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# Best Practice in Outpatient Hysteroscopy

RCOG/BSGE Joint Guideline



# Best Practice in Outpatient Hysteroscopy

This is the first edition of this guideline.

## Executive summary of recommendations

### Service provision

All gynaecology units should provide a dedicated outpatient hysteroscopy service to aid management of women with abnormal uterine bleeding. There are clinical and economic benefits associated with this type of service.

A

Outpatient hysteroscopy should be conducted outside of the formal operating theatre setting in an appropriately sized, equipped and staffed treatment room with adjoining, private changing facilities and toilet.

✓

Outpatient hysteroscopy should be performed in an appropriately sized and fully equipped treatment room. This may be a dedicated hysteroscopy suite or a multi-purpose facility.

✓

The healthcare professional should have the necessary skills and expertise to carry out hysteroscopy.

✓

There should be a nurse chaperone regardless of the gender of the clinician.

✓

Written patient information should be provided before the appointment and consent for the procedure should be taken.

✓

### Analgesia

Routine use of opiate analgesia before outpatient hysteroscopy should be avoided as it may cause adverse effects.

B

Women without contraindications should be advised to consider taking standard doses of non-steroidal anti-inflammatory agents (NSAIDs) around 1 hour before their scheduled outpatient hysteroscopy appointment with the aim of reducing pain in the immediate postoperative period.

B

### Cervical preparation

Routine cervical preparation before outpatient hysteroscopy should not be used in the absence of any evidence of benefit in terms of reduction of pain, rates of failure or uterine trauma.

A

### Type of hysteroscope

Miniature hysteroscopes (2.7 mm with a 3–3.5 mm sheath) should be used for diagnostic outpatient hysteroscopy as they significantly reduce the discomfort experienced by the woman.

A

There is insufficient evidence to recommend 0° or fore-oblique optical lenses (i.e. 12°, 25° or 30° off-set lenses) for routine outpatient hysteroscopy. Choice of hysteroscope should be left to the discretion of the operator.



Flexible hysteroscopes are associated with less pain during outpatient hysteroscopy compared with rigid hysteroscopes. However, rigid hysteroscopes may provide better images, fewer failed procedures, quicker examination time and reduced cost. Thus, there is insufficient evidence to recommend preferential use of rigid or flexible hysteroscopes for diagnostic outpatient procedures. Choice of hysteroscope should be left to the discretion of the operator.



### Distension medium

For routine outpatient hysteroscopy, the choice of distension medium between carbon dioxide and normal saline should be left to the discretion of the operator as neither is superior in reducing pain, although uterine distension with normal saline appears to reduce the incidence of vasovagal episodes.



Uterine distension with normal saline allows improved image quality and allows outpatient diagnostic hysteroscopy to be completed more quickly compared with carbon dioxide.



Operative outpatient hysteroscopy, using bipolar electrosurgery, requires the use of normal saline to act as both the distension and conducting medium.



### Local anaesthesia and cervical dilatation

Blind cervical dilatation to facilitate insertion of the miniature outpatient hysteroscope is unnecessary in the majority of procedures. Routine cervical dilatation is associated with pain, vasovagal reactions and uterine trauma and should be avoided.



Cervical dilatation generally requires administration of local cervical anaesthesia. Standard protocols regarding the type, maximum dosage and route of administration of anaesthesia should be developed and implemented to help both recognise and prevent rare but potentially serious adverse effects resulting from systemic vascular absorption.



Instillation of local anaesthetic into the cervical canal does not reduce pain during diagnostic outpatient hysteroscopy but may reduce the incidence of vasovagal reactions.



Topical application of local anaesthetic to the ectocervix should be considered where application of a cervical tenaculum is necessary.



Application of local anaesthetic into or around the cervix is associated with a reduction of the pain experienced during outpatient diagnostic hysteroscopy. However, it is unclear how clinically significant this reduction in pain is. Consideration should be given to the routine administration of intracervical or paracervical local anaesthetic, particularly in postmenopausal women.



**Miniaturisation of hysteroscopes and increasing use of the vaginoscopic technique may diminish any advantage of intracervical or paracervical anaesthesia. Routine administration of intracervical or paracervical local anaesthetic should be used where larger diameter hysteroscopes are being employed (outer diameter greater than 5 mm) and where the need for cervical dilatation is anticipated (e.g. cervical stenosis).**



**Routine administration of intracervical or paracervical local anaesthetic is not indicated to reduce the incidence of vasovagal reactions.**



### **Conscious sedation**

**Conscious sedation should not be routinely used in outpatient hysteroscopic procedures as it confers no advantage in terms of pain control and the woman's satisfaction over local anaesthesia.**



**Life-threatening complications can result from the use of conscious sedation. Appropriate monitoring and staff skills are mandatory if procedures are to be undertaken using conscious sedation.**



### **Vaginoscopy**

**Vaginoscopy reduces pain during diagnostic rigid outpatient hysteroscopy.**



**Vaginoscopy should be the standard technique for outpatient hysteroscopy, especially where successful insertion of a vaginal speculum is anticipated to be difficult and where blind endometrial biopsy is not required.**



## 1. Purpose and Scope

The aim of this guideline is to provide clinicians with up-to-date, evidence-based information regarding outpatient hysteroscopy, with particular reference to minimising pain and optimising the woman's experience.

## 2. Background

Outpatient hysteroscopy is an established diagnostic test<sup>1-3</sup> that is in widespread use across the UK.<sup>4-6</sup> The procedure involves the use of miniaturised endoscopic equipment to directly visualise and examine the uterine cavity, without the need for formal theatre facilities or general or regional anaesthesia. Outpatient hysteroscopy is indicated primarily in the assessment of women with abnormal uterine bleeding,<sup>1-3</sup> but is also employed in the diagnostic work-up of reproductive problems. More recently, advances in endoscopic technology and ancillary instrumentation have facilitated the development of operative hysteroscopic procedures in an outpatient setting with or without the use of local anaesthesia. Common procedures include endometrial polypectomy,<sup>6-8</sup> removal of small submucous fibroids,<sup>9</sup> endometrial ablation,<sup>10-13</sup> removal of lost intrauterine devices and transcervical sterilisation.<sup>14</sup>

Outpatient hysteroscopy, whether diagnostic<sup>1,15</sup> or operative,<sup>6-14</sup> is successful, safe and well tolerated. However, as with any procedure requiring instrumentation of the uterus, outpatient hysteroscopy can be associated with significant pain,<sup>16,17</sup> anxiety and embarrassment.<sup>18</sup> This not only impacts upon women's satisfaction with their experience, but also limits the feasibility and possibly the safety, accuracy and effectiveness of the procedure. To minimise pain and discomfort, variations in hysteroscopic equipment, adaptations to the technique and use of pharmacological agents have been advocated. This guideline assesses these components along with issues relating to optimal service provision.

## 3. Identification and assessment of evidence

Four databases were systematically searched: MEDLINE (from 1950 to September 2008), EMBASE (from 1980 to September 2008), CINAHL (from 1981 to September 2008) and the Cochrane library. No restrictions were placed on the searches in an attempt to reduce selection bias. The databases were searched using the relevant MeSH terms and keywords. The main keywords used were 'hysteroscopy and vaginoscopy', which were used with combinations of the following words depending upon the area of hysteroscopy being examined: 'anaesthesia', 'analgesia', 'distension media', 'flexible', 'rigid', 'cervical preparation', 'conscious sedation', 'prostaglandins' and 'laminaria'. The results of the searches were systematically reviewed.

Systematic reviews of the literature were conducted, with meta-analyses where possible, to assess pain and feasibility of outpatient hysteroscopy. The definitions of the types of evidence used in this guideline originate from the US Agency for Healthcare Research and Quality. Where possible, recommendations are based on, and explicitly linked to, the evidence that supports them. Areas lacking evidence are highlighted and annotated as 'good practice points'.

## 4. Service provision

### 4.1 *What is the ideal setting for performing hysteroscopy?*

**All gynaecology units should provide a dedicated outpatient hysteroscopy service to aid management of women with abnormal uterine bleeding. There are clinical and economic benefits associated with this type of service.**

**A**

**Outpatient hysteroscopy should be conducted outside of the formal operating theatre setting in an appropriately sized, equipped and staffed treatment room with adjoining, private changing facilities and toilet.**



An outpatient hysteroscopy service offers a safe, convenient and cost-effective means of diagnosing and treating abnormal uterine bleeding as well as aiding the management of other benign gynaecological conditions (e.g. fertility control, subfertility and miscarriage and abnormal glandular cervical cytology).<sup>19</sup> A randomised controlled trial reported more rapid mobilisation postoperatively (0 minutes [range 0-5] versus 105 minutes [range 80-120],  $P < 0.001$ ) and quicker recovery to preoperative levels (2 days [range 1-2.7] versus 3 days [range 2-4],  $P < 0.05$ ) favouring diagnostic outpatient hysteroscopy compared with traditional day-case hysteroscopy under general anaesthesia.<sup>20</sup> The same study demonstrated high and equivalent levels of women's satisfaction with outpatient hysteroscopy in conscious women compared with day-case procedures under general anaesthesia. There were also economic benefits for women, the health service and society at large. Compared with day-case procedures under general anaesthesia, women undergoing outpatient hysteroscopy required significantly less time off work compared with the day-case group (0.8 days versus 3.3 days,  $P < 0.001$ ) and experienced reduced loss of income and reduced travel costs. Costs per woman to the National Health Service were estimated to be substantially less for outpatient procedures.<sup>21</sup>

Evidence level 1+

#### 4.2 What are the requirements for running an effective outpatient hysteroscopy service?

**Outpatient hysteroscopy should be performed in an appropriately sized and fully equipped treatment room. This may be a dedicated hysteroscopy suite or a multi-purpose facility.**



**The healthcare professional should have the necessary skills and expertise to carry out hysteroscopy.**



**There should be a nurse chaperone regardless of the gender of the clinician.**



**Written patient information should be provided before the appointment and consent for the procedure should be taken.**



Outpatient hysteroscopy should be performed in an appropriately sized and fully equipped treatment room. This may be a dedicated hysteroscopy suite or a multipurpose facility. Outpatient hysteroscopy can be associated with substantial anxiety,<sup>18</sup> so the treatment room should be private and patient friendly, with a separate, and ideally adjoining, changing area with a toilet. Adequate resuscitation facilities should be available, as should a comfortable recovery area with refreshment-making facilities. Access to onsite or offsite decontamination facilities of an appropriate standard is necessary. Outpatient hysteroscopy should not be performed in a formal operating theatre setting because this environment is likely to provoke anxiety in the woman and negate the economic advantages associated with avoiding use of expensive operating theatres. Appropriate staffing levels are required; these will vary according to local circumstances (patient populations, numbers seen per clinic) and the type of service offered (concomitant pelvic ultrasound, pure diagnostic service or diagnostic and therapeutic service). In general, there will be a complement of up to three support staff consisting of at least one registered general nurse and healthcare assistants. When possible, one of the staff members should act as the woman's advocate during the procedure to provide reassurance, explanation and support. Communication with the woman in this way may help alleviate anxiety and divert their attention, thereby minimising pain and embarrassment (the so-called 'vocal local').

Adequate, clear and simple written patient information should be provided with the appointment letter. The information will vary according to local circumstances and the type of service offered. Where simultaneous treatments are offered ('see and treat' services), it is important that this fact is reflected in the patient literature to facilitate informed choice. It is good clinical practice to obtain formal consent for outpatient hysteroscopy before the procedure. Practice should conform to recommendations on consent from the General Medical Council and the RCOG. The RCOG has produced Consent Advice No. 1: *Diagnostic hysteroscopy under general anaesthesia*,<sup>22</sup> which should be used in conjunction with RCOG Clinical Governance Advice No. 6: *Obtaining valid consent*.<sup>23</sup> Women should be able to access advice following any intervention (e.g. a direct line to the clinic and an out-of-hours contact number). Consideration should be given to allow direct access for GPs according to locally developed criteria and selected groups of women to aid streamlining of the service.

Evidence level 4

## 5. Analgesia

5.1 Do analgesics given before diagnostic hysteroscopy reduce the pain felt by women during the procedure?

**Routine use of opiate analgesia before outpatient hysteroscopy should be avoided as it may cause adverse effects.**

B

**Women without contraindications should be advised to consider taking standard doses of non-steroidal anti-inflammatory agents (NSAIDs) around 1 hour before their scheduled outpatient hysteroscopy appointment with the aim of reducing pain in the immediate postoperative period.**

B

A systematic review<sup>24</sup> identified six studies which examine the use of analgesics compared with controls before outpatient hysteroscopy.<sup>25-30</sup> All of these studies were randomised controlled trials. Three of the studies examined the use of opiate drugs<sup>25-27</sup> and three examined NSAIDs.<sup>28-30</sup>

Two of the opiate studies examined the use of 100 mg tramadol administered approximately 50 minutes before the outpatient hysteroscopy, one study giving the tramadol intramuscularly<sup>25</sup> and the second giving it as an intravenous infusion.<sup>26</sup> The first study found that the women who had received tramadol had significantly less pain at the end of the procedure than women in the intracervical block group and the women who received no medication ( $P = 0.001$  and  $P < 0.001$ , respectively).<sup>25</sup> Although this was a low-quality study, the result was supported by those from the second, high-quality study which reported significantly lower pain scores in the tramadol group compared with placebo both during ( $P < 0.012$ ) and 15 minutes after ( $P < 0.008$ ) the procedure.<sup>26</sup> The third opiate study examined the use of sublingual buprenorphine 0.2 mg 40 minutes before the procedure compared with placebo. There was no significant pain reduction with the use of buprenorphine overall and when stratified for menopausal status and parity.<sup>30</sup> Two studies reported adverse effects.<sup>26,30</sup> The tramadol study found no significant difference between the groups in terms of incidence of nausea, vomiting or bradycardia.<sup>26</sup> Conversely, in the buprenorphine study there was a high incidence of adverse effects (nausea, vomiting and drowsiness) in the intervention group (38.8%) and none in the control group.<sup>30</sup>

Evidence level 1-

Three trials examined the use of NSAIDs before outpatient hysteroscopy.<sup>28-30</sup> One of these studies assessed the use of 50 mg oral diclofenac 1-2 hours before the procedure and found that it did not significantly reduce the pain experienced compared with placebo: mean (standard deviation) in the diclofenac group 3.0 (2.5) versus 3.0 (2.9) in the control group.<sup>30</sup> Vasovagal reactions were not reduced in the diclofenac group compared with the placebo group (four reactions and five reactions, respectively). The only adverse effects were in the diclofenac treatment group, but these were mild and self-limiting (one woman reported drug rash and one complained of epigastric pain). The second NSAID study compared the use of 500 mg oral

Evidence level 1-

mefenamic acid 1 hour before the procedure with placebo.<sup>29</sup> This study found that mefenamic acid did not significantly reduce the pain of the hysteroscopy; however, it did significantly reduce the pain experienced at 30 minutes ( $P < 0.01$ ) and 60 minutes ( $P < 0.05$ ). Adverse effects were not reported for either group. The final study examined the use of ketorolac 30 mg intramuscularly given with an intracervical block 45 minutes before the procedure, compared with cervical block alone.<sup>28</sup> The paper reports a significant reduction in pain with the addition of ketorolac; however, it does not report  $P$  values and there were only 12 women in each arm of the study, making it difficult to draw strong conclusions from the results.

Evidence level 1-

No studies were identified addressing the issue of timing of analgesia before outpatient hysteroscopy. The onset of action of these drugs means that to be effective they need to be given in advance of the woman's appointment. Optimal timing depends upon the agent used (half-life, rate of absorption, etc.) and the route of administration, but in general simple, non-opioid analgesics given orally, such as 1000 mg paracetamol or 400 mg ibuprofen, should be taken around 1 hour before the scheduled appointment time. Thus, it is likely to be more practical to advise women to take simple analgesics in advance of their appointment rather than administer them in hospital. Routine patient information leaflets posted to the woman with details of their appointment can advise them to consider taking simple analgesics before they attend their appointment, with the proviso that they have taken them before without ill effects. This approach is likely to be of more benefit in those units offering simultaneous hysteroscopic diagnosis and treatment (i.e. the 'see and treat' clinic), where the levels of discomfort experienced are likely to be increased.

Evidence level 4

## 6. Cervical preparation

### 6.1 *Does cervical preparation reduce uterine trauma, failure to access the uterine cavity or pain associated with outpatient hysteroscopy?*

**Routine cervical preparation before outpatient hysteroscopy should not be used in the absence of any evidence of benefit in terms of reduction of pain, rates of failure or uterine trauma.**

A

Uterine trauma (lacerations to the cervix or uterine perforation) is recognised with blind and endoscopic instrumentation of the uterus,<sup>1,31-34</sup> with an estimated perforation incidence of 0.002-1.7%. The incidence of uterine trauma is low for diagnostic outpatient hysteroscopy performed with small-diameter endoscopes (outer sheath diameter under 5.5 mm) under direct vision.<sup>1</sup> Factors associated with uterine trauma include the need for blind dilatation, cervical stenosis (e.g. atrophy, cervical surgery, previous caesarean section, nulliparity), a tortuous cervical canal (e.g. in association with fibroids) and a deviated uterine cavity (e.g. acute flexion, pelvic adhesions, fibroids).<sup>15,19</sup>

Prostaglandin or misoprostol administration before diagnostic hysteroscopy performed under general anaesthesia is associated with a reduction in cervical resistance and need for cervical dilatation in premenopausal women<sup>35-37</sup> compared with placebo, although no such benefit was noted in postmenopausal women.<sup>41,41</sup>

A systematic review of the use of cervical preparation before outpatient hysteroscopy identified five randomised controlled trials,<sup>42-46</sup> with administration of prostaglandin regimens varying from 4 hours to 30 hours before hysteroscopy.<sup>47</sup> No reduction in the incidence of lacerations to the cervix with the use of vaginal prostaglandins was demonstrated in the three trials<sup>42,43,46</sup> assessing this outcome (OR 0.59, 95% CI 0.22-1.55).<sup>47</sup>

Evidence level 1+



Prostaglandins are associated with gastrointestinal adverse effects and are contraindicated in severe uncontrolled asthma, chronic adrenal failure, acute porphyria, renal or hepatic impairment and breastfeeding.<sup>48</sup> Four heterogeneous trials assessed the incidence of genital tract bleeding associated with vaginal prostaglandins before outpatient hysteroscopy<sup>42,44-46</sup> and found no increased risk with the use of prostaglandins (OR 1.32, 95% CI 0.52-3.40).<sup>47</sup>

Evidence level 1+

The main reason for failure to successfully perform an outpatient hysteroscopy is inability to access the uterine cavity as a result of cervical stenosis; this is most commonly encountered in the postmenopausal population.<sup>19</sup> Two randomised controlled trials<sup>43,44</sup> have assessed the feasibility of outpatient hysteroscopy after vaginal prostaglandins and a meta-analysis showed no reduction in failure rates (OR 2.12, 95% CI 0.64-7.04).<sup>47</sup>

Evidence level 1+

One randomised controlled trial included in the systematic review examined the use of oral mifepristone. There were no failed hysteroscopies in the study.<sup>47</sup>

Evidence level 1+

Two studies examined the use of misoprostol 400 micrograms given vaginally before hysteroscopy to premenopausal women. The drugs were administered 4 hours before hysteroscopy in one of the studies<sup>42</sup> and 6 hours before hysteroscopy in the other.<sup>45</sup> The low-quality study<sup>42</sup> found that pain during cervical dilatation was significantly reduced after the use of prostaglandin compared with placebo ( $P < 0.05$ ); however, the other, high-quality study<sup>45</sup> found no significant reduction in pain during the hysteroscopy with the use of misoprostol ( $P = 0.72$ ).

Evidence level 1+

One study<sup>43</sup> examined the use of misoprostol 200 micrograms given vaginally 8 hours before hysteroscopy to postmenopausal women. The median pain scores as the hysteroscope passed through the cervical os were five in the intervention group and seven in the placebo group ( $P = 0.02$ ). When the pain severity was assessed by comparing the number of women scoring more than six on the visual analogue scale (i.e. considerable pain), there were significantly fewer in the intervention group ( $P = 0.0132$ ). However, no significant difference between the groups was identified when assessing the presence of pain during clamping of the cervix ( $P = 0.74$ ), during the examination ( $P = 0.32$ ) or during the endometrial biopsy ( $P = 0.19$ ).

Evidence level 1+

Two studies included both pre- and postmenopausal women in their study populations.<sup>44,46</sup> One of the studies<sup>42</sup> gave misoprostol 400 micrograms vaginally 4-6 hours before the hysteroscopy and found that pain at the end of the procedure was significantly less in the intervention group compared with the group receiving no medication ( $P = 0.03$ ). This was judged to be a low-quality study owing to the lack of blinding. The second study<sup>46</sup> gave the same dose of misoprostol 12-24 hours before the procedure and assessed pain after the cervix was dilated to 6 mm. Pain was found to be significantly less in the misoprostol group ( $P = 0.004$ ; when adjusted for baseline pain score  $P = 0.01$ ). This study subgrouped the women according to menopausal status and found that there was a significant reduction in pain for postmenopausal women given misoprostol ( $P = 0.004$ ; when adjusted for baseline scores  $P = 0.006$ ) but not for premenopausal women ( $P = 0.56$ ; when adjusted for baseline scores  $P = 0.77$ ). This was a high-quality study.

Evidence level 1+

One trial assessed oral mifepristone in premenopausal women<sup>49</sup> and found no benefit in terms of reduction in pain experienced during outpatient hysteroscopy (mean pain score  $33.4 \pm 23.5$  versus  $37.0 \pm 30.0$ ,  $P = 0.60$ ).

Evidence level 1+

No comparative studies were identified for other methods of cervical dilatation before outpatient hysteroscopy (e.g. local/systemic administration of estrogens or osmotic agents).

## 7. Type of hysteroscope

### 7.1 What size and angle of hysteroscope should be used in the outpatient setting?

**Miniature hysteroscopes (2.7 mm with a 3–3.5 mm sheath) should be used for diagnostic outpatient hysteroscopy as they significantly reduce the discomfort experienced by the woman.**

A

**There is insufficient evidence to recommend 0° or fore-oblique optical lenses (i.e. 12°, 25° or 30° off-set lenses) for routine outpatient hysteroscopy. Choice of hysteroscope should be left to the discretion of the operator.**



Four randomised controlled trials have examined how the diameter of hysteroscopes with an outer sheath affects pain during outpatient hysteroscopy.<sup>50–53</sup> One of the studies looked exclusively at postmenopausal women and found that there was significantly less pain associated with outpatient hysteroscopy when a 3.5 mm diameter hysteroscopy system as opposed to a 5 mm diameter system was used ( $P < 0.01$ ), although the procedural success rate was not significantly increased.<sup>52</sup> The remaining three papers compared 5 mm hysteroscopy assemblies with 3 mm,<sup>53</sup> 3.3 mm<sup>51</sup> or 3.5 mm<sup>50</sup> mini-hysteroscopy set-ups. Procedural pain was significantly reduced with the smaller-diameter hysteroscopes in two of the trials ( $P < 0.0001$  in both studies);<sup>50,51</sup> however, the third trial found no significant difference.<sup>53</sup> One of the studies reported the procedural success rate and visualisation of the cavity to be significantly better with mini-hysteroscopy ( $P < 0.0001$ );<sup>50</sup> by contrast, the procedural success rate was not significantly better in the other trial reporting this outcome.<sup>53</sup>

Evidence level 1+

No studies were identified that compared 0° hysteroscopes with off-set distal lenses (e.g. 12°, 30°). Off-set lenses offer a wider field of view, a property that can be advantageous in visualising the corneal recesses and tubal ostia within the uterine cavity with minimal external movement of the hysteroscope. Fore-oblique lenses facilitate visualisation of ancillary instrumentation and so are advantageous for operative hysteroscopy. However, 0° hysteroscopes are more intuitive, facilitating entry into the uterine cavity through the cervical canal, which may reduce the need for cervical dilatation as well as minimising discomfort and uterine trauma.

Evidence level 4

### 7.2 Should rigid or flexible hysteroscopes be used routinely in the outpatient setting?

**Flexible hysteroscopes are associated with less pain during outpatient hysteroscopy compared with rigid hysteroscopes. However, rigid hysteroscopes may provide better images, fewer failed procedures, quicker examination time and reduced cost. Thus, there is insufficient evidence to recommend preferential use of rigid or flexible hysteroscopes for diagnostic outpatient procedures. Choice of hysteroscope should be left to the discretion of the operator.**

B

Two small randomised controlled trials compared the pain experienced during outpatient hysteroscopy with the use of a flexible hysteroscope versus a rigid hysteroscope.<sup>54,55</sup> Neither study presented data according to menopausal state or parity. Both studies found that use of the flexible hysteroscope significantly reduced the woman's pain experience during the procedure ( $P = 0.0001$  and  $P < 0.001$ , respectively). One of the studies reported no difference between the flexible and rigid groups in terms of procedure time and image view. There were no failed hysteroscopies in either group.<sup>54</sup> The other study found that rigid scopes gave significantly better image quality ( $P < 0.001$ ) and significantly shortened the time taken to perform the procedure ( $P = 0.003$ ). There were two failed hysteroscopies in the flexible group owing to cervical stenosis and these women were excluded from the analysis. Five more women in the flexible group had to be changed to a rigid hysteroscope because of inability to negotiate the cervical

Evidence level 1+

canal or inadequate visualisation. There were no failed hysteroscopies or change to flexible scopes in the rigid group. This study also reported that rigid hysteroscopes were cheaper to purchase and easier to sterilise and maintain than flexible hysteroscopies.<sup>55</sup>

Evidence level 1+

Operative outpatient hysteroscopy using miniature mechanical and electrosurgical equipment is becoming more established. These technologies generally require the use of rigid hysteroscopies.<sup>19</sup> Units offering both hysteroscopic diagnosis and treatment in the outpatient setting should consider the versatility of respective hysteroscopes and relative resource implications when planning the composition of endoscopic equipment.

## 8. Distension medium

### 8.1 Which uterine distension medium should be used during outpatient hysteroscopy?

**For routine outpatient hysteroscopy, the choice of distension medium between carbon dioxide and normal saline should be left to the discretion of the operator as neither is superior in reducing pain, although uterine distension with normal saline appears to reduce the incidence of vasovagal episodes.**

A

**Uterine distension with normal saline allows improved image quality and allows outpatient diagnostic hysteroscopy to be completed more quickly compared with carbon dioxide.**

A

**Operative outpatient hysteroscopy, using bipolar electrosurgery, requires the use of normal saline to act as both the distension and conducting medium.**

✓

### 8.2 Does the type of distension medium affect pain experience during outpatient hysteroscopy?

A systematic review identified seven studies<sup>56-62</sup> that looked at whether normal saline or carbon dioxide uterine distension media were associated with less pain during outpatient hysteroscopy.<sup>62</sup> One study was considered a duplication of data<sup>61</sup> from an earlier study by the same group.<sup>56</sup> Therefore, six studies were included in the meta-analysis.<sup>56-60,62</sup> The meta-analysis showed there to be no significant difference between the pain experienced with the use of carbon dioxide versus normal saline for outpatient hysteroscopy (standard mean difference [SMD] 0.34, 95% CI -0.12 to 0.80).<sup>63</sup>

Evidence level 1++

Uterine distension pressures need to be sufficient to allow systematic inspection of the entire uterine cavity. However, care is needed to ensure that pressures are minimised to avoid overdistension of the uterus and consequent pain.

Evidence level 4

### 8.3 Which distension medium causes the fewest vasovagal episodes during outpatient hysteroscopy?

The incidence of vasovagal episodes was reported in three of the randomised controlled trials.<sup>57,59,60</sup> A meta-analysis of these results showed there to be significantly fewer vasovagal episodes with the use of normal saline compared with carbon dioxide (OR 3.24, 95% CI 1.23-8.54).<sup>63</sup>

Evidence level 1++

#### 8.4 Which distension medium produces the best image quality during outpatient hysteroscopy?

Four randomised controlled trials evaluated image quality for each of the distension media.<sup>56,57,59,62</sup> Three studies reported no significant difference in image quality between carbon dioxide and normal saline;<sup>56,57,59</sup> however, one of these studies reported changing the distension medium from carbon dioxide to normal saline in eight (10.1%) women. One study found a statistically significant increased risk of unsatisfactory view on hysteroscopy (RR 4.75, 95% CI 1.61–16.4) with the use of carbon dioxide. This was mainly attributed to bubbles and bleeding. Of the 19 women who had an unsatisfactory view at hysteroscopy using carbon dioxide, 17 were changed to normal saline and an improved view was reported in 11 (64.7%).<sup>62</sup> Normal saline produces lavage of the cavity and so washes away any blood or mucus which otherwise might obscure the view.

Evidence level 1+

#### 8.5 Which distension medium allows the quickest procedure?

Four randomised controlled trials compared procedure times between normal saline and carbon dioxide.<sup>56–59</sup> All four found that hysteroscopies using normal saline were significantly quicker. This remained significant when the results were meta-analysed (SMD 1.32, 95% CI 1.17–1.48).<sup>63</sup>

Evidence level 1++

#### 8.6 Which distension medium should be used for operative procedures?

Normal saline should be used as the distension medium when bipolar intrauterine equipment is used for hysteroscopic surgery. Thus, it is more practical to perform diagnostic procedures with normal saline in units offering simultaneous diagnosis and treatment as this avoids having to swap distension media should operative procedures need to be carried out. Hysteroscopic sterilisation requires fluid distension medium; the choice of normal saline or glycine depends upon the specific technology adopted.

Evidence level 4

### 9. Local anaesthesia and cervical dilatation

#### 9.1 Should routine dilatation of the cervical canal be used before insertion of the hysteroscope in an outpatient setting?

**Blind cervical dilatation to facilitate insertion of the miniature outpatient hysteroscope is unnecessary in the majority of procedures. Routine cervical dilatation is associated with pain, vasovagal reactions and uterine trauma and should be avoided.**

C

**Cervical dilatation generally requires administration of local cervical anaesthesia. Standard protocols regarding the type, maximum dosage and route of administration of anaesthesia should be developed and implemented to help both recognise and prevent rare but potentially serious adverse effects resulting from systemic vascular absorption.**

✓

Blind dilatation of the cervix to instrument the uterine cavity is commonly performed under general anaesthesia and is associated with cervical and uterine trauma.<sup>1,31–34</sup> In addition, in the conscious woman, dilatation of the cervix causes pain and discomfort and generally requires the use of local anaesthesia.<sup>19</sup> No randomised controlled trials or large comparative observational studies examining the routine or selective use of blind cervical dilatation before outpatient hysteroscopy were identified.

Evidence level 4

### 9.2 *Should topical local anaesthetic be administered before outpatient hysteroscopy?*

**Instillation of local anaesthetic into the cervical canal does not reduce pain during diagnostic outpatient hysteroscopy but may reduce the incidence of vasovagal reactions.**

A

**Topical application of local anaesthetic to the ectocervix should be considered where application of a cervical tenaculum is necessary.**

A

A systematic review identified three randomised controlled trials comparing the application of topical local anaesthetic to the ectocervix.<sup>64-66</sup> Two of these studies were meta-analysed.<sup>65,66</sup> One used lidocaine 5% spray on the ectocervix and canal,<sup>65</sup> while the other used 2% lignocaine gel rubbed over the surface of the cervix;<sup>66</sup> both used a placebo as a control. Meta-analysis of these two studies found that there was no significant pain reduction with the use of topical application of local anaesthetic to the cervix (SMD -0.32, 95% CI -0.97 to 0.33).<sup>67</sup> Another randomised controlled trial using lignocaine 2% aerosol spray, which could not be included in the meta-analysis as it reported its results as medians rather than means, demonstrated a reduction in pain as measured on a 100 mm visual analogue scale when applying a cervical tenaculum as part of the hysteroscopy procedure using a rigid 5.5 mm diagnostic hysteroscope (visual analogue scale score 9 versus 18,  $P = 0.005$ ), but no significant reduction in the pain associated with the hysteroscopic procedure itself.<sup>64</sup>

Evidence level 1++

A systematic review identified five randomised controlled trials comparing the transcervical application of local anaesthetic.<sup>62,68-71</sup> Three trials injected the anaesthetic through the cervical canal into the uterine cavity.<sup>68,69,71</sup> Two of these studies used 5 ml of 2% lignocaine<sup>69,71</sup> and one used 2 ml of 2% mepivacaine.<sup>68</sup> All three used normal saline as their control substance. Two of the studies mixed lignocaine with the distension medium. One used 18 ml of lignocaine (strength not stated) per 250 ml of normal saline combined with an intracervical block and compared it with normal saline as the distension medium with an intracervical block.<sup>70</sup> The second study used 40 ml of 2% lignocaine per 500 ml of normal saline and compared it with normal saline as the distension medium.<sup>62</sup> No significant reduction in pain during hysteroscopy was demonstrated (SMD -0.11, 95% CI -0.31 to 0.10).<sup>67</sup>

Evidence level 1++

Vasovagal episodes were significantly reduced with the use of topical anaesthesia (Peto OR 0.35, 95% CI 0.15-0.79), but this apparent reduction was limited to the use of transcervical topical application only (Peto OR 0.29, 95% CI 0.12-0.74).<sup>67</sup>

Evidence level 1++

### 9.3 *Should injectable local anaesthetic be administered to the cervix and/or paracervix before outpatient hysteroscopy?*

**Application of local anaesthetic into or around the cervix is associated with a reduction of the pain experienced during outpatient diagnostic hysteroscopy. However, it is unclear how clinically significant this reduction in pain is. Consideration should be given to the routine administration of intracervical or paracervical local anaesthetic, particularly in postmenopausal women.**

A

**Miniaturisation of hysteroscopes and increasing use of the vaginoscopic technique may diminish any advantage of intracervical or paracervical anaesthesia. Routine administration of intracervical or paracervical local anaesthetic should be used where larger diameter hysteroscopes are being employed (outer diameter greater than 5 mm) and where the need for cervical dilatation is anticipated (e.g. cervical stenosis).**

✓

**Routine administration of intracervical or paracervical local anaesthetic is not indicated to reduce the incidence of vasovagal reactions.**

A

A systematic review identified five randomised controlled trials comparing the use of direct intracervical injection of local anaesthetic before outpatient hysteroscopy with control (placebo, vaginoscopy or nil).<sup>25,72-75</sup> No significant reduction in pain was noted in the four trials<sup>25,72,73,75</sup> included in the meta-analysis (SMD -0.05, 95% CI -0.71 to 0.60).<sup>67</sup> However, intracervical injection of local anaesthetic was found to reduce pain with hysteroscopy (SMD -0.36, 95% CI -0.61 to -0.10) when the trial comparing local anaesthesia with vaginoscopy was excluded.<sup>75</sup>

Evidence level 1++

A systematic review identified six randomised controlled trials comparing the use of paracervical injection of local anaesthetic before outpatient hysteroscopy with control (placebo or nil).<sup>52,76-80</sup> Meta-analysis showed a significant reduction in pain (SMD -1.28, 95% CI -2.22 to -0.35),<sup>67</sup> although the studies were heterogenous. If the analysis was stratified by menopausal status, the heterogeneity between studies remained, but a significant reduction in pain was observed in the two studies with a purely postmenopausal population<sup>52,78</sup> (SMD -1.12, 95% CI -2.23 to -0.01).<sup>67</sup>

Evidence level 1++

The same systematic quantitative review did not find a reduction in vasovagal reactions associated with diagnostic outpatient hysteroscopy with the use of injectable cervical anaesthetics<sup>52,74,77-79</sup> (OR 0.89, 95% CI 0.54-1.46).<sup>67</sup> However, the heterogeneity of study populations and variations in the definition of vasovagal episodes are likely to have affected this finding. Larger-scale studies of homogeneous populations with standardised interventions (equipment, technique, etc.) and definitions of vasovagal episodes are required to confirm or refute these findings.

Evidence level 1+

## 10. Conscious sedation

### 10.1 *Should conscious sedation be used to reduce pain associated with outpatient hysteroscopic procedures?*

**Conscious sedation should not be routinely used in outpatient hysteroscopic procedures as it confers no advantage in terms of pain control and the woman's satisfaction over local anaesthesia.**



**Life-threatening complications can result from the use of conscious sedation. Appropriate monitoring and staff skills are mandatory if procedures are to be undertaken using conscious sedation.**



Conscious sedation is used widely in outpatient endoscopic procedures of the gastrointestinal system. It is less commonly employed in outpatient hysteroscopy. One randomised controlled trial reported the use of conscious sedation using 0.25 mg fentanyl intravenous with 0.5 mg atropine and 2 mg midazolam immediately before operative outpatient hysteroscopy - polypectomy, myomectomy, septoplasty and adhesiolysis using the Versapoint™ (Ethicon Inc.) bipolar electrode intrauterine system - compared with paracervical anaesthesia with 10 ml 1% mepivacaine hydrochloride without sedation. There were no significant differences between local anaesthesia and conscious sedation in terms of pain control during the procedure, postoperative pain or the woman's satisfaction.<sup>78</sup>

Evidence level 1+

Sedative drugs (anaesthetics, anxiolytics and opioids) are administered by oral, intravenous, transmucosal or inhalational routes. Any drug that depresses the central nervous system has the potential to impair respiration, circulation or both. Close monitoring of the woman must be undertaken by a designated staff member to ensure maintenance of continuous verbal contact and adequate oxygen saturation. Monitoring of blood pressure and electrocardiogram should be considered in high-risk cases and staff trained in acute airway management and anaesthetic support should be immediately available.

Evidence level 4

## 11. Vaginoscopy

11.1 Does a vaginoscopic approach to outpatient hysteroscopy reduce pain and increase the feasibility of the procedure?

**Vaginoscopy reduces pain during diagnostic rigid outpatient hysteroscopy.**

A

**Vaginoscopy should be the standard technique for outpatient hysteroscopy, especially where successful insertion of a vaginal speculum is anticipated to be difficult and where blind endometrial biopsy is not required.**



Vaginoscopy or the 'no touch' approach to hysteroscopy refers to a technique where the hysteroscope is introduced into the vagina, through the cervical canal and into the uterine cavity without the need for a vaginal speculum or cervical instrumentation. A systematic review identified six small randomised controlled trials comparing the vaginoscopic versus traditional outpatient hysteroscopy.<sup>75,81-85</sup> There were no significant differences in feasibility (failed procedures) between the techniques (OR 1.28, 95% CI 0.74-2.24), but vaginoscopy was associated with significantly less procedural pain (SMD -0.44, 95% CI -0.65 to -0.22)<sup>86</sup> in the four studies evaluating this outcome.<sup>75,81,82,84</sup>

Evidence level 1++

Larger studies are indicated to better assess the feasibility of vaginoscopy in relation to the characteristics of the woman (e.g. body mass index, menopausal status, parity, caesarean section) and type of hysteroscope (size, angle, rigid/flexible endoscopes) and the risk of ascending pelvic infection. Vaginoscopy allows increased external movement of the hysteroscope. Future studies should assess whether this manoeuvrability improves the feasibility and effectiveness of operative hysteroscopy.

## 12. Suggested audit topics

- Patient satisfaction with elements of the outpatient hysteroscopy service.
- Complications (e.g. infection, vasovagal reactions, uterine trauma) of diagnostic and operative outpatient hysteroscopy.
- Failure rate of diagnostic and operative outpatient hysteroscopy and reasons for failures.
- Rates of cervical dilatation in outpatient hysteroscopy stratified by parity and menopausal status.
- Standards of documentation.
- Use of analgesia post-procedure.
- Percentage of women provided with written information and asked for written consent.

## 13. Recommendations for research

- Optimal type and timing of analgesia in diagnostic and operative outpatient hysteroscopy.
- Effect of cervical preparation with prostaglandins and/or local estrogens on pain relief and feasibility of outpatient hysteroscopy in postmenopausal women.
- Safety and acceptability of hysteroscopy according to angle of distal optical lens.
- Effect of local anaesthetic on pain reduction according to menopausal status and parity.
- Effectiveness of vaginoscopic approach to outpatient hysteroscopy in relieving pain compared with traditional approaches with and without local anaesthesia.
- Feasibility and safety of vaginoscopy in relation to the woman's characteristics and type of hysteroscope.
- Effect of vaginoscopy and local anaesthesia on the incidence of vasovagal episodes associated with diagnostic and operative outpatient hysteroscopy.
- Effectiveness of warming fluid distension media on relieving pain in outpatient hysteroscopy.

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## APPENDIX 1 Terminology

### Conscious sedation

Conscious sedation refers to an arousable but drowsy state in which a woman can communicate and maintain an airway. Sedation techniques aim to make potentially unpleasant interventions more acceptable. However, there is potential for the drugs to impair respiration, circulation or both. This dictates that the operator should have advanced training in airway management and anaesthesia.

### Direct 'intracervical' cervical anaesthesia

Local anaesthetic is injected directly into the cervix ('intracervical' or 'direct' cervical block). The anaesthetic solution should be distributed equally to all cervical quadrants. The majority of the anaesthetic should be injected at the deepest possible point in each quadrant, with some distributed evenly along the length of the cervix as the needle is withdrawn.

### Outpatient hysteroscopy (office/ambulatory)

The term outpatient hysteroscopy encompasses 'office' and 'ambulatory' hysteroscopy.

### Paracervical anaesthesia

Local anaesthetic is injected into the vaginal mucosa at the cervicovaginal junction. One to two millilitres of anaesthetic is injected to produce swelling and blanching of the tissue around the cervix. The needle is then advanced into the vaginal vault and the anaesthetic is delivered to a depth of 1–2.5 cm. Care should be taken to aspirate before injection to avoid inadvertent intravascular injection. The injection site may be 'tracked' by injecting as the needle progresses. The standard bilateral injections are at the 4 o'clock and 8 o'clock positions, although 3 o'clock and 9 o'clock positions are often used.

### Procedural pain

For the purpose of this guideline, 'procedural pain' is defined as an overall, global assessment of pain associated with outpatient hysteroscopy. If a global score was not given, the pain experienced during inspection of the cavity was used.

### Topical anaesthesia/transcervical

Anaesthetic gels such as Instillagel® (Clinined Ltd, High Wycombe, UK: lidocaine hydrochloride 2% and chlorhexidine gluconate solution 0.25%), creams such as emla® (AstraZeneca Pty Ltd, North Ryde, Australia: lidocaine 2.5% and prilocaine 2.5%) or sprays such as xylocaine (lidocaine 10%) are applied to the ectocervix, cervical canal or into the uterine cavity. Absorption through mucous membranes may be slow and unreliable, so sufficient time should be allowed for the anaesthetic to work.

### Vaginoscopy

The vaginoscopic or 'no-touch' technique involves introducing the hysteroscope into the vagina without a speculum or cervical instrumentation. The labia minora are then held closed and the table tilted backwards to keep the distension medium inside the vagina. The hysteroscope is slowly advanced to visualise the cervix and identify the cervical os. The scope then traverses the cervical canal and passes into the uterine cavity.


## Vasovagal reaction

Vasovagal reactions are caused by stimulation of the parasympathetic nervous system. The cervix receives parasympathetic innervation from the sacral nerves. Manipulation and dilatation of the cervix can lead to stimulation of the parasympathetic nervous system, which causes hypotension and bradycardia and causes women to feel sick and faint. They may display clinical signs such as pallor, sweating and reduced conscious state. Most women will recover rapidly if the procedure is stopped and instruments removed and they are put in the supine or recovery position. Cool fanning, fluids and reassurance will hasten recovery. In rare cases, atropine may need to be given.

## Appendix 2

Clinical guidelines are: 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No.1: *Development of RCOG Green-Top Guidelines* (available on the RCOG website at <http://www.rcog.org.uk/womens-health/clinical-guidance/development-rcog-green-top-guidelines-policies-and-processes>). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels	Grades of recommendations
1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias	<b>A</b> At least one meta-analysis, systematic review or randomised controlled trial rated as 1++ and directly applicable to the target population; or  A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results
1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias	<b>B</b> A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or  Extrapolated evidence from studies rated as 1++ or 1+
1- Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias	<b>C</b> A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; or  Extrapolated evidence from studies rated as 2++
2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal	<b>D</b> Evidence level 3 or 4; or  Extrapolated evidence from studies rated as 2+
2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal	
2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal	
3 Non-analytical studies, e.g. case reports, case series	
4 Expert opinion	
	<b>Good practice point</b>   Recommended best practice based on the clinical experience of the guideline development group

This guideline was produced on behalf of the British Society of Gynaecological Endoscopists and the Royal College of Obstetricians and Gynaecologists by:

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The final version is the responsibility of both the Guidelines Committee of the RCOG and the Guidelines and Audit Committee of the British Society of Gynaecological Endoscopists.

The guideline review process will commence in 2014 unless evidence requires earlier review.

#### DISCLAIMER

The British Society of Gynaecological Endoscopists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available. This means that BSGE guidelines are unlike protocols or guidelines issued by employers, not being intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

The Royal College of Obstetricians and Gynaecologists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available. This means that RCOG guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.