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Gender differences in clinical trials of binge eating disorder: An analysis of aggregated data

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Abstract

Objective—The aim of the study was to examine gender differences in baseline and outcome variables in clinical trials for binge eating disorder (BED).

Method—Data from 11 randomized controlled psychosocial treatment studies were aggregated (N=1,325: 208 male, 1,117 female). Baseline and outcome symptoms were assessed via the interview and questionnaire versions of the Eating Disorder Examination (EDE). Multilevel analyses were conducted investigating gender differences at baseline and post-treatment, defined as EDE scores, objective binge episode (OBE) reduction, and OBE remission at termination.

Results—Few males from low SES or minority groups participated in the outcome studies. Males reported significantly lower EDE global, shape, weight, and eating concerns at baseline. No main effects of gender were found in treatment outcome scores when controlling for baseline differences; however, baseline EDE global score (which showed gender differences at baseline) and OBEs directly predicted outcome for both males and females. A significant interaction between gender, treatment length, and shape/weight concerns indicated that males with lower shape/weight concerns achieved OBE remission in shorter treatments, whereas men with high weight/shape concerns and women with either high or low weight/concerns were more likely to achieve OBE remission in treatments of longer duration.

Conclusions—These results suggest BED treatment studies must improve their recruitment of men and appeal to men with lower shape/weight concerns. Additionally, longer-term treatments,

while more efficacious for women and men with more severe shape/weight concerns, may not be necessary for men with low shape/weight concerns.

Keywords

Binge eating disorder; gender differences; eating disorders; treatment outcome

Although the rates of binge eating disorder (BED), in contrast to other eating disorders (EDs), are comparable between men and women (Striegel-Moore & Franko, 2003), research investigating gender differences in baseline and outcome symptoms in clinical trials for BED is severely limited by the underrepresentation of males in published studies (Striegel, Bedrosian, Wang & Schwartz, 2012; Thompson-Brenner et al., 2013). Community samples of women are more likely to receive treatment for BED despite these comparable rates of diagnoses (Kessler et al., 2013) and it is theorized that this may be due to lower awareness of EDs in men and/or greater reluctance in men to seek treatment for a “female” disorder (Striegel et al., 2012). A small number of studies have examined baseline differences in eating disorder (ED) pathology between males and females with BED in clinical samples (Barry, Grilo, & Masheb, 2002; Guerdjokova, McElroy, Kotwal, & Keck, 2007; Tanofsky, Wilfley, Spurrell, Welch, & Brownell, 1997). A few significant gender differences have been found, higher body dissatisfaction, drive for thinness, dietary restraint and emotional eating among women (Barry et al., 2002; Tanofsky et al., 1997). No consistent pattern of differences in the Eating Disorder Examination cognitive subscales (shape concern, weight concern, and eating concern; Fairburn & Cooper, 1993) have been identified; however, studies investigating differences in these variables have been underpowered to find them (Barry et al., 2002; Tanofsky et al., 1997). The few studies that have examined gender differences in BED treatment outcome have not found significant differences associated with gender, although all were also underpowered to detect these effects (e.g., Munsch et al., 2007; Safer, Hagler-Robinson & Jo, 2010; Ricca et al., 2010). For example, in the three studies cited above, the subsamples of male participants with BED ranged from $n = 9$ to 17, while the subsamples of female participants from $n = 86$ to 127. Other studies have shown that ED-associated psychopathology such as pre-treatment concerns with shape and weight predict treatment outcome in BED (e.g., Masheb & Grilo, 2008, Peterson, Crow, Nugent, Engbloom, & Mussell, 2000); however, baseline gender differences in these factors have not been linked to gender differences in outcome.

It is essential to better understand treatment outcome among men with BED. Differences in baseline symptoms and treatment response may help guide the design of more effective treatments that will better address the clinical presentation of BED in men (Striegel et al., 2012). To address the observed underrepresentation of males in clinical trials, and to guide the design and hypotheses of future studies including more males, this study aimed to investigate gender differences in an aggregated database of multiple clinical trials. The specific aims were to investigate gender differences in baseline symptoms and treatment outcome, and to examine how gender may moderate response to common treatment parameters (i.e., length of treatment, group vs. individual treatment, self-help vs. therapist-led).

Method

Participants

In this study, investigators aggregated data from eleven psychosocial BED treatment trials published and/or funded in the United States since 1995. The aim of the original study was to investigate racial/ethnic and educational predictors of treatment outcome (see see Franko et al., 2012, for extensive description of the methods and list of trials included); the current study represented a secondary analysis of existing data to examine gender differences. The original criteria for inclusion of study data were: 1) a randomized control trial of a psychosocial treatment for BED with at least ten total participants; 2) published and/or funded through the peer review process; and 3) conducted in the United States. Participants who did not receive active psychotherapy (e.g., participants on a waiting list) were excluded from outcome analyses. The complete database was titled “The Clinical Trials for Binge Eating Disorder” (CT-BED) Database (N=1,325). Of this sample, n=208 were male and n=1,117 were female. Institutional Review Boards at all sites approved the study methods.

Measures

Demographic information: All studies collected data concerning gender/sex, age, race/ethnicity, and level of education. Gender and sex were treated as equivalent constructs, and collected by indicating “male” or “female” on self-report forms.

Body Mass Index (BMI): In-person height and weight data were collected and BMI was calculated for all participants.

Eating Disorder Examination (EDE, Fairburn & Cooper, 1993; Fairburn & Beglin, 1994): The EDE interview is the gold standard measurement of eating pathology and has a questionnaire version (EDE-Q; Fairburn & Beglin, 1994). Both forms of the EDE measure symptoms in the past 28 days and yield four subscale scores (shape concern, weight concern, eating concern, dietary restraint), a global score, and an objective binge episode (OBE) count. Subscale scores are measured on a 0 – 6 scale with zero indicating absence of ED symptoms and six indicating severe ED symptomatology or presence of ED symptoms daily. Previous research has shown the EDE interview has acceptable inter-rater reliability and internal consistency (Cooper, Cooper, & Fairburn, 1989; Fairburn & Cooper, 1993) as well as adequate psychometric properties when used in BED samples (Grilo, Masheb, Lozano-Blanco, & Barry, 2004). Reliability and validity has been demonstrated in both the interview and questionnaire versions of the EDE (Fairburn & Beglin, 1994; Grilo, Masheb, & Wilson, 2001). Nine of the trials used the interview version; two of the trials used the questionnaire version (Gorin, LeGrange, & Stone, 2003; Kristeller, 2007) and made the BED diagnosis using the Structured Clinical Interview for Axis I DSM-IV Disorders (First, Spitzer, Gibbon, & Williams, 1996). It was determined that given the small number of data points collected using the EDE-Q (n=18 males assessed using the questionnaire vs. n=190 using the interview), the relatively equal gender representation (females to males ratio) across data collection methods, and documented good agreement on the frequency of OBEs and subscales between the EDE-Q and EDE in patient with BED (Grilo, Masheb, & Wilson, 2001), aggregating data from both was unlikely to produce bias. To verify this was the case,

we conducted parallel analyses with the EDE interview alone and pooled EDE interview and questionnaire data, and the results were substantially similar. Thus we have described and reported the results of the pooled analyses in this manuscript.

Statistical Analyses

Gender differences in baseline and post-treatment EDE global scores (calculated by averaging the four subscale scores), subscale scores (dietary restraint, eating concern, weight concern and shape concern), and OBEs in the past 28 days were examined. Treatment outcomes also included OBE remission, defined as no OBEs in the last 28 days and drop-out, defined as stopping participation prior to treatment conclusion. EDE scores and OBEs were modeled using multiple linear regression while OBE remission and drop-out were modeled using logistic regression. All models adjusted for age, education, ethnicity, and BMI. Treatment outcome models also adjusted for baseline global EDE scores, baseline OBE frequency, group vs. individual treatment, and treatment length. Consistent with previous BED trials (e.g., Grilo et al., 2008), a composite score of the baseline shape and weight concern subscales was created and was included as a covariate in analyses of treatment outcomes. In order to assess whether gender moderated treatment response, the treatment outcome models included the following interactions: gender x group vs. individual treatment, gender x treatment with or without a self-help component, gender x each EDE subscale, and gender x treatment length.

Because data were collected at different treatment sites, participant responses were non-independent. Therefore, multi-level models were used to adjust for nesting of individuals within study sites. We elected to analyze individual subject data pooled across studies (as opposed to meta-analysis). Although some argue pooling data may lead to non-clinically significant effects, we chose this method because of advantages including greater statistical power, ability to ensure uniform analytic techniques across studies, and ability to model aspects of data such as the within-study (intra-class) correlation (Cooper & Patall, 2009; Curran & Hussong, 2009). Missing data were handled by multiple imputation (Allison, 2001). MI settings were based on Allison (2001), i.e., the Markov chain Monte Carlo algorithm was used for imputation (10,000 burn-in iterations and 2,000 iterations) and convergence was checked using plots of the estimates and autocorrelation by iteration. All variables were analyzed in their original scale except for OBE frequency, which was log transformed. Effect sizes were also calculated for all baseline and treatment outcome variables. All reported results were significant at $p < 0.05$. Analyses were conducted using SAS 9.1 (SAS Institute, Cary, NC).

Results

A total of $N=1,325$ participants ($n=208$ males and $n=1,117$ females) were included in baseline data analyses. Descriptive analyses for the sample are reported in Table 1. Among the $n=208$ males, few individuals with less than some college ($n=26$) and minority race/ethnicity ($n=10$ African American, $n=12$ Hispanic) were observed. A total of 523 respondents (40%; by gender, 28% of males and 42% of females) exhibited baseline shape/weight concerns of 4 or greater, indicating clinically significant pathology.

Table 2 shows means, standard deviations, significance levels, and effect sizes for eating disorder symptoms. At baseline, males reported significantly lower shape, weight, and eating concerns as well as lower global EDE score (controlling for baseline BMI, education, age, and ethnicity) than females. Males and females reported similar levels of dietary restraint and very similar frequency of OBEs at baseline.

Treatment outcome data were available for $n=1,024$ participants. At post-treatment, men and women did not differ significantly on global EDE score, number of OBEs in the past 28 days, OBE remission, or premature drop-out. A significant three-way interaction was found between gender, treatment length, and shape/weight concerns on OBE cessation ($p = 0.03$). Specifically, males with low levels of shape/weight concerns at baseline were equally likely to achieve abstinence in shorter and longer treatments, whereas all other groups (males with higher levels of shape/weight concerns and females regardless of shape/weight concerns) were more likely to achieve OBE abstinence if they participated in longer treatment protocols (Table 3). No other interactions were statistically significant.

Discussion

The current study is a unique investigation of gender differences in baseline symptoms and treatment response in a large clinical sample of individuals with BED, including 208 male participants. The baseline results indicate that males in clinical trials for BED reported lower levels of weight and shape concerns than women and the majority of men (i.e., more than seventy percent) do not report clinically significant shape/weight concerns at the outset of treatment. In contrast, men and women did not report significantly different levels of dietary restraint or frequency of OBEs at baseline. Previous research conducted in treatment-seeking samples has generally suggested males and females do not show different ED symptom severity (Barry et al., 2002; Tanofsky et al., 1997). However, a few studies have identified greater distress among women (Grilo & Masheb, 2005; Roehrig et al., 2009, Tanofsky et al., 1997) and two studies with very small male samples showed non-significant gender differences in EDE scores in the same direction observed at a statistically significant level in this study (Barry et al., 2002; Tanofsky et al., 1997¹). This study suggests that it may be important to offer treatments to males that do not assume or highlight the presence of shape and weight concerns. Several forms of empirically-supported psychotherapy may be useful in this regard; for example, transdiagnostic enhanced cognitive behavior therapy, interpersonal psychotherapy, and guided self-help cognitive behavioral therapy are all highly flexible (Fairburn, 2008; Wilson, Wilfley, Agras, & Bryson, 2010). Furthermore, typical assessment instruments do not generally capture motivations to enter treatment or assess non-shape/weight related BED concerns. Research is needed to assess whether there are concerns other than shape and weight as well as different types of shape/weight concerns (e.g., desire to be more muscular rather than thinner) not assessed in the EDE that are particularly characteristic of men with BED.

The treatment outcome analyses indicated no main effects of sex on treatment outcome (i.e., global EDE scores, OBE frequency in the past 28 days, and OBE remission at termination,

¹The data described in Tanofsky et al. (1997) was with one of the single samples that are aggregated in the present study.

and premature drop out), but interestingly, there was a significant interaction effect of gender, treatment length, and shape/weight concerns on OBE remission. Males with lower shape/weight concerns achieved sustained BED remission independent of treatment length, compared to men with high shape/weight concerns as well as females with both low and high levels of shape/weight concerns, who achieved higher rates of OBE remission when participating in longer treatments. Recently published data from the same aggregated dataset suggested that longer treatment protocols were associated with better outcomes overall (Thompson-Brenner et al., 2013). These data identify a subset of individuals—males with low shape/weight concerns—who typically benefit from short-term treatment. In this study, 57% of males with low shape/weight concerns achieved remission in protocols of 12 to 16 sessions. Therefore, while at first glance our results align with the previous studies suggesting minimal differences between men and women in treatment outcome (Munsch et al., 2007; Safer, Hagler-Robinson & Jo, 2010), our interaction analysis indicates at least one gender difference in treatment response. In contrast to males with low shape/weight concerns, our data suggested that women in general and men with high shape/weight concerns may require longer treatments to achieve comparable results.

Another important unique finding concerns the serious lack of data regarding men with BED. Although this aggregated data set included the majority of all of the published and/or federally funded large-scale trials of psychosocial treatments for BED from 1995 through 2010 in the United States, there were only 208 males represented. Given that epidemiological data suggest comparable prevalence rates for BED among men and women in the United States (Hudson et al., 2007; Striegel et al., 2012), it is notable how few men have been treated in clinical trials. Moreover, although the percentages of ethnic minority and education status are similar between genders, the dearth of males (i.e., $n = 22 - 25$ out of 1,325) with lower levels of education and minority racial/ethnic background was striking and requires additional research attention, particularly given other epidemiological data indicating that binge eating is equally or more prevalent among individuals with lower SES and minority ethnic backgrounds (Reagan & Hersch, 2005; Striegel-Moore & Franko, 2003). Researchers and clinicians must examine methods of recruitment, advertisement, and outreach to assess whether these materials are somehow biased against men. Efforts must be made to understand how to best assess men for BED, identify where men with BED are likely to enter the healthcare system, and identify the treatment options that will most appeal to them.

There are some important limitations to note. The sample size was much smaller for men than women, we lacked follow-up data, and we were only able to examine treatment-seeking individuals with BED. Additionally, the variables examined were limited by the methods employed in and shared by the original studies. Important related variables (e.g., duration of illness, presence of emotional eating) were not assessed in enough original trials to aggregate. Despite these limitations, our data add to the growing literature indicating the importance of examining gender differences in BED. Although some variables were comparable between genders, differences in baseline EDE scores and the three-way interaction suggesting men with lower shape and weight concerns do not require the same length of treatment as other groups indicate that gender differences may be important to take into consideration when planning treatment and research for individuals with BED.

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Public health significance

The current study highlights the importance of improving recruitment of men, particularly from lower SES and minority ethnic backgrounds, in binge eating disorder treatment trials. The findings also underscore the importance of taking into consideration gender when treating binge eating disorder.

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Table 1

Site and Demographic Information

Site / education / gender	Gender	
	Male	Female
Total	208 (%)	1,117 (%)
Study site		
University of Minnesota	13	85
University of North Dakota	17	137
University of Connecticut	0	89
Stanford University *	30	174
Washington University	28	133
Stanford University II	13	80
Indiana State University	18	132
Columbia University	26	89
Yale University I	32	55
Yale University II	13	58
Yale University III	12	41
Yale University IV	6	44
Education		
Less than high school degree	1 (0.5%)	14 (1.3%)
High school grad / GED	25 (12%)	128 (11.5%)
Some college (<4 years)	63 (30.3%)	344 (30.8%)
College grad (4 years)	69 (33.2%)	346 (31.0%)
Post grad (>4 years)	39 (18.8%)	235 (21.0%)
Missing	11 (5.3%)	50 (4.5%)
Ethnicity		
Caucasian	186 (89.4%)	973 (87.1%)
African American	10 (4.8%)	92 (8.2%)
Hispanic	12 (5.8%)	52 (4.7%)
Age	47.67 (10.31)	46.41 (10.85)
BMI	39.97 (6.68) **	37.84 (7.23) **

* Stanford University was compiled of aggregated data from Rutgers University and Washington University in St. Louis

** $p = .023$

Table 2

Baseline Symptoms by Gender

Outcome Measure	Female N=1,117		Male N=208		Significance	
	Mean (SD)	95% CI	Mean (SD)	95% CI	<i>P-value</i>	Effect Size
Global EDE	2.95 (0.93)	[2.75, 3.15]	2.56 (0.88)	[2.54, 2.57]	<.0001*	.33
Restraint Subscale	1.89 (1.37)	[1.67, 2.11]	1.71 (1.25)	[1.70, 1.72]	0.29	.08
Shape Concern Subscale	3.99 (1.08)	[3.77, 4.21]	3.51 (1.18)	[3.48, 3.53]	<.0001*	.34
Weight Concern Subscale	3.57 (1.06)	[3.38, 3.76]	3.16 (1.07)	[3.15, 3.17]	<.0001*	.29
Eating Concern Subscale	2.35 (1.39)	[2.10, 2.61]	1.85 (1.39)	[1.80, 1.90]	<.0001*	.31
OBEs	19.31 (13.02)	[17.17, 21.45]	18.95 (10.90)	[16.17, 21.73]	.56	.01

Note. CI = Confidence Interval; EDE = Eating Disorder Examination; OBE = Objective Bulimic Episodes

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Table 3

Percent with no OBE episodes at post-treatment (i.e., OBE cessation) with 95% confidence interval by gender, length of treatment and baseline EDE shape/weight concerns.

Gender	Treatment length	Baseline EDE shape/weight concerns	
		3.7	> 3.7
Male	12 or 16 weeks	57% (48%, 66%)	23% (4%, 42%)
	20 or 24 weeks	53% (39%, 67%)	57% (29%, 86%)
Female	12 or 16 weeks	35% (20%, 51%)	31% (13%, 48%)
	20 or 24 weeks	59% (35%, 82%)	54% (40%, 68%)

Note: All cells in the table represent sample sizes of 22 or more. EDE shape/weight concerns was split at the sample median of 3.7.