

IRRISEPT® Study

THE NEW STANDARD

Comparative Study to Demonstrate the Effectiveness of IrriSept® at Eradicating MRSA in Splatter Generated from Wound Irrigation



ABSTRACT

Background: Wound care procedures, including irrigation, are the second most commonly performed procedures in the emergency department setting. Wound irrigation is capable of generating significant splatter and aerosolized contamination in a treatment area. **Objective:** To study the efficacy of the IrriSept Wound Debridement and Cleansing System with CHG (chlorhexidine gluconate) in eradicating MRSA (Methicillin-Resistant Staphylococcus aureus) found in splatter produced during wound cleansing and irrigation. **Study:** In this two arm comparative study, the splatter produced from cleansing and irrigating a MRSA-inoculated wound model with normal saline in a syringe with an 18 gauge needle (Control) was compared to the splatter produced from cleansing and irrigating the wound model using the IrriSept system. The splatter from each arm was captured in Petri dishes, agar plated, incubated for 36 hours at 95°F and analyzed for any growth of MRSA. **Results:** The normal saline arm (Control) produced an average of $(1.05 \times 10^6 \text{ CFU/ml})$ of MRSA from the splatter, while IrriSept arm produced no MRSA growth $(0/\text{CFU/ml})$ from the splatter. **Conclusion:** The splatter produced from irrigation during the IrriSept arm contained no MRSA growth. Conversely, the splatter produced from irrigation during the Control arm contained a very high MRSA load. Test results show that IrriSept eradicates MRSA during wound cleansing and irrigation.

INTRODUCTION

Pressurized wound irrigation is a proven, effective method of cleansing open wounds to reduce the risk of infection. The American College of Emergency Physicians (ACEP) treatment guidelines for penetrating extremity trauma recommends copious irrigation with normal saline at pressures of 7 to 8 pounds per square inch (7-8 psi).¹

However, wound irrigation can produce splatter and aerosolized contamination when pressurized normal saline is directed at open, contaminated wounds. Blood, blood products, tissue, debris, and microorganisms dispersed by irrigation are potential sources of contamination for other patients, healthcare workers, and the environment. Earlier investigations of wound irrigation focused on blood-borne illnesses and transmissions to medical care workers, particularly cutaneous and mucous membrane exposure with possible transmission of HIV and hepatitis B or C viruses during jet wound irrigation.² Subsequently, effective barrier precautions were developed and implemented. However, today the medical community is faced with continued threats from environmental contamination with pathogenic bacteria.

These environmental contaminations may occur at a significant distance from the treatment area. *Staphylococcus aureus*, *methicillin-resistant S. aureus (MRSA)*, *Streptococcus*, *vancomycin-resistant enterococcus (VRE)*, *Clostridium difficile* and other pathogenic bacteria can survive on inanimate objects for prolonged periods.³ Indeed, an outbreak of multi-drug resistant *Acinetobacter baumannii* has been associated with pulsatile wound lavage.⁴

Community-associated (CA) MRSA has more than tripled the number of skin and soft tissue infections treated in emergency departments (EDs) in recent years, increasing potential hospital environmental exposure.⁵ The Centers for Disease Control and Prevention (CDC) reports that wound care procedures, including irrigation, are the second most commonly performed procedures in the emergency department setting.⁶ Although no studies directly compare hospital-acquired infections to wound lavage environmental contamination in the ED, a proportional relationship is likely given studies in other wound treatment clinical settings.⁷ The results of one study suggested that patients occupying a room in which the previous occupant was a MRSA carrier had an increased risk of acquiring MRSA.⁸

Most ED staff perform wound irrigation with syringes or other methods that offer little-to-no device protection from splatter and aerosol contamination that contains microorganisms. This study investigates the potential role of a novel irrigation device in reducing microbial levels in splatter resulting from wound irrigation.

STUDY OBJECTIVE

The study compared the effectiveness of the IrriSept Wound Debridement and Cleansing System with chlorhexidine gluconate (CHG) to a traditional syringe wound irrigation method (60ml syringe with 18-gauge needle) with standard normal saline solution in eradicating MRSA bacteria in splatter resulting from wound irrigation.

MATERIALS AND METHODS

The study was conducted in a static chamber created from a plastic bio-waste container. The chamber contained 4 sterile Petri dishes, one on each side, to catch splatter during the wound irrigation, with the “wound” in the middle (Figure 1).

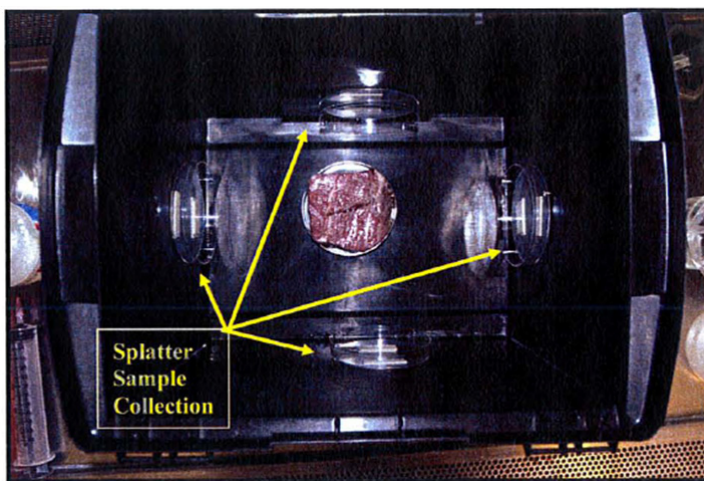


Figure 1

Test chamber with wound model in biosafety cabinet

The wound model was created from bovine skeletal muscle (rump roast) cut into a 3” x 3” piece and placed in a sterile Petri dish. An incision was made in this tissue, which was then exposed to 15 minutes of UV light to sterilize the wound model by destroying any naturally occurring bacteria. The wound model was then inoculated with approximately 1×10^9 CFU of MRSA (250ul, with a titer concentration of approximately 4.5×10^9 CFU/ml). The wound model was incubated for 4 hours at 95°F and then placed into the test chamber.

Once in the chamber, the “wound” was irrigated with 200ml of either IrriSept or the sterile normal saline solution (Control) with a syringe and an 18 gauge needle attached. Both devices were held about 2 inches away from the wound during irrigation.*

The splatter was captured, plated and incubated for 36 hours at 95°F. The quantitative amount of pathogen in the splatter samples were then analyzed.

Each test (IrriSept and Control) was conducted 3 times to ensure statistical accuracy.

**The IrriSept system directs the user to place the SplatterGuard directly on the wound. It was placed 2 inches away from the wound in this study to ensure adequate splatter for evaluation.*

RESULTS

Figure 2 depicts the average MRSA concentration in splatter for each of the three trials for the IrriSept system and the normal saline control group. No MRSA contamination was found in any splatter created during any of the 3 separate IrriSept wound irrigation tests. The normal saline control group splatter contained an average concentration of active, live MRSA of 1.05×10^6 CFU/ml. In addition, the IrriSept arm created less splatter volume (Figure 3), even when the device was improperly placed 2 inches away from the wound rather than directly over it, as is recommended. This may be a result of the SplatterGuard protection mechanism utilized on the IrriSept product.

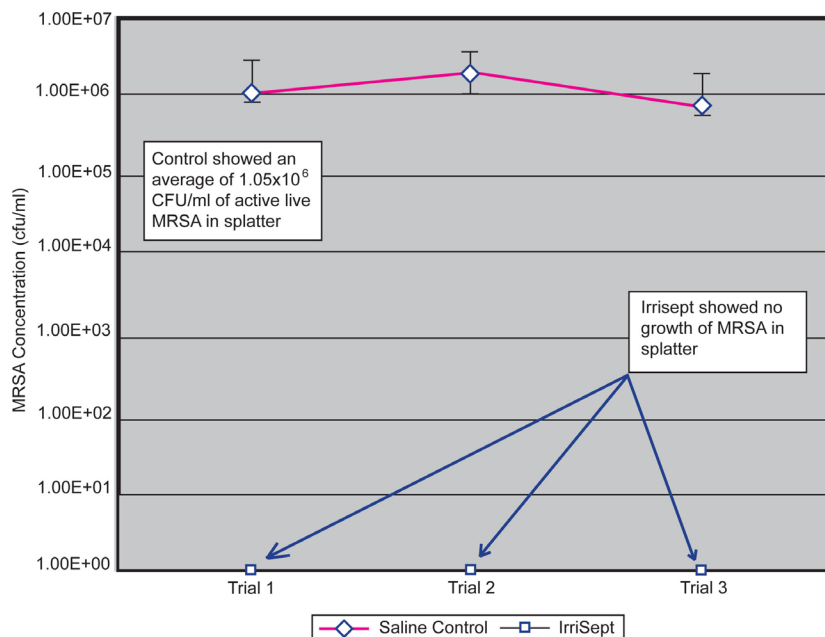


Figure 2 Average MRSA Concentration in splatter for Each Trial

Irrigation Solution		Splatter volume collected (ul)				Total collected
		Location 1	Location 2	Location 3	Location 4	
Saline	trial 1	450	670	710	240	2,070
	trial 2	610	550	1,200	120	2,480
	trial 3	830	370	800	360	2,360
IrriSept	trial 1	265	350	520	250	1,385
	trial 2	250	380	670	180	1,480
	trial 3	430	480	480	190	1,580

Figure 3 Average Splatter Volume Collected in micro liters (ul) for each run

CONCLUSION

Wound irrigation is capable of generating significant splatter and aerosol contamination over a considerable portion of patient treatment areas, exposing healthcare professionals and patients to infection. Environmental contamination associated with wound lavage is a serious concern.

A previous study found that the IrriSept system was effective at controlling splatter while delivering a higher volume of irrigation in less time than a syringe-only or syringe-splashcup method.⁹

This study demonstrated that not only did the IrriSept system produce less splatter during wound irrigation, but that the resulting splatter did not contain any MRSA. Conversely, while the splatter produced by a traditional irrigation method (sterile normal saline solution with a syringe and an 18 gauge needle) was not only greater in overall volume, but was heavily contaminated with live, active MRSA.

REFERENCES

- ¹American College of Emergency Physicians: Clinical policy for the initial approach to patients presenting with penetrating extremity trauma. *Ann Emerg Med.* 2009;33:612-636.
- ²Pigman EC, Karch DB, Scott JL. Spatter during jet irrigation cleansing of a wound model: A comparison of three inexpensive devices. *Ann Emerg Med.* 1993;22:1563-1567.
- ³Cimolai N. MRSA and the Environment: Implications for comprehensive control measures. *Eur J Clin Microbiol Infect Dis.* 2008; 27(7):481-93.
- ⁴Maragakis LL, Cosgrove SE, Song X, et al. An outbreak of multidrug-resistant acinetobacter baumannii associated with pulsatile lavage wound treatment. *JAMA.* 2004; 292(24):3006-3011.
- ⁵Pallin DJ, Egan DJ, Pelletier AJ, et al. Increased US emergency department visits for skin and soft tissue infections, and changes in antibiotic choices, during the emergence of community-associated methicillin-resistant Staphylococcus aureus. *Ann Emerg Med.* 2008 Mar;51(3):291-8.
- ⁶Centers for Disease Control. National Hospital Ambulatory Medical Care Survey: 2005 Emergency Department Summary. June 29,2007;386.
- ⁷Ho CH, Johnson T, Miklacic J, et al. Is the use of low-pressure pulsatile lavage for pressure ulcer management associated with environmental contamination with *Acinetobacter baumannii*? *Arch Phys Med Rehabil.* 2009; 90:1723-1726.
- ⁸Huang SS, Datta R, Platt R. Risk of acquiring antibiotic-resistant bacteria from prior room occupants. *Arch Intern Med.* 2006;166(18):1945-51.
- ⁹IrriMax Corp. Emergency Department Irrigation Comparative Splatter Study (on file at IrriMax Corp.).



IrriMax Corporation develops wound solutions that incorporate an innovative delivery method to obtain unmatched efficacy and safety. IrriMax's goal is to treat and prevent infection, improve patient outcomes and increase the safety of medical staff. Continual innovation and ongoing clinical research guide the development of IrriMax products.

U.S. Patent No. 5,830,197; 6,468,253; 7,662,125; D588,692; and D556,595. Additional U.S. and Foreign Patents Pending.

IRR201MRSAsplatter100510