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AN EPIDEMIOLOGIC STUDY OF RISK FACTORS ASSOCIATED WITH PREGNANCY FOLLOWING FEMALE STERILIZATION

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An epidemiologic study of risk factors associated with pregnancy following female sterilization

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Data on 14,700 female sterilization patients were collected by the International Fertility Research Program (IFRP) from 1972 to 1978 and analyzed to determine risk factors associated with the incidence of pregnancy following sterilization. With a case-control approach, it was found that younger patients (≤34 years old) and those who did not lactate after sterilization had a higher risk of becoming pregnant. Patients who were sterilized in the early phases of a service program had a higher risk of pregnancy than those sterilized later. In the laparoscopic series, the relative risk of pregnancy was four times greater in patients who had the prototype spring clip than in patients who had the Falope ring. The relative risk increased to 7.0 when patients who had the prototype spring clip were compared to those who had the Falope ring, electrocoagulation, or the Rocket clip. Patients sterilized by electrocoagulation had a low pregnancy risk, but the risk of an ectopic pregnancy was significantly higher than for those sterilized with mechanical devices. In the culdoscopic series, the tantalum clip had an unacceptable pregnancy risk. (AM. J. OBSTET. GYNECOL. 136:768, 1980.)

VOLUNTARY STERILIZATION has become the most desired method of controlling family size among the populations of both the developed and the developing worlds. It is estimated that 76 million sterilization procedures were performed between 1950 and 1977; a majority of these were requested by women.[1] Many women select sterilization because it is usually presented as a safe, effective, one-time procedure that is guaranteed to terminate fertility.

During the last ten years, investigators have tested and reported on the ease and safety of many innovative methods and techniques for female sterilization.[2-6] However, the literature includes very few adequate evaluations of the efficacy of these methods relative to the incidence of pregnancies following sterilization. The International Fertility Research Program (IFRP) is uniquely able to study these rare events through analysis of a large pool of international data recorded on standardized data-collection instruments. This paper presents an analysis of various female sterilization methods by routes of approach and tubal occlusion technique and identifies the possible risk factors associated with subsequent pregnancies.

Table I. Selected characteristics of study population (14,694 cases)

Mean age (yr.)	32.3
Mean parity	4.7
Time of sterilization:	
Post abortion (%)	12.3
Post partum (%)	18.6
Interval (%)	69.1
Method of sterilization:	
Laparoscopy (%)	66.8
Minilaparotomy (%)	27.1
Culdoscopy (%)	6.1

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Table II. Laparoscopic procedures

Technique	*Patients*	*Total failures*	*Corrected failures**	*Corrected rate/1,000*	*Corrected one-year life-table rate/1,000*	*SE*
Electrocoagulation	4,309	14	9	2.1	1.9	0.7
Falope ring	3,536	19	10	2.8	3.3	1.1
Prototype spring-loaded clip	1,514	66	41	27.1	27.1	4.5
Spring-loaded clip (Rocket)	457	3	3	6.6	5.9	4.3
Total	9,816	102	63	6.4	–	–

*Failures due to technical errors were excluded.

Table III. Minilaparotomy procedures

Technique	*Patients*	*Crude failures*	*Corrected failures**	*Corrected rate/1,000*	*Corrected one-year life-table rate/1,000*	*SE*
Pomeroy	2579	6	6	2.3	2.0	1.0
Falope ring	892	4	3	3.4	4.9	3.1
Fimbriectomy	517	1	1	1.9	0.0†	0.0
Total	3988	11	10	2.5	–	–

*Failures due to technical errors were excluded.
†One pregnancy occurred during the thirteenth month following sterilization.

Material and methods

From 1972 to the middle of 1978, the IFRP collected data on 20,000 female sterilization patients for whom 6 or more months of follow-up data were available. Factors studied included the patient's biologic and sociodemographic characteristics, as well as provider variables. Studies were included in the current analysis when data were available from the same center on 100 or more patients sterilized by the same approach. It was the intent to include only those centers with sufficient experience to make meaningful comparisons of the data. Patients were eliminated from analysis when they had concurrent major gynecologic surgery or systemic disease or when unusual or multiple occlusion techniques were used. The analysis also excluded techniques where data were available on fewer than 100 patients. In the remaining study population of 14,700 (Table I), 222 patients were pregnant at follow-up and 62 patients were determined to be in the luteal phase of the cycle and were excluded from the analysis. One hundred sixty pregnancies were conceived following sterilization and eight of these were ectopic.

To determine the factors associated with pregnancies that occur following sterilization, a matched case-control analysis was performed.[7] The 160 pregnant patients were compared with two groups of control subjects selected from the nonpregnant patient pool. The rigorous matching criteria used in this study provide assurance that the principal findings are not spurious.

To determine risk factors associated with patient characteristics, one control group was created by individually matching a pregnant patient with a nonpregnant patient by the following provider variables: center (identical), anesthesia (analgesia/local, regional, or general), surgical approach (minilaparotomy, laparoscopy, or culdoscopy), tubal occlusion technique (identical), and sterilization performed within 30 days.

The second control group was created to determine risk factors in the provider variables by individually matching a pregnant patient with a nonpregnant patient by center (identical) and the following characteristics: age (≤34 or 35+), parity (≤4 or 5+), timing of sterilization (interval, postabortion, or postpartum), pelvic infection, and presence or absence of previous abdominal surgery and lactation following sterilization.

For both groups, the first candidate encountered in the data pool by admission order who had matching criteria and a longer observation period than that of her counterpart case subject was selected. By a series of computer programs, 131 patient pairs were successfully matched by provider variables and 129 pairs, by patient characteristics.

Pair-wise analysis was used to calculate the relative risks (RRs)* for a number of variables that might have related to pregnancy following sterilization.

Clinical results

To evaluate the efficacy of the various occlusive techniques, the methods studied were categorized by

RR and its 90% two-sided confidence limits (CL) were calculated with Mettienen's method. When the CL does not include 1.0, the RR is statistically significant at $p < 0.10$.

Table IV. Culdoscopic procedures

Technique	*Patients*	*Crude failures*	*Corrected failures**	*Corrected rate/1,000*	*Corrected one-year life-table rate/1,000*	*SE*
Pomeroy	392	0	0	0.0	0.0	0.0
Tantalum clip	498	47	46	92.4	81.9	15.8
Total	890	47	46	51.7	–	–

*Failures due to technical errors were excluded.

Table V. Comparisons by age in 102 pairs* and lactation status in 58 pairs†

Members ≤34	*Members 35+*	*Case ≤34 and control 35+*	*Case 35+ and control ≤34*	*RR*	*90% Confidence limits*
45	17	25	15	1.7	0.98-2.85
Members—no lactation	*Members—lactation*	*Case—no lactation and control—lactation*	*Case—lactation and control—no lactation*	*RR*	*90% Confidence limits*
44	1	11	2	5.6	1.60-19.29

*Pairs due to technical errors were excluded.
†Pairs due to technical errors or having no information on lactation status were excluded.

Table VI. Comparison between case and control subjects by type of procedure

Procedure	*Case subjects*	*Control subjects*
Minilaparotomy	8	4
Laparoscopy	78	82
Culdoscopy	43	43
Total	129	129
	$p > 0.05$	

surgical approach. Tables II to IV summarize the total patients and pregnancy rates for the laparoscopy, minilaparotomy, and culdoscopy series. There were 39 failures due to technical (operator) errors in the laparoscopy series; five of these occurred with electrocoagulation, nine with the Falope ring, and 25 with the prototype spring clip. These errors were confirmed by a subsequent operative procedure.

In the minilaparotomy series, there was only one failure due to technical error and all the pregnancy rates were low. There was no significant difference between the techniques.

Culdoscopic procedures performed with the tantalum (Week) clip had a very high failure rate, which is consistent with findings of other investigators.[9, 10] The popularization of laparoscopy and minilaparotomy, as well as the infection and hemorrhage associated with vaginal procedures, has contributed to the reduced interest in the vaginal approach.

The prototype spring clip designed by Hulka and Clemens warrants further definition. The original prototype clip proved to have less than the specified pressure of 75 gm.[11] The next prototype fulfilled the inventor's specifications regarding spring tension and jaw gap prior to application and when retrieved after a sterilization failure. Recently a design modification has reduced the gap in the jaws from 0.005 to 0.001 inch to conform to the configuration of the Rocket clip.[12]

Case-control results

Of the patient pairs matched for provider variables, no significant differences between case and control subjects were discerned in patient characteristics with regard to surgical difficulties during the procedures, timing of the sterilization, contraceptive use prior to sterilization, incidence of previous abortions, pelvic surgery, parity, obesity, education, residence, and the time when intercourse was resumed. Surgical technical errors eliminated 29 patient pairs from this analysis. These 29 patient pairs had no significant differences in patient characteristics from the 102 patient pairs available for study. Two patient characteristics, age and lactation, showed significant differences (Table V). There were more pairs in which the study patient was younger than 35 years and the control subject was aged 35 or older.* The RR of sterilization failures for the younger patient is 1.7 times greater, which is of borderline statistical significance. There were significantly more pairs in which the study case did not lactate following sterilization while the control did lactate.† The RR for nonlactating women was over five times greater than that for lactating women. Unfortunately, lactation

*RR = 1.7; CL = 0.98 to 2.85.
†RR = 5.6; CL = 1.60 to 19.29.

Table VII. Comparisons between prototype spring clip and Falope ring in discordant laparoscopic pairs

Subgroups with both members	*Case—clip and control—ring*	*Case—ring and control—clip*	*RR*	*90% Confidence limits*
<35 years old	12	3	4.0	1.42-12.84
Postabortion or postpartum	10	3	3.3	1.18-9.24
No lactation	11	2	5.5	1.60-18.91
No surgical difficulties	9	2	4.5	1.32-15.29
No technical errors	9	3	3.0	1.05-8.57

Table VIII. Comparisons between prototype spring clip and other techniques* in discordant laparoscopic pairs

Subgroups with both members	*Case—clip and control—other techniques*	*Case—other techniques and control—clip*	*RR*	*90% Confidence limits*
<35 years old	18	3	6.0	1.50-23.96
Postabortion or postpartum	11	3	3.7	1.30-10.06
No lactation	18	2	9.0	2.37-34.18
No surgical difficulties	15	2	7.5	2.42-23.24
No technical errors	16	3	5.3	1.85-15.38

*Includes Falope ring, electrocoagulation, and Rocket clip.

status of these patients was only collected through the 6-month follow-up. The contraceptive efficacy of lactation is well known; when coupled with a sterilization procedure, one would anticipate minimal failures. Studies are needed to determine if lactation influences the long-term success rate of sterilization procedures.

There were 44 patient pairs who did not lactate and were classified by age. These patient pairs demonstrated the same increased risk related to younger age.

For the provider variables study group, 129 patient pairs were matched by patient characteristics. In addition, the following characteristics showed no statistically significant differences between the cases and controls: contraceptive use prior to sterilization, previous abortions, residence, and the time when intercourse was resumed.

Of the provider variables examined, the incidence of pregnancy was significantly associated with the tubal occlusion technique and the center experience. Neither the type of anesthesia nor the route of approach (Table VI) showed a statistically significant difference.

There were 78 laparoscopic patient pairs for whom four types of occlusion techniques were used: electrocoagulation with or without division, Falope ring, prototype spring clip, and Rocket clip. Patients in whom the prototype spring clip was used appear to have a higher pregnancy risk than patients sterilized by any of the other techniques.

Meaningful comparison was possible for the 54 pairs where either the prototype spring clip or the Falope ring was used. Thirteen of the 16 discordant pairs were those in which the clip was used for the case subject and the ring for the control subject. In the three remaining discordant pairs, the study patient had the ring and the control subject had the clip. The prototype spring clip had an RR four times greater than the Falope ring.* For the entire series, the RR of pregnancy was seven times as great following the use of the prototype spring clip compared to the other three techniques combined.†

The laparoscopic patient pairs were further evaluated by the following subgroups: age less than 35 years, postabortion or postpartum status, no lactation, no surgical difficulties, and no technical errors. Comparisons between the prototype spring clip and the Falope ring revealed an RR from 3.0 to 5.5 times greater for the clip (Table VII). For the three alternate techniques combined, there was a significantly higher number of discordant pairs where the case subject had the prototype spring clip but the control subject had one of the other techniques. The RR for the clip varied from a 3.7-fold to a nine-fold increase (Table VIII).

The relationship between center experience and the incidence of poststerilization pregnancies can be evaluated by intracenter comparisons according to the patient's admission order. Three centers had sufficient numbers of patient pairs for analysis in which both the case and control member had the same tubal occlusion technique. In each center, all the discordant pairs were those in which the case subject was operated on in the first 100 patient series while the control subject was operated on later. Patients admitted within the first 100 of a series have at least a threefold increased risk of pregnancy.‡

*RR = 4.3; CL = 1.53 to 12.35.
†RR = 7.0, CL = 2.29 to 21.40.
‡Lower CL of RR = 2.97.

Ectopic pregnancies

After pregnancies due to technical errors were excluded, six of the 119 pregnancies were tubal, a rate of 5.0 per 100 pregnancies. Comparisons between patients with tubal pregnancy and those with intrauterine pregnancy revealed no significant differences in age, parity, previous contraceptive method, pre-existing pelvic infection, incidence of surgical difficulties, or operative route. In the single ectopic pregnancy that followed culdoscopy, the tantalum clip had been used. There were 34 pregnancies following an interval laparoscopic sterilization and five of these were ectopic. Four of the ectopic pregnancies (80.0%) followed electrocoagulation, and one occurred after the prototype spring clip. Of the 29 intrauterine pregnancies, only 10.3% followed electrocoagulation. This highly significant statistical difference* indicates the increased risks of a tubal pregnancy when electrocoagulation is used compared to mechanical devices. Because of the life-threatening aspect of ectopic pregnancy, providers should select those techniques which will reduce the chances of an ectopic pregnancy should a sterilization failure occur.

Comment

Controversies exist about whether a pregnancy is more likely to occur following a sterilization performed concurrently with an induced abortion or one performed during the puerperium.[13, 14] No association could be found in this study. This may be due to the exclusion of more postabortion and postpartum patients in the case group because of the rigorous matching of provider variables and the relatively short follow-up period in this study.

No statistically significant differences in pregnancy risks among the routes of operative approach could be detected. Two risk factors in patient characteristics, age and lactation status, and two risk factors in provider variables, tubal occlusion techniques and center experience, were independently associated with incidences of poststerilization pregnancies.

Patients who were sterilized early in a program had a significantly higher pregnancy risk. Paired comparisons were performed with both patient characteristics matched and provider variables controlled. In most centers more than one operator was involved. The incidence of major complications was also related to operator experience.[15]

Laparoscopic electrocoagulation has a reduced risk of pregnancy when compared to the mechanical occlusive devices but has a risk of an ectopic pregnancy at least nine times higher than that of other techniques. Other studies have suggested a similar association.[16-18] The possibility of burns with electrocoagulation and the difficulty in achieving sterilization reversal pose additional problems for its use.[19, 20] For these reasons, a mechanical occlusive device is most desirable. The lower pregnancy risk associated with the Falope ring compared to the prototype spring clip appears to be a distinct advantage. The efficacy of the redesigned spring clip delivered by second puncture and other mechanical devices remains to be evaluated.

Summary

Data on 14,700 female sterilization patients for whom follow-up was available were studied for method and tubal occlusion technique to determine the relative risks of pregnancy. The total failure rate was 10.9/1,000 procedures, and the rate corrected for technical errors was 8.2.

The younger the woman at the time of sterilization, the greater the risk of future pregnancy. Women who lactate following sterilization have an increased protection during that period, but no data are available about long-term effects on the risk of a future pregnancy.

Women who are sterilized in the early phases of a service program have a higher risk of failure than those sterilized later.

Culdoscopic procedures, although attractive to certain patients and providers, have an increased risk of major complications and technical failures that make them undesirable.[21] The tantalum clip should be abandoned because of the high pregnancy risk. In the minilaparotomy series, all three techniques studied appear to have low pregnancy risks. In the laparoscopic group, the prototype spring clip, when corrected for technical error, still had a one-year life-table rate of 27.1 pregnancies per 1,000 procedures, which was significantly greater than that of other techniques. The lowest risk of pregnancy occurred in patients with electrocoagulation (1.9/1,000), but these patients had a significantly higher risk of tubal pregnancy. The Falope ring had a failure rate of 3.3/1,000 procedures. For the laparoscopic series, this is the lowest failure rate for mechanical occlusive devices with a single-puncture technique.

No method of female sterilization is foolproof. Fecundability is not totally nullified by a supposedly permanent contraceptive method. Providers must be knowledgeable about the complications and efficacy of the method they choose to use. Prior to sterilization, patients must be informed of the relative risks of the procedure.

*P = 0.004 by Fisher's exact test; RR = 34.7; CL = 8.96 to 134.38.

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