Original Article

Microsurgical Reversal of Sterilisation – Is This Still Clinically Relevant Today?

Heng Hao Tan,[1] *MBBS, MMed O&G (Spore), MRCOG (UK)*, Seong Feei Loh,[1] *MBBS, MRCOG (UK), FRACOG (Aust)*

Abstract

Introduction: Women with previous tubal sterilisation seeking fertility are faced with treatment options of reconstructive tubal surgery or in vitro fertilisation (IVF) techniques. The aim was to assess the current viability of tubal anastomosis in a local clinical practice. Materials and Methods: A retrospective cohort review of all sterilisation reversal cases from January 1998 to January 2008. The main outcome measures included first pregnancy success and live birth after surgery. Subsequent live births, ectopic pregnancies, miscarriages, duration of surgery and hospitalisation within the study period were also reported. We included cases aged less than 40 years, without any known semen abnormalities, and performed by only one operator. Cases with only unilateral reversal were excluded. Results: Nineteen cases with previous Filshie clip ligation (9 laparoscopic/10 open) were reviewed. Cumulative pregnancy rates with surgery were 47.4% (<6 months), 57.9% (6 to 12 months), 68.4% (12 to 48 months) and 73.7% (>48 months). Pregnancy (77.8% vs 70.0%) and live birth rates (66.7% vs 60.0%) were similar between laparoscopy and open surgery. The mean interval to pregnancy was marginally lower via laparoscopy (11.3 vs 13.6 months). Hospitalisation stay was significantly halved (1.43 vs 3.00 days) but ectopic pregnancies were increased 3-fold (3 vs 1) with laparoscopy. Compared with IVF, the estimated average cost per delivery for laparoscopic reversal was reduced for laparoscopic reversal with no multiple pregnancies. Conclusion: Our results favour surgical reversal after sterilisation for patients younger than 40 years old. It avoids hyperstimulation risks and the economic burdens associated with multiple pregnancies. Where expertise is available, laparoscopic reversal should be performed.

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Introduction

Different contraceptive options are available today; however, tubal sterilisation is still one of the most prevailing contraceptive alternatives.[1] Locally, many prefer mechanically occluding the tubes with Filshie clips. Unfortunately, some patients may express regret at their decision for tubal ligation and common reasons include a young age (<30 years) at the time of surgery, a change of spouse or even a loss of a child.

In our centre alone, an average of 815 cases of tubal ligation per year, with a median age of 35 years, utilising this method were performed over a 3-year period spanning 2005 to 2007. As such, even if a small percentage of these young women later regret their decision, a significant number requesting for future fertility may be present. For this group, the only realistic hope includes either undergoing a surgical tubal reversal or an alternative in vitro fertilisation (IVF) procedure. Interestingly, though the probability for requesting reversal of sterilisation has been reported to be as high as 14.3%, only 1.1% of the patients had actually undergone a reversal proper.[2]

With the introduction of local healthcare schemes that increase the availability of IVF recently, it was deemed appropriate to review the results of our microsurgical reversal of sterilisation. Conventionally, the gold standard has always been through the laparotomy route with quoted pregnancy rates ranging from 70% to 80%.[3,4] With the emergence of advanced laparoscopy techniques in recent times, many centres have demonstrated good success through laparoscopy and this has been widely regarded as the alternative route to perform microsurgical reversal of a ligated tube.[5]

[1] Reproductive Medicine Department, Reproductive Surgical Unit, KK Women's and Children's Hospital, Singapore
Address for Correspndence: Dr Tan Heng Hao, Reproductive Medicine Department, Reproductive Surgical Unit, KK Women's and Children's Hospital, 100 Bukit Timah Road, Singapore 229899.
Email: tan.heng.hao@gmail.com

Our aim was to assess the viability of tubal anastomosis (open vs laparoscopic surgery) in a local clinical practice.

Materials and Methods

We conducted a retrospective cohort review of all cases of sterilisation reversal performed in our centre between January 1998 and January 2008.

We included only cases aged less than 40 years, without any known semen abnormalities, and performed by only one operator in each surgical arm. This cut-off age was chosen as it seemed to be the pivotal age for success after IVF in our centre. Any cases with unilateral reversal were excluded from this review.

The main outcome measures included first pregnancy success and live birth after surgery. All cases were followed up till the outcome of interest occurred or till the end of the study. Subsequent live births, ectopic pregnancies, miscarriages, duration of surgery and hospitalisation within the study period were also reported. Patients were considered lost to follow-up if they had defaulted their appointments and were no longer contactable via telephone at the point of review.

Non-parametric testing at 2-sided significance was used for baseline characteristics, while Log-Rank test was used for cumulative pregnancy rates. The hospital's Institutional Review Board had consented to the review of these cases.

Results

A total of 19 cases were reviewed. Ten cases had been performed via laparotomy (all before 2001) while 9 cases (all after 2001) were via laparoscopy. All the cases had undergone Filshie clip ligation and the reversal proceeded only if the remaining tubal length was longer than 4 cm. One of the laparoscopic cases had to be converted to an open surgery owing to dense adhesions that increased the technical difficulty.

The median age was similar between the 2 surgical arms (Table 1). The 2 surgical arms were similar in the prognostic factors for reversal success[6] except for a significantly higher body mass index (BMI) (>25) in the laparoscopic arm. Hospitalisation stay was significantly halved (1.43 vs 3.00 days) in laparoscopy *(P* = 0.001*)* but was associated with a slightly longer (195 vs 160 minutes) overall mean surgical duration *(P* = 0.71*)*.

Table 1. A Comparison of Baseline Patient Characteristics between Laparoscopic and Open Microsurgical Sterilisation Reversal

Clinical parameter	Laparoscopic (n = 9)	Open (n = 10)	
Median age (y)	36 (range 33-38)	35 (range 28-38)	NS
Average parity	2.67	2.70	NS
Body mass index (kg/m^2)	25.1	21.8	P = 0.022
Interval from ligation (y)	5.9	7.0	NS

In laparoscopy, the pregnancy and live birth rates were 77.8% (follow-up period of 79 months) and 66.7% (follow-up period of 102 months), respectively. Similar results were obtained with open surgery at 70.0% (follow-up period of 95 months) and 60.0% (follow-up period of 88 months), respectively.

There was also a higher incidence of ectopic pregnancies (3 vs 1) with laparoscopy, all of which were treated surgically. Three miscarriages occurred with laparoscopic reversal, 2 were managed expectantly while 1 had undergone an evacuation of the uterus. A total of 4 cases were lost to follow-up (Table 2).

Table 2. A Comparison of Outcome Measures between Laparoscopic and Open Microsurgical Sterilisation Reversal

Clinical parameter	Laparoscopic (n = 9)	Open (n = 10)
No. of cases pregnant	7 (77.8%)	7 (70.0%)
No. of live births	6 (66.7%)	6 (60.0%)
No. of ectopic pregnancies	3 (33.3%)	1 (10.0%)
No. of miscarriages	3 (33.3%)	0
Cases lost to follow-up	2	2

With surgery, we achieved cumulative pregnancy rates of 47.4% (<6 months), 57.9% (6 to 12 months), 68.4% (12 to 48 months) and 73.7% (>48 months). The difference between cumulative pregnancy rates was not significant between laparoscopy and open surgery (P >0.05). With laparoscopy alone, the pregnancy rates were 55.6% (<6 months), 55.6% (6 to 12 months), 77.8% (12 to 48 months) and 77.8% (>48 months). With the open surgical method, pregnancy rates were 40.0% (<6 months), 60.0% (6 to 12 months), 60.0% (12 to 48 months) and 70.0% (>48 months).

The mean interval to pregnancy was marginally lower via laparoscopy (11.3 vs 13.6 months).

Discussion

To the best of our knowledge, this is the first published local report on tubal reversal results as the number of these procedures had been limited locally in earlier data.[7] Interestingly, 52.6% of our patients (10 out of 19) had a change in relationship while 47.4% (9 out of 19) desired more children after ligation.

In our series, we achieved cumulative pregnancy rates of 47.4% at 6 months and 57.9% at 12 months with tubal surgery. Cumulative pregnancy rates at 6 and 12 months

for open microsurgery[8] have been quoted at 40% and 53%, whereas the rates for laparoscopic microsurgery are 55% and 71% respectively.[9] Our results compare quite favourably with these rates.

Prognostic Factors

Many prognostic factors for surgical success, such as age, parity status, method of ligation, BMI, time interval from ligation and length of fallopian tube remaining after surgery have been described.[6] There has been no consensus about all the above-mentioned prognostic factors except for the age of the woman at the time of surgery.[10] In our study, a higher BMI of 25.1 in the laparoscopic arm had been associated with a poorer prognosis for success,[6] and might theoretically reduced the success rate in that cohort.

Various methods of sterilisation have been described and it is accepted that mechanical occlusion by Filshie clips should be the method of choice for tubal occlusion as it destroys a smaller part of the tube and the reversal, if performed subsequently, is more likely to succeed.[11] In all our cases, the ligation had been via Filschie clips at the isthmus. Although the lumen may be as small as 0.5 to 1 mm, equivalent luminal size and a thick muscularis allow a technically easier anastomosis.[9]

Laparoscopy vs Conventional Open Surgery

Laparoscopic microsurgery has introduced a new dimension for tubal reconstruction as the magnification obtained is similar to that obtained with an operating microscope.

All cases of tubal reversal in our series were performed via the laparoscopic route after 2001. However, given the widespread view that open microsurgery is still considered the gold standard, validation of laparoscopic microsurgery locally will require that reversals of sterilisation performed with this technique are attended by results equal to or better than that achieved in an open microsurgical technique.[9]

In our patients, the overall pregnancy rates (77.8% vs 70.0%) and live birth rates (66.7% vs 60.0%) were similar between the 2 surgical routes. In addition, there was no significant difference in cumulative pregnancy rate trend and mean time to pregnancy between laparoscopy and open surgery. Interestingly, Bissonnette et al[12] have demonstrated a reduced mean interval from surgery (5.5 vs 9 months) to pregnancy with laparoscopy.This time factor, being an important consideration for any subfertile couple, allows us to counsel patients on their pregnancy chances within a specific time frame better.

At first glance, the overall mean surgical duration seemed higher in laparoscopy. But this mean surgical duration for laparoscopy ranged from 221.7 minutes in the first 5 cases to 168.3 minutes for the next 5 cases. Such time trends compare quite favourably with the mean operating times in open surgery of 127.8 minutes in the first 5 cases and 177.2 minutes for the next 5 cases. This highlights an obvious learning curve with laparoscopy and has been observed in other studies as well.[9,13]

Additionally, laparoscopy brings with it the associated advantages of minimally invasive surgery. In our series, the mean hospitalisation was significantly reduced wit laparoscopy. This 2-fold reduction observed was also shown in another study.[13] The laparoscopic approach potentially involves less manipulation of intraperitoneal organs and causes less bleeding. These advantages may result in fewer adhesions and further enhance the pregnancy rate.

Nonetheless, it has been stated that reproductive surgeons should have expertise in both open microsurgical tubal anastomosis and laparoscopic suturing.[14] Thus, we should be mindful of the need to convert a laparoscopic case into open surgery should technical difficulties arise. This was clearly illustrated in one of our cases where the decision was made to laparotomise the patient in view of dense adhesions. The outcome was good, as the patient conceived 12 months after surgery.

Laparoscopic Technique

We utilised a standard 4-port laparoscopic technique used in most common gynaecological operations. Various forms of tubal anastomosis have been described over the years. They included using biological glue,[15] a 2-layer intracorporeal anastomotic stitch of the tube, to even employing intraluminal stents to help align the tube.[5]

In our cases, after the initial adhesiolysis and excision of the scarred tubal segment, we anastomosed the tubes by stitching up both the serosa and muscularis in a single plane with 6-0 PDS suture at 2 or 3 places. Unlike the open technique of avoiding the mucosa, a few authors adopting this simplified technique to facilitate laparoscopic stitching had also attained favourable results.[12,16,17] Live birth rates achieved by authors utilising this method of suturing ranged from 40.6% to 53.6%.[12,16-18] Stents had not been used because of the risk of traumatising the distal tubal segment. Slight leakage at the anastomotic site after the surgery is not a cause for concern as long as dye emerges from the distal fimbria.[9]

The main concern with this simplified approach of stitching is an increased incidence of ectopic pregnancies. Although the absolute number is small, studies have indicated a possible 3-fold increase of an ectopic pregnancy[16,19] – a trend observed in our own study as well.

Tubal Reversal vs IVF

To date, Cochrane reviewers were unable to find any study on this subject in the literature comparing the efficacy

and safety of the 2 treatment modalities.[20] Therefore, the decision-making process requires a detailed discussion on the effectiveness, adverse effects and cost of the 2 procedures with the patient.

Though our numbers are small, comparing the clinical outcomes between laparoscopic reversal and IVF in tubal factor infertility for those less than 40 years, the pregnancy and live birth rates were higher via surgery (77.8% and 66.7% respectively). Although the rates of miscarriage and ectopic pregnancies were higher, the great advantage of a tubal reversal is avoiding multiple pregnancies once fertility is restored. Furthermore, women are able to conceive in every cycle without requiring further treatment and that more than one pregnancy is possible (Table 3). In fact, there had been a total of 8 live births with laparoscopy and 7 live births with open surgery in our patients over the entire study period.

The quoted hospital bill for a tubal reversal procedure over a 2-day stay was about $7611 in an unsubsidised ward. This can be potentially lower if the patients were discharged earlier (average hospital stay of 1.43 days in our series). Similarly, the estimated cost for a fresh cycle IVF procedure was about $8000, depending on the total amount of folllicle stimulating hormone (Puregon) used during the oocyte stimulation process. With 6 live births in 9 patients operated upon, the estimated average treatment cost per live birth delivery with laparoscopic reversal was S$14,200 compared with S$23,446 for fresh IVF cycles in those with tubal factor infertility (Table 4). These included the costs incurred in treating the ectopic pregnancies surgically, as it was the most important complication associated with surgery. The estimated cost in surgically treating an ectopic pregnancy over a 2-day stay was about $5567 in an unsubsidised ward. The calculations did not include the costs of neonatal care, potential morbidity of follicular aspiration and ovarian hyperstimulation syndrome treatment – all of which are indirect costs that would increase the cost of delivery via IVF. Our findings are almost similar to a Belgian study that had found an almost 2-fold reduction with the cost per delivery via the surgical route in younger patients.[21]

We need to be mindful of some possible disadvantages with surgery.[22] These include a delayed time to pregnancy, increased risk of ectopic pregnancy, potential for further adhesion formation and surgical risks, although none happened in our series. When considering surgery over IVF, it is important to remember that success cannot be fully appreciated for 2 to 4 years after the operation,[23] an issue that may be pertinent in older patients. We only achieved maximal success with our patients at 46 months and 60 months with laparoscopy and open surgery respectively. It may, however, be reasonable to discuss IVF with any couple without pregnancy 12 months after tubal surgery.[10]

Table 3. Comparison between Laparoscopic Reversal and IVF in Those with Tubal Factor Infertility (<40 years)

Clinical indicator	Laparoscopic reversal (n = 9)	IVF* (n = 327)
Pregnancy rate	77.8% (7)	46.8% (153)
Live birth rate	66.7% (6)	34.6% (113)
Miscarriage rate	33.0% (3)	9.79% (32)
Ectopic pregnancy rate	33.0% (3)	1.83% (6)
Multiple pregnancy rate	0% (0)	12.8% (42)
Ovarian hyperstimulation syndrome rate	0% (0)	4.89% (16)

* Fresh cycle embryo transfer between 2002 and 2006

Table 4. Estimated Costs between Laparoscopic Reversal and IVF in Those with Tubal Factor Infertility (<40 years)

	Laparoscopic reversal		IVF*	
	Occurrences	Cost (S$)†	Occurrences	Cost (S$)‡
Number of cases performed	9	68,499	327	2,616,000
Ectopic pregnancy	3	16,701	6	33,402
Live birth	6	-	113	-
Cost per live birth	-	14,200	-	23,446

* Fresh cycle embryo transfer between 2002 and 2006

† Based on the quoted unsubsidised hospital package of $7611 for a Table 5C surgery for reversal and $5567 for a Table 4A surgery for ectopic pregnancy

‡ Based on centre's estimated cost of $8000 per fresh cycle

Robotic Surgery

Robotic surgery in tubal reversal has been advocated to bridge the learning gap between an open approach and laparoscopy. In one of the largest published series on robotic tubal reversal, the authors have found comparable pregnancy rates with similar costs per delivery between robotic surgery and open surgery. Furthermore, robotic surgery resulted in a shorter hospital stay but needed a significantly longer mean surgical duration (201 min), and was associated with a 4-fold increase in ectopic pregnancy rates.[24] Extrapolating these findings to our earlier discussion on laparoscopic and open surgery, and given the equipment and resources needed for the robotic technology, the role of robotic surgery may appear limited currently within the confines of our institution.

Limitations

Given that this particular study had been retrospective in nature, we faced certain inherent limitations. Although most of the patients had a full subfertility workup before

the surgery, some of them were not subjected to pre-operative investigations such as a serum follicle stimulating hormone, semen analysis, mid-luteal progesterone or a hysterosalpingogram. In addition, 4 cases were lost to follow-up and all these factors could have somewhat affected the success figures.

Conclusion

Within the limits of this study, it is reasonable to recommend surgical reversal to patients younger than 40 years. In addition, it avoids the risks of hyperstimulation and can reduce the economic burdens associated with multiple pregnancies. In older patients where the time factor and a reduction in fecundity matter, IVF is still the superior choice.[22]

Given the potential for reduced morbidity, laparoscopic reversal should be performed where level IV laparoscopic expertise[25] is available. We acknowledge the need to standardise and tighten our selection criteria for tubal reversal, and this further reiterate the holistic importance of developing and incorporating reproductive surgery into our fertility management guidelines.

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