CLINICAL ARTICLE SUMMARY

The Effect of Bupivacaine on the Efficacy of Antibiotic Coating on Penile Implants in Preventing Infection

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ABSTRACT

Background: In an effort to reduce dependence on opioids following inflatable penile prosthesis placement, intra-operative soaking of the implant in Bupivacaine (BUP) has been proposed as part of a multimodal approach to pain control. However, no study has shown if the addition of BUP affects the antimicrobial properties of InhibiZone on AMS700 (Boston Scientific, Marlborough, MA) and/or of antibiotic soaked Titan Coloplast (Coloplast Corporation, Minneapolis, MN).

Aim: To determine if BUP alters the zone of inhibition (ZOI) against *Staphylococcus epidermidis (S epidermidis)* and *Escherichia coli (E coli)*, common gram-positive and gram-negative bacterial causes of infection, respectively, created by InhibiZone coated AMS and/or by antibiotic-soaked Coloplast implant**.**

Methods: *S epidermidis* and *E coli* were spread on agar plates. After a 30-minute incubation, four AMS with InhibiZone strips treated with sterile saline or BUP (1.25 mg/mL) were placed on a plate. 4 Coloplast strips were dipped in varying routinely used concentrations of Rifampin (0-10 mg/mL) plus Gentamicin (0-1 mg/mL; rifampin and gentamicin (R+G)) solution with or without BUP. The ZOI for AMS with InhibiZone and Coloplast dipped in antibiotic solution was measured using ImageJ software. Normalized ZOI was calculated as (ZOI area/plate area) x 100. Unpaired *t*-test compared the mean ± SD ZOI between BUP and no BUP groups (n=4/group).

Outcomes Measures: The primary outcome of the study was the ZOI against *E coli* and *S epidermidis* at 24 and 48 hours

Results: Growth of both *S epidermidis* and *E coli* at 24 and 48 hours of incubation was inhibited in both implants and the addition of BUP did not alter the ZOI. Coloplast strips dipped in R+G produced a ZOI in a dose-dependent manner. Interestingly, the ZOI *against S epidermidis* compared to that of *E coli* was much wider for both implants.

Clinical Implications: This suggests that the use of BUP does not affect the protective effects of antibiotic dips and can potentially be used during penile prosthesis surgery pending clinical trials.

Strengths and Limitations: This is the first study to evaluate the effect of BUP on anti-bacterial dips. As with all in vitro analysis, further research must be done to see if these findings hold true in the clinical setting.

Conclusions: The addition of BUP does not impede the in vitro antibacterial activity of InhibiZone-coated AMS or R+G-soaked Coloplast. Whether these in vitro findings translate to surgical outcomes needs to be evaluated in future preclinical trials

COLOPLAST KEY TAKEAWAYS

- Bupivacaine (BUP) did not affect the ZOI at each R+G dosage of the Coloplast Titan.
- The mean ZOI against *S epidermis* of the R+G soaked Titan with BUP was 4x larger than the InhibiZone coated AMS with BUP.
- The mean ZOI against *E Coli* of the R+G soaked Titan with BUP was 2x more than the InhibiZone coated AMS with BUP.
- For *S epidermis* the R+G soaked Titan with BUP ZOI measured at a mean of 20.08 while AMS only measured at a mean of 4.9 at 24 hours.
- For *E* coli the R+G soaked Titan with BUP ZOI measured at a mean of 2.93 while the InhibiZone coated AMS with BUP only measured at 1.33 at 48 hours.
- The ZOI for Coloplast with R+G against gram-positive *S epidermis* outgrew the confines of each quadrangle of the plate between 12-48 hours for all but the lowest tested concentration.

Indications: The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are candidates for implantation of a penile prosthesis.

Contraindications: The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is contraindicated in patients with an active infection present anywhere in the body, especially urinary tract or genital infection; with a documented sensitivity to silicone; with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder; or, unwilling to undergo any further surgery for device revision.

Warnings: Implantation of the device may make latent natural erections, as well as other interventional treatment options, impossible. Men with diabetes or spinal cord injuries, as well as immunocompromised patients, may have an increased risk of infection associated with a prosthesis. Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition, leading to infection and loss of tissue. Implantation of a penile prosthesis may result in penile shortening, curvature or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical.

Precautions: Surgeons implanting penile prostheses should be familiar with the currently available techniques for measuring the patient, determining implant size, and performing the surgery. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible.

Potential Complications: Potential complications include scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.us.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. See the device manual for detailed information regarding the implant procedure, contraindications, warnings, precautions, and potential complications/adverse events.

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