

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1	“Effects of nifuratel-based therapy combined with vaginal lactobacillus probiotics on microecological restoration in pregnant women with abnormal vaginal flora: A retrospective cohort study”
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1	“This retrospective cohort study assessed nifuratel-nystatin therapy plus Lactobacillus probiotics ... Participants were allocated via 1:1 propensity score matching ... combination group (93.1%) vs monotherapy (77.6%) ... combination therapy as an independent protective factor (aOR=4.25, 95% CI: 1.42-12.71).”
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1	“Due to the changes in hormone levels during pregnancy, the vaginal microecological balance is easily disrupted ... linked to detrimental pregnancy outcomes including preterm birth, membrane rupture and intrauterine infection.”
Objectives	3	State specific objectives, including any prespecified hypotheses	2	“The study hypothesized that, compared to nifuratel-nystatin monotherapy, the combination with vaginal Lactobacillus probiotics would lead to: (1) a higher total clinical effectiveness rate; (2) greater improvement in vaginal microecological parameters; (3)

				lower recurrence rates; and (4) a reduced incidence of adverse pregnancy outcomes, without increasing drug-related adverse events.”
Methods				
Study design	4	Present key elements of study design early in the paper	2	“This retrospective cohort study ... Patients were grouped based on the actual treatment they received ... 1:1 PSM analysis using nearest-neighbor matching ... caliper of 0.02 ... resulted in 58 cases per group.”
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	2	“medical records of pregnant women diagnosed with vaginal microecological abnormalities during obstetric examinations at our hospital's gynecology clinic from March 2023 to March 2024.”
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	2	Inclusion: singleton, age ≥18, gestational age 14-28 weeks, diagnostic criteria, no antibiotics within 7 days, etc. Exclusion: habitual abortion, reproductive anomalies, gestational complications, allergy, severe dysfunction, recurrent vaginitis. Follow-up: “monitored until delivery.”
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	2	“1:1 propensity score matching using nearest-neighbor matching ... matching variables included age, gestational age, parity, miscarriage history, previous history of vaginitis, type of vaginitis, pre-treatment vaginal pH and Nugent score.” After matching: 58 combination (exposed), 58 monotherapy (unexposed).

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	2-4	Primary outcome: clinical effectiveness (cured/markedly effective/effective/ineffective). Secondary: vaginal pH, Lactobacillus normal rate, diversity normal rate, recurrence, adverse pregnancy outcomes, adverse drug reactions. Exposure: combination therapy vs monotherapy. Confounders balanced by PSM (age, gestational age, parity, etc.).
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	2-4	Data from electronic medical records, communication systems, nursing documentation. Vaginal flora assessed by Nugent score, Lactobacillus grading (I-IV), semi-quantitative diversity, pH measurement.
Bias	9	Describe any efforts to address potential sources of bias	4	Propensity score matching (1:1, caliper 0.02) to balance baseline characteristics; multivariate logistic regression to adjust for remaining confounders.
Study size	10	Explain how the study size was arrived at	4	Based on prior efficacy (78.9% monotherapy vs 94.4% combination), $\alpha=0.05$ , $\beta=0.2$ , 1:1 ratio. PASS 15.0 gave 52 per group; increased by 10% for missing data → 58 per group (total 116).

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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4	Normal continuous data: mean $\pm$ SD, independent t-test. Non-normal: median (IQR), Mann-Whitney U. Categorical: n (%), chi-square or Fisher's exact test.
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	4	PSM; independent/paired t-tests; Mann-Whitney U; $\chi^2$ /Fisher; McNemar; multivariate logistic regression (forward stepwise likelihood ratio) with aOR and 95% CI.
		(b) Describe any methods used to examine subgroups and interactions	Not applicable	Not reported (no subgroup or interaction analyses specified).
		(c) Explain how missing data were addressed	4	"Given the potential missing data and loss to follow-up in the retrospective study, the sample size was increased by 10%." Actual missing data not reported.
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	3(Figure 1), 4	Oversampling (10%) to account for loss. Flow diagram shows 116 included after PSM; no loss reported after matching.
		(e) Describe any sensitivity analyses		None reported.
<b>Results</b>				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3(Figure 1), 5	"The study initially included 165 pregnant women ... 86 assigned to combination therapy and 79 to monotherapy. After matching, 116 patients (58 per group) were included."
		(b) Give reasons for non-participation at each stage		Reasons for exclusion from the initial 165 not detailed.
		(c) Consider use of a flow diagram	3(Figure 1)	Flow chart provided showing initial screening, PSM, and final groups.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5	Table 1 presents age, BMI, education, gestational age, gravidity, parity, abortion history, prior vaginitis, vaginitis type, baseline pH, Nugent score, Lactobacillus grade, diversity

				abnormalities. All balanced with P>0.05.
		(b) Indicate number of participants with missing data for each variable of interest	Not applicable	No explicit reporting of missing data.
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	6	“from the end of treatment to delivery” – actual mean/median follow-up time not provided.
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	5-7(Tables 2-8)	Table 2: clinical efficacy (cured, markedly effective, effective, ineffective, total effective rate). Table 3: Lactobacillus and diversity normal rates. Table 4: vaginal pH. Table 5: symptom relief times. Table 6: recurrence rates. Table 7: adverse pregnancy outcomes. Table 8: adverse drug reactions.
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	Not applicable	cohort study
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	Not applicable	cohort study
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-7( Table 9)	Multivariate analysis: combination therapy aOR = 4.05 (95% CI 1.25-13.15), P = 0.020. Univariate OR = 4.12 (1.28-13.27).
		(b) Report category boundaries when continuous variables were categorized	Not applicable	No continuous variables were categorised for analysis (except gestational age inclusion criteria 14-28 weeks).
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable	Not provided.

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6	Multivariate analysis to identify independent predictors of clinical effectiveness.
Discussion				
Key results	18	Summarise key results with reference to study objectives	7	“The combination therapy showed significant advantages in improving the total clinical effectiveness rate, accelerating symptom relief, promoting recovery of microecological indicators, reducing the long-term recurrence rate, and improving pregnancy outcomes, without increasing drug-related risks.”
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8-9	Lists retrospective design, single-center, semi-quantitative microscopy (Nugent, Lactobacillus grading), no molecular profiling (16S rRNA), limited power for individual rare adverse pregnancy outcomes.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9	“This retrospective cohort study suggests that for pregnant women with vaginal microecological abnormalities, combining nifuratel-nystatin with vaginal Lactobacillus probiotics is associated with enhanced clinical and microbiological effectiveness ... Future research should focus on validating these results in prospective, randomized settings.”
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9	“As a single-center study, the patient population and clinical protocols were relatively homogeneous, which may affect the generalizability of the results to other settings.”
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Not applicable	“None”

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).