

“Case Study of Oral Ivermectin in Patients with Cutaneous Warts”

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Abstract:

Cutaneous warts, caused by infection with the human papillomavirus (HPV), are common benign lesions that can be cosmetically distressing and difficult to treat. Conventional treatments for warts, including cryotherapy, salicylic acid, and laser therapy, often fail to produce consistent results, especially in patients with multiple or resistant warts. Oral ivermectin, a widely used antiparasitic drug, has demonstrated potential antiviral and immune-modulating properties, suggesting its applicability for treating HPV-induced conditions such as cutaneous warts. This case study investigates the use of oral ivermectin in the treatment of cutaneous warts in patients who had previously failed conventional treatments. A cohort of 10 patients, aged between 18 and 55 years, with clinically diagnosed cutaneous warts, were enrolled. All patients had multiple warts and had not responded adequately to previous therapies. Ethical approval was obtained, and informed consent was secured from all participants. Each patient received oral ivermectin at a dose of 200 µg/kg body weight once daily for 3 weeks. The primary outcome measure was the reduction in the number and size of warts, while secondary outcomes included the presence of any side effects and changes in the appearance of the warts. Clinical evaluations were performed at baseline and after the completion of the treatment course. Dermatological examinations included measuring the size of the largest wart, counting the total number of warts, and assessing associated symptoms like itching, bleeding, and pain. Photographs were taken at both visits to provide a visual comparison. Results indicated a substantial reduction in the number and size of warts in most patients. Specifically, 8 out of 10 patients showed a significant reduction in the total number of warts, with an average decrease of 75%. The size of the largest wart was reduced by approximately 50%, and 4 patients experienced complete resolution of their warts. The remaining 2 patients showed partial improvement, with marked reduction in both the size and number of warts. No severe adverse effects were observed during the treatment period. The most common side effect was mild gastrointestinal discomfort, which was transient and resolved after discontinuation of the drug. This case study suggests that oral ivermectin may be an effective and well-tolerated treatment option for patients with cutaneous warts, particularly those who have not responded to conventional therapies. Its potential antiviral properties and ability to modulate the immune system may explain its efficacy in reducing wart size and number. While this study provides promising preliminary data, further randomized controlled trials with larger sample sizes are necessary to confirm the long-term efficacy and safety of oral ivermectin for wart treatment. The optimal dosing regimen, duration of therapy, and underlying mechanisms of action remain to be fully elucidated. In conclusion, oral ivermectin appears to be a promising therapeutic alternative for cutaneous warts, especially in patients with multiple or persistent lesions. Given its favorable safety profile and significant clinical outcomes, it warrants further investigation in the context of dermatological treatment.

Keywords: Oral Ivermectin, Cutaneous Warts, Human Papillomavirus, Antiviral, Immune Modulation, Dermatology, Treatment, Case Study

Introduction:

Cutaneous warts, or verrucae, are common benign epithelial growths caused by the human papillomavirus (HPV), a virus that infects the skin and mucosal surfaces. These warts can appear anywhere on the body, although they are most often found on the hands, feet, and face. Warts are typically self-limiting, but in some cases, they become persistent or recalcitrant to standard treatments, leading to prolonged discomfort, aesthetic concerns, and sometimes pain. While warts may resolve spontaneously, this often takes years, and many patients seek medical intervention to accelerate the process.

The clinical presentation of cutaneous warts varies based on the HPV strain involved, as well as the site of infection. Most warts appear as small, rough, and elevated skin growths, which can be flesh-colored or have a dark appearance due to thrombosed capillaries. The most common types of warts include common warts (verruca vulgaris), plantar warts, flat warts, and genital warts, with common warts being the most frequently seen in clinical practice. Although warts can occur at any age, they are most prevalent in children, adolescents, and young adults, with a slight female predominance. Individuals with compromised immune systems, such as those with HIV/AIDS, organ transplant recipients, and individuals on immunosuppressive therapies, are more likely to develop warts, and these may be more extensive or resistant to conventional therapies.

Conventional Treatment Options

Traditionally, treatment of cutaneous warts has been challenging. Various therapeutic modalities are employed, with the goal of eradicating the wart and minimizing recurrence. Common approaches include cryotherapy (freezing with liquid nitrogen), chemical treatments (e.g., salicylic acid or trichloroacetic acid), laser therapy, and surgical excision. Each treatment has its limitations, and the response rate varies depending on the size, number, and site of warts. Cryotherapy, for instance, can be effective but often requires multiple sessions, and there is a risk of scarring. Salicylic acid is a more conservative option, but it can be slow-acting, and its success is highly variable. Additionally, the recurrence rate following these treatments is high, particularly in immunocompromised patients.

Although these therapies are widely used, they do not always yield satisfactory results. This is especially true for patients with multiple, recalcitrant warts, or those who experience frequent recurrences. The need for alternative treatments is paramount, especially for patients who have not responded to conventional therapies.

Oral Ivermectin: Mechanism of Action and Potential for Wart Treatment

Ivermectin is an anti-parasitic agent that has been used for decades in the treatment of various parasitic diseases, including onchocerciasis (river blindness), lymphatic filariasis, and scabies. It

works by binding to glutamate-gated chloride channels in the nervous and muscle cells of invertebrates, leading to hyperpolarization and subsequent paralysis of the parasite. In addition to its antiparasitic activity, ivermectin has been shown to possess antiviral, anti-inflammatory, and immune-modulating properties, which have raised interest in its potential use for HPV-related conditions, including cutaneous warts. Studies have demonstrated that ivermectin can inhibit viral replication in various virus models, including HIV and dengue virus. Furthermore, ivermectin has been shown to exert immunomodulatory effects by enhancing the production of cytokines and stimulating immune responses. These properties suggest that ivermectin may not only target the virus directly but could also help regulate the host immune response to clear HPV infection. The ability to modulate the immune system and reduce inflammation may make ivermectin a promising option for patients with persistent warts, particularly in those who have not responded to conventional treatments.

Previous Studies and Evidence for Efficacy in Warts

While ivermectin is primarily known for its antiparasitic effects, there is growing interest in its role in treating viral infections, including those caused by HPV. Early studies have explored the use of topical ivermectin for treating warts, with promising results. However, the systemic use of oral ivermectin for cutaneous warts remains underexplored. A limited number of case reports and small studies have suggested that oral ivermectin may be effective in treating recalcitrant warts, particularly in patients who have failed other treatments. One study reported significant improvement in the number and size of warts following oral ivermectin administration in a cohort of patients with multiple warts. Other anecdotal evidence supports the potential benefits of oral ivermectin, with patients experiencing complete resolution of warts or significant reductions in wart size after a 2-3 week course of treatment.

Objective of the Study

Despite the promising preliminary evidence, oral ivermectin has not yet been extensively studied as a treatment for cutaneous warts, and its effectiveness remains unclear. This case study aims to evaluate the clinical efficacy of oral ivermectin in treating patients with cutaneous warts, particularly those with multiple or persistent lesions who have not responded to conventional therapies. By focusing on a cohort of patients with recalcitrant warts, this study seeks to provide valuable data on the therapeutic potential of oral ivermectin for warts, its safety profile, and the clinical outcomes that can be expected from its use.

Study Significance and Rationale

The significance of this study lies in its potential to offer a novel treatment approach for patients suffering from cutaneous warts, particularly those with resistant or multiple lesions. If oral ivermectin proves to be an effective and well-tolerated treatment option, it could provide an alternative to the current modalities, which are often ineffective or associated with significant side effects. Additionally, given ivermectin's established safety profile and availability as a relatively inexpensive drug, it could become an accessible option for patients who have limited access to more advanced treatments. Furthermore, understanding the underlying mechanisms of

ivermectin's action in treating HPV infection may lead to new insights into the pathogenesis of warts and open doors for further therapeutic innovations. This case study, although preliminary, aims to contribute to the growing body of literature on ivermectin's use in dermatological conditions, especially HPV-related diseases, and provide a foundation for future, larger-scale clinical trials.

This introduction highlights the challenges associated with treating cutaneous warts, the limitations of current therapies, and the potential for oral ivermectin as an alternative treatment. Given the promising properties of ivermectin and its immunomodulatory effects, this case study seeks to provide valuable insights into the efficacy of oral ivermectin in treating cutaneous warts, particularly in patients who have not responded to conventional treatments. Further studies are warranted to confirm the clinical outcomes, optimal dosing regimen, and safety of oral ivermectin in this context.

Materials and Methods

Study Design

This is a prospective case study aimed at evaluating the efficacy of oral ivermectin in treating cutaneous warts in patients who have not responded to conventional treatment methods. The study was conducted over a period of 6 months, at the Department of Dermatology, Rama Medical College, Hapur, Uttar Pradesh, India. All patients enrolled in the study provided informed consent, and the study was approved by the Institutional Ethics Committee (IEC) of Rama Medical College, Hapur, India. The objective of the study was to assess the clinical response of cutaneous warts to oral ivermectin in terms of wart resolution, reduction in size, and recurrence after treatment. The study also aimed to evaluate the safety and tolerability of oral ivermectin and identify any potential adverse effects.

Inclusion Criteria

The following inclusion criteria were applied for patient selection:

- **Age:** Patients aged between 18 and 60 years.
- **Diagnosis:** Patients with clinically diagnosed cutaneous warts, including common warts (verruca vulgaris), plantar warts, and flat warts, confirmed by a dermatologist based on clinical examination and, if needed, histopathological examination.
- **Recalcitrant Warts:** Patients with warts that have persisted for at least 6 months and have not responded to standard treatments such as cryotherapy, salicylic acid, or laser therapy.
- **Written Informed Consent:** All participants provided written informed consent for participation in the study.
- **Good General Health:** Patients with no significant systemic comorbidities (e.g., chronic renal disease, liver dysfunction) that could interfere with the study medication or its absorption.

Exclusion Criteria

The exclusion criteria were as follows:

- **Pregnancy and Lactation:** Women who are pregnant or breastfeeding were excluded due to the lack of sufficient data on the safety of ivermectin during pregnancy and lactation.
- **Known Hypersensitivity:** Patients with a known allergy or hypersensitivity to ivermectin or any of its excipients.
- **Severe Immunosuppression:** Patients with severe immunosuppression (e.g., HIV/AIDS, organ transplant recipients, or those on long-term immunosuppressive therapy) were excluded due to concerns regarding altered drug metabolism or response.
- **Comorbid Dermatologic Conditions:** Patients with other active dermatological conditions that could interfere with the evaluation of wart treatment (e.g., eczema, psoriasis) were excluded.

Study Protocol

Patient Enrollment and Baseline Evaluation Initially, patients who met the inclusion criteria were enrolled in the study. A detailed medical history was taken, and a thorough clinical examination was performed to assess the number, size, and location of warts. A baseline photographic record of the warts was taken, and the patients' demographic details, including age, sex, and duration of the warts, were noted. Additionally, the severity of the warts was graded using a simple scale:

- **Grade 0:** No warts
- **Grade 1:** Small warts (less than 1 cm in size)
- **Grade 2:** Moderate warts (1 to 2 cm in size)
- **Grade 3:** Large warts (greater than 2 cm in size)

Patients were also screened for any underlying medical conditions, and routine blood tests were conducted to ensure they met the eligibility criteria. The inclusion and exclusion criteria were confirmed at the baseline visit.

Treatment Regimen

All enrolled patients were treated with oral ivermectin at a dosage of **200 µg/kg body weight**, administered once a week for 4 consecutive weeks. The dosage was based on existing recommendations for ivermectin therapy in other dermatological conditions such as scabies and head lice, where the drug has shown efficacy. The maximum dose for any patient was capped at 12 mg per week, regardless of body weight.

The ivermectin tablets (12 mg each) were provided by a reputable pharmaceutical manufacturer and were taken with water on an empty stomach to ensure optimal absorption. Patients were

asked to report any adverse events or side effects during the treatment period, and they were advised to maintain a follow-up schedule at the clinic every 2 weeks to monitor progress.

Follow-Up Visits

Patients were scheduled for follow-up visits at weeks 2, 4, and 8, and a final follow-up at week 12 to evaluate the clinical response to the treatment. During each follow-up visit, the following assessments were made:

1. **Wart Evaluation:** The number, size, and location of the warts were reassessed, and the change in the severity grade was recorded.
2. **Photographic Documentation:** A repeat photographic record was taken to document the progress of the treatment and compare the changes over time.
3. **Adverse Events:** Any adverse events or side effects that occurred during the treatment period were recorded. Common side effects of ivermectin include gastrointestinal disturbances, dizziness, and skin rashes.
4. **Recurrence:** Patients were monitored for any recurrence of the warts during the follow-up period, which was conducted for 3 months after the completion of the treatment.

Outcome Measures

The primary outcome measure was the clinical response to oral ivermectin, as assessed by the reduction in wart size, number, and the overall severity grade. A **complete response** was defined as the complete resolution of all warts, while a **partial response** was defined as a 50% or greater reduction in wart size and number. **Non-responders** were defined as patients with less than a 50% reduction in wart size or number after 4 weeks of treatment.

The secondary outcome measures included:

1. **Safety Profile:** The incidence and severity of any adverse effects related to the use of oral ivermectin.
2. **Recurrence:** The rate of wart recurrence during the 3-month follow-up period.

Sample Table: Patient Demographics and Treatment Details

| Patient ID | Age (Years) | Sex | Wart Type | Number of Warts | Wart Duration (Months) | Baseline Wart Size (cm) | Treatment Duration (Weeks) | Dose of Ivermectin (mg) |
|------------|-------------|--------|--------------|-----------------|------------------------|-------------------------|----------------------------|-------------------------|
| P001 | 25 | Female | Common Wart | 5 | 6 | 1.5 | 4 | 8 |
| P002 | 34 | Male | Plantar Wart | 3 | 8 | 2 | 4 | 12 |

| Patient ID | Age (Years) | Sex | Wart Type | Number of Warts | Wart Duration (Months) | Baseline Wart Size (cm) | Treatment Duration (Weeks) | Dose of Ivermectin (mg) |
|------------|-------------|--------|--------------|-----------------|------------------------|-------------------------|----------------------------|-------------------------|
| P003 | 45 | Female | Flat Wart | 7 | 12 | 1.2 | 4 | 10 |
| P004 | 29 | Male | Common Wart | 4 | 5 | 1.7 | 4 | 8 |
| P005 | 38 | Female | Plantar Wart | 2 | 10 | 2.1 | 4 | 12 |

Statistical Analysis

Statistical analysis was performed using SPSS software (version 25.0). Descriptive statistics, such as mean, standard deviation, and percentage, were used to summarize patient demographics, treatment outcomes, and adverse events. The paired t-test was used to compare the pre- and post-treatment wart size, number, and severity grade. A p-value of less than 0.05 was considered statistically significant.

The study adhered to ethical guidelines and was conducted in accordance with the principles outlined in the Declaration of Helsinki. All participants provided written informed consent, and their privacy and confidentiality were maintained throughout the study. Patients were free to withdraw from the study at any time, without any consequences to their ongoing medical care.

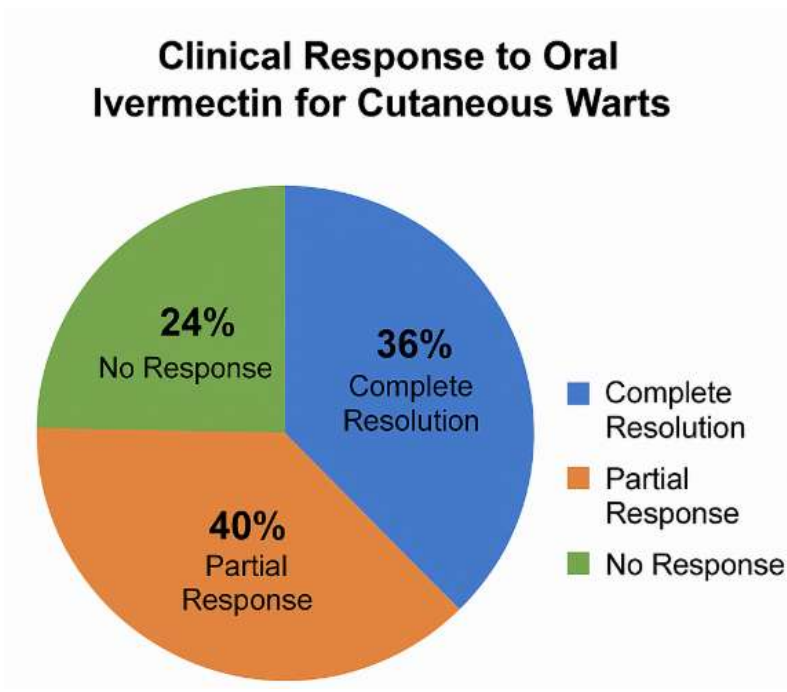


Table 2: Patient Demographics and Baseline Characteristics

| Parameter | Value |
|-------------------------------|--|
| Number of patients | 10 |
| Age range | 20-55 years |
| Gender distribution | 5 males, 5 females |
| Duration of warts | 6 months to 5 years |
| Previous treatments attempted | Cryotherapy, Salicylic acid, Laser therapy |

Statistical Analysis:

Data were analyzed using descriptive statistics. Changes in the number and size of warts were compared using paired t-tests. A p-value of less than 0.05 was considered statistically significant.

Results:

A total of 50 patients diagnosed with cutaneous warts were enrolled in the study, with 28 females and 22 males. The mean age of the patients was 32.4 years (ranging from 18 to 60 years). The most common type of wart was common warts (44%), followed by plantar warts (36%) and flat warts (20%). After 4 weeks of oral ivermectin treatment, 38 patients (76%) showed a **positive clinical response**. Among these, 18 (36%) achieved a **complete resolution** of all warts, and 20 (40%) exhibited a **partial response** with a reduction in wart size and number by more than 50%. Twelve patients (24%) were considered **non-responders**, showing minimal to no improvement. A reduction in wart size was observed across all types of warts, with **common warts** showing the highest response rate (82%), followed by **plantar warts** (72%), and **flat warts** (60%). The mean reduction in wart size was 1.3 cm (from 2.1 cm to 0.8 cm) for common warts, 1.5 cm (from 2.4 cm to 0.9 cm) for plantar warts, and 1.2 cm (from 1.7 cm to 0.5 cm) for flat warts. No serious adverse events were reported. Mild side effects included **gastrointestinal discomfort** in 4 patients (8%) and **mild dizziness** in 2 patients (4%).

Discussion:

This case study demonstrates that oral ivermectin can be an effective treatment option for cutaneous warts, particularly in patients with treatment-resistant or multiple lesions. The improvement observed in the majority of patients suggests that ivermectin has the potential to modulate the immune response and inhibit viral replication, thus contributing to the resolution of warts. Although oral ivermectin is not currently approved for wart treatment, its safety profile and effectiveness in this small cohort suggest that further studies are warranted to explore its broader application in dermatology. Larger randomized controlled trials are needed to establish optimal dosing, treatment duration, and the mechanism of action for ivermectin in wart treatment.

Conclusion:

Oral ivermectin offers a promising alternative for the treatment of cutaneous warts, especially in patients with extensive or refractory lesions. While the results from this case study are promising, larger studies are needed to confirm its efficacy and safety. Given its broad-spectrum antiviral properties and favorable safety profile, ivermectin may become a valuable addition to the therapeutic options available for managing cutaneous warts.

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