

# The Effect of Patient and Semen Characteristics on Live Birth Rates Following Intrauterine Insemination: A Retrospective Study<sup>1</sup>

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**Purpose:** To identify characteristics of female patients and of semen that were associated with live birth following intrauterine insemination (IUI).

**Methods:** Retrospective review of medical and laboratory results from 533 women who underwent IUI with partner's sperm from 1993 through 1995.

**Results:** Among 1728 cycles, 116 (6.7%) resulted in live deliveries. Among the 38 patient and semen variables analyzed, only 3 were associated with successful IUI outcome: female age <37.7 years at the time of treatment ( $P = 0.02$ ); the absence of any corrective pelvic surgery ( $P < 0.001$ ); and postwash sperm motility ( $P = 0.006$ ). Couples with none of these three risk factors achieved per-cycle pregnancy rates of 12.4%. Women with two risk factors (age and pelvic surgery) achieved per-cycle pregnancy rates of 4.6% when sperm had good postwash motility. No pregnancies were achieved when low postwash motility was combined with any other risk factor.

**Conclusions:** Advanced female age, poor postwash sperm motility, and a history of corrective pelvic surgery are significant risk factors for poor IUI success rates. Poor postwash

sperm motility in combination with either of these other two risk factors resulted in no successful pregnancies.

**KEY WORDS:** infertility—male; infertility—female; insemination—artificial; sperm motility; pregnancy rate.

## INTRODUCTION

Intrauterine insemination (IUI) with the husband's sperm is commonly employed in the treatment of infertile couples. Intrauterine insemination has been advocated for both female and male infertility (1), as well as unexplained infertility (2,3). In counseling patients, it is useful to be able to predict the likelihood that a therapy will succeed. But as yet, this cannot be done accurately for IUI. Some studies have examined the influence of various characteristics of women patients on success of IUI, while other authors have examined the influence of semen quality (4–10). To date, few large studies have assessed both patient and semen characteristics in predicting IUI outcomes.

We studied a large group of couples who had undergone IUI to determine which pretreatment patient and semen characteristics significantly affected treatment outcomes. In the women, these variables included age, body mass index, menstrual and reproductive history, and whether a diagnosis of male factor infertility has been made. The semen characteristics included ejaculatory volume, prewash and postwash motion characteristics and sperm count, and number of leukocytes. Altogether, 38 variables were considered as potential risk factors.

The purpose of our study therefore was to help clinicians predict IUI outcomes based on factors that can be assessed during preliminary patient evaluations. The accompanying article addresses the value of ovulatory stimulation in the same group of patients.

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## MATERIALS AND METHODS

### Study Design

This study was approved by the Institutional Review Board. In this retrospective study, we reviewed the medical records of women who underwent IUI at the Cleveland Clinic Foundation between January 1993 through December 1995. These were the first 3 years during which data collection at our institution was standardized for the variables under investigation. Records of 533 women who had undergone 1728 IUI cycles using sperm from their partners were reviewed. Patients were excluded based on the lack of sufficient clinical pre- or posttreatment data.

### Patient Evaluation

Each patient's records included the pretreatment history and physical examination as well as the results of each cycle of IUI. As part of the pretreatment physical, the woman's age and body mass index were recorded. If a diagnosis of male factor infertility had been made, it was also recorded. A menstrual disorder was diagnosed if menstrual cycle duration was longer than 35 days or shorter than 21 days, or when the duration of menstrual flow was longer than 7 days. The presence and severity of dysmenorrhea was assessed by patient descriptions, and dysmenorrhea was graded as absent, mild, moderate, or severe. The history of contraceptive use and the type of contraception were detailed. The fertility history of both members of the couple was obtained. Any history of laparoscopy or open pelvic surgery was recorded, and surgical findings and treatments were reviewed. Pelvic examinations were performed on all patients. Hysterosalpingograms and endometrial biopsies were performed when indicated. Ovulatory disorders were identified and treated before IUI was attempted. When indicated, laparoscopy was performed, and corrective pelvic surgery was performed by laparoscopic or open surgical procedures when it was clinically appropriate. Corrective pelvic surgery procedures included laparoscopic adhesiolysis and ablation of endometrial implants.

### Sperm Preparation

Semen specimens obtained by masturbation after 2 to 3 days of sexual abstinence were examined following liquefaction. Both manual and computer-assisted semen analyses were performed. Complex sperm

motion parameters were assessed using a computer-assisted semen analyzer (Motion Analysis VP-50, Motion Analysis Corporation, Santa Rosa, CA). Endtz tests (myeloperoxidase staining) were performed to identify granulocytes in all specimens in which round cell concentrations exceeded  $1 \times 10^6/\text{ml}$  (1).

Specimens were prepared using PerWash (Irvine Scientific, Santa Ana, CA), a suspension of coated silica particles used to prepare a density gradient for centrifugation. Three-milliliter aliquots of liquefied semen were placed on the upper phase of bilayered PerWash in a sterile conical centrifuge tube. Specimens were centrifuged for 20 min at  $600 \times g$  in an International Equipment company 5000 centrifuge. Supernatant was then removed from the level directly below the second layer. Two to three milliliters of human tubal fluid (Irvine Scientific, Santa Ana, CA) was then added and the pellet resuspended. The specimen was then centrifuged for 7 min at  $600 \times g$ , and the supernatant was again removed. The final pellet was resuspended in 0.4 ml of human tubal fluid. Postwash analysis by the computer-assisted semen analyzer was performed on a small, well-mixed aliquot of the specimen. A repeat manual analysis along with an Endtz test was performed on all specimens that had more than  $1 \times 10^6$  round cells on prewash analysis.

Before the semen preparation, the following characteristics were recorded: ejaculate volume, sperm concentration, total sperm count, numbers of leukocytes, and six types of sperm motion characteristics: motility, straight-line velocity, curvilinear velocity, average path velocity, linearity, and amplitude of lateral head displacement. After the sperm washing, the following measurements were made: sperm count, final volume, and the six sperm motion characteristics.

### Insemination Procedures

Intrauterine insemination was performed using a simple catheter, with the patient in lithotomy position. Single insemination procedures were performed in 1709 cycles of IUI and two inseminations were performed on successive days in 19 cycles.

### Statistical Analysis

Logistic regression using generalized estimating equations was used to assess clinical characteristics and their relationship to pregnancy. Cycles of IUI that failed to result in pregnancy or that resulted in spontaneous abortions were considered unsuccessful. Initially, each variable was analyzed independently to determine its

relationship to success rates. All variables from these univariate analyses with significance of  $P < 0.10$  were included in a stepwise multivariate analysis that identified all variables with  $P < 0.05$ . Another pass through all the variables was then performed, including each of the 38 variables in the multivariate model. This process was continued until all the variables that were not in the final model had significance levels of  $P > 0.05$  when added to the model. Interactions of the variables in the final model then were assessed for significance. Odds ratios, their 95% confidence intervals, and logistic regression estimates of success rates were computed for each significant variable, while all the others were held constant. Although analyzed as continuous variables, age and motility classifications were utilized to illustrate trends for discrete groups. Success rates were examined across the ranges of age and sex to determine significant cut-points. Life tables were constructed for the entire sample and for subsets with significant risk factors. Kaplan–Meier methods were used to calculate cumulative pregnancy rates. Summary statistics are presented as mean  $\pm$  standard error. Calculations were performed with SAS version 6.12 (SAS Institute, Cary, NC).

## RESULTS

The 533 women underwent a total of 1728 cycles, averaging  $3.2 \pm 0.1$  cycles per patient. Of the 1728 cycles, 116 (6.4%) resulted in live births (an additional 42 or 2.4% of cycles resulted in pregnancy ending in spontaneous abortion). Of the 533 women, 141 (26.5%) had at least one pregnancy and 111 (20.8%) eventually had a successful delivery resulting from IUI, including five with more than one successful pregnancy. Life table analysis and Kaplan–Meier estimates (Table I) were based on 1695 cycles prior to each woman's first IUI successful pregnancy (therefore, excluding 33 cycles performed with women with one successful IUI pregnancy already achieved). During the first nine cycles, the success rate remained relatively stable (4.3–9.5%).

The majority of the variables examined had no significant effect on birth rates in multivariate analyses. The analysis of the clinical characteristics of the women is summarized in Table II and that of the semen characteristics in Table III. Three variables were significantly related to IUI outcomes: the woman's age at the time of the IUI treatment cycle ( $P = 0.02$ ), a history of corrective pelvic surgery ( $P < 0.001$ ), and postwash sperm motility ( $P = 0.006$ ), as summarized in Tables II and III. Examination of these variables

indicated that increasing female age reduced the IUI success rate, as did decreasing postwash motility percentage. In addition, a history of pelvic surgery also correlated with lower IUI success rates. No interactions between these three risk factors were statistically significant. To illustrate significant trends, women were classified as above or below the median age (37.7 years), and postwash sperm motility was classified as above and below 40%. Examination of these two risk factors indicated that the influence of age was a consistent increase; therefore, the median was chosen as a cutoff. In contrast, examination of success rates over percentiles of the distribution of motility indicated a sharp decline in success below 40%.

Per-cycle success (birth) rates taking all three significant factors into account are shown in Fig. 1. Patients with multiple risk factors had lower pregnancy rates than those with one or no risk factors. Couples without any risk-factors achieved per-cycle pregnancy rates of 12.4%. Per-cycle pregnancy rates were 8.1% for women over 37.7 with no other risk factors, 5.3% for women who had pelvic surgery and no other risk factors, and 2.0% for couples with poor postwash sperm motility and no other risk factors. Women over age 37.7 with pelvic surgery had pregnancy rates of 4.6%. No pregnancies were achieved when sperm had low postwash motility and the woman had either or both of the other two risk factors. Only one pregnancy was achieved with sperm having a postwash motility lower than 40%, and in that case the postwash motility was 39%. A multiple logistic regression model predicting full-term pregnancy rate and based on the woman's age, the postwash motility of the sperm, and the woman's history of pelvic surgery is shown in Table IV, and is graphically depicted in Fig. 2.

## DISCUSSION

This study identifies three pretreatment variables that are significant risk factors for IUI failure. Poor sperm motility after therapeutic semen wash was associated with poor success rates with IUI. Older women had lower pregnancy rates with IUI, a finding consistent with those of other studies. Anatomic pelvic abnormalities for which surgical correction had been attempted, regardless of the postoperative results, also conferred a greater likelihood of failure with IUI.

Our finding that inseminated sperm dose (total inseminated sperm count) did not correlate with pregnancy rates is supported by Cressman *et al.* (12), who found no significant relationship between sperm dose and preg-

**Table I.** Life Table Showing Pregnancies Among 533 Women Undergoing Intrauterine Insemination

Cycle (n)	Patients who dropped out without a live birth (n)	Full-term pregnancies (n)	Patients in this cycle (n)	Term pregnancy rate/cycle (% SE)	Cumulative term pregnancy rate <sup>a</sup> (% SE)	Kaplan–Meier cumulative pregnancy rate <sup>b</sup> (% SE)
1		40	533	7.5 (1.1)	7.5 (1.1)	7.5 (1.1)
2	110	25	383	6.5 (1.3)	12.2 (1.5)	13.5 (1.6)
3	95	12	263	4.6 (1.4)	14.4 (1.6)	17.5 (1.9)
4	80	12	171	7.0 (2.1)	16.7 (1.7)	23.3 (2.4)
5	44	5	115	4.3 (2.1)	17.6 (1.7)	26.6 (2.7)
6	20	8	90	8.9 (3.3)	19.1 (1.8)	33.1 (3.3)
7	23	4	59	6.8 (3.7)	19.9 (1.8)	37.7 (3.8)
8	17	2	38	5.3 (4.4)	20.3 (1.8)	41.0 (4.2)
9	15	2	21	9.5 (7.5)	20.6 (1.8)	46.6 (5.4)
10	10	0	9	0.0 (8.6)	20.6 (1.8)	46.6 (5.4)
11	4	0	5	0.0 (13.3)	20.6 (1.8)	46.6 (5.4)
12	0	1	5	20.0 (18.1)	20.8 (1.8)	57.3 (10.5)
13	1	0	3	0.0 (18.1)	20.8 (1.8)	57.3 (10.5)
Total		111	1695			

<sup>a</sup> Total full-term pregnancies achieved to this point divided by 533 patients.

<sup>b</sup> [(Term pregnancy rate for each cycle × number of patients not yet pregnant] + previous pregnancies)/533 patients.

nancy rate when analyzing 1761 cycles of IUI. Campana and colleagues (10) have reported that sperm quality is one of the most important predictors of successful IUI. In contradistinction to their findings, however, ours show that the inseminated number of motile spermatozoa (total motile sperm) was not significantly correlated with pregnancy rates, but rather the percentage of sperm that were motile after washing was significant.

The age at which the woman presents for assisted reproduction is beyond the physicians control, as is her history of pelvic surgery. Of the three risk factors we have identified, only sperm motility might be able to be improved at the fertility clinic.

Poor postwash semen motility may be indicative of a correctable condition in the man such as varicocele, partial ductal obstruction, exposure to toxins, anti-

**Table II.** Characteristics of Women with Successful and Unsuccessful Intrauterine Insemination

Variable	Evaluable patients/cycles (n)	Patients with live births (mean ± SE)	Patients without live births (mean ± SE)	P <sup>a</sup>
Age at IUI cycle (yr)	524/1707	36.8 ± 0.4	37.8 ± 0.1	0.02
Body mass index	510/1656	25.9 ± 0.6	24.6 ± 0.1	0.06
Primary infertility diagnosis	532/1724	57.8%	59.5%	0.65
Male infertility diagnosis	533/1728	19.5%	19%	0.66
Ovulatory dysfunction	533/1728	27.6%	18.2%	0.06
Cycle duration normal (%)	514/1653	69.9%	61.5%	0.18
Dysmenorrhea severity <sup>b</sup>	282/942	0.63 ± 0.11	0.74 ± 0.03	0.61
Flow volume (% of normal)	476/1559	94.9%	96.9%	0.34
Prior contraceptive use	465/1540	81.0%	75.7%	0.25
History of laparoscopy	533/1728	41.4%	61.0%	0.14
Endometriosis grade <sup>c</sup>	350/1239	0.81 ± 0.12	0.90 ± 0.03	0.82
History of corrective pelvic surgery	514/1663	39.0%	58.6%	<0.001
Abnormal endometrial biopsy	526/1709	11.4%	13.4%	0.75
Abnormal hysterosalpingogram	529/1717	13.0%	15.2%	0.86
Previous pregnancies (n)	526/1709	0.61 ± 0.07	0.72 ± 0.03	0.48
Previous full-term pregnancies (n)	523/1703	0.33 ± 0.05	0.26 ± 0.01	0.28
Prior abortions or miscarriages (n)	524/1704	0.4 ± 0.1	0.5 ± 0.02	0.56
Age at menarche (yr)	353/1167	12.8 ± 0.2	12.8 ± 0.05	0.99

<sup>a</sup> Results from multivariate analyses when all significant variables are included.

<sup>b</sup> Dysmenorrhea severity scale: None = 0, Mild = 1, Moderate = 2, Severe = 3.

<sup>c</sup> Endometriosis grade: None = 0, Stage 1 = 1, Stage 2 = 2, Stage 3 = 3, Stage 4 = 4.

**Table III.** Semen Characteristics in Successful and Unsuccessful Intrauterine Insemination Attempts

Variable	Evaluable patients/cycles ( <i>n</i> )	Patients with live births (mean ± SE)	Patients without live births (mean ± SE)	<i>P</i> <sup>a</sup>
Ejaculate volume (ml)	533/1725	3.2 ± 0.2	3.4 ± 0.1	0.78
Concentration (10 <sup>6</sup> /ml)	533/1725	54.5 ± 4.8	53.8 ± 1.3	0.93
Pre-wash characteristics				
Total count (10 <sup>6</sup> )	533/1723	151.6 ± 16.4	136.0 ± 3.4	0.45
Motility (%)	533/1722	56.1 ± 1.9	53.8 ± 0.1	0.62
Leukocytes (10 <sup>6</sup> )	356/924	0.38 ± 0.10	0.55 ± 0.07	0.41
Leukocyte count (>1 × 10 <sup>6</sup> /ml)	356/924	7.8%	10.6%	0.56
Straight-line velocity (μm/sec)	530/1665	18.8 ± 0.7	17.4 ± 0.2	0.24
Curvilinear velocity (μm/sec)	530/1665	44.4 ± 1.6	41.6 ± 0.5	0.25
Average path velocity (μm/sec)	399/1136	25.9 ± 1.1	23.3 ± 0.3	0.08
Linearity (%)	530/1668	42.9 ± 1.0	43.3 ± 0.2	0.57
Amplitude of lateral head movement (μm/sec)	530/1668	2.7 ± 0.1	2.5 ± 0.03	0.44
Postwash characteristics				
Total count (10 <sup>6</sup> )	532/1723	35.4 ± 4.4	36.8 ± 1.3	0.30
Total motile sperm (10 <sup>6</sup> )	532/1723	29.9 ± 4.2	29.2 ± 1.0	0.38
Final insemination volume (ml)	530/1721	0.53 ± 0.01	0.59 ± 0.04	0.20
Motility (%)	532/1722	79.3 ± 1.4	74.6 ± 0.6	0.006
Straight-line velocity (μm/sec)	524/1639	25.7 ± 0.9	25.3 ± 0.3	0.46
Curvilinear velocity (μm/sec)	524/1639	75.3 ± 1.5	74.1 ± 0.4	0.91
Average path velocity (μm/sec)	394/1114	40.8 ± 1.4	39.8 ± 0.4	0.90
Linearity (%)	524/1641	34.7 ± 1.2	33.7 ± 0.3	0.80
Amplitude of lateral head displacement (μm/sec)	524/1641	3.08 ± 0.09	3.00 ± 0.03	0.95

<sup>a</sup> Results from multivariate analyses when all significant variables are included.

sperm antibodies, or infections. Treating the man may improve semen quality; treatments that improve the postwash sperm motility might be expected to improve the IUI success rates. Therefore, the male partner should be examined whenever postwash sperm motility is poor, and if indicated he should be treated. Also, semen-processing techniques can improve postwash motility by removing nonmotile and poorly motile spermatozoa. Exogenous motility stimulants, such as pentoxifylline, may also be of benefit in therapeutic semen processing (13).

The importance of postwash sperm motility raises other issues as well. First, it means that diagnostic sperm washing may help clinicians select the most effective assisted reproduction therapy. Second, it suggests that improved sperm-processing techniques might increase pregnancy rates for couples in whom poor postwash motility is the only risk factor. During the 3 years of this study, a density-gradient sperm wash technique using Percoll was employed in our clinical laboratory. With the withdrawal of Percoll from the market last year, it has become necessary to use other products. Recent studies in our laboratory have found that the ISolate density gradient (Irvine Scientific, Santa Ana, CA) provides similar sperm quality as Percoll-based gradients. ISolate is a sterile colloidal suspension of silica particles stabilized with covalently

bound hydrophilic silane in a HEPES-buffered human tubal fluid medium.

Any history of attempted corrective pelvic surgical therapy was correlated with worse outcomes in our patients. We did not have any patients with significant pelvic abnormalities for which some form of surgical correction had not been attempted, and therefore we were unable to compare patients undergoing attempted surgical correction with those in whom anatomic abnormalities were identified but not treated. Hence, we cannot determine whether it was the anatomic pelvic abnormality, the corrective pelvic surgery, or the combination of these two factors that resulted in worse IUI outcomes. Although we do not discount the likelihood that these patients' IUI outcomes may have been improved by their corrective pelvic procedures, it was not the purpose of this study to assess this issue.

In cases where the woman is relatively old, our bias is to attempt IUI immediately. However, using the results in this paper, we feel that it is possible to quickly assess each patient's likelihood of achieving pregnancy with IUI. Although these data have yet to be borne out prospectively, we believe that they will prove to be highly predictive. Based on the results of this study, we have modified our treatment recommendations: When poor postwash sperm motility is combined with another risk factor (the woman's age or history of

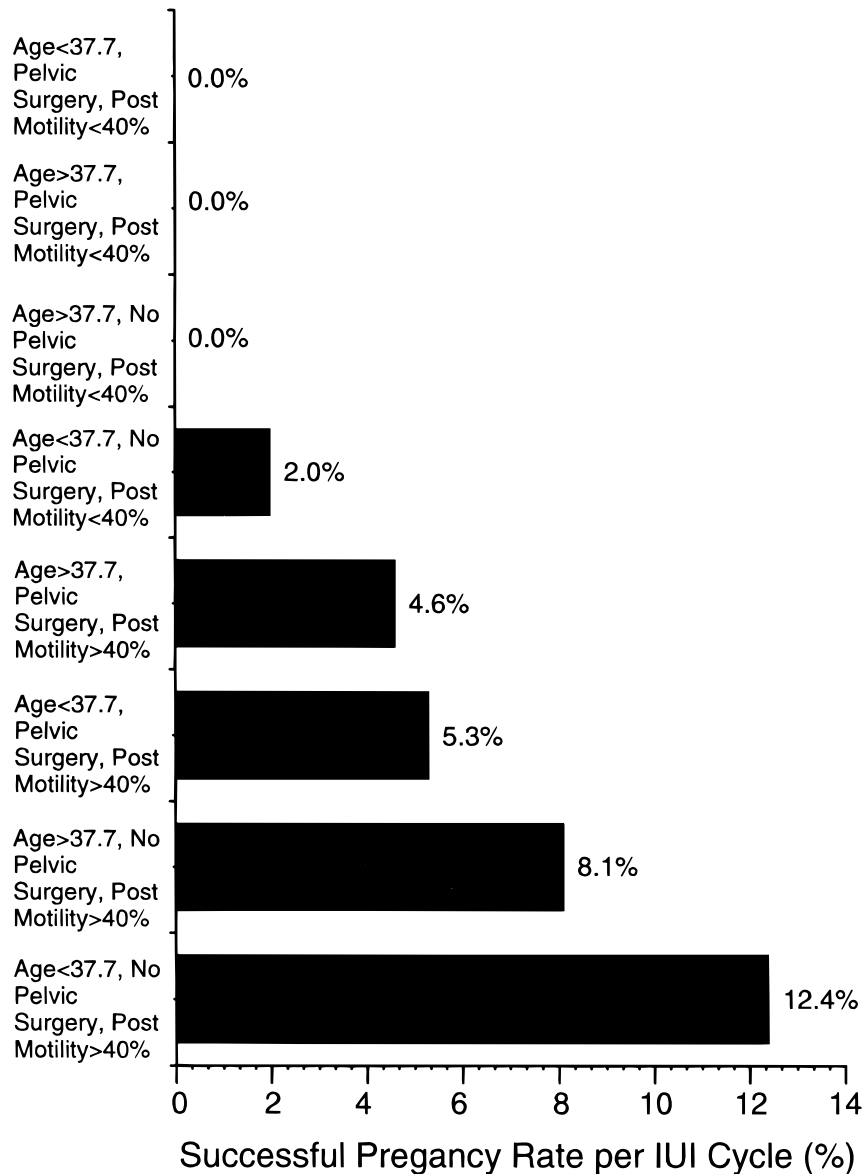


Fig. 1. Per-cycle success (birth) rates among couples undergoing IUI when all three risk factors were taken into account.

Table IV. A Multiple Logistic Regression Model Showing the Effect of Female Age, History of Pelvic Surgery, and Postwash Sperm Motility on Pregnancy

Variable	Coefficient	Standard error	Wald $\chi^2$	P value	Odds ratio	95% CI
Intercept	-3.13					
Age at IUI <sup>a</sup>	-0.05	0.02	5.26	0.02	0.95	0.92-0.99
No pelvic surgery	0.85	0.21	16.40	0.0001	2.34	1.55-3.54
Postwash motility (%) <sup>b</sup>	0.012	0.005	7.48	0.006	1.01	1.002-1.02

<sup>a</sup> Per year increase in age.

<sup>b</sup> Per percentage point increase in motility.

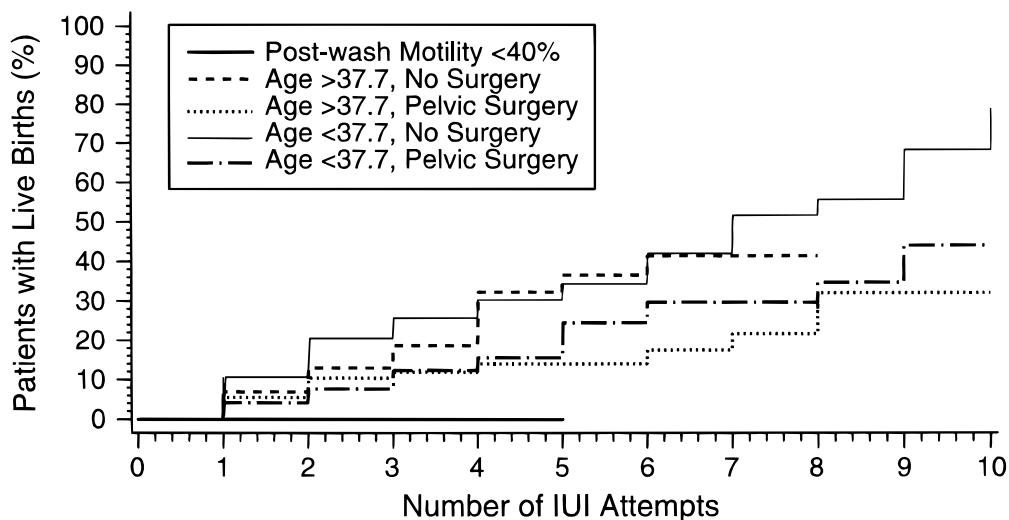


Fig. 2. Cumulative intrauterine insemination per-cycle pregnancy rates among couples with different risk factors using Kaplan–Meier estimates.

pelvic surgery), and examination of the male partner fails to reveal a treatable condition, we advise our patients to consider in vitro fertilization or possibly intracytoplasmic sperm injection.

One of the drawbacks of this retrospective study is that chart reviews were not able to document every variable for every cycle. However, the final logistic regression model is based on 1636 of the 1728 cycles, so that 95% of the reviewed cycles were included. In addition, the per cycle rates and Kaplan–Meier estimates of Table I are probably influenced by the fact that the patients with the lowest chances of success are most likely to drop out after only a few cycles.

## CONCLUSIONS

Advanced age or history of corrective pelvic surgery in the woman and poor postwash sperm motility are all predictors of poor IUI success rates. Poor postwash sperm motility in combination with either of the other two risk factors was associated with a 0% success rate. Men with poor postwash sperm motility should be evaluated for correctable etiology. If none is present and if the woman has one of the risk factors, the couple should be counseled that IUI will have little chance of success and should be advised to consider in vitro fertilization or intracytoplasmic sperm injection.

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