ORIGINAL ARTICLE

Effect of topical lignocaine on postoperative pain after laparoscopic tubal sterilisation in awake patients

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Objective. To evaluate postoperative pain after administration of topical lignocaine during laparoscopic sterilisation in awake patients using Falope rings.

Study design. Thirty-six women who underwent laparoscopic tubal sterilisation were assigned randomly to receive topical lignocaine (1%, 10 ml) or placebo. A 4-point verbal rating score was used to assess pain at ring application, 15 minutes and 1 hour thereafter, and at discharge. Side-effects, complications, extra pain medication requirements and satisfaction rates at follow-up were assessed postoperatively.

Results. The pain scores were significantly lower in the lignocaine group than in the placebo group at 15 minutes (2.06 v. 2.94) and 1 hour (1.187 v. 2.33) and at discharge (0.18 v. 1.1). The side-effects and complications were similar in the two groups. Procedure satisfaction and acceptability were higher in the lignocaine group (p=0.005).

Conclusion. Topical lignocaine applied to the fallopian tubes at the time of laparoscopic tubal sterilisation decreases postoperative pain and improves satisfaction rates even if done under sedation and local anaesthesia.

The introduction of laparoscopic sterilisation resulted in a more than twofold increase in the number of tubal sterilisations.[1] Tubal ligation is a widely accepted method of contraception, in India chosen by 37.3% of women.[2] Initially regional anaesthesia was considered to be safer and produced better surgical results than local anaesthesia. In a retrospective descriptive study conducted on 2 827 cases, laparoscopic tubal ligation with Silastic rings was safely carried out under local anaesthesia with a technical failure rate of 0.14% and a mean operating time of 10 minutes.[3]

Tubal ligation is associated with significant pain, both during and after the operation. Tubal rings produce more pain than clips, both during and after occlusion, as ischaemia from occlusion devices releases pain mediators such as prostaglandins.[4,5] In addition to analgesics, local anaesthetics such as lignocaine and bupivacaine have been applied topically as solutions,[6] injected into the mesosalpinx[7] and instilled cervically into the fallopian tubes.[8] However, either these studies were done under general anaesthesia[9] or they were not placebo-controlled and lacked randomisation.[6,10,11]

This randomised study evaluated whether, compared with a placebo, topical application of 1% lignocaine on the fallopian tubes reduces intra- and postoperative pain in tubal ligation under local anaesthesia.

Materials and methods

A randomised prospective clinical study was conducted in the Obstetrics and Gynaecology department of the All India Institute of Medical Sciences. To achieve power of 0.9 and an alpha coefficient of 0.5, it was determined that at least 15 patients in each group would be required to detect a difference of 2 in the verbal rating pain score. Using a computer-generated random number table, the

patients were randomised to receive either 1% lignocaine or normal saline solution dripped onto each fallopian tube (5 ml of solution per fallopian tube) before tubal occlusion, which resulted in two groups: the study lignocaine group and the control placebo group.

All the enrolled patients were undergoing interval tubal ligation, had no history of prior surgery, pelvic inflammatory disease or pelvic mass; all were assessed as ASA1 (American Society of Anesthesiologists physical status 1 – healthy), and were medically eligible for tubal ligation. All were told that the surgery would be done under local anaesthesia plus topical application of a solution over the tubes. Informed consent for tubal ligation was taken from both the partners, and they consented to be part of the trial. A detailed history was taken and physical examination was done. Height, weight, pulse and blood pressure were recorded in all patients, and baseline haemoglobin levels were measured. Intravenous sedation using pentazocine (0.5 mg/kg) and diazepam (0.1 - 0.2 mg/kg) was given to all patients 5 minutes before the procedure. Pain was assessed using a 4-point verbal rating score (VRS) (0 = no pain, 1 = minimal, 2 = mild, 3 = moderate and 4 = severe).[12] Ten millilitres of 1% lignocaine was infiltrated at the incision site. The VRS score at incision was measured. Carbon dioxide gas was used to create pneumoperitoneum. The procedure was done using a 10 mm single-puncture, zero-degree laprocator (Karl Storz, Germany). In the study group 10 ml of 1% lignocaine (5 ml over each fallopian tube) was dripped under vision at the isthmus and ampullary region; normal saline was used in the control group. After 60 seconds, Falope rings were applied over each tube at the isthmic region. The VRS at application was noted. The patients were then moved to the recovery room, where the postoperative pulse rate and blood pressure were measured. Intramuscular diclofenac was given to patients who required additional analgesia. VRS scores were measured 15 minutes and 1 hour after the procedure. The nature and site of pain were noted, and side-effects were noted and suitably treated. Intra-operative and postoperative complications were recorded. All patients were discharged 4 - 5 hours after the procedure, and the VRS was measured at the time of discharge. When the patients came to the outpatient department for stitch removal after 7 days, they were questioned about their recovery at the end of 1 week (expressed as a percentage), whether they would have preferred the surgery to have been done under general anaesthesia, and whether the procedure had been as they had expected, worse or better.

Statistical analysis

The data were analysed using SPSS version 16. The continuous independent samples were analysed using Student's *t*-test, while continuous non-numerical variables were evaluated using the rank sum test. For categorical variables, Fisher's exact test was applied. The VRS scores at the various time points were analysed using generalised estimating equations.

Results

Of 40 eligible women only 36 were included in the study, 17 in the study group and 19 as controls. One patient had tubal transection, 1 had congenital absence of the left tube, and 2 had dense adhesions. The baseline characteristics were comparable in the two groups (Table I). The mean operative time was 8 minutes (standard deviation (SD) 2.5 minutes, range 4.5 - 11 minutes). There were no unexpected complications in either group, and pulse and blood pressure measurements before and after the procedure did not differ significantly between the groups.

All patients had a pre-operative VRS score of 0. The mean VRS at incision was minimal (0.7 (SD 1.4) v. 0.4 (SD 0.8) in the study and control groups, respectively). The difference in the pain score in the two groups at 15 minutes, at 1 hour and at discharge was statistically significant. There was no difference in the pain score at ring application between the two groups (Table II). Three patients in the control group required additional analgesia in the form of 1 ml intramuscular diclofenac (75 mg). The site of pain was predominantly abdominal (68% in the study group v. 78% in the controls, not statistically significant);, 31% of study and 20% of control patients had pelvic pain. The total incidence of pain was similar in the two groups. There were only a few minor side-effects such as nausea, vomiting and giddiness, which were similar in the two groups; 94% of study and 89% of control patients had no side-effects. All patients were discharged in a stable condition. Recovery at the end of 1 week was 93% in the two groups. Of the patients in the study group, 68.7% considered the procedure better than they expected, as opposed to 16.7% in the control group; this difference was statistically significant. In the study group 6% of patients and in the control group 11% found the procedure worse than expected, and 33% of control but only 11% of study patients stated that they would have preferred surgery under general anaesthesia. This last difference was also statistically significant.

Discussion

Topically applied local anaesthetic significantly reduced postoperative discomfort after laparoscopic sterilisation. Unlike other studies, this study indicates that application of local anaesthetic at the time of occlusion (pre-emptive analgesia) reduces postoperative pain.[13] It emphasises the usefulness of topical application of 1% lignocaine in providing postoperative analgesia and thereby reducing the requirement for other analgesics. It is speculated that this difference may be due to differening methods of occlusion, as clips result in more ischaemia[13] than the Silastic bands used in our study.

Several studies have looked at local anaesthesia in conjunction with general anaesthesia for pain relief after laparoscopic sterilisation.[6,14] Garwood *et al*. observed that visceral pain, particularly genito-urinary, is frequently associated with nausea and vomiting.[13] They speculated that the reduction in nausea and vomiting in their study group was due to reduced opiate use as well as afferent inputs to the nervous system

Table I. Baseline characteristics of the study and control groups

	Study group (*N*=17)	Control group (*N*=19)	*p*-value
Age (yrs) (mean (SD))	29.3 (4.1)	28.6 (3.2)	0.55
Parity (%)			
2	33.3	18.7	
3	50	62.5	0.66
4	11.1	18.7	
5	5.56	0	
Weight (kg) (mean (SD))	48.3 (5.2)	45.5 (6.9)	0.19
Height (cm) (mean (SD))	151 (5.96)	149.8 (5.5)	0.53
Cycle length (d) (mean (SD))	28.9 (1.8)	28.5 (1.9)	0.55
Duration of menses (d) (mean (SD))	3.9 (0.68)	4.2 (0.8)	0.4
Retroverted uterus	8	9	0.65
Pre-procedure pulse rate (/min) (median)	82	84	0.91
Pre-procedure blood pressure, systolic (mmHg) (mean (SD))	115 (10.9)	110 (12.2)	0.9
Pre-procedure blood pressure, diastolic (mmHg) (mean (SD))	76 (7)	70.7 (18.4)	0.9
Haemoglobin (g/dl) (mean (SD))	9.1 (1.2)	8.9 (0.8)	0.32
VRS at incision (mean (SD))	0.7 (0.6)	0.6 (0.8)	0.73

SD = standard deviation.

Table II. Pain scores in the control and study groups

	0	15 minutes	60 minutes	At discharge
Control group (mean (SE))	3.6 (1.8)	2.9 (0.2)	2.3 (0.1)	1.1 (0.1)
Study group (mean (SE))	3.3 (0.2)	2 (0.2)	1.2 (0.2)	0.2 (1)
Difference in pain scores	0.42	-0.88	-1.15	-0.9
95% CI	-0.9 - 0.2	-1.4 - -0.3	-1.6 - -0.7	-1.2 - -0.6
p-value	0.13	0.002	0.000	0.00

SE = standard error; CI = confidence interval.

being blocked by previous application of lidocaine. However, we found a similar incidence of nausea and vomiting in our two groups.

In conclusion, topical application of lignocaine is a safe, easy and effective means of improving pain control. It reduces the requirement for supplemental analgesia and can be used as an effective alternative to general anaesthesia. This technique can be especially useful at primary health centre level, where facilities for general anaesthesia are not available in a developing country like India. Larger, double-blind studies are needed to confirm its efficacy so that it can be incorporated into routine practice. It should reduce morbidity and prove extremely useful in low-resource settings.

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