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Camp Laparoscopic Sterilization Deaths in Gujarat State, India, 1978-1980

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Abstract

An early experience of camp laparoscopic sterilization in Gujarat State, India, resulted in 22 deaths among 106,500 women undergoing the operation during 1979 and 1980. Increased risk of death was seen when larger numbers of procedures were performed by year or month of year. The least experienced surgeons had the highest case-fatality rate. Improvised settings (i.e., school buildings) exacerbated the risk of death, as did advanced age, and, to a lesser extent, high parity. Errors in clinical judgment were identified in some fatal procedures. A system of health audit of large sterilization programs is needed.

Key words: sterilization deaths, laparoscopic sterilization, camp sterilization

Introduction

Female sterilization is by far the most prevalent contraceptive method used in India. Only breastfeeding has a greater demographic impact. From 1978 to 1982, female sterilizations increased in the entire country from almost 1 to over 3 million before declining, and in Gujarat State alone, they grew from 143 to 198 thousand before leveling off.[1] The slackening in recent years may be related to reports of deaths at the camps where many women appear for this procedure to be performed by a traveling surgical team. Since 1980, laparoscopic surgery has become popular both with women requesting sterilization and their doctors. Compared to minilaparotomy, the operating time is shorter for the surgeon as is the recovery period for the patients. It is widely believed, however, that sterilization deaths are attributable to the excessive numbers of these procedures performed daily, especially in laparoscopic sterilization camps.[2] Government regulations imposing limits ate frequently ignored. On the other hand, there are reports of camps doing very large numbers of sterilizations without deaths, and with only reasonable numbers of complications.[3–5]

To identify programmatic and clinical risk factors in these camps, we analyzed 22 laparoscopic deaths among 106,500 women undergoing sterilization in camps in Gujatat State, India, from 1978 to 1980, giving a mortality of 20.65 per 100,000 procedures. There were three additional deaths after 42 days of this surgery that could not be attributed to these

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procedures. In contrast, recent experience in the United States reports a death rate of 1.5 per 100,000 hospital sterilization procedures, mostly performed by laparoscopy.[6]

This paper analyzes data from an earlier program of laparoscopic camp sterilizations in Gujarat State. The skill of their surgeons has since improved, but insight into the problems that arose and how they were addressed can be of considerable benefit to those who are initiating similar camps in other states and countries.

Methods

Laparoscopic sterilization camps are organized by government health personnel to take place in district hospitals, primary health centers, and school buildings. Counseling, screening examinations and follow-up care are the responsibility of health personnel in the camp area. The operations we evaluated were performed by ten gynecologists who formed 10 teams with their surgical nurses and other assistants. These teams traveled to the camp locations, with laparoscopic and other surgical equipment and supplies, performed the procedures in one or a few days and returned to their home base.

The surgical equipment included single-puncture operating laparoscopes with silicone rubber band applicators, Veress needles, trocar and cannulae, light source and air pumps for pneumoperitoneum. In school buildings, any available table was used for operating, with bricks placed at the foot to produce a Trendelenburg position. Primary health centers and district hospitals were equipped with standard operating tables.

All procedures were performed under local aaesthesia, after premedication. An anesthetist was seldom part of the surgical team. The local anesthetic used was 3-5 *ml* of 1% lignocaine infiltrated at the site of the periumbilical incision. Pneumoperitoneum was produced with 500–3,000 *ml* of atmospheric air.

Gloves were changed by team members after each procedure, but gowns only at the time of rest breaks. Instruments were supposed to be sterilized with formalin vapor or Cydex solution (Johnson and Johnson, Bombay) for at least 10 minutes. All deaths were investigated by a review committee of which the author was a member. Their scrutiny revealed that these precautions were frequently inadequate because of the short intervals between them. It was also evident that patients were often not monitored for pulse and blood pressure during surgery.

Results-Clinical

The cause and timing of deaths is shown in Table 1. Of the 5 occurring on the operating table, 2 were reported as due to lignocaine sensitivity, 2 to cardiac arrest and 1 to air embolism. Time of other deaths ranged from 1 to 20 days. The 2 tetanus cases were postpartum sterilizations of mothers following home delivery and may not have been due to the operation. On the other hand, errors in clinical judgment were evident. Bowel injury caused infection in 4 cases and uterine perforation in 1; these women were not hospitalized. The death due to hemorrhage involved laceration of the mesentery, apparently not

Table 1. Cause, time and number of camp laparoscopic sterilization deaths in Gujarat State, India, 1978-1980

Cause of death	Time of death	No. deaths	No. autopsied
Air embolism	**On operating table**	1	1
Lignocaine sensitivity	**On operating table**	**2**	1
Cardiac arrst	**On operating table**	**2**	**0**
Hemmorrhagic **shock**	**10 hours**	1	1
Pulmonary embolism	**16 hours**	1	**0**
Peritonitis (4 bowel injury)	**2-8 days**	**9**	**7**
Septicemia	5–20 **days**	**4**	**3**
Tetanus	**> 15 days**	**2**	**0**

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visualized through the laparoscope.

Results-Programmatic

Table 2 shows the pattern of laparoscopic camp sterilizations and deaths by age and number of living children of the women and by year, month of year and sterilizations per camp. There is a trend of increased risk of death by age and number of living children as an estimate of parity. The trend is strongest for age and, indeed, there were no deaths among women less than 30 years old with 4 or more living children, while there were 6 deaths among women older than 30 with fewer than 4 children. As expected, at greatest risk are women 30 or more years of age with 4 or more living children who accounted for 10 of the 22 sterilization deaths.

Table 2. Number of laparoscopic camp sterilizations, deaths and case fatality rate by age, number of living children, year, month of year, and sterilizations per camp in Gujarat State, India, 1978-1980

Variable	Sterilization	Death	Rate per 10^5
Age (years)			
<25	6,603	0	
26-30	52,822	9	17.0
31-35	35,674	9	25.2
36-40	9,904	4	40.4
41+	1,594	0	
Living children			
1	640	0	
2	25,240	3	11.9
3	36,636	9	24.6
4	37,275	8	21.7
5+	6,709	2	29.8
Year*			
1978-9	19,167	3	15.7
1979980	62,219	17	27.3
1980**	25,450	2	7.8
Month			
January	22,154	5	22.6
February	17,040	5	29.3
March	27,690	6	21.7
April-November	17,251	1	5.8
December	22,365	5	22.4
Sterilization per camp			
<50	23,430	3	12.8
50-100	20,650	6	29.0
101-200	35,795	8	22.3
200+	26,625	5	18.8

* Fiscal years April 1 through March 31
** April 1 through December 31

There was a tripling of the number of sterilizations in fiscal year 1980 compared to 1979, with a near doubling of risk of death. Camp sterilizations in India tend to occur mainly from December through March. This period avoids both the hot and rainy seasons and corresponds to a government sponsored campaign to meet targets set for each state by end of the fiscal year. There is a uniformly high risk of deaths in camps in this campaign season and a markedly reduced risk in the balance of the year.

Camps with SO-100 sterilizations each had a higher risk of 29 per 100,000 procedures compared to other sized camps. The reason is that in 1979-80, laparoscopy in a camp setting had just been introduced. The patient demand was greater than the availability of trained surgeons. Therefore, surgeons with lesser experience in laparoscopy were sent to small camps carrying out up to 100 procedures per day and more experienced surgeons were sent to places where the case load was high. Four of the 6 deaths occurring in camps with 50-100 operations each were attributed to sterilizations performed by surgeons with less than 6 months' experience in laparoscopic sterilization, and 4 of the 6 deaths occurred in operations in school buildings. A striking effect of experience on risk of camp laparoscopic sterilization death is reflected in Table 3.

Nevertheless, a marked increased risk of 71

Table 3. Number of camp Iaparoscopic sterilizations, deaths and case fatality rate by months of experience and number of sugeons in Gujarat State, India, 1978-1980

Experience (months)	Surgeons No.	Sterilizations No.	Deaths No.	Rate per 10^5
<6	3	9,220	5	54.2
6-12	3	24,560	8	32.6
13-24	2	35,520	6	16.9
25+	2	37,200	3	8.1

Table 4. Number of camp laparoscopic sterilizations and camps, average number of sterilizations **per camp, deaths and case fatality rate by site of camps in Gujarat State, India, 1978-1980**

Camp site	Sterilizations No.	Camps No.	Sterilizations per camp	Deaths No.	Rate per 10^5
District hospital	19,490	120	162	3	15.4
Primary Health Centre	74,340	412	180	10	13.5
School building	12,670	62	204	9	71.0

deaths per 100,000 operations performed in school buildings is shown in Table 4. Four of the 9 deaths were in smaller camps of 50-100 sterilizations per camp, where less experienced surgeons were in attendance. But large camps in school buildings still appear to have an independent increased risk.

Discussion

The salient findings of the study are the association of risk of death with large numbers of sterilizations, evident in fiscal year 1980 and in the larger camps situated in school buildings. Advanced age appears as a risk factor. These are frequently high parity women who tend to be more anemic, and require careful preoperative screening and meticulous monitoring during surgery. They should be operated on only by the most experienced surgeons, such as those who performed fully one-third of the procedures with a risk of death to their patients of one quarter of surgeons with 6 to 12 months' experience. Camps are clearly not the place to train surgeons in laparoscopic sterilization, as observed in the extraordinary risk of women dying when their surgeons have less than six months' experience.

However, our analysis shows that even if school buildings were excluded as camp sites, and training in laparoscopic sterilization in camps ended, an unacceptable risk of death would remain in these facilities. There is evidence in this study and from investigations of these deaths that more of them could be prevented through improved surgical technique, including sterilization of equipment, and improved surgical judgment in the case of complications.

The need for speedy completion of the sterilizations is felt by the surgical teams who are anxious to return to their home base. The payment of fees to the surgeon per operation performed and the pressure by the local camp organizers to assure that women requesting the operation be served and government quotas be filled are additional factors contributing to unsatisfactory outcomes. Government regulations concerning number of sterilizations to be performed per surgical team per day in different types of camp facilities are largely ignored.

While reductions in risks in laparoscopic sterilization camps can be achieved through better training, sufficient experience and more suitable facilities, it is our opinion that the greatest need is for a system of medical audit of these services, to be performed by a panel of distinguished gynecologists. All deaths and cases of serious complications would be audited. Information to be reviewed by peers of the operating surgeons at a regular meeting arranged for this purpose would be gleaned from three records: first, a screening examination form (indicating that the women is not pregnant, severely anemic, hypertensive, or with pelvic infection), signed by the screening physician; second, a surgical complication form signed by the surgeon; and third, a 48-hour follow-up visit by a nurse, recording temperature, blood pressure and signs of wound infection. The confidential examination of such records would, we predict, markedly improve the quality of surgical services in camp sterilizations. At present, medical personnel responsible for these services work in the confidence that any complication related to poor medical practice will never be traced back to them as individuals nor will it ever affect their reputation among their peers. A system of medical audit would change this and

very likely encourage all health personnel involved in these camps to perform their duties in a more responsible manner. There is actually no substitute for such an audit if these surgical services are to be improved.

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References

1. **Ross JA, Rich M, Molzan JP, Pensak M. Family Planning and Child Survival: 100 Developing Countries. Center for Populations and Family Health, New York. 1988**
2. **Rai U. High sterilisation death toll. New Delhi: The Times of India, August 31, 1989**
3. **Bhatt** RV, **Engineer AD, Gupta S, et *al*. Evaluation of laparoscopic sterilisations in rural camps.** Demography India 1988; 17: 148-160
4. Mehta PV. A total of 250, 136 laparoscopic sterilisations by a single operator. ***Br J Obstet*** *Gynaecol* 1989; 96: 1024-1034
5. Sheth SS, Desai VJ, Pawar A, Pawar V. India laparoscopic female sterilisation camps. *Lancet **1988;*** ii: 1415-1416
6. Escobedo LG, Peterson MB, Grubb GS, Franks AL. Case fatality rates for tubal sterilisation in U.S. hospitals, 1979 to 1980. Am ***J Obstet*** *Gynecol* 1989; ***160: 147-150***