Bacterial colonization with balloon uterine stent placement in the uterus for 30 days: a randomized controlled clinical trial

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Objective: To assess bacterial colonization following balloon uterine stent placement in the uterus for 30 days.
Design: Prospective randomized controlled study.
Setting: Tertiary medical center.
Patient(s): Sixty-eight women scheduled for hysteroscopy.
Intervention(s): Women who were undergoing hysteroscopic surgery were randomly assigned to receive a balloon uterine stent or not. Before starting surgery, the uterine cavity was swabbed for bacterial culture. The device was placed in the uterus after surgery in the stent group. After 30 days, the stent was removed and sent for culture and the uterine cavity also swabbed and cultured. The uterine cavities of the control patients were swabbed before and 30 days after surgery.
Main Outcome Measure(s): The primary outcome was the incidence of bacterial colonization of the uterus. Secondary outcomes were pain intensity and species of colonizing bacteria.
Result(s): Excluding eight women, 30 women in each group were included in this analysis. In the stent group, three women (10.0%) demonstrated bacterial colonization before surgery compared with nine women (30.0%) after 30 days. In the control group, four (13.3%) and ten (33.3%) women had microorganisms detected in the uterus before and after 30 days after surgery, respectively. In neither group did the percentage of women with uterine microorganisms increase significantly after 30 days. The percentages of women with uterine bacterial colonization before and 30 days after surgery were similar between both groups.
Conclusion(s): Balloon uterine stents may be placed after surgery for up to 30 days without increasing bacterial colonization.
Clinical Trial Registration Number: ClinicalTrials.gov (www.clinicaltrials.gov) NCT01167296.
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Key Words: Intrauterine adhesions, balloon uterine stent, bacteria colonization, infection, hysteroscopy

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Intrauterine adhesions (IUAs) are caused by injury to the endometrium, usually resulting from dilation and curettage in a gravid uterus. IUAs may result in hypomenorrhea or amenorrhea, miscarriage, and infertility. The standard treatment of IUAs is adhesiolysis by means of hysteroscopy. A major concern after adhesiolysis is recurrence of adhesions. Although adhesion reformation may be absent in mild to moderate IUAs, the incidence may be up to 60% in severe IUAs (1). Moreover, hysteroscopic surgeries for myomectomy, IUAs, and uterine septum result in a 40%–88% incidence of new IUA formation (2).

To prevent adhesion reformation, many gynecologists leave an intrauterine device (IUD) or a Foley catheter in the uterine cavity after surgery.

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However, the small contact areas of these devices with endometrium may limit their effectiveness. The rates of adhesion reformation were 16.7% and 41.9%, respectively, in moderate and severe IUAs even if an IUD was placed in the uterus (3). The Foley catheter can better expand the center of the uterine cavity but still leaves dead space at the margin of the uterine cavity. In addition, the long tail of the Foley catheter can cause discomfort.

The Cook balloon uterine stent (Cook Medical) was designed to reduce bleeding following intrauterine surgery. Because it can conform to the cavity of a normal uterus and maintain separation at the margins of the uterine cavity, some authors have suggested placing it after hysteroscopic adhesiolysis to prevent adhesion reformation (4, 5). However, the manufacturer restricts the use of the stent to <24 hours. To prevent adhesion reformation, the stent would ideally be left in the uterine cavity until the endometrium heals, likely from 1 to 3 months (2, 6). It is not known whether extended placement of the stent would cause bacterial colonization or even infection in the uterus. Therefore, we conducted a study to evaluate bacterial colonization after leaving a balloon uterine stent in the uterus for 30 days. The primary objective of this study was to compare the incidences of bacterial colonization in the uterus with or without stent placement 30 days after hysteroscopic surgery. The secondary objectives were pain intensity during the study period and species of colonizing bacteria.

MATERIALS AND METHODS

This prospective randomized controlled clinical trial occurred from July 2010 to April 2011 at Shin Kong Wu Ho-Su Memorial Hospital. Participants were recruited following the guidelines of the Helsinki Declaration of 1975 on human research. The study was approved by the Institutional Review Board of the hospital (ECIRB 9812-001) and was registered with www.clinicaltrials.gov (no. NCT01167296). Each woman entered this study only after signed informed consent was obtained.

One investigator (J.-L.H.) was responsible for subject recruitment. Women 20–45 years old undergoing hysteroscopic surgery were eligible for enrollment. Exclusion criteria consisted of earlier pelvic inflammatory disease (PID), evidence of PID, or vaginitis. According to estimates that ~60% of healthy women harbored microorganisms in the uterus (7), we determined that 30 women were needed in each group to yield an 80% power to detect a 20% difference between the groups at a significance level of 0.05.

Randomization was based on a one-to-one computer-generated scheme in balanced blocks of four. Randomization codes were sealed in sequentially numbered opaque envelopes by the study coordinator. Immediately before surgery, the coordinator opened the envelope and assigned participants to receive balloon uterine stent insertion (stent group) or not (control group). Women assigned to the stent group had the balloon uterine stent present for a total of 30 days after surgery. The endometrium was swabbed before and 30 days after surgery, and the stent was removed and sent for bacterial culture. For the women in the control group, endometrial swabbing was done before and 30 days after surgery as well, but no stent was inserted. The coordinator, patients, and gynecologists were not blinded to intervention after assignment.

Hysteroscopic Procedures

Per routine practice, the women self-administered 400 μg misoprostol (Cytotec; Pharmacia) into the vagina 24 and 12 hours before surgery to prime the cervix. After anesthesia, the perineum and vagina were disinfected and draped. The cervix and vagina were subsequently thoroughly disinfected with povidone-iodine as in vaginal surgery. An applicator swab (Copan Venturi Transystem; Copan Italia) was then inserted into the uterine cavity, taking care to avoid contact with the vaginal wall. The whole endometrium was swabbed from fundus to cervix. The applicator swab was placed in a transport tube and sent to the laboratory immediately for bacterial culture.

Operative hysteroscopies were performed with the use of a 22-F resectoscope (Karl Storz) and 5% glucose solution for uterine distension and irrigation. For the women in the stent group, the stent was inserted into the uterine cavity at the conclusion of hysteroscopy and the balloon inflated with 8 mL sterile water. Postoperatively, the women were prescribed 3 days of diclofenac (Cataflam; Novartis Farma) for pain relief. Prophylactic antibiotics were not given. One surgeon (Y.-H.L.) performed all operative procedures and swabbing. The women were instructed to return if any symptoms of PID developed.

Participants were instructed to assess their pain intensity with the use of a visual analog scale (VAS) (8). They recorded their worst pain score from 3 days to 30 days after surgery.

Follow-up

Thirty days after surgery, all subjects returned to the hospital for bacterial culture and second-look hysteroscopy. After disinfection of the vagina and cervix with povidone-iodine, the endometrium was swabbed as previously described. For stent group patients, after the balloon was deflated, the stent was removed carefully without touching the vaginal wall. The balloon was cut from the stem and placed in a sterile jar. Then the endometrium was swabbed as previously described, and the balloon and swab were sent to the laboratory immediately for bacterial culture.

After cultures were collected, all subjects received a second-look hysteroscopy to assess the endometrium.

Bacterial Culture of Swabs

All cultures were prepared within 30 minutes of sampling. The swab was vortexed in 1 mL thioglycolate broth medium (Creative Microbiologicals) for 3 minutes. Then the medium was plated with 10-μL inoculating loops (Copan) on the following plates for aerobic bacteria: blood agar (Creative), eosin–methylene blue agar (Creative), chocolate agar (Creative), and phenylethyl alcohol blood agar (Becton Dickinson). The plates were incubated in 5% CO_2 in air (Forma) at 35°C for 3 days.