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What is This?
Validation of a New Scale for Measuring Concerns of Women Undergoing Assisted Reproductive Technologies (CART)

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Abstract

A new instrument was developed and assessed for internal consistency, validity and test–retest reliability. A total of 151 women undergoing IVF/GIFT in California rated concern levels about anesthesia, surgery, recovery time, side-effects, finances, missing work, pain, insufficient information and delivering a healthy baby. Validity was assessed by comparing CART to the Infertility Reaction Scale and Bipolar Profile of Moods States, and reliability was investigated by calculating correlations between repeat CARTs. Factor analysis identified three domains: procedural concerns; missing work; and achieving a successful delivery. CART is a new, valid and reliable instrument, which measures concerns during IVF/GIFT not previously identified by existing instruments.

Keywords

- concerns
- gamete intrafallopian transfer (GIFT)
- in vitro fertilization (IVF)
- scale
- validity
Introduction

Despite the psychological and physical stress of undergoing assisted reproductive technologies (ART), no instrument is currently available for assessing ART-specific concerns. Studies have primarily focused on the stress of being infertile (Newton, Sherrard, & Glavac, 1999) and undergoing in vitro fertilization (IVF), the emotional effect of IVF treatment, treatment failure and implications for counseling women undergoing IVF (Klonoff-Cohen, 2005).

Three instruments, two designed to measure psychosocial issues associated with more general fertility problems, and one given after successful delivery of an IVF child, have been used in studies with IVF patients. The Fertility Problem Inventory (FPI) (Newton et al., 1999) identifies problems in five infertility-related domains; however, there is no information on the specific stresses experienced by IVF patients. The Infertility Reaction Scale (Collins, Freeman, Boxer, & Tureck, 1992) consists of 15 items describing perceptions and feelings about infertility, rather than one IVF process. Finally, Braverman Boxer, Corson, Coutifaris and Hendrix (1998) administered a questionnaire about medical issues, concerns and choices to parents who had successfully delivered at least one child using IVF; it is unknown how much these retrospective concerns reflect those of patients undergoing the procedure.

Thus, while some instruments have been used with IVF patients, no instrument appears to address the unique concerns women may have through the process. The current article describes the development of the Concerns of Women Undergoing Assisted Reproductive Technologies (CART) instrument, in order to identify the specific concerns of women undergoing IVF or GIFT (gamete intrafallopian transfer), prior to, during and after treatment.

Methods

Subjects

Data from all subjects were obtained as part of a prospective study to evaluate the effects of lifestyle habits (e.g. smoking, alcohol and caffeine) on success rates of IVF. Details regarding the sample have been previously reported (Klonoff-Cohen, Chu, Natarajan, & Seiber, 2001). The initial cohort consisted of 221 women who were recruited while attending seven centers in Los Angeles, Orange and San Diego counties between July 1993 and June 1998.

All women were at least 20 years of age; in a marital or co-habitating relationship; and diagnosed with primary or secondary infertility problems (e.g. tubal, endometriosis, male factor, unexplained). Women with pre-existing illnesses (i.e. high blood pressure, heart disease, diabetes, thyroid disease) were excluded.

Of the original 221 women, 151 completed the questionnaire at baseline, but only 132 completed the second administration at the time of the procedure, primarily due to time commitments. The mean age was 36.81 years (SD = 4.3, range: 26–49), while the mean education was 17 years (SD = 2.6); 89 percent were employed at baseline. The majority of the sample (78%) was White and subjects reported a mean infertility duration of four years.

The sample was representative of the age, race and education level of couples enrolling in IVF and GIFT programs in United States (Stephen & Chandra, 2000). This study was reviewed and approved by the IRB at UCSD and other participating institutions; written informed consent was obtained from all subjects.

Development of CART Scale

Most of the items came from the first 70 women participating in the larger prospective study (Klonoff-Cohen et al., 2001). Subjects were routinely asked which questions were unclear and what important topics had been omitted. Almost universally, the 70 women reported the stress they were experiencing had been omitted and they gave various examples of that stress. After reviewing the content of other scales, and consulting with reproductive endocrinologists, the items suggested by the women were combined into a scale. This scale was pilot tested on 30 infertility patients undergoing IVF (who were not included in the final sample).

The final scale asked women to rate their concern on a three-point Likert-type scale (not concerned, moderately concerned and very concerned) for each of the following nine items: anesthesia; surgery; length of recovery; side-effects; finances; missing work; pain from the procedure; not having enough information; and delivering a healthy baby. There was one question on each topic to maintain the brevity of the questionnaire and reduce subject burden.

Procedure

The scale was administered twice to all subjects: at the initial visit prior to treatment (baseline), and at the time of embryos transfer. Women underwent...
only one treatment cycle during the course of the study. Theoretically, we would expect the questions to be sensitive to changes from going through the procedure, with scores decreasing as concerns are alleviated.

**Results**

**Factor analysis**

Responses to the nine items were evaluated using a principal component analysis with an orthogonal rotation; factors retained were based on eigenvalues greater than one, a screen plot and factor loadings greater than 0.40. These results are presented in Table 1, along with mean score, standard deviation and factor loading for each of the items. As shown, three factors were identified: (1) procedural concerns (six items, accounting for 24 percent of the variance); (2) work-related concerns (two items, accounting for 12 percent of the variance); and (3) success in achieving the desired result—healthy, live birth delivery (two items, accounting for 8 percent of the variance). Only one item (concern about recovery time) loaded on more than one factor. Cronbach’s alpha was good for factor one (0.78), marginal for factor two (0.68) and poor for factor three (0.40). Responses to each were treated separately in subsequent analyses because of the relatively low Cronbach’s alpha values for the items comprising factors two and three. Scores for factor one were obtained by taking the mean of the six procedural items.

**Validity and reliability**

Concurrent validity was assessed by correlating the four individual CART scores with scores on one instrument measuring general stress (POMS), and another measuring general fertility-related concerns (the Infertility Reaction Scale). Correlations between the CART and the POMS ranged from 0.26 ($p = .003$) to 0.28 ($p = .001$), while correlations between the CART and the Infertility Reaction Scale ranged from 0.06 ($p = .44$) to 0.45 ($p < .0001$), suggesting adequate validity.

Test–retest reliability was assessed by correlating baseline responses with responses at the time of the procedure (two to four weeks later). Correlations were 0.75 for procedural concerns, 0.74 for financial concerns, 0.66 for achieving the desired birth outcome and 0.65 for missing work (all significant at $p < .0001$). Although these correlations are somewhat lower than what is typically obtained via test–retest procedures, this may be because subjects had obtained additional knowledge in the interim (e.g. details of the procedure, and discussion about missing work and chances of a successful outcome) that may have affected their later scores.

In order to test this, paired $t$-tests comparing each of the scores at baseline to the scores at the time of the procedure were computed. For three of the four scores, responses at the time of the procedure were significantly lower than responses at baseline: ‘procedural concerns’, baseline $= 1.83$ (SD $= 0.52$), at the procedure $= 1.7$ (SD $= 0.48$), $t$ (d.f. $= 124$) $= 5.04$, $p < .0001$; ‘finances’, baseline $= 2.13$ (SD $= 0.72$), at the procedure $= 1.93$ (SD $= 0.76$), $t$ (d.f. $= 130$) $= 4.03$, $p = .0001$; and ‘missing work’, baseline $= 1.80$ (SD $= 0.76$), at the procedure $= 1.59$ (SD $= 0.66$), $t$ (d.f. $= 130$) $= 3.04$, $p = .003$. The only score that did not change from baseline to the time of the procedure was ‘achieving the desired result’ (baseline mean $= 2.66$, SD $= 0.52$, at the procedure mean $= 2.61$, SD $= 0.56$, $t$ (d.f. $= 129$) $= 1.30$, $p = 0.19$).

**Table 1.** Rotated factor loadings for the CART scale (all loadings $> 0.4$)

<table>
<thead>
<tr>
<th>Concerns</th>
<th>Mean</th>
<th>SD</th>
<th>Factor one</th>
<th>Factor two</th>
<th>Factor three</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Procedural</td>
<td>Work-related</td>
<td>Outcome</td>
</tr>
<tr>
<td>Undergoing surgery</td>
<td>2.02</td>
<td>0.74</td>
<td>0.80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side-effects from anesthetics</td>
<td>1.88</td>
<td>0.80</td>
<td>0.70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not having enough information</td>
<td>1.64</td>
<td>0.75</td>
<td>0.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>1.71</td>
<td>0.74</td>
<td>0.47</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side-effects from hormones</td>
<td>2.14</td>
<td>0.72</td>
<td>0.45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long recovery time</td>
<td>1.58</td>
<td>0.76</td>
<td>0.59</td>
<td>0.55</td>
<td></td>
</tr>
<tr>
<td>Missing work</td>
<td>1.8</td>
<td>0.76</td>
<td></td>
<td>0.77</td>
<td></td>
</tr>
<tr>
<td>Not achieving desired result (live birth)</td>
<td>2.66</td>
<td>0.52</td>
<td></td>
<td></td>
<td>0.61</td>
</tr>
<tr>
<td>Finances</td>
<td>2.13</td>
<td>0.72</td>
<td></td>
<td></td>
<td>0.40</td>
</tr>
<tr>
<td>% variance</td>
<td></td>
<td></td>
<td>24</td>
<td>12</td>
<td>8</td>
</tr>
</tbody>
</table>
Relationship to demographic and fertility measures

The relationship among CART scores and demographic and fertility characteristics was assessed. More detailed descriptions of these women have been previously reported (Klonoff-Cohen et al., 2001). Correlations between the four CART scores and both age and years of education were computed, and none were significant.

Finally, women were grouped on the basis of attempt number (one versus more than one), type of infertility and parity; three separate ANOVAs compared these groups on the four CART scores and no statistically significant differences in scores were found.

Discussion

The CART captures unique concerns experienced by women undergoing IVF that are not evaluated by other existing instruments. Validity and reliability are adequate, and the instrument does not appear to be related to demographic factors.

There are, however, a number of limitations to the current study and the resulting scale. First, this instrument was developed using a relatively small sample of infertile women that did not include those who elected to pursue only minimal medical intervention, rather than ART. Second, although 151 women completed the CART at baseline, only 132 did so at the time of the procedure, and this may have affected the results.

Third, despite our reliance on women, who themselves were undergoing the procedure to suggest the items, it may be that other important concerns were omitted including: cancer risks, multiple births (Seibel, 1997), miscarriages, birth defects, premature labor and delivery, selective reductions (Braverman et al., 1998), advancing age and effects of the procedure on the spouse. Future studies should include these concerns, as well as additional items that might enlarge the three individual variables into full scales. Fourth, because the primary focus of this study was female infertility, questions were not administered to male partners, although the CART could be adapted for this purpose in the future. In summary, CART is a new, valid and reliable instrument, which measures concerns experienced during IVF/GIFT not previously identified by existing instruments.

References


Author biographies

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