Sutureless re-anastomosis by laparoscopy versus microsurgical re-anastomosis by laparotomy for sterilization reversal: a matched cohort study*

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BACKGROUND: Sutureless re-anastomosis per laparoscopy is an alternative for microsurgical re-anastomosis by laparotomy in the treatment of sterilized women with renewed child wish. Our aim was to compare pregnancy rates after both surgical techniques. METHODS: We performed a retrospective cohort study in which consecutive women who underwent sutureless re-anastomosis per laparoscopy were compared to women who underwent microsurgical re-anastomosis by laparotomy. Both procedures were performed in neighbouring hospitals in Northern-Brabant, The Netherlands, and women were matched for age. The primary outcome was time to ongoing pregnancy. RESULTS: Overall, we included 41 women who had sutureless re-anastomosis by laparoscopy, and 41 age-matched women who underwent microsurgical re-anastomosis by laparotomy. The number of women who conceived was 20 (15 ongoing pregnancies) in the sutureless laparoscopic group versus 26 (24 ongoing pregnancies) in the laparotomic group, a difference due to a longer follow-up period in the laparotomic group. Time to ongoing pregnancy was comparable in both groups (P = 0.46), with 3 year cumulative ongoing pregnancy rates of 45 and 52% respectively. After adjustment for other prognostic factors, the fecundity rate ratio was 0.97 (95% CI 0.26–3.6), indicating a similar performance of the two techniques. CONCLUSION: The simplified stitchless laparoscopic procedure for reversal of tubal sterilization with the use of a tubal splint, clip fixation of the muscularis and fibrin glue resulted in a promising pregnancy rate, which was similar to the pregnancy rate obtained with the microsurgical re-anastomosis per laparotomy.

Key words: laparoscopy/re-anastomosis/sterilization/sutureless

Introduction

It is estimated that 2–13% of women develop post-sterilization regret, leading in 1–3% to an operative reversal procedure (Liskin et al., 1985). Among reasons for the reversal request, a change in partnership is the most frequent one. Younger age is a risk factor for the occurrence of regret. Microsurgical reconstruction of the tubes at laparotomy has been for decades the standard procedure of sterilization reversal. The development of high quality endoscopic magnifying cameras and delicate instruments has paved the way to a laparoscopic approach. Laparoscopic tubal reanastomosis yields a high success rate in skilled hands (Yoon et al., 1999; Koh and Jannick, 1999; Bissonnette et al., 1999; Cha et al., 2001).

Thus far, laparoscopists have applied microsurgical principles from laparotomy to laparoscopy by replicating the microsurgical suturing technique. We focused on a simplification of the laparoscopic technique, using a tubal splint, microclip fixation and biological glue. To assess the effectiveness of the sutureless reanastomosis by laparoscopy, we performed a matched cohort study, in which we compared fertility outcome in women who underwent the new approach to fertility outcome in a cohort of women who were treated with microsurgical suturing per laparotomy.

Materials and methods

We performed a retrospective cohort study, in which we matched women with a request for sterilization reversal who were treated with sutureless reanastomosis per laparoscopy (index group) to women with a similar request who were treated by microsurgical reanastomosis by laparotomy (control group). The sutureless reanastomosis...
per laparoscopy has been developed in the Máxima Medical Centre, Veldhoven, The Netherlands and has been used since 1997. To compare the effectiveness of this technique to a more traditional approach, we matched consecutive women who were treated by sutureless reanastomosis per laparoscopy to women who were treated in the TweeStedenziekenhuis, Tilburg, The Netherlands with microsurgical reanastomosis by laparotomy. Both the Máxima Medical Centre and the TweeStedenziekenhuis are teaching hospitals in the South of the Netherlands. Women were matched for age on a 1:1 ratio. No laparotomic re-anastomosis procedure was done in cases where women had an estimated remaining tubal length of < 6 cm after re-anastomosis, judged by prior laparoscopy for selection. Tubal length was not a selection parameter in the laparoscopic re-anastomosis group.

In the laparoscopic approach, an umbilical port, two lateral ports and one 5 mm midline port were created, and warm CO₂ was insufflated. Vasocostriction was obtained by injecting an epinephrine–NaCl 0.9% solution into the mesosalpinx with a small diameter needle. The tubal serosa was cut using Koh microscissors and the muscularis exposed. The tube was transected perpendicularly at 1 cm from the obstruction. The quality of the tubal lumen was assessed visually. We obtained haemostasis with the use of fine bipolar forceps (Ethicon Endo-Surgery, Inc.*, USA) and rinsing using sorbitol 5% if necessary. Subsequently, we removed the occluded part. Via the vaginal route we inserted a guiding catheter (Modified 5.5Fr cornual introducing catheter; Cook®, Australia) to the uterine tubal ostium. We tested the patency of the proximal tubal part by flushing a methylene blue saline solution through the guiding catheter. As a vascular occlusion, we used self-designed steering forceps embracing the distal tube to facilitate the passage of the roadrunner splint through the distal part beyond the fimbrial part. The distal part over the splint was aligned to the proximal anastomosis site. We obtained fixation of the seromuscularis at 3 and 9 o’clock using microclips (3 mm), a technique that was not used in the initial 17 procedures. In addition we applied fibrin glue (Tissucol®, Baxter, The Netherlands) on the anastomosis surface for fixation using a Duplocath 35 instillator. The roadrunner splints were taped outside the vulva to the vesical balloon catheter and removed 4 h after the end of the procedure.

In the microsurgical approach, a Pfannenstiel incision was performed in order to obtain access to the abdominal cavity (Boeckx et al., 1981). A microsurgical technique was applied including magnification, intermittent irrigation and fineatraumatic instrumentation. The proximal and distal occluded segments were excised until healthy tissue was identified, and a split was inserted to both the uterine cavity as well as to the fimbriae (Winston, 1980); with the help of an operating microscope, microsutting began by first approximating the tube at the 6 o’clock position with a 6–0 prolene suture. Additionally, three sutures using 9–0 prolene for the first layer of muscularis including the serosa were applied. For the second layer serosa and muscularis, 6–0 prolene sutures were applied. Finally, patency was confirmed by retrograde dye injection. The splints were removed 24 h after the procedure with a Novak curette (Appgar and Newkick, 1997). For each woman who was treated laparoscopically in the Máxima Medical Centre, we selected one woman who was treated in the TweeStedenziekenhuis. The women had to have a similar age ± 2 years. All women had a male partner with a total motile sperm count of ≥ 5 × 10⁹. For each woman we recorded the obstetric history, previous pelvic or abdominal surgery, previous subfertility, as well as the body mass index. We also recorded the time since sterilization, type of sterilization (clips, silastic rings or coagulation), and whether sterilization had been performed by laparoscopy or by laparotomy.

With respect to the re-anastomosis, we recorded whether re-anastomosis was performed one-sided or two-sided, the duration of the procedure and the duration of hospital stay. Subsequently, we recorded fertility outcome, i.e. whether and when an ongoing pregnancy occurred. An ongoing pregnancy was defined as a viable pregnancy at a gestational age of ≥12 weeks. Furthermore, we registered the occurrence of miscarriage and ectopic pregnancy. In the case of a woman not conceiving, we registered the last date at which it was certain that the woman had not conceived, or the date at which a couple started with assisted reproductive technology.

Analysis
Baseline characteristics of patients in both treatment groups were compared using Student’s t-test or χ²-test. For both treatments, Kaplan–Meier curves were constructed, estimating the time to spontaneous ongoing pregnancy (Altman, 1991). Time to pregnancy was censored on the last day of follow-up, or when a patient started treatment with assisted reproductive technology. The Kaplan–Meier curves were tested for statistically significant differences using the log-rank test (Altman, 1991).

The effect of the laparoscopic sutureless approach compared to the microsurgical approach per laparotomy was expressed as a fecundity rate ratio (FRR) with a 95% confidence interval (CI), calculated through Cox proportional hazard regression analysis (Cox, 1972). A FRR expresses the probability of ongoing pregnancy per time unit for patients treated with the laparoscopic sutureless approach, relative to the probability in those treated with the conservative technique. The treatment effect was considered to be statistically significant if it was not included in the 95% CI. A Cox proportional hazard model only estimates a FRR correctly if this FRR is constant over time. Proportionality was tested visually from the Kaplan–Meier curves. To adjust the FRR of conservative surgery for other potential prognostic factors mentioned above, multivariable analysis was performed. The latter is especially important since potential prognostic factors for fertility also affect the choice between conservative and radical surgery. Differences in prognostic factors between patients undergoing radical surgery and patients undergoing conservative surgery can be adjusted in a multivariable analysis.

In a second analysis, we compared time to any type of conception (i.e. ongoing pregnancy, ectopic pregnancy or non-viable intraterine pregnancy) in each of the two groups. Again, the Kaplan–Meier curves were compared using the log-rank test, and univariable and multivariable Cox regression analysis were used to calculate FRR.

Results
We identified 44 women who had a laparoscopic tubal sterilization reversal operation in the Máxima Medical Centre between 1997 and December 2002. Of these women, 41 could be matched to women who were treated by laparotomy in the TweeSteden hospital, and who could be matched. In the laparoscopic group, 50% of the procedures were performed after January 1, 2001, versus 23% in the laparotomic group. The baseline characteristics of the two groups are shown in Table I. The two groups were comparable with respect to most of the baseline characteristics. However, the method of sterilization differed significantly between the two groups: in the laparoscopic group, sterilization had been performed by clips or a silastic ring in >90% of the procedures, versus 73% in the laparotomic group.
The re-anastomosis was one-sided in three of the patients in the laparoscopic group and in seven of the patients in the laparotomic group. The duration of the procedure was significantly longer in the laparoscopy group than after laparotomy (156 versus 72 min, \(P<0.01\)), but hospital was significantly shorter (1.2 versus 3.7 days, \(P<0.01\)). None of the women undergoing laparoscopic surgery had a conversion to laparotomy.

In the laparoscopic group, 20 women conceived. There were 15 women with an ongoing pregnancy, four women with a spontaneous abortion and one woman with an ectopic pregnancy. In the laparotomic group, 26 women conceived: 24 had an ongoing pregnancy, whereas there was one miscarriage and one ectopic pregnancy. This difference is due to the longer follow-up time in the laparotomic group (2.2 versus 2.8 years).

Among the 21 women who did not conceive in the laparoscopy group, seven had additional tubal testing. Of the three patients undergoing hysterosalpingography (HSG), two had patent tubes. The one patient with occluded tubes at HSG showed bilateral patency at subsequent laparoscopy. Four patients had laparoscopy, two demonstrating bilateral patency and two demonstrating one-sided patency.

Figure 1 shows the Kaplan–Meier curves demonstrating time to ongoing pregnancy in the two groups. The 3 year cumulative rate of ongoing pregnancy was 45% after the laparoscopic procedure and 52% after the microsurgical procedure (FRR 0.78, 95% CI 0.41–1.5; \(P=0.46\)). After adjustment for other factors, the FRR changed to 0.97 (95% CI 0.26–3.6; \(P=0.96\)), indicating a similar performance of the two techniques.

The 3 year cumulative conception rate was 55% in both groups (FRR 0.94, 95% CI 0.52–1.7; \(P=0.84\)). After adjustment for other factors, the FRR changed to 1.3 (95% CI 0.36–4.5; \(P=0.71\)), indicating a similar performance of the two techniques.

Table I. Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Sutureless approach by laparoscopy (n = 41)</th>
<th>Microsurgical approach by laparotomy (n = 41)</th>
<th>(P^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>34.9 (4.0)</td>
<td>34.5 (3.5)</td>
<td>0.62b</td>
</tr>
<tr>
<td>Nulligravida</td>
<td>3 (7)</td>
<td>2 (5)</td>
<td>0.79</td>
</tr>
<tr>
<td>Previous pelvic infection</td>
<td>2 (5)</td>
<td>2 (5)</td>
<td>1.0</td>
</tr>
<tr>
<td>Previous pelvic surgery</td>
<td>8 (20)</td>
<td>4 (10)</td>
<td>0.21</td>
</tr>
<tr>
<td>Previous abdominal surgery</td>
<td>16 (40)</td>
<td>8 (20)</td>
<td>0.05</td>
</tr>
<tr>
<td>Smoking</td>
<td>10 (24)</td>
<td>17 (42)</td>
<td>0.10</td>
</tr>
<tr>
<td>Body mass index, mean (SD)</td>
<td>24.2 (4.3)</td>
<td>24.4 (3.9)</td>
<td>0.89</td>
</tr>
<tr>
<td>Previous sterilization by laparotomy</td>
<td>2 (5)</td>
<td>2 (5)</td>
<td>1.0</td>
</tr>
<tr>
<td>Duration of the procedure (min)</td>
<td>212</td>
<td>73</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duration of hospital stay (days) (range)</td>
<td>2.2 (1–4)</td>
<td>4.7 (4–6)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Values in parentheses are percentages unless otherwise stated.

\(^a\)All \(P\)-values calculated with the \(\chi^2\)-test, except

\(^b\)calculated with the Student’s \(t\)-test.

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Figure 1. Kaplan–Meier curves demonstrating the proportion of women with ongoing pregnancies after both treatments.

**Discussion**

In this study, we found a similar time to ongoing pregnancy after sutureless laparoscopic or microsurgical laparotomic tubal sterilization reversal: the simplified stitchless laparoscopic procedure with the use of a tubal splint, clip fixation of the muscularis and fibrin glue resulted in a promising pregnancy rate.

Laparoscopic tubal reconstruction after sterilization without microsuturing is technically feasible and might prove to be a successful alternative to laparoscopic microsuturing. A key factor to success of the procedure seems to be a meticulous approximation of the lumen of both anastomosis sites. This can be achieved by multiple microsuturing. If no microsutures are applied, the use of a splint will be mandatory to obtain a precise approximation. The anastomosis site needs fixation of the muscularis at minimally two sites per tube to prevent dislocation of the lumen by torsion after removal of the splint.

Laparotomic microsurgical tubal reanastomosis is considered as the traditional sterilization reversal procedure.
In a large cohort of 1600 documented cases of tubal sterilization reversal, the overall intrauterine pregnancy rate was 64% and the ectopic pregnancy rate was 4% (Gomel, 1980).

Sedbon et al. (1989) were the first to describe a case of a laparoscopic tubal reversal procedure. Since then, a series of laparoscopic modifications of tubal sterilization reversal has been published, most applying multiple microsutures (Barjot et al., 1999; Koh and Jannick, 1999; Yoon et al., 1999; Cha et al., 2001) or single sutures (Dubuisson and Chapron, 1998; Bissonette et al., 1999; Mettler et al., 2001). Stadtmauer and Sauer (1997) published preliminary experience with laparoscopically placed titanium staples. Degueldre et al. (2000) showed the feasibility of a robotically assisted laparoscopic approach.

Cha et al. (2001) compared laparoscopic tubal re-anastomosis to a laparotomic approach in a non-matched cohort study, and reported overall pregnancy rates of 80% in both groups. In their study, in which both groups were not matched for female age, it was not possible to distinguish between ongoing pregnancies and non-viable intrauterine pregnancies, thus explaining the higher pregnancy rate as compared to our results. Moreover, in the present study, the follow-up time in a considerable number of patients in the laparoscopic group was relatively short. In the laparotomic group, nine out of 24 patients who conceived successfully did so at > 3 years after the procedure, whereas only two out of 15 successful conceptions were > 3 years after the procedure. This difference is explained by the relatively short follow-up of the laparoscopic group, in which 50% of the procedures were performed after January 1, 2001 versus 23% in the laparotomic group. Indeed, both the Kaplan–Meier curves and the Cox regression showed a similar performance of the two groups in the first 3 years.

Ideally, the effectiveness of new therapies should be evaluated in randomized clinical trials. However, such a randomized study is difficult to perform for sterilization reversal. The 41 patients included in the present study who were treated per laparoscopy were treated in a 6 year period. Many of these patients had contacted the Máxima Medical Centre specifically for the laparoscopic procedure, thus making it questionable whether they would have consented to randomization. We feel that in view of these difficulties a matched cohort study is the best alternative to a randomized study.

Age is the most significant predictive factor of the fertility result accounting for a reduction of 24 months cumulative pregnancy rate by 25% comparing the age group of < 35 years with > 40 years (Dubuisson et al., 1995; Rouzi et al., 1995). Other factors influencing the success rate of the reversal procedure are the method of sterilization, clips giving more favourable results than falope rings, and rings better results than coagulation. A post-operative tubal length of < 4 cm is associated with a reduced pregnancy rate (Rouzi et al., 1995). However, Kim et al. (1997) showed only age to be of importance in the prediction of successful re fertilization.

Perfect healing and abundant microvilli at the anastomosis site after fixation with biological fibrin glue has been demonstrated (Gauwersky et al., 1993; Detweiler et al., 1999). In our re-anastomosis procedure, accidental spillage of Tissucol onto the splint has no consequence on the quality of the anastomosis, as the ultra-smooth surface of the roadrunner does not adhere to the fibrin. Handling of the Duplocath Tissucol applicator, designed for laparoscopic use, was simple and well controlled. We cannot exclude the possibility that the tubal splint might cause damage to the endosalpinx.

In conclusion, the simplified stitchless laparoscopic procedure for reversal of tubal sterilization with the use of a tubal splint, clip fixation of the muscularis and fibrin glue resulted in a promising pregnancy rate, which was equal to the pregnancy rate obtained with the traditional re-anastomosis per laparotomy.

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