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Research Article

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Effects of Coriolus Versicolor Vaginal Gel on Vaginal Microbial Resistance: A Prospective Analysis

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ABSTRACT

Background: Human Papillomavirus (HPV) infection and vaginal microbiota imbalance are common reproductive health problems in women. A vaginal gel based on Coriolus versicolor, has shown effectiveness in improving HPV- related cervical lesions, but its effect on vaginal microbiota and bacterial resistance culture has not been extensively studied.

Objectives: This study aimed to analyze changes in resistance culture results from vaginal swabs before and after administration of Coriolus versicolor Vaginal Gel, and to evaluate their relationship with other clinical and demographic parameters.

Methods: This research is a quasi-experimental clinical trial conducted on women with positive VIA (Visual Inspection with Acetic Acid) and low-grade precancerous lesions, using colposcopy at Dr. Hasan Sadikin General Hospital Bandung from July 2024 to December 2024, involved 28 female patients who underwent vaginal swab examination and clinical evaluation. Vaginal swab samples were collected before and after administration of Coriolus versicolor Vaginal Gel for bacterial culture analysis. Demographic and clinical parameters evaluated included age, HPV status, Pap smear results, and other medical history.

Results: From 28 patients (mean age 37.11 years), 60.7% had negative HPV status and 39.3% positive. Before administration of Coriolus versicolor Vaginal Gel, 67.9% of patients showed negative cultures, while 17.9% were infected with Escherichia coli. After administration of Coriolus versicolor Vaginal Gel, there was a significant increase in the number of patients with negative culture results (from 67.9% to 92.9%), and a decrease in positive cultures (from 28.6% to 7.1%). E. coli was no longer detected in post- treatment cultures.

Conclusions: Initial results indicate the potential of Coriolus versicolor Vaginal Gel in normalizing vaginal flora by reducing pathogenic bacterial growth. Further research with more complete follow-up data is needed for a more comprehensive analysis of the effectiveness of Coriolus versicolor Vaginal Gel in influencing resistance culture from vaginal swabs and its relationship with clinical and demographic parameters.

Keywords: Coriolus Versicolor Vaginal Gel, Resistance Culture, Vaginal Swab, Hpv, Vaginal Microbiota

Introduction

Background

Human papillomavirus (HPV) infection is one of the most common sexually transmitted infections and a leading cause of cervical cancer [1]. To date, over 396 HPV subtypes have been reported, with 13 identified as high-risk HPV (Hr-HPV), which plays a key role in the development of cervical cancer [2,3]. Although approximately 70% of cervical cancer cases worldwide are caused by high-risk HPV, not all HPV infections progress to cancer, indicating that additional factors may be involved in the carcinogenesis process [4-7].

The vaginal microbiota plays a crucial role in women's reproductive health and has been shown to influence susceptibility to HPV infection, viral persistence, and the development of

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cervical lesions [8-10]. A healthy vaginal microbiota is generally dominated by one of the four most prevalent Lactobacillus species: Lactobacillus crispatus, Lactobacillus iners, Lactobacillus gasseri, and Lactobacillus jensenii [11,12]. Lactobacillus bacteria form a barrier against colonization by pathogenic bacteria by maintaining a low vaginal pH and maintaining the barrier function of the cervical epithelium, which inhibits HPV infection of basal keratinocytes [13].

Disruption of the vaginal microbiota balance, or dysbiosis, has been associated with an increased risk of HPV infection and viral persistence [14-17]. Several studies have shown that a vaginal microbiota dominated by non-Lactobacillus bacteria is associated with an increased risk of HPV infection and the development of cervical lesions [18-21]. Conversely, some Lactobacillus species, such as L. gasseri, may aid in HPV clearance [18,22].

Coriolus Versicolor Vaginal Gel is a Coriolus versicolor-based vaginal gel that combines ingredients with known properties, such as moisturizing, tissue regeneration, and vaginal microbiota balancing (hyaluronic acid, Asian centella, Aloe vera, and α-glucan oligosaccharides) [23]. Several clinical studies have demonstrated the effectiveness of Coriolus Versicolor Vaginal Gel in improving HPV-related cervical lesions and aiding viral clearance. The PALOMA study, a multicenter, randomized, parallel, open-label, controlled clinical trial involving 91 HPV-positive women with low-grade Pap smear changes, showed that treatment with Coriolus Versicolor Vaginal Gel significantly improved cytologic normalization and HPV clearance compared with the conventional watchful waiting approach [23].

A sub analysis of the PALOMA study focusing on HPV-positive women over 40 years of age also showed promising results. At 6 months, lesion improvement was observed in 74.0% and HPV clearance in 61.1% of women over 40 years of age who received Coriolus Versicolor Vaginal Gel [24]. These results are particularly relevant given the higher persistence of HPV in older women due to immunosenescence.

Although the effectiveness of Coriolus Versicolor Vaginal Gel in improving cervical lesions and aiding HPV clearance has been well documented, its effects on the vaginal microbiota and bacterial resistance patterns have not been extensively studied. A better understanding of how Coriolus Versicolor Vaginal Gel affects the vaginal microbiota composition and bacterial resistance patterns could provide valuable insights into its mechanism of action and its potential broader therapeutic applications.

Research Gaps

Although several studies have evaluated the effectiveness of Coriolus Versicolor Vaginal Gel in improving HPV-related cervical lesions and aiding viral clearance, there are several significant research gaps:

1. **Lack of Microbiota Data:** Most research on Coriolus Versicolor Vaginal Gel has focused on its effects on cervical lesions and HPV clearance, with little attention paid to changes in vaginal microbiota composition.
2. **Limitations of Culture Analysis:** Previous studies generally did not perform comprehensive bacterial culture analysis before and after administration of Coriolus Versicolor Vaginal Gel, thus limiting the understanding of its effects on vaginal flora.
3. **Bacterial Resistance:** No studies have specifically evaluated how Coriolus Versicolor Vaginal Gel affects bacterial resistance patterns in the vaginal microbiota.
4. **Correlation with Clinical and Demographic Parameters:** The relationship between changes in vaginal microbiota after administration of Coriolus Versicolor Vaginal Gel with clinical parameters such as HPV status, Pap smear results, and demographic factors has not been explored in depth.

This study aims to fill this gap by analyzing changes in resistance culture results from vaginal swabs before and after administration of Coriolus Versicolor Vaginal Gel, and evaluating its relationship with other clinical and demographic parameters.

Research Objectives

The main objective of this study was to analyze changes in resistance culture results from vaginal swabs before and after administration of Coriolus Versicolor Vaginal Gel.

The secondary objectives of this study include: 1. Evaluating the relationship between changes in vaginal microbiota and other clinical parameters (HPV status, Pap smear results) and demographic factors. 2. Identifying factors influencing response to Coriolus Versicolor Vaginal Gel therapy. 3. Assessing the safety and tolerability of Coriolus Versicolor Vaginal Gel in the study population.

Table 1: Demographic Characteristics and Clinical Research Subjects

Characteristics	n (%) or Mean ± Elementary School
Age (year)	37.11 ± 11.39
HPV status	
Negative	17 (60.7%)
Positive	11 (39.3%)
Results Pap Smear	
Normal	16 (57.1%)
CIN I	2 (7.1%)
CIN II	1 (3.6%)
Atypical Glandular	1 (3.6%)
Exclusion / No There is	8 (28.6%)
Complaint Main (n=20)	
No There is	10 (50.0%)
vaginal discharge	6 (30.0%)
Bleeding	4 (20.0%)

Method

Research Design

This study design is a quasi-experimental clinical trial on intervention subjects. All samples that met the inclusion criteria

and did not meet the exclusion criteria were included as study subjects. This study was conducted to evaluate changes in resistance culture results from vaginal swabs before and after administration of Coriolus Versicolor Vaginal Gel. The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. The study protocol was evaluated and approved by the ethics committee.

Population and Samples

The study sample was collected using consecutive sampling method on patients with positive IVA who were monitored at the obstetrics and gynecology clinic of Dr. Hasan Sadikin General Hospital, Bandung, from July 2024 to December 2024. The baseline characteristics of the study subjects were recorded, including age, HPV status, Pap smear results, and other medical history.

Research Variables

The main variables evaluated in this study include:

1. **Vaginal Swab Culture Results:** Types of bacteria isolated from vaginal swabs before and after Coriolus Versicolor Vaginal Gel administration, including resistance patterns, if available.
2. **HPV Status:** HPV infection status (positive or negative) at baseline and after Coriolus Versicolor Vaginal Gel administration (if available).
3. **Pap Smear Results:** Pap smear results at baseline.
4. **Demographic Parameters:** Age, marital history, smoking status, reproductive history, and sexual activity history.
5. **Other Clinical Parameters:** Chief complaint, history of STIs, contraceptive use, and laboratory data (Hb, leukocytes, platelets).

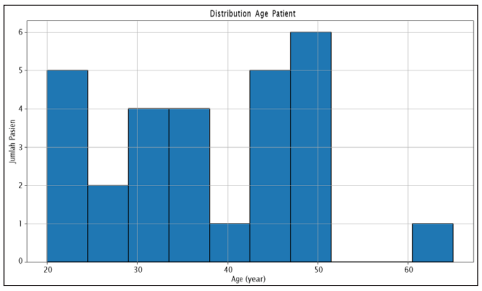
Table 2: Distribution of Vaginal Swab Culture Results Before and After Coriolus Vaginal Gel Administration Versicolor

Type Bacteria	Before Gel Vagina Coriolus Versicolor, n (%)	After Gel Vagina Coriolus Versicolor, n (%)
No growth of pathogenic acteria	19 (67,9%)	26 (92,9%)
Escherichia coli	5 (17,9%)	0 (0%)
Staphylococcus epidermidis	2 (7,1%)	0 (0%)
Klebsiella pneumoniae	1 (3,6%)	0 (0%)
Fungal colonies with morphology microscopic yeast cells	0 (0%)	1 (3.6%)
Staphylococcus saprophyticus	0 (0%)	1 (3.6%)
No recorded	1 (3.6%)	0 (0%)

Procedure Research

The research procedures include

1. **Vaginal Swab Collection:** Vaginal swabs were collected at the initial visit (before Coriolus Versicolor Vaginal Gel administration) and at the follow-up visit (after Coriolus Versicolor Vaginal Gel administration).
2. **Bacterial Culture:** Vaginal swab samples were cultured using standard methods for bacterial identification and determination of resistance patterns.
3. **Coriolus Versicolor Vaginal Gel Administration:** Coriolus Versicolor Vaginal Gel was administered according to the established protocol.
4. **Clinical Evaluation:** Other clinical parameters were evaluated at the initial and follow-up visits.
5. **Data Collection:** Demographic data, culture results, HPV status, Pap smear results, and other clinical parameters were recorded in a standardized format.



Picture 1: Distribution Type Bacteria on Culture Swab Vagina Before And After Giving Gel Vagina Coriolus Versicolor

[*Description:* Bar chart shows a comparison of the distribution of bacterial types in vaginal swab cultures before and after And after giving Gel Vagina Coriolus Versicolor, highlight decline prevalence E. coli , S. epidermidis , and K. pneumoniae as well as improvement culture negative after intervention.]

Analysis Data

Data were analyzed using appropriate descriptive and inferential statistical methods. Descriptive analysis included calculating frequencies, percentages, means, medians, standard deviations, and ranges for relevant variables. Inferential analysis to compare results before and after Coriolus Versicolor Vaginal Gel administration was performed using tests appropriate to the type of data. The statistical significance level was set at $p < 0.05$.

Results

Demographic Characteristics of Research Subjects

This study involved a total of 28 female patients with a mean age of 37.11 years (SD = 11.39) and an age range of 20-65 years. The majority of patients (18 of 20 patients with available data, 90%) had a history of marriage once, with a mean age of marriage of 21.75 years (SD = 6.54). The mean age at menarche was 12.60 years (SD = 1.39), and the mean age at first sexual activity was 22.20 years (SD = 4.99). The majority of patients (17 of 20 patients with available data, 85%) did not smoke, but a large proportion (12 of 20, 60%) had a husband who smoked. The mean parity was 2.05 (SD = 1.28).

Clinical Characteristics of Research Subjects

HPV status showed that 17 patients (60.7%) were HPV negative, while 11 patients (39.3%) were HPV positive. Pap smear results showed that 16 patients (57.1%) had no detectable abnormalities, 2 patients (7.1%) had CIN I, 1 patient (3.6%) had CIN II, and 1 patient (3.6%) had Atypical Glandular. In terms of chief complaints, 10 patients (50% of 20 patients with available data) did not report specific complaints, 6 patients (30%) reported

vaginal discharge, and 4 patients (20%) reported bleeding. A history of sexually transmitted infections (STIs) and a history of oral contraceptive use were each positive in 7 patients (35% of 20 patients with data). The current contraceptive method was predominantly injectable (12 patients, 60%).

Vaginal Swab Culture Results Before Coriolus Versicolor Vaginal Gel Administration

Vaginal swab culture results before Coriolus Versicolor Vaginal Gel administration showed that 19 patients (67.9%) did not exhibit significant growth of pathogenic bacteria. Escherichia coli was the most common pathogenic bacteria found (5 patients, 17.9%), followed by Staphylococcus epidermidis (2 patients, 7.1%) and Klebsiella pneumoniae (1 patient, 3.6%).

Vaginal Swab Culture Results After Coriolus Versicolor Vaginal Gel Administration

After administration of Coriolus Versicolor Vaginal Gel, significant changes in culture results occurred. Twenty-six patients (92.9%) showed no significant growth of pathogenic bacteria. Only one patient (3.6%) showed growth of fungal colonies with microscopic yeast cell morphology, and one patient (3.6%) showed growth of Staphylococcus saprophyticus.

Analysis of Cultural Change

Comparison of culture results before and after Coriolus Versicolor Vaginal Gel administration showed a significant increase in the number of patients with negative culture results, from 19 patients (67.9%) to 26 patients (92.9%). The number of patients with positive cultures decreased from 8 patients (28.6%) to only 2 patients (7.1%). Escherichia coli, previously found in 5 patients, was no longer detected after Coriolus Versicolor Vaginal Gel administration. Similarly, Staphylococcus epidermidis and Klebsiella pneumoniae were no longer found in post-treatment cultures.

Relationship between Culture Changes and Clinical Parameters

Further analysis is needed to evaluate the association between changes in culture results with HPV status, Pap smear results, and other demographic and clinical factors. Limited follow-up data for some clinical parameters limits this analysis to the current stage.

Discussion

Main Findings

This study aimed to analyze changes in resistance culture results from vaginal swabs before and after administration of Coriolus Versicolor Vaginal Gel. The main findings demonstrated the potential of Coriolus Versicolor Vaginal Gel in normalizing vaginal flora. Before administration of Coriolus Versicolor Vaginal Gel, Escherichia coli was the most common pathogenic bacteria found. After administration of Coriolus Versicolor Vaginal Gel, there was a significant increase in the number of patients with negative culture results (from 67.9% to 92.9%), and a decrease in the number of patients with positive culture results (from 28.6% to 7.1%). Escherichia coli previously found in 5 patients was no longer detected after administration of Coriolus Versicolor Vaginal Gel. These findings indicate the potential positive effect of Coriolus Versicolor Vaginal Gel in reducing the growth of pathogenic bacteria and normalizing vaginal flora.

Comparison with Previous Research

The findings of this study can be compared with the results of the PALOMA study and other relevant studies.

The PALOMA study demonstrated that treatment with a Coriolus versicolor-based vaginal gel (in this case, Coriolus Versicolor Vaginal Gel) significantly improved cytologic normalization and HPV clearance compared with the conventional watchful waiting approach [23]. At the 6-month follow-up, overall HPV clearance was achieved by more patients receiving the Coriolus versicolor-based vaginal gel (59.6%) compared with those not receiving treatment (41.9%), particularly in high-risk HPV patients (62.5% vs. 40.0%).

A subanalysis of the PALOMA study focusing on HPV-positive women over 40 years of age also showed promising results. At 6 months, lesion improvement was observed in 74.0% and HPV clearance in 61.1% of women over 40 years of age who received the Coriolus versicolor-based vaginal gel [24].

Research by Zeng et al. showed that differences in vaginal flora patterns were associated with HPV persistence and viral clearance [25]. They found that patients with HPV clearance had significantly lower alpha diversity, and flora patterns also differed between the groups showing HPV clearance and persistence. Patients with persistent HPV infection had significantly higher levels of Bacteroidaceae, Erysipelotrichaceae, Helicobacteraceae, Neisseriaceae, Streptococcaceae (family level), and Fusobacterium, Bacteroides, Neisseria, and Helicobacter (genus level) than patients who had cleared HPV.

The current study findings, although limited to culture data, are consistent with the hypothesis that Coriolus Versicolor Vaginal Gel may help balance the vaginal microbiota and potentially facilitate HPV clearance. The increase in patients with negative culture results after Coriolus Versicolor Vaginal Gel administration supports this hypothesis.

Mechanism Potential

Several potential mechanisms may explain the effects of Coriolus Versicolor Vaginal Gel on vaginal microbiota and bacterial resistance cultures.

First, Coriolus Versicolor Vaginal Gel contains ingredients with moisturizing and tissue-regenerating properties (hyaluronic acid, Asian centella, and aloe vera) that can help improve the integrity of the vaginal and cervical epithelium. Good epithelial integrity is essential for preventing colonization by pathogenic bacteria and HPV infection [13].

Second, Coriolus Versicolor Vaginal Gel contains α-glucan oligosaccharides, which function as prebiotics, supporting the growth of beneficial bacteria such as Lactobacillus spp. and helping balance the vaginal microbiota [23]. Lactobacillus dominance in the vaginal microbiota has been associated with a reduced risk of HPV infection and more effective viral clearance [18,22].

Third, Coriolus versicolor, the main component of Coriolus Versicolor Vaginal Gel, has been shown to have immunomodulatory and anti-inflammatory properties [23].

Modulating the local immune response may aid in HPV clearance and reduce inflammation that can facilitate viral persistence and the development of cervical lesions.

Fourth, the combination of C. versicolor and neem extract in Coriolus Versicolor Vaginal Gel has been shown to induce local immune responses in in vitro studies and animal models, inhibiting the oncogenic action of HPV [23].

Although the specific mechanisms by which Coriolus Versicolor Vaginal Gel affects bacterial resistance cultures are not fully understood, normalization of the vaginal microbiota and improvement of epithelial integrity may contribute to decreased colonization of pathogenic bacteria and changes in resistance patterns.

Clinical Implications

The findings of this study, although preliminary, have several potential clinical implications.

First, a significant increase in the number of patients with negative culture results after administration of Coriolus Versicolor Vaginal Gel indicates that Coriolus Versicolor Vaginal Gel may be a safe and effective therapeutic option for normalizing vaginal flora in women with microbiota imbalance.

Second, the combination of Coriolus Versicolor Vaginal Gel's effects in improving cervical lesions (as demonstrated in the PALOMA study) and its potential in normalizing vaginal flora makes it a promising therapeutic option for the comprehensive management of HPV infection and related vaginal health problems.

Third, therapeutic approaches targeting the vaginal microbiota, such as Coriolus Versicolor Vaginal Gel, may be an effective strategy to enhance HPV clearance and prevent the development of cervical lesions, particularly in women at high risk for HPV persistence, such as older women.

Research Limitations

This study has several limitations that need to be considered in interpreting the results.

First, the sample size was relatively small (28 patients) and some demographic and clinical data were not available for all patients. This limited the ability to conduct comprehensive statistical analyses and draw strong conclusions.

Second, follow-up data for several clinical parameters, such as the Sweede score and changes in HPV status, are not yet available. This lack of data limits the evaluation of the effectiveness of Coriolus Versicolor Vaginal Gel in improving cervical health and influencing HPV status.

Third, there is variation in data recording formats for some variables (such as NLR and PLR), which makes accurate analysis difficult.

Fourth, this study did not have a control group that did not receive Coriolus Versicolor Vaginal Gel, making it difficult to isolate the specific effects of Coriolus Versicolor Vaginal Gel from other factors that may have influenced the results.

Recommendations for Further Research

Based on the findings and limitations of this study, several recommendations for further research can be identified.

First, studies with larger sample sizes and longer follow-up periods are needed to evaluate the long-term effects of Coriolus Versicolor Vaginal Gel on vaginal microbiota, bacterial resistance cultures, and clinical parameters such as Sweede score and HPV status.

Second, standardizing data recording formats will facilitate more accurate and comprehensive analysis.

Third, a more comprehensive microbiome analysis using next-generation sequencing technology may provide deeper insights into changes in vaginal microbiota composition following Coriolus Versicolor Vaginal Gel administration.

Fourth, mechanistic studies to reveal the specific mechanisms by which Coriolus Versicolor Vaginal Gel affects vaginal microbiota and bacterial resistance cultures would be invaluable.

Fifth, comparative studies comparing the effects of Coriolus Versicolor Vaginal Gel with other interventions known to affect the vaginal microbiota, such as probiotics or antibiotics, could provide a broader perspective on the position of Coriolus Versicolor Vaginal Gel in the management of vaginal health problems [26,27].

Conclusion

This study aimed to analyze changes in resistance culture results from vaginal swabs before and after administration of Coriolus Versicolor Vaginal Gel. Initial findings indicate the potential of Coriolus Versicolor Vaginal Gel in normalizing vaginal flora.

Before Coriolus Versicolor Vaginal Gel administration, Escherichia coli was the most common pathogenic bacteria found. After Coriolus Versicolor Vaginal Gel administration, there was a significant increase in the number of patients with negative culture results (from 67.9% to 92.9%), and a decrease in the number of patients with positive culture results (from 28.6% to 7.1%). Escherichia coli was no longer detected in post-treatment cultures.

The main limitations of this study are the relatively small sample size, limited follow-up data for some clinical parameters, and variations in data recording formats. More comprehensive follow-up data collection and standardization of recording formats are needed for a more comprehensive analysis of the effectiveness of Coriolus Versicolor Vaginal Gel in influencing culture resistance from vaginal swabs and other clinical parameters.

Nevertheless, preliminary findings indicate the potential of Coriolus Versicolor Vaginal Gel as a safe and effective therapeutic option for normalizing vaginal flora and potentially facilitating HPV clearance. Further studies with larger sample sizes and longer follow-up periods are needed to confirm these findings and explore the specific mechanisms by which Coriolus Versicolor Vaginal Gel affects the vaginal microbiota and bacterial resistance cultures.

Conflict Interest

The authors declare no conflict of interest in the conduct and reporting of this research.

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