Symposium: Tubal disease and fertility outcome

Reversal of tubal sterilization versus IVF in the era of assisted reproductive technology: a clinical dilemma

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Abstract

Two treatment options are available to women who wish to become pregnant after having had tubal sterilization: microsurgical reversal or IVF. The first approach is designed to restore tubal function, whereas the second replaces it. The first, to be successful, requires the presence of sufficient tubal length and normal or treatable fertility parameters. Treatment should therefore be individualized, based upon the findings of the couple's investigation, their wishes and the costs involved. The age of the female is the most important factor that affects the outcome with both treatment options. The live birth rate per cycle with IVF is 28%, but only 65.8% are singletons; 31.0% are twins and 3.2% triplets or more. Microsurgical tubal anastomosis yields a birth rate that exceeds 55%, without increased risk of multiple pregnancy. It offers the couple multiple cycles in which to achieve conception naturally, and the opportunity to have more than one pregnancy from a single intervention. The real dilemma lies with the 'industrialization' of IVF, and its frequent use as primary treatment for infertility. The dilemma is heightened by the fact that reconstructive tubal microsurgery is being taught and practised less and less, thereby eliminating this credible surgical option in most centres.

Keywords: *IVF, microsurgery, reversal, tubal anastomosis, tubal sterilization*

Introduction

Two treatment options are available to women who wish to become pregnant after having had tubal sterilization: microsurgical reversal or IVF. The first approach is designed to restore tubal function, whereas the second replaces it. The first, to be successful, requires the presence of sufficient tubal length and normal or treatable fertility parameters. Treatment therefore needs to be individualized, based upon the findings of the couple's investigation, their wishes and the costs involved.

The age of the female is the most important factor that affects the outcome with both treatment options. The average live birth rate per cycle of treatment with IVF is around 28%. Of the pregnancies that result, only 65.8% are singletons; 31.0% are twins and 3.2% triplets or more. The significant increase in the multiple pregnancy rate is a side effect of IVF. Microsurgical tubal repair yields a birth rate that exceeds 55%, without an increased risk of multiple pregnancies. It offers the couple multiple cycles in which to achieve conception naturally, and the opportunity to have more than one pregnancy from a single operation.

Proper selection of one or the other method of treatment

demands the treating centre to have equal expertise in both. The dilemma lies with the trend that makes IVF readily available though an ever increasing number of centres, while there is a continuing decline in the teaching and practice of reconstructive tubal microsurgery, eliminating a credible surgical option in most centres.

Tubal sterilization has become increasingly popular, and in the last 3 decades, women have increasingly selected this approach to control their fertility. Currently, more than 700,000 of these procedures are performed each year in the United States, of which about half are performed during the post-partum period. Eleven million US women aged 15–44 years rely on surgical tubal sterilization as a means of contraception, and more than 190 million worldwide.

A multitude of factors induce women to request restoration of fertility; the most important (>60%) of these is change in marital status. This is understandable, in view of the significant divorce rate, especially in the developed countries. The other factors are the desire to have more children in the same union, usually after the improvement of the couple's economic conditions; death of a child, tragedies and psychological reasons (Gomel, 1978).

Until the mid-1980s, the only option to restore fertility in women with prior tubal sterilization was a reversal procedure. The outcome dramatically improved after the introduction of microsurgical techniques in the early 1970s (Gomel, 1977). The marked improvement in the results of IVF, during the decade of the 1990s, made this approach a credible alternative to achieve a pregnancy for a woman who had a tubal sterilization (Centers for Disease Control and Prevention, 2004). Where is the clinical dilemma?

Microsurgical reversal of tubal sterilization and IVF are two very different approaches in offering the opportunity to achieve a pregnancy to women who have had a prior sterilization. The first approach is designed to restore the function of the Fallopian tube(s), whereas the second replaces tubal function. The first, to be successful, requires other factors of fertility to be normal or to be readily treatable. The second is able to overcome male factor infertility with the use of intracytoplasmic sperm injection (ICSI), and/or ovulatory dysfunction with gonadotrophins used to achieve ovarian stimulation. This readily implies the necessity to individualize treatment on the basis of the findings resulting from the investigation of the couple, their wishes and the costs involved. Selection must also take into account the level of expertise of the centre treating the patient in both of these approaches.

Investigation

The investigation, which must be carried out quickly and inexpensively, is designed to determine the fertility status of the couple and the reversibility of the prior tubal sterilization. It is important to obtain copies of the operative and pathology reports of the prior sterilization procedure, and video if available, before the date of consultation of the patient. The operative report will usually provide information about the status of the pelvis, and more specifically of the Fallopian tubes, at the time of sterilization. This, and the description of the technique of sterilization used, will give the physician a fairly good idea about reversibility of the previous sterilization and the potential of success associated with a reversal. A pathology report will only be present in the event of removal of tissue, which is the case with older sterilization techniques that are now rarely used. The initial investigation will include a semen analysis, evidence of ovulation, and a hysterosalpingography (HSG). The HSG, when performed properly, will provide valuable information about the status of the uterine cavity and the luminal architecture of the tube(s) up to the site of interruption. It will also clearly indicate the type of prior sterilization, if a clip or a ring was used for this purpose (Gomel, 1980, 1983a, 2003). If the patient's clinical assessment includes a sonography, a hysterosalpingo-contrast-sonography may be performed in place of a HSG (Strandell *et al.*, 1999).

Selection of treatment

Reconstructive surgery and IVF must not be regarded as competitive treatments but rather as complementary options necessary to achieve the desired goal. The choice of treatment is ideally dependent on various considerations, both technical and non-technical (Gomel and Taylor, 1992).

Technical considerations

IVF is the only treatment option for women whose Fallopian tubes have been extensively damaged, markedly shortened, or large portions of their distal segment removed during the sterilization procedure and/or the presence of another important fertility factor, such as male factor infertility.

The provision of accurate information regarding both IVF and tubal surgery is essential in the decision-making process of the couple. The couple must be given the live birth rate per cycle with IVF, the cumulative birth rate after multiple cycles of treatment, and the potential complication rates including multiple pregnancy, abortion, and ectopic pregnancy. In addition, the effect of frozen embryo replacement on the cumulative pregnancy rate must be considered in the analysis. Similar information must also be provided regarding reconstructive tubal surgery. It is imperative that such figures reflect the experience of the centre in which treatment will be performed. This text, by necessity, will use published data.

IVF and embryo transfer

Data collected prospectively and tabulated by the Centres for Disease Control for assisted reproductive treatments during the year of 2003, from 399 programmes in the United States, demonstrated a further slight improvement in outcomes. There were 91,032 standard IVF cycles (fresh, non-donor gametes); the live birth rate per cycle initiated was 28.3% and the live birth rate per embryo transfer was 34.7%. In cycles that resulted in a clinical pregnancy, 82.2% resulted in a live birth. Of live births, 65.8% were singleton births and 34.2% multiple births (Centers for Disease Control and Prevention, 2004).

ICSI represents very important progress in the treatment of male infertility. In such cases the use of ICSI is associated with a success rate that equals that of standard IVF in the absence of male factor infertility (Centers for Disease Control and Prevention, 2004).

With IVF–embryo transfer the major risk (other than ovarian hyperstimulation syndrome, which fortunately is relatively rare) is multiple pregnancy, especially triplets and higher order multiples.

Reconstructive surgery

The overall risks of reconstructive tubal surgery are small, and include the recognized complications of anaesthesia and surgery.

Microsurgery finds its ultimate application in tubo-tubal anastomosis. The precision afforded by this technique and the use of magnification allows precise dissection of the occluded ends and proper alignment, and excellent apposition of each layer of the proximal and distal tubal segments. Furthermore, since in the vast majority of cases of reversal of tubal sterilization the available tubal segments are normal, the outcome is an anatomically and physiologically normal, albeit shortened, Fallopian tube (Gomel, 1977, 1980, 1983a, 2003). The reported live birth rates following microsurgical anastomosis vary between 55 and 81% (Winston, 1980; Gomel, 1983b; Boeckx *et al*. 1986; Rock *at al.,* 1987; Xue and Fa, 1989; Kim *et al.,* 1997; Wiegerinck *et al.,* 2005).

Non-technical considerations

Non-technical considerations include age, cost and the wishes of the couple. Female fecundity is adversely affected by age. Fecundity begins to decline at about 31 years of age. This decline becomes more evident after 37 years of age. In women of advanced reproductive age, the marked decline of fecundity per cycle of IVF must be weighed against the fact that reconstructive surgery offers multiple cycles during which conception can occur. Health insurance coverage, depending on the jurisdiction, the cost of the procedure and the resources of the couple will play an important role in the decision-making process. Another, often underestimated, potential factor is the economic impact of a multiple pregnancy, which occurs much more frequently with IVF. The perceptions and wishes of the couple, including their own values and ethical views, will also weigh in the selection of treatment.

Discussion

The age of the woman is a very important factor in the outcome of both treatment options (Centers for Disease Control and Prevention, 2004; te Velde *et al*., 1990; Trimbos-Kemper, 1990; Rouzi *et al*., 1995). Experience at the University of British Columbia has clearly demonstrated that age at the time of reversal of sterilization is the most important factor in the outcome (Rouzi *et al*., 1995). In the absence of another significant cause of infertility, women who are less than 35 years of age at the time of reversal can anticipate a cumulative intrauterine pregnancy rate of greater than 70%, with most pregnancies occurring within 18 months after surgery (Gomel and McComb, 2006). The pregnancy rate declines in adverse proportion to the age; those who are over 35 years of age can expect an intrauterine pregnancy rate of about 55%. The only other factor that predicts adverse fertility outcome is a total reconstructed tubal length of less than 4 cm. This probably reflects insufficient ampullary length and consequent loss of oviductal oocyte retention (Rouzi *et al*., 1995). The tubal sterilization techniques (Falope-ring, tubal clips), largely used in the last 15–20 years, are much less destructive than earlier methods; they permit easier reconstruction of the tube, which yields a fairly good tubal length. The type of sterilization, the length of time between the sterilization and reversal, the location and type of anastomosis, and whether one or both tubes are anastomosed, do not seem to affect the outcome (Rouzi *et al*., 1995).

A true microsurgical technique continues to be used at the University of British Columbia, through an operation microscope. Since 1985, a suprapubic horizontal minilaparotomy incision has been used to access the peritoneal cavity (Gomel, 2003). The procedure is performed in a surgicentre, where the patient is admitted a couple of hours before the procedure and discharged a few hours after.

Much discussion of reversal by laparoscopic access has arisen. There are no proper randomized trials with sufficient patient numbers to ascertain whether a certain surgeon can achieve the same pregnancy rates by laparoscopic access. Experience has been gained with both approaches, but the approach via minilaparatomy is preferable. The special peri-operative measures, the use of local anaesthesia prior to the placement of the incision and establishment of bilateral ilio-inguinal block at the end of the procedure, along with the small size of the incision, the lack of bowel manipulation and gentle handling of tissues during the procedure reduce post-operative discomfort and analgesia requirements. These patients return to normal activity as rapidly as those who have had their procedures performed via laparoscopic access (Gomel, 2003; Gomel and McComb, 2006).

Tubo-tubal anastomosis by laparoscopic access to reconstruct a previous tubal sterilization is being performed in some centres. Whereas some investigators who use a truly microsurgical, two-layer anastomosis technique obtain satisfactory outcomes (Cha *et al*., 1999; Yoon *et al*., 1999), others report significantly inferior results in comparison with open access (Bisonette *et al.,* 1998; Dubuisson and Chapron, 1998; Mettler *et al.,* 1999; Ribero *et al.,* 2004). The latter is largely due to modification of the recognized microsurgical technique to make the laparoscopic procedure simpler to perform. Most surgeons who attempted tubo-tubal anastomosis by laparoscopic access using the microsurgical technique described earlier, found that operating times are prolonged. Many attempted to simplify the technique, by using glue instead of sutures or using only two sutures for the apposition of the prepared tubal segments, as first reported by Dubuisson and Swolin (1995).

Microsurgical reconstruction provides a couple, without any other serious factor(s) of infertility, a high rate of success in achieving a uterine pregnancy, without a significant increase in the rate of ectopic gestation, abortion or multiple pregnancy.

Assisted reproduction procedures are associated with a significant increase in the rate of multiple pregnancy (relative risk; RR > 20). The Centers for Disease Control and Prevention Assisted Reproductive Technology report for 2003 indicated that of the resulting live births, only 65.8% were singleton; 31.0% were twins, 3.2% were triplets or higher order. Prenatal morbidity and mortality are markedly increased in pregnancies

complicated by multiple gestations. It is also noteworthy that monofetal pregnancies resulting from IVF are associated with elevated risk as compared with non-assisted reproduction singleton pregnancies: more than 10% of monofetal births are preterm and the perinatal mortality rate (about 19 per 1000) is higher than non-assisted reproduction singleton pregnancies (Rufat *et al*., 1994).

An important study from Sweden comparing the obstetric outcomes of babies conceived with IVF ($n = 5856$) to all babies born in the general population during a span of 13 years (1982–1995) demonstrated the following: children resulting from an IVF conception had increased rates of low birth weight (RR = 5), major malformations (RR = 1.4), cerebral palsy (RR = 4) and death (RR = 2) (Bergh *et al*., 1999). The high rate of multiple births has a tremendous personal and social impact. The cost, both emotionally and financially, of caring for premature or abnormal children is considerable.

Taking into account the current average rates of success with IVF, the mathematical potential of having a baby for a woman who attempts three cycles of IVF is around 60%. However, the rates of success are not constant and tend to decline after the second cycle, in a fashion that is similar to natural conception (Zinaman *et al*., 1996). Furthermore, studies demonstrate conclusively that the majority of couples undergoing IVF–embryo transfer do not wish to complete three cycles of IVF–embryo transfer (Land *et al*., 1997; Olivius *et al*., 2002).

The advantage of IVF is that success or failure is recognized during the same treatment cycle. If there are good quality supernumerary embryos that can be successfully cryopreserved and thawed, this permits another replacement cycle to be performed. These characteristics provide an argument in favour of this approach, as the primary mode of treatment, with women in advanced reproductive age.

Based on the preceding discussion, it is evident that there is no clinical dilemma, provided the selection of treatment is arrived at by taking into account many factors that include the woman's history, type of sterilization, her age, and the status of other infertility factors of the couple, costs and their wishes. Considering the current rates of success with both procedures, the author's approach is to recommend reconstructive microsurgery as the primary form of treatment to couples who have no other significant fertility problems. So where is the dilemma?

The dilemma lies with the industrialization of assisted reproduction, and its use almost as a primary form of infertility treatment. The number of assisted reproduction cycles performed in the United States has almost doubled from 64,036 cycles in 1996 to 122,872 in 2003. In this particular instance, the dilemma also lies in the fact that reconstructive tubal microsurgery is being taught and practised less and less, eliminating it, in most centres, as a treatment option for women with prior tubal sterilization who wish to restore their fertility (Gomel, 1995, 2005).

Reconstructive microsurgery and assisted reproduction have always been viewed as complementary approaches that can be used singly or in combination to improve the outcome for couples suffering from tubal infertility (Gomel, 1983a, 2003, 2005). Infertile couples may wish to avail themselves of either or both options. These decisions will be influenced by the findings of each couple's investigation, their individual needs and often their ability to pay. This is especially important, since several studies have shown conclusively that the majority of couples undergoing IVF–embryo transfer do not wish to complete three cycles of IVF (Land *et al*., 1997; Olivius *et al*., 2002). Microsurgical reversal of sterilization is front-line therapy, the outcome of which can exceed even multiple attempts at IVF. Successful surgery offers the couple multiple cycles in which to achieve conception naturally, and the opportunity to have more than one pregnancy after a single surgical intervention.

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Received 10 April 2007; refereed 9 May 2007; accepted 18 May 2007.