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ORIGINAL ARTICLE

A double-blind randomized controlled trial of two different doses of misoprostol for cervical priming prior to office hysteroscopy☆

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KEYWORDS

Office hysteroscopy;
Misoprostol;
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Abstract *Objective:* To evaluate and compare the effectiveness of 200 μg vaginal misoprostol vs. 400 μg vaginal misoprostol administrated 3 h prior to office hysteroscopy, in cervical priming. Design: Randomized controlled trial.

Setting: Outpatient clinic of the Cairo University Hospital, Cairo, Egypt.

Materials and methods: One hundred and thirty-two women scheduled for office hysteroscopy; were randomized into two groups. Patients were divided into two groups: group I; 66 patients received 200 μg vaginal misoprostol and group II; 66 patients received 400 μg vaginal misoprostol. Primary outcome was pain score (visual analogue scale).

Major outcome measures: 400 μg vaginal misoprostol significantly minimized pain score and procedure time, a significant increase in the ease of entry and the patient acceptability was observed in the 400 μg vaginal misoprostol group. Side effects of misoprostol were minor and transient with no statistically significant difference between both groups.

Major conclusions: 400 μg vaginal misoprostol 3 h prior to office hysteroscopy appears to be more effective than 200 μg vaginal misoprostol in facilitating cervical ripening, minimizing pain score and procedure time, without any increase in side effect occurrence.

1. Introduction

Hysteroscopy has gained popularity and becomes an important tool for the diagnosis and management of intrauterine abnormalities; it can be used for both diagnostic and operative purposes (1).

Acceptability and feasibility are limited by difficulty in cervical dilatation; it represents a real challenge during operative as well as office hysteroscopy (OH), particularly in nulligravidae, postmenopausal women and women with cervical stenosis (2).

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☆ N.B. the study has been approved by the Institutional Review Board. ClinicalTrials.gov Identifier: NCT01612065.

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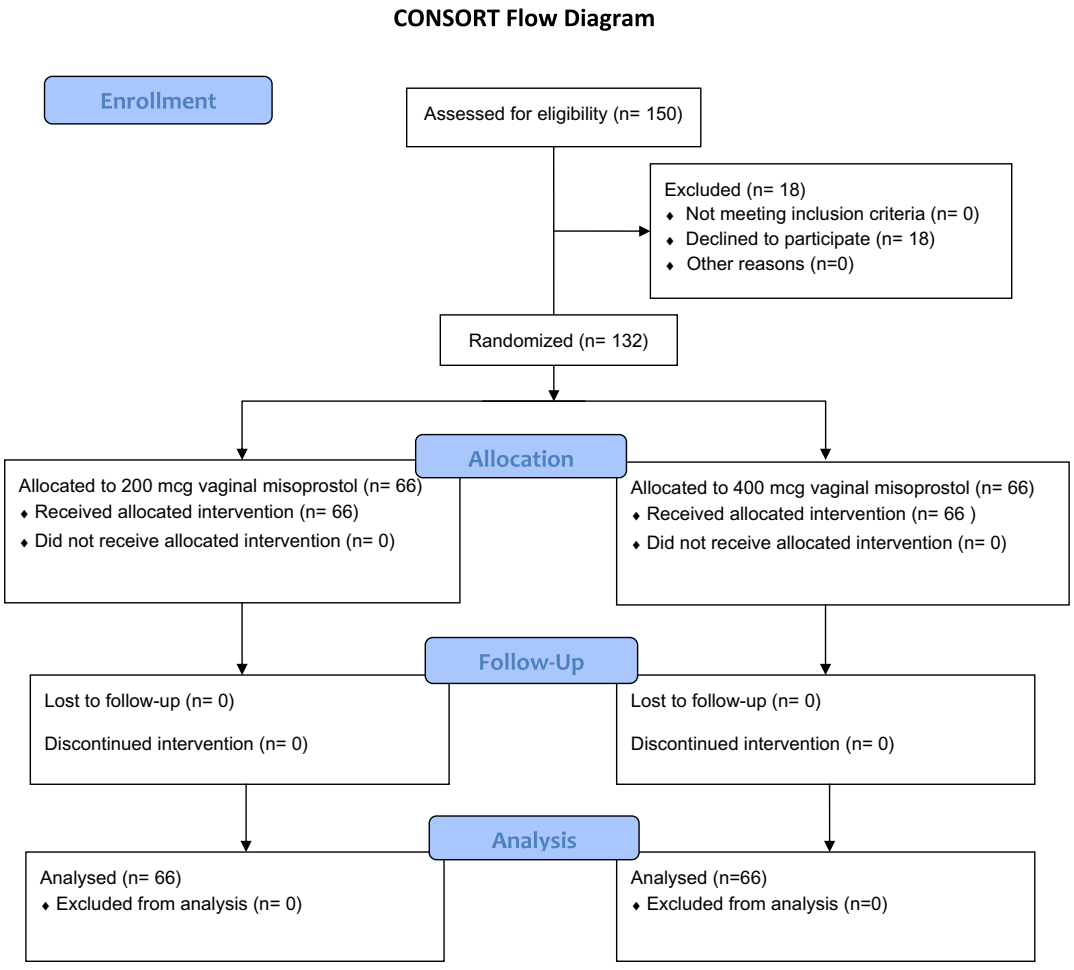

Figure 1 Flow chart.

Difficult cervical dilatation during hysteroscopic procedures may cause some complications which include; pain, cervical tears, creation of a false track, bleeding, uterine perforation requiring laparoscopy, or difficulty in entering the internal cervical os with the resectoscope (3).

The incidence of those complications can be reduced significantly by ripening and softening of the cervix before office hysteroscopy procedures by using laminaria, Sulprostone gel or misoprostol (2).

Misoprostol is superior because of many advantages: easy application, more economic, patient convenience, and greater acceptability (2).

Misoprostol appears to make the cervix softer and more easily dilatable; decreasing the accompanying pain with office hysteroscopy (4).

A recent meta-analysis showed that misoprostol prior to hysteroscopy appears to facilitate an easier procedure only in premenopausal women (5).

The aim of our study was to evaluate and compare the efficacy and safety between two doses; 400 μg and 200 μg of misoprostol administered vaginally, in regard to pain, ease of cervical entry, procedural time, and patient acceptability. This study is the first powered randomized controlled trial to compare 400 μg and 200 μg vaginal misoprostol prior to office hysteroscopy.

2. Materials and methods

This study was a double-blind randomized controlled trial; conducted at the OH Clinic of the Department of Obstetrics and Gynecology, Faculty of Medicine, Cairo University, from June 2012 to March 2013. The study population consisted of 132 patients requiring a diagnostic OH for investigation of infertility, abnormal uterine bleeding (AUB) in the reproductive age or recurrent abortion. The study protocol was approved by the Scientific Research Committee of the department and informed consent was obtained from each of the patients.

Exclusion criteria include; Contraindications to hysteroscopy such as, marked cervical stenosis, recent or current pelvic inflammatory disease, known cervical malignancy, pregnancy, profuse uterine bleeding, or recent uterine perforation.

Other exclusion criteria are; Contraindications to prostaglandins, known sensitivity to prostaglandins, cardiovascular disease, hypertension, severe bronchial asthma, renal failure, or glaucoma, previous cervical surgery and neurologic disorders affecting the evaluation of pain.