Predicting ongoing pregnancy chances after IVF and ICSI: a national prospective study


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BACKGROUND: The Dutch IVF guideline suggests triage of patients for IVF based on diagnostic category, duration of infertility and female age. There is no evidence for the effectiveness of these criteria. We evaluated the predictive value of patient characteristics that are used in the Dutch IVF guideline and developed a model that predicts the IVF ongoing pregnancy chance within 12 months. METHODS: In a national prospective cohort study, pregnancy chances after IVF and ICSI treatment were assessed. Couples eligible for IVF or ICSI were followed during 12 months, using the databases of 11 IVF centres and 20 transport IVF clinics. Kaplan–Meier analysis was performed to estimate the cumulative probability of an ongoing pregnancy, and Cox regression was used for assessing the effects of predictors of pregnancy. RESULTS: 4928 couples starting IVF/ICSI treatment were prospectively followed. On average, couples had 1.8 cycles in 12 months for both IVF and ICSI. The 1-year probability of ongoing pregnancy was 44.8% (95% CI 42.1–47.5%). ICSI for severe oligospermia had a significantly higher ongoing pregnancy rate than IVF indicated treatments, with a multivariate Hazard ratio (HR) of 1.22 (95% CI 1.07–1.39). The success rates were comparable for all diagnostic categories of IVF. The highest success rate is at age 30, with a slight decline towards younger women and women up to 35 and a sharp drop after 35. Primary subfertility with a HR of 0.90 (95% CI 0.83–0.99) and duration of subfertility with a HR of 0.97 (95% CI 0.95–0.99) per year significantly affected the pregnancy chance. CONCLUSIONS: The most important predictors of the pregnancy chance after IVF and ICSI are women’s age and ICSI. The diagnostic category is of no consequence. Duration of subfertility and pregnancy history are of limited prognostic value.

Keywords: IVF/ICSI; pregnancy; prediction model; prognostic factors

Introduction

In 1983, in vitro fertilization (IVF) was introduced in the Netherlands as a treatment for women suffering from bilateral tubal occlusion. Later on, couples with other reasons for subfertility were treated with IVF as well. With the development of ICSI in 1992, a new treatment option became available for couples with severe male subfertility.

As far as we know, the Netherlands are unique in the world for having a national guideline for starting IVF, which considers different diagnostic categories, age of the woman and duration of subfertility. All gynaecologists use the ‘IVF guideline’ (Dutch Society for Obstetrics, Gynaecology, 1998). The IVF guideline is based on prognostic models regarding pregnancy without treatment (Eimers et al., 1994; Collins et al., 1995; Snick et al., 1997) and models regarding pregnancy after IVF (Haan et al., 1991; Templeton et al., 1996; Stolwijk et al., 1996). The IVF models were developed on the basis of retrospectively collected data of selected populations. The largest study thus far was of Templeton et al. They studied factors as female’s age, previous pregnancies, duration and cause of subfertility. Male causes were not included. The IVF guideline has not yet been examined on prospectively gathered data. Additionally, there is a need for an update of the IVF guideline, since the overall IVF success rates have improved, and the models did not include ICSI. To evaluate the IVF guideline, we planned to develop a model that predicts the ongoing pregnancy rate 12 months after the start of IVF or ICSI treatment, using data on patient characteristics and pregnancies. We initiated a study in which we prospectively evaluated the probability of pregnancy in relation to age of the woman, duration of subfertility, previous pregnancy history and different diagnostic categories.
Most fertility studies present the IVF outcome per treatment cycle. However, what really matters for a couple is the outcome of the whole treatment. We will, therefore, notably concentrate on the ongoing pregnancy rate per couple treated, from the moment they start treatment up until 1 year later. For comparison with other studies, we also calculate the pregnancy rate per cycle.

**Materials and Methods**

From January 2002 to until December 2004, a national prospective observational cohort study of IVF-patients was carried out in the Netherlands. In the present paper, we will focus on prognostic factors. All 13 Dutch IVF centres and all 23 IVF transport clinics agreed to participate in the study. In a transport IVF clinic, the couples are treated from the hormonal stimulation up to the ovum pick-up. Subsequently, the couple transports the follicle fluid containing the oocytes to the laboratory of an IVF centre. The laboratory phase including the embryo transfer takes place at the IVF centre.

Two IVF centres and three transport clinics later withdrew from participation, because they were not able to meet the data requirements of the study.

All new couples consulting a gynaecologist in one of the IVF centres or transport clinics were included in the study if they had an indication for IVF (or ICSI) according to the IVF guideline (Dutch Society for Obstetrics, Gynaecology, 1998). Couples were treated according to the centre specific treatment protocols. Only cycles with ‘conventional’ ovarian stimulation with gonadotrophins, combined with pituitary down-regulation through GnRH agonists or GnRH antagonists co-treatment, were included. The results of cycles with frozen embryo transfers were not used because many IVF treatment registries did not enclose this variable.

All IVF clinics are compelled to register their IVF treatments, but there is no central national registry of fertility treatments and the included patient characteristics may differ between clinics.

**Patients**

In the period of study, 9016 new couples with an indication for IVF or ICSI treatment consulted a gynaecologist. The couples that actually started IVF or ICSI were followed, from the date of last menstruation just before the first IVF treatment up until at least 12 months in case no pregnancy occurred. In case of pregnancy, follow-up continued until an ongoing pregnancy was confirmed by ultrasound (>8 weeks). For pregnancies ending in a spontaneous abortion, follow-up continued until an ongoing pregnancy occurred or otherwise at least for 12 months. For 4928 new couples, we were able to do a complete follow-up from the start of IVF or ICSI until at least 1 year. Figure 1 shows the flow diagram from all patients originally included in the study to those used in the analysis.

**Indication**

Whether couples are indicated to start IVF or ICSI treatment according to the IVF guideline depends on the cause and duration of subfertility, and on women’s age. Six diagnostic categories for IVF are considered. When the subfertility is caused by pathology of the tubal function, such as tubal blockage (i) or severe endometriosis (ii), IVF can be offered directly. In case of relative tubal pathology, the subfertility should be at least of 1 or 2 years duration. In case of unexplained subfertility (iii), IVF is only indicated after a duration of subfertility of at least 3 years and should be preceded by intrauterine insemination (IUI). Minimal endometriosis is treated as unexplained subfertility. In case of ovulation disorders, mainly caused by polycystic ovary syndrome (PCOS) (iv), at least 12 cycles of ovulation induction should precede IVF. When there is a disturbance in the interaction between semen and mucus (cervical hostility or immunological subfertility) (v), IVF is offered after a subfertility of at least 2 years and is preceded by IUI. An identical advice applies for mild male oligospermia (vi): if the multiplication of the volume, concentration and motility (VCM) of the semen after analyses is between 1 and 10 million, IVF is offered after at least 2 years of subfertility and unsuccessful IUI. For severe oligospermia (VCM < 1 × 10⁶), there is a direct indication for ICSI. For all diagnostic categories, IVF can be offered 1 or 2 years earlier, if women are over 36 or 38 years.

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**Figure 1:** Flow diagram of all patients included in this study
respectively. There is no upper age limit mentioned, but the guideline advises not to treat women over 40 years of age, because of poor treatment outcome. The guideline for IVF is developed for primary subfertility. One recognises that women with secondary subfertility are somewhat different, but this is not taken into account in the guideline.

Definitions
In case of total fertilization failure, or if only 10% or less of the oocytes are fertilized, IVF treatment may be changed into ICSI in the next cycle. When the first cycle was an IVF cycle, the couple was included in the category ‘IVF’, regardless whether later they changed into ICSI treatment. Primary subfertility indicates that the woman had no pregnancy before. Duration of subfertility is defined as the time between the date of active child wish, or the date of last spontaneous abortion or delivery date, and the date of first IVF. The end-point of the study was ongoing pregnancy, defined as a pregnancy with heartbeat of one or more foetuses confirmed by ultrasound, at 8 weeks gestation. Ongoing twin pregnancy was defined as a pregnancy with heartbeat of two foetuses.

Prognostic variables
Prognostic variables found to be important in previous studies were analysed: women’s age, duration of subfertility, pregnancy history (defined as primary or secondary subfertility of the woman treated) and all diagnostic categories of IVF, being tubal pathology, unexplained subfertility, mild male, hormonal, cervical or immunological subfertility and endometriosis. In addition, ICSI treatment, applied in case of severe oligospermia, was included as a separate category.

Data analyses
We used Kaplan–Meier analysis to estimate the cumulative probability of ongoing pregnancy after IVF or ICSI. If couples dropped out of the IVF programme within 12 months, their follow-up time was allowed to continue until 12 months assuming that they had no chance of pregnancy, so no censoring was applied (Daya, 2005).

In addition, we analysed the cumulative probability of ongoing pregnancy against cycle number. This analysis was done twice, once with the usual censoring of patients who stopped treatment without pregnancy (giving the ‘potential’ cumulative curve) and once with censoring as described above, giving the ‘realistic’ cumulative curve (Stolwijk et al., 2000). In the sequel, we will often drop the adjective ‘cumulative’ for brevity.

Multivariate Cox regression analysis was used to estimate the predictive effect of the following prognostic variables on the probability of ongoing pregnancy: age of the woman, duration of subfertility, diagnostic category and whether the woman’s subfertility was primary or secondary. To check for a non-linearity of the effect of the woman’s age, a restricted cubic spline curve was used (Harrell et al., 1988), with five knots at ages 23, 27, 32, 37 and 42 years.

To assess the internal validity of the resulting prediction model, the bootstrap method was used with 200 replications. The optimism corrected c-statistic was assessed, which is equivalent to the ROC curve (AUC), to measure how well the model is able to make a distinction between pregnant and non-pregnant couples (‘discrimination’). Further, the bootstrap method assesses whether the pregnancy chances predicted by the model are reliable, i.e. whether they agree with the observed proportion of pregnant couples (‘calibration’).

The results of the Cox regression were converted into a ready-to-use score chart that may be used by clinicians to calculate the chance of an ongoing pregnancy within 1 year for a given couple.

Missing data occurred in women’s age (0.7%), duration of subfertility (6.4%), pregnancy history (6.4%), diagnostic category (6.9%), outcome of IVF treatment (pregnant or not) (3.8%) and whether a registered pregnancy was ongoing or not (7.0%). These missing items were imputed to avoid the loss of data in multivariate analysis and to avoid potential bias. For this purpose, single imputation with the AregImpute method in S-plus (MathSoft Inc., Seattle, WA, version 2000) was used.

Results
Table 1 gives the characteristics of the 4928 couples starting IVF or ICSI in one of the 11 IVF centres or 20 transport clinics in the Netherlands, subdivided by diagnostic category. The mean age of the women at the beginning of the treatment was 34.0 years (SD = 4.0) for IVF and 32.6 (SD = 4.2) for ICSI. The mean number of cycles in 12 months was 1.8 for both IVF and ICSI. The overall 1-year ongoing pregnancy rate was estimated to be 44.8% (95% CI 42.1–47.5%) (the upper panel of Fig. 2). The ongoing pregnancy chances for couples who will sustain treatment for four cycles are as high as 63%, whereas the realistic chances after the fourth cycle are only 42% (the lower panel of Fig. 2). In Table 2, univariate results of the effect of patient characteristics on the ongoing and twin pregnancy rates are shown. With increasing female age, both rates decreased significantly. For women under 25, the effect was different. In fact, the relationship between age and pregnancy chance was non-linear (P < 0.001, Fig. 3), with the highest chance at age 30 and a slight decline towards younger and older women up to age 35. After 35, the pregnancy chance sharply decreased. The curve shown in Fig. 3 was calculated for one specific patient profile: women with primary unexplained subfertility with a duration of ≥3 years. The shape of this curve did not depend on the duration of subfertility, pregnancy history and diagnostic category (all tests for interaction had P > 0.05). Thus the level of the curve will differ between patient profiles, but not the shape.

With an increasing duration of subfertility, there was a trend of decreasing pregnancy rate, but no effect on the twin rate. Pregnancy history did neither influence the pregnancy rate nor the twin rate. There were significant differences between the different diagnostic categories: severe oligospermia with ICSI gave the highest pregnancy chances and immunological and tubal pathology the lowest ones.

In Table 3, the results of the multivariable Cox regression model are shown. The impact of woman’s age is presented in Hazard ratios compared with the age 35. For example, a woman of 38 has a 28% lower chance to become pregnant in 1 year IVF-treatment, compared with a woman of 35. Age, duration of subfertility and pregnancy history had a statistically significant effect. The chance of pregnancy did not differ between diagnostic categories for IVF. In case of ICSI, for severe male subfertility couples had a 22% higher ongoing pregnancy chance.

The c-statistic, measuring the discriminative ability of this model, was 0.583 and 0.577 after correction for optimism. Calibration was very good, the correction factor needed to make the model predictions agree with observations was 0.94, i.e. very close to unity (=no correction necessary) (Harrell et al., 1996).
In Fig. 4, a score chart is presented that may be used to calculate the predicted ongoing pregnancy rate for a given couple. For example, a couple with female age of 39 years (11 points), duration of infertility of 4 years (11 points), a regular indication for IVF (0 points) and primary infertility (0 points) has a sum score of 22 points and therefore a prospect of achieving an ongoing pregnancy within a year from start of IVF treatment of 28%, as can be read from the curve. Had the woman instead been 29 years (49 points), the sum score would have been 60 points and the predicted pregnancy chance 50%.

Discussion

This large prospective study on prognostic factors predicting the chance of pregnancy with IVF is the first one, in which all diagnostic categories that are considered in the IVF guideline are studied. The most important predictive factor is women’s age. Duration of subfertility and pregnancy history are also of concern for the couple’s prospect of achieving a pregnancy with IVF or ICSI. Both in univariate and in multivariate analyses, the effects of duration of subfertility, pregnancy history and diagnostic category are modest. Only for women older than 35, pregnancy chances become much lower, and for ICSI, in case of severe oligospermia, chances are higher than for IVF. The chance of pregnancy for other categories is not very different from the chance for tubal pathology, the IVF indication par excellence.

We think that the pregnancy rate with ICSI is not higher because of the technical procedure see also Bhattacharya et al., 2001, but because women selected for ICSI have themselves, in most cases, no factor of subfertility. The ICSI indication is indeed primarily due to the severe fertility problem of their partner. This does not explain the lower twin rate for this group. Presumably, these women more often had elective single embryo transfer; unfortunately, we could not check this in our data.

We emphasize that after 35 the pregnancy rate strongly declines. In this respect, the IVF guideline advises not to treat women over 40 because of poor treatment outcome. However, in our sample, women in the oldest age group (40–45) had a fair 1-year ongoing pregnancy chance of 24%. Probably, women over 40 with positive prospects were selected by pre-screening of the ovarian reserve by ultrasound based antral follicle count and serum basal follicle stimulating hormone (Klinkert et al., 2005).
It seems contradictory that women in the youngest age group (25 years) had lower pregnancy rates than women in the subsequent age group, but Templeton et al. (1996) and Human Fertilization and Embryology Authority data (NICE, 2004) showed a similar trend for live birth rates per cycle for this age group. Despite the relatively small number of patients in this age group, this repeated finding suggests that it may be a real phenomenon, not a chance finding. The relationships between child wish at young age, lower social class and detrimental lifestyle habits such as smoking and overweight may be the reason for the lower pregnancy rate.

The IVF guideline advises on when to start IVF, depending on the diagnostic category. This advice is based on prognostic models for pregnancy chances without treatment (Collins et al., 1995; Snick et al., 1997). For couples with unexplained subfertility, the spontaneous conception rate during the first 3 years of subfertility is substantial (Pandian et al., 2005). Therefore, the advice is to wait at least 3 years before starting IVF treatment. We found that the overall cumulative ongoing pregnancy rate with IVF for couples with unexplained subfertility is comparable with the pregnancy rate of other diagnostic categories, which according to the guideline, can be treated sooner. This means that the differences in duration of subfertility as formulated in the Dutch IVF guideline are probably appropriate.

Whether unexplained subfertility can be seen as a separate diagnosis is under debate (Gleicher and Barad, 2006). It is most likely a mixture of potentially good prognosis couples and women with a low chance to become pregnant, for example, because of imminent premature ovarian failure. It would be ideal if we were able to differentiate for unexplained subfertility, between couples with a fair chance and couples with a low chance of conception without treatment. We would then be able to counsel individually when to start IVF, or maybe sometimes to advise not to start treatment at all.

The fertility treatment history of a patient is also of importance for the overall IVF treatment outcome. Before starting IVF, ovulation induction or ovarian hyperstimulation and/or IUI will be the main treatment options. Only the unsuccessful couples, probably a selection with lower pregnancy chances, are referred for IVF. Regrettably, we do not have data on the treatment history and can only suppose that the patients in our study were referred for IVF according to the IVF guideline and that in case of mild male, hormonal and unexplained subfertility, the conventional treatments had preceded IVF.
We compared our results with those of Templeton et al. (1996). The impact of duration of subfertility was comparable. They found that only after a very long duration of subfertility (>13 years), the impact on the IVF-pregnancy chance is substantial. We did not have couples with such an extreme duration of subfertility. It was difficult to compare the value of pregnancy history. Since we did not have detailed information on the previous pregnancy, we could only distinguish between primary and secondary subfertility. According to Templeton et al. (1996) and Stolwijk et al. (2000), it is of supplementary prognostic value if the previous pregnancy has led to live birth and if this life birth has been due to IVF. Diagnostic categories cannot be compared as Templeton et al. had only tubal pathology in their model.

In the period of our study, the first three IVF treatments were reimbursed by health insurance. Economic reasons for delaying or dropping out of the programme are therefore not plausible. The reason for dropping out is often related to the outcome, although earlier research is contradictory (Roest et al., 1998; De Vries et al., 1999; Smeenk et al., 2004). We assigned a zero probability of pregnancy to couples that discontinue treatment, see Daya (2005). The resulting curve is the one that couples should expect when they start treatment. We named

![Figure 4: Score chart with corresponding curve to calculate the 12-months predicted ongoing pregnancy rate for a patient of a given age, indication, duration and type of infertility](https://academic.oup.com/humrep/article-abstract/22/9/2455/609505/2460)

| Table 3: Multivariate analysis with HRs for ongoing pregnancy with IVF and ICSI |
|-----------------|-------|---------|
| 25              | 0.99  | 0.83–1.18 | <0.0001 |
| 27              | 1.14  | 0.98–1.32 |
| 29              | 1.21  | 1.08–1.35 |
| 31              | 1.20  | 1.14–1.28 |
| 33              | 1.14  | 1.12–1.16 |
| 35              | 1     | 1        |
| 37              | 0.82  | 0.75–0.91 |
| 38              | 0.72  | 0.64–0.80 |
| 39              | 0.58  | 0.51–0.66 |
| 40              | 0.46  | 0.39–0.54 |

Duration of subfertility (per year) 0.97 0.95–0.99 0.01

Primary subfertility 0.90 0.83–0.99 0.03

Diagnostic category 0.11

Tubal pathology 1

Unexplained 1.10 0.95–1.27

Male mild 1.06 0.91–1.24

Male severe (ICSI) 1.22 1.07–1.39

Endometriosis 1.05 0.88–1.26

Hormonal 1.07 0.89–1.30

Immunologic/cervical subfertility 1.04 0.78–1.40

1HRs for age are expressed relative to a reference age of 35 years.

2Tubal pathology was taken as the reference category.
this curve ‘realistic’ instead of ‘pessimistic’ (Stolwijk et al., 2000), as it represents what really happened, and therefore what is relevant for patients. Because patients might also want to have information on the cumulative chances after a given number of cycles, we made a separate curve of the cumulative chances against cycle number, in which dropouts are censored. This curve gives chances that could potentially be realised, given that a patient is able to sustain treatment for that number of cycles. We were not able to correct this curve for informative censoring, so the predicted chances will be too optimistic (Stolwijk et al., 2000).

Life style like smoking, body weight and psychological factors influence the outcome of IVF (Klonoff Cohen, 2005; Lintsen et al., 2005; Smeenk et al., 2001), but are not investigated in this study. Unexpectedly, most registers we received did not include an accurate registration of the cryopreserved embryos. We regret that the lack of the relevant information of pregnancies obtained from frozen embryos could not be included in the model, although according to De Jong et al. (2002), the supplementary pregnancy chances by using cryopreserved supranumerical embryos are of limited size. Five IVF clinics did not deliver their IVF treatment registries. The Dutch society of Obstetricians and Gynaecologists website (www.nvog.nl) reports on the number of IVF and ICSI treatments and the average ongoing pregnancy rate of every IVF centre. These results are not on an individual level and could therefore not be used in our analyses. Using the per centre information, we could conclude that the results of the missing clinics were in the same range as the included clinics and that their dropout, therefore, will not have biased our results.

Over 1000 women were lost to follow-up because of incomplete or sometimes incompatible registration files. To carry out a large prospective study as we did, a national registration of all fertility treatments is ideal. Only compelled uniform registration can overcome the problem of loss.

The advantage of the present study in relation to earlier research is that the analyses were based on complete data with a long follow-up, and that, next to results per cycle, we also analysed the results per woman/couple treated. The pregnancy chances are therefore easier to interpret for counselling. Contrary to others (Dor et al., 1996; Stolwijk et al., 1996; Templeton et al., 1996; Hunault et al., 2002), we studied all causes of subfertility and both IVF and ICSI. A clear description of diagnostic categories and restriction of treatment to couples that comply with the IVF guideline has led to a well-defined group of couples with subfertility.

In the present study, we estimated the predictive value of patient characteristics on pregnancy chances with IVF and ICSI. Female age has an eminent influence on the pregnancy prospect of a couple. The woman’s pregnancy history and the duration of subfertility have a modest but significant effect on the ongoing pregnancy chance. The diagnostic category does not influence the pregnancy chance, except for severe male subfertility treated with ICSI. With these patient characteristics, we developed a prognostic model to predict the cumulative ongoing pregnancy chance within 1 year after the start of treatment.

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