Pilot Randomized Controlled Trial of Interpersonal Counseling for Subsyndromal Depression Following Miscarriage

Richard Neugebauer, Ph.D., M.P.H.; Jennie Kline, Ph.D.; John C. Markowitz, M.D.; Kathryn L. Bleiberg, Ph.D.; Laxmi Baxi, M.D.; Mark A. Rosing, M.D., M.P.H.; Bruce Levin, Ph.D.; and Jessica Keith, M.A.

Objective: Miscarriage, which occurs in 10% to 20% of clinically recognized pregnancies, is associated with an increased risk for subsyndromal depression. We examined whether Interpersonal Counseling (IPC) was superior to treatment as usual (TAU) in reducing subsyndromal depression among miscarrying women and, secondarily, superior to TAU in improving role functioning.

Method: Nineteen of 20 eligible women participated in a randomized controlled trial of 1 to 6 weekly telephone sessions of IPC versus TAU, which consisted of whatever lay counseling or professional care women sought on their own initiative, from October 2001 to April 2002. The 2 trial arms were compared on mean within-subject change in Hamilton Rating Scale for Depression–17-item (HAM-D-17) scores and in role functioning scale scores (a 5-item modification of the 36-item Medical Outcomes Study questionnaire) from baseline to post-intervention.

Results: In the primary intent-to-treat analysis, the baseline mean HAM-D-17 scores were 18.0 (SD ± 8.4) and 14.8 (SD ± 6.6) in the IPC (N = 10) and TAU (N = 9) arms, respectively; post-intervention, the corresponding means were 11.6 (SD ± 8.2) and 12.9 (SD ± 8.3). The mean within-subject decline in HAM-D-17 scores was significantly greater in the IPC (6.4) than in the TAU (1.9) arm (difference in mean within-subject score decline, adjusted for design features, baseline HAM-D-17 scores and for baseline ethnic imbalance between study arms, 6.2 [95% CI = 0.4 to 12.0]). In a subordinate completers' analysis (N = 15), the corresponding mean decline and difference in adjusted mean decline were 8.0, 2.4, and 6.7 (95% CI = 0.4 to 13.1), respectively. Treatment was unrelated to improved role functioning.

Conclusion: The efficacy of telephone-administered IPC for subsyndromal depression after miscarriage warrants testing in a full-scale randomized controlled trial.

(J Clin Psychiatry 2006;67:1299–1304)

Received Dec. 25, 2005; accepted April 10, 2006. *From the Epidemiology of Developmental Brain Disorders Department, New York State Psychiatric Institute, and the G.H. Sergievsky Center, Columbia University, New York, N.Y. (Drs. Neugebauer and Kline); the Departments of Epidemiology (Dr. Kline), and Biostatistics (Dr. Levin), Mailman School of Public Health, Columbia University, New York, N.Y.; the Department of Psychiatry, Weill Medical College of Cornell University, New York, N.Y. (Drs. Markowitz and Bleiberg); the Department of Psychiatry, College of Physicians and Surgeons, Columbia University, and Personality Studies Unit, New York State Psychiatric Institute, New York, N.Y. (Dr. Markowitz); the Department of Obstetrics and Gynecology, College of Physicians and Surgeons, Columbia University, New York, N.Y. (Drs. Baxi and Rosing); the Department of Obstetrics and Gynecology, St. Barnabas Medical Center, Bronx, N.Y. (Dr. Rosing); and the Teachers College, Columbia University, New York, N.Y. (Ms. Keith).*

This trial was supported by Independent Investigator Award 001395 from the National Alliance for Research on Schizophrenia and Depression, Great Neck, N.Y.; and grant NIH 1 RO3 MH59179-01A1 from the National Institutes of Health, Bethesda, Md.

Dr. Markowitz reports minor royalties from IPT books at Basic Books, American Psychiatric Press. Ms. Keith is a consultant to Pfizer. The other authors report no additional financial or other relationships relevant to the subject matter of this article.

The authors thank Kathleen F. Clougherty, M.S.W., and Judith Rabkin, Ph.D.

Corresponding author and reprints: Richard Neugebauer, Ph.D., M.P.H., Box 53, New York State Psychiatric Institute, 1051 Riverside Dr., New York, NY 10032 (e-mail: RN3@columbia.edu).

Involuntary intrauterine pregnancy loss up to 28 completed weeks of gestation (hereafter "miscarriage") occurs in 10% to 20% of clinically recognized pregnancies. Approximately 25% of women miscarry during their life span, with the proportion increasing as childbearing is postponed to more advanced maternal ages. Miscarriage, the spontaneous termination of an ongoing pregnancy, constitutes an unanticipated bereavement that may cause some women to doubt their reproductive capacity. For these reasons, miscarriage is likely to raise risk for psychiatric symptoms and clinical disorder.

Numerous observational epidemiological studies document that miscarrying women experience substantially increased levels of depressive symptoms, or "subsyndromal depression" (SSD), as compared with pregnant, community, or postpartum women in the weeks and months after loss.[1–8] Miscarriage also raises risk for major depressive disorder (MDD)[9–11] and suicide.[12] Subsyndromal depression is considerably more prevalent than MDD,[13–15]

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and SSD tends to persist,[16] impair role functioning,[13,15,17–19] and increase risk for more serious psychiatric and somatic morbidity.[20–22] Recent randomized controlled trials (RCTs) of treatments for SSD[23–26] attest to growing recognition of its public health and clinical importance.

Numerous programs exist for women depressed in the aftermath of pregnancy loss, providing psychoeducation about the mourning process, supportive listening, and practical assistance (e.g., burial options).[27–29] Typically, such care is provided in person and, if appropriate, by telephone after the woman has left the medical facility. However, these programs, rarely manualized, typically focus on bereavement after later losses, i.e., stillbirth and neonatal death, which comprise less than 5% of pregnancy losses. No controlled trials of these intervention programs appear in the peer-reviewed literature.

In reviewing candidate treatments for the experimental intervention, we excluded psychopharmacology from consideration. Many miscarrying women quickly resume efforts to conceive and wish to avoid medication for fear of its possible teratogenicity. Optimal psychotherapeutic interventions for women of reproductive age, especially for women with young children and socially disadvantaged women, should be (1) brief in number and length of sessions, (2) problem-focused, (3) inexpensive, and (4) accessible, with flexible hours and telephone availability. Interpersonal Counseling (IPC),[30,31] a variant of Interpersonal Psychotherapy (IPT),[30] fits these criteria.

IPT is a manualized, time-limited, symptom-focused psychotherapy efficacious in treating ambulatory, nonpsychotic patients with MDD.[30] IPT assumes that depression develops within an interpersonal context and concentrates on solving an interpersonal crisis and on improving the patient's role functioning. A key premise of IPT—that stressful life events influence mood—underscores its suitability for the current patient population. IPC differs from IPT in targeting psychologically distressed, not clinically depressed, individuals; counselors need not be mental health professionals; and sessions are fewer, shorter, and more highly scripted. IPC is self-dosing; the patient determines the number of sessions, up to a maximum of 6. Both IPC and IPT, originally designed as in-person treatments, include specific bereavement modules. Controlled trials of patients in general practice and in geriatric settings afford preliminary evidence of the efficacy of IPC. However, neither of these trials delivered care via telephone. One other trial, adapting IPT for telephone administration, reported efficacy in treating women with a history of MDD and baseline Hamilton Rating Scale for Depression (HAM-D) scores less than 18.[32–34]

We conducted a small RCT to test whether telephone-administered IPC was superior to treatment as usual (TAU), the control condition, in reducing SSD among miscarrying women.

METHOD

Participants and Procedures

Participants were women seeking medical care for miscarriage from October 2001 to April 2002 in the emergency departments, the clinics, or the private practice settings at New York-Presbyterian Medical Center in Manhattan and St. Barnabas Hospital in the Bronx, New York, serving predominantly low-income populations. All participants completed informed consent procedures approved by the institutional review boards of the 2 medical centers. Potential trial participants were identified by the treating clinician or through record review by study staff.

After medical staff described the research goals to the patients, including the possible psychological intervention, and obtained consent for telephone contact, a clinically trained rater phoned patients and administered the HAM-D-17, following Williams' structured interview guide.[35] Administration of the HAM-D by telephone has become common in recent years, especially in clinical trials.[23,36] Observational ratings for agitation and psychomotor retardation are not possible via telephone except for response latency during the interview as a measure of retardation. Consequently, agitation and retardation are assessed by asking the participant about fidgeting and slowed movement, respectively; in addition, the participant is asked whether other people have commented on these behaviors, and whether these behaviors have interfered with the respondent's life. This approach to measuring agitation and retardation was developed and extensively fielded by O'Hara et al.[36] in their study of postpartum depression. Trial eligibility and primary trial outcome are based on HAM-D-17 scores (internal consistency reliability, 0.89). We also administered the Structured Clinical Interview for DSM-IV–Clinical Version (SCID-IV-CV) during the baseline interview to assess psychiatric exclusionary criteria.[37]

Interviewers were psychiatric social workers with at least 10 years of clinical experience or clinical psychologists with doctorates completed within the previous 5 years. All interviewers were trained previously on the HAM-D and on the SCID at our facility. They were required to review the HAM-D training video and to complete mock HAM-D-17 and SCID telephone interviews with other staff members. An external senior trainer-evaluator from our institution monitored the quality of these interviews and subsequent taped interviews with study participants. No formal assessment of interrater reliability on these measures was conducted.

Impaired functioning, a secondary outcome measure, was assessed with a 5-item Role Functioning scale derived from the 36-item Medical Outcomes Study questionnaire.[38] This Role Functioning measure combines the 3-item "Role Limitations from Emotional Problems" (RLE) scale that assesses whether emotional difficulties

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reduced the person's time, productivity, or care taken with work or other activities and the 2-item "Social Functioning" (SF) scale for assessing interference in an individual's social life from emotional or physical problems. Item time frame was the preceding 4 weeks. Standardized scores range from 0 to 100, with higher scores indicating better functioning.

Women were trial eligible if they were 18 years or older, English- or Spanish-speaking, reachable by telephone, had a medically documented pregnancy loss within 18 weeks prior to the baseline interview, and reported at least mildly elevated depressive symptoms (HAM-D-17 score > 7). Exclusion criteria were suicidality, current MDD, substance use disorder, history of psychosis, life threatening physical illness, mental retardation, and refusal to have sessions audio-taped. Consistent with the perspective adopted in DSM-IV, "V62.82 Bereavement," elevated depressive symptoms were counted towards a diagnosis of MDD only if they had persisted for more than 2 months since loss or were characterized by marked suicidality, psychomotor retardation, morbid preoccupation with worthlessness, or hallucinatory experiences (other than the bereaved experiencing a phantom symptom such as the baby moving inside of her).

Enrolled women were randomly assigned to IPC or to TAU. TAU constituted whatever lay counseling or professional care women sought on their own initiative. In this trial, therefore, TAU corresponds to "real world" practice and does not necessarily involve treatment per se. Women in the IPC arm were also free to seek other mental health care during the trial. In anticipation of a larger trial than proved feasible, participants were randomly assigned after being stratified by hospital payment status (public, private insurance) and by weeks between miscarriage and baseline interview (≤ 4, 5–7, 8–12, 13–18). A post-intervention assessment with the HAM-D-17 and Role Functioning scale, blind to treatment assignment, was scheduled 9 weeks after randomization. Any mental health treatment initiated by study participants outside of the study protocol was documented with a health services questionnaire, the Cornell Services Index.[39] Women completing this trial received $20.

We drafted a manual for pregnancy loss based on the original IPC manual (M. M. Weissman, G. L. Klerman, unpublished paper, 1988), epidemiological work on miscarriage and depression,[1,40] and the perinatal bereavement literature.[41] Further adaptations were introduced to the manual during an open trial of this intervention. In that open trial, which involved participants other than those in the current RCT, we observed a substantial decline in depressive symptoms among women receiving the intervention.[31]

The first IPC session lasted approximately 1 hour, the remaining sessions 30 minutes each. During the first session, the counselor gathered the patient's history, particularly the account of the miscarriage and the chronology of depressive symptoms relative to the miscarriage. Each IPC session included a brief review of depressive symptoms, exploration of the established interpersonal problem area(s), psychoeducation about depression and its interpersonal context, and techniques for solving interpersonal difficulties. Information secured in the baseline interview about reproductive history and prior losses was addressed in sessions to increase counselor-patient rapport. Women concluded treatment whenever they wished, without counselor interference. Three female therapists provided counseling; one was an experienced psychiatric social worker without prior IPT or IPC training, and the others were IPT-certified psychotherapists. A senior IPT therapist (J.C.M.) audited session tapes and discussed counseling standards with the treating clinicians.

Analysis

The primary outcome measure was within-subject change in HAM-D-17 score from baseline to the post-intervention assessment. We compared the mean within-subject change in HAM-D-17 score between the 2 trial arms using multiple regression, adjusting for baseline HAM-D-17 score, the trial's design features, namely, the 2 stratification variables—payment status (public/private) and weeks between miscarriage and baseline interview–and ethnicity (Table 1). The parallel analysis for the mean within-subject Role Functioning change scores adjusts for baseline Role Functioning score and the 2 stratification variables.

We conducted a primary intent-to-treat (ITT) analysis—with women who missed the post-intervention assessments on the HAM-D-17 and Role Functioning scales included by imputing their baseline scores as their post-intervention scores. We also conducted a completer analysis, comprising only women assessed post-intervention. Statistical significance for all analyses was set a priori at $p < .05$, 2-tailed.

Despite randomization, the trial arms differed in ethnicity, which, in turn, was associated with HAM-D-17 scores. Hispanic women comprised 80% (8/10) of the IPC arm and 44% (4/9) of the TAU arm. Further, the post-intervention HAM-D-17 mean score for Hispanic women (15.3, SD ± 7.2) (both arms combined) was significantly higher than that for non-Hispanic women (7.0, SD ± 7.0, $p < .03$). Consequently, the final multiple regression model for the HAM-D-17 analysis adjusts for ethnicity (Hispanic/non-Hispanic) because of its role as a confounder, thereby reducing error variance and providing the model with greater predictive power.

To determine how effectively interviewers remained blind to treatment status, their guess as to the participant's assignment status, recorded after completion of the post-intervention HAM-D-17, was compared with participant's true status.

Table 1. HAM-D-17 and Role Functioning Scores at Baseline and Post-Intervention, Score Change, and Difference in Mean Score Change Among Women Receiving Interpersonal Counseling (IPC) and Treatment as Usual (TAU) for Subsyndromal Depression After Miscarriage

Outcomes	Intent-to-Treat Sample			Completer Sample		
HAM-D-17	IPC (N = 10)	TAU (N = 9)		IPC (N = 8)	TAU (N = 7)	
Baseline score, mean (± SD)	18.0 (8.4)	14.8 (6.6)		18.6 (9.3)	13.7 (6.8)	
Post-intervention score, mean (± SD)	11.6 (8.2)	12.9 (8.3)		10.6 (8.8)	11.3 (8.5)	
Observed score change, mean (± SD)[a]	6.4 (5.0)*	1.9 (4.8)		8.0 (4.2)*	2.4 (5.4)	
Difference in mean score change adjusted for:	Difference (95% CI)	t	p	Difference (95% CI)	t	p
Baseline HAM-D-17 and stratification variables[b]	3.6 (–2.1 to 9.2)	1.4	.19	5.1 (–1.2 to 1.4)	1.8	.1
Baseline HAM-D-17, stratification variables,[b] and ethnicity	6.2 (0.4 to 12.0)	2.3	.04	6.7 (0.4 to 13.1)	2.4	.04
Role functioning	IPC (N = 10)	TAU (N = 9)		IPC (N = 8)	TAU (N = 7)	
Baseline score, mean (± SD)	40.1 (25.8)	48.1 (26.4)		36.1 (27.6)	51.2 (33.0)	
Post-intervention score, mean (± SD)	52.2 (29.2)	62.3 (21.4)		51.0 (29.7)	69.2 (18.7)	
Observed score change, mean (± SD)[c]	12.1 (18.3)	14.2 (22.7)		15.1 (19.5)	18.3 (24.6)	
Difference in mean score change, adjusted for baseline	Difference (95% CI)	t	p	Difference (95% CI)	t	p
role functioning and stratification variables	4.4 (–16.9 to 25.7)	0.5	.7	6.1 (–20.0 to 32.3)	0.5	.6

*p < .03.
[a]Data indicate mean within-subject change in HAM-D-17 scores from baseline to post-intervention assessment with positive values representing score reduction from baseline to post-intervention. For the intent-to-treat analysis, no change was assumed for participants lacking post-intervention data.
[b]The adjusted mean score change is calculated using ordinary least squares multiple regression with individual within-subject change scores constituting the dependent variable. Independent variables comprise treatment assignment, baseline HAM-D-17 score, the 2 stratification variables (payment status [public/private] and weeks between miscarriage and baseline interview), and ethnicity (Hispanic/non-Hispanic). No participants were recruited in weeks 5–7 after loss. Consequently, the original categorization of weeks into 4 categories (≤ 4, 5–7, 8–12, 13–18) was collapsed into 3: ≤ 7, 8–12, and 13–18.
[c]Data indicate mean within-subject change in Role Functioning scores from baseline to post-intervention assessment with positive values representing score increase from baseline to post-intervention. For the intent-to-treat analysis, no change was assumed for participants lacking post-intervention data.
Abbreviation: HAM-D-17 = Hamilton Rating Scale for Depression–17-Item version.

RESULTS

Of 151 women seeking care for miscarriage, 54 could not be reached by phone in time to participate; 25 declined the telephone interview. Among the 72 interviewed women, 20 were eligible (most others were ineligible because of HAM-D-17 scores < 8), and 19 (95%) consented to randomization. The IPC arm comprised 10 women; TAU, 9. For interviewed women, the mean number of days from miscarriage to baseline interview was 34.5 (SD = 35.5); for women entering the trial, 25.0 days (SD = 33.1) The mean number of days from baseline interview to first counseling session was 7 (range, 3–9). Of the 19 participants, 15 (79%) completed the post-intervention assessment.

Mean age of randomly assigned women was 29.7 years (SD ± 7.6); 63% (12/19) were Hispanic, 21% (4/19) were non-Hispanic white, and 16% (3/19) were Asian. Fifty-eight percent (11/19) were clinic patients. Approximately 25% (5/19) had not graduated high school; 32% (6/19) reported some college and 5% (1/19) had advanced degrees. Half (10/19) were cohabiting, and 32% (6/19) were married; 58% (11/19) had Medicaid or were uninsured, and the remainder (8/19) had private insurance. Mean gestation at loss was 12 weeks (SD ± 5.8); 37% (7/19) of women had prior pregnancy losses. Two women in each treatment arm had a history of MDD, and 1 woman, a control, had a history of alcohol dependence.

Small sample sizes precluded interpretable comparisons on the above characteristics between women in the completer sample (N = 15) and the remaining women in the ITT sample (N = 4). Two women requested 6 IPC sessions; no others had more than 3 sessions.

At baseline, the 2 trial arms did not differ significantly on mean HAM-D-17 scores (Table 1). Both groups experienced symptom decline. In the ITT analysis, mean within-subject decline in HAM-D-17 score was significantly greater in the IPC than in the TAU arm. Adjusting for baseline HAM-D-17 score, the 2 stratification variables and ethnicity, the difference in mean within-subject score decline between the 2 arms of the trial was 6.2 (95% CI = 0.4 to 12.0). In a secondary completer analysis, decline in mean within-subject HAM-D-17 score was significantly greater in the IPC arm (8.0) than in the TAU arm (2.4). The difference in mean within-subject score change, adjusting for baseline HAM-D-17 score, the 2 stratification variables, and ethnicity, was 6.7 (95% CI = 0.4 to 13.1). Three completers experienced symptom increase, none of them in the IPC arm.

At baseline, the 2 trial arms did not differ significantly on mean Role Functioning scores (Table 1). In the ITT analysis, both the IPC and TAU arms exhibited statistically nonsignificant increases in Role Functioning scores. These null findings held in adjusted as well as unadjusted analyses, for the 2 original scales considered separately, and in the completer sample.

In the interval from baseline to the post-intervention assessment, 1 woman in the IPC arm, and no women in the TAU arm, sought mental health care. Interviewers' "guess" as to treatment status was not significantly associated with participants' true status, thereby evidencing effective blindedness.

DISCUSSION

These trial results suggest that telephone-administered IPC may be an acceptable means of treating SSD following miscarriage, including among socially disadvantaged women. Many of the trial participants were on Medicaid and had limited formal education. Two thirds were Hispanic. While 25% of women reached by telephone declined the baseline interview, 95% of eligible women invited to enter the trial consented. Women in the IPC arm experienced a greater decline in HAM-D-17 scores than those in the TAU arm. As noted, we have reported a substantial decline in depressive symptoms in an open trial of telephone-administered IPC in the same patient population.[31] The current findings afford some specific evidence of possible intervention efficacy and concur with earlier studies demonstrating the equivalence or superiority of telephone-administered psychotherapy, including IPT, over office-based psychotherapy for SSD and for MDD.[32,42,43]

Telephone counseling aimed to overcome barriers to mental health care. Two possible indicators of treatment acceptability require comment. First, a large proportion of identified miscarrying women could not be reached after their hospital visit. However, we found similarly low recontact rates in an observational study at our medical center,[40] suggesting that the difficulty in recontacting patients after hospital departure may not reflect any specific reluctance to receive telephone mental health counseling. Second, 20% (2/10) of women in the IPC arm of the trial could not be reached for the post-intervention assessment. However, the average completion rate in other counseling trials recruiting participants from among bereaved individuals generally, not from among persons seeking mental health care, is 56%.[44–50]

IPC did not improve role functioning. This null finding may reflect the low statistical power associated with the small sample size or the insensitivity of our brief measures to change.[51] Alternatively, IPC may not influence role functioning,[34] or such influence may emerge later. Most IPT trials document benefits for role functioning but sometimes only months after treatment concludes.[52] More generally, the reduction in depressive symptoms achieved by psychopharmacology or psychotherapy does not necessarily translate into amelioration of social impairment.[53,54]

Our findings remain preliminary because of the small sample size and the lack of comparability in ethnicity and depressive symptom levels between the 2 arms at baseline. Additionally, women who proved eligible for study entry may not be representative of all eligible miscarrying women among those initially identified at the time of their hospital visit. However, based on these results together with previous literature documenting the efficacy of IPT, IPC, and telephone-administered mental health care generally, a larger scale RCT of this intervention appears warranted.

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Editor's Note: We encourage authors to submit papers for consideration as a part of our Focus on Women's Mental Health section. Please contact Marlene Freeman, M.D., at marlenef@email.arizona.edu.

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