

The role of intrauterine balloon after operative hysteroscopy in the prevention of intrauterine adhesions: a prospective controlled study

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ABSTRACT

Objective: To assess the efficacy of intrauterine Balloon in preventing intrauterine adhesions after operative hysteroscopy.

Setting: Ain Shams University Hospitals.

Design: A prospective controlled study.

Materials and methods: 50 women for whom operative Hysteroscopy were indicated, 20 (40%) with intrauterine adhesions (group A), 20 (40%) with uterine fibroids (group B) and 10 (20%) with uterine septa (group C). Each group was classified to two subgroups, subgroup (I) with balloon and subgroup (II) without balloon. Adhesion grade was compared for each patient preoperative and 6-8 weeks postoperative. Foley catheter balloon No 10 F inflated with 3.5 ml of saline with cutting its stem above the cervix, were left intrauterine in patients in subgroup (I). The balloon removed one week postoperative under paracervical anesthesia. Diagnostic Hysteroscopy was performed 6-8 weeks postoperative to evaluate for intrauterine adhesions in all groups.

Results: In group (A), 12 (60%) patients were in sub-group I, 8 (66.7%) developed no adhesions and 4 (33.3%) developed adhesions, 8 (40%) patients were in sub-group II, 3 (37.5%) developed no adhesions and 5 (62.5%) developed adhesions. for group (B), 15 (75%) were in sub-group I, from which 13 (86.7%) developed no adhesions and 2 (13.3%) developed adhesions and 5 (25%) patients were in sub-group II, from which 3 (60%) developed no adhesions, and 2 (40%) developed adhesions. In-group (C), 5 (50%) were in sub-group (I) from which 4 (80%) developed no adhesions and 1 (20%) developed adhesions, the other 5 (50%) in-sub-group (II), 3 (60%) developed no adhesions and 2 (40%) developed adhesions. These results are of clinical and practical importance, although it shows no statistical significance in each group separately (P value >0.05), but when comparing patients in subgroup I to those in subgroup II in the three groups (P value 0.04), it is statistically significant.

Conclusion: Intrauterine balloon application after operative Hysteroscopy is of great value in preventing intrauterine adhesions.

Keywords: Intrauterine balloon, Operative Hysteroscopy, intrauterine adhesions.

The universal incidence of intrauterine adhesions (IUA) is steadily increasing as any factor leading to destruction of the endometrium may engender adhesions of the myometrium at opposing walls of the uterus as after myomectomy

and uterine septum excision. The main etiologic factor is trauma to a recently pregnant uterus and the incidence is high in countries with increased therapeutic and illegal abortions, also in areas with high incidence of genital tuberculosis. Certain patients develop severe form of IUA and others are unaffected while undergoing the same traumatic procedures. This concept may also explain why some patients respond well to treatment whereas others suffer from recurrent adhesions (1). The

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diagnosis of IUA is made by hysterosalpingography, and mainly by hysteroscopy. Hysteroscopy has become accepted as the optimum route of surgery, the aims being to restore the size and shape of the uterine cavity, normal endometrial function and fertility. Treatment can range from simple cervical dilatation in the case of cervical stenosis but an intact uterine cavity, to extensive adhesiolysis of dense intrauterine adhesions using scissors or electro- or laser energy. The success of treatment regarding term deliveries and rate of abortions depends on the severity of the adhesions (2, 3). Patients in whom the uterine fundus is completely obscured and those with a greatly narrowed, fibrotic cavity present the greatest therapeutic challenge. Several techniques have been described for these difficult cases, but outcome is far worse than in patients with mild, endometrial-type adhesions. Non-hysteroscopic techniques are also beginning to be developed, but whether they will replace the current 'gold' standard of hysteroscopy remains to be seen (4).

There does not appear to be a defined uniform approach to prevent occurrence of intrauterine adhesions after operative hysteroscopy and the topics of intrauterine contraceptive device (IUCD) insertion, Balloon Catheter, Estrogen / Estrogen and Progestins, Antibiotics/ Corticosteroids are constantly debated (5). The use of an inflated pediatric Foley catheter balloon in the uterine cavity with its stem coming out of the cervical canal, instead of an IUCD to mechanically maintain the uterine cavity separated after adhesiolysis had been reported with equally good results with fewer complications (6,7).

The aim of the present study is to evaluate the role of lifting intrauterine Balloon, without stem coming out of the cervix, in preventing IUA after operative hysteroscopy, and to evaluate its risk for

postoperative intrauterine infection. This prospective controlled study was conducted at Ain Shams Maternity Hospitals, Department of Endoscopy, in the years 2003 –2004.

MATERIALS AND METHODS

Fifty women (mean age: 31.4 years; range: 27-38.4 years) for whom operative Hysteroscopy were indicated, 20 (40%) with intrauterine adhesions (IUA) of various grades (8) (group A), 20 (40%) with submucous fibroids (group B) and 10 (20%) with uterine septa (group C). Patients were allocated to two subgroups, Subgroup (I) in which intrauterine balloon was applied postoperative and Subgroup (II) without balloon (Table1). The approval for the study was granted by the Ethics Committee, Faculty of medicine, Obstetrics and Gynecology department, Ain Shams University of Egypt. Oral informed consent was taken from each woman to participate in this study.

Operative Hysteroscopy were performed early in the follicular phase under general anesthesia using the electrosurgical resectoscope with Glycine 1.5% as distention medium by means of Hamou Hysteromat (Karl Storz, Tuttlingen, Germany) for all patients. The same technique was used in each group (incision of Uterine septum and adhesions was done using electrosurgical cutting knife, and shaving of myoma was done with electrosurgical cutting loop in a double sheath resectoscope that allows a two way flow of the distending medium for continuous suction irrigation.). A 4 mm forward oblique 30° telescope and a video camera were used after cervical dilatation to No 8 Hegar dilator. A blended monopolar current (100 Watts cutting and 50 Watts coagulation) was the power setting used for all patients.

Table 1. Clinical data: Operative hysteroscopy and Intrauterine Balloon application

	Adhesiolysis (n=20)	Myomectomy (n=20)	Septal incision (n=10)	Total (n=50)
Subgroup I	12 (60%)	15 (75%)	5 (50%)	32
Subgroup II	8 (40%)	5 (25%)	5 (50%)	18

Subgroup I: with intrauterine balloon application

Subgroup II: without intrauterine balloon application

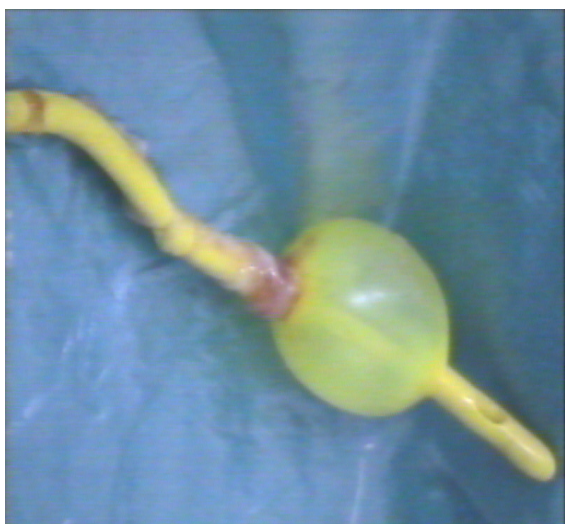


Figure 1. Pediatric Foley catheter Balloon after making a knot and cutting its stem

All the surgical procedures were performed by the same surgeon. Postoperative intrauterine application of pediatric Foley catheter balloon No 10 F In all patients in Subgroup (I) was done using a straight artery forceps, the balloon then inflated with 3.5 ml of normal saline, a tight knot was made by the catheter stem itself just below the inflated balloon then the stem was cut just below the knot after applying traction on the catheter stem while holding the balloon in its place inside the uterine cavity with the forceps, so that the inflated balloon with the knot retract intrauterine above the level of the internal os (Figure 1). A single intravenous dose of an antibiotic (one of the third generation cephalosporin) was given 30 minutes preoperative. Postoperative observation for any clinical signs of infection (in the form of increased body

temperature, abnormal vaginal discharge or pelvic pain or tenderness) for one week postoperative was performed. Postoperative medications in the form of sequential estrogen-progestative medication for one month (5 mg conjugated equine estrogens daily for 30 days with 10 mg medroxyprogesterone acetate daily during the last 5 days of conjugated estrogens). Diagnostic hysteroscopy, under paracervical anesthesia (using 6ml Xylocaine 2% plus 0.5-mg atropine in the same syringe), was performed one week postoperative to locate the inflated balloon and its removal with a crocodile forceps transcervically without cervical dilatation where the balloon is compressible, it is an outpatient procedure. Diagnostic Hysteroscopy was performed 6-8 weeks postoperative to evaluate for IUA in all groups. Endocervical swabs for bacteriological examination on aerobic and anaerobic media, were taken preoperative and at the time of removal of the balloon, in all patients in subgroup I.

Statistical analysis was performed using Chi square-test and T-test.

RESULTS

All surgical procedures were performed without any complications. The postoperative intrauterine adhesions (IUA) in various subgroups presented in Table 2 showing that there is decrease in the number of patients who develop postoperative IUA in subgroups (I) than those in subgroup (II) in each separate group which is of clinical and practical importance but is of no statistical significance which might be due to the small number of patients in each group.

Table 2. Intrauterine adhesions after operative hysteroscopy

Adhesions	Adhesiolysis (n=20)		Myomectomy (n=20)		Septal incision (n=10)	
	With balloon (n=12)	Without balloon (n=8)	With balloon (n=15)	Without balloon (n=5)	With balloon (n=5)	Without balloon (n=5)
Absent	8(66.7%)	3(37.5%)	13(86.7%)	3(60%)	4(80%)	3(60%)
Present	4(33.3%)	5(62.5%)	2(13.3%)	2(40%)	1(20%)	2(40%)
P value	0.1990*		0.1967*		0.4902*	

*Statistically not significant.

All patients with recurrent IUA in subgroup (I) the adhesions was of lower grade than that present preoperative but in patients of subgroup II the recurred adhesions were of the same grade. On comparing all patients in subgroup (I) to those in subgroup (II) in all groups, we find that there is statistically significant difference ($P = 0.04$) indicating that the use of intrauterine balloon decreases the incidence of IUA after operative hysteroscopy. Also bacteriological examination of endocervical swabs taken preoperative and one week postoperative revealed that no intrauterine bacteriological contamination, also no clinical evidence of any pelvic infection in all patients in subgroup I.

DISCUSSION

The universal incidence of intrauterine adhesions (IUA) is increasing as any factor leading to destruction of the endometrium may engender adhesions of the myometrium at opposing walls of the uterus as after myomectomy and uterine septum incision. The main offender is trauma to the uterus after Dilatation and Curettage (D&C) after a delivery or after a miscarriage (9). However, IUA from infections such as tuberculosis is also increasing in poorly developed countries and in immunocompromised patients. The clinical implications of IUA vary with the degree of pathology (2). When more scarring is present, the treatment is usually less successful. Direct hysteroscopic view of the endometrial cavity is the only way to determine the degree of IUA and can easily be performed in the office. Diagnostic hysteroscopy has the fewest risks, followed by operative hysteroscopic adhesiolysis, metroplasty, and myomectomy. Fluid management is critical for intraoperative safety. Meticulous detail should be paid to fluid management, and consultation sought with a critical care specialist when fluid overload or hyponatremia is suspected. Lingering pain, fever, or pelvic discomfort after surgery requires prompt evaluation (10).

Hysteroscopic surgery replaced abdominal metroplasty and is today the treatment of choice for congenital uterine malformations. This is not just because of its reproductive results, which are

comparable to those achieved with the abdominal approach, but mainly because of several post-operative benefits (reduced morbidity, convalescence and costs, and no scar tissue on the abdominal and uterine walls), improved reproductive performance (no reduction in uterine volume, shorter interval to conception after operation) and the mode of delivery (avoiding Caesarean section). Indications for treatment have been broadened to include not only the septate uterus associated with adverse reproductive outcome, but also patients before any potential obstetric accidents, especially in those with declining fecundity (>35 years), with reproductive problems (unexplained infertility) and before assisted reproductive techniques, as well as in women with no actual desire of pregnancy (11). Hysteroscopic myomectomy also is a reliable alternative to hysterectomy and has an acceptable surgical time and minimum hospital stay. Appropriate patient selection and improved technique are necessary to reduce the need of re-intervention for IUA or recurred myoma. The technique also offers significant economic savings compared with the conventional surgical methods (12).

The ideal treatment of IUA consists not only of physically removing the adhesion but also preventing the formation of new ones by the use of other adjunctive measures. The prevention of adhesion formation after operative hysteroscopy is commonly done by the dual approach of maintenance of the freshly separated uterine cavity by some physical means and enhancement of the endometrial growth, which is often facilitated by cyclic estrogen and progesterone treatment regimen (13). An IUCD may provoke local inflammation and favor the formation of IUA (14). In addition the insertion of Balloon of Foley catheter and keeping its stem coming out of the cervix will invite ascending infection from the vagina.

In the present study we applied intrauterine balloon slightly inflated (with only 3.5 ml saline) to separate the opposing uterine walls, not maximally inflated to avoid increased pressure on the uterine walls which might result in decreased blood flow to uterine walls affecting endometrial regeneration, also we cut the stem of the catheter

above the cervix to avoid ascending infection from the vagina. The obvious advantages are immense. It is cheap and accessible which is a special advantage in the developing countries with poor resources and appears to be more acceptable to the patients who view the IUCD as a psychological barrier in itself to conception. Furthermore, the Foley catheter balloon appears to achieve a greater and more effective separation of the uterine cavity because of the larger surface area, which enables it to maintain the separated uterine cavity while the endometrial regeneration is going on (6). In the present study there is decrease in the number of patients who develop postoperative IUA after balloon application than those who did not apply the balloon in each separate group which is of clinical and practical importance but is of no statistical significance which might be due to the small number of patients in each separate group, but on comparing patients in whom the balloon was applied to those who did not apply the balloon in all groups together, we find that there is statistically significant difference ($P = 0.04$) indicating that the use of intrauterine pediatric Foley catheter balloon postoperatively after cutting its stem above the cervix, decreases the incidence and grade of IUA after operative hysteroscopy. Also bacteriological examination of endocervical swabs taken just preoperative and at the time of removal of the balloon one week postoperative revealed that no intrauterine bacteriological contamination with no clinical evidence of pelvic infection in all patients for one week postoperative.

In conclusion the use of intrauterine balloon without a stem coming out of the cervix, after operative Hysteroscopy is of great value in decreasing the incidence and grade of intrauterine adhesions after operative Hysteroscopy without increasing the risk of pelvic infection.

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