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New clinical evidence:
Reducing the risk of stopcock colonization in the operating room and intensive care unit with Marvelous™ (MRVLS)

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Catheter use and catheter-related blood stream infections

Intravascular catheters are indispensable in modern medical practice. Although these catheters provide necessary vascular access, their use puts patients at risk for local and systemic infections[1-4]. Catheter-related blood stream infections (CRBSIs) are common, costly and potentially lethal. CRBSIs represent an increasingly significant problem in hospitals, especially in intensive care units (ICUs).

Contamination of the catheter hub contributes substantially to intraluminal colonization in long-term catheters[5-8], a major factor associated with blood stream infections (BSIs) resulting from injection through device injection ports[9-13].

Contamination may derive from the valve, stopcock or another port. Stopcocks present a potential port of entry for microorganisms into vascular access catheters and IV fluids. According to the CDC, stopcock contamination occurs in 45% and 50% in the majority of series[14]. Therefore, reducing the chance of microbial colonization on stopcocks can contribute to reducing the rate of catheter colonization.

Recent studies

Recent work in the operating room (OR) environment has demonstrated an association between bacterial contamination of conventional open-lumen three-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[15-17].

The study, "Transmission of pathogenic bacterial organisms in the anesthesia work area[15]", addresses stopcocks as a potential contamination source in the anesthesia work area. Contaminated stopcocks were associated with a trend toward increased nosocomial infection and mortality rates. Sampling the internal female luer connection surface of three-way stopcocks, the results demonstrated that bacterial organisms are transmitted during the (1) administration of general anesthesia and (2) through intravenous stopcock sets. Stopcock sets became contaminated with potentially pathologic bacteria in 32% of studied cases (61 patients undergoing various surgical procedures). The authors observed an increase in mortality that might be attributable to stopcock contamination, secondary to poor aseptic practice.

These findings provide the impetus for further investigation of alternative intravascular devices* for use in ORs and ICUs.

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*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[18-19]. However, while in vitro experiments suggest DNCC hub disinfection may augment the intrinsic septal barrier[18-21], the relative importance of DNCC hub disinfection in the clinical environment remains unknown and untested.

The Marvelous stopcock

Marvelous, developed by Elcam Medical, is a novel stopcock that integrates two features specifically intended to increase patient safety by reducing the risk of infection: a swabbable luer-activated valve and circumferential channel.

1. The **luer-activated valve** serves as a bacterial barrier to enable access to the line without having to open it and to create a closed system that allows a needle-free connection.
2. The **circumferential channel** directs fluid flow throughout the entire internal volume of the handle and facilitates ongoing flushing, resulting in minimal residual volume, which can reduce the risk of bacterial colonization.

Marvelous ™ stopcock

Two clinical studies

In the last few years, two important studies were conducted with the Marvelous stopcock. This paper will describe both these studies.

1. Intensive Care Unit, Rambam Medical Center (Haifa, Israel)

This study evaluated the effect of using a Marvelous-configured stopcock on the rates of stopcock colonization and CRBSIs.

Protocol

- Study site: 30-bed ICU of a tertiary hospital
- Study type: Single-center, open labeled, retrospective-prospective-comparative study (retrospective analysis and prospective intervention), illustrated in Figure 1 below.
- Sample size: entire ICU patient population for the duration of the study (approximately 1,200 patients)
- Duration: Two years, divided into two one-year periods. In the first one-year period, conventional stopcocks were used; in the second one-year period, all stopcocks were converted to the study device (Marvelous-configured stopcock with a valved port and circumferential channel enabling continuous flushing of internal valve volume).

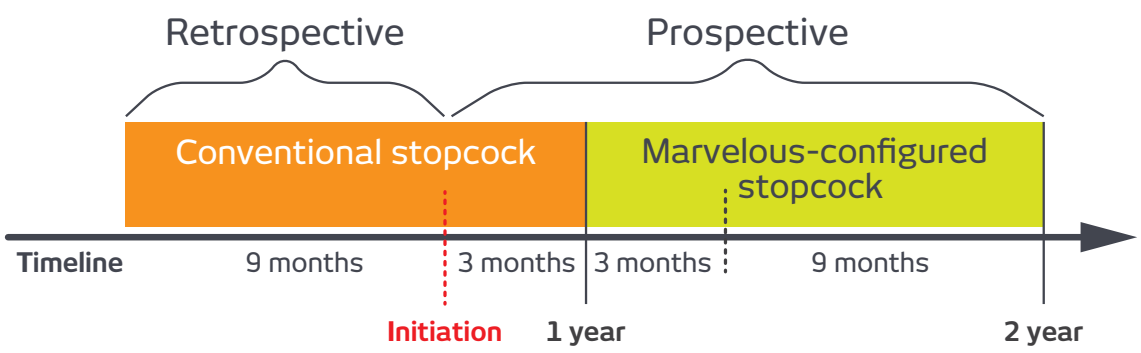

Figure 1: Study type

Primary endpoints

70% reduction of stopcock colonization
25% reduction of CRBSIs

Study course

In the first three months of the prospective period of the study, the ICU continued using conventional stopcocks (no change in department's stopcocks). One stopcock of each patient's CVC (second stopcock of the middle lumen) was marked and sent to microbiology when the set was replaced (see figure 2).

Figure 2: The second stopcock of the middle lumen of each CVC was marked and sent for microbiological examination.

In the next five months of the prospective period*, all stopcocks used were replaced with a Marvelous-configured stopcock, the novel studied stopcock (Figure 3). One stopcock of each patient's CVC (the second stopcock of the middle lumen) was marked and sent to microbiology when the set was replaced.

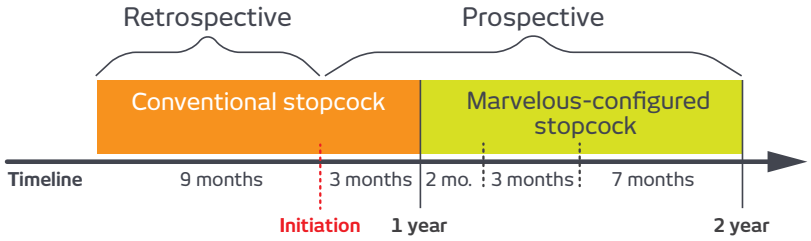

Figure 3: Study timeline after protocol amendment (retrospective-prospective periods)

Microbiology test for stopcock colonization

The stopcock handle was detached from its body using a designated fixture. The inner barrel and all ports of the stopcock were swabbed. The swab was submerged in 1 milliliter(ml) of substrate (thioglycolate) and mixed/separated by vortex/centrifugation. Of the liquid substrate, 100 microliters (µl) was put in agar and incubated at 36°C for 48 hours. Colonies were counted using VITEK® II and microorganisms were identified using bioMérieux diagnostic tests. Stopcock colonization rates were evaluated for the 3 different periods as described in the results section below and outlined in figure 4.

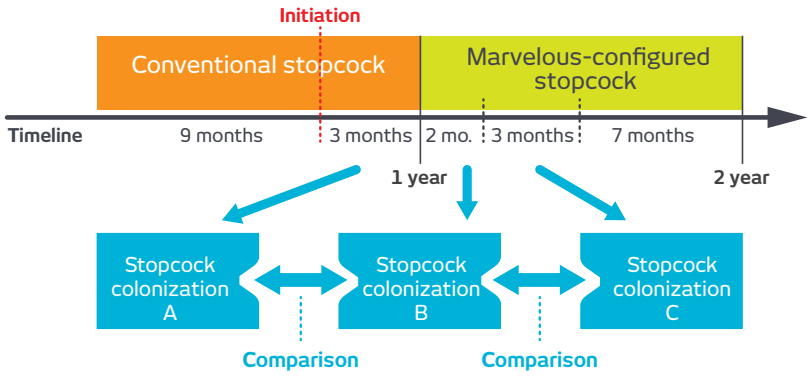

Figure 4: Stopcock colonization comparison

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*The second period actually took five months instead of three (protocol amended). In the first two months, the study device wasn't used properly due to a difficulty with swabbing. After clarification of the IFU, the study device was swabbed properly and the study continued for three months (see figure 3).

CRBSI rates were scheduled to be gathered and compared for the two one-year periods .

Results

The stopcock colonization data was divided into three groups:

1. Group A: conventional stopcock.
2. Group B: Marvelous-configured stopcock with insufficient swabbing by the medical staff.
3. Group C: Marvelous-configured stopcock with swabbing.

Group A showed 37% colonization rate (15/35 stopcocks). Group B showed 60% colonization rate (15/25 stopcocks), and Group C, a 22% colonization rate (10/46 stopcocks).

CRBSI rates were not analyzed due to two main reasons:

1. There was not enough data collected during the trial.
2. Catheter tips weren't sent to culture as a routine.

During the prospective phase, Central Line-Associated Blood Stream Infections (CLABSIs) were investigated, which are slightly different than CRBSIs, one of the endpoints in the retrospective phase.

The CLABSI rates measured in Rambam's ICU since the switch to the Marvelous-configured stopcock in January 2012 showed a reduction tendency to the acceptable levels (2-5/1000 cvc days) after an initial period with a few peaks of high levels. From an average annual rate of 28.21/1000 cvc days in 2008, rates decreased to an average annual of 7.44/1000 cvc days measured during 03/12 - 03/13, and 3.07/1000 CVC days measured from 03/2013 until 02/2014. The monthly CLABSI rates measured in Rambam's ICU from March 2012 until October 2014 appears in figure 5 below.

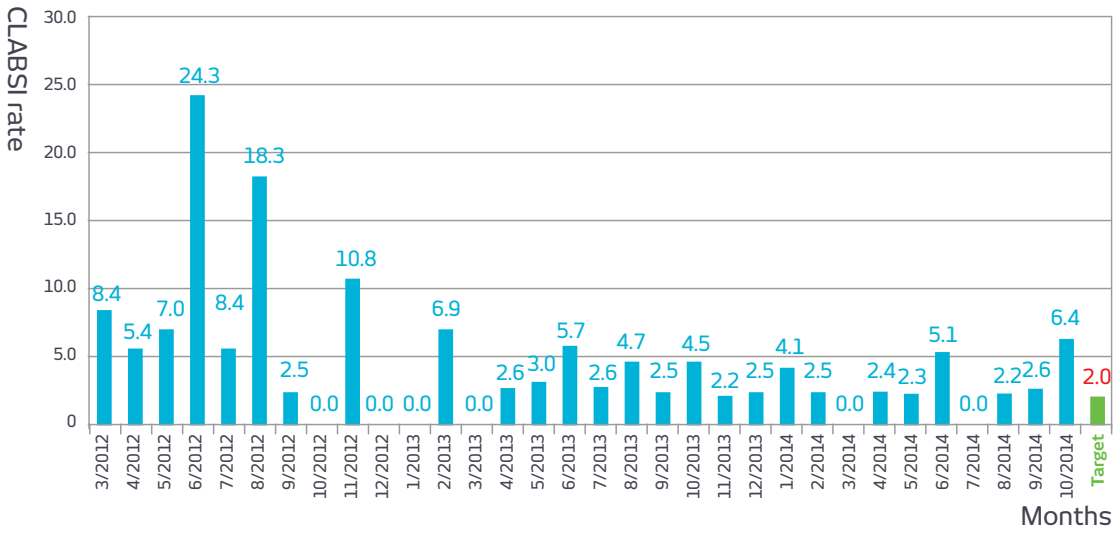

Figure 5: Rambam Medical Center ICU CLABSI rate March 2012 - October 2014

Conclusions

The stopcock colonization results indicate that using a Marvelous-configured stopcock with valve swabbing reduced the rates of stopcock colonization. Future studies should further examine the reduction in stopcock colonization and the influence of using a Marvelous-configured stopcock on the rates of CLABSIs.

2. Department of Anesthesiology, Dartmouth-Hitchcock Medical Center (Lebanon, New Hampshire)

A second study, conducted by Dr. Randy Loftus[22] assessed the relative efficacy of the Marvelous stopcock* with and without hub disinfection, as compared to a standard open-lumen stopcock in preventing bacterial injection from the anesthesiologist's hands during routine anesthesia care.

The **primary aim** of the study was to investigate the relative efficacy of a novel closed, disinfectable, minimal residual volume stopcock, Marvelous, with and without hub disinfection in reducing intraoperative injection of potential bacterial pathogens, as compared to a conventional open-lumen stopcock intravascular device.

Methods

Four hundred sixty-eight OR environments were randomized (computer-generated list) indicating one of three different device-injection schemes:

1. Injection into the Marvelous stopcock with hub disinfection before injection.
2. Injection into the Marvelous stopcock without prior hub disinfection.
3. Injection into the conventional open-lumen stopcock closed with sterile caps, according to usual practice.

After induction of general anesthesia, the primary anesthesia provider in each OR was asked to perform a series of five 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 Marvelous stopcock with hub disinfection before injection, 4% (7/162) for the Marvelous stopcock without hub disinfection before injection, and 3.2% (5/154) for the conventional open-lumen stopcock. The Marvelous 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%) (Figure 6).

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*In this study and the published article, the Marvelous stopcock was branded Ultraport Zero by Elcam Medical's local partner.

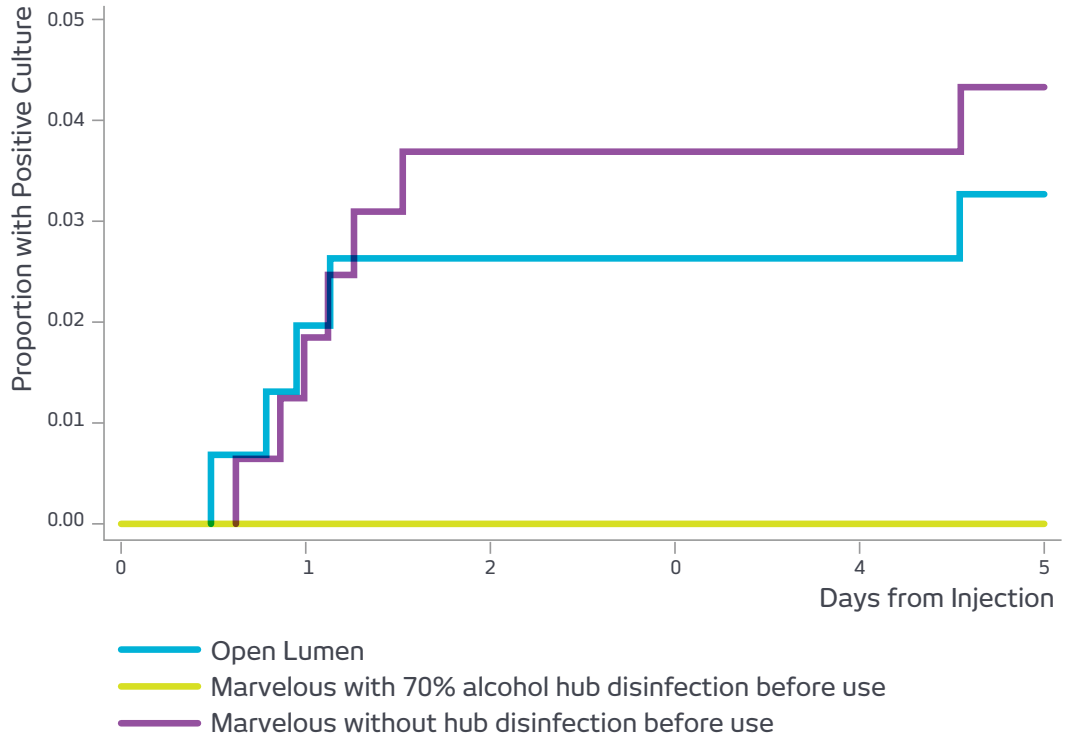

Figure 6: Kaplan-Meier analysis of time to effluent contamination in the ex vivo trial

Conclusions

The Marvelous 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.

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