

Interval female sterilization : a comparative study between Falope rings and Filshie clips.

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This study is a preliminary report comparing two methods of fallopian tubal occlusion for interval female sterilization via laparoscopy. Four hundred fifty four cases were included in this study during the period of March, 1986 to March, 1989 at Family Planning Unit, Department of Obstetric and Gynecolog Faculty of Medicine, Chulalongkorn University, Bangkok. A block, randomized single blind method was used in this study with chi-square and t-test by using SPSS PC+package.

There was no difference in client characteristics or epidemiologic profile of two methods. Falope rings were applied at isthmus ampulla junction more often than the Filshie clips ($P = 0.05$) and showed moderate to severe pain during the recovery period more than with the Filshie clips ($P = 0.01$). Application of clips was more difficult than with the rings ($P = 0.05$). Surgical injuries were found only in the Falope ring method. There were two cases of luteal phase pregnancy in each group. The impact to family planning program is that, in the case of restoring infertility, the clip may have a greater advantage because of less tubal-lengthed damage.

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วิรัช วิศวกรรมงคล, กอบจิตต์ ลิ้มปพยอม. การทำหมันในสตรีระยะไม่ตั้งครรรภ์ : การศึกษาเปรียบเทียบระหว่างแฟลลอปริงส์ และฟิลชีคลิปส์. จุฬาลงกรณ์เวชสาร 2533 ธันวาคม:34(12): 945-952

การศึกษาครั้งนี้เป็นรายงานเบื้องต้นของการทำหมันในสตรีในระยะไม่ตั้งครรรภ์ด้วยลาพาโลสโคป โดยเปรียบเทียบวิธีทำให้หลอดมดลูกอุดตัน 2 วิธี ระหว่าง Falope rings และ Filshie clips ผู้รับบริการ 454 คน ณ หน่วยวางแผนครอบครัว ภาควิชาสูติศาสตร์-นรีเวชวิทยา คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ในช่วงระหว่างเดือนมีนาคม พ.ศ. 2529 ถึงเดือนมีนาคม พ.ศ. 2530 ถูกแบ่งกลุ่มและศึกษาแบบ block, randomized single blind โดยมีการติดตามผลทั้งระยะสั้นและระยะยาวนาน 1 ปี สถิติที่ใช้วิเคราะห์ข้อมูล ได้แก่ chi-square และ t-test โดยใช้โปรแกรมคอมพิวเตอร์ SPSS

ผลการศึกษา ลักษณะทั่วไปของผู้รับบริการทั้งสองกลุ่มไม่แตกต่างกัน แต่พบว่าในกลุ่ม Falope rings มีการรั่วหลอดมดลูกบริเวณรอยต่อ isthmic ampulla บ่อยกว่ากลุ่ม Filshie clip ($P < 0.05$) และพบการปวดท้องน้อยรุนแรงในระหว่างพักฟื้นในกลุ่ม Falope rings มากกว่ากลุ่ม Filshie clips ($P < 0.05$) ถิ่นตรายจากการผ่าตัดพบเฉพาะในกลุ่ม Falope rings เท่านั้น และพบการตั้งครรรภ์หลังการทำหมัน ซึ่งเกิดจาก luteal phase pregnancy กลุ่มละ 1 ราย ผลกระทบของวิธีทำหมันดังกล่าวคือโครงการวางแผนครอบครัว มีกล่าวในรายละเอียด

Interval female sterilization employing the laparoscope has been practiced during the last two decades. The method of tubal occlusion was mainly electrocoagulation : unipolarcoagulation,⁽²⁻⁵⁾ and bipolarcoagulation in which accidental burns also occurred.⁽⁶⁾ The non electrical device technique, Falope rings, was widely used after 1973,⁽⁷⁾ followed then by clips in 1980.^(8,9) In Thailand, unipolar electrocoagulation was used for tubal occlusion since 1972⁽¹⁰⁾ and converted to rings in 1978.⁽¹¹⁾ Researchers had developed many reliable tubal occlusion methods in the search for an appropriate, better method of female sterilization, which minimizes complications.

Most women who decide on female sterilization remain satisfied with their choice. Careful counseling for contraceptive choice may help women who may request reversal of sterilization later. At present, younger and younger women are requesting sterilization, the younger these women are, the possibility of serious sequelae increases.^(12,13) The family formation pattern of these younger women who already had female sterilization will be influenced by unpredictable events such as changes in their marital status, death of their spouse or children and also a renewed desire for more children. About one-third of these women will request reversal of sterilization.⁽¹⁴⁻¹⁶⁾ Thus, the tubal occlusion method should be developed for its potential of reversibility as well as still maintaining its efficacy and efficiency.

In Thailand, the Demographic and Health Survey, conducted in 1987, showed that voluntary surgical contraception is the most popular of all contraceptive method.⁽¹⁷⁾ Reports of sterilization reversal requested also exist in Thailand.⁽¹⁸⁾

This paper is to report the result of a comparative study of interval female sterilization, utilizing Falope rings and Filshie clips through laparoscopy. The objective of this study is to evaluate the safety, ease of performance and effectiveness of each method.

Materials

There were 454 clients from Family planning Unit, Department of Obstetric and Gynecology, Faculty of Medicine, Chulalongkorn University, whose selection criteria were met, included in this study during the period of March 1986 to March 1989. The clients were allocated into two groups by a block, randomized single blind method resulting in 227 clients each for the Falope rings and Filshie clips.

Criteria for clients' selection

1. Women of 21 years of age or older.
2. Duration since last delivery must be over 6 weeks.

3. Free of any communicable disease and any severe medical condition.

4. Legally capable of consenting to sterilization

Methods

On admission the clients were interviewed. A general physical examination and a pelvic examination were performed. The consent form was signed. The client entered the out-patient operating theatre and was prepared for sterilization. The Filshie clip and Falope ring methods were assigned by block randomized allocation, according to a computer-generated code. The operation proceeded as indicated for that particular client.

Intravenous 10 mg of diazepam and 75 mg pethidine were given slowly for neuroleptalgia. The KLI Laparoscope TM was utilized for the Falope ring occlusion method while Filshie clips were applied through the Wolf laparoscope with 8 mm. working channels. Both devices were applied at the isthmic portion of the normal fallopian tubes. But if it could not be applied to the isthmic portion which may have been due to either chronic infection or peritubal adhesion, it would be applied to another part of the fallopian tube instead.

After the sterilization procedure, the client was observed in the recovery room for a period of time. During this time blood pressure, pulse and respiration rate were monitored by the evaluator who was not the operating physician. Clients were asked about pain during recovery and whether they needed any pain medication or not. Signs of any bleeding were also monitored. All 454 clients were sent home on the same day of the sterilization procedure.

Clients were requested to come back for follow-up at 30 days, 6 months one year and two years after sterilization or at any time a problem occurred. The evaluators who conducted the follow-up examinations were not the operating physicians to ensure the "blind" design of this study. At the six month, one year and two year follow-up, clients were thoroughly interviewed about the menstrual pattern and any symptoms related or not related to sterilization. Also the pelvic examination plus Papanicolaou smear were given.

Results

The data was analysed using chi-square and t-test.

Characteristics of clients are virtually the same in both groups. The ages are between 21-45 years with average ages of 31.5 and 32.1 in Falope Ring and Filshie groups respectively (Table 1). Parity is 2.4 in both groups with the same number of male and female children. The open interval is 3.6 years and 3.9 years in the Falope and

Filshie group respectively. More than half of each group had children age 3 or under at the time of their sterilization

which implied that these women were satisfied with their family size. Most of the clients had only Primary education or less (Tables 2).

Table 1. Characteristic of clients.

Characteristics	Falope rings (n=227)	Filshie clips (n=227)
Age (years) : $X \pm SD$	31.52 \pm 5.16	32.09 \pm 4.98
Range	21.45	22.45
Parity (%)		
1	3.96	3.96
2-3	84.58	89.43
≥ 4	11.46	6.61
Average parity : $X \pm SD$	2.48 \pm 0.85	2.4 \pm 0.68
Male :	1.33 \pm 0.85	1.25 \pm 0.80
Female	1.12 \pm 0.91	1.15 \pm 0.80
Last delivery (years) : $X \pm SD$	3.62 \pm 2.70	3.88 \pm 2.91
Educational level (%)		
None	3.52	6.17
Level 1-4	58.15	61.67
Level 5-6	10.13	10.57
Level 7-12	21.59	16.74
University	6.61	4.85

Table 2. Age of last living child at time request.

Age (years)	Falope rings			Filshie clips		
	Number	%		Number	%	
<1	25	11.01	} 52.86	32	14.09	} 51.98
1-3	95	41.85		56	37.89	
4-6	61	26.87		50	22.03	
≥ 7	46	20.27		59	25.99	
Total	227	100.00		227	100.00	

In each groups of clients, more than 85% had used some kind of contraception at least 3 months prior to the sterilization. The majority of those with parity 2,3 and 4 practiced some form of modern contraception as shown in Table 3.

For the tubal occlusion in the Filshie clip group,

the clips were applied at the Isthmic area in more cases than for the ring group. The right tube, Falope rings were applied at isthmic ampulla junction more than for the Filshie group ($P < 0.05$). When examined deeply into occlusion site of the right and left tubes, the majority of occlusion in both group were at isthmic-isthmic junction (Table 4).

Table 3. Contraception prior to sterilization.

Contraceptive method	Falope rings (n=227)						Filshie clips (n=227)					
	Total	NO. Parity					Total	NO. Parity				
		1	2	3	4	≥5		1	2	3	4	≥5
None	33	2	11	11	7	2	27	1	11	12	3	-
IUD	31	-	23	5	5	-	34	1	19	11	3	-
OC	86	2	53	22	5	4	89	5	53	28	3	-
Inject	62	3	36	19	4	-	63	2	38	17	5	-
Condom	13	2	8	2	4	-	11	-	8	3	-	-
Natural	2	-	1	1	-	-	3	-	3	-	-	-
	227		132	60	20		227		132	71	14	

Table 4. Tubal occlusion site

Tubal occlusion site	Falope rings		Filshie clips	
	RT(%)	LT(%)	RT(%)	LT(%)
Isthmic - isthmis	208(91.6)	210(92.5)	221(97.4)	221(97.4)
Ampullary - ampullary	2(0.9)	2(0.9)	2(0.9)	1(0.4)
Isthmis - ampullary	16*(7.0)	14(6.2)	3*(1.3)	4(1.8)
Infundibulum	1(0.4)	1(0.4)	1(0.4)	1(0.4)

*P < 0.05

During the operation, pain was recorded if the patient made a flinch or a movement during the application of the applying devices. Three hours after sterilization in

the recovery room, there was more moderate to severe pain in the ring group ($P < 0.01$). The majority of the clips group had either no pain or only mild discomfort (Table 5).

Table 5. Pain.

	Falope rings				Filshie clips			
	None	Mild	Mod.	Severe	None	Mild	Mod.	Severe
During operation	173	41	13	—	182	34	10	1
During recovery	83	84	45*	15*	100	94	29*	4*
	None	Observe	Med	None	Observe	Med		
Medication	90	22	115 (50.6)	102	17	108 (48.4)		

*P < 0.01

There were some difficulties encountered during the operation, mostly from the equipment in the ring group. These problems can be avoided by good care and maintenance of the units. Applying the clips is more difficult than the rings ($P < 0.05$) especially during the grasping of the tubes. This can be overcome by more training and experience, but a mesosalpingeal tear occurred in the ring group more than the clip group ($P < 0.05$). No

active management was needed in these cases however (Table 6,7). Of 454 study cases, 40 or 8.8% had previous abdominal surgery, but required open laparoscopy in only 6(1.3%). The rest of these cases received the conventional approach ($P < 0.001$) (Table 8).

This study showed a good rate of follow up (Table 9). There were two cases of pregnancy reported in this series and both were from luteal phase pregnancy.

Table 6. Difficulties encountered during operation.

Cause of difficulties	Falope rings	Filshie clips
1. Equipment	5	1
2. Entering peritoneal cavity	1	5
3. Visualizing tubes	1	6
4. Grasping tubes	2	7*
5. Occluded technic	4	1

*P < 0.05

Table 7. Injury to tubes.

Injury	Falope rings	Filshie clips
None	220	226
Tear tubes without bleeding	7*	1

*P < 0.05

Table 8. Surgical approach for clients with previous abdominal surgery.

Surgical approach	Closed	Open
No previous surgery	414	—
With previous surgery	34*	6

*P < 0.001

Table 9. Follow up.

Follow up	Falope rings		Filshie clips	
	(n=227)	%	(n=227)	%
With in 30 days	199	87.66	203	89.4
With in 6 months	148	65.19	152	66.96
With in 1 Yr.	96	42.29	101	44.49
With in 2 Yrs.	50	22	50	22

Discussion

For interval female sterilization utilizing laparoscope at the present time, clips and rings are more widely used for tubal occlusion than electricity which causes more tubal damage. In this comparative study the epidemiologic profile of the patients in two groups was not dissimilar. The system of information, education and counseling about family planning were given through mass communication channels, so that women with no or little education knew about sterilization. That more than 85% of these women in this study had used some kind of contraception prior to this study implies that all clients were satisfied with their family size and were eligible for permanent contraception.

The technique of tubal occlusion using rings destroyed about one to 3cm. of the tube, while clips caused considerably less damage to the tubes (0.5cm). More pain occurred in the rings group during recovery which was due to 10-15 millimeters of the tube which was damaged. In the Filshie clips group, only 3-4 millimeters of the tubes were damaged. The rings required more tissue than clips, especially in the cases of stiff and thick tubes. In this study, there were a certain number of clients whose fallopian tubes were not occluded at isthmic-isthmic site as shown on Table 4. The reason is that when one attempts to put

rings on thick and stiff tubes, one is prone to tearing of tube next to cornual end which is obviously a serious complication. If one moves a little further down the tubes, towards the ampulla, the tissue itself will slide inside the forceps tongs more easily and a tear is less likely to occur. However, this isthmic-ampulla junction is not the ideal site for tubal occlusion because incomplete occlusion may occur. Surgical injuries occurred only with the falope rings group and which were due to chronic inflammation of tubes which were seen under the laparoscope. In this study, clinically chronic inflammed tubes are major cause of tubal tearing. The rings are not usually difficult to apply unless the woman had pelvic adhesion or swollen tubes from chronic infection, which will lead to transection or tearing of the tubes. Short term post-operative pain was common in this study. In this study the pain during operation is unlikely to be interpreted correctly because the patients are under neuroleptalgia. But the pain during recovery, when the patients are fully concious, can be assessed and compared.

One should be very cautious with method of reaching the tubes. Open laparoscopy was utilized in cases of previous abdominal surgery, but for the specialist with an experienced hand, open laparoscopy may not be necessary.

In case of restoring fertility, both methods may have impact on family planning program. Restoring fertility is likely to be more successful in both clip and ring sterilization, compared to electrocoagulation or the complex ligation technique. But between clips and rings, the former may have a greater advantage, because the tubal length left is considered as the single most important prognostic factor for reversal.⁽⁹⁾ If one attempts to do a cost analysis of the different reversal methods, several items such as capital cost relevant to the method of sterilization and reversal, recurring costs associated with each method of reversal, all needed to be considered.

References

1. Yuzpe AA, Rioux JX, Loffer FD, Pent D. Laparoscopic tubal sterilization by the "burn only" technic. *Obstet Gynecol* 1977 Jan; 49(1) : 106-9
2. Loeffler FD, Pent D. Risks of laparoscopic fulguration and transection of the fallopian tube. *Obstet Gynecol* 1977 Feb; 49(2) : 218-22
3. Loeffler FD, Pent D. Indications, contraindications and complications of laparoscopy. *Obstet Gynecol Surv* 1975 Jul; 30(7) : 407-27
4. Peterson HB, Ory HW, Greenspan JR, Tyler, CW Jr. Death associated with laparoscopic sterilization by unipolar electrocoagulating devices, 1978 and 1979. *Am J Obstet Gynecol* 1981 Jan 15; 139(2) : 141-3
5. Lubell I, Neuwirth RS, Frischer R. A hidden risk : extrauterine pregnancy after tubal sterilization. *Adv Planned Parenthood* 1978; 13(3-4) : 24-9
6. Rioux JE, Cloutier D. A new bipolar instrument for laparoscopic tubal sterilization. *Am J Obstet Gynecol* 1974 Jul 15; 119(6) : 737-9
7. Poliakoff SR, Yoon IB, King TM. A four-year experience with the Yoon ring. In : Phillips JM, ed. *Endoscopy in Gynecology : Proceeding of the Third International Congress on Gynecologic Endoscopy San Francisco, California. Missouri : Christian Board of Publication, 1978. 197-208*
8. Hulka JE. The spring clip. In : Phillips JM, ed. *Laparoscopy. Baltimore : Williams & Wilkins, 1977. 167-73*
9. Hulka JF, Mercer JP, Fishburne. Spring clip sterilization : one year follow-up of 1079 cases. *Am J Obstet Gynecol* 1976 Aug 15; 125(8) : 1039-43
10. Limpaphayom, K, Reinprayoon D, Aribarg A, Snidvongs V, Young J, Amatayakul A, Sindhu-phak S, Witoonpanich P, Vaivanijkul B. Laparoscopic tubal Electrocoagulation for sterilization : 5000 cases. *Int J Gynecol Obstet* 1980; 18(6) : 411-3
11. Limpaphayom K. Female Sterilization utilizing Falope Rings through Laproscator. *Chula Med J* 1980 May; 24(5) : 405-15
12. National Center for Health Statistics, Public Health Service, Us Department of Health and Human Services. *Contraceptive use-United States, 1982.*
13. Siegler AM, Hulka JF, Peretz A. Reversibility of female sterilization. *Fertil Steril* 1985 Apr; 43(4) : 499-510
14. Alder E, Cook A, Gray J, Tyrer G, Warner P, Bancroft J London NB. The effect of sterilization : a comparison of sterilized women with the wives of vasectomized men. *Contraception* 1981 Jan; 23(1) : 45-54
15. Aribarg S, Aribarg A. Emotional reaction of female sterilization : a prospective study. *J med Assoc Thai* 1982 Apr; 65(4) 167-71
16. Bordahl PE. The social and gynecological long-term consequences of tubal sterilization. A personal six-year follow-up investigation. *Acta Obstet Gynecol Scand* 1984; 63(6) : 487-95
17. Institute for population Studies. *Thailand Demographic and Health Survey. Chulalongkorn University. Bangkok, 1988.*
18. Limpaphayom K. Tubotubal anastomosis for reversal of female sterilization in Thailand. *J Reprod Med* 1986 Jul; 31(7) : 601-4
19. Hulka JF, Halme J. Sterilization reversal. results of 101 attempts. *Am J Obstet Gynecol* 1988 Sep; 159(3) : 767-74

Conclusion

This study is a preliminary report of a comparative study of interval female sterilization using Falope rings and Filshie clips through laparoscope. There was no difference in client characteristics or epidemiological profile of the two groups. Rings cause more pain during recovery possibly from longer tubal segment damage than the clips. Restoring fertility can be achieved but many factors need to be considered.

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