Office hysteroscopy: a scientific overview

Histeroskopia ambulatoryjna z naukowego punktu widzenia

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Streszczenie

Minihisteroskopia (histeroskopia ambulatoryjna) wykonywana bez użycia wzierników (waginoskopia) i kuleciągów oraz bez konieczności analgezji jest metodą diagnostyczno-leczniczą o bardzo niskim ryzyku powikłań i może być wykonana z minimalnym dyskomfortem dla pacjentki. Rzadko wymaga znieczulenia ogólnego pacjentki. Metoda ta wykazuje niski odsetek niepowodzeń przy zachowanej wysokiej efektywności. Zakres wskazań do minihisteroskopii obejmuje nie tylko procedury diagnostyczne, w tym również stany przednowotworowe i nowotwory, ale również procedury operacyjne w zakresie zbliżonym do tradycyjnej histeroskopii wykonywanej przy użyciu „tradycyjnego" resektoskopu. W relacji do innych metod diagnostycznych (USG, SIS, badania radiologiczne, NMR) umożliwia nie tylko precyzyjną wizualizację zmian, lecz także celowane pobranie tkanek do badań mikroskopowych. Te cechy minihisteroskopii sprawiają, że zarówno w wymiarze ekonomicznym (krótki czas trwania procedury, brak konieczności znieczulenia), jak i psychologicznym (szybka diagnoza i niezwłoczne leczenie) jest metodą z wyboru w diagnostyce i leczeniu patologii jamy macicy i kanału szyjki. Pomimo swoich zalet, w porównaniu z USG, nie jest polecana, mimo sugestii pewnej grupy klinicystów, do rutynowego skriningu u pacjentek niemających objawów.

Słowa kluczowe: histeroskopia ambulatoryjna, zalety, skuteczność, przeciwwskazania, powikłania.

Introduction

Hysteroscopy (direct endoscopic visualization of the endometrial cavity) is considered the golden standard as a means to visualize the cervical canal and uterine cavity and to treat benign uterine pathology [1, 2]. It is relatively well established that hysteroscopy has equal or greater diagnostic accuracy than ultrasound, SIS (Saline Infusion Sonography) or blind endometrial biopsy techniques. It is also highly accurate in the identification and diagnosis of endometrial cancer, making it a powerful diagnostic tool in the investigation of abnormal uterine bleeding, one of the most frequent reasons for which women seek gynaecological outpatient care. The past decade has seen rapid advances in this area with new instruments and modified techniques so that this procedure can now be performed in an outpatient setting, so called ambulatory or office-hysteroscopy. There is an emerging consensus among clinicians that this procedure is equally safe, has equal diagnostic potential and provides greater patient satisfaction than traditional hysteroscopy.

Despite the consensus among researchers and specialists in this field, discussion continues concerning the tolerability, feasibility and limitations of diagnostic and operative hysteroscopy in the ambulatory setting. Furthermore, despite its advantages, outpatient hysteroscopy is so far not widespread among outpatient clinics and has not gained general acceptance among clinicians [3]. This article aims to review hysteroscopy as a diagnostic and operational tool as well as to outline the major points in question concerning office hysteroscopy as compared to conventional hysteroscopy: its diagnostic and operational potential, and limitations.

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The diagnostic and operational role of hysteroscopy

The challenge of outpatient gynaecological diagnostics is to clearly identify the relatively few patients in need of further inpatient investigation or surgery, from the majority with benign underlying pathology. Up to 25% of women at some point seek health care due to abnormal uterine bleeding [4] making this one of the most common, as well as physically and psychologically burdensome gynaecological conditions. Investigation of abnormal bleeding can be a lengthy process involving several patient visits and procedures, but using office hysteroscopy most conditions can be diagnosed and treated during one routine visit. This method can therefore, in enabling a quick diagnosis of the most common underlying pathologies and their removal, significantly decrease the incidence of major surgery due to abnormal uterine bleeding [1]. As opposed to blind techniques, hysteroscopy allows for a targeted biopsy of the uterine cavity in the case of a suspect endometrium. Apart from the advantage of lower costs and surgeon time sparing, there is an enormous psychological gain for the majority of patients who avoid the anxiety and further inpatient procedures would entail.

Hysteroscopy as a diagnostic tool is relevant for the following conditions [1]:

- evaluation of abnormal uterine bleeding,
- investigation of infertility,
- investigation of recurrent miscarriage.

In addition, the following operational procedures are performed using hysteroscopy:

- diagnosis and treatment of focal intrauterine lesions (polyps, fibroids, myomas),
- diagnosis and treatment of intrauterine adhesions and septa,
- localisation and removal of difficult-to-retrieve intrauterine devices (IUD),
- ablation of the endometrium,
- hysteroscopic sterilisation (in Poland forbidden by law).

Hysteroscopic diagnosis of cancer and endometrial hyperplasia

A key task of any accurate gynaecological diagnostic tool is to distinguish the more frequent benign pathology underlying common symptoms from the less frequent malignant or pre-malignant cases. Between 5% and 10% of postmenopausal women with abnormal uterine bleeding will prove to have cancer [1]. When it comes to diagnosing cancer, hysteroscopic visual accuracy varies amongst studies. A large retrospective study of women diagnosed hysteroscopically with endometrial polyps found that hysteroscopy had sensitivity of 36% and specificity of 98% in the detection of cancerous polyps or atypical hyperplasia [5]. Another study assessed hysteroscopic diagnostic sensitivity for endometrial cancer at 100%, but specificity at 49.6%, positive predictive value at 81.3% and negative predictive value at 100% [6]. A meta-analysis surveying over 25 000 patient cases concluded that the diagnostic accuracy of hysteroscopy is high for endometrial cancer, but only moderate for endometrial disease [7]. Thus, hysteroscopic visual diagnostics based on the macroscopic characteristics of the endometrium may be useful in identifying suspect cases, but biopsy and histological examination is mandatory to confirm the diagnosis of atypia. Although there are still no studies in this area, as of now there is no indication that endometrial biopsy by hysteroscopy (EBHR) in patients with uterine malignancy increases the risk of cancer dissemination [8].

Advances in hysteroscopy: office hysteroscopy

When first developed, hysteroscopy was almost exclusively performed under general anaesthesia, involved scopes of 5 mm diameter with 8 mm sheaths, and distension of the uterine cavity by means of CO_2 insufflation. The miniaturization of instruments and the use of alternative distension media have in recent decades had a revolutionary effect on the field of hysteroscopy. Firstly, smaller-diameter instruments now allow for a virtually pain-free procedure. Secondly, the use of physiological isotonic saline infusion as a distension media reduces the risk of painful uterine spasms and irritation from the accumulation of gas under the diaphragm [9]. Recently the development of flexible hysteroscopes has increased the range of vision (though arguably not the visual accuracy) possible during the procedure.

Although hysteroscopy has been performed in an outpatient setting for several decades, it has been impeded by a low level of patient tolerability and therefore has not become widespread as a diagnostic and operational tool. Conventional hysteroscopy involves insertion of a vaginal speculum, grasping of the cervix by a tenaculum, traction of the uterus and sometimes the injection of paracervical anaesthesia, all of which are painful for the patient. Pain has been reported as the most common cause of interrupted investigation and many patients report pain despite local anaesthesia [2]. In the mid-90s Bettocchi demonstrated the possibility of performing hysteroscopy vaginoscopically, i.e. with the entry canal under direct visualisation and without the need of a tenaculum, speculum, traction or local anaesthesia.

Sagiv *et al*. [10] have compared groups undergoing vaginoscopic and conventional hysteroscopy using a 3.7 mm hysteroscope. Patient satisfaction was similar in both groups but pain scores were significantly lower in the group having undergone the vaginoscopic investigation (mean pain value by VAS 3.8 as compared to 5.3,

$p = 0.01$). Similarly, Garbin *et al.* [11] compared vaginoscopic with traditional hysteroscopy using a smaller 2.7 mm (3.5 mm sheath diameter) hysteroscope. In this study, mean pain was 4 times higher in the traditional approach (mean VAS value 2 vs. 0.5, $p < 0.0001$). These results underscore the fact that it is often the steps leading up to the introduction of the hysteroscope that are the greatest source of pain for the patient. The length of the procedure and the investigative quality were not compromised using the vaginoscopic approach in these studies.

Tolerability, efficacy and factors influencing success

In one of the largest studies to date investigating the tolerability of office hysteroscopy, between 71.9% and 93.5% of patients, depending on the kind of intervention, underwent office hysteroscopy without any discomfort at all. Among patients with endometrial polyps larger than the internal cervical one however, 63.6% experienced low or moderate pain [12]. A randomized trial comparing parameters of recovery after outpatient as compared to conventional hysteroscopy found that patient satisfaction, as well as the need of postoperative analgesia, was the same in both groups. The time to recovery of preoperative fitness (2 days vs. 3 days, $p < 0.05$), as well as time to postoperative mobility (0 min vs. 105 min, $p < 0.001$), was however considerably shorter in the outpatient group. 78% of patients considered the pain from outpatient hysteroscopy smaller than that usually experienced during menstruation [13].

The failure rate of office hysteroscopy varies between two and 13% but is estimated, in a review of existing articles, to be four to five percent on average [1, 2, 4, 14]. This is comparable to an inpatient failure rate of approximately three percent. The failure rates for pre- and postmenopausal women are not significantly different. A study performed by Campo *et al.* [15] found that the size of the hysteroscope, patient parity and surgeon experience were all factors influencing the success of operative hysteroscopy and patient experience. Significantly better visualisation and higher success rates were achieved for patients with previous vaginal delivery. Surgeon experience has only a slight influence on all parameters. The most influential factor regarding all parameters was the diameter of the hysteroscope. In the above study, the effect of patient parity and surgeon experience ceased to be significant in the patient groups in which a mini-hysteroscope was used. This finding is confirmed by a larger retrospective study [14].

Other studies have further evaluated the effect of hysteroscope diameter in vaginoscopic hysteroscopy. Comparing the classical 5 mm vaginoscopic sheath with a mini-hysteroscope (3.3 mm sheath) one study found that the mean level of pelvic pain during the procedure was halved with the use of the mini-hysteroscope ($p < 0.0001$) [3]. Probably as a consequence of this, the failure rate using the mini-hysteroscope was also less than half. Unfried *et al*. [16] found flexible hysteroscopes to be significantly better tolerated by the patients in the vaginoscopic approach at all stages of the investigation (average VAS 3.1 vs. VAS 1.2, $p < 0.001$). However, surgeons judged visibility, view and visual diagnostic accuracy far superior when the rigid scope was used ($p < 0.0001$) and diagnostic procedure time shorter (mean time 70 vs. 120 seconds, $p = 0.003$).

The efficacy of hysteroscopic surgical interventions is high in the short term. A large study mentioned above found persisting pathology in 5.6% of patients 3 months after operational hysteroscopy [12]. However the recurrence of symptoms over time following hysteroscopic polypectomy is probably high, figures of up to 60% recurrence after 4 years have been found [17].

Hysteroscopy and other diagnostic methods

Hysteroscopy is used as the golden standard of visual diagnostics. The studies comparing hysteroscopy to saline infusion sonography (SIS) are too small to be able to draw any clear conclusions. One study involving 113 patients assessed the SIS specificity as 88% and the sensitivity as 96% as compared to that of hysteroscopy [18]. Several studies have however compared the diagnostic accuracy of hysteroscopy with ultrasound and concordantly found hysteroscopy to be a somewhat more accurate visual diagnostic tool. Vercinelli *et al*. judged that ultrasound had 96% sensitivity, 86% specificity, 91% positive predictive value and 94% negative predictive value of hysteroscopy [19]. A recent study has concluded that ultrasound diagnostic specificity for polyps is inadequately low in women with postmenopausal bleeding and endometrial thickening in whom carcinoma has been ruled out [20]. Ultrasound and SIS are however, for the majority of patients, diagnostic methods with both high specificity and high negative predictive value, making them both reliable initial investigations or, in the case of ultrasound, screening procedures. However in 45-85% [21] of women with abnormal uterine bleeding, a focal pathology requiring further investigation is found. Given this, there is a clear advantage in having a diagnostic tool which enables direct sampling of the endometrium.

Hysteroscopic visualisation of the endometrium is by all accounts very accurate in diagnosing uterine pathology [22]. A study comparing hysteroscopic visual diagnosis with the verified histopathological diagnosis after hysterectomy found hysteroscopic diagnostic sensitivity to be 98%, specificity 95%, positive predictive value 96%, and negative predictive value 98% [23]. However it

is the possibility of taking targeted biopsies of a suspect endometrium that constitutes the diagnostic potential of hysteroscopy. A recent study estimated the sensitivity of blind biopsy for endometrial polyps at 11%, the specificity at 93%, and the diagnostic accuracy at 59% [24]. The values for diagnosing endometrial hyperplasia were 25%, 92%, and 80%, respectively. Comparatively, hysteroscopy showed sensitivity of 100%, specificity of 97%, and diagnostic accuracy of 91% in diagnosing endometrial polyps, sensitivity and specificity of 100% and 98%, respectively, with accuracy of 99% for submucous myomas. EBHR is in many studies used as verification of a predicted diagnosis by other methods.

A large meta-analysis evaluating the accuracy of outpatient endometrial biopsies, both blind and visually guided, found diagnostic accuracy to be high for all techniques provided that enough material was obtained, something which is more or less assured in hysteroscopic biopsies [25]. Dilatation and curettage on the other hand, misses focal lesions in up to 58% of polyps and 50% of hyperplasias [26]. Pipelle has diagnostic accuracy of 97-100% as long as an adequate sample is obtained, however this is successful in only 27% of cases when the endometrial thickness is below 5 mm [27]. It is the elimination of this large percentage of false negative results that a visually targeted biopsy is more advantageous than hysteroscopy.

Complications and contraindications to office hysteroscopy

A systematic review of hysteroscopy as a diagnostic and surgical method lists no contraindications applicable exclusively to office hysteroscopy. Below, there are the current conditions under which hysteroscopy should not be performed:

- cervical cancer,
- heavy uterine bleeding,
- pelvic inflammatory disease.

Relative contraindications, however, should be taken more seriously in the ambulatory setting:

- pregnancy,
- uterine perforation,
- cervical stenosis,
- cardio-respiratory disease.

For high-risk patients, for whom hysteroscopy is considered indicated, proximity to inpatient and intensive care is highly advisable, making these patients less suitable for ambulatory hysteroscopy. Furthermore there is a consensus that outpatient hysteroscopy, irrespective of the patient involved, cannot function in total isolation from a hospital setting.

Complications during hysteroscopy are rare. A systematic review estimated the incidence of serious complications during ambulatory hysteroscopy (defined as pelvic infection, uterine perforation, bladder perforation) at 0.03% [14]. The risk of local infection has been reported at 0.2% [1], the risk of uterine perforation at 0.016% [14]. Vasovagal reaction is the most common complication during the procedure and is reported in 0.3-3.3% of cases [1] being up to ten times lower when a mini-hysteroscope is used [28]. Operative procedures during hysteroscopy are more risky mainly because of the risk of uterine perforation. However, this risk is lower when the patient is conscious because she is more likely to respond to pain to the extent that engagement of the myometrium can be averted in time.

Summary and conclusions

Office hysteroscopy, when defined as the vaginoscopic procedure, is a method which can be performed with very little discomfort for the patient and at an extremely low risk for serious complications. It has a low failure rate and high efficacy. It can be used for routine diagnostics but also for small operational interven-

Fig. 1. Submucous myoma

Fig. 2. Endometrial polyp

Fig. 3. Normal uterine cavity

Fig. 4. Internal cervical os atresia

tions and diagnosis of malignancy and pre-malignancy. It has proved to be superior to other diagnostic tools in the unique possibility of visualization and simultaneous visually-controlled biopsy. Primarily and foremost however, it represents an enormously beneficial gain in both time and psychological impact for the patients undergoing the procedure, who often obtain immediate diagnosis and treatment.

There is a further advantage in minimizing the diameter of the hysteroscope, the so-called mini-hysteroscope of 3.3 mm sheath diameter being significantly better tolerated than the wider 4 mm hysteroscope. The use of mini-hysteroscopes may also obviate the need to restrict the patient population to those having undergone vaginal delivery or the need for a very experienced surgeon. At present, however, there seems to be no clear advantage in using a flexible scope, as the gain of greater patient comfort is outweighed by the fact of greater visibility, shorter procedure time and thus lower cost of rigid hysteroscopy.

Given that this procedure is still more expensive, more time-consuming and somewhat less comfortable for patients than routine ultrasound it may at this time be premature to recommend, as suggested by some authors [29, 14], it as a screening tool for asymptomatic patients. Most asymptomatic patients will after all present to the clinic without uterine abnormality or cause for intervention.

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