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A COMPARATIVE STUDY OF THE FILSHIE CLIP AND POMEROY METHODS OF TUBAL OCCLUSION AS USED FOR POSTPARTUM STERILIZATION

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I. Introduction

From February 1984 to August 1988, a comparative study of female sterilization using the Filshie clip and the Pomeroy method via minilaparotomy was conducted at the Tri-Service General Hospital in Taipei, Taiwan. Two hundred women requesting sterilization for family planning purposes were included in the study. All of the women were postpartum ($\leq$ 42 days since last delivery) at the time of sterilization. Of the 200 women, 100 were sterilized using the Filshie clip and 100 were sterilized using the Pomeroy method.

Random allocation labels preprinted at Family Health International (FHI) and sealed in opaque envelopes were opened by the operator at the time of the procedure to determine which occlusive technique was to be performed on each woman. Six random allocation errors occurred, three in the Filshie clip group and three in the Pomeroy group; the cases were included in the group of the actual performed method. Sociodemographic and medical data were recorded on standard forms by the hospital staff and sent to FHI for processing and analysis.

II. Patient Characteristics

Sociodemographic Characteristics

Women randomly assigned to the two tubal occlusion groups were compared with respect to selected sociodemographic characteristics (Table I). The mean age of the Filshie clip

patients (31.1 years) was similar to that of the Pomeroy patients (31.4 years). The mean education of the Filshie clip group (11.4 years) was similar to that of the Pomeroy group (11.8 years). Of the Filshie clip patients, 63% were residents of urban areas; 72% of the Pomeroy patients were urban residents (data not shown). The mean number of live births prior to the recent delivery was 2.0 in the Filshie clip group and 1.9 in the Pomeroy group.

The pattern of contraceptive use during the three months prior to the recent pregnancy was similar between the two groups; 37% of the women in the Filshie clip group and 34% of the women in the Pomeroy group had not practiced contraception; 35% of the Filshie clip group and 36% of the Pomeroy group had used an IUD prior to their pregnancy; 11% of the Filshie clip group and 6% of the Pomeroy group had used withdrawal or rhythm method while 9% of Filshie clip patients and 15% of the Pomeroy patients had used condoms; 7% of the Filshie clip women and 9% of the Pomeroy women had used oral contraceptives.

Medical History and Pelvic Examination

Women were queried about relevant medical history and were given a preoperative pelvic examination. Five patients in the Filshie clip group (5.0%) and one patient in the Pomeroy group (1.0%) reported a history of pelvic inflammatory disease; 8 women (8.0%) in the Filshie clip group and 15 women (15.0%) in the Pomeroy group had undergone previous intraperitoneal surgery. All of the

women but two in the Filshie clip group (2.0%) had a normal pelvic exam.

III. Procedure and Results

Sterilization Procedures

All procedures were performed via a minilaparotomy incision. Tubal occlusion was affected by either the application of Filshie clips or by the Pomeroy method; 88% of the women in the Filshie clip group and 92% in the Pomeroy group received a regional anesthetic. Twenty-five women in the Filshie clip group (25.0%) and 22 in the Pomeroy group (22.0%) were sterilized at the time of delivery. Thirty-seven women in the Filshie clip group (37.0%) and 49 women in the Pomeroy group (49.0%) were sterilized within one day of delivery. Twenty-six women in the Filshie clip group (26.0%) and 17 in the Pomeroy group (17.0%) were sterilized within two days of delivery. Twelve women in each group (12.0%) were sterilized at three or more days following delivery (data not shown).

Technical Failures

A technical failure is defined as a procedure that could not be performed or completed as planned. One Pomeroy patient had only the right tube occluded by Pomeroy method. Because the uterus was involuted, difficulty was encountered in grasping the left tube and bleeding resulted. Occlusion was affected by a partial salpingectomy.

Surgical Difficulties, Injuries and Complications

Surgical difficulties are defined as problems encountered by the **operator** during the sterilization procedure (Table II). No significant differences were found upon comparison of difficulties encountered during Pomeroy procedures or Filshie clip application. Four cases (4.0%) of difficulty grasping the tubes were reported in the Filshie clip group and five (5.0%) were reported in the Pomeroy group. Three cases (3.0%) of difficulty visualizing the tubes were reported in the Filshie clip group and six (6.0%) were reported in the Pomeroy group. One case (1.0%) of difficulty entering the peritoneum during a Filshie clip procedure was reported.

Surgical injuries and complications are defined as problems experienced by the **patient** during the sterilization procedure (Table II). One case of mesosalpingeal bleeding and one case of tubal injury were reported among Pomeroy patients (2.0%). Three cases (3.0%) of pelvic pain were reported in the Filshie clip group, and five cases (5.0%) in the Pomeroy group. Two women (2.0%) in the Filshie clip group experienced nausea.

The complaints from sterilization to discharge included 27 cases of pelvic pain among Filshie clip patients (27.0%) and 26 cases (26.3%) among Pomeroy patients. Two cases of shoulder pain were reported in the Pomeroy group (2.0%).

Thirty percent of the patients in the Filshie clip group and 49.5% of the patients in the Pomeroy group required four or fewer nights of hospitalization; 45% of the Filshie clip group and 33.3% of the Pomeroy group required 5-6 nights of hospitalization; 25% of the Filshie clip patients and 17.2% of the Pomeroy patients required 7 or more nights of hospitalization. Tri-Service General is a military hospital and it is not uncommon for a woman to remain hospitalized for several days following delivery.

Early Follow-up Complications and Complaints

The women were requested to return to the hospital for an early follow-up visit within 31 days of the sterilization procedure. A total of 85 women (85.0%) from the Filshie clip group and 86 women (86.0%) from the Pomeroy group returned during that time (Table III). No complications or hospital readmissions were reported at this visit.

Long-Term Follow-up Complications and Complaints

Long-term follow-up visits were scheduled at six, twelve and twenty-four months after sterilization. Ninety-six Filshie clip patients (96.0%) and 97 Pomeroy patients (97.0%) returned for at least one follow-up visit during this time (Table III).

One pregnancy was reported in the Pomeroy group at 6-months post-surgery; the estimated gestational age was 6 weeks. The woman accepted an IUD as a fertility control method following an

induced abortion. The investigator suspected recanalization of the tubes. There were no other complications or hospital readmissions in either group during this period.

IV. Summary

This report presents the results of a comparative study of minilaparotomy female sterilization procedures performed among 200 postpartum women at the Tri-Service General Hospital in Taipei, Taiwan. The women were randomly assigned at the time of the operation to undergo tubal occlusion by the Filshie clip or Pomeroy method.

Women in the two groups were similar with respect to sociodemographic characteristics, relevant medical history and preoperative pelvic examination findings. More than 34% of both groups had not practiced contraception prior to the most recent conception. There was one technical failure; a Pomeroy patient had the left tube occluded by partial salpingectomy due to bleeding. There were no significant differences with regard to surgical difficulties between the Filshie clip and Pomeroy groups. Two injuries (2.0%) were reported in the Pomeroy group. The complaints from sterilization to discharge included 27 cases of pelvic pain among Filshie clip patients (27.0%) and 26 cases (26.3%) among Pomeroy patients.

Over eighty-five percent of the women in both groups returned for

an early follow-up visit. There were no complications or hospital readmissions reported at this visit.

Ninety-six percent of the women in the Filshie clip group and 97% of women in the Pomeroy group returned for at least one visit during the long-term follow-up interval. One pregnancy was reported in a Pomeroy patient. There were no complications or hospital readmissions reported during the long-term follow-up period.

Table I

Selected Sociodemographic Characteristics,
Previous Contraceptive Use and Medical History

Characteristic	Filshie Clip (N=100) No.	%	Pomeroy (N=100) No.	%
Age (years)				
20-24	2	2.0	1	1.0
25-29	33	33.0	30	30.0
30-34	46	46.0	53	53.0
35-39	16	16.0	15	15.0
40+	3	3.0	1	1.0
Total	**100**	**100.0**	**100**	**100.0**
Mean	**31.1**		**31.4**	
Total live births*				
1-2	78	78.0	81	81.0
3-4	20	20.0	18	18.0
5-6	1	1.0	1	1.0
7-8	1	1.0	0	-
Total	**100**	**100.0**	**100**	**100.0**
Mean	**2.0**		**1.9**	
Contraceptive practice three months prior to pregnancy				
None	37	37.0	34	34.0
IUD	35	35.0	36	36.0
Condom	9	9.0	15	15.0
Withdrawal/rhythm	11	11.0	6	6.0
Orals	7	7.0	9	9.0
Foam/Diaphragm/Jelly	1	1.0	0	-
Total	**100**	**100.0**	**100**	**100.0**
Total women with previous or current medical conditions	14	14.0	16	16.0

*does not include recent delivery

Table II

Events During Surgery and Post-operative Recovery

Event	Filshie Clip (N=100)		Pomeroy (N=100)	
	No.	%	No.	%
Surgical difficulties				
Grasping tubes	4	4.0	5	5.0
Visualizing tubes	3	3.0	6	6.0
Entering peritoneum	1	1.0	0	-
Total	**8**	**8.0**	**11**	**11.0**
Surgical injuries/complications				
Mesosalpingeal bleeding	0	-	1	1.0
Tubal injury w/o bleeding	0	-	1	1.0
Pelvic pain	3	3.0	5	5.0
Nausea	2	2.0	0	-
Total	**5**	**5.0**	**7**	**7.0**
Postoperative complaints/complications				
Pelvic pain	27	27.0	26	26.3
Shoulder pain	0	-	2	2.0
Total	**27**	**27.0**	**28**	**28.3**

Table III

Women Returning at Follow-up

Follow-up period	Filshie Clip (N=100) No.	%	Pomeroy* (N=99) No.	%
≤ 31 days	85	85.0	86	86.0
Six months	87	87.0	89	89.0
Twelve months	81	81.0	81	81.0
Twenty-four months	78	78.0	70	70.0
No. and % of women returning for at least one follow up ≥ 6 months post sterilization:	96	96.0	97	97.0

*technical failure case is excluded