Review

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Safety of non-return valves in infusion systems in radiology: integrative review

Segurança de válvulas antirrefluxo em sistemas de infusão na radiologia: revisão integrativa

Seguridad de las válvulas antirreflujo en sistemas de infusión de radiología: revisión integradora

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ABSTRACT

Objective: to analyze, from the literature, the scientific production related to the safety of non-return valves in radiology. **Method:** an integrative review (IR). The terms used during the search were classified by PubMed, Web of Science and SCOPUS, performed from March 2017 to March 2019. **Results:** the sample consisted of 139 articles, of which 7 were from PubMed; 7 (LILACS), 1 (CINAHL), 33 (Web of Science) and 91 (SCOPUS). In addition, the reference analysis of selected texts and related articles was performed. In this IR, only 5 (3.6%) studies were selected and evaluated, pointing out a scarce world scientific production in this area. **Conclusion:** the safety of non-return valves usage in infusion system in radiology is not a consensus yet and depends on various physical, chemical and microbiological aspects.
Descriptors: Contamination; Infection; Microbiology; Radiology; Vascular access devices.

RESUMO

Objetivo: analisar, a partir da literatura, a produção científica relacionada à segurança de válvulas antirrefluxo em radiologia. **Metodo:** uma revisão integrativa (RI). Os termos utilizados durante a busca foram classificados pelo PubMed, Web of Science e SCOPUS, realizada de março de 2017 a março de 2019. **Resultados:** a amostra foi composta por 139 artigos, dos quais 7 eram do PubMed; 7 (LILACS), 1 (CINAHL), 33 (Web of Science) e 91 (SCOPUS). Além disso, foi realizada a análise da referência de textos selecionados e artigos relacionados. Nessa RI, apenas 5 (3,6%) estudos foram selecionados e avaliados, apontando uma escassa produção científica mundial nessa área. **Conclusão:** a segurança do uso de válvulas antirrefluxo no sistema de infusão em radiologia ainda não é um consenso e depende de vários aspectos físicos, químicos e microbiológicos.
Descritores: Contaminação; Infecção; Microbiologia; Radiologia; Dispositivos de acesso vascular.

RESUMÉN

Objetivo: analizar, a partir de la literatura, la producción científica relacionada con la seguridad de las válvulas antirreflujo en radiología. **Método:** una revisión integradora (RI). Los términos utilizados durante la búsqueda se clasificaron mediante PubMed, Web of Science y SCOPUS, que se realizó entre marzo de 2017 y marzo de 2019. **Resultados:** la muestra se compuso de 139 artículos, 7 de los cuales eran de PubMed; 7 (LILACS), 1 (CINAHL), 33 (Web of Science) y 91 (SCOPUS). Además, se realizó análisis de referencia de textos elegidos y artículos relacionados. En esta RI, solo se seleccionaron y evaluaron 5 estudios (3,6%), señalando una escasa producción científica global en esta área. **Conclusión:** la seguridad del uso de válvulas antirreflujo en el sistema de infusión radiológica aún no es un acuerdo general y depende de muchos aspectos físicos, químicos y microbiológicos.
Descriptores: Contaminación; Infección; Microbiología; Radiología; Dispositivos de acceso vascular.

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INTRODUCTION

Non-return valves (NRVs) usage is fundamentally important for energy generation in nuclear power plants and hydraulic systems. Although its usage has begun in other areas, it was in health that a great increase was noticed in the last decade, so much so that they came to be present in surgeries with propofol, in vesical catheters and patients with urinary tract infection.[1-6]

For use in health field, such valves are designed, but not all are evaluated, before they are commercialized. Through contrast injectors, their main purpose is to prevent backflow of blood,[7-8] with particular application in Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) fields.

Despite significant diagnostic gains using this technology in examinations, questions about risk assessment remain. In this sense, there are questions related to the safety of patients who use this infusion system, since to consider NRVs safe for the patients, physical, functional and microbiological tests would be required before making them available. Thus, there is an urgent need for institutional guidelines and protocols[9] so that there is scientific support in using infusion system in radiology. Moreover, investigations into operational costs involved in clinical practice are essential to enable the best value for money.

Nursing staff is directly related to clinical practice in radiology section, which plays an important role in preventing iatrogenic occurrence, as it participates in the maintenance of a biologically safe environment. Besides, the nursing staff is responsible for venipuncture, contrast injection and possible patients' adverse reactions.

Considering the lack of publications that have as research object connectors with NRVs, this study aimed to analyze, from the literature, the scientific production through an integrative review (IR) related to safety and viability of NRVs in clinical practice of radiology.

METHODS

This is an IR with six stages defined as: establishment of the guiding question; sample selection; definition of study characteristics (inclusion and exclusion criteria); analysis of studies included in the review; interpretation of the results and presentation of the review or knowledge synthesis.

The IR guiding question was: "What is the reliability of non-return valves (NRVs) used in the health field, regarding physical, functional and microbiological aspects, aiming at patient safety?".

To answer this important question in the clinical practice of radiology, an IR was carried out in the following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), *Literatura Latino-Americana e do Caribe em Ciências da Saúde* (LILACS), Web of Science, SCOPUS and PubMed portal from National Library of Medicine was conducted in May 2017 by two independent researchers and experts on the subject.

As inclusion criteria, the following were defined: articles published on the subject in any language and with no period delimitation, with

crossing of keywords and descriptors, belonging to the same category were separated by "OR" and between them by "AND". Terms used during the search were classified by database and portal (Table 01):

- ✓ PubMed, Web of Science and SCOPUS: Valve AND Artificial OR Valves AND Non-return;
- ✓ CINAHL: Valve OR Artificial Valves AND Non-return;
- ✓ LILACS: Válvulas AND Antirrefluxo;

In LILACS database, the terms were written in Portuguese, English and Spanish, while in the other databases and portal, only English terms were used.

The exclusion criteria were duplicate studies in the databases and portal, as well as an application in engineering and areas not related to human health.

Table 01: Results of cross-referencing of descriptors, Boolean operators and databases and portal.

Databases/Portal	Descriptors	
PubMed	Valve AND Artificial OR Valves AND Non-return	MeSH
Web of Science	Valve AND Artificial OR Valves AND Non-return	MeSH
SCOPUS	Valve AND Artificial OR Valves AND Non-return	MeSH
CINAHL	Valve OR Artificial Valves AND Non-return	MeSH
LILACS	Válvulas AND Antirrefluxo	DeCS

RESULTS

The selected studies in the databases and portal were analyzed and preselected according to the inclusion and exclusion criteria, by reading their titles and abstracts. Among 139 references found, 7 were from PubMed; 7 from LILACS, 1 from CINAHL, 33 from Web of Science and 91 from SCOPUS. Twenty-four duplicate studies were excluded and 115 were considered eligible studies. However, 100 studies were excluded because did not answer the guiding question and only 15 studies were selected for reading in full. In addition, the reference analysis of the selected texts and related articles was performed. The final review sample for inclusion in IR consisted of five articles (3.6%), which met the inclusion and exclusion criteria (Figure 01).

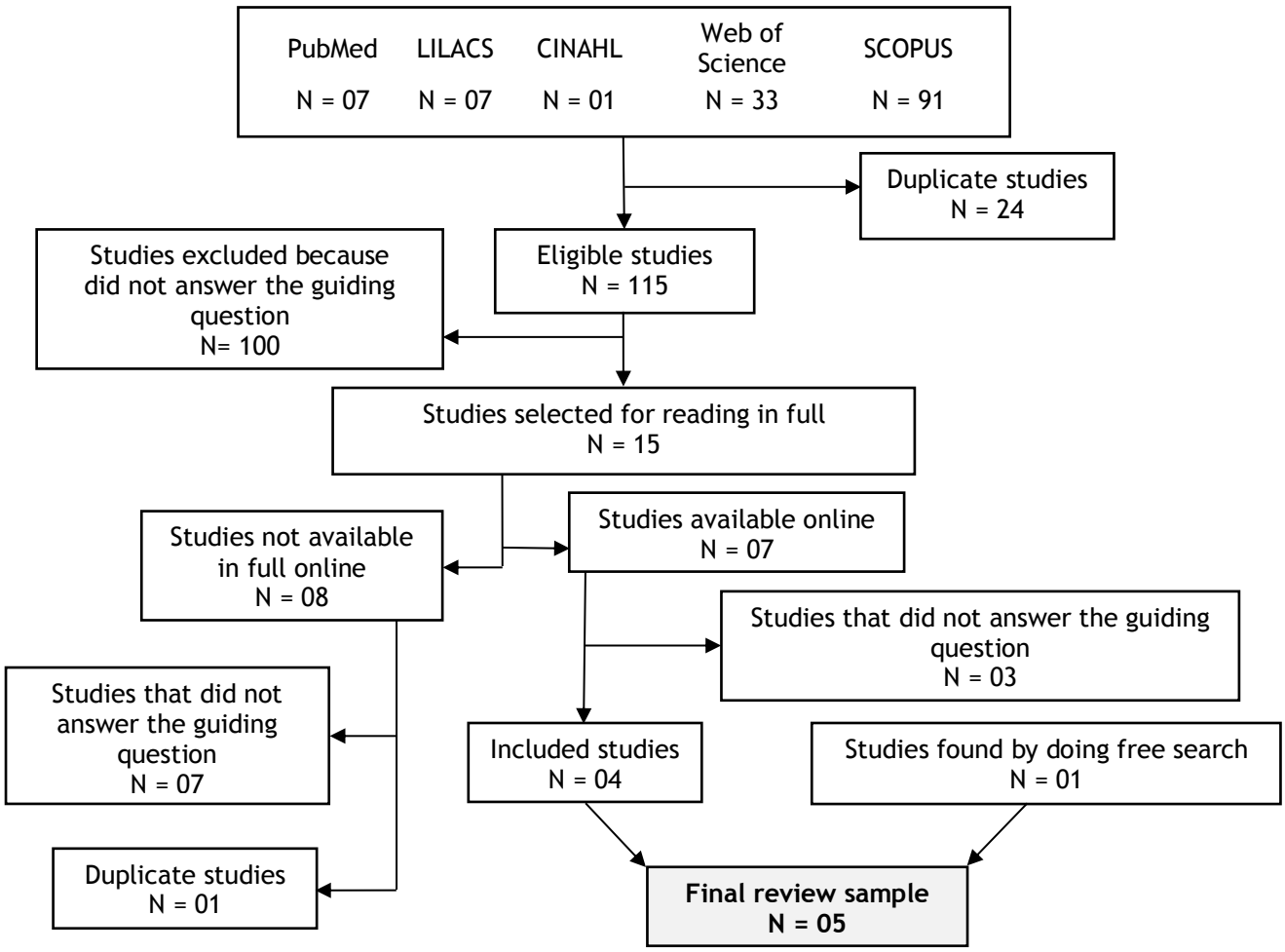

Figura 01: Results of the integrative review with inclusion and exclusion criteria of studies.

Table 02: Synthesis of articles presentation included in the integrative review.

Study	Objective / Methodology	Main Results	Recommendations and Conclusions
E1 Non-return valves do not prevent backflow and bacterial contamination of intravenous infusions.	To evaluate *in vitro* integrity and bacterial contamination in connectors with NRVs. In total, 200 latex NRV samples were used in this study, 40 from each brand (*Braun Melsungen*®, *Braun Spezial*®, *Infudrop*®, *Becton-Dickinson*®, *Smith-Medical*®). An infusion system connected to a syringe pump with water was simulated, in continuous backflow. Infusion rates of the pump were of 0.1 and 1mL/h for integrity experiments for up to 20min. In bacterial contamination experiment, *Staphylococcus aureus* (ATCC25923), *Staphylococcus epidermidis* (ATCC35984) and *Proteus mirabilis* (ATCC35659) are used at two rates (0.1 and 1mL/h) for 2h. Subsequently, bacterial contamination was investigated in the infusion system, in a backflow at 2mL/h for 72h, with 1% propofol drip (*Disoprivan*®, AstraZeneca GmbH, Wedel, Germany) or physiological solution (B. Braun, Melsungen, Germany).	The integrity experiment showed that there was no difference between the five NRV brands. Moreover, closure occurred in 47 (23.5%) and 80 (40%) of NRV samples at 0.1 and 1mL/h rates, respectively. In bacterial contamination experiment, 20 (30%) of NRV samples presented backflow contamination by *S. epidermidis* (5/50%), *S. aureus* (1/10%) and *P. mirabilis* (5/50%) at 0.1mL/h; *S. epidermidis* (2/20%) and *P. mirabilis* (7/70%) at 1mL/h. In drip experiment, propofol presented higher bacterial contamination than physiological solution; however, this result did not show statistical difference.	NRVs did not reliably prevent fluid backflow and do not work as a filter for microorganisms.
E2- Preliminary report: biosafety analysis of one-way backflow valves for multiple patient use of low osmolar intravenous contrast solution.	To determine *in vitro* integrity of NRVs in preventing multi-use contamination of intravenous contrast in radiology. Three *Medex Inc.*® (Hilliard, Ohio, USA) NRVs with spring every 10 batches (n=30) and three springless *Merit Medical System*® (Salt Lake City, Utah, USA) NRVs from two batches (n=6) were used for the experiments: structural, functional and biological. Besides, a single springless *Namic*® (Namic Contrast Saving Delivery System, Glenn Falls, New York, USA) NRV was used for the structural experiment. For the NRV structural / functional experiment, a pressure of 60psi was exerted in backflow for 15s (short period) and 60min (long period) with the aid of a syringe pump. Furthermore, a contrast injector (Liebel-Flarsheim Company, Cincinnati, Ohio, USA) was used to simulate clinical practice in an experiment with radionucleotide and a biological one. In	In the structural experiment, the opening pressures of *Medex Inc.*® NRVs (with spring) were of 3.4±0.9psi (mean and standard deviation), while pressures of *Merit Medical System*® and *Namic*® NRVs (springless) were less than 0.1psi. One (10%) of 10 *Medex Inc.*® NRVs showed a change in the pressure profile during the short-period return with 15psi. On the other hand, there was no change in the pressure profile in NRVs with 60psi for 60min. The other NRV brands showed changes in profile pressures in short period (*Merit Medical System*®) and long period (*Namic*® and *Merit Medical System*®). In the functional experiment, no radionucleotide was detected in *Medex Inc.*® NRVs; however, one (50%) of	The results suggest that only *Medex Inc.*® (with spring) NRVs can be used to prevent multi-use contamination of intravenous contrast in radiology. Thus, authors recommended the use of a second NRV.

	the biological experiment, a viral inoculum of $8x10^{10}$ plaque-forming units per milliliter (PFU/mL) with bacteriophage (Group II, phage 55) from *Staphylococcus aureus* was used.	two *Merit Medical System*® NRVs showed failure. In the biological experiment, with bacteriophage, no *Medex Inc.*® NRV showed contamination by bacteriophage, but one (50%) *Merit Medical System*® NRV showed failure. It should be noted that the NRVs which showed failure were from the same batch number of the functional experiment.	
E3 - Two Serial Check Valves Can Prevent Cross-Contamination Through Intravenous Tubing During Total Intravenous Anesthesia.	To determine *in vitro* bacterial load contamination from "patient model" connected to IV tubing. An infusion pump (*Infusomat*® fmS, B. Braun, Melsungen, Germany) was connected and powered for 5h to a "patient model" with bacterial (10^6CFU/mL) and viral inocula from *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Proteus mirabilis*, *Pseudomonas aeruginosa* and bacteriophage T3 from *E. coli* B14, IV tubing (two connectors with four NRVs) and two 50mL syringes (B. Braun, Melsungen, Germany). One of syringes was filled with 1% propofol (*Disoprivan*®, Astrazeneca GmbH, Wedel, Germany), and the other with physiological solution. In total, 55 microbiological experiments (bacteria and bacteriophage) were performed from the "patient model" and from three different parts of the IV tubing and the two syringes. Before and after 5h, the "patient model" showed increased microbial load of 67 times (*P. mirabilis*), 10 times (*S. aureus*), 3 to 6 times (*S. epidermidis, E. coli*, *P. aeruginosa*) and 10 to 333 times (bacteriophage T3).	Even with increased microbial load (bacteria and bacteriophages) in the "patient model", no contamination was presented from three different parts of the IV tubing and the two syringes.	Experimental data suggest that the design with multiple NRVs (four) in paired configuration prevents IV tubing contamination, during five hours of anesthesia with propofol.
E4 - Microbial Safety Assessment of a Double Check-Valve Patient	To investigate *Secufill*® safety of multiple uses of contrast injectors, under worst-case clinical conditions. This study was performed in three stages. In the first one, 100 *Secufill*® samples (connector with two NRVs) were evaluated *in vitro* (four batches and two manufacturing processes) for the opening and closing time (use of contrast and physiological solution) with two ADDIX (Medex) and *Dual Shot Alpha* (Nemoto Kyorindo Co., Ltd.) contrast injectors used for magnetic resonance imaging	According to the first stage, the worst NRV closure condition was with the use of contrast. In addition, there was no difference between batches, manufacturing processes and injectors. In the second stage, the increase of the contact time of *Patent Blue V*® with NRVs was directly proportional to dye diffusion through *Secufill*®. Moreover, backflow was more evident using contrast medium and a 45-	***Secufill*® showed the safety of multiple uses of contrast injectors under worst-case clinical conditions.**

Line in a Multiuse Contrast Delivery System.	and computed tomography submitted to a pressure of 10mmHg (psi). In the second stage (n=96), an *in vitro* experiment in backflow with a blue dye (*Patent Blue V*®) was carried out. And the third stage (n=9) consisted of an *in vivo* experiment with monkeys (baboons), simulating worst-case clinical conditions, by measurement of radiotracer in the arterial blood (every 15min) as well as *Secufill*® samples – (pilot, condition A and condition B): before contrast injection (2, 15 and 2min) and during contrast injection (30, 30 and 60min), respectively.	degree angle. In the third stage, the results confirm the absence of radiotracer in the distal part of *Secufill*®.	
E5 - Study on the Microbial Safety of an Infusion Set for Contrast-Enhanced Imaging.	To evaluate *in vivo* the risk of cross-contamination, in multiple uses of contrast injectors, from a new infusion system with NRVs. To simulate clinical conditions, a contrast injector (*Dual Shot GX*, Nemoto Kyorindo, Tokyo, Japan) coupled to two disposable syringes (100 and 200mL), T-connector and injection set to *Transflux*® (P & R, Diepenbeek, Belgium) – (connector with two NRVs) as well as connector without NRV. In total, 12 *Transflux*® systems were evaluated according to Protocol A: multiple uses of disposable syringes with physiological solution (n=6); and Protocol B: multiple uses of disposable syringes with physiologic solution and contrast (n=6). The experiments were carried out on two New Zealand rabbits (Animal House, KU Leuven, Belgium) inoculated with radiotracer. 10min after the completion of protocols A and B, *Transflux*® were, carefully, disconnected from the rabbits and replaced with new ones. The radioactivity readings of the two rabbits and 12 *Transflux*® were obtained every minute.	In protocols A and B, the detection of radioactivity was higher in the rabbit bloodstream than in the connector without NRV ($p<0.0001$). In fact, there was no radioactivity detection in *Transflux*® as well as in the injection set ($p=0.003$).	*Transflux*® were suitable and safe, that is, they prevented the cross-contamination risk in multiple uses of automatic contrast injection system.

DISCUSSION

There is no consensus on the reliability of non-return valves (NRVs), concerning the physical, spreading and microbiological aspects, to guarantee microbiological safety and thus guide the clinical practice in Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) examinations. Consequently, E1 to E5 studies were analyzed to clarify the compilation of published information on the subject.

Several *in vitro*[7-8,12-13] and *in vivo*[8,14] studies were developed with NRVs employed in health field with only one type of NRV,[7-8,14] three types of NRVs[13] and five types of NRVs.[12] Furthermore, the NRVs were from brands: *Medex Inc.*® (with spring), *Merit Medical System*® (springless), *Namic*® (springless),[13] *Braun Melsungen*®, *Braun Spezial*®, *Infudrop*®, *Becton-Dickinson*®, *Smith-Medical*®,[12] *Transflux*®,[14] *Secufill*®[8] and were used in a unique way,[12-13] double[8,14] and strategically positioned[7] in connectors.

The devices employed to simulate blood and contrast injector pressures were: syringe pump,[12-13] infusion pump,[7] contrast injector,[13-14,8] at 60psi for 15s (short period) and 60min (long period) in backflow,[13] during 5h;[7] for 20min, 2h and 72h in backflow;[12] 10min in flow direction;[14] 0.19psi for 2, 15, 30 and 60min.[8]

In addition, a study[8] used *Patent Blue V*®, while other researchers utilized radiotracers.[13-14,8]

According to microbiological experiments, different microorganisms: *Staphylococcus aureus, Staphylococcus epidermidis,*[7,12] *Escherichia coli,*[7] *Proteus mirabilis,*[7,12] *Pseudomonas aeruginosa*[7] and bacteriophages[7,13] were reported in the scientific literature.

Conforming to PHAC,[13] no *Medex Inc.*® NRV showed contamination by bacteriophage, but 1 (50%) *Merit Medical System*® NRV showed failure. It is noteworthy that the NRVs which showed failure were from the same batch number of the functional experiment.

In 2010, a study[7] presented that before and after 5h, the "patient model" had an increase in the microbial load of 67 times (*P. mirabilis*), 10 times (*S. aureus*), 3 to 6 times (*S. epidermidis, E. coli*, *P. aeruginosa*) and 10 to 333 times (bacteriophage T3). Even with increased microbial load (bacteria and bacteriophages) in the "patient model", no contamination was presented from three different parts of the IV tubing and the two syringes.

According to a study,[12] 20 (30%) of NRV samples presented backflow contamination by *S. epidermidis* (5/50%), *S. aureus* (1/10%) and *P. mirabilis* (5/50%) at 0.1mL/h; *S. epidermidis* (2/20%) and *P. mirabilis* (7/70%) at 1mL/h.

Among the studies described in our literature review, one pointed out a failure in NRVs within 72h.[12] Furthermore, the results of PHAC [13] suggest that *Medex Inc.*® NRVs (with spring) can be used in up to 60min, but with recommendation of using a second NRV. On the other hand, *Transflux*® in up to 10min[14] and *Secufill*® in up to 60min[8] showed safety of NRVs. Moreover, conforming to a study,[7] the design with multiple NRVs (four) in paired configuration prevented the contamination within 5h.

The limitation of this integrative review is supported by the reduced number of scientific publications worldwide, that were used for its production.

Conversely, with the science and technology advancement in the radiology field, contrast injectors and NRVs have been employed more often in CT and MRI examinations.

Then, this study proved relevant to public health, since it carefully analyzed the methodology used in the five scientific articles, according to physical-chemical and microbiological experiments, aiming at the understanding of NRVs working in prevention of cross-contamination and Healthcare-associated Infections (HAI).

This research has limitations. The national and international scientific literature is very scarce in relation to the safety of NRVs usage in infusion system in radiology.

CONCLUSION

In conclusion, the safety of non-return valves usage in infusion system in radiology is not a consensus yet and depends on various physical, chemical and microbiological aspects. Besides, well-designed experimental studies with methodological rigor are needed to address gaps on the safety of non-return valves and to help in making the proper decision in clinical practice.

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COLLABORATIONS

MPFA, RMM and EW: contribution in the collection, analysis and interpretation of the data; contributed in critical review and writing of the manuscript. AMR and DA: contributed in critical review and writing of the manuscript. All authors agree and are responsible for the contents of this version of the manuscript to be published.

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Does not apply.

CONFLICTS OF INTEREST

There are no conflicts of interest to declare.

AVAILABILITY OF DATA

Available upon request to the authors.

FUDING SOURCE

Does not apply.

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