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THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Instruments and Techniques

AlphaScope vs Lens-Based Hysteroscope for Office Polypectomy without Anesthesia: Randomized Controlled Study

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ABSTRACT In this randomized controlled study, effectiveness, operative time, and acceptability of endometrial polypectomy were compared using an AlphaScope vs an office operative lens-based hysteroscope (LBH). One hundred fifty women with a diagnosis of endometrial polyp were operated on using an AlphaScope or LBH in the office setting. In 73 procedures using the AlphaScope (97.3%) and 68 using the LBH (90.7%), the polyp was successfully removed completely. In the AlphaScope group, 2 procedures were incomplete because of excessive endometrial mucosa thickness. In the LBH group, 3 procedures were incomplete because of difficulty in management of a large polyp, and 4 procedures were stopped because of patient pain and low compliance. Time to completion of the procedure and complete removal of the polyp was significantly shorter in the AlphaScope group than in the LBH group ($p < .05$). Similarly, the pain score at the end of the procedure was significantly lower in the AlphaScope group than in the LBH group ($p < .05$). The AlphaScope is an effective operative hysteroscope that increases the possibility of performing endometrial polypectomy in the office setting without anesthesia and improves the indications for and acceptability of office hysteroscopy. Journal of Minimally Invasive Gynecology (2011) 18, 796–799

Keywords: AlphaScope; Fibrohysteroscope; Hysteroscopy; Pain; Polypectomy

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As a result of recent improvements in technology, modern hysteroscopy is a completely different technique than traditional hysteroscopy insofar as feasibility, acceptability, and effectiveness [1–4]. Instruments that combine endoscopes smaller than 3 mm and 5F forceps with a total external diameter less than 5 mm have made it possible to perform diagnostic and operative procedures in an office setting [5].

Polypectomy is the most frequently performed hysteroscopic procedure. In recent years, several authors have demonstrated that endometrial polypectomy can be performed successfully in the office setting without any form of anesthesia [5–9], with obvious advantages insofar as costs and risks. However, performance of a painless office polypectomy without anesthesia is not always simple. Several factors may influence pain experienced during the procedure and the feasibility of the procedure. Factors related to the instruments such as the size of the hysteroscope that must negotiate the internal cervical ostium, the need to perform repeated intrauterine maneuvers, and characteristics of the polyp such as location, size, and shape influence the operative time and determine the degree of pain experienced by the patient [6].

In 2002, Bettocchi et al [5] published an observation study of 4863 office hysteroscopic procedures performed without use of analgesia or anesthesia. No discomfort was experienced by 71.9% to 93.5% of women who underwent the procedure to treat any pathologic condition with the

The authors have no commercial, proprietary, or financial interest in the products or companies described in this article.

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Submitted January 2, 2011. Accepted for publication August 12, 2011.
Available at www.sciencedirect.com and www.jmig.org

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doi:10.1016/j.jmig.2011.08.009

Fig. 1

Gynecare AlphaScope for use in the outpatient setting affords the possibility of a "one-stop see and treat."

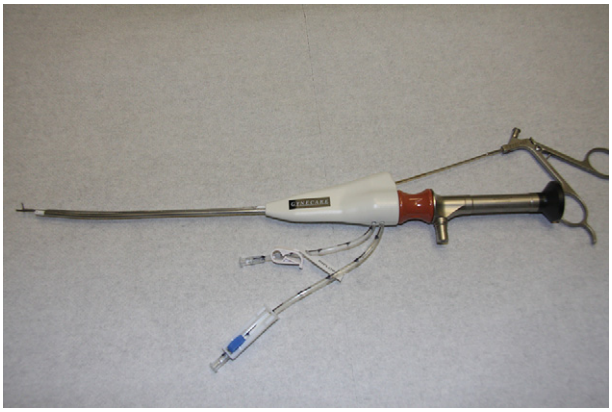
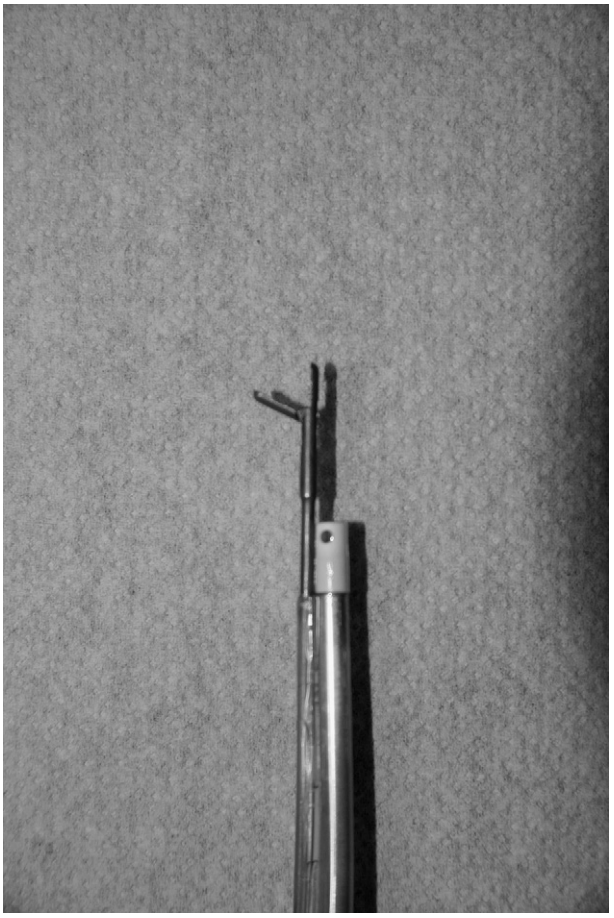


Fig. 2

AlphaScope with forceps inserted and open.



exception of endometrial polyps larger than the internal cervical ostium, in which 63.6% experienced little or moderate pain [5,6].

The limiting factors in terms of pain and compliance for office procedures in which 5F instruments have been used are the size of the polyp and the duration of the procedure. In 253 polypectomy procedures, Litta et al [9] observed that a visual analog score of 4 or lower was obtained when polyps were 2 cm or smaller or the procedure lasted 15 minutes or less.

The AlphaScope is a thin fiberoptic hysteroscope of 1.7 mm caliber that uses a plastic distensible external sheath so that its final diameter including the forceps does not exceed 3.5 mm. The device enables introduction of 7F forceps rather than the 5F instruments of most lens-based operative office minihysteroscopes. These characteristics may result in less pain, greater effectiveness, and rapidity in performing biopsies and removing polyps.

This randomized controlled study was performed to compare the effectiveness and acceptability of endometrial polypectomy using the AlphaScope vs an office operative lens-based hysteroscope (LBH).

Materials and Methods

Between September 2010 and March 2011, 150 consecutive women (median age 47.5 years; age range, 25–81 years) with a diagnosis of endometrial polyp who had been referred to our departments were randomized to be operated on in the office setting using either the AlphaScope (Fig. 1) or an LBH. Randomization was via a computer-generated randomization list. The study was approved by our institutional review board. The study and procedures were explained to the women before entering the study, and written consent was obtained. Exclusion criteria were suspected pregnancy, hormone therapy such as tamoxifen, history of neoplastic disease of the cervix (cervical intraepithelial neoplasia or carcinoma), and Papanicolaou test with evidence of cervical cancer. All polyps were smaller than 2 cm as measured at transvaginal ultrasonography. All women in of childbearing age were operated on during the follicular phase of the menstrual cycle (days 5–11).

Polypectomy was performed in the office setting without use of any anesthesia or analgesia. The women were divided into 2 groups. In Group 1, a fiberscope (AlphaScope; Gynecare, division of Ethicon, Inc., Somerville, NJ) (Fig. 2) equipped with 7F forceps was used, and in group 2, an LBH (Gimmi GmbH, Tuttlingen, Germany) equipped with 5F forceps was used. When appropriate, a Versapoint Twizzle (Gynecare) was used to cut the polyps and to facilitate extraction of fragments using the forceps. A 300 W xenon lamp and an HD videocamera were used. Distention fluid pressure was generated using a simple fall-form bag suspended 1 m above the patient. Time to completion of the procedure and degree of pain experienced by the patients were recorded. At the end of the procedure, patients were asked to grade their pain on a visual analog scale of 1 to 10.

The χ^2 test was used for statistical analysis. All variables were expressed as median and range. The *t* test was used for