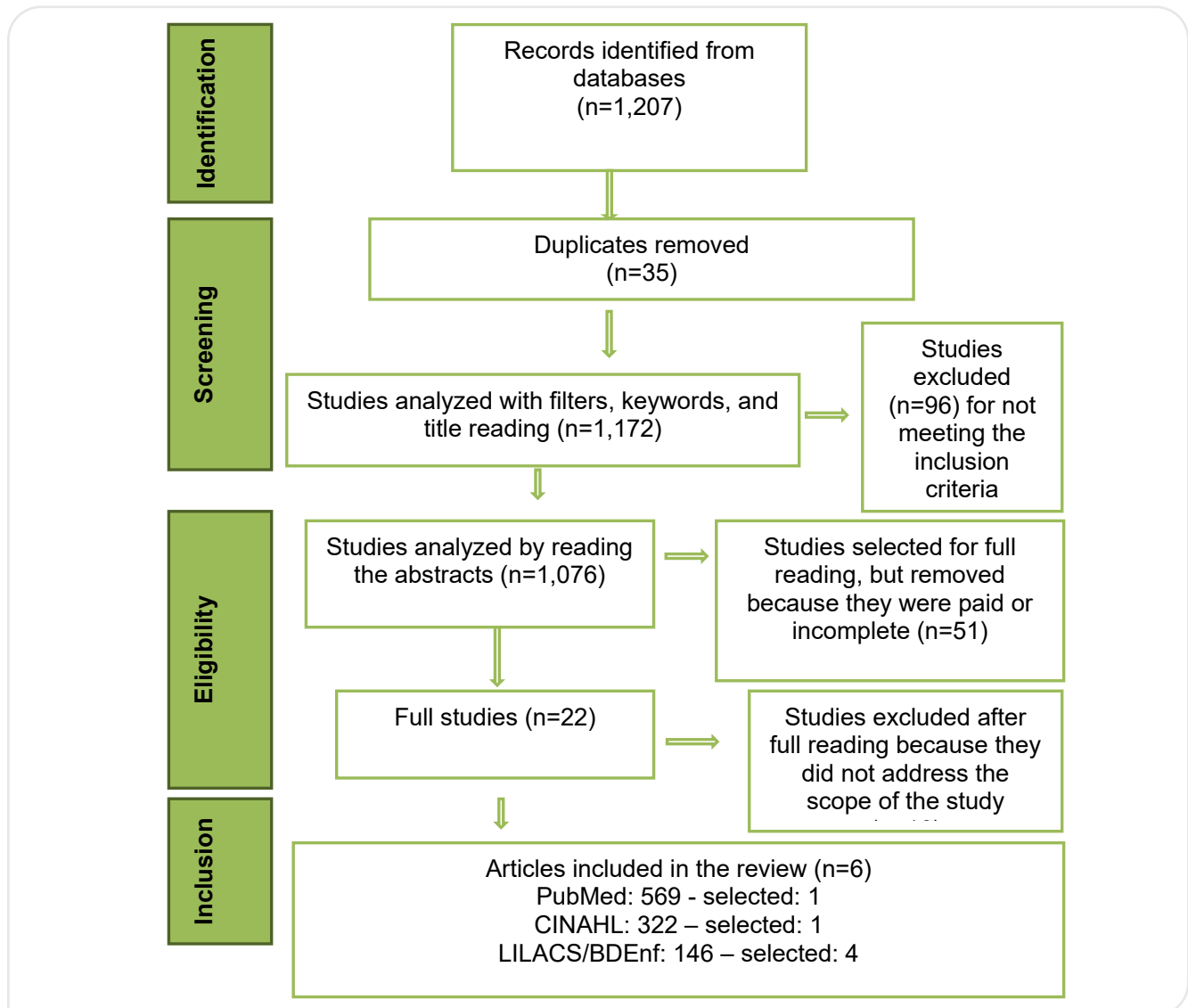

Figure 1. Steps of each process and selection of articles that comprised the sample.

Chart 1. Article characterization according to authors, title, journal, year of publication, database, objective, method, and results.

Authors and title	Journal, year, and database	Objective	Method	Results
Madeira et al.[2] Processing of health products in material and sterilization centers	Revista SOBECC; 2015 LILACS/ BDEnf	To analyze the processing of health products in Material and Sterilization Centers (MSC) in Health Care Establishments of the city of Teresina – PI.	Cross-sectional observational study.	For the proper processing of healthcare products, the sector should have: a clean and bright environment, unidirectional product flow, and autoclave chamber filled with 80% load. Inadequacies identified: lack of identification label on packages, no use of Bowie & Dick or class V or VI chemical indicators, no monitoring of physical and biological parameters, and no documentation archive.
Alvim et al.[3] Monitoring of health products cleaning with adenosine triphosphate testing	Revista SOBECC; 2019 LILACS/ BDEnf	Evaluating the cleaning quality of health products by using the surface adenosine triphosphate (ATP) test in a Central Sterile Services Department.	Quantitative, descriptive, cross-sectional study.	Adenosine triphosphate tests are not specific enough to ensure the quality of the cleaning of healthcare products, but they suggest the lack of residues in all instruments.
Mussel et al.[5] Storage of health products in hospital sterilization centers	Revista Enfermagem em Foco; 2017 LILACS/ BDEnf	Describe storage conditions for sterile products in Sterilized Material Centers of large hospitals.	Quantitative descriptive study.	Packaging of healthcare products is made in closed cabinets (60%), with a washable surface (100%), and humidity and temperature control. All sterile processing departments reported controlling the expiration date of products, and 80% of them transported materials in exclusive carts. 30% of the facilities did not have an exclusive physical area for sterile products.
Díaz et al.[9] Validation of manual and automated washing procedures for surgical instruments prior to sterilization	Metas de Enfermería; 2018 CINAHL	To validate the manual and automated cleaning process of surgical instruments prior to sterilization in the sterilization unit of a university hospital.	Quantitative, descriptive, cross-sectional, prospective study.	134 residual control tests were performed in automated washing; 56% were valid, while 44% of controls had visible remains of residual contamination, mainly due to mechanical problems during the procedure. A total of 85 protein tests were analyzed to validate manual cleaning. No protein was detected in the material before sterilization in 88.3% of cases.
Mendonça et al.[17] Quality indicators of health product processing in steam autoclaves	Revista de Enfermagem UFPE Online; 2017 LILACS-BDEnf	To analyze quality indicators of health product processing using saturated steam under pressure in Material Sterilization Centers.	Quantitative descriptive study.	Most (83.3%) of the six hospitals in the study performed annual reviews of the standards and operational routines of each stage of healthcare product processing and had appropriate physical space for cleaning, preparation, and storage, as well as a physical barrier between areas. The findings evidence the need to invest in aspects related to the improvement of processing for health.
Basu[18] Reason behind wet pack after steam sterilization and its consequences: an overview from Central Sterile Supply Department of a cancer center in eastern India	Science; 2017 PubMed	To analyze the reasons that cause wet packs after sterilization and its consequences.	Qualitative descriptive study	The causes identified for wet packs are: poor quality of the packaging material and of the steam, improper packaging and autoclave loading technique. Measures to prevent wet packs include: using good-quality water (steam), periodically performing autoclave maintenance, avoiding overloading the sterilizer, allowing enough time to cool the material after sterilization, using good-quality packages, maintaining adequate temperature and humidity during and after the process.

categories: cleaning process of HPs, packaging and sterilization of HPs, and storage of HPs.

Category 1: cleaning process of health products

This category covers aspects related to the cleaning process, which includes manual and automated cleaning steps, followed by tests to validate these steps, with chemical surface tests[3,9].

Cleaning consists of removing organic and inorganic residues from the HP surface, dents, joints, lumens, and other internal spaces to maximize the reduction of microbial load. It can be done manually with water, standard detergents, and cleaning supplies suitable for the material. Automated cleaning, such as high-pressure cleaning, washer disinfectors, or ultrasonic cleaners, provides agility, standardization, monitoring, and process validation, in addition to decreasing the workers' exposure to biological risks. However, we emphasize that these devices and materials should be cleaned beforehand to reduce organic and inorganic matter as much as possible[1,10,11].

When workers do not pay attention to the importance of the cleaning process, doing it ineffectively, the residues that cumulate on the materials are not entirely removed and may form barriers or biofilms that protect the microorganisms[12]. Moreover, all stages of this process are influenced by the use of appropriate accessories, the action of detergents, water quality, work environment, trained staff, and evidence-based protocols[13].

This aspect leads us to reflect on the matter and raises concerns over the adequate pre-wash of HPs since this process is crucial for the effectiveness of the others.

From this perspective, the articles listed in this review recommend using the adenosine triphosphate (ATP) protein test[3]. Protein tests allow the effective validation of the cleaning process, both manual and automated, because they determine the levels of organic matter in HPs and assess parameters beyond visual cleaning, ensuring safety to the process[14]. After this validation and the implementation of corrective measures, we can achieve excellence in HP reprocessing[9].

Yet, the Brazilian legislation does not specify the best chemical test for cleaning validation. Some investigations indicate that the ATP-bioluminescence assay can be an effective method for cleaning validation, providing fast and objective results[15,16].

In one of the studies in this review, relative light unit values were below 204 RLU when considering all instruments (cannulated or not) and 250 RLU in cannulated instruments[3].

Corroborating this finding, a study pointed out that ATP concentrations below 500 RLU are acceptable for characterization of clean surfaces[16].

Of note, the proper cleaning process validated through ATP testing is extremely important for reducing adverse events. ATP is considered a strong control variable for cleaning monitoring, capable of confirming instrument decontamination, and is regarded as a best practice that should be disseminated among health services[6].

Therefore, cleaning and its validation steps should follow protocols based on scientific studies with a high level of evidence[3].

Category 2: packaging and sterilization of health products

After the cleaning and inspection processes, HPs must be adequately packed to be effectively sterilized. Thus, this category covers aspects related to these steps and lists processes relevant to the implementation of best reprocessing practices. One of these processes is validating the sterilization, particularly regarding wet packs and the appropriate ways of preventing this condition, in addition to the adoption of quality indicators[5,17,18].

After cleaning, the HP should be inspected to detect organic and inorganic matter, which interferes with sterilizing agents and causes adverse events in patients. To that end, the use of magnifying lenses is recommended to assist in the examination[1].

The HP must then be dry for packaging and placed in validated and standardized packages. In turn, the receptacle must ensure integrity, resistance, safety, and atoxicity, allow thermal sealing, impermeability, and compatibility with the sterilization method, and guarantee sterility. These packages must follow the standards recommended by regulatory bodies and have product identification labels in the external area[2]. The available barriers that meet these criteria include: Spunbond Meltblown Spunbond (SMS), medical paper, Tyvek, and metal boxes, trays, and containers[1,19].

Next, the product is sterilized to destroy micro-organisms in such a way that they are no longer detectable in the standard culture medium, that is, the probability of survival of these micro-organisms must be less than 1:1,000,000[1].

Several sterilization methods are available, depending on the HP. For critical heat-resistant HPs, the ideal method is autoclave (pressurized saturated steam). In the case of heat-sensitive items, the process is more complex[4].

The control of the sterilization process relies on the type and safety of the equipment, the nature of the product to be sterilized, packaging compatible with the sterilization method, the sterilization method itself, proper loading and unloading. Preventive maintenance and performance assessment should be done and documented every year in all SPD machinery[20].

Tests to validate sterilization must be performed according to load release monitoring methods by process indicators such as chemical, biological, and physical controls. Chemical indicators, like Bowie & Dick (class II indicator), should be used to check the vacuum pump (air removal) in the first cycle of the day. Class V and VI chemical indicators are part of routine monitoring for sterilization cycle validation and load release. Biological tests are performed in the first load of the day and in implant loads. Physical tests are generated by the autoclave. These parameters should be manually or digitally controlled and archived for five years[1,2,7].

Using autoclave tape (class I indicator) externally in all packages is also recommended, as it differentiates processed from unprocessed products, with the advantages of having low cost and allowing immediate reading[1,21].

We underline that any residual moisture inside or outside a sterile material results in wet packs. This residual moisture can create a potential route for micro-organisms to move from the external to the internal environment and possibly contaminate products after sterilization. One of its causes is the poor quality of packaging materials (materials must be packed in such a way that steam and air can circulate in the package but be impervious to bacteria). Large extensions of rigid HPs, low load distribution, and poor packaging techniques should be avoided[18].

The following factors must also be assessed: autoclave steam quality, water quality, sterilization cycle duration, autoclave vacuum pump, faulty planning, poor sterilizer conditions, drying time, vacuum pump operation, vacuum drain cleanliness, presence of leaks, and quality of the generator/boiler. Lack of preventive sterilizer maintenance and inadequate inventory management system also compromise the effective sterilization process[18].

We also stress the importance of the proper HP organization in the autoclave, placing: concave-convex instruments in the vertical or inclined position; products like jugs and buckets with the opening facing down; packages inside the autoclave in the vertical position, with space between them; larger packages on the bottom of the chamber and smaller ones on the top. We should also pay attention not to use more than 80% of the autoclave capacity and properly record the temperature, pressure, and time parameters of all autoclave cycles[17].

Category 3: storage of health products

After sterilization, one of the last steps of HP processing is storage. Proper storage is associated with related care to avoid non-conformities linked to environment and ambiance and is especially covered in two articles of this review[1,5].

The entire HP sterility may be compromised if the storage does not ensure its maintenance with actions like: storage in drawers, package stacking, package folds, non-restricted location, excessive handling, inefficient cleaning of the site, lack of temperature and humidity control, poor product distribution, lack of donning and/or inadequate donning, lack of air conditioning, presence of sunlight, among others[1,7,22]. Therefore, the following aspects are imperative to maintain optimum storage conditions for the sterile product: organization, cleaning, and humidity and temperature control of the environment[23,24].

Storage site dimensions should be based on the number of beds in the facility. The site must be centralized, exclusive, and restricted. The minimum distance recommended from the storage shelves is 45 cm to the ceiling, 20 cm to the floor, 5 cm to the wall, and 60 cm between shelves[5,7].

The storage site should be cleaned with sponges and 70% alcohol at least once a week or whenever it is dirty. A specific cart is also required to transport the sterile HP in order to preserve its sterility[5].

Another important aspect is the sudden variation in relative humidity and temperature, which may influence the preservation of packages, interfering with their resistance. The literature disagrees when it comes to temperature and humidity ranges, for instance: temperature from 18 to 25°C and humidity between 30 and 60%[1]; temperature between 18 and 24°C and humidity below 70%[19]; temperature up to 24°C and humidity between 30 and 70%[22]. Adjustments and adaptations are allowed according to regional climate differences and the storage site infrastructure.

The limitations of the study include not having articles about validation methods for automated cleaning equipment and on the use of detergents in the cleaning process of HPs.

As for nursing contributions, this research discusses best practices in HP sterilization processes and can serve

as a guide for the work of nursing professionals on their SPD routine.

CONCLUSION

The study reached the objective of knowing the scientific production on the practice for reprocessing hospital HPs. In the cleaning process, we identified the ATP protein test as a validation method for both manual and automated cleaning. In the packaging and sterilization process, we discussed the importance of visually inspecting the materials during cleaning and encasing them in validated packages. In sterilization, we explored the proper loading, using chemical, physical, and biological indicators to validate the sterilization cycle. In addition, the wet pack, which represents a contamination risk, should have its cause identified and fixed. In the storage process, we highlighted the importance of adequate infrastructure and safe handling of sterile materials, as well as of keeping the humidity and temperature of the site within safe parameters. These steps should be described in institutional protocols.

This study detected a gap in validation methods for automated cleaning equipment (ultrasonic cleaners and washer disinfectors), its validation tests, and the use of detergents. We concluded that we lack research with a high level of evidence aimed at HP processing.

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None.

CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTION

ABC: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing — original draft, Writing — review & editing. **JBRG:** Conceptualization, Formal analysis, Investigation, Methodology, Project management, Supervision, Validation, Visualization, Writing — original draft, Writing — review & editing. **LFS:** Validation, Visualization, Writing — original draft, Writing — review & editing. **LNA:** Validation, Visualization, Writing — original draft, Writing — review & editing. **AGA:** Validation, Visualization, Writing — original draft, Writing — review & editing. **RW:** Validation, Visualization, Writing — original draft, Writing — review & editing.

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