Prevention of Intravenous Bacterial Injection from Health Care Provider Hands: The Importance of Catheter Design and Handling

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BACKGROUND: Device-related bloodstream infections are associated with a significant increase in patient morbidity and mortality in multiple health care settings. Recently, intraoperative bacterial contamination of conventional open-lumen 3-way stopcock sets has been shown to be associated with increased patient mortality. Intraoperative use of disinfectable, needleless closed catheter devices (DNCCs) may reduce the risk of bacterial injection as compared to conventional open-lumen devices due to an intrinsic barrier to bacterial entry associated with valve design and/or the capacity for surface disinfection. However, the relative benefit of DNCC valve design (intrinsic barrier capacity) as compared to surface disinfection in attenuation of bacterial injection in the clinical environment is untested and entirely unknown. The primary aim of the current study was to investigate the relative efficacy of a novel disinfectable stopcock, the Ultraport zero, with and without disinfection in attenuating intraoperative injection of potential bacterial pathogens as compared to a conventional open-lumen stopcock intravascular device. The secondary aims were to identify risk factors for bacterial injection and to estimate the quantity of bacterial organisms injected during catheter handling.
METHODS: Four hundred sixty-eight operating room environments were randomized by a computer generated list to 1 of 3 device-injection schemes: (1) injection of the Ultraport zero stopcock with hub disinfection before injection, (2) injection of the Ultraport zero stopcock without prior hub disinfection, and (3) injection of the conventional open-lumen stopcock closed with sterile caps according to usual practice. After induction of general anesthesia, the primary anesthesia provider caring for patients in each operating room environment was asked to perform a series of 5 injections of sterile saline through the assigned device into an ex vivo catheter system. The primary outcome was the incidence of bacterial contamination of the injected fluid column (effluent). Risk factors for effluent contamination were identified in univariate analysis, and a controlled laboratory experiment was used to generate an estimate of the bacterial load injected for contaminated effluent samples.
RESULTS: The incidence of effluent bacterial contamination was 0% (0/152) for the Ultraport zero stopcock with hub disinfection before injection, 4% (7/162) for the Ultraport zero stopcock without hub disinfection before injection, and 3.2% (5/154) for the conventional open-lumen stopcock. The Ultraport zero stopcock with hub disinfection before injection was associated with a significant reduction in the risk of bacterial injection as compared to the conventional open-lumen stopcock (RR = 8.15×10^{-8}, 95% CI, 3.39×10^{-8} to 1.96×10^{-7}, $P = <0.001$), with an absolute risk reduction of 3.2% (95% CI, 0.5% to 7.4%). Provider glove use was a risk factor for effluent contamination (RR = 10.48, 95% CI, 3.16 to 34.80, $P < 0.001$). The estimated quantity of bacteria injected reached a clinically significant threshold of 50,000 colony-forming units per each injection series.
CONCLUSIONS: The Ultraport zero stopcock with hub disinfection before injection was associated with a significant reduction in the risk of inadvertent bacterial injection as compared to the conventional open-lumen stopcock. Future studies should examine strategies designed to facilitate health care provider DNCC hub disinfection and proper device handling. (Anesth Analg 2012;115:1109–19)

Intravascular device-related bloodstream infections (BSIs) are associated with increased patient morbidity and mortality and lead to increased economic burden through prolonged intensive care unit and hospital stay duration.[1] Each year >500,000 preventable BSIs are thought to occur and are associated with both long- and short-term intravascular devices. A major factor associated with BSI development is intraluminal colonization after bacterial

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Reprints will not be available from the authors.

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injection through device injection ports.[2–6] Recent work in the operating room (OR) environment has demonstrated an association between bacterial contamination of conventional open-lumen 3-way stopcock sets and increased patient mortality, with bacterial contamination from anesthesia provider hands, patients, and the surrounding patient environment shown to contribute to stopcock contamination events.[7–9] These findings provide the necessary impetus for the investigation of alternative intravascular devices for intraoperative use.

Intraoperative use of disinfectable needleless closed catheters (DNCCs) may be advantageous as laboratory evidence suggests that DNCCs may reduce endoluminal bacterial entry via an intrinsic septal barrier associated with valve design.[10,11] However, although in vitro experiments suggest that DNCC hub disinfection may augment the intrinsic septal barrier,[10–13] the relative importance of DNCC hub disinfection in the clinical environment has remained unknown and untested.

The Ultraport zero (B. Braun Medical., Bethlehem, PA) is a novel stopcock device with an integrated DNCC. It is uniquely suited for intraoperative use because it offers a disinfectable surface and directional control of the fluid column without intrinsic flow-rate limitations. These characteristics are extremely important for the fast-paced anesthesia environment.

The primary aim of the current study was to assess the relative efficacy of the Ultraport zero stopcock with and without hub disinfection as compared to a standard open-lumen stopcock in prevention of bacterial injection from anesthesia provider hands during routine anesthesia care. As such, we planned to evalute (1) the potential benefit of a novel, closed stopcock device as compared to a standard open-lumen device potentially derived from a device-related barrier to bacterial entry; and (2) the relative efficacy of closed stopcock hub disinfection in attenuation of intraoperative bacterial injection. We hypothesized that the novel Ultraport zero stopcock device, when disinfected before injection, would reduce the risk of bacterial injection when compared to the conventional open-lumen. To determine the potential significance of these injection events, we also sought to explore the quantity of colony forming units (CFUs) injected from the hands of anesthesia providers in the clinical environment. Finally, we planned to ascertain risk factors for intraoperative bacterial injection.

METHODS

We conducted a randomized, single-blinded, and controlled ex vivo (simulated) study to compare a novel disinfectable stopcock (Ultraport zero, B. Braun Medical, Bethlehem, PA) with and without hub disinfection before injection to a conventional open-lumen stopcock (Set Source, San Clemente, CA) handled according to usual practice (closed with sterile caps) as recommended by the Centers for Disease Control (CDC).[5]

This study was conducted over a 2-month period (May 2011 to July 2011) at Dartmouth-Hitchcock Medical Center, a tertiary care and level one trauma center for the state of New Hampshire with 400 inpatient beds and 28 operating suites. Approval was obtained from the IRB for the Protection of Human Subjects. A waiver for informed, written patient consent was obtained. Patients were given a study handout, and all participants provided verbal consent for study participation. OR involving at least 2 consecutive patients undergoing surgery requiring general anesthesia and IV catheter placement were considered eligible for enrollment. Surgeries requiring only monitored anesthesia care and/or a lack of scheduled sequential operative cases were excluded.

Primary Outcome

The incidence of and time to effluent bacterial contamination during simulated clinical conditions. Effluent is the fluid column injected through the study devices in simulation. Time to effluent contamination is an indirect assessment of the burden of bacteria injected. This is based on the premise that a higher load of bacerial injectate will lead to a shorter contamination time (earlier detection time) via a faster growth rate.

Secondary Outcome: Risk Factors for Bacterial Injection

After completion of the ex vivo trial, we performed a controlled laboratory experiment to generate an estimate of the quantity of CFUs that may have been injected through each device during the trial (see below).

Protocols

Randomized, Controlled, Ex Vivo Trial

Four hundred sixty-eight OR environments (patients, anesthesia providers, and surrounding environmental surfaces and equipment) were randomized for study via a computer-generated list. The OR environment was selected as the unit of randomization because prior work has shown that intraoperative bacterial reservoirs including but not limited to anesthesia provider hands, patients, and the surrounding patient environment contribute to open-lumen stopcock bacterial transmission events and are intricately related.[7–9] This randomization strategy was intended to include a wide variety of patients, anesthesia providers, aseptic practice techniques, and surgical procedures. It was also intended to account for the effect of case on patient IV tubing contamination[9] and variables associated with BSI development.[4]

Each of the 468 OR environments was randomized to 1 of 3 device injection schemes: (1) Ultraport zero stopcock injected with prior disinfection with 70% alcohol and allowing 30 seconds for air drying; (2) Ultraport zero stopcock injected without prior disinfection; and (3) injection of a conventional open-lumen closed with sterile caps according to usual practice (Fig. 1). A study arm involving disinfection of a conventional open-lumen before injection was not included because (1) disinfection of the conventional open-lumen is not recommended by the CDC[5] and (2) because there were no practical means at study initiation by which to execute this intervention. Within each OR environment, the primary anesthesia provider caring for each patient was asked to inject sterile saline according to their usual practice into the ex vivo catheter system according to the randomization assignment; the saline was drawn up by the provider according to their own technique and injected into the

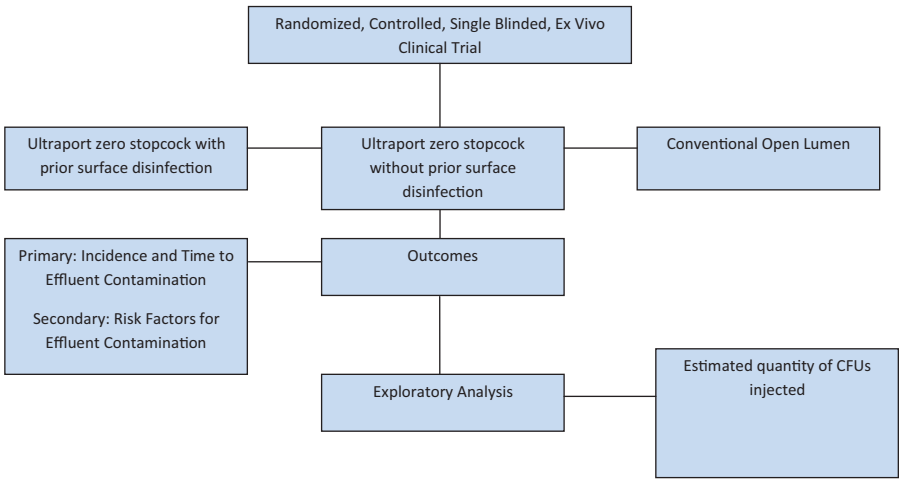

Figure 1. Study design. CFU = colony forming units.

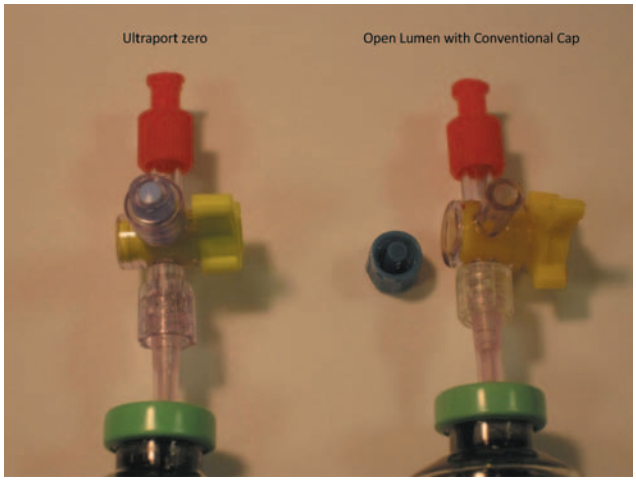

Figure 2. Ex vivo trial conventional open-lumen and Ultraport zero stopcock study units.

device according to the randomization assignment. In addition, OR environments were randomized to the first or second case of the day because prior work has demonstrated an association between stopcock contamination and the second operative case.[9] As this was an ex vivo catheter system, the study devices were not connected to patients (see below). This study design was selected to minimize patient harm. However, the sterile study devices were brought into the OR and were injected while anesthesia providers were providing patient care, such that the incidence of bacterial contamination associated with each device would reflect a burden of bacterial exposure commonly encountered in the intraoperative setting.

Each study device consisted of a bottle of aerobic blood culture (BacT/Alert, Biomerieux, Durham, NC) into which an 18-G peripheral venous catheter (Venflon, BD, Franklin Lakes, NJ) was inserted[10] with strict aseptic practice under a laminar flow hood. The catheters were closed with the Ultraport zero stopcock or the standard system incorporating a conventional open-lumen stopcock with sterile caps. The remaining open port of the three-way stopcock set (cephalad port) was closed with a sterile cap under the same sterile conditions to allow forward flow into the culture medium during injection of the study unit (Fig. 2). The Ultraport zero stopcock incorporates a Halkey Roberts Valve (a split septum that does not occlude high flow) with a directional handle that diverts the internal fluid pathway, allowing directional control of fluids. The conventional stopcock is an open-lumen system (3 gang 4-way), with closure only when a conventional cap is placed by the provider. Assembly was completed by one laboratory assistant during the study period. We chose 30 seconds for air drying based on general recommendations.[5,14] The disinfecting agent was chosen based on prior work demonstrating a beneficial effect of 70% alcohol above that of other disinfectants for hub disinfection. [a,15]

After induction of general anesthesia and patient stabilization, the primary anesthesia provider caring for each patient in the 468 randomized OR environments was asked to inject the assigned device 5 times in series with 1 mL of sterile saline drawn up by the provider according to a previously used, standardized protocol.[16] The standardized injection protocol involved the following 3 components for the injection series: (1) avoidance of glove use or hand decontamination (although hand hygiene and glove use were allowed at will before injection, these activities were avoided in the standardized protocol); (2) use of 1 syringe, 1 needle, and 1 saline vial; and (3) avoidance of vial surface disinfection between injections.[16] This protocol was intended to minimize variability between groups for factors such as handling of saline vials, frequency of syringe or needle use, and frequency of hand decontamination or glove use events during the injection series. Furthermore, although the disinfection arm required use of 70% alcohol for disinfection and 30 seconds for drying between injections, we did not control the method required for disinfection such as the technique, scrubbing versus wiping, and the source, use of 70% alcohol from dispensers from the cart versus prepackaged alcohol pads. Because it was expected that some providers would be reluctant to follow the standardized protocol, provider variability in hand decontamination, glove use, syringe, and needle use were monitored

[a] Kaler W, Chinn R. Successful Disinfection of Needleless Access Ports: A Matter of Time and Friction. JAVA 2007; 12: 140-2.

and recorded during the injection series. Devices were removed from the sterile packaging material (sterility confirmed, see below) by providers and immediately injected with the fluid column collected in the attached BacT/Alert culture bottles. Once injected, the study units were immediately disassembled, returned to the sterile packaging in the OR, the packaging material was sealed, transported to the laboratory, removed by the laboratory assistant, and the bottles were directly incubated in the BacT/Alert system for 5 days or until positive. BacT/Alert automatically monitors bacterial growth using a colorimetric system. A sensor inserted in the bottom of the bottle changes color on detecting the CO_2 produced by the growth of the bacteria (Fig. 2).[10] Once positive, the liquid in the bottle was examined to identify the organism as previously described.[7–9] At the end of the study, the sterility of the liquid in the negative bottles was confirmed in 15 randomly selected samples by plating onto 5% sheep's blood agar plates (BAPs) and incubating at 37°C for 48 hours. In addition, in a randomly selected subset of study units after packaging for OR entry, sterility was confirmed via injection of sterile saline through each device using sterile, aseptic technique, and incubating for 5 days or until positive. The primary outcomes were the incidence and time to effluent contamination.

We acquired baseline demographic and procedural information including professional status, years of training, the presence or absence of hand hygiene performance immediately before or during device injection, glove use during injections, syringe and needle use, the surgical procedure, case urgency, case (1 or 2), patient age, patient comorbidities, American Society of Anesthesiologists (ASA) physical classification status, sex, preoperative location, discharge location, days of preoperative chlorhexidine or nasal mupirocin therapy, and use of prophylactic antibiotics.

All information was compiled and entered into an Access database system and linked to a unique bar code. The randomization code was linked to the unique barcode but separated from the access database containing the results of the primary outcomes to insure that the research coordinator, laboratory research assistant, principal investigator, and providers remained blinded to the study results. A statistician and epidemiologist outside of the principal investigator's division were asked to analyze the study protocol and data as an additional effort to avoid bias.

Estimation of Injected CFUs

We used a laboratory experiment to estimate the CFUs injected during the clinical study. This was a controlled experimental analysis designed to generate growth curves of bacterial organisms isolated from contaminated effluent during the clinical trial. *Staphylococcus*, the most common organism injected through the conventional open-lumen stopcock, and streptococcus, the most common organism injected through the Ultraport zero stopcock, were selected from frozen samples, subcultured onto BAPs, and grown for 24 hours at 37°C. Cells were harvested from the BAP into sterile 0.9% saline to generate turbidity consistent with a commercially available 0.5 McFarland standard. From this working suspension, 7 serial dilutions were generated for each organism from 1.5×10^8 to 1.5×10^0 CFU/mL. Inoculated bottles were inserted into the BacT/Alert machine and incubated at 37°C for 5 days or until positive. The time to contamination was automatically recorded.

The experimentally derived growth curve for the most common organism injected through each respective device was then used to generate an estimate of the CFUs injected through each respective device during the ex vivo trial. This was achieved by comparing the time to effluent contamination for clinical samples to the time for effluent contamination for the 7 serial dilutions of the most common organism injected through each device in the controlled laboratory study. This was based on the premise that a higher load of bacerial injectate would lead to a shorter contamination time in the BacT/Alert system. Each dilution was considered a loading dose for the purpose of the statistical analysis used to generate CFU projections (see statistical section).

Statistical Analysis

We used χ^2 or Fisher's exact test where appropriate for binary and categorical variables and one-way ANOVA to evaluate the difference in continuous variables by the three treatment arms (see Table 1).

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Effluent contamination: We used Fisher's exact test to compare the incidence of effluent contamination across groups. We then used Poisson regression analysis to assess the risk of effluent contamination for each intervention arm as compared to the open-lumen standard. Poisson regression analysis was used to calculate the relative risk, which was then adjusted for the patient ASA score, renal insufficiency, days of nasal mupirocin, and provider glove use. An alpha of 0.05 was defined as statistically significant.

Time to effluent contamination: Kaplan-Meier time to event analysis was conducted to evaluate the difference between devices in time to contamination after injection. We used the log rank test for equality of survivor functions to compare the time to contamination differences across the 3 device arms. Cox's proportional hazards regression was used to calculate hazard ratios for the intervention arm as compared to the open-lumen. The results of the primary analysis were adjusted for the type of bacterial organism injected. An alpha of 0.05 was defined as statistically significant.

Risk factors for effluent contamination: Chi-square and Fisher's exact tests where appropriate were used for binary variables. A 2-tailed Student's *t*-test was used for comparisons of continuous variables. An α of <0.025 was considered statistically significant to address multiple comparisons.

Estimation of CFUs Injected During the Clinical Trial

The log of the loading dose CFUs for each organism was used to create 2-way scatter plots, including the log of the loading dose and contamination time (time to positivity). We then used linear regression to predict values for the log dose CFUs of the model intercept, and the coefficients for contamination time and device (conventional open-lumen stopcock, Ultraport zero stopcock without disinfection, Ultraport zero stopcock with hub disinfection) to calculate the predicted log value of CFU load in the clinical trial for

Table 1. Patient, Provider, and Procedural Demographics

	Open-lumen (n = 154) Mean (SD) or N/%	Ultraport with HD (n = 162) Mean (SD) or N/%	Ultraport without HD (n = 152) Mean (SD) or N/%	P value/ probability >F
Provider characteristics				
Professional status				0.164
Attending physician	23/14.9	31/19.1	13/8.6	
Resident physician	76/49.4	75/46.3	72/47.4	
Certified-registered nurse anesthetist	54/35.1	54/33.3	62/40.8	
Other	1/0.65	2/1.2	5/3.3	
Training (y)	5.78 (9.0)	7.03 (10.2)	6.93 (10.2)	0.425
Gloves used	24/15.6	29/17.8	22/14.5	0.698
Procedure characteristics				
Operating room				0.261
1–9	58/37.7	59/36.4	67/44.1	
10–20	47/30.1	40/24.5	40/26.3	
21–28	47/30.1	63/38.9	45/29.6	
Case duration	1.95 (1.33)	1.93 (1.47)	2.2 (1.49)	0.186
Procedure§				
2–6*	68/44.07	82/50.1	67/44.1	0.276
7–13†	84/54.5	80/49.4	83/54.6	
Urgency				0.530
Elective	143/92.9	151/93.2	138/90.8	
Emergent	1/0.7	2/1.2	5/3.3	
Urgent	10/6.5	9/5.6	9/5.9	
Case				0.784
1	76/50.0	79/48.8	80/52.6	
2	76/50.0	83/51.2	72/47.4	
Patient characteristics				
Patient age	53.2 (21.6)	48.2 (23.0)	50.9 (20.5)	0.131
Gender (male)	86/55.8	86/53.1	82/53.9	0.882
ASA‡				0.040
1	18/11.8	32/19.8	14/9.2	
2	80/52.3	80/49.4	78/51.3	
3	48/31.4	48/29.6	50/32.9	
4	7/4.6	2/1.23	10/6.6	
Comorbidities				
Cardiovascular	65/42.2	64/39.5	65/42.8	0.820
Pulmonary	16/10.4	21/12.9	23/15.1	0.462
Neurological	13/8.4	11/6.8	12/7.9	0.854
Renal	16/10.4	4/2.5	9/5.9	0.013
Endocrine	25/16.2	17/10.5	20/13.2	0.322
Infectious	3/1.9	3/1.9	6/3.9	0.476
Hematological	2/1.3	5/3.1	4/2.6	0.599
Rheumatological	4/2.6	7/4.3	3/1.9	0.490
Gastrointestinal	11/7.1	12/7.4	16/10.5	0.491
Other	10/6.5	7/4.3	5/3.3	0.400
Patient origin				0.870
Same day	143/92.9	153/94.4	142/93.4	
Hospital ward	8/5.2	9/5.6	8/5.3	
Intensive care Unit	1/0.65	0/0	1/0.66	
Other	2/1.3	0/0	1/0.66	
Patient discharge				0.109
Same day	61/39.6	78/48.2	55/36.2	
Hospital ward	82/53.3	81/50.0	87/57.2	
Intensive care Unit	7/4.6	2/1.2	8/5.3	
Other	4/2.6	1/0.6	2/1.3	
Patient chlorhexidine days	0.36 (0.78)	0.25(0.66)	0.27 (0.65)	0.365
Nasal mupirocin days	0.49 (1.46)	0.22 (1.02)	0.11 (0.66)	0.009

*Other, general abdominal, general breast, orthopeadic, vascular, or neurosurgical procedures.
†Gynecological, ear/nose/throat, urological, plastics, cardiothoracic, neurological, or other procedures.
‡ASA physical status classification.
§1 = procedure unassigned.
Without HD = without hub disinfection before injection; With HD = with hub disinfection before injection.

contaminated effluent samples. We then took the antilog of those predicted values to generate the estimated quantity of CFUs injected through each device during the trial. A 2-sample t-test with equal variances was used to compare the estimated injected CFU means for the conventional open-lumen stopcock and Ultraport zero stopcock without prior disinfection arms. An alpha of 0.05 was defined as statistically significant.

Power

We assumed that the Ultraport zero stopcock would be equally effective at prevention of bacterial entry in the clinical environment as compared to a previously tested straight valve DNCC (microClave, ICU Medical, San Clemente, CA).[10] Assuming an improvement in sterile bottles from 70% (conventional open-lumen, standard practice) to 86% (Ultraport zero stopcock with or without proper aseptic technique) and

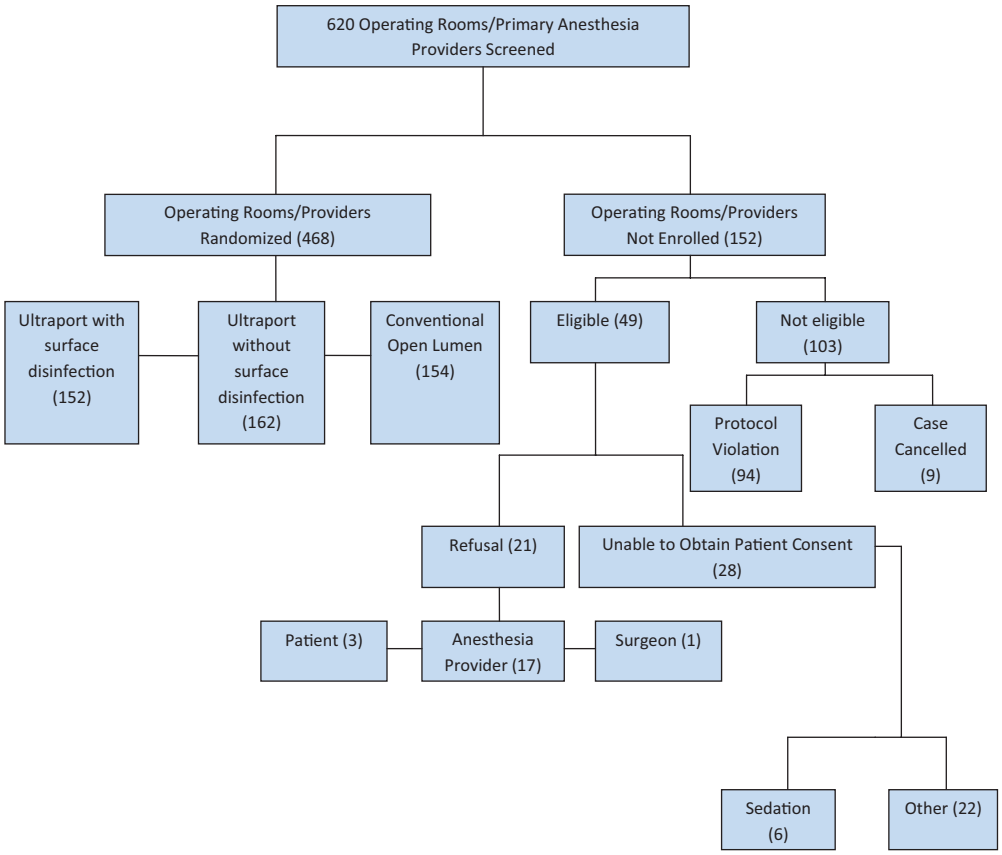

Figure 3. Study enrollment.

Table 2. Poisson Regression of the Incidence of Effluent Contamination for the Ultraport With and Without Disinfection Before Injection as Compared to the Open-Lumen for the Randomized Ex Vivo Trial

Ex vivo clinical trial	RR	95% CI	*P* value
Unadjusted			
Ultraport zero stopcock without disinfection	1.34	0.434–4.14	0.612
Ultraport zero stopcock with disinfection	1.74×10^{-7}	7.23×10^{-8}–4.18×10^{-7}	<0.001
Adjusted*			
Ultraport zero stopcock with prior disinfection	1.64×10^{-7}	5.81×10^{-8}–4.63×10^{-7}	<0.001
Ultraport zero stopcock without prior disinfection	1.98	0.585–6.67	0.273
ASA status	1.09	0.558–2.15	0.789
Patient renal comorbidities	2.94	0.426–20.88	0.274
Patient nasal mupirocin days	1.17×10^{-29}	1.52×10^{-35}–8.96×10^{-24}	<0.001
Provider glove use	14.66	3.88–55.37	<0.001

ASA = ASA physical status classification; RR = relative risk.

*Variables included are those that differed between groups as shown in Table 1 (ASA, renal, and nasal mupirocin days), and glove use given that increased glove use was associated with effluent contamination).

an odds ratio of at least 2, we estimated 156 samples in each group provided a power of 0.95 with a type I error rate of 0.025.

RESULTS

Six hundred twenty OR environments were screened for inclusion criteria with 468 ORs and 468 providers included in the final analysis (Fig. 3). One hundred fifty-two OR environments were screened but not randomized. There was no significant difference in ASA status, case (1 or 2), age, and sex for those ORs enrolled as compared to those screened but not enrolled (data not shown). There were no missing data pertaining to the primary outcome. All ORs and providers randomized for study were included in the analysis.

As shown in Table 1, study groups were generally comparable with differences between study groups including only patient ASA status, renal comorbidities, and days of preoperative nasal mupirocin.

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Effluent Contamination

The rate of effluent contamination was 0% (0/152) for the Ultraport zero stopcock with hub disinfection before

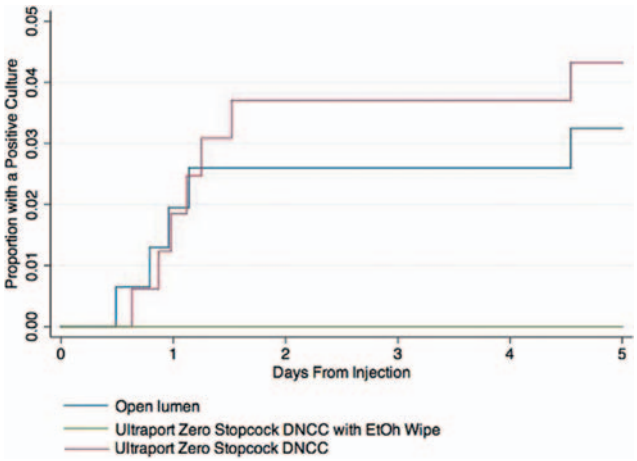

Figure 4. Kaplan-Meier analysis of time to effluent contamination in the ex vivo trial. DNCC = disinfectable, needleless closed catheter devices.

injection, 4% (7/162) for the Ultraport zero stopcock without hub disinfection before injection, and 3.2% (5/154) for the conventional open-lumen stopcock. The rate of effluent contamination differed across the three arms (P = 0.026). As shown in Table 2, the Ultraport zero stopcock with disinfection before injection was associated with a significant reduction in the risk of bacterial injection as compared to the conventional open-lumen stopcock (RR = 1.74×10^{-7}, 95% CI, 7.23×10^{-8} to 4.18×10^{-7}, $P < 0.001$), with an absolute risk reduction of 3.2% (95% CI, 0.5% to 7.4%).

This difference remained after adjustment for ASA status, renal comorbidities, days of nasal mupirocin, and provider glove use (RR = 1.64×10^{-7}, 95% CI, 5.81×10^{-8} to 4.63×10^{-7}, $P < 0.001$). There was no protective effect of the device without hub disinfection before injection.

Time to Effluent Contamination

Time to effluent contamination differed across study arms(P value = 0.045) (Fig. 4). The Cox's proportional hazard ratio for the Ultraport zero stopcock without disinfection before injection as compared to the conventional open-lumen stopcock was 1.43, P = 0.617. The Cox's proportional hazard for the Ultraport zero stopcock device with disinfection as compared to the conventional open-lumen stopcock was 0, P = 1 (with no events).

Risk Factors for Overall Effluent Contamination

Provider glove use was identified as a risk factor for effluent contamination (Table 3). All patients received prophylactic antibiotics. Hand washing was performed by only one provider immediately before or during the injection series.

Estimation of Quantity of CFUs Injected During the Ex Vivo Trial

The estimated geometric mean of staphylococcus CFUs injected through the conventional open-lumen stopcock was 14,792 ± 16,675 versus an estimated geometric mean of 7290 ± 7910 streptococcus CFUs injected through the Ultraport zero stopcock without disinfection before injection. This difference was not statistically significant (P = 0.159). The largest predicted injected CFU (99th percentile) for the conventional open-lumen stopcock was 42,628 as compared to 23,176 for the Ultraport zero stopcock.

DISCUSSION

These data show that the Ultraport zero stopcock, when disinfected before injection, is a more effective barrier to bacterial entry as compared to the standard open-lumen stopcock when used according to current recommendations. The main benefit of the Ultraport zero stopcock is derived from the ability to disinfect the hub, as opposed to an intrinsic barrier to bacterial entry potentially associated with the split septum. These findings reinforce the body of literature pertaining to the importance of DNCC hub disinfection for prevention of bacterial injection during patient care and offer an alternative to conventional open-lumen stopcocks. These contributions are important, because intraoperative bacterial contamination of conventional open-lumen intravascular devices has recently been associated with increased patient mortality across multiple medical centers.[9]

The Ultraport zero is a novel stopcock incorporating a DNCC with a split septum valve. DNCCs have been shown to reduce the incidence of hub colonization and associated BSI rates.[11,17,18] This is thought to be due to greater endoluminal protection offered by DNCCs as compared to open-lumens closed with conventional caps.[10,11,19] The availability of different DNCC designs, however, has resulted in clinical variability in their use, and changes in the model of DNCCs used have been associated with increases in BSI rates.[20,21] This may be because although the efficacy of DNCC hub disinfection for prevention of bacterial injection has been demonstrated in the laboratory environment,[10,12,13] the relative importance of hub disinfection versus the intrinsic septal barrier alone has not been described in the clinical environment. This may partially explain poor compliance with hub disinfection in the clinical arena.[14] Thus, the current study used the Ultraport zero stopcock to critically evaluate 2 important factors pertaining to intravascular devices, design, and handling.

We used a randomized, single-blinded, and controlled ex vivo trial to evaluate the efficacy of the Ultraport zero stopcock with and without hub disinfection and a conventional open-lumen stopcock device when used according to standard guidelines[5] in attenuation of bacterial injection in the clinical arena. To our knowledge, this is the first study that has directly evaluated the efficacy of a DNCC device with and without disinfection in prevention of bacterial injection from provider hands during patient care. Although the Ultraport zero stopcock when disinfected before injection was a more effective barrier to bacterial entry as compared to the standard open-lumen stopcock when used according to current recommendations,[5] we were unable to demonstrate a significant difference in either the incidence of contamination or the time to contamination between a standard open-lumen and the Ultraport zero without disinfection. Because time to contamination is an indirect measure of intrinsic device-related barrier properties, in that it considers the burden of bacteria injected as opposed to the presence or absence of contamination, the major preventive

Table 3. Risk Factors for Effluent Contamination

	Effluent negative (*N* = 456) N/% or mean (SD)	Effluent positive (*N* = 12) N/% or mean (SD)	Mean difference/ RR	95% CI	*P* value
Provider characteristics					
Professional status					0.362
Attending physician	67/100	0/0			
Resident physician	214/95.96	9/4.04			
Certified-registered nurse anesthetist	167/98.24	3/1.76			
Anesthesia technologist	7/100	0/0			
Other	8/100	0/0			
Years of training	6.69 (9.87)	2.08 (1.51)	4.61	−1.00–10.21	0.054
Gloves used	67/89.33	8/10.67	10.48	3.16–34.80	<0.001
Cap replaced	0.337 (0.500)	0.416 (0.514)	0.079	−0.367–0.209	0.705
New syringe used	0.998 (0.105)	1 (0)	0.002	−0.062–0.057	0.529
New needle used	1.01 (0.155)	1 (0)	0.007	−0.082–0.095	0.442
Hub disinfection	1.63 (2.34)	0 (0)	1.625	0.295–2.96	<0.001
Procedure characteristics					
Operating room					0.288
1–9	181/98.37	3/1.63			
10–20	121/95.28	6/4.72			
21–28	154/98.09	3/1.91			
Case duration	2.05 (1.45)	1.31 (0.763)	0.739	−0.084–1.56	0.052
Procedure§					0.301
2–6*	211/96.79	6/2.75			
7–13†	242/97.58	6/2.42			
Urgency					0.263
Elective	422/97.69	10/2.31			
Emergent	8/100	0/0			
Urgent	26/92.86	2/7.14			
Case					0.539
1	230/97.87	5/2.13			
2	224/96.97	7/3.03			
Patient characteristics					
Age	50.68 (21.89)	53 (19.79)	2.32	−14.88–10.23	0.642
Gender (male)	247/97.24	7/2.76			0.775
ASA†					0.86
1	63/98.44	1/1.56			
2	232/97.48	6/2.52			
3	142/97.26	4/2.74			
4	19/100	0/0			
Comorbidities					
Cardiovascular	189/97.42	5/2.58			0.988
Pulmonary	58/96.67	2.3.33			0.686
Neurological	36/100	0/0			0.311
Renal	28/96.55	1/3.45			0.756
Endocrine	60/96.77	2/3.23			0.723
Infectious disease	12/100	0/0			0.569
Hematological	10/90.91	1/9.09			0.166
Rheumatological	13/92.86	1/7.14			0.271
Gastrointestinal	38/97.44	1/2.56			1
Other	22/100	0/0			0.436
Origin					0.358
Same day	428/97.72	10/2.28			
Hospital ward	23/92.00	2/8.00			
Intensive care unit	2/100	0/0			
Other	3/100	0/0			
Discharge					0.831
Same day	188/96.91	6/3.09			
Hospital ward	244/97.60	6/2.40			
Intensive care unit	17/100	0/0			
Other	7/100	0/0			
Chlorhexidine bath	82/97.62	2/2.38			0.907
Nasal mupirocin days	0.257 (1.07)	0.833 (1.95)	0.576	−1.21–0.057	0.963

RR = relative risk.
*Other, general abdominal, general breast, orthopedic, vascular, or neurosurgical procedures.
†Gynecological, ear/nose/throat, urological, plastics, cardiothoracic, neurological, or other rocedures.
‡ASA physical status classification; RR = relative risk.
§1= Procedure unassigned.

benefit of the Ultraport zero stopcock in the clinical environment appears to be derived from the ability to disinfect the hub. Without hub disinfection, there is no apparent difference in either the overall contamination rate or the burden of bacteria injected through the Ultraport zero stopcock as compared to the open-lumen. This premise is further supported by the lack of difference in the estimated quantity of CFUs injected through the Ultraport zero stopcock without disinfection as compared to the conventional open-lumen stopcock. Thus, of the 2 known contributing factors to device permeability, valve design and provider handling techniques,[10] proper hub disinfection is clearly the most important factor when subjected to clinical exposure. An important consideration for the Ultraport zero stopcock is that the IV tubing incorporates a closed, disinfectable stopcock manifold, obviating the need to individually connect DNCCs to a conventional open-lumen device. This is an important factor, because additional catheter maniuplations are associated with device contamination and increased risk of subsequent BSIs.[2–6]

We did not mandate an Ultraport zero stopcock disinfection technique by providers. Instead, providers used various sources (alcohol pads, alcohol dispensers with gauze) of 70% alcohol readily available to them in the OR environement. Clinical variability in disinfection technique did not appear to matter, because there was zero contamination in the Ultraport zero stopcock with disinfection arm. Furthermore, 70% alcohol was universally effective after 30 seconds. However, as suggested by Lockman et al.,[22] the duration required for scrubbing must be better defined. We show that 30 seconds (as per manufacturer recommendation) is effective, but less time may actually be required.

We have shown that glove use was associated with intraoperative bacterial injection and hypothesize that this was due to glove contamination occurring during induction of anesthesia. The implications of this finding are unclear but do offer support for current CDC guidelines suggesting that clean gloves should be used before device manipulation.[5] In fact, the failure of anesthesia providers to change gloves after induction of anesthesia may increase the risk of bacterial transmission to patients. The finding that the predominant bacterial organism injected differed for the conventional open-lumen and Ultraport zero stopcock devices also suggests that bacterial adherence properties may have important implications for future DNCC designs.

Finally, we have generated a reasonable estimate for the burden of bacteria that are likely to be injected during improper device handling during intraoperative patient care. This estimate of approximately 50,000 CFU far exceeds the quantity of bacteria thought to colonize dry skin surfaces, 10^2 to 10^4 CFU/mL.[10] Furthermore, it far exceeds the concentration used previously in in vitro experiments to evaluate the intrinsic barrier properties of various DNCC designs.[10] Injection of 50,000 CFUs per a series of 5 injections might explain the prior association of stopcock contamination with increased patient morbidity and mortality[7–9] and the prior association of DNCCs with increased risk of health care-associated infections.[20,21] Furthermore, this finding clearly justifies the use of an ex vivo study design to minimize patient risk while studying device efficacy.

A limitation of this study is that we used a simulated model deployed in the clinical arena to evaluate only the impact of provider hand contamination on intraoperative bacterial injection through various intravascular devices. Although prior work has shown that provider hand contamination contributes to standard open-lumen stopcock contamination events,[8] recent work has shown that patients and the surrounding patient environment also contribute significantly to standard open-lumen stopcock contamination.[9] However, as intraoperative bacterial reservoirs are intricately related,[9] hand contamination leading to effluent contamination in this study likely represented the contributions of multiple intraoperative bacterial reservoirs. An additional limitation is that this trial relied on provider compliance with hub disinfection. Because prior studies have shown that providers are often noncompliant,[14] future efforts should be directed toward facilitating the process of hub disinfection, especially in complex, fast-paced, critical care environments. We also recognize that the randomization scheme did not include a study arm involving disinfection of a standard open-lumen stopcock set. However, the conventional open-lumen stopcock is not considered to be a disinfectable device by the CDC.[5] Furthermore, to the best of our knowledge, no practical, evidence-based technologies were available to disinfect open-lumen stopcocks at the time of study execution. We recognize that a rapid series of 5 injections may increase the risk of bacterial contamination, but hub disinfection was universally effective even under these conditions. Finally, we recognize that there were differences across study arms involving renal comorbidities, ASA status, and nasal mupirocin days. These findings were not surprising given that (1) 5% of characteristics will differ by chance (>40 variables were assessed) and (2) the unit of randomization was the entire OR environment, not simply patients or providers. Furthermore, the Ultraport zero stopcock with disinfection arm favored a higher ASA status and fewer nasal mupirocin days as compared to the conventional open-lumen. Because these are all factors that could potentially increase the risk of patient bacterial colonization and subsequent stopcock contamination,[9] this would only serve to strengthen the efficacy of the novel closed stopcock. Finally, the greater efficacy of the Ultraport zero stopcock in attenuation of bacterial injection remained significant despite adjustment for these factors. The adjusted model also included provider glove use, because this was a strong predictor for effluent contamination.

In conclusion, proper handling of the Ultraport zero stopcock after induction of general anesthesia reduces the incidence of bacterial injection from anesthesia provider hands when compared to a conventional open-lumen stopcock device. Of the factors associated with device bacterial permeability, valve design and provider handling, proper handling appears to be most important in the clinical arena. Future efforts should be directed toward facilitating provider hub disinfection in the complex clinical arena, and the efficacy of various DNCCs in prevention of bacterial injection should be examined after prolonged clinical exposure.

Ultimately, it will be important to examine the impact of properly handled DNCCs on health care-associated infection rates. ■

DISCLOSURES

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