American Journal of Infection Control 000 (2019) 1–6

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Peripheral intravenous catheter needleless connector decontamination study—Randomized controlled trial

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Key Words:
Blood stream infection
Microbiology

Background: Needleless connectors (NCs) were introduced to reduce health care work needlestick injuries (NSIs). If not decontaminated prior to use, NCs can be a portal for patient blood stream infections. The optimal disinfectant, and its application duration, for NC decontamination has not been empirically established.

Methods: Factorial design randomized controlled trial comparing 70% isopropyl alcohol (IPA) and 2% chlorhexidine gluconate (CHG) in 70% IPA for 5, 10, or 15 seconds, in adult medical patients with peripheral intravenous catheters.

Results: At baseline, 153 of 300 NCs (51%) grew microorganisms commonly found on the skin. Decontamination was successful in 150/153 (98%). There was no significant difference in decontamination between 70% IPA or 2% CHG in 70% IPA ($P = .62$), or decontamination for 5, 10, or 15 seconds ($P = .21$).

Conclusions: There was no difference in the effectiveness of 70% IPA and 2% CHG in 70% IPA for NC decontamination for peripheral intravenous catheters in the clinical environment. Successful decontamination was not different for applications of 5, 10, and 15 seconds; 15 seconds did not always remove all microorganisms. Factors such as cost, feasibility of compliance, and low risk of allergy support 5 seconds decontamination with 70% IPA as an acceptable approach.

Needleless connectors (NCs) were introduced in the 1990s to reduce the risk of health care worker needlestick injuries (NSI).[1] Although successful in reducing NSI,[2] an unintended consequence was an increase in patient blood stream infections (BSI) in some institutions.[3-7] The 2 major identified causes for this are the design of the NC, which can influence the ease of decontamination of the NC injectable surface prior to use, and health care worker noncompliance with infection control and prevention guidelines for NC decontamination.

Rates of patient BSI differ depending on the type of vascular access device, but are considered largely preventable for all devices. While PIVCs are relatively low risk, with a BSI rate of 0.1% per 100 devices[8] in adults, the huge volume inserted makes them a device of concern as the source of many health care-associated infections. Without decontamination, about 50% of NC attached to PIVCs in the clinical environment are contaminated with microorganisms commonly found on the skin or respiratory tract.[9] The most common sources of contamination are the patients' own skin flora and the hands of health care workers.[4,10] The type of organism and extent of contamination vary greatly.[9]

Disinfection is a form of decontamination, and can be defined as the process whereby physical or chemical methods are used to reduce the amount of pathogenic microorganisms on a surface.[11] The purpose of NC disinfection is to reduce the number of microorganisms to a level that does not cause risk to patients.[12] The recommended disinfectants for NC decontamination are 70% isopropyl

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Disclosures: Dr Cooke reports other from Baxter, grants from Becton, Dickinson and Company, Centurion Medical Products and Entrotech Lifesciences, outside the submitted work. Dr Rickard reports grants and other from 3M, grants from Angiodynamics, grants from Baxter, grants from BD-Bard, grants from Cardinal Health, grants from Medtronic, grants from Smiths Medical, other from BBraun, other from ResQDevices, outside the submitted work.

https://doi.org/10.1016/j.ajic.2019.11.030

alcohol (IPA), chlorhexidine gluconate (CHG) in 70% IPA, and 10% povidone iodine.[13,14] Use of 10% povidone-iodine although recommended is infrequently used as it is poorly accepted by health care workers and is excessively slow to dry.[15]

There are many in vitro studies looking at NC decontamination.[16-21] The sampling techniques, type and manufacturer of NC used, microorganism type and level of contamination, method of plating, incubation time, drying time, type of disinfectant, and length of decontamination protocols vary significantly. There are few decontamination studies in clinical environments. A recent systematic review and meta-analysis suggests that it is unclear if 70% IPA alone or 70% IPA with CHG is the most effective agent.[22] This work highlighted the low quality of current evidence. Two clinical studies were undertaken in the United Kingdom comparing 70% IPA and CHG in 70% IPA in pediatric and neonatal patients. The focus was on central access devices. Both studies were observational rather than randomized controlled trials. They concluded that 70% IPA with CHG resulted in significantly lower rates of CABSI than 70% IPA alone.[23,24] The control group in the Soothill et al study had a CABSI rate of 10-12/1,000 catheters days, reducing to 3/1,000 with the change to 70% IPA with CHG.[24]

The optimal timeframe for NC decontamination (scrub time) has not been empirically established,[13,14] and recommended timeframes vary from 5 to 60 seconds,[3] with many results being contradictory. Rupp used a split-septum NC to demonstrate no significant difference in decontamination times of 5, 10, 15, and 30 seconds in terms of effective disinfection.[18] None of these decontamination times removed all microorganisms. Smith et al using an experimental design compared decontamination durations of 5, 8, 10, 12, and 15 seconds.[19] They concluded that decontamination durations of 5 and 8 seconds were inadequate to remove bacteria. Scrub times of 10, 12, and 15 seconds showed comparable rates of decontamination.[19] Safdar and Maki suggest that it may not be possible to remove all bacteria from the NC septum where there is extensive contamination.[25]

There is a lack of clinical evidence both for antiseptic type and decontamination time. This makes clinical decision-making and guideline recommendations uncertain. When there is not clear evidence, it is difficult to standardize and ensure best infection prevention practice.

AIM

The aim of the study was to establish the most effective disinfection method, using 70% IPA or 2% CHG in 70% IPA with decontamination (scrub) times of 5, 10, or 15 seconds for NC attached to PIVCs in a clinical environment.

METHODS

Study design

The study design was a factorial randomized controlled trial with 2 levels of intervention, the first being antiseptic type (2 types tested), and the second being duration of scrub (3 tested timeframes; Fig 1).

Participants and baseline data collection

Adult patients on the internal medical units in a metropolitan university-affiliated hospital in Australia were recruited for the study. Inclusion criteria were PIVC in situ for >24 hours, patient gave verbal consent, NC not connected to an infusion. Patients could have more than 1 NC enrolled if the PIVC had multiple access ports, or if they had 2 PIVCs, concurrently or sequentially. Allergy to chlorhexidine was an exclusion factor. Data were collected on gender, age, dominant hand, insertion location, insertion site and side of body, level of dependence, room type, PIVC dwell time, and indication for insertion. This information was collected from the electronic medical record and the patient. Data were manually collected over a 13-month period into a purpose-designed data collection sheet.

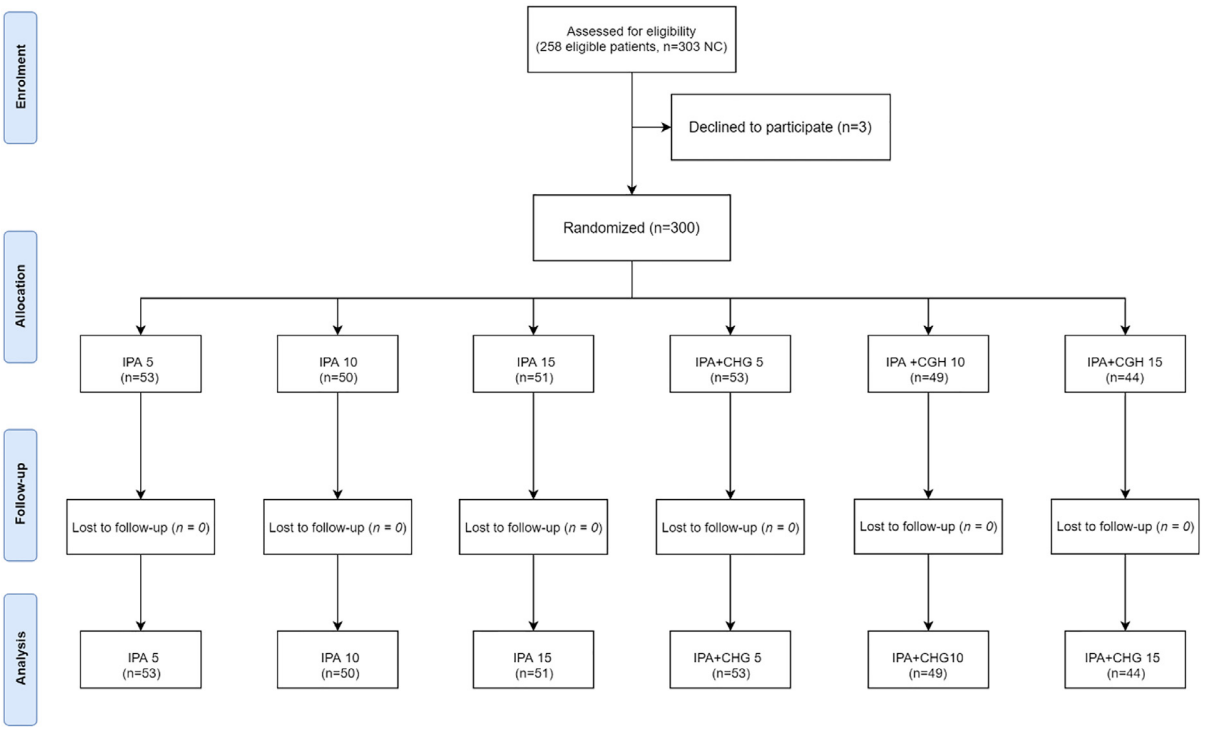

Fig 1. Consort flow diagram—needleless connector—randomized controlled trial.

Baseline samples were collected from the injection surface of 300 NC (Smartsite Needlefree Valve; BD-Care Fusion, Franklin Lakes, NJ) using a sterile cotton-tip stick (Transystem culture swab transport system, COPAN, Brescia, Italy) that had been moistened with a small amount of sterile sodium chloride 0.9% using a zig-zag motion sampling technique. No NC decontamination occurred before the baseline sample was taken. The cotton-tip stick was immediately placed in the collection container and marked with the study number and the word "red." Strict hand hygiene was employed prior to gathering the sample. Two researchers were present for all data collection, one randomizing, collecting the samples and decontaminating the NCs, the other recording data, timing the scrubs and opening and sealing specimen containers.

Randomization

After the initial swab was collected, patients were randomized. Randomization was undertaken using a central web-based randomization service (Griffith Randomisation Service). There was no stratification, and block sizes varied randomly. The groups were 70% IPA 5, 10 and 15 seconds, and 2% CHG in 70% IPA at 5, 10, and 15 seconds.

Interventions

The same researcher (an experienced Registered Nurse) performed all 300 NC decontaminations with another researcher present to monitor protocol compliance. Each NC was scrubbed by 1 research nurse using a standard technique, with the NC being held by the nondominant hand, at the end of the catheter or end of the line extension (depending on whether the NC had an extension line), so that the fingers were not in contact with where a line or syringe would be attached. The entire NC (top and side surfaces) was covered by the prep pad and the dominant hand used to scrub the NC. For the 5-second scrub, the top of the NC (septum) was wiped firmly twice, then again with pressure the side of the connector was scrubbed anticlock wise and clock wise at least 3 times. A research assistant counted loudly the time to ensure each scrub phase was timed exactly to the randomized time. For the 10-second scrub, the top (septum) was scrubbed 4 times, and the side of the NC 6 times using pressure and cleaning in an anticlock wise, clock wise manner. The 15-second protocol was an exact replica of the 5- and 10-second scrubs. At the completion of all scrubs, the NC was allowed to air dry for 30 seconds (as per NC manufacturer recommendations for use). At the completion of the randomized decontamination, the researcher again performed hand hygiene. A sterile swab stick was again moistened with a sodium chloride 0.9% and the NC top (septum) was swabbed in a zig-zag manner. This swab stick was then placed in the collection container and labeled with the date, time, study number, and the word "green."

All labeled specimens were transported to the hospital pathology laboratory by one of the researchers within an hour of collection. Each specimen was plated onto a Horse Blood Agar plate, which was then incubated at 35°C for 3 days. Plate analysis was undertaken by the Microbiologist at day 3 with growth quantification established by manually counting the number of colonies (CFU) present and organism identification determined using the VITEK MS MALDI-TOF (bioMérieux) platform. Results were entered into a database and any growth of microorganism identified by the microbiologist was considered to be evidence of NC contamination. Growth of >15 CFU, sufficient to cause biofilm and potential bacteremia were further analyzed.[3]

Blinding

Due to the nature of the intervention, the research nurses were not able to be blinded to antiseptic type or scrub time. The microbiologist was blinded to antiseptic solution and scrub time. There was no indication on the samples as to decontamination time or disinfection solution, only sample number, time, and date of collection were visible to the scientist. The scientist did not have access to patient randomization data.

Primary outcome and analysis

Data were imported into Stata 15 (StataCorp, College Station, TX) for analysis. The primary outcome (failed decontamination, ie, any microorganism growth) was set up as a dichotomous variable ("yes" or "no"), other variables were either categorical or ordinal. The NC was the unit of analysis. To examine the association between NC growth and other variables of interest, a Fisher exact test was performed. The interaction effect between the antiseptic type and duration was checked as per the factorial design. P values less than .05 were considered statistically significant.

A new dataset was created for all devices, complete with group (factors: antiseptic and time) allocations and an outcome variable. Antiseptic values were entered as "1" and "2," time values were entered as 5, 10, or 15. The outcome variable was coded as 0 if the lab test returned with "clean," and as "1" if the test returned with "contaminated." Risk ratios (RR—relative risk) were calculated for the "antiseptic" variable and the "time" variable using a multivariable generalized linear model. The RR was calculated for each factor while holding the level of the other factor fixed (controlling). Interaction between the factors was not included in the model (as it was not significant).

RESULTS

Sample

Only 3 of 258 eligible patients declined participation (Fig 1), and there were no exclusions for CHG allergy. Two hundred and fifty-five patients gave consent, with 300 NCs randomized and tested. No patients withdrew consent or were lost to follow-up. Table 1 shows the participant characteristics, with just over half of all patients having ward inserted PIVCs, and over one third having emergency department PIVC insertions. Half (50%) of PIVCs had dwelled 25-48 hours, with the remainder either shorter or longer periods.

Baseline contamination

Of the 300 NC swabbed, 153 (51%) grew microorganisms from the injectable surface, and 147 (49%) were not contaminated (Table 2). Twenty NCs were contaminated with <15 CFU (6.67% of the total sample). Two different microorganisms were cultured from 72 (24%) NCs and 3 different microorganisms from 25 (8.3%) NCs, with 6 different microorganisms being the most identified. The most common microorganisms cultured were coagulase-negative staphylococci, with *Staphylococcus epidermidis, Staphylococcus hominis*, and *Staphylococcus haemolyticus* collectively being identified on half of the NC. *Staphylococcus aureus* was only cultured on 1 NC (Fig 2).

Risk factors for contamination at baseline

The association between various demographic and clinical factors with reduced risk of NC contamination at baseline is displayed in Table 3. Two variables, younger age and PIVC wrist insertion, had a weak association with less NC contamination ($P < .2$). The final multivariable model found only PIVC insertion in the wrist (compared to all other insertion sites) to be significantly associated with reduced NC contamination ($P < .05$).

Table 1
Participant characteristics and outcomes for 300 NCs

Characteristics	Descriptive Statistic	Outcome No growth	Outcome Growth
Group size	300 (100)	147 (49)	153 (51)
Age <21	4 (1)	1 (1)	3 (2)
21-30	9 (3)	3 (2)	6 (4)
31-40	9 (3)	5 (3)	4 (3)
41-50	37 (12)	19 (13)	18 (12)
51-60	48 (16)	20 (14)	28 (18)
61-70	60 (20)	25 (17)	35 (22)
71-80	81 (27)	41 (28)	40 (26)
81-90	43 (14)	27 (18)	16 (10)
91-100	9 (3)	6 (4)	3 (2)
Patient level of dependence			
Dependent	112 (37)	57 (39)	55 (36)
Independent	188 (63)	90 (61)	98 (64)
Insertion location			
PAH ED	114 (38)	55 (37)	59 (39)
Ambulance	12 (4)	6 (4)	6 (4)
Wards	169 (56)	83 (56)	86 (56)
Radiology/procedure	4 (1)	2 (1)	2 (1)
Other hospital	1 (1)	1 (1)	0 (0)
Insertion site			
Hand	40 (13)	19 (13)	21 (14)
Wrist	45 (15)	31 (21)	14 (9)
Forearm	80 (27)	31 (21)	49 (32)
Upper arm	7 (2)	4 (3)	3 (2)
Cubital fossa	125 (42)	59 (40)	66 (43)
Other	3 (1)	3 (2)	0 (0)
Dwell time			
24 hours	29 (10)	17 (12)	12 (8)
25-48 hours	150 (50)	70 (48)	80 (52)
49-72 hours	79 (26)	38 (26)	41 (27)
73-96 hours	29 (10)	16 (11)	13 (9)
	13 (4)	6 (4)	7 (5)

Decontamination results

Of the 153 contaminated NCs at baseline, only 3 (2%) grew microorganisms after the randomized decontamination (Table 2). Of the more heavily contaminated NCs (>15 CFU) all but 1 was successfully decontaminated. The initial growth on this NC was *S haemolyticius* 56 CFU, *S capitis* 20 CFU, *S epidermidis* 13 CFU, after decontamination with 70% IPA for 15 seconds, 5 CFU *S haemolyticus* remained. With regards to the antiseptic solution, of the 77 NCs decontaminated with 70% IPA, 76 (99%) did not culture microorganisms after decontamination (Table 4). Of the 70% IPA with 2% CHG decontaminated NCs, 74/76 (97%) were cleaned successfully. There was no statistical difference in decontamination rates between the 2 antiseptics tested ($P = .62$), RR = 2.16 (95% confidence interval: 0.20-22.9).

Regarding the decontamination duration outcome, all 5-second scrubs (100%) were effective in completely eliminating microorganisms. One 10-second scrub (2%) and two 15-second scrubs (4%) were unsuccessful in removing microorganisms (Table 4). There was no statistical significance in decontamination time between the 3 tested timeframes ($P = 0.21$), RR = 1.29 (95% confidence interval: 0.88-1.89).

DISCUSSION

International Guidelines for NC decontamination suggest that multiple disinfectant agents can be used, with a recommended scrub time of at least 15 seconds.[11-13] This is the first randomized controlled trial comparing 70% IPA and 2% CHG in 70% IPA in a clinical environment. Both 70% IPA and 2% CHG in 70% IPA were effective in cleaning NCs attached to PIVCs at 5-, 10-, and 15-second scrub times. There was no statistical significance between the 3 timeframes in terms of successful decontamination. Decontamination of 15 seconds did not always remove all microorganisms, and we believe this was likely due to remaining organic matter, especially dried blood. The process is however disinfection rather than sterilization. Friction/scrub may be the mechanism of action resulting in decontamination, not necessarily the properties of the disinfectant. Visibly contaminated NCs should be replaced as per the Infusion Therapy Standards of Practice guidelines.[14]

In the hospital setting, it is known that about half of all NCs connected to PIVCs are contaminated with microorganisms, commonly those found on the skin.[9] This study further reinforces those findings that without decontamination approximately half of all NC are contaminated. NCs need to be effectively decontaminated prior to use to prevent patient risk of BSI. Disinfection efficacy is affected by previous cleaning, the type and level of microbial contamination, concentration and exposure time of the disinfection agent, and the design characteristics of the object.[26] Due to poor documentation, it was not possible to establish how NCs had been cared for. NC flushing and administration of sodium chloride were not reliably recorded in patient records. Many patients indicated that the PIVC NC had not been accessed since insertion, in some cases for several days. How the NC, especially those with extension tubing are secured, may also have a significant impact on microorganism growth. Connectors that are secured over the occlusive dressing and covered with a clean tubular bandage so that they are not in direct contact with the skin may have fewer microorganisms, or alternatively the use of disinfecting caps/ports may be effective. This would be a worthwhile future study.

This study confirms that decontamination efficacy of 70% IPA and 2% CHG in 70% IPA is very similar. It also confirms that there is little difference in scrub times of 5, 10, and 15 seconds in terms of successful decontamination. User acceptability, cost of prep pads, potential allergies, and drying time may be the factors that influence choice between approaches allowed in guideline recommendations.

This study has the potential to influence current clinical care and policy recommendations. Factors such as alcohol is cheaper and does not pose the same risk of allergy as IPA, and CHG may be the determining factor in product use.[15] Alcohol is not sticky and

Table 2
Needleless connector baseline and decontamination outcomes by study group (n = 300)

Antiseptic	Scrub time	Initially contaminated n = 153 (51%)	Successfully decontaminated, 150/153 (98%)	Contaminated >15 CFU organism (n = 20)	Successful decontamination 19/20 (95%)
IPA 70%	5s	25/53 (47.2%)	25/25 (100%)	4	4/4 (100%)
	10s	26/50 (52%)	26/26 (100%)	3	3/3 (100%)
	15s	26/51 (51%)	25/26 (96.2%)	5	4/5 (80%)*
IPA 70% +2% CHG	5s	28/53 (52.8%)	28/28 (100%)	1	1/1 (100%)
	10s	25/49 (51%)	24/25 (96%)	4	4/4 (100%)
	15s	23/44 (52.3%)	22/23 (95.7%)	3	3/3 (100%)

*Predecontamination *S haemolyticus* 56 CFU, *S capitis* 20 CFU, *S epidermidis* 13 CFU; postdecontamination *S haemolyticus* 5 CFU.

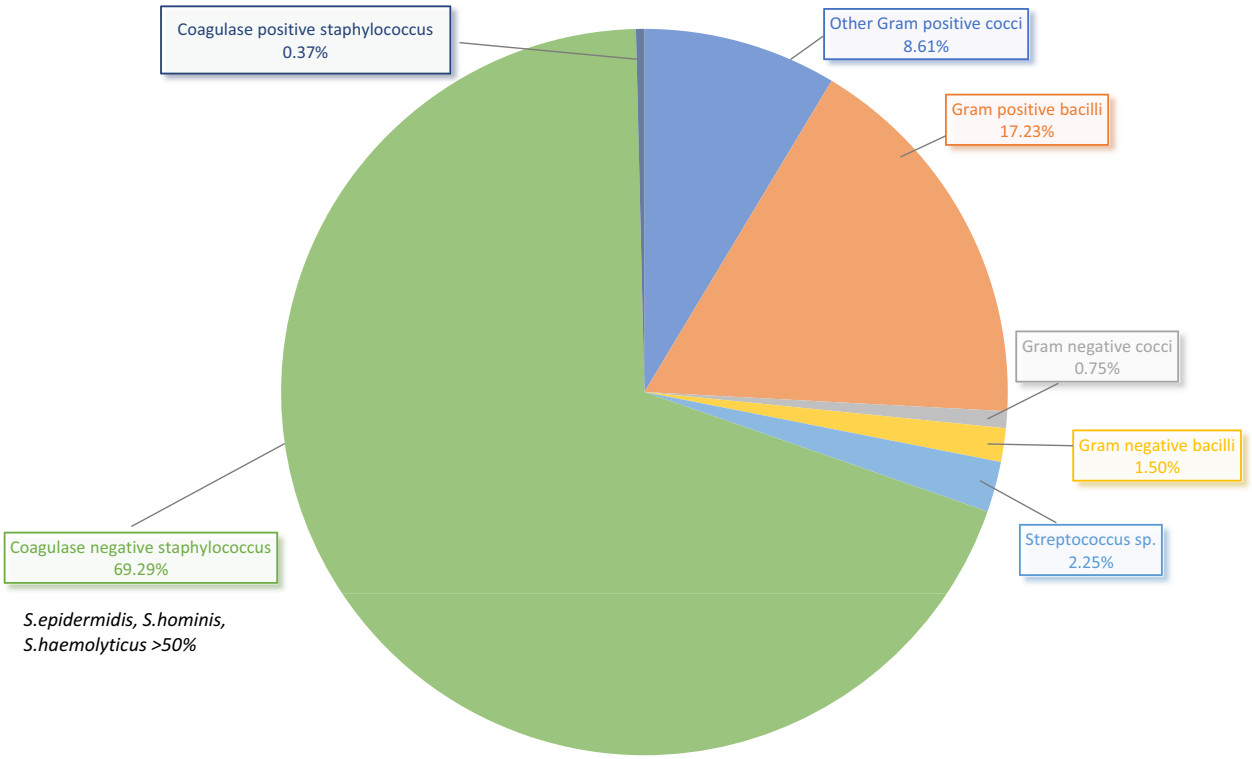

Fig 2. Micro-organism growth on needleless connectors (at baseline).

there is evidence that alcohol alone dries quicker than IPA and CHG.[15] Cautious consideration should be given to changing the guidelines from at least a 15-second scrub to a 5-second scrub, with the proviso that all visibly unclean NCs should be replaced immediately.

Limitations

This study focused on the microorganisms present on the exterior septum of the NC, both prior to and after cleaning. It did not look at microbial contamination of the internal lumen. Contamination of the internal lumen is far more serious, and once biofilm is established may be impossible to eradicate.[27] It is however reasonable to assume that contamination of the exterior surface of the NC is the most likely cause of contamination of the internal lumen.

Table 3
Risk factors for NC contamination at baseline (without decontamination)

	Univariable	Multivariable
Age category (next higher)	0.87 (0.76-1.00)*	†
Female sex	0.99 (0.62-1.57)	‡
Independent	1.13 (0.71-1.80)	‡
Inserted at:		‡
- general ward	reference	
- PAH emergency	1.04 (0.32-2.33)	
- other	0.86 (0.32-2.33)	
Inserted in wrist	0.38 (0.19-0.74)*	0.38 (0.19-0.74)§
Inserted on dominant side	0.96 (0.61-1.51)	‡
Needleless connector:		‡
- extension tubing	reference	
- connector only	0.78 (0.42-1.45)	

*Statistically significant at $P < .2$.
†Dropped from multivariable model at $P \geq .05$.
‡Not eligible for multivariable analysis at $P \geq .2$.
§Statistically significant at $P < .05$.

A further limitation of this study was that it only looked at active decontamination methods, impregnated caps were not included. Povidone iodine was excluded due to its slowness to dry and poor user acceptability.[15] This study could have been improved by linking actual BSI to microorganism growth on NCs. The focus however was on cleaning of NCs.

Evidence suggests that neither hand hygiene immediately before NC decontamination nor decontamination using a nontouch technique is performed reliably.[28] This may mean that the results of this study, undertaken with very strict adherence to guidelines, may not be generalizable to "normal" clinical practice.

Strengths

A strength of this study was the same researcher completed all 300 NC decontaminations. There was a high degree of standardization of the decontamination method, with accurate timing. The decontamination method was undertaken every time with clean hands and used an aseptic nontouch method, with the prep pad completely covering the entire NC on all occasions.

Table 4
Antiseptic type and duration of decontamination

	Decontaminated (N = 150)	Not decontaminated (N = 3)	Total	*P* Value
Antiseptic type				.62
IPA 70%	76 (99)	1 (1)	77 (100)	
IPA 70%+2% CHG	74 (97)	2 (3)	76 (100)	
Duration of application				.21
5 seconds	53 (100)	0 (0)	53 (100)	
10 seconds	50 (98)	1 (2)	51 (100)	
15 seconds	47 (96)	2 (4)	49 (100)	

This randomized controlled trial of NC decontamination has confirmed an issue that has been debated extensively for many years, that there is no statistical significance between 70% IPA and 2% CHG in 70% IPA in terms of decontamination efficacy. In addition, there is no statistical difference in decontamination efficacy of timeframes of 5, 10, and 15 seconds while adhering to aseptic technique and hand hygiene recommendations.

CONCLUSIONS

There have been no previous randomized controlled trials of PIVC NC decontamination in the clinical environment. There was no statistical difference between 70% IPA and 2% CHG in 70% IPA in terms of their efficacy in decontaminating the external surface of NCs contaminated in the clinical environment. Both are highly effective as a disinfectant agent, however neither removed all contaminants. Human behavior in relation to adherence to basic infection control practices also needs to be considered when making recommendation to ensure that risk of harm to patients is minimized.

ETHICS

Ethics approval and consent: Ethics approval was obtained from the human research ethics committee. Patient verbal consent was obtained. It was explained that there would be no risk or benefit to the patient. The patient was told that they would not be given the results of the test. It was written into the protocol that if there were results that were of concern, the Scientist was to contact the researcher (ie, *S aureus* growth). The researcher was to ensure that the PIVC had been removed (result only available 72 hours after collection). Results were not entered into the electronic medical record. The PIVC of the one patient that cultured *S aureus* was already removed by the time the result was available.

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