Comparison of Vaginoscopic No Touch Method with The Traditional Method of Outpatient Hysteroscopy

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INTRODUCTION

Optimal management of endometrial disease requires accurate and timely diagnosis followed by effective treatment. Modern outpatient hysteroscopy can be utilized as a first-line method for both a diagnostic and therapeutic procedure (1). Outpatient hysteroscopy have many advantages over inpatient hysteroscopy under general anesthesia, including reduced anesthetic risks, enhanced time, cost-effectiveness, and patient preference but the majority of women regard an outpatient hysteroscopy as acutely painful since it involves placement of a cervical tenaculum, traction on the cervix, and insertion of the...
hysteroscope into the cervical canal and the uterine cavity (1). No touch technique have been introduced by, Bettocchi and Selvaggi used in attempt to make the procedure less painful (2). In the present prospective randomized study, we compared the traditional outpatient hysteroscopic technique using intracervical local anesthesia with the vaginoscopic no touch approach without anesthesia in terms of patient’s pain perception in various stages of the procedures.

**MATERIAL AND METHODS**

A prospective, randomized, treatment-controlled study was conducted at the Bakırköy Dr. Sadi Konuk Education and Research Hospital Obstetrics and Gynecology Outpatient Clinic, in Istanbul, Turkey. All participants received a detailed explanation about the study and signed an informed-consent form. Patients were encouraged to observe images of their procedure on the screen. Ninety-two consecutive women referred to our center were enrolled in the study. The patients were randomized into two groups.

The no-touch group included 48 women who underwent vaginoscopic hysteroscopy without analgesia or anesthesia. The patient was placed in dorsolithotomy position, and the vagina was cleansed with a noniodide disinfectant using a small swab positioned on a thin Collins forceps. The hysteroscope was then inserted into the vagina, while distending it by the flowing saline, obviating the need to assist the introduction of the scope into the cervix using a tenaculum. The anatomy could be followed by gentle movements of the hands that correctly drove the hysteroscope into the cervix and through the internal cervical os.

The control group consisted of 44 women who underwent traditional hysteroscopy technique 2-3 minutes after an intracervical injection of 10 mL prilocaine 2% solution. The solution was injected with a 22-gauge spinal needle on two sites (at 3:00 and 9:00 positions). In premenopausal women, all procedures were performed during the early proliferative phase of the menstrual cycle. All the procedures were performed with a rigid 3.7-mm hysteroscope in a medium of 0.9% saline, and the video image was transmitted to a screen visible to the patient.

A VAS score on a 10-cm line was used to assess the intensity of pain experienced at three stages during and 15 minutes after the procedure (0: no pain to 10: worst pain). Stage I: insertion of speculum, tenaculum placement, intracervical block for the traditional hysteroscopy group and insertion of hysteroscope into the vagina, vaginoscopy for the no touch method. Stage II: passage through the internal cervical os. Stage III: observation of the uterine cavity. Stage IV: 15 minutes later, after hysteroscopy.

Samples’ size were calculated to provide 80% power to detect a true difference, by no touch group, of at least 40% in VAS, assuming a difference in VAS of ±1.5, by no touch group, and a two-sided $\alpha$ of 0.05. Using these assumptions and a randomization ratio of 1, it was calculated that a total of 36 participants would provide adequate power. Analysis of data was carried out with NCSS 2007 & PASS 2008 Statistical Software (Utah, USA). For continuous variables, descriptive statistics were calculated and are reported as mean±standard deviation. Distributions of continuous variables were tested for normality using the Kolmogorov-Smirnov test. Normally distributed continuous data were compared by group using the t test for independent samples. Variables with distributions differing significantly from normal were compared by using the Mann Whitney U. Chi-square test and Fisher’s exact test were used to detect differences in categorical variables. All tests were considered significant at $P<0.05$.

**RESULTS**

Characteristics of study participants are described in Table 1. As can be seen, patients were similar by

<table>
<thead>
<tr>
<th>Table 1: Patient characteristics</th>
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<tr>
<td><strong>No touch group N=48</strong></td>
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<tr>
<td>Age 41.68±10.14</td>
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<tr>
<td>Parity 1.52±1.20</td>
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<tr>
<td>Weight 68.45±14.85</td>
</tr>
<tr>
<td>Menopause 31.25%</td>
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<td>Failure 10.4%</td>
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Data are expressed as mean±standard deviation. Continuous variables were compared using the t test for independent samples; categorical variables (percentage menopausal patients and failure rate) were compared using the Chi-square test.
treatment assignment. The indications for hysteroscopy did not differ between the two groups (Table 2). No complications occurred in any of the patients in either group. Five procedures in the no touch group were unsuccessful because of cervical stenosis [abnormal uterine bleeding (n: 1), infertility (n: 2), thick endometrium (n: 1), postmenopausal bleeding (n: 1)] and were performed successfully using a traditional method. Nevertheless, these patients were analyzed in their originally assigned treatment group. Failure rate was not statistically significant between two groups p>0.05.

Visual analog scale scores are shown in Table 3. The mean pain score was significantly low only at stage I in the no touch group <0.01.

DISCUSSION

Since the introduction of hysteroscopy, it has been proved to be a powerful diagnostic tool for visualizing the cervical canal and the uterine cavity (3-6). The main limitation to its widespread use is pain and low patient tolerance leading to perform the procedure under general anesthesia. Outpatient hysteroscopy reduces risks associated with general anesthesia. Using the “traditional technique” of diagnostic hysteroscopy, patients may experience pain during speculum insertion into the vagina, grasping and traction of the cervix by the tenaculum, passage of the hysteroscope through the cervical canal, and distention of the uterine cavity with the distention medium requiring local anesthesia. Various methods of local anesthesia have been tested to reduce the discomfort of hysteroscopy with controversial results (7-18).

Bettocchi and Selvaggi, reported more than 11000 hysteroscopic procedures performed using the vaginoscopic no touch technique and found that as many as 99.1% of the patients reported no discomfort related to the procedure (19,20). Sagiv et al, in a randomized controlled trial; also reported significantly lower pain perception in patients undergoing office hysteroscopy with vaginoscopic method compared with the traditional method despite application of intracervical anesthesia (6). In our study, pain perception was statistically significantly lower in patients who underwent the office hysteroscopy with the no touch method than in those who underwent the traditional procedure with the local intracervical anesthesia in only first stage of the procedures. We have not found any significant difference in pain scores in the stages that hysteroscope has been introduced through the cervical canal, passing through the internal cervical os and examination of the uterine cavity. Patients also did not described different pain scores 15 minutes after the both procedures. In our study despite the application of local anesthesia we have not found any significant difference in pain scores between two methods. This may be due to the experienced gynecologist and use of low diameter office hysteroscope that causes low pain perception. Savig et al. did not examined the procedures in various stages and compared the procedures as during and after in their study. They also found similar satisfaction rates between the two procedures. In our

### Table 2: Indications for hysteroscopy

<table>
<thead>
<tr>
<th>Indication</th>
<th>No touch group N=48</th>
<th>Traditional group N=44</th>
<th>Significance</th>
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<tr>
<td>Abnormal uterine bleeding</td>
<td>22 (45.8%)</td>
<td>20 (45.5%)</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>Infertility</td>
<td>11 (22.9%)</td>
<td>10 (22.7%)</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>Thick endometrium</td>
<td>8 (16.7%)</td>
<td>8 (18.2%)</td>
<td>P&gt;0.05</td>
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<tr>
<td>Postmenopausal bleeding</td>
<td>7 (14.6%)</td>
<td>6 (13.6%)</td>
<td>P&gt;0.05</td>
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Data are expressed as n (%). Groups were compared using the Chi-square test.

### Table 3: Pain Evaluation by Visual Analog Scale

<table>
<thead>
<tr>
<th>Stage</th>
<th>No touch group N=48</th>
<th>Traditional group N=44</th>
<th>Significance</th>
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<tbody>
<tr>
<td>Stage I</td>
<td>1.93±0.43</td>
<td>3.31±0.47</td>
<td>P&lt;0.05</td>
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<tr>
<td>Stage II</td>
<td>4.85±0.77</td>
<td>4.97±0.76</td>
<td>P&gt;0.05</td>
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<tr>
<td>Stage III</td>
<td>6.37±0.57</td>
<td>6.11±0.72</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>Stage IV</td>
<td>2.18±0.39</td>
<td>2.18±0.39</td>
<td>P&gt;0.05</td>
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</table>

Data are expressed as mean±standard deviation. Visual analog scale scores were compared by the Mann-Whitney U test.
study patients had similar pain scores 15 minutes after the both procedures (6).

Limitation of our study is; none of the participating patients had prior experience with either vaginoscopy or the traditional approach, so it is unrealistic to presume that patients would be predisposed to report their experience of pain differently by treatment.

In our study failure rate was 10.4% in the no touch method and it was not statistically significant. Two of five patients were nulliparous with infertility and two of them were at menopause with cervical stenosis. Neither menopause nor infertility was not significant confounders in the failure rate. Because of the low sample size, new studies with big sample size in specific patient subgroups are needed.

Inconsistent with observational studies and the randomized study by Sagiv et al. Sharma et al. failed to observe any advantage of no touch hysteroscopy, compared with traditional hysteroscopy (6,19,20,21). Small sample size and different diameters may also be the limitation of their study.

In summary, we have only found significantly less pain in the vaginoscopic stage of the no touch method compared with the traditional method including the insertion of the speculum, application of the tenaculum and the local anesthesia. This technique has the advantage of elimination of any type of premedication, analgesia, or anesthesia, making the procedure faster with acceptable failure rate. These findings support the use of vaginoscopy over the traditional method.

REFERENCES