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ORIGINAL RESEARCH

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Comparative effects of hypochlorous acid and povidone-iodine on infection and allergy risks in penile prosthesis surgery

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Abstract

Background: Penile prosthesis implantation carries an unavoidable risk of infection, which can lead to severe morbidity. This study aims to evaluate the efficacy of hypochlorous acid (HOCl) compared to povidone-iodine (PI) for surgical site antisepsis, with particular emphasis on infection prevention and allergic reaction rates. **Methods**: A retrospective analysis was conducted on 159 patients who underwent penile prosthesis implantation by a single surgeon. Patients were categorized into two groups: the PI group (n = 80, surgeries performed before 2023) and the HOCl group (n = 79, surgeries performed in 2023 and 2024). Postoperative infection rates and allergic reactions were recorded and statistically analyzed. **Results**: The number of infection and allergic reaction events was lower in the HOCl group (n = 4 and n = 1, respectively) compared to the PI group (n = 5 and n = 4, respectively), although the differences were not statistically significant. No cases required revision surgery due to infection and related interventions. HOCl demonstrated antimicrobial efficacy comparable to PI, while offering a substantial reduction in allergic reactions. **Conclusions**: HOCl appears to be an effective and well-tolerated antiseptic alternative to PI in penile prosthesis surgery. As the first study to investigate HOCl in this context, these findings provide a foundation for future research and clinical applications.

Keywords

Hypochlorous acid; Povidin-iodine; Penile prosthesis surgery; Infection; Allergy

1. Introduction

Penile prosthesis implantation (PPI) is widely recognized as a reliable and effective surgical method for the treatment of erectile dysfunction. However, this procedure carries the risk of serious complications, with infection being regarded as a relatively common and debilitating one. Infection increases morbidity and may lead to consequent surgical interventions, including repeated removal and re-implantation of the prosthesis [1]. Such complications significantly reduce patients' quality of life and create additional costs for healthcare systems [2].

Penile prosthesis infections typically occur through contamination of the surgical site during or before implantation, resulting in the formation of biofilm on the implant surface by microorganisms. Biofilm suppresses the host immune response and creates an environment resistant to antibiotics. Therefore, effective antisepsis of the surgical site plays a critical role in reducing the risk of infection [3]. Traditionally, povidone-iodine (PI) has been the preferred antiseptic agent for surgical site cleansing in penile prosthesis surgery. However, it is known that PI can cause allergic reactions, skin irritations and delay wound healing. Comparison of PI in scrubbing, as well as traditional antibiotics-containing dip and irrigation preparations, with novel antiseptic compounds remains a subject of ongoing research [4–6]. Hypochlorous acid (HOCl) has recently attracted attention as a potential alternative for surgical site cleansing due to its broad-spectrum antimicrobial effect, low risk of allergenicity, biofilm-inhibiting and disrupting efficacy, wound healing supportive properties, and ease of use [7]. In this study, the effectiveness of hypochlorous acid in terms of infection prevention and reducing allergy risks was retrospectively examined and compared with PI. The findings provide important evidence for evaluating whether hypochlorous acid is a reliable alternative for surgical antisepsis.

2. Materials and methods

2.1 Study design and participants

In this retrospective cohort study, a total of 159 patients who underwent penile prosthesis implantation by a single surgeon were included. All surgeries were performed under standard operating room conditions in the same hospital. Patients with any specific condition that could increase the risk of infection

(*e.g.*, immunodeficiency) were excluded from the study.

2.1.1 Group formation

Patients were divided into two groups based on the antiseptic agents used for surgical site cleaning:

Group 1 (PI: ST08049, Batticon, Adeka Medical Therapeutics Company, İstanbul, Türkiye): 80 patients who underwent surgery between 2020 and 2023 and had PI used for surgical site cleaning.

a. Group 1a (n = 65): 57 Infla10® AX (Inflatable penile prothesis, Rigicon Inc., Ronkonkoma, NY, USA), 8 Titan® (Inflatable penile prothesis, Coloplast Co., Minneapolis, MN, USA) implants.

b. Group 1b (n = 15): 13 Rigi10^{TM} (Malleable penile prothesis, Rigicon Inc., Ronkonkoma, NY, USA), 2 Genesis® (Malleable penile prothesis, Coloplast Co., Minneapolis, MN, USA) implants.

Group 2 (HOCl: lot011220, Crystalin, NPS Medical Therapeutics Company, İzmir, Türkiye): 79 patients who underwent surgery in 2023 and 2024 and had hypochlorous acid used for surgical site cleaning.

a. Group 2a (n = 65): 54 Infla10® AX (Inflatable penile prothesis, Rigicon Inc., Ronkonkoma, NY, USA), 11 Titan® (Inflatable penile prothesis, Coloplast Co., Minneapolis, MN, USA) implants.

b. Group 2b (n = 14): 12 Rigi10^{TM} (Malleable penile prothesis, Rigicon Inc., Ronkonkoma, NY, USA), 2 Genesis® (Malleable penile prothesis, Coloplast Co., Minneapolis, MN, USA) implants.

2.1.2 Implant types and preparation of the implants

All inflatable, hydrophilic coated penile devices were three-piece prostheses, either Infla10® AX (Rigicon Inc., Ronkonkoma, NY, USA) or Titan® (Coloplast Co., Minneapolis, MN, USA), while the malleable prostheses were either Rigi10^{TM} (Rigicon Inc., Ronkonkoma, NY, USA) or Genesis® (Coloplast Co., Minneapolis, MN, USA). All implants were soaked in a solution mix containing a total of 1 g rifampicin (13292-46-1, Rifocin, Sanofi Healthcare Products, İstanbul, Türkiye) and 800 mg gentamycin (1403-66-3, Genta, İ.E. Ulugay Medical Therapeutics Co., İstanbul, Türkiye) dissolved in 100 mL physiological saline before implantation of the prostheses. A separate solution of the same antibiotic concentration was prepared and used for cavernous irrigation.

2.1.3 Surgical and antisepsis protocol

All patients were prepared according to standard surgical and anesthesia protocols. The antisepsis protocol was applied as follows, according to the groups:

• PI group: The PI was used to clean the surgical site, followed by the placement of surgical drapes.

• HOCl group: The surgical site was disinfected with hypochlorous acid, a sponge was applied once for mechanical cleaning and HOCl was sprayed again.

In both groups, the same brand of penile prostheses was used during surgery, and antibiotic prophylaxis (fluconazole 400 mg, vancomycin 1 g, ceftriaxone 1 g) was administered.

2.1.4 Evaluation criteria

Postoperative infections and allergic reactions were defined according to the following criteria:

• Infection: Redness, edema, local increase in temperature at the surgical site, and detection of signs of infection in laboratory tests (*e.g.*, leukocytosis).

• Allergic reaction: Rash, itching or urticaria on the skin.

2.2 Statistical analysis

The data were analyzed using SPSS 25.0 software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp., USA). For continuous variables, the mean $\pm$ standard deviation was calculated, while percentage rates were calculated for categorical variables. Chi-square test and independent samples *t*-test were used to analyze differences between groups. A p-value of < 0.05 was considered statistically significant.

3. Results

3.1 Demographic and clinical characteristics of the study group

A total of 159 patients were included in the study. The PI group consisted of 80 patients, while the HOCl group included 79 patients. The average age of the patients was 60.01 $\pm$ 9.4 years in the PI group and 59.56 $\pm$ 9.8 years in the HOCl group ($p > 0.05$). Data on comorbidities and types of surgery are summarized in Table 1.

3.2 Postoperative infection rates

No cases requiring surgical revision due to serious infections were reported in either group. However, the infection rate was 6.25% (5 patients) in the PI group and 5.06% (4 patients) in the HOCl group ($p = 0.7$). Most infections manifested as localized redness and edema, were classified as subcutaneous surgical site infections, and occurred within the first postoperative week. These cases were successfully managed with intravenous antibiotic treatment.

• Inflatable Prosthesis: Infection rates were similar between the two groups ($p > 0.05$).

• Malleable Prosthesis: Infection was observed in 1 patient in the PI group, while no infections were recorded in the HOCl group.

3.3 Allergic reactions

A significant difference was observed between the groups regarding allergic reactions. Skin rash and itching occurred in 4 patients (5%) in the PI group, whereas only 1 patient (1.27%) in the HOCl group developed a mild allergic reaction ($p = 0.17$). The allergic reaction in the HOCl group resolved completely upon discontinuation of treatment.

4. Discussion

Device infection remains a significant and challenging complication in genitourinary (GU) prosthetic surgery, frequently necessitating reoperation and resulting in considerable mor-

TABLE 1. Demographics and clinical data of the cohort.

Characteristic	Group 1 (PI, n = 80)	Group 2 (HOCl, n = 79)
Age (years)[1]	60.01 ± 9.4	59.56 ± 9.8
Diabetes mellitus[2,3]	42 (52%)	43 (54%)
Hypertension[2,3]	8 (10%)	10 (13%)
Diabetes mellitus and hypertension[2,3]	16 (20%)	23 (29%)
Radical prostatectomy[2,3]	12 (15%)	11 (14%)
Peyronie's Disease[2,3]	12 (15%)	12 (15%)
Secondary surgery[2,3]	17 (21%)	17 (22%)
Infection[2,3]	5 (6%)	4 (5%)
Allergic reaction[2,3]	4 (5%)	1 (1%)

[1] *Ages are presented as mean ± standard deviation and compared by Student's t-test.*
[2] *Clinical data are given as numbers with percentages and compared by Chi-square tests.*
[3] *Comparison between the groups did not reveal a significant difference.*
PI: povidone-iodine; HOCl: hypochlorous acid.

bidity [3]. The primary etiology of such infections is the contamination of the prosthetic during implantation, which facilitates biofilm formation. Biofilm consists of extracellular polymers and matrix produced by microorganisms adhering to the implant surface, suppressing the host immune response and promoting antibiotic resistance [8]. Given this, effective surgical site antisepsis is essential for preventing biofilm formation and subsequent infections.

PI exerts its antiseptic effects by releasing free iodine, which disrupts microbial proteins and DNA. The recommended surgical preparation protocol includes a five-minute scrub, followed by a painting process and adequate drying time. This two-step process typically takes about ten minutes, aligning with expert recommendations for GU prosthetic implantation [9].

HOCl, an endogenous substance present in all mammals, exhibits broad-spectrum antimicrobial properties. It is naturally produced by neutrophils, eosinophils, mononuclear phagocytes, and B lymphocytes through the mitochondrial membrane-bound enzyme known as respiratory burst nicotinamide adenine dinucleotide phosphate oxidase [10]. HOCl exerts its antimicrobial effect by disrupting cellular integrity, primarily through selective binding to unsaturated lipid layers. Notably, HOCl is most effective in its antimicrobial action within a pH range of 4 to 7 [7, 11]. As a potent oxidizing agent, HOCl dissociates into H^+ and OCl^- in aqueous solution, leading to protein denaturation and aggregation. In addition to its effects on proteins, HOCl neutralizes viruses by forming chloramines and nitrogen-centered radicals, which induce DNA strand breakage and viral inactivation. Moreover, HOCl impairs enzymatic antioxidant defenses and disrupts glucose metabolism, thereby contributing to oxidative stress within the microbial cells [10, 12].

PI demonstrates a rapid onset of microbial action, but its efficacy is significantly diminished upon contact with organic matter such as blood or sputum [9]. Conversely, HOCl is widely used as an antiseptic across various fields due to its low allergenic potential and antimicrobial effectiveness. It is particularly preferred in dermatology and interventional procedures where skin integrity is a major concern, such as in plastic surgery for wound management and treatment of inflammatory dermatitis. Compared to chlorhexidine, which has been associated with hypersensitivity reactions and anaphylaxis, HOCl offers a safer alternative, particularly in aesthetic and dermatologic applications [11–13]. Importantly, sodium hypochlorite (NaOCl) and HOCl are distinct clinical entities; while NaOCl is commonly used for disinfecting non-living surfaces, purified HOCl is considered safe for application to human skin and mucous membranes [14].

A recent systematic review underscores the importance of infection prevention strategies in penile prosthesis implantation, highlighting that the introduction of antibiotic-impregnated implants has led to a substantial reduction in infection rates, decreasing from 2.5% to 1.1% over long-term follow-up [15]. However, the emergence of antibiotic-resistant bacterial strains has prompted the exploration of alternative antimicrobial approaches such as HOCl, which provides broad-spectrum antimicrobial activity without fostering resistance [16, 17]. HOCl effectively penetrates bacterial cell walls and disrupts essential cellular processes, making it highly effective against both planktonic and biofilm-associated bacteria [18].

A recent study also evaluated an innovative high-pressure pulsed irrigation system using HOCl for salvaging infected penile prostheses. The results demonstrated significant improvements compared to traditional irrigation techniques, highlighting HOCl as a safe and effective antimicrobial irrigation solution [19]. This approach has potential implications not only for managing existing infections but also for preoperative care, as HOCl can be used for disinfecting the surgical field to minimize postoperative infection risk [20].

The safety profile of HOCl is well-documented, with studies confirming its non-cytotoxicity at effective concentrations, making it suitable for use in sensitive anatomical regions such as the penile region [21]. Its role in wound care and infection

management is further supported by evidence demonstrating microbial load reduction across various clinical settings [11, 22]. This is particularly relevant for patients with increased infection risk, such as those with diabetes [23].

Beyond infection control, HOCl's minimal allergenic effects make it valuable in surgical applications. It is frequently utilized for wound cleaning and management due to its potent antibiofilm and broad-spectrum antimicrobial properties. Additionally, its favorable tolerability renders it a viable option for acute wound treatments. HOCl has also been effectively applied in orthopedic infections involving biofilm formation on implants [24]. Some practitioners use 0.025% HOCl for device maintenance by administering it via drainage postoperatively [20]. Furthermore, HOCl is utilized in ophthalmic clinics for blepharitis treatment [18]. Collectively, these findings emphasize HOCl's potential in both infection control and reducing allergenic reactions. Notably, our study found a lower incidence, though not statistically significant, of allergic reactions with HOCl compared to povidone-iodine.

Our study evaluated the efficacy of HOCl in penile prosthesis surgery, demonstrating its effectiveness in surgical sterilization. Its ease of application and shorter preparation time offer significant advantages over other antiseptics. From this standpoint, our study brings the initial comparison of HOCl against PI-based routine surgical site cleansing to the literature. However, the study is subject to several important limitations. Firstly, the data were evaluated retrospectively using routine clinical records, which reduces the evidence level compared to a prospective study with supervised clinical data collection; in particular, the earlier cohort's data may not fully reflect contemporary practice, as those cases were conducted before 2023. Moreover, even though all surgeries were carried out by a single surgeon, the cases spanned different years of practice, which may have influenced the results. Given that the HOCl group was treated more recently, we cannot exclude the possibility that improved clinical outcomes were due to increased surgical experience rather than the antiseptic itself. While we acknowledge that the observed lower (albeit not significant) infection rates in the HOCl group may partially reflect this experience, the difference in allergic reaction rates is more likely attributed to the chemical properties of the antiseptics. To fully exclude the effect of surgical experience, future studies should compare two cohorts, both operated on by a single surgeon using the identical aseptic protocols; however, achieving comprehensive standardization, even regarding patients' hygiene practices, remains challenging. Nonetheless, our findings suggest that HOCl-based surgical cleansing is at least non-inferior to PI-based asepsis and may offer advantages in terms of safer allergic profile. The absence of thorough allergy histories and the potential underreporting of minor allergic reactions are additional study limitations. Similarly, the reliance on clinical rather than culture-proven diagnoses of surgical site infections may have led to missed or misclassified cases. While our study is mainly based on clinical diagnoses, it is widely recognized that routine cultures are essential for definitive documentation of infection. Unfortunately, we cannot bring any evidence on culture-proven infections or differentiation of clinical infections from contaminations after penile prosthesis surgery. Lastly, we endorse for design and execution of prospective, randomized, if feasible, blinded studies comparing various antisepsis agents for surgical site cleaning to generate more robust evidence in this area.

5. Conclusions

Hypochlorous acid demonstrated comparable efficacy to povidone-iodine in preventing infection, while exhibiting a lower incidence of allergic reactions. These findings suggest that hypochlorous acid may serve as a reliable and effective alternative in surgical site antisepsis. Furthermore, as the first study to examine the use of hypochlorous acid in penile prosthesis surgery, our findings provide a foundation for future research and clinical applications.

AVAILABILITY OF DATA AND MATERIALS

All clinical data, in blinded fashion, is open to undergo external evaluation and will be shared in case required. Further inquiries that would require access to the personal information of the cohort can also be externally evaluated, albeit would not be shared with third parties, after institutional approval.

AUTHOR CONTRIBUTIONS

AEE—carried out the cases and claimed responsibility for ethical board approval. MSB, OE and EEA—reviewed and documented the clinical records. EÖ and UCT—transferred raw data to a blinded electronic data sheet. MEİ and AEE—performed the statistical analysis. ÖUÇ—performed a *post-hoc* analysis of the data. ÖUÇ and OE—drafted the initial manuscript. MEİ and ÖUÇ—supervised the manuscript and the dataset. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study has been approved by the relevant ethics committee and conducted in accordance with the Declaration of Helsinki (Antalya Training and Research Hospital Ethics Committee Approval Number: 2024-350). Informed consent was obtained from all patients prior to surgery.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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