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Original Article

Evaluation of a Novel, Disposable and Low-Cost Valve (Faheem Valve) for reducing the distension fluid leak in vaginoscopic hysteroscopy: A Comparative Study

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Abstract

Keyword:

Vaginoscopy -Vaginal lesions- cervical lesions - Faheem Valve.

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Objective: Continuous leakage of distension medium from the vagina during vaginoscopy consider one of the most important item that hindering proper visualization and prolong operation time. This study evaluates the effectiveness of performing vaginoscopy by using a self-retaining semi-conical silicon (platic) low cost valve (Faheem Valve) to minimize fluid leakage, improve visualization and minimize operative time.

Patients and Methods: Females referred for vaginoscopy were randomly selected to either conventional vaginoscopy (CV) group A, or the second group (group B) using Faheem valve vaginoscopy (FV). The study includes 30 cases, 15 cases in each group.

Results: Faheem valve group (FV) was more feasible with excellent visualization if compared with conventional vaginoscopy group (CV). The mean infused distension fluid volume was 376.67ml in FV versus 676.67 ml in conventional vaginoscopy (CV), and the mean amount of leaked fluid volume was 36 ml in FV versus 283.33 ml in conventional vaginoscopy (CV). Clear vision in Vaginoscopy using Faheem valve was 94% while 70% in conventional vaginoscopy (CV) and in the mean operation time 4 minutes in Faheem valve group, the mean operation time was 8 minutes in conventional group.

Conclusions: Faheem valve is a self-retaining novel tool, it provides an excellent visualization of vagina and cervix. Faheem Valve ensures less amount of fluid leakage and shortens operation time.

Introduction

Vaginoscopy, a diagnostic and therapeutic new procedure involving the inspection of the vagina wall .cervical fornices and the uterine cavity, has proven effectiveness in the management of all vaginal and intrauterine defects, including septum, synechia, polyps, myoma, and various structural anomalies such as unicornuate, bicornuate, T-shaped uterus, and Didelphis[1].

While conventional hysterscopy instruments such as cusco speculum and vollslum have been the standard tools in gynecological practice, their high cost and leak of distension media from vagina significant challenges. These limitations not only elevate healthcare expenditure but also restrict access to this vital procedure for a wide range of patients and lost much fluid, undermining the fundamental principle of equitable healthcare[2].

To our knowledge a small number of trials addressed this problem, one small but excellent study conducted by Prof. Atef Darwish, introduced a tight self-retaining external vulvar sheet (Darwish sheet) to minimize the leakage and improve the visualization via vaginoscopy[3].

Rational:

During conventional vaginoscopy, usually the operator starts by "closing" the vulva, the labia minora are often held together with the hands or gauze to prevent the leakage of distension fluid, which helps maintain a clear view of the vaginal canal and apex. This helps to create a closed environment for the fluid to expand the cavity and improve visualization, ensuring proper evaluation of vaginal lesions or other structures[4].
Vaginoscopy uses distension fluid to expand the vaginal cavity for better visualization. Holding the vulva together prevents this fluid from leaking out, allowing for clearer images. By containing the fluid, the entire cavity can be effectively expanded, providing a panoramic view of the vaginal walls and apex.
Proper fluid retention helps in accurately identifying lesions and anomalies, which is crucial for avoiding misdiagnosis[5].

Traditional instruments used during conventional hysteroscopy are shown in Fig (1)

Fig 1: instrument to be ready to be used during conventional vaginoscopy

In response to these limitations, we introduce the "Faheem valve," an innovative and purpose-driven tool designed to overcome the shortcomings of fluid leakage, offering enhanced ease of use, safety, durability, and cost-effectiveness.

The concept of Faheem valve was conceived as a response to the growing demand for a more accessible, efficient, and economical alternative to conventional vaginoscopy.

Aim

The primary aim of the study is to assess the effectiveness, safety, cost-effectiveness, and efficiency of the novel instrument (Faheem valve) in vaginoscopy. A comparative study has been conducted to evaluate its utility in treating leakage of distension media from vagina in case of vaginoscopy.

Patients and methods

A prospective cohort comparative study was performed at Obstetrics and Gynecology department Aswan specialized hospital, Aswan, Egypt, between December 2024 and January 2025.

Discerption of the instrument:

It is a permanent plastic barrier with a diameter of about 10 cm, with a 2 mm diameter opening in the middle through which the hystroscopic sheath is inserted. It is thick and thick at the ends so that it is fixed to the vaginal wall. (Fig 2)

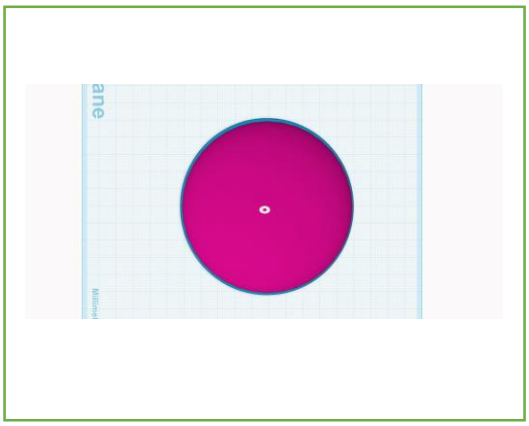


Fig 2: a diagram for Faheem Valve

There are two designs for the device.

1. The first type:

It consists of a flat, smooth, circular barrier made of reinforced plastic at the edges. The total area is approximately 10 cm, with a cavity or hole in the middle of approximately 2 mm to allow the easy entrance of the hysteroscope without leakage. (Fig 3)

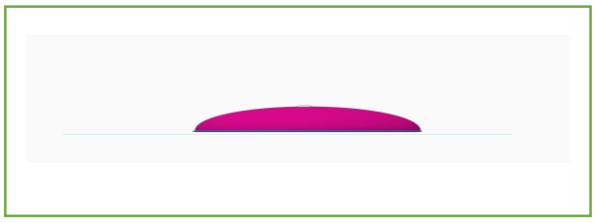


Fig 3: Flat Type Faheem Valve

2. The second type:

It is a conical, smooth-curved barrier made of reinforced plastic at the edges. The circumference is approximately 10 cm and the cavity in the middle is approximately 2 mm. (Fig 4).

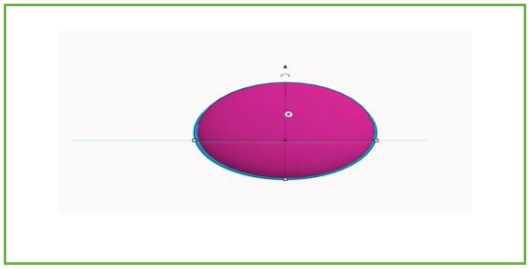
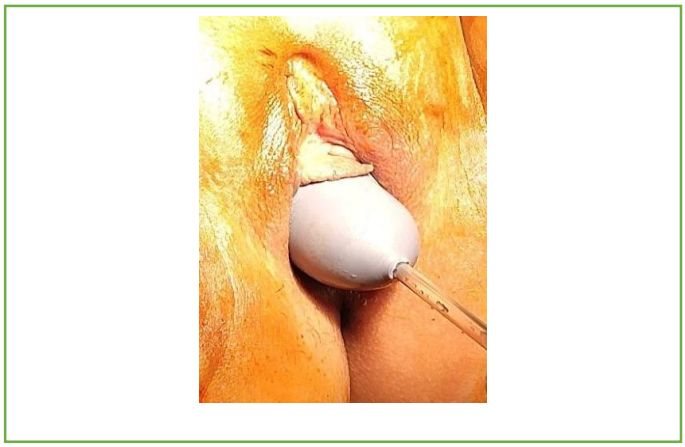


Fig 4: The conical type

Fig 4,5,6 showing clinical application and a descriptive diagram



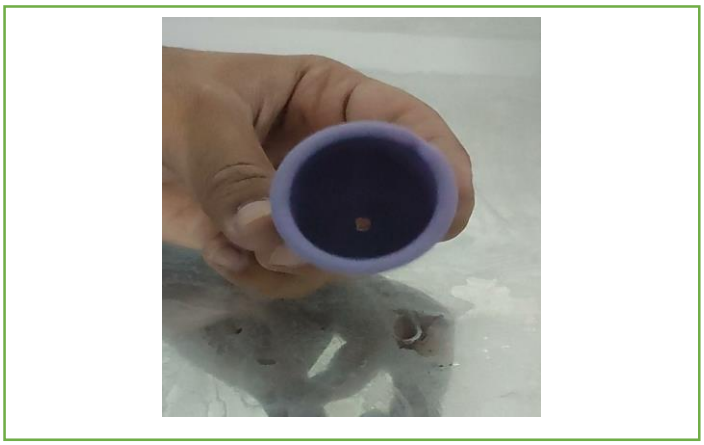


Fig 5: Faheem valve applied in the vulva **Fig 6: Faheem Valve outside the valva.**

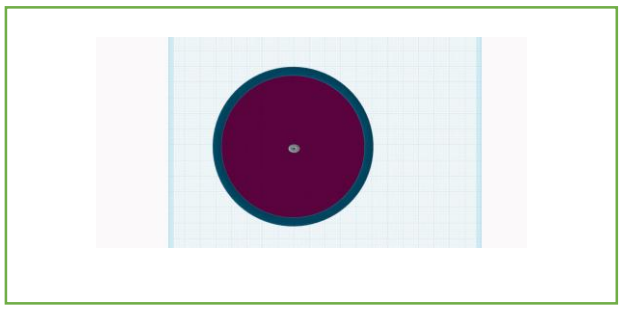


Fig 7: A diagram of Faheem Valve

Descriptive video for the diagram of Faheem Valve in the following link:
https://drive.google.com/file/d/1s-FFgIEEbJphrnqsHkA0AzWy32NCWYPS/view?usp=sharing&t=13

Patients:

Participants were selected from outpatients with referral to diagnostic hysteroscopy, after informed consent patients were enrolled in this study. All of them were mulliparous females scheduled for diagnostic vaginoscopy to confirm either vaginal or cervical lesions. Pre-operative history, laboratory investigation and high resolution 2D ultrasonography were done for all participant. Patients with definite or suspected vaginal or cervical lesions were included in this study. All cases were prepared for routine vaginoscopic surgery in the immediate postmenstrual period. The study was single-blinded, meaning the participants will not be aware of which group they are in, but the medical staff performing the procedures will be. The study group will be subjected to diagnostic vaginoscopy with Faheem Valve (Fig 1) and the control group will perform routine conventional vaginoscopy. All patients were placed in the dorsal lithotomy position, under general anaesthesia.

Group A:

The cases were subjected to conventional vaginoscopy group used a 2.9-mm 30-degree telescope loaded inside a 4-mm outer sheath and connected to a light cable, it was inserted inside the vaginal introitus and 0.9% saline irrigation with a pneumatic infusion pump was used. The vaginoscope was gradually advanced inside the vagina with reporting on the vaginal walls till the ectocervix. Proper examination of the vagina and cervix included the endocervical canal and the internal os.

Group B:

The experimental group (Faheen valve group), the same procedure was done but with application of Faheem valve the vaginoscope penetrates a sterile self-retaining tight external silicone semi-conical valve (Faheem valve) measuring 10 to 15 cm, which is applied at the introitus of the vulva with a narrow central opining 3 mm to allow entrance of the vaginoscope and prevent reflux of the irrigating fluid from the vagina.

A descriptive video for the application of Faheem valve in the following link:

Case 1:

https://drive.google.com/file/d/18TeHNe9XF-A1_MXtYgSO6YYkqs-LXsle/view?usp=sharing&t=11

Case 2:

https://drive.google.com/file/d/1SwVbrGNVXSpLWyB44BAIiFYP2Z23eqWo/view?usp=sharing&t=3

A comment on the clarity of visualization and access to diagnosis, operative time and any possible complications was made. The amount of irrigated distension medium as well as escaped amount in the suction unit and that collected in a sterile plastic bag embedded under the buttocks of the patient was collected and measured after every case. All endoscopic equipment's were manufactured by Storz Co. (Tuttlingen, Germany).

Postoperatively, the patients were kept under observation for 2–4 h and discharged whenever stable. All cases were followed up at least once after the next menses and examined clinically and by ultrasonography.

Data entry and analysis were done using SPSS (Statistical Package for Social Science) version 19. Data were presented as frequency, percentage, mean and standard deviation. Chi-square test for categorical variables and t-tests for continuous variables. *P*-value was considered statistically significant when $P \leq 0.05$.

Results

This study comprised 30 consecutive patients referred for vaginoscopy. All were adult multiparous females, the mean age in conventional vaginoscopy group is 30.5 (19-39), and in Faheem Valve using group is 30.3 (22-38) with no statistical significant difference. The reasons for vaginoscopy mainly were secondary infertility (23 cases) and the other (7 cases) were complaining of persistent vaginal discharge associated with pruritus. During Vaginoscopy a cervical or vaginal polyp were diagnosed in 3 cases (10%), chronic non-specific cervicitis in 6 cases (20%) and in 21 cases no abnormal finding (70%). Diagnostic conventional vaginoscopy (CV) significantly required more fluid volume (mean volume 676. 67 ml), fluid volume in FC group was significantly less amount (mean 367.67 ml). (Table 1). Fluid Leakage of vagina is more escaped in CV group than FV group, 283 and 36 mL respectively. Clinical presentation of each group are shown in (Fig 8) Conventional Vaginoscopy (CV): infertility 80% (n=12) and discharge 20% (n=3)

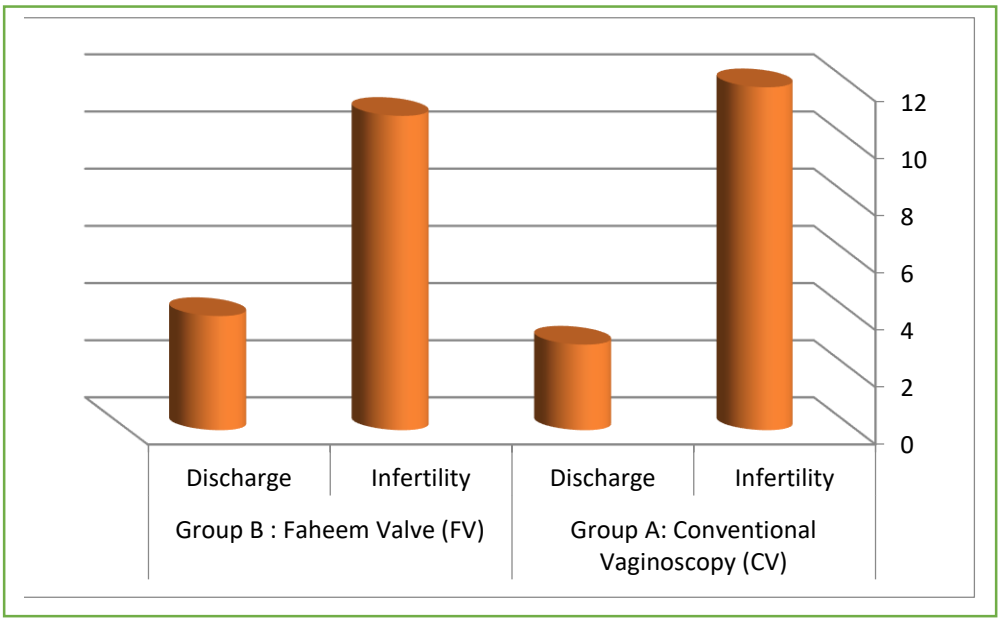


Fig 8: Clinical presentation

Operative time during conventional vaginoscopy group is double the time using Faheem valve, Mean 3.957 and 8, (P-Value < 0.05).

Clear vision is more in Faheem valve group (94%), than conventional hysteroscopy (70%) Poor visualization mainly due to fluid escape and poor distension is more in CV group (5 cases and two cases respectively) (Fig 9)

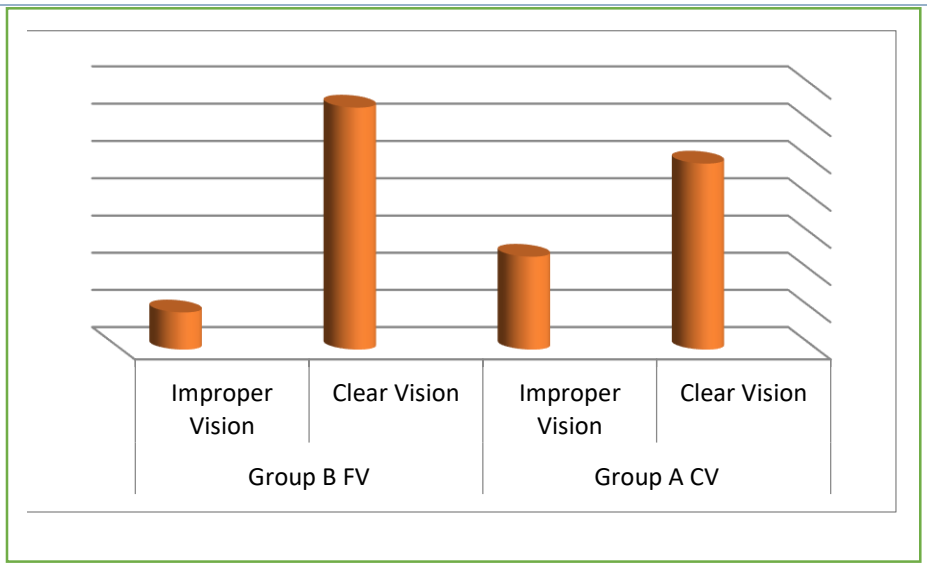


Fig 9: clarity of vision

Discussion

Clinical use of vaginoscopy in modern practice is limited due to many factors like scare publications, the rarity of vaginal lesions, lack of experience and orientation and poor visualization due to distending medium leakage from the vagina. In a systematic review[6], only 13 studies on vaginohysteroscopy have been reported. Ten of them (77%) were published after 2005. Eleven papers described a single case report, one paper reported two case reports and one paper reported a case series of 28 cases[7]. Between 2004 and 2013, only 20 girls with persistent vaginal discharge were examined by vaginoscopy at a university hospital[8]. Difficult vaginoscopy is usually expected, particularly in girls due to the natural narrowing of the vagina, their desire to keep intact hymen, and the restricted view[9] . Unlike hysteroscopy, even on maximal fluid flow, vaginal distension is very difficult due to low intravaginal pressure as the vagina is opened to the exterior with continuous leakage of fluid. This study highlights an innovative simple modification to improve visualization and surgical success whenever performing vaginoscopy in girls and nulliparous patients with narrow vaginas.

During vaginoscopy, minimizing fluid leakage from the vagina can be accomplished by manual compression of the labial tissue to narrow the vaginal introitus as recommended by ACOG[10]. Unfortunately, it leads to incomplete elimination of irrigating fluid leakage. Moreover, the surgeon is usually busy during vaginal surgery in a narrow space and usually uses both hands during vaginal resectoscopy. In this study, we used a sterile self-retaining well-fitted external vulvar sheet (Darwish sheet) omitting vulvar tightness by hands. Moreover, there is no need for a nurse or assistant compression of the labia using this technique. This modification allows proper fitting with free hands of the surgeon. Limitations of this study include small sample size, which is attributed to the rarity of cases. The same cause stands behind using the same case to compare CV and TV sequentially without a comparison group. Heterogeneity of cases is another limiting issue of this study. Any research on a novel procedure for rare indications with limited clinical experience would be defective. Although it is a case series with some methodological limitations, it can be helpful in generating a hypothesis that can be tested in further analytic studies[11]. All these limitations would be overcome whenever a large sample-sized multi-centric study would be initiated in future. It is concluded that accomplishing vulvar tightness using a self-retaining tight external vulvar sheet (Darwish sheet) during vaginoscopy (TV) is associated with a

better vaginal seal to minimize escape of irrigation fluid, clearer visualization of vaginal or cervical lesions, and lesser requirement of the amount of irrigating fluid as compared to CV. Its routine use as a cheap basic step during diagnostic and therapeutic vaginoscopy is recommended.

Conclusions

Faheem valve is a self-retaining novel tool, it provides an excellent visualization of vagina and cervix. Faheem Valve ensures less amount of fluid leakage and shortens operation time.

Ethical Considerations

The study was conducted after the ethical approval of IRB at Aswan specialty Hospital. The study is adhered to the guidelines of the Declaration of Helsinki. Participants will provide informed consent. All data will be anonymized.

Abbreviations

CV: conventional vaginoscopy
FV: Faheem Valve vaginoscopy

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Conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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