Randomized, controlled trial comparing the efficacy of intrauterine balloon and intrauterine contraceptive device in the prevention of adhesion reformation after hysteroscopic adhesiolysis

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Objective: To compare the efficacy of heart-shaped intrauterine balloon and intrauterine contraceptive device (IUD) in the prevention of adhesion reformation after hysteroscopic adhesiolysis.
Design: Prospective, randomized, controlled trial.
Setting: University hospital.
Patient(s): A total of 201 women with Asherman syndrome.
Intervention(s): Women were randomized to having either a heart-shaped intrauterine balloon or an IUD fitted after hysteroscopic adhesiolysis. The devices were removed after 7 days. A second-look hysteroscopy was carried out 1 to 2 months after the surgery.
Main Outcome Measure(s): Incidence of adhesion reformation and reduction of adhesion score before and after surgery.
Result(s): Initially 201 cases were recruited; 39 cases dropped out, resulting in 82 cases in the balloon group and 80 cases in IUD group. The age, menstrual characteristics, pregnancy history, and American Fertility Society score before surgery were comparable between the two groups. The median adhesion score reduction (balloon group, 7; IUD group, 7) and the adhesion reformation rate (balloon group, 30%; IUD group, 35%) were not significantly different between the two groups.
Conclusion(s): The heart-shaped intrauterine balloon and IUD are of similar efficacy in the prevention of adhesion reformation after hysteroscopic adhesiolysis for Asherman syndrome.
Clinical Trial Registration Number: ISRCTN 69690272. (Fertil Steril® 2015;104:235–40. ©2015 by American Society for Reproductive Medicine.)
Key Words: Asherman syndrome, intrauterine balloon, intrauterine contraceptive device, hysteroscopy

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Received January 9, 2015; revised April 2, 2015; accepted April 6, 2015; published online April 30, 2015.
X.-N.L. has nothing to disclose. F.Z. has nothing to disclose. M.-L.W. has nothing to disclose. Y.Y. has nothing to disclose. Y.L. has nothing to disclose. T.C.L. has nothing to disclose. S.-Y.Z. has nothing to disclose.
This research was supported by the National Science Foundation of China (81270657), the Zhejiang Public Welfare Technology Application Research Project (2013C33236), and the Zhejiang Key Science and Technology Innovation Team Project (2011R50013-26).
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Fertility and Sterility® Vol. 104, No. 1, July 2015 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2015.04.008

Asherman syndrome is a consequence of trauma to the endometrium, producing adhesions within the uterine cavity, resulting in partial or complete obstruction of the uterine cavity and/or the cervical canal. It produces a number of clinical features: menstrual abnormalities, especially amenorrhea or hypomenorrhea, infertility, recurrent pregnancy loss, and abnormal placentation

resulting in placenta previa and accrete (1). The outcome of treatment of Asherman's syndrome has improved dramatically with the emergence of hysteroscopic techniques (2). Intrauterine adhesions can be removed with the use of hysteroscopic scissors or other cutting modality, such as diathermy or laser.

The main challenge of hysteroscopic adhesiolysis in Asherman syndrome is the high rate of reformation of adhesions, especially in those with severe adhesions, in whom the recurrence rate may be up to 62.5% (1). Postoperative estrogen therapy is often used to promote endometrial proliferation and healing. In addition, many practitioners use mechanical devices to keep opposing endometrial surfaces separated, with a view to reducing adhesion recurrence after the surgery (3). The intrauterine device (IUD) was advocated by Polishuk and Kohane initially (4) and has been used for some time, although the efficacy has never been confirmed by randomized, controlled trials. Other investigators advocate the use of a Foley catheter balloon (5–7). A retrospective analysis found that the Foley catheter is more effective in restoring normal uterine anatomy and in restoration of menstruation than the IUD (7). Recently a specially designed intrauterine balloon (Cook Medical) (Fig. 1A), which has a heart-shaped balloon, has been introduced for use after hysteroscopic surgery to prevent adhesion reformation. It is claimed that the heart-shaped intrauterine balloon fits better in the uterine cavity than the spherical Foley catheter, and it is thought to be more effective in the prevention of reformation of marginal adhesion (8). We recently conducted a retrospective cohort study and found that the heart-shaped intrauterine balloon seemed to be more effective than the heart-shaped IUD in preventing adhesion reformation after intrauterine adhesiolysis (9). However, there has never been any formal randomized, control trial directly comparing the efficacy of the intrauterine balloon and the IUD in the prevention of adhesion reformation.

In this prospective, randomized, controlled study, we wished to directly compare the efficacy of the placement of the heart-shaped intrauterine balloon vs. IUD in preventing adhesion reformation after intrauterine adhesiolysis.

MATERIALS AND METHODS

Patients

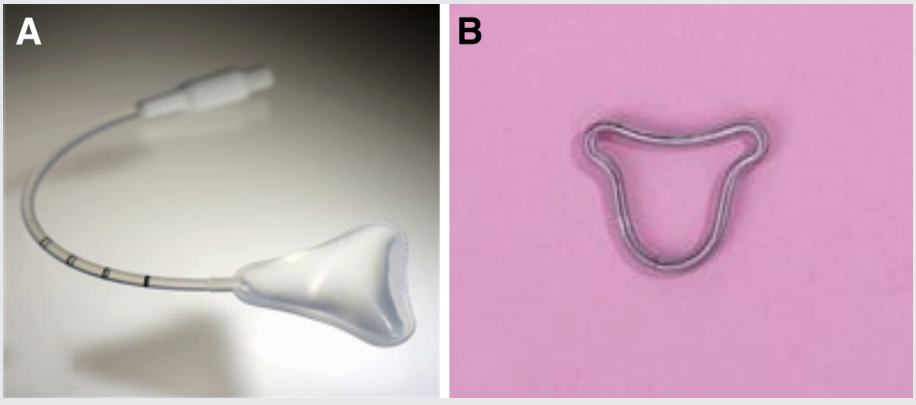
This randomized, controlled trial was approved by the review board of Reproductive Medicine of the Sir Run Run Shaw Hospital, Hangzhou, China. The patients were recruited from the Reproductive Medicine Center of the Sir Run Run Shaw Hospital, Hangzhou, China between January 30, 2013 and October 31, 2014. None of the authors has any conflict of interest. The hospital is a referral center for the treatment of Asherman syndrome in China and carried out an average of 250 intrauterine adhesiolysis procedures for Asherman syndrome annually between 2010 and 2014. Before the surgery all patients with suspected Asherman syndrome underwent preoperative evaluations, including a detailed history of the menstrual pattern, any previous intrauterine surgery, and reproductive history, as well as transvaginal ultrasonography. The severity and extent of intrauterine adhesions were scored according to a classification system recommended by the American Fertility Society (AFS) (1988 version) (10).

The inclusion criteria include [1] women aged 18–40 years; [2] moderate to severe intrauterine adhesion (AFS score ≥ 5); [3] no previous history of hysteroscopic adhesiolysis; [4] written consent obtained; and [5] agreement to have second-look hysteroscopy. The exclusion criteria include [1] minimal adhesion (AFS score <5) and [2] previous hysteroscopic adhesiolysis.

Study Design

After the completion of hysteroscopic adhesiolysis, recruited patients were randomized to one of the two treatment groups by computer-generated numbers: [1] fitting of a specially designed intrauterine balloon (Cook Medical) inflated with 3–5 mL normal saline; or [2] fitting of a heart-shaped copper

FIGURE 1



Intrauterine devices used in this study. (**A**) Heart-shaped intrauterine balloon. (**B**) Heart-shaped copper IUD.

Lin. Intrauterine adhesion reformation. Fertil Steril 2015.