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Original Article

Evaluating the Efficacy of a Novel Disposable Instrument in Operative Hysteroscopy Hossam Knife (H- Knife)

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Abstract

Keyword:

Hysteroscopy, Hossam Faheem, H-knife, operative hysteroscopy.

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Abstract:

H- Knife is a new surgical instrument innovated by Dr. Hossam Faheem to facilitate surgical intrauterine hysteroscopy operation. This instrument was tested in management of FIGO 0 myoma, intrauterine psynechia and septum removal successfully without immediate complication. The aim of this work was to evaluate the role of Hossam knife (H-Knife) management of intrauterine pathology during hysteroscopy. H-Knife is a new surgical instrument innovated by Dr. Hossam Faheem to facilitate surgical intrauterine hysteroscopy operations. This instrument was tested in the management of FIGO 0 myoma, intrauterine synechiae, and septum removal successfully without immediate complications. The aim of this work was to evaluate the role of the Hossam Knife (H-Knife) in the management of intrauterine pathology during hysteroscopy.

Methods: This prospective study was conducted at department of Obstetrics and Gynecology, Aswan specialty hospital during the period from January 2023 to June 2023. It included 5 cases of primary and secondary infertile women aged between 18-45 years. Proper preoperative investigations with Endo-vaginal ultrasonography and Hystero-salpingeography, were done.

Results: Five cases operated successfully using H-Knife during hysteroscopy, - uterine myoma FIGO 0, uterine polyp, uterine septum and uterine synchia. No immediate postoperative complications were encountered.

Conclusions: Hossam Knife (H- knife) effective in management some cases of intrauterine pathology.

Recommendation: To expand the study to include a large number of cases with design a RCT to compare using H-Knife and hyterescopic scissors in terms of; efficacy, operative time, side effect, long outcome and cost effectiveness.

Introduction

Hysteroscopy is a crucial diagnostic and therapeutic tool for identifying and treating intrauterine defects, which include structural anomalies like septate or bicornuate uterus, and acquired issues such as synechiae, polyps, and fibroids. These defects can lead to significant reproductive health problems, including infertility, recurrent miscarriages, and abnormal bleeding. By providing direct visualization and enabling intervention, hysteroscopy helps to accurately diagnose these conditions and improve outcomes for affected individuals[1].

Hysteroscopic metroplasty improved reproductive outcomes in women with a septate uterus and otherwise unexplained infertility[2]. Although hysteroscopic metroplasty seems to be indicated in patients with recurrent abortions and normal fertility, in view of its efficacy and the absence of any harmful effect on the achievement of pregnancy, there is always a debate concerning the patients presenting with infertility[3].

There is a significant challenge with traditional hysteroscopy instruments, specifically their high cost and fragility, which increase healthcare expenses and limit access to the procedure for patients. This situation hinders equitable healthcare by making a vital diagnostic and surgical tool less accessible to many[4]. Resection of the vaginal septum is easily performed; hysteroscopic resection of uterine septum requires more experience and is generally indicated, particularly in women with poor reproductive outcomes. The union of the two cervices remains controversial[5].

The hysteroscopic approach to treatment, with its simplicity, minimal postoperative sequelae, and improved reproductive outcome, has enabled a more liberalized approach to treatment that is now being extended to include not only patients with

recurrent pregnancy loss and premature labor but also patients with infertility, especially if IVF is being contemplated[6].

Rational:

In response to high cost and frangibility of hysterescopic instruments, Dr. Hossam Faheem introduced the " Hossam Knife (H- Knife), a novel and purpose-driven instrument designed to overcome the short comings of traditional scissors. The “H-Knife” represents a paradigm shift in hysteroscopic surgery, offering enhanced ease of use, safety, durability, and cost-effectiveness. In this research proposal, we embark on a journey to introduce, evaluate, and validate the potential of the (H-Knife) as a pivotal addition to the armamentarium of gynecological surgeons.

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Materials and methods

This prospective study was conducted at department of Obstetrics and Gynecology, at Aswan specialty Hospital during the period study at January 2023 to June 2023. The study included patients between the ages of 18 and 35 who experiencing secondary infertility for more than a year. Secondary infertile patients had at least one prior conception, regardless of the outcome.

Exclusion Criteria were; women with any contraindications to surgery, such as cardiac disease, chronic chest disease. All patients examined in the early proliferative phase of the cycle.

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Selection of cases:

Assuming that all cases fulfill the inclusion and exclusion criteria during the study period (6 months), 5 cases were included in the study. Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Aswan specialty Hospital.

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Methodology:

Detailed medical, menstrual and obstetrical history were done to all participants. Investigations included; Pelvic ultrasound, Hysterosalpingography (HSG) and 3D ultrasonography. General examination, abdominal examination and vaginal (P.V)

examination and bimanual examination were done. Diagnostic hysteroscopy examination was done using diagnostic mini-hysteroscopy (continuous flow rigid Hamou type II hysteroscope, 30 cm long, 2.8 mm in diameter with 30 viewing angle, the outer sheath 3.8 mm in diameter. was used during diagnostic procedure. Distension medium with Saline was used in this study. It is supplied in soft plastic bags containing 1000cc put in infusion cuff. To obtain adequate uterine distension, good view and to wash out any tissue particles or gas bubbles.

Detailed medical, menstrual, and obstetrical histories were taken from all participants. Investigations included pelvic ultrasound, hysterosalpingography (HSG), and 3D ultrasonography. General examination, abdominal examination, vaginal (P.V.) examination, and bimanual examination were performed. Diagnostic hysteroscopy was conducted using a diagnostic mini-hysteroscope (continuous flow rigid Hamou type II hysteroscope, 30 cm long, 2.8 mm in diameter with a 30-degree viewing angle; the outer sheath was 3.8 mm in diameter). Distension medium with saline was used in this study, supplied in soft plastic bags containing 1000 cc, placed in an infusion cuff. This was done to obtain adequate uterine distension, a good view, and to wash out any tissue particles or gas bubbles.

Interventions

Operative hysteroscopy using the novel, disposable hysteroscopy instrument developed for this procedures, Hossam Knife (H Kinfe). It is a sharp instrument like the scissor of hysteroscopy in its function but it designed to have only one sharp arm from two sides for hysteroscopy resection and cutting of. (Fig 1).

The length of the shaft of knife, come in two types, 30 cm and 45 cm and the width 1, 6 mm to be easily introduced throw the hysteroscopy sheath under vision of camera. The H knife can cut all the uterine defects sharply from both sides. (Fig 2). It has a blunt bulb at the end the knife to be hold by the surgeon. (FIG 3)

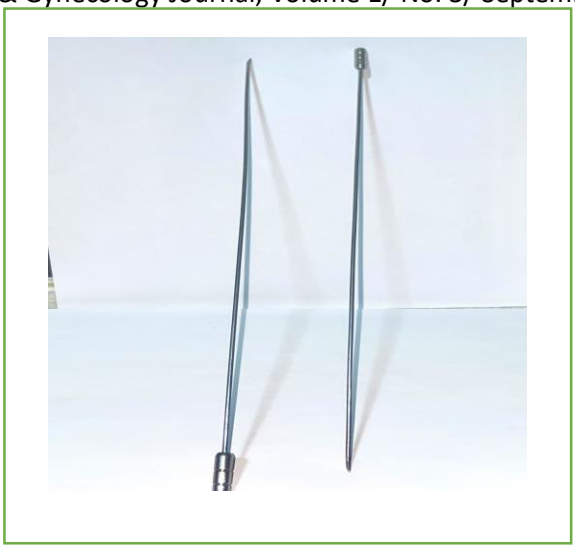

Fig (1) the tip of the H- knife

Fig (2) the shaft of H knife.

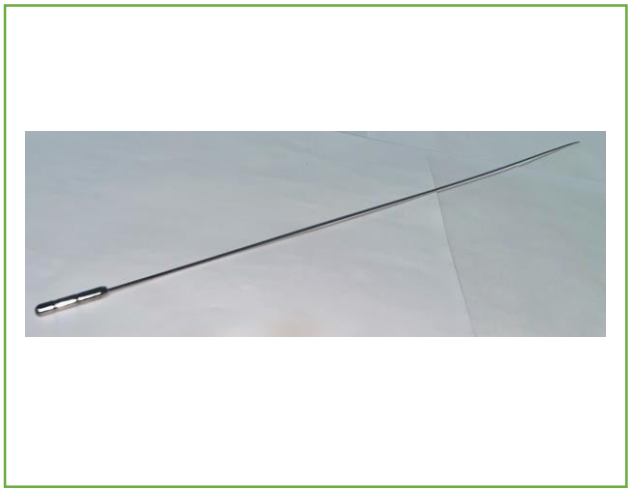

Fig (3) the end of the H knife

Video for the H- Knife:

https://drive.google.com/drive/folders/1JWVLZUb5PpKTeAR9YhndEd1FKzhBUdXp

Operative hysteroscopy using the novel, disposable hysteroscopy instrument developed for this procedure, Hossam Knife (H Knife). It is a sharp instrument similar to the scissors used in hysteroscopy in its function, but it is designed to have only one sharp arm on two sides for hysteroscopic resection and cutting (Fig. 1). The length of the shaft of the knife comes in two types: 30 cm and 45 cm, and the width

is 1.6 mm to be easily introduced through the hysteroscopy sheath under the vision of the camera.

Clinical Application & Results:

Case I

Female patient 27 years old primary infertility 4 year diagnosed as complete uterine septum by HSG. H-knife was introduced into the sheath of hysteroscopy and starts to cut the septum from right to left side, the septum resected completely. (Video2)
Female patient, 27 years old, with primary infertility for 4 years, diagnosed with a complete uterine septum by HSG. An H-knife was introduced into the sheath of the hysteroscope and started to cut the septum from the right to the left side; the septum was resected completely.
https://drive.google.com/drive/folders/1JWVLZUb5PpKTeAR9YhndEd1FKzhBUdXp

Case II

Female patient 23 years old 2nd infertility 2 year past history CS since 3 years. This case was diagnosed as incomplete intrauterine synechia by HSG. During operation the knife was introduced to hysteroscopy with carefulness and start to cut the synechia by both side till it reaches the uterine ostuim and lateral uterine wall. (video 3)
Female patient, 23 years old, with a history of 2 years of infertility and a past history of cesarean section 3 years ago. This case was diagnosed as incomplete intrauterine synechia by HSG. During the operation, the knife was introduced to the hysteroscope with care, and the synechia was cut from both sides until it reached the uterine ostium and lateral uterine wall.

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Case 11I

Female patient 31 years old P 2- 2, 2nd infertility 5 year, past history of 2 abortions during first trimester. It diagnosed as small uterine myoma (Figo grade 1) by 3D ultrasonography. During the operation H Knife was introduced then start to cut the myoma till its base. The myoma could be resected completely. (Video 4)

Female patient, 31 years old, P 2-2, with 2nd infertility for 5 years, has a past history of 2 abortions during the first trimester. She was diagnosed with a small uterine myoma (FIGO grade 1) by 3D ultrasonography. During the operation, a knife was introduced, and then the myoma was cut until its base. The myoma could be resected completely.

https://drive.google.com/file/d/11V7xvmzj8KkmQg7Akq7gFca-MIKJ4tKO/view?usp=drivesdk

Case VI

Female patient 21 years old 1ry infertility 3 years, diagnosed as small uterine myoma (FIGO grade 0) by 3D ultrasound, during operative hysteroscopy K-knife was introduced then the myoma was completely resected till its base. (Video 5)

Female patient, 21 years old, with primary infertility for 3 years, diagnosed with a small uterine myoma (FIGO grade 0) by 3D ultrasound. During operative hysteroscopy, a K-knife was introduced, and the myoma was completely resected down to its base.

https://drive.google.com/drive/folders/1JWVLZUb5PpKTeAR9YhndEd1FKzhBUdXp

Case V

Female patient 28 years old 2nd infertility 3 years, diagnosed as incomplete septum by 3D ultrasound, during operative hysteroscopy we introduced H- knife and the septum started to be cutting using two sharp direction till clear view of the level of 2 ostium at the fundus. (Video 6)

Female patient, 28 years old, with 2nd infertility for 3 years, diagnosed with an incomplete septum by 3D ultrasound. During operative hysteroscopy, we introduced an H-knife, and the septum started to be cut using two sharp directions until a clear view of the level of the two ostia at the fundus was achieved.

https://drive.google.com/file/d/13q1ewQYfoZKyAmiF8oSvKcEh2oi742rd/view?usp=drivesdk

The summary of the cases (Tab1), show that H-knife used successfully in intrauterine pathology with no immediate complication with satisfactory results.

Table 1: a summary of clinical application of H-Knife

No.	Age	Married Period	Infertility	Diagnosis
1	27	4	4	Incomplete septum
2	23	2	4	incomplete intrauterine synichia
3	31	5	5	small uterine myoma (FIGO grade I)
4	21	3	3	myoma (FIGO grade 0)
5	28	3	3	incomplete septum

Discussion

The treatment of Müllerian anomalies, such as a double uterus, where hysteroscopic metroplasty is presented as the recommended approach for most septate uteri due to its relative simplicity, low morbidity, and excellent reproductive outcomes compared to conventional methods[7]. the use of hysteroscopic metroplasty to treat women with a septate uterus, a common congenital uterine anomaly known to cause reproductive issues like recurrent miscarriage and preterm birth. Hysteroscopic metroplasty aims to improve reproductive outcomes by correcting the uterine septum, and the citation points to its role as a corrective approach for such patients[8].

The treatment of Müllerian anomalies, such as a double uterus, where hysteroscopic metroplasty is presented as the recommended approach for most septate uteri due to its relative simplicity, low morbidity, and excellent reproductive outcomes compared to conventional methods. The use of hysteroscopic metroplasty to treat women with a septate uterus, a common congenital uterine anomaly known to cause reproductive issues like recurrent miscarriage and preterm birth, aims to improve reproductive outcomes by correcting the uterine septum, and the citation points to its role as a corrective approach for such patients.

Resection of a septum has been shown to improve outcomes in patients with recurrent pregnancy loss and to decrease the likelihood of malpresentation. In the setting of infertility, it is recommended to use a shared decision-making model after appropriate counseling to determine whether or not to proceed with septum resection[9].

In one study, Hysteroscopic incision of uterine septum in women with repeated abortion. using metroplasty with resectoscope and microscissors shown to have negligible postoperative morbidity and both the resectoscope and microscissors are

equally valid instruments to correct a septate uterus, with a feasibility rate of 100 percent[10].

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In one study, hysteroscopic incision of the uterine septum in women with repeated abortion using metroplasty with a resectoscope and microscissors was shown to have negligible postoperative morbidity, and both the resectoscope and microscissors are equally valid instruments to correct a septate uterus, with a feasibility rate of 100 percent.

In another study, early and late complications were encountered. Early complications: unsuccessful cervical dilatation; uterus perforation; uterine bleeding; intravasation; impossibility of septum incision; incomplete myoma enucleation; impossibility to reconstruct womb in the whole. Late complications: post-operative bleeding; increased body temperature; pain in lower abdomen [11].

The traditional scissors are expensive and one of the most challenges of using the traditional scissor is that it is frangibility and easily breaking during changing direction inside the uterus to cut any abnormality. H-knife is very effective and low cost sheep instrument. No early or late complications encountered by using H-knife in the selected cases, so it is save as it used by experienced hands. It is disposable need no reserialization, so it can protect the patient from transmitted blood diseases.

In another study, early and late complications were encountered. Early complications included unsuccessful cervical dilatation, uterine perforation, uterine bleeding, intravasation, impossibility of septum incision, incomplete myoma enucleation, and impossibility to reconstruct the womb as a whole. Late complications included post-operative bleeding, increased body temperature, and pain in the lower abdomen.

The traditional scissors are expensive, and one of the biggest challenges of using traditional scissors is their fragility and tendency to break easily when changing direction inside the uterus to cut any abnormality. The H-knife is a very effective and low-cost surgical instrument. No early or late complications were encountered when using the H-knife in the selected cases, so it is safe when used by experienced hands. It is disposable and requires no re-sterilization, which can protect the patient from transmitted blood diseases.

Conclusions: -

Hossam Knife (H- knife) is low cost and effective instrument, it can be used in management selected cases of intrauterine pathology. It was used successfully to completely remove intrauterine myoma, intrauterine synechia and intrauterine septum without any early or late complications.

Hossam Knife (H-knife) is a low-cost and effective instrument; it can be used in the management of selected cases of intrauterine pathology. It has been used successfully to completely remove intrauterine myomas, intrauterine synechiae, and intrauterine septa without any early or late complications.

Recommendation

To expand the study to include a large number of cases, also to design a RCT to compare using H-Knife and hyterescopic scissors in terms of; efficacy, operative time, side effect, late outcome and cost effectiveness. As is a sharp instrument like

scissors so we recommend to be used by expert operator, also we highly recommend in case of using the instruments by juniors to be under complete supervision by a senior surgeon till their learning curve allow using the instrument independently.

To expand the study to include a large number of cases, we also aim to design a RCT to compare the use of H-Knife and hysteroscopic scissors in terms of efficacy, operative time, side effects, late outcomes, and cost-effectiveness. As scissors are sharp instruments, we recommend that they be used by expert operators. Additionally, we highly recommend that if juniors use these instruments, they do so under the complete supervision of a senior surgeon until their learning curve allows them to use the instruments independently.

Ethical Considerations

The study will be conducted after the ethical approval of IRB at Aswan specialty Hospital. The study was adhering to the guidelines of the Declaration of Helsinki. Participants were provided informed consent. All data have been anonymized.

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