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Original Article

Safety and Efficacy of Amnion Graft in Preventing Reformation of Intrauterine Adhesions

Xuebing Peng, MD, TinChiu Li, MD, PhD, Yuting Zhao, MD, Yan Guo, MD, and Enlan Xia, MD

From the Hysteroscopic Center, Fu Xing Hospital, Capital Medical University, Beijing, China (all authors), and Department of Obstetrics and Gynaecology, Prince of Wales Hospital, Chinese University of Hong Kong, Hong Kong, China (Dr. Li).

ABSTRACT **Study Objective:** To determine the safety and efficacy of amnion grafts in preventing the recurrence of intrauterine adhesions after hysteroscopic adhesiolysis in women with severe intrauterine adhesions.

Design: A retrospective matched cohort study including 120 patients treated during 62 months (Canadian Task Force classification II-2).

Setting: A tertiary referral center.

Patients: A total of 120 patients who underwent intrauterine adhesiolysis for severe intrauterine adhesions: 40 patients in the treatment group and 80 patients in the control group matched for age and adhesion scores. The mean duration of follow-up was 14.6 months.

Intervention: A Foley balloon with/without a fresh amnion graft was introduced into the uterine cavity after hysteroscopic adhesiolysis.

Measurements and Main Results: In both groups, the balloon was kept in place for 7 days, cyclic hormone treatment was given for 3 months, and second-look and third-look hysteroscopies were performed 1 and 3 months after the operation. Outcome measures included the incidence of the recurrence of intrauterine adhesions, the score of intrauterine adhesions (if present), and the impact of the surgery on the amount of menstrual flow. In the study group, the menstrual score at the end of 3 months was significantly higher, and the intrauterine adhesion score at third-look hysteroscopy was significantly lower compared with those in the control group. The incidences of the recurrence of intrauterine adhesions at third-look hysteroscopy in the treatment and control groups were 30% and 48.7%, respectively ($p = .05$). The adhesion scores at third-look hysteroscopy in the treatment and control groups were 1.3 and 2.1, respectively ($p < .05$).

Conclusion: The use of an amnion graft after intrauterine adhesiolysis appears to be beneficial in improving menstruation and reducing the recurrence of adhesion reformation. Journal of Minimally Invasive Gynecology (2017) 24, 1204–1210
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Keywords: Amnion graft; Intrauterine adhesions; Intrauterine balloon

The term Asherman syndrome is used to describe the presence of intrauterine (IU) adhesions (IUAs) with partial or complete obliteration of the uterine cavity after trauma to the basalis layer of the endometrium [1]. The treatment of Asherman syndrome remains a challenge partly because of the high adhesion reformation rate after IU adhesiolysis, especially in severe cases. In a literature review, the adhesion reformation rate in those with severe IUAs was reported to range from 20% to 62.5% [2].

A number of approaches have been proposed to reduce adhesion reformation after IU adhesiolysis, namely hormone treatment and IU barriers, including mechanical barriers and absorbable barriers [2]. Several recent studies have focused on the use of an IU balloon, IU contraceptive device, and hyaluronic acid gel as postoperative adjuvants [3–5]. Another postoperative adjuvant that has received relatively little attention is the amnion graft [6,7]. The human amnion membrane from the placenta is a low immunogenic substance with no or a minimal immunologic reaction when

The authors declare that they have no conflict of interest.
Corresponding author: TinChiu Li, MD, PhD, Hysteroscopic Center, Fu Xing Hospital, Capital Medical University, Fuxingmenwai Street A20, Beijing 100038, China.
E-mail: tinchiu.li@gmail.com

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transplanted. The amnion graft has been reported to facilitate epithelialization and reduce inflammation, vascularization, scarring, and adhesion formation [8,9]. The amnion was first used in 1910 for skin transplantation [10] and has since been widely used in different surgical specialties, including dermatology, ophthalmology, neurosurgery, and gynecology. In the latter specialty, it has been used in a number of situations such as vaginoplasty [11], cervicoplasty [12], and Asherman syndrome [6,7]. The successful use of the amnion graft in Asherman syndrome was first reported by Amer and Abd-El-Maeboud in 2006 [6], and the series was subsequently extended in 2010 [7]. They found that there was significant improvement in adhesion grade in the amnion graft group compared with a control group at second-look hysteroscopy. However, the positive result has not yet been confirmed by other investigators. In this cohort study, we wish to report our experience on the use of the amnion graft in the prevention of adhesion reformation in women with severe IUAs.

Material and Methods

Subjects

The study was performed at the Hysteroscopy Centre of Fu Xing Hospital, Beijing, China. The Hysteroscopy Centre is a national training center that has performed more than 2500 hysteroscopic surgeries annually for the last 5 years. During the period of study, between October 2010 and December 2015, the center performed more than 700 cases of severe IUAs (defined as an IUA score of 9–12 according to the American Fertility Society [AFS] scoring system). The retrospective study was approved by the Institutional Review Board of Fu Xing Hospital. Informed consent was obtained from each patient participating in the study.

During the study period, amnion graft treatment was introduced as a form of adjuvant therapy after lysis of severe IUAs with a view to preventing adhesion reformation by the first author (X. P.). Women considered suitable for inclusion in the study had to fulfill the following criteria: (1) IUA confirmed by hysteroscopy with an AFS IUA score >8 [13]; (2) age <40 years old; (3) written informed consent obtained; (4) no coexisting uterine pathology including uterine myomas, adenomyosis, adenomyomas, and congenital uterine anomalies; (5) no active infection; and (6) no significant medical disorder.

During the study period, a total of 40 women received the amnion graft. Another cohort of 116 women also underwent hysteroscopic adhesiolysis by the same consultant (X.P.) for severe IUAs (AFS score >8) and fulfilled the inclusion criteria but did not receive the amnion graft because of nonavailability of fresh amnion tissue. Eighty of the women in the latter group who were matched for age and AFS score in a 2:1 ratio were selected at random to constitute the comparison group.

IU Adhesiolysis

In all cases, hysteroscopic surgery was performed under general anesthesia. For cervical softening, phloroglucinol 80 mg (Wushi Pharmaceutical Ltd., Anlu, Hubei, China) was intravenously injected 20 minutes before surgery or 1 Laminaria stick (Nippon Laminaria Co. Ltd., Tajimi, Japan) was placed inside the vaginal fornix 8 to 12 hours before surgery. Hysteroscopic surgery was performed with the use of an Olympus (Tokyo, Japan) 27F (9-mm) passive continuous flow rotatable resectoscope. The distension medium used was 0.9% normal saline solution. The cervix was dilated to 9.5 to 10.0 mm with Hegar dilators. The distension pressure was set at 100 to 150 W, whereas the flow rate was set at 260 to 300 mL/min. The cutting power was set at 310 W, whereas the coagulating power was set at 90 W. Hysteroscopic surgery was performed under ultrasound or laparoscopic guidance. All operations were performed by 1 of 3 experienced surgeons in our department with the use of similar techniques. After the hysteroscope was introduced into the uterine cavity, the location, amount, and severity of IUA was documented. Adhesions were divided by the use of electrical energy using either a bipolar cutting needle or loop. At the end of the procedure, in the treatment group, a Foley balloon with a fresh amnion graft covering its surface was introduced into the uterine cavity, whereas in the comparison group a Foley balloon without an amnion graft was inserted into the uterine cavity. A drainage bag was connected to the catheter and was kept in place for 7 days [14,15]. During this period, oral antibiotics were given to prevent infections (either tinidazole [Livzon Pharmaceutical Group, Guangdong, China] 1.0 g/d or cefaclor [Tianjin Central Pharmaceutical Co Ltd., Tianjin, China] 0.375 mg twice daily). In all cases, hormone therapy was commenced on the second day of the operation, consisting of estradiol valerate 8 mg/d for 21 days and dydrogesterone 20 mg/d for the last 10 days of estrogen therapy. After the withdrawal bleed, hormone therapy was repeated for another cycle.

Amnion Graft

The amnion tissue was obtained from placentas delivered after elective lower-segment cesarean section used within 4 hours of delivery. Informed consent for the use of the placentas was obtained from the women before the cesarean section. The amnion tissue was used only if the donor tested negative for hepatitis B virus, hepatitis C virus, syphilis, and human immunodeficiency virus. A suitable piece of the amnion graft was peeled off from the placenta, washed free of blood clots with normal saline solution, and placed in a sterile basin with the epithelial layer surface upward on a sterile gauze mat. The amnion tissue was bathed in 1000 mL normal saline solution with the addition of 50 000 U penicillin and 0.5 g metronidazole.

The amnion tissue was placed over the balloon of the Foley catheter with the basement membrane surface facing outward

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