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### THE RELATIONSHIP BETWEEN ELEVATED GARDNERELLA SPECIES IN THE VAGINAL MICROBIOME AND INFERTILITY IN ASYMPTOMATIC PATIENTS

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**Title:**

THE RELATIONSHIP BETWEEN ELEVATED GARDNERELLA SPECIES IN THE VAGINAL MICROBIOME AND INFERTILITY IN ASYMPTOMATIC PATIENTS

**Submitter's E-mail Address:**

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**Preferred Presentation Type:**

Oral or Poster

**Study Type:**

Retrospective Cohort Study (includes comparator groups)

**Category - Subcategory(ies):**

**Pre-Clinical & Basic Research:** Reproductive Biology

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**OBJECTIVE:** Prior studies have demonstrated an association between alterations in the vaginal microbiome and reproductive potential, with regard to the presence of specific microbial species and fertility outcome. This study assesses whether elevated levels of *Gardnerella piovii*, *Gardnerella swidsinskii*, or *Gardnerella vaginalis* are associated with self-reported infertility diagnosis in patients without symptoms of vaginitis.

**MATERIALS AND METHODS:** This retrospective analysis included patients without reported symptoms of vaginitis who sought vaginal microbiome testing from January 2023 to January 2024, citing fertility as their primary motivation. Participants provided self-collected vaginal swabs, which underwent next-generation metagenomic sequencing (mNGS) to quantify bacterial species composition. The analysis focused on three *Gardnerella* species—*G. piovii*, *G. swidsinskii*, and *G. vaginalis*—using a 2.0% relative abundance threshold to define elevated levels. Patients were categorized by whether levels of these organisms were elevated ( $\geq 2.0\%$ ) or below-threshold ( $< 2.0\%$ ), both individually and in combination. Primary outcome was the association between levels of *Gardnerella* species and self-reported infertility. Statistical analysis was performed using chi-square tests ( $p < 0.05$ ).

**RESULTS:** A total of 1,095 patients were included in the analysis. The mean age was 35.0 (range 20 - 44) and the mean BMI was 25.3. Of these, 673 (61.5%) had levels of *G. piovii*, *G. swidsinskii*, or *G. vaginalis*—either individually or combined—greater than or equal to 2.0% relative abundance, while 422 (38.5%) had all three species combined below 2.0%. An infertility diagnosis was self-reported by 49.6% of those with elevated *Gardnerella* levels, compared to 33.6% among those with lower levels. The odds of infertility were significantly higher in the high-*Gardnerella* group (OR 1.94; 95% CI: 1.51–2.50;  $p = 2.92 \times 10^{-7}$ ).

**CONCLUSIONS:** There appears to be an association between elevated levels of *G. piovii*, *G. swidsinskii*, or *G. vaginalis* and self-reported infertility among patients without vaginitis symptoms who underwent vaginal microbiome testing. *Gardnerella* species are known to disrupt the protective *Lactobacillus*-dominant vaginal environment, potentially leading to subclinical inflammation, altered immune responses, and changes in mucosal integrity—factors that may impair sperm viability, embryo implantation, or endometrial receptivity. Further research is warranted to explore the biological pathways linking specific *Gardnerella* species to reproductive outcomes.

**IMPACT STATEMENT:** Findings underscore the potential importance of vaginal microbiome composition—specifically elevated *Gardnerella* species—in fertility, suggesting microbiome testing may offer valuable insights for patients with unexplained infertility.

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Within the past 2 years, have you or your spouse/partner had any potential COI?

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Organization Name	Relationship Type	Who has this Relationship?	
Evvy	Company Officer Relationship Began - Monday, September 16, 2024 Relationship Ended -	Self	

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Biographical Sketch Early success, marked by his first publication in CELL at Harvard Medical School, inspired Joseph to continue his research endeavors in reproductive endocrinology and infertility. Joseph has been with Reproductive Medicine Associates of New York since 2011. Joseph has authored over 400 peer-reviewed abstracts & manuscripts. Passionate about development, he cultivates relationship with investors & entrepreneurs to advance reproductive endocrinology & infertility care.

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Progyny	Company Officer Relationship Began - Friday, August 25, 2017 Relationship Ended - Thursday, June 1, 2023 Paid Consultant Relationship Began - Relationship Ended - Direct Stockholder Relationship Began - Friday, August 25, 2017 Relationship Ended - Friday, November 1, 2024	Self

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Evvy	Company Officer Relationship Began - Tuesday, March 16, 2021 Relationship Ended - Direct Stockholder Relationship Began - Tuesday, April 22, 2025 Relationship Ended -	Self	

Signature: Pita Navarro

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