Chapter 7

Diagnostic hysteroscopy and saline infusion sonography in the diagnosis of intrauterine abnormalities: an assessment of patient preference

Heleen van Dongen
Anne Timmermans
Cathrien E. Jacobi
Cor D. de Kroon
Trudy A. Elskamp
Frank Willem Jansen

Submitted
Introduction

Hysteroscopy and saline infusion sonography are both accurate in the diagnosis of intrauterine pathology [chapter 5; Clark 2002b; de Kroon 2003a]. With the introduction of saline infusion sonography, several authors showed that it gave less discomfort to patients than office hysteroscopy [Rogerson 2002; Widrich 1996]. However, since the development of smaller diameter hysteroscopes and the introduction of a vaginoscopic approach (without speculum and tenaculum), patient discomfort has been reduced considerably [Bettocchi 1997]. A great advantage of hysteroscopy over saline infusion sonography is the possibility to perform a biopsy or a small surgical intervention during the same session. Moreover, gynaecological treatments in an outpatient setting have shown to be highly acceptable and popular with patients [Kremer 2000; Marsh 2002].

Nevertheless, we showed in a randomised comparison of outpatient vaginoscopic hysteroscopy and saline infusion sonography that the latter still gave significantly less discomfort [chapter 6]. To follow up on this, we undertook a survey to determine which form of investigation (saline infusion sonography or office hysteroscopy) women prefer and what the reasons are behind their preferences.

Methods

This study was conducted at the department of Gynaecology of the Leiden University Medical Center (Leiden, The Netherlands) from January 2006 to July 2007. One hundred and forty-four women were approached to complete a questionnaire. Of these women, 94 were included in the randomised controlled trial described in chapter 6, comparing discomfort of saline infusion sonography and office hysteroscopy. These women were randomly allocated to saline infusion sonography or vaginoscopic office hysteroscopy (only for diagnostic purposes), and were therefore not influenced by their doctor’s choice or their own preference. They received the questionnaire once the investigation had been performed.

Another 50 women visiting the Gynaecology outpatient clinic for reasons other than the investigation of the uterine cavity, were randomly asked by their doctor to complete a similar questionnaire as well. All women were eligible irrespective of age, parity, general health or menopausal state. If they had previously undergone saline infusion sonography or office hysteroscopy, they were excluded from analysis. Ethical approval for this study was obtained from the Leiden University Medical Center Ethics Committee.

Questionnaire

A questionnaire was designed and consisted of a general part and a problem specific part. The general part addressed demographic data, including employment and the number of children, and a brief medical history, including questions relating to the patient’s past experience with outpatient procedures (e.g. colposcopy or mini-curettage). It also
addressed the patients’ preferred role in the decision making process, including to what extent they would like to be informed about advantages and disadvantages.

The problem specific part focused on the preference of saline infusion sonography or hysteroscopy. For this purpose, a full description with advantages and disadvantages of both investigations was provided (appendix A). In an attempt to minimise bias, the descriptions were based on patient information of the Dutch Society of Obstetrics and Gynaecology. The order of the descriptions was randomly allocated. With reference to these descriptions, women were asked to state which of the two investigations they would choose if they needed an investigation of the uterine cavity (again), and to declare what they found most important in their decision and preferences scored on a Likert scale. Since controls had no experience with any of the investigations, these questions were rewritten for better understanding. Following this, women were specifically asked to what extent they would accept pain in exchange for certain advantages of the investigations, and what the required benefit should be in terms of successful therapy. In addition, they were asked what level of pain they would expect to experience during both investigations, scored on a visual analogue scale (VAS) of 10cm. Finally, they were asked in what setting (i.e. outpatient without anaesthesia or day case with general or regional anaesthesia) they would prefer treatment if during investigation an abnormality would be found. To maximise the response rate the non-responders were sent a reminder after six weeks.

The results were entered in statistical software (SPSS, version 14, SPSS Inc., Chicago, IL). Patient characteristics of the study groups were analysed with the one-way-ANOVA test in cases of normally distributed continuous variables and the Pearson’s Chi-square test in cases of dichotomous data. Confidence intervals (95%-CI) for difference in means were calculated. The Pearson’s Chi-square test was also used to analyse differences of preference among the study groups. A paired-samples t-test was used to compare expected VAS scores for both investigations. All tests were two-sided and p-values <0.05 were considered statistically significant.

**Results**

Of the 144 women approached, 113 (83.7%) women completed the questionnaire: 79 in the trial, and 34 in the control group. Of the trial patients, 36 (31.9%) underwent saline infusion sonography and 43 (38.1%) underwent office hysteroscopy.

Table 1 presents data on the personal characteristics of the participating women, stratified by study group. Twenty-four (21.2%) women would opt for saline infusion sonography, whereas 52 (46.0%) would opt for office hysteroscopy, and 37 (32.7%) had no preference. Because preferences were strongly related to the previous investigation, we present them by group as well (figure 1). The percentage of women preferring saline infu-
Table 1 | Patient characteristics stratified by study group.

| Outcome                                      | Saline infusion sonography (n=35) | Office hysteroscopy (n=42) | Controls (n=40) | p-value |
|----------------------------------------------|-----------------------------------|----------------------------|----------------|---------|
| Mean age in years (95%-CI)                   | 44.3 (41.0-47.6)                  | 45.4 (42.9-47.9)           | 42.2 (37.5-47.0) | 0.436<sup>a</sup> |
| Employment                                   | 28 (75.0%)                        | 33 (76.8%)                 | 28 (82.4%)     | 0.950<sup>b</sup> |
| Married / living together                     | 27 (77.8%)                        | 36 (83.7%)                 | 28 (82.4%)     | 0.748<sup>b</sup> |
| Children                                     | 28 (77.8%)                        | 31 (72.1%)                 | 20 (58.8%)     | 0.208<sup>b</sup> |
| Attainableness of hospital good              | 33 (91.7%)                        | 42 (97.7%)                 | 32 (94.1%)     | 0.184<sup>b</sup> |
| Premenopausal                                | 31 (86.1%)                        | 34 (79.1%)                 | 25 (73.5%)     | 0.423<sup>b</sup> |
| Postmenopausal                               | 5 (14.3%)                         | 9 (20.9%)                  | 9 (26.5%)      | 0.423<sup>b</sup> |
| Previous surgery                             | 29 (80.6%)                        | 34 (79.1%)                 | 26 (76.5%)     | 0.782<sup>b</sup> |
| Previous intervention in outpatient setting  | 21 (58.3%)                        | 31 (72.1%)                 | 21 (61.8%)     | 0.317<sup>b</sup> |

<sup>a</sup>One-way-ANOVA test,  <sup>b</sup>Pearson’s Chi-square test.

Figure 1 | Preferences in percentages of diagnostic investigation after carefully weighing advantages and disadvantages stratified by study group.
Patients’ preference for uterine cavity evaluation differs significantly when women are stratified by the allocated investigation ($\chi^2; p=0.011$). There were no differences found by social characteristics, when stratified according to preference (data not shown). Women preferring saline infusion sonography expected to experience significantly less pain during saline infusion sonography than during hysteroscopy (VAS scores 3.0 and 4.9 respectively, $p=0.006$), whereas women preferring hysteroscopy expected to experience similar pain levels during both investigations (VAS scores 3.1 and 3.5 for saline infusion sonography and hysteroscopy, $p=0.120$). There were no differences in preference considering the pain scores measured during the investigation the patients were allocated to (data not shown).

Different aspects of preferences with regard to investigating the uterine cavity and possibly necessitating therapy were scored on a Likert scale (0=unimportant, 5=very important) and are detailed in table 2. Except for having or not having anaesthesia during therapy, every aspect was considered important. When stratifying the Likert scores by preference (saline infusion sonography or office hysteroscopy), the following differences were found; women with a preference for office hysteroscopy found it of utmost importance that diagnosis and therapy are offered in one visit ($p=0.004$), whereas women preferring saline infusion sonography felt time to consider treatment options more important than women preferring office hysteroscopy ($p=0.014$). With regard to what extent women would accept pain in exchange for certain advantages of the investigation, sixty-eight (60.2%) women would accept more pain if the diagnostic investigation and therapy

| Table 2 | Reason behind patient preferences for diagnostic investigation of the uterine cavity and subsequent therapy on a Likert scale. |
|---|---|
| Regarding diagnostic investigation | Likert score |
| As little discomfort as possible | 4 (3-5) |
| Diagnosis and treatment in 1 session | 4 (4-5) |
| Time to consider treatment options | 4 (3-4) |
| Small chance failure investigation | 4 (4-5) |
| Regarding therapy | Likert score |
| Short waiting time therapy | 5 (4-5) |
| Small surgery risk | 5 (4-5) |
| Anaesthesia during therapy | 3 (3-4) |
| No anaesthesia during therapy | 3 (3-4) |
| High chance successful therapy | 5 (5-5) |

Likert scale: 1=very unimportant; 5=very important
would be offered in one visit. This accounts for 33.3% of the women preferring saline infusion sonography, and 78.8% of the women preferring office hysteroscopy (p=0.001). The median value to the required benefit in terms of successful hysteroscopic therapy was 50% (figure 2). For women specifically preferring saline infusion sonography, successful therapy following diagnostic hysteroscopy should be guaranteed in 100% of the cases (median value). If during the investigation of the uterine cavity an abnormality were to be found, 55 (48.7%) women would opt for an outpatient treatment, and 38 (33.6%) women would opt for treatment under general anaesthesia. Twenty (15.9%) women had no preference.

![Figure 2](image)

**Figure 2** | The required benefit in terms of percentage successful hysteroscopic therapy among women preferring saline infusion sonography and hysteroscopy.

**Discussion**

In this preference study, we found that, given a choice, the majority of women would prefer to undergo office hysteroscopy for further investigation of the uterine cavity. This conclusion may be even stronger with the knowledge that the women participating in this study experienced more pain during office hysteroscopy compared to saline infusion sonography (chapter 6). Especially, since pain scores had no effect on their preferences afterwards.

A limitation of this study remains that there were no validated questionnaires available, so that we had to design a questionnaire specifically for this purpose, observing the
available literature. In order to minimise bias due to experience, we included women randomly allocated to saline infusion sonography and office hysteroscopy who presumably had no strong preference beforehand, and women with no history of uterine cavity investigation, which makes our design unique.

Another possible source of bias could result from cognitive justification, a phenomenon that makes people change their perceptions to make their situation seem better. Women were included in this study after undergoing saline infusion sonography or office hysteroscopy, which might explain why the preference for the treatment they underwent was strongest. However, this accounts for both saline infusion sonography and office hysteroscopy. Moreover, it is interesting that women of the control group preferred office hysteroscopy over saline infusion sonography.

The most important reason for this preference was completeness of diagnosis and therapy in one visit. Additionally, our study showed that apart from the diagnostic investigation most women would prefer to undergo therapy in an outpatient setting rather than a day case setting. This is in concordance with previously published literature [Ferry 1994; Kremer 2000; Marsh 2002]. As proposed by Marsh et al. [Marsh 2002] we included in our questionnaire information about the risks and side-effects of general anaesthesia in order to investigate whether the need of regional or general anaesthesia with day case hysteroscopy would influence their preference for an outpatient or day case approach. Surprisingly, this was not regarded of any importance in their preference.

Further, most women prefer being informed of all the advantages and disadvantages of diagnostic and therapeutic possibilities in general, and prefer to participate in this decision. Considering this and the fact that a considerable number of the respondents preferred saline infusion sonography and treatment under general anaesthesia, women should be informed of their options completely, and not automatically be offered office hysteroscopy as the preferred choice of investigation. Especially since the prevalence of intrauterine abnormalities after selection by transvaginal ultrasound examination is only 50% [Towbin 1996], and we do not know yet what the success rates are of treatment by office hysteroscopy.

In summary, we found that given the choice the majority of women would prefer office hysteroscopy over saline infusion sonography. Additionally, if there were an indication for intrauterine surgery, an outpatient setting is preferred to a day case setting. Nevertheless, one third of the surveyed women would rather be treated under general anaesthesia. So, although our results support the establishment of outpatient one-stop-clinics, the inpatient alternative should be offered as well.
### Appendix A | The descriptions of saline infusion sonography and office hysteroscopy.

| Saline infusion sonography | Office hysteroscopy |
|---------------------------|---------------------|
| **In general** | **In general** |
| This procedure is used to determine the presence or absence of abnormalities in the uterine cavity. | This procedure is used to determine the presence or absence of abnormalities in the uterine cavity. Occasionally during this procedure treatment will immediately follow a diagnosis. |
| **Description of procedure** | **Description of procedure** |
| The patient is seated in an examination chair with the legs resting in two knee supports. The doctor or investigator places a speculum in the vagina. A thin catheter (cross-sectional plane 2mm) is inserted through the neck of the womb into the womb, through which sterile normal saline solution is injected. When filled a vaginal ultrasound is performed. | The patient is seated in an examination chair with the legs resting in two knee supports. The doctor inserts a thin telescope (cross-sectional plane 4 mm) through the vagina and neck of the womb, into the womb (without using a speculum). Through the telescope, a sterile saline solution is injected into the womb. Once the tip of the hysteroscope is in the womb, the inner wall is seen on a TV screen and can be evaluated. |
| **Duration of procedure** | **Duration of procedure** |
| 15 minutes. Directly after the procedure the patient may go home. | 15 minutes. If subsequent therapy is required an additional 15-30 minutes. Directly after the procedure the patient may go home. |
| **Anaesthesia** | **Anaesthesia** |
| None | None |
| **Therapy** | **Therapy** |
| If an abnormality is found (50% of cases), a new appointment for treatment will be made. Depending on the type of abnormality treatment will take place in the outpatient clinic by hysteroscopy (as described on the right). If this is not possible, treatment under general anaesthesia in the operating room may be required. | For the majority of cases if an abnormality is found (50% of cases), the doctor will be able to remove it with a special instrument introduced through the telescope; e.g. removal of polyps or by taking biopsies for further analysis. If this is not possible, treatment under general anaesthesia in the operating room may be required. |
| **Risk** | **Risk** |
| Complications of saline infusion sonography: 0.2% (1 out of 500) (e.g. infection) | Complications of hysteroscopy: 0.4% (1 out of 250) (e.g. infection, bleeding) |
| **Failure of procedure** | **Failure of procedure** |
| In 16% (16 out of 100) of the cases the procedure will fail or will not provide enough information on the suspected pathology. In such cases, a new appointment will be made to perform a hysteroscopy in the outpatient clinic. | In 12% (12 out of 100) of the cases the procedure will fail or will not provide enough information on the suspected pathology. In such cases the hysteroscopy will be repeated under general anaesthesia in the operating room. |