

FEMALE STERILIZATION WITH HULKA CLIPS — INITIAL EXPERIENCE AT THE UNIVERSITY HOSPITAL, KUALA LUMPUR

ASARI ABDUL RAHMAN

V. SIVANESARATNAM

A. ADLAN NURUDDIN

SUMMARY

An analysis of 86 patients sterilized laparoscopically with Hulka clips is presented. We find that the method is simple, acceptable and has minimal complication. The failure rate is similar to that reported by others. However, this method could be done under local anaesthesia thus shortening the hospital stay for the patients. This method has the advantage of safety and prospects for reversal when desired.

INTRODUCTION

The University Hospital, Kuala Lumpur has been the pioneer hospital in this country to use laparoscopic tubal sterilization in late 1960s. Since then the number of patients sterilized laparoscopically climbed up rapidly each year till we reached a peak in the 1975 to 1976 period. Initially electrocautery was used to sterilize the fallopian tubes. Subsequently by 1975 this method was abandoned because of the risk of bowel burns.¹ Since then the use of fallope rings (Silastic bands)

has become popular with both surgeons and patients.² In June 1979 we introduced the use of Hulka clips (spring loaded clips) for sterilization and we claim to be the pioneer in this country to use them. Although 100 patients have had sterilization with this method by July 1981, only 86 are being considered in this presentation, because the rest have yet to complete their first (or 3 months) follow up. Our initial experience is presented.

MATERIALS AND METHODS

From June 1979 to July 1981 about 100 patients have been sterilized using Hulka clips. Majority of the patients were recruited through the National Family Planning Board Clinic based at the University Hospital. The patients were initially given an appointment for admission and routine pap smear and haemoglobin estimation. All patients were admitted a day before operation and a detailed interview and physical and pelvic examination done. Consents for sterilization and operation were routinely taken. The sterilization was done the following day and the majority of cases were discharged the subsequent day.

Laparoscopy on most of our patients was done under General Anaesthesia. All patients were sterilized as an interval procedure. (i.e. not pregnant at the time of admission) and the indication was mainly for family limitation.

The patients were then followed up at 3, 6 and 12 months and detailed interview and pelvic examinations were done at each visit.

Asari Abdul Rahman, M.B.B.S., M.R.C.O.G.

Lecturer

V Sivanesaratnam, M.B.B.S., M.R.C.O.G.

Associate Professor

A Adlan Nuruddin, M.B.B.S., M.R.C.O.G.

Lecturer

Department of Obstetrics and Gynaecology,

University of Malaya,

Kuala Lumpur.

TABLE I
DISTRIBUTION BY AGE AND ETHNIC GROUPS

| Age (years) | Race | | | | Total |
|-------------|---------|-------|--------|--------|-------|
| | Chinese | Malay | Indian | Others | |
| 21 - 24 | 0 | 1 | 4 | 0 | 5 |
| 25 - 29 | 3 | 2 | 21 | 0 | 26 |
| 30 - 34 | 9 | 3 | 18 | 0 | 30 |
| 35 - 40 | 12 | 2 | 9 | 1 | 24 |
| Above 40 | 0 | 0 | 1 | 0 | 1 |
| TOTAL | 24 | 8 | 53 | 1 | 86 |

TABLE II
NUMBER OF LIVE BIRTHS BEFORE
STERILIZATION

| Live Births | Frequency | Percent |
|-------------|-----------|---------|
| 2 | 9 | 10.5 |
| 3 | 26 | 30.2 |
| 4 | 23 | 26.7 |
| 5 | 17 | 19.8 |
| 6 | 6 | 7.0 |
| 7 | 1 | 1.2 |
| 8 and above | 4 | 4.7 |
| TOTAL | 86 | 100.0 |
| AVERAGE | | 4.0 |
| RANGE | | 2 to 8 |

TABLE III
DISTRIBUTION BY AGE AND PARITY

| Age (years) | Parity | | | | | | | Total |
|-------------|--------|----|----|----|---|---|---------|-------|
| | 2 | 3 | 4 | 5 | 6 | 7 | 8/above | |
| 21 - 24 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 5 |
| 25 - 29 | 3 | 7 | 9 | 5 | 2 | 0 | 0 | 26 |
| 30 - 34 | 1 | 12 | 4 | 8 | 2 | 1 | 2 | 30 |
| 35 - 40 | 4 | 6 | 9 | 3 | 1 | 0 | 1 | 24 |
| Above 40 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| TOTAL | 9 | 26 | 23 | 17 | 6 | 1 | 4 | 86 |

Each Hulka clip is composed of plastic interlocking jaws hinged at one end and a stainless steel spring which when pushed over the plastic jaws will hold them tightly apposed to one another over a segment of the tube. When closed the clip is 1 cm long and 3 mm broad.

The following analysis is based on our findings in the first 86 patients.

TABLE IV
DISTRIBUTION BY ETHNIC GROUPS AND PARITY

| Parity | Race | | | | Total |
|-----------|---------|-------|---------|--------|-------|
| | Chinese | Malay | Indians | Others | |
| 2 | 6 | 0 | 3 | 0 | 9 |
| 3 | 9 | 1 | 16 | 0 | 26 |
| 4 | 7 | 4 | 11 | 1 | 23 |
| 5 | 2 | 3 | 12 | 0 | 17 |
| 6 | 0 | 0 | 6 | 0 | 6 |
| 7 | 0 | 0 | 1 | 0 | 1 |
| 8/above 8 | 0 | 0 | 4 | 0 | 4 |
| TOTAL | 24 | 8 | 53 | 1 | 86 |

RESULTS

Although a majority of our patients (93 percent) were between 25 to 40 years of age a small number (5.8 percent) was in the age group 21 and 24 years. The largest ethnic group in this study comprised Indians (61.6 percent) the Malays comprising only 9.3 percent (Table I).

The majority (76.7 percent) of the patients studied were para 3 to 5. (Table II) 10.5 percent of patients had only 2 live births.

Whilst the majority of Indians were sterilized between the ages of 25 to 34 years, the majority of Chinese sought sterilization at the later age of 30 to 40 years. The Malays (although small in number) had an even age distribution. These findings are further illustrated in Table III.

The Indians were relatively more parous than the Chinese or Malays (Table IV). The average parity for the Indians was 4.4 compared to 3.2 for the Chinese.

As shown in Table V the average age of the youngest child at the time of sterilization was 2.8 years. Twenty-three (26.7 percent) of the patients, however, had this sterilization procedure done when their youngest child was less than a year old. These patients were the relatively more parous ones.

The majority of our patients (48.8 percent) were housewives (Table VI).

General Anaesthesia was used in 97.6 percent of our cases and 2 patients had regional anaesthesia. In 80 patients (93 percent) a periumbilical incision was used for the introduction of the laparoscope and the laparocator with the Hulka clip introduced through a second incision in the right iliac fossa. In the 3 patients who had a minilaparotomy done,

TABLE V
AGE OF YOUNGEST CHILD AT TIME OF
STERILIZATION

| Youngest Child (Years) | Frequency | Percent |
|---------------------------|-----------|---------|
| 0 | 23 | 26.7 |
| 1 | 15 | 17.4 |
| 2 | 9 | 10.5 |
| 3 | 9 | 10.5 |
| 4 | 7 | 8.1 |
| 5 | 8 | 9.3 |
| 6 | 1 | 1.2 |
| 7 | 4 | 4.7 |
| 8 and Above | 10 | 11.6 |
| TOTAL | 86 | 100.0 |
| AVERAGE | | 2.8 |
| RANGE | | 0 to 8 |

laparoscopy was contraindicated, in 3 others the clip was applied at the time of laparotomy for other gynaecological surgery.

The problems encountered at laparoscopy were studied (Table VII). Creation of pneumoperitoneum was easy in all cases. In 3 patients who were obese, slight difficulty was encountered at introduction of trochar for the laparoscope. The fimbrial ends of the tubes could not be visualised in 2 cases because of peritubal adhesions. One patient had a fallopian tube transected followed by bleeding during application of fallope ring. The sterilization was completed with application of Hulka clips. In another patient, the Hulka clip could not be unloaded from the applicator and the tube was transected on withdrawing the latter. In 5 patients additional clips were used to ensure complete occlusion of the tubes. This mainly occurred in the initial stages of

TABLE VI
DISTRIBUTION BY PROFESSIONS

| Occupation | Frequency | Percentage |
|---------------------|-----------|------------|
| Lesser Professional | 10 | 11.6 |
| Skilled | 3 | 3.5 |
| Semi Skilled | 1 | 1.2 |
| Unskilled | 26 | 30.2 |
| Housewife | 42 | 48.8 |
| N/Available | 4 | 4.7 |
| TOTAL | 86 | 100.0 |

TABLE VII
PROBLEMS AT LAPAROSCOPY (N = 86)

| Problems at Laparoscopy | Frequency | Percentage |
|--------------------------------------|-----------|------------|
| Introduction of gas | - | - |
| Insertion of Trocar | 3 | 3.5 |
| Visualisation of Fimbria of Tubes | 2 | 2.3 |
| Tubes cut | 2 | 2.3 |
| Additional clip | 5 | 5.8 |
| Others | 11 | 12.8 |

the study. Other problems were encountered in 11 patients, such as clips slipping off the applicator into the peritoneal cavity, difficulty in unloading the clip and non-alignment of the clip spring. These were really mechanical problems associated with the applicator.

Majority of the patients were discharged one day after operation. Two patients who had minilaparotomy performed on them stayed 5 to 7 days post operatively.

Only 11 patients had completed their 12 months follow up. Forty patients completed their 3 months follow up and 35 their 6 month.

Patient complaints before and after sterilization are shown in Table VIII. The patients were specifically asked about these complaints at recruitment and at each follow up visit. The same patient might have more than one complaint. It is not possible to draw conclusions about the significance of these various complaints at this stage of the study. Changes, if any, in the menstrual patterns is also being studied and we hope to report this at a later time.

Pregnancy rate

Up to our present follow up, there were 2

TABLE VIII
PATIENTS COMPLAINTS PRE AND POST
STERILIZATION

| Complaints | Before | 3 Months | 6 Months | 12 Months |
|---------------------------|---------|----------|----------|-----------|
| | Surgery | F/Up | F/Up | F/Up |
| Headache and Giddiness | 16 | 9 | 12 | 3 |
| Weakness of Limbs | 22 | 26 | 14 | 3 |
| Palpitation | 9 | 9 | 5 | 5 |
| Backache | 22 | 20 | 9 | 3 |
| Others | 1 | 20 | 11 | 3 |

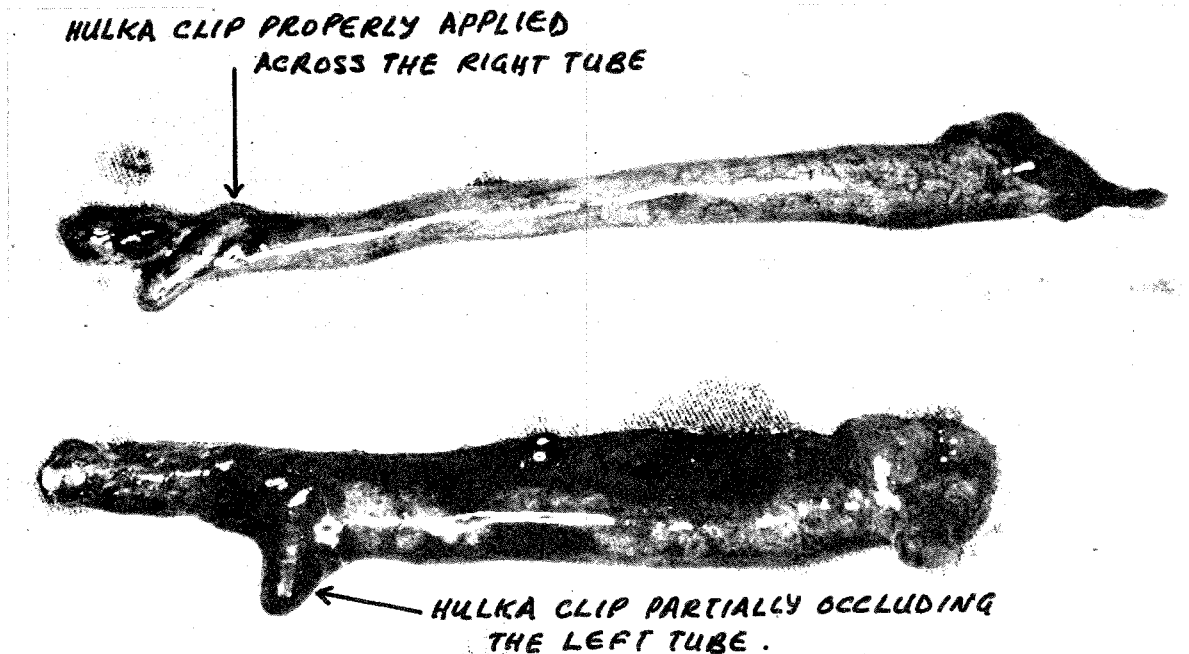


Fig. 1 Showing the right and left tubes after tubectomy. On the top showing the clip completely occluding the tube and at the bottom the clip has been applied partially across the tube.

pregnancies. The first patient had a luteal phase pregnancy. She was seen two months later with an incomplete abortion for which an evacuation of the uterus was done. Subsequent hysterosalpingogram done showed the tubes to be obliterated.

The second patient came back at 3 months post sterilization and was found to be pregnant. She opted to continue with the pregnancy and went to term. She had a spontaneous labour but at lower segment Caesarian section for foetal distress, it was found that the left tube was only partially occluded by the clip (Fig. 1). Bilateral tubectomy was done and histological examination showed that the left tube was stenosed but still patent, whereas the right tube was completely obliterated. This makes the actual failure rate in the series to be 1 in 86 (1.16 percent).

At the time it was noted that the clips had become covered by a thin membrane and there was little tissue reaction if any. There were no adhesions at the site where the clips were applied.

DISCUSSION

The University Hospital, Kuala Lumpur has been the pioneer institution in this country to use

laparoscopic sterilization procedures. We started with electrocautery but subsequently abandoned it because of the possible bowel and other visceral burns. ¹ From the mid-70s up to date we have been using silastic bands to sterilise our patients laparoscopically and this method is still popular with patients and surgeons. ²

The Hulka clip was developed in 1969 by Jaroslav Hulka M.D. (University of Carolina) and George Clemens (bioengineer from Illinois). The initial clinical trials were done in India, Thailand, Singapore and England.

Slightly more than 100 patients have been sterilized with the Hulka clips at the University Hospital but only 86 cases are analysed because the rest have not even completed their first follow up at 3 months. Table I to VI show sociodemographic characteristics and parity of our patients and they are similar to patients we have sterilized with the silastic bands. ²

Most of our patients had the sterilization done under General Anaesthesia. This is in contrast to other series. Brenner *et al* ³ reported the use of local anaesthesia in 14.6 percent of patients sterilized with Hulka clips. Khandawala *et al* ⁴ used only local

anaesthesia for all their patients. The use of local anaesthesia could be much safer if sterilization is done with Hulka clips than with electrocautery.

Problems encountered at laparoscopy (technical difficulties) were small and similar to those reported by others. It should be noted that one problem could lead to other problems, for example if pneumoperitoneum is not satisfactorily created, this could lead to difficulties in insertion of trochar and visualisation of tubes. In our study difficulty in visualisation of the tubes was encountered in only 2-3 percent of cases. Others^{3,4} have encountered similar problems in 4.9 to 7.3 percent of cases. In 5.8 percent of our patients extra clips had to be used. This mainly happened initially when our experience in its use was minimal.

The main advantage of the clips is the very low incidence of tubal transection which was relatively commoner with the use of silastic bands (1.6 percent) whereas the clips accounted for only 0.6 percent.³

Duration of hospital stay in this series is similar to our previous study with the fallope ring² and this is because in both studies General Anaesthesia had been used.

The failure rate in this study is acceptable and is similar to those reported by others. Our failure rate so far is 1.16 percent. Hulka in his initial 314 patients had a pregnancy rate of 1.28 percent⁵ and Khandawala⁴ had 2.0 percent pregnancy rate and in 2 cases out of 3 he found the clips were properly applied.

Post operative complaints reported by our patients were also minimal and nonspecific and such complaints have been found by others. However, our follow up is still not complete.

A point to bear in mind is that the clips give good prospects for reversibility later compared to other methods of tubal sterilization. Contraceptive Technology update⁶ reported successful reversal

following application of Hulka clip in 84 percent of cases. It thus appears that the clip is gaining in popularity in the West, not only for safety but also because of the ease of reversal compared to other tubal occlusion technique.

ACKNOWLEDGEMENTS

We would like to thank IDRC for sponsoring this study as part of a collaborative study. We also thank Professor T.A. Sinnathuray and Associate Professor D.K. Sen, Principal Collaborators for IDRC, for their permission to publish this initial experience and also for their encouragement. Finally we also thank the staff of the National Family Planning Board at the University Hospital for recruiting the patients and their assistance at the follow up visits.

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