- Title
 - o Is Outpatient Hysteroscopy the new Gold Standard? Results from An Eleven Year Prospective Observational Study
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Is Outpatient Hysteroscopy the New Gold Standard? Results from an Eleven Year Prospective Observational Study

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Abstract

Background:

In Australia, gynaecologists continue to investigate women with abnormal bleeding and suspected intrauterine pathology with inpatient

hysteroscopy despite some evidence in the literature that there is no difference in safety and outcome when compared to an outpatient procedure.

Aims:

This prospective study assessed the safety, effectiveness and acceptability of outpatient hysteroscopy over 11 years at a tertiary hospital in Australia. Resource savings were then calculated.

Materials and Methods:

A prospective database was analysed from March 2003 to January 2014 (130 months, 990 women).

Results:

Successful hysteroscopic access was obtained in 94% of cases. Twenty six percent of patients required a second procedure, including 132 for endometrial polyps and 33 for submucosal fibroids that were not able to be treated in the outpatient setting. On questioning, 88% of women would be happy to have the procedure again.

Factors affecting success were pre procedure pain, menopausal status and previous vaginal delivery. The difference between pain experienced versus pain expected was a major factor in patient acceptability. A vasovagal episode occurred in five percent of cases.

Conclusion:

Outpatient hysteroscopy was demonstrated to be safe, effective and acceptable to women. Provision of an outpatient hysteroscopy service saves theatre time and approximately \$1000 per case. Improved techniques and technology will allow progression to a 'see and treat' service, providing further savings.

With budget constraints, increasing wait times for major procedures and concerns about trainee surgical experience, an outpatient hysteroscopy service

should be considered the 'gold standard' investigation over hysteroscopy in theatre.

Introduction

Treatment of abnormal uterine bleeding (AUB) accounts for approximately a third of all gynaecological consultations (1). Many women will require further investigation, which in Australia, usually involves an inpatient hysteroscopy and endometrial sampling under general anaesthetic. This has previously been reported as the 'gold standard' of treatment (1, 2). Such cases utilise a significant portion of elective surgical time that could otherwise be allocated for major procedures. This impacts on elective wait list times and surgical training. Women are also exposed to a general anaesthetic with associated risks and longer return to normal duties (3, 4).

Outpatient hysteroscopy is commonly practised overseas. A British national survey in 2001 showed 56% of units had access to an outpatient hysteroscopy service (5). A 1997 survey of AAGL membership showed 36% of members performed office hysteroscopy (6).

In 1994, Gillespie and Nichols estimated that if the approximately 96,000 hysteroscopies performed in theatre Australia wide were completed as outpatient procedures, approximately \$29,000,000 could be saved. A similar analysis in 2004 by Marsh, Kremer and Duffy estimated a saving of £12.5 million if the 230,000 diagnostic hysteroscopies in the UK were performed as outpatient procedures.

The unit's experience has been that general practitioners, specialist colleagues and patients often have a reluctance to utilise the service due to concerns about perceived poor chances of successful access and potential patient discomfort.

A review of the Unit's 11 year prospective database has been conducted to assess efficacy, safety and acceptability with a view to encouraging patients and clinicians to access the benefits of the outpatient hysteroscopy service. Analysis to identify factors that impact on successful hysteroscopic access and willingness to repeat

the procedure were assessed. Cost analysis was then performed to calculate the theatre time and money saved by running such a service.

Materials and Methods

The outpatient hysteroscopy clinic has been operating since 1993. Indications for referral include abnormal uterine bleeding (heavy, intermenstrual or post-menopausal bleeding), assessment of the uterine cavity for endometrial pathology (e.g. polyps or submucosal fibroids) and removal/insertion of an intra-uterine device (IUD).

Relative contra-indications include women who are expected to tolerate the procedure poorly or in whom a low chance of success is anticipated. Such women include those unable to tolerate a vaginal examination, unwilling to undergo an awake procedure or who have a known history of cervical stenosis.

Patients should also be medically able to tolerate a vasovagal response and should not pose a nursing challenge if such a complication occurs. Therefore relative contraindications include those women who have an age greater than 65, those who have a significant cardiac history or those who weigh greater than 120kgs.

A prospective database has been collected since March 2003. Details recorded include indication, menopausal status, history of previous vaginal delivery, technique (vagoscopic or hysteroscopic), success of entry and view, use of pipelle sampling (adequacy of specimen and histopathological findings), pre-procedure/anticipated/post procedure pain scores (measured by a visual analogue scale scored out of ten), acceptability of the procedure and complications (vasovagal and perforation).

Over the last 11 years, the technique used has been modified. Carbon dioxide was used as a distension medium until 2005, after which time normal saline was the distension medium of choice as it provided better vision and less side effects. Initially, hysteroscopy was performed after insertion of a bivalve speculum into the vagina and application of 0.1% lignocaine spray and tenaculum to the anterior cervix. During 2008, a transition was made to utilise the 'vagoscopic' or no touch technique, which does not require the afore mentioned procedures.

Currently women are offered diclofenac 50 milligrams on arrival unless contraindicated, in which case paracetamol +/- codeine is used. A 3mm Olympus® (Olympus Australia, Melbourne, Victoria, Australia) rigid hysteroscope with a 4mm sheath is passed through the vagina and cervical canal into the uterine cavity using saline as a distension medium. After hysteroscopy is complete, if no levonorgestrel releasing intrauterine system (LNG-IUS, Mirena®, Bayer Schering Pharma AG, Berlin, Germany) is to be inserted, the 3mm hysteroscope is withdrawn and a H pipelle (Laboratoire C.C.D, Paris, France) passed through the 4mm sheath at least two times to sample the endometrium. If a Mirena® is to be inserted, then the hysteroscope and sheath are withdrawn, a bivalve speculum inserted and endometrial sampling is performed with a Rocket® endometrial sampler (Rocket Medical, Watford, England) prior to proceeding with Mirena® insertion.

Variations to the standard procedure include changing from a vaginoscopic approach to standard hysteroscopy if the vaginoscopic technique is not appropriate or successful. At this time, we are able to use topical cervical lignocaine spray, intracervical, paracervical, intrauterine block or cervical dilators, though this is a rare occurrence.

Verbal consent was obtained from women for inclusion into the prospective database. There was no additional risk to patients and this activity is consistent with clinical audit rather than research. Therefore institutional ethics approval was not required in line with current NHMRC guidelines for clinical audits/quality projects (9).

Data was entered into an Access/Excel Microsoft spreadsheet. Difference between experienced and anticipated pain was calculated. Univariate analysis was performed with regards to successful hysteroscopic access, pain experienced, willingness to repeat the procedure and vasovagal reactions. Comparison of continuous variables were performed via the Excel calculator using a Student's two tailed t test with unequal variance. Dichotomous data was formed into 2x2 contingency tables and then analysed with a 2 tailed Fisher's Exact test via the free online calculator by Graphpad software (<http://graphpad.com/quickcalcs/contingency1/>). A p-value <0.05 was considered statistically significant.

Results

Nine hundred and ninety women attended the outpatient hysteroscopy clinic between March 2003 and January 2014 (130 months).

Primary indications for referral and menopausal status are listed in figure 1.

Five percent (52/990) had a secondary indication of an endometrial polyp on ultrasound for investigation.

Two hundred and twenty two (22%) IUD insertions were performed.

Patient flow through the service is demonstrated in Figure 2.

Endometrial sampling results are demonstrated in Figure 3.

Mean pre procedure pain was 0.90/10, anticipated pain was 3.4/10 and experienced pain was 3.7/10.

Ninety four percent (930/990) of patients had successful outpatient hysteroscopic access. The majority of failures were due to patient pain and therefore inability to continue with the procedure. There were very few instances of failed hysteroscopic access independent of patient pain.

Women were asked at the end of the procedure if they would have the procedure again if required. Ninety four percent (930/990) had documented responses. Of the 60 undocumented responses, there were 13 unsuccessful hysteroscopies and four women who had vasovagal reactions. These 17 women were assumed for analysis to have declined to have the procedure again. Eighty eight percent (837/947) of women would be willing to have the procedure again if required.

Fifty women (5%) had a vasovagal response of varying severity, though none required admission overnight. All of these patients reported pre-syncopal symptoms during or after the procedure, with the majority resolving with supine positioning and observation. There was only one uterine perforation documented from the cohort. This woman was managed with observation and a course of oral antibiotics. The woman's post discharge progress was uneventful.

Mean pain scores analysed by procedure outcome is shown in Table 1. Baseline pre-procedure pain was significantly associated with decreased successful outpatient

hysteroscopic access ($p=0.034$). The average pre procedure pain score in patients with successful access was 0.87/10 versus 1.5/10 for those in whom access was not able to be obtained.

Mean pain scores analysed by willingness to repeat the procedure is shown in Table 2. Women who reported higher pain scores during the procedure, or had a significant disparity between expected pain versus experienced pain, were less likely to be willing to have a repeat procedure ($p<0.0001$).

Univariate analysis of menopausal state is shown in Table 3.. Successful hysteroscopic access was significantly lower in post-menopausal patients compared to premenopausal women (89% vs 96%, $p=0.0004$), though still acceptably high.

Univariate analysis of parity status is shown in Table 4. Successful access was significantly lower in nulliparous women compared to parous patients (89% vs 95%, $p=0.0017$), though still acceptably high. Nulliparous women experienced significantly more pain than women who had had a previous vaginal delivery (3.9/10 vs 3.6/10, $p=0.0047$) and were less willing to have a repeat outpatient hysteroscopy (82% vs 90%, $p=0.0016$), though overall willingness to have a repeat procedure if required was still high.

Univariate analysis of hysteroscopic access technique are shown in Table 5. Patient acceptability improved after the transition from standard hysteroscopy to vaginoscopic technique (88% vs 93%, $p=0.01$).

Discussion

This study demonstrates that outpatient hysteroscopy is a safe, reliable and acceptable alternative to hysteroscopy and endometrial biopsy under general anaesthetic for investigation of abnormal uterine bleeding and intrauterine pathology. This is consistent with other publications with smaller numbers and shorter duration that have shown outpatient hysteroscopy to be acceptable to women, with low complication rates and comparable findings to inpatient hysteroscopy (1, 2, 3, 4, 10).

Factors that may make women or referrers reluctant to utilise the service such as menopausal status and nulliparity were investigated. Although successful hysteroscopic

access was significantly lower with post-menopausal status and nulliparity, successful access was still obtained in almost 90% of these women. Nulliparous women experienced significantly more pain than women who had had a previous vaginal delivery but 82% were still willing to undergo a repeat outpatient procedure if required. Eighty seven percent of post-menopausal women were willing to undergo a repeat outpatient hysteroscopy if required. The overall rate of vasovagal reaction was low and did not differ significantly with regards to menopausal status or parity. This information should aid in reassuring women and referring clinicians about the likely success and low risks in women with potentially perceived contraindications to outpatient hysteroscopy.

Baseline pre-procedure pain was significantly associated with decreased successful outpatient hysteroscopic access. Therefore, screening during initial consultation for significant pre procedure pain should be performed to identify women less likely to tolerate or have a successful outcomes. Significant pre procedure pain should be considered a relative contra-indication for outpatient hysteroscopy which may also manifest as inability to tolerate a vaginal examination. If a decision is made to proceed with outpatient hysteroscopy, these patients should be encouraged to take pre procedure analgesia.

Women who reported high pain scores during the procedure, or had a significant disparity between expected pain versus experienced pain, were less likely to be willing to have a repeat procedure. However, this may be an indirect measure of the higher unsuccessful access rate (77% versus 6%) in the group that were unwilling to repeat the procedure who would potentially have experienced greater procedure time and instrumentation during the procedure.

To try to minimise the difference between expected pain versus experienced pain, realistic pre procedure counselling about expected pain, pre procedure analgesia and distraction techniques during the procedure may aid in further improving patient acceptability. The use of narrow diameter 'mini hysteroscopes' has also been demonstrated to cause reduction in outpatient procedure pain scores (11). This would be expected to improve patient acceptance and decrease the rate of failed procedures due to experienced pain.

Patient acceptability improved after the transition from standard hysteroscopy to vaginoscopic technique. Vaginoscopic/'no touch' insertion techniques with the use of disposable endometrial samplers long enough to pass down the hysteroscopic operating channel avoids the need for speculum and tenaculum application, minimising instrumentation and shortening intervention time resulting in improved success and patient tolerance (12, 13, 14). Although the average pain scores during the procedure are similar, there is a trend towards increased successful access and decreased vasovagal reactions with the vaginoscopic approach. Our Unit's experience is that the learning curve for this technique is short and easily adopted by doctors familiar with traditional hysteroscopy in both the general anaesthetic and ambulant setting.

The diversion of 735 cases from theatre to an outpatient setting over 11 years has major resource and training benefits. Assuming 30 minutes of operating time is required per hysteroscopy performed in theatre, over 33 hours of theatre time was saved per year or roughly 7-8 theatre lists per year of the study.

Costs of outpatient versus in theatre hysteroscopy were estimated after discussion with hospital administration. It was calculated that the additional cost of theatre staff, anaesthetic team and consumables amounted to an additional \$1000 per case performed in theatre or roughly twice the cost of an outpatient procedure. Therefore, even allowing for the 26% of women who required a second procedure in theatre, the outpatient hysteroscopy service is estimated to have cost 24% less than if all women had initially undergone a hysteroscopy in theatre. This translates to approximately \$735,000 saved over the study period. This is consistent with a cost analysis study in an American health setting, which showed significant cost benefit with the use of an outpatient diagnostic hysteroscopic service despite 42% of patients needing a second inpatient procedure and a greater than threefold difference between inpatient and outpatient provision (15).

Over the years with active education from our group about the benefits to patients and the hospital, medical staff from our hospital now routinely refer women to the unit's outpatient hysteroscopy service. In 2003, only 60 outpatient hysteroscopies were performed. This has significantly increased over the decade so that more than 400 women were managed through the service in 2014-2015. As the uptake of outpatient

hysteroscopy continues to increase each year at our institution, even accounting for the need for second procedures for resection of polyps and submucosal fibroids, it is estimated approximately 45 hours of operating time or about 11 theatre lists and \$180,000 were saved each year by diverting women away from inpatient hysteroscopy from 2014 onwards.

The introduction of a small bipolar electrodathermy system for use in normal saline (Versapoint, Gynecare Inc, Menlo Park, CA, USA) and mechanical morcellation devices e.g. Myosure (Hologic, Bedford, MA) and Truclear (Smith & Nephew, Andover, MA) allows the diagnosis and treatment of minor endometrial abnormalities such as endometrial polyps in a single outpatient visit. This results in a shorter time away from work and faster recovery compared to day case polypectomy with similar improvements in symptoms of abnormal uterine bleeding (16, 17). If applied to the study cohort, this could potentially decrease the need for a second inpatient general anaesthetic procedure to 9% (87/990). This would have a potential saving of approximately 82 hours of operating time or 20 operating lists over the study period. If applied to the 2014/2015 cohort, this would have resulted in a total of approximately 85 additional hours of operating or approximately 21 theatre lists per year.

Although not assessed in this study's cohort, outpatient hysteroscopy has also been proposed as a beneficial technique in the investigation and management of fertility patients. Investigative hysteroscopy can be performed followed by tubal catheterisation, tubal occlusion or minor hysteroscopic surgery (18).

Conclusion

The results of this study confirms the safety and acceptability of outpatient hysteroscopy. It reaffirms that potential perceived contraindications such as post-menopausal status and nulliparity still have high success rates and patient acceptability. This should help reassure women and referrers reluctant to utilise the service. We have demonstrated an outpatient hysteroscopy service can bring major cost and resource savings to individual hospitals as well as national health services. This benefit is particularly realised as increased uptake occurs with increased acceptability by women and medical staff. Units not currently providing this service should consider the

benefits of establishing an outpatient hysteroscopy unit. Published guidelines are readily accessible to aid this process (19, 20).

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Table 1: Mean Pain Scores for Successful Versus Unsuccessful Hysteroscopic Access

	Successful Hysteroscopic Access (n=930)	Unsuccessful Hysteroscopic Access (n=60)	P value
Average Pre Procedure Pain	0.87/10	1.5/10	P=0.034
Average Expected Pain	3.6/10	3.7/10	p=0.37
Average Experienced Pain	3.7/10	4.2/10	p=0.13
Difference Between Experienced and Expected Pain	0.3	0.7	p=0.44

Table 2: Mean Pain Scores for Willingness to Repeat Procedure Versus Would Not Have Repeat Procedure

	Willing to repeat procedure (n=837)	Unwilling to repeat procedure (n=110)	P value
Average Pre Procedure Pain	0.89/10	1.2/10	p=0.11
Average Expected Pain	3.5/10	3.8/10	p=0.24
Average Experienced Pain	3.6/10	5.9/10	p<0.0001
Difference Between Experienced and Expected Pain	0.14	2.1	p<0.0001

Table 3: Univariate Analysis- Premenopausal Versus Post-Menopausal Patients

	Premenopausal (n=721)	Post-menopausal (n=262)	P value
Average Pain experienced	3.7/10	3.7/10	p=0.99
Successful hysteroscopic access	96%	89%	P=0.0004
Vasovagal reaction	4.4%	7.7%	p=0.066
Willingness to have repeat outpatient hysteroscopy	91%	87%	P=0.08

Table 4: Univariate Analysis- Multiparous Versus Nulliparous Patients

	Multiparous (n=774)	Nulliparous (n=213)	P value
Average Pain experienced	3.6/10	3.9/10	p= 0.0047
Successful hysteroscopic access	95%	89%	p=0.0017
Vasovagal reaction	4.3%	7.5%	p=0.073
Willingness to have repeat outpatient hysteroscopy	90%	82%	P=0.0016

Table 5: Univariate Analysis- 'Traditional' versus Vaginoscopic Hysteroscopic Access

	'Traditional' hysteroscopic access (n=442)	Vaginoscopic access (n=473)	P value
Average Pain experienced	3.7/10	3.8/10	p= 0.36
Successful hysteroscopic access	92%	95%	p=0.09
Vasovagal reaction	6.8%	4%	p=0.07
Willingness to have repeat outpatient hysteroscopy	88%	93%	P=0.01

Figure 1- Indications for Referral and Menopausal Status

Figure 2- Patient Flow- Hysteroscopy

Figure 3- Patient Flow- Endometrial Sampling

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