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TECHNICAL FAILURES IN TUBAL RING STERILIZATION: INCIDENCE, PERCEIVED REASONS, OUTCOME, AND RISK FACTORS

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Technical failures in tubal ring sterilization: Incidence, perceived reasons, outcome, and risk factors

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Six centers participated in comparative studies of female sterilization conducted by the International Fertility Research Program. The incidence of technical failures (or failed attempts) was compared between patients sterilized with the tubal ring and those sterilized with other tubal occlusion techniques. The tubal ring was associated with a higher failure rate than electrocoagulation, the Rocket clip, or the modified Pomeroy technique. Of 1,035 tubal ring sterilizations, there were 38 technical failures. Reasons given by the operators for the failures, by frequency of occurrence, were surgical complications, conditions preexisting in the patients, and problems with the instruments. Most of these failures were remedied by changing to other techniques. In two patients, the procedure was completed by changing the approach from laparoscopy to laparotomy. In five others, sterilization was not completed. Case-control analysis was performed and three risk factors were delineated: obesity, prior use of an intrauterine contraceptive device and previous abdominal operations. (AM. J. OBSTET. GYNECOL. 138:307, 1980.)

INCREASED acceptance of female sterilization for contraceptive purposes during the last decade[1] can be partly attributed to the acceptance of the laparoscope, the widespread use of minilaparotomy, and the development of new tubal occlusion techniques. The safety and efficacy of these new techniques have been examined extensively, but the problem of technical failures, frequently referred to as failed attempts, has often been ignored, in spite of its important bearing on satisfaction of the patient and efficiency of the program. Furthermore, exclusion of patients with technical failures from these analyses has resulted in an underestimated rate of complications and a distorted picture of the benefit/risk ratio of a sterilization technique.

Use of the tubal ring for sterilization is safer than electrocoagulation,[1, 2] and is more effective in preventing poststerilization pregnancies than the other mechanical devices, namely, the prototype spring-loaded clip and the tantalum clip.[3, 4] This study compares the incidence of technical failures in patients sterilized with the tubal ring with that of failures in patients sterilized by other techniques. It also examines the natural history of the ring failures with regard to the operators' perceived reasons for failure, management, outcome, and risk factors.

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Table I. Incidences of technical failures in tubal ring and other tubal occlusion techniques, by center and surgical approach

Center	Surgical approach	Comparative tubal occlusion techniques	No. of patients	Technical failures	
				No.	Rate (%)
A	Laparoscopy	Tubal ring	131	10	7.6
		Electrocoagulation ($p < 0.01$ by Fisher's exact test)	126	0	0.0
B	Laparoscopy	Tubal ring	150	2	1.3
		Electrocoagulation (NS*)	150	0	0.0
C†	Laparoscopy	Tubal ring	300	2	0.7
		Prototype spring-loaded clip (NS*)	300	3	1.0
D‡	Laparoscopy	Tubal ring	96	9	9.4
		Rocket clip ($p < 0.01$ by Fisher's exact test)	96	0	0.0
E	Culdoscopy	Tubal ring	109	3	2.8
		Tantalum clip (NS*)	113	1	0.9
F	Minilaparotomy	Tubal ring	249	12	4.8
		Modified Pomeroy ($p < 0.01$ by χ^2 test)	250	4	1.6

*NS = Not significant.
†In this center, postabortion and postpartum patients were studied.
‡In this center, double-puncture laparoscopy was the approach used.

Table II. Reported reasons for technical failures in patients undergoing tubal ring sterilization

Reason	No. of patients
Surgical complications	
Transected tube(s)*	15
Mesosalpingian bleeding	1
Severe pain	1
Subtotal	17 (44.7%)
Preexisting conditions	
Pelvic adhesions	9
Thick tube or hydrosalpinx	4
Subtotal	13 (34.2%)
Instrument problems	
Trocar too short to reach the peritoneal cavity	4
Failure of ring applicator	2
Unspecified	2
Subtotal	8 (21.1%)
Total	38 (100%)

*Three with hematoma.

Table III. Outcome in patients undergoing tubal ring sterilization, with and without technical failures

	With technical failures (N = 38)	Without technical failures (N = 997)
% With surgical difficulties	73.7	10.2
% With surgical complications	50.0	1.7
Length of operation (in minutes)	15.3 ± 1.10*	8.4 ± 0.14*
% Hospitalized for 1 or more days after sterilization procedure	39.5	28.3
% With early complications	9.1	20.0

*Mean time ± standard error.

Material and methods

In June, 1975, the International Fertility Research Program (IFRP) started to coordinate comparative female sterilization studies among its network of contributing physicians. To qualify for participation, the physicians must have demonstrated similar competency in both tubal occlusion techniques to be compared and must have agreed to comply with the following protocol requirements: (a) patients voluntarily requesting female sterilization for contraceptive purposes were to be randomly allocated to one of the two techniques; (b) the patients were to receive follow-up care, with their complications and complaints recorded by a physician who was unaware of the technique used; (c) all the collateral procedures (e.g., type of anesthesia, preoperative medication, and surgical approach) were to be the same for the two groups of patients; (d) all contributing physicians were to use the same standardized form for recording data and the same definitions of terms. Although there was to be only one operator in each center, this requirement was not strictly enforced because of practical difficulties.

Previous abdominal and/or pelvic operations and moderate obesity were not considered to be contraindications for sterilization.

By January, 1978, six centers had completed a comparative study in which the tubal ring was one of the

Table IV. Risk factors associated with technical failures by reported reasons in patients undergoing tubal ring sterilization*

	Reasons for technical failure							
	Surgical complications		*Preexisting conditions*		*Instrument problems*		*Total*	
Risk factor	*Cases (N = 15)*	*Controls (N = 30)*	*Cases (N = 13)*	*Controls (N = 26)*	*Cases (N = 8)*	*Controls (N = 16)*	*Cases (N = 36)*	*Controls (N = 72)*
Obesity†								
No. of patients	0	1	4	2	4	0	8	3
% of patients	0.0	3.3	30.8	7.7	50.0	0.0	22.2	4.[illegible]
χ^2 value	0.50		2.08		8.00		5.45	
p value	NS‡		NS‡		<0.01		<0.05	
Odds ratios	–		–		∞		7.50	
Prior IUD use								
No. of patients	7	6	5	2	3	2	15	10
% of patients	46.7	20.0	38.5	7.7	37.5	12.5	41.7	13.9
χ^2 value	4.57		5.33		2.00		11.76	
p value	<0.05		<0.05		NS‡		<0.01	
Odds ratios	5.00		9.00		–		6.00	
Previous abdominal operations								
No. of patients	2	3	5	1	0	0	7	4
% of patients	13.3	10.0	38.5	3.8	0.0	0.0	19.4	5.6
χ^2 value	0.10		6.75		0.00		4.55	
p value	NS‡		<0.01		NS‡		<0.05	
Odds ratio	–		10.00		–		3.50	

*χ^2 value and odds ratios were calculated by matched triplet analysis.[5] This table, however, is presented in the usual manner for simplicity and clarity.

†Obesity = 120% or more than the desirable weight.

‡NS = Not significant.

two techniques used. Four centers were in Asia, and one each was in the Middle East and Europe. In five centers, only interval patients whose last pregnancies had terminated at least 42 days prior to sterilization were studied. In the other center, Center C, postabortion and postpartum patients were studied. The surgical approaches were single-puncture laparoscopy (three centers), double-puncture laparoscopy (one center), culdoscopy (one center), and minilaparotomy (one center). Tubal occlusion techniques compared with the tubal ring were electrocoagulation, the prototype spring-loaded clip, the Rocket clip, the tantalum clip, and the modified Pomeroy technique (Table I). The mean age of the patients was 32.5 years, and their mean parity was 4.7.

A technical failure was defined as a sterilization procedure that was uncompleted or that was completed by changing to a tubal occlusion technique or surgical approach other than the one originally planned.

Patients sterilized with the tubal ring and patients sterilized by other techniques were compared within each center with respect to the incidences of technical failures. Either the chi-square test or Fisher's exact test was used for statistical evaluation; differences with a p value of <0.[illegible] were considered to be statistically significant. Analysis was then confined to tubal ring patients only. Technical failures were examined for perceived reasons and management of the failures by the operators. Patients with and those without technical failure were then compared by outcome. Finally, the risk factors associated with tubal ring failures were delineated by a case-control analysis in which a case (patient with technical failure) was individually matched with two controls (patients without technical failure) by age (within 5 years), center, operator, and date of operation (one control was selected immediately before and one immediately after the operation date of each case). Since in each center the same collateral procedures were used throughout, they are automatically matched. Chi-square tests and odds ratios for matched triplets[5] were used to evaluate the statistical significance as well as the strength of association.

Results

The incidence of technical failures in patients sterilized by the tubal ring was significantly higher than that in patients sterilized with electrocoagulation (Center A), Rocket clip (Center D), or the modified Pomeroy technique (Center F) (Table I). The tubal ring patients also had a higher incidence of technical failures than electrocoagulation patients in Center B and tantalum clip patients in Center E, but the number of failures in

these two centers was too small for meaningful comparison. Only the prototype spring-loaded clip showed an incidence of failure similar to that of the tubal ring (Center C).

The reasons reported by the operators for the technical failure in 38 tubal ring patients were (a) surgical complications in 17 cases, (b) preexisting conditions in 13 cases, and (c) instrument deficiency in eight cases (Table II).

In all but seven failures, sterilization was completed by changing the technique but still using the original approach. In most cases, the alternate technique was the one being used for comparison in that center, apparently because of the operator's experience and the convenience of equipment. The other seven failures were more serious: two laparoscopic procedures were completed by subsequent laparotomy (one failure was due to transected tubes, the other to pelvic adhesions), and in five cases (two via laparoscopy and three via culdoscopy) the procedure was abandoned without resort to other techniques.

The outcome in the 38 tubal ring patients with technical failure was assessed by comparison with the outcome in the remaining 997 tubal ring patients without failure. These two groups had a generally similar distribution by surgical approach. It is not surprising that the failure patients had (a) a much higher rate of surgical complications and surgical difficulties since, in many cases, these were the conditions that led to the change in technique, (b) a longer operation time as a result of the change, and (c) a longer hospitalization after the sterilization procedure, which may have been, in part, a result of the more frequent use of general anesthesia in the failure patients (44.7%) than in the patients without failure (18.4%). What is surprising is the lower early complication rate reported at the 7- to 21-day follow-up visit by the failure patients (9.1%) than by the nonfailure patients (20.0%) (Table III).

Thirty-six tubal ring patients with technical failures were each successfully matched with two controls; operators could not be matched for the other two patients. The following risk factors were delineated in association with the ring failures, and their respective odds ratios were calculated: obesity* (7.50), prior use of an intrauterine contraceptive device (IUD) (6.00), and history of abdominal operation (3.50) (Table IV).

Besides age, which was matched at the outset, the mean parity and the husbands' mean level of education were similar between cases and controls. Reported incidences of induced abortions were low in both groups. Prevalence of pelvic infection* was higher in the cases, but the difference was at borderline significance ($0.05 < p < 0.10$; odds ratio = 2.67). However, the proportion of women who previously used oral contraceptives was significantly lower in cases than in controls ($p < 0.05$, odds ratio = 0.46).

When the triplets were broken down by the reported reasons for failure of the case member, failures due to complications during the procedure were significantly associated with prior use of an IUD, failures due to preexisting conditions were associated with prior use of an IUD, as well as a history of abdominal operation; and failures due to instrument problems were associated with obesity (Table IV).

Comment

Pooling data on tubal ring patients from the six comparative studies gives a technical failure rate of 3.7 per 100 procedures, which is identical to the surgical complication rate. Thus, ignoring the incidence of technical failures when evaluating a sterilization technique is not justified.

Use of the tubal ring for sterilization is associated with a statistically higher technical failure rate than use of electrocoagulation, the Rocket clip, or the modified Pomeroy technique. This finding cannot be attributed to differences in characteristics of the patients, since random allocation eliminates this potential bias. However, since each of these results came from a single center, similar comparative studies in other centers are needed to ensure that these findings were not a result of a center effect.†

The actual reason for the technical failures may not be so clear-cut as reported, since most failures probably were caused by an interplay among the host factors, the operator's skill, and the instrument used. Tubal transections, for example, may have been due to a combination of adhesions, lack of operator experience, and difficulty with the instrument. However, analysis of risk factors by a breakdown of the technical failures according to reported reasons yielded results with biologic plausibility, and it appears that the operators' report of the primary reason for technical failure carries considerable validity.

*Obesity was defined as 120% or more of the desirable weight for different heights, with use of the Metropolitan Life Insurance Company's actuarial tables for women.[6]

*Pelvic infection was defined as any infection of the uterus, adnexa, or other pelvic organs. This definition is admittedly vague, and there may be some variations in diagnostic criteria used among the study centers.

†For instance, in Center A, there was concern that training in the tubal ring technique was not adequate.

Technical failures can also be due to the surgical approach.* However, the majority of the technical failures in the ring patients can be attributed to the ring technology itself. Close to half of these failures were due to tubal tears, a common complication due to the necessary mobilization of the tube for application of the ring.[7]

In spite of the difficulties encountered during the operation, fewer tubal ring patients with technical failures than nonfailure patients reported early complications. There are at least three possible explanations for this interesting finding. (a) when surgical conditions indicate the need for a change in operative technique, it is to the patient's benefit to change to another procedure; (b) patients who had a change in operative technique received more attention and perhaps better care; or (c) the techniques that were used to complete the procedure are associated with a lower early complication rate.

Tubal ring patients with technical failures had a lower 6-month follow-up rate (47.4%) than those with no failures (80.6%). No poststerilization pregnancies were reported by the former, whereas five pregnancies were reported by the latter group.

One risk factor, obesity, was the reason for four of the eight failures due to instrument problems—the trocar was not long enough to reach the peritoneal cavity.

The second risk factor, prior use of an IUD, was associated with technical failures that were reportedly due to either surgical complications or patients' preexisting conditions. Previous studies have suggested that use of an IUD is one of the etiologic factors in pelvic inflammatory disease.[8-13] In this study, 38.7% of the users of an IUD and 25.9% of the nonusers had pelvic infection, a statistically nonsignificant difference. It is possible that in some cases the prior use of an IUD could have caused tubal changes in the absence of clinically overt pelvic infection and may have contributed to these technical failures. Discretion should be employed in regard to tubal ring sterilization in a patient who has used an IUD. Prior use of oral contraceptives was significantly less frequent among cases than among controls, but the strength of its negative association with ring failures is much weaker than that of the positive association of IUD use. Whether the use of oral contraceptives, as some studies have suggested,[14, 15] may exert some protective effect against pelvic infection, and, hence, technical failures in tubal ring sterilization, needs to be clarified.

The third risk factor, previous abdominal operations, is associated with technical failures claimed to be due to conditions preexisting in the patients. Eleven patients included in the case-control analysis had previously undergone abdominal operations (nine had had an appendectomy, one had had a cesarean section and an appendectomy, and one had had an abdominal bladder operation); seven were failure cases and only four were controls (the expected number of controls is 1.4, under the null hypothesis). The outcome of the seven failure cases was more serious: in only three patients was the sterilization completed by changing the technique, two required laparotomy for completion of the procedure, and sterilization could not be completed in two. This finding suggests that caution must be used when patients with previous abdominal operations undergo tubal ring sterilization procedures, especially those done via laparoscopy or culdoscopy.

Results from any case-control study should be reviewed carefully for possible biases. Our data were from prospectively conducted clinical trials, and information on all possible risk factors was obtained before sterilization. Technical failure, the dependent variable, is a clear-cut surgical event, which could categorize the cases and the controls with little ambiguity. Careful matching has further eliminated most of the important confounding variables, including operators and their experience.[16, 17] The weakness of this study is the lack of a wider range of detailed information to confirm the possible causal role of the risk factors identified. The small number of triplets, as well as the heterogeneity of the technical failures with regard to their reported reasons, prevented us from attempting a multivariate analysis. However, the fact that only six of the 36 failure cases simultaneously possessed two of the three identified risk factors, and that the odds ratio increased to 12.0 for these patients suggests that the effects of these risk factors on ring failures are generally independent and probably additive.

Confirmation of whether the findings from this case-control analysis of tubal ring sterilization are applicable to other tubal occlusion techniques awaits the results from similar studies on other techniques. However, it would not be surprising to find similar risk factors delineated, possibly with different strengths of associations because of the particular characteristics of each of these techniques.

We would like to thank Dr. Lawrence L. Kupper for reviewing the draft of this paper.

*For instance, at Center E, all three failures, in which the sterilization procedures were not completed, were sterilizations attempted via culdoscopy, thus illustrating the reduced maneuverability in that approach.

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