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Breast

Comparison of Breast Reconstruction Outcomes Using Oxychlorosene versus Triple Antibiotic Solution for Pocket Irrigation

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Background: Breast pocket irrigation with antiseptic solutions is performed to reduce contamination with breast implants. The optimal antiseptic irrigation solution and the efficacy of individual practices are unclear. Oxychlorosene sodium is frequently used at our institution. Oxychlorosene is bactericidal with a mechanism of action of oxidation and hypochlorination. The purpose of our study was to compare the outcomes of oxychlorosene sodium irrigation with triple antibiotic solution (TAS) in implant-based breast reconstruction.

Methods: All patients who underwent implant-based reconstruction after mastectomy were reviewed. The primary predictive variable was type of solution used for pocket irrigation (TAS or oxychlorosene). Outcome variables included surgical site infection, device removal, and wound complications.

Results: Between 2013 and 2018, 331 implant-based breast reconstructions were performed. Of these, 62% (n = 206) received oxychlorosene for surgical pocket irrigation (group I), and 38% (n = 125) received TAS (group II). Group I had an 11.7% (n = 24) 90-day surgical site infection rate, with 4.9% (n = 10) requiring oral antibiotics, 2.4% (n = 5) requiring intravenous antibiotics without device removal, and 4.4% (n = 9) requiring prosthetic removal. Group II had an 11.2% (n = 14) 90-day infection rate, with 5.6% (n = 7) requiring oral antibiotics, 2.4% (n = 3) requiring intravenous antibiotics without device removal, and 3.2% (n = 4) requiring removal ($P = 0.90$). When comparing the cost of oxychlorosene irrigation with TAS irrigation, oxychlorosene was less expensive.

Conclusions: Oxychlorosene and TAS have similar surgical site infection rates in prosthetic breast reconstruction. Ease of preparation and cost make oxychlorosene a more favorable option for antibiotic irrigation in reconstructive breast surgery with prosthetic devices. *(Plast Reconstr Surg Glob Open 2022;10:e3975; doi: 10.1097/GOX.0000000000003975; Published online 18 August 2022.)*

INTRODUCTION

Over 400,000 patients undergo breast implant placement annually for augmentation or reconstruction.[1] Bacterial contamination of implants can lead to acute infection and chronic biofilm. Infection in breast reconstruction occurs in up to 22%.[1–5] Studies frequently report 30-day surgical site infection rates. However, 47%–71% of infections occur beyond this period.[5] Therefore, implant infection is likely even more common than reported. Mild infections may be treated with outpatient therapy but still require antibiotics and additional office visits. More severe infections may necessitate inpatient hospitalization, intravenous antibiotics, and implant removal. Chronic bacterial biofilm has been implicated in breast implant illness and anaplastic large cell lymphoma (ALCL).[6–19]

Breast pocket irrigation with antiseptic solutions is used in attempt to reduce implant contamination. As operative practices have considerable heterogeneity, the optimal antiseptic irrigation solution and outcomes of individual practices are unclear. The most commonly used antibiotic irrigation solution is triple antibiotic solution (TAS).[20] However, recent studies have shown efficacy of

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other antiseptic solutions such as hypochlorous acid and povidone-iodine.[21,22] Currently, there is no current consensus on breast implant pocket irrigation.

Oxychlorosene sodium (Clorpactin WCS-90, United Guardian, Hauppauge, N.Y.) has been used historically as an antiseptic, but there are limited data for breast implant surgery.[23] It is a derivative of hypochlorous acid and is a powerful bactericidal, fungicidal, and virucidal.[24] A recent survey of American Society of Plastic Surgeons members showed that 14% of responders used oxychlorosene for breast implant irrigation.[25] Our institution has commonly used oxychlorosene irrigation for implant-based breast reconstruction because of low cost and ease of use.[23] Comparative studies between surgical irrigation solutions are needed. The purpose of this study was to compare triple antibiotic and oxychlorosene surgical irrigation for implant-based breast reconstruction.

Takeaways

Question: Is oxychlorosene irrigation equivalent to triple antibiotic solution irrigation in breast reconstruction?

Findings: Patients who underwent breast reconstruction with the use of oxychlorosene and triple antibiotic solution for irrigation had similar rates of postoperative infection and complications.

Meaning: Oxychlorosene and triple antibiotic solution have similar surgical site infection rates in prosthetic breast reconstruction.

METHODS

Study Design

The institutional review board at Indiana University reviewed and approved this retrospective study. The inclusion criteria were women who underwent postmastectomy breast reconstruction with unilateral or bilateral prosthetic devices (ie, either tissue expanders or direct to implant) between 2012 and 2019. Patients were divided into two groups based on pocket irrigation fluid: group I (oxychlorosene) and group II (TAS; cefazolin, gentamycin, and bacitracin). Those who underwent autologous breast reconstruction were excluded from the study. Records that did not specify irrigation or used other fluids that were not oxychlorosene or TAS were also excluded. Patients who did not have documented follow-up 3 months after surgery were also excluded.

Data Collection

Demographic variables, including age, medical comorbidities, body mass index (BMI), and smoking history, were collected. Additional data collected were operative details, surgical irrigation utilized, timing of reconstruction, location of implant, use of mesh, use of adjuvant/neoadjuvant chemotherapy, use of radiation therapy, and staging of cancer. Postoperative complications within 90 days of surgery including infection requiring oral antibiotics, infection requiring intravenous antibiotics, implant removal, wound dehiscence, and reoperation rates were also collected. The Center for Disease Control defines surgical site infections within 90 days for those with implantable devices. Therefore, infections within 90 days were used in this study to define a postoperative infection.[26]

Data were collected and managed using the Research Electronic Data Capture electronic data capture tools hosted at Indiana University. Research Electronic Data Capture is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources.[27] Statistical analysis was performed within SPSS Statistics version 19 (IBM Corporation, Chicago, Ill.). Two-tailed values of P less than 0.05 were considered significant. Continuous variables were compared using t tests. Categorical data were evaluated using Fisher exact test. Means are presented with SD.

RESULTS

During the study period, inclusion criteria were met by 202 patients who underwent implant-based breast reconstruction including tissue expander and direct to implant (n = 331 devices). Unilateral reconstruction occurred in 36.6% (n = 73), and 63.4% (n = 129) were bilateral. The average age was 50.2 ± 11.4 years. The mean BMI was 27.5 ± 6.0 kg/m^2. Breast cancer was the indication for mastectomy in 79.7%. Other reasons for mastectomy included ductal carcinoma in situ, (13.3%), lobular carcinoma in situ (0.4%), and prophylactic (10.3%). The most common medical comorbidities included hypertension (26.2%, n = 53), hyperlipidemia (16.3%, n = 33), depression (13.9%, n = 28), and diabetes (7.9%, n = 16).

There were 124 patients who underwent 206 breast reconstructions performed with oxychlorosene surgical irrigation (group I). The average age was 49.2 ± 11.5 years. The average BMI was 27.1 ± 6.1 kg/m^2. The indication for mastectomy was breast cancer in 76.6%. The most common medical comorbidities included hypertension (17.7%, n = 22), hyperlipidemia (17.7%, n = 22), depression (12.1%, n = 15), and diabetes (8.1%, n = 10). Of these patients, 11.3% (n = 14) were tobacco users (Table 1). There were 78 patients who underwent 125 breast reconstructions performed with TAS irrigation (group II). The average age was 51.8 ± 11 years. The average BMI was 28.1 ± 5.9 kg/m^2. Mastectomy was performed for breast cancer in 84.6%. The most common medical comorbidities included hypertension (39.7%, n = 31), hyperlipidemia (19.2%, n = 15), depression (16.7%, n = 13), and anxiety (9.0%, n = 7). Of these patients, 10.4% (n = 8) were tobacco users (Table 1). When comparing the oxychlorosene and TAS group, there were no baseline demographic differences between the two groups with the exception of a higher prevalence of hypertension in the TAS group (39.7% versus 17.7%; P = 0.0005) (Table 1).

Immediate reconstruction was performed in 95.2% (n = 118) in group I and 89.7% (n = 70) in group II

Table 1. Demographic Characteristics of Patients Undergoing Prosthetic-based Breast Reconstruction

Category	Clorpactin	Triple Antibiotic	*P*
Total patients	124	78	-
Total breast reconstructions	206	125	-
Age	49.2 (11.5, 24–75.4)	51.8 (11, 30.4–77)	*0.11*
BMI	27.1 (6.1)	28.1 (5.9)	*0.27*
Smoking	11.3% (n = 14)	10.4% (n = 8)	*1.0*
Breast disease			
Breast cancer	76.6% (n = 95)	84.6% (n = 66)	*0.17*
Ductal carcinoma in situ	14.5% (n = 18)	11.5% (n = 9)	*0.54*
Lobular carcinoma in situ	0.8% (n = 1)	0% (n = 0)	
BRCA mutation	7.3% (n = 9)	9% (n = 7)	*0.66*
Prophylactic	1.6% (n = 2)	3.8% (n = 3)	*0.32*
Benign breast disease	3.2% (n = 4)	0% (n = 0)	
Diabetes	8.1% (n = 10)	7.7% (n = 6)	*0.92*
Hypertension	17.7% (n =22)	39.7% (n = 31)	*0.0005*
Coronary artery disease	0.8% (n = 1)	3.8% (n = 3)	*0.13*
Hyperlipidemia	14.5% (n = 18)	19.2% (n = 15)	*0.38*
Depression	12.1% (n = 15)	16.7% (n = 13)	*0.36*
Anxiety	5.6% (n = 7)	9.0% (n = 7)	*0.36*
Reconstruction timing			
Immediate	95.2% (n = 118)	89.7% (n = 70)	0.14
Delayed	4.8% (n = 6)	10.3% (n = 8)	
Mastectomy type			
Skin-sparing mastectomy	51.6% (n = 64)	74.4% (n = 58)	0.001
Nipple-sparing mastectomy	48.4% (n = 60)	25.6% (n = 20)	
Type of reconstruction			
Tissue expander	89.5% (n = 111)	85.9% (n = 67)	0.44
Direct to implant	10.5% (n = 13)	14.1% (n = 11)	
Prepectoral implant/tissue expander	15.3% (n = 19)	11.5% (n = 9)	0.45
Subpectoral implant/tissue expander	84.7% (n = 105)	88.5% (n = 69)	
Alloderm use	39.8% (n = 49)	62.8% (n = 49)	0.001
Additional oncologic treatment			
Neoadjuvant chemotherapy	29% (n = 36)	41% (n = 32)	0.08
Adjuvant chemotherapy	38.7% (n = 48)	37.1% (n = 29)	0.83
Adjuvant radiation	32.2% (n = 40)	29.5% (n = 23)	0.68

BMI, body mass index; BRCA, breast cancer gene.

(*P* = 0.14). In group I, 51.6% (n = 64) had skin-sparing mastectomy, and 48.4% (n = 60) had nipple-sparing mastectomy compared with 74.4% (n = 58) having skin-sparing mastectomy and 25.6% (n = 20) having nipple-sparing mastectomy in group II (*P* = 0.001). Group I had tissue expander reconstruction in 89.5% (n = 111) compared with 85.9% (n = 67) in the group II (*P* = 0.44). Subpectoral positioning of the tissue expander/implant was used in 84.7% (n = 105) in group I and 88.5% (n = 69) in group II (*P* = 0.45). Acellular dermal matrix was used in 39.8% (n = 49) in group I and 62.8% (n = 49) in group II (*P* = 0.001) (Table 1). All patients received postoperative antibiotics.

For oncologic treatment, neoadjuvant chemotherapy was used in 29% (n = 36) in group I and 41% (n = 32) in group II (*P* = 0.08). Adjuvant chemotherapy was used in 38.7% (n = 48) in group I and 37.1% (n = 29) in group II (*P* = 0.83). Adjuvant radiation therapy was used in 32.2% (n = 40) in group I and 29.5% (n = 23) in group II (*P* = 0.68). A total of 11.9% of patients in our study cohort (n = 24) had prior radiation to the implant site. In the oxychlorosene group, 11.3% (n = 14) had prior radiation, and in the TAS group, 12.8% (n = 10) had prior radiation (*P* = 0.74) (Table 1).

Group I had an 11.7% (n = 24) 90-day surgical site infection rate, with 4.9% (n = 10) requiring oral antibiotics, 2.4% (n = 5) requiring intravenous antibiotics without device removal, and 4.4% (n = 9) requiring prosthetic removal. Group II had an 11.2% (n = 14) 90-day infection rate, with 5.6% (n = 7) requiring oral antibiotics, 2.4% (n = 3) requiring intravenous antibiotics without device removal, and 3.2% (n = 4) requiring removal (*P* = 0.90). Infection occurred on an average of 34 days postoperatively (range, 8–86 d) in the oxychlorosene group and 34 days in the TAS group (range, 15–82 d) (*P* = 0.98) (Table 2). In group I, 5.8% (n = 12) had wound dehiscence requiring surgical closure compared with the 5.9% (n = 8) in group II (*P* = 0.83).

Table 2. Infectious and Wound Outcomes of Patients Undergoing Prosthetic-based Breast Reconstruction

Category	Oxychlorosene	Triple Antibiotic	*P*
Total patients	124	78	-
Total breast reconstructions	206	125	-
Infectious complications	11.7% (n = 24)	11.2% (n = 14)	0.90
Infection requiring oral antibiotics	4.9% (n = 10)	5.6% (n = 7)	0.77
Infection requiring IV antibiotics (w/o removal)	2.4% (n = 5)	2.4% (n=3)	0.99
Infection requiring device removal	4.4% (n = 9)	3.2% (n = 4)	0.60
Wound dehiscence requiring surgical debridement and closure	5.8% (n = 12)	5.9% (n = 8)	0.83

IV, intravenous.

DISCUSSION

The use of antiseptic irrigation with implant placement has been associated with improved outcomes and reduced morbidity.[28] Currently, there is limited literature on comparisons of available antibiotic irrigation. Our experience with oxychlorosene has been positive. Our study shows that it is a safe and effective antiseptic irrigation solution for breast reconstruction. In this retrospective study, we demonstrated comparable 90-day outcomes between oxychlorosene and TAS. Our study exhibited that oxychlorosene is a viable alternative to TAS for antibiotic irrigation in breast reconstruction.

An early report on oxychlorosene in 1955 as a surgical irrigation solution demonstrated activity against organisms such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Bacillus* species in a rapid manner.[29] Other early studies showed efficacy in a variety of settings such as breast surgery, skin grafting, and facial reconstruction.[24,30] Despite encouraging findings in a variety of surgical settings, oxychlorosene caught the most traction in the treatment of interstitial cystitis most notably for its ability to treat resistant cases.[31] Ngaage et al[22] recently examined oxychlorosene in an in vitro study and found similar efficacy as TAS in reducing bacterial load of Staphylococci species. Oxychlorosene was found to have a statistically significant bacterial effect against *Staphylococcus epidermidis*, a common organism isolated in breast implant colonization and infections.[22]

Oxychlorosene has been shown to be safe and efficacious in a multitude of routes of administration including orally, subcutaneously, intraperitoneally, and intrapleurally.[29] The contact time required for effect has been reported at 3 minutes, but there have been reports of efficacy at 1-minute contact time.[29] Oxychlorosene irrigation solution is easily prepared and inexpensive. At our institution, oxychlorosene is made by adding 2 g of oxychlorosene to 1 liter of sterile water (0.2% oxychlorosene) (Fig. 1). Our institutional cost of a 2-g vial of oxychlorosene is approximately $5 each, which is less than other antibiotic irrigations including bacitracin, povidone-iodine, hypochlorous acid, and TAS (Table 3).

There has been recent concern for the role of chronic biofilm in breast implant-associated ALCL and breast implant illness.[6–19] One theory is that the chronic biofilm infection around the implants induces T-cell hyperplasia, which may contribute to ALCL.[14] As a derivative of hypochlorous acid, oxychlorosene is able to penetrate bacterial biofilm, which has made it useful for wound care.[29] Given oxychlorosene's antimicrobial and antibiofilm activities, its relationship to chronic biofilm reduction and incidence of ALCL requires more investigation.

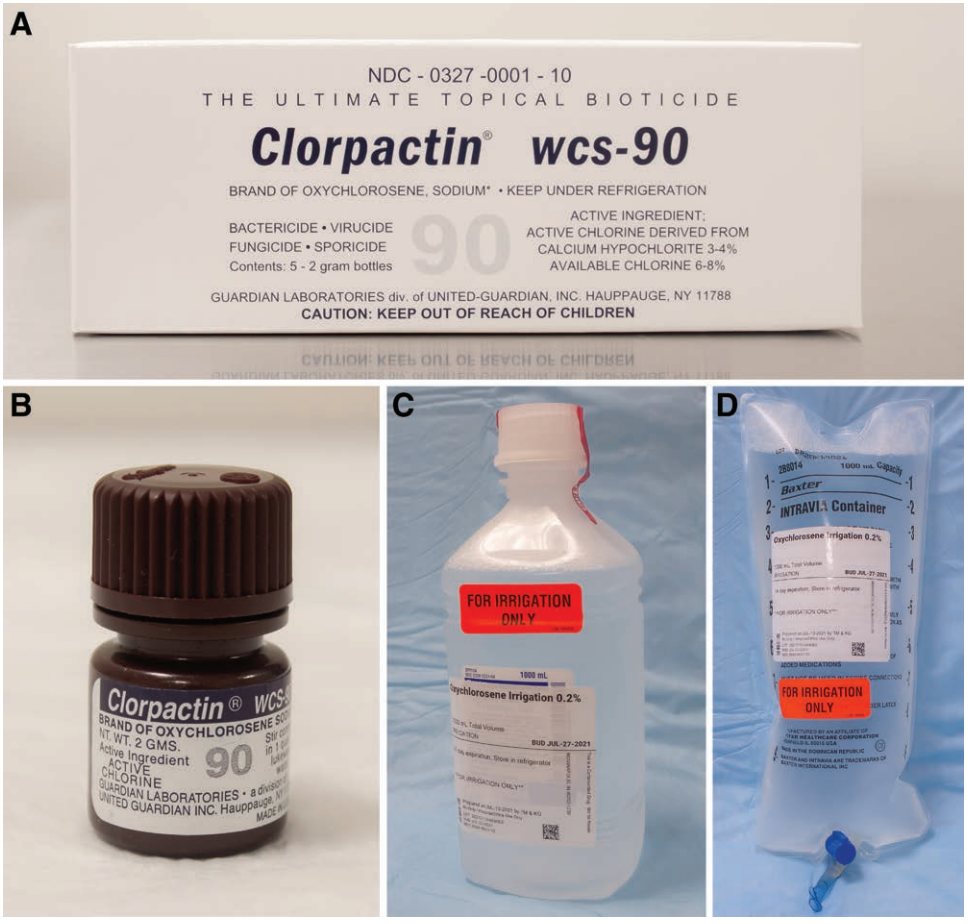

Fig. 1. Preparation of oxychlorosene. (A, B) Oxychlorosene packaging and unmixed bottle. (C, D) Preparation of oxychlorosene in irrigation bottle or intravenous bag of normal saline.

Table 3. Cost of Commonly Used Surgical Antibiotic Irrigation Solutions

Agent	Cost	Quantity
Oxychlorosene	$5.00	2 g mixed with 1-L normal saline
Triple antibiotic	$20.43	Bacitracin (50,000U) + cefazolin (1g) + gentamicin (80mg) mixed with 1-L normal saline
Povidone-iodine	$50.00	500 mL
Hypochlorous acid	$42.75	250 mL
Chlorhexidine	$35.95	950 mL
Bacitracin	$12.00	50,000 U mixed with 1-L normal saline

Antibiotic irrigation for both breast augmentation and breast reconstruction is a standard technique.[20,25] Although there is some evidence that sterile surgical technique supersedes use of antibiotic irrigation in breast augmentation,[32,33] most surgeons will utilize at least one antiseptic irrigation, especially in breast reconstruction where complication rates are higher.[1–5] American Society of Plastic Surgeons members were surveyed about pocket irrigation techniques, and the most commonly used were TAS (cefazolin, gentamycin, and bacitracin), TAS-povidone-iodine, dilute povidone-iodine, and bacitracin.[25] TAS has especially became popular after concern about delamination of silicone shell with povidone-iodine use.[34] Additionally, use of agents, such as chlorhexidine and hypochlorous acid, was investigated during the time period of the Food and Drug Administration warning on breast implants and the use of povidone-iodine.[21,35–37] There are potential contraindications to surgical irrigation fluids, such as povidone-iodine and TAS, which make alternative solutions appealing. Iodine or cephalosporin allergies can preclude the use of povidone-iodine or TAS. Other contraindications to povidone-iodine include hyperthyroidism/thyroid cancer, pregnancy, and breast feeding.[36] Antibiotic resistance would not prevent the use of TAS but would render it less effective compared with other irrigation solutions. With these limitations in mind, it would be best to determine equivalency among various surgical irrigation solutions.

Decreasing costs in breast reconstruction has been a topic of emphasis. Yan et al[38] found that the mean reconstructive cost in implant-based reconstruction is $22,323, which was increased by $12,554 if complicated by infection. Breast augmentation complications are not covered by insurance, and these additional costs are a burden for the patient and surgeon. Thacoor et al[39] found breast augmentation complications to have an average cost of $18,361. Breast implant infections have both a costly clinical and economic effect on the health system. With the decreased cost and comparable efficacy of oxychlorosene compared with TAS, oxychlorosene is great alternative to TAS.

In our study, oxychlorosene had similar infection and wound complication rates as TAS. Although our study did not show superiority of oxychlorosene to TAS, there are benefits with oxychlorosene over TAS. Oxychlorosene has lower cost than TAS. There are no known reported allergies to oxychlorosene. In addition, no antibiotic resistance mechanisms for oxychlorosene have been found. Interestingly, there was a higher rate of nipple-sparing mastectomy in the oxychlorosene group, which is a potentially higher risk reconstruction population. Nipple-sparing mastectomy is a higher risk reconstruction because of the lack of surgical exposure and higher risk of mastectomy skin flap necrosis.[40–42] Despite these potentially higher risk reconstructions in the oxychlorosene group, the outcomes of the oxychlorosene and TAS groups were similar.

Our retrospective study has several limitations. Postoperative infections and wound complications in breast reconstructive surgery are multifactorial, and it can be difficult to discern how much an impact surgical irrigation fluid has on outcomes. We developed our inclusion criteria so that our patient populations were comparable. Our study involved several different reconstructive surgeons who had different practice patterns for breast reconstruction, with dwell time being the important one. With the retrospective nature of this study, we were unable to assess how long breast implant pockets were irrigated for. However, dwell times were likely comparable given the usual time period surgeons utilized surgical antibiotic irrigation solution at our institution. Additionally, we recognize that a larger study would have been ideal to compare antibiotic irrigation solutions. Given the low incidence of infection after breast reconstruction, a larger study may have shown a difference between the two groups. We performed a power calculation to detect a 5% difference in infection and complication rates, which required a sample size of 1,178 patients ($1\text{-}\beta = 0.8$). However, at this time, we did not have more patients to include in the study. Despite these limitations, we believe our study showed equivalency between oxychlorosene and TAS.

In conclusion, our study demonstrated that oxychlorosene is a safe and effective agent for breast implant pocket irrigation. Oxychlorosene is not a widely known or utilized irrigation solution, but our study showed that its efficacy was comparable with TAS. Oxychlorosene is easy to use, inexpensive, and well tolerated.

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