

Is it possible to perform all Diagnostic Hysteroscopies in the Outpatient Hysteroscopy Clinic?

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Abstract

Objectives: To assess the viability of increasing the proportion of diagnostic hysteroscopies performed in an outpatient setting (OPH), versus those under general anaesthetic; and to establish factors which may determine the choice of operative setting.

Method: A comparison of two audits of theatre hysteroscopy procedures (at Whipps Cross University Hospital), with an assessment of the trend in the use of both outpatient and theatre hysteroscopies.

Results: Between April-2012 and October-2015 3381 patients underwent hysteroscopies, with a relatively consistent number of procedures per month (average 79.5). There was a significant ($P=0.001$) change in how diagnostic hysteroscopies were performed (OPH rose by 65.5% and in-theatre hysteroscopies fell by 42.6%).

In a one-month audit of patients who underwent theatre hysteroscopies in 2012, 50 patients underwent the procedure of which: 6 (12%) met the exclusion criteria and were unsuitable for OPH; 44 (88%) had no factors that met the exclusion criteria (disregarding patient preference or a failed OPH); 36 (72%) met the inclusion criteria and could have received OPH. In a further audit conducted over two months in 2015, of the 42 patients who underwent theatre hysteroscopies 20 (47.62%) met the exclusion criteria for OPH. Of the remaining 22 (52.38%); nine (21.43%) were unsuitable due to patient preference, for five (11.90%) no reason was recorded and eight (19.05%) were booked under general anaesthetic to prevent breaches of suspected cancer targets.

Conclusions: Hysteroscopies have been performed in the outpatient setting in increasing numbers, resulting in reduced risks to the patient, faster, cheaper treatment, and shorter recovery times. There has been a marked improvement in documenting the justification for the chosen referral option. This suggests an increased awareness of the inclusion and exclusion criteria for OPH by staff and promotion of OPH to patients. This improvement was achieved by better patient awareness of OPH, and changing the attitudes of clinicians. More could be done to increase further the number OPH referrals, including providing dedicated time in clinic for treatment where cancer is suspected, and further normalisation of OPH for patients. Consideration could be given to introducing a see-and-treat clinic model, and requiring the reasons for general anaesthetic referral to be recorded.

Introduction

Diagnostic hysteroscopies are being conducted increasingly in the outpatient setting rather than under general anaesthetic, given the benefits of shorter patient recovery time and the reduction in anaesthetic risk. However, this transition has not been as swift or as complete as might be assumed given the benefits of the newer approach. This paper asks why this might be the case by assessing the impact of a quality improvement project into diagnostic hysteroscopy procedures carried out at Whipps Cross University Hospital (Whipps), to understand the clinical and other factors behind the choice of setting for hysteroscopies, and determine if it is possible to perform all diagnostic hysteroscopies in an outpatient hysteroscopy (OPH) clinic. It is clear there are important reasons for the two approaches and this paper explores these and draws conclusions about how judgments can be made about the balance between the uses of the two approaches.

Background

Hysteroscopy is a minimally invasive procedure that involves passing an endoscope through the vagina and cervix to visualize the uterine cavity. It has both diagnostic and therapeutic uses. Diagnostic uses include the investigation of abnormal uterine bleeding and postmenopausal bleeding. Other indications include the retrieval of intrauterine contraceptive devices, the resection of polyps/fibroids/adhesions, Müllerian abnormalities and sterilisation.

Traditionally hysteroscopy has been performed in day theatre under a full general anaesthetic. However, in 2011 the Royal College of Obstetricians and Gynecologists issued a green top guideline about providing OPH having concluded that OPH is a safe and effective procedure. It is recommended that all gynecological units should provide an OPH service [1].

OPH has become feasible due to the development of small (2.7mm with sheath 3.5mm or less) endoscopes which reduces patient pain ($p < 0.0001$) when compared to 5mm designs. This pain reduction increases patient compliance and allows the procedure to be performed without general anaesthesia or cervical dilation. OPH has now advanced to the point it is the gold standard for the investigation of postmenopausal bleeding [2, 3, 4, 5].

Benefits of the outpatient setting

OPH is the preferable way of performing a diagnostic hysteroscopic procedure (and minor surgical

procedures), as it results in faster patient recovery and mobilisation and is more cost effective. Outpatient hysteroscopy is considered acceptable to patients [6].

Marsh conducted a randomised controlled trial to determine cost benefits of outpatient hysteroscopy (OPH). They were able to show financial benefits to the patient, by reducing lost income, and reduced travel expense. They showed there is also a fiscal benefit to the National Health Service (NHS); in 2004 an OPH cost £53.88 less than a day case procedure. While there is an initial outlay required to establish an outpatient service, this cost is recouped after treating approximately 38 patients. There is also a direct fiscal benefit to gynaecology units that perform OPH- in the 2015/2016 financial year, an OPH carries a £501 tariff, while a combined day case/ordinary elective spell tariff commands £286 [7,8].

Kremer *et al* [7] performed a randomised trial and found that patients benefit from faster recovery: two days (range 1-2.7) after OPH versus three days under GA. There is also evidence of faster patient mobilisation after outpatient hysteroscopy (range 0-5 minutes), versus a delay of 105 minutes (range 80-120 minutes) [7, 8, 9].

Risks of general anaesthetics

While general anaesthesia (GA) is a well-practised and carefully monitored procedure it continues to bring risks to the patient. Some are common such as damage to the lips or tongue which occur as often as 1 in 20 patients. More seriously Anaphylaxis may occur (in between 1 in 10,000 and 1 in 20,000 patients) and death may occur (in 1 in 100,000 patients). These are risks that could be avoided if patients undergo OPH rather than theatre hysteroscopy under GA [10,11,12,13]

How patients are Assessed for suitability for OPH?

Whipps Cross Outpatient Hysteroscopy Referral Criteria:

- endometrial pathology identified on ultrasound scan (polyps or fibroids less than two centimetres)
- over 45 years of age with more than three months of irregular vaginal bleeding
- over 45 years of age with over a three-month history of heavy periods less than 45 years old with over a three-month history of failed treatment

Whipps Cross Outpatient Hysteroscopy Exclusion Criteria

- endometrial or submucosal lesions larger than two centimetres

- coexisting pelvic pathology such as large ovarian cysts on ultrasound,
- Possible Tamoxifen induced pathology,
- Cervix is flush with the vaginal vault/ severe cervical stenosis.
- OPH hysteroscopy unacceptable to patient.

Methods

Following good practice OPH is performed by a gynaecologist or nurse practitioner who has been trained in the OPH procedure, using a 1.8mm semi-rigid hysteroscope with a 3.5mm sheath [1, 8, 14]. The uterus is dilated using saline. Neither conscious sedation nor local anaesthesia are routinely offered however, women are advised to take a single dose of an anti-inflammatory one hour before the procedure providing there are no contraindications. OPH performed in this way has proved to be well tolerated by patients with very few being failures referral for hysteroscopy under general anaesthesia.

A report of patient hysteroscopy procedures performed was captured from the Whipps procedure summary software in October 2015. These data covers procedures performed between the 1st April 2012 and 14th October 2015, referenced under 'diagnostic hysteroscopy' (HGA code MA21Z). Any procedures not generating this code or which were combined with other procedures were excluded. This data was analysed using the chi squared statistical analysis (the null hypothesis that there was no change in the location where hysteroscopies were being conducted). System limitations mean that further exclusion criteria regarding suitability of procedures for outpatient hysteroscopy are unobtainable. Therefore, trends may be commented upon but further analysis was required to reveal the reasons why diagnostic hysteroscopies were performed under GA.

To monitor the effective usage of out-patient hysteroscopy an initial audit of one month of hysteroscopies performed under general anaesthesia (GA) was completed in 2012. In 2012/13 an average of 54 hysteroscopies were performed per month. In order to achieve a 95% confidence/0.05 degree of error 48 sets of notes were required, (though in practice 50 procedures carried out under GA were sampled). These data were taken retrospectively from patients attending the Plane Tree Theatre and audited according to a standardised proforma which was developed in line with the current protocol for determining where patients should be scanned.

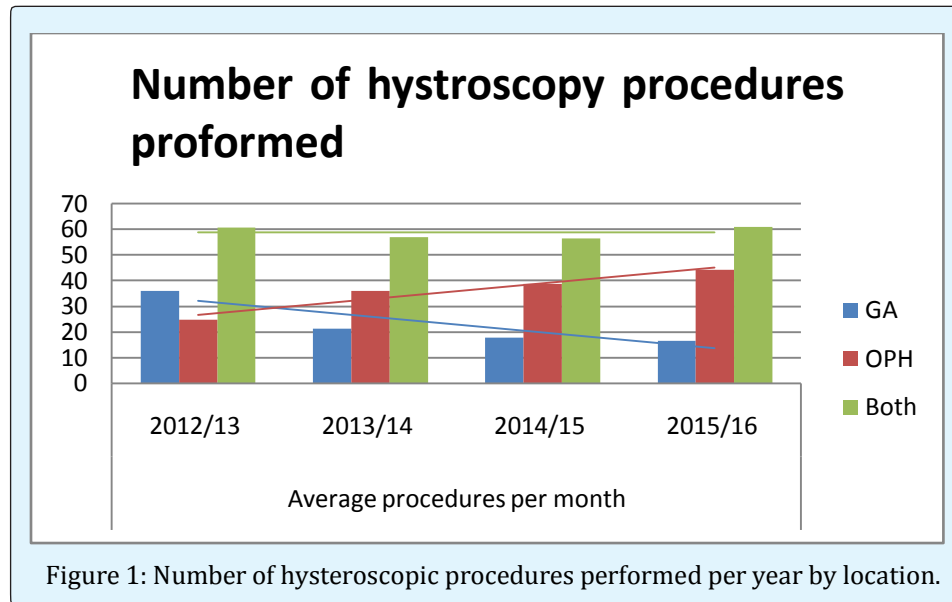
The proforma criteria is as follows. Inclusion criteria: patient underwent hysteroscopy under GA at Whipps, and the patient was referred from gynaecology outpatients. OPH referral criteria [9, 4]: endometrial pathology (polyps <2cm/ fibroids <2cm); or over 40 years of age with more than three months of irregular vaginal bleeding; or under 40 years of age with heavy or irregular bleeding, more than three months of failed medical treatment; or persistent intermenstrual vaginal bleeding; or postmenopausal vaginal bleeding or thickened endometrium greater than 5mm on scan. OPH exclusion criteria: coexisting pelvic pathology, tamoxifen, thin endometrium <4mm, unable to tolerate speculum exam, on examination cervix is not visible or flush with the vaginal vault, patient uncomfortable with the concept of an OPH.

A further re-audit of procedures completed under GA was completed in 2015 to observe uptake of the OPH service. In 2015/16 an average of 31 hysteroscopies were performed per month (in order to achieve a 95% confidence/0.05 degree of error a 29 sets of notes were required). The initial intention to audit another one-month period of August 2015 resulted in only 26 data points. The search criteria were therefore expanded to include September 2015 resulting in 43 data points in total. Of these one set of notes could not be retrieved for audit so 42 went forward for analysis. These data were collated against the current protocol.

Results

A total of 2486 patients underwent hysteroscopic procedures for diagnosis or resection and ablation of intra-uterine lesions over the three-and-a-half-year period (April 2012 to October 2015). A monthly average was calculated for those performed in theatre (under GA) and in the clinic (OPH). This shows the monthly number of hysteroscopic procedures performed has remained consistent with an average 58.8 (1dp) procedures per month (range 56.4 to 60.9 (1dp), standard deviation 2.35).

However, there is a marked trend away from theatre (under GA) into the clinic. Between 2012/13 and 2015/16 the number of OPH performed rose by 78.3%, while over the same time theatre hysteroscopies have decreased by 53.9% (Figure 1). Analysis using the chi squared statistical analysis and the null hypothesis that there was no change in the location where hysteroscopies between 2012/13 and 2015/16 showed a probability of 0.001; demonstrating a significant change in the location of hysteroscopies from theatre to OPH, effect size 1.52.



In the 2012 audit 50 patients who underwent diagnostic hysteroscopy under GA were selected from a one-month time period, all 50 patients were eligible for inclusion for the audit. Of these six (12%) met the exclusion criteria and were unsuitable for OPH. The remaining 44 (88%) patients met the referral criteria, when known excluding factors such as patient preference or a failed OPH were disregarded; 36 (72%) met the inclusion criteria and could have been offered referral for OPH but were not.

In the repeat audit in 2015 only 26 patients underwent diagnostic hysteroscopy under GA in a one-month time period, therefore the time period was extended to two

months resulting in 43 patients who underwent diagnostic hysteroscopy under GA. One set of notes was not available for audit so 42 sets of patient notes were audited. The need to double the data collection time is the first indication that the number of diagnostic hysteroscopies performed under GA had reduced. Of the 42 patients 20 (47.62%) were unsuitable for OPH procedure, as they required surgical procedures, were unable to maintain the lithotomy position, had failed an OPH, or were incorrectly coded operative hysteroscopy. (Table 1) for a detailed break-down of the reasons for theatre hysteroscopies both determined medically and otherwise.

	Reason	Number of Patients	Percentage of Patients (%)	Subtotal percentage by medical suitability (%)
Medically unsuitable for OPH	Ablation	1	2.38	47.62
	complex atypical endometrial hyperplasia	1	2.38	
	lesion > 2 cm (polyp/fibroid)	11	26.19	
	Not suitable due to comorbidity	1	2.38	
	Failed outpatient	4	9.52	
	Severe cervical stenosis	1	2.38	
	resection of the endometrium	1	2.38	
Medically fit for OPH	Pt preference	9	21.43	52.38
	None	5	11.9	
	None- 2 week wait	8	19.05	
	Total	42	100	100

Table 1: 2015 audit: Reasons for performing hysteroscopies under general anaesthetic.

Discussion

Since the introduction of OPH to Whipps in the late 1990's there has been an increasing uptake of the facility. Initially provision was made for one OPH clinic per week. In 2011 the Green Top Guidance was issued confirming OPH as "safe, convenient and cost-effective means of diagnosing and treating abnormal uterine bleeding as well as aiding the management of other benign gynaecological conditions"[1]. When in 2012 the existing OPH provision was reliably fully booked an audit was performed to determine if increased capacity was required given the favourable nature of OPH. That audit showed over 70% of GA hysteroscopies could be performed as OPH if the facility was available. In response to these findings it was found that increasing capacity would be appropriate. Therefore, OPH clinic capacity was doubled to two clinics per week. In order to staff this one third of the obstetric consultants (four of twelve) and one nurse practitioner have been trained to perform OPH. Having provided the increased capacity a programme of clinician awareness sessions were provided for both hospital doctors and allied health professionals to ensure appropriate referral to OPH and encourage maximum uptake of the service. To aid in hospital referrals for OPH clear protocols were written, circulated to hospital personnel and made freely available on the intranet. Further to this the OPH service was opened up to general practice through the choose and book service meaning general practitioners (GPs) are able to directly refer for OPH. As shown by Robertson and Jochelson active educational strategies are the most effective to initiate change, therefore seminars were given to GPs to train them in the service that is available to use and on the benefits of direct referral for OPH in appropriate cases [15].

Since 2012 the number of patients undergoing diagnostic hysteroscopy either in the clinic or under GA has remained stable at an average of 58.8 patients per month (range 56.4 to 60.9, standard deviation 2.35). However, a significant change ($P=0.001$) in location has occurred. Over this time period the number of diagnostic hysteroscopies performed under GA has dropped by 53.9% while the number performed as OPH has risen by 78.3%. When viewed together these trends, along with the static nature of the total number of diagnostic hysteroscopies performed, show that there is a marked move to perform diagnostic hysteroscopies patients in the clinic rather than in theatre. Diagnostic hysteroscopies that would previously have been performed under GA have been successfully transitioned into the clinic. While there is a large improvement in the utilisation of OPH, in

the financial year 2015/16 to date 16.6% of diagnostic hysteroscopies are still being performed under GA.

Two audits have been performed to understand why diagnostic hysteroscopies are still being performed under GA. In 2012/13 59.2% of diagnostic hysteroscopies performed each month were performed in theatre. At this time 12% of the patients undergoing GA hysteroscopy were having procedures unsuited for OPH. The remaining 88% of patients met the criteria for referral for OPH, when known excluding factors such as patient preference or a failed OPH were disregarded, 72% met the inclusion criteria and could have been offered referral for OPH but were not. Following the 2012 audit recommendations were made to the staff that the majority of patients they were sending for diagnostic hysteroscopy were suitable for OPH. They were asked to discuss OPH with patients and to document the discussion and decision.

In 2015 a further audit was performed to investigate why 27.3% of diagnostic hysteroscopies were still being performed in theatre. The breakdown of why patients were having diagnostic hysteroscopy showed that 47.62% were not suitable for OPH. The remaining 22 (52.38%) cases were divided into three categories: patient preference accounting for nine (21.43%); no reason recorded five (11.90%); and those referred to meet the suspected cancer target 8 (19.05%).

A similar breakdown is not available for 2012 however there was a marked reduction in those who have no reason recorded to indicate why GA hysteroscopy was performed; from 36 (72%) in 2012 to five (11.90%) in 2015. This decrease together with the decrease in GA hysteroscopies indicates that the training and increased service provision has improved awareness among staff of those suitable for OPH and therefore the number of patients referred for OPH. Furthermore staff seems to have accepted OPH as the normal facility to provide diagnostic hysteroscopy this clinician confidence will reassure patients into accepting an OPH. It remains important that all patient notes should contain a complete record of the decision making process leading to any treatment course to support the future aim that no patient should fit into this category.

Post-menopausal women who present with vaginal bleeding are seen under the two week wait pathway, this is a national protocol requiring that any patient that a general practitioner suspects cancer in must be seen by a specialist, and undergo the diagnostic procedures required within a maximum of two weeks [16]. From the data it may be concluded that patients who are on the two

week wait protocol are being put on the theatre list rather than the OPH list, despite OPH being a faster and less invasive procedure without the risks of GA. In addition to a lack of outpatient hysteroscopy slots being available, there may also be a fear that if outpatient hysteroscopy fails, then the resulting delay caused repeating the hysteroscopy (under general anaesthetic), would cause the target to be breached.

A solution to either of these concerns would be to provide dedicated two week wait OPH appointments. These dedicated appointments could form a weekly or twice-weekly clinic or be protected time within every clinic. This would mean delay would be minimal and any failed OPH patients would be identified quickly and added to the theatre list. In addition, pressure would be removed from the general gynaecology clinic. Facilities for transvaginal ultrasound would also need to be available, if a truly one-stop clinic was to be provided allowing patients to be seen, fully investigated and treated during a single contact with gynaecology [17].

It was shown by Kremer *et al.* [6] that when patients are randomised to receive OPH their satisfaction with the procedure is equivalent to those undergoing GA hysteroscopy, however patient preference accounts for 21.4% of hysteroscopies still performed under GA at our unit. Further investigation is required to establish the reasons for the unacceptability of the procedure, to many of our patients. Some patients will undoubtedly be concerned about pain during OPH. Currently during pre-procedure counselling non-steroidal anti-inflammatory drugs (NSAIDs) are often recommended to women, despite evidence suggesting it is not beneficial for intra-procedure pain [18]. The use of paracervical block may be of some benefit for these women [19], but ensuring the smallest diameter hysteroscope possible has the greatest impact on pain. It is likely that patient counselling and good management of patient expectation will be important in this group of women, and the facilitation of relaxation techniques may also be beneficial [20,21]. It is also possible that cultural and language issues may be a factor, and further analysis of those that refuse the procedure as an outpatient may be beneficial, so counselling can be more effectively targeted.

In the event that all hysteroscopies currently performed under GA for non-medical reasons were transferred to OPH, savings would result. Although a breakdown of the savings is not available, based on the cost analysis conducted in 2004 by Marsh *et al.* [8] which saw a saving of £53.88 per patient, over £1185 could be saved per month across the 22 patients treated

(depending on an assessment of the current costs of GA and OPH). This together with the new tariff of £501 per OPH makes the procedure cost effective.

While the study showed a marked trend from GA hysteroscopy towards OPH at Whipps Cross University Hospital, it would be useful to compare data across a number of different clinical sites to confirm whether the trends and factors observed are repeated more widely. It would also be useful to compare and contrast the effects of employing different inclusion criteria where policies differ between clinical settings to evaluate the impacts on recovery time, efficacy of treatment, safety and patient satisfaction. Further research needs to be undertaken to identify why patients are choosing not to have an outpatient hysteroscopy: it is possible that a number of these women have clinical factors that they are aware of that were not recorded as such that would make OPH impracticable.

Conclusions

There has been a marked improvement in documenting the justification for the locations where diagnostic hysteroscopies are to be performed. This has been coupled with a drop in the number of hysteroscopies performed in theatre and increased numbers being performed in the clinic setting ($P=0.001$). This suggests an increased awareness of the inclusion and exclusion criteria for OPH, by staff and promotion of OPH to patients.

It was possible to bring about this improvement by improving patient awareness of OPH, and changing the attitudes of clinicians. This was accomplished by designing patient leaflets, using local press, presenting success stories and data at the governance meeting, as well as updating hospital policy for OPH referrals and increasing outpatient hysteroscopy clinic capacity.

The areas that may still be improved are provision of dedicated time for two week wait patients suspected of having cancer and the normalisation of OPH for patients allowing them to accept the outpatient procedure. In time it may be expected that no OPH will be performed under general anaesthetic without medical need just as has become the case with colonoscopies.

Next steps

A study into why women are choosing to have hysteroscopies under GA instead of OPH and what would help them accept an OPH would give useful data. This may

be linked to developing a “one-stop, see and treat clinic” as detailed by Gupta *et al.* which may aid in the normalisation of the OPH procedure [17].

Recommendations

- Introduction of dedicated 2 week wait clinic provision.
- Work on normalising the outpatient procedure for patients to reduce the refusal rate resulting in admission for general anaesthesia. Should OPH be the default, and should reluctant patients not be given the choice of GA, if not medically indicated?
- Consideration of introducing a see-and-treat clinic model. This could result in a reduced number of appointments and faster treatment resolution for the patient which may also help normalise the clinic setting for the procedure, if the patient can be examined immediately [17].
- Notes should always record that OPH has been considered and if not appropriate for the patient the reasons recorded. This will allow ongoing monitoring and allow the protocol to be reviewed and if necessary updated periodically.
- Update exclusion criteria to include co-morbidities, that prevent outpatient hysteroscopy

Compliance with Ethical Standards

Emma Carey declares that she has no conflict of interest. Saira Sundar declares that she has no conflict of interest. Anupama Shahid declares that she has no conflict of interest.

Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.

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