Commentary

Commentary on: Surgical Site Irrigation in Plastic Surgery: What is Essential?

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"There Is Nothing New Except What Has Been Forgotten."—Marie Antoinette

Bacteria are Bad and More Bacteria are Worse

This simple concept is critical to understand the nuances of device-associated infection, including capsular contracture and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

We are honored to discuss this paper on a topic that we have had a keen interest in for over 20 years.[1] This topic has been important for all breast surgeons and has continued to be, especially with the recent confirmation of the role of bacteria in BIA-ALCL.[2-9] The authors have done a nice analysis in this study, and I will attempt to highlight certain portions to emphasize and sometimes clarify.

The authors state, "Numerous studies and recommendations exist regarding the choice of intravenous antibiotics, timing, and duration of their administration. But the use of topical antibiotic prophylaxis agents in plastic surgery is not specified and nonstandardized."[1] We agree with this statement, but not because the details of standardization are not available. They have been readily available for the past 15 to 20 years.[10-13] The problem is with surgeons inaccurately implementing these practices. With the recent developments of BIA-ALCL and the role of bacteria, surgeons have a renewed interest in minimizing bacterial load, including breast pocket irrigations. This study brings up some salient aspects of breast pocket irrigation to which we hope surgeons will finally pay attention.

The authors state, "The relationship between subclinical infection and capsular contracture was confirmed in multiple studies."[1] Unfortunately, they left out the most important one. The study that had been missing for many years that proved a cause-effect of bacteria and capsular contracture.[14] It is a good one for your files.

The authors have detailed the specific solutions that they tested; however, I would like to clarify some of the details and historical facts. The chosen abbreviations for the solutions are also confusing, and I will detail all of them below.

Triple Antibiotic Solutions

Many surgeons have confused this topic for the past 15 years. We described two triple antibiotic solutions. Betadine triple (in 2000) consisting of 50 cc full-strength 10% Povidone-iodine ("stock" Betadine), 1 g cefazolin, 80 mg gentamicin, 500 cc normal saline (NS).[10] Non-Betadine Triple (in 2001)—50,000 u Bacitracin, 1 g cefazolin, 80 mg gentamicin, 500 cc NS.[11] In this study, the authors made an error in their summary of our 2006 study stating that the irrigation was non-Betadine triple when it actually included Betadine triple.[12]

Additionally, the authors' solution "PCG" was intended to be the Betadine triple, but the authors did not prepare

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this properly, because they utilized 50 cc of (1/2 strength [5% povidone iodine]) when it should have been 50 cc of stock 10% povidone iodine. This will be explained in more detail later. This is not a huge deal, and I do not want to have it overshadow the important contributions of the study. The first important contribution of the study is awareness. There are two triple antibiotic solutions: Betadine triple and non-Betadine triple.

Quadruple Antibiotic Solutions

Following the lead from #1, some surgeons (probably the same ones that make terrible cooks and cannot follow recipes) have decided to combine Betadine and the non-Betadine triple solution. This is called a quadruple solution (the authors call this BPCG). They found that this had no advantage over the triple solutions.

The authors state, "Adams et al studied the effect of various combinations of topical antibiotics that will eliminate bacteria commonly cultured around breast implants. They compared the efficacy of in vitro serial dilutions of povidone-iodine and two double antibiotic solutions: gentamicin/polymyxin B and gentamicin/cefazolin against *S. epidermidis*, *S. aureus*, *E. coli*, *P. aeruginosa*, and *P. acnes* … They concluded that neither povidone-iodine nor a polymyxin B/gentamicin antibiotic alone were effective separately, but their combination worked synergistically with improved efficacy. The authors recommended 50 mL of povidone-iodine, 1g of cefazolin, and 80 mg of gentamicin in 500 mL of sterile saline for irrigation of breast pockets with incomplete evacuation of the solution before implant placement."

We need to further clarify our first publication that brought this whole topic to light in 2000.[10] The study was performed because the lead author observed that there were many surgeons utilizing a variety of breast implant irrigations with no logic behind their use. For this reason, the original study in 2000 was crafted to scientifically define how commonly utilized breast implant irrigations performed vs the most common bacteria found around breast implants. There were data at that time to suggest that Betadine itself inhibited wound healing and fibroblasts. The original recommendation was a Betadine triple irrigation (50 cc Povidone-iodine [Betadine], 1 g cefazolin, 80 mg gentamicin, 500 cc NS) that performed highest overall while at the same time minimizing the Betadine concentration.

In 2001,[11] we published another paper after the FDA came out following the saline breast implant pre-market approval hearings restricting the use of Betadine around implants. We studied a variety of non-Betadine-containing irrigations and found that the most effective was the non-Betadine triple antibiotic (50,000 u Bacitracin, 1 g cefazolin, 80 mg gentamicin, 500 cc NS). It should be noted that in this 2001 paper, we detailed the logic of the FDA restriction of Betadine, which was suspect and misguided. In 2006,[12] we published a clinical study utilizing both the Betadine triple and the non-Betadine triple antibiotic irrigations. Results included the capsular contracture rate being three to five times lower in breast augmentation compared to FDA clinical trials and three times lower for breast reconstruction compared to FDA clinical trials. Practice guidelines synergistic with the proven irrigation to minimize the bacterial load were detailed as well, which were subsequently later codified as the 14-point plan.[4,13]

The cytotoxicity of Betadine was an important factor in our ultimate recommendation for an irrigating agent; however, the studies that show Betadine to be cytotoxic are accurate, although they were generated in a laboratory—not in the human body. Clinicians know that Betadine can be utilized and the wounds will heal. Nevertheless, our triple Betadine solution was the lowest concentration of Betadine possible that still produced full broad-spectrum coverage.

The contact time was examined in this study. Correlation to the clinical setting is critical. We know that antibiotic irrigation is present in the properly irrigated implant pocket for at least 18 hours, because we have seen this in a patient who returned to the operating room 18 hours after a procedure. The critical question is whether the contact times in this study are clinically valid, and we contend that they indeed are, the longest being 30 minutes, which clearly occurs in the clinical setting.

Another salient point is the recent data supporting the role of Gram-negative bacteria in the pathogenesis of BIA-ALCL. The primary Gram-negative bacteria implicated is *Ralstonia Pickettii*. This bacteria was not tested in this study; however, the following should be noted. In recent testing in our laboratory, Ralstonia and other gram negative bacteria was best eradicated with Betadine-containing irrigations; however, the non-Betadine triple can kill Ralstonia, but it requires a longer contact time.

We do not fully agree with the authors' conclusions based on their data. The authors recommend utilizing the non-Betadine triple solution or chlorhexidine for breast pocket irrigation. First, we conclude that even the authors' current data on Betadine triple showed that it has excellent full-spectrum coverage for all bacteria testing except for slight MRSA growth. Furthermore, we submit that if the proper mixture of the Betadine triple (ie, 50 cc of full strength—10% Betadine) was utilized, MRSA would have been fully covered as well. The data in this study do support the use of Betadine triple in addition to the non-Betadine triple, and we also deduce that 50% Betadine is another viable alternative to breast implant irrigation.

The authors have discounted Betadine due to its wound-healing effects; however, in reality, especially the lower concentration such as in the Betadine triple, these negative effects are minimized. With that being said, we agree with the authors that full-strength Betadine should not be utilized due to it tissue toxicity.

Regarding chlorhexidine, we would caution surgeons to be wary about new recommendations of unproven breast pocket irrigations, especially when there are excellent

proven alternatives readily available. It does not make a lot of sense or may not even be safe to utilize alternative irrigations without long-term clinical trials that demonstrate their efficacy around breast implants compared to the three proven breast implant irrigations (Betadine triple, non-Betadine triple, and 50% Betadine) that for nearly 20 years have been shown to be safe with their effects on breast implants as well as their efficacy in preventing bacterial load in capsular contracture/bacterial-associated device infection.

Conversely, there are no good data, even short-term data, regarding the effect of chlorhexidine on the breast implant pocket or implants. For this reason, we would not recommend utilizing chlorhexidine or any other irrigation that somebody simply tests and touts as being effective/superior. Furthermore, with the FDA warning bulletin in February 2017 regarding allergic reactions to chlorhexidine, the future track record of this product is in serious doubt.[15]

We do congratulate the authors on an excellent study and one that has helped clarify important aspects of one of the most common surgical techniques practiced in plastic surgery. The reader should make sure to focus on the important distinctions elucidated in this study.

The proven breast pocket irrigations remain and include:

1. Betadine triple: 50 cc Betadine (stock), 1 g cefazolin, 80 mg gentamicin, 500 cc NS.
2. Non-Betadine Triple: 50,000 u Bacitracin, 1 g Cefazolin, 80 mg gentamicin, 500 cc NS.
3. 50% Betadine, if Betadine triple is not available. It should be noted that Betadine was re-approved by the FDA in August of 2017, and is no longer off-label to use.[16]

No additional benefit is gained with: Quadruple Irrigation - Betadine + Non-Betadine triple antibiotic.

Chlorhexidine (0.05%) is effective vs the bacteria of interest, but it lacks the robust clinical usage data needed over time for the proven irrigations (above), and it also has an issue with an FDA allergy warning.

Reducing the bacterial load around implants is the end objective. As history has proven, surgeons should avoid putting their "spin" on the specifics of these irrigations, and simply utilize the proven ingredients and ratios as recommended. Furthermore, it is the proper irrigation plus additional techniques (14 Point Plan) tested and data driven over time that are recommended to minimize device-associated infection, capsular contracture, and BIA-ALCL.[10-13]

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