LAPAROSCOPIC STERILIZATION WITH FALLOPE RINGS — A MALAYSIAN EXPERIENCE

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SUMMARY

The early Malaysian experience of laparoscopic sterilisation with the Fallope tubal rings, as undertaken at the Obstetrical and Gynaecological Unit of the University Hospital, University of Malaya in Kuala Lumpur, Malaysia is reported in a study of 291 consecutive females that had had the procedure undertaken during the one year period, May 1975 to April 1976. Of the 291 cases, 247 women were sterilised in the "interval" period, 43 after "menstrual regulation" procedure and one after a spontaneous abortion. General anaesthesia was used in all except one case.

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K H Ng, MBBS (S'pore), MRCOG,FRCS (Edin) Department of Obstetrics & Gynaecology, Royal Newcastle Hospital, Newcastle, N.S.W. 2300, Australia. The salient socio-demographic, contraceptive and reproductive characteristics of study cases are presented and discussed. The technical problems, the early complications and morbidity encountered in this study are presented and discussed in the light of other similar studies, and in relation to sterilisation by laparoscopic tubal electrocoagulation.

The overall impression is that laparoscopic sterilisation with the Fallope tubal rings is preferred to that by tubal electrocoagulation, in view of the possible inadvertent serious electrical burns of other structures during the use of the latter procedure.

INTRODUCTION

From May 1975 through April 1976, a study of 291 cases of females sterilised using laparoscopic Fallope rings at the University Hospital, University of Malaya in Kuala Lumpur was conducted. The study included only those women sterilized for the purpose of limiting family size. For analysis, the study patients were divided into two groups by "time of sterilization":

- 247 women sterilized in the interval period and
 44 women sterilized after either a spontaneous
- abortion (1 case) or after "menstrual regulation" (M.R.) (43 cases).

MATERIALS AND METHODS

In all 291 patients, laparoscopic sterilization was undertaken using the Fallope rings. The patients

were admitted through the routine gynaecological clinic of the University Hospital or through the Family Planning Clinic run by the Family Planning Board of Malaysia, which has a clinic at the University Hospital. Forty-three of the females had early pregnancy terminations performed by "Menstrual Regulation" prior to the laparoscopic sterilization. The "menstrual regulations" were done by aspiration using Karman's Syringe and were done within one week prior to laparoscopic sterilization. Most of the patients had their "menstrual regulation" procedures undertaken about one day prior to sterilization. This meant that the patients who had missed their periods by within 2 weeks (LMP + 44 days) were seen at the clinic where the terminations were done with Karman's aspiration syringe and thereafter admitted for sterilization on the following day.

General anaesthesia was used in 290 cases (99.6 percent) and regional anaesthesia was used for 1 case (0.4 percent). In this last case, the patient was also given intravenous pethidine (50 mg.) and valium (10 mg.), in addition to local anaesthesia.

The laparoscopy technique used was the two-hole method.

The present study was undertaken with the purpose of evaluating the spectrum of the patientprofile, which included their socio-demographic characteristics, age-parity distribution, reproductive events, and their contraceptive use prior to sterilization. Previous surgery and existing medical conditions were also looked into. In to the procedure itself, surgical complications, the experience of the surgeon, early follow-up complications and complaints, were analyzed.

SOCIO DEMOGRAPHIC CHARACTERISTICS

Table I shows the salient socio-demographic characteristics for interval and postabortal (M.R.) patients. The mean education for both groups is 4.7 years. For the interval group, 176(71.2 percent) had less than 6 years, education. Post abortal group only 33(75 percent) had less than 6 years education.

TABLE I
SOCIO—DEMOGRAPHIC CHARACTERISTICS
291 CASES OF FEMALES STERILIZED WITH
FALLOPE RINGS (PERIOD: MAY 1975 TO APRIL 1976)

PATIENT PROFILE	INTER	VAT (N	- 247	POST	POSTABORTAL (M.R.			
I THILE WITH TROTTEE	No.				(N = 44)	1)		
D. C. P. D. C.	No.		%	No.		%		
Patients Education (years)								
0	71		28.7	11		25.0		
1-6	105		42.5	22		50.0		
7-12	55		22.4	8		18.2		
13+	7		2.8	1		2.3		
Unknown	9		3.6	2		4.5		
Mean		4.7			4.7			
Husband's Educatio	n							
0	14		5.7	3		6.8		
1- 6	95		38.5	20		45.4		
7-12	76		30.7	10		22.7		
13+	20		8.1	4		9.2		
Unknown	42		17.0	7		15.9		
Mean		7.4			7.1			
Residence				en e				
Urban	134		54.3	27		61.4		
Rural	113		45.7	17		38.6		
Employment Status								
Gainfully employed	1 128		51.8	15		34.1		
Unemployed								
(Housewife)	. 119		48.2	29		65.9		
Religion								
Hindu	131		53.1	26		59.1		
Buddhist	70		28.3	10		22.7		
Muslim	23		9.3	5		11.4		
Christian	20		8.1	3		6.8		
None	3		1.2	, 0		0.0		
Community Group								
Indian	152	1	61.5	31		70.5		
Malay and Chines	e 93	5	37.7	13		29.5		
Others	2		0.8	0		0		

More than 50 percent of the interval group and more than 60 percent of the postabortal (M.R.) group were urban residents. This is probably due to the location of the University Hospital, which is situated in the urban area of Petaling Jaya. Those patients that come from the rural areas were mainly

TABLE II
AGE-PARITY DISTRIBUTION

Age		Interval (N = 247)						Postabortal (M.R.) (N = 44)					
	< 35	< 35 years 35 +		+ years Al		1 Ages 35 years		35 + years		All Ages			
Parity	No.	%	No.	%	No.		No.	%	No.	%	No.	%	
2	9	3.6	12	4.9	21	8.5	1	2.3	0	0.0	1	2.3	
3 to 4	76	30.8	32	12.9	108	43.7	9	20.4	5	11.4	14	31.8	
5 to 6	58	23.5	17	6.9	75	30.4	11	25.0	5	11.4	16	36.4	
7 & over	20	8.1	23	9.3	43	17.4	5	11.4	8	18.1	13	29.5	
All Parities	163	66.0	84	34.0	247	100.0	26	59.1	18	40.9	44	100.0	

from the rubber estates, being brought or referred to the Hospital by Family Planning personnel. These patients were mainly of the Indian community group and belong to the Hindu religion.

The postabortal (M.R.) group was less gainfully employed only 15 (34.1 percent) compared with the interval women 128 (51.8 percent). Over half of the patients sterilized were Hindus 131 (53.1 percent) in the interval group and 26 (59.1 percent) in the postabortal (M.R.) group. The Muslims and the Christians were relatively less, totalling 43 (17.4 percent) in the interval group and 8 (18.2 percent) in the postabortal (M.R.) group.

REPRODUCTIVE HISTORY

Table II shows that the mean age for both groups was 32 years. Mean parity for the interval group of women was 4.8, compared to 5.6 for postabortal (M.R.) group. A further breakdown shows that for ages below 35 years old and those above 35 years, a major proportion of the interval group had parity of 3 to 4, but for the postabortal (M.R.) group slightly more of them were in the 5 to 6 parity range.

PREVIOUS CONTRACEPTIVE USE

Postabortal (M.R.) patients reported their contraceptive practice for the three months before conception, and interval patients reported their contraceptive practice for the three months before sterilization. Table III shows 65.9 percent of the postabortal (M.R.) patients were not on any form

TABLE III
CONTRACEPTIVE USE PRIOR TO STERILIZATION

Contraceptive	2	erval = 247)	Postabortal (M.R.) (N = 44)		
Туре	No.	%	No.	%	
None	94	38.1	29	65.9	
Oral pill	101	40.9	10	22.9	
Condom	23	9.3	3	6.8	
IUCD	15	6.1	0	0.0	
Rhythm/Withdrawal	6	2.4	1	2.3	
Other methods	8	3.2	1	2.3	

of contraception compared to 38.1 percent in the interval group. Amongst those who used contraceptives, the oral contraceptive pill was the most popular method, being used by 40.9 percent of the interval women and 22.7 percent of the postabortal (M.R.) women. There were persons who previously used the condom, the IUCD, and the rhythm or withdrawal and other methods, but their numbers were few in both groups. No one was found to use the IUCD in the postabortal (M.R.) group.

TECHNICAL FAILURES

In five (1.7 percent) of the 291 patients, the planned sterlization technique could not be performed; and these cases were categorised as technical failures. In one interval case, in which routine dilatation and currettage (D&C) was done concurrently, the reported reason for failure to complete the procedure was severe obesity, such that the second trocar could not be successfully inserted; the sterilization procedure was completed by electro-cautery. In four cases, three interval

TABLE IV
SURGICAL COMPLICATIONS

Surgical Complications	Interwith I (N =) & C	Inter Without (N =	D & C	Postabortal (M.R.) (N = 42)*	
	No.	%	No.	%	N.	%
Bleeding from Mesosalpinx/ Tube Requiring Laparotomy	0	0.0	3	1.6	1	2.4
Not requiring laparotomy	0	0.0	1	0.7	0	0.0
Excessive bleeding caused by trocar puncture	0	0.0	2	1.1	0	0.0
Excessive blood loss requiring						
transfusion	1	1.4	0	0.0	0	0.0
Shock	1	1.4	0	0.0	0	0.0
Patients with one or more surgical complication	1	1.4	6	3.4	1	2.4

^{*} Data for 2 cases not available

cases in which D & C was not done concurrently and one postabortal (M.R.) case, immediate laparotomy was required before completion of the sterilization procedure to control bleeding from either the meso-salpinx or the fallopian tubes.

SURGICAL DIFFICULTIES AND COMPLICATIONS

The only reported surgical failure was due to excessive obesity in one patient. Table IV shows the complications that have occurred during the procedure. The five failed procedures are included in this analysis. Generally, the complication rate was very low. One patient, in whom a D & C was performed, had excessive vaginal blood loss, requiring blood transfusion. Of the complications, bleeding from the mesosalpinx or the tube was the most common, occurring in 4(2.3 percent) of the "interval" females and in 1 (2.4 percent) of the "postabortal" (M.R.) group. Four of the cases, that had such bleeding, had to be followed by laparotomy to arrest the bleeding.

LEVEL OF SURGICAL SKILL

The consultant gynaecologists performed an average of 58 of the procedures per surgeon, the middle echelon surgeons (Lecturers) 19 each, and

TABLE V
NUMBER OF PROCEDURES PERFORMED AND
SUBSEQUENT SURGICAL COMPLICATIONS

	Group*				
1 (N = 3	II (N = 3)	III (N = 11)		
No. of procedures per surgeon (Range)	39-68	18-20	1-10		
Mean number of procedures per surgeon	n 58	19	5		
Rate of Surgical Complications:	1.7	0.0	9.1		
Requiring laparotomy	1.2	0.0	3.6		
Not requiring laparotomy	0.6	0.0	5.5		

*Group I - included 3 Consultant Gynaecologist

Group II —included 13 Gynaecologists from the Hospital Lecturers (Senior Registrars), middle echelon surgeons.

Group III — included 11 Trainee Medical Officers and residents (doing the procedure under supervision of Groups 1 and II)

the residents or trainee medical officers performed an average of 5 procedures each.

It can be seen from Table V that more complications were found in those cases operated on by the Group III staff (residents and trainee medical officers). Of the 11 cases operated on 9.1 percent had surgical complications of which 3.6 percent needed laparotomy. The Consultant Staff (Group I) had the least number of surgical complications 1.7 percent

TABLE VI
EARLY FOLLOW-UP COMPLICATIONS AND COMPLAINTS

Complications/Complaints	Int with (N	Interval Without D&C (N = 177)		Postabortal (M.R.) (N = 42)*		
•	No.	%	No.	%	No.	%
Complications						
Incisional Wound	0	0.0	5	2.8	1	2.4
Significant fever requiring antibiotics	0	0.0	2	1.1	0	0.0
Significant vaginal discharge	0	0.0	2	1.1	0	0.0
Secondary amenorrhoea	1	1.4	0	0.0	0	0.0
Total	1	1.4	9	5.0	1	2.4
Complaints						
Abdominal Pains	1	1.4	2	1.1	1	2.4
Backache	0	0.0	1	0.6	0	0.0
Total	1	1.4	3	1.7	1	2.4

^{*} Data for 2 cases not available

surgical complications, in which 1.2 percent laparotomy. required These complications occurred in their early phases of laparoscopic experiences in the case of the Consultant Staff. No complication was reported in the Group II staff (Lecturers). Thus, it appears that the gynaecologist's experience is an important factor in minimising the complication rates.

COMPLICATIONS AND COMPLAINTS

No "immediate" complications were recorded (that is complication arising after the surgery but before discharge from hospital). The "early" complications and complaints were those diagnosed or reported between time of discharge until 7 to 21 days of follow-up. Table VI shows that the "early" complications and complaints at the follow-up visits were minor in nature and occurred infrequently. The patients were either reassured, or specific symptomatic treatment was given. The early follow-up complications were noted in 9 (5.0 percent) of the "interval without D & C Group" and more than half of them were due to mild incisional wound infection.

Of the early follow-up complaints, lower abdominal pain constituted most of them. Most of

those patients were reassured or given only mild analgesics, such as paracetamol.

DISCUSSION

At the University Hospital, University of Malaya, in Kuala Lumpur, various methods of female sterilization are available for patients who want to limit their family. These include postpartum abdominal tubal ligation under local anaesthesia or epidural block, vaginal tubal ligation (though not a popular procedure now), mini-laparotomy with the help of the Minilaparotomy kit, and laparoscopic tubal sterilization by either tubal electrocautery or the application of Fallope tubal rings. The latter technique (laparoscopic Fallope tubal ring application) has become popular both among patients and surgeons.

In multi-racial Malaysia, it is noted that the different community groups view tubal sterilization differently from a socio-cultural viewpoint. The community does not accept tubal sterilization as readily as the Indian or Chinese community. the hand. On other University Hospital is located in an urban area where the predominant population is Chinese. The Indians are mainly from the rubber estates around

the city of Kuala Lumpur. It is interesting to note that in Indonesia, Soeprono (1974) from Jogjakarta reported 94 Muslims in his series of his 155 patients. But Sitompul et al (1977) from Medan, Indonesia did laparoscopic sterilization by electro-cautery on 850 patients. of whom 73.9 percent were Prostestants, 18.2 percent were Muslims; and Catholics and other religious denominations only constituted 3.0 percent and 4.9 percent respectively.

Our study shows that a significant proportion of the patients were not gainfully employed and were having parity of more than four. These figures are similar to those patterns seen in Singapore, where the mean parity is 4.5 (Kessel *et al*, 1976).

The significance of this observation has a bearing on the choice of sterlization technique. Since the parity of our patients is high, quite a proportion of them have children who are still young requiring close maternal care. Thus the mothers are not keen on being hospitalized for a long period, during which there will be no one to take care of their children at home.

I Bae Yoon of the Department of Gynaecology and Obstetrics of the John Hopkins University, School of Medicine, in association with his colleagues, Clifford Wheeles and Theodore King, pioneered in the early 1970's the Fallope Ring, which is a silicone rubber band, and which now often bears his name - Yoon Ring. Concomitantly, they devised their new laparoscopic silicone rubber applicator and their laparoscopic technique. In their 1974 preliminary report (Yoon et al, 1974), they reported favourably on their first 100 cases.

The technical failure rate due to obesity and other anatomical causes has been observed by other workers too. Khandawala, et al, (1977) did a comparative study of laparoscopic spring-loaded clip and Fallope ring technique of sterilization in postabortal cases. Out of the 150 cases in which they used Fallope tubal rings, they had only one case of technical failure in which the fallopian tubes were thick. They also reported 8.0 percent of surgical difficulties mainly due to thick and

tortuous tubes (3.3 percent) and adhesions (1.3 percent). The other technical difficulties were due to operative interference by omentum, sigmoid colon or cystic ovaries.

The surgical complications reported in our study are within acceptable limits. There have been no life-threatening complications. Bleeding from the mesosalpinx or the tube, occurred in three of the "interval without D & C" group of cases. In the John Hopkin's Hospital Study (Yoon et al, 1976 and 1977) and in the studies of other American investigators, tubal transections with attendant bleeding and occurrence of lower abdominal pain have also been documented. Tubal transection occurred in 2.5 percent of the John Hopkins' study series. Vengadasalam et al (1977) in their personal series of 291 cases did not encounter any tubal transections or mesosalpingeal tears and bleeding. They stated that these two complications can be best avoided by care and correct technique in that the surgeon must be certain, immediately before application of the Fallope ring, that each fallopian tube is freely mobile and not adherent to other pelvic structures. They further stated that, after grasping the fallopian tube with the forceps, the laparoscope must be moved forward slowly as the tube is retracted into the inner cylinder of the applicator of the laparoscope. All their 291 patients were discharged from hospital on the day of the procedure, and there were no serious complications necessitating further hospitalization.

Our study also showed that complications were mainly related to the lack of experience of the surgeons, in that the majority of complications were found in cases done by house-officers or medicalofficers in training for MRCOG: But, at our Hospital, this procedure is only done by such junior medical staff under the direct supervision of trained gynaecologists. Thus, from our study, it is quite apparent that in order to minimise morbidity from the procedure, the experience of the clinical staff and their familiarity with the technique is an important factor. Case-selection is another factor that could contribute towards the decrease in the technical failure rate and in the surgical complication rate. Thus obesity may be relative contra-indication for laparoscopic sterilization; and

patients with past history of pelvic surgery and pelvic inflammatory disease are not suitable candidates for such procedure too, because of the possibility of existent pelvic adhesions.

The early complications were also minimal in our study, contributed mainly by incisional wound infections in 5 (2.8 percent) of the "interval without D & C" group of cases. The next type of minor complication was lower abdominal Khandawala et al (1977) reported 3.3 percent of early post-operative complications, and mild wound infection was also the complication most frequently (2.0 percent) observed by them. The "postalbortal" group of patients had 2.4 percent of them complaining of abdominal pains at the early follow-up period. Among the "interval without D & C" group of patients 1.1 percent complained of pains, as compared to 1.4 percent of the "interval with D & C" group of patients. Khandawala et al (1977) stated that 12.7 percent of their patients who had laparoscopic sterilization with Fallope rings had pelvic pain, a figure which is much higher than seen in our study. Bhatt et al (1977) reported 8.0 percent of their 100 cases so sterilized complained of pelvic pain. However, both these groups of workers from India performed their operations under local anaesthesia with supportive sedation.

Other possible late complications that have been reported are dysfunctional uterine bleeding, pelvic inflammatory disease and chronic pelvic pain (Neil, et al, 1975) and of course pregnancy.

As mentioned earlier, the duration of hospitalization is an important factor in making laparoscopic tubal sterilization popular to our patients. Short hospitalization will cause little inconvenience to the family, particularly to their young children at home. It is reported that many surgeons, especially those from the developing countries do their laparoscopic sterilization as outpatient procedures. In Indonesia, there have been reports of laparoscopic sterilization using electro-coagulation being done as outpatient procedures (Soeprono, 1974).

The Fallope ring method appears to be safer than tubal electro-cautery. Though the intestinal mesentery and bowel knuckle can be accidentally banded by the Fallope ring, this rarely happens and is not as dangerous as cauterising them. The Fallope rings are also said to cause less damage to the tubes whereas the electrocautery may cause extensive damage to the tubes mesosalpinges. Suporn et al, (1978) concluded that despite the slightly higher incidence of minor surgical complications and pain associated with the Fallope tubal ring, many gynaecologists prefer this method of sterilization because it eliminates the possibility, inherent in electrocoagulation, of inadvertent serious electrical bowel burns. Earlier reports by the pioneer Yoon and his research team (Yoon and King, 1975 and 1976, Yoon et al, 1977) on larger and longer follow-up series of cases have consistently maintained the superiority of the "Fallope Ring" to "Electrocoagulation" in safety and efficacy in the field of laparoscopic sterilization. In a recent comparative study, Lean et al (1978) have found that difficulties encountered at surgery and pregnancy rates were higher for the spring-loaded clip than for the Fallope ring procedure.

In general selection of patients for laparoscopic sterilization is important. Technical difficulties can arise from patients who are unduly obese, and those who have had previous abdominal surgery. However, previous pelvic or abdominal operations are not absolute contraindications to laparoscopic sterilization. If the procedures were to be performed under general anaesthesia, then patients for whom concomitant general anaesthesia and pneumoperitoneum induction would be dangerous, such as those with serious heart or lung diseases should preferably be excluded.

Finally, it must be reiterated that although laparoscope and laparoscopic sterilizing instruments are the most versatile instruments used in female sterilization, they are also the most expensive items in the array of human sterilization equipment. This last factor together with the availability of trained personnel and operating facilities are major considerations limiting the popularization of laparoscopic sterilization in the socio-economically disadvantaged developing countries of the world.

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