

June 9, 2009

An Investigation into the Potential Transmission of Infection via Vacuum Regulators

**Keith S. Kaye, MD, MPH; Chester Smialowicz MD,
Lauren Bentley, MSBME; Kevin Klocek, BSBME MBA**

Presented at APIC 2009

Clinical Education Presented By:

BOEHRINGER[®]

Background

- An average of 1.7 million people contract a Hospital Acquired Infection (HAI) every year.
- For ICU patients, the rate of acquiring an infection is 5 to 10 times higher than someone in a general ward.
- A patient with an HAI will cost an estimated \$15,275 additionally and stay in the hospital for an average of 14 extra days.
- The increased risk of attaining an HAI is associated with three major risk factors:
 - 1) Intrinsic factors related to the requirement for intensive care
 - 2) General ward crowding
 - 3) Medical device contamination
- Suction regulators are a standard piece of medical equipment in an ICU and are employed in a wide array of applications, such as naso-gastric drainage.
- Naso-gastric circuits require a regulator to function on an intermittent mode, as a clinical safety measure, to alternately apply suction to vent the circuit.
- As the regulator cycles on and off, air is vented back into the canister through the flow path of the regulator.
- Should this flow path become contaminated, there exists the potential to spread infectious agents from the regulator back to the patient.
- This study aims to reveal the device as a possible source of infection by challenging three assumptions:
 - 1) Regulators cannot become contaminated.
 - 2) A contaminated regulator cannot release contaminants back into a suction canister.
 - 3) A patient cannot become infected when connected to an NG circuit with a contaminated regulator.

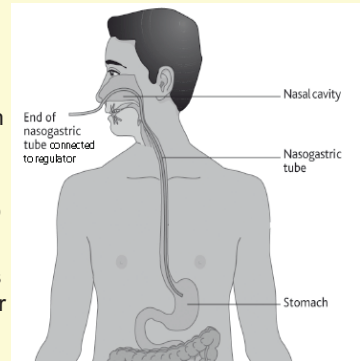


Diagram of an NG Circuit

Methods

Assumption 1

Regulators were obtained from 11 medical facilities. Using the BD Culture Swab Collection System (BD Biosciences #220099), a sample was collected from the patient port of the regulator. All cultures were streaked onto Tryptic Soy Agar Plates and incubated at 37C for 24-48 hours. All plates that presented with bacterial growth were sent to North American Science Associates, INC. (NAMSA) for identification.

Assumptions 2 and 3

Once regulators were identified as possessing infectious material, a simulated patient naso-gastric circuit was created (Figure 1). This circuit enabled the determination that a sterile circuit could become infected if the controlling regulator was contaminated.

Infesting the Regulator

Escherichia coli ATCC 29425 was grown in Nutrient Broth Media for 5 hours. The bacteria solution was diluted to 1×10^6 cfu/ml. A 0-200mmHg regulator was set to 100mmHg in intermittent mode. 100ml of the *E. coli* solution was pulled through the regulator. After the entire 100ml of the solution was pulled through the regulator, the regulator was turned off and placed in a test stand for further use.

Setting up the Naso-Gastric Circuit

The Naso-Gastric (NG) circuit was set up according to the diagram in Figure 1 below. The contaminated regulator was connected to a 6' piece of sterile suction tubing. This tubing was then attached to the VAC port in the lid of the hospital wall canister. The patient port on the canister was connected with another 6' piece of sterile tubing to the port in the simulated stomach. The simulated stomach was comprised of a 1200ml glass beaker with a polyethylene lid. The lid was equipped with a .001" orifice with a .22um filter (Milled-GV; #SLGV013SL) to allow a controlled amount of air into the system. The entire simulated stomach was autoclaved prior to use to ensure sterility. The simulated stomach was then filled with 1000ml of sterile Nutrient Broth Media (BD# 233000).

Figure 2

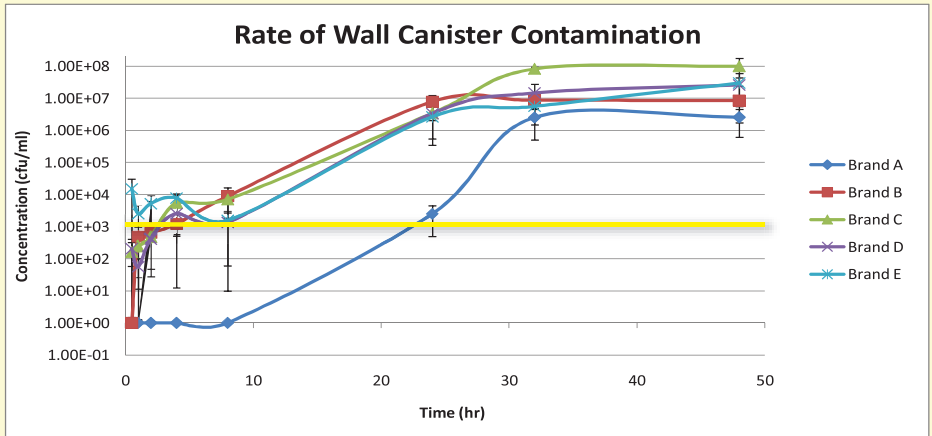


Figure 2: This graph displays the progression of bacteria from the regulator to the wall collection canister (n=4).

Figure 3

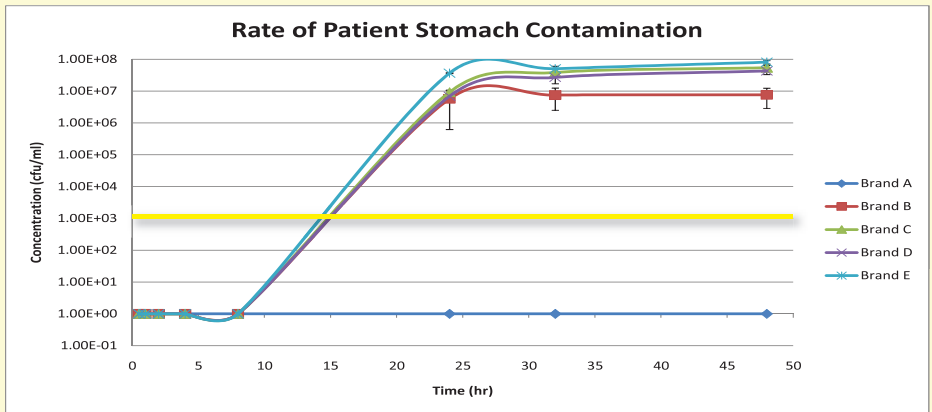


Figure 3: This graph shows the progression of bacteria from the canister to the patient stomach for each tested regulator (n=4). Note that Brand A had no growth in the patient stomach.

Conclusions

- Suction regulators are frequently (more than 1/3) contaminated and are a notable source and reservoir for pathogens.
- In a test model, the patient stomach became infected via reflux of material from/through a suction regulator in as little as 24 hours.
- At the conclusion of this trial (48 hrs.), only one brand of suction regulator showed no colonization in the stomach.
- Contaminants in a patient's stomach may not survive in the acidic environment. However, many patients on an NG circuit are given antacids, proton pump inhibitors or H₂ blockers to control reflux. These medications can facilitate colonization by organisms within the stomach. Gastric colonization may lead to respiratory or systemic infections.
- In the ICU, the frequent use of NG suctioning and medications to control acid reflux presents the suction regulator as a possible vector for hospital acquired infections based on the frequency of contamination found and ability to transmit contaminants.
- Studies are needed to evaluate the methods and frequency of disinfection and sterilization of suction regulators.

Running the Experiment

The contaminated regulator was set to 100mmHG and run in intermittent mode for 48 hours. 500ul samples were removed from the wall collection canister and the simulated stomach at .5, 1, 2, 4, 8, 24, 32, and 48 hour time points. Each sample was plated onto Nutrient Agar Plates and incubated at 37C for 24 hours.

Figure 1

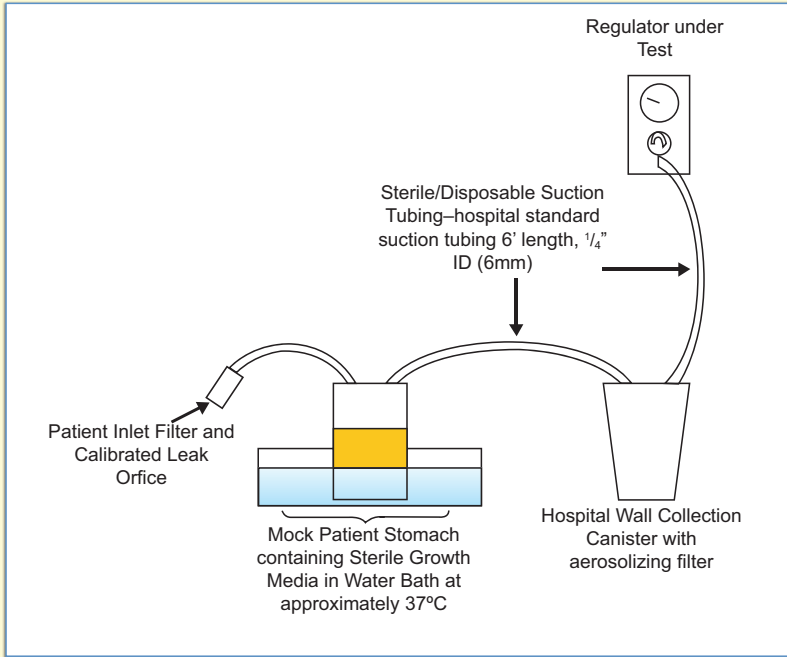


Figure 1: Simulated NG circuit for evaluating the flow of contamination from the regulator to the patient circuit.

Results

Assumption 1

Suction regulators from 5 major manufacturers were evaluated for bacterial contamination. Of the 470 regulators swabbed, 173 (36%) produced growth when streaked onto TSA plates. Upon evaluation by a third party testing facility, the following organisms were identified:

<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>	<i>Enterococcus faecium</i>
<i>Bacillus cereus</i>	<i>Staphylococcus warneri</i>	<i>Staphylococcus lentus</i>
<i>Aerococcus viridians</i>	<i>Micrococcus lylae</i>	<i>Alloccoccus Otitis</i>
<i>Kytococcus sedentarius</i>	<i>Bacillus megaterium</i>	<i>Bacillus circulans</i>
<i>Bacillus fusiformis</i>	<i>Bacillus subtilis</i>	<i>Bacillus mycoides</i>
<i>Bacillus flexus</i>	<i>Bacillus licheniformis</i>	<i>Bacillus coagulans</i>
<i>Bacillus thuringiensis</i>	<i>Brevibacillus choshinensis</i>	<i>Paenibacillus circulans</i>
<i>Bacillus sporothermodurons</i>	<i>Brevibacillus laterosporus</i>	

Assumptions 2 and 3

Running a contaminated regulator in a simulated NG circuit proved that it is possible for the canister and ultimately the patient to become infected. In this study, 0-200mmHg intermittent regulators, from five different manufacturers, infected the canister within the first 24 hours. All but one regulator was able to transmit microorganisms in as early as 30 minutes. The patient stomach became colonized at 24 hours for all brands except one.

Boehringer Laboratories, LLC • 300 Thoms Dr., • Phoenixville, PA 19460
1-800-642-4945 • www.boehringerlabs.com

(0000.068 Rev A)
L068