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An open-label efficacy trial of escitalopram for night eating syndrome ☆

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ABSTRACT

Objective: Night eating syndrome (NES) has become increasingly recognized as a disorder in need of effective treatments. Selective serotonin reuptake inhibitors have shown efficacy in previous trials, so we sought to expand our understanding of the efficacy of escitalopram in the current trial.
Method: Thirty-one adults with NES participated in a 12-week open-label trial of escitalopram. Outcome measures included the Night Eating Symptom Scale (NESS), percent of daily intake after the evening meal (% intake) and number of nocturnal ingestions/week (NI), weight, total awakenings/week, mood, and quality of life. Mixed-effects models were used to assess change over time.
Results: Significant reductions were observed from week 0 to week 12 for the NESS (30.2 to 15.2), % intake (46% to 17%), NI (5.8 to 1.2), weight (90.2 to 88.6 kg), awakenings (8.1 to 2.7), and BDI-II (12.1 to 7.7). Outcomes did not differ significantly by gender, age, race, or psychiatric co-morbidity status. Eighteen of 31 completed 12 weeks of treatment.
Discussion: This open-label trial of escitalopram showed significant reductions in symptoms associated with NES. Randomized controlled trials are warranted to test these findings.
Trial Registration: clinicaltrials.gov identifier: NCT01401595.

1. Introduction

Night eating syndrome (NES) affects about 1.5% of the general population (Rand, Macgregor, & Stunkard, 1997; Striegel-Moore, Franko, Thompson, Affenito, & Kraemer, 2006). The core features include a delayed circadian pattern of eating manifested by evening hyperphagia (consumption of at least 25% of daily food intake after the evening meal) and/or nocturnal ingestions (waking to eat) at least twice a week (Allison et al., 2010). Three of five additional modifiers are also required: morning anorexia, insomnia, strong cravings to eat in the evening or night, depressed mood, and the belief that one must eat to fall (back) asleep, along with distress or impairment in functioning. It is not currently included in the Diagnostic and Statistical Manual, Fourth Edition (DSM) (American Psychiatric Association, 2000), but it will likely appear in DSM 5 (American Psychiatric Association, 2012) under the category Feeding and Eating Conditions Not Elsewhere Classified. As such, more data regarding treatment efficacy are needed.

NES occurs in persons of all weights, but the prevalence seems to grow with increasing body mass. Tholin et al. (2009) showed an increased risk for obesity (2.5 times for men and 2.8 times for women) among participants in the Swedish Twin Register STAGE cohort who screened positive for night eating. In a clinical sample, psychiatric patients with NES were five times more likely to be obese than patients without NES (Lundgren et al., 2006). Night eating is also predictive of weight gain in prospective studies (Andersen, Stunkard, Sorensen, Pedersen, & Heitman, 2004; Gluck, Venti, Salbe, & Krakoff, 2008). However, some epidemiological studies have not shown a positive relationship between weight and night eating symptoms (Striegel-Moore et al., 2006).

While research on the treatment of NES is still sparse, the disorder has been successfully treated with selective serotonin reuptake inhibitors (SSRIs) in a limited number of trials. Open label trials have shown efficacy with sertraline (O'Reardon, Stunkard, & Allison, 2004; Stunkard et al., 2006), and one randomized controlled trial has illustrated the superiority of sertraline over placebo (O'Reardon et al., 2006). In this 8-week controlled trial, 71% of participants on sertraline (n = 17) were considered "responders" on the Clinical Global Impression of Improvement Scale

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(CGII) (Guy, 1976) as compared to 18% of those on placebo (n = 17); 41% of participants in the sertraline condition were considered remitters.

More recently, Vander Wal, Gang, Griffing, and Gadde (2012) reported large improvements in night eating symptoms in their randomized controlled trial of escitalopram, with 60% vs. 35% much improved or very much improved on the CGII in the drug vs placebo group. However, these reductions were not significant between groups, likely due to sample size limitations (n = 20 in each group). While fairly typical of placebo-controlled trials, the 35% placebo response rate was double that of the 18% response rate found in the RCT of sertraline (O'Reardon et al., 2006).

Escitalopram is an enantiomer of citalopram and is currently approved by the Food and Drug Administration for the treatment of depression and generalized anxiety disorder. With consistent symptom reductions found across these studies (O'Reardon et al., 2004, 2006; Stunkard et al., 2006; Vander Wal et al., 2012), we sought to extend the treatment literature with another trial of escitalopram, wanting to confirm the results reported by Vander Wal et al. (2012), and expecting that it would reduce the core features of NES significantly in this sample.

2. Material and methods

2.1. Participants

Potential participants were recruited through television and Internet advertisements, along with flyers posted at the University Hospital and around campus targeting persons who experienced overeating at night and/or waking during the night to eat. Men and women between the ages of 18–70 of all races and ethnicities were included. Exclusion criteria were: pregnancy; insulin-dependent diabetes; thyroid or other metabolic disorders; use in the past month of any psychotropic medication, oral steroids, diuretics or hypnotics; the presence of anorexia nervosa or bulimia nervosa; current participation in an organized weight reduction program or the use of weight loss medication, current participation in psychotherapy treatment for NES or another eating disorder, an occupation requiring night-shifts or other unusual nighttime requirements; severe major depressive disorder; suicidal risk; bipolar disorder; current or past psychosis; or substance use or abuse within the past 6 months. Weight greater than 400 lb and an allergy to shellfish or iodine were also exclusions, as participants were also completing a brain imaging study.

This study's protocol was reviewed and approved by the University of Pennsylvania's Institutional Review Board, with all participants providing informed consent.

2.2. Procedures

Participants were screened by phone for inclusion and exclusion criteria before being scheduled for their baseline assessment. At the baseline visit, participants completed a psychological assessment during which the diagnosis of NES was confirmed through questionnaires, clinical interviews, and, subsequently, a 10-day food and sleep log. Study personnel analyzed data from the logs with the Food Processor® program (ESHA research, Salem, OR). All participants included in the study met the full research criteria for NES (Allison et al., 2010). Using the available data, the authors confirmed that participants consumed at least 25% of their caloric intake after their evening meal and/or after waking up during the night to eat at least twice per week. Participants were also required to meet at least three of the five modifiers, have awareness of their nighttime eating, and show distress or impairment in functioning due to their night eating. The NES symptoms had to be present for at least three months.

The baseline assessment also included a history and physical examination; drug screen, measurement of height, weight, and blood pressure; metabolic panel; and an electrocardiogram to establish that the participants were healthy enough to participate in a medication trial. After completing the assessment, participants with confirmed NES were eligible for a brain imaging study (to be described elsewhere) and treatment. Participants were paid for completing the comprehensive assessment and brain imaging portion of the study. Treatment was subsequently provided at no charge.

A total of 342 individuals responded to ads to participate in the current study. Of the 342 whom we contacted, 75 individuals provided consent to enroll in the study as night eating participants. Of the 75 who provided consent, 21 were found to be ineligible during their baseline screening appointment for the following reasons (some participants met more than one exclusion): 3 had uncontrolled or undiagnosed diabetes, 3 used illicit drugs, 4 met criteria for severe depression or suicidal ideation, 2 had anemia, 2 had abnormally high blood pressure, 2 had abnormal ECG, 4 had other medical issues deemed unstable or needing further medical care, 1 met criteria for bipolar disorder and 1 for purging disorder, 2 used other psychotropic/sleep medications, and 1 weighed greater than 400 lb. Additionally, 22 did not continue after the baseline assessment: 9 were found to be eligible, but never returned their screening materials (i.e., food/sleep log and survey packet), 3 had scheduling difficulties, 3 did not meet full NES criteria after assessment, 3 declined the study/lost to follow-up after baseline, and 4 did not keep their baseline (week 0) treatment appointments. The remaining 32 entered treatment. Of the 32 who entered treatment, 1 did not return after the initial treatment week and was not included in analysis (as she did not have more than one datapoint).

2.2.1. Treatment

Treatment visits occurred at week 0 (start of treatment) and weeks 1, 2, 4, 6, 8, 10, and 12. Dosing of escitalopram began at 10 mg. If participants experienced significant side effects, dose was cut to 5 mg. At week 4, if participants' symptoms were still present, the dose was increased to 20 mg. Likewise, if significant side effects were experienced at 20 mg, dose was cut to 15 mg.

2.3. Measures

2.3.1. Baseline

In addition to collecting demographic information, several measures were used at baseline to characterize the sample and to assess for exclusion criteria. The *Night Eating Questionnaire* (NEQ) (Allison et al., 2008) was completed at baseline. This is a 14-item questionnaire that assesses behavioral and psychological symptoms of NES. Total scores range from 0 to 52. The *Beck Depression Inventory-II* (BDI-II; Beck, 1996) was also administered; it is a widely used 21-item questionnaire that measures symptoms of depression present during the past week. Total scores range from 0 to 63; the BDI-II has high internal consistency, test–retest reliability and convergent and discriminant validity. The *Night Eating Syndrome History and Inventory* (NESHI) (Lundgren, Allison, Vinai P, Gluck) was used to confirm a diagnosis of NES. The NEQ is embedded in the NESHI, and additional items describe typical meal and snack patterns, level of distress, and severity and course of NES symptoms. The diagnostic criteria for NES are assessed with the NESHI.

Eating disorder psychopathology was assessed with the Eating Disorder Examination, 16th edition (Fairburn, Cooper, & O'Connor, 2008). This measure has been found reliable and valid for assessment of eating pathology (Fairburn, Cooper, & O'Connor, 2001; Grilo, Masheb, Lozano-Blanco, & Barry, 2004). The EDE includes assessment of binge eating and overeating episodes, four subscales (Restraint, Eating Concern, Shape Concern, and Weight Concern), and a global disordered eating score. The Eating Inventory was used to characterize common psychological factors related to eating, including cognitive restraint, disinhibition, and hunger (Stunkard & Messick, 1985). Axis I psychopathology was broadly assessed with the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I/P) (First, Spitzer, Gibbon, Williams, & Benjamin, 1996).