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ORIGINAL RESEARCH

Changes of Swede Score in Low-Grade Cervical Precancerous Lesions After Administration of *Coriolus versicolor* Vaginal Gel: A Prospective Single-Arm Pilot Study in Indonesia

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Background: *Coriolus versicolor* vaginal gel has been extensively studied and shown to enhance the epithelialization of low-grade precancerous lesions and improve cervical microbiota. Swede score was used as tools in evaluating regression of the precancerous lesion. This study aims to evaluate the changes of Swede score on low-grade precancerous lesions after the use of *Coriolus versicolor* vaginal gel.

Methods: This was a prospective, non-comparative cohort study conducted between July and December 2024. Twenty-two women with positive visual inspection with acetic acid (VIA) and low-grade colposcopic lesions (Swede score <5) were included. Colposcopy with Swede scoring and VIA were performed at baseline, 3 months, and 6 months. The primary endpoint was change in Swede score over time. Repeated measures were analyzed using non-parametric tests.

Results: All participants were VIA-positive at baseline (22/22). At 3 months, 12/22 (54.5%) remained VIA-positive, decreasing to 6/22 (27.3%) at 6 months. Median Swede scores decreased from 3 (range 2–4) at baseline to 2 (0–4) at 3 months and 0 (0–5) at 6 months, with a statistically significant overall difference across timepoints ($p<0.001$).

Conclusion: The use of *Coriolus versicolor* vaginal gel was associated with decreases in Swede score and increased VIA negativity over 6 months in this small, single-arm cohort.

Keywords: vaginal gel, *Coriolus versicolor*, precancerous lesion, regression

Introduction

Cervical cancer is the fourth most common cancer in women worldwide, with an estimated 569,847 new cases and 311,365 deaths in 2018. Higher numbers of cervical cancer cases are found in Sub-Saharan Africa, East Africa, South and Southeast Asia, the Western Pacific, and Central and South America. Indonesia has the highest incidence of cervical cancer in Asia, with 23.3 per 100,000 population, according to GLOBOCAN 2020 data. The cause of cervical cancer is HPV (Human Papilloma Virus) infection. HPV infection occurs in 11.7% worldwide, with 5.2% in Indonesia. HPV infection is most often found in urban women aged 35–44 years, 80% of them are at high-risk HPV.[1,2] Persistent infection with high-risk HPV remains the central etiologic factor in cervical carcinogenesis and continues to pose a substantial public health burden worldwide, particularly in low and middle-income countries where access to organized screening and timely treatment is limited. Although many HPV-related low-grade cervical lesions regress spontaneously, the prolonged observations recommended for these lesions can generate patient anxiety and loss to follow up, highlighting the need for safe, non-ablative strategies that may support lesion regression while preserving cervical integrity.[3] Before developing into cancer, cervical cancer can be detected in the pre-cancerous lesion phase (CIN 1, 2, and 3).

Patients with CIN 1, including low-grade squamous intraepithelial lesions (LSIL), atypical squamous cells of undetermined significance (ASC-US), or cytology-negative intraepithelial lesions but positive for HPV, are at low risk for developing cervical cancer. Therefore, observation is recommended for patients with CIN 1/LSIL.[4] Low grade

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cervical precancerous lesions may be defined using cytology (LSIL), histology (CIN1), or colposcopic impression. In the present study, eligibility was based on positive visual inspection with acetic acid (VIA) and low grade colposcopic findings defined by a Swede score <5, without routine histologic confirmation. Accordingly, the term low-grade lesions herein refers to colposcopically low-grade changes rather than histologically confirmed CIN 1. The 1–3-year observation period recommended for low-grade lesions raises anxiety among patients. In a study by Gesundh et al, when diagnosed with low-grade lesions (mild dysplasia), the women reported not receiving much information about their condition.[5] Therefore, additional therapy is needed to increase the regressivity of precancerous lesions during observation.

One natural therapy being developed for the treatment of precancerous lesions is *Coriolus versicolor*. The effectiveness of C. versicolor polysaccharides has been well documented. Several studies have demonstrated the effectiveness of C. versicolor against various types of cancer, most of which utilize polysaccharopeptides (PSPs) and polysaccharide K (PSKs), called krestin, extracted from this fungus. Patients with precancerous changes in the cervix may also benefit from the use of C. versicolor products. The observed clinical changes may be biologically plausible given prior evidence that *Coriolus versicolor* based formulations can modulate local immune response and support cervical epithelial repair. However, these mechanisms remain hypothetical in this study and should not be interpreted as proof of clinical efficacy.[6–8] Topical vaginal formulations containing *Coriolus versicolor* and other bioactive compounds have been evaluated in several clinical studies, including PALOMA trials, which reported improvements in HPV clearance and cervical epithelial repair in women with HPV-related low-grade lesions. These studies support the biological plausibility and tolerability of such interventions.[9]

Despite growing interest in non-ablative vaginal therapies, prospective data using standardized colposcopic scoring system, such as Swede score, to quantify lesion regression over time remain limited. Moreover, real-world evidence from settings where histologic confirmation is not routinely feasible is scarce. Therefore, this prospective single-arm pilot study aimed to evaluate changes in Swede score and VIA status over a 6-month period following the use of a *Coriolus versicolor* based vaginal gel in women with colposcopically low grade cervical lesions.

Materials and Methods

Study Design

This was a clinical study of prospective cohort and non-comparative study that was conducted from July 2024 until December 2024. Patients were recruited from Hasan Sadikin General Hospital. Inclusion criteria included women with VIA positive and LSIL based on colposcopy (Swede Score <5). LSIL was confirmed based on colposcopic impression and VIA only. On the other hand, exclusion criteria included women with pregnancy and breastfeeding, women who had undergone cervical surgery within 1 year, immunosuppressive or autoimmune disease, history of gynecological malignancy within 6 months. In addition, all patients were required to read the patient information sheet and to sign the informed consent form to be included in the study. HPV testing was performed by using Cerviscan, a local diagnostic kit for detecting high-risk HPV types using cervical swab samples via PCR technology from Bio Farma, Indonesia's state owned pharma company.

The intervention consisted of commercially available *Coriolus versicolor* based vaginal gel (Papilocare®, Procare Health Iberia S.L., Barcelona, Spain). It contains *Coriolus versicolor* extract combined with additional bioactive compounds, including hyaluronic acid, Centella asiatica, Aloevera, *Azadirachta indica* (neem), and carboxymethyl-β-glucan. Each single-use applicator contained 5 mL of vaginal del. Participants were instructed to administer one canula/day for 21 days during the first month, followed by one cannula/alternate days during subsequent five months. The product was stored at room temperature in accordance with manufacturer instruction. Each participant had clinical examination months (baseline, month 1, month 2, month 3, month 4, month 5, month 6) and only at baseline, month 3, and month 6 they had colposcopy examination. They were questioned directly to monitor compliance of the treatment. After six months, all patients were examined through colposcopy and the applicator was counted. Those who continued with high Swede scores and positive VIA were offered a Loop Electrosurgical Excision Procedure (LEEP). This study was approved by the Ethics Committee of Hasan Sadikin General Hospital. All procedures followed were in accordance with the Declaration of Helsinki.

Data Collection and Study Variables

Data were collected from the medical reports of each subject. The primary endpoint was the result of VIA and Swede scores which showed the repair of cervical low-grade lesions based on colposopic and clinical examination. All colposcopic examinations were performed by fellow gynecology oncologists at Hasan Sadikin General Hospital, Universitas Padjadjaran. Colposcopists were blinded to prior Swede score and to previous examination results. Digital colposcopic images were systematically recorded at each timepoint (baseline, 3 months, and 6 months). Side effects of the treatment were also measured during the treatment. It was assessed at each scheduled study visit through active solicitation of adverse events using structured patient interviews and standardized questionnaires. Participants were specifically asked about local and systemic symptoms potentially related to vaginal gel use, including burning sensation, itching, numbness, abnormal discharge, or other discomfort. We divided side effects into 3 categories, mild, moderate, and severe adverse event. Mild adverse events (transient itching, tingling, or mild burning not interfering with daily activities) were managed with patient reassurance and continuation of treatment without modification. Moderate adverse event (symptoms causing discomfort or partial interference with daily activities) prompted clinical evaluation, symptomatic management (eg temporary treatment interruption or supportive therapy if needed). Severe adverse events were predefined as events requiring medical intervention, hospitalization, or permanent treatment discontinuation. No participants discontinued treatment due to adverse events, and all reported symptoms resolved spontaneously.

Sample Size

Given the exploratory nature of the study and the lack of published data, the sample size was determined by consecutive sampling. Twenty-eight subjects was gathered, during 1 month after treatment 3 out of 28 were drop out due to pregnancy and gynecological disease. Three months after treatment, 3 out of 25 were drop out due to loss of follow up. Therefore, it was determined that a sample size of 22 patients (Figure 1). The statistical power of the present study is underpowered due to the small sample size.

Statistical Analysis

Continuous and ordinal variables were summarized using median and interquartile range (IQR), while categorical variables were presented as counts and percentages. Normality was assessed using the Kolmogorov–Smirnov test. Changes in Swede scores across three timepoints (baseline, 3 months, and 6 months) were analyzed using the Friedman test for repeated non parametric ordinal data. Changes in VIA status (positive vs negative) over time were analyzed using McNemar's test for paired binary data. Statistical analyses were performed using IBM SPSS Statistics version 30. Only participants with complete Swede score and VIA data at all three predefined timepoints (baseline, 3 months, and 6 months) were included in the final analysis. No imputation methods (including last observation carried forward) were applied to missing data due to dropouts. Given the exploratory nature of this pilot study and the limited sample size, no formal adjustment for multiple comparisons was applied. All statistical tests were considered exploratory and interpreted descriptively.

Result

Based on the demographic data, the average age of the subjects was 37 years, with the highest number of parities and abortions being 2 and 0, respectively. The HPV status of the subjects was positive in 8 (36.4%) and negative in 14 (63.6%) participants. All of the subjects were unvaccinated for HPV. BMI classification was based on the Asia-Pacific category, with an average BMI of 22.78, which is within the normal range. Subjects presented with complaints in the following order: none (50%), vaginal discharge (31.8%), and bleeding (18.2%). The most common age of menarche among the subjects was 13 years, and the median age of first sexual activity was 20 years. Promiscuity was noted in 36.4% of subjects. The majority of subjects were non-smokers (72.7%), while 27.3% had a smoking history. The types of contraception used were DMPA injections (54.5%), birth control pills (41%), and condoms (4.5%), as shown in Table 1.

The inclusion criterion for this study was a positive VIA test result. Three periodic anamneses and colposcopy examinations were performed—at baseline, three months after intervention, and six months after intervention. The second examination, held during the third month post-intervention, yielded positive VIA results in 12 subjects (54.5%) and negative results in

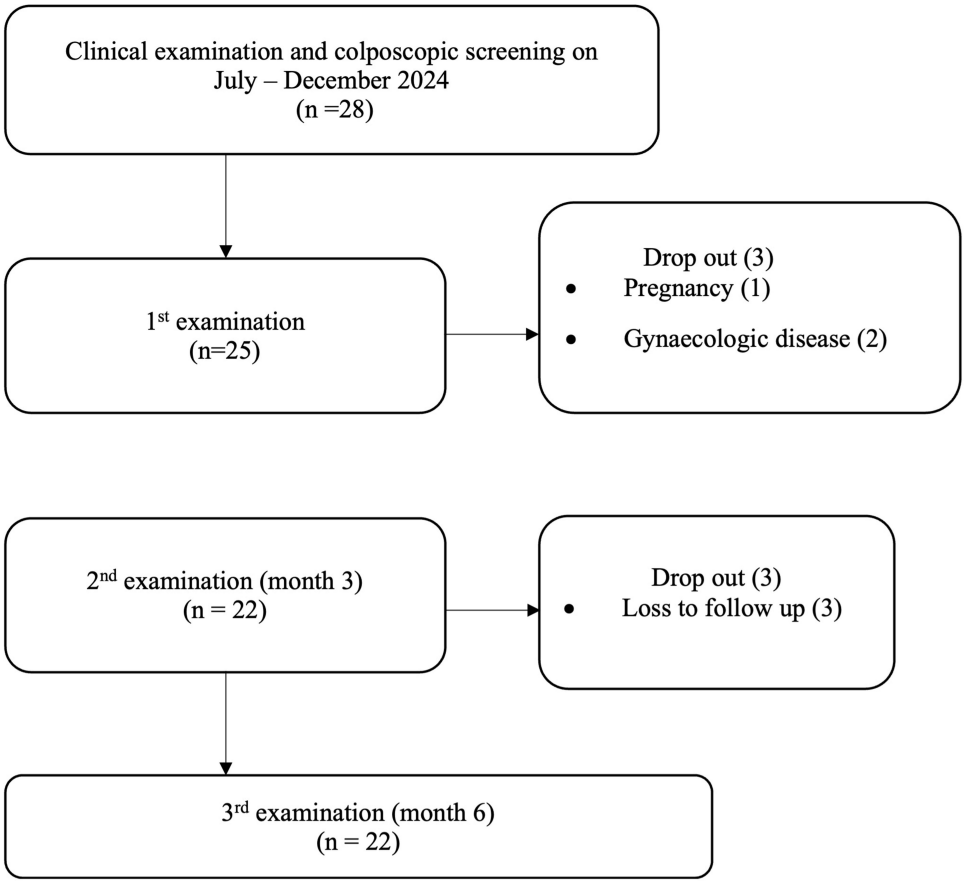

Figure 1 Data collection.

10 subjects (45.5%). The absolute reduction in VIA positivity from baseline to 6 months was 72.7% (95% CI 49.8%–882%), and changes in VIA status over time were statistically significant (McNemar test, p = 0.00012) as summarized in Table 2 and illustrated in Figure 2.

The Swede score was measured based on colposcopy findings, consisting of several variables, namely acetowhite fluid uptake, precancerous lesion boundaries, blood vessel appearance, lesion size, and iodine staining. Based on the inclusion criteria, the initial Swede score was <5. Swede score assessments were carried out consecutively before the intervention, at

Table 1 Demographic and Clinical Characteristics of the Patients

Age, *mean* (SD)	37.8 (9.8)
Parity, med (min – max)	2 (0–5)
Abortion, med (min – max)	0 (0–2)
HPV status, n (%)	
Positive	8 (36.4)
Negative	14 (63.6)
HPV vaccination status	
Vaccinated	0 (0)
Unvaccinated	22 (100)

(*Continued*)

Table 1 (Continued).

BMI, *mean* kg/m^2 (SD)	22.78 (21.18)
Underweight, n (%)	1 (4.5)
Normoweight, n (%)	11 (50)
Overweight, n (%)	7 (31.8)
Obese grade I, n (%)	3 (13.7)
Symptoms	
Vaginal discharged, n(%)	7 (31.8)
Bleeding, n (%)	4 (18.2)
None, n (%)	11 (50)
Age of menarche, med (min - max)	13 (10–14)
Smoking	
Yes, n (%)	6 (27.3)
No, n (%)	16 (72.7)
Age of sexual activity, med (min - max)	20 (14–30)
History of sexual transmitted disease	
Yes, n (%)	8 (36.4)
No, n (%)	14 (63.6)
Contraception history	
Condom, n (%)	1 (4.5)
DMPA, n (%)	12 (54.5)
Oral Contraceptive Pill, n (%)	9 (41)

Table 2 VIA Status Within Subjects

VIA	Baseline	3 Months	6 Months	P values
Positive, n (%)	22 (100%)	12 (54.5%)	6 (27.3%)	0.00012
Negative, n (%)	0 (0%)	10 (45.5%)	16 (72.7%)	95% CI (49.8% - 88.2%)

three months, and at six months post-intervention. Normality testing using the Kolmogorov–Smirnov test indicated non-normal distribution. At baseline, Swede scores were predominantly in the moderate range, with most participants scoring 3 (45.5%) or 4 (40.9%), and no participants exhibiting scores of 0 or 1. At 3-month follow-up, a marked shift toward lower scores was observed: 27.3% of participants achieved a Swede score of 0, and 18.2% scored 1, while proportion with scores ≥3

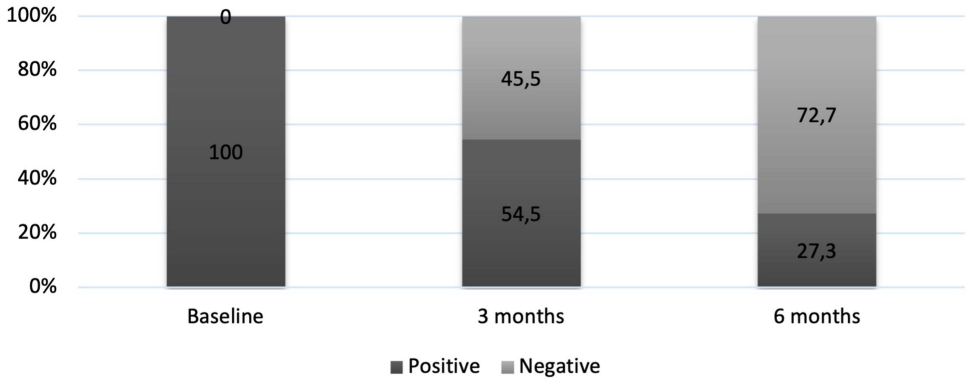

Figure 2 VIA Status within Subjects.

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Table 3 Distribution of Swede Score Categories at Each Timepoint

Swede Score	Baseline	3 Months	6 Months
0	0	6 (27.3%)	13 (59.1%)
1	0	4 (18.2%)	4 (18.2%)
2	3 (13.6%)	8 (36.4%)	2 (9.1%)
3	10 (45.5%)	3 (13.6%)	1 (4.5%)
4	9 (40.9%)	1 (4.5%)	1 (4.5%)
5	0	0	1 (4.5%)

Table 4 Swede Score Within Subjects

	First Exam	Second Exam	Third Exam	P value
Mean Swede Score, 95% CI	3.27 (2.96–3.58)	1.50 (0.97–2.02)	0.91 (0.27–1.55)	0.0003

declined substantially. By 6 months, further improvement was evident, with the majority of participants demonstrating minimal or no colposcopic abnormalities: 59.1% had a Swede score of 0, and 18.2% scored 1. Only 13.6% of the participants had Swede scores ≥3 at 6 months, including one participant (4.5%) with a score of 5. The median Swede score before intervention was 3 (range: 2–4). At three months post-intervention, the median decreased to 2 (range: 0–4), and at six months, the median score was 0 (range: 0–5), as shown in Table 3 and Table 4 and depicted in Figure 3. The significance test using Friedman was carried out, and the result was $p = 0.0003$ which showed a statistically significant difference between the initial Swede score and the final Swede score of therapy.

Side effects were evaluated through questionnaires during each visit. At baseline, most subjects (59.1%) reported no symptoms, while 22.7% experienced tingling, 13.6% itching, and 4.5% a burning sensation. At the second examination, 77.3% reported no side effects, with tingling reduced to 13.6%, burning to 1%, and itching to 1%. By the third examination, no subjects reported side effects, as detailed in Table 5.

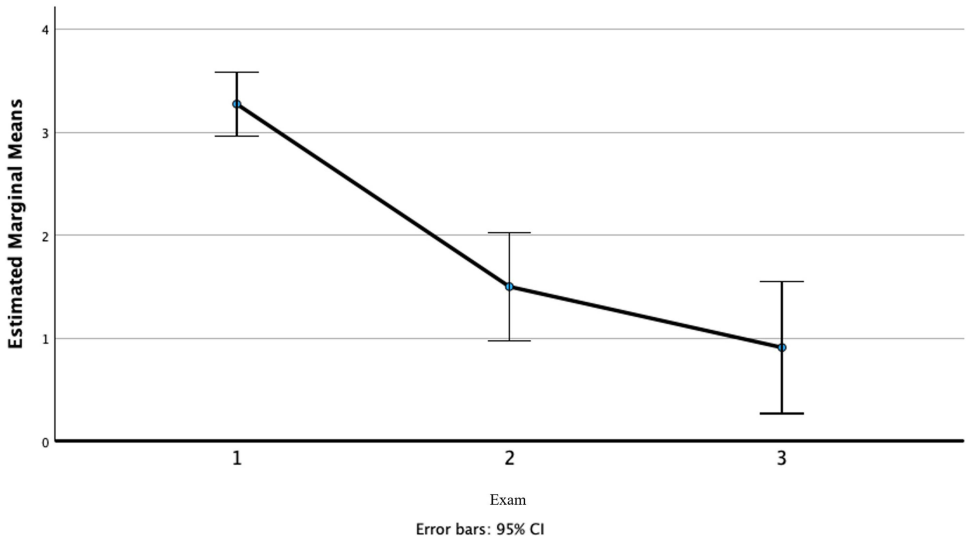

Figure 3 Swede Score within Subjects.

Table 5 Adverse Effect Within Subjects

Adverse Effect	First Exam	Second Exam	Third Exam
None, n (%)	13 (59.1)	17 (77.3)	22 (100)
Numb, n (%)	5 (22.7)	3 (13.6)	0 (0)
Hot sensation, n (%)	1 (4.5)	1 (4.5)	0 (0)
Itchy, n (%)	3 (13.6)	1 (4.5)	0 (0)

Discussion

The subjects in this study had a mean age of 37±9.8 years. These results are similar to those of the PALOMA I study, with a mean age of 40 years. Age is a factor that can influence the regression of precancerous lesions. Regression and progression rates are lower in younger individuals. The older the woman, the lower the regressivity of precancerous lesions. Regression rates for women aged <25, 25–30, 30–35, 35–40, and >40 years were 44.7%, 33.7%, 30.9%, 27.3%, and 24.9%, respectively.[10] Clearance of low-grade precancerous lesions after a conservative approach is approximately 59% within 2 years of diagnosis. However, the probability of these lesions progressing to high-grade squamous intraepithelial lesions within 5 years is 12.7%.[5] Excisional and ablative treatments can reduce the risk of progression of precancerous lesions. However, a systematic review by Kyrgiou et al found that these therapies increase the rate of prematurity in women of childbearing age after excisional and ablative treatments.[11] The average BMI of the study subjects was 22.78 kg/m2, indicating a normal body weight. Research by Aivara et al showed that BMI plays a significant role in the progression of precancerous lesions. The study found that overweight and obesity increase the incidence of cervical cancer and decrease the detection of precancerous lesions.[12]

The VIA method itself was chosen because it is able to describe the condition of precancerous cervical lesions accurately, with the sensitivity and specificity of VIA being found to be 94.7% and 88%, respectively.[13] Although HPV DNA testing is a promising procedure with higher sensitivity and potential for mass screening, VIA testing is preferred in developing countries, particularly Indonesia, due to limited facilities and funding.[14] Application of 3–5% acetic acid causes cell dehydration and coagulation of surface proteins in active cells, resulting in a white appearance called acetowhite areas. Its main advantages are that it is simple, inexpensive, and not time-consuming; it provides instant results, and treatment of abnormal lesions can be performed immediately.[15] Acetowhite lesion conditions may indicate metaplastic changes in the transformation zone and regeneration processes.[16] According to Javier et al, *Coriolus versicolor* vaginal gel improves epithelialization of the cervical mucosa and microbiota composition.[6]

There was a statistically significant difference ($p = 0.0003$) between the mean Swede score of the first examination and the Swede score of the last examination. Findings from the present study are consistent with other preliminary single-arm investigations evaluating topical vaginal therapies for low grade cervical lesions. Terrinoni et al reported significant regression of CIN 1 following treatment with a vaginal spray containing carboxymethyl-B-glucan, curcumin, resveratrol, and epicatechin gallate in a prospective pilot study. Similar to our study, lesion regression was assesed without a parallel control group, supporting the feasibility and biological plausibility of local non-ablative therapies while underscoring the exploratory nature of these findings.[7] This study is in line with the PALOMA 1 clinical trial which stated that the percentage of treated patients achieving normal cytology with appropriate colposcopy was significantly higher compared to the control group (84.9% vs 64.5%; $p = 0.031$) within 6 months.[6] Although there was no control group, the normalization rate was higher than that achieved spontaneously as described in the literature that the probability of regression during 2 years of observation was 62.3%.[17] The Swede score was chosen to provide objective, quantitative results. This differs from the PALOMA 1 study, which used a Likert score to assess cervical re-epithelialization. The Likert score was derived from observations based on the degree of ectopy visible on the cervix. Meanwhile, the Swede score assesses based on colposcopic assessment. The PALOMA 1 study focused only on a general population sample, not a specific sample.[18] The observed decreases in Swede score may be biologically plausible based on previously reported immune-modulatory and epithelial reparative properties of *Coriolus versicolor* and other bioactive components of the vaginal gel. Preclinical and clinical studies suggest that C. versicolor derived polysaccharides can enhance local immune responses and support mucosal repair, while adjunct ingredients have been associated with improved cervical

epithelialization and vaginal microbiota balance.[19] However, these mechanisms were not directly assessed in the present cohort, and therefore should be regarded as hypotheses supported by prior literature rather than as proven mechanism underlying the observed clinical changes.

A total of 40.9% of study subjects reported no symptoms, with the number gradually increasing from the second and third examinations to 63.6% and 100%, respectively. This study had good tolerability, as evidenced by the absence of dropouts due to unmanageable side effects. All the study subjects experienced mild side effects, with symptoms not interfering with daily activities, improving within 24 hours, and requiring no treatment. This is because *Coriolus versicolor* extract is a lymphocyte mitogen that increases the production of Th1 cytokines, which are associated with the risk of allergies.[19] This finding is in line with Serrano et al, who stated that side effects were experienced in 31.8% and improved at the end of therapy.[9]

Several sources of bias should be considered when interpreting the results of this study. Selection bias may be present, as participants were women who presented for screening at a tertiary referral hospital and consented to participate, which may not represent the broader population of women with low-grade cervical lesions. In addition, measurement bias cannot be excluded, as lesion assessment relied on VIA and colposcopic findings rather than histologic confirmation; thus, observed changes may partly reflect variability in visual assessment rather than true histopathologic regression. To minimize observer bias, colposcopy examinations were done with different user with the same competency.

The 3–6-month follow-up period used in this study is appropriate for evaluating early regression of low-grade cervical lesions and short-term changes in colposcopic appearance. However, regression of low-grade lesions is known to occur spontaneously over longer period, typically ranging from 12 to 24 months.[10] The limited duration of follow up in this study therefore restricts conclusions regarding the persistence of regression. In the present study, a comparable degree of regression was observed within a shorter 6-month follow-up period, which compares favorably with published natural history data. However, because this was a single-arm study without control group, the observed reductions in Swede score, and VIA positivity cannot be attributed solely to the intervention, and the contribution of natural regression cannot be excluded. The statistical power of the present study is limited for several reasons. The limited power is primarily attributable to the small sample size (n=22) and lack of control group. These factors reduce the ability to detect modest effects and preclude definitive efficacy conclusions. Although the Swede score provides a structured colposcopic assessment, it remains a semi-objective tool. Inter-observer reliability was not formally assessed in this study and may represent a source of measurement variability. Histologic confirmation was not routinely performed in this study, as lesions were classified based on VIA and colposcopic findings with Swede score <5. Moreover, Swede score was applied because of its sensitivity, specificity, positive and negative predictive values of 94.9%, 88.4%, 75.5%, and 92.9%, respectively.[20] This limitation is inherent to low resource screening approaches and should be considered when interpreting the magnitude of treatment associated regression.

Future studies should include randomized, blinded controlled trials with histologic confirmation as primary endpoints, incorporating cervical biopsy where ethically justified. Longer follow-up periods of at least 12–24 months are needed to distinguish treatment-associated effects from spontaneous regression. Primary outcomes should be pre-specified, accompanied by appropriate sample-size calculations to ensure adequate statistical power. In addition, stratification or subgroup analyses based on baseline HPV status are recommended to better characterize differential responses and clarify the role of viral persistence in lesion regression.

Conclusion

In this prospective single-arm pilot study, use of *Coriolus versicolor* based vaginal gel was associated with decreases in Swede score and increased rates of VIA negativity over a 6-month follow-up period in women with low grade cervical lesions. These findings should be interpreted as preliminary and hypothesis generating, given the small sample size, single-arm design, and limited duration of follow up. Consequently, causality cannot be inferred, and the contribution of spontaneous regression cannot be excluded. Nevertheless, the observed trends, together with the favorable tolerability profile, support the feasibility of this approach and justify further investigation in randomized, controlled trials with histologic endpoints and longer follow up to determine efficacy.

Ethical Approval and Informed Consent

This research has been reviewed and approved by the Research Ethics Committee of Dr. Hasan Sadikin General Hospital Bandung (Ethical Approval Number: DP.04.03/D.XIV.6.5/204/2024). All patients have agreed and signed the consent form. This research has complied with the guidelines outlined in the Declaration of Helsinki.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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