



Research Article

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Hysteroscope or Mini-Hysteroscope: HTA in a University Hospital in Italy

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Abstract

Objective: The HTA Committee of University Hospital "G. Rodolico" of Catania received the form with the purchase request of four hysteroscopes.

HTA report was developed to answer the following questions:

Policy question: What is the optimal use for mini hysteroscope for gynecological problems in terms of effectiveness, safety and economic costs compared to the alternatives?

Research question: Are the mini hysteroscope for all gynecological problems safe, painless, effective and cost-effective?

Methods: We have identified and described some different types of hysteroscopes available on the Italian market and performed a context analysis to show their impact in terms of spending and consumption. We performed a systematic review of literature in order to synthesize the evidence on comparative efficacy, safety, and pain relating to the use of technology in question.

The evaluation was conducted using a multidisciplinary approach and has provided an analysis of the seven following domains:

Health problem and current use of the technology

Description and technical characteristic of technology

Clinical effectiveness

Safety

Costs, economic evaluation

Organizational aspects

Ethical aspects

Results: We have reported a summary for each domain analyzed and conclusions of HTA Committee. Research questions domains were ranked using a 5-point scale.

For clinical effectiveness, economic and safety evaluation, rigid hysteroscopes have the best results.

The trophoscope has a very small caliber and is particularly painless.

There are no big differences in the organizational aspects; all these tools are used for outpatient basis.

Conclusions: On the market there are hysteroscopes with even smaller diameters but primarily used for diagnostics. The purchase of these has not been considered necessary and there is no evidence in the literature on the conversion times from diagnosis to operation. Evidence is still limited for the trophoscope. We recommend decision makers to consider carefully the effectiveness and safety aspect related to the use of the technology in each contest.

Keywords

Hysteroscopy; Pain; Scope size; Mini-hysteroscope; Office hysteroscopy; Anxiety; Outpatient hysteroscopy; HTA domains

Introduction

The rationale for this assessment comes from the purchase request for new efficient hysteroscopes. The new devices may cause less pain than the others. This evaluation is intended to provide an example of a guide for an evidence-based use of this technology and could help improve the allocation of public funds.

We have identified and described some different types of hysteroscopes available on the Italian market and performed a context analysis to show their impact in terms of spending and consumption. We performed a systematic review of literature in order to synthesize the evidence on comparative efficacy, safety, and pain relating to the use of the technology in question.

The gynecologists asked for the mini hysteroscope but, given the recent publications that deny the reduction of pain with the use of mini hysteroscope [1], the Health Department has asked the HTA Committee to conduct an evaluation to assess the appropriateness of use and to provide objective tools of assessment for decision-maker spending.

This rapid HTA report has been developed to answer the following questions:

Policy questions: What is the optimal use for mini hysteroscope for gynecological problems in terms of effectiveness, safety and economic costs compared to the alternatives? Can a mini hysteroscope be useful for the work to be carried out at our unit, and can it cause less pain than the classic ones?

Research question: Is the mini hysteroscope safe, painless, effective and cost-effective for all gynecological problems?

Method

The HTA Committee of University Hospital "G. Rodolico" of Catania received the form with the purchase request of four hysteroscopes that provides a detailed description of the object and the relative consumable material support. The proposal should be submitted to the opinion of the Council of Health, but, if there are no particularly complex problems, the consent of the Department's Head is enough to arrange the purchase.

Different types of hysteroscopes and different indications were assessed.

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We analyzed the report of outpatient services from the Unit of Obstetrics and Gynecology and the cases of patients who performed hysteroscopy. We evaluated the list prices of the most common equipment in Italy. A systematic review of the effectiveness and safety of use of the instrument was conducted on comparative studies, which reported outcomes for patients treated in the office. We adapted—as well as an adapted HTA report requires—the results to the local situation.

The evaluation was conducted using a multidisciplinary approach and has provided an analysis of the seven following domains:

CUR domain – Health problem and current use of the technology

TEC domain – Description and technical characteristic of technology

EFF domain – Clinical effectiveness

SAF domain – Safety

ECO domain – Costs, economic evaluation

ORG domain – Organizational aspects

ETH domain – Ethical aspects

We have reported a summary for each domain analyzed and conclusions of HTA Committee.

Results

Given the debate that is currently present in the international community on the benefits of mini hysteroscope, it is considered useful to report on what it finds. The female condition is varied, and the two instruments, though similar, have different levels of appropriate indications today.

CUR domain – Health problem and current use of the technology

Hysteroscopy is an endoscopic surgical procedure that has become an important tool to evaluate the intrauterine pathology. It provides direct visualization of the whole uterine cavity and provides the possibility to perform a biopsy of suspect lesions that may be missed by dilation and curettage. It is used in outpatient endoscopic diagnostics for the morphological study of the cervical canal, uterine cavity and the tubal ostia, in case of abnormal uterine bleeding, infertility and medically assisted procreation [2]. Endometrial polyps can be diagnosed and removed; intrauterine adhesions can be released in the outpatient setting, without the need for an operating room [3].

One of the major problems for the gynecologist is the introduction of a hysteroscope through the internal uterine orifice, whose diameter is generally 4-5 mm in diameter and constituting a technical obstacle to the introduction. The circular gauge of 5 mm diameter requests a spatial change of the muscle fibers that have to adapt to the passage stimulating the sensitive fibers and causing pain [4].

The oval shape (Figure 1) facilitates a traumatic introduction: it corresponds better to the anatomy of the cervical canal, which has a larger cross-axis and rotating the optics can be easily inserted following the morphology of the canal without force (Figure 2). The tool lets you inspect the uterine cavity and withdraw so hysteroscopes targeted biopsies of suspect areas.

The hysteroscopic examination includes the infusion of sterile water into the vagina, which then dilates the cervical canal and gently

relaxes the uterine cavity. The extension of the cervical canal with water hysteroscope allows the passage and the vision of the uterine cavity. The uterus responds to this by contracting distension as during menstruation and sometimes evoking a menstrual-like cramping pain over the groin or at the shoulder, which disappears within minutes without requiring any therapy. In 5% of patients, examination evokes a greater pain. In these cases, as soon as the patient requests it, the doctor immediately suspends the procedure and the patient goes directly under anesthesia in the operating room with execution.

The vaginoscopy approach devised by Bettocchi or “no-touch hysteroscopy” is a technique through which the hysteroscope is introduced into the vagina, into the cervical canal and into the uterine cavity without the need to use a vaginal speculum, a tenaculum or cervical dilator: the use of vaginoscopy was associated with a significantly lower perception of pain [5-7] and make surgery even in young people “virgins” that otherwise would face surgical defloration.

TEC domain – Description and technical characteristic of technology

Advances in technology have led to the miniaturization of high-definition hysteroscopes without compromising the optical performance, therefore making hysteroscopy a simple outpatient procedure, safe and well tolerated [8]. The introduction of new optical systems, like the rod lens with a diameter of 2 to 3 mm has allowed us to produce very thin shirts.

The mini hysteroscope operating in continuous flow has an outer jacket of 4 mm in diameter. The instrument consists of two shirts, one for the irrigation and the other for aspiration and of a semi-rigid channel for surgical instruments 5 Fr. The mini hysteroscope allows the doctor to perform the hysteroscopy without the use of local or general anesthesia and without pharmacological preparation [9]. The exam can be run at any time of the menstrual cycle, except in flow days. The examination allows for formulating a diagnosis based on direct observation of the cervical canal, uterine cavity and the tubal ostia and their epithelial lining, ensuring a more accurate diagnosis,

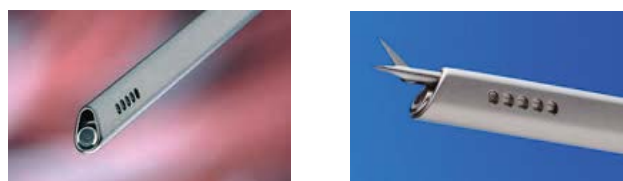


Figure 1: Oval shape of hysteroscope: view a section of working channel and a profile with 5 Fr scissors.

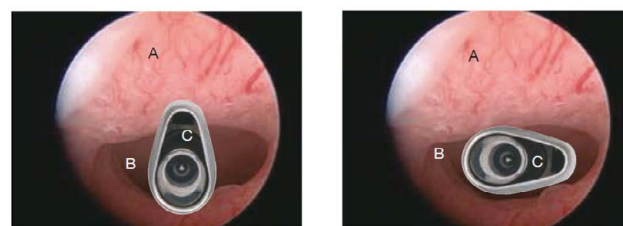


Figure 2: A) Perspective view internal uterine orifice and the hysteroscope profile with the traditional introduction. B) Internal uterine orifice and perspective view of the hysteroscope profile after a rotation of 90° and adapt to the shape of the os to find the entry of least resistance.

even in postmenopausal women. In the examination photos can be taken or video recordings made.

Mini hysteroscope is indicated for postmenopausal women or women with medical conditions that result in a cervical canal stenosis, a procedure which makes it impossible to execute the traditional hysteroscopy.

The trophoscope is a compact hysteroscope based on the 2 mm rod lens telescope with integrated irrigation channel that has an outer diameter of only 2.9 mm. Two different outer sheaths are available: a continuous-flow sheath and an operating continuous –flow sheath with an integrated 5 Fr. working channel. With the sheath the trophoscope reaches an outer diameter of 4.4 mm. The thin outer diameter enables easy examination of the uterine cavity without dilation of the cervix. The use of the trophoscope is particularly indicated for infertility patients.

The flexible hysteroscope is most commonly used for diagnostic hysteroscopy. The tip that curves of 120°-160° makes it very useful in uterine anatomical irregularities, in cornual areas and accurately inspecting the uterus distinctly retroverted, antiverso or flexed. Sometimes the flexible hysteroscopy may be less painful than with rigid optics.

Research question domains were ranked by the Committee using a 5-point scale (1 = insufficient to 5 = excellent), and duration of the hysteroscopy was measured (Table 1).

EFF domain – Clinical effectiveness

The 5 mm rigid Bettocchi hysteroscope (Figure 3) gives brilliant image quality thanks to its Hopkins® lens system. It presents an atraumatic insertion in the cervical canal due to oval sheath. The working channel allows the use of operating system. In recent literature, the success rate was 90-100% [10].

The rigid Bettocchi 4 mm hysteroscope (Figure 4) is less painful in the introduction. Remains indicated in special conditions (virgin, particularly stenotic canal), it allows you to run diagnostic hysteroscopy with equal precision of 5mm with the same optics but in cases of large tumors may be less effective than 5 mm.

The trophoscope (Figure 5) it is basically used for diagnostic hysteroscopy. The miniature size limits its use in case of tumors but made the instrument suitable for studies of infertility and uterine plants.

Flexible hysteroscopes (Figure 6) are easier to handle but the main use remains the diagnostic hysteroscopy. It is reported that hysteroscopy with this instrument was successful in 87.5% of patients [10].

ECO domain – Costs, economic evaluation

Hysteroscopy allows identifying the cause of the symptoms with certainty, or confirming an ultrasound suspicion without using anesthesia and use of the operating room with the attending costs. We did not find economic studies for cost utility or cost benefit published in the last 10 years, nor cost effectiveness analysis of mini hysteroscope compared to the classic hysteroscope. We only found studies that evaluated the procedures performed in the hospital versus office hysteroscopy [11,12]. Direct instrument costs were considered.

Rigid hysteroscopes of diameter 5 mm or 4 mm have overlapping costs (€ 7166,28). For the same cost, however, the 5 mm hysteroscope has the possibility to be used for diagnostic hysteroscopy and operative in a safe and effective way. The instruments can be properly decontaminated with the same device.

The trophoscope has a similar cost to the two rigid hysteroscopes (€ 7494,46) but it is basically used for diagnostic hysteroscopy. The ancillary tools (5Fr) for rigid ones are interchangeable between 5mm, 4mm and trophoscope that do not affect the assessment of costs.

Flexible hysteroscopes cost more (€ 14.000) and have a lower yield.

ETH domain – Ethical aspects (pain)

From the ethical point of view, the new technology has advantages and deserves a very positive assessment: this provides the possibility of pain reduction that should, in a modern health system, be optimal, although terms of increased costs or need for prolonged periods may result.

What causes pain, stimulating the inferior hypogastric nerve plexus, is the distension of the uterine cavity: the lower the pressure distension, the lower the discomfort brought. The minimum pressure to separate the uterine walls is 30 mmHg. Relaxation through the use of saline solution results in a minor abdominal pain and less shoulder pain compared to the use of carbon dioxide [13]. An inadequate distention causes more discomfort in nulliparous women compared with multiparous women. The rigid 4 mm Bettocchi hysteroscope is less painful in the introduction [14]. The presence of cervical synechia was the major factor that influenced pain during hysteroscopy [15].

Dialogue with the patient seems crucial to relieve pain. If possible, one of the nurses should assist the woman during the procedure, and talking to her calm her, give her information about the procedure, and offer her support [16]. This approach, which distracts the woman, may decrease the anxiety and limit the pain and embarrassment (the so-called “local-anesthesia voice”). A proper preparation of the woman is the key element of a successful outcome of the procedure and it should begin from the moment of the decision to perform the

Table 1: Research question domains were ranked by the committee using a 5-point scale (1= insufficient to 5= excellent).

Domains of research question	EFF domain diagnostic	EFF domain operative	EFF TOTAL	ECO domain	ETH domain	SAF domain	ORG domain	Total
Rigid hysteroscopes diameter 5 mm	5	5	5	5	3	5	5	23
Rigid hysteroscopes diameter 4 mm	5	3	4	4	5	4	5	22
Trophoscope	4	1	2,5	4	5	2	3	16,5
Flexible hysteroscopes	4	2	3	2	4	3	3	15

Note: EFF domain – Clinical effectiveness; SAF domain – Safety; ECO domain – Costs, economic evaluation; ORG domain Organizational aspects; ETH domain – Ethical aspects

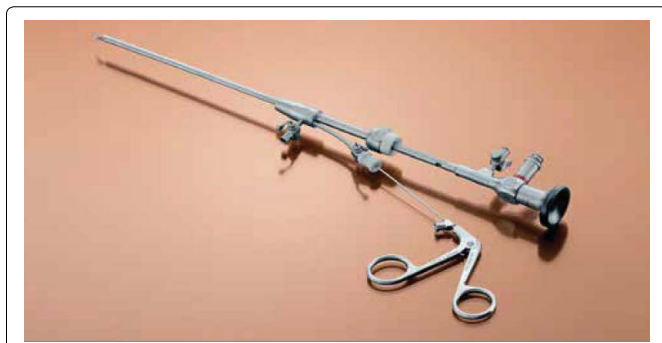


Figure 3: Campo Trophyscope®.

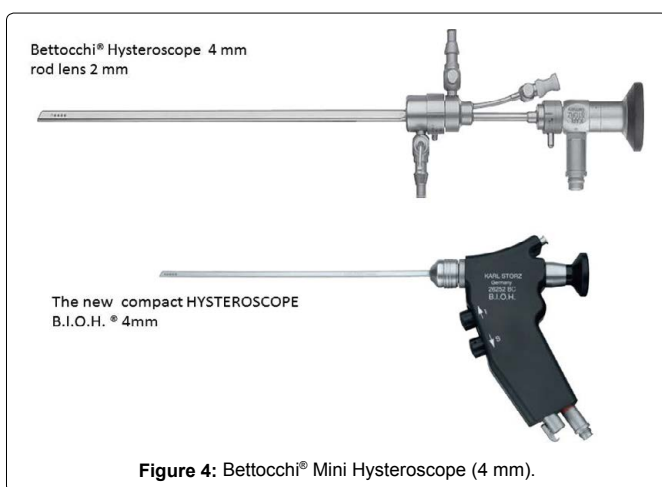


Figure 4: Bettocchi® Mini Hysteroscope (4 mm).

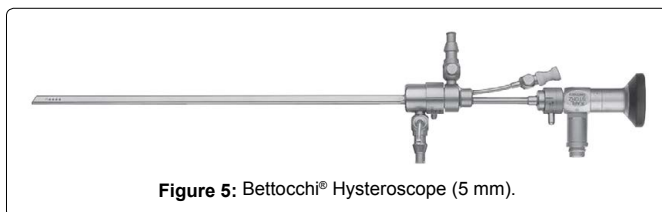


Figure 5: Bettocchi® Hysteroscope (5 mm).

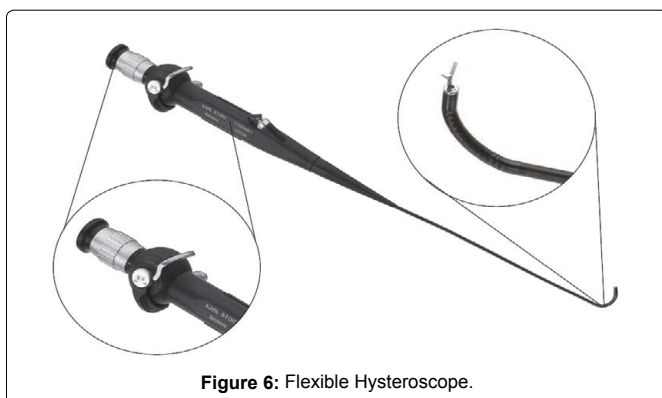


Figure 6: Flexible Hysteroscope.

outpatient hysteroscopy. They must be given simple information about the procedure, making sure the information is clear and understood; the patient must also have the opportunity to ask questions and discuss any concerns, particularly in the case when the patient is also given the option of a simultaneous treatment (see and treat).

The trophyscope is basically used for diagnostic hysteroscopy: in this field the very small caliber was deemed particularly painless.

SAF domain – safety

The safety reported in both diagnostic and operative hysteroscopy was measured. The duration of the hysteroscopy was also determined.

Cervical preparation before an outpatient hysteroscopy should not be carried out in view of the absence of any evidence of benefit in terms of pain reduction, the rate of failures and traumatic injuries [17].

The safety use of 5.0 mm diameter operative hysteroscope has been reported since Bettocchi in 2004 [18]. Pathological disorders such as cervical and endometrial polyps and myomas identified are safely treated immediately (see-and-treat approach), anatomical impediments can be repaired using a vaginoscopic technique with little discomfort. With this tool the operative hysteroscopy is successfully concluded in 92-95% of the cases. The possibility to remove masses and use this tool for the surgical treatment of intracavitary uterine pathology contributes to elevating the patient safety because this procedure is independent of the hospital circuit not requiring the use of the operating room, hospital admission or loco regional anesthesia, thus avoiding risk of adverse events associated to hospitalization or complications of general or loco regional anesthesia [19].

The peculiarity of the mini 4 mm hysteroscope makes it suitable to run the diagnostic and operative hysteroscopy in postmenopausal women or women with medical conditions that result in a cervical canal stenosis, which make it sometimes impossible to execute the traditional hysteroscopy and allows the immediate resignation. The mini hysteroscope allows a lower morbidity for this type of patient but in cases of large tumors may be less effective than the 5 mm.

Trophyscope has a single flow version with an outer diameter of 2.9 mm, which needs to be used with sheaths providing more stability. It seems to not have great stability, because of the extremely thin gauge. Studies investigating the safety of the instrument still need to be published.

ORG domain – Organizational aspects

There are no big differences in the organizational aspects: all these tools are used on an outpatient basis. Our gynecologists are used to working with the 5 mm hysteroscope. The 4 mm hysteroscope has the same structure and operation of the 5 mm and can be immediately implemented. The use of the trophyscope and the flexible hysteroscope require a learning period. Trophyscopes and flexible hysteroscopes must be sterilized with extra attention, given its very small size.

Discussion

In order to upgrade the technological heritage of Unit of Obstetrics and Gynaecology of the University Hospital “G. Rodolico” of Catania, it was required to purchase four hysteroscopes to be used in outpatient service. The HTA Committee adapted a report to local context.

Outpatient hysteroscopy represents a simple and safe approach for intrauterine evaluation [19,20]. Recent advances in technique and instrumentation facilitate this approach and, we encourage its higher adoption by the wider gynecology community. The female condition is varied, and, as such, the instruments analyzed, though similar, have appropriate uses for different prognoses.

The evidence showed no useful administration of prostaglandins to reduce pain in cases of hysteroscopy in the office [21], and suggest

effective music or local vocal anesthesia. The presence of music could be used to reduce anxiety and thus the perception of pain [22].

The pain is related to the type of means inflated, the speed of execution of the examination, the presence of synechiae, and the experience of the operator. The vaginoscopic examination approach significantly reduces the pain. The flexible type causes less painful while the rigid one, Bettocchi, has superior optical qualities, which ensures more rapid performance, a higher success rate and lower costs. The distension with saline solution has resulted in better patient compliance and better vision in case of intrauterine bleeding. The fastest running examination helps to reduce discomfort. Rigid hysteroscopes are cheaper to purchase and easier to sterilize and store than flexible hysteroscopes, becoming indispensable if they are to carry out operating procedures.

The mini-hysteroscopic system offers a simple, safe and efficient diagnostic method in the office for the investigation of abnormal uterine bleeding, the evaluation of the cervix and uterine cavity in the infertile patient [23], for the screening of endometrial changes in patients under hormone replacement therapy or anti-estrogens as adjuvant treatment and the interpretation of uncertain findings in other diagnostic techniques such as ultrasound, magnetic resonance imaging, blind biopsy or hysterosalpingography [24,25]. The delicate procedures require great skill and are made with a high-quality precision instrumentation.

For some procedures, the use of the trophoscope is more suitable, even though its primary studies are limited. The trophoscope has a similar cost to rigid hysteroscopes but is basically used for diagnostic hysteroscopy. The miniature size limits its use in case of tumors but made the instrument suitable for studies of infertility and uterine plants. There is no consensus on the effectiveness of hysteroscopic surgery for improving the prognosis of subfertile women but, in patients with at least two failed cycles of assisted reproductive technology, diagnostic hysteroscopy or operative hysteroscopy is mandatory to improve reproductive outcome [26].

Among the various devices available on the market we prefer those for which clinical trials have been published and consider the others only in cases of studies that have generated evidence.

We did a context overview and concluded that in the Unit of Obstetrics and Gynaecology, 80% of hysteroscopies requests have been performed in postmenopausal women. Pathological disorders such as polyps, myomas and other tumors identified are safely treated immediately (see-and-treat approach) with the 5mm hysteroscope. The study of infertility is not very accomplished in our structure; however, it has a great tradition of oncological gynecology.

The Bettocchi rigid hysteroscopes are those with a better cost-effectiveness in our contest.

The purchase of a mini hysteroscope is a good decision even if the data is not unique on the reduction of pain perception, but certainly not more than the pain caused by the classic hysteroscope. In cases of large tumors mini hysteroscopes may be less effective than the 5 mm. With 5 mm hysteroscopes, it is feasible to remove the masses, but only an experienced hysteroscopist who knows how to balance the patient's pain tolerance and the control of the uterine cavity, can do it. Our gynecologists have experience with the Bettocchi 5 mm hysteroscope.

Valued services performed at our operating Units of Gynecology are appropriate purchasing of three 5mm hysteroscopes and one mini 4mm hysteroscope.

Having analyzed all the examinations performed at our operating units of Gynecology, it is appropriate to provide funds for the purchase of three five-millimeter-hysteroscopes and one mini 4 mm hysteroscope.

The clinician will consider whether it is appropriate to examine with one device or the other.

Conclusions

On the market there are hysteroscopes with even smaller diameters but primarily for diagnostic use. The purchase of these has not been considered necessary, and there is no evidence in literature on the conversion times from diagnosis to operation. Evidence is still limited for the trophoscope and we recommend decision makers consider carefully the effectiveness and safety aspect related to the use of the technology in each situation.

We believe that we must encourage the greater adoption of operative hysteroscopy by the wider community of gynecologists, but we paid attention to the five domains before determining the purchase. Based on available evidence, the purchase of the mini hysteroscope is considered useful, safe, convenient and can be connected to the improvement of some outcomes, in particular conditions that represent no more than 20% of our hysteroscopies.

The smaller diameter reduces pain in the introduction of the instrument. There was no evidence of efficacy superiority over 5 mm hysteroscopes for operative hysteroscopy.

Choosing the right tool for the medical needs is one of the fundamental elements for the success of a hysteroscope examination.

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