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二次剖宫产术中放置吉娜固定式宫内节育器的效果和安全性研究*

李 晖 宁艳辉 许常娟 申茹萌 朱蒙蒙

(广州军区总医院一五七分院妇产科 广东 广州 510510)

摘要 目的:观察二次剖宫产术中放置吉娜固定式宫内节育器(GyneFixPP IUD)的疗效,并评价其安全性。**方法:**选择本院 2011 年 1 月至 2013 年 2 月既往曾行 1 次剖宫产的疤痕子宫孕妇共 316 例,其中上环组 156 例受术者均为自愿选择再次剖宫产术中放置吉娜环,对照组 160 例行常规再次剖宫产术,未上环或结扎。术后 42d、3 个月、6 个月、12 个月对两组患者进行随访,收集并分析两组术后出血、恶露及避孕环在位及不良反应等情况。**结果:**两组出血量、血性恶露持续时间及恶露持续时间差异均无统计学意义($P>0.05$)。产后 3 个月、6 个月、12 个月均出现经量增多、不规则出血、疼痛、白带增多及男方性交痛等副反应,但主诉不适逐渐减少,经相关处理后症状缓解或消失。上环组 S-S 距离为 1.4-2.2 cm 的在 42d 占 77.50%,在 3 月占 72.41%,在 6 月占 82.14%,在 12 月占 81.25%,其差异无统计学意义($P>0.05$)。上环组随访的 151 例产妇有 4 例(占 2.65%)避孕环 1 年内自行脱出,因症取出 2 例(占 1.32%),续用率为 96.04%。上环组 2 年内意外妊娠 0 例,对照组 5 例,约占 3.1%,5 例均选择行人工流产结束妊娠。**结论:**二次剖宫产术中放置吉娜环安全,脱落率低,续用率高,避孕效果好,值得推广应用。

关键词:二次剖宫产;吉娜固定式宫内节育器;疗效;安全性

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Effect and Safety of GyneFixPP IUD in the Second Cesarean Section*

LI Hui, NING Yan-hui, XU Chang-juan, SHEN Ru-meng, ZHU Meng-meng

(Department of Obstetrics and Gynecology, THE 157th Hospital Affiliated to General Hospital of Guangzhou Military Command, Guangzhou, Guangdong, 510510, China)

ABSTRACT Objective: To observe the effect of GyneFixPP IUD in second cesarean section and evaluate its safety. **Methods:** A total of 316 pregnant women who had undergone 1 cesarean section in our hospital from January 2011 to February 2013 were selected, 156 patients were voluntarily chosen to GyneFixPP IUD in the second cesarean section as the Upper ring group, and 160 cases underwent routine cesarean section again as the control group, which were no upper ring and ligation. The two groups were followed up for 42d, 3, 6, and 12 months after operation, and the postoperative bleeding, lochia and contraceptive ring in two groups were collected and analyzed. **Results:** There was no significant difference in bleeding volume, bloody lochia duration and lochia duration between the two groups ($P>0.05$). There were side effects such as increased volume, irregular bleeding, pain, leucorrhea and male sexual intercourse pain at 3, 6, and 12 months after delivery. However, complaints were gradually reduced and symptoms relieved or disappeared after treatment. The S-S distance of 1.4-2.2 cm in the upper ring group was 77.50% in 42d, 72.41% in 3 months, 82.14% in 6 months and 81.25% in 12 months, and there was no significant difference between them ($P>0.05$). 4 cases (2.65%) of the contraceptive rings came out spontaneously within one year, 2 cases (1.32%) were removed because of symptoms in 151 cases of parturients followed up in the upper ring group, and the rate of continuation was 96.04%. There were 0 cases of accidental pregnancy in the upper ring group in 2 years, 5 cases in the control group, accounting for 3.1%, and 5 cases were terminated by artificial abortion. **Conclusion:** The GyneFixPP IUD is characterized by safety, low dropout rate, high rate of continued use and good contraceptive effect. It is worthy of popularization and application.

Key words: Second cesarean section; GyneFix PP IUD; Efficacy; Safety

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前言

随着近十几年来剖宫产率的不断上升及二孩时代的到来,目前有剖宫产史的孕妇再次剖宫产的人数大量增加^[1-2]。对于这组产妇术后避孕的问题则亟需妇产科医生解决。目前剖宫产术后和哺乳期选择的避孕方法比较有限,除输卵管结扎这种绝对

避孕方式外,常规上环需等待 6 个月以后^[3-5]。由于产后子宫软而脆,且有疤痕的形成,哺乳期妊娠或流产都成为棘手的问题^[6,7]。吉娜环是专为剖宫产术中同时放置而设计的节育环,我科自 2011 年以来,采用剖宫产术中即时放置宫内节育器对二次剖宫产并需要可逆性避孕方法的产妇进行即时避孕,通过观察二次剖宫产术中放置吉娜固定式宫内节育器避孕的效果和安

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作者简介:李晖(1967-),女,硕士,副主任医师,主要从事产科方向的研究,E-mail: lihui196712@126.com

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全性,为今后在疤痕子宫即时避孕提供理论依据和数据参考。

1 资料与方法

1.1 研究对象

经我院伦理委员会审核批准后,选择本院 2011 年 1 月至 2013 年 2 月既往曾行 1 次剖宫产的疤痕子宫(距离上次剖宫产时间 2-8 年)的孕妇共 316 例,年龄 26-40 岁之间。纳入标准:(1)自然受孕且单胎妊娠;(2)孕期定期产检,孕前孕期无明显并发症,无潜在感染及出血的高危因素;(3)孕足月,有或无临产;(4)要求剖宫产终止妊娠,且剖宫产术中宫缩好,术中无明显并发症,术中出血小于 500 mL。排除标准:(1)不定期产检;(2)孕前有并发症;(3)潜在感染者,严重肝肾功能障碍者或凝血功能障碍者;(4)宫缩差,依从性差者。将 156 例自愿选择再次剖宫产术中放置吉娜环的受术者作为上环组(n=156),将 160 例行常规再次剖宫产术,未上环或结扎的受术者作为对照组(n=160)。上环组年龄 26-39 岁,平均(28.25±3.37)岁,平均产检(8.33±2.03)次,孕期并发症 0 例,术中并发症 0 例,术中平均出血(254.35±41.52)mL;对照组年龄 26-40 岁,平均(31.20±3.29)岁,平均产检(7.91±2.14)次,孕期并发症 0 例,术中并发症 0 例,术中平均出血(368.17±43.73)mL。两组在年龄、孕期产检及手术情况等各方面的差异无明显统计学意义($P>0.05$),临床基线资料均衡可比。本研究获得我院伦理委员会批准、通过。所有患者均自愿术中放置宫内节育器,并签知情同意书。

1.2 方法

上环组:均在胎盘娩出前子宫体常规注射缩宫素 20IU,一侧三角肌同时注射卡前列三丁氨醇 250 μg,并清理子宫腔,确认无胎盘残留、宫缩好的情况下放置吉娜环。吉娜环放置器由

塑料套管和推杆组成,推杆的顶端顶在降解锥底部的凹槽里,放置时术者轻轻向前推动推杆约 1.2cm,即可将吉娜的线结和降解锥植入子宫肌层,使宫内节育器(IUD)悬挂在子宫腔内。退出放置器,牵拉尾丝确认吉娜 IUD 已固定于宫底,去除套在环形尾丝上的活动丝线,放置完毕。常规缝合子宫。156 例中 149 例 1 次放置成功,7 例 2 次放置成功。对照组产妇均于胎盘娩出前子宫体常规注射缩宫素 20IU,一侧三角肌同时注射卡前列三丁氨醇 250 μg,常规缝合子宫。

1.3 观察指标

术中通过负压吸引瓶中血量及纱布吸血量记录两组受试者术中出血量;术后用记血量纸称重计算产后 2h 及产后 24h 出血量(累计血量);记录术后血性恶露时间、恶露持续时间。产后 42d、3 个月、6 个月和 12 个月复查时,收集月经卡进行统计,同时统计经量增多、不规则出血、疼痛、白带增多、男方性交痛等副反应。B 超检查子宫复旧情况、IUD 位置及尾丝状况。随访时,详细记录有无脱落、带器妊娠、中途取出和失访等情况。通过观察 S-S 来评估吉娜环的在位情况。S-S 距离为 B 超测量吉娜宫内节育器第一个铜片到宫底距离。S-S 距离在 1.4 cm-2.2 cm 为安全距离^[8]。

1.4 统计学方法

录入数据,采用 SPSS 15.0 统计软件进行统计分析。计量资料采用独立样本 t 检验。计数资料采用 χ^2 检验。检验水准 $\alpha=0.05$ 。

2 结果

2.1 出血量和恶露时间比较

两组术中、术后 2h、术后 24h 出血量、血性恶露持续时间及恶露持续时间差异均无统计学意义($P>0.05$)。见表 1。

表 1 两组术中、术后出血量与恶露持续时间比较($\bar{x}\pm s$)

Table 2 Comparison of bleeding volume and lochia duration in two groups during and after operation($\bar{x}\pm s$)

Groups	Cases(n)	Bleeding volume during operation(mL)	Postoperative 2h bleeding volume	Postoperative 24h bleeding volume(mL)	Bloody lochia duration(d)	Lochia duration(d)
Upper ring group	156	279.20±71.59	338.30±75.40	402.40±83.40	8.80±3.20	24.60±7.70
control group	160	268.50±61.86	329.00±65.30	388.80±68.70	8.30±2.60	24.10±5.80
t	-	1.423	1.172	1.583	1.530	0.653
P	-	0.161	0.240	0.114	0.132	0.511

2.2 上环后不适主诉

产后 42d 上环组无主诉不适,产后 3 个月主诉不适有 45 例,占 29.80%,其中经量增多 3 例,不规则出血 12 例,疼痛 6 例,白带增多 14 例,男方性交痛 10 例;产后 6 个月后主诉不适减少且症状减轻,主诉不适有 33 例,占 21.85%,其中经量增多 8 例,不规则出血 10 例,疼痛 3 例,白带增多 12 例,男方性交痛 0 例;对出现男方性交痛者,经处理尾丝后症状消失;产后 12 个月主诉不适明显减少,主诉不适有 18 例,占 11.92%,其中经量增多 5 例,不规则出血 2 例,疼痛 1 例,白带增多 10 例,男方性交痛 0 例。对照组因术中未上环,术后经量、不规则出血、疼痛、白带异常、性交痛等情况与术前无明显差异。

2.3 妇科检查及 B 超检测吉娜宫内节育器位置

产后 42d,随访 156 例上环组患者,失访 5 例,其余 151 例查环均在位。产后 3 个月、6 个月、12 个月,宫内置环的随访人数分别为 116 例、84 例、80 例,查环均在位。所有宫内置环、环未脱落的产妇,环的位置均正常。上环组 S-S 距离为 1.4-2.2cm 的在 42d 占 77.50%,在 3 月占 72.41%,在 6 月占 82.14%,在 12 月占 81.25%,其差异无统计学意义($\chi^2=5.549, P=0.467$),见表 2。

2.4 上环组使用效果

上环组随访的 151 例产妇有 4 例(占 2.65%)避孕环 1 年内自行脱出,均给予再次上避孕环(吉娜环);2 例(占 1.32%)因反复阴道流血药物治疗无效术后 1 年内取环,后未采取其他长效避孕措施,续用率为 96.04%;无带器妊娠发生,带器妊

表 2 B 超检测吉娜宫内节育器位置的 S-S 距离

Table 2 S-S distance of GyneFixPP IUD location detected by B-mode ultrasonography

Follow up date	Cases(n)	S-S<1.4 cm		S-S 1.4-2.2 cm		S-S>2.2cm	
		n	%	n	%	n	%
42d	151	32	21.19	117	77.48	2	1.32
3 months	116	30	25.86	84	72.41	2	1.72
6 months	84	15	17.86	69	82.14	0	0.00
12 months	80	15	18.75	65	81.25	0	0.00

娠率 0%。

2.5 长效避孕措施的落实情况

目前剖宫产术后常用的长效避孕措施除术中上环外,还有术中同时结扎、术后 6 个月后上环、皮下埋植等。剖宫产术后很多产妇因为哺乳、不重视等原因,不能及时落实长效避孕措施。

本实验中对照组 160 例术中结扎 16 例,1 年内上环 32 例;术后 2 年,累计结扎 16 例,上环 62 例;术后 3 年,累计结扎 16 例,上环 76 例。而剖宫产术中及时上环,很大程度上弥补了该方面的不足。见表 3。

表 3 术后长效避孕措施落实情况对比

Table 3 Comparison of the implementation of long-term contraceptive measures after operation

Groups	1 years after the operation		2 years after the operation		3 years after the operation	
	n	%	n	%	n	%
Upper ring group	151	98.67	151	98.67	151	98.67
Control group	48	30.00	78	48.75	92	57.50

2.6 避孕效果

因剖宫产术后要求避孕 2 年左右,有生育要求的产妇 2 年后不再避孕。本研究 2 年内意外妊娠情况,上环组 0 例,对照组 5 例,约占 3.1%,5 例均选择行人工流产结束妊娠。

3 讨论

1996 年,世界卫生组织(WHO)的第一版《避孕方法选用的医学标准》^[9]建议产后哺乳或不哺乳(包括剖宫产)者可以在产后 48 小时内放置带铜节育器。该指南为我们剖宫产术中放置 IUD 提供了有力的依据。相关研究表明,产后宫腔大、宫口松弛或宫颈管消失等均可能在一定程度上影响放置 IUD 的效果,导致脱落率增加^[10-12]。吉娜环宫内节育器是专门为产后即时避孕而设计的一种无支架宫内节育器,其主要由 6 个高纯度铜套组成,悬吊铜套上端的固定系统中增加了一个可生物降解的固定锥体,有助于降低其的脱落率^[13,14]。放置吉娜环时,手术线和锥体同时植入子宫底剖肌层,放置后的 6-12 周时间内,锥体缓慢降解,但手术线小结仍保留在子宫肌层,使其较为结实地钉在肌壁上,使其环上的 6 个铜套悬吊在宫腔内^[15]。吉娜环没有支架,可随意弯曲,可适用于任何大小和形状的子宫。另外,吉娜环可减少对子宫内膜的干扰,降低机械性无菌性炎症的发生,且术后异常出血较其他带铜避孕环明显减少,是剖宫产术后放置的最佳选择^[16]。吉娜环不含任何激素,且不影响内分泌及哺乳,产后即能发挥避孕作用,大大降低了意外妊娠率,减少了疤痕子宫妊娠给妇女和医生带来的困扰^[17,18]。

有学者研究^[19-22]指出剖宫产术中放置吉娜固定式 IUD 的产妇与未放置 IUD 的剖宫产产妇进行比较,观察结果认为,剖

宫产术中放置吉娜固定式 IUD 未增加产后出血量及恶露持续时间,不影响子宫复旧。本研究结果与上述结果相似,二次剖宫产术中即时放置吉娜环,可不增加术中、术后出血量,对子宫复旧无不良影响。放置吉娜环者的产后恶露持续时间略长于对照组。表明吉娜环具有较好的安全性,不影响子宫复旧。相关研究表明,因不良反应(出血、感染、腹痛、腰痛)严重而导致取出宫内节育器,是描述宫内节育器不良反应的一项重要指标^[22-25]。2 例取环患者均为产后血性分泌物始终未净,时多时少,呈鲜红色。妇科检查及 B 型超声检查均未发现明显异常,药物治疗无效,分别于产后 3 个月和 5 个月取出吉娜环。探讨出血原因,一般产后血性恶露时间延长可能与产后子宫缩复欠佳、子宫内膜炎或宫腔内组织残留有关。在我们对放置吉娜环产妇的随访中,B 超观察放器的产妇产后子宫复旧良好,宫腔内未发现明显残留组织。因此,吉娜环引起的产后血性恶露时间延长考虑与上述因素无明显关系。可能是因为异物或铜离子的释放而致宫腔局部的止血反应改变等原因导致出血不止。也可能是由于子宫切口为二次疤痕切口,容易发生切口愈合不良造成不规则流血^[26-30]。

本研究中,上环组随访的 151 例产妇吉娜环脱落 4 例,脱落率 2.65%,低于文献中术中放置其它 IUD 者^[7],12 个月内续用率 96.04%,无带器妊娠,避孕效果良好。产后 12 个月复查时随访仍续用者,B 超可见子宫腔内吉娜环无异位。分析避孕环脱落的原因,考虑脱落病例均为技术开展初期产妇,与实施上环操作不熟练,降解锥植入深度未达到要求有关。因疤痕子宫再次剖宫产术中发生宫缩乏力的几率要比第一次剖宫产术中的发生率要高,因此我们常规术中肌注卡前列三丁氨醇预防宫

缩乏力。常规子宫体部注射缩宫素 10 μ , 并肌注卡前列三丁氨醇 250 μ g, 待宫底部收缩硬时再放入节育器。少数情况子宫收缩但宫底部软, 放置困难, 不可强行放入, 否则容易发生子宫穿孔或节育器脱落, 此种情况不建议放入吉娜环。

综上所述, 二次剖宫产术中放置吉娜环操作安全性高, 脱落率低, 避孕效果好, 可以大大提高二次剖宫产妇女的生活质量, 减轻心理负担, 值得在二次剖宫产手术中推广。但吉娜环的远期脱落率和避孕效果及其他并发症, 还有待进一步观察及研究。

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