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Usage time and microbiological safety of multipurpose systems with anti-reflux valves in radiology: a review

Tempo de uso e segurança microbiológica de sistemas multiuso com válvula antirrefluxo na radiologia: revisão

Tiempo de uso y seguridad microbiológica de sistemas multipropósito con válvulas antirreflujo en radiología: una revisión

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ABSTRACT

Objectives: to investigate scientific literature on time of use and microbiological safety of multipurpose systems with anti-reflux valves in magnetic resonance and computed tomography scan. **Methods:** scoping review conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews, structured with guiding question formulation; relevant study careful search/screening; systematic data organization/extraction; comparative analysis, and synthesis of results. **Results:** of the 276 studies found, 55 duplicates were excluded. After initial screening by reading titles and abstracts, 14 of 221 studies were selected, six of which were read in full and 12 were excluded because they did not answer the guiding question. The final set of selected studies comprised two scientific articles. **Final Considerations:** the multipurpose system with anti-reflux valves in magnetic resonance and computed tomography scan showed that there is only scientific evidence of absence of bacterial contamination for up to eight hours of use in radiology.
Descriptors: Equipment Contamination; Biosecurity; Microbiology; Contrast Media; Scoping Review.

RESUMO

Objetivos: investigar literatura científica sobre o tempo de uso e segurança microbiológica de sistemas multiuso com válvulas antirrefluxo em exames de ressonância magnética e tomografia computadorizada. **Métodos**: revisão de escopo foi realizada conforme o *Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews*, estruturada com a formulação da pergunta norteadora; busca/triagem criteriosa por estudos relevantes; organização/extração sistemática dos dados; análise comparativa, síntese dos resultados. **Resultados**: dos 276 estudos encontrados, 55 duplicados foram excluídos. Após triagem inicial por leitura dos títulos e resumos, dos 221 estudos, 14 foram selecionados, sendo seis lidos na íntegra e 12 excluídos, pois não respondiam à questão norteadora. O conjunto final de estudos selecionados compreendeu dois artigos científicos. **Considerações Finais**: o sistema multiuso com válvulas antirrefluxo em exames de ressonância magnética e tomografia computadorizada mostrou que somente há evidências científicas da ausência de contaminação bacteriana até oito horas de uso na radiologia.
Descritores: Contaminação de Equipamentos; Biossegurança; Microbiologia; Meios de Contraste, Revisão de Escopo.

RESUMEN

Objetivos: investigar la literatura científica sobre el tiempo de uso y la seguridad microbiológica de los sistemas multipropósito con válvulas antirreflujo en exámenes de resonancia magnética y tomografía computarizada. **Métodos:** se realizó una revisión exploratoria siguiendo las directrices del *Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews*, que incluyó la formulación de una pregunta guía, búsqueda y selección rigurosa de estudios, organización y extracción sistemática de datos, análisis comparativo y síntesis de resultados. **Resultados:** de 276 estudios identificados, 55 fueron excluidos por duplicidad. Tras la revisión de títulos y resúmenes, se seleccionaron 14 de los 221 restantes; seis fueron evaluados íntegramente y 12 excluidos por no responder a la pregunta. El análisis final incluyó dos artículos científicos. **Consideraciones finales:** la evidencia disponible indica ausencia de contaminación bacteriana en sistemas multipropósito con válvulas antirreflujo durante un uso continuo de hasta ocho horas en radiología.
Descriptores: Contaminación de Equipos; Biossegurança; Microbiología; Meios de Contraste; Revisión de Alcance.

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INTRODUCTION

The use of anti-reflux valves (ARVs) plays a fundamental role in power generation in nuclear power plants and hydraulic systems. Although their initial application was linked to other contexts, significant growth in the healthcare field has been observed, particularly in surgical procedures involving propofol and in medical devices and health products (HPs) such as urinary catheters. Furthermore, over the past two decades, ARVs have been used in multipurpose intravenous infusion systems for saline solution (SS) and contrast media (CM), and in computed tomography (CT) and magnetic resonance imaging (MRI) scan, which are part of radiology services[1-6].

The multipurpose system consists of a set of materials for intravenous infusion, namely: item 1 - syringes of different volumes (60, 65, 100, 130, 150, 190, or 200 mL); item 2 - multipurpose connectors with registration, requirements and time of use governed by the Brazilian National Health Regulatory Agency (In Portuguese, *Agência Nacional de Vigilância Sanitária* - ANVISA)[7]; and item 3 - connectors with individualized ARVs, i.e., one per patient. This multipurpose system uses contrast injectors to save resources and optimize time. The main purpose of the connector in item 3 is to prevent backflow of patients' bloodstream into the connector in item 2, thus avoiding cross-contamination[8,9].

Although this system provides significant advances in diagnostics, uncertainties remain regarding its risk assessment. In this context, concerns arise about the safety of patients using this type of multipurpose system, since proving its safety would depend on physical, functional, and microbiological testing before its release for clinical and commercial use in radiology. Therefore, it is urgent to establish official standards and protocols based on scientific evidence that clearly guide the use of this multipurpose system in radiology[10].

The valves are designed to reduce the potential for cross-contamination between patients; and the multipurpose system must present clinical evidence, through articles published in recognized journals in the scientific field, to guarantee and guide clinical practice in a safe manner, since multipurpose systems are routinely used to save time and reduce costs, reduce materials and waste, and simplify the SS and CM administration process[11].

Currently, single-use connectors are rarely used in contrast injectors in MRIs and CTs. To support this, Pepin *et al*., in a comparative study between multipurpose and single-use injectors, highlighted the significant impact of multipurpose systems on significantly reducing waste[12]. The authors reported a 50% reduction in CM waste if multipurpose vials were used exclusively. Additionally, they highlighted the efficiency of the work, i.e., in optimizing CT and MRI scans. However, it is important to ensure that multipurpose systems have approval from ANVISA and other regulatory agencies, as well as clinical evidence from evidence-based practice[13].

To regulate and guide clinical practice in the handling of multipurpose systems in CT and MRI, we suggest the creation of guidelines and protocols, i.e., regulatory standards that clarify handling and the pre-established shelf life on the packaging of products used in clinical practice. These guidelines and protocols would clarify doubts regarding standardization and regulations specific to multipurpose systems.

OBJECTIVES

To investigate scientific literature that proves the determination of time of use of the multipurpose system in radiology (MRI and CT) and the microbiological safety of this system.

METHODS

Study design

This research is characterized as a scoping review, with five defined stages, structured according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews[14]: (1) guiding research question formulation; (2) structured search for relevant studies; (3) careful screening of studies; (4) data organization and systematic extraction; and (5) comparative analysis, synthesis and detailing of results.

Identifying the guiding research question

The guiding research question formulation, together with the choice of descriptors, was based on the mnemonic PCC: Population (P): multipurpose systems and ARVs in MRI and CT; Concept (C): safety and time of use; and Context (C): microbiological. Thus, the question resulted: is there microbiological scientific evidence to guide the time of use of the multipurpose system in MRI and CT?

Identifying relevant studies and selection

The search for scientific articles on microbiological assessment was based on the Latin American and Caribbean Literature on Health Sciences (LILACS), Web of Science, Scopus, and the National Library of Medicine (PubMed) portal databases. Furthermore, the study was conducted in October 2023 by two independent researchers with proven expertise in the topic in question.

In LILACS, the search strategy was conducted with descriptors in Portuguese, while in the other databases and on the portal, only terms in English were used.

Studies published on the topic, regardless of language, as long as they were included within the time frame, between January 2019 and October 2023, since prior to this period the search had already been carried out and an integrative review published, were included[15]. The search strategy involved combining keywords and descriptors belonging to the same category, interconnected by "OR" and "AND" between them. The terms used in the search strategy were categorized according to the database and portal as well as defined based on the Medical Subject Headings and Descriptors in Health Sciences (Chart 1). Repeated studies in the databases and portal, as well as diverse areas of radiology and topics not specific to the proposal of this scoping review, were excluded.

Data analysis

Data extraction and synthesis occurred after a full reading of selected articles and strict application of inclusion and exclusion criteria. A single reviewer organized the information in a spreadsheet developed in Microsoft Office Excel® 365, which enabled the systematization and description of results. The results were

Chart 1 - Search results

Cross-reference descriptors and Boolean operators	Number of articles found in the databases and portal
Valve AND Artificial OR Valves AND Non-return	PubMed = 6 Web of Science = 71 Scopus = 45
Valves AND Anti-reflux AND infusion	Web of Science = 12 Scopus = 6
"Computed tomography" AND "Contrast injectors" AND "Infection control"	PubMed = 1 Scopus= 3
"Multi-use Contrast" AND radiology	Scopus = 2
"Anti-reflux valve" AND infusion	Web of Science = 10 Scopus = 2
Anti-reflux valve AND infusion	Web of Science = 10 Scopus = 2
radiology AND multi-use AND contrast	PubMed = 4 Scopus = 8 PubMed = 2
contrast injector AND multi-use	Web of Science = 3 Scopus = 3 PubMed = 2
MRI AND contrast injector AND infusion	Web of Science = 1 Scopus = 31
one way valves AND contamination AND infusion	Web of Science = 2 Scopus = 43
"*sistemas de infusão*" AND *radiologia*	LILACS = 1

MRI - magnetic resonance Imaging.

summarized descriptively and presented in charts to facilitate observation and interpretation of the data obtained. The discussion was conducted to promote a critical analysis of results, contextualizing them based on the scientific evidence available in the literature related to the topic addressed.

RESULTS

The studies selected from the databases and portal underwent an initial screening based on the application of previously defined inclusion and exclusion criteria. Thus, of the 272 references found, 17 were from PubMed, one from LILACS, 109 from Web of Science, and 145 from Scopus. Furthermore, four articles were found through independent exploration or gray literature, three of which did not answer the guiding question. This exploration consisted of searching for articles outside of traditional search sources, conducted through Google and attempting to contact multipurpose system manufacturers via email, requesting scientific evidence. Of the 276 studies, 55 were duplicates and were excluded. Initially, 221 studies were identified and subjected to preliminary screening. Careful assessment of titles and abstracts resulted in the exclusion of 207 articles, of which 14 were considered eligible. Of these 14, eight studies were excluded because they did not answer the guiding question, and six were selected and read in full. Of these six, four studies did not answer the guiding question, and only two studies were included. Therefore, of the 276 studies found in the search, only two articles were included in the final sample for this scoping review (Figure 1 and Chart 2).

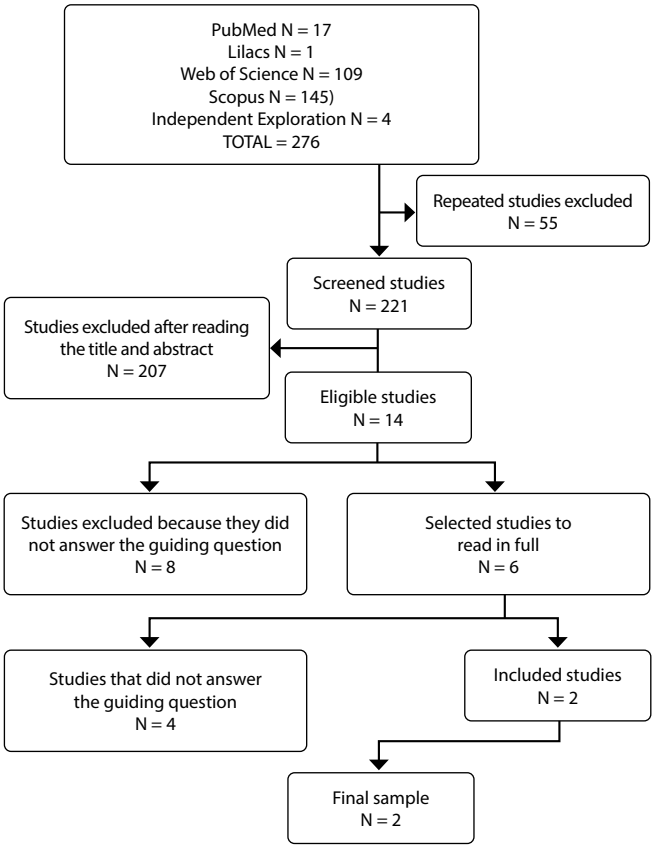

Figure 1 – Results of the scoping review with study inclusion and exclusion criteria

Chart 2 – Presentation of the synthesis of studies selected in the scoping review

Title
Study 1. Bacterial contamination of automated MRI contrast injectors in clinical routine (Goebel *et al*. 2019)[16]
Year of publication: 2019
Country of study: Germany
Objective
To quantify the frequency of bacterial contamination of CM/SS in a contrast injection system in clinical routine and to assess whether a new tube system with shielded threaded connections can reduce the potential risk of bacterial contamination
Material and Methods
All patients received a standard dose of 0.1 mmol of contrast per kg at a flow rate of 2 mL/s, via injections using a Medrad® Spectris Solaris® injector, using only the syringes from the disposable MRI kit for the 65/115 injector (Bayer Medical Care, Maastricht, the Netherlands). The system, consisting of two syringes and a T-extension with ARVs and separate delivery lines for CM and SS, was connected by an ARV (R-Lock, Codan Pvb Medical GmbH, Lensahn, Germany) and an infusion line (Original Perfusor Line, Braun Melsungen, Melsungen, Germany). The ARV and infusion line were replaced for each patient. The syringes, the T-connector tube, and the spiral infusion line were used in multiple sessions for up to eight hours. An injector (Bayer Medical Care, Maastricht, Netherlands) was used with disposable MRI kit syringes. For tubing, the tubing system from a Medrad® Stellant multipatient kit (Bayer Medical Care, Maastricht, Netherlands) was used, which is approved for multiple use for up to 12 hours and has shielded screw connections, minimizing the risk of bacterial contamination of the connectors. The T-connector tubing was connected to a single-patient disposable spiral infusion line (Bayer Medical Care, Maastricht, Netherlands), which has shielded screw connections to the T-connector tubing and two ARVs in series. Similar to standard procedure, the supply lines were connected to the CM and SS vials, and only the patient line was replaced between consecutive patients, while the rest of the system was used throughout the eight-hour workday without replacement. Sampling was performed consecutively on two MRI systems (Magnetom, Siemens Healthcare, Erlangen, Germany) using the aforementioned automated injection systems, alternating daily, until at least 100 samples were collected. During the eight-hour workday, technicians collected 3 to 5 mL of CM/SS from the injection system after connecting the new patient line and before connecting this tubing to the patient's intravenous access. This was done using the standard contrast injector and tubing configuration in 104 patients. The new contrast injector and tubing configuration were used. Microbiological analysis was performed by transferring 1 mL of the CM/SS sample to vials containing BacT/Alert iAST and iNST culture media (bioMérieux, Nürtingen, Germany).
Results
Using standard contrast injectors, samples collected from CM/SS were microbiologically contaminated with *Staphylococcus epidermidis*, *Micrococcus luteus*, and *Oligella ureolytica*. Detailed analyses showed that contaminations occurred in all MRIs participating in this study and that no consecutive samples were contaminated. Time to positivity was >24 hours for all samples. Using the new injector tube, only two of 101 (2.0%) samples collected from CM/SS were contaminated with contaminating bacteria: *S. epidermidis* and *M. luteus*.
Conclusion
Bacterial contamination of the CM injection tubing system for MRI occurs at a non-negligible frequency, particularly with *S. epidermidis*, which can cause nosocomial infections. Furthermore, bacterial contamination occurred only in the threaded connections of the tubing system during patient line replacement, while the rest of the contrast injection system showed no bacterial contamination during the eight-hour period of use. Furthermore, the study indicates that the use of the new tubing system with shielded threaded connections may reduce the risk of bacterial contamination.
Title
Study 2. Biosafety of Non-Return Valves for Infusion Systems in Radiology (Azevedo *et al*. 2020)[12]
Year of publication: 2020
Country of study: Brazil
Objective
To investigate the operation of connectors with check valves in extreme situations to contribute to biosafety and provide contamination and infection risk controls for infusion systems in radiological examinations.
Material and Methods
Of the 256 connector samples (20 cm) with ARVs (ARVs - (Patient-set, *Alko do Brasil Indústria e Comércio Ltd*a., Rio de Janeiro, RJ, Brazil - lot: P07230215), 100 samples were subjected to a device (HB-LT - Crescent Design, San Diego, California, USA) until the FDs ruptured at a maximum pressure of 1,200 psi. The 100 ruptured samples were divided into two groups: A and B. Fifty samples were subjected again to the HBLT device to assess the reflux of the ruptured FD. In the other group, samples were connected to an air compressor to verify if there were failures in its functionality during reflux due to the emission of air bubbles in a beaker containing 500 mL of water. Subsequently, the samples were opened for visual assessment of the morphology and integrity of ARVs and FDs. Fifty samples underwent air column displacement analysis in ARV connectors, assessing displacement (cm) and the possibility of liquid passage through the ARVs. The procedure was repeated after the FDs ruptured. Another 50 units underwent crystal violet diffusion measurements through ARV connectors to simulate the diffusion distance of crystal violet, using it as a blood analog. Fifty infusion systems were filled with MRSA and were used to assess the effectiveness of ARV connectors as bacteriological barriers during backflow. Finally, regarding the multipurpose system, a clinical study was conducted related to bacteriological contamination by syringes. Of a total of 90 samples, 49 were SS, 25 were paramagnetic contrasts, and 25 were iodinated contrasts.

To be continued

Chart 2 (concluded)

Results
In the FD rupture assessment, the FD rupture pressures of ARVs were, on average, 148 times greater than the maximum arterial pressure of 4.25 psi. In ARV functionality assessment after FD rupture, in subgroup A, there was an 85% reduction in the maximum pressures supported by the FDs after rupture. Two samples showed no resistance to water flow (0 psi). In subgroup B, none of the 50 ruptured FD samples presented failures in ARV functionality, based on the absence of air bubble emission in the beaker containing water. After valve opening, lateralized FD rupture was observed, with no other deformations in the system. During the analysis of the displacement of air columns in connectors with ARVs, no differences were observed in the distances traveled by the air columns between the connectors with ARVs with intact FDs and those with ruptured FDs, when subjected to a constant pressure of 10 psi for 30 seconds. Regarding the assessment of the diffusion of crystal violet dye in connectors with ARVs, of the 50 samples, 25 (50%) showed no dye diffusion. The greatest distance observed for crystal violet diffusion was 6.0 cm. Eight samples had 1 cm diffusion; seven samples had 2 cm diffusion; and one sample had 5 cm diffusion. Regarding ARVs assessment as a barrier to bacteriological contamination, none of the 50 samples from the infusion system or negative controls showed bacterial growth. MRSA was isolated only in the positive controls. Finally, the clinical study on bacteriological contamination from syringes demonstrated the absence of bacterial growth in samples assessed from seven different radiological institutions that used ARVs for biosafety in their clinical practice and as contamination and infection risk controls in infusion systems in radiology.
Conclusion
Assessing ARV functionality and safety in terms of contamination and infection risks in radiology infusion systems should be part of the assessment of this medical device release, which is not currently a regulatory requirement. Furthermore, it was possible to emphasize the importance of developing technically and economically viable research that demonstrates the contribution of the use of these medical devices to infection control and, consequently, cost reduction related to the management of healthcare-associated infections. In conclusion, biosafety depends on ARV functionality as well as on adequate practical clinical performance.

MRI - magnetic resonance imaging; CM - contrast media; SS - saline solution; ARVs - antireflux valves; HB-LT - hydraulic burst-leak tester; FDs - flexible diaphragms; MRSA - methicillin-resistant Staphylococcus aureus.

The results were subjected to a descriptive analysis, with the preparation of an individualized summary of each study, as presented in Chart 2.

DISCUSSION

This study sought scientific literature that demonstrated the determination of the duration of use of multipurpose systems in radiology (MRI and CT) and their microbiological safety. The findings address the critical issue of the lack of scientific support for the duration of use of multipurpose extenders with ARVs, exploring their impact on microbiological safety. Given the lack of scientific evidence on duration of use, and to ensure biosafety in the use of multipurpose systems in MRI and CT, guidelines and protocols must be developed to regulate and direct clinical practice for the handling of these systems. Such guidelines must be supported by scientific evidence, and in this context, studies investigating the efficacy and safety of multipurpose extenders are essential.

Regarding the time of use of multipurpose connectors, it should be considered that in study 1, bacterial contamination of the multipurpose system for MRI occurs at a non-negligible frequency, especially with *S. epidermidis*, which can cause hospital infections[16]. Furthermore, the study indicated that the use of a new multipurpose system with shielded threaded connections, approved for 12 hours, can reduce the risk of bacterial contamination compared to eight hours[16].

On the other hand, study 2 reported no contamination of SS and CM in the multipurpose system for up to eight hours of use. The study used a microbiological analysis of the Transfer-fill multipurpose system (*Alko do Brasil Ind. E Com. Ltda*, Rio de Janeiro, RJ, Brazil), in addition to a physical, chemical, and microbiological study of the individualized Patient-set connector (*Alko do Brasil Ind. E Com. Ltda*, Rio de Janeiro, RJ, Brazil), highlighting the need to follow a standard operating procedure (SOP) in clinical practice[12].

Furthermore, it is worth noting that the single-use system has fallen into disuse compared to the multipurpose system. When comparing a multipurpose MRI contrast injector to a single-use injector in terms of efficiency, radiology technician satisfaction, and disposable material costs, the multipurpose system optimizes the average total time, from 4:55 minutes to 2:24 minutes, and there is less wasted CM and SS[17]. Additionally, costs of disposables for the single-use system consist of one set of connectors and syringes per examination. On the other hand, the costs of disposables used in the multi-use system were lower[17], as they are divided by the number of CT and MRI examinations, according to the time of use of the multi-use connector, which has scientific proof of eight hours[12]. On average, CT technologists spent 63.6 seconds less in the exam room with the multipurpose system compared to the single-use system, and 23.1 seconds more per exam interacting with the multipurpose system in CT compared to the single-use system. Thus, they spent an average of 40.5 seconds less per exam using the multipurpose system[18].

The multipurpose system was found to be overall more time-efficient and more suitable for daily practice. The use of a multipurpose MRI contrast injector was found to lead to greater time efficiency with shorter contrast preparation times, lower disposable costs, and increased radiology technician satisfaction[17]. It is also worth noting that the multipurpose system is used worldwide, frequently in different countries on the American and European continents[12,16].

The article by Struik *et al*. (2020) presents a multipurpose, syringe-free system connected directly to contrast and SS vials, approved for use up to 24 hours, but without scientific evidence to support this time of use. Therefore, this time of up to 24 hours is disregarded in current clinical practice, with no scientific evidence to support it[17].

The study by Azevedo *et al*. (2020) refers to a field collection of up to eight hours of use of syringes and Transfer-fill connectors with ARVs, which proved the absence of bacterial contamination, when used in conjunction with an extender with a Patient-set ARV[12]. It is important that this handling in clinical practice be based on the SOP to minimize the risks of contamination of the multipurpose system; and for this, continuing education is

necessary for teams composed predominantly of nursing professionals new to and already working in radiology.

The nursing team works directly in clinical practice in the radiology department (MRI and CT), playing a fundamental role in preventing iatrogenic events by contributing to maintaining a biologically safe environment. Furthermore, this team is responsible for performing venipuncture, administering contrast, and monitoring patients for any adverse reactions, strictly following evidence-based protocols that guide clinical practices[19].

According to Azevedo *et al*., assessing the functionality and safety of ARVs in radiology infusion systems, while not a regulatory requirement, is crucial for the approval of HPs as medical devices[12]. It is also important to conduct technical and economic feasibility studies to demonstrate how these devices help control infections and reduce costs related to infection management. Biosafety depends on the effectiveness of ARVs and their clinical performance. Furthermore, analyzing the operational costs inherent to clinical practice is a crucial step in achieving an optimized cost-benefit ratio, contributing to the efficient management of healthcare resources. Concomitantly, environmental issues must be considered, as using a multipurpose system, with a period pre-established by scientific evidence, will reduce the waste generated by healthcare services, significantly contributing to sustainability and the environment[12,19].

Study limitations

The limitation of this scoping review is based on the limited number of global scientific publications used in its development. However, with scientific and technological advances in radiology, contrast injectors and connectors with ARVs have become more frequently used in CT and MRI examinations.

Contributions to nursing, health, or public policy

This study demonstrates scientific relevance by providing important insights for Nursing and Public Health, especially in the field of biosafety. Investigating the use times and microbiological safety of multipurpose systems in radiology represents a strategic measure to ensure contamination and infection risk controls in multipurpose systems in radiology.

FINAL CONSIDERATIONS

This scoping review demonstrated that the multipurpose ARV system in radiology (MRI and CT) guaranteed the absence of bacterial contamination, specifically in the Transfer-fill and Patient-set sets, within eight hours of use, with the adoption of SOP by nursing professionals. However, there is currently no scientific support for the use of these multipurpose ARV systems for periods longer than eight hours.

CONTRIBUTIONS

Azevedo MPF, Moda-Monteiro LS and Watanabe E contributed to the conception or design of the study/research. Azevedo MPF, Moda-Monteiro LS and Watanabe E contributed to the analysis and/or interpretation of data. Azevedo MPF, Moda-Monteiro LS, Oliveira VC, Andrade D and Watanabe E contributed to the final review with critical and intellectual participation in the manuscript.

AVAILABILITY OF DATA AND MATERIAL

The research data are available within the article.

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