



## Prevention of Postoperative Adhesion Reformation by Intermittent Intrauterine Balloon Therapy

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### Abstract

**Objective:** Objectify the efficacy of intermittent intrauterine balloon dilatation in the prevention of adhesion reformation.

**Design:** Single group interventional study (pre-post study).

**Setting:** Hospital center of obstetric gynecology Ben Attou-Mira, Sidi Bel Abbes.

**Population:** Thirty-five patients with mild to severe (European Society for Gynaecological Endoscopy Grade  $\geq$ 1) intrauterine adhesions who underwent hysteroscopic adhesiolysis.

**Methods:** The group received intrauterine balloon dilatation therapy once every week and 04 weeks after surgery. All patients underwent follow-up hysteroscopy at 8 weeks postoperatively.

**Main Outcome Measures:** The adhesion reformation rate.

**Results:** A total of 30 patients successfully completed the study protocol. According to hysteroscopic evaluation at the 8th week, the overall adhesion reformation rate was significantly low in our study group (26.7%).

**Conclusions:** Postoperative intermittent intrauterine balloon dilatation therapy can significantly reduce postoperative adhesion reformation. Randomized controls trials are needed to confirm our results.

**Keywords:** Intrauterine Adhesions (IUAs); Intrauterine Contraceptive Device (IUD)

### Introduction

Intrauterine adhesions (IUAs) are bands of fibrous tissue that form in the endometrial cavity, often in response to a uterine procedure. Disease severity can range from thin strings of tissue to complete obliteration of the cavity. IUAs appear to result from trauma to layer of the endometrium. The basalis layer appears to be most susceptible to damage in the first four postpartum or postabortal weeks.

In a study of 1856 cases examined by Schenker and Margalioth, pregnancy was the predominant risk factor, and 66.7% of Asherman's cases occurred after postabortion/miscarriage curettage, 21.5% after postpartum curettage, 2% after cesarean section [2], and 0.6% after evacuation of hydatidiform mole [3]. Rare cases of IUAs have been seen in C-sections even after the use of B-lynch procedure in the event of postpartum hemorrhage.

Risk factors	Frequency (%)
Miscarriage curettage	66.7
Postpartum curettage	21.5
Caesarean curettage	2
Trophoblastic disease evacuation	0.6
Mullerian duct malformation	16
Infection (genital tuberculosis)	4
Diagnostic curettage	1.6
Abdominal myomectomy	1.3
Uterine artery embolization	14
Hysteroscopic surgery: metroplasty	6
Insertion of IUCD	0.2
Uterine comprehensive sutures for PPH	18.5
Hysteroscopic surgeries	
Metroplasty	6
Myomectomy (single myoma)	31.3
Myomectomy (multiple myomas)	45.5
Endometrial ablation	36.4
Polypectomy	0.3
Septoplasty	6.7

**Table 1:** Relation between risk factors and frequency of occurrence of Intrauterine adhesions [3].

Despite intrauterine adhesions being documented for well over a century now, the treatment of this disease still poses a significant clinical challenge. The traditional blind ‘dilatation and curettage’ employed several decades ago has now been widely replaced by treatment under direct vision with hysteroscopy. For severe cases, this is typically coupled with either laparoscopic or ultrasound guidance to reduce the risk of uterine perforation, although in refractory cases even performing open hysterotomy has been described [4]. Which represent our main dilemma that we were aiming to solve and propose an efficient management of this outcome.

Some novel methods described to prevent of adhesion reformation after hysteroscopic adhesiolysis in the last couple of decades have included the use of heart-shaped intrauterine balloon and intrauterine contraceptive device (IUD) [5], the use of auto-cross-linked hyaluronic acid gel [6], exosomes derived from mesenchymal stem cells [7], application of bioactive hydrogels [7]. However, none of them seem to have been adopted for different reasons.

Recently, we reported preliminary observations from a simple outpatient technique in which a Foley-catheter was used under ultrasound guidance to dilate the intrauterine cavity in order to resolve early IUA or prevent the adhesions from recurring [8,9]. We conducted a pre-post interventional study to test the hypothesis that intermittent use of intrauterine balloon dilatation in the postoperative period may reduce adhesion reformation rates. Our technique was inspired by the work of X Shi and SH Saravelos “Prevention of postoperative adhesion reformation by intermittent intrauterine balloon therapy: a randomized controlled trial in 2019”.

## Methods

### Study design

This was a descriptive prospective interventional pre-post study, performed at the specialized Hospital center of obstetric gynecology Ben attou-mira, sidi bel abbes, Algeria. which is a tertiary University hospital referral center.

Patients suspected to be suffering from IUA were recruited following a systematic pre-operative assessment process. This included a detailed history of the menstrual pattern, previous intrauterine surgery, and reproductive history, as well as 2D/3D transvaginal ultrasound. The severity and extent of intrauterine adhesions were scored according to the European Society of Gynecological Endoscopy (ESGE) classification system of 1995 [10].

The inclusion criteria included the following: (1) women aged 18–40 years; (2) mild to severe intrauterine adhesion (ESGE Grade  $\geq$ I); and (3) first episode of hysteroscopic adhesiolysis at Hospital center of obstetric gynecology Ben attou-mira.

The exclusion criteria included the following: (1) a previous hysteroscopic adhesiolysis procedure at Hospital center of obstetric gynecology Ben attou-mira or other hospitals.

### Sample

Our study was conducted on 35 patients with 02 years of follow-up from December 2019 to December 2021.

### Standard care

Standard care referred to the usual practice in our hospital. In all cases, a Foley-catheter filled with 4.5 ml normal saline was inserted into the uterus for 5–7 days after surgery combined with oral antibiotic treatment. The catheter was removed when the patient was discharged. Combine estrogen-progesterone Hormone therapy also began from the day of operation, consisting of ethinylloestradiol at a dose of 0.03 mg/day for 7 days, with the addition of levonorgestrel at a dose of 0.2 mg/day for 7 days and the last 7 days only levonorgestrel 0.2 mg/day. After the withdrawal bleed, the hormone therapy was repeated for a further cycle that is 8 weeks in total. A second-look hysteroscopy was carried out in 8 weeks after the index surgery and after.

### Intervention operation technique

All patients received hysteroscopic adhesiolysis in their follicular stage. Once the presence of adhesions had been confirmed and uterine anatomy had been assessed, an 34cm Semi-rigid, pointed cold scissor (Bettocchi Storz) was introduced into the uterine cavity to divide the adhesions [11]—with the aid of ultrasound guidance as necessary—The filmy and central adhesions were divided first, followed by marginal and dense adhesions.

Normal saline was used as the distention medium pressure with a pressure of 120–150 mmHg and a flow rate of 320–360 ml/min.

The second look hysteroscopy, at 8 weeks following the index surgery, respectively, was carried out. A 4.5-mm rigid hysteroscope with normal saline infusion was used under 100 mmHg pressure as an outpatient procedure in the day surgery unit. Ultrasound guidance was routinely available if required. After assessment of the extent and severity of any reformed adhesions, blunt dissection using the tip of the hysteroscope was carried out as reported in the literature [12].

### Intermittent Intrauterine balloon dilatation

All the Patients received intermittent IUB dilatation therapy. The dilatation therapy was performed every week for 4 weeks after the initial surgery in the day surgery unit. In brief, a Foley catheter (size 14fr) was prepared by cutting the excess catheter tip protruding beyond the balloon edge. The balloon catheter was then gently

inserted through a Cusco speculum into the uterine cavity under ultrasound guidance. Once the catheter had reached the fundus, 10 ml of normal saline was slowly introduced into the balloon. The volume introduced was based on the ultrasound images confirming adequate distention (inflation of the Foley balloon with the use of at least 10 ml of saline solution) of the uterine cavity, while ensuring that the patient did not experience too much discomfort. After the procedure, the balloon was deflated and removed immediately.

### Outcome measures

A Core Outcome Set was not used in this research. The primary outcome measure was defined as the adhesion reformation rate 8 weeks postoperatively including the ESGE grade at each follow up. Secondary outcomes included (1) the menstrual improvement, which was evaluated according to Pictorial Blood Loss Assessment Chart (PBAC) score [13] at each follow up, (2) the pregnancy rate, miscarriage rate, and ectopic rate, and (3) the patient reported pain scores via use of the Visual Analogue Scale (VAS) [14] from no pain (0) to worst pain imaginable (10). All follow-up data were collected via direct contact or telephone follow up every 2 weeks by one of the investigators. The total duration of follow up was 24 months.

### Results

A total of 35 women were assessed for eligibility between 01 December 2019 and 31 December 2021. Of these women, 30 were eligible. five patients did not complete the full protocol.

The baseline patient demographic characteristics are presented in Table 2. At the second-look hysteroscopy, the adhesion reformation rate was significantly lower 26.7% (8 patients from 30) there was a significant reduction in ESGE grade compared with their pre-operative grade.

All the eight patients diagnosed with a adhesion reformation were with severe adhesions according to ESGE grade.

### Patient-centered outcomes

In terms of the improvement of menstrual flow, our group demonstrated a high rate of improvement in PBAC scores at 8 weeks postoperatively. This included all women presenting with amenorrhea/ oligomenorrhoea. 18 women wished to conceive after the surgery, at the 12-month follow up, 08/18 (44.5%) women in the group achieved a pregnancy.

The miscarriage, ectopic pregnancy, ongoing pregnancy (beyond 20 weeks) rate in the group (0/30 [0%], 0/30 [3.8%], and 8/30 [66.6%], respectively).

No complications (such as uterine perforation, fluid overload, severe bleeding or infection) were observed in our group.

Egfc3	
Age (years)	18-45
Parity	0-4
Presenting complaints	
Amenorrhoea /Oligomenorrhoea	32/35
Infertility	21/35
Cyclic pain	17/35
Recurrent miscarriage	3/35
Previous intrauterine operation	
Caesarean section	23/35
dilation and curettage procedure	19/35
Hysteroscopic resection of intrauterine adhesions	3/35
Hysteroscopic resection of uterine septum	1/35
No intrauterine operation	1/35
Grade	
Mild	4/35
Moderate	10/35
Severe	21/35

Table 2

### Discussion

#### Main results

In the present study, we found that patients who received intermittent IUB dilatation therapy following hysteroscopic adhesiolysis experienced a significant reduction in adhesion recurrence and severity (as assessed by the ESGE grade), as well as a significant improvement in menstruation flow (as assessed by PBAC score).

This was assessed over an 8-week postoperative period which included a second-look hysteroscopy. These surrogate outcomes may prove to have important practical implications for clinicians treating women with IUA.

Typically, most studies describe the insertion of a balloon catheter (such as a Foley) at the end of the primary hysteroscopic adhesiolysis procedure, with a view to it being removed after a total of 3– 30 days [15,16]. However, our study is different to use intermittent IUB dilatation as an additional barrier prevention method for reducing adhesion reformation rates.

Intermittent IUB dilatation may divide early reformed adhesions via simple blunt dissection along the physiological uterine cavity plane, before denser adhesion bands are formed. We elected to perform IUB dilatation once every week for 4 weeks after the index hysteroscopic surgery.

Our preliminary observations prior to this study have shown favorable outcomes and patient acceptability when using this technique.

The advantages are that it is simple, quick, of low-cost and can be performed in the outpatient office setting without the need for hysteroscopic equipment, analgesia or anesthesia.

There was significant decrease in the incidence of adhesion reformation and adhesion score at 8 weeks, the adhesion reformation interested only 8 patients with a severe grade according to (ESGE) classification.

### Strengths and limitations

In terms of strengths, to our knowledge, this is the first study to use an additional barrier method (intermittent IUB dilatation therapy with a protocol of a dilatation per week for 04 weeks) to prevent the adhesion reformation inspired by the work of X Shi and SH Saravelos.

In terms of limitations, this study didn't include a control group and it was not randomized. The promising results of our study encouraged us to plan randomized controls trials in the near future.

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