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Comparison of Office Hysteroscopy versus Blind Cervical Probing in Tight Primary Cervical Stenosis in Nulliparous Women: A Randomized Controlled Trial

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Abstract

Objective: This study aims to estimate if performing an office hysteroscopic cervical negotiation would succeed to bypass tight markedly stenotic cervix (failed introduction of a uterine sound on vaginal examination) in comparison to blind cervical probing done under general anesthesia. Moreover, the impact of drawing a detailed diagram after this procedure on the success of ET in patients with failed mock or actual trials of embryo transfer (ET) was evaluated.

Patients and Methods: It comprised 122 nulliparous women with failed cervical sounding on routine vaginal examination in the office or failed mock or actual embryo transfer due to severe cervical stenosis. Women were divided into 2 groups. Group A comprised 64 cases subjected to small-caliber office hysteroscopic cervical negotiation while 58 cases were subjected to cervical probing under general anesthesia. Main outcome measures included success to bypass primary cervical stenosis and complication rate.

Results: There was no statistically significant difference between both groups regarding sociodemographic data. In group A, cervical stenosis was bypassed in 49 (76.5%) cases with 24 cases with filmy thin adhesions that were cut with the edge of the telescope, while false passage occurred in 4 cases (6.2%) and failed cervical canal bypass in 11 cases (17.3%); 7 of them were due to dense intracervical adhesions. Cervical canal kinking was diagnosed in 28 cases (43.7%). In group B, cervical stenosis was overcome in 14 cases (24.5%) while false passage occurred in 21 cases (36.2%) and failed cervical dilatation in 23 cases (39.3%). These results were significantly lower that the results of group A (P=0.001). Patient merits improved significantly in group A except spasmodic dysmenorrhea which improved more significantly in group B.

Conclusion: This study added a novel use of office hysteroscopy which is under vision cervical canal negotiation of severe tight cervical stenosis which was proved to be superior to blind cervical probing. Furthermore, it offers excellent guidance for subsequent easier embryo transfer with more patient satisfaction. Study findings are valuable for day to day practice and deserve large sample sized future research.

Keywords: Hysteroscopy; Cervical Stenosis; Probing; Embryo Transfer; Nulliparity

Introduction

Cervical stenosis refers to narrowing of the cervical canal than it should typically be many intrauterine operations could be cancelled even after induction of anesthesia due to failed access to the endometrial cavity. Intolerable pain or cervical stenosis represents the main reasons for failed hysteroscopy. Technically difficult embryo transfer (ET) due to cervical stenosis is associated with reduced chance of pregnancy after assisted reproductive procedures [1]. Many studies addressed different medical [2] or surgical lines of management of cervical stenosis [3-5]. For instance, one study classified cervical stenosis into 4 types on the basis of localization: stenosis of external cervical ostium (ECO; type I); stenosis of distal third of cervical channel and the internal cervical ostium (ICO; type II); stenosis of the ICO (type III), and combined stenosis of ECO and ICO (type IV) [6]. The usual surgical treatment of cervical stenosis is cervical dilatation which would be impossible if failed cervical sounding. Upon failure of uterine sounding to navigate the stenosis, cervical probing with dilators of small caliber as low as 2 mm is usually performed little attention has been exerted towards this important troublesome problem. Most of the gynecologists consider it a trivial problem and start to use force with subsequent traumatic complications and risks [3]. As a pre-procedure adjunct especially in nulliparous women, the efficacy of

vaginal misoprostol versus laminaria tents was compared in a randomized controlled trial [7] prior to operative hysteroscopy but it didn't include cases with failed cervical sounding due to tight cervical stenosis.

Nowadays, hysteroscopy with a caliber as small as 2.6 mm telescope and 3.2 mm outer sheath has been extensively used all over the word. Its role is valuable in many indications [8] up to considering it as a complementary step in infertility work up by some authors [9]. Due to these valuable clinical implications of primary cervical stenosis This study was constructed to estimate if performing small caliber hysteroscopic cervical negotiation would bypass stenosis in cases of primary tight cervical stenosis (internal os caliber is less than 4 mm, 1.33 French) in comparison to blind cervical probing. Moreover, the impact of drawing a detailed diagram after this procedure on the success of ET in patients with failed mock or actual trials of transfer was tested.

Materials and Methods

After obtaining the acceptance of the ethics committee of Assiut Faculty of Medicine, Assiut, Egypt this study was conducted at the Endoscopy Unit of Woman's Health University Tertiary Hospital, Assiut, Egypt from January 2012 to February 2018. This unit performs weekly 3 lists of operative hysteroscopy and serves daily out-patient office hysteroscopy lists. This study is internationally registered at Clinical Trial.gov (Identifier NCT03457350). Inclusion criteria were infertile nulliparous women with failed cervical sounding on routine vaginal examination in the office or patients with failed mock or actual embryo transfer due to severe cervical stenosis. Postmenstrual sounding was done in all cases to confirm stenosis as the cervix is more slightly dilated at this time. All cases were confirmed by a senior consultant (AD) with a clinical experience of more than 32 years. As shown in figure 1, for assessment of eligibility, 214 women with failed cervical sounding on vaginal examination due to tight internal os (less than 4 mm) were evaluated. To eliminate any bias due to previous cervical dilatation, a total of 92 cases were excluded due to multiparty whether delivered vaginally or by cesarean section. Cases delivered by cesarean section were excluded to eliminate patient heterogeneity. Participants gave a history of previous operation on the cervix (79 cases) were also excluded. Nor use of any medication to prime the cervix in all cases was a must. Based on published studies on the same topic [2,3], sample size calculation was carried out using Epi Info software (version 7) using confidence interval 95% and power 80%. So, total sample size was 128 patients that were divided into two groups. After obtaining patients' consent, eligible 122 women were prepared as usual for any gynecologic endoscopy operation. They were randomized into 2 groups using cards; one hundred twenty eight were sequentially numbered. Opaque sealed envelopes were used containing 64 cards were labeled office hysteroscopy and 64 cards were labeled cervical probing. All envelops were mixed together randomly in a box. The cards were selected randomly and once selected never changed.

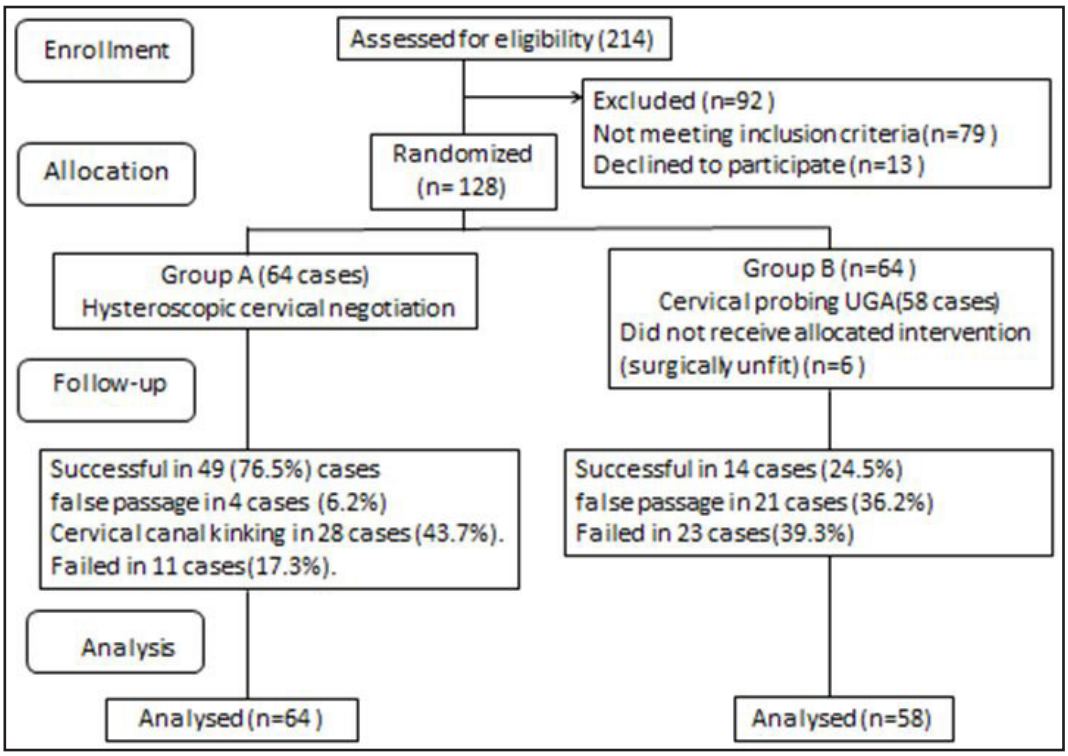

Figure 1: Flow chart of the study

Group A comprised 64 cases who were subjected to small caliber office hysteroscopy in the out-patient endoscopy unit without local or general anesthesia. Office hysteroscopy 30° 2.6 mm telescope with an outer sheath of 3.2 mm (Storz Co., Tutlingen, Germany) was utilized. The cervix was grasped with a multi-tooth tenaculum aiming at correction of any kinking of the cervical canal. It was applied either on the anterior lip or the posterior lip of the cervix according to preoperative transabdominal and transvaginal examination to know the real direction of the cervix. Hysteroscopy was performed as usual by proper examination of the vagina and the ectocervix for any abnormality followed by introduction of the hysteroscope into the cervical canal. At this step, the hysteroscopist waited for a while until the distending fluid created a micro cavity. At this point, the telescope was

advanced with necessary rotatory movements of the 300 telescope guided by the vision of the dark spot which is the internal os. If it was reached, again waiting for some time to allow fluid distension of the internal os area. Moreover, the infusion pump pressure was increased to a maximum of 170-200 mmHg. Thereafter, the telescope was gently introduced towards the dark spot to enter the endometrial cavity. Once the endometrial cavity was entered, a detailed comment on tubal ostea, the endometrium and any lesion in-utero was reported. Aiming at a better visualization, a detailed description of the internal os and the cervical canal was reported during extraction of the hysteroscope. The hysteroscopist draw a detailed diagram for all cases describing the shape and directions of the cervical canal and the internal os in addition to endometrial cavity findings. If hysteroscopy couldn't bypass the internal os, the procedure was considered failed. If the telescope entered a cavity other than endometrial cavity, a false passage was considered. All cases of false passage were given systemic antibiotic and were put under observation for at least 2 hours. Group B comprised 64 cases that were planned for cervical probing under general anesthesia. In 58 suitable cases, probing was started with a 2 mm cervical probe after grasping the cervix with a multi-tooth tenaculum put anteriorly or posteriorly according to prior trans abdominal or transvaginal sonographic examination of the cervical canal. If the probe succeeded to bypass the internal os, a higher caliber probe was used. Thereafter, a uterine sound (4mm = 1.33 Fr) was introduced into the endometrial cavity. Lastly, to ensure persistent cervical patency, gentle cervical dilatation up to Hegar's 8 was performed as usual with classic leaving each dilator for 30 seconds inside the internal os. Any complication of cervical dilatation using Hegar's dilatation after 4mm is excluded from comparison with group A. If probes couldn't bypass the internal os, the procedure was considered failed. If the probe entered a cavity other than endometrial cavity, a false passage was considered. All cases of false passage were given systemic antibiotic and were put under observation for at least 2 hours at office hysteroscopy unit. The main primary outcome measures of this study were success to overcome primary cervical stenosis and getting inside the endometrial cavity (end point) and complication rate. Secondary outcome was patient satisfaction and success of embryo transfer in selected cases.

Categorical data were described as percentages and compared with chi square and exact Fischer tests together with calculation of correlation and agreement. Continuous data were described as mean +/- SD or median (according to data distribution) and compared using t test, Man Whitney test, and ANOVA test with LSD post hock test when appropriate. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using SPSS 16 program (Statistical Package for the Social Science; SPSS Inc., Chicago).

Results

After exclusion of 92 unsuitable cases, this study comprised eligible 122 nulliparous women with a diagnosis of failed cervical sounding on vaginal examination. Women were randomized into 2 groups. Group A comprised 64 cases subjected to hysteroscopic negotiation of the cervix while 58 cases were subjected to cervical probing under general anesthesia. Their mean age was 20 years. Their main complaints were primary infertility and failed embryo transfer (Table 1). There was no statistically significant difference between both groups regarding the sociodemographic data (p value >0.05) as shown in Table 1. Operative and clinical outcomes are shown in Table 1. In group A, 24 cases with filmy thin endocervical adhesions were cut with the edge of the telescope while 7 cases with dense intracervical adhesions failed to bypass. There was no case of cervical tear, uterine perforation or fluid overload in group A. All hysteroscopic complications were managed conservatively with a need for laparoscopy. Detailed drawing of the hysteroscopic findings resulted in success of subsequent embryo transfer in 38/41 cases (92.6%) while successful ET was achieved in 32/34 (94%) after cervical probing followed by cervical dilatation up to Hegar's 8 without statistically significant difference. Patients' merits after this procedure are shown in Table 1.

	Group A 64 cases		Group B 58 cases		P Value
	No.	%	No.	%	
Residence					
• Urban	32	50	29	50	0.994^{Ns}
• Semi	15	23	14	24	
• Rural	17	27	15	25	
Age (Mean+SD)	23+4. 7		24. 8+4. 4		0. 818^{Ns}
Weight (Mean+SD)	72. 3+14. 7		70+21. 8		0. 488^{Ns}
Height (Mean+SD)	158. 2+5. 8		158. 1+6. 7		0. 933^{Ns}
BMI (Mean+SD)	29. 3+5. 2		28. 4+4. 7		0. 532^{Ns}
Spasmodic dysmenorrhea	14 cases (21%)		14 cases (24%)		0.767^{Ns}
Operative outcomes					
Bypass stenosis	49 cases (87.5%)		14 cases (24%)		0.000
false passage#	4 cases (6%)		21 cases (36.2%)		0.000
failed cervical dilatation	11 cases (17%)		23 cases (39.6%)		0.006
Cervical canal kinking#	28 cases (43%)		0		0.000

	Group A 64 cases		Group B 58 cases		P Value
	No.	%	No.	%	
Clinical outcomes					
Improvement of spasmodic dysmenorrhea	6 of 14 (43%)		11 of 14(78.6%)		0.053^{Ns}
Pre-procedure failed mock or actual embryo transfer	41(64%)		34 (58%)		0.537^{Ns}
Successful post-procedure ET	38 (59.3%)		32 (55.1%)		0.693^{Ns}
Patient satisfaction	57 (89%)		39 (76.2%)		0.003

P value between group A and B; # Fisher Exact; X2; Less 5: Fisher; More than 5; Mean: t test
Table 1: Sociodemogrphic and study outcomes

Discussion

This study comprised 122 cases with tight cervical stenosis that were classified into 2 groups according to the modality to overcome this problem. Primary cervical stenosis with tight internal os (less than 4 mm) is a real challenge for gynecologists particularly hysteroscopic surgeons. Many hysteroscopic procedures failed to perform due to tight internal os. Cervical tears, creation of a false passage, uterine perforation, vasovagal reaction, pain, and inability to complete the procedure, are uncommon hysteroscopic difficulties caused by inadequate cervical dilation and an inability to insert the hysteroscope [10]. One study noted that almost half of hysteroscopic complications were related to cervical entry [11]. A systematic review of diagnostic hysteroscopy in more than 26,000 women reported a failure rate of 4.2% for ambulatory hysteroscopy and 3.4% for inpatient procedures. Failed ambulatory procedures were mainly attributed to technical problems, including cervical stenosis, anatomic and structural abnormalities pain and intolerance [3,12]. A recent study on 31,052 office hysteroscopies [6], diagnosed cervical stenosis in 10,156 women (32.7% of all procedures) and was significantly more frequent in postmenopausal than in fertile women (70.1% vs. 29.9%), except for stenosis of the external os which was more frequent in fertile than in postmenopausal women. Despite being a study of large sample size, yet they used operative office hysteroscopy which requires a minimal degree of cervical dilatation (at least 5 mm) which is unfortunately not feasible in cases with tight cervical stenosis and failed sounding of the 4 mm uterine sound insertion. Classically, cases with failed sounding in the office are subjected to another trial of sounding under general anesthesia which overcomes stenosis in many cases but the risk of perforation and false passage formation is usually high due to blind aggressive trials. More importantly, planned intrauterine operations including operative hysteroscopic procedures should be postponed for few months due to these complications. Some authors described alternative blind techniques to overcome stenotic cervix like transcervical insertion of a 16-22 French Malecot catheter [3], coated nitinol stent [4], and absorbable adhesion barrier - (Interceed; Gynecare, Ethicon, Somerville, NJ) [5] . The catheter and temporary cervical stent may get dislocated and may be associated with uterine infection due to prolonged dilated cervix. Using an absorbable adhesion barrier in the cervical canal eliminates some of these potential complications. The coated nitinol stent appears to be a valid alternative as it is elastic, flexible and self expanding with a continuous dilative force on the cervical canal. The permanent dilative force - optimally exerted in an elastic manner over 8 to 9 months - is claimed to have a long term effect. It should be mentioned that these procedures are not suitable at all for our cases of failed cervical sounding which means that the cervix didn't accept a 4 mm (1.33 French) uterine sound. A recent case report on three cases [13] reported insertion of hysteroscopically-assisted cervical stents prior to ET without any clinical success.

The current study supports the concept that the indications hysteroscopy are expanding in modern practice [14,15] and hence training on hysteroscopy should be extended to cover all gynecologists. In a recent study [16], hysteroscopy could overcome cervical stenosis using microscissors, micrograspers, a cutting loop electrode or cervical canal excision if future fertility was not desired. Again, these tools could not be inserted via a tight cervix which basically fails to pass a uterine sound.

Despite being a cheap and accessible procedure, blind cervical probing carries a risk of false passage and cannot diagnose the cause of stenosis. On the other hand, hysteroscopic cervical negotiation is an under vision procedure that can diagnose the cause of stenosis specially endocervical kinking. Office hysteroscopy offers three simultaneous important advantages. Firstly, under vision introduction of the telescope is a basic step in all hyseteroscopic procedures. Hysteroscopists should not advance the telescope forward unless the next part of the cervical is visualized. This advantage over blind techniques allows overcoming many cases of cervical canal kinking that makes sounding impossible as diagnosed in this study (28/64 cases). Secondly, the use of fluid for distension of the cervical canal as well the endometrial cavity is a good attributing factor. Waiting for a while to allow fluid to distend the cervical canal is a basic step in hysteroscopy. This microcavity created in the cervical canal would guide the telescope to the correct way and would facilitate overcoming the cervical canal isthmical narrowing. Lastly, as used in this study, utilizing a 30° telescope allows more chance to negotiate for the internal os against this procedure is the fact that hysteroscopy is not designed to overcome stenosis. This is true if we relied on force to overcome stenosis. As shown in the results section, many cases of cervical canal kinking were easily bypassed with hysteroscopy. Again, microcavity formation and increasing pressure of the distension

media are important contributing factors to overcome stenosis in many cases. In 24 cases with filmy thin endocervical adhesions, adhesiolysis was done with the edge of the telescope. In one study [6], adhesiolysis with the distal tip of the hysteroscope by rotating the scope on the endocamera was the significantly more used strategy to overpass all types of cervical stenosis (39.8% of cases).

Overall, surgical management of cervical stenosis can be managed by hysteroscopic methods or conversely managed using ultrasound guidance during cervical dilation as described above. This important step helps to prevent a false tract or uterine perforation. Using ultrasound guidance is also very helpful in the placement of IUD's for women with ante flexed or retroflexed uterus [17]. Comparative success rates have not been determined for resolutions by morcellator; resect scope or LEEP, but Lin, *et al.* report only one failed entry in 30 procedures performed using a resectoscope [18]. Operative hysteroscopy procedures to overcome cervical stenosis were described [1,6,19,20]. However, resectoscopic trials would add more scars to the cervical canal with subsequent more cervical stenosis. Moreover, practically, a stenotic cervix can't tolerate a 27 F (9 mm) resectoscope. Even if smaller caliber resectoscopes (21 Fr, 7mm) are used, the marked tightness of the cervix over the resectoscope would hinder perfect hysteroscopic procedure. An important issue against these procedures is the lack of postoperative supportive measures in these case reports in the form of cervical canal tubing for many days to allow creeping of the normal epithelium to line this row area and the usage of some drugs like estrogens. Lastly, case reports without repetition for many years would weaken the clinical implementation of such procedures. Actually, in cases of failed sounding (less than 1.33 Fr), there is no way to use any operative instrument through the cervix unless dilatation has been achieved. In this study, the advantages of small caliber hysteroscopy included proper visualization and micro cavity formation without any aggressive hysteroscopic procedure that would result in remote recurrence.

To make access to the internal os easy, cervical canal straightening was attempted by traction of a cervical tenaculum applied anteriorly or posteriorly according to preoperative transvaginal and trans abdominal ultrasonography examination. Some authors use intraoperative transabdominal ultrasonography guidance of the cervical dilatation procedure or difficult dilation and curettage procedures especially in women with a history of uterine perforation [21]. However, transabdominal ultrasound requires filling the urinary bladder, which may hinder vaginal surgery including hysteroscopy.

In this study, there were no hysteroscopy complications due to fluid overload as reported by others [22] because the procedure was short and we used normal saline. In this study, patient satisfaction was more significant with office hysteroscopy due to lack of hospital admission, non-use of general anesthesia and fast procedure. Moreover, easy ET after performing hysteroscopic negotiation of the cervix highlights the importance of hysteroscopy prior to ET despite being a controversial topic. It achieved similar results to cervical dilatation under general anesthesia. Nevertheless, improvement of spasmodic dysmenorrhea was more manifest in group B as it was a real therapy to overcome stenosis by dilatation up to Hegar's 8 while hysteroscopy was just negotiation of the cervix. A need for larger studies, preferably in the form of randomized controlled trials, is an obvious limitation of this study. This study added a novel use of office hysteroscopy which is under vision cervical canal negotiation of severe tight cervical stenosis which was proved to be superior to blind cervical probing. Furthermore, it offers excellent guidance for subsequent easier embryo transfer with more patient satisfaction. Study findings are valuable for day to day practice and deserve large sample sized future research.

Conflict of Interest

Darwish A, Darwish D and Zareh Z have no conflict of interest.

Ethical approval

"All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

Informed consent

"Informed consent was obtained from all individual participants included in the study."

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