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ORIGINAL ARTICLE

Evaluation of Vaginoscopic versus Traditional Office Hysteroscopy in Nulliparous Infertile Patients (prospective Cohort study)

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ABSTRACT:

Background: Diagnostic hysteroscopy is a minimally invasive technique that provides immediate direct vision of the uterine cavity. Therefore, in order to improve the acceptability and comfort level of office hysteroscopy and to increase the success of the outcome, we compared the vaginoscopic and standard hysteroscopy methods in this study. Zagazig University has never conducted research in this area before.

Methods: This prospective cohort study was conducted at Gynecology Outpatients, Obstetrics and Gynecology Department at Zagazig University Maternity Hospital. The study included 108 patients divided into 2 groups, vaginoscopic and traditional hysteroscopic groups, and then the outcomes were compared between the 2 studied groups.

Results: Those who underwent Traditional hysteroscopy had more pain, higher procedural time median values than vaginoscopic hysteroscopy.

Conclusion: Compared to the standard hysteroscopy using the speculum, the vaginoscopic approach is more successful as it is quicker, less painful and better tolerated. It should be preferred in an outpatient setting.

Keywords: Vaginoscopic;Hysteroscopy;Diagnosis ; Nulliparous ; Infertility.

INTRODUCTION:

The word "hysteroscopy" is derived from the Latin word "haustra," which signifies "womb." The current gold standard for examining the uterus, cervix, vagina, and cervical canal is office diagnostic hysteroscopy. With this minimally invasive treatment, patients who are conscious can view the uterus right away without the need for medication or anesthesia. Its indications include the assessment of abnormal uterine bleeding (AUB), intrauterine lesions or foreign bodies, infertility, recurrent miscarriages, obtaining samples from histological biopsy under ocular observation, and postoperative follow-up. Worldwide, the number of diagnostic hysteroscopies conducted is rapidly increasing due to its safety and viability [1].

During a hysteroscopy, a rigid or flexible hysteroscope is inserted into the uterus through the cervical canal. The endometrial cavity is then fully visible thanks to the use of distending media. Thereafter, two distinct methods of doing diagnostic hysteroscopy were employed. The conventional method involves inserting a Sims speculum into the vagina to view the cervix [2].

A small-diameter irrigating endoscope may gently penetrate the hymen, vaginal canal, and cervix using the no-touch technique, also known as vaginoscopy, which eliminates the need for a cervical grasper or vaginal speculum. The hysteroscope and distention medium are then used to dilate the vagina, aiming them toward the cervix, cervical canal, and finally the uterine cavity. [3].

The endoscopes used in the two methods are identical in terms of brand and diameter. Furthermore, both strategies made advantage of rigid scopes. But there were differences between the two methods when it came to using a vaginal speculum and grabbing forceps. [4].

Infection, bleeding, pelvic inflammatory disease, uterine tears (rare), and cervix injury are a few potential hysteroscopy risks. One serious worry is the possibility of complications from the gas or fluid used to enlarge the uterus. After the surgery, the

patient can experience mild vaginal bleeding and cramping for a day or two. [5].

The current study aims to improve the acceptability and comfort level of office hysteroscopy. Methods:

Office hysteroscopy was performed as part of this prospective cohort study, which was conducted on gynecology outpatients at the Obstetrics and Gynecology Department at Zagazig University Maternity Hospital. The same operator conducted the trial for a nine-month period, from August 2023 to April 2024. In every instance, informed consent was acquired. The study was approved from ethical committee of faculty of Medicine, Zagazig university (IRB number 10873-11-7-2023).

Every patient was split up into the following two groups: group A: 54 individuals The hysteroscope will be inserted via the cervical canal under direct view with the aid of group B (54 patients) and Cusco: the hysteroscope being inserted without the use of a cervical grasper or vaginal speculum.

Inclusion criteria included all participants without a hysteroscopy contraindication who have primary infertility (failure to conceive after a year of regular sexual activity) and who have given their consent to participate in the trial.

Exclusion criteria included expectant mothers. colorectal cancer. History of cervical surgical intervention. genital tract infection that is active. heart-related conditions. severe illness of the obstructed airways. widespread acute peritonitis. Clotting disorders and blood dyscrasias.

Every patient underwent a comprehensive history taking and clinical examination, which included a pelvic examination to rule out any gross pelvic pathology and to determine the size and orientation of the uterus.

METHODS:

1. Gravity infusion system: using gravity, this involves setting up a three-liter glycine at a height of one to one and a half meters off the table. The infusion pressure will be between 85 and105 mm Hg at this height. Achieved good distention, with a typical flow rate of 300–500 ml/min.

2. Fiberoptic light: Storz-manufactured Xenon nova, type 20 13 15 20

3. Hysteroscopic apparatus: stiff, Model 26157 BT, a 30º HamouII hysteroscope with a Hopkins II lens system, was produced in Tuttlingen, Germany by Karl Storz (Figure 1). The sheath's operating channel has an outside diameter of 5 mm, and the instrument used is a type 26163 V with 2.9 mm rod lens.

4.C Camera: Telecom DXpal model 20 23 20 20 by Storz, Karl Storz-endoskope.

5. Use the TVCR Goldstar model No. KKV-9050, 50/60 Hz, AC 100-270 V, as a monitor to record and show hysteroscopic incidents on video (Figure 2).

1. ***Technique:***

It was requested of the patient to empty her bladder. The patient received a detailed description of the process before being put in the dorsal lithotomy position. To provide the surgeon enough room to maneuver the hysteroscopy, the thighs should be 90 degrees to the table. The perineum of the patient ought to be somewhat beyond the table's edge. Uterine distension linked to the sheath's inflow channel was treated with glycine.

Group A: (Non-contact method) Without using a speculum, the hysteroscopy tip was inserted into the vaginal introitus while the labia were slightly parted using fingers. The vagina grew larger after taking glycine. The scope was shifted to the posterior fornix in order to more easily view the portio. The scope was then progressively moved backward to identify the external cervical os. Once this was recognized, the scope was carefully moved to track the black spot toward the internal os and the uterine cavity, inclined 30 degrees, with the goal of avoiding side walls to minimize stress and cause no pain.

Group B: (Traditional method) After looking at the cervix with a Sims speculum inserted into the vagina, it was simpler to place the hysteroscope.

The uterine cavity was carefully inspected by rotating the fore-oblique scope to look for any abnormalities in the uterine walls and/or the right and left tubal ostia. In order to minimize patient discomfort at this point, it is imperative to prevent lateral motions as much as possible. The scope was then taken out, and in order to avoid a vasovagal episode, the patient was told to remain in the dorsal position for a little while. In order to calculate their pain score using the Wong-Baker Faces pain rating scale, patients were additionally questioned about any pain they may have had during the course of treatment. Ultimately, the surgeon wrote up the evaluation and findings in great detail, and the treatment was carried out in accordance with the patient's condition and the surgeon's assessment. If necessary, operational intervention was carried out. All side effects, including pain, bleeding, vasovagal attack, and perforation, were noted on the patient record.

statistical analysis:

All of the data were collected, tabulated, and statistically analyzed using SPSS 26.0 for Windows

(SPSS Inc., Chicago, IL, USA). Quantitative data was expressed using the mean ± SD and median (inter-quartile range), whereas qualitative data was expressed using absolute frequencies (number) and relative frequencies (%). distinct samples The Student's t-test was used to compare two groups for variables that were regularly distributed, whereas the Mann Whitney U test was used for variables that were non-normally distributed. The percentage of categorical variables was compared using the Chi-square test. There were two sides to every test. P values were classified as statistically significant (S) if they were less than 0.05 and statistically insignificant (NS) if they were more than 0.05.

RESULTS:

This prospective cohort study included 108 patients divided into 2 groups, their baseline data were mentioned in (Table 1).

The mean PAIN During speculum placement was 6.19±1.13 with median 6 (5-7) IQR. There is a significant difference in evaluation of Postoperative pain ($p < 0.05$) between both procedures. Those who underwent Traditional hysteroscopy had more postoperative pain median values than "Vaginoscopy". On the other hand, there is non-significant difference in evaluation of pain during introduction of hysteroscopy ($p > 0.05$) between both procedures. (Table 2)

The procedure times for the two methods during diagnostic hysteroscopy varied significantly ($p < 0.05$). Compared to traditional hysteroscopy, those who underwent "Vaginoscopy" had less time (Figure 3)

There was a non-statistically significant difference between the two groups' procedure results ($P > 0.05$). The number of unsuccessful procedures differed between the vaginoscopic and conventional hysteroscopy techniques in a non-statistically significant way ($P > 0.05$). Although the conventional system had fewer failed cases (Table 3).

While bleeding was discovered in two patients and cervical stenosis in one, there was no discernible difference in the reasons for procedure failures between the vaginoscopic and conventional techniques to hysteroscopy. In traditional hysteroscopy, causes of failure of procedure was bleeding in three patients (5.6%) (Table 4).

The percentage of complications is rarely seen. No statistically significant difference was detected between the studied groups. Two patients (3.7%) had experienced vasovagal attack, and three (5.5%) patients had bleeding during traditional hysteroscopy (Table 5).

Table (1): Basic characteristic of the studied group:

Characteristic			Group I (Vaginoscopy hysteroscopy) (n=54)	Group II (Traditional hysteroscopy) (n=54)	t	P value
Age Mean ±SD			28.02±5.35	30.15±6.49	-1.861	0.066
Habitat	Urban	N	30	36	1.403	0.236
		%	55.6%	66.7%		
	rural	N	24	18		
		%	44.4%	33.3%		
Socio-economic status	Low	N	27	27	0.0	1.00
		%	50.0%	50.0%		
	High	N	27	27		
		%	50.0%	50.0%		

(t) Independent Samples Test.

Table (2): Evaluation of pain among the studied group:

Characteristic	Group I (Vaginoscopy hysteroscopy) (n=54)	Group II (Traditional hysteroscopy) (n=54)	z	P value
PAIN During speculum placement Mean ±SD Median (IQR)	_____	6.19±1.13 6 (5-7)	----	-------
pain during introduction of hysteroscopy Mean ±SD Median (IQR)	3.31±1.52 3 (2-4)	3.78±1.13 4 (3-5)	-0.087	0.931
Postoperative pain Mean ±SD Median (IQR)	1.15±0.71 1 (1-2)	1.67±0.79 1 (1-2)	-2.064	0.039*

(Z) Mann-Whitney Test

Table (3): Findings during procedures and the success of the procedure in both groups

Characteristic			Group I (Vaginoscopy hysteroscopy) (n=54)	Group II (Traditional hysteroscopy) (n=54)	X^2	P value
Finding during procedures	Normal	N	31	37	1.429	0.232
		%	57.4%	68.5%		
	Abnormal	N	23	17		
		%	42.6%	31.5%		
Success of the procedure	Failed	N	5	3	0.540	0.462
		%	9.3%	5.6%		
	successful	N	51	49		
		%	90.7%	94.4%		

(X^2) Chi-Square Tests

Table (4): Evaluation of causes of the failure in both groups

Characteristic			Group I (Vaginoscopy hysteroscopy) (n=54)	Group II (Traditional hysteroscopy) (n=54)	X^2	P value
Cause of failure	bleeding	N	2	3	1.200	0.549
		%	3.7%	5.6%		
	cervical stenosis	N	1	0		
		%	1.9%	0.0%		
Successful		N	51	51		
		%	94.4%	94.4%		

(X^2) Chi-Square Tests

Table (5): Procedural complications of the studied group:

Characteristic				Group I (Vaginoscopy hysteroscopy) (n=54)	Group II (Traditional hysteroscopy) (n=54)	X^2	P value
Complication	No		N	51	49	10.906	0.053
			%	94.4%	90.7%		
	Abnormal	Bleeding	N	2	3		
			%	3.7%	5.5%		
		Vasovagal	N	1	2		
			%	1.9%	3.7%		

(X^2) Chi-Square Tests

Figure (1): Karl storz endoscope power LED 175, Model 2016, Germany.

Figure (2): Hysteroscope flexible /rigid, camera, light source, inner and outer sheath, inflow tube.

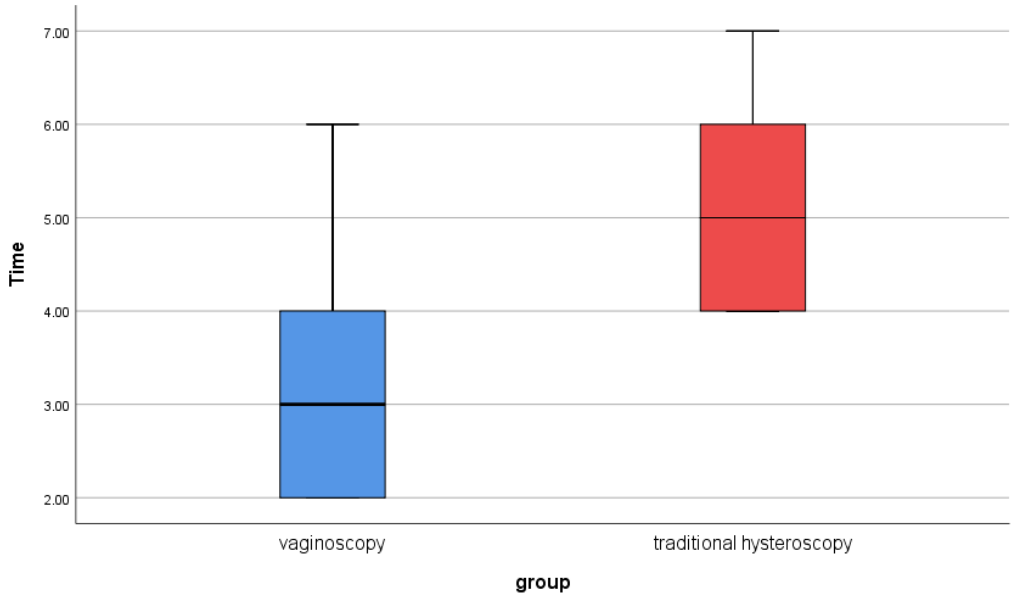

Figure (3): box blot showing procedure time among the studied group.

DISCUSSION:

Hysteroscopy is one of the most important diagnostic methods in gynecology. In order to identify intrauterine lesions, it is the gold standard [6]. It offers a more comprehensive examination of the surface of the endometrium. However, it's frequently limited to treating tumors discovered with less invasive techniques [7].

This study involved women with primary infertility, and the findings indicated that there was no statistically significant difference in age, place of residence, or socioeconomic status between the two groups.

The primary obstacle to the widespread adoption of office hysteroscopy is pain. But while it is undeniably beneficial to minimize pain during outpatient procedures in order to maximize patient acceptability, the review fails to show how reducing discomfort improves procedural feasibility—that is, the capacity to successfully complete a hysteroscopy [8].

Throughout the three stages of the operation, women were asked to rate how much pain they were experiencing:1. when placing a speculum. 2. the development of hysteroscopy 3. Pain after the procedure. In our study, speculum installation pain during conventional hysteroscopy was taken into consideration. When placing speculums, the average level of pain was 6.19±1.13 with median 6 (Range 5-7) IQR.

A hysteroscope is directly inserted into the cervix through the vagina in vaginoscopic hysteroscopy. Pain is only experienced in two stages.

The assessment of postoperative pain differs significantly ($p < 0.05$) between the two techniques. Comparing "Vaginoscopy hysteroscopy" to "Traditional hysteroscopy," the latter group's postoperative pain median values were lower. However, there is no discernible difference in the assessment of discomfort during hysteroscopy introduction ($p > 0.05$) between the two methods.

A speculum and a tenaculum were not needed for any of the more than 11,000 hysteroscopic procedures that Bettocchi and Selvaggi described as having been carried out using the vaginoscopic approach. It was shown that 99.1% of the patients experienced no discomfort at all from the operation. The group that did not utilize speculum had a noticeably lower mean pain score [9].

Smith reported pain scores for vaginoscopy and standard hysteroscopy in a randomized study of 42.7 and 46.4 (maximum of 100), respectively ($p = 0.02$) [10].

Tein found that, in a retrospective cohort analysis, compared to traditional hysteroscopy, vaginoscopy resulted in decreased discomfort (standardized mean difference, −0.44; 95% CI: −0.65 to −0.22). Nevertheless, the study included all patients who were older than 18 [10].

Gupta published data on pain score at different stages in a randomized case-control study, which is

similar to our findings. The results of the analysis indicated that there was a significant difference in the pain score (p = 0.026). The majority of patients (68%) reported experiencing discomfort at a rating 4 when the cervix was grasped with the vulselum during a standard hysteroscopy. Pain is only noticed in two steps during vaginoscopic hysteroscopy since the hysteroscope is introduced directly. Nonetheless, Gupta documented cases of aberrant uterine hemorrhage among postmenopausal patients [7].

According to Garbin, vaginoscopy resulted in lower VAS scores (up to 10) than normal hysteroscopy (0.5 vs. 2; p < 0.001). Almeida also noted that the group undergoing vaginoscopy experienced less pain than the group undergoing standard hysteroscopy (1.60 vs 3.39; p = 0.01). Lower pain levels during vaginoscopy were also reported by Sagiv (3.8 vs. 5.3 for standard hysteroscopy; p = 0.008) [11].

Consistent with our results, which indicated that the vaginoscopy group experienced less pain than the standard hysteroscopy group, the majority of prior research report less pain during vaginoscopy than during standard hysteroscopy. Sharma did find no differences in pain scores between normal hysteroscopy and vaginoscopy, but [11].

In our study, the median time to complete examination for vaginoscopy was less than that of normal hysteroscopy (3 vs. 5 minutes; p <0.001). With relation to that, the usual procedure's insertion of the speculum.

Tein observed that compared to the normal hysteroscopy group, the vaginoscopic group experienced less pain and a shorter procedural time (median time, 135 vs 190 seconds; p = 0.02; median VAS score, 3 vs 5; p = 0.01) [10].

Furthermore, according to Gupta, the vaginoscopic group performed more quickly. Thirty-two patients, or seven6.19%, finished the vaginoscopic operation in three to five minutes, according to the diagnostic study conducted during the treatment. 34 patients (77.27%) require 5 to 7 minutes for a standard hysteroscopy procedure [7].

Similar findings to our investigation were found in the study of Guida et al., which showed that 32 patients (76.19%) finished their vaginoscopic operation in three to five minutes. The remaining ten patients, or 22.72%, finished in five to seven minutes. 34 patients (77.27%) had a standard hysteroscopy, which takes 5 to 7 minutes to complete. The remaining ten patients, or 22.72%, finished in three to five minutes. During diagnostic hysteroscopy, there is a substantial difference in procedure time (p <0.05) between the two procedures [11].

In comparison to hysteroscopy, Smith observed that vaginoscopy examination times were shorter (2 vs. 3 minutes; p < 0.001). A reduced vaginoscopy examination time (5.9 vs. 7.8 Sharma also revealed the minutes for normal hysteroscopy (95% CI: 0.7-3.1). However, Garbin claims that there were no discernible differences between the two groups (240 vs. 240 seconds, p>0.05) [9].

In our study, bleeding was discovered in two patients and cervical stenosis in one, indicating no discernible difference in the reasons for operation failure between the vaginoscopic and conventional techniques to hysteroscopy. In three patients (5.6%), bleeding was the reason for the procedure's failure during a conventional hysteroscopy. Although the conventional system had fewer failed cases.

According to Gupta, there is no discernible difference between the vaginoscopic and conventional hysteroscopy approaches in terms of the number of unsuccessful procedures. Cervical stenosis accounts for five of the patients' vaginoscopic hysteroscopy failures. In cases of classical hysteroscopy, the most common reasons for procedure failure include bleeding (2%) and acutely anteverted or retroverted uterus (2%) in two patients each, and cervical stenosis (4%) in two patients [7].

According to Tien, there were no notable variations in the high success rates in the two groups Groups for vaginoscopy (43/45 [95.5%]) and hysteroscopy 53/55 [96.3%] had relative risks [RR] 1.23 and 95% confidence intervals [CI], 0.16–9.11, respectively, with p = 1.0. Most of the unsuccessful procedures were excruciating [10].

Our results were in line with another study by Smith, which showed a comparable success rate in both groups (94.4% for vaginoscopy vs. 90.7% for traditional hysteroscopy; p=0.462). [11].

Higher success rates for routine hysteroscopy and vaginoscopy were found in a large multicenter randomized experiment (RR 1.11; 95% CI: 1.02-1.19) [11].

Higher success rates for routine hysteroscopy and vaginoscopy were found in a large multicenter randomized experiment (RR 1.11; 95% CI: 1.02-1.19). Nonetheless, a different study found that both groups had success rates that were comparable to ours (94.4% for vaginoscopy vs. 90.7% for normal hysteroscopy; p=0.462) [10].

According to a previous RCT, vaginoscopy was linked to fewer issues than standard hysteroscopy (RR 0.26, 95% CI: 0.10-0.69). We could not find any

statistically significant differences between the groups under study, nevertheless. Seldom is the percentage of complications visible. During a conventional hysteroscopy, two patients (3.7%) had suffered a vasovagal crisis, and three patients (5.5%) had hemorrhage [10].

Because office diagnostic hysteroscopy is successful in examining the uterine cavity and is convenient in that it does not involve the use of anesthetic, it is currently utilized extensively throughout the world. Nonetheless, because vaginoscopy is not commonly utilized, physicians have less expertise carrying out this operation. Operators in the office should be skilled in both vaginoscopy and standard hysteroscopy to provide patients with an alternative method, especially for women who have never had intercourse. [12].

Conclusion:

In our study, we discovered that, in comparison to traditional hysteroscopy, vaginoscopy offers the following benefits: reduced discomfort, a shorter examination duration, and a similar success rate. Consequently, we advise using vaginoscopic exams in the context of office hysteroscopy.

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