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Major article

Preventing microbial contamination during radiological imaging: Experimental evaluation of a multiuse contrast media infusion system incorporating sequential one-way valves within a dual-safety design

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Background: Health care-associated infections are a significant cause of patient morbidity, mortality, and health care expenditure. In diagnostic imaging, multiuse contrast media infusion systems are increasingly common; however, their use raises concerns regarding cross-contamination risk.

Methods: A controlled experimental model was used to assess the ability of a multiuse infusion system to prevent microbial contamination during simulated clinical conditions. *Escherichia coli* and MS2 bacteriophage were selected to model bacterial and viral contamination risks, respectively. Inocula were introduced at key connection points during two 12-hour experimental sessions. The primary outcome was the presence or absence of microbial growth in retrieved fluid samples. Control testing was conducted to validate sterility, microbial viability, and experimental integrity.

Results: Positive and negative control testing performed as expected. No microbial growth was detected in any of the 51 experimental fluid samples. This corresponds to a 95% confidence upper bound of 5.8% for undetected contamination events.

Conclusions: The system's design, including sequential dual 1-way valves effectively prevented bacterial and viral contamination under laboratory conditions. These findings support its potential for safe multiuse in radiological settings.

BACKGROUND

Health care-associated infections (HAIs) remain a leading cause of patient harm and mortality in hospitals across the United States.[1] As a result, infection prevention and control practices represent a critical aspect of clinical care,[2-5] including in radiology departments.[6,7] In diagnostic imaging, balancing efficient patient throughput, optimal use of imaging technologies (eg, computed tomography [CT], magnetic resonance imaging [MRI]), continuity of contrast media supplies, and infection prevention remains a persistent challenge.[6-11]

Inadvertent microbial entry into infusion systems—whether due to design limitations or lapses in adherence to infection prevention protocols—can result in these systems becoming vectors for

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Ethics approval: This was a laboratory bench study that did not involve human or animal participants. Ethical approval was therefore not required.

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infection.[2,12] Intravenous contrast media is integral to many medical imaging procedures, and preventing its microbial contamination is essential to both patient safety and the safe functioning of radiology departments.

Globally, millions of CT and MRI scans are performed each year, and demand continues to grow.[13,14] This increasing volume presents a challenge for health care systems striving to balance throughput and infection prevention with operational efficiency and environmental sustainability. Traditionally, single-use disposable contrast media delivery systems have been considered the gold standard for minimizing contamination and cross-infection risks. However, these systems are often costly, generate substantial medical waste, and contribute to high disposal expenses and environmental harm.[15-17]

The economic and environmental impact of single-use systems has led to increased interest in sustainable alternatives across various areas of health care.[16-21] In medical imaging, multiuse contrast media delivery systems have become widely adopted.[22] These systems typically involve a shared reservoir circuit used across multiple patients, with single-use connectors attached for each individual.[23,24] While this approach offers advantages such as lower procurement costs, reduced waste, and more efficient contrast media usage, concerns have been raised regarding the potential risk of cross-contamination and infection.[22,24-27]

The risk of microbial ingress into medical devices is influenced by both device design and the ability of microorganisms to bypass built-in protective features.[24,25,27] Characteristics such as microbial concentration, motility, and size play a critical role. However, in addition organizational processes, background environmental contamination levels and human behavioral factors interact and play a critical role in determining the overall risks of microbial contamination of medical devices.[1-5,12,28,29] This study experimentally evaluated a novel multiuse contrast media delivery system incorporating a patented dual safety valve design to determine its effectiveness in preventing bacterial and viral contamination. By addressing contamination risks, the study aimed to support infection prevention efforts while advancing sustainability and operational efficiency in clinical practice.

METHODS

Design

An in vitro experimental model was used to assess microbial contamination in the test infusion system during simulated radiological contrast media administration cycles. Standardized laboratory procedures were followed throughout.[30-32]

Materials

Proprietary microbial culture samples from American Type Culture Collection (ATCC) microorganisms were obtained under commercial license. The ATCC trademark, trade name, and all catalog numbers are trademarks of the ATCC. *Escherichia coli* (ATCC 11229) was selected as a clinically relevant bacterial surrogate due to its association with HAIs and medical device contamination.[1,2,33] Its motility and size make it a suitable challenge organism for contamination testing. MS2 bacteriophage (ATCC 15597-B1), approximately 27 nm in diameter, was chosen as a viral surrogate because it is smaller than bloodborne viruses such as HIV and hepatitis B/C.[34] Its inclusion ensured a stringent assessment of the test system's ability to prevent viral contamination—an essential aspect of infusion safety.

The test contrast media infusion system consisted of 2 components: the Transset multiuse contrast media filling set and the Transflux single-use patient line (P&R Medical BV). The Transflux incorporates a novel sequential dual 1-way valve system housed within a patented "safety zone" to serve as a microbial barrier (Fig. 1). The MedRad Stellant contrast injector (MedRad Stellant) was

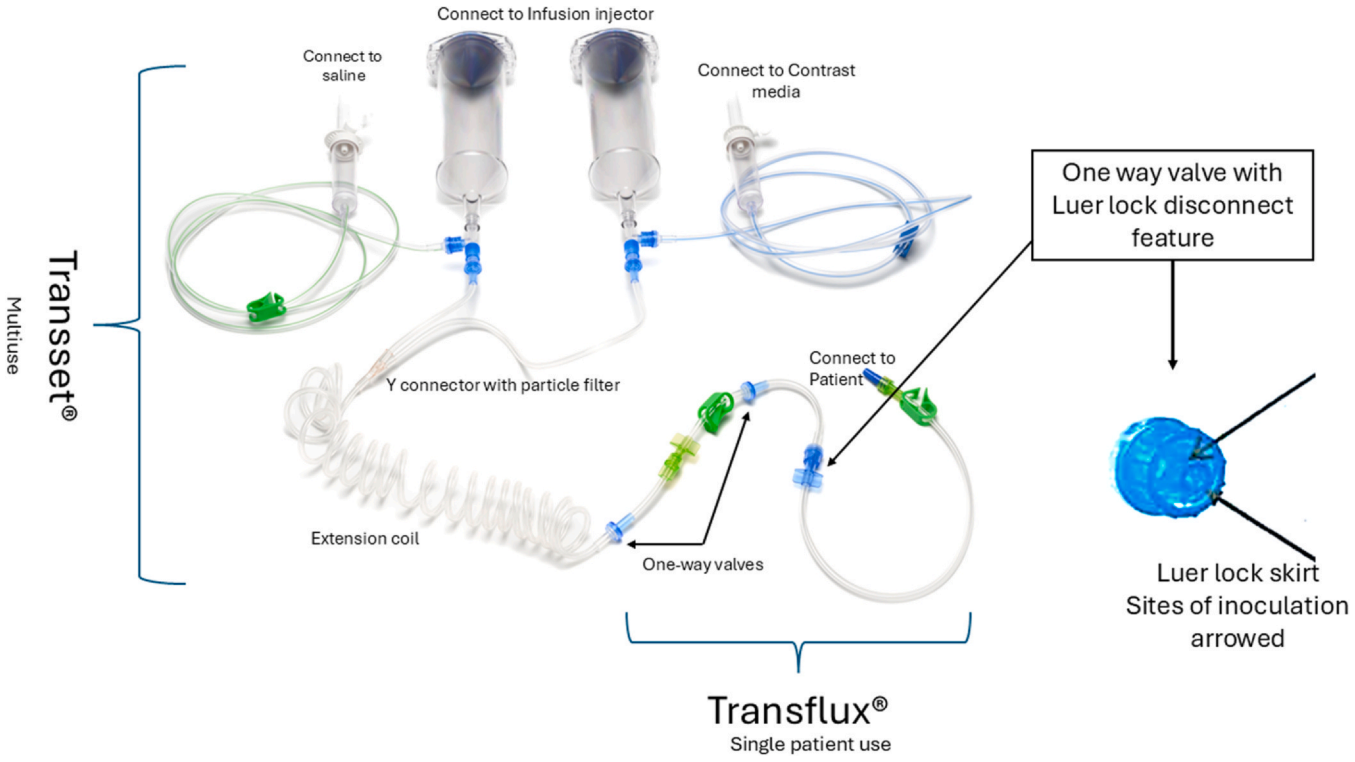

Fig. 1. The test Transset and Transflux contrast media infusion system.

used as the contrast delivery platform in both control and experimental conditions.

General procedure

Injector preparation and setup

Throughout all assembly, priming, system accessing, control testing and experimentally simulated patient activations strict aseptic technique within a Biological Safety Cabinet (BSC) was maintained. Luer-lock connectors were disinfected before accessing, carefully separated and reattached, consistent with common clinical handling. Contrast and saline containers were disinfected at the septum and connected to the infusion circuit within the BSC. The injector was activated using a remote-control panel, initiating preprogrammed infusion protocols in line with experimental parameters.

Microbial culture preparation

Challenge microorganisms *E coli* [ATCC 11229] and MS2 bacteriophage [ATCC 15597-B1] and the host strain (*E coli* [ATCC 15597]) were cultured using Tryptic Soy Broth and Tryptic Soy Agar, incubated at 36 ± 1 °C, and diluted to target concentrations. All microbial preparations and control testing for purity, sterility and viability were performed at Microchem Laboratory by a single experimental operator to ensure consistency across testing sessions.

Experimental execution

Strict procedural controls were followed throughout the experimental phase to ensure reproducibility and maintain system sterility.[30-32] Simulated patient cycles (activations) were performed using the injector system according to predefined protocols. During designated "hold times" (representing intervals between patient uses), the Luer-lock connection was partially disengaged to separate the 2 infusion lines. A 0.010 mL volume of microbial inoculum containing a target concentration of 1×10^3 colony-forming units (CFU) or plaque-forming units (PFU) was introduced, with the volume equally divided between the tubing lumen and the Luer-lock skirt (see Fig. 1). Target CFU or PFU concentrations were confirmed by inoculum concentration testing. Table 4, Supplementary Materials reports on the average inoculum CFU or PFU concentration per mL across replicates on the 4 test days. Following reintegration of the lines, activation cycles resumed. Microbial samples were collected at predefined intervals to simulate clinical usage patterns and analyzed individually to assess contamination levels.

Measurements and data collection

FDA guidance,[30] on the conduct of microbial ingress testing for intravascular administration sets states that "the number of microbial challenges in the study should approximate the number of user interactions with the access site that would be expected clinically."[30(p9)] Publicity materials for the test system highlight that the reusable Transset component can be safely left in place for up to 24 hours of 50 patients, when the instructions for use are strictly followed. For pragmatic reasons concerning the working hours of the laboratory and the experimental operator we choose to simulate patient activations over a reasonable estimate of nonemergency radiological department operating time of 12 hours and use the suggested maximum number of patients as our testing baseline.

This approach provided a robust dataset across two 12-hour sessions while maintaining laboratory feasibility. As this was a bench safety test with a binary outcome (presence/absence of contamination), formal power calculations were not applicable. Instead, statistical confidence was estimated post hoc using binomial confidence intervals.

A total of 51 simulated patient activations were conducted across two 12-hour testing periods, with 25 activations during the first and 26 during the second. Distal fluid samples were collected at predetermined intervals and processed for microbial analysis. Samples were incubated under standardized conditions to support microbial growth and enable enumeration. Multiple control procedures—including media sterility checks, microorganism purity and viability tests, and positive, negative, and low-count controls—were incorporated to ensure methodological integrity and result reliability.[30-32] The presence or absence (zero CFU/PFU) of microbial growth in the samples served as the primary indicator of the system's contamination prevention performance.

RESULTS

Control testing phase

Control testing confirmed the validity and reliability of the experimental setup. Positive process controls consistently yielded pure growth of *E coli* and MS2 bacteriophage with recovered counts greater than 250 CFU or PFUs – "too numerous to count." These results verify microorganism viability and confirm the absence of extraneous contamination (purity). Negative process controls exhibited no microbial growth, demonstrating the sterility of the system and growth media. Small numbers control tests showed 7 CFU for *E coli* and 5 PFU for MS2 bacteriophage, indicating a positive result for microbial growth. These results further validated the system's sensitivity to minimal levels of microbial contamination. Collectively, these findings support adherence to established standards of good laboratory practice,[31,32] and reinforce the reliability of the experimental results. Summary tables for the control testing results can be found in the Supplementary Materials.

Experimental testing phase

A total of 51 fluid samples were collected and analyzed, 1 per simulated patient activation. Each sample volume was 5.0 mL, and all were incubated on Tryptic Soy Agar and in broth culture. The detection limit for both CFU (*E coli*) and PFU (MS2) was 1 organism per 0.1 mL plated volume. No CFU or PFU were observed in any of the collected samples. This negative growth result indicates an absence of bacterial or viral growth during the experiment suggesting a zero (0/51) microbial contamination rate for the tested system. Using a binomial model, this corresponds to a 95% confidence upper bound of 5.8% for undetected contamination events.

No visible trends were observed over time; contamination absence was consistent across early and late activations in both 12-hour test sessions. Inoculum volumes were precisely measured (0.010 mL total per test), and no procedural anomalies or deviations occurred during Luer-lock disconnection or reconnection. Inoculum volumes (0.010 mL per activation) were delivered with high precision using micropipettes, and the Luer-lock disconnection/reconnection process was consistent across all tests. No deviations, manipulation issues, or mechanical variability were observed during either of the two 12-hour sessions, confirming reproducibility across batches.

DISCUSSION

These findings provide evidence that the infusion system's design incorporating sequential 1-way valves can effectively prevent microbial contamination under simulated real-world test conditions. The implications for clinical practice, particularly in high-throughput imaging environments are potentially significant.

However, it is important to highlight that this was a controlled laboratory study and real-world imaging environments have complex confounding variables that affect microbial contamination risks. Factors such as infrastructure design (eg, negative pressure, turbulent airflow, patient flows and preparation space), operational policies (eg, infection prevention and control, environmental cleaning), human factors (eg, workloads, inconsistent aseptic technique, insufficient training and education) and others (eg, environmental background contamination and biofilm formation) can affect the performance of infusion systems.[1-12,28,35,37] These factors may compromise barrier systems in unpredictable ways and should be evaluated under actual imaging conditions in clinical trials.

Colonization rates for intravenous infusion line intraluminal spaces are relatively low when compared to those reported in vascular catheters or on external hubs.[2] The duration of time in use, the number of times that the system is accessed and its design influences contamination rates.[2,38,39] Evidence about the effectiveness of 1-way valves incorporated into infusion systems in preventing microbial ingress is largely supportive of their use. Prior studies have demonstrated the biosafety of nonreturn valves in radiological infusion systems.[24,26,27] However, Ellger et al[25] emphasized the limitations of poorly designed valves in preventing backflow and microbial contamination, underscoring the importance of robust valve engineering and the integration of additional safety features. The current findings provide further reassurance regarding the safety and efficacy of incorporating 1-way valves into infusion systems to provide a barrier to microbial contamination. The incorporation of 2 sequential 1-way safety valves within a designated "safety zone" in the test system likely played a key role in minimizing contamination risk and explaining the results.

Understanding contamination pathways in multiuse infusion systems is essential, as microorganisms may circumvent protective features due to device related or human factors. The effectiveness of such systems depends heavily on adherence to biosafety protocols, proper training, and rigorous disinfection routines between patients, including external connectors, user interfaces and environment.[28,29,36-39] While the system under study demonstrated consistent performance potential factors there are potential factors which might limit its performance. These include degradation of mechanical integrity (valve fatigue), and misuse during repeated disconnection and reconnection. Estimating the impacts of these risks warrants attention in future real-world studies.

Transitioning from single-use to multiuse medical devices has been associated with significant cost savings in procurement, storage and waste disposal and environmental benefits (eg, reduced contamination of water courses, raw material processing).[15-22] The multiuse design of the test system streamlines workflow by eliminating the need to replace syringes and fill lines between patients. This reduces setup and preparation time, conserves contrast media, and improves operational efficiency, particularly in high-volume radiology departments. Enhanced efficiency may also contribute to improved patient experience through reduced waiting times. However, shorter intervals between patients may elevate the risk of environmental cross-contamination, particularly in settings where surface disinfection is suboptimal.[6,7,10,22,34-37] To ensure continued patient safety, such risks must be addressed through compliance with robust infection prevention protocols and standard operating procedures.[2-5,7-11,35-37]

Quantitatively, multiuse contrast systems may reduce plastic waste by several hundred grams per patient by avoiding repeated use of syringes, tubing, and connectors.[19-21] Life cycle assessment studies further support that reusable infusion systems lower both procurement and disposal costs in high-volume departments.[16,22] A formal economic and environmental sustainability evaluation was beyond the scope of this study, but it is clear that reusing components will likely reduce operating costs and conserve contrast media supplies. Anecdotal reports,[40] suggest waste volume reductions in the order of 90% and reduced contrast media usage by 25%.

The inclusion of viral test samples in this study exceeds current FDA requirements for microbial ingress testing of intravascular administration sets.[30] The performance of the test system in this study could inform future updates to technical guidance from health protection agencies such as the FDA and establish a new benchmark for microbial contamination testing. Such a development could provide further clinician and public assurance about the safety and operational benefits of multiuse infusion systems incorporating barrier technologies.

Broader adoption of multiuse infusion systems could be supported through design and process reviews of hospital radiological imaging departments to promote improved workflows and functionality. These reviews could enable the integration of multiuse devices into infection control protocols and bundles, and support cost reduction and sustainability initiatives.

Study limitations

This study was conducted under controlled conditions, which may differ from those encountered in real-world clinical environments and may limit the generalizability of the findings. However, the controlled setting enabled precise measurement and isolation of variables, ensuring that outcomes could be attributed solely to device performance. The microorganisms selected for testing—*E coli* and MS2 bacteriophage—were chosen for their clinical relevance and stringent challenge characteristics. *E coli* is a motile, gram-negative bacterium commonly associated with HAIs, while MS2 bacteriophage, at 27 nm, is smaller than many bloodborne viruses and exceeds current FDA standards for microbial ingress testing.[30] The test duration (12 hours) may not fully reflect the mechanical endurance of the system over the 24 hours replacement timeframe suggested by the manufacturer nor the effects of increased interval times between clinical use in departments which are less busy and do fewer imaging procedures. While the study captured 51 simulated patient activations, prolonged use that exceeds the manufacturer guidance in high-throughput departments may warrant further investigation.

Although additional organisms may demonstrate different behaviors, the microorganisms used in this study provide a meaningful and conservative assessment of the system's microbial barrier effectiveness. These limitations do not diminish the strength of the findings. Instead, they provide a solid foundation for future clinical research under diverse clinical conditions and with a broader range of challenge organisms.

CONCLUSIONS

The test contrast media delivery system used in this study effectively prevented bacterial and viral contamination under controlled laboratory conditions. These findings highlight the potential of this system to reduce HAIs, enhance patient safety, and improve economic and operational efficiency in radiology departments. By combining robust design with sustainability benefits, this system represents a significant advancement in contrast media administration.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at doi:10.1016/j.ajic.2025.06.006.

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