Original Article

Menstrual Abnormalities and Pain after Five Tubal Sterilization Methods: A Randomized Controlled Trial

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Abstract

Background and Objective: Tubal sterilization is the most popular method of permanent female contraception, yet there is considerable debate concerning the influence of this procedure on the women's health and menstrual pattern.

Methods: We randomized 1358 women to one of the five methods of tubal sterilization; unipolar electrocauterization, bipolar electrocauterization, minilaparatomy, Pomeroy method, Falope ring, and Hulka clips to evaluate the effect of each method on menstrual pattern. Each woman was interviewed before sterilization and followed for 3 years. 850 women who did not undergo sterilization served as control group and were interviewed and followed. 248 women of study group and 503 cases of the control group did not fulfill the study criteria and were excluded.

Results: Menstrual indices were significantly different between the control group and those women who were sterilized by unipolar, ring, and Pomery methods. The amount of bleeding, was increased by 28.3% in unipolar group (p=0.001), 19.9% in ring group (p=0.001), and by 23.9% in Pomeroy group (p=0.0001). Significant menstrual pain lasted for a maximum of 18 months was noted in unipolar coagulation group (p=0.0001).

Conclusion: Sterilization methods which destroy the vascular communications along and immediately subjacent to the tube and that also disturb the countercurrent exchange of biologically active factors between the uterus and ovaries, are more likely to cause menstrual abnormalities.
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Introduction

Tubal sterilization is the most popular method of contraception in the world.[1] Although many researchers have examined the relationship between tubal sterilization and subsequent development of menstrual abnormalities,[2-10] there is still considerable debate. As early as 1950's Williams et al[11] reported a significant

abnormal bleeding.among women who had received tubal sterilization compared to a nonsterilized control group. It was therefore suggested that there might be a causal relationship between tubal sterilization and subsequent higher rates of hysterectomy[12,13] and change in hormonal profile.[2,5,14] Many authors have reported increased premenstrual distress, heavier and prolonged menstrual bleeding, and increased frequency of dysmenorrhea. However, failure to control for confounding variables such as age, parity, obesity, previous use of contraceptive methods, menstruation intervals after sterilization, and type of sterilization may have affected the results. Concerning the women's health, it is important to resolve the debate on the menstrual abnormalities after tubal sterilization. We designed this prospective controlled study to evaluate the influence of five sterilization techniques on both menstrual pain and indices, using both the pre-surgical menstrual status of the same women and a group of nonsterilized women as control.

Patients and Methods

In this randomized controlled clinical trial we compared the effect on menstrual cycle indices and pain of five tubal sterilization methods: laparoscopic unipolar electrocauterization (unipolar), laparoscopic bipolar electrocauterization (bipolar), laparoscopic sterilization by Falope ring (ring), laparoscopic sterilization by Filshi Clips (clips), and minilaparotomy Pomeroy technique (pomeroy). These were all interval sterilizations; that is, they occurred at least one year after a subject's recent pregnancy.

Between January 1990 and December 1999, 2122 women who had referred for tubal sterilization to Shiraz University of Medical Sciences, Shiraz, Iran, were enrolled into the study. From the socioeconomic point of view, all women were selected from a low-income population. Those a least 25 and at most 40 years of age by the time of sterilization, normal menstruation cycles with a mean length of 21 to 35 days , intra-individual variation of ±3 days (but never outside the 21 to 35 days range), and a good physical and mental health were included into the study. Anyone who was on hormonal contraception, had intrauterine device or suffered from endocrine abnormality at the time of sterilization was excluded from the study. The Ethic committee of the Shiraz University of Medical Sciences approved the study design. All subjects and their husbands gave written informed consent.

Of 2122 women enrolled, 764 did not fulfill the study protocol and were excluded from the study. The remaining 1358 subjects were randomized into one of the five previously-mentioned treatment arms. Before the sterilization procedure, a resident or trained nurse obtained information on each woman's demographic, medical, obstetrics, and also detailed baseline menstrual history. Women were asked about the duration of bleeding, length of cycle (number of days from the beginning of one menstrual period to the beginning of the next), intermenstrual bleeding or spotting (women had a choice between yes and no), amount of bleeding (subjects were indicated on a three point scale for the amount of bleeding in each menstrual cycle), menstrual pain (women had a choice between none, mild, moderate and severe categories of menstrual cramps). Moderate and severe categories were considered to need analgesics. Before assigning for each treatment arm, patients were randomized depending on the baseline characteristics that might potentially affect changes in menstrual function over time, including body mass index, age, gravidity, and parity. An operating room nurse using a random table, performed randomization. We used a standard method of sterilization with general anesthesia and intubation for all women.[15] Meanwhile, a control group consisting of 815 nonsterilized women who had completed child bearing, were not on hormonal contraception, were under routine follow up of gynecology clinics and who fulfilled the inclusion criteria were interviewed. Subjects were followed every six months for three years after sterilization. In each follow up session, every single change in the patient's menstrual indices was noted. The persistent change in the menstrual indices was defined as any change from the baseline that persisted for at least two postoperative follow up visits. Regarding the duration of bleeding, significant changes were categorized into either less than four days, between four and eight, and more than eight days. For the length of the menstrual cycle, significant changes were categorized into either less than 21 days, between 21 and 35, and more than 35 days persisted at least in two follow up visits. For each indices under study, we compared the proportions of women underwent one of the sterilization methods to their baseline data as well as their control group. The patient's follow up considered to be completed if she had participated in all post-operative visits up to three years. Follow up visits were discontinued if a woman became pregnant, used hormonal contraception, or underwent either tubal reconstruction or hysterectomy.

Statistical Methods

We used Kruskal-Wallis test to compare each group's post-sterilization persistent menstrual changes to their own menstrual status before operation. We then carried out the Mann-Whitney U

Table 1: Baseline characteristics of women who underwent tubal sterilization and women in control group

Parameter	Groups						p value
	Clips	Bipolar	Unipolar	Ring	Pomeroy	Control	
N	191	202	212	252	262	312	
Age	32.2±3.5	33.2±3.4	31.6±3.2	31.5±3.8	31.7±3.9	33.6±3.9	0.525
Gravidity	3.2±11.1	3.0±1.2	2.8±1.0	2.8±1.0	2.9±1.1	2.8±1.0	0.742
Parity	3.1±0.9	3.0±1.0	2.8±0.9	2.8±0.9	2.9±0.9	2.8±0.9	0.665
BMI	23.8±2.8	23.0±3.5	24.1±1.1	23.3±3.6	22.9±4.2	23.4±2.3	0.723

test restricted to subjects with significant changes in the first analysis to compare each group to the control. Kolmogrov-Smirnof Z test was used to compare the incidence of pain in each group to their pre-operation and control group.

Results

Over a period of nine years, 1358 women, eligible for study were allocated for randomization. Data were incomplete for 248 patients because they were lost to follow up or excluded for other reasons, leaving 1115 patients in the final analysis. There were 212 women in the unipolar group, 202 in the bipolar group, 191 in the clips group, 252 in the ring and 262 in the Pomeroy group. Of 815 women assigned to the control group, 503 were either lost to follow up or excluded and 312 completed the study protocol.

Demographic information is given in Table 1. The demographic characteristics were similar in the six studied groups. During the three-year follow up of each patient, there was one failure in the ring group, and one in the Pomeroy group. Although statistically not significant, in an unadjusted analysis, the incidence of pain requiring medication in all sterilized women during the first three follow up visits was 2.7%. After three years only 1.16% of subjects had significant pain. When menstrual pain was evaluated according to the sterilization method, a significant change was observed in unipolar group (p=0.001). Most (67.5%) of the post-sterilization menstrual pain in the unipolar groups lasted for a maximum of eighteen month (Fig 1).

In an unadjusted analysis, the majority of women did not report changes in any of the menstrual characteristics. Menstrual changes were seen in 13.8% of unipolar, 13.2% of Pomeroy, 12.3% of ring, 7.1% of bipolar, 4.2% of clips, and 5.0% of the control group that were not statistically significant. The change in the menstrual indices compared to the pre-sterilization status of each group and to the control group are shown in Table 2. Among the subjects, a larger group reported an increase in both the amount of bleeding and occurrence of inter-menstrual bleeding. In the adjusted model, there was a statistically significant increase in the amount of bleeding in the groups of unipolar

(p=0.0001), ring (p=0.001), and Pomeroy (p= 0.0001) as compared to the control group. Inter-menstrual bleeding was also increased by 7.5% in unipolar group (p=0.293), by 7.2% in ring (p=0.829) and by 6.9% in Pomeroy group (p=0.345). No menstrual changes were reported before six months an after two years after strelization.

Discussion

Concerning the demographic information including the socio-economic status among the six groups, all participants were of a low-income population. In the unadjusted analysis, when the sterilized groups were compared to the control group, slight but not statistically significant changes were noted in menstrual indices and menstrual pain. The results are similar to those of Peterson et al,[6] Bhiwandiwala et al,[8] who showed that the majority of women experienced no menstrual pattern change following sterilization. Kosande and Bonar [16] actually measured menstrual blood loss prior to the tubal sterilization up to 6-12 months afterwards, and found that the operation made no significant difference in menstrual blood loss. They also noted that menstrual abnormalities after tubal sterilization might be pri-
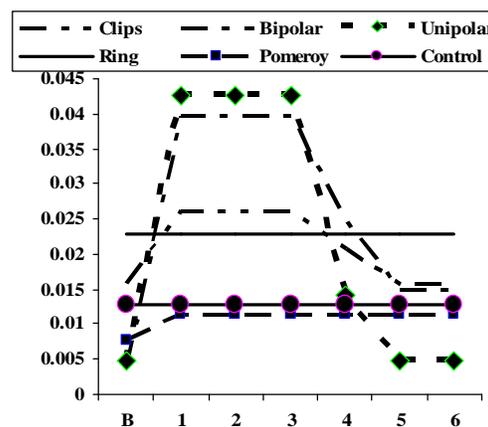

Figure 1: Percentage of the women who had pain requiring medications in the six follow up visits (B=befor operation,1,2,3= post operative follow up visits)

Table 2: Post-sterilization persistent changes in menstrual function of each group when compared to control.

Sterilization method	Number (%) change			
	No change	Increase	Decrease	P Value
Amount of bleeding				
Clips	173 (91.5%)	12 (6.3%)	4 (2.1%)	0.682
Bipolar	174 (86.1%)	18 (8.9%)	10 (5.0%)	0.758
Unipolar	141 (66.5%)	60 (28.3%)	11 (5.2%)	0.0001
Ring	186 (74.1%)	50 (19.9%)	15 (6.0%)	0.001
Pomeroy	182 (70.3%)	62 (23.9%)	15 (5.8%)	0.0001
Control	289 (92.9%)	16 (5.1%)	6 (1.9%)	-
Cycle length				
Clips	185 (96.9%)	4 (2.1%)	2 (1.0%)	0.354
Bipolar	199 (98.5%)	1 (0.5%)	2 (0.1%)	0.354
Unipolar	201 (94.5%)	4 (1.9%)	7 (3.3%)	0.354
Ring	237 (94.4%)	3 (1.2)	11 (4.4%)	0.354
Pomeroy	245 (93.5%)	5 (1.9%)	12 (4.6%)	0.354
Control	296 (95.2%)	5 (1.6%)	10 (3.2%)	-
Intermenstrual bleed				
Clips	186 (97.4%)	4 (2.1%)	1 (0.5%)	0.981
Bipolar	179 (88.6%)	13 (6.4%)	10 (5.0%)	0.982
Unipolar	188 (88.6%)	16 (7.5%)	8 (3.8%)	0.293
Ring	220 (87.6%)	18 (7.2%)	13 (5.2%)	0.829
Pomeroy	235 (89.7%)	18 (6.9%)	9 (3.4%)	0.345
Control	304 (97.7%)	6 (1.9%)	190.3%)	-
Duration of bleeding				
Clips	186 (97.4%)	3 (1.6%)	2 (1%)	0.828
Bipolar	199 (98.5%)	2 (1.0%)	1 (0.5%)	0.633
Unipolar	202 (94.3%)	5 (2.4%)	5 (2.4%)	0.593
Ring	238 (94.8%)	9 (3.6%)	4 (1.6%)	0.656
Pomeroy	246 (93.9%)	11 (4.2%)	5 (1.9%)	0.758
Control	293 (94.2%)	11 (3.5%)	7 (2.3%)	-

marily the result of discontinuation of oral contraceptives or intrauterine device rather than tubal sterilization per se. In the present study we did not include women who were using oral contraceptives or intrauterine device at the time of sterilization. Thus previous method of contraception was not considered to make any confounding effect.

When the menstrual pain was evaluated with regard to the sterilization method, significant difference was noted; women who had undergone the unipolar electrocoagulation method were most likely to report menstrual pain (p=0.0001). In a small group of these patients pain lasted for eighteen months and few patients continued to have this problem for 24 months or more. Although there is no explanation for the increased pain in unipolar group, this may be attributed to the higher tissue destruction and necrosis caused by this method. Destefano and co-workers[9] followed 2456 women for two years after tubal sterilization and reported an increased menstrual pain among women who had undergone unipolar electrocoagulation. Similarly, Rulin et al,[17] Neil et al,[18] reported an increase in the menstrual pain. However, other reports failed to show any increased pain [2,6] after tubal sterilization.

When the risk of menstrual changes was evaluated with regard to the method of sterilization, sig-

nificant changes were seen among women undergoing sterilization by Pomeroy, ring and unipolar method as compared with their own pre-operation status and the control group. Regarding the sterilization technique, it seems that Pomeroy, ring and unipolar methods cause more damage to the uterotubal and utero-ovarian communication. This may support the hypothesis that post-sterilization menstrual changes depend on the extent of peritubal and ovarian vascular damage. Most studies of post-sterilization menstrual changes have a follow up period of two years or less. Shain et al[19] described the findings of their prospective study, including follow up data for twelve months after sterilization. They concluded that the only pattern of association among adverse menstrual changes, occurred significantly more in the cauterization and to some extent the Pomeroy groups.

We found that almost all menstrual changes occurred between 6 and 24 months after sterilization. Thus it may be concluded that sterilization-related menstrual changes usually do not occur after two years of the sterilization procedure. DeStefano et al[9] in their long term follow up of sterilized women found an increased risk of menstrual abnormalities even after a long period of 49 to 87 months after sterilization. These late menstrual changes are difficult to explain, because it is not easy to postu-

late a physiologic mechanism that would take more than four years to develop and adversely affect menstrual cycles.

We included women in the age range of 25 to 40 years to avoid any age related abnormal menstruation. Thus, age-related menstrual abnormalities are not considered as a factor in our series.

Some women who had undergone tubal sterilization were reported significant ovarian hormonal imbalance as compared to normal controls.[5,14] However, laboratory studies comparing women before and after sterilization have shown no consistent abnormalities in ovarian function,[2,3,14,20] Another report showed that different methods of tubal sterilization may have different effects on the function of corpus luteum. Mahghoub et al[21] reported a significant difference in progesterone levels in the ring but not in the Pomeroy group. In a report by Donnez et al[22] Pomeroy and unipolar coagulation groups showed significantly lower mean mid-luteal progestrone level than the control and Hulka clips groups. The most acceptable explanation for these differences is that some sterilization methods destroy the utero-ovarian and uterotubal vascular communications to a higher extent. Tubal sterilization procedures might cause an increase in ovarian artery resistance [23] and also an acute increase in the utero-ovarian arterial loop pressure, which causes ovarian damage. El Minawi et al[24] reported abnormally high prevalence of uterovaginal and ovarian varicosities after Pomeroy technique.

Ovarian blood flow and hormonal profile were not evaluated in this study. However, we were able to show that most menstrual abnormalities were occurred after those sterilization methods that possibly damage utero-tubal and utero-ovarian vascular communication more frequently. Although a biological mechanism explaining such association has not yet been demonstrated, Bonnin et al,[25] Hoyer et al,[26] and Meidan etal [27] showed that prostaglandins produced and secreted by the endometrium have regulatory effects on corpus luteum and luteolysis. Stefanczyk-Krzymowska et al[28] and Verco et al[29,30] believe that the vascular pattern of uterine and ovarian arteries and their related veins allows counter current exchange of materials. The existence of ovarian vein-to-artery counter current exchange and complex vascular and perivascular arrangement of the uterus, ovary, and tube enable the local regulation of uterine, tubal and ovarian functions that may alter concentrations of bioactive substances (e.g., prostaglandins and ovarian steroids) so that target organs (i.e., endometrium and corpus luteum) are exposed to higher local levels of hormones than that normally circulates peripheral vessels.[31] Some sterilization methods might destroy the vascular communication along and immediately subjacent to the tube.[32,33] Thus the counter current exchange of biologically active factors may be disturbed either because these factors do not enter the venous drainage on the appropriate side of the blockage or because the arterial supply is unable to deliver these factors to their target organs at a greater level than general circulating levels.[34]

In conclusion, there is a strong association between tubal ligation and increased amount of bleeding. Sterilization methods that more possibly affect utero-ovarian and utero-tubal vascular communication are more likely to cause local hormonal imbalance and menstrual abnormalities. Although complete dissection of the tube is necessary for sterilizatin, a surgeon should try to preserve vascular communications between the uterus, tubes, and ovaries. Further studies works on human vascular communication of the tubes, ovaries and uterus is mandatory to evaluate the local concentrations of prostaglandins and other ovarian steroids after different methods of tubal sterilization.

Acknowledgments

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