Research Article

THE COST EFFECTIVE CURE WITHOUT SCAR: THREE CASES OF WARTS SUCCESSFULLY TREATED WITH KAALAANI KALIMPU (A TRADITIONAL SIDDHA DRUG)Amuthan A¹, DhasSelvin Innocent², Bhandarkar Anoosha Panduranga*³, Devi Vasudha⁴¹Lecturer, Department of Pharmacology, Melaka Manipal Medical College, Manipal University, Manipal, Karnataka, India²Chief Consultant, Selvin clinic, Muthalakurichy, Thuckalay post, Kanyakumari district, Tamilnadu, India³Assistant Professor, Department of Pharmacology, Melaka Manipal Medical College, Manipal University, Manipal, Karnataka, India⁴Professor, Department of Pharmacology, Melaka Manipal Medical College, Manipal University, Manipal, Karnataka, India

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DOI: 10.7897/2230-8407.06564**ABSTRACT**

Cutaneous (nongenital) warts are benign epithelial proliferations caused by infection with human papillomavirus (HPV) -1,-2,-3, and - 4. Salicylic acid and cryotherapy are the most popular treatments. At the same time they may cause pain, scarring, and have high failure as well as recrudescence rates. As per the traditional Indian medical (Ayurveda and Siddha) literature, warts are effectively treated with numerous herbal and herbo-mineral formulations which follow chemical cauterization principle. Hereby, we report three cases of warts treated effectively using Kaalaanikalimpu, a Siddha medicinal product. All three of them were healthy, physically-active middle aged adults with history of cutaneous warts on the hand. The warts had recurred after either being treated with salicylic acid or some home remedy taken as self-medication. A total of 3 - 5 daily topical application of Kaalaanikalimpu led to complete removal of all the warts. To hasten the process of wound healing without scarring and prevent superinfection at the treated site as well, Kaya thirumeniennai, a herbal oil was used simultaneously. The appearance of normal skin took about 10 - 20 days. Kaalaanikalimpu should be further investigated in controlled studies to determine their effectiveness in treating common warts.

Keywords: Human papilloma virus, warts, Siddha, Kaalaanikalimpu, Kaya thirumeniennai**INTRODUCTION**

Attention of health research all over the world is focused towards the alternative systems of medicine in the recent past. The reason being, none of the currently practiced medical systems is complete enough to cure all the ailments encountered till date. WHO currently recommends, encourages and promotes traditional as well as natural remedies in national healthcare programs as they are easily available at low cost, comparatively safe and culturally acceptable. Ayurveda and Siddha, the ancient Indian medicinal sciences are considered to be the oldest medical systems known to mankind dating back to ten thousand years.^{1,2} Ayurveda became famous in North India, while Siddha system gained popularity in South India. The ancient yogis who involved in Siddha medical practice were called as Siddhars. Siddha traditional medicine has been in use since time immemorial for treating various disorders of skin (psoriasis, leukoderma), genito-urinary system (pyuria and ureteric coli), reproductive system (menstrual disorders, male and female infertility), musculoskeletal system (rheumatoid arthritis, osteoarthritis, post-stroke paresis), cardiovascular disorders (hyperlipidemia, hypertension), endocrine system (diabetes, hyper/hypothyroidism) etc. Traditionally, knowledge about the medicines was inherited by the disciples from their Vaidyars (medical teachers) and probably very less got documented in writing. Unfortunately, over generations this knowledge and the previously documented literature got gradually dissipated and meagre.

KaalaaniKalimpu (KK) is a popular Siddha medicine used for treating warts and corn. It is available in cream formulation as an

over-the-counter medication in majority of the medical stores in the state of Tamil Nadu. Since decades it is quite popular in the region as an effective topical medicine for warts and corn.

Warts, also known as verrucae, are common, benign epidermal proliferations of the skin and the adjacent mucous membrane, associated with Human Papilloma Virus (HPV) infection. The incidence of warts is around 10% in the general population and is found to be higher in children and young adults. The transmission occurs through direct contact including autoinoculation and indirectly through fomites. The warts may disappear after a few months and recur, sometimes may even last for years.³

HPVs are non-enveloped double-stranded, circular, epitheliotropic DNA viruses of which more than 100 different genotypes have been identified. Certain HPV types tend to occur at particular anatomic sites. However, warts of any HPV type may occur at any site. Often associated with distinct regional predilection, histopathology, and biology, HPV types are divided into three categories: cutaneous (nongenital) types such as HPV-1,-2,-3, and -4; genital-mucosal types such as HPV-6,-11,-16, and -18; and those usually isolated from epidermodysplasia verruciformis such as HPV-5 and -8. HPV-16 and -18 are known to cause benign warts that may undergo neoplastic transformation and are associated with vaginal, anal, and cervical intraepithelial dysplasia, and squamous cell carcinoma.^{4,5}

There are as many as 10 varieties of warts, which differ in their shape and site, as well as the type of human papillomavirus involved. These include common wart (verruca vulgaris), flat wart (verruca plana), filiform or digitate wart, plantar wart (verruca,

verruca pedis), periungual wart, mosaic wart, anogenital wart (venereal wart, condyloma acuminatum, verruca acuminata), burrowing wart (myrmecia), oral wart and respiratory papillomas.⁶ Common warts represent the most frequent clinical lesions produced by the HPV. The clinical manifestation are rough, scaly, spiny papules or nodules with their size ranging from smaller than 1 mm to larger than 1 cm that can be found on any skin surface, most commonly on hands and feet.⁴ HPV does not produce acute sign or symptoms but induces a slow, focal expansion of epithelial cells. Lesion may remain subclinical for long periods or may grow to large fulminating masses that persists for month or even years.^{7,8} These warts should be differentiated from callus, irritated achrochordon, arsenic keratosis, molluscum contagiosum, acrokeratitis verruciformis, epidermodysplasia verruciformis, and syphilitic condylomata. Many times, squamous cell carcinoma and amelanotic melanoma may be confused with common warts. The diagnosis of warts usually confirms by visual examination.^{6,9} Warts are identified by a change in the regular papillary skin lines with independent vascular sources. Dilated capillaries in the wart bleed subsequent to shaving the hyperkeratotic surface. These capillaries help to differentiate warts from corns or calluses.⁹

There are many different treatments and procedures associated with wart removal. The choice of therapy is based on the number, size, site, and morphology of lesions, as well as patient preferences, cost, convenience, adverse effects, and clinician experience. The treatment modalities include chemical cautery with keratolytics viz., topical salicylic acid, silver nitrate, dinitrochlorobenzene and trichloroacetic acid, cryotherapy, thermal cautery (ultrasound hyperthermia, radiofrequency ablation, infrared coagulation etc.), antimitotic drugs like intralesional bleomycin, topical podophyllin and retinoids (systemic acetrein/tretinoin), virucidal drugs (formaldehyde, formic acid, glutaraldehyde and antiviral drugs like cidofovir), immune therapy (topical imiquimod, topical 5FU, oral zinc sulphate, intralesional interferons etc.), electrodesiccation, duct tape occlusion therapy, laser therapy, surgical excision using scissors and many more. These often are costly, cause local pain and require long time to show their beneficial effects. The matter of concern with the aforementioned treatment modalities is high rate of wart recurrence, hypo- / hyperpigmentation and scar formation.⁹⁻¹¹

KK is being effectively used for wart and corn removal from about 60 years by MSS Asan (a popular Siddha Vaidyar) group of companies at Kanyakumari, India. Each 1 gm of KK cream contains limestone 167 mg, arsenic trisulphuratum 167 mg, bee wax 167 mg, copper sulphate 167 mg, mercuric perchloride 167 mg and lead sulphidum 165 mg (Figure 1a). It is being manufactured by Zigma herbal remedies, Nagercoil, Tamil Nadu, India (GMP & ISO 9001:2008 certified company) since 2005. About 25,000- 50,000 containers are being marketed every year since then. It gets distributed to the surrounding states like Kerala, Karnataka, Maharashtra Andhra Pradesh and also Delhi. Despite the claim that KK has been successful in treatment of warts and corn in such a wide population, there is no ongoing attempt for its scientific validation.

Figure 1: The photograph of kaalaanikalimbu pack mentioning its ingredients

Despite our extensive search on major search engines, we found not even a single documented report of warts being treated with KK. We report three interesting cases (2 cases of verruca vulgaris and 1 case of verruca plana) which responded excellently to few daily applications of KK cream.

CASE 1

A 30 year old male presented to us in the month of December 2013 with a prominent, hyperkeratotic, round, firm, non-tender growth located on the ventral surface of right thumb, which consisted of 2 nodules each of 2-3 mm in diameter, which looked gray-black in color with a roughened surface and clearly demarcated from surrounding normal tissue (Figure 2a). The morphological features were characteristic of common wart (verruca vulgaris). There was a one year old history associated with the lesion and was being unsuccessfully treated with topical preparation of salicylic acid six months ago. He was otherwise healthy and was not taking any other medications. There was no history related to immunodeficiency in the past.

We decided to treat him with topical Kaalaani Kalimpuc cream (KKC) on OPD basis. The patient was first instructed to clean the warts area with hot water and allow it to dry. Under our supervision, on the first day the KKC was applied topically on the affected area alone with the applicator attached to the lid-stick of the medication container. The medication was kept intact for a contact period of one hour following which the cream was washed off. This treatment procedure was followed for next five days under our direct supervision with an interval of 24 hours maintained between two subsequent applications. On day 2, the earlier dome-shaped papules had significantly reduced in their dimensions. This may be due to epidermal erosion which had left a concavity at the treated site, exposing the thrombosed capillaries in the floor which appeared blackish in color, and an annular ring surrounding the concavity (Figure 2b). On his day 3 visit, the lesion looked similar to day 2, but the patient had experienced tolerable pain on the treated area after day 2 treatment along with little oozing of blood, for which he was prescribed Kaya Thirumeni Ennai (KTE - a Siddha wound healing oil) to be applied during the day time not letting the treated site to dry. On day 4, the remnant tissue of the warts appeared as black scab. On day 6, the lesions were completely uprooted leaving behind the normally appearing tissue (Figure 2c). The tolerable pain was observed on day 3-5 may be due to the erosion of the surrounding healthy tissue. The KTE was topically applied on the site from day 3 onwards until it normalized. On day 20, the site looked healthy and normal with no scar formation (Figure 2d). Patient neither had treatment complication nor recurrence during the next twelve months of monthly observation period.

CASE 2

A 34 year old male presented with one year history of wart located at base of the nail on the dorsal surface of right thumb in January 2014. It was a single well-demarcated gray-brown lesion with a roughened surface, of approximately 4 mm in diameter (Figure 3a). There was no tenderness on palpation. This was his first medical consultation for warts. He was otherwise healthy with no history of illness in the recent past, and was not on any medications.

We came to a conclusion that it was flat warts (*verruca plana*) and we decided to treat him with topical KKC on OPD basis under direct supervision. The instructions prior to application were exactly the same as mentioned above (for case 1). Topical application of KKC as a thin layer over the affected area was started on that evening (i.e. day 1) and similarly for next two days with a time-gap of 24hrs between two subsequent applications. On day 2, the major portion of the wart tissue got rooted out, leaving behind a well-shaped concavity and blackish floor (Figure 3b). Following this visit

he was asked to apply KTE at that eroded site so as to avoid the local pain that is usually felt following the treatment with KKC. When observed on day 4, the blackish scab which was present on day 3 had completely uprooted and healthy tissue started growing (Figure 3c). On day 10, there was complete clearance of the lesion with no scarring (Figure 3d). The patient was followed up monthly for next twelve months and there was no complications or recurrence of warts observed during that time period.

CASE 3

A 28 year old female presented in February 2014, with one year history of multiple warts on the ventral surface of right index finger. They had recurred after about 1 month of self-medication with some home remedies. There was no significant medical or drug history. They were 3 in number, greyish white, non-tender papules, each approximately 2-3 mm in diameter (Figure 4a).

Figure 2a: Two common warts located on the ventral surface of right thumb, **Figure 2b:** After single application of kaalaanikalimbu, exposing the thrombosed capillaries in the floor which appeared blackish in color with concavity due to erosion. **Figure 2c:** Five applications of kaalaanikalimbu make lesions completely uprooted leaving behind the normally appearing tissue. **Figure 2d:** On day 20, the warts sites looked healthy and normal with no scar formation due to daily application of topical kaya thirumeniennai

Figure 3a: A single wart located at base of the nail on the dorsal surface of right thumb, **Figure 3b:** After single application of kaalaanikalimbu, exposing the blackish floor with well-shaped concavity. **Figure 3c:** Three applications of kaalaanikalimbu make wart completely uprooted leaving behind the healthy tissue started growing. **Figure 3d:** On day 10, the wart site looked healthy and normal with no scar formation due to daily application of topical kaya thirumeniennai

Figure 4a: Three warts on the ventral surface of right index finger. **Figure 4b:** Two applications application of kaalaanikalimbu, exposing the remnant blackish warts tissue after eroding major warts, **Figure 4c:** Five applications of kaalaanikalimbu make lesions completely uprooted leaving behind the normally appearing tissue. **Figure 4d:** On day 18, the warts sites looked healthy and normal with no scar formation due to daily application of topical kaya thirumeniennai

The morphological features suggested that one among the three was a common wart (*verruca vulgaris*) and remaining two were flat warts (*verruca plana*). The patient was decided to be treated with KKC on OPD basis under our direct supervision. The instructions prior to therapy initiation and steps of topical application of KKC were followed as mentioned in Case-1. Starting from day 1, the medicament was applied every evening maintaining a 24-hr interval between two successive applications. On day-2 and day-3 visits, part of the wart tissue had got eroded (Figure 4b). With three daily applications of KKC (i.e. during day 4 visit) she complained of a sharp localized burning sensation for which she was prescribed KTE and the treatment was withheld from day 4 till she was comfortable to resume the treatment. After three days of treatment-free period, the patient visited us seeking continuation of the treatment. Two more KK applications were done on day 7 and day 8 visits. In this case, complete removal of all 3 warts was possible with a total of 5 daily applications of KKC (Figure 4c). KTE application was asked to be continued till the pain subsided and affected site normalized. On day 18, the affected site appeared completed normal without leaving behind any scars (Figure 4d). In her monthly follow up visits, she did not report any kind of adverse effects post-treatment and no recurrence is observed till date.

DISCUSSION

As observed in the literature, an enormous variety of wart treatment approaches have been attempted. Choosing the best wart treatment from this armamentarium can be difficult. Invasive methods are often painful and require long recovery periods. It is important that primary care physicians are familiar with common cutaneous conditions and their differential diagnosis to ensure that appropriate therapy is selected.

KK removed warts by chemical cauterization principle. Limestone present in KK makes it caustic and erosive in nature. The duration of therapy is dependent on thickness of the tissue involved. Warts were removed completely in 3-5 daily applications of KKC. It took 10 days in case 2 (dorsal surface of thumb) and about 18-20 days in case 1 & 3 (palmar surfaces of fingers) respectively, for their complete healing with normalization of the affected sites. The latter cases took a bit longer time for their complete resolution because involved tissue is thicker than in the former case. As recurrence was not observed in all three cases; it is possible that KKC destroyed entire colony of viruses owing to the presence of heavy metals (viz., arsenic, mercury and lead) and copper in it.¹²⁻¹⁴

The main adverse effect of the treatment was transient local pain during third and fourth days of treatment which was tolerable on application of KTE. KTE is said to play an important role in relieving the pain experienced due to the acidic nature of the medication, in promoting a faster wound healing, in preventing superinfection and post treatment scar formation.¹⁵ So overall, this traditional practice of using KKC along with KTE for management of warts can be considered as holistic.

It is observed that one container of KKC which currently costs INR (₹) 40 (1 USD = ₹63, on 15 March 2015) would be sufficient to uproot the wart-affected tissue in a patient with up to 4 warts. In comparison with other treatment options available, KKC will be a much more cost-effective one to the population, especially in the developing nations like India.

Limitations, precautions and future scope

The diagnosis was made solely based on clinical examination. Owing to the caustic nature of KK, site of the warts for its application should be carefully chosen; it is probably better to avoid its application on the warts which are located in the sensitive

areas (genital warts) and those which are in the close vicinity of eyes. Infective tissue exposed during treatment with KK may be contagious which needs to be confirmed by further research. There is a risk of secondary infection in the treatment-exposed tissue, hence appropriate precautions need to be taken by the patient as well as treating doctor. The course of complete healing may be longer in diabetics and immunosuppressed individuals. The safety and effectiveness of KK in larger warts (>4mm size) and in multiple warts (>4 located in close proximity to one another) is not studied so far, thus necessitating future studies to look into these aspects. The systemic absorption and other pharmacokinetic properties of this topical application which contains heavy metals (viz., arsenic, mercury and lead) and copper are not yet investigated. Hence, as of now, the use of this formulation among pediatric population and pregnant women is not recommended.

CONCLUSION

The contribution of ancient Indian traditional Siddha medicine to the field of therapeutics is priceless. Looking back at the age old experience of various Siddhars in treating warts with Kaalani Kalimpu, as well as observing the outcome in our patients, we appreciated its immense therapeutic value in the management of warts. The treatment is minimally invasive, well-tolerated, effective, economical, user-friendly, and of short duration with no recurrence observed during the follow-up for an year. In spite of enormous clinical benefits obtained, unfortunately there have been no scientific trials testing the efficacy of Kaalani Kalimpu in treatment of warts and corn. Hence randomized clinical trials are warranted to explore and establish its mechanism of action and optimize the dosage regimen for warts and corn treatment, so as to make this time-tested, richly benefitting, traditional medicine credible, more acceptable and evidence-based to scientific community as well as to the healthcare system.

Informed Consent

Obtained from the subjects for presentation / publication of these case report and the images

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