Cervical priming prior to office hysteroscopy using different doses of misoprostol: Randomized controlled trial

Thesis

Submitted in partial fulfillment of M.Sc. degree in Obstetrics & Gynecology

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2013

Acknowledgment

First and foremost, I would like to begin my utmost thanking to God for granting me the ability to complete this work.

I would like to thank my husband and my two sons for their continuous support and encouragement.

It is with deep appreciation and gratitude that I acknowledge the great help of **Prof. Dr. Omaima Abdel fatah Idris,** Professor of Obstetrics & Gynecology, Faculty of medicine, Cairo University, for her kind assistance, continuous support and supervision, which was essential for the completion of this work.

I am also extremely indebted to **Prof. Dr. Heba Ali Fahmy El-sawah,** assistant Professor of Obstetrics & Gynecology, Faculty of medicine, Cairo University, for her help and continuous guidance throughout all stages of this work.

I am heartily thankful to **Prof. Dr. Waleed Mamdouh El-Khayat,** assistant Professor of Obstetrics & Gynecology, Faculty of medicine, Cairo University, for his encouragement, guidance and support without which this work could not have been accomplished.

Abstract

Objective: to detect optimum dose of vaginal misoprostol for cervical priming by comparing between two doses (200µgm and 400µgm vaginal misoprostol) prior to office hysteroscopy by 3 hours.

Design: randomized controlled trial**.** This study done on 132 patients to whom done office hysteroscopy as a part of investigation of (primary infertility, secondary infertility, recurrent miscarriage or abnormal uterine bleeding) .those patients divided into two groups each group 66 patient**,** Group I, received 200µgm vaginal misoprostol dissolved in saline 3 hours before office hysteroscope and group II received vaginal 400µgm vaginal misoprostol dissolved in saline 3 hours before office hysteroscope**.** Our Main outcome measures was pain score (visual analogue scale), ease of entry (Likert scale), procedural time in seconds, patient acceptability (Likert scale) and also to detect side effects of misoprostol and complication of its use.

Result: in group II which received 400µgm vaginal misoprostol, pain score was lower (3.45± 1.372) compared to group I (5.36± 1.260). procedural time shorter in group II (98.94 ± 18.389)than group I(134.15 ± 27.083) , cervical entry was easier in group II(4.02 ± 0.832) than group I (2.98 ± 0.540), patient acceptability was higher in group II(3.53 ± 0.638) than group I(3.03 ± 0.495) which received200µgm vaginal misoprostol. No complication detected in both groups. Side effects were minimal and transient.

Conclusion: use of 400µgm vaginal misoprostol 3 hours before hysteroscopy is better than 200µgm vaginal misoprostol in facilitating cervical ripening with minimal side effects without use of anasthesia.as it decrease pain score, decrease procedure duration, increase ease of cervical entry, higher patient acceptability and with minimal side effects.

Key word: office hysteroscopy, misoprostol, cervical priming.

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List of abbreviations

- **OH** — **Office Hysteroscopy**
- **RCTs** — **Randomized controlled trials**
- **FDA** — **Food and Drug Administration**
- **AUB** — **abnormal uterine bleeding**
- **IVF** — **Invitro fertilization**
- **HSG** — **Hysterosalpingography**
- **D&C** — **Dilatation and Curettage**
- **D&E** — **dilation and evacuation**
- **SD** — **Standerd deviation**
- **P value** — **prediction value**
- **VAS** — **visual analog scale**
- **MMPs** — **Metalloproteinases**
- **PGE2** — **Prostaglandin E2**
- **IUAs** — **Intra Uterine Adhesions**
- **GnRH** — **Gonadotropin-Releasing Hormone**
- **PGs** — **prostaglandins**
- **DES** — **Di Ethyl Stilbesterol**
- **IUD** — **Intra Uterine Device**
- **A.C.O.G.** — **American College Of Obestetrics And Gynecology**
- **MAP** — **Mean Arterial Pressure**
- **NS** — **Normal Saline**
- **LR** — **Lactated Ringer's Solution**
- **ACOG** — **American Congress of Obstetricians and Gynecologists**
- **AAGL** — **American Association of Gynecologic Laparoscopists**
- **MAC** — **Monitored Anesthesia Care**
- **NSAID** — **Nonsteroidal Anti-inflammatory Drugs**
- **β-hCG** — **β-human Chorionic Gonadotropin**

- **AFS** **American Fertility Society**

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Chapter 1

INTRODUCTION

Chapter (1): Introduction

Hysteroscopy is the process of viewing and operating in the endometrial cavity from a transcervical approach. It is the gold standard procedure for uterine cavity exploration (Golan et al., 1996).

In many practices, diagnostic hysteroscopy is the preferred procedure for the diagnosis of uterine pathology (Wong et al., 2000). Hysteroscopic treatment of intrauterine anomalies is also possible at the same time (Merviel et al., 2000; Hucke et al., 2000).

Hysteroscopy allows direct visualization of the uterine cavity, the endometrium and the cervical canal. The examination may be practiced on an out-patient basis, without anesthesia, using appropriate small-caliber instruments and irrigation with physiological saline (Isaacson, 2002).

Over recent years hysteroscopy is being increasingly used in out-patient facilities which alongside the standard advantages of hysteroscopy also provide greater comfort for the patients, since it excludes the need to stay in hospital and decreases the time of treatment, but also the time needed to prepare the patient for further procedures, e.g. medically assisted conception (Ozturk et al., 2010; Ait et al., 2010; Bosteels et al., 2010).

In post-menopausal women with abnormal uterine bleeding, hysteroscopy with endometrial biopsy shows a high diagnostic accuracy in diagnosing endometrial cancer or hyperplasia (Clark et al., 2002), whereas premenopausal infertile patients with recurrent IVF failures may experience substantial benefits in terms of increased pregnancy rates (El-Toukhy et al., 2008).

However, despite the high efficacy of the procedure in the above mentioned settings, both as a diagnostic or therapeutic tool, hysteroscopy may be associated with certain complications (Paschopoulos et al., 2006). Although the incidence of these complications is low, 1–1.5% (Jansen et al., 2000), almost 50% of them are related to insertion of the hysteroscope or to the dilatation of the cervical canal (Jansen et al., 2000).

Taking into account that an efficient method to facilitate an easier uncomplicated entry during the hysteroscopic procedure could substantially minimize the risk of complications,

several modalities for cervical ripening prior to hysteroscopy have been adopted (Darwish et al., 2004; El-Toukhy et al., 2008; Lin et al., 2009).

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).

Cervical priming refers to dilating or softening of the cervix by mechanical (e.g., laminaria) or medical (e.g., prostaglandins) means before an intervention in pregnant (cervical ripening) or nonpregnant women (Weeks et al., 2007).

The synthetic analogue of prostaglandin E_1, misoprostol, is the agent used most often for cervical preparation prior to hysteroscopy and has been tested in RCTs (Thomas et al., 2002; Preutthipan and Herabutya, 2006).

Consequently, given its high efficacy in dilating the cervix in pregnant women one could hypothesize that misoprostol would also facilitate dilatation in women undergoing hysteroscopy (Polyzos et al., 2012).

It can be given orally, vaginally, sublingually, buccally, or rectally (Fa_undes & Weeks 2007). There is evidence supporting the use of misoprostol as a cervical priming agent before some gynecologic procedures, such as intrauterine device insertion (Saav et al., 2007) and hysteroscopy (Crane & Healey 2006).

The vaginal route appears to be superior to the oral route (Batukan et al., 2008).

Based on the available evidence from a recent meta-analysis, on the use of misoprostol prior to hysteroscopy, no solid guideline can be provided with regards to the optimum dose of misoprostol prior to the office hysteroscopy (Polyzos et al., 2012).

So we tried in our study to test for optimum dose by comparing between 200 μgm versus 400 μgm vaginal misoprostol.

CHAPTER 2

OBJECTIVES

Chapter (2): Objectives

This study is done to compare patients' pain sensation, procedural time, the efficacy and safety of different doses of vaginal misoprostol in cervical priming prior to office hysteroscopy.

CHAPTER 3

HYSTEROSCOPY

Chapter (3): Hysteroscopy

INTRODUCTION

Hysteroscopy is the process of viewing and operating in the endometrial cavity from a transcervical approach. It involves the passage of a small diameter telescope either flexible or rigid, through the cervix to directly inspect the uterine cavity, the basic hysteroscope is a long, narrow telescope connected to a light source to illuminate the area to be visualized. It can be used for both diagnostic and operative purposes, (Bradley, 2004), it is a safe, highly sensitive diagnostic procedure that provides useful information about the uterine cavity (Sonja et al., 2011).

History of the Procedure

The development of hysteroscopy is rooted in the work of Pantaleoni, who first reported uterine endoscopy in 1869 (Marlow, 1995). However, at that time, instrumentation was elementary, and expansion of the uterine cavity was insufficient. In 1925, Rubin first used CO2 to distend the uterus (Marlow, 1995). Around the same time, Gauss was experimenting with the use of fluids to achieve uterine expansion. Hysteroscopy did not become popular until the 1970s, when technology afforded more practical and usable instruments than before. The use of liquid distention media became routine by the 1980s, and many new hysteroscopic procedures, including endometrial ablation, were developed (Marlow, 1995). Initially used by urologists for transurethral resection of the prostate, the resectoscope was modified for hysteroscopic procedures, allowing for resection of intrauterine pathology with monopolar cautery. By the mid-1980s, hysteroscopic procedures had nearly replaced dilation and curettage (D&C) for diagnosing intrauterine pathology (Jansen et al., 2000).

Over the past few decades, refinements in optic and fiberoptic technology and inventions of new surgical accessories have dramatically improved visual resolution and surgical techniques in hysteroscopy. Many hysteroscopic procedures have replaced old, invasive techniques. Now, as instruments become smaller than before, office hysteroscopy is