Effectiveness of Warm Saline Distension Media On Relieving Pain In Outpatient Office Hysteroscopy: A Randomized Controlled Clinical Trial

Thesis

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Last but not least, I dedicate this work to the spirit of my father

Melad Eskander Tawfek

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Abstract

Background : Outpatient hysteroscopy is the preferred examination procedure for diagnosis of intrauterine pathology and abnormal uterine bleeding causes , in addition for therapeutic operative management . It is desirable to apply as many procedures as possible with an office hysteroscopy, as long as they are implemented in a safe and effective fashion.

Aim: Evaluation and investigation of the effectiveness of warm saline distensability media in reducing the pain perceived in women undergoing diagnostic hysteroscopy procedure .

Methodology:A randomized controlled clinical research trial that recruited 82 women scheduled for outpatient office hysteroscopy in Early cancer detection unit in Ain Shams Maternity Hospital from April 2017 **till May 2018.Two research groups were categorized into warm saline and normal room temperature saline research groups each contained 41 cases .comparitive analysis of pain perceived in both groups was conducted to assess efficiency of warm saline to reduce pain perception.**

Results: Hysteroscopic findings didn't differ significantly between the two groups, namely ease of introduction of hysteroscope, position of uterus and morphological appearance of the ectocervix, endocervical canal, endometrium, endometrial cavity and tubal ostia. Also, no statistically significant differences were observed between the two groups in the duration of procedure. Parameters of pain assessment differed statistically significantly between the two research groups.p value <0.001 .Simple analysis of VAS scores revealed a statistically significantly lower VAS score at the end of the procedure in the warm distention medium group in comparison to the room-temperature distention medium group. The same finding remained constant after 15 minutes from the end of the procedure.Assessment of variation of VAS score with combined variation of temperature of distention medium over time was assessed using repeated measure ANOVA analysis. Patient satisfaction, indicated by the proportion of the patients who would undergo the hysteroscopic examination again by usage of same method, was statistically significantly higher in the warm distention medium research group in comparison to the room-temperature medium research group (**89.74% vs 71.05%** consecutively).(**p value <0.04**)

Conclusions

Pain is measured by VAS score is statistical significantly lower at the end of the procedure in warm saline distension medium research group in comparison to room temperature distension medium research group (1.64$\pm$0.82vs 3.05$\pm$1.17) consecutively.denoting possible effectiveness of warm saline in reducing pain perceived in office hysteroscopy.

List of Abbreviations

AAGL	:	American Association of Gynecological Laparoscopists
ACOG	:	American College of Obstetricians and Gynecologists
ANOVA	:	Analysis of variance
ARDS	:	Adult respiratory distress syndrome
BSGE	:	British Society for Gynaecological Endoscopy
CONSORT	:	CONsoildated Standards of Reporting Trials
CT	:	Computed tomography
GnRH	:	Gonadotrophin releasing hormone
IASP	:	International Association for the Study of Pain
IUP	:	Intrauterine pressure
IV	:	Intravenous
KTP	:	The potassium – titanyl – phasphate
Nd:YAG	:	Neodymium yttrium alumibum garnet
NMDA	:	N-methyl D-Aspartate or
NS	:	Normal saline
NSAIDs	:	Nonsteroidal anti-inflammatory drugs
OD	:	Outer diameter
PG2	:	Prostaglandin
RCOG	:	Royal college of obstetric and gynecology
TCRE	:	Transcervical resection of the endometrium
VAS	:	Visual analoge scale
VMM	:	Verification Methodology Manual
WDR	:	Wide dynamic range cells
WS	:	Warm saline

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Introduction

Outpatient hysteroscopy is an established diagnostic test. The procedure involves the use of miniaturized endoscopic equipment to directly visualize and examine the uterine cavity, without the need for formal theatre facilities or general or regional anesthesia ***(Clark et al., 2001)***. Outpatient hysteroscopy is indicated primarily in the assessment of women with abnormal uterine bleeding, but is also employed in the diagnostic work-up of reproductive problems ***(Farquhar et al., 2003)***.

To have an effective outpatient hysteroscopy service, the procedure should be performed in an appropriately sized and fully equipped treatment room. 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 and written patient information should be provided before the appointment and consent for the procedure should be taken ***(RCOG Green top Guidline no.59, 2011)***.

The uterine cavity is a potential cavity and needs to be distended to allow for inspection. Thus, during hysteroscopy distention media are introduced to expand the cavity. The choice is dependent on the procedure, the patient's condition and the physician's preference ***(Van et al., 2010)***.

Distension media used in hysteroscopy can be classified into: (i) Carbon dioxide gas, which should be used as a distending medium for diagnostic hysteroscopy only, as

it is not suitable for operative hysteroscopy, in part because CO_2 gas does not allow the clearing of blood and endometrial debris during the procedure, which makes the imaging visualization difficult ***(Brusco et al., 2003)*** (ii) High viscosity distension media, which have the advantage of being immiscible with blood, thereby facilitating evaluation of the endometrial cavity in the presence of bleeding. The most commonly used high-viscosity fluid for uterine distention is a hyperosmolar solution of 32% dextran 70 in 10% glucose ***(Mangar, 1992)*** (iii) Low viscosity Distension media, which include the electrolyte-free low viscosity media, e.g. normal saline, 3% sorbitol, 1.5% glycine, 5% mannitol and combined solutions of sorbitol and mannitol ***(Ayus et al., 1997)***. Normal saline (NS) and other isotonic electrolyte-rich solutions are safer media, for even if there is absorption of a substantial volume of solution, normal saline does not cause electrolyte imbalance and consequently are a good choice for minor procedures performed in the office ***(Berg et al., 2009)***.

The myometrium responds to distention of the uterine cavity during the examination, with contractile activity that patients describe as colicky pain of medium to high intensity. Pain may be greater in nulliparous women or during endometrial biopsy. Some authors have reported greater intensity of pain at the age extremes and in patients who had undergone previous cervical procedures ***(De Iaco et al., 2000)***. New approaches that prevent great degrees of pain have emerged including the vaginoscopy examination technique described by ***Bettocchi and Selvaggi (1997)***,

which does not use a speculum and cervical grasping forceps. In addition, optics and instruments of smaller caliber are now available. Use of paracervical block or anesthetic sprays has not been shown to be effective in diminishing pain during hysteroscopic examination as it probably would not block all nociceptive stimuli from introduction of equipment and from all of the possible manipulations of the uterus ***(De Carvalho et al., 2007)***.

When physiologic saline solution is the distention medium, it is used at room temperature. It is possible that colic provoked by uterine contractility could be triggered by this cooler temperature, which is hostile to the uterus ***(Stritzhavoc et al., 1991)***.

Evangelista et al. studied the comparison of pain with warmed saline solution and room temperature saline solution and reported that, immediately after the examination, mean pain intensity in the warmed saline solution group was 3.84±2.7 and the room temperature saline solution group was 4.31±3.02. At one and fifteen minutes after the procedure, pain intensity in the two groups was respectively, 2.41±2.30 and 1.85±2.06. Difference were not significant. Time to complete the examination was 3.80±1.32 minutes in the test group and 3.75±1.10 minutes in the control group. The satisfaction rate with the warmed distension media was 84% and with the room temperature saline solution was 85% ***(Evangelista et al., 2011)***.

AIM OF THE WORK

This study aim to assess the efficacy of warm saline distension media in decreasing the pain in women undergoing office hysteroscopy.

Null hypothesis:

Warm saline distensions media is effective in decreasing pain in women undergoing office hysteroscopy.

Alternative hypothesis:

Warm saline distensions media is not effective in decreasing pain in women undergoing office hysteroscopy.

Hysteroscopy

Hysteroscopy is the procedure that view and operate in the uterine cavity through atranscervical approach. It is a minimally invasive intervention that can diagnose and treat many intrauterine and endocervical problems. Diagnostic hysteroscopy provides information not obtained by blind endometrial sampling, such as detection of endometrial polyps or submucous leiomyomas (***Trew, 2004).***

Hysteroscopy has been done in the hospital, surgical centers and the office. It is best done when the endometrium is relatively thin, that is after a menstruation. Diagnostic can easily be done in an office or clinic setting on suitably selected patients. Hysteroscopy can also be done in an office or clinic setting. Analgesics are not always necessary ***(Agostini et al., 2008).*** Hysteroscopy offers a valuable extension of the gynecologist's work. It can improve the diagnostic accuracy and can permit better treatment of uterine diseases. After hysteroscopy, the elective surgery of the patient can be planned better ***(Cohen et al., 1973)***.

Parts of hysteroscope:

The hysteroscope consists of 3 parts: the eye piece, the barrel, and the objective lens, the focal length and angle of the distal tip of the instrument are important for visualization. Angle options include: 0o, 120, 15o, 30o and 70o, A 0 hysteroscope provides a panoramic view, where as angled one might improve the view of the ostia in an abnormally shaped cavity (***Petrozza and Attaman, 2010).*** Each

hysteroscope is attached to an internal or external light source for illumination at the distal tip. Energy sources include tungsten, metal halide, and xenon. A xenon light source with a liquid cable is considered the superior option ***(ACOG, 1994).***

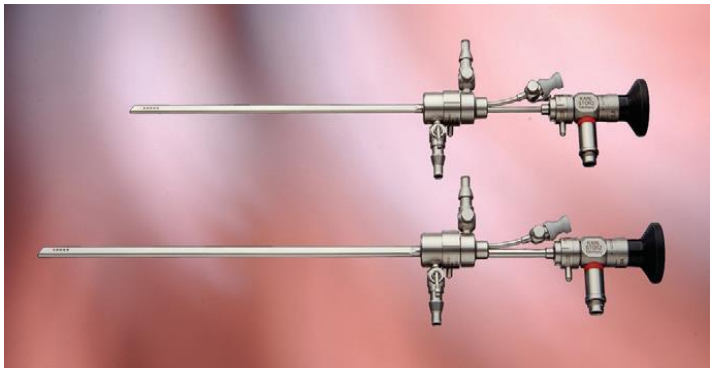
Types of hysteroscopy

The rigid hysteroscope

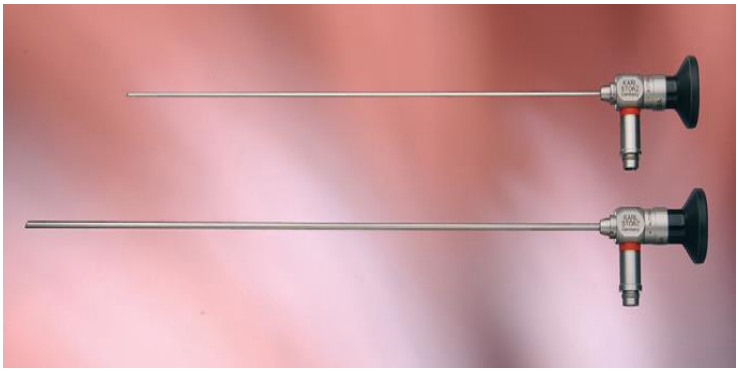
Rigid hysteroscopes are the most commonly used instruments. Their wide range of diameters allows for in-office and complex operating-room procedures. Of the narrow options (3-5 mm in diameter), the 4-mm telescope (lens) offers the sharpest and clearest view. It accommodates surgical instruments but is small enough to require minimal cervical dilation ***(Petrozza & Attaman, 2010).***

Operative hysteroscopes typically range from 8 mm to 10 mm in diameter and contain a working element. They require increased cervical dilation for insertion. Therefore, they are most frequently used in the operating room with intravenous (IV) sedation or general anesthesia. An outer sheath fits over the telescope to introduce and remove distending media from the intrauterine cavity and to provide parts to accommodate large and varied surgical instruments (***Bettocchi et al., 2003).***

A



B



C

Figure (1): Typical instruments feature two sheaths, one for irrigation and another for suction (**A)** 4-mm and 5-mm sheaths.
(B) 2.9-mm and 2.0-mm rod lens telescope.
(C) The oval tip allows atraumatic introduction ***(Bradley and Tommaso, 2009).***

The flexible hysteroscope

Flexible (fiberoptic) hysteroscopes range in diameter from 2.7 mm to 5 mm and have a bendable tip that can be

deflected in two directions ranging from 120 degrees to 160 degrees. Most also contain an operating channel for tubal catheterization or endometrial biopsy. The flexible hysteroscope is most commonly used for office hysteroscopy. Its most appropriate use is to accommodate the irregularly shaped uterus and to navigate around intrauterine lesions ***(Corfman, 1988).***

They generally do not require cervical dilation, and have a longer working length than rigid hysteroscopes. The smaller outer diameter (OD) compared to a rigid hysteroscope is advantageous in patients with nulliparity or prior cervical conization, and the longer working length is helpful in morbidly obese patients ***(Greenfield et al., 2008).***

However, use of flexible hysteroscopes is potentially hampered by higher costs for purchase and maintenance of the equipment; increased effort for cleaning, disinfection, and sterilization; a reduced image size on the monitor screen compared to panoramic full-size view with standard hysteroscopy; and greater fragility of the equipment ***(Cicinell et al., 2005).***

Figure (2): Karl Storz flexible hysteroscope (***Bradley and Tommaso, 2009).***