Patient satisfaction with outpatient hysteroscopy versus day case hysteroscopy: randomised controlled trial

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Abstract

Objective To compare outpatient hysteroscopy with day case hysteroscopy in terms of patient satisfaction and acceptability.
Setting Gynaecology clinic of a teaching hospital.
Participants 100 women.
Design and interventions Patients were randomly allocated to outpatient hysteroscopy or day case hysteroscopy provided they had no preference for either procedure.
Main outcome measures Satisfaction rate, requirements for postoperative analgesia, speed of recovery, time away from home, and time off work.
Results The outpatient group recovered preoperative fitness more quickly than the day case group (2 days (range 1-2.7) versus 3 days (2-4), $P < 0.05$). After the procedure, the outpatient group were also fully mobile more quickly than the day case group (0 minutes (0-5) versus 105 minutes (80-120), $P < 0.001$). Requirements for postoperative analgesia were similar in both groups. Overall, 78% of patients considered that the pain from outpatient hysteroscopy was less than that usually experienced during menstruation. Patient satisfaction was similar in both groups (83.6% in the outpatient group versus 77.0% in the day case group).
Conclusions Outpatient hysteroscopy and day case hysteroscopy were equally acceptable to patients. Patients recovered significantly more quickly from outpatient hysteroscopy than from day case hysteroscopy.

Introduction

Abnormal uterine bleeding is the second most common gynaecological symptom. Hysteroscopy combined with endometrial biopsy has almost replaced dilatation and curettage for the investigation of this symptom.[1] Most hysteroscopies are performed under general anaesthetic despite evidence suggesting it is a well tolerated and acceptable outpatient procedure.[2,3] We describe the first randomised controlled trial of outpatient hysteroscopy versus day case hysteroscopy. We hypothesised that satisfaction rates with the whole process would be similar in the outpatient and day case arms of the study.

Participants and methods

Participants

Our study was approved by the local ethics committee. One hundred patients were recruited at the gynaecology clinic of a teaching hospital. The inclusion criteria were bleeding from the vagina requiring investigation (menorrhagia, intermenstrual bleeding, and postmenopausal bleeding). We excluded patients who were unfit for day case surgery and those who preferred either outpatient hysteroscopy or day case hysteroscopy. In total, 454 patients were invited to participate in the study: 235 (52%) and 118 (26%) patients opted for outpatient and day case hysteroscopy respectively. One hundred patients (22%) agreed to participate. Each was randomly allocated at the gynaecology outpatient clinic to one of the two investigations. Randomisation was achieved with sealed envelopes containing computer generated block randomisation numbers. Randomisation and recruitment to the study were carried out independently of the clinician who later performed the hysteroscopy and the person who performed the outcome assessments.

We reviewed 100 patients for analysis. Three patients failed to return follow up questionnaires (table 1). None of the 100 patients had had an outpatient hysteroscopy. Sixteen women (32%) in the outpatient group and 14 (28%) in the day case group had had day case hysteroscopy. Each patient was also asked to complete a hospital anxiety and depression scale questionnaire.[4]

Hysteroscopy

Outpatient hysteroscopy was performed with a 3.6 mm semiflexible hysteroscope (HYF-P, Keymed Olympus, Southend) and without anaesthesia. Cervical dilatation up to Hegar number 4 was carried out when deemed necessary. Any endometrial polyps were resected under general anaesthesia at a later date. When the endometrium looked abnormal sampling was performed with a Pipelle device (Laboratoire CCD, Paris).[5] Immediately after the investigation the patient was asked to quantify the pain experienced during hysteroscopy. Analgesia was provided if required. Patients were allowed home when they felt ready.

Day case hysteroscopy was performed with a standard 5 mm rigid hysteroscope (Keymed Olympus, Southend). Cervical dilatation before hysteroscopy was performed when required. Endometrial curettings were obtained after each procedure. Each patient was informed about the findings at hysteroscopy after the operating list. Once the patient was fully mobile she was allowed home. Time away from home and time off work were recorded for each patient.

In all other aspects these two procedures were clinically similar. Carbon dioxide was the distension medium. Navigation of the cervix was carefully performed to prevent any false passage or bleeding from the cervix. A panoramic view of the uterine cavity was obtained followed by inspection of both cornua. Finally, the carbon dioxide was released to facilitate endometrial sampling.

Assessment of recovery

Recovery was assessed 30 minutes after the procedure with a modified Steward scale (scale 0-12),[6,7] which included an appreciation of the extent of consciousness, the quality of the airway, the level of activity, and the presence of nausea or vomiting. A Likert scale (scale 0-10) was used to assess the extent of pain

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Table 1 Details of patients with incomplete data who failed to return follow up questionnaire

Variable	Patient No 1	Patient No 2	Patient No 3
Study group	Day case	Outpatient	Day case
Age (years)	35	37	42
Parity	2	1	2
Previous vaginal delivery	Yes	No	Yes
Indication	Irregular heavy periods	Intermenstrual bleeding	Menorrhagia
Preoperative anxiety score	8	4	12
Cervical dilatation	No	No	No
Duration of procedure (mins)	3	3	5
Finding	Normal cavity	Normal cavity	Submucous fibroid
Intraoperative pain score:			
Expected	—	1.8	—
Maximum	—	8.2	—
Overall	—	1.5	—
Steward scale score	12	12	11
Visual analogue scale at 30 minutes	0	0	1
Other event	—	Vagal reaction	—
Time to full mobility (mins)	60	20	75

Table 2 Demographic data and risk factors for difficult outpatient hysteroscopy. Values are numbers (percentages) of patients unless stated otherwise

	Outpatient group (n=50)	Day case group (n=50)	Difference (95% CI)	P value
Age (SD) in years	45.8 (7)	45.0 (8)	0.8 (–2.4 to 3.9)	0.63
Employed	41 (82)	39 (78)	2.0 (–7.8 to 15.8)	0.61
Nulliparous	6 (12)	3 (6)	3.0 (–5.1 to 17.1)	0.27
Postmenopausal	12 (24)	9 (18)	3.0 (–9.9 to 21.9)	0.46
No previous vaginal delivery	9 (18)	7 (14)	2.0 (–10.3 to 18.3)	0.58
Previous cervical surgery	7 (14)	10 (20)	3.0 (–20.6 to 8.6)	0.42
Preoperative anxiety trait	14 (28)	17 (34)	3.0 (–12 to 24)	0.51

experienced on return to the ward in the day case group and on return home in the outpatient group.[8]

Each patient was given a diary to record analgesia requirements and fitness after discharge. Duration of recovery was recorded together with satisfaction with the procedure one week after discharge. Satisfaction with the procedure, the main outcome measure, was assessed by asking patients what type of hysteroscopy they would choose if investigation was required again.

Statistical analysis

Statistical significance was assessed by the Mann Whitney test, χ^2 test, Fisher's exact test, and unpaired *t* test. When non-parametric tests and χ^2 tests or Fisher's exact tests were used interquartile ranges and 95% confidence intervals of the difference between proportions are given respectively.

Results

Fifty patients were randomised to each procedure. Both groups were homogeneous for demographic data, anxiety levels, and risk factors for difficult hysteroscopy (table 2).

Two outpatient procedures failed (4%, 95% confidence interval 0% to 9%); one because of cervical stenosis and the other at the patient's request because of pelvic discomfort. Cervical dilatation was necessary in 11 patients in the outpatient group (22%, 10% to 33%).

Patient satisfaction

No difference was found in patient satisfaction rate between outpatient hysteroscopy and day case hysteroscopy (table 3). In the outpatient group, 13 (81%, 61% to 100%) of those patients who had had hysteroscopy under general anaesthesia would opt for outpatient hysteroscopy again. Endometrial sampling was performed in 31 patients (62%) in the outpatient group. No significant difference in satisfaction rates was found between the patients in whom endometrial sampling was carried out and those in whom it was not (80.6% versus 88.8%, – 11.6% to 28%).

Recovery

All patients who had undergone outpatient hysteroscopy scored the maximal mark on the modified Steward scale (12/12) indicating full recovery at 30 minutes. Seven out of 46 patients (14%) in the day case group scored less than 12, mainly because of postoperative nausea or vomiting. Two other patients were unable to communicate within 30 minutes of the procedure. Patients in the day case group took significantly longer to recover full mobility and full fitness than those in the outpatient group. Forty patients (80%) in the outpatient group were fully mobile immediately after the procedure. Women in the outpatient group spent significantly less time away from home and less time off work than those in the day case group. Requirements for postoperative analgesia were similar in both groups (table 3). Table 4 shows the intraoperative pain levels for the outpatient group.

Factors associated with reduced patient satisfaction

Pain and the need for cervical dilatation during the procedure were associated with a reduced level of satisfaction in the outpatient group. There was a trend towards a lower satisfaction rate in postmenopausal patients (table 5). Patients who required a repeat

Table 3 Main outcomes

Variable	Outpatient group (n=49)	Day case group (n=48)	Difference (95% CI)	P value
No (%) of patients satisfied	41 (84)	37 (77)	4.0 (–9 to 22)	0.42
No (%) of patients who needed analgesia at end of hysteroscopy	6 (12)	7 (14)	1.0 (–10 to 17)	0.74
Pain score at 30 minutes (scale 0-10)	0.4 (0-1.2)	0.3 (0-2.2)		0.34
Minutes to recovery of full mobility (interquartile range)	0 (0-5)	105 (80-120)		<0.001
No (%) of patients needing pain relief D0*	15 (30)	16 (33)	–1.0 (–13 to 24)	0.77
No (%) of patients needing pain relief D1†	11 (22)	11 (23)	0 (–14 to 19)	0.93
Median No (range) of days of analgesia	0 (0-2)	0 (0-4)		0.27
Full recovery on day (interquartile range)	2 (1-2.7)	3 (2-4)		<0.05
Days away from work (interquartile range)	1 (0-1.6)	3(2-4)		<0.0001
Minutes away from home (interquartile range)	120 (110-170)	480 (450-525)		<0.0001

*Patients who need some form of oral or injectable analgesia on day of procedure (immediately after procedure or at home).
†Patiens who need some form of oral or injectable analgesia on day after procedure.

procedure (10 of 49, 20%) were less satisfied than those who did not (60% (6 of 10) versus 89% (35 of 39) respectively, −61% to 2%). No association was found between the level of preoperative anxiety, the use of analgesia, and the satisfaction rate.

Reduced patient satisfaction in the day case group was associated with prolonged recovery of preoperative fitness (3 days (range 1-3) in satisfied patients versus 4 days (4-6) in unsatisfied patients, $P < 0.01$). There was also a trend towards a lower satisfaction rate in postmenopausal patients than in premenopausal patients (table 5).

Table 4 Intraoperative pain levels (scale 0-10) in outpatient group (n=50). Values are numbers (percentages) of patients unless stated otherwise

	Overall pain	Maximum pain	Expected pain
Mean (SD)	2.3 (1.8)	3.1 (2.3)	5.1 (2.5)
Median	2.0	2.8	4.7
Interquartile range	0.8-3.5	1.6-4.8	3.7-7.2
Pain score <3	36 (72)	29 (58)	11 (22)
Pain score <1	15 (30)	8 (16)	1 (2)
Pain score >5	8 (16)	12 (24)	23 (46)
Pain less than period pain	39 (78)	NA	NA

NA=not available.

Table 5 Satisfaction rates in relation to menopausal status. Values are numbers (percentages) of patients unless stated otherwise

	Postmenopausal	Premenopausal	Difference (95% CI)	P value
Outpatient	8/12 (66)	32/37 (86)	20.0 (–48.4 to 8.8)	0.12
Day case	5/9 (55)	32/39 (82)	27.0 (–60.2 to 8.1)	0.08

Discussion

Outpatient investigation of abnormal uterine bleeding is a comparatively new concept in gynaecology. Whereas endoscopy is accepted as an outpatient procedure in gastrointestinal medicine, the same is not true in gynaecology. There are potential advantages to an outpatient approach to investigation, least of which is the ability for direct access to services by general practitioners. We present the first randomised controlled trial of a strategy for outpatient investigation of women with abnormal uterine bleeding. Our trial compared traditional day case hysteroscopy, using general anaesthesia, with the novel outpatient approach.

Patient satisfaction and recovery

We set out to determine the differences in recovery and acceptability between the two procedures, concentrating on the whole process and not merely the technique of hysteroscopy. We found that outpatient hysteroscopy was associated with equal patient satisfaction to day case hysteroscopy. From the patients' and the healthcare provider's perspective outpatient hysteroscopy is likely to be more convenient than day case hysteroscopy as it is quicker and avoids undue hospital stay.

Outpatient hysteroscopy was better than day case hysteroscopy for all aspects of patient recovery. This has important social implications for patients and employers: time off work, childcare arrangements, and cost implications in particular (patient, employer, and service provider). These issues will be addressed in a subsequent publication.

Factors associated with patient satisfaction

Failure to gain access to the uterine cavity has been a concern in outpatient hysteroscopy. Failure rates range from 1.5%[9] to 9%.[10] The failure rate in our study was 4%. A satisfaction rate of 97% had been reported in a previous cohort study[11 12] despite a 6% failure rate and a mean visual analogue score of 3.25.[11] The inference is that patients tolerate acceptable failure and discomfort and still remain satisfied.

In our study the need for a repeat procedure after an endometrial polyp had been diagnosed was also associated with a lower satisfaction rate. Reducing this need by removing the polyp in the outpatient department may improve patient satisfaction but would prolong the procedure.

Patients may favour outpatient hysteroscopy because they spend less time in hospital. They may also perceive their care as being more personalised. Indeed, each patient is counselled, investigated, and finally informed of the findings, in sequence. In addition, the patient can observe the procedure on a television monitor thereby perhaps enhancing understanding of her condition.

We used two different types of hysteroscopes, which differed by 1.4 mm in diameter. This difference was not thought to influence patient satisfaction with the overall investigative process. This assumption is supported by the similar and low pain scores in both groups shortly after the procedure.

Only 21% of the eligible patients agreed to participate in our study. When patients were initally approached one quarter decided to opt for a day case procedure in the belief that this was the conventional procedure. Half of the patients opted for an outpatient procedure because of its perceived convenience. In undecided patients, the satisfaction rate with either of the procedures was similar. It would seem therefore that for most women outpatient hysteroscopy is a satisfactory alternative to day case hysteroscopy.

The perceived benefits of outpatient hysteroscopy may not apply equally to premenopausal and postmenopausal patients. Our study was not large enough to detect a significant difference in satisfaction rates between these two subgroups. Interestingly, the same difference in satisfaction rates between premenopausal and postmenopausal women was seen in both the day case group and the outpatient group.

Further studies

Recovery and requirements for analgesia were the main clinical outcomes addressed in our study. The comparison of aspects such as diagnostic value and morbidity can not be assessed in a study of this size. Our results provide an interesting preliminary finding that should lead to a much larger randomised study addressing these other important clinical issues. Data from large cohort studies suggest that outpatient hysteroscopy is just as safe as hysteroscopy under general anaesthesia.[3 13]

Despite the well documented advantages of outpatient hysteroscopy there is a perceived reluctance to implement this type of service. There may be concerns about patient discomfort and acceptance. This procedure is thought to provoke anxiety in patients, thus influencing satisfaction. The present study does not support these concerns.

Key messages

- Patients' satisfaction rates with outpatient hysteroscopy and day case hysteroscopy were similar
- The outpatient group recovered preoperative fitness more quickly than the day case group
- Requirements for postoperative analgesia were similar in both groups
- 78% of patients considered that the pain from outpatient hysteroscopy was less than that usually experienced during menstruation
- Postmenopausal women may benefit less from outpatient hysteroscopy than premenopausal women

Conclusion

Patients are not disadvantaged by the introduction of outpatient hysteroscopy. Several advantages may prove attractive to patients and healthcare providers: return to mobility, full fitness, and work occur more quickly after outpatient hysteroscopy than after day case hysteroscopy. Increased attention should be paid during counselling of patients at higher risk of dissatisfaction with hysteroscopy, such as postmenopausal patients. The development of outpatient hysteroscopy is a potentially significant advance in gynaecological investigation. It lends itself to a greater accessibility for general practitioners and patients, especially if a direct referral service from a general practitioner is contemplated.

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Prenatal ultrasound examinations and risk of childhood leukaemia: case-control study

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Obstetric ultrasound examination is part of routine antenatal care and is regarded as safe for both the fetus and the mother. In vitro, however, ultrasound has been shown to cause membrane changes that could affect embryogenesis and late prenatal and postnatal development.[1] Studies have also shown an association between exposure to ultrasound and an increased frequency of non-righthandness, indicating that fetal development may be affected by the ultrasonic waves.[2]

Concerns over a possible association between exposure to ultrasound in utero and an increased risk of childhood malignancies have not been substantiated, but previous studies have been hampered by low statistical power or based on interviews with the parents done retrospectively, or both.[3–5]

To assess the impact of ultrasound and the risks of childhood lymphatic and myeloid leukaemia, we performed a nationwide population based case-control study using prospectively assembled data on prenatal exposure to ultrasound.

Subjects, methods, and results

The cases in this study comprised all children born and diagnosed as having leukaemia between 1973 and 1989 and reported to the nationwide Swedish registers of birth, cancer, and causes of death—in all, 752 cases. One control was randomly selected for each child with leukaemia from the Swedish Birth Registry and matched by sex and year and month of birth. The study was restricted to cases and controls without Down's syndrome (n = 731), and medical records of 652 (89%) matched case-control pairs could be retrieved (578 cases with lymphatic leukaemia and 74 with myeloid leukaemia).

Altogether, 361 (48%) of the children with leukaemia had developed it before the age of 4, and 21 children were born in twin pregnancies. Information on exposure was extracted from antenatal, obstetric, and other standardised medical records by one of us (EN), who was blind to whether the child was a case or control. Conditional logistic regression was performed to study the association between prenatal exposure to ultrasound and childhood leukaemia (lymphatic and myeloid leukaemia). Maximum likelihood methods were used to estimate the odds ratio and 95% confidence intervals.

In all, 200 children with lymphatic leukaemia and 214 controls had been exposed prenatally to ultrasound (odds ratio 0.85; 95% confidence interval 0.62 to 1.17) (table). The risk of lymphatic leukaemia was not influenced by either the number of ultrasound