Microbial Safety Verification on an Infusion Set for Contrast Enhanced Imaging

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Abstract

Multiple uses of automatic contrast injection systems may impose septic risks on patients. The purpose of this study was to check whether a newly developed replaceable patient-delivery system may allow multiple uses of the system but without such risks. The experiment was conducted on rabbits with intravenous injection of ^{99m}Tc-dimercaptopropionyl-human serum albumin (^{99m}Tc-DMP-HSA). The tracer was monitored by sampling the delivery system for checking if the radiotracer from the patient line in contact with blood is able to cross the safety zone and reach the dual-syringe injector system. The tested patient-delivery system proves convenient and safe.

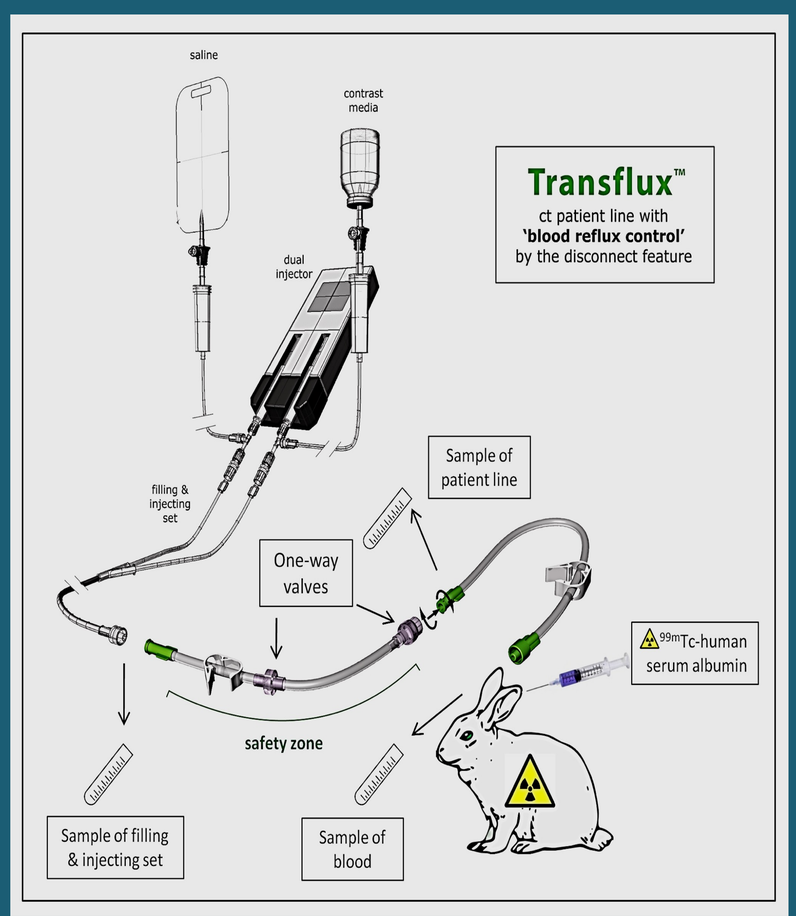
Introduction

Automatic contrast injection systems are used for delivery of contrast media during enhanced imaging procedures. But, accidental patient cross contaminations with microbial flora and pathogens associated with infectious diseases may occur. To prevent this limitation, the injection system including the power syringes and filling & injecting set has to be changed for each patient. However, this proves expensive and time consuming owing to the wasted contrast materials left over in the setup from each exam, the growing consumptions of disposable devices, and the prolonged pauses for replacing the entire set-up with each patient. More institutions worldwide have been applying multiple usages of the syringes with automatic injectors for serial patients. Commercially available injection systems containing a special one-way-valve tube device have been mostly used. Nevertheless, nosocomial infections between patients have been reported.

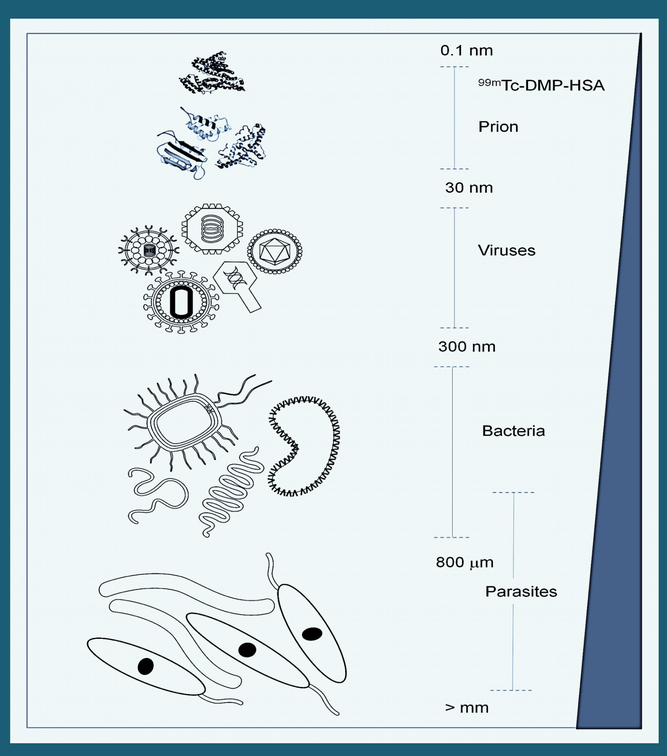
Transflux™ is a patient-delivery system that contains a safety zone composed by a length of tubing and two one-way valves. It permits to flush the delivery system and the vein but prevents blood reflux during contrast-enhanced imaging. This system is replaced for each new patient, whereas the power syringes need to be changed only once a day after multiple uses for a series of patients. It has been applied for several years in many radiology units without any contaminative infections reported. To verify the microbial safety of Transflux™ system and to justify its current clinical use, we performed this experiment in rabbits with intravenous injection of a diffusible radiotracer.

Methods & Materials

Twelve Transflux™ patient-delivery systems (Dipenbeek, Belgium) were tested according to a multiple-use approach using an automatic contrast injection system consisting of dual syringes and one filling & injecting set. Two protocols with normal saline only (n=6) or contrast media plus normal saline (n=6) loaded in the injection system were performed. Each patient-delivery system was connected through an infusion catheter to the ear vein of a rabbit that was intravenously pre-injected with ^{99m}Tc-dimercaptopropionyl-human serum albumin (^{99m}Tc-DMP-HSA). Aliquots were sampled from the filling & injecting set, patient line and animal blood for radioactive analysis after the replacement of each patient-delivery system.



^{99m}Tc-DMP-HSA is a diffusible radiotracer with molecular size (~14 nm) comparable to those of small pathogens.



Results

For the protocol performed using only normal saline, radioactivity was found in the blood circulation of the rabbit (1655903 ± 593221 CPM) and in the patient line (52894 ± 33080 CPM) but in none of samples from the filling & injecting set (8 ± 3 CPM), relative to the background (7 ± 3 CPM) (p = 0.726).

Experimental results attained using contrast plus saline show radioactivity in the blood circulation of the rabbit (1119107± 183174 CPM) and in the patient line (32991 ± 20232 CPM) but in none of samples from the filling & injecting set (6 ± 6 CPM), relative to the background (6 ± 4 CPM) (p = 0.955).

		Animal blood (0.2 mL) CPM (n = 6)	Patient line CPM (n = 6)	Filling & injecting set CPM (n = 6)	Natural background radiation CPM (n = 6)
		Before Safety zone		**After Safety zone**	
protocol	Samples	2056151	88259	6	6
		2580793	36427	5	5
		1411901	95484	11	13
		1707872	30787	7	5
		1230304	12328	5	4
		948399	54081	12	9
	Mean	**1655903**	**52894**	**8**	**7**
	SD	593221	33080	3	3
	p values	Filling & injecting set vs. Natural background			**0.726**
		Patient line vs. Natural background radiation			0.003
		Animal blood vs. Natural background radiation			<.0001
		Filling & injecting set vs. Patient line			**0.003**
		Filling & injecting set vs. Animal blood			<.0001
		Patient line vs. Animal blood			<.0001
Contrast protocol	Samples	1269190	60928	5	9
		1401743	52357	7	12
		1067618	14303	2	0
		1086509	10062	5	6
		965634	30246	0	3
		923948	30052	16	4
	Mean	**1119107**	**32991**	**6**	**6**
	SD	183174	20232	6	4
	p values	Filling & injecting set vs. Natural background			**0.955**
		Patient line vs. Natural background radiation			0.003
		Animal blood vs. Natural background radiation			<.0001
		Filling & injecting set vs. Patient line			**0.003**
		Filling & injecting set vs. Animal blood			<.0001
		Patient line vs. Animal blood			<.0001

Conclusions

This study proves the convincing advantage of using the Transflux™ patient-delivery system in terms of microbial safety and cost-benefits. This system allows safe multiple use of the automatic injector system for several patients without risk of contamination and extravasation but with improved clinical efficiency. It reduces unnecessary waste of contrast media with each patient procedure and of the costly automatic injector systems.