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RESEARCH ARTICLE

The use of an intrauterine balloon in preventing adhesion recurrence after hysteroscopic adhesiolysis: a feasibility study

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ABSTRACT

We aimed to evaluate the feasibility of a heart-shaped intrauterine balloon as antiadhesion method immediately after hysteroscopic adhesiolysis in terms of surgeon's and patient's experience. This feasibility study was performed at the Ghent University Hospital (Belgium) from 2018 to 2020. A heart-shaped intrauterine balloon was inserted in 10 women immediately after hysteroscopic adhesiolysis and left in place for 7 days under antibiotic prophylaxis. Insertion and removal of the balloon was easy in 7 women out of 10 (5-point Likert scale), and successful in all cases. The median pain score during balloon wearing on a visual analogue scale (VAS) was 1.7 (IQR 1.0–4.2). Seven out of 10 women were satisfied (5-point Likert scale). Eight out of 10 women would probably or certainly recommend the procedure to a friend (5-point Likert scale) and would use the balloon again. The heart-shaped intrauterine balloon as antiadhesion method is feasible in terms of surgeon's and patient's experience. Designing a proper Randomised Controlled Trial (RCT) is worth the effort.

Clinical trial registration: https://clinicaltrials.gov (NCT03446755). Initial release on 27th February 2018.

IMPACT STATEMENT

- **What is already known on this subject?** Intrauterine adhesion (IUA) reformation is high and different methods to prevent this subsequent to an operative hysteroscopy have been assessed. The use of antiadhesion gel, acting as a mechanical barrier, may decrease the occurrence of IUAs compared to no treatment or placebo. A heart-shaped intrauterine balloon is another example of a mechanical barrier. A small number of studies, of varying quality and with heterogeneous results, have been performed. A proper RCT, comparing the intrauterine balloon to no treatment or placebo, is needed.
- **What the results of this study add?** The heart-shaped intrauterine balloon as antiadhesion method is feasible in terms of surgeon's and patient's experience.
- **What the implications are of these findings for clinical practice and/or further research?** Designing a proper RCT is worth the effort.

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Antiadhesion treatment; Asherman's syndrome; hysteroscopic adhesiolysis; intrauterine adhesions; intrauterine balloon

Introduction

Hysteroscopic adhesiolysis aims to restore the uterine anatomy. Unfortunately, intrauterine adhesion (IUA) reformation may occur in around 28.7% of patients (Hanstede *et al.* 2015). Different methods to prevent IUAs subsequent to an operative hysteroscopy have been assessed in a Cochrane review (Bosteels *et al.* 2017). Subgroup analysis demonstrated that the use of antiadhesion gel, acting as a mechanical barrier, may decrease the occurrence of IUAs compared to no treatment or placebo.

Another treatment evaluated in the Cochrane review are intrauterine balloons, which are also an example of a mechanical barrier used to avoid new adhesions. A Foley catheter can serve for this purpose, but it is not ideal because of its shape and long insufflation and irrigation line. COOK medical® developed a heart-shaped intrauterine balloon with a smaller insufflation line to reduce bleeding after intrauterine surgery.

Four studies examined the heart-shaped intrauterine balloon (ISB or COOK medical®) and the IUA reformation rate at second-look hysteroscopy (X. Lin *et al.* 2013, X. N. Lin *et al.* 2015a, Y. H. Lin *et al.* 2015b, Zhu *et al.* 2018). One randomised controlled trial (RCT) could not demonstrate a significant difference compared to a heart-shaped intrauterine copper device (X. N. Lin *et al.* 2015a). A RCT evaluating the incidence of intrauterine bacterial colonisation with or without balloon placement for 30 days after hysteroscopic surgery, revealed no IUAs at second-look hysteroscopy (Y. H. Lin *et al.* 2015b). It was only significantly better for severe adhesions compared to the use of a Foley catheter in a retrospective study (Zhu *et al.* 2018). Retrospective comparison with an intrauterine copper device, hyaluronic acid and no treatment showed a significantly better adhesion reduction (X. Lin *et al.* 2013).

Research is needed to study the efficacy of a heart-shaped intrauterine balloon in comparison to antiadhesion gel or to no antiadhesion treatment. Before designing such type of

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RCTs, we need to elucidate in our own experience whether its usage is feasible for both the patient and the clinical practice.

We aimed to perform a feasibility study of 10 procedures with insertion of a heart-shaped intrauterine balloon as antiadhesion method subsequent to a hysteroscopic adhesiolysis, to study its feasibility in terms of surgeon's and patient's experience.

Materials and methods

This feasibility study was performed in a prospective cohort treated for IUAs at the Ghent University Hospital (Belgium) from February 2018 to November 2020. Ethical approval was obtained. The trial was registered at Clinicaltrials.gov (NCT03446755). Written informed consent was acquired before inclusion.

Women aged 18–45 years with IUAs on diagnostic hysteroscopy, scheduled for hysteroscopic adhesiolysis were eligible for inclusion. Three different classification systems were used in order to determine different aspects of the adhesions because of the lack of a validated classification method. The American Fertility Society (AFS) classification is based on the degree of uterine cavity involvement, the appearance of the adhesions and menstrual characteristics of the patient (Buttram *et al*. 1988). Valle and Sciarra classified the adhesions according to their appearance and the extent of occlusion (Valle and Sciarra 1988). March *et al*. classified the adhesions based on the degree of uterine cavity involvement (March *et al*. 1978).

Exclusion criteria were minimal adhesions that did not require hysteroscopic repair, adhesiolysis insufficient for balloon insertion, congenital uterine malformations and the presence of a contraindication for operative hysteroscopy.

Vaginal and cervical swabs for culture and Chlamydia and Gonorrhoea PCR were taken after enrolment and patients were treated accordingly. Hysteroscopic adhesiolysis was carried out in the operating room under spinal or general anaesthesia in a day care setting. The procedure was performed using a 5 mm Bettocchi® hysteroscope (Karl Storz, Tuttlingen, Germany) with 5.0 french scissors or forceps. Ultrasound guidance or fluoroscopy was used if necessary. Normal saline was used for distention. Fluid balance was closely monitored using an automatic fluid management system. No cervical ripening agents were administered preoperatively.

The heart-shaped intrauterine balloon (COOK® medical balloon uterine stent) was inserted subsequent to a successful hysteroscopic adhesiolysis. Insertion was done if adhesiolysis was deemed sufficient by the surgeon for balloon placement. The heart-shaped intrauterine balloon is made from silicone, is disposable and contains a 9.0 French inflation line. Two sizes are available, namely a balloon with a diameter of 3 cm, a length of 2.8 cm and a volume of 5 ml (G17080, J-BUS-253000) and a balloon with a diameter of 4 cm, a length of 4 cm and a volume of 8 ml (G17562, J-BUS-404000). The balloon size was chosen according to surgeon's preference and based on a subjective assessment of the uterine cavity size using a hysterometer. For measurements up to 8 cm a small balloon will be used, otherwise a large balloon will be selected. Cervical dilation until Hegar 10 was necessary for balloon insertion. The lateral sides of the balloon were held together by a Desjardin's choledocholithotomy forceps to allow for insertion. This appeared to be much easier than to roll the balloon around the forceps, which caused the balloon to come out again during the first procedure. The technique was therefore modified after the first procedure. The balloon was inflated until resistance appeared to be significant.

The surgeon noted the ease of the balloon placement on a 5-point Likert scale (very difficult, difficult, moderate, easy or very easy), whether any complication took place during the procedure and the adhesion classification after the adhesiolysis according to March *et al*. and Valle and Sciarra (March *et al*. 1978, Valle and Sciarra 1988).

Antibiotic prophylaxis (amoxicillin/clavulanic acid 500 mg) was administered 3 times a day during balloon wearing, starting on the day of the procedure.

During balloon wearing, women were asked to note their daily pain scores on a 10-point Visual Analogue Scale (VAS), their general discomfort (yes/no), whether they developed fever (yes/no) and to report any complaints resulting in an additional treatment, consultation or hospitalisation.

Seven days after the hysteroscopic adhesiolysis, the intrauterine balloon was removed in the office. Deflation was most easily performed by cutting the insufflation line. The surgeon noted the ease of removal on a 5-point Likert scale (very difficult, difficult, moderate, easy or very easy).

After balloon removal, women were asked on a 5-point Likert scale whether they were satisfied with the treatment (very satisfied, satisfied, neutral, not really satisfied, totally not satisfied), if they would recommend this to a friend (certainly not, probably not, maybe, probably, certainly), and whether they would want to participate again (yes/no). Work productivity and the ability to perform activities of daily living was investigated by the use of The Work Productivity and Activity Impairment Questionnaire (WPAI). It is a validated instrument used to measure the effect of general health on work productivity and daily tasks (Reilly *et al*. 1993).

A second-look hysteroscopy was performed between 5 to 10 weeks postoperatively in an office setting. It was noted whether reintervention (hysteroscopic adhesiolysis) was needed and whether complications had occurred.

We aimed to perform 10 procedures.

The statistical program SPSS version 27 was used for data collection and analysis. For non-normally continuous variables median and interquartile range (IQR) were reported. Categoric data are presented as frequency and percentage.

Results

Ten women participated in the study and their characteristics are shown in Table 1.

Eight women (8/10) had a history of at least one curettage. One woman (1/10) had a history of hysteroscopic polypectomy, and in 1 woman (1/10) IUAs probably developed after a difficult secondary Caesarean section. Hysterocopic adhesiolysis had been performed previously in 4 of the women (4/10). One woman (1/10) with only mild adhesions

Table 1. Patient characteristics.

		$N = 10$
Age		34.0 (32.0–36.0)
BMI		23.7 (21.6–26.6)
Race	Caucasian	8.0 (80.0)
	Asian	1.0 (10.0)
	African	1.0 (10.0)
Gravidity	1	3.0 (30.0)
	2	5.0 (50.0)
	3	1.0 (10.0)
	4	1.0 (10.0)
Parity	0	1.0 (10.0)
	1	6.0 (60.0)
	2	3.0 (30.0)
Miscarriage	0	4.0 (40.0)
	1	6.0 (60.0)
Ectopic pregnancy	0	8.0 (80.0)
	1	2.0 (20.0)
Ceasarean section		4.0 (40.0)
Curettage		8.0 (80.0)
Manual placental removal[a]		1.0 (11.1)
History of hysteroscopic procedures		5.0 (50.0)
Preoperative AFS classification	Mild	1.0 (10.0)
	Moderate	7.0 (70.0)
	Severe	2.0 (20.0)
Preoperative Valle and Sciarra classification	Mild – partial occlusion	1.0 (10.0)
	Moderate – partial occlusion	3.0 (30.0)
	Moderate – complete occlusion	1.0 (10.0)
	Severe – partial occlusion	5.0 (50.0)
Preoperative March classification	Mild	2.0 (20.0)
	Moderate	8.0 (80.0)

Data are median (interquartile range [25–75%]) or *n* (%). [a]1 missing value. AFS: American Fertility Society.

according to all three classification systems was scheduled for operative hysteroscopy because of the concomitant presence of retained products of conception (RPOC).

The 3 classification systems revealed a discrepant result in 1 woman (1/10). The AFS score and the Valle and Sciarra score were severe and severe with partial occlusion, respectively, but the March score was only mild. This was because the adhesions were identified as dense but they were not extensive.

Preoperative vaginal culture showed candida albicans ($n = 2$), group B streptococcus ($n = 1$) and enterococcus faecalis ($n = 1$). Both candida albicans infections were asymptomatic and the vaginal culture was doubtful in one case. Only the confirmed case of candida albicans was treated with Fluconazole (Diflucan® 150 mg once) postoperatively together with the antibiotic prophylaxis. There were no cases of Chlamydia and Gonorrhoea.

The surgeon's experience is shown in Table 2. Insertion of the balloon was easy to very easy in 7 women (7/10). The placement was difficult in 2 cases (2/10). One case was the first procedure, where introduction was not possible while the balloon was rolled around a Desjardin's choledocholithotomy forceps. It was found to be better to hold it on the lateral sides, and dilation to Hegar 10 was found to be necessary to allow for insertion. The insertion was also difficult in the second last procedure, which was preceded by a difficult cervical dilation. The large balloon was used in only 1 case (1/10) and inflated with 7 ml.

No complications occurred during balloon placement. The median volume of the small balloon was 3.50 ml (IQR 3–4). Removal of the balloon was easy to very easy in 7 women (7/10). In 1 case (1/10) removal was difficult (small size balloon).

The patient's experience is shown in Table 2. Only 2 women (2/10) did not experience discomfort during balloon wearing. The reported pain score (VAS) was the highest on the day of the surgery (median 5.9 ((IQR) 1.0–7.0)). The overall median pain score during balloon wearing was 1.7 (1.0–4.2). Two women (2/10) reported remarkably higher median pain scores (7.0 and 7.5). One patient visited her general practitioner on postoperative day 3 because of nausea, abdominal

Table 2. Surgeon's and patient's experience.

		$N = 10$
Ease of balloon insertion	Difficult	2.0 (20.0)
	Moderate	1.0 (10.0)
	Easy	4.0 (40.0)
	Very easy	3.0 (30.0)
Balloon size	5 mL	9.0 (90.0)
	8 mL	1.0 (10.0)
Balloon volume		3.3 (3.0–4.0)
Ease of balloon removal	Difficult	1.0 (10.0)
	Moderate	2.0 (20.0)
	Easy	4.0 (40.0)
	Very easy	3.0 (30.0)
Pain scores	Day of surgery	5.9 (1.0–7.0)
	Postoperative day 1	2.1 (1.0–6.3)
	Postoperative day 2	1.9 (1.0–4.5)
	Postoperative day 3	2.3 (1.1–3.3)
	Postoperative day 4	2.1 (1.2–3.0)
	Postoperative day 5	1.3 (0.7–2.0)
	Postoperative day 6[a]	1.0 (0.5–1.2)
	During removal[b]	1.3 (0.9–4.6)
Additional visit		2.0 (20.0)
Satisfaction	Very satisfied	2.0 (20.0)
	Satisfied	5.0 (50.0)
	Neutral	3.0 (30.0)
Recommend to a friend	Probably not	1.0 (10.0)
	Maybe	1.0 (10.0)
	Probably	3.0 (30.0)
	Certainly	5.0 (50.0)
Would you use the balloon again?		8.0 (80.0)

Data are median (interquartile range [25–75%]) or *n* (%). [a]1 missing value, [b]2 missing values. Data are median (interquartile range [25–75%]) or *n* (%).

pain and backpain. Although she was satisfied with the antiadhesion procedure, she would probably not recommend this to a friend, and she does not want to wear the balloon again. The other patient was admitted for 1 night because of urinary retention. The reported satisfaction was neutral, but she would probably recommend this to a friend. This patient does not want to participate again.

One woman (1/10) reported vaginal itching on postoperative day 4. Fluconazole (Diflucan® 150 mg) was administered once because of the suspicion of a candida infection related to the prophylactic antibiotic treatment. The reported satisfaction was neutral, but she would certainly recommend this to a friend, and she would wear the balloon again.

Eight women (8/10) were employed. Only 3 women resumed professional activities, the others were advised by their treating gynaecologist to stay at home during balloon wearing. The median reported impairment of the productivity while working was 5 on a VAS scale (IQR 2.5–5). The overall median reported impairment of the ability to perform regular daily activities on a VAS scale, other than work at a job, was 2.5 (IQR 0.8–5.3).

Second-look hysteroscopy was performed in all participants. During 1 office procedure (1/10), filmy adhesions were removed bluntly through the use of the hysteroscope. Cervical adhesions with a normal uterine cavity were seen in 2 women (2/10). An overview of the IUA classification pre-, intra- and postoperative is provided in Table 3. The IUA classification at second look hysteroscopy was lower in 2 women (2/10) and higher in only 1 woman (1/10), compared to the classification at the end of the operative hysteroscopy.

Discussion

Findings and interpretation

This feasibility study indicates that the intrauterine balloon is a feasible antiadhesion strategy, it could have an additional adhesiolytic effect, and further research can be designed.

Strengths and weaknesses of the study

To our knowledge, this is the first report of the use of an intrauterine balloon as antiadhesion method in European women in an outpatient setting.

Surgeon's and patient's experience with an intrauterine balloon were not yet reported before. Those measures are important before moving on to further research considering the efficacy of the intrauterine balloon.

We do acknowledge that our study has some important limitations: the sample size was small and volunteer bias could have occurred. Also, surgeon and patients reported outcomes were unblinded and we did not register the use of pain medication during balloon wearing. Lastly, a control group was lacking.

Differences and similarities in relation to other studies

Surgeon's experience with the use of a heart-shaped intrauterine balloon as antiadhesion method has not been described before. Our study shows that surgeons are satisfied with this technique.

Guidelines to insert the heart-shaped intrauterine balloon were unavailable, and during the study we had to optimise our technique. The need for cervical dilation might be a disadvantage (Roman *et al.* 2016). Lin *et al.* mentioned that insertion of this type of balloon is more difficult because it has to be rolled up and dilation until Hegar 9 is necessary (X. N. Lin *et al.* 2015a). Huang *et al.* described the need for dilation until Hegar 8 (Huang *et al.* 2020). Other studies reporting on the use of the heart-shaped intrauterine balloon failed to provide their insertion technique (X. Lin *et al.* 2013, Y. H. Lin *et al.* 2015b, Zhu *et al.* 2018, Huang *et al.* 2020). However, a larger diameter hysteroscope was often used implying that the cervix was already dilated before insertion.

Ultrasound guidance was not used for insertion, and this is in line with other studies reporting on the heart-shaped intrauterine balloon (X. Lin *et al.* 2013, X. N. Lin *et al.* 2015a, Zhu *et al.* 2018, Huang *et al.* 2020). In literature, ultrasound guidance was only used for the insertion of a Foley catheter (Gan *et al.* 2017, Saravelos and Li 2017, Shi *et al.* 2019, Sun *et al.* 2020).

The heart-shaped intrauterine balloon is an acceptable antiadhesion method for women.

The higher reported pain score on the day of the operation may be related to the surgery as well as the balloon. Huang *et al.* reported lower mean pain scores, using the Numerical Rating Scale (NRS), 30 min after hysteroscopic adhesiolysis with insertion of a heart-shaped intrauterine balloon (COOK medical®) or insertion of a Foley balloon together with a heart-shaped intrauterine copper device (3 (95%CI (2–3)) and 2 (95% CI (1–2)), $p < .01$)) (Huang *et al.* 2020). Lin *et al.* reported mean pain scores (VAS) of 2.2 (±

Table 3. Pre-, intra- and postoperative IUA classification.

	Preoperative		Intraoperative[a]		Postoperative	
	Valle and Sciarra score	March score	Valle and Sciarra score	March score	Valle and Sciarra score	March score
Patient 1	Moderate – partial occlusion	Moderate	/	/	Mild – partial occlusion	Mild
Patient 2	Severe – partial occlusion	Moderate	Moderate – partial occluded	Moderate	Moderate – partial occlusion	Moderate
Patient 3	Moderate – complete occlusion	Moderate	Moderate – partial occluded	Mild	[b]	Mild
Patient 4	Moderate – partial occlusion	Moderate	Mild – partial occluded	Mild	Mild – partial occlusion	Mild
Patient 5	Severe – partial occlusion	Moderate	/	/	/	/
Patient 6	Severe – partial occlusion	Moderate	/	/	[b]	/
Patient 7	Severe – partial occlusion	Mild	/	/	/	/
Patient 8	Severe – partial occlusion	Moderate	Mild – partial occluded	Mild	/	/
Patient 9	Mild – partial occlusion	Mild	Mild – partial occluded	Mild	/	/
Patient 10	Moderate – partial occlusion	Moderate	/	/	/	/

[a]At the end of the hysteroscopic procedure, [b]only cervical adhesions. / = no adhesions.

2.0) during 30 days of wearing the larger (8 ml) heart-shaped intrauterine balloon (COOK medical®) (Y. H. Lin *et al.* 2015b). This was significantly higher compared to women without an intrauterine balloon, however the larger balloon was still associated with mild pain scores. In our population, the large balloon was used in one woman. She reported a VAS score of 0.8 for both the median pain score during balloon wearing and the overall median pain score.

The adverse event rate in our study was relatively high (3/10). Only two studies reported on their adverse event rate (moderate to severe pain (NRS $\geq$ 4) 30 min postoperatively (12/62), failure of insertion (2/62), abdominal cramps (3/78) and endometritis despite antibiotic prophylaxis (1/38)) (Huang *et al.* 2020, Yang *et al.* 2020). This is an important finding when other, less invasive, antiadhesion methods (for example gel) are available. On the other hand, the need for antibiotic prophylaxis is questioned by Y. H. Lin *et al.* (2015b).

An advantage of the heart-shaped intrauterine balloon may be the additional adhesiolytic effect as seen in our trial. This has only been demonstrated using Foley catheters for intermittent balloon dilation in an office setting (Shi *et al.* 2019, Sun *et al.* 2020). However, the reported pain scores (VAS) 1 min and 30 min after balloon dilation were 5.40 (±1.20) and 1.39 (±1.03), respectively.

Research is needed to study the efficacy of a heart-shaped intrauterine balloon in comparison to antiadhesion gel or to no antiadhesion treatment.

The optimal duration of balloon wearing has yet to be determined and it is suggested that even deflated it could have an antiadhesion effect (Yang *et al.* 2020).

In addition, other indications (intrauterine balloon after other types of operative hysteroscopic procedures) and another practical approach (adhesiolytic effect of intermittent balloon dilation) should be examined.

Conclusion

The heart-shaped intrauterine balloon as antiadhesion method is feasible in terms of surgeon's and patient's experience. Patient's daily pain scores are low. Although most patients experienced some discomfort, they are satisfied, would recommend the antiadhesion method to a friend and would use it again.

Moreover, it could have an additional adhesiolytic effect, and further research can be designed.

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Data availability statement

Data available on request due to privacy/ethical restrictions.

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