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LONG-TERM FOLLOW-UP OF LAPAROSCOPIC STERILIZATIONS BY ELECTROCOAGULATION, THE HULKA CLIP AND THE TUBAL RING

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ABSTRACT

A follow-up study of 499 women who underwent sterilization between August 1973 and May 1976 at the Siriraj Hospital in Bangkok, Thailand, and had long-term (4-12 years post-surgery) follow-up is described. Women were sterilized through participation in one of three studies conducted at this hospital. In the first study, 124 underwent sterilization using the Hulka clip via laparoscopy; 67.7% of these women returned for a long-term follow-up visit. In the second study, 300 women were randomly allocated to the Hulka clip or to unipolar electrocoagulation (cautery) via laparoscopy; 70.7% of the women from this study returned for a long-term follow-up visit. The final study was a randomized trial comparing the tubal ring and unipolar electrocoagulation occlusion techniques in 300 cases. Long-term follow-up visits were recorded for 207 women (69.0%) from this study. Five technical failures (procedures not performed or completed as planned) and six non-interval cases were excluded from follow-up analyses.

A total of 713 interval patients were eligible for follow-up. Long-term follow-up was initiated in 1978 and continued through 1986.

Late sequelae of sterilization, including pregnancies and pelvic surgery, are discussed with regard to type and time of tubal occlusion. One intrauterine and two ectopic pregnancies were reported among women who were sterilized with cautery; one ectopic pregnancy was reported by a woman sterilized with the Hulka clip. Pelvic or abdominal surgeries were reported in 27 cases. Most (>98%) women indicated that they were satisfied with their sterilization procedure.

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INTRODUCTION

The demand for female sterilization has been high in Thailand for several years. A 1969-1970 national survey reported that 18% of the women in Bangkok had been sterilized.[1] In 1975, ten percent of Thai married women of reproductive age (MWRA) were sterilized; by 1981, 23% of MWRA had accepted the method.[2] The most common tubal occlusion method used for interval laparoscopic sterilization during the 1970s was unipolar electrocautery.

For several years there has been debate over the long-term effects of contraceptive female sterilization. Most recent studies show no ill effect; sterilized women do not seem to require gynecologic surgery to any greater degree than non-sterilized women, although Cohen[3] recently found that younger women (25-29) had a higher rate of hysterectomy at two years post-sterilization than did women sterilized at a later age. This finding was questioned by Fortney who suggested that physicians had less reason to preserve the reproductive function of a woman who had been sterilized and thus when hysterectomy is an option, it would become the treatment of choice.[4]

This study was designed to follow-up women sterilized between 1973 and 1976 at one hospital in Bangkok. The follow-up interviews took place between 1981 and 1986.

MATERIALS AND METHODS

This long-term (≥ 48 months) follow-up study of women who underwent sterilization between August 1973 and May 1976 was conducted at the Siriraj Hospital in Bangkok, Thailand. Women were sterilized through participation in one of three studies conducted at this hospital. (These studies have been detailed in earlier papers.)[5,6,7] After interval tubal sterilization (≥ 42 days since last pregnancy), women were asked to return to the hospital for follow-up at seven days, six and twelve months post-surgery and yearly thereafter.

Between August 1973 and May 1974, 124 women underwent sterilization using the Hulka clip via laparoscopy. Eighty-four of these women (67.7%) returned for a long-term follow-up visit. In the second study, 300 women were randomly allocated to the Hulka clip or unipolar electrocoagulation (cautery) via laparoscopy and were sterilized between June 1974 and June 1975. About 71% (213) of the women from this study returned for a long-term follow-up visit (48+ months after sterilization). The final study was a randomized trial comparing the tubal ring and unipolar electrocoagulation occlusion techniques in 300 women via laparoscopic sterilizations which began in August 1975 and continued until May 1976. Long-term follow-up visits were recorded for 207 women (69.0%) in this study. Five technical failures (procedures not performed or completed as planned) and six non-interval cases were excluded from follow-up analyses.

A total of 713 interval patients were eligible for follow-up. Long-term follow-up (LTFU) was initiated in 1978 and continued through 1986. In all, 499 women returned for a long-term follow-up visit 4 to 6 years post-surgery. Of those women returning, 209 (41.9%) had been sterilized using electrocoagulation, while 184 (36.9%) and 106 (21.2%) had been sterilized by the Hulka clip and tubal ring, respectively. At the time of surgery, women in each group were similar with respect to age and parity.

Of the 499 women who returned 4 to 6 years post-sterilization, 418 also returned 6 to 10 years post-sterilization and 112 women were again contacted more than 10 years after their surgery; 214 women could not be located for this long-term follow-up study. Table I shows these follow-up visits by tubal occlusion technique. Since the ring study was conducted later than the other studies, fewer ring patients were eligible for 10+ year follow-up. As is shown, the 214 women who were not able to be contacted 4+ years post-sterilization are quite evenly distributed across the three occlusion techniques (27.9% to 31.1%).

Table I

Timing of Long-Term Follow-up Visit*
by Tubal Occlusion Technique

Timing of Long-term Follow-up Visit	Electrocautery (N=299)		Clip (N=267)		Ring (N=147)		Total
	No.	%	No.	%	No.	%	
4-6 years post-sterilization	209	70.0	184	68.9	106	72.1	499
6-10 years post-sterilization	179	60.0	157	58.8	82	55.8	418
Greater than 10 years post-sterilization	51	17.1	51	19.1	10	6.8	112
No long-term (4+ years) follow-up visit	90	30.1	83	31.1	41	27.9	214

* Long-term follow-up visit is a visit 48+ months after the sterilization.

Data collection at LTFU included items on pregnancy, subsequent surgery and hospitalization, and satisfaction. Gross cumulative life-table rates were used to calculate pregnancy rates for each occlusion technique. Because 61% of the women had been oral contraceptive users and 15% IUD users, and because of the varying lengths of follow-up, it was not possible to conduct a meaningful analysis of menstrual pattern changes.

The Methods of Occlusion

The tubal ring, the most commonly used tubal occlusion device in Thailand, is a silastic band applied with a laprocator. The ring is usually applied to the isthmus or ampullary-isthmic junction of the fallopian tube. The failure rate with the tubal ring has been shown to be 0.1 pregnancies per 100 women.[1] About 1-3 centimeters (cm) of the tube is destroyed with the ring.

The spring-loaded, or Hulka clip, was first introduced in 1972. A plastic clip, it has two jaws with interlocking teeth. The jaws are held together by a stainless-steel spring.[8] Failure rates for clips with this design have been reported as less than 0.5 pregnancies per 100 interval women sterilized by laparoscopy. Less than 1 cm of the tube is destroyed with the clip which is placed on the isthmus of the tube.[1]

Twenty to 50 percent of the tube (3-6 cm) is destroyed with unipolar coagulation. An electric current passes from the laparoscopic forceps through the woman's body to a ground plate beneath her. This coagulates and burns the tubes. Most studies have reported pregnancy rates of less than one percent.[1]

RESULTS

Patient Characteristics

Characteristics of the women who were followed-up were similar to those not followed-up with regard to parity, age, education, and residence. The two groups of women did not have significantly different experiences with regard to their surgery or earlier complications or complaints (Table II). Selected characteristics of the women who returned for long-term follow-up are shown by technique in Table III. There was little difference between the occlusion groups with regard to age, education, parity or incidence of early complications.

Pregnancies

A total of three ectopic pregnancies and one intrauterine pregnancy were conceived post-sterilization, three in the electrocoagulation group and one in the clip group; all were reported at the time of long-term follow-up. Figure 1 shows pregnancies with reference to their timing after sterilization and sterilization technique. One of the pregnancies in the cautery group was conceived two years and four months after sterilization. The patient reported that she had undergone a hysterectomy for cervical carcinoma while she was thirteen weeks pregnant. The second woman in the cautery group to report a pregnancy said that she had undergone a bilateral salpingectomy for an ectopic pregnancy three and one-half years after the sterilization procedure. The third woman in the cautery group also reported an ectopic pregnancy at seven years and one month after her sterilization and had undergone a right tubectomy as a result. The pregnancy in the clip group occurred in a woman who was sterilized six and one-half years earlier; she indicated that she had had both tubes removed for an ectopic pregnancy. All of these pregnancies were confirmed by medical records including histological examination.

Table II

Characteristics of Women Returning for Long-term Follow-up Visit* and Those Not Returning

Characteristics	Women Returning (N=499)	Women Not Returning (N=214)
Mean Parity	3.3	3.6
Mean Age at Surgery	31.1	31.1
Mean Years of Education	5.1	4.9
Percent Rural	84.6	85.4
Percent with Previous Pelvic Surgery	8.4	7.0
Percent with Surgical Difficulties	7.0	6.1
Recovery		
Percent reporting:		
Complications	1.6	0.5
Complaints	31.9	25.4
Early Follow-up**		
Percent returning:	100.0	100.0
Percent reporting:		
Complications	1.6	1.9
Complaints	44.3	37.1
Later Follow-up		
Percent returning at:		
6 months post-surgery	100.0	100.0
12 months post-surgery	99.6	100.0
24 months post-surgery	100.0	79.3
48+ months post-surgery	100.0	-

*Long-term follow-up (LTFU) = 48+ months.
**Early Follow-up = 7-21 days post-sterilization.

Table III

Selected Characteristics of Women Followed-up by Tubal Occlusion Technique

Characteristic	Electrocautery (N=209) No.	%	Clip (N=184) No.	%	Ring (N=106) No.	%
Age at surgery (years)						
20-24	23	11.0	17	9.2	8	7.5
25-29	68	32.5	58	31.5	31	29.2
30-34	51	24.4	63	34.2	40	37.7
35-39	47	22.5	41	22.3	23	21.7
40+	20	9.6	5	2.7	4	3.8
Mean (S.D.)	31.3	(5.6)	30.8	(4.9)	31.1	(4.8)
Total Live Births						
2-3	135	64.6	103	56.0	69	65.1
4-5	55	26.3	63	34.2	30	28.3
6+	19	9.1	18	9.8	7	6.6
Mean (S.D.)	3.4	(1.5)	3.6	(1.5)	3.3	(1.3)
Education						
Mean no. of years (S.D.)	5.3	(3.8)	5.1	(3.1)	4.8	(3.5)
Women with complications at early follow-up*	4	1.9	4	2.2	0	-

*7-21 days post-surgery

Years Post-sterilization:	1	2	3	4	5	6	7	8	9	10	11
		E*	E			C	E				

*Technique codes
E = Electrocautery
C = Clip

Figure 1: Timing of Pregnancies in Relation to Sterilization and Technique*

Overall, the eight-year gross cumulative life-table pregnancy rates per 100 women were 2.6 for electrocoagulation patients and 1.1 for clip patients ($p>0.1$).

Other Gynecologic Conditions

Table IV details the conditions requiring post-sterilization treatment during the long-term follow-up interval. There were four cases of adnexal mass, two among clip patients and two after ring procedures. The masses were found between five and seven years post-surgery. In all of these cases, the condition subsided after antibiotics and symptomatic treatment. Two cases of mild pelvic infection in cautery patients, and one in a clip patient, were also treated with antibiotics.

Table IV

Post-sterilization Treatment Reported at Long-term Follow-up by Tubal Occlusion Technique

Treatment	Electrocautery (n=209)	Clip (n=184)	Ring (n=106)
Antibiotics for:			
Adnexal mass	0	2	2
Pelvic infection	2	1	0
Bilateral salpingectomy for:			
Peritubal abscess	0	2	0
Hysterectomy for:			
Cancer in situ of cervix	1	1	1
Invasive cancer of cervix	1	3	2
Severe cervical dysplasia	2	1	1
Severe dysplasia/small myoma uteri	0	1	0
Peritubal abscess	0	1	0
Myoma uteri	0	2	0
Salpingectomy-oophorectomy for:			
Benign ovarian cyst	1	1	0
Diagnostic laparoscopy for:			
Severe abdominal pain	0	1	0
Dilatation and curettage for:			
Endometrial hyperplasia	2	0	0
Cervical biopsy for:			
Erosion of posterior lip	0	1	0
Colpoperineorrhaphy for:			
Vaginal reconstruction	0	2	0
Tubal reanastomosis	1	0	0

Peritubal abscesses were found in three additional clip patients. In each case the clip was inside a mass. In two cases, the clips were embedded in the right tube; one was diagnosed as an inflammatory reaction (three years and two months post-sterilization), the other was diagnosed as a tubal abcess (one year and 10 months post-sterilization). A bilateral salpingectomy was performed in each case. In the third case both clips in both tubes were embedded and the masses were found more than ten years post-sterilization. The purulent fluid in the masses showed no bacterial growth. The uterus was removed with both uterine tubes including masses on both sides.

Figure 2 shows the hysterectomy cases with reference to their timing after sterilization and sterilization technique. Five cases of severe dysplasia were reported at long-term follow-up visits. Two were among cautery patients, two were reported for clip patients and one was reported for a ring patient. One woman in the clip group was diagnosed as having severe dysplasia and small myoma uteri. All five women had hysterectomies between two and six years post-sterilization.

Years Post-sterilization:	1	2	3	4	5	6	7	8	9	10	11
	E*		E		E		E				
		C	CCC			C	C		C		C
		R	RRR		R						

*Technique codes:
E = Electrocautery
C = Clip
R = Ring

Figure 2: Timing of Hysterectomies in Relation to Sterilization and Tubal Occlusion Technique*

Cancer in situ was reported for one patient in each group. Hysterectomies were performed at two, three and 10 years after sterilization. Invasive cancer of the cervix was reported in three clip patients, one cautery patient and two ring patients. Radical hysterectomies were performed between one and four years post-sterilization. There were two cases of myoma uteri among the clip patients. One woman in the cautery group underwent a salpingectomy-oophorectomy for a benign ovarian cyst. In the clip group, a right salpingectomy-oophorectomy was performed and the left tube was

also removed. The histological examination showed a benign serous cyst of the right ovary. One clip patient reported severe pelvic pain two years and nine months after sterilization. A diagnostic laparoscopy found no disease. Two cautery patients had endometrial hyperplasia and each had a D&C. Another woman in the clip group had a cervical biopsy for erosion of the posterior lip of the cervix which showed a benign lesion. Four cases from the electrocautery group and two cases in the ring group had small myoma uteri; only observation was required for these cases. Two women in the clip group had a colpoperineorrhaphy for elective vaginal reconstruction. A tubal reanastomosis was performed six years after a cautery procedure on a woman who had remarried; she was pregnant eight months after the tuboplasty procedure.

Overall Satisfaction

Women were asked a series of questions designed to assess their satisfaction with the procedure. In response to a question concerning adequacy of information provided prior to sterilization, one woman in the study felt she had received too little information. Over 85% of the women were satisfied with the timing of sterilization in their lives, while approximately 13% would have preferred it earlier. Only 2% said they desired a pregnancy after sterilization and 96% of the women said they had recommended sterilization to others. Of women sterilized by electrocoagulation or ring, 100.0% were satisfied or very satisfied with the sterilization. Among the clip patients, 182 (98.9%) were satisfied with the procedure while two (1.1%) were undecided.

DISCUSSION

The long-term follow-up of almost 500 women sterilized at one center presents some interesting findings. The overall 8-year gross cumulative pregnancy rate was 1.5 per 100 with a standard error of 0.7. The results show that pregnancy after sterilization can occur as late as seven years post-surgery. Short-term (one or two years) follow-up results may not represent true failure rates.

Peritubal abscess or inflammatory adnexal mass occurred in five clip patients (2.7%) and in two ring patients (1.9%). These complications were not observed in the cautery group. It is still not certain whether these complications are directly related to the clip or ring. The longer obliteration of the tubes after electrocautery may prevent direct extension of infection from the lower genital tract. Long-term study of a larger group of patients is needed to draw any conclusion.

The need for hysterectomy after sterilization has also been of concern. In this study 17 hysterectomies were reported. Most were for conditions that take several years to develop (except possibly for those indications which include tubal infections) and were not related to the sterilization; Chi, et al.[9] report similar findings.

Female sterilization has been popular in Thailand for over three decades, accounting for the high level of satisfaction reported here.

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REFERENCES

1. Liskin L, Rinehart W. Minilaparotomy and laparoscopy: safe, effective and widely used. Population Reports. Series C, No. 9. Population Information Program, Baltimore, 1985.

2. Ross J, Hong S, Huber D. Voluntary sterilization: an international fact book. Association for Voluntary Sterilization, New York, 1985.

3. Cohen MM. Long-term risk of hysterectomy after tubal sterilization. Am J Epid 1987;125:410-419.

4. Fortney JA. Long-term risk of hysterectomy after tubal sterilization. Am J Epid 1988;127:200.

5. Koetsawang S, Pachauri S. Female sterilization by laparoscopy: a comparative study of tubal occlusion with electrocoagulation and spring-loaded clip with one-year follow-up. Annalies Chirurgiae et Gynecological 1977;66:240-246.

6. Koetsawang S, Srisupandit S, Cole LP. Laparoscopic electrocoagulation and tubal ring techniques for sterilization: a comparative study. Int J Gynaecol Obstet 1978;14:455-458.

7. Koetsawang S, Omran KF, Wallman JA. Laparoscopic sterilization using spring-loaded clips: early experience in Bangkok, Thailand. Adv Plann Parent 1975;10:82-89.

8. Hulka JF, Omran KF, Phillips JM, et al. Sterilization by spring clip: a report of 1000 cases with a six-month follow-up. Fertil Steril 1975;26:1122-1131.

9. Chi I-C, Potts M, Wilkens L. Rare events associated with tubal sterilizations: an international experience. Obstet Gynecol Surv 1986;41:7.