

## Bleeding Evaluation of Uterine Straightening by Bladder Distention as Anew Modality in Office Hysteroscopy

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**Abstract:** Abnormal uterine bleeding (AUB) is one of the most common presenting complaints encountered in a Gynecologist's office and accounts for almost 10% consultations in any busy outpatient clinic. AUB is defined as 'bleeding that is excessive or occurs outside of normal cyclic menstruation' and accounts for two-thirds of hysterectomies. Office hysteroscopy (OH) is a common gynecologic procedure, mainly used to detect uterine pathologies, that requires the cervix to be dilated. Complications such as uterine perforation, cervical laceration, failure to dilate, and creation of a false track can occur during cervical entry (Bastu et al., 2013). The indications for hysteroscopic procedures in gynecologic practice are ample and clearly charted: hysteroscopy is considered the gold standard not only for visualizing the cervical canal and the uterine cavity, but also for treating many different kinds of benign pathologies localized to that region (Soguktas et al., 2012). Our objective: was to evaluate the effect of uterine straightening by bladder distention for minimizing time, pain and easy cervical entry during office hysteroscopy **Conclusion:** Bladder distension seems to be an effective method for decreasing the duration and making ease of cervical entry during office hysteroscopic procedure. Bladder distension doesn't have a significant effect on pain score or patient acceptability. The effect of bladder distension was prominent among multiparous women, while there was no evidence of such effects in relation to the age of the patient and the indication of hysteroscopy.

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**Keywords:** Abnormal uterine bleeding (AUB), three dimensional ultrasound, endometrial hyperplasia, hysteroscopy endometrial polyp and sub mucous myoma

### 1. Introduction

Office hysteroscopy (OH) is a common gynecologic procedure, mainly used to detect uterine pathologies, that requires the cervix to be dilated. Complications such as uterine perforation, cervical laceration, failure to dilate, and creation of a false track can occur during cervical entry (Bastu et al., 2013). The indications for hysteroscopic procedures in gynecologic practice are ample and clearly charted: hysteroscopy is considered the gold standard not only for visualizing the cervical canal and the uterine cavity, but also for treating many different kinds of benign pathologies localized to that region (Soguktas et al., 2012). There are several causes of pain during and after hysteroscopy. 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 hysteroscopy to pass through it. Pain stimuli from the cervix and vagina are conducted by visceral afferent fibers to the S2 to S4 spinal ganglia via the pudendal and pelvic splanchnic nerves, along with parasympathetic fibers. Pain from intraperitoneal structures, such as the uterine body, is conducted by visceral afferent fibers with sympathetic fibers via the

hypogastric nerves to the T12 to L2 spinal ganglia. Destruction of the endometrium and endometrial biopsy can cause further pain as they may induce uterine contraction. There may also be additional delayed pain caused by the release of prostaglandins from the cervical manipulations as well as distension of the uterus (Ahmad et al., 2011).

### 2. Aim of the work

Was to evaluate the effect of uterine straightening by bladder distention for minimizing time, pain and easy cervical entry during office hysteroscopy.

### 3. Patient and methods

The present study is a prospective case control study which was carried out at the outpatient gynecological clinic, at Al-Azhar university hospital of (New Damietta). It included 100 patients indicated for office hysteroscopy.

**Inclusion criteria:** Indication for office hysteroscopy: abnormal uterine bleeding, suspicion of endometrial polyps or other endometrial pathological findings based on ultrasound.

**Exclusion criteria:** pregnant Women, profuse uterine bleeding, cervical malignancy and retroverted uterus.

For each woman asked to join the study the nature of the procedure was explained carefully, a written consent and scientific committee agreement was taken and the following was done: careful history taken, the complaint of the patient was taken and carefully analyzed Transvaginal ultrasound was done.

### Technique

Patients were randomly classified into two groups:

- ❖ Full bladder group: included 50 patients. They were encouraged to drink 500 ml of water and were not allowed to urinate before the OH. Prior to the OH, we performed an ultrasound examination to ensure the status of the patient's bladder. The urine volume was measured and also the patients were asked whether they felt the sensation for urination. Uterine straightening was accepted when the angle between the uterine cavity and cervix was greater than 120 degrees, as determined by transabdominal ultrasonography.

- ❖ Empty bladder (control) group: included 50 patients. Patients who did not have an empty bladder were asked to urinate.

### I. Office hysteroscopy

It's performed to all patients in the proliferative phase of the menstrual cycle using a rigid continuous flow panoramic hysteroscopy 25 cm in length, with an outer sheath of 5.5 mm and a 30-degree fibro optic lens (Karl Storz, Germany). Fiber optic light: Xenon nova, model 495 manufactured by Storz. With the patient lying in a lithotomy position position, the cervix was visualized through a small-size vaginal speculum, which was removed after the entry of the hysteroscope. Afterwards, the OH was introduced into the uterine cavity without the use of a cervical tenaculum. The uterine cavity was distended with normal saline solution at a pressure of 80–100 mm Hg.

### II. Outcome assessment

#### a) primary outcome measures

1. Analog pain score: it was recorded by the patient on a 10-point visual analogue scale (VAS) (Huskisson, 1974).

2. Ease of cervical entry: it was judged by the individual surgeons using a 5-point Likert scale (very difficult = 1, difficult = 2, fair = 3, easy = 4, and very easy = 5)

#### b) secondary outcome measures

1. Duration of the procedure: it was measured in seconds from the introduction of the hysteroscopy through the external cervical os to when the tubal Ostia and a panoramic view of the cavity were obtained.

2. Patient acceptability: recorded by the patient on a 5-point Likert scale.

Three-dimensional vaginal ultrasonography was done to all patients with Voluson 730D MT 3D system with an S-VDW 5- 8 probe. Once the B – mode had been completed, three-dimensional images were recorded. The volumes were generated by the automatic rotation of the mechanical transducer 360 degrees. The probe was kept steady, the patient was asked to holdher breath and volume mode was switched on. With the use of the medium line density, the typical acquisition time was from 4 to 20seconds. Volume calculation of the endometrium in the three planes was done to detect endometrial volume. Endometrial margin, echogenicity and presence of intrauterine fluid were examined to notice the presence of any heterogenic pattern, irregularity, asymmetry in the margin or local thickening denoting the presence of polyp, endometrial hyperplasia, or myoma.

### III. Diagnostic Hysteroscopy

In the next day full explanation of the procedure for patient , and with empty her urinary bladder, and after in the dorsal lithotomy position, with thighs at 90 o angle to the pelvis in order to create enough space for the surgeon to manipulate the hysteroscopy. The patient perineum should be just past the edge of the table. Normal saline was used for uterine distension connected to the inflow channel on the sheath with intravenous tubing. A vaginal disinfection with a non-irritating watery disinfection solution was performed without use of a speculum. The labie being gently separated with fingers, the tip of the hysteroscope was positioned in the vaginal introitus, the vagina was distended with saline, the scope was driven to the posterior Fornix to readily visualize the portio and slowly backwards to identify the external cervical os. When this is become visible, the scope was carefully moved forward to the internal os and then the uterine cavity with the least possible trauma. The uterine cavity was systemically explored by rotating the hysteroscopy in order to identify any anomaly in the uterine walls and/or the right and left tubal Ostia. At this stage it was crucially important to avoid lateral movements as much as possible to minimize patient discomfort .Endometrial biopsy was obtained and sent for histopathology. After that, the scope was removed and the patient was asked to remain in the dorsal position for few minutes to avoid vasovagal attack. Finally, the evaluation and found data were written in details in patient file by the Doctors.

#### Statistical analysis of data:

The collected data were organized, tabulated and statistically analyzed using SPSS version 16 running on IBM compatible computer. Qualitative data were represented as relative frequency and percentage

distribution; while quantitative data represented as mean, standard deviation (SD); minimum and maximum. Chi square test and independent samples t-test were used for comparison between groups; for comparison between two points of time, the paired samples (t) test was used.

#### 4. Results

In the present work, age, BMI and parity were nearly comparable between full bladder and control groups without statistically significant difference; the mean age of full bladder and control groups was (44.3 and 46.1 respectively). The mean BMI was (30.9 and 31.8) in full bladder and control groups. Finally, most of our cases were multiparous in both groups (Table 4). Indications for OH in our study included abnormal uterine bleeding and infertility. The main diagnostic findings were endometrial hyperplasia and normal finding (Table 5).

Regarding ultrasonic finding, mean bladder volume among full bladder and control group was (369.2±75.6 and 57.7±10.2 respectively) and the angle between uterine cavity and cervix was (135.8±6.5 and 102.9±5.8 respectively). Results are shown in table (6).

The main outcome measures are presented in tables (7-10) and figures (11, 12). We found that pain score was lower among full bladder group (4.13 and 4.52 respectively), but with no statistically significant difference. Also, patient acceptability was higher among full bladder than control group (3.17 and 2.83 respectively), but with no statistically significant difference. On the other hand, the duration of the procedure was longer with empty bladder (2.1±1.2 min) than full bladder (1.37±0.52 min), with

statistically significant difference. Similarly, cervical entry was easier among full bladder than control group (3.73 and 3.17 respectively), with statistically significant difference.

Tables (11, 12) demonstrated the effect of bladder filling in relation to parity; we found that bladder filling was associated with statistically significant decrease of procedural time among nulliparous women, while there was no statistically significant difference as regard other parameters. Among multiparous women, bladder filling was associated with statistically significant decrease of procedural time, ease of cervical entry and more patient acceptability .while there was no significant difference as regard pain score.

In relation to menopause, bladder filling was associated with statistically significant ease of cervical entry in premenopausal women; while there was no statistically significant difference as regard other parameters. In postmenopausal women, bladder filling was associated with statistically significant decrease of procedural time; while there was no statistically significant difference as regard other parameters (Tables 13, 14).

In relation to the main presentation, bladder filling was associated with statistically significant decrease of procedural time among women presented with abnormal uterine bleeding; while there was no statistically significant difference as regard other parameters. In women presented with infertility, bladder filling was associated with statistically significant decrease of procedural time; while there was no statistically significant difference as regard other parameters (Tables 15, 16).

**Table (4): General characteristics of studied cases**

	Full bladder (n=50)	Control (n=50)	<i>u</i> *	P value
<b>Age</b> (mean ± SD) <b>Range</b>	44.3±11.3 22-72	46.15±12.2 26-67	0.9	0.32
<b>Body mass index</b> (mean ± SD) <b>Range</b>	30.9±4.8 20-40	31.8±3.7 25-36	1.2	0.21
<b>Parity</b> (mean ± SD) <b>Nullipara</b> <b>Primipara</b> <b>Multipara</b>	2.1±1.7 13 9 28	1.8±1.3 12 6 32	0.6	0.52

**Table (5): Indications and diagnostic findings of studied cases**

	Full bladder (n=50)	Control (n=50)
<b>Indications</b>		
Abnormal uterine bleeding (%)	37 (74)%	39 (78)%
Infertility (%)	13 (26)%	11 (22)%
<b>Diagnosis</b>		
Endometrial polyp (%)	8 (16)%	9 (18)%
Endometrial hyperplasia (%)	16 (32)%	24 (48)%
Submucous Myoma (%)	8 (16)%	6 (12)%
Normal (%)	13 (26)%	8 (16)%
Atrophic endometrium (%)	2 (4)%	0 (0)%
Subseptal uterus (%)	2 (4)%	1 (2)%
Endometrial carcinoma (%)	1 (2)%	2 (4)%

**Table (6): Ultrasonic finding of studied groups**

	Full bladder (n=50)	Control (n=50)
<b>Bladder volume</b>		
(mean ± SD)	369.2±75.6	57.7±10.2
Range	230-600	40-80
<b>Uterine angle</b>		
(mean ± SD)	135.8±6.5	102.9±5.8
Range	130-150	90-110

**Table (7): Pain score among studied cases**

	Full bladder (n=50)	Control (n=50)
<b>Mean ± SD (VAS)</b>	4.13±1.24	4.52±1.23
<b>Range (VAS)</b>	2-8	3-8
<b>Mann-Whitney test: 1.5; P value: 0.11</b>		

**Table (8): Patient acceptability among studied cases**

	Full bladder (n=50)	Control (n=50)
<b>Mean ± SD (Likert scale)</b>	3.17±1.1	2.83±0.9
<b>Range (Likert scale)</b>	1-5	1-4
<b>Mann-Whitney test: 1.7; P value: 0.086</b>		

**Table (9): Duration of the procedure among studied cases**

	Full bladder (n=50)	Control (n=50)
<b>Mean ± SD (minutes)</b>	1.37±0.52	2.1±1.2
<b>Range (minutes)</b>	0.7-3.1	0.75-4.3
<b>Mann-Whitney test: 2.6; P value: 0.007</b>		

**Table (10): Ease of cervical entry among studied cases**

	Full bladder (n=50)	Control (n=50)
<b>Mean ± SD (Likert scale)</b>	3.73±1.21	3.17±1.1
<b>Range (Likert scale)</b>	1-5	1-5
<b>Mann-Whitney test: 2.26; P value: 0.023</b>		

**Table (11): Effect of bladder filling among nulliparous women (n=25)**

	Full bladder (n=13)	Control (n=12)	<i>u</i>	P value
Cervical entry (Likert scale)	3.6±1.4	2.8±1.4	1.3	0.19
Procedural time (min)	1.4±0.6	2.5±1.4	2.1	0.041*
Patient acceptability (Likert)	2.9±1.3	2.7±1.25	0.36	0.72
Pain score (VAS)	4.8±1.5	5.2±1.5	0.58	0.57

**Table (12): Effects of bladder filling among multiparous women (n=60)**

	Full bladder (n=28)	Control (n=32)	<i>t</i>	P value
Cervical entry (Likert scale)	3.8±1.2	3.2±0.9	2.2	0.03*
Procedural time (min)	1.3±0.4	1.9±1.1	3.1	0.003*
Patient acceptability (Likert)	3.4±1	2.8±0.8	2.5	0.012*
Pain score (VAS)	3.8±1.1	4.3±1	1.9	0.052

**Table (13): Effects of bladder filling in premenopausal women (n=49)**

	Full bladder (n=25)	Control (n=24)	<i>t</i>	P value
Cervical entry (Likert scale)	3.7±1.3	3±1	2.4	0.022*
Procedural time (min)	1.5±0.6	2.1±1.2	2	0.056
Patient acceptability (Likert)	3.1±1.3	2.7±0.9	1.2	0.23
Pain score (VAS)	4.3±1.4	4.6±1.2	0.84	0.4

**Table (14): Effects of bladder filling in postmenopausal women (n=51)**

	Full bladder (n=25)	Control (n=26)	<i>t</i>	P value
Cervical entry (Likert scale)	3.7±1.2	3.3±1.1	1	0.3
Procedural time (min)	1.2±0.4	2.1±1.2	3.5	0.001*
Patient acceptability (Likert)	3.2±1	2.9±1.1	0.9	0.43
Pain score (VAS)	3.9±1.1	4.4±1.2	1.4	0.16

**Table (15): Effects of bladder filling in women presented with abnormal uterine bleeding (n=76)**

	Full bladder (n=37)	Control (n=39)	<i>t</i>	P value
Cervical entry (Likert scale)	3.8±1.16	3.3±1.1	1.9	0.07
Procedural time (min)	1.35±0.5	2±1.15	3.2	0.002*
Patient acceptability (Likert)	3.2±1.1	2.9±0.9	1.6	0.12
Pain score (VAS)	3.95±1.1	4.4±1.1	1.7	0.09

**Table (16): Effects of bladder filling in women presented with infertility (n=24)**

	Full bladder (n=13)	Control (n=11)	<i>t</i>	P value
Cervical entry (Likert scale)	3.6±1.4	2.7±1.1	1.7	0.1
Procedural time (min)	1.4±0.6	2.6±1.4	2.2	0.048*
Patient acceptability (Likert)	2.9±1.4	2.7±1.1	0.43	0.67
Pain score (VAS)	4.7±1.6	5.1±1.5	0.54	0.6

## 5. Discussion

Diagnostic hysteroscopy is the gold standard in the study of uterine cavity morphology and in diagnosis of endocavitary pathologies, as it offers elevated sensitivity and specificity, a high feasibility and a low complication rate (Mazzon et al., 2014a). Nonetheless, hysteroscopy is often considered a painful procedure that is poorly tolerated by patients, with difficulties in reaching the uterine cavity (Cicinelli, 2010). Moreover, Pain and low patient

tolerance have been the primary limitations to the widespread performance of office hysteroscopy without anesthesia. Although OH is well tolerated in most cases, great discomfort or unacceptable pain occurs in some situations (Fonseca et al., 2014).

For pain control, numerous studies have evaluated the effectiveness of alternative solutions in an attempt to make the investigation less painful. These include the use of normal saline instead of carbon dioxide (CO<sub>2</sub>), the use of small-calibre or

flexible hysteroscopes, a vaginoscopic approach, the administration of prostaglandins to induce cervical dilation, and recourse to analgesia or local anaesthesia. Some studies have sought to identify the variables responsible for pain during diagnostic hysteroscopy (Mazzon et al., 2014b).

Thus, the present study was designed to evaluate uterine straightening by bladder distention in minimizing time and pain during office hysteroscopy. It's a case control study which included 100 women indicated for office hysteroscopy and they were divided into 2 groups; full bladder group (50 women) and control group (50 women). Each patient subjected to full history and clinical examination, Ultrasonography and hysteroscopy. Outcome measures used were pain score, patient acceptability, duration of the procedure and ease of cervical entry. In the present work, the mean age of full bladder and control groups was (44.3 and 46.1 respectively). This age was slightly higher than reported by Celik et al. (2014) in a randomized clinical trial to study the effect of uterine straightening by bladder distention before outpatient hysteroscopy. In their work, the mean age was 39.5 and 41.1 years respectively. The mean BMI was (30.9 and 31.8) in full bladder and control groups. Finally, most of our cases were multiparous in both groups. Those numbers were slightly different from numerous studies evaluated the effect of pain during OH. Fonseca et al., (2014) reported that mean BMI was 26 and mean parity of 2 with range of 0-5 in a study used to identify predictors of unacceptable pain during office hysteroscopy without anaesthesia. Indications for OH in our study included abnormal uterine bleeding (37 cases and 39 cases) in full bladder and control groups respectively and infertility (11 cases and 9 cases). Both conditions are always the main indication for OH as confirmed by Keyhan and Munro, (2014) finding in which abnormal uterine bleeding constituted 61.8% and infertility 33%. Other indications included contraception management, Müllerian anomaly and cervical stenosis. The main diagnostic findings were endometrial hyperplasia and normal finding which was different from the main finding of OH. In a large study included 1028 hysteroscopic procedure conducted to evaluate the long term complications of OH, 290 (28%) cases were normal and 292 (28%) had Endometrial polyp, 119 (12%) had fibroid and 62 (6%) had hypertrophic endometrium (Kerkvoorde et al., 2012).

To the best of our knowledge, this is the second randomized trial comparing the OH procedure performed on patients with a full bladder versus an empty bladder. In our study, the main outcome measures, we found that pain score was lower among full bladder group (4.13 and 4.52 respectively), but with no statistically significant difference. Also,

patient acceptability was higher among full bladder than control group (3.17 and 2.83 respectively), but with no statistically significant difference. On the other hand, the duration of the procedure was longer with empty bladder ( $2.1 \pm 1.2$  min) than full bladder ( $1.37 \pm 0.52$  min), with statistically significant difference. Similarly, cervical entry was easier among full bladder than control group (3.73 and 3.17 respectively), with statistically significant difference. Previous study by Celik et al. (2014) in Turkey which included 97 patients divided into 2 groups: Group A (empty bladder) and Group B (full bladder). They demonstrated that the duration of the procedure was significantly longer in patients who underwent the OH with empty bladders. Cervical entry (as measured by the Likert scale) was easier in Group B ( $4.00 \pm 0.9$ ) than in Group A ( $3.55 \pm 0.9$ ;  $P = 0.013$ ). Pain score was significantly lower in full bladder ( $3.87 \pm 1.2$ ) than control ( $5.04 \pm 2.4$ ;  $P = 0.014$ ). Although patient acceptability (as measured on a Likert scale) was higher in Group B ( $3.39 \pm 0.9$ ) than in Group A ( $3.36 \pm 0.9$ ;  $P = 0.985$ ), the difference was statistically insignificant. Those differences may be explained by the fact that perception of pain may vary among population subgroups (Paulo et al., 2015). There are several studies which evaluated the effect of various modalities in reducing pain during OH. Administration of 1 g paracetamol and 600 mg ibuprofen one hour prior to office hysteroscopy demonstrated no differences in pain scores (Teran-Alonso et al., 2014). In contrast, music was found to be associated with highly statistically significant decrease of pain during OH (4.8 for control and 2.9 for music group;  $P < 0.001$ ) (Angioli et al., 2014). Also, transcutaneous electrical nerve stimulation device (TENS) was associated with significant decrease of pain during OH (3.71 for TENS and 5.1 for control groups) (De Angelis et al., 2003). There are few studies that used the duration of the procedure as an outcome measures for considering the efficacy during OH. In a study conducted to investigate the effects of music on anxiety and perception of pain during office hysteroscopy, Angioliet al. (2014) found no significant difference of operative time between music and control groups. In a randomized, prospective trial conducted to evaluate the efficacy of oral and vaginal misoprostol versus placebo to facilitate OH without anaesthesia, Pain was low in the vaginal misoprostol group. Mean visual analogue scale in the oral misoprostol group was  $6.04 \pm 1.5$ ; in the vaginal misoprostol group  $2.85 \pm 1.2$ ; and in the placebo group  $7.50 \pm 1.5$ . Procedural time for office hysteroscopy was shorter in the vaginal misoprostol group ( $2.7 \pm 1.0$  minutes) compared with group A ( $5.5 \pm 1.1$  minutes) and group C ( $6.3 \pm 3.8$  minutes) (Sordia-Hernández et al., 2011). Regarding the effect of bladder filling in

relation to parity; we found that bladder filling was associated with statistically significant decrease of procedural time among nulliparous women, while there was no statistically significant difference as regard other parameters. Among multiparous women, bladder filling was associated with statistically significant decrease of procedural time, ease of cervical entry and more patient acceptability .while there was no significant difference as regard pain score.

In Fonseca et al., (2014) study, they reported that there is no relation between parity and the occurrence of pain during OH. Moreover, in parous women, the procedure could be associated with less discomfort, and the observed differences may be less noticeable (Pluchino et al., 2010). This augments the results of our study as regard the effect of bladder filling on various outcomes especially in multiparous women. In relation to menopause, premenopausal women benefited from bladder filling by ease of cervical entry, while bladder-filled postmenopausal women had short procedural time.

According to Keyhan and Munro, (2014), pain score was nearly similar in their study to evaluate the effectiveness of a multimodality local anesthetic protocol for office diagnostic and operative hysteroscopy. Mean pain score among pre and post menopausal women was 3.7 and 3.9 respectively. Menopausal status, which causes a narrowing of the cervical canal, and the use of a speculum or tenaculum for the purpose of the introduction of the instrument were indicated as other factors that can lead to pain (Cooper et al., 2010).

In relation to the main presentation, bladder filling was associated with statistically significant decrease of procedural time among women presented with either abnormal uterine bleeding or infertility; while there was no statistically significant difference as regard other parameters. The similar effect of bladder filling in both conditions indicates that it hasn't effect in nulliparous women who are usually more susceptible to the associated discomfort and supposed high level of expertise needed to perform the procedure (Pluchino et al., 2010). In the present study, our investigation was based on the mechanism of bladder filling, which causes uterine straightening, to make the OH procedure less difficult due to the less traumatic passage through the cervical canal and internal ostium. Subsequently, this approach may be more feasible by increasing the cervical entry and decrease duration of the procedure. However, in addition to all the factors mentioned above, other factors, such as waiting periods before the OH, can

affect patient compliance due to varying anxiety levels, which could be another limitation of our study (Carta et al., 2012).

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