

Vaginal Misoprostol for Cervical Priming Before Outpatient Hysteroscopy: A Randomized Controlled Trial

Thesis

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List of Abbreviations

Abb.	Full term
AIDA.....	Advanced Image and Data Archiving
AUB	Abnormal uterine bleeding
AUC	Area under the curve
BPS	Behavioral Pain Scale
CBNPS.....	Colorado Behavioral Numerical Pain Scale
CO ₂	Carbon dioxide
D&C	Dilatation and curettage
EUO	External uterine orifice
IUDs.....	intrauterine devices
IUO	Internal uterine orifice
IVF.....	In vitro fertilization
LCD.....	Liquid Crystal Display
MOBID	Mobilizations- Observation- Behaviour- Intensity - Dementia Pain Scale
MPQ.....	McGill Pain Questionnaire
MU	Montevideo Units
NRS.....	Numerical Rating Scale
NSAIDs	Non-steroidal anti-inflammatory drugs
OD.....	Outer diameter
OH.....	Outpatient hysteroscopy
PC	Personal computer
PCMCIA	Personal Computer Memory Card International Association
PG E1.....	Prostaglandin E1
PID.....	Pelvic Inflammatory Disease
PRT	Personal rapid transit
R.C.T.....	Randomized controlled trial
SPSS	Statistical Package for Social Sciences
TVS.....	Transvaginal sonography
VAS.....	Visual Analogue Scale
VRS.....	Verbal Rating Scale

INTRODUCTION

Hysteroscopy is considered the “gold standard” for diagnosing intrauterine Pathology (*Birinyi et al., 2004*). With the invention of the miniature hysteroscopy, it is possible to perform hysteroscopy in an office setting (outpatient hysteroscopy [OH]) without anesthesia for diagnostic indications and certain operative procedures (*Bettocchi et al., 2004*). However, the experience of pain related to the procedure can be a major limitation for OH as a standard of care (*De Iaco et al., 2000*). This is often caused by the diameter of the hysteroscopy and/or cervical resistance (*Campo et al., 2005*).

Several alternatives have been proposed to perform the procedure with an acceptable patient compliance. Local anesthetic reduces the pain experienced by women during OH. This occurs with paracervical and intracervical injections of anesthetic but not with transcervical and topical application; paracervical injection seems to be the most effective method of administering local anesthetic for the procedure (*Cooper et al., 2010*). Nevertheless, the injection of paracervical anesthetic may cause pain and bleeding (*Vercellini et al., 1995*).

Although hysteroscopy has been considered as a safe and less invasive procedure, some complications such as cervical tear, bleeding, uterine perforation, pain and discomfort may occur during the process (*Jansen et al., 2000*). Many women need dilatation prior to hysteroscopy to make the procedure simpler.

Traditional methods of cervical dilatation pre-procedure include the use of hegar's dilators or luminaria tents, which could cause significant patient discomfort, and at the same time potentially induce bleeding and hamper views obtained at hysteroscopy. The efficacy of misoprostol as a cervical ripening agent in the pregnant uterus is well established (*Lokugamage et al., 2003*). However, there are varying reports regarding efficacy and incidence of side effects when misoprostol is used prior to hysteroscopy (*Preen et al., 2002*).

Misoprostol (prostaglandin E1 analog) is a drug of choice for cervical ripening, labor induction, post-partum hemorrhage and pregnancy termination (*Goldberg et al., 2001*).

There is evidence supporting the use of misoprostol as a cervical priming agent before some gynecologic procedures, such as intrauterine device insertion and hysteroscopy (*Crane et al., 2006*).

The most common side effects with use of misoprostol in non-pregnant women are mild abdominal cramps, vaginal bleeding, febrile episodes, nausea and diarrhea (*Preutthipan et al., 2006*).

AIM OF THE WORK

The present study aims to assess the efficacy and safety of vaginal misoprostol for cervical priming before diagnostic outpatient hysteroscopy without anesthesia.

*Chapter One***HYSTEROSCOPY**

Although operative hysteroscopy has progressively been accepted for the treatment of intrauterine pathologies, diagnostic hysteroscopy is still not widely and routinely used. Whereas almost all urologists utilize office cystoscopy to evaluate bladder pathology, it is estimated that less than 20% of gynecologists utilize office hysteroscopy to evaluate uterine pathology (*Isaacson, 2002*).

Types of diagnostic hysteroscopy:

1- Conventional hysteroscopy: It is the hysteroscopy in which the procedure is performed with an instrument of 5.0 mm total diameter and with CO₂ or normal saline as a distention medium and the insertion of the hysteroscope is facilitated by the use of a speculum and a tenaculum. It was the standard hysteroscopy for decades (*Campo and Molinas, 2007*).

2- Office hysteroscopy (vaginoscopic or *no-touch* technique). It was developed by Bettocchi and Selvaggi in 1995 to reduce patients' pain and discomfort (*Bettocchi and Selvaggi, 1997*). This technique avoids the need to introduce a vaginal speculum to visualize the cervix and a cervical tenaculum to grasp the cervix. The vagina can be distended by introducing the watery distention medium through the hysteroscopy placed in the lower vagina, the telescope is then

driven to the posterior fornix, the external uterine orifice (EUO). When the EUO is visible, the scope is introduced into the cervical canal, and after distending it, the scope is carefully moved forward to the internal uterine orifice (IUO) and then into the uterine cavity with the least possible trauma (*Bettocchi et al., 2009*).

The Office Diagnostic Hysteroscopy:

In order to propose the systematic use of diagnostic hysteroscopy and to avoid the still well established delay in indication, it is mandatory to perform the technique in the office, ideally at the same time as transvaginal sonography (TVS). The most important challenge for the office approach is to be able to perform the procedure with an acceptable patient compliance. This should not be underestimated, since many patients still prefer the inpatient approach, believing that it will be pain-free (*Kremer et al., 2000*). Several alternatives have been proposed for pain reduction during conventional office diagnostic hysteroscopy, but the results are inconclusive (*Davies et al., 1997; De Angelis et al.^b, 2003*). The scientific evidence gathered over the last years and the major technical improvements in the manufacturing of high-quality small-bored scopes (mini-hysteroscopes) have provided an answer to the question of how diagnostic hysteroscopy should be implemented successfully in an office environment (*Nagele et al., 1996; Shankar et al., 2004*).

Instruments for office diagnostic hysteroscopy

Hysteroscope:

Outer diameter

The outer diameter indicates the width of the barrel including the sheath. For diagnostic hysteroscopes that do not use a sheath, the OD refers only to the width of the optic barrel. Modern hysteroscopes range from 2.7-10 mm; the OD of a diagnostic scope typically ranges from 2.7-5.0 mm, while the OD of an operative sheath ranges from 5-10 mm. Rigid scopes with an OD exceeding 5.0 mm usually require some degree of cervical dilation, while use of a narrow caliber (or flexible) hysteroscope usually requires no cervical dilation. Not surprisingly, the OD also correlates with the amount of operative pain. In a study of hysteroscopy in postmenopausal women, subjects undergoing small diameter hysteroscopy (<3.5 mm) without local injection had less pain than those with paracervical blocks undergoing the procedure with a 5.0 mm hysteroscope (*Giorda et al., 2000*).

Working length

The working length measures the distance between the distal lens to the proximal eyepiece and ranges from 160-302 mm (*Bradley, 2010*). Longer working lengths permit the surgeon to operate farther from the vagina and may be of strategic importance in the morbidly obese patient. Working

lengths typically do not vary enough to produce differences in picture quality between hysteroscopes of similar build and quality.

The 3 parts of the hysteroscope (excluding the sheath) are the lens, the barrel, and the eyepiece. The depth of field on the scope is usually between 2-3 cm, and magnification can reach up to 35X with certain liquid distention media and lens positioning (*Baggish et al., 2002*) Hysteroscopes are available in a variety of viewing angles: 0°, 12°, 15°, 25°, 30°, and 70°. Zero degree scopes provide a wide-angled view in-line with the barrel (Figure 1).

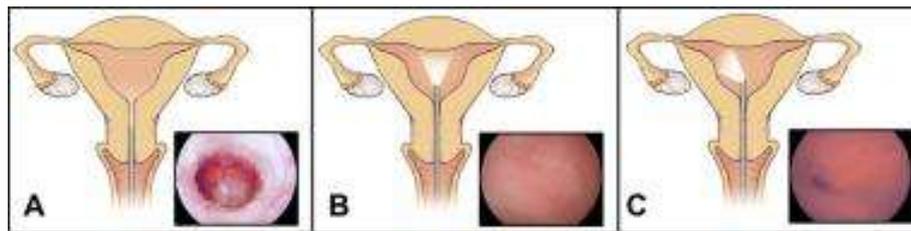


Figure (1): Schematic and hysteroscopic view of the cervical canal and uterine cavity. A: 0° hysteroscope in the endocervical canal. B: 0° hysteroscope viewing the fundus. C: Angled hysteroscope viewing the right tubal ostia. Illustration by Daniel Fu. Austin, TX, 2010.

Angled scopes allow for clear views of the periphery without requiring excessive operator movement and are often helpful to visualize the tubal ostia. Cameras that attach to the eyepiece are frequently used to transmit images to a video monitor. Electronic displays allow the operating room personnel to watch the procedure and are convenient for intraoperative teaching. These systems are also capable of

electronically documenting the procedure with still images and video clips for future reference.

Rigid versus flexible

Hysteroscopes can be classified into rigid (Figure 2) and flexible (or semi rigid) (Figure 3) Types. Rigid hysteroscopy require some assembly. Most designs require that the telescope be inserted into a sheath that is then attached to a bridge. Bridges for a diagnostic scope may only have a single inflow port. Operative bridges typically have 2 media ports with additional ports for instruments. Dual media ports for inflow and outflow can produce a steady laminar flow to improve image clarity during procedures in which blood can obscure the field of view.



Figure (2): Rigid diagnostic hysteroscope with only one inflow port. © 2010 Photo Courtesy of KARL STORZ Endoscopy-America.