



ORIGINAL ARTICLE

Outpatient hysteroscopic polypectomy: bipolar energy system (Versapoint®) versus diode laser – randomized clinical trial

Maria D. Lara-Domínguez¹, Jose E. Arjona-Berral¹, Rafaela Dios-Palomares², and Camil Castelo-Branco³¹Department of Gynecology, Hospital Reina Sofía, Córdoba, Spain, ²Department of Statistics and Operational Research, University of Córdoba, Córdoba, Spain, and ³Faculty of Medicine-University of Barcelona, Institut Clínic de Gynecology, Obstetrics and Neonatology, Hospital Clínic-Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Spain

Abstract

Objective: To compare the resection of endometrial polyps with two different devices: the Versapoint bipolar electrode and the Diode Laser.

Methods: One hundred and two patients diagnosed with endometrial polyps were randomly assigned to undergo hysteroscopic polypectomy: one group ($n=52$) performed with Versapoint bipolar electrode through a 5Fr working channel and the other group with Biolitec Diode Laser ($n=50$) using a specific fiber for polyps in a 7Fr working channel. All cases were managed on an outpatient basis, without anesthesia and using a rigid 30° hysteroscope and saline solution as a distention medium.

Main outcome measures: Complete resection rate, operative time, complications, intraoperative pain and relapse rate after three months.

Results: Intraoperative pain and polyp resection time was similar in both groups. Upon second look hysteroscopy at 3-month, a higher percentage of women of the Versapoint group presented polyp relapse (32.6 versus 2.2%, $p=0.001$). Elimination of the polyp after incomplete resection was higher in the Laser group. A significantly higher number of patients in the Laser group considered the procedure to be highly recommendable ($p=0.02$).

Conclusion: Polypectomy with Diode Laser resulted in fewer relapses and a higher procedure satisfaction rate as compared to Versapoint.

Keywords

Diode Laser, endometrial polyp, hysteroscopy, polypectomy, Versapoint

History

Received 6 June 2015

Revised 27 September 2015

Accepted 4 October 2015

Published online 30 October 2015

Introduction

Endometrial polyps are lesions with an unknown incidence. They are usually asymptomatic and are discovered as an incidental finding; in other cases, they are responsible for abnormal uterine bleeding. Polyps have also been linked to infertility [1]. They can occur at any age but are more common during the early menopause and depending on the study population their prevalence may vary between 7.8 and 34.9% [2].

The stromal cells of most polyps have a 6p21 rearrangement, which explains the neoplastic component and therefore their clinical importance. The overall risk of malignancy is 0.5–5% depending on different studies [3–5]. Koi et al. [6] have made reference to p53 overexpression in the endometrial glands of postmenopausal women, being this fact responsible for high proliferative activity in endometrial cells, which lead to polyp growth. The risk of malignancy of polyps in patients without symptoms may vary from 0.1 to 3% [7,8]. Therefore, polypectomy is accepted even in the absence of symptoms.

Polyps that are less than 4 cm are candidates for resection with a rigid hysteroscope, using electrosurgery or Diode Laser, both techniques evaluated in the present study. This technology allows the performance of surgical procedures without anesthesia and the

treatment of large number of patients on an outpatient basis [9]. The bipolar generator Versapoint is considered as an excellent ablation and cutting tool that has brought numerous benefits to outpatient hysteroscopy [10]. Laser technology in gynecology began to be used for treating cervical lesions. Recently, diode laser has been incorporated into hysteroscopy. Due to its 980 nm wavelength, it achieves high absorption simultaneously by hemoglobin and water, providing its hemostatic properties, and thus offering a high capacity for ablation and vaporization.

There is scant evidence about the advantages of the different methods for resecting polyps. Therefore, the objective of the present randomized study was to compare polypectomy using Versapoint and Diode Laser in terms of pain, complete resection rate, safety, satisfaction and relapses after three months.

Methods

Study design

This study compares the resection of endometrial polyps using Versapoint bipolar electrode versus Diode Laser. The sample size was established in order to detect a difference of one point in the mean value of the Visual Analogue Scale (VAS) of pain between both procedures, with a power of 90% ($p=0.05$); as such, 98 patients were required. Therefore, a total of 102 patients were included in this study.

After signing the informed consent, subjects were randomly assigned to the Versapoint or the Diode Laser group. Before the

Address for correspondence: Dr Camil Castelo-Branco, Institut Clínic de Gynecology, Obstetrics and Neonatology, Hospital Clínic, C/Villarroel 170, 08036-Barcelona, Spain. Tel: 34-93-2275436. Fax: 34-93-2279325. E-mail: castelobranco@ub.edu

hysteroscopy, patients were requested to fulfill the EuroQol questionnaire in order to determine the impact that symptoms caused by the polyp were having on their quality of life. Hence, they self-reported their state of health from 0 (the worst state of health imaginable) to 10 (the best state of health) [11]. Once the presence of the polyp was confirmed by hysteroscopy, it was resected without anesthesia. Women who requested for any type of anesthesia, as well as those with suspected malignant polyps and polyps larger than 40 or smaller than 10 mm were excluded from the study. Patients who had more than one polyp were included, and in these cases the millimeters of resected polyps were added together.

Ethical considerations

The ethical approval of this study was obtained from the Committee for Research Ethics in Córdoba and the Hospital Universitario Reina Sofía on 29 January 2013. Protocol registration receipt was completed when the study was ended on 7 August 2014 (clinical trials identifier NCT02126397).

Procedure

All procedures were performed with a 30° Bettocchi hysteroscope (Karl Storz GmbH & Co. KG, Tuttlingen, Germany), introduced by vaginoscopy without the use of a speculum or tenaculum forceps. Resection was performed once the polyp was identified.

Polyp resection in the Versapoint group was performed using a rigid 5 mm hysteroscope with a 5Fr (1.67 mm) working channel through which a bipolar electrode was introduced that had a twizzle tip connected to an electric generator (Gynecare, Ethicon Inc., NJ). Polypectomy in the Diode Laser group was performed using a rigid 6 mm hysteroscope with a 7Fr (2.3 mm) working channel through which a polyfiber was introduced and connected to a 980 nm Biolitec Ceralas HPD laser device (Biolitec AG, Vienna, Austria).

Intraoperative pain was assessed using a VAS with intensity rated from 0 to 10 (0 being no pain and 10 being unbearable pain). A categorical scale of the pain was also considered (0 no pain, 1–3 mild pain, 4–7 moderate pain and 8–10 intense pain).

Patients were discharged after the procedure and were requested to attend a follow-up three months later. At this point, they filled out a questionnaire to assess the level of post-procedure bleeding, pain and quality of life (improvement or not). The degree of satisfaction *with* and recommendation *of* the procedure was estimated using ordinal visual scales (very satisfied, satisfied, rather unsatisfied or very unsatisfied, *for satisfaction*, and highly recommendable, recommendable, not recommendable, not at all recommendable, *for recommendation*). After filling all questionnaires, a second-look hysteroscopy was performed in order to assess the persistence or relapse of the previous polyp.

Statistical analysis

Data were analyzed using a personal computer-based software package (SPSS 20, SPSS Inc. Chicago, IL) and presented as a mean $\pm$ standard deviations (SD, quantitative variables) and as absolute values and percentages (categorical variables).

Contingency tables and chi-square test were used to compare between groups demographic data, polyp location, complications, and ordinal scales of satisfaction and recommendation of the procedure, improved quality of life and symptoms. Student's *t*-test was used to compare quantitative data between studied groups, such as the mean pain score in VAS, the mean resection time and the size of the polyp. Analysis of variance (ANOVA) was used for the comparison of multiple variables between both groups. Spearman's coefficients (ρ) were calculated to test correlations

between resection time, polyp size, and pain and regression lines with the confidence intervals were plotted. Logistic regression was used to assess the occurrence of relapse in accordance with the type of resector adjusting for the influence of age. The alpha error was set at 5% and significance was established at $p < 0.05$.

Results

Of a total of 129 women who were assessed for participation in the study between February 2013 and February 2015, 102 were finally included. Of these, 50 were assigned to the Diode Laser polypectomy group, of which 46 (92.0%) achieved a complete resection. The other 52 women were allocated to the Versapoint bipolar electrode polypectomy group of which complete resection was achieved in 50 (96.1%). A total of 45 (90.0%) and 46 (88.5%) women attended the second-look hysteroscopy in the Diode Laser and in the Versapoint group, respectively (Figure 1).

The baseline characteristics of the women finally included are shown in Table 1. Women in the Versapoint group were older than those allocated to the Diode Laser group. Most of the polyps were benign endometrial polyps. One patient was diagnosed with a well-differentiated adenocarcinoma on the polyp and another with an atypical complex hyperplastic polyp. In both cases, a hysterectomy was performed. The mean polyp resection time with a Diode Laser was lower than with Versapoint (245.96 ± 181.9 versus 329.56 ± 245.0 s, respectively; $p = 0.01$). The greater the polyp size the longer the duration of the resection ($p < 0.01$). Complications related with the procedure included three vaginal syndromes after the polypectomy, one in the Versapoint group and two in the Laser group; all resolved by resting and none required hospital admission. Additionally, there was one case of pelvic inflammatory disease three days after the procedure in the Diode Laser group. No differences were found regarding intraoperative pain as measured with the VAS or in the ordinal scale (Table 2). The influence of the polyp location in the uterine cavity on pain scores was also considered but no differences were found ($p = 0.56$). Finally, incomplete resection of the polyp occurred in 4 and 2 cases in the laser and Versapoint group, respectively.

Upon second-look hysteroscopy, a relapse of the polyp in the same location was observed in 15 (32.6%) cases in the Versapoint group, whereas in the Diode Laser group polyp relapse was observed in only 1 (2.2%) patient ($p = 0.001$) (Table 2). To corroborate the occurrence of polyp relapse depending on the procedure and to assess the potential effect of age on the polyp relapse, a logistic regression was carried out using age as a covariate. The OR estimated for the resection procedure indicates that the likelihood of there being a relapse with Versapoint compared with Laser is 19.2 (95% CI 2.24–164.75). Of the four patients with an incomplete resection in the Laser group, three attended to the second-look hysteroscopy and in all of them no polyp was observed. The fourth patient rejected the check-up due to moving to a different city. Contrary to this, at the second-look, the polyp persisted in the two patients of the Versapoint group who had incomplete resection.

In terms of quality of life, 26 (52.4%) patients in the Diode Laser group referred an improvement in their quality of life after resection of the polyp. This figure was similar to that observed in the Versapoint group ($n = 22$, 45.8%). A total of 12 patients in the Versapoint group, who said that there was no improvement in their quality of life had persistence of the polyp upon the control hysteroscopy.

The symptoms during the three months after the polypectomy included irregular bleeding [11 (22%) patients in the Diode Laser group and 13 (25%) in the Versapoint group ($p = 0.89$)] and pain [9 (18%) patients in the Laser group and 7 (13.5%) in the

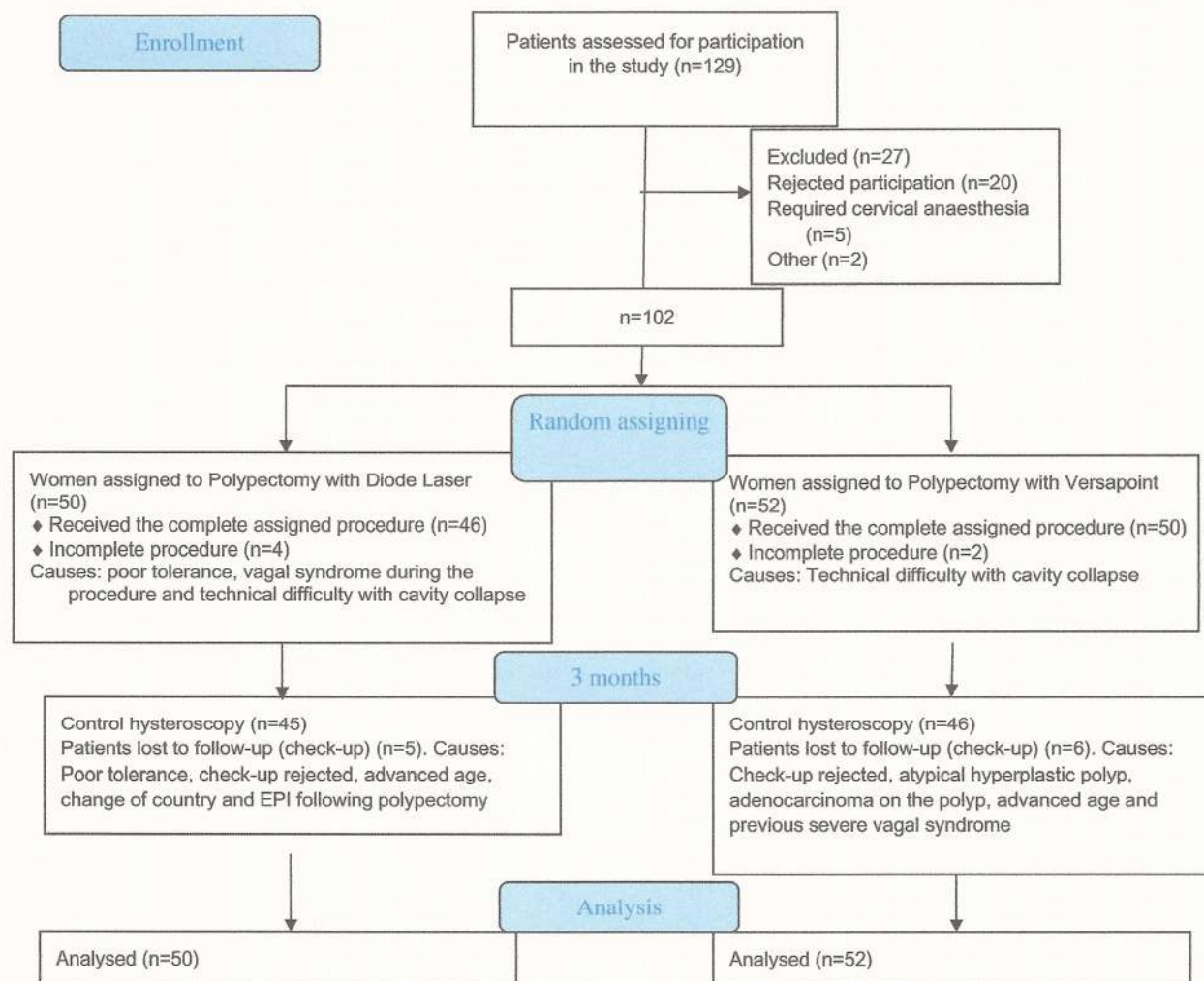


Figure 1. Consort flow chart of patients of the clinical trial.

Table 1. Baseline clinical characteristics and polypectomy data from all patients included in the study.

	Diode laser group (n = 50)	Versapoint group (n = 52)	p Value
Mean age (years)	49.1 ± 10.3	53.9 ± 10.2	0.02
Mean BMI (kg/m ²)	27.4 ± 6.3	30.1 ± 7.9	0.06
Nulligravid (n, %)	6 (12.0)	5 (9.6)	0.69
Mean parity	2.1 ± 1.1	2.0 ± 1.0	0.51
Menopausal (n, %)	25 (50.0)	35 (67.3)	0.07
Mean Quality of Life in accordance with symptoms	7.8 ± 2.5	8.1 ± 2.5	0.47
Symptoms at consultation (n, %)			
• Asymptomatic	23 (46.0)	23 (44.2)	0.53
• Hypermenorrhea	7 (14.0)	4 (7.7)	
• Metrorrhagia	20 (40.0)	25 (48.1)	
Mean total size of the resected polyp (mm)	20.1 ± 10.6	24.6 ± 13.0	0.06
Mean polyp resection time (s)	245.96 ± 181.9	329.56 ± 245.0	0.01
Pathology (n, %)*			
• Benign endometrial polyp	48 (47.0)	50 (49.0)	
• Simple hyperplastic polyp	2 (2.0)		
• Atypical hyperplastic polyp		1 (1.0)	
• Adenocarcinoma		1 (1.0)	

Data are presented as mean ± standard deviations or n, %.

*Percentages referred to the entire sample (n = 102).

Versapoint group ($p=0.48$]. In most of the cases, these complaints were limited to the first week following the resection.

The rate of very satisfied patients with this outpatient procedure tended to be higher in the Diode Laser group compared

with the Versapoint group (62.2 versus 39.1%). In addition, 71.1% of patients in the Laser group as compared with 28.3% in the Versapoint group referred the procedure as highly recommendable ($p=0.02$) (Table 2).

Table 2. Intraoperative pain assessment (VAS and ordinal scale) and the rate of polyp relapse and satisfaction and procedure recommendation three months after the outpatient hysteroscopic polypectomy.

	Diode laser (n = 50)	Versapoint (n = 52)	p Value
Pain VAS (0–10)	4.4 ± 2.9	4.4 ± 2.9	0.91
Pain – Ordinal Scale n, (%)			
No pain	3 (6.0)	5 (9.6)	0.88
Mild pain	19 (38.0)	17 (32.7)	
Moderate pain	21 (42.0)	23 (44.2)	
Intense pain	7 (14.0)	7 (13.5)	
Control 3 months after hysteroscopy n, (%)*			
Polyp relapse	1 (2.2)	15 (32.6)	0.001*
Elimination of the polyp after incomplete resection	3/4 (75)	0/2 (0)	0.37
Satisfaction with the procedure n, (%)*			
Very satisfied	28 (62.2)	18 (39.1)	0.21
Satisfied	16 (35.6)	24 (52.2)	
Rather unsatisfied	1 (2.2)	3 (6.5)	
Very unsatisfied	0 (0.0)	1 (2.2)	
Procedure recommendation n, (%)*			
Highly recommendable	32 (71.1)	13 (28.3)	0.02*
Recommendable	11 (24.5)	27 (58.6)	
Not recommendable	1 (2.2)	5 (10.9)	
Not at all recommendable	1 (2.2)	1 (2.2)	

Data are presented as mean ± standard deviations or n, %. VAS, Visual Analog Scale.

*Percentages referred to the number of women who attended follow-up at three months (n = 45 for the Diode Laser group and n = 46 for the Versapoint group).

Discussion

It is currently well accepted that outpatient polypectomy is preferred by both physicians and patients when compared to one-day hospitalization [12]. However, there are scant data when it comes to comparing the different instruments that are most suitable for outpatient hysteroscopic polypectomy. To the best of our knowledge, this is the first randomized clinical trial comparing outpatient polypectomy using Diode Laser versus Versapoint.

A recent study by Smith et al. [13] compared the polyp resection time of Bipolar Electrode versus Morcellator. Resection time was significantly lower for the Morcellator group (5 min and 28 s versus 10 min and 12 s). In the present study, a mean time of 4 min and 6 s was required for polypectomy with the Diode Laser and 5 min and 29 s with the Versapoint. The time difference between both studies may be explained by the fact that in Smith's study, time was measured from the vaginoscopy, while in the present study time was measured upon entry into the uterine cavity.

In general, it has been accepted that outpatient polypectomy is a safe technique with few complications, being in most cases vaginal syndromes that resolve spontaneously [14,15]. In the present series, there was one case of pelvic inflammatory disease after the Diode Laser procedure, which resolved with antibiotics. Outpatient polypectomy without anesthesia is a tolerable procedure for most patients, but in this study, the intraoperative mean pain score assessed with the VAS was higher than 4 for both the Diode Laser and for the Versapoint patients, corresponding to moderate pain. In Smith's study [13], pain referred by patients who underwent polypectomy with Bipolar Electrode was higher compared with Morcellator (5.20 versus 3.59, respectively). However, cervical anesthesia was used in 50% of Morcellator patients and in 58% of Bipolar Electrode patients. Therefore, providing local anesthesia to reduce patient's pain should be considered in most cases.

It is noteworthy to highlight that in the present study, mean pain was somewhat similar between studied groups; despite the fact that diode laser uses a bigger working channel than the Versapoint group (7Fr versus 5Fr). Results of studies addressing instrument size and pain may vary [16,17]. For instance, Cicinelli

et al. [16] upon comparing 3.5 mm AlphaScope with 5 mm Lens Based Hysteroscope and 7Fr with 5Fr Forceps observed that larger instruments and forceps resulted in lower effectiveness and acceptability. Contrary to this, Litta et al. [17] make reference to lower pain when smaller hysteroscopes are used. Equally, Dealbert et al. [18] reported a mean pain score of 2.49 (VAS of 0 to 10) when using a mini-resectoscope of 16Fr for polyp resection.

The most interesting finding of the present study was the higher percentage of patients with polyp relapses in the Versapoint group as compared to the Laser group at three months (32.6 versus 2.2%, $p = 0.001$). This may be explained by Laser's capacity to engage with water and hemoglobin allowing greater penetration in the soft tissues and consequently an adequate ablation and vaporization effect. Therefore, this may have allowed that Laser assigned patients with an incomplete resection, subsequently eliminated the polyp three months later; obviously, this did not occur in the Versapoint group. The logistic regression model corroborated that the Laser procedure is more efficient than Versapoint in the prevention of relapses. Another study focused on the risk of relapses after hysteroscopic polypectomies found that relapse is also higher in the resection group using monopolar energy as compared to morcellation [19].

In the present series, only one case of adenocarcinoma on the polyp and one case of atypical hyperplastic polyp was observed, both in patients with postmenopausal metrorrhagia. Similar figures have been reported in 770 asymptomatic postmenopausal women undergoing hysteroscopic polypectomy. One case presented with adenocarcinoma on the polyp and 1.2% atypical hyperplastic polyps [7].

Finally, patients in laser group were more prone to indicate an improvement of their quality of life. In addition, there were a higher number of patients in this group who felt very satisfied with the procedure. Moreover, it is noteworthy to highlight that three out of four patients in the Laser group reported the procedure to be highly recommended. This figure was less than 30% in the Versapoint group because of the higher relapse rate observed in the Versapoint group.

In conclusion, polypectomy with Diode Laser resulted in fewer relapses and a higher procedure satisfaction rate as compared to Versapoint.

Acknowledgements

The authors thank the members of the hysteroscopy unit at the Reina Sofia hospital in Córdoba.

Declaration of interest

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

References

1. Stamatellos I, Apostolides A, Stamatopoulos P, Bontis J. Pregnancy rates after hysteroscopic polypectomy depending on the size or number of the polyps. *Arch Gynecol Obstet* 2008;277:395–99.
2. American Association of Gynecologic Laparoscopists. AAGL Practice Report: practice guidelines for the diagnosis and management of endometrial polyps. *J Minim Invasive Gynecol* 2012;19:3–10.
3. Lee SC, Kaunitz AM, Sanchez Ramos L, Rhatigan RM. The oncogenic potential of endometrial polyps: a systematic review and meta-analysis. *Obstet Gynecol* 2010;116:1197–205.
4. Baiocchi G, Mancini N, Pazzaglia M, et al. Malignancy in endometrial polyps: a 12-year experience. *Am J Obstet Gynecol* 2009;201:462.e1–4.
5. Ben-Arie A, Goldehmit C, Laviv Y, et al. The malignant potential of endometrial polyps. *Eur J Obstet Gynecol Reprod Biol* 2004;115:206–10.
6. Koi C, Hachisuga T, Murakami M, et al. Overexpression of p53 in the endometrial gland in postmenopausal women. *Menopause* 2015;22:104–7.
7. Ferrazzi E, Zupi E, Leone FP, et al. How often are endometrial polyps malignant in asymptomatic postmenopausal women? A multicenter study. *J Obstet Gynecol* 2009;200:235.e1–6.
8. Uglietti A, Mazzei C, Deminico N, et al. Endometrial polyps detected at ultrasound and rate of malignancy. *Arch Gynecol Obstet* 2014;289:839–43.
9. Gambadauro P, Martínez-Maestre MA, Torrejón R. When is see-and-treat hysteroscopic polypectomy successful? *Eur J Obstet Gynecol Reprod Biol* 2014;178:70–3.
10. Vilos GA. Intrauterine surgery using a new coaxial bipolar electrode in normal saline solution (Versapoint): a pilot study. *Fertil Steril* 1999;72:740–3.
11. Herdman M, Badia X, Berra S. EuroQol-5D: a simple alternative for measuring health-related quality. *Aten Primaria* 2001;28:425–9.
12. Marsh FA, Rogerson LJ, Duffy SR, et al. A randomized controlled trial comparing outpatient versus daycase endometrial polypectomy. *BJOG* 2006;113:896–901.
13. Smith PP, Middleton JL, Connor M, et al. Hysteroscopic morcellation compared with electrical resection of endometrial polyps. A randomized controlled trial. *Obstet Gynecol* 2014;123:745–51.
14. Povedano B, Arjona JE, Velasco E, et al. Complications of hysteroscopic Essure® sterilisation: report on 4306 procedures performed in a single centre. *BJOG* 2012;119:795–9.
15. Arjona JE, Miño M, Cerdón J, et al. Satisfaction and tolerance with office hysteroscopic tubal sterilization. *Fertil Steril* 2008;90:1182–6.
16. Cicinelli E, Tinelli R, Loiudice L, et al. AlphaScope vs Lens-Based hysteroscope for office polypectomy without anesthesia: randomized controlled study. *J Minim Invasive Gynecol* 2011;18:796–9.
17. Litta P, Cosmi E, Saccardi C, et al. Outpatient operative polypectomy using a 5 mm-hysteroscope without anaesthesia and/or analgesia: advantages and limits. *Eur J Obstet Gynecol Reprod Biol* 2008;139:210–14.
18. Dealberti D, Riboni F, Prigione S, et al. New mini-resectoscope: analysis of preliminary quality results in outpatient hysteroscopic polypectomy. *Arch Gynecol Obstet* 2013;288:349–53.
19. Mariam M, Al Hilli M, Kayla E, et al. Long-term outcomes after intrauterine morcellation vs hysteroscopic resection of endometrial polyps. *J Minim Invasive Gynecol* 2013;20:215–21.