Biocompatibility of a cervical dilating rod made of absorbent polymer materials

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Abstract

BACKGROUND: YOUMET cervical dilating rod is made of absorbent polymer materials and has non-toxic side effects, which can avoid cross-infection in one-time use.

OBJECTIVE: To observe the clinical effects of YOUMET cervical dilating rod used for cervical orifice dilation before intrauterine device insertion and removal as well as before artificial abortion operations.

METHODS: Totally 275 female subjects schedule for cervical dilation during intrauterine device insertion and removal operations, and suction abortion for pregnancy within 10 weeks were randomly divided into two groups: 137 were included in observation group in which YOUMET cervical dilating rods were applied and 138 were included in control group in which Gongshuning glue sticks were used. Their cervical softening and dilatation situation, analgesic effect, and combined reactions during operation were observed.

RESULTS AND CONCLUSION: Between the two groups, no statistical significance in general biological characteristics was found; Dilating effects in intrauterine device removing operations during child-bearing period and menopause were better in the observation group than the control group ($P < 0.05$). Rates of pain during insertion were higher in the observation group than the control group ($P < 0.05$). Rates of pain during indwelling period for both groups were comparatively low, which showed no statistical significance. There was no record related to the application of cervical orifice dilating products in postoperative follow-up visit. Both products were safe with no cervical injury, slow heart rate and drop in blood pressure. YOUMET cervical dilating rod has trustworthy and safe dilating effects, which can remarkably alleviate pain.

Subject headings: Biocompatible Materials; Intrauterine Devices; Cervix Uteri

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INTRODUCTION

Family planning operation such as intrauterine device inserting and removing as well as artificial abortion operations are characterized as fast surgery and less pain, but preoperative cervical dilatation can result in pain and discomfort in some women, and even lead to side injury. With the continuous improvement of people's quality of life, women have an increasing attention on reproductive health; therefore, how to safely and effectively perform cervical dilation with minimum pain has been the attention of scholars.

Gongshuning glue stick is a kind of one-time surgical product that is easy to use[1-5], which contains anisodamine, lidocaine and lubricating jelly. When the cervical canal is inserted preoperatively, part of lubricating jelly adheres to the cervix, causing lubrication, reducing friction and damage of metal straw to the cervix. Drug ingredients in the glue stick are absorbed by the cervical mucosa. Anisodamine has obvious effect on smooth muscle relaxation, which can relieve spasms, improve microcirculation, and relieve vagal inhibition of the heart; lidocaine can reduce the excitability of vagus nerve, local use of which can show a strong role in muscle relaxation. Gongshuning glue sticks have lubrication, cervical dilation and analgesic functions[6-10], and can create favorable conditions for the abortion operation, reducing the intraoperative cervical dilatation resistance, reducing the incidence of abortion syndrome, thereby reducing patient's pain and mental tension as well as shortening the operation time.

The newly developed YOUMET one-time cervical dilatation rod is made of absorbent polymer materials, which is safe and effective, has non-toxic side effects and can avoid cross-infection[11-13]. When used, the YOUMET cervical dilatation rod is inserted into the cervical canal, and runs within 3–5 minutes, which was smooth and painless and placed

behind the cervical canal. It can absorb body fluids and self-expand at body temperature and cervical temperatures and induce a series of biochemical changes by exerting effects on the lower uterine segment and cervical tissue[14-15]--to destroy cell lysosomes, release phosphatase A, promote the synthesis and release of endogenous prostaglandins, increase collagen cervical tissue, thereby softening and relaxing the cervix smooth muscle and reducing vagal reflex intensity, for the purpose of cervical dilation effects and pain relief. Meanwhile, it can exert as a soft probe to explore the uterine cavity. The cervical dilation rod is able to use for mechanical cervical dilatation, cervical oppression, uterine contractions, so as to passively dilate the cervix, thereby playing double roles of mechanical cervical dilatation and passive cervical dilation, which can make it easier to insert the rob into the cervical canal. The cervical dilatation rod has fixed length and can be bent, to avoid uterine perforation, cervical fracture and other injuries caused by the metal stent, which is particularly suitable for early pregnancy, abnormal position of the uterus, uterine scar, and fear nervous women. YOUMET one-time cervical dilatation rod has been widely used in various clinical settings and its main advantages are as follows[16-20]: rapid dilatation that can shorten the operation time; it can significantly reduce the incidence of abortion syndrome; avoid pain caused by mechanical cervical dilation; intraoperative pregnant women stay awake to avoid anesthetic accidents; one-time use can eliminate cross-infection; it is easy to use in pregnant women; it cannot increase blood loss; it has stable biologically inert that cannot cause acute and chronic inflammation; it is safe, non-toxic, non-carcinogenic, non-teratogenic, which does not spread potential known or unknown infections; it has good histocompatibility good and no rejection. This study aimed to observe the effectiveness and safety of YOUMET cervical dilatation rod.

MATERIALS AND METHODS

Design

A randomized controlled clinical trial.

Subjects

Totally 275 female patients who underwent intrauterine device insertion and removal as well as induced abortion for pregnancy within 10 weeks at Shengjing Hospital Affiliated to China Medical University and the Sino-Japanese Friendship Hospital from 2013-01-04 to 2013-04-09. Preoperative cervical dilation and excluding contraindications were necessary, and all subjects provided written informed consent before operations began. All the subjects were randomly divided into two groups: 137 in observation group undergoing YOUMET cervical dilation rod and 138 in control group undergoing Gongshuning glue sticks. No lost case was found at the end of follow-up (2013-04-28).

Inclusion criteria: induced abortion after 6–10 weeks of menopause; family planning operations such as intrauterine device insertion and removal; normal blood routine examination, normal clotting time and normal vaginal discharge routine examination; no abortion contraindications; no contraindications for family planning operations such as intrauterine device insertion and removal; no glaucoma, cardiovascular disease, asthma and severe allergies; non-menstrual period.

Exclusion criteria: patients have genital tract inflammation and are in the acute phase of various diseases; poor general conditions that cannot tolerate surgery; the preoperative body temperature is above 37.5 ℃ (twice); with a history of steroid use; liver and kidney dysfunction; mental or legal disabled patients.

Materials

YOUMET cervical dilation rod was purchased from Liaoning Aimu Medical Technology Co., Ltd. (registration number: liao (2013) 2660150, for a single use. It consists of dilation rod (seven specifications) and accessories (water), which are individually wrapped, belonging to II class medical equipment, and made of absorbent polymer biomaterials. After water absorption, it has smooth surface and is easily inserted into the cervical canal, and has no acellular toxicity, blood and tissue compatibility problems.

Gongshuning glue sticks (Q/LYZ01-2001) were purchased from Liaoning Medical Products Development Company, with a rod diameter of 0.5 cm, length of 5 cm, consisting of the push rod, tail wire, glue sticks and glue stick coating containing tetracaine and anisodamine, which can be used for mechanical cervical dilation and anti-pain function. The pH value of glue stick coating was 6.0–6.5 with good thermal stability. The separating force between the push rod and glue stick should not exceed 15 N.

Methods

The performer used the Hegar cervical dilator in a decremented manner from No. 7 until the dilator passed through the cervix[1]. This number is a natural relaxation before the cervix is dilated. Patients who required for the cervical dilation were enrolled and subjected to different dilation products. The procedures were in strict accordance with the operating instructions: After preoperative routine disinfection, the rod was slowly inserted into the mouth of cervical canal for dilatation 3–10 minutes, and the rod was removed until the cervix was dilated. After that, the dilator was used to test the degree of cervical relaxation in accordance with the above method. If the surgical instruments were still not well into the uterine cavity, the different types of dilators were used in turn for a satisfied dilation outcome.

Main outcome measures

During the operation, subject's pain, blood pressure, heart rate, nausea and vomiting were recorded. The participants were followed for 20 days, and the follow-up items included the patient's own feelings, vaginal bleeding duration and amount of bleeding. Ultrasonic review of uterine involution and lower uterine segment recovery was done.

Expansion efficiency: ⩾ 2 dilators used during the

operation meant that the surgery was invalid. According to WHO classification, 0= no pain and 1–10=pain.

Statistical analysis

The data were doubly recorded by two persons using Epidata3.1 and statistically analyzed using SPSS 20.0. Enumeration data and measurement data were analyzed using chi-square test or *t* test. A value of $P < 0.05$ was considered statistically significant.

RESULTS

Quantitative analysis of participants

All the 275 participants were enrolled in result analysis.

Randomized grouping flowchart (**Figure 1**)

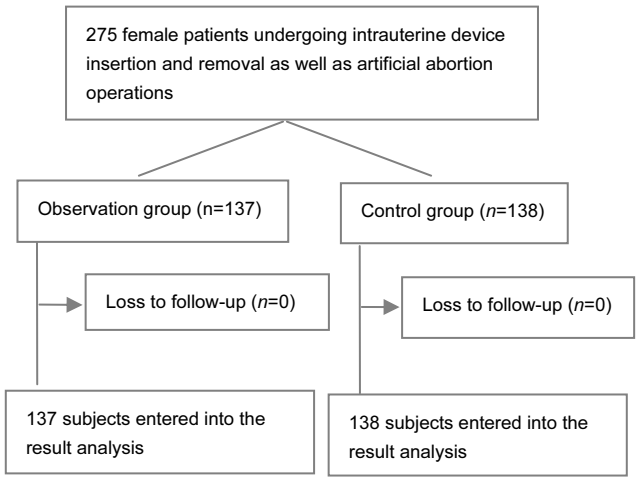

Figure 1 Flow chart of randomized grouping

Baseline data comparison between two groups

The mean age was (39±11) years in the observation group and (38±9) years in the control group. There were no significant differences in age, pregnancy history, use of time, degree of cervical relaxation between the two groups ($P > 0.05$; **Tables 1**, **2**).

Clinical results

Cervical dilation effect: the dilating effectiveness during intrauterine device insertion and removal at child-bearing period was 100% in the observation group and 96% in the control group, and there was no difference between the two groups ($P > 0.05$), but during induced abortion and intrauterine device removal at menopause period, the dilating effectiveness of the observation group was better than that of the control group ($P < 0.05$; **Table 3**). Because the dilator was used before and after insertion of Gongshuning glue sticks in the control group, the incidence of pain was higher in the control group than the observation group ($P < 0.05$). The incidence of pain during retention period was lower in both two groups, and no significant difference was found ($P > 0.05$; **Table 4**).

Degree of cervical dilation: the difference value of cervical dilation degree before and after dilation was higher in the observation group than the control group ($P < 0.05$) between the groups before and after the test cervix dilation laxity, the observation group than the control group ($P < 0.05$; **Table 5**).

Adverse reactions: there were six unfavorable cases (4.4%) in the observation group and six unfavorable cases (4.3%) in the control group, and the main cause was the poor elasticity of the cervix and over-bending of the uterus. But there was no implantation failure case in the two groups. These two groups exhibited no difference in surgical results and security ($P > 0.05$). The rods were successfully removed in both groups, with no cervical injury, intraoperative drop of blood pressure, decreased heart rate and no adverse events associated with the cervical dilation. During the follow-up, no product-related adverse events occurred in the two groups.

In vitro soak time of YOUMET cervical dilating rod: the soak time was 20 seconds in 72 cases (53%), 15 seconds in 65 cases (47%). The retention time was 3 minutes in 32 cases (23%) and 1.0–2.0 minutes in 105 cases (87%). There were seven sizes, and φ4.5 was mostly used (58%). φ4.5 was used in 75% cases undergoing intrauterine device insertion and removal during child-bearing period, φ3.0–φ3.5 were used in 41% cases undergoing cases intrauterine device removal during menopause period, and φ5.0 was used in 63% cases undergoing induced abortion (**Table 6**).

DISCUSSION

Cervical dilation is the main reason for surgical pain during intrauterine device insertion and removal as well as induced abortion, and sometimes results in abortion syndrome and even cervical injury. With the continuous improvement of people's quality of life, women's reproductive health has attracted more and more attentions. Many women want to minimize the pain due to cervical dilatation in various surgical processes. Cervical dilation can induce the release of algogenic substance from the intrauterine tissue. Mechanical stimulation during the cervical dilation can excite the uterus and the vagus nerve to produce a large amount of acetylcholine, resulting in inadequate myocardial blood supply, inhibiting sinus node excitation, promoting coronary artery spasm, thereby leading to arrhythmia, bradycardia and even cardiac arrest. Decreased cardiac contractility can cause insufficient cardiac output and hypovolemia, which is prone to producing hypoxia and even shock. When cerebral insufficiency, there will be a coma, dizziness, seizures, vagus nerve excitation, and because of enhanced gastrointestinal motility and smooth muscle spasm, vomiting, nausea and other adverse reactions can appear.

There are many clinical cervical dilation methods, such as Hegar cervical dilator, vaginal carboprost[21-24], oral administration of misoprostol[25-27], postmenopausal usage of estrogen[28]. Some problems, however, still exit: slow cervical dilation by using apparatuses, incomplete number, drug absorption for a long time, contraindications for estrogen use. In recent years a series of cervical dilating methods using apparatuses have been introduced,

Table 1 Comparison of pregnancy history and the opportunity of usage between the two groups (*n*/%)

Group	Pregnancy history				Opportunity of usage			
	No	Natural delivery	Cesarean section	Induced abortion	Intrauterine device insertion during child-bearing period	Intrauterine device removal during child-bearing period	Abortion (containing painless)	Intrauterine device removal during menopause period
Observation (*n*=137)	5/4	82/60	48/35	98/72	48/35	36/26	19/14	34/25
Control (*n*=138)	6/4	78/57	53/38	92/67	54/39	41/30	15/11	28/20
P	0.898				0.631			

Table 2 Comparison of degree of cervical relaxation between the two groups

Group	No. of dilator (diameter, mm)					
	3.0	3.5	4.0	4.5	5.0	5.5
Observation (*n*=137)	15/11	14/10	53/39	52/38	2/1	1/1
Control (*n*=138)	10/7	9/7	59/43	57/41	2/1	1/1
P	0.853					

Table 4 Comparison of pain incidence between the two groups (*n*/%)

Group	Insertion			Retention		
	No	Yes	Total	No	Yes	Total
Observation (*n*=137)	132/96	5/4	137/100	135/99	2/1	137/100
Control (*n*=138)	103/75	35/25	138/100	135/98	3/2	138/100
P	0			0.658		

Table 3 Comparison of dilating effectiveness between the two groups (*n*/%)

Group	Intrauterine device insertion during child-bearing period		Intrauterine device removal during child-bearing period		Induced abortion		Intrauterine device removal during menopause period	
	Valid	Invalid	Valid	Invalid	Valid	Invalid	Valid	Invalid
Observation (*n*=137)	48/100	0	36/100	0	17/89	2/11	34/100	0
Control (*n*=138)	54/100	0	38/93	3/7	8/53	7/47	21/75	7/25
P	1.000		0.098		0.018		0.002	

Table 6 No. of YOUMET cervical dilating rod used and the mean diameter distribution

Project	Diameter (mm)(*n*/%)							Total	Mean diameter ($\bar{x}$±*s*, mm)
	3.0	3.5	4.0	4.5	5.0	5.5	6.0		
Intrauterine device insertion and removal during child-bearing period	1/1	9/11	8/10	63/75	3/4	0	0	84/100	4.4±0.4
Intrauterine device removal during menopause period	5/15	9/26	9/26	11/32	0	0	0	34/100	3.9±0.5
Induced abortion	0	1/5	1/5	4/21	12/63	1/5	0	19/100	4.8±0.5
Total	6/4	19/14	18/13	78/57	15/11	1/1	0	137/100	4.3±0.5

Table 5 Comparison of the difference value of cervical dilation degree before and after dilation between the two groups (*n*/%)

Group	No. of dilator				
	1.0	1.5	2.0	2.5	3.0
Observation (*n*=137)	0	48/35	65/47	22/16	2/1
Control (*n*=138)	4/3	75/54	52/38	7/5	0
P	0				

Gongshuning glue sticks[29-34], one-off cervical dilator[35-37], one-off hydrophilic cervical dilator[38], and YOUMET cervical dilating rods. Findings from the present study show that the YOUMET cervical dilating rod has a higher efficiency and lower incidence of adverse reactions, which has seven sizes and is applicable to women with various conditions of the cervix at childbearing age and menopausal age. The Gongshuning glue stick is a single-size rob with a diameter of only 0.5 cm and with no expansion function. In cases with tight cervix undergoing Gongshuning glue stick, a dilator is necessary. In some subjects, the dilator is used secondarily after the removal of Gongshuning glue sticks, thus influencing the dilating efficiency and leading to more pain.

The YOUMET cervical dilating rod is made of non-toxic biomaterials, with an diameter of 5 mm and a length of 50 mm. It can expand naturally after absorption of cervical secretions, with an expansion rate of 100% to 150%, and this rod can slow the cervical dilation and soften the cervix through promoting the synthesis and release of endogenous prostaglandins. In previous years, the YOUMET cervical dilating rod was mostly used for cervical dilation prior to hysteroscopic surgery; currently, it has been widely applied in intrauterine device insertion and removal as well as induced abortion. Luo and colleagues[39] found that the cervical dilating rod for induced labor can reduce reduce soft birth canal injury, uterine rupture and postpartum infection rates, characterized as little trauma, effectiveness and safety, short-term production process and simple

operation, which provides a reference for trimester pregnancy of scarred uterus. Similar experience from Han and co-workers[35] also confirmed that the cervical dilating rod has a better dilating effect than vaginal misoprostol in a short term, and it is easy to operate and produces less pain with no remarkable adverse reactions. Another study from Yin *et al* [40] also demonstrated that during the removal, the cervical dilating rod can reduce surgical pain effectively and successfully remove the intrauterine device in postmenopausal women with ovarian failure, low estrogen levels, uterine atrophy and atrophy of the cervix. The use of cervical dilating robs can reduce the incidence of complications when the intrauterine device removes, rapidly dilate the cervix, have shorter operative time, have good histocompatibility, no rejection, non-toxic, non-carcinogenic, non-teratogenic effects. It can effectively reduce the incidence of abortion syndrome and avoid pain caused by mechanical cervical dilatation.

In the present study, the difference value of the degree of cervical relaxation was significantly higher in the observation group than the control group. It is probably because the YOUMET cervical dilating rod is made of absorbent biomaterial with good biocompatibility that can be soaked *in vitro*, and implanted into the cervix to absorb the water from cervical secretions and gradually expand, thereby playing a better effect to dilate the cervical canal reliably.

The YOUMET cervical dilating rod is easy to operate. *In vitro* soak time of YOUMET cervical dilating rod is determined according to the degree of cervical relaxation. Generally, the soak time is 15 seconds and the retention time is 1.0–2.0 minutes. For some poor cases, the soak time and retention time are increased to 20 seconds and 3 minutes, respectively. YOUMET cervical dilating rods have seven sizes, and φ4.5 used in intrauterine device insertion and removal at child-bearing age can be expandable to 6 or above; φ5.0 used in pregnancy period can be expandable to 6.5–7.0 or 7.5, which can basically meet the requirements that No. 6 sucker can pass through the cervix freely; φ3.5 used in menopausal cases or those with over-tight and hard cervix can be expandable to 5 or more.

Taken together, the YOUMET cervical dilating rod is easy to operate, reliable, safe and has few adverse reactions, which can relieve patient's pain. Moreover, as a one-off dilating rob, it is used with no anesthesia, thus avoiding anesthetic accidents, reducing the cost of surgery, and easing the financial burden on patients.

REFERENCES

[1] Zhu HJ. Gongshuning glue stick used in 100 cases of induced abortion. Zhongguo Fuyou Baojian. 2009;24(31): 4467-4468.

[2] Zhu ZY. Nitrous oxide combined with Gongshuning glue stick in induced abortion. Zhongguo Fuyou Baojian. 2010; 25(29):4300-4301.

[3] Wang SX. Clinical observation of Gongshuning glue stick in induced abortion. Zhongguo Linchuang Yanjiu. 2010;23(9): 794-795.

[4] Li H, Cheng W. Second trimester abortion in scarred uterine patients. Zhongguo Shiyong Fuke yu Chanke Zazhi. 2010; 25(8):586-588.

[5] Zhang XX. Gongshuning glue stick for intrauterine device removal in menopausal women. Anhui Yixue. 2012;33 (7): 870-871.

[6] Li GH. Tibolone tablets combined with Gongshuning glue stick for intrauterine device removal in menopausal women. Hebei Yixue. 2012;18(12):1779-1781.

[7] Ying HC, Ying TS, Lu J. Effect of misoprostol combined with gongshuning on postmenopausal women before hysteroscopy. Shiyong Yaowu yu Linchuang. 2013;16(8): 692-694.

[8] Qian WY. Mifepristone combined with Gongshuning glue stick for intrauterine device removal in menopausal women. Neimenggu Zhongyiyao. 2013;32(25):36.

[9] Zhang SB. Gongshuning glue stick in induced abortion. Zhongguo Xiandai Yaowu Yingyong. 2014;8(6):121-121.

[10] Miao DX, Lu P, Hu HF. Experiences of gongshuning glue stick in removal of intrauterine device in menopausal women. Jilin Yixue. 2012;33(28):6153-6153.

[11] Zhong HL. One-off cervical dilating rod with diazepam in 50 cases of induced abortion. Xiandai Zhenduan yu Zhiliao. 2014;25(5):1150-1151.

[12] Bo QF. Cervical dilating rod with oxytocin for abortion in 105 cases of late pregnancy. Shandong Yiyao. 2007;47(22):21.

[13] Yi XJ. Application and therapeutic efficacy of cervical dilating rod for abortion in 434 cases of second or third trimester. Xiandai Yiyao Weisheng. 2014;30(4):555-556.

[14] Nicolaides KH, Welch CC, MacPherson MB, et al. Lamicel: a new technique for cervical dilatation before first trimester abortion. Br J Obstet Gynaecol. 1983;90(5):475-479.

[15] Norström A, Bryman I, Hansson HA. Cervical dilatation by Lamicel before first trimester abortion: a clinical and experimental study. Br J Obstet Gynaecol. 1988;95(4): 372-376.

[16] Wang H, Zou MH, Li DC, et al. Mifepristone and misoprostol to terminate the pregnancy at 10-16 weeks of gestation. Zhongguo Shiyong Fuke yu Chanke Zazhi. 1999;15(7): 441-442.

[17] Guo QY. Mifepristone and misoprostol combined with cervical dilating rod to terminate 10-16 weeks of gestation. Zhongguo Jihua Shengyuxue Zazhi. 2009;165(7):435-436.

[18] Yuan J, Yu S. Effect of mifepristone combining misoprostol and disposable cervical dilatation rod for terminating 12-18 weeks of gestation in 100 cases. Zhongguo Yaoye. 2014;23(15):101-102.

[19] Ye XJ, Yu SN, Cai YR, et al. Cervical dilating rod used for clinical induced abortion. Yixue Xinxi. 2013;26(1):215-216.

[20] Yu Y, Liu Q. Analgesic Effect of one-off cervical dilating rod combined with one-off uterine suction tube for abortion. Keji Xinxi. 2012;29(23):449.

[21] Bian CY, Ni FX, Zou MH, et al. Dilating effect of carboprost methylate on the cervical neck. Zhonghua Fuchanke Zazhi. 1995;30(4):239-240.

[22] Gao SF, Wang JL. Clinical analysis of induced abortion in teenage. Zhongguo Fuyou Baojian. 2010;25(22):3140-3142.

[23] Lin Y, Yuan LP, Huang HY, et al. Phloroglucinol misoprostol for induced abortion in 50 cases. Shiyong Fuchanke Zazhi. 2012;28(6):509-511.

[24] Han RY, Huo CF. Clinical observation of carprost combined with lidocaine for induced abortion. Xiandai Zhongxiyi Jiehe Zazhi. 2010;19(17):2115-2116.

[25] Ma SQ, Ren FY, Fan GS, et al. Vaginal misoprostol and carprost applied before an early abortion. Zhongguo Jihua Shengyuxue Zazhi. 2000;9(10):446-448.

[26] Chen WH, Zhu CF, Yu SF. Observing on results of combining mifepristone with rivanol and misfoprostol combined with rivanol for labor in induction of second trimester in women with scarred nterus. Linchuang Yixue. 2007;33(6):50-51.
[27] Fang HY. Mifepristone in combination misfoprostol for labor in induction of second trimester in women with scarred uterus. Bengbu Yixueyuan Xuebao. 2004;29(3):246-247.
[28] Jiang ZW. Application of estradiol valerate and carboprost methylate in removal of intrauterine device in menopausal women. Dangdai Yixue. 2011;17(6):233.
[29] Guo XH. Application of Gongshuning glue stick in removal of intrauterine device in menopausal women. Zhongguo Fuyou Baojian. 2011;26(2):247-248.
[30] Guo AQ, Guo WW, Liu Y. Clinical outcomes of Gongshuning glue stick in artificial abortion. Qiannan Minzu Yizhuan Xuebao. 2009;22(3):177-178.
[31] Hu Q. Gongshuning glue stick for insertion of intrauterine device that is difficult to place. Dangdai Yixue. 2010;16(28): 69,164.
[32] Zhang JH. Gongshuning glue stick for removal of intrauterine device in menopausal women. Zhongguo Shiyong Yiyao. 2008;3(25):63.
[33] Yang C, Cong L. The clinical observation of menopausal women taking Gongshuning glue stick during removal of intrauterine device. Anhui Yixue. 2014;35(2):164-166.
[34] Zhu TT. Application of gongshuning glue stick in the difficult removal of IUD. Zhongguo Chuji Weisheng Baojian. 2012; 26(7):60-61.
[35] Han CY, Wu YH, Zou WQ. One-off cervical dilating rod used in intrauterine device removing during menopause period. Zhongguo Jihua Shengyuxue Zazhi. 2013;21(1):57-58.
[36] Hu HM. Mifepristone and misoprostol combined with one-off cervical dilating rod to terminate 12-18 weeks of gestation. Zhongguo Jihua Shengyu he Fuchanke. 2012; 4(1):33-35.
[37] Ma JF. Comparison of preoperative cervical preparations for removal of intrauterine devices in postmenopausal women. Zhongguo Jihua Shengyu Zazhi. 2010;18(3):173.
[38] Zou Y, Wu SC. The Application of Laminaria to expand and ripen cervical canal before surgical abortion. Guoji Shengzhi Jiankang/Jihua Shengyu Zazhi. 2010;29(1): 59-61.
[39] Luo H. Cervical dilating rod for second trimester abortion in scarred uterine. Zhonghua Fuyou Linchang Yixue Zazhi. 2010;6(6):435-436.
[40] Yin S, Lei L. Clinical observation of tibolone and misoprostol combined with cervical dilating rod in intrauterine device removing during menopause period. Jianyan Yixue yu Linchuang. 2013;10(15):1972-1973.

高分子吸水材料宫颈扩张棒的生物相容性

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文章亮点：

试验对比优美特宫颈扩张棒与宫术宁胶棒在置、取宫内节育器及人工流产术前扩张宫颈的临床效果，发现优美特宫颈扩张棒操作简便，效果可靠、安全，不良反应少，并可显著减轻疼痛感。

关键词：

生物材料；材料相容性；宫颈扩张棒；优美特宫颈扩张棒；宫术宁胶棒；宫颈扩张；随机；对照

主题词：

生物相容性材料；宫内避孕器；子宫颈

摘要

背景：优美特宫颈扩张棒由高性能吸水性好的高分子生物材料制成，无毒副作用，一次性使用，可避免交叉感染。

目的：观察优美特宫颈扩张棒用于置、取宫内节育器及人工流产术前扩张宫颈的临床效果。

方法：将置、取宫内节育器、妊娠 10 周内负压吸引人工流产术需扩张宫颈的 275 名女性，随机分为两组，观察组 137 名，应用优美特宫颈扩张棒扩张宫颈；对照组 138 名，应用宫术宁胶棒扩张宫颈。观察两组术中宫颈软化扩张情况、镇痛效果、综合反应程度。

结果与结论：两组育龄期置、取宫内节育器的宫颈扩张效果比较差异无显著性意义，观察组人流和绝经期取宫内节育器的宫颈扩张效果优于对照组($P < 0.05$)；观察组置入时的疼痛发生率低于对照组($P < 0.05$)，两组留置时的疼痛发生率均较低且无差异；两组手术结果及安全情况比较差异无显著性意义。两组均顺利取出扩张棒，无宫颈损伤发生，术中无血压下降、心率减慢等心脑综合征发生，未发生与扩张宫颈相关的不良事件。表明优美特宫颈扩张棒扩张宫颈效果安全、可靠，可显著减轻疼痛感。

作者贡献：试验构思及设计为第一作者和通讯作者；第三、四作者共同完成实验实施、文献查询及论文写作；通讯作者审校；第一作者与通讯作者对本文负责。

利益冲突：文章及内容不涉及相关利益冲突。

伦理要求：患者对治疗知情同意。

学术术语：优美特一次性宫颈扩张棒-由高性能吸水性好的高分子生物材料制成，无毒副作用，一次性使用，可避免交叉感染，安全速效，使用时将其插入宫颈管内，3–5 min 即迅速起效，柔滑无痛，吸水后表面光滑，放置在宫颈管后，在人体温度及宫颈温度条件下能吸收体液并自行膨胀，能够通过对子宫下段及宫颈组织的作用诱发生化改变，达到扩张宫颈和减轻疼痛的效果，同时又起到软探针探宫腔的作用。

作者声明：文章为原创作品，无抄袭剽窃，无泄密及署名和专利争议，内容及数据真实，文责自负。

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