MINILAPAROTOMY VERSUS LAPAROSCOPIC STERILIZATION*

(One-Year Follow-Up Study of 1060 Cases)

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SUMMARY

To compare the complications, failure and cost-effectiveness of minilaparotomy and laparoscopic voluntary sterilizations, 1060 cases were followed for one year. Eight hundred and forty cases had opted for laparoligation (Group A), while 220 cases desired minilaparotomy (Group B). In 280 and 70 cases in Groups A and B respectively M.T.P. was also done. Follow-up was done in the hospital or by house-visits.

There was no mortality or serious morbidity in either group. However, complications were significantly higher (21.36%) in Group B as compared to Group A (7.74%). Cases with M.T.P. had higher complication rate in both groups. There were 7 pregnancies (4 true failure and 3 apparent due to luteal phase pregnancy) in Group A, but none in Group B. The hospital stay was significantly shorter (mean=0.31 days) in Group A compared to a mean of 7.07 days in Group B. Complete resumption of normal activities was also significantly earlier in Group A (mean=0.9 week) than in Group B (mean=2.32 weeks).

The greater preponderance (3.9:1) of cases in Group A shows a strong preference of our women for laparoligation. Fewer complications, shorter hospital stay and early resumption of normal activity make it more cost-effective and popular. However, higher failure rate (0.83%) is a drawback.

Introduction

Female sterilization is currently the most

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commonly used method of population control all over the world. This is especially true for India where 20 million married women of reproductive age are estimated to have been sterilized for family planning (Soni, 1983). Both minilaparotomy (minilap) and laparoscopic (laparoligation) techniques have been employed, although the latter has been adopted on a significantly mass scale in India only recently.

We have not found any comparative studies to prove the superiority of one procedure over the other. At our institution, we have been employing both these techniques, depending largely upon woman's own preference.

Material and Methods

From August'82 to February'84, a total of 1931 female sterilizations were done in the Gynaecology Department of Govt. Medical College Hospital, Patiala. However, only cases seeking voluntary sterilization with or without Medical Termination of Pregnancy (M.T.P.), and with a complete follow-up for a minimum of one year were included in this study. Sterilizations within six weeks after child birth or spontaneous abortion and cases with associated gynaecological surgery were excluded. Thus out of 1931 cases only 1060 cases qualified for this study.

Out of these, 840 cases had opted for laparoligation (Group A) and 220 cases had desired minilap (Group B). Minilap was done by the modified Pomeroy ligation technique (Howkins and Hudson, 1977) under spinal (138 earlier cases) or local anaesthesia (82 later cases). Laparoscopic sterilization was done by KLi Laparocator (with ring) using single puncture technique under local anaesthesia supplemented by intravenous diazepam and pentzocine. The abdomen was inflated by 1-2 litres of nitrous oxide.

Follow-up was done on a special proforma. Complications were recorded during the hospital stay and at the periodic outpatient revisits at regular intervals of one and six weeks, and one year. Whenever the cases failed to report in the hospital. the follow-up was completed by housevisits by the medical or para-medical staff. The clinical details of both groups are shown in Table I.

Observations and Results

There was no mortality or major complications in either group. Table II shows the immediate and long-term complications in the two groups. The complication rate was higher in Group B (21.36%) as compared to Group A (7.74%). The corresponding figures in M.T.P. cases were 40%and 13.21%.

There was no failure in Group B, but there were 7 pregnancies (0.83%) in Group A (Table III) with 4 true and 3 apparent failures. No ectopic pregnancy occurred in the entire series.

Table IV shows the comparative costeffectiveness of the two techniques as judged by the hospital stay and time required for the complete resumption of normal activities. The respective mean values were 0.31 days and 0.9 weeks in Group A as compared to 7.07 days and 2.32 weeks in Group B.

Discussion

Female sterilization, by laparoscopy or minilap, is relatively safe. Major complications occur in less than one per cent of cases and mortality is extremely rare (2-20 per 100,000 procedures) (Editors, Population Reports, 1985). However, in a recent editorial, Parikh (1985) questioned the safety of laparoscopic sterilization camps in India where the mortality figures appear to be ten times higher. In the present series, there was no mortality or major

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the choice depend of less and	(Laparo)		(Minilap)		
T ALM T III LAND	No.	Percentage	No.	Percentage	
. Total	840		220		
Without MTP	560	66.7	150	68.2	
With MTP	280	33.3	70	31.8	
2. Education					
Uneducated	737	87.7	198	90.0	
Educated	103	12.3	22	10.0	
8. Rural/Urban					
Rural	410	48.8	118	53.7	
Urban	430	51.2	102	46.3	
4. Occupation					
Housewife	756	90.0	204	92.8	
Labourer	65	7.7	16	7.2	
Office jobs	19	2.3	Nil	0.0	
5. Socio-economic status					
Poor	750	89.4	198	90.0	
Middle class	82	9.7	22	10.0	
Upper class	8	0.9	Nil	0.0	
6. Previous contraception					
Oral	17	2.0	Nil	0.0	
I.U.D.	55	6.5	20	9.0	
Condom/Jelly	195	23.2	62	28.2	
None/erratic	573	68.2	138	62.7	

TABLE I Clinical Details of Cases

* Mean age (\pm SD) = 26.2 \pm 1.9 years (range 22-40 years).

** Mean age $(\pm SD) = 29.4 \pm 2.7$ years (range 25-38 years).

(The difference between the two means is significant (p<0.001) by the two-tailed student's t-test).

morbidity in either group. All cases included in this report were operated upon only in the hospital by a team of skilled surgeons fully trained in the two procedures. This explains the absolute safety record of this series.

However, the rate of complications in this series is seemingly very high (7.74% in Group A and 21.36% in Group B) (Table II) as compared to some other recent reports (Bhiwandiwala *et al* 1982); Bhatena *et al* 1985; Sud and Malan, 1985; Sharma *et al* 1985). There can be many explanations for this disparity. First, different criteria of reporting may be responsible. We also included long-term side effects upon 1 year while other workers have reported only the immediate complications. Furthermore, we actively sought medical problems at the follow-up visits. Also, a majority of our minilap cases were operated under spinal anaesthesia (138 cases, 62.7%) as per our hospital policy in the earlier phase of this study. Spinal anaesthesia is known to cause greater morbidity than the local anaesthesia. Thus 12 cases of backache in Group B were actually due to tissue injury caused by spinal puncture.

These complications, though numerically high, never posed any serious problems. In both groups, it was observed that when M.T.P. was combined with sterilization, the

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	Group A	(Laparo)	Group B	(Minilap)	, p
Complication	No.	Percentage	No.	Percentage	(Chi square test)
Fotal (Overall)	65/840	7.74	47/220	21.36	<0.001
With M.T.P.	37/280	13.21	28/70	40.00	<0.001
Without M.T.P.	28/560	5.00	19/150	12.66	<0.001
(a) Operative/Post-					
operative (upto					
6 weeks)	124				
Vaginal bleeding*	12	1.42	7	3.13	
(In M.T.P. cases)					
Fever/infection	2	0.24	1	0.45	
Incisional sepsis	3	0.36	1	0.45	
Injuries to tube/	8	0.95	3	1.36	
mesosalpinx					
Backache/abdominal	20	2.38	23	10.45	
pain					
Total	45	5.36	35	15.90	
(b) Long-term side-effects					
("Post-tubal ligation					
syndrome") (Upto 1					
year)**					
Disturbed menstrual	10	1.19	6	2.73	
pattern (irregular or					
excessive bleeding)					
Abdominal pain	3	0.36	1	0.45	
Backache/pelvic pain	2	0.24	2	0.91	
Weight gain	3	0.36	2	0.91	
Changed libido	2	0.24	1	0.45	
Total	20	2.38	12	5.45	

TABLE II Complications and Long-term Side Effects

* 3 cases required rehospitalization for repeat D & C (2 in Group A and 1 in Group B).

** None regretted sterilization except one (Table III) who desired to continue pregnancy despite failure.

complication rate was much higher in contrast to those without M.T.P. (Table II). Weil (1978) had a similar experience. Any woman seeking sterilization and M.T.P. together, should be forewarned about the greater likelihood of complications to maintain the popularity of the former.

There was no failure, true or false, in our minilap cases (Group B). This absolute effectiveness could be fortuitous cr may be due to superiority of minilap in this regard. Domenzain *et al* (1982) also reported no pregnancy with minilap upt \odot 5 years. The manipulation at the time of bringing the tubes into the abdominal incision may disturb the corpus luteum resulting in discontinuation of luteal phase pregnancy.

In contrast, with laparoligation (Group A), there were 7 pregnancies (0.83%) (Table III). This is in accord with the

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TABLE IIIPregnancies* Following Laparoligation(Group A, 840 cases)

					nated by	
7	0.83			Pregnancy Test	Cashir M	*
4	0.48			+		
		Tubal fistula	-1	Minilap	M.T.P.	-1
		Slipped ring	1	Laparoscopy repeated	M.T.P.	
		Improper		Laparoscopy	M.T.P.	
		application (partial occlusion)	-1	repeated		
		(due to desire to	—1	-	No. 1. WIL	
)			
3	0.35	Luteal phase pregnancy		menstruation	м.т.р.	
		4 0.48	4 0.48 Tubal fistula Slipped ring Improper application (partial occlusion) Unknown (due to desire to continue pregnancy 3 0.35 Luteal phase	4 0.48 Tubal fistula -1 Slipped ring -1 Improper application -1 (partial occlusion) Unknown -1 (due to desire to continue pregnancy) 3 0.35 Luteal phase	4 0.48 Test 4 0.48 + Tubal fistula -1 Minilap Slipped ring -1 Laparoscopy repeated Improper Laparoscopy application -1 repeated (partial occlusion) -1 - Unknown -1 - (due to desire to continue pregnancy) - - 3 0.35 Luteal phase Failure of expected	4 0.48 Tubal fistula -1 Minilap M.T.P. Slipped ring -1 Laparoscopy M.T.P. Improper Laparoscopy M.T.P. application -1 repeated (partial occlusion) -1 - Unknown -1 - (due to desire to continue pregnancy) 5 Luteal phase pregnancy 3 0.35 Luteal phase pregnancy Failure of expected m.T.P.

* None in Group B (Minilap).

TABLE IV Comparative Cost-effectiveness

	Group A (Laparo)		Group B (Minilap)		
	No. of cases	Per cent	No. of cases	Per cent	
(a) Hospital stay		terrer of Article Contractor and an			
6-12 hours	735	87.5	Nil	0	
12-24 hours	95	11.2	Nil	0	
1-7 days	10	1.3	214	. 97.3	
7-10 days	Nil	0.0	6	2.7	
Mean $(\pm S.D.)$	7.44 ± 0).36 hrs.			
	0	r			
	0.31 ± 0	.01 days	7.07 ±	0.46 days	
		p<.0001			
		(Chi sq	square test)		
b) Resumption of normal duties					
Within 1 week	600	72.5	Nil	0	
Within 1-4 weeks	239	27.4	168	78.8	
Within 4-6 weeks	1	0.1	52	22.7	
Mean (±\$.D.)	0.9 ± 0.0	.69 weeks	2.32 ± 0	.33 weeks	
	p<.0001				
	(Chi square test)				

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worldwide figure of 1% (Editors, Population Reports, 1985). Three unrecognised pregnancies in Group A at the time of sterilization accounted for 42.9% of the total failures. To avoid this pitfall, we now prefer to do sterilization in the pre-ovulatory phase of the menstrual cycle. However, we do not routinely perform a dilatation and curettage or vacuum aspiration as has been done by Goel *et al* (1985) as it unnecessarily increases the risk of complications.

The greater preponderance (3.9:1) of cases in Group A clearly speaks of a strong preference of our women for laparoligation. The fewer complications (Table II) and shorter hospital stay and early resumption of activities (Table IV) may be responsible for this preference. Also, the women in Group A were younger, somewhat more educated and more commonly urban (Table I). Perhaps these factors made them aware of this scientific innovation and led them to this choice.

In conclusion, both minilap and laparoligation are safe and effective. Laparoscopic female sterilization holds greater promise because of fewer complications and cost-effectiveness as found in this study. However, efforts should be made to reduce the failure rates still further by proper case selection and meticulous technique of laparoligation only by properly trained surgeons.

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