Sublingual Piroxicam (Feldene Flash) for Relief of Pain during Diagnostic Hysteroscopy

"Randomized Controlled Study"

Thesis

Submitted for Partial Fulfillment of Master Degree
In Obstetrics and Gynecology

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رسالــة

توطئة للحصول على درجة الماجستير

فى امراض النساء و التوليد

مقدمة من

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٢٠١٣

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Abdelrahem Mohamed Abdelrahem


بسم الله الرحمن الرحيم
قَالُوا سُبْحَانَكَ لاَ عِلْمَ لَنَا
إِلاَّ مَا عَلَّمْتَنَا إِنَّكَ أَنتَ
الْعَلِيمُ الْحَكِيمُ
صدق الله العظيم
سورة البقرة الآية (٣٢)

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List of Abbreviations

Abb.	Mean
AUB	Abnormal uterine bleeding
COX	cyclooxygenase enzyme
D&C	dilatation and curettage
DEX	Dexketoprofen
FDDF	Fast dissolving dosage form
FT	flash tablet
HSG	Hysterosalpingography
IUCD	intrauterine contraceptive device
IUD	Intrauterine device
NSAIDS	Non steroidal anti inflammatory drugs
RCTS	Randomized control trials
RT	regular tablets
RPL	Recurrent pregnancy loss
THBs	targeted hysteroscopic biopsies
VAS	Visual analogue scale

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Introduction

Hysterescopy is a diagnostic gynecological procedure that enables a clinician to visualize the uterine cavity and take endometrial biopsies as required. As one of the principal investigations of abnormal uterine bleeding, hysteroscopy has an integral role in the identification of structural abnormalities of the endometrium (**NICE guidelines 2007).**

Although it is generally well tolerated, it is associated with a certain degree of pain and possible vasovagal reaction. Nagele 1997 reported that an increasing number of diagnostic hysteroscopies were being performed in an outpatient setting, but pain was the most common cause for failure to complete the investigation **(Nagele et al 1997).**

During hysteroscopy, the first cause of pain is usually cervical manipulation, the cervix is often grasped with an instrument, such as a tenaculum, and may be cannulated and dilated to allow a hysteroscope pass through. Pain stimuli from the cervix and vagina are conducted by visceral afferent fibres to the S2 to S4 spinal ganglia via the pudendal and pelvic splanchnic nerves, along with parasympathetic fibres **(Moore 2006).**

Destruction of the endometrium and endometrial biopsy can cause further pain as they may induce uterine contraction

(Zupi et al 1995). There may also be additional delayed pain caused by the release of prostaglandins from the cervical manipulation as well as distension of the uterus.

Various methods of analgesia have been proposed to suppress the pain associated with hysteroscopy: general anesthesia, paracervical block **(Lau et al 2000, Cicinelli et al 1998),** intracervical injection **(Broadbent et al 1992)**, lidocaine Spray **(Davis et al 1997, Soriano et al 2000)** and intrauterine instillation of lignocaine **(Lau et al 2000).**

Downes and Al-Azzawi used routinary intracervical block to provide analgesia in 100 perimenopausal women and in this way demonstrated that outpatient hysteroscopy is well tolerate by perimenopause patients **(Downes And Al-Azzawi 1993).**

However, the results are controversial, and there are no established guidelines for the use of analgesia in office hysteroscopy **(Yang,Vollenhoven 2002)**.

For the first time, Nagele and others have assessed a prostaglandin synthesis inhibitor during outpatient hysteroscopy; the patients were instructed to take one tablet of mefenamic acid 500 mg one hour before the hysteroscopy **(Nagele et al 1997).**

Mefenamic acid appeared to have minimal effects on the discomfort associated with the hysteroscopy itself but significantly reduced the after pains of the procedure. The partial failure of this treatment was ascribed by the authors to the relatively minor effect of the drug, with respect to uterine manipulation as well as the longer time to achieve plasma peak levels of the drug **(Nagele et al., 1997)**.

Piroxicam is a non-steroidal anti-inflammatory drug (NSAID) with analgesic properties, and is used mainly for treating rheumatic disorders. In 2005, there were over 150,000 prescriptions for piroxicam in the United Kingdom **(PACT, 2006)**. It has been suggested that non-steroidal anti-inflammatory drugs (NSAIDs) may be superior to opioid analgesics in some forms of postoperative pain **(Hardman et al., 1996).**

Aim of the Work

To assess the efficacy of sublingual Piroxicam (feldene flash) in relief of pain associated with diagnostic hysteroscopy.

Patients and Methods

This will be randomized controlled trial and will compare the effect of sublingual piroxicam (feldene flash) versus placebo in relief of pain in outpatient diagnostic hysteroscopy, it will be carried in the period from August 2011 to December 2011.

One hundred and thirty six patients will be included in the study according to sample size calculation. Women will be randomly assigned to two groups using numbered sealed opaque envelopes, store in the physicians" offices each group is 68 patients. Within each envelop a card indicating the word felden flash or placebo.

Hysteroscopic examinations will be performed in the Unit for Early Detection of Cancer at Ain Shams University, Maternity Hospital, as an office procedure in an outpatient suite.

One hospital staff physician who usually handles the outpatient hysteroscopies in the unit for early detection of cancer will perform all the procedures of present study.

Study design:

The study will include patients suspected or diagnosed to have one of the following:

1-Abnormal uterine bleeding (AUB):

- Diagnosis and treatment of intrauterine polyp.
- Diagnosis and treatment of retained product of conception.
- Diagnosis of pre and post menopausal bleeding.
- Diagnosis of endometrial carcinoma.

2-Assessment of patients with missed IUD threads.

3- Infertility.

- Intrauterine synechia.
- Uterine septum.
- Exploration of the cervical canal.
- Tubal cannulation.

Patients will be excluded from the study if they have any of the following:

1- Pregnancy.

2- Cervical cancer.

3- Acute pelvic infection.

4- Known history of hypersensitivity to piroxicam.

5- History of active peptic ulcerations.

6-patients with sever renal or hepatic failure.

7- Heavy uterine bleeding, not because of any risk to the patients, but because the blood may obscure the view and reduce the value of the examination.

8- Patients refuse to sign an informed consent form.