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ARTICLE

Randomized controlled trial of benzocaine versus placebo spray for pain relief at hysterosalpingogram

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Abstract Many women experience pain during hysterosalpingogram (HSG). This prospective, randomized, double-blinded, placebo-controlled study assessed whether the use of benzocaine spray during HSG is associated with reduced pain as compared with placebo. Thirty women presenting for HSG were enrolled and randomized to either benzocaine or saline spray. Treatment groups were similar in age, race, parity, pre-procedure oral analgesic use and history of dysmenorrhoea and/or chronic pelvic pain. Median change in pain score from baseline to procedure was 50.6 mm (−7.4 to 98.8 mm) in the benzocaine group and 70.4 mm (19.8 to 100 mm) in the placebo group. There was no difference between groups after adjusting for history of dysmenorrhoea. There was no difference in resolution of pain in benzocaine versus placebo groups at 5 min post procedure — median pain score difference −11.1 (−90.1 to 18.5) versus −37.0 (−100 to 1.2) — or at 30 min post procedure. Satisfaction scores did not differ by treatment and did not correlate with pain score during the procedure (rho = 0.005). The use of benzocaine spray does not significantly improve pain relief during HSG nor does it hasten resolution of pain post HSG. Of interest, patient satisfaction was not correlated with pain.
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KEYWORDS: analgesia, benzocaine, HSG, hysterosalpingogram, pain relief, randomized controlled trial

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Introduction

Hysterosalpingogram (HSG) is an integral part of the evaluation of subfertile women, as it can be used to both evaluate intrauterine pathology and tubal patency. Poor pain control can often limit the quality of the examination. Furthermore, anticipation of pain may preclude patient acceptance of the examination and cause unnecessary anxiety. Up to 72% of women complain of pain during hysterosalpingography (Ayida et al., 1996). There is little consensus regarding the optimal management of pain during HSG. A Cochrane review of the current literature investigating pharmacological interventions for pain relief during HSG found no evidence of benefit when using pain relief medication compared with placebo both during and immediately after the procedure, but did demonstrate that there was a limited benefit 30 min after the procedure (Ahmad et al., 2007).

Oral, intrauterine and topical analgesics have been evaluated for pain relief at HSG (Ahmad et al., 2007; Ayida et al., 1996; Cengiz et al., 2006; Costello et al., 2002, 2005; Elson and Ridley, 2000; Frishman et al., 2004; Kafali et al., 2003; Liberty et al., 2007; Lorino et al., 1990; Owens et al., 1985; Peters et al., 1996; Robinson et al., 2007). Application of 20% benzocaine gel to the cervix has been shown to provide significant relief during HSG in one study (Lorino et al., 1990) while another suggested that application of lidocaine to the uterine cervix significantly reduces pain at the time of cervical instrumentation, but not during uterine filling and spillage (Robinson et al., 2007). However, interpretation of the current literature is limited by lack of blinding, placebo control, randomization and unclear allocation. Only two of the eight studies included in the Cochrane review performed a power calculation. In addition, the pain scales used were not always reliable and valid. Also, in cases where the pain scores were significantly different when compared with placebo, patient satisfaction was not always assessed. Given these limitations in the literature, there is currently no consensus on the optimal analgesic regimen during HSG.

This work performed a randomized, double-blinded, placebo-controlled investigation to address these limitations. The primary objective was to assess if benzocaine spray was associated with greater pain relief during and after HSG compared with placebo. The secondary objective was to assess if the use of benzocaine spray was associated with greater patient satisfaction after HSG.

Materials and methods

This randomized, double-blinded, placebo-controlled trial was conducted from December 2011 to April 2012 at the University of Pennsylvania after approval was obtained from the Institutional Review Board (protocol no. 809399, approved 15 December 2011). All women over the age of 18 who had been referred for hysterosalpingography during this period were deemed eligible. All patients scheduled for HSG at the institution were contacted to enrol in the study. Patients were excluded if they had a positive pregnancy test on the day of HSG or if they reported a hypersensitivity to benzocaine or related analgesic agents. As per routine procedure in this practice, pre-procedure ibuprofen was recommended. Informed consent was obtained on the day of HSG. Patients who consented were randomized to either benzocaine or saline placebo spray. Randomization was performed by the Investigational Drug Service at the Hospital of the University of Pennsylvania via a computer-generated random-number sequence in blocks of four. Drug canisters were blinded to both patient and clinician.

All hysterosalpingograms were performed in a single centre by the same group of physicians in a similar fashion. The hysterosalpingogram was performed with the patient in modified dorsal lithotomy position. A sterile speculum was placed by the provider and the cervix cleansed with chlorhexidine solution. Benzocaine or placebo saline was sprayed on the anterior lip of the cervix prior to application of a single-tooth tenaculum. The acorn cannula was inserted into the cervix. Approximately 5—10 ml water-soluble contrast dye was injected under fluoroscopy. Pain scores were obtained using a validated visual analogue scale (DeLoach et al., 1998) pre-procedure, immediately after HSG (designated as time 0) and at 5 and 30 min post procedure. Satisfaction was assessed at 30 min post procedure. Satisfaction was measured using a validated satisfaction survey (Barnhart et al., 2007) on a 5-point scale, 1 representing least satisfied and 5 extremely satisfied. The primary outcome was defined as the difference in pain score from pre-procedure to procedure (time 0). Secondary outcomes included pain resolution (time 0 to time 5, and time 0 to time 30) and patient satisfaction.

Statistical analysis

An a priori sample size calculation determined at least 28 patients were needed to detect a clinically significant 13 mm difference in pain score ($\alpha = 0.05$, power = 0.80) with a standard deviation of 12 mm. Intention-to-treat analysis was performed. t-Test or Fisher's exact test was used to evaluate differences in risk factors. Differences in the median change in pain scores were assessed using Wilcoxon rank-sum test. Fisher's exact test was used to assess differences in satisfaction scores by treatment group. Correlation between pain and satisfaction scores was assessed by Spearman's correlation coefficient. To analyse the change in pain score over time, a random-effects linear regression model was used to account for each individual's baseline in pain scores. STATA statistical software version 12.0 (StatCorp, College Station, TX, USA) was used for all statistical analyses.

Results

Thirty women consented the day of procedure (**Figure 1**). Only 29 patients received either benzocaine or placebo saline spray due to a single canister malfunction. Fifteen patients were analysed in the placebo group and 15 in the benzocaine group. The baseline characteristics were not statistically different between both groups. Patients were similar in age, race, parity, history of dysmenorrhoea and history of chronic pelvic pain (**Table 1**). Additionally, there was no difference in the groups with respect to the use of pre-procedure ibuprofen or other oral medication.

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