Outcome study using an administrative database: terminal salpingostomy, physician case load and live birth rates

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Information on the outcome following salpingostomy performed for infertility in everyday practice is needed to counsel patients, determine the best approach to this condition and clarify whether the outcome is superior when surgery is performed by a physician who maintains a high volume of ongoing experience. A total of 547 consecutive subjects were identified over a 5 year period using the Alberta Health Care Claims Database. Their claims history was analysed over a follow-up of 2–7 years, to identify pregnancy-related events, loss to follow-up and events which would result in sterility. Pregnancies were cross-checked with the only in-vitro fertilization programme serving the region. The overall cumulative live birth and tubal pregnancy rates were 11.7 and 7.2% respectively. Live birth rates were significantly higher when practitioners had performed >10 procedures within the study period. Live birth rates would appear to be substantially lower in everyday practice than following surgery performed by acknowledged experts. A high volume of ongoing experience appears to be associated with superior live birth rates. It is unclear whether this association relates to case selection, surgical expertise or both variables.

Key words: everyday practice/live birth/outcome/salpingostomy/surgical experience

Introduction

Outcome following terminal salpingostomy for distal tubal occlusive disease has been well documented in centres of excellence (Swolin, 1975; Gomel and Swolin, 1980; Singhal et al., 1991; Dubuisson et al., 1994), with live birth rates of between 27.0 and 33.7% being reported. Watson et al. (1990) undertook a follow-up study of the outcome following tubal surgery in two non-specialist hospitals. A homogeneous group of 40 patients with bilateral unipolar distal tubal occlusion was identified. A live birth following salpingostomy was recorded in only two of the patients. These data might suggest that outcome improves in experienced microsurgical hands. However, the number of subjects was small and the severity of the disease process (Singhal et al., 1991) could not be compared adequately with previous studies. Furthermore, Watson et al. (1990) did not provide information about the past or ongoing experience of their surgeons.

The choice between surgery and in-vitro fertilization (IVF) as the most appropriate first-line intervention for distal tubal occlusion is debatable. Registries are now available which document the success rates following IVF across a wide spectrum of centres (American Fertility Society and The Society for Assisted Reproductive Technology Registry, 1994). However, no data are available examining the outcome following tubal surgery in a large number of patients in everyday practice where the number of procedures performed by individual surgeons is documented.

The purpose of our study was to document the live birth rate following salpingostomy in everyday practice using a provincial health care insurance plan database, and to relate the outcome to the number of procedures performed by each surgeon in the series.

Materials and methods

Subjects

Subjects were identified using the Provincial Alberta Health Care Insurance Plan database (Alberta Health, Edmonton, Alberta, Canada). Because of the nature of health care coverage in Alberta, Canada, tubal surgery to correct occlusion of the Fallopian tube is deemed a necessary service. There are no exceptions to this rule. Because all physician claims for reimbursement were processed through the Alberta Health Care Insurance Plan, our data are complete.

A 5 year study period extending from January 1, 1986 to December 31, 1990 was selected. The fee code for salpingostomy was used as the selection parameter from the Health Care Insurance Plan database. Individuals were identified, and then every investigation and clinical event from January 1, 1986 to December 31, 1992 was included in the database. Subjects were cross-referenced with the Alberta Health Registration database, using their unique lifetime identifier to detect any change such as an altered name, death or a termination in registration which would indicate a move out of the province. Data were checked visually/manually for discrepancies and the diagnostic code (infertility) was confirmed. Age and the length of follow-up were calculated using the database.

IVF database

For those women with a record of a live birth or tubal pregnancy, it was necessary to determine whether or not they conceived as a result of IVF. The only province in Canada which insures IVF is Ontario.
and there is no reciprocal agreement for payment between Ontario and other provinces. Therefore, IVF was not an insured procedure for any of our study population. The Foothills Hospital (Calgary, Alberta, Canada) Regional Fertility Programme was the only IVF programme (insured or uninsured) functioning during the study period in the area of Canada extending from British Columbia to Ontario. Pregnancy rates and costs were extremely competitive, and it is unlikely that many individuals living in Alberta would seek treatment in another IVF programme. Ethical approval was sought to compile a list of women who had a pregnancy-related event following IVF therapy, including Alberta Health Registration information for cross-referencing with the Alberta Health Care Insurance Plan database. If a live birth, miscarriage or tubal pregnancy had occurred following IVF, this was recorded as an independent variable in the study database, and follow-up following salpingostomy was terminated 9 months prior to any live birth; these individuals were treated as censored observations for the purposes of a life-table analysis.

Statistical analysis

Fee codes for hysterectomy, sterilization, live birth, therapy for an ectopic pregnancy and therapy for a miscarriage, together with the date of service, were identified. Follow-up was terminated by a live birth, a hysterectomy, sterilization, the termination of registration with Alberta Health or a change in registration data that would suggest separation or divorce (a censored variable for the purposes of the life-table analysis). Where a live birth occurred, this event was taken as the end of follow-up in exclusion to a prior miscarriage or tubal pregnancy. Where a tubal pregnancy occurred, follow-up to this point was calculated as an independent variable so as to obtain the cumulative tubal pregnancy rate. The interval between the initial salpingostomy and the terminating event was calculated in months for the purpose of performing a life-table analysis. We did not include miscarriage as an outcome as these data would not be complete because of conservative management of some of these patients at home, and although miscarriage demonstrates that an intrauterine pregnancy has occurred, it does not represent a successful outcome.

Provider information was coded so as to determine the physician responsible for performing each procedure and the number of procedures performed by each physician in the series. Statistical analyses and a Cox's proportional hazards model of life-table analysis were performed, as implemented by Stata (Stata Corporation, College Station, TX, USA).

Results

A total of 547 consecutive patients underwent a terminal salpingostomy in Alberta, Canada, between January 1, 1986 and December 31, 1990 as treatment for infertility. No repeat procedures were undertaken; 83 practitioners performed one or more of these procedures. Follow-up ranged from 2 to 7 years (mean ± SD, 45.6 ± 20.7 months). The mean ± SD age was 29.2 ± 4.4 years. In all, 68 women had a live birth during the period of follow-up, and of these, 12 had a live birth resulting from treatment with IVF. Figure 1 documents the cumulative live birth rate independent of births resulting from IVF, together with the 95% confidence intervals (CI). The curve reached a plateau at 53 months following surgery, with a cumulative live birth rate of 11.7% (95% CI 9.1 and 15.1%).

During the study period, 32 women underwent a procedure for tubal pregnancy. Figure 2 documents the cumulative rates of procedures for tubal pregnancy. The curve reaches a plateau at 66 months following surgery, with a cumulative tubal pregnancy rate of 7.18% (95% CI 4.9 and 10.5%).

A stepwise Cox’s regression analysis was performed entering patient age and the number of procedures performed by each surgeon. Neither variable was significantly associated with either the live birth rate or the tubal pregnancy rate. Table I documents the number of live births, the cumulative live birth rate and the 95% CI subdivided by surgeons grouped by the number of procedures which they undertook in this series.

Although surgeon experience was not significantly related to live birth rate on a Cox’s regression analysis, a possible association can be seen in Table I between a higher order surgical case load and a higher cumulative live birth rate. In view of this apparent trend, a further analysis was undertaken. Subjects were divided into two roughly equal groups: those where the surgeon had undertaken ≤10 procedures within the study group (n = 264, 48.3% of subjects), and those where the surgeon had undertaken >10 procedures within the study group (n = 283, 51.7% of subjects). The former group had a cumulative live birth rate of 8.9% (95% CI 5.8 and 13.5%). The latter group had a cumulative live birth rate of 14.1% (95% CI 10.2 and 19.2%). The two groups were compared by a life-table analysis, demonstrating that subjects where the...
surgeon had performed >10 cases in this series had a significantly higher pregnancy rate than where the surgeon had performed ≤10 cases in this series (Z = 1.97, P = 0.049).

Discussion

This is the first study to examine the live birth rate following tubal surgery performed in everyday practice using an administrative database which includes a large number of physicians and centres and documents their surgical case load. Because of the system of universal health care coverage in Canada and the procedure for physician reimbursement, we have a large database in which all subjects undergoing surgery are included. However, because the Health Care Insurance Plan database was not designed primarily for assessing outcomes, there are a number of potential deficiencies in our data set. We did not contact the subjects directly, and therefore we may not have detected where a marriage or relationship had dissolved or a woman had voluntarily commenced contraception. Although this could be argued to partly account for the lower than expected live birth rate, data suggest that such a change in relationship status occurs in only 4% of a study group with infertility (Dunphy et al., 1989). Furthermore, there is a legal requirement in Alberta to inform Alberta Health of a change in address or registration details, which we would have detected when cross-checking with our registration database. We could not document the training of surgeons who contributed to this series. Clinical data such as ovulatory and male factor status were unavailable. There was insufficient information in the database to allow us to stratify cases by surgical technique, the gross appearance of the Fallopian tubes, whether surgery was performed for complete occlusion or a phimosis, whether surgery was performed on one or both Fallopian tubes and whether a concomitant adhesiolysis was performed. Furthermore, clinical data such as semen parameters and ovulatory status were not available. However, these potential deficiencies do not detract from our aim to examine the overall outcomes following surgery in everyday practice. Such clinical data were (or should have been) available to every surgeon prior to each procedure, and would have been considered during the selection process.

A more significant cause of concern relates to the accuracy of our live birth rates and the cross-referencing with our IVF database. Because health care coverage is universal, the termination of registration would indicate that a woman had moved out of the area, and therefore these data were appropriately handled as censored observations. In some countries such as The Netherlands there is a significant population of women who are delivered at home by midwives and who would therefore escape documentation in a database such as ours. However, independent midwives were only legalized in Alberta in 1994. Approximately 40 000 live births occur per year in Alberta. It is estimated that 200–400 live births are now performed by independent midwives per year (0.5–1.0%). Therefore, we would anticipate a low chance of missing one live birth in our study because of independent midwives. Unlike a simple register of births, the physicians who supervised the live births recorded in our study were rewarded financially for contributing to the Alberta Health Claims database. Therefore, it is unlikely that many live births were unreported. Although subjects in this study would have had to travel long distances to participate in another IVF programme, there is a possibility that a few IVF pregnancies escaped our notice. However, such a discrepancy would only emphasize the lower live birth rates resulting from surgery performed in everyday practice.

There appears to be an association between the volume of surgical practice and the outcome following surgery. Although the reason(s) for this association could not be provided by our database, there are a number of factors which may contribute. A significantly higher live birth rate may simply reflect greater expertise with the procedure because of the maintenance of surgical skills. Surgeons with a higher volume of practice may have an established referral pattern due to acknowledged subspeciality skills or training in tubal microsurgery. Furthermore, higher volumes of surgery may take place in centres which have the appropriate equipment to support the optimal

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technique. We were unable to stratify cases by the severity of the disease process. The gross appearance of the Fallopian tube (Singhal et al., 1991) and the appearance of the lumen at salpingoscopy (De Bruyne et al., 1989), laparoscopy (Dubuisson et al., 1994) or Falloposcopy (Menashe et al., 1993) have all been demonstrated to be prognostic indicators. Tubal surgeons who practise in a subspecialty centre may apply more rigorous selection criteria (e.g. undertake surgery where the disease process is milder) and still maintain a high surgical case load by virtue of a large referral base. Whatever the reason(s), these data suggest that superior outcomes are attained where an adequate volume of surgical practice is maintained.

The live birth rate in this series is lower than figures published by acknowledged microsurgical experts (Swolin, 1975; Gomel and Swolin, 1980; Singhal et al., 1991; Dubuisson et al., 1994). Although the outcomes in our series are superior to those published by Watson et al. (1990), our data support their conclusion that the outcome following tubal surgery in everyday practice is less likely to be favourable than would be anticipated by a review of the available literature. The North American delivery rate following IVF is 14.3% per cycle commenced and 16.8% per oocyte retrieval (American Fertility Society and The Society for Assisted Reproductive Technology Registry, 1994). Furthermore, there is an 11.6% delivery rate following the replacement of cryopreserved embryos.

A simple comparison with our data would suggest that IVF might be a better primary intervention for distal tubal occlusion. However, the choice of the best primary intervention is much more complex. As stated previously, the careful selection of patients for microsurgery by the external visual appearances of the oviducts (Singhal et al., 1991) and/or using an assessment of the condition of the oviductal lumen may lead to an improved pregnancy rate (De Bruyne et al., 1989; Dubuisson et al., 1994). As demonstrated by these data, there is considerable variation in outcome between surgeons. Outcomes following IVF may also vary between centres, and not all programmes have a successful embryo cryopreservation program (American Fertility Society and The Society for Assisted Reproductive Technology Registry, 1994). Therefore, because of these regional variations and variations in individual patient prognosis, there is still a place for both IVF and microsurgery as primary interventions. Outcome following both IVF and microsurgery should ideally be audited continually in each centre.

The cost of each intervention may vary widely between centres, and regions may wish to analyse the cost per live birth following each intervention. In some regions, surgery or IVF is insured to the exclusion of the other. Therefore, in the absence of local flexibility or a clinical algorithm, funding mechanisms have the potential to adversely influence clinical care. Other local factors, such as a long waiting list, may influence the patient or clinician to choose a less satisfactory primary intervention.

Although we have focused on outcomes in this study, there are a number of other potential applications of examining an administrative database. Each health care-related consultation is recorded for every patient. Therefore, other indicators could be examined, such as the use of investigations, consultation rates and diagnostic categories occurring after an intervention. When visually checking our database, we were struck by the numerous occurrences of psychological and psychiatric diagnostic codes, although we have not yet quantified their frequency. Furthermore, it may be possible to gain an estimate of indirect costs incurred in the management of these patients. However, where each health care encounter is recorded over many years, a massive database is generated and there may be logistical problems in analysing such a database.

In summary, we have documented live birth rates following surgery for distal tubal occlusive disease in everyday practice, and related these to the surgical case load during the study period. Outcomes in everyday practice do not appear to be as good as those published following surgery performed by acknowledged experts. A higher volume of case load per surgeon appeared to be associated with a significantly better live birth rate following surgery, although it is unclear how much of this is caused by surgical expertise and how much relates to case selection criteria (e.g. disease severity).

References


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