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Body Mass Index and Intercourse Compliance

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Abstract

Objective—To investigate the relationship between body mass index and intercourse compliance in the PPCOS Trial.

Design—Post ad hoc data analysis of subjects in the RMN PPCOS Trial

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Setting—Academic medical centers

Intervention(s)—None

Patients—Six hundred twenty-six infertile women with PCOS with a mean age of 28.1 ± 4 years and mean body mass index of $35.2 \text{ kg/m}^2 \pm 8.7$

Main Outcome Measure(s)—Intercourse compliance and body mass index

Result(s)—Overall, body mass index was not associated with increased intercourse compliance. However, although patients with BMI ≥ 35 were less likely to ovulate than patients with BMI < 35 , they tend to be more compliant with intercourse frequency in ovulatory cycles than patients with BMI < 35 .

Conclusion(s)—Body Mass Index was not associated with intercourse compliance or non-compliance. An elevated BMI in infertile women with PCOS is not associated with poor intercourse compliance.

Keywords

body mass index; intercourse frequency; ovulation; polycystic ovary syndrome

The NICHD-sponsored multicenter trial of the Reproductive Medicine Network (Pregnancy in Polycystic Ovary Syndrome or PPCOS) reported a higher livebirth delivery in women with PCOS treated with clomiphene citrate alone or the combination compared to metformin XR alone. (1). Further, independent of treatment, subjects with a body mass index (BMI) below 30 had a significantly higher rate of live births than did women whose BMI was 30 or more ($P < 0.001$) (1). The relationship between treatment and live birth was similar in post ad hoc analyses of subgroups stratified to BMI (< 30 , 30–34, and ≥ 35). What were not explored were plausible explanations for this observation.

There is no dispute that ovulation is the key event in the menstrual cycle that determines the timing of the fertile interval during which intercourse can result in a pregnancy. Hence, a critical predictor, is the timing of non contraceptive intercourse during the menstrual cycle. Intercourse compliance is a potential confounding variable as behavior differences between exposure groups may exist while also having a large impact on conception probabilities. Poor or non compliance in the adherence in following intercourse instructions can bias the effectiveness of treatments. Although the rates of compliance in the PPCOS trial were similar across groups at all cycles except cycle number four, possible effect modulators of intercourse compliance were not determined. Clinical experience suggests that BMI may be such a modulator. It has been suggested that women with PCOS and a high baseline BMI have decreased sexual desire compared to normal ovulatory women on the basis of altered body image while others dispute this notion (2–4). It is possible that categories of BMI may adversely impact intercourse frequency and hence decrease conception rates.

Based on the above observations, we examined the interaction between intercourse compliance and body mass index. The study is a post ad hoc secondary analysis of the interaction between intercourse compliance and subgroups of subjects stratified according to BMI in the RMN PPCOS trial. The purpose of this study was to examine if intercourse compliance was affected by body mass index.

MATERIALS AND METHODS

In the PPCOS Trial, 626 women with PCOS were randomly treated with clomiphene citrate alone (“C”; $n=209$), metformin alone (“M”; $n=208$) or the combination (“B”; $n=209$). Medication was blinded to investigators and subjects. Subjects were instructed to have

regular intercourse every 2 to 3 days and to keep a diary recording intercourse, vaginal bleeding and symptoms. Live birth delivery was over 3 times more likely in the clomiphene citrate containing arms than in the metformin alone group ("C" 22.5% livebirths per subject versus "B" 26.8% livebirths per subject versus "M" 7.2% livebirths per subject). Further, independent of treatment, subjects with a body mass index (BMI) below 30 had a significantly higher rate of live births than did women whose BMI was 30 or more ($P<0.001$). However, the ovulation rate was significantly higher in the combination group than in either of the single-agent groups.

All subjects were required to maintain a handwritten daily prospective diary, in which symptoms such as vaginal bleeding, GI upset, etc., medications taken, and the occurrence of intercourse were recorded. These diaries were brought in by subjects for the weekly visits with study staff, and reviewed to make sure that medications were taken as prescribed, intercourse was occurring at a 2–3 times weekly interval, and to discuss any symptoms or medication side effects. Patients were not instructed to perform any home self assessment of ovulation. In this study we examined the relationship between intercourse compliance and BMI in both ovulatory and non-ovulatory cycles.

Compliance status was based on patients' written prospective diaries, as reviewed weekly by study staff. Intercourse frequency of two-three times per week, as recommended for all subjects in the study, was considered compliant. Patients who had intercourse 1 per week were considered non-compliant. If the compliance status was missing from the data base, subjects were considered as non-compliant.

The body mass index (weight in kg/height in meters²) of each subject was recorded at study initiation but did not serve as exclusion criteria. Stratification of BMI into the following categories, <30, 30–34, and 35 were chosen and in keeping with the National Institute of Health's definition of normal weight, overweight and obesity and the associated category of health risk. There were no subjects in any treatment arm with a BMI of less than 25.

There were no significant differences in baseline variables between treatment groups. The overall mean ($\pm$ SD) age of the subjects was 28.1 ± 4.0 years, and the mean body mass index was $35.2 \text{ kg/m}^2 \pm 8.7$. Further, there was no statistically significant difference observed among the treatments groups with stratification of BMI into the following categories, <30, 30–34, and 35.

Statistical Analysis

Data management and analysis were performed at the Data Coordinating Center at the Duke Clinical Research Institute. Frequency and percentage are used to describe the data. Generalized estimating equations approach was used for computing the P-value to account for correlation of multiple cycles for each subject. Odds ratios point estimates and 95% Wald confidence limits are also reported to determine the effects. All analyses were performed with SAS software, version 8.2 (SAS Institute). Given the post hoc analysis of the data set, the sub-segmentation and multiple comparisons of the data, P-values of 0.02 were considered statistically significant.

RESULTS

When considering all cycles with known ovulation status and baseline BMI, 81.1% were intercourse compliant. There were a total of 179, 135 and 311 patients in the BMI groups of <30, 30–34 and 35, who contributed 783, 620 and 1519 cycles, resulting in mean cycles per patient of 4.4, 4.6 and 4.9 cycles, respectively. Body mass was not significantly associated with intercourse compliance (Table 1, 79.6% vs. 82.4% and 81.4%, $P = 0.61$, Odds

Ratios of 0.88, (95% CI 0.66 – 1.18) and 1.05 (95% CI 0.75 – 1.46) for comparing the two lower BMI groups to BMI ≥ 35 respectively).

Patients with a BMI ≥ 35 were less likely to ovulate than the groups with lower BMI (58.0% vs. 54.2% vs. 36.2%, $P < 0.0001$, odds ratios of 2.46 (95% CI 1.87 – 3.24) and 2.04 (95% CI 1.53 – 2.72) for comparing the two lower BMI groups to BMI ≥ 35). When considering only ovulatory cycles, patients with a BMI ≥ 35 were significantly more likely to comply with intercourse instructions than those with lower BMI's (79.5% vs. 83.6% vs. 86.0%, $P=0.02$, Table 2, odds ratios of 0.57 (95% CI 0.38 – 0.86) and 0.75 (95% CI 0.46 – 1.22) for comparing the two lower BMI groups to BMI ≥ 35, respectively).

When considering all non-ovulatory cycles and baseline BMI, body mass was not associated with intercourse compliance, $P=0.072$, Table 3, odds ratio of 1.01 (95% CI 0.70 – 1.46) and 1.17 (94% CI 0.79 – 1.74) for comparing the two lower BMI groups to BMI ≥ 35, respectively).

In a separate analysis (results unpublished), we found that PCOS women are more compliant with intercourse frequency in ovulated cycles than in non-ovulated cycles. Based on the above data, together with baseline BMI data, it appears that this association mainly occurred in the group of BMI ≥ 35.

DISCUSSION

Controversy exists in the literature with regard to the impact of an elevated BMI on sexual desire and frequency. (2–4) Behavioral studies indicate that an increase in body mass has been associated with poor sexual self-image and decreased intercourse frequency in married couples (4). Other lines of evidence indicate that as body mass increases, SHBG decreases and free androgens rise (5). Elevated androgens exert a major influence on sexuality in women, thus, the increased effect of sexual desire known to be affected by testosterone plus the documented increase in peri-ovulatory sexual frequency (2–3) may override body-image effects in PCOS women with an elevated BMI. Our data provide definitive evidence that ovulatory women with an elevated BMI who are attempting to conceive is more likely to have frequent intercourse. Thus, concerns that poor body-image women with an elevated BMI may lower sexual desire in such women may be overridden by the stimulatory effects of ovulation on sexual frequency and the desire to achieve a pregnancy.

It was beyond the scope of this study to examine the reasons for the association between body self-image and intercourse frequency. This is a post-hoc analysis of a study not designed to assess adherence to intercourse direction and thus is subject to the limitations of such analyses. Hence, extrapolation of the above observations beyond this study population should be guarded. Because this study relied upon prospective, written diaries checked by study staff during weekly visits with study staff, the chances that a non-compliant subject would “edit” her intercourse diary to reflect compliance with intercourse instructions is lessened. There could be over or under reporting of intercourse, however, if subjects were embarrassed or uncomfortable with admitting to what they perceived of as “too little” or “too much” sexual activity. Further, other study limitations not accounted for given the post ad hoc data set that could influence the observations described include but are not limited to subjects knowledge of ovulation to include use of home self-assessment of ovulation, intercourse frequency prior to entry into the study or behavioral influence on intercourse compliance and associated BMI among the male partners.

Conclusion

In conclusion, contrary to many behavioral studies, increased body mass index was positively associated with increased intercourse compliance in ovulatory cycles in the RMN PPCOS trial.

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TABLE 1

Baseline BMI and intercourse compliance in all cycles.

	BMI < 30 n=783	BMI 30–34 n=620	BMI > 35 n=1519
Intercourse Compliant	623/783 (79.6%)	511/620 (82.4%)	1237/1519 (81.4%)
Intercourse Non- compliant	160/783 (20.4%)	109/620 (17.6%)	282/1519 (18.6%)

P=0.61

TABLE 2

Baseline BMI and intercourse compliance in ovulatory cycles

	BMI < 30 n=454	BMI 30–34 n=336	BMI ≥35 n=550
Intercourse Compliant	361/454 (79.5%)	281/336 (83.6%)	473/550 (86.0%)
Intercourse Non- compliant	93/454 (20.5%)	55/336 (16.4%)	77/550 (14.0%)

P=0.02

TABLE 3

Baseline BMI and intercourse compliance in non-ovulatory cycles

	BMI < 30 n=329	BMI 30–34 n=284	BMI ≥35 n=969
Intercourse Compliant	262/329 (79.6%)	230/284 (81.0%)	764/969 (78.8%)
Intercourse Non- compliant	67/329 (20.4%)	54/284 (19.0%)	205/969 (21.2%)

P=0.72