Vaginoscopy Against Standard Treatment: a randomised controlled trial

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Objective To evaluate whether vaginoscopy or standard hysteroscopy was more successful in the outpatient setting.

Design Randomised controlled multicentre trial.

Setting Outpatient hysteroscopy clinics at two UK hospitals.

Population 1597 women aged 16 or older undergoing an outpatient hysteroscopy.

Methods Women were allocated to vaginoscopy or standard hysteroscopy using third party randomisation stratified by menopausal status with no blinding of participants or clinicians.

Main outcome measures The primary outcome was 'success', a composite endpoint defined as: a complete procedure, no complications, a level of pain acceptable to the patient, and no sign of genitourinary tract infection 2 weeks after the procedure.

Results Vaginoscopy was significantly more successful than standard hysteroscopy [647/726 (89%) versus 621/734 (85%), respectively; relative risk (RR) 1.05, 95% CI 1.01–1.10; $P = 0.01$]. The median time taken to complete vaginoscopy was 2 minutes

compared with 3 minutes for standard hysteroscopy ($P < 0.001$). The mean pain score was 42.7 for vaginoscopy, which was significantly less than standard hysteroscopy 46.4 ($P = 0.02$). Operative complications occurred in five women receiving vaginoscopy and 19 women receiving standard hysteroscopy (RR 0.26, 95% CI 0.10–0.69).

Conclusions Vaginoscopy is quicker to perform, less painful, and more successful than standard hysteroscopy and therefore should be considered the technique of choice for outpatient hysteroscopy.

Keywords Ambulatory hysteroscopy, hysteroscopy, office hysteroscopy, outpatient hysteroscopy, vaginoscopy.

Tweetable abstract Vaginoscopy is quicker to perform, less painful, and more successful than standard hysteroscopy.

Linked article This article is commented on by BS Hurst p. 900 in this issue. To view this mini commentary visit https://doi.org/10.1111/1471-0528.15686.

Introduction

Hysteroscopy refers to direct, endoscopic visualisation of the uterine cavity and represents one of the commonest tests in modern gynaecology, used in the diagnosis of abnormal bleeding, endometrial cancer, and reproductive problems. The recently updated National Institute for Health and Care Excellence (NICE) Heavy Menstrual Bleeding guideline recommends an enhanced role for use of outpatient hysteroscopy during diagnostic workup, with an estimated 15 000 more hysteroscopies being undertaken each year.[1]

The standard approach requires passage of a vaginal speculum to separate the vaginal walls to visualise the cervix, cleansing of the genital tract, and on occasion application of traumatic forceps to the cervix in order to better visualise and stabilise it. One technical modification identified to potentially reduce pain from hysteroscopy is 'vaginoscopy', otherwise known as the 'no touch' technique.[2–4] This describes a method where the hysteroscope is guided into the uterus without the need for potentially painful vaginal instrumentation. Miniaturisation of hysteroscopes has facilitated the development of this approach because resistance to advancement of the hysteroscope through the cervical canal is minimised. However, despite these modifications in instrumentation, few practitioners use vaginoscopy, routinely preferring more invasive traditional

approaches. This may reflect a lack of familiarity with the technique as well as concerns over the ability to identify and traverse the cervical canal in order to access the endometrial cavity. Furthermore, there is concern that vaginoscopy is technically more challenging, leading to prolonged procedures which may not be completed. There are also concerns that because the cervix is not cleaned prior to the hysteroscope being inserted into the uterine cavity, there is a higher likelihood of postoperative genital tract infections. This has led the Royal College of Obstetricians and Gynaecologists (RCOG) evidence-based guideline of best practice in outpatient hysteroscopy[2,5] to recommend high quality and adequately powered randomised controlled trials (RCTs).

In view of the uncertainty over the effectiveness of vaginoscopy, a large RCT was designed (Vaginoscopy versus Standard Treatment for office hysteroscopy trial; VAST). The aim was to evaluate whether vaginoscopy or standard hysteroscopy was potentially more successful in the outpatient setting by comparing failure rates, complications, infection rates, patient acceptability, and pain scores.

Methods

A parallel-group, unblinded RCT comparing vaginoscopy with standard hysteroscopy was designed. Women were recruited by the practitioners performing the procedure from two NHS outpatient hysteroscopy clinics in the UK: the Birmingham Women's and Children's Hospital Foundation Trust and the Royal Derby Hospital.

Patients were eligible if they were 16 years of age or older, attending for an outpatient hysteroscopy and were able to give written informed consent. Women were excluded from participation if (1) they preferred the procedure under general anaesthesia, (2) it was known that cervical dilation would be needed based upon previous reports of severe cervical stenosis or (3) they would not tolerate a speculum prior to the procedure beginning; for example: a documented history of vaginismus, virginal status or severe lichen sclerosis.

Women were allocated prior to examination in a 1:1 ratio to either of the interventions through a telephone or computer-based system managed by the Birmingham Clinical Trials Unit (BCTU). The computer-generated randomisation blocks (from four to six) were kept centrally in the BCTU and the sizes varied, so that the allocation could not be deduced pre-randomisation. Blocks were stratified by menopausal status (premenopausal versus post-menopausal). Menopausal status was chosen because of the influence that oestrogen has on the elasticity of the female genital tract.

Details of the hysteroscopic procedures and equipment can be found in Supporting Information Appendix S1.

This study was designed prior to the widely accepted benefits of core outcome sets and there are currently no relevant core outcomes for research in hysteroscopy.

A lay advisor and lay members of the Clinical Studies Group in Menstrual Disorders, Endometriosis and Gynaecological Endoscopy prioritised the research question and helped develop the initial protocol, particularly in relation to defining research outcomes. There was no patient involvement for the analysis or interpretation of this study.

The primary clinical outcome was procedural success, defined as a completed hysteroscopy with an acceptable level of pain for the patient without intraoperative complications or postoperative genital tract infection. A composite outcome was chosen, as it was felt that all of these factors were important to classify a hysteroscopy as 'successful' based upon the evidence from the literature[2] and data from our cross-sectional survey of the British Society of Gynaecological Endoscopy.[6] Each of the individual constituents of the primary clinical outcome was also examined individually as a secondary outcome. An incomplete hysteroscopy was defined as inability to enter the uterine cavity or obtain a satisfactory view for a duration of time sufficient to allow complete systematic examination of the uterine cavity (panoramic and magnified views of all cavity walls, the uterine cornual regions including tubal ostia) and cervical canal. The reason for failure was documented: patient factors (pain, anxiety), adverse anatomy (cervical stenosis, inability to identify cervix, acute uterine deviation, adhesions) or suboptimal visualisation.

Serious complications in the office setting such as uterine perforation are rare, but vaso-vagal reactions have been reported to complicate between 2.3 and 9.0% of procedures.[2,7,8] For the purpose of this trial, vaso-vagal reactions were defined clinically as a woman being unable to leave the operating couch within 5 minutes of cessation of the procedure due to feeling faint, dizzy or nauseous. Procedural pain and patient acceptability were collected on an iPad mini™ (Apple™, Cupertino, CA, USA) device. A novel system was designed, programming the iPad mini™ device to allow easy patient input; all patients were familiarised with the system before they undressed for their procedure. Additionally, all women were informed that their responses were confidential and, once completed, the screen would become 'blank', at which point the device should be returned to the clinical team. In this way it was hoped that the validity of the patient response would be optimised by facilitating an immediate response (minimal recall bias) and blinding their response from the clinical team (reducing observer bias). This was administered to the participating women immediately after the diagnostic procedure but before any further intervention (e.g. endometrial biopsy, polypectomy or intrauterine device insertion). To assess

acceptability women were asked 'Did you find the procedure acceptable?' with response categories 'Yes' or 'No'. Pain was assessed using a slider on a 100-mm visual analogue scale (0 for no pain and 100 for worst imaginable pain).

The patients were contacted via email or telephone 2 weeks after the procedure. Infection was defined as any of the following: (1) if the woman had received antibiotics for a urinary tract infection; (2) if the woman had received antibiotics for vaginal discharge; (3) if the women had two of the following three symptoms: offensive vaginal discharge, pelvic pain, and pyrexia.

Surgeons completed a standard form following the procedure to record technical aspects of the procedure including: the use of local anaesthesia; the need for dilation of the cervix; the use of a vaginal speculum; the use of tenaculum/vulsellum forceps; completeness of procedure; any further procedures after the diagnostic hysteroscopy; the time taken to complete the procedure (defined as the time from insertion of vaginal instrumentation or hysteroscope post-randomisation until the end of the diagnostic procedure); and details of any adverse events.

Analysis for all parameters was modified intention-to-treat. If women withdrew their consent they were removed from the analysis. The statistical plan was approved by a senior BCTU biostatistician who was not involved in the trial (see Acknowledgements). Details of the power calculation can be found in Supporting Information Appendix S2. All outcome data were collected at the time of the hysteroscopy apart from infection data, which were collected from the patient 2 weeks after the procedure. For the primary analysis of the composite outcome, if patients had missing infection information but other components indicated a procedure failure, these were classified as an overall failure. When patients had the infection component missing but other components did not indicate failure, these cases were still considered missing and these patients were excluded from analysis. A sensitivity analysis was performed where all missing infection data were considered negative (i.e. no infection) and a separate analysis where missing infection data were imputed. Multiple imputation was conducted using an iterative Markov chain Monte Carlo method to impute missing data for the model created from the whole data set. All patient characteristics and outcome measures were included in the imputation process to maximise the precision of the imputations. The primary outcome was analysed using a chi-square test and was presented as relative risks with 95% confidence intervals. The individual components along with pain and time to complete the procedure were compared as secondary outcomes using a Mann–Whitney U-test, t-test and chi-square test as appropriate. Median values, interquartile ranges, mean

differences and 95% confidence intervals were presented alongside results of significance testing where appropriate. Planned subgroup analysis was performed for menopausal status, raised BMI, and a history of vaginal birth using the primary composite outcome of successful procedure. All analyses were carried out using SPSS software version 21 (IBM, Armonk, NY, USA).

This trial was registered on clinicaltrials.gov (identifier: NCT01972945). The National Research Ethics Service, UK, granted ethical approval (identifier: 13/WM/0471). Research and Development approval was sought and granted at Birmingham Women's Hospital. The trial was conducted according to the principles of Good Clinical Practice (GCP).[9] The original protocol can be found in Supporting Information Appendix S3.

Results

In total, 1600 women requiring hysteroscopy were randomised over 42 months between April 2014 and October 2017. Three women withdrew consent after randomisation and 1443/1597 (90.4%) women responded to follow up to check for postoperative genital tract infection. Figure 1 summarises the flow of participants through the trial in line with the recommendations of the consolidation standards of reporting trials (CONSORT) statement.[10]

The baseline variables were balanced between the groups post-randomisation (Table 1).

The majority of hysteroscopies performed were classified as successful because they had an acceptable level of pain and the procedure was satisfactorily completed without complications or postoperative genital tract infection. Vaginoscopy was significantly more successful than standard hysteroscopy [647/726 (89%) versus 621/734 (85%) respectively; RR 1.05, 95% CI 1.01–1.10; $P = 0.01$] (Table 2).

Sensitivity analysis where all missing infection data were considered negative (i.e. no infection) and a separate analysis where missing infection data were imputed did not alter the results.

Planned subgroup analyses were done for menopausal status, raised BMI, and a history of vaginal birth using the primary outcome of a successful procedure (Table 3). In premenopausal women, significantly more procedures were successful with vaginoscopy than with standard hysteroscopy [respectively 377/408 (92%) versus 356/416 (86%); RR 1.08, 95% CI 1.03–1.13; $P = 0.002$], but no
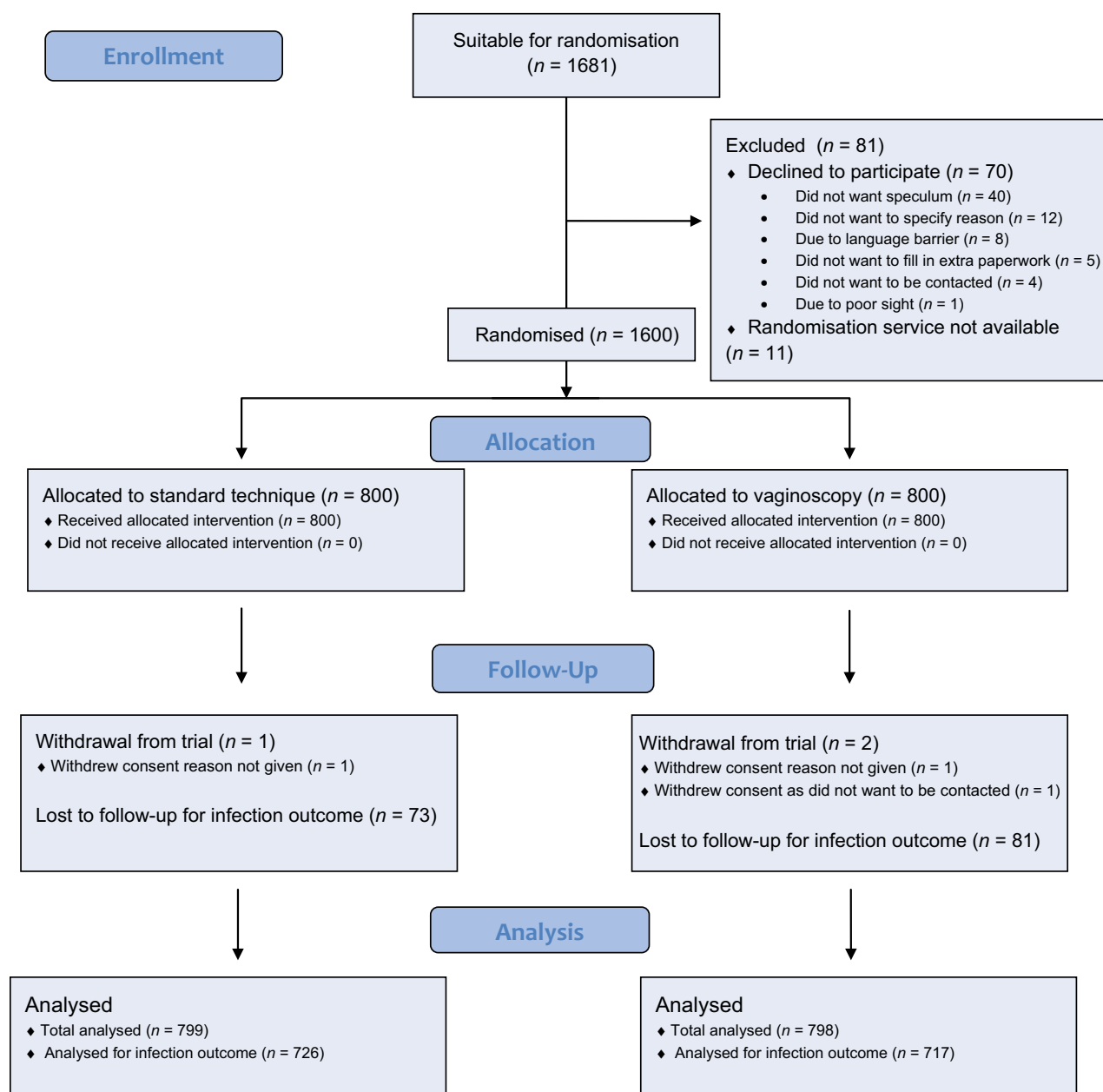
Figure 1. Flow diagram for women in Vaginoscopy Against Standard Treatment trial.

difference was seen according to technique in post-menopausal women. In women who had never had a vaginal birth, significantly more procedures were successful with vaginoscopy than with standard hysteroscopy [188/211 (89%) versus 212/263 (81%); RR 1.11, 95% CI 1.02–1.19; $P = 0.01$], but no difference was seen according to technique in women who had given birth vaginally. No differences between approaches to hysteroscopy according to BMI above and below 30 kg/m^2 in terms of success were observed (Table 3).

Diagnostic hysteroscopy conducted by vaginoscopy was quicker than a standard hysteroscopic technique [median time 2 minutes, interquartile range (IQR) 1.0 versus 3 minutes, IQR 2.0; $P < 0.001$].

There was no significant difference in the proportion of failed procedures with vaginoscopy than with standard hysteroscopy [respectively 40 (5%) versus 59 (7%); RR 0.68, 95% CI 0.46–1.00; $P = 0.051$]. The most common reason for inability to complete a hysteroscopy satisfactorily differed between groups: for vaginoscopy, 33 of the failures

Table 1. Baseline characteristics for trial of vaginoscopy against standard technique

	Vaginoscopy (n = 798)	Standard technique (n = 799)
Age (years)		
Mean (SD)	49.3 (12.9)	50.0 (13.4)
BMI (kg/m²)		
Mean (SD)	29.8 (7.6)*	29.0 (6.8)**
Parity		
Mean (SD)	1.9 (1.5)***	1.7 (1.4)
Previous caesarean		
Yes	114 (14%)	140 (18%)
No	682 (86%)	659 (82%)
Missing	0 (0%)	2 (0.3%)
Menopausal status		
Premenopausal	447 (56%)	447 (56%)
Postmenopausal	351 (44%)	352 (44%)
Indication		
Bleeding	532 (67%)	523 (66%)
Thickened endometrium/polyp	146 (18%)	124 (16%)
Fertility	65 (8%)	96 (12%)
Lost intrauterine device	36 (5%)	40 (5%)
Pregnancy loss/retained products	7 (1%)	9 (1%)
Dysmenorrhoea	7 (1%)	6 (1%)
Amenorrhoea	2 (0.3%)	0 (–)
Endometrial cells on smear	2 (0.3%)	0 (–)
Vaginal discharge	1 (0.1%)	0 (–)
Missing	0 (–)	1 (0.1%)
Endometrial biopsy		
Yes	301 (38%)	316 (40%)
No	497 (62%)	483 (61%)
Other surgical procedure performed after diagnostic hysteroscopy		
None	520 (65%)	514 (64%)
Polypectomy	145 (18%)	140 (18%)
IUCD fitted	97 (12%)	117 (15%)
Retrieval of 'lost' IUCD	33 (4%)	23 (3%)
Removal of products of conception	0 (–)	3 (0.4%)
Myomectomy	2 (0.3%)	0 (–)
Hysteroscopic sterilisation	0 (–)	2 (0.3%)
Endometrial ablation	1 (0.1%)	0 (–)
Operator		
Consultant	365 (46%)	362 (45%)
Specialist trainee	276 (35%)	251 (31%)
Nurse specialist	156 (20%)	180 (23%)
Specialist doctor	1 (0.1%)	6 (1%)
Centre		
Birmingham	645 (81%)	630 (79%)
Derby	153 (19%)	169 (21%)

*30 patients missing.
**32 patients missing.
***2 patients missing.

were due to cervical stenosis, whereas for standard hysteroscopy 30 failures resulted from pain (Table 2). When the procedure failed with the allocated treatment, the procedure was ultimately successful with the other technique in the majority of cases 73/99 (74%). So overall failure rate of outpatient procedures was much lower 26/1597 (2%) with appropriate use of either approach. There was significantly less pain as measured on a 100-mm visual analogue scale with vaginoscopy [42.7 (31.8 SD)] than with standard hysteroscopy [46.4 (30.3 SD); $P = 0.02$]. In the minority of total hysteroscopies where a tenaculum forcep was applied to the cervix 173/1597 (11%), this occurred significantly more often in the standard hysteroscopy group than in the vaginoscopy group [respectively 137/799 (17%) versus 36/798 (5%); RR 0.26, 95% CI 0.18–0.37; $P \leq 0.001$]. Overall, there were no differences between vaginoscopy and standard hysteroscopy in the use of local cervical anaesthesia (respectively 39/798 (5%) versus 57/799 (7%); RR 0.69, 95% CI 0.46–1.02; $P = 0.06$]) or need for dilation of the cervix [33/798 (4%) versus 49/799 (6%); RR 0.67, 95% CI 0.44–1.04, $P = 0.07$]).

Overall, 98% of women found outpatient hysteroscopy to be acceptable; 13/798 (2%) women receiving vaginoscopy reporting the procedure as unacceptable, compared with 22/799 (3%) women in the standard hysteroscopy group [RR 1.01, 95% CI 1.00–1.03; $P = 0.1$] (Table 2).

The most common complications of diagnostic hysteroscopy were self-limiting vasovagal reactions, which occurred in five women receiving vaginoscopy and 14 women receiving standard hysteroscopy. All other recorded complications were observed in women receiving the standard technique: cervical trauma (two women), admission for analgesia (two women), and post-procedural haemorrhage (one woman). Thus, complications occurred in 5/798 (0.6%) women receiving vaginoscopy and 19/799 (2%) of women receiving standard hysteroscopy [RR 0.26, 95% CI 0.10–0.69; $P = 0.007$] (Table 2).

A total of 27/717 (3%) women after vaginoscopy and 31/726 (4%) women after standard hysteroscopy were classified as having a genital tract infection within 2 weeks of their hysteroscopy (Table 2). There was no significant difference in postoperative genital infection between the groups (RR 0.88, 95% CI 0.53–1.46; $P = 0.6$). Of the 58 (4%) women who were considered to have a genital tract infection, 35 (60%) were treated with antibiotics for a presumed infection of the urinary or genital tract. Twenty-three (40%) of the women had at least two of the following symptoms within the 2 weeks of the procedure: offensive discharge, pyrexia, and pelvic pain. When stratifying women by those who underwent one diagnostic procedure [37/936 (4%)] and those who underwent a further surgical procedure [21/507 (4%)], there was no difference in infection rates.

Table 2. Surgical technique and outcomes for trial of vaginoscopy against standard hysteroscopy

	Vaginoscopy (n = 798) (%)	Standard technique (n = 799) (%)	Relative risk (95% CI)	P
Composite outcome				
Successful procedure*	647 (89)	621 (85)	1.05 (1.01–1.10)	0.01
Non-successful procedure	79 (11)	113 (15)	0.71 (0.54–0.92)	
Missing	72	65		
Procedure failures				
Cervical stenosis	33 (4)	8 (1)		
Pain	5 (0.6)	30 (4)		
Unable to access cervix	2 (0.3)	20 (3)		
Bleeding cervical mass	0 (–)	1 (0.1)		
Total failures	40 (5)	59 (7)	0.68 (0.46–1.00)	0.051
Acceptability				
Acceptable	785 (98)	777 (97)	1.01 (1.00–1.03)	0.1
Unacceptable	13 (2)	22 (3)		
Complications				
Vasovagal reactions	5 (0.6)	14 (2)		
Cervical trauma	0 (–)	2 (0.3)		
Admitted for analgesia	0 (–)	2 (0.3)		
Haemorrhage	0 (–)	1 (0.1)		
Total complications	5 (0.6)	19 (2)	0.26 (0.10–0.69)	0.007
Infection				
Antibiotics for urinary tract infection	13 (2)	9 (1)		
Antibiotics for vaginal discharge	8 (1)	5 (1)		
Offensive discharge	22 (3)	28 (4)		
Pelvic pain	142 (18)	132 (17)		
Pyrexia/fever	17 (2)	21 (3)		
Missing	81 (10)	73 (9)		
Total infections**	27 (3)	31 (4)	0.88 (0.53–1.46)	0.6

CI, confidence interval.

*Composite outcome of success defined as: no infection, no complications, complete procedure and acceptable level of pain. If patients had missing infection information but any other components indicated a procedure failure, these were classified as failure. When patients had the infection component missing but other components did not indicate failure, these cases were considered missing.

**Total infections defined as receiving antibiotics or at least two of the following: pelvic pain, offensive discharge and pyrexia/fever.

Table 3. Subgroup analysis using composite outcome of 'success' defined as: no infection, no complications, complete procedure, and acceptable level of pain

	Vaginoscopy (%)	Standard technique (%)	Relative risk (95% CI)	P
Menopausal status				
Premenopausal	377/408 (92)	356/416 (86)	1.08 (1.03–1.13)	0.002
Postmenopausal	270/318 (85)	265/318 (83)	1.02 (0.95–1.09)	0.6
Effect of BMI				
BMI ≥30 or more	252/284 (89)	214/258 (83)	1.06 (1.00–1.15)	0.06
BMI <30	374/416 (90)	387/451 (86)	1.05 (1.00–1.10)	0.07
Effect of previous vaginal birth				
No previous vaginal birth	188/211 (89)	212/263 (81)	1.11 (1.02–1.19)	0.01
Previous vaginal birth	459/515 (89)	409/471 (87)	1.03 (0.98–1.08)	0.3

Likewise, there was no difference in infection rates between those women who did not have an endometrial biopsy and those who did [38/892 (4%) versus 20/551 (4%), respectively]. Almost one in five women reported pelvic pain within 2 weeks of the hysteroscopy procedure (Table 2).

Discussion

Main findings

This RCT provides evidence that vaginoscopy is more successful than standard hysteroscopy, meaning that more diagnostic hysteroscopy procedures were fully completed with an acceptable level of pain and without complications. Women of reproductive age and those women who have never had a vaginal birth benefit most from vaginoscopy. The evidence also shows that vaginoscopy is quicker to perform and is less painful than conventional approaches utilising a vaginal speculum with or without manipulation of the cervix. Vaginoscopy was associated with a lower procedure failure rate, but both approaches were equally acceptable. Irrespective of the technique used, nearly one in five women reported pelvic pain in the 2 weeks following the procedure and infection rates were higher than previously reported.

Strengths and limitations

The strengths of our trial relate to its large sample size, the strict randomisation process, assessment of important clinical outcomes, and the completeness of follow up, with over 90% of women providing complete data. A range of outcome measures identified as important to women and gynaecologists were evaluated, which included an assessment of postoperative infection, an outcome not previously reported. Our adoption of a composite outcome, in addition to evaluating the comprehensive range of relevant outcomes individually, enhances clinical decision-making. Furthermore, this study used a bespoke, electronic VAS that allowed immediate, blinded responses, limiting recall and observer bias. The multicentre design, range of operators inclusive of doctors and specialist nurses, use of contemporary, miniature hysteroscopes, and our unselected population of women make the results generalisable to all units performing modern, outpatient hysteroscopy.

One of the weaknesses was the lack of blinding. Operating on conscious women makes it difficult to blind participants to their allocated intervention unless they are indistinguishable. Women were not informed of the allocated procedural technique, but it is likely that many were aware of the allocated intervention from the pre-randomisation information provided and familiarity with the experience of a vaginal speculum examination. We did not specifically record the proportion of women excluded because of refusal to have an outpatient procedure or because they were considered unsuitable by the operator. However, this was a large trial with few exclusions such that any bias upon estimates of procedural success is likely to be small. Our study assessed the effect of menopausal status, BMI, and previous vaginal birth on the primary outcome but did not adjust for other potential prognostic variables such as the type of hysteroscope used. Further work is needed to evaluate the impact of the diameter and angle of the distal lens and surgical proficiency.

Interpretation

Only a small number of outpatient procedures failed, due to problems negotiating the endocervical canal, cervical stenosis, bleeding or pain. It is of interest that of the procedures that failed with the allocated treatment, the procedure was ultimately successful with the other technique in the majority of cases. So the overall failure rate of outpatient procedures was much lower with appropriate use of either approach. This shows the importance of becoming proficient in both vaginoscopy and standard hysteroscopy if one is to perform procedures in the office setting. However, vaginoscopy failed almost exclusively due to cervical stenosis, when a speculum was needed to administer cervical anaesthesia to allow cervical dilation. In contrast, standard hysteroscopy most commonly failed because of pain associated with insertion of the speculum. Another potential advantage of avoiding vaginal instrumentation is that it allows a greater freedom of movement, enabling enhanced manoeuvrability of the hysteroscope and avoiding stimulating the parasympathetic innervation of the cervix. These considerations may explain why vaginoscopy was more successful, quicker, and less likely to cause the most common side effect of outpatient hysteroscopy—vaso-vagal reactions. Thus, although further work is needed to improve patient selection, the evidence suggests that vaginoscopy should be the default technique unless it is known that cervical dilation is needed.

One potential benefit suggested by advocates of standard hysteroscopy is that passing a speculum allows the cervix to be sterilised, hypothetically reducing the incidence of ascending infection. However, the risk of infection associated with hysteroscopy is thought to be less than 1%, although few studies have ever reported this outcome.[11,12] Rates of infection in relation to outpatient hysteroscopy have not to our knowledge been previously investigated as rigorously in an RCT. The current study did not demonstrate any difference in infection rates between the two techniques and concerns over inducing more genital tract infections using vaginoscopy, where antiseptics are not used, appear misplaced. However, this study found infection rates of 3%, three times higher than previously thought. This finding probably reflects the strict, pragmatic criteria and thorough follow up specifically to identify possible genital tract infection. This systematic postoperative follow up also identified that nearly one in five women experience pelvic pain within 2 weeks of the procedure. It is unlikely that all the pelvic pain reported was related to the preceding hysteroscopy, and the severity and nature of this pain was not recorded.

However, in the absence of previous data about prolonged pelvic pain following outpatient hysteroscopy, the prevalence is higher than anticipated. Thus, women should be informed about post-procedural pelvic pain and relevant advice given regarding pain relief. Further detailed qualitative research into postoperative pain seems necessary to corroborate these findings using a control group to ascertain the amount of pain attributable to the prior hysteroscopy.

Previous work comparing vaginoscopy with standard hysteroscopy has focused on pain scores.[13–18] A meta-analysis of this work concluded that vaginoscopy significantly reduced pain compared with standard hysteroscopy.[2] In keeping with these findings, our study showed significantly less pain with vaginoscopy, but the difference was less pronounced because the average pain scores for the comparison group undergoing the standard technique were lower than in previous trials.[2] This could be explained by the fact that the four studies included within the meta-analysis routinely applied a tenaculum forceps during standard hysteroscopy. In the current study, cervical instrumentation was optional, such that only 137/799 (17%) of cases used a tenaculum, and avoidance of the step may have minimised pain. Another disparity observed in our study compared with the studies included in the meta-analysis was the lower procedural failure rate in the vaginoscopy group than in the standard group. This could have been because the majority of hysteroscopes used in the current study were of a smaller diameter, thus negating the need for cervical dilation in most cases. The systematic review concluded by recommending the conduct of large RCTs such as the current one, where all relevant outcomes are rigorously assessed and these outcome data collected according to pertinent patient factors.

Conclusions

Vaginoscopy should become the default method for outpatient hysteroscopy. Clinicians familiar with standard hysteroscopy in this setting will require minimal training to become proficient in this simple technique. In addition to improving women's experience of outpatient hysteroscopy, widespread implementation of vaginoscopy could save resources by reducing the need for inpatient procedures under general anaesthesia because of technical failure. Women should be counselled that pain in the 2 weeks following the procedure is common and should be given verbal and written advice regarding analgesia. Women should also be informed that there is a low risk of genital tract infection that may require antibiotic treatment. Guidance should be provided about the symptoms and signs of possible infection.

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Details of hysteroscopic procedures and equipment.

Appendix S2. Details of power calculation.

Appendix S3. VAST study protocol. ■

References

1 Heavy menstrual bleeding: assessment and management| Guidance and guidelines | NICE [Internet] [www.nice.org.uk/guidance/ng88]. Accessed 09 March 2019

2 Cooper NAM, Smith P, Khan KS, Clark TJ. Vaginoscopic approach to outpatient hysteroscopy: a systematic review of the effect on pain. *BJOG* 2010;117:532–9.

3 Clark TJ, Gupta JK. *Handbook of Outpatient Hysteroscopy: A Complete Guide to Diagnosis and Therapy*. Vol. 1. Boca Raton, FL: CRC Press, 2005.

4 Busquets M, Lemus M. Practicability of panoramic hysteroscopy with CO_2. Clinical experience: 923 cases. *Rev Chil Obstet Ginecol* 1993;58:113–8.

5 Clark TJ, Cooper NA, Kremer C. Best practice in outpatient hysteroscopy. RCOG Press Greentop Guideline No. 59.

6 Smith P. The practice of office hysteroscopy. PhD thesis. The University of Birmingham, 2015.

7 Smith PP, Middleton LJ, Connor M, Clark TJ. Hysteroscopic morcellation compared with electrical resection of endometrial polyps: a randomized controlled trial. *Obstet Gynecol* 2014;123:745–51.

8 Di Spiezio Sardo A, Taylor A, Tsirkas P, Mastrogamvrakis G, Sharma M, Magos A. Hysteroscopy: a technique for all? Analysis of 5,000 outpatient hysteroscopies. *Fertil Steril* 2008;89:438–43.

9 Medical Research Council. Good clinical practice [Internet]. 1998 [www.mrc.ac.uk/documents/pdf/good-clinical-practice-in-clinical-trials/]. Accessed 09 March 2019.

10 Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c869.

11 Brooks PG. Complications of operative hysteroscopy: how safe is it? *Clin Obstet Gynecol* 1992;35:256–61.

12 Agostini A, Cravello L, Shojai R, Ronda I, Roger V, Blanc B. Postoperative infection and surgical hysteroscopy. *Fertil Steril* 2002;77:766–8.

13 Sharma M, Taylor A, di Spiezio Sardo A, Buck L, Mastrogamvrakis G, Kosmas I, et al. Outpatient hysteroscopy: traditional versus the 'no-touch' technique. *BJOG* 2005;112:963–7.

14 Garbin O, Kutnahorsky R, Göllner JL, Vayssiere C. Vaginoscopic versus conventional approaches to outpatient diagnostic hysteroscopy: a two-centre randomized prospective study. *Hum Reprod* 2006;21:2996–3000.

15 de Almeida ZMMC, Pontes R, Costa HLFF. [Evaluation of pain in diagnostic hysteroscopy by vaginoscopy using normal saline at body temperature as distension medium: a randomized controlled trial]. *Rev Bras Ginecol Obstet* 2008;30:25–30.

16 Sagiv R, Sadan O, Boaz M, Dishi M, Schechter E, Golan A. A new approach to office hysteroscopy compared with traditional hysteroscopy: a randomized controlled trial. *Obstet Gynecol* 2006;108:387–92.

17 Guida M, Di Spiezio Sardo A, Acunzo G, Sparice S, Bramante S, Piccoli R, et al. Vaginoscopic versus traditional office hysteroscopy: a randomized controlled study. *Hum Reprod* 2006;21:3253–7.

18 Paschopoulos M, Paraskevaidis E, Stefanidis K, Kofinas G, Lolis D. Vaginoscopic approach to outpatient hysteroscopy. *J Am Assoc Gynecol Laparosc* 1997;4:465–7.