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PRIMARY PREVENTION OF VERRUCA PLANTARIS THROUGH TOPICAL HERBAL AND VITAMIN DERIVATIVE

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ABSTRACT

Objective: Verrucae plantaris (VP) results from environmental exposure to human papillomavirus causing plantar warts of the foot, resistant to treatment, and high recurrence rates. Current treatment paradigms focus on the treatment of lesions as opposed to primary prophylaxis. We hypothesize that a topical combination of herbal supplement with anti-viral properties and a vitamin derivative* can be used prophylactically to decrease the primary incidence.

Methods: We initiated a double-blinded clinical study with participants (n=282) randomization into control (lotion emollient only) (n=120), treatment (herbal and vitamin derivative) (n=110) and no treatment (NT) (n=52). Participants underwent examination of the feet at baseline (0 months) to exclude VP lesions and were randomized to receive a bottle containing topical lotion with emollient only, control (C), lotion with an herbal and vitamin derivative, treatment (T), or NT, where participants did not apply anything to their feet. C and T participants applied lotion topically to the feet once daily and were examined at 3, 6, 9, and 12 months to document the incidence of VP.

Results: No incidence of VP occurred in the T group (0/110=0% incidence), two lesions in the C group (2/120=1.7% incidence), and five lesions in the NT group (5/52=9.6% incidence).

Conclusion: Treatments for VP rely on treating lesions after they occur, have high degrees of variability in success, risk of continued transmission during treatment, and have high rates of recurrence. Although the study number is relatively low, early indications show decreasing incidence of VP from 9.6% in participants with NT to 1.7% in participants who used lotion only, suggesting increased health of the plantar epidermis, and 0% incidence in those participants applying topical herbal and vitamin derivative*. Additional study with increased numbers of participants is warranted.

Keywords: Verruca plantaris, Human papillomavirus, Plantar wart.

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INTRODUCTION

Verrucae plantaris (VP), commonly known as plantar warts, is the result of environmental exposure to human papillomavirus (HPV) resulting in lesions on the plantar aspect of the foot [1-5] with an annual incidence of 14% [6] in the United States. Patients complain of esthetic embarrassment and pain or pressure sensation with activities increasing pressure on the foot [7-9] and fear of transmitting the infection [8].

VP is spread through desquamated epithelial cells to new hosts most commonly through the disruption of plantar epithelium [10]. Current treatment paradigms focus on the treatment of lesions once acquired, as opposed to primary prophylaxis, with variable success as deep penetration into the dermis makes lesions resistant to treatment and high recurrence rates [9,11]. Most treatment focuses on the destruction of the lesion rather than HPV itself [12]. To date, preventative measures focus on behavioral modification limiting primary exposure to HPV, such as avoiding bare feet in areas of high contamination. We hypothesize that a topical combination of herbal supplement with anti-viral properties and vitamin derivative* can be used prophylactically to decrease primary incidence in high-risk populations.

Etiology

VP is caused by HPV, a group of non-enveloped DNA viruses. Twelve HPV types have been identified in VP lesions; HPV-1, -2, -3, -4, -27, -29, -57, -60, -63, -65, -66, and -69 [2,4,8,9]; however, most are attributed to HPV-1 with -2, -27, and -57 also having higher incidence [11]. Host infection occurs through direct contact with a wart shedding viral particles or indirectly through fomites found on floor surfaces or in footwear [4-9] which can survive for years outside the host [5]. Disrupted plantar epithelium provides a nidus for implantation of HPV [4,7] into the basal epithelial layer [13]. Viral DNA is then established within the host cell after an incubation period of 1–20 months [4]. The infected cells may then be cleared, become latent, or manifested as VP [6]. With manifestation, basal keratinocytes replicate resulting in hyper keratinized papules which release infectious viral particles from desquamated cells to infect other sites or hosts [10]. Due to pressure on the lesion, deeper penetration occurs, contributing to their resistance to therapy [1,7,8]. Spontaneous regression occurs in 65–78% in children within 2 years [6,11]; however, the rate significantly decreases [12] after the age of 12.

Epidemiology

It is estimated that 40% of the US population is infected with HPV [4], with an annual incidence of VP of 14% in the general population [6]. Increase risk factors include increased exposure to HPV, epidermal barrier disruption, and inappropriate immune responses. Two percent of the adult population and 6% of the pediatric population seek care for a plantar wart annually [11]. VP is rare in patients under 5 years of age [5,8], occurring most frequently in children with a peak incidence between 12 and 16 years of age [4]. Lesions in adults are more resistant to treatment [14]. Children of higher educational and income, two-parent households, who have family members or close contacts with VP, or have preexistent VP are at increased risk [4,5,7,8]. Other at-risk groups include communal shower users, athletes, dancers, those who are immunocompromised [6].

Treatment

Treatment options for VP include observation for self-resolution in immunocompetent patients, salicylic acid applied topically [9], and

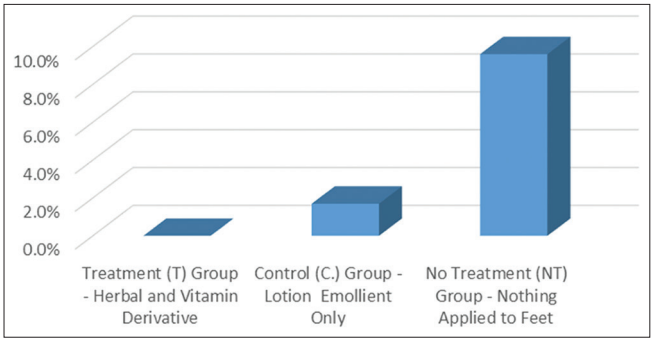

Fig. 1: Incidence of Verruca Plantaris per treatment group

cryotherapy with liquid nitrogen which has been shown to be less effective than salicylic acid [11] and may be associated with mobility-limiting pain [15] and is not recommended for small children. Both may require weeks to months of daily applications and paring of the hyperkeratotic tissues [3,4,8]. With poor treatment outcomes and high rates of recurrence, primary prevention of VP by use of topical anti-viral prophylaxis in high-risk populations coupled with diminishing risk factors and maintenance of the integrity of the epidermal barrier would represent a shift in treatment paradigm moving from the current standard of treating after the occurrence which is often costly and ineffective

METHODS

We initiated a double-blinded clinical research study consisting of two arms: Control (lotion emollient only) and treatment (herbal and vitamin derivative). The study Group I (SGI) consisted primarily of university age (18–24 years) participants with an attempt to recruit participants with high-risk activities such as participation in sports and communal recreational facility use. Participants underwent an examination of the feet at baseline (0 months) to document the presence of active lesions. Of the 161 participants, 5 had active VP with 5 participants being excluded due to primary VP at enrollment resulting in SGI (n=156). Participants were randomized into one of the two study arms; Green Bottle and Blue Bottle. One bottle contained topical lotion with emollient only control (C) (n=82) and the other a lotion with an herbal and vitamin derivative combination treatment (T) (n=74). Participants applied the lotions topically to the feet on a once-daily through metered-dose pumping. Participants were then examined at 3, 6, 9, and 12 months to document the incidence of VP occurrence.

RESULTS

At the conclusion of the 12-month study, no incidence of VP occurred in either the control or treatment groups. Although this study group is relatively small (n=156), 80 (49.7%) participants self-identified with high-risk activities such as locker room use without shoes, swimming, karate, and yoga. With an estimated 14% annual incidence, some incidence of new lesions would be expected [6]. No incidence of new-onset VP in either treatment group suggests that lotion alone may decrease the incidence of VP, likely due to increased integrity of the epidermis. This identified the lack of a study arm with no lotion for comparison. A second study group enrolled 131 participants, of which five were again excluded due to VP at enrollment resulting in study group 2 (SG2) with (n=126). This double-blinded study randomized participants into three study arms: No treatment (NT) (n=52), control (C) (n=38) – lotion emollient only, and treatment (T) (n=36) – herbal and vitamin derivative. NT participants do not apply anything to their feet. At study conclusion, there was no incidence of VP in the T group (0/36=0%), two in the C group (2/38=5.3%), and five in the NT group (5/52=9.6%).

Combined data from SG1 and SG2 (n=282) demonstrate no incidence of VP in the T group, herbal and vitamin derivative (0/110=0% incidence), two VP lesions in the C group, emollient only (2/120=1.7% incidence) group, and five VP lesions in the NT group, NT (5/52 = 9.6% incidence) Fig. 1.

CONCLUSION

Treatments for Verruca Plantaris have high degrees of variability in success requiring lengthy duration of treatment, risk of continued transmission during treatment, and high rate of recurrence. Current treatment relies on treating lesions after they occur. Although the study number is relatively low (n=282), early indications show decreasing incidence of VP from 9.6% in participants with NT to 1.7% in participants who used lotion only, suggesting increased health of the plantar epidermis, and 0% incidence in those participants applying topical herbal and vitamin derivative*.

*The herbal and vitamin derivatives used in this study constitute proprietary information.

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