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Evaluation of Laparoscopic Sterilisations in Rural Camps*

Introduction

THE cumulative number of couples choosing sterilization for fertility control has increased tremendously in India in recent year* [1]. This increase can be partly attributed to improvements in technology and liberal sterilization services offered by governments and private clinics in all urban and rural areas, since the inception of the National Family Welfare Programme. To meet the demand of sterilization in rural areas, camp approach is utilized in addition to operations performed in Primary Health Centres and District hospitals, etc., thereby taking the health services to the doorsteps of the community.

With the advent of laparoscopic sterilization, the procedure has gained popularity and there has been an increase in frequency of laparoscopic camps in rural areas during the last few years. However, a multicentre institutional based study [2] on female sterilization carried out by the Indian Council of Medical Research (ICMR) had revealed that laparoscopic sterilization was associated with a higher incidence of complications and failure rates as compared to the traditional minilaparotomy operation. Though laparoscopic sterilization camps have been held in different parts of the country, the data on

**Comp*—The camp is an approach under the N.F.P.P. where the required services (in this laparoscopic sterilization) are made easily accessible to community on temporary basis using the available infrastructure. This involves setting up of services with the involvement of medical personnel, local village leaders and health workers.

sequelae of procedure performed in a camp setting is very limited. Therefore, it became important and relevant to evaluate the efficacy and safety of the rural laparoscopy sterilization camps, and feed back the results to the programme administrators so that they can be utilized in improvement of the services.

The ICMR at the request of Ministry of Health and Family Welfare, Government of India, New Delhi, initiated this study in two states where rural camps were routinely being conducted. An attempt has been made in this report to present information on the characteristics of acceptors, site and organization on the camps, surgical difficulties and complications following the procedure.

Material and Methods

The material for the study was drawn from the laparoscopic sterilization camps conducted in rural areas in the state of Gujarat by a team from Baroda Medical College and of Maharashtra by a medical team from KEM, Bombay. Subjects undergoing ligation were recruited for the study and these were followed up for a period of one year thereafter.

Information regarding training and experience of operators, organization of the rural camps including the site and facilities, demographic profile of the clients, details of sterilization procedure and sequelae were recorded on uniform preceded proformae. Acceptors were followed-up at 3 months and one year after ligation and details including method failures were recorded. Tr e Bombay team travelled about 300 kms away from their headquarters and organized large camps in the district hospitals in the state of Maharashtra. The team stayed at the camp site for a maximum period of one week. In contrast, the Baroda team organized small camps—in the "Home Territory" in rural areas i.e. within a radius of 50-60 miles from their institution in Baroda. The team returned to the institution on the same day from the camp site.

In both areas, the women seeking laparoscopic sterilization were motivated by the paramedical staff of the local health infrastructure and underwent routine systemic and pelvic examination before the procedure. All the sterilization procedures were performed under local anaesthesia.

The following variables were used to evaluate the safety and efficacy of the camp approach: (i) site and organization of camp, (li) surgical difficulties and complications and (in) method failures.

Observations

Site and Organisation of Rural Camps

Site of Camp. The Baroda team organised a total of 240 small camps in the rural area of two districts of Gujarat namely Baruch (68 camps) and Baroda district (172 camps) during 1981 to 1982. Of these, 87.1 per cent were at Primary

Health Centres (PHCs), 3.8 per cent at district hospitals and remaining at the village school building and/or at rural community centres, indicating that majority of the camps organised by this team were within easy reach of the rural population, with minimal facilities of water and power supplies (Table 1). On the other hand, Bombay team organized only five large camps, 3 in Jalna and 2 in Parbhani district hospitals, during the same period.

TABLE I—THE NUMBER OF CAMPS CONDUCTED BY TWO TEAMS

	Teams	
Site	*Baroda*	*Bombay*
Primary Health Centres	209	—
District Hospital	9	5
Others'	22	—
Total	24O	5

*Including village school and community centres.

With regard to the accessibility by the community, the camps organised by Baroda team could be reached by travelling a short distance of 15 kms on an average, while to approach she operating site of the Bombay team, the potential acceptors had to travel more than twice this distance (35 kms).

Team Composition. The Baroda team consisted of a gynaecologist trained in laparoscopy, assisted by a trainee who also performed the operations under supervision There was no anaesthetist in the team. la contrast the Bombay team consisted of four to six operators assisted by two to four assistants. The most salient feature of the Bombay team was that it was always accompanied by an anaesthetist.

All the women in camps organised by Bombay team were operated by surgeons who had considerable amount of experience in performing laparoscopic sterilizations (i.e. 3 years or more), in contrast to the camps organised by Baroda team, where 11.7 per cent procedures were performed by trainees, additional 7.1 per cent by operators with one to two years of experience and the remaining 81.2 per cent by experienced surgeons (Table 2).

TABLE 2-EXPERIENCE OF OPERATORS

Experience (years)	*Centres*	
	Baroda (Percent)	*Bombay* (Percent)
Nil (Trainees)	11.7	—
1-2	7.1	—
3-5	48.1	57.6
6-10	33.1	42-3
10	.0	0.1
Total Number	7,103	2,073

Sterilization of instruments. While the Baroda team boiled the instruments for achieving asepsis and used Cidex solution for cleaning the laparoscopes, the Bombay team autoclaved the instruments; the laparoscopes were sterilized with formalin vapour.

Number of sterilizations performed, A total of 9,176 tubal sterilisations were performed by the two teams, of which 7,103 (77.4%) were performed by the Baroda team and remaining 2,073 (22,6%) were done by the Bombay team. The Bombay team which stayed for a comparatively longer period, performed on an average 415 sterilizations per camp whereas the Baroda team performed on an average 29 sterilizations per camp. The maximum number of sterilizations performed by the Baroda team was 66 per day and this figure was 207 for Bombay team. However, the case load per surgeon per hour for Bombay was half compared to that for the Baroda team (8/hour/surgeon in Bombay, 16/ hour/surgeon in Baroda).

Demographic profile. The average age of women who underwent ligation in camp settings organised by Bombay and Baroda teams were 31.9 and 28 9 years and average parity was 4.0 and 3.5 respectively. The literacy rate compared with the 1981 Census (i.e. literacy rate of 24.06% and 24.88% for rural women in Gujarat and Maharashtra respectively) indicated that women seeking terminal method of contraception in the camp settings were predominantly illiterates. It was observed that more than 98 per cent of these subjects had not used any spacing method before adopting a terminal method (Table 3),

TABLE 3— PROFILE OF ACCEPTORS

	Baroda	*Bombay*
Average parity	3.5	4.0
Age in years	28.9	31.9
Literacy rate	9.8%	8.1%
Past contraceptive use	1.1%	0.5%
n	7,103	2,073

Surgical Difficulties and Complications

Surgical Technique. Different sterilization techniques were used by the two teams. Air to create pneumopentoneum and single incision procedure was adopted by Baroda team. On the other hand, the Bombay team used carbon dioxide and used both single and two incision procedures (Table 4). Falope rings were used to occlude the fallopian tubes in all the subjects.

TABLE 4—SURGICAL TECHNIQUE USED BY CENTRES

Surgical Technique	*Baroda* (Percent)	*Bombay* (Percent)	*Total* (Percent)
Gas used	99.5	48.4	88.0
Air	0.5	51.6	12.0
CO_2 Incision Single	100.0	83.1	96.2
Duble	0.0	16.9	3.8
	100.0	1000	100.0
n	7,103	3,073	9,176

Surgical difficulties. Surgical problems which impeded the operative procedure such as difficulty in creating pneumopentoneum, passing trocar and achieving tubal occlusion are indicated in Table 5.

TABLE 5— SURGICAL PROBLEMS AT THE *TIME* OF STERILIZATION BY CENTRES

Surgical Problems	*Baroda* (Percent)	*Bombay* (Percent)	*Total* (Percent)|
Creating pneumoperitoneum	0.5	02	0.4
	(33)	(4)	(37)
Passing trocar	0.1	0.0	0.1
	(9)	—	(9)
Difficulties in occluding	1.4	0.5	1.2
the tubes	(101)	(11)	(112)
No problem	98.0	99.3	98.3
	(6,960)	(2,058)	(9,018)
	100.0	100.0	100.0
n	7,103	2,073	9,176

(Figures in parenthesis are actual number of observations).

The Baroda team had difficulty in occluding the tubes in 101 women because of adhesions and in only 69 of such cases Falope ring could be applied, to both the tubes i.e. the operation remained incomplete in the remaining 32 cases. The Bombay team had difficulty in occluding both tubes in all of them.

Time of discharge after sterilization. Majority of the women who underwent laparoscopic ligation by both the teams were able to go home within 12 hours after the operation. Fifty women(2.4%) operated by the Bombay team needed longer duration of hospitalization (12-24 hours) (Table 6).

TABLE 6-TIME OF DISCHARGE AFTER LAPAROSCOPY STERILIZATION

Time of Discharge	*Centres*	
	Baroda (percent)	*Bombay* (Percent),
Upto 6 hours	0.0	0.5
7-12 hours	99.7	97.1
13 -24 hours	0.2	24
After 24 hours	0.0	0.0
Transferred to appex	0.1	00
Institution	(5)	
	100.0	1000
n	7,103	2,073

(Figures in parenthesis are actual number of cases).

Five women (0.1 %) operated in Baroda camps had to be admitted to the apex institution, immediately following operation, for complications such as omental prolapse (2 subjects), suspected omental vessel injury (1 subject), ectopic pregnancy (1 subject) and incomplete abortion (!) All these five cases were managed at apex institution and were discharged in good health. Transfer to the apex institution was necessary as Baroda camps were held in PHCs, school buildings or village health centres, where necessary facilities for emergency laparotomy were not available

Surgical complications. A total of 64 women at Baroda camps and 32 women at Bombay camps experienced surgical complications within *s.* week of the operation giving a complication rate of 9 0 per thousand ligations for Baroda and 15.4 per thousand ligations for Bombay. Uterine perforation was the commonest complication observed in both camps (7.7 per 1000 for Baroda and 12.5 per 1000 for Bombay). The other complications included injury to omental vessels, ovarian ligament and to cervix, etc. (Table 7).

TABLE 7-SURGICAL COMPLICATION RATES*

Complication}	*Baroda Rate*	*Bombay Rate*	*Total Rate*
Uterine perforation	7.7	12.5	8.8
	(55)	(26)	(81)
Blood stained fluid	0.6	0.0	0.4
in pouch of douglas	(4)		(4)
Other**	07	2.9	1.2
	(5)	(6)	(11)
No complication	991.0	984.6	989.5
	(7,039)	(2,041)	(9,080)
n	7 103	2,073	9,176

*Complication rate expressed for 1,000 women.
**Includes bleeding from cervical bite, omental injury and injury to utero-overian ligament
(Figures in parenthesis are actual number of observations)

Resumption of normal duties. The time after operation when the subject resumes normal duties is important from the view point of acceptability of a method of tubal sterilization. About sixty five per cent of women operated by Baroda team resumed their normal duties within a week following laparoscopy and of these 35.9 per cent resumed the duties within 4 days following the oper-

ation. A total of 978 women (13.9%) resumed normal duties after 15-30 days. On the contrary, the Bombay team reported that 79.4 per cent of their subjects resumed normal duties within 4 days after the procedure and 98.3 per cent within one week, indicating a marked variation in resumption of normal duties following laparoscopy by the two teams (Table 8).

TABLE 8-TIME INTERVAL BETWEEN OPERATION AND RESUMPTION **OF** NORMAL **LUIJES**

Interval	*Centres*	
(days)	*Baroda* (Percent)	*Bombay* (Percent)
1-4	35.9	79.4
5-7	29.5	18.9
8-10	19.4	1.5
11-14	0.3	0.0
15-21	9.7	0.1
22-30	4.2	0.0
30+	1.0	0.1
	100.0	100.0
n	7,049	1,625

This observation does not support the advantage usually claimed for laparoscopic ligations that subjects can resume normal duties earlier than after minilaparotomy. It is striking to note that. as many as 1,051 (14.9%) women operated by Baroda team resumed their normal duties only after i5 days of laparoscopy. However, this information could be obtained for 7,049 (99.2%) women operated at Baroda camps and 1,625 (78.4%) women from Bombay camps.

Resumption of coitus. A total of 2,883 women (40,9%) operated by Baroda team resumed coitus within a month following ligation. This number increasei to 6,083 (86.3%) within two months. The remaining 966 women resumed coitus after two months. Comparing these with the figures repented by Bombay, where 36.7 per cent resumed coitus within one month and the remaining within two months, one does not find a marked variation, and the slight difference may be due to complexity in obtaining *a.* true response to *this* kind of question.

Follow up. The follow up rate at 3 months for the Baroda camps was 99.3 per cent, of which 60.2 per cent had reported for the follow up examination

while the remaining were followed by home visits. On the other hand, though the Bombay team reported a follow up rate of 78 4 at 3 months, yet in majority of women (71.1%) information was recorded during home visits by personnel other than from the health sector e.g. Patwari and staff of the Block Development Office (Table 9). The difference in the pattern and rate of follow up became more pronounced at the end of one year.

TABLE 9—PERCENTAGE OF WOMEN WHO CAME FOR THREE MONTHS AND ONE YEAR FOLLOW UP BY CENTRES

Place of Follow up / *Visit*	*Baroda* (Percent)	*Bombay* (Percent)	*Total* (Percent)
3 Months follow-up			
Clinic	60.2	7.3	48.2
Home	39.1	71.1	46.3
Did not come	0.7	21.6	5.5
Total	100.0	100.0	100.0
12 Months Follow-up			
Clinic	82.0	0.5	63.6
Home	16.2	80.2	30.6
Did not come	18	19.3	5.8
Total	100.0	100.0	100.0
n	7,103	2,073	9,176

Women seeking medical advice, A total of 47 women (out of 7,049) who had been operated by Baroda team and 11 women (out of I,o25), on whom the surgery was performed by Bombay team sought medical advice during the study period following ligation (Table 10).

TABLE 10—THE REASONS FOR SEEKING MEDICAL ADVICE DURING THE STUDY PERIOD

Medical Reasons	*Baroda (Rate*)*	*Bombay (Rate*)*
Pregnant at the time of surgery	4.5 (32)	—
Method failure	1.1 (8)	—
Omental prolapse	0.6 (4)	—
Stitch abscess	0.1 (1)	6.8 (11)
Dehydration with meningismus	01 (1)	—
Menorrhagia	0.1 (1)	—
n	7,049	1,625

*Rate per 1,000.

Out of 47 women who sought medical advice after operation in the Baroda Camps, 40 were because of pregnancy (32 women were pregnant at the time of operation and remaining were method failure), 4 cases for omental prolapse, one had a stitch abscess, one had dehydration with meningismus and one had complaint of menorrhagia. From the Bombay camps all the 11 subjects sought medical care due to development of stitch abscess. Pregnancy and stitch abscess were the two common reasons for seeking medical advice following the surgery.

Method Failures

A total of 8 method failures were reported by Baroda team during a period of one year following laparoscopic sterilization giving a rate of 1.1/1000 ligations. However, no method failure was reported by Bombay team.

Mortality in the camps. There were no deaths directly attributable to the sterilization procedure or to the practice of anaesthesia, in both types of camps. However, there were *three* deaths reported by Baroda centre. None of the deaths could be attributed to the operation procedure. *One* death was due

to infective hepatitis and the patient died on the !8th day following ligation, *another* death was due to suspected meningismus on 21st day of operation, while, the t*hird* death occurred one year after the procedure due to severe dehydration following acute attack of food poisoning.

Discassioa

The results of this study suggest that the organisational structure of the camps for laparoscopic Iigation plays an important ro!e in terms of successful and unsuccessful outcome. There has been a significant variation in the structure of the camps organised by the two teams. The approach by Baroda team was based on taking the family planning services to the community by holding camps at the Primary Health Centres (PHC) and other sites which could be easily approached by the women. However, such camp sites lacked few essential facilities, these lacunae probably necessitated transportation of five women to the apex institution for management of complications. On the other hand, Bombay team operated at District Hospitals, which had adequate facilities, but had the disadvantage of being distantly located from rural population. Thus the Bombay team while had the advantage of having necessary back up facilities to take care of complications, was comparatively less accessible to the community.

The ICMR study is based on two types of laparoscopy camps organised in two different states. The essential difference in the camps was that the Bombay team consisted of 4-6 members including an anaesthetist, all of whom were experienced Gynaecologists, The team travelled with all equipment to a distance as far as 300 kms from their institution. The camps were organised at the distiict hospital with the team staying for a period of 3-7 days. Once the team members returned to Bombay, the follow up of the subjects was delegated to block level staff

The Baroda team on the other hand, organised small camps in their home territory, which were held at PHC or even in school building in rural areas. The team had two operators—one of whoh was an experienced laparoscopist and was accompanied by a trainee who was also permitted to operate under guidance. All operations were performed under local anaesthesia and no anaesthetist accompanied the team. Though transport was available to bring the surgical emergencies to the hospital, yet, in many women who had extensive adhesions, only one tube could be ligated. They were advised to visit the hospital subsequently for ligation of the other tube.

The Baroda team had arranged a large number of small camps, and performed less number of operations per camp but the number of operations performed per burgeon per hour were more, as compared to the Bombay team, because same team of surgeons went to use the one camp on the same day in an attempt to cover the larger population. Also the Baroda team had no accompanying anaesthetist and included trainee surgeons. However, the higher

incidence of wound sepsis (stitch abscess) reported by the Bombay team is difficult to explain particularly since only autoclaved instruments were used by this team

The failures were reported only by Baroda team, however the total absence of method failures reported by the Bombay team should be interpreted with caution It could be due to the fact that all the operations were performed by experienced laparoscopists but since the follow up of the clients was extremely poor, it is equally likely that some method failures were missed and were not reported. Baroda team reported more difficulties probably because the camp sites were not equipped to handle medical emergencies. Though this happened in relatively small number of cases, the question may be posed; "Is one justified in taking the additional risk"?

The results of a multi-national study of WHO (1982) as well as other studies [4, 5, 6] indicate that incidence of complications is greater with laparoscopic approach as compared to laparotomy. Laparoscopic sterilization is suitable for interval and concurrent MTP cases; whereas the maximum number of sterilizations performed in India are [7] during the postpartum period. Laparoscopic ligations are technically more complex. It is, therefore, recommended that these be performed only by gynaecologists with specialized training with adequate experience. Minilaparotomy on the other hand, can be safely performed by physicians after minimal training in the procedure m?king it more cost effective.

The main advantage of laparoscopy is the shorter hospital stay. However, there is sufficient evidence to indicate that subjects who undergo minilaparotomy procedure can also be discharged in the same manner (within 24 hours) as their counterparts on whom laparoscopic technique has been used [5, 10].

Laparoscopic sterilization need to be performed by experienced operators. However, in the rural areas of the developing countries neither the well equipped hospitals nor the technical manpower to operate with such devices are available Camp approach may continue to fill this lacuna for the community living in the remote areas, with the following suggestions:

1. Only adequately trained and experienced laparoscopists should perform operations.
2. Camps should preferably be organised at District Hospital level or at an upgraded Primary Health Centre (PHC) so that any complication that may arise can be dealt with immediately. Alternatively, transport facilities should be available to shift the women to a hospital.
3. Potential acceptors must have a medical check up before the operation, including examination to rule out a pregnancy.
4. The number of operations performed per surgeon m a day should not exceed 30.

5. The team should include a trained anaesthetist to deal with anaesthetic complications.
6. The local medical and para-medical personnel should be given the major responsibility of organising the camps to ensure better rapport with the community and more importantly to follow up the sterilized subjects.

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