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Outpatient hysteroscopy: traditional *versus* the 'no-touch' technique

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Objective To assess whether outpatient hysteroscopy using the 'no-touch' technique confers any advantages in terms of patient discomfort over the traditional technique.

Design Prospective randomised controlled study.

Setting Outpatient hysteroscopy clinic in a large university undergraduate teaching hospital.

Population All women referred for outpatient hysteroscopy in a 12-month period.

Interventions Women were randomised to undergo either traditional saline hysteroscopy requiring the use of a speculum and tenaculum, or a 'no-touch' vaginoscopic hysteroscopy which does not require a speculum or tenaculum. Each group was further subdivided to have hysteroscopy with either a 2.9-mm or 4-mm hysteroscope. Patients were asked to complete pre- and postprocedure questionnaires ranking pain scores.

Main outcome measures The relative success of each of these techniques, requirement for local anaesthetic and pain scores at different times during the hysteroscopy were recorded at the end of the procedure. The time taken to carry out each procedure was also measured.

Results One hundred and twenty women were recruited in this study: 60 were randomised to traditional hysteroscopy and 60 to 'no-touch' hysteroscopy. The overall success rate for hysteroscopy was 99%. There was no significant difference in the requirement for local anaesthetic between the two groups, but those who underwent 'no-touch' hysteroscopy with a 2.9-mm hysteroscope had the lowest requirement of local anaesthetic (10% compared with 27% in the no-touch hysteroscopy with a 4-mm hysteroscope group). The time taken to perform hysteroscopy and biopsy was significantly shorter with 'no-touch' hysteroscopy (5.9 *vs* 7.8 min; difference 1.9, 95% CI 0.7–3.1). There were no differences in pain scores between the groups at different times during hysteroscopy.

Conclusions 'No-touch' or vaginoscopic hysteroscopy is significantly faster to perform than the traditional technique. Although there was no difference in pain scores between the two techniques, local anaesthetic requirements were least in those who underwent 'no-touch' hysteroscopy with a narrow bore hysteroscope.

INTRODUCTION

Hysteroscopy is widely accepted to be the gold standard for direct visualisation of the endometrial cavity. The most common indications are abnormal uterine bleeding and subfertility. It has been shown to be well tolerated as an outpatient procedure with a high success rate.[1] However, one of the most common reasons for failure is pain, especially during introduction of the hysteroscope, and this can occur even if local anaesthesia is used. Pain may arise as the cervix is dilated with the hysteroscope, or when the uterine walls are distended with the distension medium. Anaesthetic requirements tend to be greater in nulligravid and postmenopausal women. The rate of local anaesthetic use is around 30% with the use of traditional hysteroscopic techniques.[1,2]

A variety of refinements have been tried to improve tolerability of the procedure. Local anaesthetic has been used in the form of either intracervical or paracervical instillation, or topically with a gel or spray, often with conflicting results. Intracervical local anaesthetic was found to be no more effective than placebo in a study involving 100 women.[3] Two randomised studies of paracervical anaesthesia reached opposite conclusions about the efficacy of the preparation to reduce pain in postmenopausal women.[4,5] Lignocaine spray to the cervix has been compared with placebo and failed to show any significant difference in pain scores for hysteroscopy, the only benefit being reduction in pain as the cervix was grasped.[6] Local anaesthetic cream, local anaesthetic gel and placebo, all applied to the cervix, resulted in significantly less pain than treatment with placebo,[7] but local anaesthetic gel alone was not found to confer any benefit to outpatient hysteroscopy.[8]

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Large diameter hysteroscopes have been compared with narrower scopes in terms of tolerability and accuracy in evaluating the endometrium. Narrow hysteroscopes reduce pain while giving equally satisfactory views of the endometrial cavity with lower failure rates and fewer incidences of vasovagal side effects compared with standard 4 mm hysteroscopes.[9–11]

A vaginoscopic or 'no-touch' approach to hysteroscopy has been described, avoiding the need to introduce a vaginal speculum and tenaculum to expose and grasp the cervix.[11–14] We have conducted a randomised controlled trial to ascertain whether there was a true difference in the discomfort of outpatient hysteroscopy using this approach compared with the traditional technique, and whether this led to a difference in the need for local anaesthesia.

METHODS

Ethical approval for this study was obtained from the Royal Free Hospital Local Research Ethics Committee (No. 6056). Women who attended for outpatient hysteroscopy were invited to take part. Following a detailed history, the women were asked to complete a preprocedure questionnaire scoring their level of anxiety, concurrent abdominal pain and backache utilising a 10-cm visual analogue scale (0 = no symptoms, 10 = worst possible symptoms).

Following informed consent, the women were randomised to one of two groups:

Group 1: Traditional technique with speculum and tenaculum
Group 2: 'No-touch' technique

Both groups were further randomised to different size of hysteroscopes:

A: 4 mm 30° single-flow rigid hysteroscope (5 mm sheath)
B: 2.9 mm 30° single-flow rigid hysteroscope (3.7 mm sheath)

Randomisation was based on a computer-generated randomisation table, and was performed using opaque envelopes immediately prior to the hysteroscopy. The hysteroscopy was performed by one of seven operators attending the clinic each of whom had performed at least

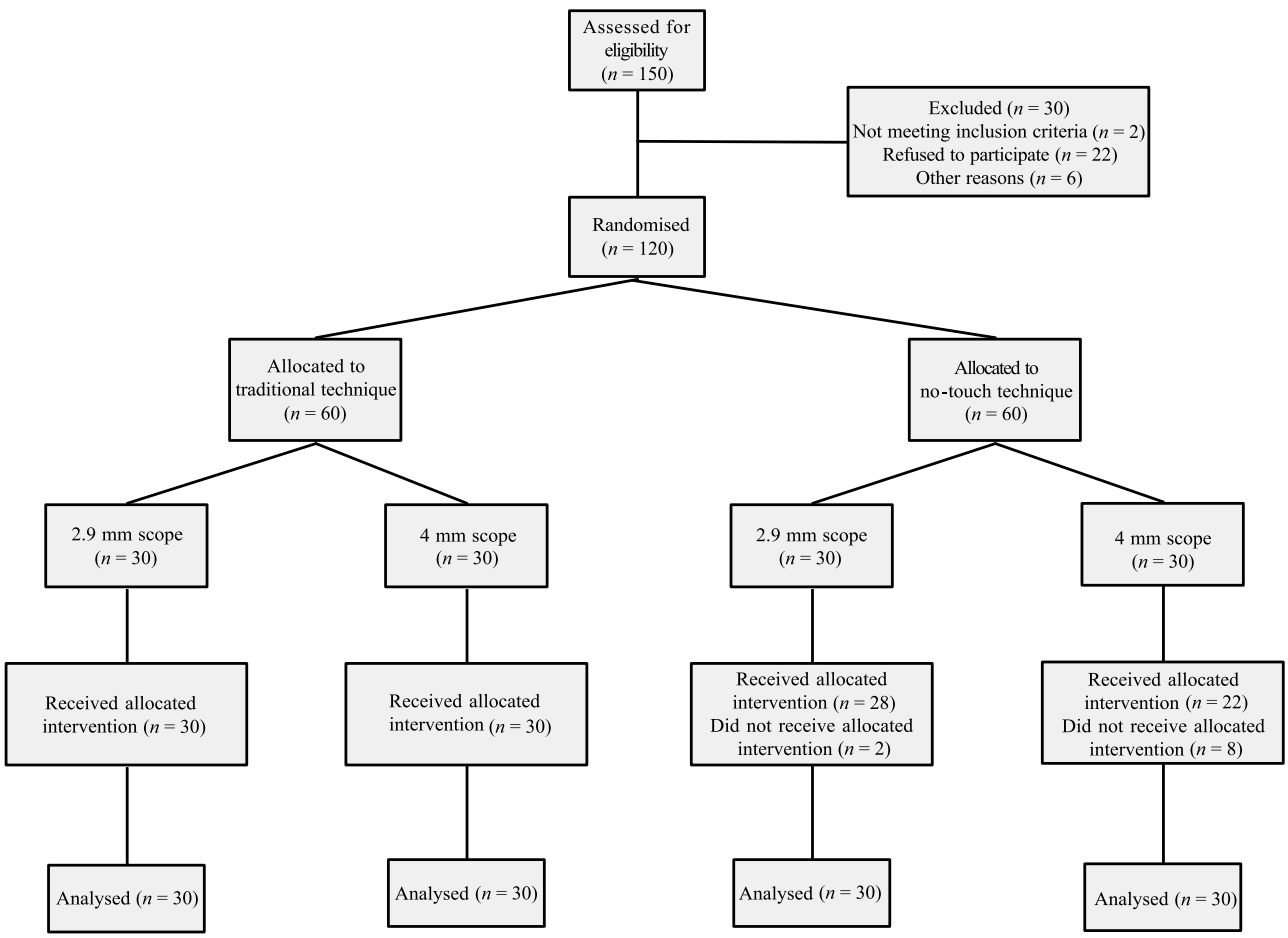

Fig. 1. Consort diagram.

Table 1. Patient characteristics. Data are mean [SD]; median (range) or number (%).

	Traditional technique ($n = 60$)	'No-touch' technique ($n = 60$)
Age (years)	45 [7.5]	43 [8.0]
Parity	2 (0–5)	2 (0–10)
Nulliparous/multiparous	18 (30)	20 (33)
Postmenopausal	9 (15)	6 (10)
Indications*		
Menorrhagia	35 (58)	36 (60)
Prolonged periods	10 (17)	5 (8)
Postmenopausal bleeding	9 (15)	5 (8)
Intermenstrual bleeding/ Postcoital bleeding	10 (17)	10 (17)
Subfertility	4 (7)	6 (10)
Miscellaneous indications	2 (3)	1 (2)

* Some patients had more than one indication for hysteroscopy.

20 traditional and 'no-touch' diagnostic hysteroscopies previously.

For the traditional technique, following a bimanual examination, a Collins bivalve speculum was inserted into the vagina to expose the cervix. The anterior cervical lip was grasped with Littlewood's forceps. The cervical canal was only dilated if it was judged to be too narrow to admit the hysteroscope. Intracervical local anaesthesia (2.2 mL of 3% prilocaine with felypressin 0.03 U/mL) was not given routinely but was available if requested by the patient. Hysteroscopy was performed using normal saline as the distension medium at a pressure of 150 mmHg, and was guided through the cervix making adjustments to allow for the angle of the optic.[15] The uterine cavity and the endocervical canal were inspected in a systematic fashion. If an endometrial biopsy was required, a Pipelle de Cornier sampler was used.

For the 'no-touch' technique, following a bimanual examination, the hysteroscope was placed into the lower vagina and the normal saline was turned on at 150 mmHg pressure. The instrument was directed towards the cervix, and on identifying the external os, was introduced into the cervical canal and guided into the uterine cavity. The uterus was inspected as previously described before being withdrawn. If an endometrial biopsy was indicated, a speculum was inserted to expose the cervix and the cervix was held with Littlewood's forceps. Cervical dilatation or intracervical local anaesthesia was only used if needed, in which case the hysteroscopy was converted to the traditional technique.

Success of the investigation (defined as adequate inspection of the canal and endometrial cavity) by the intended technique, and need for local anaesthesia were recorded. Other parameters assessed included the need for cervical dilatation and the duration of the procedure (defined as the interval between the vagina being instrumented to the time the last instrument was removed from the vagina). Patients were asked to complete a postprocedure questionnaire immediately following the investigation scoring their discomfort at various phases of the hysteroscopy [e.g. insertion of speculum (if used), local anaesthetic injection (if required), insertion of the hysteroscope, inspection of the uterine cavity, endometrial biopsy (if done), and immediately after and 30 min after hysteroscopy]. In addition, they were asked if they would recommend the procedure to a friend, if they would prefer general anaesthetic in future and how acceptable they found the procedure.

We used the need for local anaesthesia as our primary outcome measure. We hypothesised that with a no-touch technique only 10% of patients would require analgesia compared with the figure of 30% for the group who had traditional hysteroscopy.[1,2] For the probability of a type 1 statistical error to be less than 0.05 and the probability of a type 2 statistical error to be less than 0.2, we calculated that we would need 60 patients in the traditional and 'no-touch' groups, respectively. Our secondary outcome measures included procedure time and the effect of hysteroscope size, but we made no attempt to power the study for these particular variables.

Analysis was by intention to treat. Data were analysed using Student's t test for continuous variables which were normally distributed, and the Mann–Whitney U test if they were not. Confidence intervals for difference in means were calculated for continuous variables if the distribution was normal. Relative risk and confidence intervals were calculated for nominal variables. All tests were two-sided and a result of $P < 0.05$ was considered statistically significant.

Table 2. Outcomes between traditional and 'no-touch' hysteroscopy. Data are number (%) except where indicated.

	Traditional technique	'No-touch' technique	Difference between means or relative risk	95% CI
Procedure time (min), mean (SEM)	7.8 (0.5)	5.9 (0.4)	1.9	0.7–3.1
Cervical dilatation	15 (25)	10 (17)†	0.8	0.4–1.3
Local anaesthetic	13 (22)	11 (18)*	0.9	0.6–1.5
2.9 mm optic	7	3		
4 mm optic	6	8		
Biopsy taken	42 (70)	40 (67)	1.1	0.8–1.3

* Eleven patients required local anaesthetic (one for biopsy only).

† These 10 patients were converted to traditional technique.

Table 3. Pain scores during hysteroscopy. Data are median (range). Comparisons are by Mann–Whitney *U* test.

	Traditional technique	'No-touch' technique	*P*
Insertion of hysteroscope	5 (0–10)	3 (0–9)	0.62
Hysteroscopic inspection	5 (0–10)	5 (0–10)	0.12
Speculum	3 (0–8)	3 (0–9)	0.84
Local anaesthetic	4 (0–6)	6 (2–9)	0.15
Biopsy	5 (0–9)	5 (0–10)	0.04
End of procedure	3 (0–10)	3 (0–10)	0.52
30 minutes after procedure	1 (0–8)	1 (0–9)	0.49

RESULTS

The flow of patients through the trial is shown in Fig. 1. Patient characteristics and indications for hysteroscopy are shown in Table 1. There were no significant differences in any demographic variables, preprocedural anxiety, stomach pains and backache scores. The outcomes for the two groups are shown in Table 2. Overall, 119/120 hysteroscopies (99%) were carried out successfully; only one hysteroscopy was judged to be non-diagnostic because of bleeding which obscured the hysteroscopic view. No-touch hysteroscopy was significantly quicker to perform. A fifth of patients required local anaesthesia during hysteroscopy with no statistical significance between treatment groups. The influence of optic size was not statistically significant, but women undergoing 'no-touch' hysteroscopy using a 2.9-mm hysteroscope had the lowest requirement for local anaesthesia (3 of 30, 10%) (Table 2).

Pain scores at various stages of the hysteroscopy are also shown in Table 3. The only statistically significant difference in pain scores between the two main groups at any phase of the hysteroscopy was in relation to endometrial sampling, which was more painful in the 'no-touch' group. Overall, the highest pain scores were for pain from local anaesthetic injections in women allocated to the no-touch group who had to be converted to the traditional technique (median score 6).

Ninety-three percent of our patients said that they would recommend this procedure to a friend who needed this investigation. Twenty-one percent of participants said that if they required hysteroscopy again they would prefer a general anaesthetic (15% with a 2.9-mm hysteroscope and 27% with a 4-mm hysteroscope, $P = 0.18$). Ninety-two percent of women found outpatient hysteroscopy very or fairly acceptable with no difference between the two groups.

DISCUSSION

This is the first randomised controlled trial to compare traditional hysteroscopy with the vaginoscopic or 'no-touch' approach. Our findings confirm that outpatient hysteroscopy is a successful procedure which is generally well tolerated by patients. Although we have failed to demonstrate significant differences in pain for the 'no-touch' technique, we have shown that it is significantly quicker to perform. The advantage that the 'no-touch' technique was found to be about 25% quicker to perform is important for those patients who are anxious about undergoing what they consider to be an embarrassing procedure.

Our results are at considerable variance with the scant published data. In our study, only one patient scored zero for pain during the hysteroscopy, and one in six requested local anaesthesia. In contrast, in an observational study, Bettocchi and Selvaggi[12] reported that 96% of women undergoing vaginoscopic hysteroscopy reported no discomfort or pain, and none were given local anaesthesia. In that study, CO_2 was used as the distension medium, which typically causes more discomfort than fluid distension because of diaphragmatic irritation. It is difficult to explain the discrepancy between our results and that of the Italian study and we wonder if there are cultural reasons for these differences.

Nonetheless, the lack of advantage of 'no-touch' hysteroscopy in terms of the need for local anaesthesia was unexpected, both from the published literature and our prior clinical experience. We can think of three reasons for this. Firstly, based on our earlier studies,[1,2] we expected 30% of women undergoing traditional hysteroscopy to require local anaesthesia, but in fact only 20% did so. As a result, our study was underpowered and we would have had to investigate 200 patients in each group to confirm that 'no-touch' hysteroscopy reduced this rate to 10%. Secondly, the finding that 'no-touch' hysteroscopy with the larger optic proved to be the most painful of all the techniques further compromised our study. Over 25% of patients required local anaesthesia, a rate quite different from the 10% with the narrow optic. It may be relevant that fewer women required cervical dilatation with the smaller hysteroscope. Our overall results were, therefore, distorted by including two sizes of hysteroscopes in this study. Although such a large effect of optic size was not expected, it is noteworthy that the surface area of the larger hysteroscope is almost twice as large as that of the narrower optic (19.64 mm^2 *vs* 10.756 mm^2). Thirdly, we analysed our data by intention to treat, which means that the results for the no-touch group includes those who required conversion, whereas there was no similar conversion option for the traditional group. This aspect of our study was likely to dilute any real difference between the two techniques.

Similarly, there were no major differences in pain scores recorded by our patients. However, this finding is more difficult to interpret because of the use of local anaesthesia in some. What our data does confirm is that cervical injection remains the most painful part of outpatient hysteroscopy.

In summary, our study confirms that no-touch hysteroscopy is feasible in the majority of patients attending for outpatient hysteroscopy. We have found that 'no-touch' hysteroscopy was no less painful than when a traditional

technique is used but was significantly quicker by an average of 2 min. We did, however, find some evidence that the 'no-touch' approach is less uncomfortable when a narrow optic is used, and this deserves further study. Since completing this study, we have developed a device for obtaining an endometrial biopsy without the need for a vaginal speculum which is applied through the diagnostic sheath of the hysteroscope once the optic has been removed.[16] It is anticipated that this will not only reduce the time taken for hysteroscopy and biopsy even further, but hopefully will also reduce the discomfort of the biopsy process.

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