Cumulative Live-Birth Rates after In Vitro Fertilization

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BACKGROUND
Outcomes of in vitro fertilization (IVF) treatment are traditionally reported as pregnancies per IVF cycle. However, a couple’s primary concern is the chance of a live birth over an entire treatment course.

METHODS
We estimated cumulative live-birth rates among patients undergoing their first fresh-embryo, nondonor IVF cycle between 2000 and 2005 at one large center. Couples were followed until either discontinuation of treatment or delivery of a live-born infant. Analyses were stratified according to maternal age and performed with the use of both optimistic and conservative methods. Optimistic methods assumed that patients who did not return for subsequent IVF cycles would have the same chance of a pregnancy resulting in a live birth as patients who continued treatment; conservative methods assumed no live births among patients who did not return.

RESULTS
Among 6164 patients undergoing 14,248 cycles, the cumulative live-birth rate after 6 cycles was 72% (95% confidence interval [CI], 70 to 74) with the optimistic analysis and 51% (95% CI, 49 to 52) with the conservative analysis. Among patients who were younger than 35 years of age, the corresponding rates after six cycles were 86% (95% CI, 83 to 88) and 65% (95% CI, 64 to 67). Among patients who were 40 years of age or older, the corresponding rates were 42% (95% CI, 37 to 47) and 23% (95% CI, 21 to 25). The cumulative live-birth rate decreased with increasing age, and the age-stratified curves (<35 vs. ≥40 years) were significantly different from one another (P<0.001).

CONCLUSIONS
Our results indicate that IVF may largely overcome infertility in younger women, but it does not reverse the age-dependent decline in fertility.
When a couple presents to a physician for a fertility evaluation and requires in vitro fertilization (IVF), their main question is whether this treatment will result in a baby. The statistic commonly quoted to couples is the outcome per cycle according to maternal age. The primary reason for the frequent use of this cross-sectional statistic is the simplicity with which it can be calculated. The national reporting systems in North America, Europe, the Middle East, Australia, and New Zealand are cross-sectional and list IVF outcomes as pregnancies per cycle. However, this statistic has limited value for individual patients because it does not account for the potential need for multiple IVF cycles and the likely difference in success between the first-time patient and one who did not become pregnant in previous attempts. In contrast to cross-sectional reporting, longitudinal analysis makes use of repeated observations from a cohort over time and provides a better estimate of a woman’s history over multiple IVF cycles. The cumulative live-birth rate is used to estimate the outcome of the entire course of treatment.

Studies reported in the literature that estimate the cumulative live-birth rate have many limitations, including small samples and inconsistent inclusion criteria and outcome measures. Previous studies have not included IVF cycles that involve the transfer of frozen embryos and have not reported live-birth rates, including multiple deliveries as the primary outcome. Some studies have calculated cumulative success rates over IVF cycles simply by summing the rates from all cycles or only with the standard Kaplan–Meier method. However, the cumulative live-birth rate may be overestimated with the use of these methods.

We conducted this study to provide accurate, evidence-based estimates of the likelihood that a couple presenting for IVF will have a pregnancy resulting in a live birth. We report the cumulative live-birth rates among more than 6000 patients undergoing multiple IVF cycles (both fresh and frozen) in a single large center.

**Methods**

**Patients**

We performed a retrospective cohort study including all patients undergoing their first fresh-embryo, non-donor IVF cycle during the period from 2000 through 2005 at Boston IVF (Waltham, MA). Patients were followed during treatment at our center for at least 1 year until either discontinuation of treatment or delivery of a live infant. The primary outcome was delivery of one or more live infants in up to six IVF cycles. We believe this represents a reasonable range of cycles, since many patients in Massachusetts have insurance benefits for up to six cycles. Furthermore, there is a marked reduction in success after four to six cycles, and after six cycles the number of patients treated decreases significantly.

All patients without a live birth in an IVF cycle were eligible for the subsequent cycle, including patients with cancelled cycles and those with a pregnancy that did not result in a live birth. The group that did not return for treatment included women who transferred to another IVF center, used oocyte donation or a gestational carrier, or discontinued treatment for any reason.

The study was approved by the institutional review board at Beth Israel Deaconess Medical Center, and the approval allowed for retrospective chart review and anonymous results reporting without informed consent.

**Fresh-Embryo Transfer**

Patients underwent protocols for ovarian stimulation, monitoring, and oocyte retrieval as previously described. Intracytoplasmic sperm injection is the direct injection of sperm into the oocyte to enhance fertilization. Assisted hatching involves the disruption of the zona pellucida before the embryo transfer to potentially enhance implantation. In general, the embryo transfer took place 3 days after the oocyte retrieval. The number of embryos transferred reflected national guidelines, with some variation according to individual patient needs. Cryopreservation was generally performed 3 days after oocyte retrieval and included only embryos that were deemed viable according to morphologic criteria.

**Frozen-Embryo Transfer**

IVF cycles with the use of cryopreserved embryos were performed after priming the uterus with exogenous estradiol (Vivelle-Dot, Novartis, or Estrace, Bristol-Myers Squibb) with or without the down-regulation of gonadotropin-releasing hormone. Luteal-phase support with progesterone was provided as it was in fresh-embryo IVF cycles. Thawed embryos were deemed viable for placement if more
than 50% of the blastomeres and the zona pellucida survived intact. Frozen-embryo–transfer cycles were analyzed as unique treatment events.

DATA COLLECTION
Baseline information included characteristics of the patients and details of each IVF cycle and outcome. Ovarian reserve was assessed by measurement of the follicle-stimulating hormone (FSH) level on day 3 of the menstrual cycle. Pregnancies were confirmed on the basis of increasing levels of β-human chorionic gonadotropin and fetal heartbeat on transvaginal ultrasonography. All pregnancies were followed, and the primary outcome was delivery of one or more live infants, confirmed on the basis of medical records.

STATISTICAL ANALYSIS
All analyses were conducted with the use of SAS software, version 9.1.3 (SAS Institute). The cumulative probability of the first live birth during the study period was estimated with the Kaplan–Meier method, according to the IVF cycle number. When data were stratified, the log-rank test was used to compare survival curves.

We used the Kaplan–Meier method, which censors data for patients who do not return for treatment, to estimate the cumulative live-birth rate and 95% confidence intervals. This method assumes that women who did not return for subsequent IVF cycles had the same chance of a pregnancy resulting in a live birth as those who did return for treatment; we refer to this as the “optimistic” cumulative live-birth rate. Since many women will not return after a poor response to IVF treatment, this method may overestimate the cumulative live-birth rate. Therefore, we also present the “conservative” cumulative live-birth rate, calculated with the assumption that patients who did not return for subsequent IVF treatment had no chance of a pregnancy resulting in a live birth. Our population’s cumulative live-birth rate probably lies between these estimates.

To evaluate the potential fertility of women who did not return for treatment, we used a t-test or the Mann–Whitney U test, as appropriate, to compare the characteristics of these women with the characteristics of those who returned for treatment. A two-sided P value of less than 0.05 was considered to indicate statistical significance.

For the Kaplan–Meier analysis of data stratified according to age, cohorts were constructed according to the following maternal age groups at the start of cycle 1: younger than 35 years, 35 to younger than 38 years, 38 to younger than 40 years, and 40 years or older. These age strata are similar to those used by the Centers for Disease Control and Prevention and the Society for Assisted Reproductive Technology.

RESULTS
CHARACTERISTICS OF THE PATIENTS
Our cohort included 6164 patients who underwent a total of 14,248 IVF cycles during the study period. Baseline characteristics of the patients at the start of cycle 1 are summarized in Table 1. Clinical characteristics according to the cycle are shown in Table 2. The patients underwent a maximum of 10 cycles and a mean (±SD) of 2.3±1.5 cycles; however, we limited our analysis to 6 IVF cycles.

Table 2 also shows the percentage of cycles that involved intracytoplasmic sperm injection, assisted

| Table 1. Characteristics of the 6164 Women at the Start of Cycle 1.※ |
|-------------------------|-------------------|
| Characteristic          | Value             |
| Age                     |                   |
| Mean — yr               | 35.8±4.7          |
| <35 yr — no. (%)        | 2678 (43.4)       |
| 35 to <38 yr — no. (%)  | 1360 (22.1)       |
| 38 to <40 yr — no. (%)  | 836 (13.6)        |
| ≥40 yr — no. (%)        | 1290 (20.9)       |
| Body-mass index†        | 25.1±4.9          |
| Gravidity — no. (%)     |                   |
| 0                       | 3077 (49.9)       |
| 1                       | 1499 (24.3)       |
| ≥2                      | 1456 (23.6)       |
| Unknown                 | 132 (2.1)         |
| Parity — no. (%)        |                   |
| 0                       | 4466 (72.5)       |
| 1                       | 1137 (18.4)       |
| ≥2                      | 334 (5.4)         |
| Unknown                 | 227 (3.7)         |
| FSH, day 3 of menstrual cycle — mlU/liter‡ | 7.1±3.4 |

※ Plus–minus values are means ±SD. Percentages may not sum to 100 because of rounding.
† The body-mass index is the weight in kilograms divided by the square of the height in meters.
‡ The follicle-stimulating hormone (FSH) level on day 3 of the menstrual cycle is a marker of ovarian reserve.
hatching, and fresh-embryo rather than frozen-embryo transfer. The use of intracytoplasmic sperm injection and assisted hatching increased with subsequent cycles, whereas the percentage of cycles involving frozen-embryo transfer remained stable.

**CYCLE OUTCOME**

Table 3 shows the number of women undergoing oocyte retrieval and embryo transfer, as well as pregnancy and live-birth rates, among the 6164 women presenting for their first fresh-embryo IVF cycle. The data for subsequent cycles are reported for patients who returned to our center. Table 3 also shows the singleton, twin, and triplet deliveries in our population. Of the 3126 live births in our cohort, 70.9% involved singletons, 27.3% twins, and 1.7% triplets. There were no multiple births beyond triplets in this population. Of the eight patients who had four fetal heartbeats (quadruplets) on the first prenatal ultrasound study, seven delivered twins and one lost the pregnancy.

**OVERALL CUMULATIVE LIVE-BIRTH RATE**

Figure 1 shows the optimistic and conservative cumulative live-birth rates. After three IVF cycles, the conservative cumulative live-birth rate was 45% (95% confidence interval [CI], 44 to 46) and the optimistic rate was 53% (95% CI, 51 to 54). After six cycles, the conservative and optimistic cumulative live-birth rates were 51% (95% CI, 49 to 52) and 72% (95% CI, 70 to 74), respectively.

**CUMULATIVE LIVE-BIRTH RATE ACCORDING TO AGE**

The optimistic and conservative cumulative live-birth rates calculated according to maternal age at the start of cycle 1 are shown in Figure 2. Among patients younger than 35 years of age, the optimistic cumulative live-birth rate after six IVF cycles was 86% (95% CI, 83 to 88) and the conservative estimate was 65% (95% CI, 64 to 67). Both the optimistic and conservative cumulative live-birth rates decreased with increasing age, and the age-specific rates were significantly different from one another (P<0.001).

**PATIENTS WHO DID NOT RETURN FOR TREATMENT**

To assess the validity of our estimates, we compared patients who did not return for the next IVF cycle with patients who did. Women who did not return for cycles 2 through 4 tended to have poorer potential for fertility due to their older age, higher levels of FSH on day 3 of the menstrual cycle and higher gonadotropin doses received, lower peak estradiol levels, and fewer oocytes retrieved and embryos frozen, as compared with the women who did return for a subsequent cycle. On average, women who did not return for treatment had had

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**Table 2. Clinical Characteristics According to IVF Cycle.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
<th>Cycle 4</th>
<th>Cycle 5</th>
<th>Cycle 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall cohort — no./total no. (%) †</td>
<td>6164/6164 (100.0)</td>
<td>3837/4653 (82.5)</td>
<td>2228/3053 (73.0)</td>
<td>1170/1753 (66.7)</td>
<td>573/949 (60.4)</td>
<td>276/474 (58.2)</td>
</tr>
<tr>
<td>Type of cycle — %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fresh-embryo</td>
<td>100.0</td>
<td>83.2</td>
<td>84.9</td>
<td>86.5</td>
<td>85.9</td>
<td>84.1</td>
</tr>
<tr>
<td>ICSI‡</td>
<td>23.4</td>
<td>34.4</td>
<td>36.5</td>
<td>39.4</td>
<td>39.4</td>
<td>44.4</td>
</tr>
<tr>
<td>AH‡</td>
<td>2.6</td>
<td>8.2</td>
<td>16.5</td>
<td>30.8</td>
<td>34.6</td>
<td>40.5</td>
</tr>
<tr>
<td>Total dose of gonadotropin — IU‡</td>
<td>2762±1497</td>
<td>3447±1738</td>
<td>3595±1736</td>
<td>3821±1808</td>
<td>4047±1840</td>
<td>3735±1974</td>
</tr>
<tr>
<td>Peak estradiol level — pg/ml‡</td>
<td>1408±1105</td>
<td>1229±966</td>
<td>1271±1015</td>
<td>1330±1155</td>
<td>1256±1042</td>
<td>1236±1008</td>
</tr>
<tr>
<td>Oocytes retrieved — no.‡</td>
<td>9.9±6.2</td>
<td>9.0±5.4</td>
<td>9.4±5.7</td>
<td>9.6±5.9</td>
<td>9.5±5.9</td>
<td>9.5±6.2</td>
</tr>
<tr>
<td>Embryos cryopreserved — no.‡</td>
<td>1.3±2.4</td>
<td>0.8±1.8</td>
<td>0.8±1.8</td>
<td>0.8±1.9</td>
<td>0.8±2.1</td>
<td>0.5±1.2</td>
</tr>
<tr>
<td>Embryos transferred — no.§</td>
<td>2.3±1.1</td>
<td>2.4±1.2</td>
<td>2.6±1.3</td>
<td>2.7±1.4</td>
<td>2.7±1.5</td>
<td>2.8±1.6</td>
</tr>
</tbody>
</table>

* Plus–minus values are means ±SD. AH denotes assisted hatching of embryos before transfer, and ICSI intracytoplasmic sperm injection. To convert the values for estradiol to picomoles per liter, multiply by 3.671.
† The denominator is the number of women eligible to return for that IVF cycle (the number of women in the previous cycle minus the number of women with a pregnancy resulting in a live birth).
‡ These data were calculated only for fresh-embryo IVF cycles.
§ These data were calculated for all IVF cycles (both fresh-embryo and frozen-embryo cycles).
more pregnancies and had more children before their first IVF cycle. For cycles 2, 3, and 4, all these differences were significant (P<0.05), with the exception of the FSH level in cycle 4 (P = 0.17). (See the table in the Supplementary Appendix, available with the full text of this article at NEJM.org.) The population of women who did not return for treatment included patients who pursued treatment with the use of donor oocytes or a gestational carrier. Seven percent of our population proceeded to this form of treatment at our center.

Discussion

The cumulative live-birth rate in our population of more than 6000 patients undergoing up to six cycles of IVF was between 51% and 72%. The higher (optimistic) estimate of the cumulative live-birth rate, which assumed that women who did not return for subsequent IVF cycles had the same chance of a pregnancy resulting in a live birth as those who remained in treatment, was probably an overestimate. Like other investigators, we found that women who did not return for treatment had a poorer prognosis than those who did return.2,7,18 However, the conservative estimate, which assumed that the live-birth rate in the population of women who did not return for treatment was zero, was probably overly pessimistic. Even with a poorer prognosis, patients may have become pregnant without IVF treatment, at another IVF center, or with the use of donor oocytes, or they may have had a child with a gestational carrier. Thus, the true cumulative live-birth rate in our population was probably between the conservative and optimistic estimates.

There is a natural decline in fertility with age, both in the general population19 and in the population with decreased fertility,17 and our age-stratified cumulative live-birth rates decreased with increasing age. Our cumulative live-birth rates among women 39 years of age or younger who were treated with up to six cycles of IVF appeared to be similar to or higher than those reported in the general population20-22; this suggests that IVF overcomes infertility in younger women. However, women 40 years of age or older should be informed that IVF does not completely reverse the age-dependent decrease in fertility.

Age is an important factor to consider in counseling women before IVF treatment; however, the available literature is limited to studies that have not reported age2 or have reported outcomes only for a subgroup of the population.1,3,4,6,9 In the few studies that report results stratified according to age, the numbers are too small in the subgroups of older women and those with multiple IVF cycles to draw meaningful conclusions.3,10 In our study, there was a large number of patients in each age group through six IVF cycles, and we report specific cumulative live-birth rates that can be used to counsel patients of any age.

Previous studies have also been limited by small samples,5,8 the use of pregnancy (rather than live birth) as the primary outcome,5,7,9,13 and the failure to report multiple births.1,3,5,11 In addition,
Figure 1. Kaplan–Meier Curves for Optimistic and Conservative Cumulative Live-Birth Rates among 6164 Women.

The optimistic cumulative live-birth rate is based on the assumption that patients who did not return for treatment had the same chance of a pregnancy resulting in a live birth as those who remained in treatment. The conservative cumulative live-birth rate assumes that patients who did not return for treatment did not have a pregnancy resulting in a live birth. These two curves show the best-case and worst-case estimates of the cumulative live-birth rate in the study population.

since some studies have been performed outside the United States, the findings may not reflect the chance of success in a U.S. population. The earliest studies to report cumulative live-birth rates were performed more than a decade ago and reflect outcomes before the widespread use of intracytoplasmic sperm injection. The previous studies used life-table analysis to calculate the cumulative live-birth rate without taking into account the possibility that live-birth rates were lower among patients who discontinued treatment than among those who remained in treatment; thus, they probably overestimated this rate.

Several investigators have sought to account for this potential overestimation. A recent study reported rates of realized and potential pregnancy; however, the authors did not evaluate live-birth rates and did not include frozen-embryo–transfer cycles. Two studies reported optimistic, realistic, and pessimistic cumulative rates; yet neither study defined the patient groups or the estimated pregnancy or live-birth rate used in the analysis. Although we observed that patients who discontinued treatment at our center had a poorer prognosis than those who continued treatment, we lacked information to make valid assumptions about their live-birth rate. We therefore report the optimistic and conservative curves to allow physicians to accurately present the best-case and worst-case cumulative live-birth rates to patients.

Although our focus is cumulative rates, per-cycle comparisons with 2005 national data indicate that the average patient age and percentage of fresh-embryo cycles in our study are similar to the national average, whereas our rates of pregnancy and live births per cycle are slightly lower. Approximately one quarter of IVF deliveries at our center result in twins, and we have a very low percentage of triplet births; our rate of multiple deliveries is lower than both the national average and the results of the study conducted by Witsenburg et al., which, to our knowledge, is the only other study to report multiple cumulative live-birth rates. Our lower pregnancy, live-birth, and multiple-delivery rates per cycle may have been influenced by insurance coverage for infertility care in Massachusetts; this coverage encourages the transfer of fewer embryos. The number of embryos transferred has decreased both over the period of our study and since the 2005 national statistics were published. Furthermore, single-embryo transfer, highlighted in the most recent national guidelines, may reduce the rate of multiple live births without compromising the cumulative live-birth rate when consecutive fresh and frozen single-embryo transfer is used.

Previous studies have either excluded frozen-embryo–transfer cycles from the cumulative live-birth rate or included the outcome with the corresponding fresh-embryo cycle. With advances in embryo cryopreservation, live-birth rates associated with frozen-embryo cycles have nearly doubled over the past decade. Although a frozen-embryo–transfer cycle does not involve intensive
hormonal treatment or oocyte retrieval, as in a fresh-embryo IVF cycle, it still involves a substantial commitment from the patient’s perspective. Therefore, frozen-embryo–transfer cycles warrant inclusion as well as separate consideration in estimating cumulative live-birth rates.

Among the women who did not become pregnant or who had a pregnancy that did not result in a live birth, less than 10% returned to our center for six IVF cycles. This rate is similar to the high dropout rate reported elsewhere and highlights the physical, emotional, and financial strain of IVF. Financial constraints were probably mitigated in our study, since it was performed in Massachusetts, where most patients with health insurance have fertility benefits. In states with full insurance coverage of infertility treatment, as in Massachusetts, the use of IVF is greater than it is in states without such coverage. Our results may more accurately reflect the potential effec-

Figure 2. Cumulative Live-Birth Rates Stratified According to Maternal Age at the Start of Cycle 1.
Panel A shows the optimistic cumulative live-birth rates stratified according to age. These rates are based on the assumption that patients who did not return for treatment had the same chance of a pregnancy resulting in a live birth as those who remained in treatment. Panel B shows the conservative cumulative live-birth rates stratified according to age. These rates are based on the assumption that patients who did not return for subsequent IVF cycles had no chance of a pregnancy resulting in a live birth. In both panels, the age-stratified curves are significantly different from one another (P<0.001). These optimistic and conservative rates reflect the best-case and worst-case estimates, respectively, of the cumulative live-birth rate for each age group in the population.
tiveness of IVF treatment for patients whose deci-
sions are influenced by factors other than fi-
nancial limitations.

We did not classify patients according to the
cause or causes of infertility; however, other stud-
ies have shown that the cumulative live-birth rate
does not vary substantively with the indication for
IVF. 2-3,7 We also did not exclude women on the
basis of age, results of ovarian-reserve testing, or
other prognostic factors. The inclusion of all pa-
tients presenting for their first IVF cycle and un-
dergoing all combinations of treatment increases
the generalizability of our results.

Our goal was to calculate a meaningful cumu-
lative live-birth rate to answer a couple’s primary
question — what is the chance that IVF will re-
sult in a baby? These age-specific optimistic and
conservative cumulative live-birth rates can facil-
itate individualized counseling in a large popula-
tion of patients considering IVF treatment.

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