Gynecology and Minimally Invasive Therapy 4 (2015) 87–90

Contents lists available at ScienceDirect

Gynecology and Minimally Invasive Therapy

journal homepage: www.e-gmit.com

Original article

Invention of a new Lin soft outer sheath as a continuous flow system for diagnostic flexible hysteroscopy

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ARTICLE INFO

Article history:
Received 27 May 2014
Received in revised form
18 December 2014
Accepted 18 January 2015
Available online 8 April 2015

Keywords:
continuous flow
flexible hysteroscopy
uterine bleeding

ABSTRACT

Objectives: This study aims to evaluate the efficacy of a newly developed Lin soft outer sheath that is used as a continuous flow system for outpatient flexible hysteroscopy.
Materials and methods: Diagnostic hysteroscopy was performed in 134 patients who presented to our center with uterine bleeding over the 25-month study period. The flexible hysteroscope was equipped with a Lin soft outer sheath.
Results: Hysteroscope insertion failure was observed in six cases of, i.e., an insertion failure rate of 4.5%. Out of the other 128 women, accurate diagnosis of four patients could not be made because of intrauterine blood clots, i.e., a success rate of 92.5%. No complication, except postprocedure bleeding for a few days, was encountered.
Conclusion: The new Lin soft outer sheath is effective as a continuous flow system for outpatient flexible hysteroscopy.

Introduction

Outpatient flexible hysteroscopy is well established as a diagnostic and sometimes even as a therapeutic procedure.[1,2] However unexpected uterine bleeding may lead to examination failure due to a poor operative view. We introduced a new Lin soft outer sheath as a continuous flow system for flexible hysteroscopy. We aim to explain its mechanism and demonstrate its effective use in our center.

A small-caliber flexible hysteroscope can be used for intrauterine diagnosis without cervical dilatation, anesthesia, analgesia, or even using a tenaculum. However, the hysteroscope may easily cause traumatic endometrial bleeding during the examination. The bleeding may, in turn, impair visualization, leading to a failed examination. In cases of menstrual or abnormal uterine bleeding, it is the usual practice to postpone the examination. The same problem is encountered if the bleeding cannot be stopped by tranexamic acid, progesterone, progestogens, Gonadotropin-releasing hormone (GnRH) analogues, etc. The best way to tackle this issue is to develop a continuous flow system for the flexible hysteroscope that can constantly provide a clear intrauterine view. In rigid hysteroscopy, this is already provided by the combined use of an inner and an outer sheath as an inflow and an outflow channel, respectively. However, no such continuous flow system is available for flexible hysteroscopy. We invented type 1 continuous-flow soft outer sheath for flexible hysteroscopy in 1997[3] and type 2 in 2010. In 2012, type 3 prototype was built, and it was modified in 2013. Here, we report our results of using a type 3 soft outer sheath as a continuous flow system.

Materials and methods

The Lin soft outer sheath (4.5 mm outer diameter, 110 mm in length; Hakoshoji Co., Saitama, Japan; Fig. 1A) is made of polyvinyl chloride. It consists of two parts: the front main shaft and the rear part that is used to hold the sheath. Fig. 1B shows the Lin soft outer sheath that holds a 3.1 mm flexible hysteroscope (Olympus Optical Co., Tokyo Japan).

Prior to examination, the flexible hysteroscope is introduced into the soft sheath. The tip of the sheath is positioned 1 cm behind

Conflicts of interest: The authors declare no conflicts of interest.

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http://dx.doi.org/10.1016/j.gmit.2015.01.007
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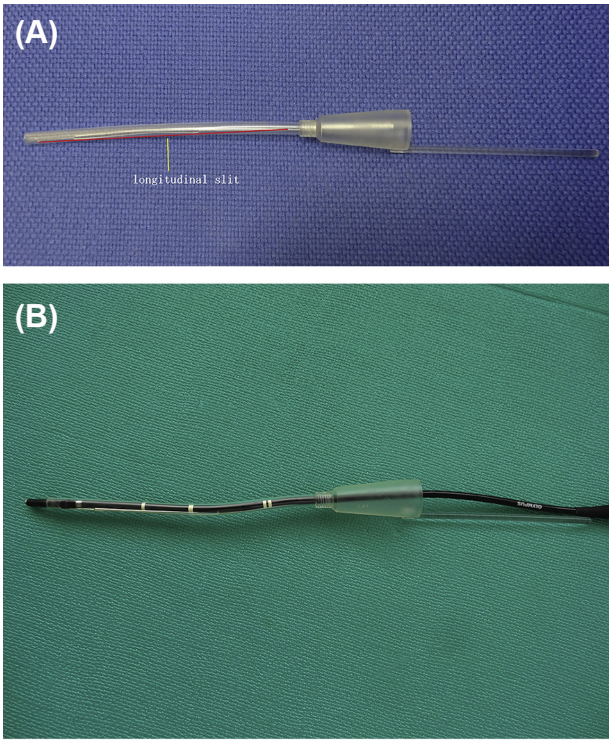

Fig. 1. (A) Type 3 soft outer sheath. It consists of two parts: the front main shaft and the rear part that is used to hold the sheath. A longitudinal slit (red line) on the sidewall of the shaft is incised for drainage of the fluid. (B) Lin soft outer sheath holds a flexible hysteroscope. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

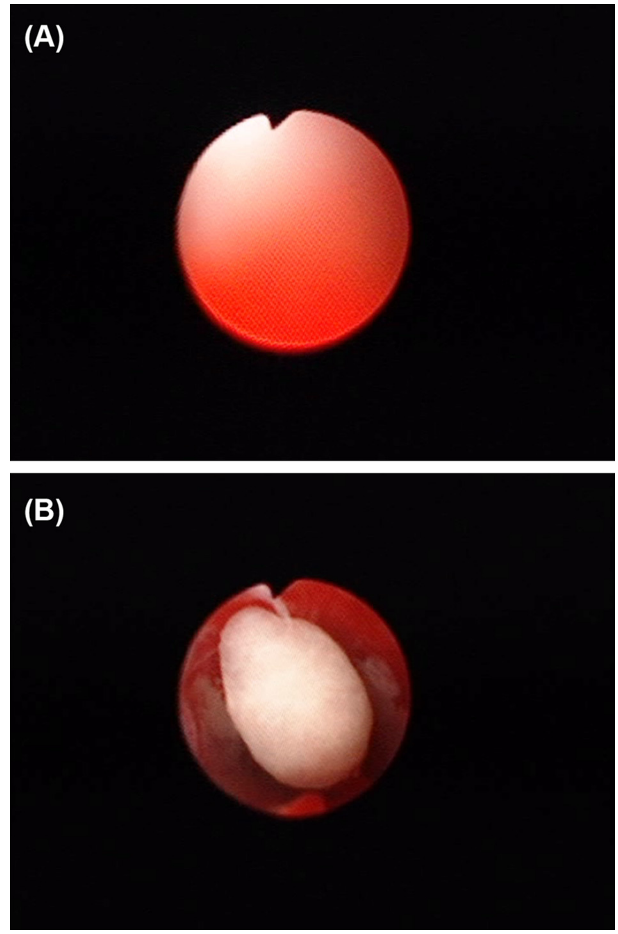

Fig. 2. (A) Cloudy hysteroscopic visual field caused by intrauterine bleeding at the time of hysteroscopic insertion. (B) An endometrial polyp is seen clearly 20 seconds after the insertion.

the tip of the hysteroscope. Tenaculum, cervical dilation, analgesia, and anesthesia are not used. A 5% glucose bag is suspended approximately 80 cm above the level of the uterus and is connected to the scope through an intravenous infusion set. If distension is insufficient, a pressure cuff with a pressure of 50 mmHg is placed around the plastic bag to increase the irrigation pressure. Holding together the shaft of the hysteroscope and the rear part of the sheath, the hysteroscope is inserted into the cervical canal and the intrauterine cavity under direct vision. Fig. 2A shows the cloudy hysteroscopic visual field developed due to intrauterine bleeding at the time of hysteroscopic insertion. Twenty seconds after the insertion, an endometrial polyp is seen (Fig. 2B).

From May 1, 2012 to May 31, 2014, a total of 134 patients who presented with uterine bleeding to our center were recruited into the study and underwent diagnostic examination using a 3.1-mm-diameter flexible hysteroscope. Their data were collected and studied in details.

Results

Patients' age ranged from 25 years to 68 years. The indications for hysteroscopic examinations were as follows: abnormal uterine bleeding in 71 patients, early second-look hysteroscopy after hysteroscopic operation in 51 patients, suspected endometrial polyps in four patients, infertility in four patients, missing intrauterine contraceptive device (IUCD) in two patients, and suspected Asherman's syndrome in two patients. Seventy-four hysteroscopic examinations were carried out between Day 1 and Day 8 of the menstrual cycle. The rest had abnormal uterine bleeding at the time of examination. Hysteroscope insertion failure was observed in six cases, i.e., an insertion failure rate of 4.5%. Observations could be made in all of the other 128 patients, except in four patients where an accurate diagnosis could not be made because of intrauterine blood clots, i.e., the success rate was 92.5%.

Hysteroscopic diagnoses were as follows: submucosal myoma in 56 patients, normal uterine cavity immediately after removal of FD-1 (Fuji latex Co., Tochigi, Japan) IUCD in 32 patients, FD-1 IUCD in place in 13 patients, endometrial polyps in six patients, intrauterine adhesions in four patients, adenomyoma in three patients, multiload IUCD in two patients, thread foreign body in one patient, and normal uterine cavity in seven patients. Two women with lost multiload IUCD underwent subsequent successful retrieval in the office.[4] Women with adenomyoma often complained of abnormal uterine bleeding. An adenomyoma usually appears gray in color and looks like a submucosal myoma, but with the engorgement of superficial blood vessels. Sometimes, it may be difficult to be differentiated from a submucosal myoma. No complication except for a few days of postprocedure bleeding was encountered.

Discussion

Two types of distension media are commonly used for diagnostic hysteroscopy.[5] One is carbon dioxide and the other is a low-viscosity fluid. Fluid hysteroscopy provides a better vision than CO_2 hysteroscopy during uterine bleeding. According to the results of our blood dilution test,[6] glucose solution allows a clearer vision when it is compared to normal saline, if intrauterine bleeding is

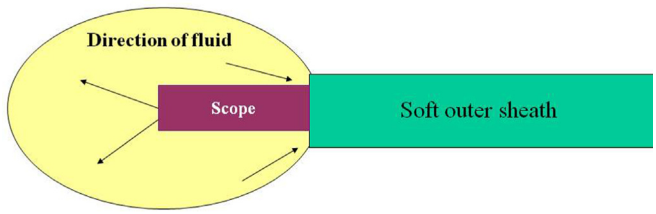

Fig. 3. Type 1 soft outer sheath flow mechanism. The fluid that flows into the intrauterine cavity from the irrigating channel washes the entire cavity and is drained out through the space between the hysteroscope and the sheath.

encountered. We used 10% glucose solution as the uterine distension medium in the past. However, we found that high osmolarity of 10% glucose might affect cell chromatin and disturb intraoperative cytological diagnosis. Hence, we switched to 5% glucose solution for uterine distension. Despite using 5% glucose solution, it may still be difficult to get a clear vision when increased bleeding occurs.

In 1997, we developed type 1 soft outer sheath as a continuous flow system for diagnostic flexible hysteroscopy. The fluid that flowed into the intrauterine cavity from the irrigating channel washed the entire cavity and was drained out through the space between the hysteroscope and the sheath (Fig. 3). However, the space for draining the fluid was so narrow that it was easily blocked by either blood clots or the exfoliated endometrium, impairing the function of the continuous flow system. To counter this problem, we developed type 2 soft outer sheath in 2010. This sheath ($7 \times 110\ mm^2$) was composed of two channels, one for the insertion of the hysteroscope and the other for the drainage of the irrigation fluid. The fluid that came from the irrigating channel of the hysteroscope was drained from the second minor channel that ran parallel to the main shaft (Fig. 4). The irrigating effect was very good. Clear visualization of the hysteroscope could be achieved. Owing to the diameter of a type 2 sheath, insertion of the hysteroscope equipped with a type 2 sheath became difficult, especially for nulliparous women.

In 2012, we developed type 3 (Fig. 1A) soft outer sheath, in which we made a longitudinal incision on the sidewall of type 1 sheath. Fig. 5 shows its mechanism for a continuous flow. Due to the increased intrauterine pressure and the capillary phenomenon of the incised part, the fluid is drained out of the intrauterine cavity quickly and smoothly. The drainage system is rarely blocked by either the flaking-off pieces of the endometrium or the blood clots. A high success rate of 92.5% in our study elicits the effectiveness of the latest Lin soft outer sheath. The sheath diameter is small, making the insertion of the hysteroscope into the cervix easy. This is demonstrated by a low insertion failure rate of 4.5%.

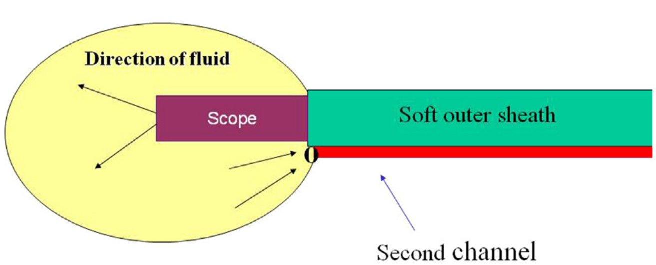

Fig. 4. Type 2 soft outer sheath flow mechanism. This sheath is composed of two channels, one for insertion of the hysteroscope and the other for drainage of the irrigating fluid. The fluid that comes from the irrigating channel of the hysteroscope is drained out from the second channel.

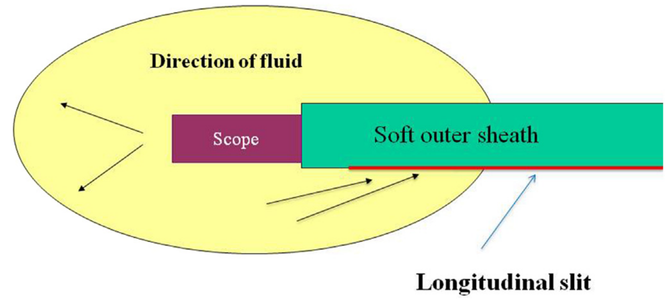

Fig. 5. Type 3 soft outer sheath flow mechanism. A longitudinal slit on the sidewall of the shaft is incised for drainage of the fluid. Increased intrauterine pressure and the capillary phenomenon of the incised part cause the fluid to be drained out of the intrauterine cavity.

Originally, the sheath was made partly by polyvinyl chloride and partly by metal. In the process, we realized that the metal part might damage the hysteroscope if we did not pay careful attention. We then replaced this sheath with a softer variety that was made using polyvinyl chloride only.

A Lin sheath provides a continuous flow system that enables intrauterine examination even with uterine bleeding. If the initial view is poor, further advancement into the uterine cavity may increase the outflow of the fluid and provide a better visualization. Unfortunately, common coexistence of blood clots creates diagnostic challenges. Moving the blood clot using the tip of the hysteroscope allows one to check the lesion behind the blood clot. Performing either simultaneous abdominal ultrasound or vaginal ultrasound immediately after the hysteroscopy[7] can improve the diagnosis. A second hysteroscopic examination after profuse uterine bleeding is stopped by medication is still recommended whenever it is deemed necessary.

In women who wish to retain fertility after transcervical resection of myomata,[8] we insert an FD-1 IUCD to prevent intrauterine adhesions and remove the IUCD 1 month later at the time of second-look hysteroscopy. It is easy to perform the hysteroscopic examination with the FD-1 IUCD in place and when the woman is not having her menstruation. If menstruation is encountered, we suggest to remove the FD-1 IUCD first, as this may remove intrauterine blood clots at the same time. Although IUCD removal may induce uterine contractions and cause excessive bleeding, leading to a difficult hysteroscopic examination, this is still preferred in our opinion. With an effective Lin soft outer sheath and positive pressure of the irrigation medium, removal of IUCD allows more intrauterine space for improved hysteroscopic examination.

Conclusion

The new Lin soft outer sheath (type 3) is effective as a continuous flow system for outpatient flexible hysteroscopy. It provides a clear view for diagnostic hysteroscopy even during intrauterine bleeding.

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