

1 Association between obesity and bacterial vaginosis as assessed
2 by Nugent score

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42 **Condensation:** Obese and overweight women exhibit higher Nugent scores and an increased
43 prevalence of bacterial vaginosis than lean women.

44 **Short Title:** Obesity and the prevalence of bacterial vaginosis

45 **AJOG at a Glance:**

46 **A.** Although several risk factors for bacterial vaginosis have been identified, whether
47 obesity/overweight is a risk factor for bacterial vaginosis is not clear. This study was conducted
48 to determine whether an association between obesity/overweight and prevalence of bacterial
49 vaginosis exists and to examine the role of race in this context.

50 **B.** Key findings of this study are that obese and overweight women have higher Nugent scores
51 and increased prevalence of bacterial vaginosis. We also show that race is an effect modifier of
52 the relationship between body mass index and prevalence of bacterial vaginosis.

53 **C.** This study uncovers an association between obesity/overweight and frequency of bacterial
54 vaginosis, as well as demonstrating that, unlike white women, black women exhibit higher
55 Nugent scores and increased prevalence of bacterial vaginosis regardless of body mass index.

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66 **Abstract**67 **BACKGROUND:** Bacterial vaginosis is one of the most common vaginal conditions in the U.S.

68 Recent studies have suggested obese women have an abnormal microbiota reminiscent of BV;

69 however, few studies have investigated the prevalence of bacterial vaginosis in overweight and

70 obese populations. Moreover, despite the increased prevalence of obesity and bacterial vaginosis

71 in black women, it is not known whether racial disparities exist in the relationship between

72 obesity and bacterial vaginosis.

73 **OBJECTIVE:** The objective of this study was to examine the relationship between body mass

74 index and bacterial vaginosis as determined by Nugent score and to determine the influence of

75 race in this context.

76 **STUDY DESIGN:** We performed a cross-sectional study using patient data and vaginal smears

77 from 5,918 participants of the Contraceptive CHOICE Project. Gram stained vaginal smears

78 were scored using the Nugent method and categorized as BV-negative (Nugent score 0-3), BV-

79 intermediate (Nugent score 4-6), or BV-positive (Nugent score 7-10). Body mass index was

80 determined using Centers for Disease Control and Prevention guidelines and obese individuals

81 were categorized as Class I, II, or III obese based on NIH and World Health Organization body

82 mass index parameters. Linear regression was used to model mean differences in Nugent scores

83 and Poisson regression with robust error variance was used to model prevalence of bacterial

84 vaginosis.

85 **RESULTS:** In our cohort, 50.7% of participants were black, 41.5% were white, and 5.1% were

86 of Hispanic ethnicity with an average age of 25.3 years old. Overall, 28.1% of participants were

87 bacterial vaginosis-positive. Bacterial vaginosis was prevalent in 21.3% of lean, 30.4% of

88 overweight, and 34.5% of obese women ($p < 0.001$). The distribution of bacterial vaginosis-
89 intermediate individuals was similar across all body mass index categories. Compared to lean
90 women, Nugent scores were highest among overweight and obese Class I women (adjusted mean
91 difference; overweight 0.33 [95% CI 0.14, 0.51] and Class I obese 0.51 [95% CI 0.29, 0.72]).
92 Consistent with this, overweight and obese women had a higher frequency of bacterial vaginosis
93 compared to lean women, even after adjusting for variables including race. Among white
94 women, the prevalence of BV was higher for overweight and Class I and Class II/III obese white
95 women compared to lean white women, a phenomenon not observed among black women,
96 suggesting an effect modification.

97 **CONCLUSION:** Overweight and obese women have higher Nugent scores and a greater
98 occurrence of bacterial vaginosis compared to lean women. Black women have a greater
99 prevalence of bacterial vaginosis independent of their body mass index compared to white
100 women.

101 **KEYWORDS:** bacterial vaginosis, obesity, body mass index, Nugent score, race, overweight,
102 microbiome

103

104 **Introduction**

105 Bacterial vaginosis (BV) is one of the most common vaginal conditions in the U.S. and is
106 present in approximately one out of every three women.¹ BV is characterized by lower levels of
107 beneficial *Lactobacilli* and an overgrowth of fastidious anaerobic bacteria such as *Gardnerella*
108 *vaginalis*, *Atopobium vaginae* and species of *Prevotella* and *Mobiluncus*.² Women with BV are
109 at an increased risk for sexually transmitted infections (STIs; e.g., gonorrhea, chlamydia, HIV,
110 and trichomoniasis), urinary tract infection, pelvic inflammatory disease, and adverse pregnancy
111 outcomes including preterm birth.³⁻¹³

112

113 Nugent scoring is the gold standard for laboratory-based BV diagnosis and uses morphotype
114 evaluation of Gram-stained slides to quantify the representation of Gram-positive
115 (*Lactobacillus*), small Gram-negative or -variable (*Gardnerella*, *Bacteroides*), and curved
116 organisms (such as *Mobiluncus*) in vaginal fluid smears.¹⁴ These measurements are reported as a
117 score ranging from 0 to 10, with scores 0-3 indicative of a “normal” *Lactobacillus*-dominant
118 microbiota and 7-10 indicating a positive BV diagnosis. Women with a score of 4 to 6 have an
119 “intermediate” microbiota, and, similar to BV-positive individuals, may be at greater risk for
120 acquiring STIs compared to women with a “normal” *Lactobacillus*-dominant microbiota.^{8,15-17}

121 Although the pathologic significance of BV-intermediate status is still not clear in all situations,
122 this type of vaginal microbiota is often considered along with BV as an “abnormal

123 microbiota”.^{8,18,19} It is known that several factors including menstruation,^{20,21} douching,^{1,22,23} and
124 high numbers of sexual partners²⁴ are associated with disruptions of the vaginal microbiota.

125 Many questions still remain about how BV negatively influences women’s reproductive health.

126 Unfortunately, there is little mechanistic information about how the dysbiotic BV microbiome

127 develops or how individual bacteria interact with the host to produce disease. However, recent
128 studies in mouse models have further implicated *Gardnerella vaginalis* as a cause of features
129 related to BV.^{25,26} These unknowns and the fact that BV is a common condition in the U.S.
130 underscore the importance of identifying BV-associated risk factors to identify women at high
131 risk for adverse gynecologic and obstetric outcomes and to design more effective treatments and
132 prevention strategies.

133

134 While a relationship between increased body mass index (BMI) and gut dysbiosis has been
135 widely studied,²⁷⁻³² little is known about the relationship between BMI and BV prevalence.
136 Most recently, it has been reported that the vaginal microbiota of overweight and obese Korean
137 women exhibited a larger proportion of *Lactobacillus iners* and *Prevotella* compared to lean
138 women.^{33,34} This is of interest since both of these taxa have been previously associated with
139 BV.^{35,36} While these studies suggest there may be an increased prevalence of BV in
140 overweight/obese women, participant BV status was not reported.^{33,34} One study conducted
141 among U.S. women reported a positive correlation between high BMI and BV; however, after
142 multivariable modeling, this study showed BMI was not independently associated with BV.³⁷
143 This study had several caveats including that less than one third of the women examined were
144 black, and it did not examine the relationship between BMI and women with an “intermediate”
145 microbiota (Nugent score 4-6). Moreover, all obese women were categorized into a single BMI
146 group regardless of the subclass of obesity. Both NIH and WHO categorize obese individuals
147 into three subclasses based on BMI: Class I (30-34.9 kg/m²), Class II (35-39.9 kg/m²) and Class
148 III (≥ 40 kg/m²),^{38,39} and reports have shown an association between obesity class level and an
149 increased prevalence of disease.^{40,41} Given the racial disparities among overweight and obese

150 women, and the higher prevalence of BV in black women, understanding the relationship
151 between BV and BMI, and the role of race, is highly warranted.^{1,42-44}

152
153 To increase our understanding of the vaginal microbiota among overweight/obese women, and
154 the extent to which this association may be influenced by race, we examined the correlation
155 between BMI, Nugent score, and BV prevalence among women in the St. Louis region.
156 Specifically, we examined whether BMI positively correlated with higher Nugent scores and
157 increased BV prevalence. To test whether factors such as race influenced the proposed
158 relationships, we performed multivariable modeling using information gathered from 5,918
159 reproductive aged women, of whom 50.7% were black.

160

161 **Materials and Methods**

162 **Study design**

163 We conducted a cross-sectional sub-study of participants from the Contraceptive CHOICE
164 Project (CHOICE).⁴⁵ CHOICE obtained written informed consent from all participants before
165 enrollment in accordance with its approved IRB protocol from Washington University in St.
166 Louis. CHOICE participants consented to the use of questionnaire data and stored vaginal
167 samples by future sub-studies. The current sub-study obtained IRB approval (ID# 201108155)
168 from Washington University in St. Louis and followed the principles outlined in the Declaration
169 of Helsinki for human research.

170

171 Over a 4-year period, CHOICE enrolled 9,256 women from the St. Louis region and provided
172 FDA-approved reversible contraceptive methods at no-cost.⁴⁵ Eligibility criteria included women

173 14 to 45 years of age, self-reported sexual activity in the past 6 months or plans to become
174 sexually active with a male partner, and a desire to prevent pregnancy through the use of a
175 reversible contraceptive method. Participants with a history of tubal ligation or hysterectomy
176 were excluded from the study. The CHOICE cohort predominantly consisted of black and white
177 participants, which is representative of the racial make-up of the St. Louis region. The current
178 sub-study only included women with a complete baseline questionnaire survey, BMI
179 measurement, and Nugent score (n= 5,918). The baseline questionnaire included age, self-
180 reported race and ethnicity, highest level of education obtained, monthly income, receipt of
181 public assistance, difficulty paying for basic necessities, tobacco history, number of sexual
182 partners, history of douching in last 30 and 180 days, history of STIs or positive for an STI at
183 enrollment. Menstrual status was estimated as last menstrual period within 6 days of enrollment
184 and a flag for recent hormonal contraceptive method use was created for those who reported
185 contraceptive pills, patch, ring or injection, the levonorgestrel intrauterine system or subdermal
186 implant. History of STI was defined as ever told by a healthcare provider that had one of the
187 following sexually transmitted infections: chlamydia, gonorrhea, trichomoniasis, syphilis, human
188 papillomavirus or genital warts, human immunodeficiency virus or herpes; current STI was
189 defined as positive test for *Chlamydia trachomatis*, *Neisseria gonorrhoeae* or *Trichomonas*
190 *vaginalis* at enrollment.

191

192 **Assessment of Bacterial Vaginosis**

193 At the time of CHOICE enrollment and prior to LARC method insertion, participants were
194 instructed by a medical professional for self-collection of vaginal fluid from a mid-vaginal site
195 (approximately 2 inches into the vagina) using a double-headed rayon swab (Starplex Scientific

196 Inc., Etobicoke, Ontario, Canada). Vaginal swabs were immediately rolled onto glass slides to
197 create vaginal smears, which were Gram-stained and scored using the Nugent method.¹⁴ The
198 Nugent method consisted of microscopic evaluation of bacterial morphotypes to score the overall
199 character of the vaginal flora.¹⁴ Nugent scores range from 0 to 10 based on the prevalence of
200 three bacterial morphotypes that roughly correspond to *Lactobacillus*, *Gardnerella vaginalis* or
201 *Bacteroides*, and *Mobiluncus*. The number of long rod-shaped Gram-positive bacilli are scored
202 0-4, where 0 indicates high numbers of *Lactobacillus*; small Gram-negative and Gram-variable
203 rods and coccobacilli (*Bacteroides* and *G. vaginalis*) scored 0-4, with 4 denoting the highest
204 observed number of these bacteria; and curved rods (e.g. *Mobiluncus* spp.) scored 0-2, where 2
205 indicates the highest observed numbers. To ensure consistency in the amount of vaginal fluid on
206 each slide and Gram-staining and Nugent scoring, all swabs were rolled by the same technician
207 and all slides were stained and scored by the same technician. To assess the reliability of our
208 scoring, a subset of smears we scored were also scored by the laboratory of Dr. Sharon Hillier
209 (who established the Nugent score method¹⁴) at the Magee-Womens Research Institute,
210 University of Pittsburgh and was reproducible between both research groups. Samples were
211 categorized as BV-negative (score 0-3), BV-intermediate (score 4-6), or BV-positive (score 7-
212 10).

213

214 **BMI determination**

215 Weight and height of participants were measured at the clinics by research personnel using a
216 standardized protocol at the time of enrollment. Weight was recorded in pounds and height in
217 feet and inches. Participants removed shoes and heavy outer clothing before being measured.
218 This data was converted to BMI using the formula published by the Centers for Disease Control

219 and Prevention:⁴⁶ $(\text{weight (lb)}/[\text{height(in)}]^2) \times 703$. Women were categorized by BMI based on
220 NIH and WHO recommendations: underweight ($<18.5 \text{ kg/m}^2$), lean ($18.5\text{-}24.9$, overweight (25-
221 29.9 kg/m^2), and Class I obese ($30\text{-}34.9 \text{ kg/m}^2$), Class II ($35\text{-}39.9 \text{ kg/m}^2$) obese and Class III
222 ($\geq 40 \text{ kg/m}^2$) obese.^{38,39}

223

224 **Statistical analysis**

225 Participant characteristics were described for all women and among strata of BMI categories. P-
226 values for these comparisons were estimated using chi-square tests (all categorical variables) or
227 linear regression (age). We examined multiple metrics of BV in relation to BMI: Nugent score
228 category (including intermediate), Nugent-defined bacterial vaginosis, and symptomatic BV
229 (report of discharge, itching, odor or pain during urination⁴⁷ during the 7 days prior to the clinic
230 visit and sample collection).

231

232 Crude and adjusted mean differences and 95% confidence intervals were estimated using linear
233 regression stratified by BMI among all participants and by self-identified race group (black or
234 white). Potential confounders (listed in Table 1) were evaluated for association with body mass
235 index and Nugent score. All variables that were significant at the $\alpha < 0.05$ level were
236 retained for inclusion in the fully adjusted model. Hispanic ethnicity and ever use of tobacco
237 were not associated with Nugent score and were excluded. Variables that were significant in the
238 fully adjusted model (public assistance, education, current smoker, douching in the last 30 days,
239 sexually transmitted infection at baseline, and current hormonal contraception) were included in
240 the final adjusted model. The All Participant models were also adjusted for race. Prevalence
241 ratios of BV were estimated using Poisson regression with robust error variance. This approach
242 provides an unbiased estimate of the prevalence ratio in the instance of a common binary

243 outcome. The p-value for the interaction term for BMI and race served as an indicator of effect
244 modification. P-values for two-tailed tests less than $\alpha = 0.05$ were considered statistically
245 significant. All analyses were conducted in Stata 13.0 (StataCorp LP, College Station, TX).

246

247 **Results**

248 **Participant characteristics**

249 Of the 9,256 CHOICE participants, 6,022 (65.1%) had a baseline questionnaire survey, BMI
250 measurement, and Nugent score. The main reason for missingness (N=2,417, 26.1%) was
251 absence of a vaginal smear for Nugent scoring, an element added to the protocol after enrollment
252 began. Of the 6,022 eligible participants, 5,918 (98.3%) had complete data and were included in
253 the current analysis. Participant data and vaginal specimens were obtained at the time of
254 enrollment. Participants averaged 25.3 years old, and 50.7% self-identified as black (Table 1).
255 Over half of participants (52.9%) reported a monthly income of \$800 or less and 38.1% reported
256 some form of public assistance at enrollment. One third of participants (33.9%) reported a high
257 school diploma as the highest degree obtained. Most women reported multiple lifetime sexual
258 partners (median=3); 27.5% of participants reported 2-4 partners, 29.2% reported 5-7, 14.2%
259 reported 8-12, and 19.7% reported 13 or more lifetime sexual partners. Forty-six percent had a
260 history of smoking, with 23.1% self-reporting as current smokers at the time of enrollment.

261

262 In this cohort, 27.3% of women were BV-intermediate and 28.1% were BV-positive (Table 2).
263 Of the women diagnosed as BV-positive, 17.2% reported symptoms associated with BV (i.e.,
264 abnormal discharge, foul odor, and vaginal itching⁴⁷) at the time of enrollment.

265

BV prevalence by BMI category

Of the 5,918 study participants, 2.9% were underweight (BMI <18.5 kg/m²), 39.1% were lean (BMI 18.5-24.9 kg/m²), 26% were overweight (BMI 25-29.9 kg/m²), and 32% were obese (BMI ≥30 kg/m²) (Table 1). As shown in Table 2, 34.5% of obese, 30.4% of overweight, and 21.3% of lean women were BV-positive. Given that we observed no relationship between BMI and BV-intermediate scores in this cohort, we examined the number of women below the threshold of BV (BV-negative and -intermediate) and found it to be highest among lean women (78.7%) and lowest among obese women (65.5%) (Table 2).

We next examined whether a relationship existed between obesity class and BV prevalence. Due to the limited number of Class II and III obese individuals in this cohort, members of these two classes (BMI ≥35 kg/m²) were grouped together (n=958) and members of Class I (n=934) remained separate. Nugent scores were higher in overweight (0.33 [95% CI 0.14, 0.51]), Class I obese (0.51 [95% CI 0.29, 0.72]), and Class II/III obese groups (0.37 [95% CI 0.16, 0.59]) compared to lean women (Table 3). Consistent with this observation, the adjusted prevalence ratio of BV was 1.25 (95% CI 1.12, 1.39) for overweight, 1.31 (95% CI 1.16, 1.47) for Class I obese, and 1.25 (95% CI 1.11, 1.41) for Class II/III obese women compared to lean women (Table 4, 5th column).

The role of race in the BMI-BV relationship

To determine whether the relationship between BMI and BV was influenced by race, we performed a within race analysis of the mean difference in Nugent scores and the prevalence ratio of BV among black women (n=3,001) in each BMI category. Adjusted Nugent scores were

289 higher in overweight (0.30 [95% CI 0.01, 0.58]) and Class I obese (0.41 [95% CI 0.10, 0.73])
290 black women, compared to lean black women (Table 3). However, the adjusted Nugent scores of
291 Class II/III obese black women were not significantly different compared to lean counterparts.
292 Among white women (n=2,457), Nugent scores were higher for Class I (0.56 [95% CI 0.23,
293 0.89]) and Class II/III (0.58 [95% CI 0.21, 0.95]) obese white women compared to lean white
294 women. We observed no significant difference in Nugent scores for overweight white women
295 compared to lean white women (Table 3).

296
297 We next examined the adjusted prevalence ratio of BV for black women across all BMI
298 categories. We observed that only Class I obese black women had an increased occurrence of BV
299 (1.14 [95% CI 1.00, 1.31]) compared to lean black women, while the prevalence of BV for
300 overweight and Class II/III obese black women was not statistically different than lean black
301 women (Table 4). Among white women, the adjusted prevalence ratio of BV was greater in
302 overweight (1.44 [95% CI 1.16, 1.79]), Class I (1.73 [95% CI 1.35, 2.22]), and Class II/III (1.63
303 [95% CI 1.23, 2.15]) obese white women compared to lean white women (Table 4). We next
304 examined the effect modification of race on the BMI-BV relationship. The statistical interaction
305 of increasing BMI and race in relation to BV prevalence was significant for overweight (p
306 =0.024) and obese (class I, p = 0.001 and class II/III, p = 0.002) women (Table 4). No interaction
307 of race was observed in the association of BMI and Nugent score (Table 3).

308

309 **Comment**

310 We report that Nugent scores were higher in overweight (4.53) and obese (class I - 4.87, and
311 class II/III - 4.93) women compared to lean (3.90) women. Overweight and obese women also

312 had a higher frequency of BV (overweight - 25%, and obese class I - 31% and class II/III - 25%;
313 adjusted). Because black race is a risk factor for both BV and obesity in women,^{1,44-46} we
314 examined the relationship between BMI and BV by race. Among white women, Nugent scores
315 were higher in obese (class I - 3.99 and class II/III - 4.08) women than in lean (3.21) women.
316 White overweight (19.9%) and obese (class I - 24.7% and class II/III - 24.2%) women had a
317 higher prevalence of BV compared to lean (12.5%) white women. However, among black
318 women, this phenomenon was not present, suggesting that BV occurrence in black women is
319 independent of their BMI. We observed a significant interaction of race and increasing BMI in
320 relation to BV prevalence for overweight ($p = 0.024$) and obese (class I $p = 0.001$ and class II/III
321 $p = 0.002$) women, suggesting race is an effect modifier of the association of increasing BMI and
322 BV prevalence. While the interaction of race on the BMI-BV relationship has not been
323 previously reported, studies have shown obese white women exhibit a higher avoidance of
324 female preventative health care services (e.g., Papanicolaou test and breast cancer screening), a
325 phenomenon not observed in obese black women.^{48,49} Multiple factors likely contribute to the
326 significant interaction between race, BMI, and BV in our study; the previously observed higher
327 level of delay and avoidance toward preventative genital health services among obese white
328 women may be one factor.⁵⁰
329
330 Few studies have explored the relationship between BMI and BV prevalence, and a consensus
331 on whether BMI is a risk factor for BV has not been reached. In one study of 2,906 U.S. women,
332 of which 26.2% were black, 36% of obese women were BV positive; however, after adjusting for
333 confounders, there was no relationship between BMI and BV.³⁷ This apparent discrepancy may
334 be due to our larger sample size ($n=5,918$), a larger representation of black women (50.7%), and

335 potential differences in the differential control of confounders and levels of residual confounding
336 between our study and Koumans *et al.* A recent longitudinal study reported obesity was
337 associated with nearly a 20% decrease of BV risk in a cohort of 1,946 Kenyan female sex-
338 workers.⁵¹ The longitudinal Kenyan study measured relative risk of BV in obese populations
339 while our cross sectional study measured prevalence (e.g., one infers a causal relationship while
340 the other offers association). Differences in the characteristics of the Kenyan cohort and our
341 cohort may also account for the discrepancy between the two studies, for example, our larger
342 sample size (n=5,918 total and n=3,001 black women versus their n=1,946). Additionally, their
343 cohort consisted of only African women, while our analysis included women of white (41.5%),
344 black (50.7%), and other (7.8%) races. This difference may be important since African and black
345 women exhibit a higher incidence of vaginal microbiota disruption compared to white
346 women,^{52,53} thus results of one race may vary from results of other races. Expanding on this
347 point, our within race analyses (Tables 3-4) show that in white women, increasing BMI is
348 associated with a higher incidence of a disrupted vaginal microbiota and increased prevalence of
349 BV; however, for black women, the same comparison did not reach statistical significance. Other
350 differences include a high HIV prevalence (41.8%) and the women studied were sex workers; the
351 obese women in the study also appeared to be more likely to have high CD4 counts compared to
352 normal women. Whether these characteristics influenced BV risk in the Kenyan population was
353 not explored. Additional studies are needed to fully understand the relationship between BMI
354 and BV prevalence in different geographic populations.

355

356 Given the complex nature of obesity, mechanisms contributing to the increased occurrence of
357 BV in obese women are expected to be multifactorial. While reports have shown a positive

358 correlation between overweight/obese women and the presence of BV-associated microbiota,^{33,34}
359 the mechanisms at play remain unknown. Obesity may generate a favorable environment for BV
360 through disturbances in host hormonal, metabolic, and/or immune functions. Diet may also
361 influence the BMI-BV relationship, since certain dietary habits have been associated with
362 BV.^{54,55} A potential role for the gut microbiota in BV is also plausible, since the gut microbiota
363 has been suggested to influence the composition of the vaginal microbiota by serving as an
364 extravaginal reservoir of bacteria.⁵⁶ In addition, given the higher prevalence of menstrual
365 irregularity in obese women, the presence of blood may alter vaginal flora. The role of douching
366 in the BMI-BV relationship should also be considered, since douching is associated with BV and
367 was found in one study to be practiced more often among obese women.³⁷ The mechanisms that
368 contribute to the BMI-BV relationship may best be explored via established animal models of
369 obesity and BV,²⁵ which would allow for a causal analysis of the role of specific factors such as
370 obesity-associated hormonal and metabolic dysfunctions, dietary habits, the gut microbiota, and
371 the synergistic effects these factors may exhibit.

372
373 This study had both strengths and limitations. Our 5,918 cohort represented a diverse group of
374 women socioeconomically and racially. BMI and Nugent score were determined for each
375 participant by trained clinical staff using universally approved and established guidelines.^{14,46}
376 Reproducibility of our Nugent scoring was verified by Dr. Sharon Hillier's laboratory (developer
377 of the Nugent scoring method¹⁴), for a sample of specimens. In this cohort, 28.1% of women
378 were BV-positive, a figure similar to estimates from a representative sample of U.S. reproductive
379 aged women (29%),⁵⁷ and at the time of enrollment, 17.2% of BV-positive women reported
380 symptoms associated with BV, a percentage consistent with another report (15.7%),³⁷ thus

381 underscoring the commonly asymptomatic nature of BV from the patient perspective.
382 Limitations in our study included small numbers of underweight and Class II and III obese
383 women, a cross-sectional design, and a lack of information on recent antibiotic use. Also, our
384 study focuses on two races, black and white, and does not focus on the relationship between BMI
385 and BV in other racial populations, since the sample size of other races in our cohort was small.
386
387 Obesity and BV pose serious threats to women's health and black race is a risk factor for both of
388 these conditions. Our study demonstrates overweight and obesity are associated with higher
389 Nugent scores and increased prevalence of BV, and the relationship between BMI and BV
390 prevalence varies between black and white women. Our observations indicate additional efforts
391 to understand the relationship between obesity and BV and the influence of BMI on the vaginal
392 microbiome in racially diverse cohorts are highly warranted.

393

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403

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588 **Table 1.** Demographics of CHOICE Participants by BMI Category, N=5,918

	All Participants N=5918	Participants by BMI Category (kg/m ²)					p-value*
		<i>Underweight</i> < 18.5 N=174	<i>Lean</i> 18.5-24.9 N=2,312	<i>Overweight</i> 25-29.9 N=1,540	<i>Class I Obese</i> 30-34.9 N=934	<i>Class II/III Obese</i> ≥ 35 N=958	
Age, mean(SD)	25.3 (5.9)	23.2 (4.7)	24.1 (5.4)	25.6 (6.0)	26.1 (6.2)	26.9 (6.1)	<0.001
Race							
Black	3001 (50.7)	72 (41.4)	870 (37.6)	809 (52.5)	570 (61.0)	680 (71.0)	<0.001
White	2457 (41.5)	84 (48.3)	1250 (54.1)	604 (39.2)	296 (31.7)	223 (23.3)	
Other	460 (7.8)	18 (10.3)	192 (8.3)	127 (8.3)	68 (7.3)	55 (5.7)	
Hispanic	300 (5.1)	9 (5.2)	105 (4.5)	99 (6.4)	53 (5.7)	34 (3.6)	0.014
Monthly income							
None	1226 (20.8)	35 (20.1)	524 (22.7)	304 (19.8)	187 (20.1)	176 (18.4)	<0.001
\$1-800	1903 (32.3)	75 (43.1)	780 (33.9)	494 (32.1)	258 (27.7)	296 (31.0)	
\$801-1600	1666 (28.2)	45 (25.9)	587 (25.5)	436 (28.4)	295 (31.7)	303 (31.7)	
\$1601+	1106 (18.7)	19 (10.9)	413 (17.9)	304 (19.8)	190 (20.4)	180 (18.9)	
Receiving public assistance	2250 (38.1)	48 (27.8)	639 (27.7)	625 (40.6)	445 (47.7)	493 (51.5)	<0.001
Trouble paying for basic necessities	2393 (40.5)	62 (35.6)	828 (35.9)	625 (40.6)	433 (46.4)	445 (46.5)	<0.001
Education							
≤ High school	2007 (33.9)	71 (40.8)	734 (31.8)	535 (34.8)	345 (37.0)	322 (33.6)	<0.001
Some college	2512 (42.4)	67 (38.5)	895 (38.7)	670 (43.5)	408 (43.8)	472 (49.3)	
College graduate	1396 (23.6)	36 (20.7)	683 (29.5)	334 (21.7)	179 (19.2)	164 (17.1)	
Ever smoking	2765 (46.7)	79 (45.4)	1123 (48.6)	731 (47.5)	514 (55.0)	546 (57.0)	0.037
Current smoking	1367 (23.1)	48 (27.6)	550 (23.8)	374 (24.3)	199 (21.3)	196 (20.5)	0.044
Sexual partners last 30 days							
None	1125 (19.2)	21 (12.4)	390 (17.1)	316 (20.7)	191 (20.7)	207 (21.8)	0.004
One	4356 (74.5)	136 (80.0)	1750 (76.8)	1124 (73.6)	673 (72.8)	673 (70.9)	
2 or more	370 (6.3)	13 (7.7)	139 (6.1)	88 (5.8)	61 (6.6)	69 (7.3)	
Lifetime sexual partners							
None	39 (0.7)	0	12 (0.5)	14 (0.9)	4 (0.4)	9 (1.0)	<0.001
One	516 (8.7)	14 (8.1)	253 (10.9)	128 (8.3)	72 (7.7)	49 (5.1)	
2-4	1630 (27.5)	56 (32.2)	680 (29.4)	433 (28.1)	231 (24.7)	230 (24.0)	

5-7	1727 (29.2)	56 (32.2)	646 (27.9)	428 (27.8)	303 (32.4)	294 (30.7)	
8-12	839 (14.2)	15 (8.6)	308 (13.3)	225 (14.6)	136 (14.6)	155 (16.2)	
13 or more	1167 (19.7)	33 (19.0)	413 (17.9)	312 (20.3)	188 (20.1)	221 (23.1)	
Douching in the past 180 days	1340 (22.7)	32 (18.4)	407 (17.6)	354 (23.0)	248 (26.6)	299 (31.2)	<0.001
Douching in the past 30 days	590 (10.0)	19 (10.9)	168 (7.3)	162 (10.6)	99 (10.6)	142 (14.9)	<0.001
Past sexually transmitted infection	2461 (41.6)	63 (36.2)	801 (34.7)	660 (42.9)	441 (47.2)	496 (51.8)	<0.001
Sexually transmitted infection at baseline	518 (8.8)	17 (9.8)	170 (7.4)	132 (8.6)	85 (9.1)	114 (11.9)	0.001
Current menstruation flag	856 (14.5)	19 (10.9)	342 (14.8)	216 (14.0)	129 (13.8)	150 (15.7)	0.458
Current hormonal contraceptive method prior to enrollment	1520 (25.7)	38 (21.8)	636 (27.5)	412 (26.8)	199 (21.3)	235 (24.5)	0.003

589 Except for age, all demographics are reported as N (%). SD – standard deviation; BMI – body mass index
590 *p-values were determined using chi-square test (all categorical variables) or linear regression (age). For categorical variables, p-
591 values represent the distribution of a given categorical variable for All Participants and within a specific BMI category, as shown.
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594 **Table 2.** Nugent Score and Prevalence of BV by BMI Category

Nugent score - BV status	All	Participants by BMI Category (kg/m²)					p-value*
	Participants	<i>Underweight</i> < 18.5 N=174	<i>Lean</i> 18.5-24.9 N=2,312	<i>Overweight</i> 25-29.9 N=1,540	<i>Class I Obese</i> 30-34.9 N=934	<i>Class II/III Obese</i> ≥ 35 N=958	
Nugent score							
0-3	2639 (44.6)	78 (44.8)	1170 (50.6)	657 (42.7)	370 (39.6)	364 (38.0)	<0.001
4-6	1618 (27.3)	48 (27.6)	649 (28.1)	415 (27.0)	247 (26.5)	259 (27.0)	
7-10	1661 (28.1)	48 (27.6)	493 (21.3)	468 (30.4)	317 (33.9)	335 (35.0)	
Bacterial vaginosis							
No	4257 (71.9)	126 (72.4)	1819 (78.7)	1072 (69.6)	617 (66.1)	623 (65.0)	<0.001
Yes	1661 (28.1)	48 (27.6)	493 (21.3)	468 (30.4)	317 (33.9)	335 (35.0)	
Symptomatic BV							
No	1376 (82.8)	41 (85.4)	406 (82.4)	379 (81.0)	261 (82.3)	289 (86.3)	0.371
Yes	285 (17.2)	7 (14.6)	87 (17.7)	89 (19.0)	56 (17.7)	46 (13.7)	

595 All variables are reported as N (%). BV – bacterial vaginosis; BMI – body mass index

596 *p-values were determined using chi-square test for categorical variables. p-values represent the distribution of a given categorical

597 variable for All Participants and within a specific BMI category, as shown.

598 **Table 3.** Mean Difference in Nugent Score by BMI Category Overall and Within Each Race

BMI Category (kg/m ²)	Mean Nugent Score (SD)	Mean Difference in Nugent Score (95% Confidence Interval)			Black v. White Interaction p-value
		Crude	Fully Adjusted*	Final Adjusted**	
All Women†					
< 18.5	4.27 (3.01)	0.30 (-0.14, 0.73)	0.15 (-0.29, 0.58)	0.19 (-0.24, 0.62)	0.557
18.5-24.9	3.90 (2.85)	Referent	Referent	Referent	Referent
25-29.9	4.53 (2.94)	0.40 (0.22, 0.59)	0.29 (0.11, 0.48)	0.33 (0.14, 0.51)	0.891
30-34.9	4.87 (2.99)	0.61 (0.39, 0.83)	0.44 (0.23, 0.66)	0.51 (0.29, 0.72)	0.401
≥ 35	4.93 (2.96)	0.53 (0.31, 0.75)	0.28 (0.07, 0.50)	0.37 (0.16, 0.59)	0.064
Black Women					
< 18.5	5.08 (3.02)	0.10 (-0.62, 0.83)	0.00 (-0.72, 0.72)	0.00 (-0.72, 0.71)	
18.5-24.9	4.98 (3.01)	Referent	Referent	Referent	
25-29.9	5.24 (3.01)	0.26 (-0.03, 0.55)	0.23 (-0.06, 0.52)	0.30 (0.01, 0.58)	
30-34.9	5.37 (3.06)	0.39 (0.07, 0.71)	0.34 (0.02, 0.66)	0.41 (0.10, 0.73)	
≥ 35	5.19 (3.00)	0.21 (-0.09, 0.51)	0.07 (-0.23, 0.38)	0.18 (-0.12, 0.48)	
White Women					
< 18.5	3.63 (2.79)	0.43 (-0.15, 1.01)	0.23 (-0.34, 0.81)	0.30 (-0.28, 0.87)	
18.5-24.9	3.21 (2.51)	Referent	Referent	Referent	
25-29.9	3.62 (2.70)	0.42 (0.16, 0.67)	0.24 (-0.02, 0.49)	0.24 (-0.01, 0.49)	
30-34.9	3.99 (2.78)	0.78 (0.45, 1.11)	0.51 (0.18, 0.84)	0.56 (0.23, 0.89)	
≥ 35	4.08 (2.71)	0.88 (0.50, 1.25)	0.51 (0.13, 0.88)	0.58 (0.21, 0.95)	

599 BMI – body mass index; SD – standard deviation; statistically significant values are in bold.

600 * Fully adjusted model included income, public assistance, trouble paying for basics, education,
601 number of sex partners in the last 30 days, lifetime number of sex partners, current tobacco use,
602 douching in last 30 days, douching in last 180 days, history of sexually transmitted infection,
603 current sexually transmitted infection.604 ** Final model adjusted for public assistance, education, current smoker, douching in the last 30
605 days and sexually transmitted infection at baseline.

606 † The All Women model was also adjusted for race.

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617 **Table 4.** Prevalence Ratio of BV by BMI Category Overall and Within Each Race

BMI Category (kg/m ²)	BV Prevalence	Prevalence Ratio (95% Confidence Interval)			Black v. White Interaction p-value
		Crude	Fully Adjusted*	Final Adjusted**	
All					
Women†					
< 18.5	27.6%	1.25 (0.98, 1.60)	1.18 (0.92, 1.51)	1.20 (0.94, 1.54)	0.314
18.5-24.9	21.3%	Referent	Referent	Referent	Referent
25-29.9	30.4%	1.28 (1.15, 1.43)	1.23 (1.10, 1.36)	1.25 (1.12, 1.39)	0.024
30-34.9	33.9%	1.36 (1.20, 1.53)	1.26 (1.12, 1.42)	1.31 (1.16, 1.47)	0.001
≥ 35	35.0%	1.31 (1.16, 1.48)	1.20 (1.07, 1.35)	1.25 (1.11, 1.41)	0.002
Black					
Women					
< 18.5	38.9%	1.11 (0.82, 1.50)	1.08 (0.80, 1.46)	1.07 (0.79, 1.45)	
18.5-24.9	35.2%	Referent	Referent	Referent	
25-29.9	39.1%	1.11 (0.98, 1.26)	1.09 (0.97, 1.24)	1.12 (0.99, 1.27)	
30-34.9	39.8%	1.13 (0.99, 1.30)	1.11 (0.97, 1.27)	1.14 (1.00, 1.31)	
≥ 35	37.8%	1.07 (0.94, 1.23)	1.03 (0.90, 1.17)	1.07 (0.98, 1.18)	
White					
Women					
< 18.5	19.1%	1.53 (0.96, 2.43)	1.37 (0.86, 2.18)	1.44 (0.92, 2.25)	
18.5-24.9	12.5%	Referent	Referent	Referent	
25-29.9	19.9%	1.59 (1.28, 1.98)	1.42 (1.14, 1.76)	1.44 (1.16, 1.79)	
30-34.9	24.7%	1.98 (1.54, 2.53)	1.69 (1.31, 2.17)	1.73 (1.35, 2.22)	
≥ 35	24.2%	1.94 (1.47, 2.55)	1.56 (1.18, 2.07)	1.63 (1.23, 2.15)	

618 BV – bacterial vaginosis; BMI – body mass index; statistically significant values are in bold.

619 * Fully adjusted model included income, public assistance, trouble paying for basics, education,
620 number of sex partners in the last 30 days, lifetime number of sex partners, current tobacco use,
621 douching in last 30 days, douching in last 180 days, history of sexually transmitted infection,
622 current sexually transmitted infection.623 ** Final model adjusted for public assistance, education, current smoker, douching in the last 30
624 days and sexually transmitted infection at baseline.

625 † The All Women models also adjusted for race.