

ORIGINAL ARTICLE

# An Innovative Method for the Evaluation of Vaginal Lubrication in Pregnant Women: The Relationship Between Vaginal Lubrication Kit (VLK) Results, Vaginal Symptoms, and Sexual Function

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## Abstract

**Objective:** This study aimed to investigate the relationship between vaginal symptoms, sexual function, and vaginal lubrication levels, measured objectively with the Vaginal Lubrication Kit (VLK), in pregnant women.

**Material and Methods:** This observational, cross-sectional study included 105 pregnant women (age:  $30.2 \pm 5.8$  years, height:  $161.4 \pm 5.6$  centimeter (cm), weight:  $68.1 \pm 10.3$  kg, Body Mass Index (BMI):  $26.2 \pm 4.4$  kg/m<sup>2</sup>) admitted to the Obstetrics and Gynecology Clinic of İstanbul Training and Research Hospital between January and August 2024. Sociodemographic and obstetric characteristics were recorded, and participants were assessed using the Female Sexual Function Index (FSFI) and Visual Analog Scale (VAS) for vaginal dryness, burning, and dyspareunia. The VLK scores were obtained using a modified Schirmer test strip adapted for vaginal application. Correlation analyses were performed using Spearman's rank test.

**Results:** The mean number of pregnancy weeks of participants was  $20.5 \pm 11.4$  weeks, and the mean parity was  $2.0 \pm 1.4$ . The mean VLK score was  $24.6 \pm 11.0$  mm. The mean FSFI score was  $16.6 \pm 11.2$ , whereas the mean VAS scores were  $1.9 \pm 2.6$  cm for vaginal dryness,  $2.1 \pm 2.7$  cm for burning, and  $1.9 \pm 2.7$  cm for dyspareunia. VLK scores were significantly positively correlated with FSFI scores ( $r = 0.230$ ,  $p = 0.018$ ) and moderate-to-strong negative correlations with VAS dryness ( $r = -0.680$ ), burning ( $r = -0.530$ ), and dyspareunia ( $r = -0.530$ ), ( $p < 0.001$ ).

**Conclusion:** VLK is a safe and non-invasive method to evaluate vaginal lubrication in pregnant women, lower scores being associated with more symptoms and reduced sexual function.

**Keywords:** atrophic vaginitis, dyspareunia, pregnancy, sexual activity

## INTRODUCTION

Vaginal lubrication is a physiological event that occurs through increased transudation of the vaginal walls during sexual activity (1). It increased vaginal wall transudation during sexual activity, thereby reducing

friction (1). Vaginal dryness is defined as a decrease in vaginal lubrication. Vaginal dryness leads to burning and dyspareunia (2). Vaginal dryness and related symptoms negatively affect women's quality of life, sexual function, and self-perception (3,4).

Vaginal symptoms are common during pregnancy and the postpartum period (5,6). Approximately 27% of women experience vaginal dryness and 41% experience dyspareunia during pregnancy, while the prevalence of decreased lubrication and dyspareunia increases further in the postpartum period. These findings indicate that vaginal symptoms during pregnancy may have significant negative effects on sexual function and quality of life (5,6).

In the evaluation of vaginal lubrication, subjective methods such as the Female Sexual Function Index (FSFI) and the Vaginal Health Index are frequently used in the literature (7,8). However, these methods have certain limitations in the objective assessment of vaginal lubrication. The Vaginal Lubrication Kit (VLK) has been developed as an innovative approach to provide vaginal lubrication. Identifying the relationship between VLK-derived data and vaginal symptoms and sexual function may yield more reliable outcomes in both clinical practice and research. In this context, our study aimed to investigate the relationship between VLK results, vaginal symptoms, and sexual function in pregnant women.

## MATERIALS AND METHODS

### Study Design

This observational and cross-sectional study was designed to evaluate the relationship between vaginal symptoms, sexual function, and VLK results in pregnant women. The study was approved by the Clinical Research Ethics Committee of Istanbul Training and Research Hospital (Date: December 22, 2023; Approval No: 360) and adhered to the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment.

### Participants

This study included 105 pregnant women who were under follow-up at the Obstetrics and Gynecology Clinic of Istanbul Training and Research Hospital between January 2024 and August 2024. The inclusion criterion was the voluntary participation of pregnant women. Exclusion criteria included active vaginal or urinary tract infection, a history of active malignancy, local estrogen use, sexual intercourse within the last two days, stage 2 or higher pelvic organ prolapse, history of mesh surgery, and any disease or medication known to cause vaginal dryness (e.g., Sjögren's syndrome, lichen planus, lichen

sclerosus, use of antidepressants or antihistamines).

### Descriptive and Outcome Measures

The participants' baseline demographic, physical, and obstetric characteristics were recorded (Table 1). After completing the sociodemographic form, the participants were administered the FSFI and Visual Analog Scale (VAS). Subsequently, the VLK measurement was performed. All assessments were completed within a single session.

The VLK score was the primary outcome measure. The VLK, which was developed for the objective evaluation of vaginal dryness, was adapted from the Schirmer test used to assess dry eye (9). In this study, Schirmer strips were modified for vaginal application. The strips, measuring 5 mm × 40 mm and were free of blue dye, were folded at 5 mm within sterile packaging to prevent the passage of fluids other than vaginal lubrication. The strip was placed 2 cm proximal to the Carunculae Hymenalis using sterile forceps or by holding from its end and left in place for 5 minutes. The wetting length was measured immediately, after removal. A patent application for the test strip has been submitted to the Turkish Patent and Trademark Office (Application No: 2025/007314).

The secondary outcome measures included correlations between VLK scores and VAS values for vaginal dryness, burning, and dyspareunia, as well as the FSFI. The VAS is a 10 cm horizontal line used to measure symptoms of genitourinary syndrome of menopause (GSM), where 0 indicates no symptoms and 10 represents unbearable symptoms. The score was determined by measuring the distance marked by the participant. The FSFI is a self-report questionnaire with established validity and reliability that was developed to assess sexual function in women (10). This 19-item scale evaluates six domains: desire, arousal, lubrication, orgasm, satisfaction, and dyspareunia. Each domain is scored from 0 or 1 to 5, and the total score ranges from 2 to 36. Lower scores indicate sexual dysfunction. The FSFI was used to determine the sexual function levels of pregnant women, and the scores obtained were included in the correlation analysis with the VLK results.

### Data Analysis

Data were analysed using the Statistical Package for the Social Sciences (SPSS), version 23.0 (IBM Corp., Armonk,

NY, USA). Descriptive statistics were presented as mean  $\pm$  standard deviation (SD) and median (interquartile range, Q1–Q3) for continuous variables, and frequency and percentage (%) for categorical variables. The Shapiro–Wilk test was used to assess the normality of data distribution. Relationships between numerical variables were examined with Spearman's correlation coefficient. A *p*-value of  $<0.05$  was considered statistically significant for all tests.

## RESULTS

A total of 110 pregnant women were assessed for eligibility, of whom 105 were included in the study. Three women with a diagnosis of vaginitis and two women who declined participation were excluded for not meeting the inclusion criteria.

The baseline demographic, obstetric, and primary and secondary outcome measures of the participants are summarized in Table 1.

**Table 1.** Demographic, obstetric, and medical characteristics of the participants

| Characteristics           | n=105           |
|---------------------------|-----------------|
| Age (years),              |                 |
| mean $\pm$ SD             | 30.2 $\pm$ 5.8  |
| BMI (kg/m <sup>2</sup> ), |                 |
| mean $\pm$ SD             | 26.2 $\pm$ 4.8  |
| Pregnancy Week            |                 |
| (week)                    | 20.5 $\pm$ 11.4 |
| Employment status,        |                 |
| % (n)                     | 100 % (105)     |
| – Employed                | 28.6 (30)       |
| – Unemployed              | 71.4 (75)       |
| Educational level,        |                 |
| % (n)                     | 100 % (105)     |
| – Illiterate              | 0               |
| – Literate                | 13.3 (14)       |
| – Primary school          | 16.2 (17)       |
| – High school             | 34.3 (36)       |
| – University              | 30.5 (32)       |
| – Postgraduate            | 5.7 (6)         |
| Marital status,           |                 |
| % (n)                     | 100 % (105)     |
| – Single                  | 0               |

|  |                 |
|--|-----------------|
| – Married                                    | 100 % (105)     |
| – With partner                               | 0               |
| Parity,                                      |                 |
| median (IQR)                                 | 2 (1-3)         |
| Frequency of sexual intercourse (per month), |                 |
| median (IQR)                                 | 8 (4-8)         |
| VAS VD (cm),                                 |                 |
| mean $\pm$ SD                                | 1.9 $\pm$ 2.6   |
| VAS VB (cm),                                 |                 |
| mean $\pm$ SD                                | 2.1 $\pm$ 2.7   |
| VAS D (cm),                                  |                 |
| mean $\pm$ SD                                | 1.9 $\pm$ 2.7   |
| VLK score (mm),                              |                 |
| mean $\pm$ SD                                | 24.6 $\pm$ 11   |
| FSFI score,                                  |                 |
| mean $\pm$ SD                                | 16.6 $\pm$ 11.2 |

Data are presented as mean  $\pm$  standard deviation or number (percentage). *n*: number, BMI: Body Mass Index, IQR: Interquartile Range, FSFI: Female Sexual Function Index, VAS: Visual Analog Scale.

In the correlation analysis, a significant positive relationship was found between VLK scores and FSFI scores ( $r = 0.230$ ,  $p = 0.018$ ) (Table 2). In addition, moderate-to-strong negative correlations were observed between VLK scores and VAS dryness ( $r = -0.680$ ,  $p < 0.001$ ), VAS burning ( $r = -0.530$ ,  $p < 0.001$ ), and VAS dyspareunia ( $r = -0.530$ ,  $p < 0.001$ ) (Table 2).

**Table 2.** Spearman correlation coefficients between VLK scores, FSFI scores, and vaginal symptoms (VAS dryness, VAS burning, VAS dyspareunia)

| Outcome measurements | VLK score <i>r</i> | <i>p</i> |
|----------------------|--------------------|----------|
| FSFI                 | 0.230              | 0.018    |
| VAS dryness          | -0.680             | $<0.001$ |
| VAS burning          | -0.530             | $<0.001$ |
| VAS dyspareunia      | -0.530             | $<0.001$ |

*r*: Spearman's rank correlation coefficient; Negative values indicate an inverse relationship, while positive values indicate a direct relationship, *p*: significance level.

These findings also indicate that the VLK is an objective measurement of vaginal symptoms in pregnant women and provides valuable information related to sexual function.

## DISCUSSION

In this study, the VLK, which enables an objective assessment of vaginal lubrication in pregnant women, was used to examine the relationship between obtained scores, vaginal symptoms, and sexual function. Our findings demonstrated a significant positive correlation between VLK scores and FSFI scores. In addition, moderate-to-strong negative correlations were identified between VLK scores and symptoms such as vaginal dryness, burning, and dyspareunia. These results suggest that the VLK can serve as an objective tool for evaluating vaginal lubrication during pregnancy and can reflect both sexual function and symptom levels.

When the relationship between VLK scores and vaginal symptoms was examined, a strong negative correlation was particularly observed with dyspareunia. This finding is consistent with previous studies reporting that dyspareunia is common during pregnancy (11,12). In a prospective study involving 103 pregnant women, it was reported that vaginal burning and dyspareunia increased as pregnancy progressed (11). Similarly, Tennfjord et al. evaluated the prevalence of dyspareunia at 22 and 37 weeks of pregnancy and in the postpartum period, reporting that dyspareunia was common throughout pregnancy (12). In parallel with these studies, our findings also highlight that dyspareunia is an important vaginal symptom during pregnancy and may negatively affect sexual function. Vaginal dryness was another symptom that showed a strong negative correlation with VLK scores in our study. Consistent with findings in the literature, Kennedy et al. examined the prevalence of vulvovaginal symptoms during pregnancy and puerperium, reporting that complaints such as dryness, burning, and discharge increased as pregnancy advanced (11). Another study conducted in Turkey demonstrated that dryness and dyspareunia negatively affected FSFI scores in third-trimester pregnant women (13). Furthermore, a study conducted in 2022 assessed vaginal dryness during pregnancy and the postpartum period, reporting that it was both a common symptom and associated with various risk factors (14). Our study supports this body of evidence by demonstrating that vaginal dryness during pregnancy can negatively affect sexual function and quality of life, while the VLK offers an innovative method for the objective assessment of these symptoms.

Examining our findings, the positive relationship between VLK scores and sexual function scores in pregnant women is noteworthy. While moderate-to-strong negative correlations were found between VLK and vaginal symptoms such as dryness, burning, and dyspareunia, a positive correlation was observed with FSFI scores. These findings are in line with the literature reporting that vaginal symptoms negatively impact sexual function during pregnancy (15–18). A systematic review in 2019 emphasized that sexual dysfunctions are common among women during pregnancy (15). A recent study in 2023 showed that sexual function decreases in later stages of pregnancy while vaginal symptoms increase significantly (16). Another study by Szymanska et al. in 2024 reported that physiological and hormonal changes during pregnancy were associated with vaginal symptoms, which adversely affected women's sexual lives (17). In addition, de Amorim et al. (2025) stated that symptoms related to pelvic floor dysfunction increased throughout pregnancy and were associated with sexual dysfunction (18). Our study supports these findings, while making an original contribution by providing objective measurements with the VLK, in addition to the predominantly subjective self-reported assessments found in the literature.

One of the strengths of this study is the use of the VLK, an innovative, objective, and safe method for evaluating vaginal lubrication. The potential contributions of VLK in clinical practice are also noteworthy. At present, the assessment of vaginal symptoms largely relies on self-report scales, which depend on patients' subjective perceptions. In contrast, the VLK can provide clinicians with objective data, as it is quick to administer, non-invasive, and does not require additional laboratory equipment. Its feasibility during routine gynecological examinations may help in the early detection of symptoms such as vaginal dryness and dyspareunia, particularly during pregnancy, and contribute to the planning of appropriate treatment strategies. Moreover, the VLK may serve as a complementary tool in identifying pregnant women at risk of sexual dysfunction and in monitoring the effectiveness of interventions. The combined use of subjective (VAS and FSFI) and objective (VLK) methods in evaluating vaginal symptoms during pregnancy allows for a multidimensional assessment. The relatively large sample size ( $n = 105$ ) and evaluation of data across different stages of pregnancy are additional strengths of the study.

An important aspect of this study is the clinical applicability of the VLK. Objective tools for assessing vaginal dryness are limited, and previous studies have been conducted in populations physiologically different from pregnant women. Therefore, this study provides preliminary data on the feasibility of using the VLK during pregnancy and addresses a gap in the literature. Due to its rapid, non-invasive, and equipment-free design, the VLK may be clinically valuable in assessing symptoms such as vaginal dryness and dyspareunia. Overall, this study represents an initial step in exploring the potential role of the VLK in evaluating vaginal symptoms during pregnancy.

Nevertheless, the study had some limitations. First, it was conducted in a single center, which may limit the generalizability of the results. Furthermore, due to the cross-sectional design of the study, causal relationships cannot be established. The self-report scales (VAS, FSFI) used to evaluate symptoms rely on participants' subjective perceptions and carry the risk of bias. Although the VLK was applied for the first time in pregnant women, representing an innovative aspect, its psychometric properties (validity and reliability) have not yet been adequately tested in different populations. Finally, additional variables that could influence sexual function, such as hormonal levels or psychosocial factors, were not evaluated in this study.

## CONCLUSION

This study demonstrates the feasibility of using the VLK, developed for the objective assessment of vaginal lubrication, in pregnant women. The findings revealed that VLK scores were positively associated with sexual function and negatively associated with vaginal symptoms.

**Conflict of Interest:** The authors declare no conflicts of interest.

**Informed Consent:** Informed consent was obtained from all participants involved in the study. **Funding:** No financial support was received for this study.

**Ethical Approval:** The study was approved by the Clinical Research Ethics Committee of Istanbul Training and Research Hospital (Date: December 22, 2023; Approval No: 360)

## Author Contributions:

- **Concept and Design:** K.HG, A.T, U.N, K.DC
- **Supervision:** A.T
- **Data Collection and/or Processing:** K.HG
- **Materials:** K.HG, U.N, K.DC
- **Analysis and/or Interpretation:** K.HG
- **Literature Search:** K.HG
- **Writing and Critical Review:** K.HG, A.T, U.N, K.DC

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