

A COMPARISON OF TUBAL RING AND MADLENER'S TECHNIQUES OF TUBAL LIGATION IN POSTPARTUM CASES

by

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Introduction

New techniques of tubal ligation have been developed in recent years in an effort to make female sterilization simpler, safer and more effective. After years of conventional methods, laparoscopy opened a new avenue and brought a series of methods for tubal ligation. Laparoscopic sterilization by using electrocautery proved unsafe and sometimes fatal and hence attempts were constantly made to arrive at safer techniques.

Yoon *et al* (1974) came out with the Silastic Band technique for tubal ligation. As this was a laparoscopic approach without the use of cautery it immediately aroused interest. At present this new technique has been carried out in large numbers with adequate follow-up to make positive comments and conclusions. The

present study was conducted to scientifically compare the tubal ring—a new technique with Madlener's a traditional technique of tubal ligation in post-partum women.

Material and Methods

From April 1975 to September 1976, 300 subjects were studied at the K.E.M. Hospital in Bombay. Tubal occlusion by the tubal ring and Madlener's techniques was evaluated by the protocol developed by the India Fertility Research Programme. The patients gave written consent to participate in the study. Data on patient characteristics (Table I), medical and menstrual history including medical examination and clinical aspects of the procedure were recorded on standard forms. The patients were hospitalized for at least 7 days so data are reported for this period on completion of the study. Follow-up studies of six monthly as well as yearly were carried out. In India, follow-up is a big hurdle and despite all possible attempts, it was possible to follow-up only 213 for the six monthly check-up and 234 for the one yearly check-up. Thus 78% have been followed up at the end of 1 year. This is less

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than the target figure but it is much more than we expected at the beginning. Besides it should prove adequate to take advantage of the present study and come to a sound conclusion.

Study Methodology

All the study procedures were performed by a single operator using random allocation cards to determine the technique. Immediately before surgery, the operator opened a sealed envelope containing a card which specified the sterilization procedure for the specific subject. Patients were unaware of technique used. In order to minimize evaluator bias, a second physician (the evaluator), who was kept unaware of the specific technique used, was responsible for caring for the patient after she left the operating room and was responsible for recording data on complications, complaints and other events occurring during the patient's recovery or reported at follow-up. Thus, the operator performed the procedure and recorded data about the procedure and events that occurred while the patient was in the operating room; the evaluator provided postoperative care for the patient and recorded data on all subsequent events, without knowing which specific sterilization technique the patient has undergone.

Subjects

Only women who requested sterilization to limit the size of their family were studied. All the subjects in the study group were postpartum, having delivered within 10 days of sterilization. Patients with specific contraindications such as serious cardiac or pulmonary disorders were excluded from the study. Pre-existing, systemic or pelvic disease were not criteria for exclusion. Six patients in the Madlener's group and 5 in the tubal ring

group gave a history of caesarean section and D&C. In the Madlener's group 2 cases had mitral stenosis, 1 had tuberculosis and 1 had osteomalacia. In the tubal ring group, 1 subject had syphilis, 1 had diabetes and 1 had asthma.

Sterilization Techniques

Every patient was administered 0.6 mg. of atropine intramuscularly half an hour before surgery. The sterilization procedure was performed under general anaesthesia.

With the patient in supine position, abdomen was prepared and draped and 2 cm. transverse incision was made just below the uterine fundus. The abdomen was opened in layers and fimbrial end of the tube was identified and the tube was drawn outside the incision with Babcock's forceps. When the Madlener's technique was used, the tube was crushed with a clamp at the junction of its medial two-thirds and lateral one-third and tied with an unabsorbable linen suture which was passed through the mesosalpinx. When the tubal ring technique was used, a loop of the tube was held by the tongs of the tubal ring applicator and was drawn into the applicator to apply the tubal ring. It was then gradually pushed out to release the tube. The procedure was repeated on other tube and abdomen closed in layers. All patients were administered prophylactic antibiotics routinely.

Follow-up

All patients were followed up at the end of 7 days, 6 months and 1 year of sterilization. Practically all required reminder via a postcard and a majority required a field visit from the Social Worker to explain and coax them to come for follow-up examination. The field visit was carried out only when patient

did not respond to at least two or three communications i.e. letters.

At follow-up study a detailed history was taken and careful examination carried out. History was taken with a view to find if sterilization had given rise to any problems. They were carefully examined to find out if sterilization had resulted in any sequelae. Clinical examination was also coupled with cytological studies. All these details were very carefully entered and comparison made between the two groups.

Difficulties at Surgery

Surgical difficulty was reported for 1 subject in the tubal ring in whom the incision had to be extended laterally and in 1 subject in the Madlener Group in whom there was bleeding from the medial end of the tube. The bleeding point was sutured. No other difficulties at surgery were recorded.

Complications

Complications during pregnancy were reported for 2 (1.3%) tubal ring cases and 5 (3.3%) cases sterilized with Madlener's technique (Table II). Complications during delivery were reported for 7 (4.7%) and 17 (11.2%) Patients in the tubal ring and Madlener's groups respectively. Prematurity, stillbirths and post-partum haemorrhage were the common complications reported. Needless to say, these complications have nothing to do with method of tubal sterilization or selection of method for sterilization. No major complications were reported for any of the study subjects during or after sterilization procedure.

Following post-operative complications, unrelated to comparative aspects, were noted. They were: Pyrexia, abdominal pain, sore throat and wound infection.

TABLE I
Patient Characteristics

Patient Characteristics	Tubal Ring N = 149		Madlener N = 151	
	No.	%	No.	%
Age (years)				
21-24	24	16.1	30	19.9
25-29	63	42.3	52	34.4
30-34	39	26.2	50	33.1
35-39	21	14.1	17	11.2
40+	2	1.3	2	1.3
Parity				
1-2	39	26.27	35	23.2
3-4	95	63.7	101	66.9
5-6	13	8.7	13	8.6
7 +	2	1.3	2	1.3
Patient's Education (School Years)				
0	57	38.2	60	39.7
1-3	24	16.1	40	26.5
4-6	43	28.8	31	20.5
7-9	19	12.7	17	11.2
10-12	6	4.0	3	2.0
13 +	0	0.0	0	0.0

TABLE II
Complications Related to Pregnancy

Pregnancy Complications	Tubal Ring N = 149		Madlener N = 151	
	No.	%	No.	%
Diabetes	1	0.7	0	0.0
Placenta previa	1	0.7	0	0.0
Ante-partum				
haemorrhage	0	0.0	1	0.7
Accidental haemorrhage	0	0.0	1	0.7
Eclampsia	0	0.0	1	0.7
Mild toxæmia	0	0.0	1	0.7
Breech	0	0.0	1	0.7
Total	2	1.3	5	3.3

There was no significant difference between these two methods besides those are common and anticipated complications after such surgery.

Further these complications do not have significance as far as the methodo-

logy of sterilization and its aftermath are concerned. There was no major complication in either method, whereas minor complications were the usual encountered with any other methods of tubal sterilization i.e. there is no significant difference.

Operative Time and Hospitalization

The main surgical time was 7.9 and 9.0 minutes for subjects sterilized by the tubal ring and Madlener's techniques respectively and the mean time for which the patients were in the operating room for these two groups was 15.4 and 16.7 minutes respectively. The majority of i.e. patients in both groups were hospitalized for 7 to 8 days after sterilization, more so for follow-up at the end of 7 days.

It was the impression of the operator as well as assisting staff that tubal ring sterilization definitely took a minute or more less than Madlener's technique.

This difference may have an important bearing when sterilization is done under local anaesthesia and in rural camps with large turn over. Besides the time factor, putting tubal ring was simpler than picking tubes, crushing and ligating them.

Follow-up

Follow-up studies (Table III) show that commonest complaints were backache, leucorrhoea and general weakness. These are, even otherwise, very common in hospital class of patients.

These complaints were minor in a few but pressing ones in a significant number. Further it must be noted that the same complaints were present in a similar number who were not sterilized, as mentioned earlier. The incidence of backache was higher in the group of women sterilized by the tubal ring technique as compared with Madlener's. This needs further study.

TABLE III
Complaints

	Six Monthly		Yearly	
	Tubal Ring	Madlener's	Tubal Ring	Madlener's
Backache	69 (61.6%)	38 (37.3%)	71 (55.5%)	50 (43.1%)
Leucorrhoea	22 (19.6%)	23 (22.5%)	17 (13.3%)	15 (12.9%)
General weakness	41 (36.6%)	36 (35.3%)	39 (30.5%)	33 (28.4%)
Anaemia	68	65	72	69
No complaints	19 (17%)	23 (22.5%)	30 (23.4%)	22 (19.0%)

TABLE IV
Menstrual Cycles

	Six Monthly		Yearly	
	Tubal Ring	Madlener's	Tubal Ring	Madlener's
Normal	36 (32.4%)	33 (32.4%)	55 (43%)	46 (39.7%)
Abnormal	5 (4.5%)	8 (7.8%)	20 (15.6%)	17 (14.7%)
Lactational				
Amenorrhoea	70 (63.1%)	61 (59.8%)	53 (41.4%)	53 (45.6%)
Total	111	102	128	116

Menstrual Cycles in both the Groups were not significantly different (Table IV). There was high percentage with lactational amenorrhoea. In India, hospital class of women continue breast feeding for longer than the usual time. Abnormal menstrual cycles were present in approximately 15% at the end of 1 year, the commonest abnormality being excessive period or its scantiness (Table V).

TABLE V
Abnormal Menstrual Cycles

	Six Monthly		Yearly	
	Tubal Ring	Madlener's	Tubal Ring	Madlener's
Scanty	1 (0.9%)	4 (3.9%)	11 (8.6%)	9 (7.8%)
Excessive	4 (3.6%)	4 (3.6%)	9 (7%)	8 (6.9%)
Total	5	8	20	17

There was no statistical difference between the two groups under study.

Pelvic Findings: Table VI shows in detail the pelvic findings at the end of 6 months and 1 year. Abnormal findings were slightly more in the tubal ring as compared with Madlener's though without statistical significance. Except for pelvic infection, or tenderness all other findings were unrelated to female sterilization. Cytological findings shown in Table VI were comparable in two groups except higher number of inflammatory in tubal ring group after 1 year. There were no reported pregnancies in either group at the end of 1 year.

Comment

This comparative study shows that either the tubal ring or Madlener's tech-

TABLE VI
Pelvic Findings

	Six Monthly		Yearly	
	Tubal Ring	Madlener's	Tubal Ring	Madlener's
Cervical erosion	6 (5.4%)	7 (6.9%)	15 (11.7%)	8 (6.9%)
Uterine prolapse	4 (3.8%)	2 (1.96%)	3 (2.3%)	4 (3.5%)
Cystocele	—	1 (0.98%)	—	—
Endocervicitis	5 (4.5%)	5 (4.9%)	11 (8.6%)	8 (6.9%)
Ovaries enlarged	6 (5.4%)	6 (5.88%)	7 (5.5%)	7 (6.0%)
Tender uterus or fornices	3 (2.7%)	1 (0.98%)	1 (0.8%)	—
Abdominal wall hernia	1 (0.9%)	—	2 (1.6%)	—
Vaginitis	—	—	1 (0.8%)	—
Normal	87 (77.7%)	86 (84.3%)	94 (73.4%)	85 (73.3%)

TABLE VII
Cytology

	Six Monthly		Yearly	
	Tubal Ring	Madlener's	Tubal Ring	Madlener's
Not done	20 (18%)	22 (21.6%)	44 (34.4%)	55 (48.2%)
Normal	56 (50.5%)	42 (41.1%)	23 (18%)	26 (22.4%)
Inflammatory	34 (30.6%)	36 (35.3%)	61 (47.6%)	33 (29.4%)
Atrophic	1 (0.9%)	2 (2%)	—	1 (1%)
Total:	111	102	128	116

niques of tubal occlusion can safely be performed in postpartum women. The subjects in this study will be followed up to evaluate and compare pregnancy rates and long-term sequelae, if any, for women sterilized by these two techniques of tubal occlusion.

Follow-up study indicated that there was no difference in incidence of menstrual pattern or lactational amenorrhoea. Likewise, abnormal menstrual cycles—scanty or excessive—were also not significantly different at the end of one year's follow up. Backache was definitely more

in tubal ring group than Madlener's. However, 23.4% were without any complaint whatsoever in tubal ring group as opposed to 19% in Madlener's group. Pelvic findings showed slight increase in incidence of cervical erosion and endocervicitis in tubal ring group as opposed to Madlener's. However, these findings are only coincidental and have no bearing on the method of sterilisation.

Reference

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