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Original Article

Feasibility and Acceptability of Office-Based Polypectomy With a 16F Mini-Resectoscope: A Multicenter Clinical Study

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ABSTRACT **Study Objective:** To investigate the feasibility and acceptability of office hysteroscopic polypectomy using a novel continuous-flow operative 16F mini-resectoscope.

Design: Multicenter prospective case series (Canadian Task Force classification III).

Setting: "SS Antonio e Biagio" Hospital, Alessandria, and University "Federico II" of Naples.

Patients: One hundred eighty-two patients with endometrial polyps.

Interventions: Hysteroscopic polypectomy performed with 16F mini-resectoscope in an office setting, without analgesia and/or anesthesia.

Measurements and Main Results: Polypectomy was successfully performed in 175 patients in a single surgical step (96.15%), with only 1 patient (.54%) requiring a second office surgical step to complete the surgery. Seven patients (3.84%) were excluded from the analysis of operative parameters because of severe pelvic pain during the office procedure, which required a second inpatient surgical step. No major complications were recorded.

Conclusion: Our findings demonstrate that removal of endometrial polyps using the 16F mini-resectoscope in an office setting is a feasible and safe surgical option. Outpatient see-and-treat polypectomy is an acceptable and effective alternative to inpatient resectoscopic polypectomy. Journal of Minimally Invasive Gynecology (2016) 23, 418–424 © 2016 AAGL. All rights reserved.

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Endometrial polyps are benign growths attached to the inner wall of the uterus, consisting of a stromal axis covered by a single layer of columnar epithelium, containing variable quantities of glands and blood vessels [1]. In the international literature, the prevalence of endometrial polyps ranges from 7.8% to 34.9%, depending on how polyps are defined, diagnostic method used, and population studied [2,3]. Prevalence nevertheless appears to increase with age and is reported to be highest (11.8%) in postmenopausal women [1]. The main reasons for removing endometrial polyps include treatment of abnormal uterine bleeding and to exclude the presence of a malignant growth [4–8].

The most used method of endometrial polyp removal is hysteroscopic operation, under general or epidural anesthesia, by means of traditional resectoscopy [9–14]. The introduction of smaller-diameter instruments has allowed the hysteroscopic operation to become an office and outpatient procedure, used for various types of intrauterine pathology, whereby patients can be treated at diagnosis, that is, on a "see and treat" basis. Currently, the removal of endometrial polyps in the office setting avails itself of a variety of

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instruments, based on the experience of the surgeon and the type/size of the polyp.

In recent years many authors have described the see-and-treat polypectomy with 5F instruments as an effective and feasible technique, with very low complication rates [15–20]. However, this approach has been shown to have some limits, in particular conditions. First, the size of the polyps seems to be inversely correlated to a successful operation [18,20]. Furthermore, the required skills and maneuvers to perform operative procedures with 5F instruments are significantly different from those required during standard resectoscopic procedures, thus hampering the number of operators performing such procedures.

A new option applicable in office setting is the use of the small-sized hysteroscopic morcellator (MyoSure; Hologic, Bedford, MA, and Truclear; Smith & Nephew, Andover, MA), which has been demonstrated to be an effective, fast, and easily learned method [21]. However, it has the disadvantage of being a disposable tool and is considered too expensive for many hospitals. A novel 16F mini-resectoscope, recently developed by Gubbini Giampiero, MD ("Madre Fortunata Toniolo" Hospital, Bologna, Italy), allows surgeons the possibility of performing standard maneuvers of resectoscopic surgery in office hysteroscopic procedures with the advantages of miniaturized instrumentation. We previously published the results of a prospective pilot study on the feasibility of office hysteroscopic polypectomy using Gubbini's 16F mini-resectoscope [22]. The preliminary data on the 33 patients studied in an office setting demonstrated that the mini-resectoscope is an effective, well-tolerated alternative to inpatient resectoscopic polypectomy, also permitting removal of larger polyps with minimal patient discomfort [22].

The main objective of this multicenter study was to confirm the feasibility and effectiveness of office-based hysteroscopic polypectomy by means of Gubbini's mini-resectoscope, with various operators, in a large case series. Furthermore, we evaluated the possible correlations of polyp size with operative time and perceived pain during surgery as well as those of operative time and visual analog scale (VAS) score with operator experience.

Methods

In this multicenter prospective case series, we included all patients with ultrasonographic diagnosis of 1 or more endometrial polyps, measuring at least .5 cm, who underwent office hysteroscopic treatment in the Obstetrics and Gynecology Department of "SS Antonio e Biagio" Hospital, Alessandria, and the Hysteroscopy Unit of "University Federico II" of Naples from November 2011 to May 2013. All demographic and clinical data of the patients were recorded.

Diagnosis of endometrial polyps was performed by skilled operators on the basis of ultrasound scan (2- and/or 3-dimensional ultrasound) performed for abnormal uterine bleeding and infertility or for a standard routine check-up. Polyp size, number, and location in the uterine cavity were recorded. All patients underwent diagnostic and operative procedures contemporarily, in accordance with the "see and treat" philosophy, using the continuous-flow operative office 16F mini-resectoscope (Sopro-Comeg GmbH, Tuttlingen, Germany).

The following operative parameters were assessed: number of endometrial polyps treated for each patient, operating time, associated hysteroscopic procedures (i.e., myomectomy, adhesiolysis), eventual intra- and postoperative complications, pain perceived during the surgical procedure, and successful rate of procedure. Operating time was recorded from the introduction of the hysteroscope into the vagina (vaginoscopic phase) until the visual reassessment of the polyp base after its resection and extraction. In the case of more surgical steps, we considered the addition of separate times for the analysis. Polyp removal was deemed completed and procedure was defined as successful when no endometrial projection from the pedicle/base of the excised polyp was found at the end of the procedure.

The discomfort experienced by each patient was assessed immediately after the end of the surgical procedure and scored from values ranging from 0 (absence of discomfort/pain) to 10 (intolerable pain) on a 10-cm VAS. Pelvic pain was classified as "mild" when pain was rated from 0 to 4, "moderate" from 5 to 7, and "severe" from 8 to 10. These measures were obtained by a second operator, placed next to the patient, so as not to influence the assessment. Finally, to assess the effect of increasing experience of the gynecologist, the trends of procedure time and VAS were also evaluated.

At the end of the procedure we monitored each patient for at least 15 minutes, evaluating blood pressure and pulse. Any side effects that occurred during and after the procedure were recorded, and these included hypothermia, tremor, vagal symptoms such as syncope, hypotension, intense sweating, nausea, and vomiting. Although vital signs are not normally monitored during ambulatory procedures performed without analgesia or anesthesia, a crash cart is always available. All specimens were sent for histopathologic analysis. Approval for the study from the Institutional Review Board was obtained, and all patients signed an informed consent form.

Hysteroscopy

All procedures were accomplished by 2 trained hysteroscopists (DD and ADSS). Office hysteroscopic polypectomies were performed with a new continuous-flow operative office 16F mini-resectoscope (Sopro-Comeg Endoskopie GmbH and μ-Line Aeterna by Tontarra Medizintechnik GmbH-Germany), also known as Gubbini's hysteroscope. It is the smallest available continuous-flow resectoscopic system, with a work slide in titanium and a Quick-Locksystem of double sheath: 1 internal 14F diameter