

Evidence-Based Review of Management of Nongenital Cutaneous Warts

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GOAL

To develop a personal algorithm for the treatment of cutaneous warts

OBJECTIVES

Upon completion of this activity, dermatologists and general practitioners should be able to:

1. Diagnose a cutaneous wart.
2. Understand the evidence and rationale for available wart therapies.
3. Determine the optimal therapy for each patient based on confounding variables.

CME Test on page 226.

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Ms. Kuykendall-Ivy reports no conflict of interest. Dr. Johnson co-owns a patent for candida/mumps/trichophyton immunotherapy. The authors report no discussion of off-label use. Dr. Fisher reports no conflict of interest.

Human papillomavirus (HPV)-induced tumors of the skin are often varied in clinical presentation, ranging from benign warts to malignant neoplasms. This article reviews the natural history and recommended treatment of some of the common HPV-induced tumors, as well as reviews

many of the clinical trials for future wart therapies. This review is not meant to serve as a guideline or to be all-inclusive. Almost invariably, HPV-associated diseases are difficult to treat. The treatment options employed by health-care professionals are usually dependent on their prior experience or exposure during residency. Many wart treatments are based on anecdotal evidence rather than on carefully conducted clinical trials. A systematic review of the literature was performed using the 1966–April 2002 MEDLINE database, the 1967–2000 PubMed database (National Library of Medicine), and the Cochrane Database of

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Figure 1. Dorsum of left hand with numerous verrucous papules consistent clinically with verruca vulgaris/common warts.



Figure 2. Dorsum of fingers of left hand with verrucous papules on digits and periungual involvement. Human papillomavirus around the nail may be difficult to eradicate.

Systematic Reviews. Randomized clinical trials, controlled clinical trials, and multicenter studies were reviewed. Articles were included in the evaluation if they were printed in English, reported on human subjects, and analyzed subjects who had cutaneous nongenital warts.

Diagnosis

Symptomatic disease caused by human papillomavirus (HPV) includes common warts (verrucae vulgaris), plantar warts (verrucae plantaris), flat warts (verrucae plana), and condyloma acuminatum (venereal warts)(Figures 1 through 4). The diagnosis

of an HPV infection is usually made clinically, although the diagnosis can be confirmed with a biopsy (Figure 5), polymerase chain reaction, in situ hybridization, Southern blot analysis, blot hybridization, or hybrid capture.¹ Some conditions that impersonate HPV include seborrheic keratoses, callosities, corns, lichen planus, epidermal nevi, molluscum contagiosum, and squamous cell carcinoma.

Epidemiology

There is a lack of accurate epidemiological data on HPV infections, partly because it is not mandatory to report HPV infections to the US Centers for



Figure 3. Sole of left foot with warts grouped around the fourth toe.



Figure 4. Sole of right foot with large plantar wart on great toe. Smaller warts are also noted.

Disease Control and Prevention.² We do know, however, that verrucae have reached epidemic or even pandemic proportions. In 1990, there was an estimated 79% lifetime risk of acquiring HPV, with an annual incidence of 8%.¹ Peak incidence occurs at age 13 years for girls and 14.5 years for boys.³ Please refer to Table 1 for common clinical manifestations of HPV infections.^{1,4,5}

Natural History of Warts

One of the best studies of the natural history of warts was published in 1963. It suggests that only 40% of patients have warts that would disappear without treatment after 2 years.⁶ Therefore, it is

likely that over time warts will continue to enlarge, spread, and become more resistant to treatment. Research into treatment also must consider the possibility of spontaneous regression.

The ideal treatment would: (1) eliminate warts in all or a large percentage of patients, (2) be painless, (3) require treatment of only one or part of one wart, (4) require from 1 to 3 treatments, (5) produce no scars, (6) provide lifelong HPV immunity to prevent recurrence or reinfection, and (7) be accessible to all patients.

The American Academy of Dermatology Committee on Guidelines of Care has established the following indications for the treatment of warts:

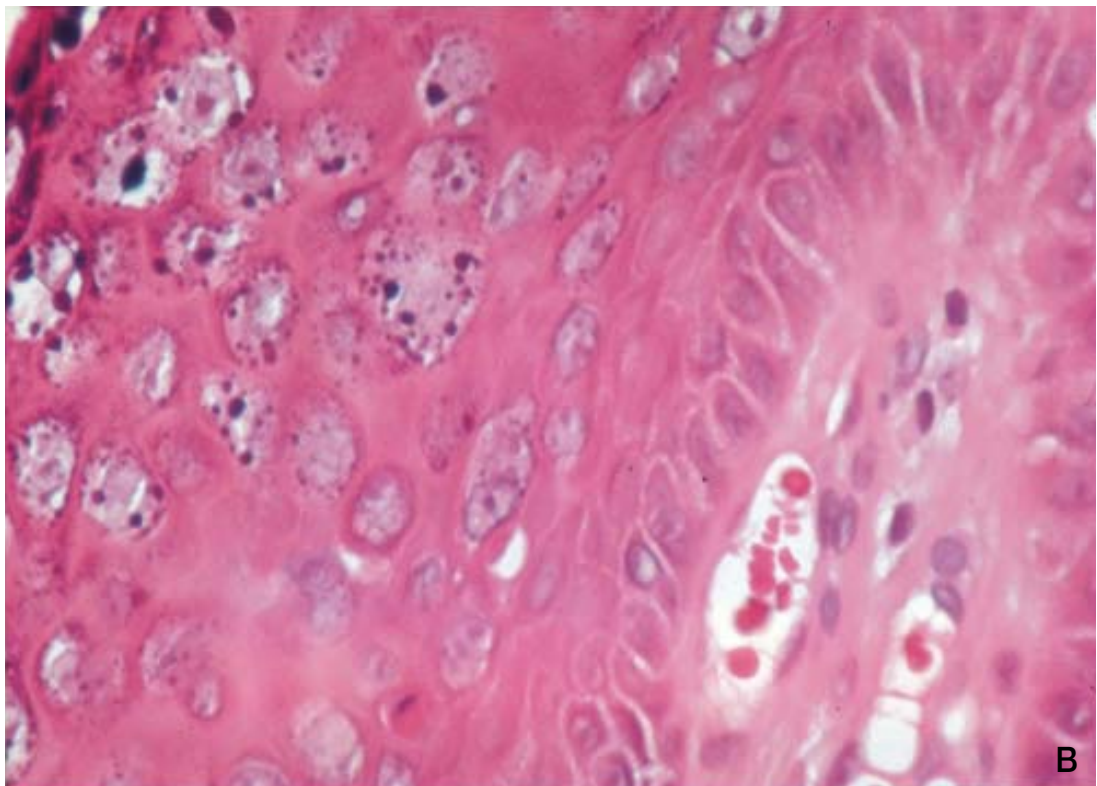
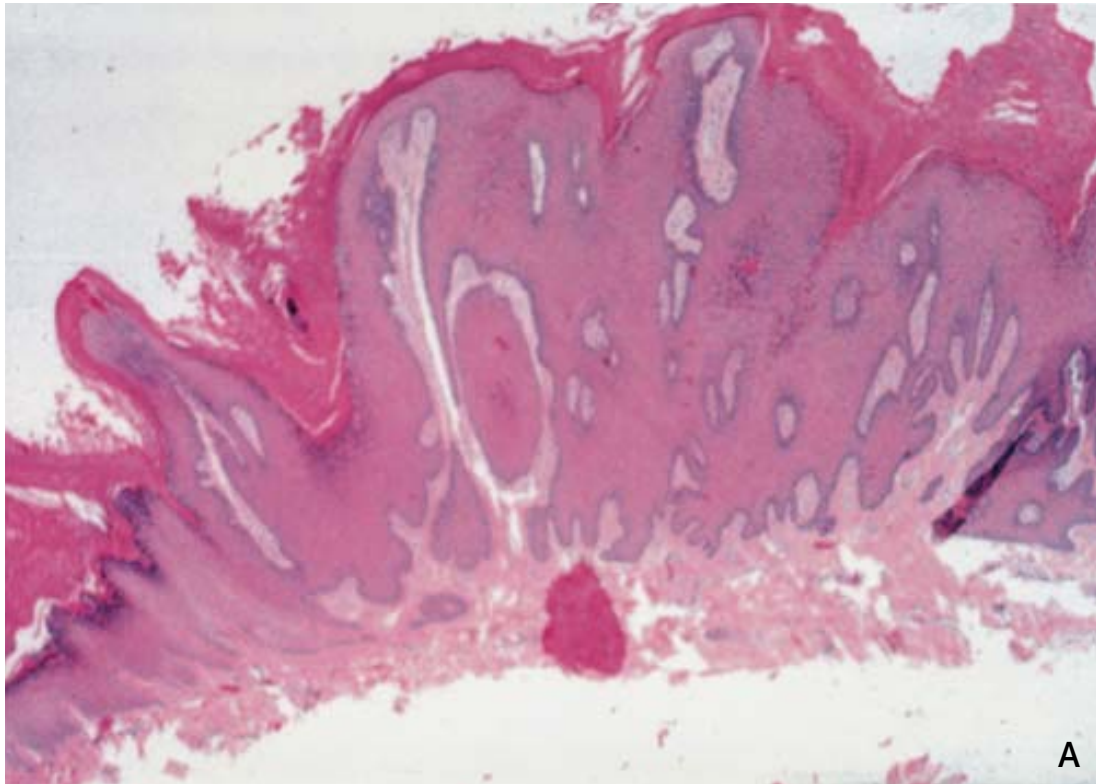


Figure 5. A shave excision of a verruca demonstrates a papillomatous-appearing lesion with overlying parakeratosis and hyperkeratosis (A). Clumped keratohyalin granules in the epidermis and dilated blood vessels within the papillary dermal tips (B)(H&E, original magnifications $\times 10$ and $\times 40$).

Table 1.

Common Clinical Manifestations of Human Papillomavirus Mucocutaneous Infections^{1,4,5}

Clinical Variant	Description	HPV Type(s)
Plantar wart	Rough keratotic surface	1, 2, 4, 5, 7, etc
Plantar mosaic wart	Large plaque of coalesced plantar warts	2
Plantar myrmecia	Deep endophytic plantar wart	1, 63
Common warts	Rough keratotic papules	1, 2, 4, 5, 7, 27, 57, etc
Periungual warts	Rough keratotic papules involving hyponychium and/or nail bed	1, 2, 4, 5, 7, 27, 57, etc
Flat warts	Slightly elevated, <5 mm papules	3, 10, 28, 49
Intermediate warts	Combination of common and flat warts	2, 3, 10, 28, 29
Condyloma acuminatum	Cauliflowerlike papules in the anogenital region	6, 11, 44
Orogenital/anogenital warts	Polymorphous, thick, sessile, soft, or keratotic papules	6, 11
Bowenoid papulosis	Multiple small pigmented papules	16, 18, 33, 39
Buschke-Löwenstein tumors	Locally destructive large plaques, giant condyloma acuminatum	6, 11
Carcinoma and carcinoma in situ	Polymorphous lesions	16, 18, 31, 33, etc
Focal oral/epithelial hyperplasia	Multiple papules of the oral mucosa; more common in Native Americans	13, 32
Laryngeal papillomas	Cauliflowerlike plaques of the oropharyngeal structures	6, 11
Epidermodysplasia verruciformis	Polymorphous lesion	5, 8, 20, 47, etc

(1) the patient's desire for therapy, (2) symptoms of pain, bleeding, itching, or burning, (3) disabling or disfiguring lesions, (4) large numbers or large sizes of lesions, (5) the patient's desire to prevent the spread of warts to unblemished skin of self or others, and (6) immunocompromised condition.⁷

Current Therapies

Salicylic acid, available in a variety of formulations with or without additives such as lactic acid, is the first-line for at-home treatment of warts.^{5,8}

Cryotherapy with liquid nitrogen is often the first-line provider-applied therapy.⁹ Other treatments commonly employed include destructive, chemotherapeutic, virucidal, immunologic, and alternative modalities. Destructive treatments include topical acids, cantharidin, surgical excision, laser ablation, and electrosurgery. Chemotherapeutic and virucidal therapies include imiquimod, interferons, bleomycin, cidofovir, acyclovir, 5-fluorouracil, tretinoin, podophylin, podophyllotoxin, formaldehyde, and glutaraldehyde. Immunologic therapies include

Table 2.

Review of Current Human Papillomavirus Therapies

Treatment	Study Design	Patients, No.	Warts, No.	Results	Reference
Liquid nitrogen 2 at 1-, 2-, and 3-wk intervals	R, C	225		After 3 mo: 43% vs 37% vs 26% cure; after 12 treatments: 43% vs 48% vs 44% cure	21
Liquid nitrogen 2 vs salicylic acid and lactic acid vs both treatments	R, C	294		69% vs 67% vs 78% cure	25
Salicylic acid vs 10% glutaraldehyde vs 40% cellosolve vs 5% 5-fluorouracil in dimethylsulphoxide vs 5% idoxuridine in dimethylsulphoxide	R, C	1802		45% vs 47% vs 30% vs 53% vs 25% cure	25
Salicylic acid vs salicylic acid and lactic acid	R, C	138		77% vs 75% cure	25
Salicylic acid vs glutaraldehyde	R, C	81		44% vs 47% cure	25
Salicylic acid vs cellosolve 40%	R, C	93		40% vs 30% cure	25
Liquid nitrogen 2 at 3-wk vs 4-wk intervals	R, C	72		75% vs 40% cure	25
Salicylic acid vs control	C	53		69% vs 35% cure	27
Liquid nitrogen 2 and salicylic acid with paring vs without paring	R, C, PC	400		46% vs 50% cure for all warts; 75% vs 39% cure for plantar warts; no benefit to continue liquid nitrogen 2 after 3 mo	28
Levamisole vs placebo	C, DB, PC	99		No difference	29
Cimetidine vs placebo	R, C, DB, PC	40		No difference	30
Cimetidine vs placebo	R, C, DB, PC	54		32% vs 30% cure	31
Cimetidine vs cimetidine and levamisole	R, C, DB	48		45% vs 85% cure in evaluable patients	32
Cimetidine vs cimetidine and levamisole	R, C, DB	39		32% vs 65% complete clearance	33
Bleomycin vs saline	C, DB, PC		151	81% vs 0% cure	34
Salicylic acid vs hypnosis vs placebo vs control	C, PC	15		0% vs 60% vs 10% vs 30% cure for at least one wart	35

Table 2. (continued)

Treatment	Study Design	Patients, No.	Warts, No.	Results	Reference
Liquid nitrogen 2 vs mumps skin test antigen vs <i>Candida</i> skin test antigen	R, C, PS	115		57% vs 71% vs 88% cure	36
Liquid nitrogen spray vs cotton wool bud	C, PR	363		44% vs 47% cure at 3 mo	39
Liquid nitrogen 2: 1 freeze vs 2 freezes	R, C, O, PG	207		57% vs 62% cure of all people who completed protocol, 41% vs 65% cure of plantar warts, and no difference in hand warts	40
Liquid nitrogen 2 vs acyclovir vs placebo	C, PC	47		9% vs 39% vs 28% cure	41
Liquid nitrogen 2 vs pulsed dye laser vs cantharidin	R, C, PR		194	No difference	42
5-aminolevulinic acid/photodynamic therapy vs placebo/photodynamic therapy	R, C, DB, PC, PG	45	232	100% vs 71% reduction of wart volume	43
Formic acid vs placebo	C, PC, O	100		92% vs 6% complete disappearance	44
Anthralin vs salicylic acid	R, C	72		56% vs 26% cure	45
Bleomycin vs saline	C	38		68% vs 3% cure	46
Proflavine in dimethylsulphoxide vs neutral red in dimethylsulphoxide	C, DB, PC, PCT	50		37% vs 43% cure	47
Silver nitrate vs black ink	R, C, PC	70		43% vs 11% cure	48
Levamisole vs placebo	C, DB, PC	40		60% vs 0.03% cure	49
Homeopathy vs placebo	R, C, DB, PC	120		30% vs 23% had 50% wart reduction	50, 51
Homeopathy vs placebo	R, C, DB, PC	162		20% vs 24% cure	52
Localized heat vs control	C		29	86% vs 41% cure	53
Distant healing vs control	R, C, DB	84		Treatment worse than control	54

*R indicates randomized; C, controlled; PC, placebo controlled; DB, double blind; PR, prospective; O, open; PG, parallel group; PS, pilot study; PCT, paired comparison treatment.

topical sensitizers, intralesional sensitizers, and cimetidine. Alternative therapies include radiation, acupuncture, ultrasound, hypnosis, localized heat therapy, folk therapies, and homeopathy.^{5,8,10}

To better evaluate the multitude of therapies available, a systematic review of the literature was performed using the 1966–April 2002 MEDLINE database, the 1967–2000 PubMed database (National Library of Medicine), and the Cochrane Database of Systematic Reviews. A MEDLINE search found 6170 articles pertaining to warts, of which 323 were clinical trials. A PubMed search found 195 articles. Only clinical trials published in English for the treatment of HPV tumors were included in the evaluation. Articles were included if they focused on nongenital cutaneous warts. Articles were excluded if they focused on genital warts or intravaginal or cervical HPV infections. Articles also were excluded if the rates of response were unclear, if the authors compared different formulations of the same product (lotion versus cream versus gel), or if the authors included products that are not available (2% imiquimod versus placebo). In addition, letters to the editor, treatments to prevent recurrence, anesthesia for various treatments, and the same treatment for various types of warts were excluded. Studies that compared the duration or the number of treatments with response were not included. Consult Bigby^{11,12} for recommended reading to help better analyze the results.

In an attempt to analyze the data for practical purposes, the treatment responses of commonly utilized treatments are discussed. Salicylic acid has response rates ranging from 40% to 84% with an average of 61%. There is good data that topical therapies with over-the-counter or prescription products containing salicylic acid have a therapeutic benefit.^{8,13-15} Reported cure rates for various cryotherapy treatment regimens range from 26% to 96%. The best results with cryotherapy occur when the patient is treated every 2 to 3 weeks. For plantar warts, it also is recommended to pare the wart first and use 2 freezes with a complete thaw between each. There is no reported therapeutic benefit to continuing cryotherapy past 2 or 3 months. The Cochrane Review agrees that there is no convincing evidence that cryotherapy is any more effective than topical salicylic acid.⁸ Also, cryotherapy is more expensive, requires a physician's office visit, is painful, and is potentially scarring. Control populations and patients treated with placebos had their warts cleared from 0% to 45% of the time, with an average of 17%.

Immunomodulators—Topical sensitizers are a popular third-line treatment for warts. The

Cochrane Review also found some evidence for the use of dinitrochlorobenzene, a topical sensitizer. It is somewhat more efficacious than placebo but is more expensive and more toxic than salicylic acid.⁸ Dinitrochlorobenzene has been found to be mutagenic in the Ames assay and is rarely used today. Levamisole is a general immunostimulant that is believed to restore delayed hypersensitivity when it is depressed. In a double-blind controlled clinical trial with 99 patients (49 patients had common warts and 50 patients had condyloma), the levamisole group failed to show wart regression compared with the control group.¹⁶

Cimetidine is a histamine H₂-receptor antagonist that is used to treat peptic ulcer disease and gastroesophageal reflux. Cimetidine has been suggested to enhance immunologic function because of its inhibitory effect on suppressor T-cell function, which possesses H₂ receptors. Two randomized, double-blind, placebo controlled clinical trials showed no difference between the placebo group and patients treated with cimetidine.^{17,18} However, two randomized, double-blind comparative trials evaluating a combination of cimetidine and levamisole versus cimetidine alone for recalcitrant warts in children showed a statistically significant improvement with the combination treatment.^{19,20}

Chemotherapeutic Therapy—Bleomycin is a chemotherapeutic agent that inhibits DNA synthesis in cells and viruses. Bleomycin has been useful when surgical removal of warts might pose problems, such as in periungual warts. Bleomycin is not used to treat multiple warts because several injections are necessary. Bleomycin has been evaluated in a double-blind placebo-controlled crossover study in recalcitrant warts that failed to respond to standard treatment. Response rates of 81% were noted. The side effects included mild pain. The most commonly used concentrations are 0.25 to 1.0 mg/mL. It is not recommended to administer a total dose of more than 10 mg.²¹ Bleomycin should not be used in children or pregnant women. It is contraindicated in patients with Raynaud disease and peripheral vascular disease.

Alternative Therapy—Hypnosis is an alternative therapeutic method that has its own variables, including the level of hypnosis, patient susceptibility, and motivation of the hypnotist. Hypnosis has been evaluated in a randomized placebo-controlled clinical trial. The hypnosis group showed a higher clearance of warts than individuals treated with salicylic acid or placebo.²²

Future Directions of Therapies—Some of the latest treatments available take advantage of stim-

ulating the immune system of the patient. These include contact immunotherapy with squaric acid and intralesional injection with skin test antigens.²³⁻²⁵ There is one literature report of a randomized clinical trial using skin test antigens, but to our knowledge, there are no reported trials using contactants. Therapy with mumps and *Candida* skin test antigens were reported to show a higher clearance of warts than treatment with liquid nitrogen.²³ The use of antivirals, such as cidofovir, is also being evaluated.²⁶

Therapies commonly employed for genital warts, including imiquimod and podofilox, may be utilized for nongenital warts. Imiquimod, which is approved by the Food and Drug Administration as a therapy for genital warts, to our knowledge has no clinical trials published to date.

Summary

Until a new therapy is proven to be both safe and effective, today's stepladder approach to the treatment of warts is the same as it was 25 years ago. First-line therapy is patient-applied salicylic acid. Second-line therapy is provider-applied liquid nitrogen. By the time most patients present to the dermatologist, they are ready for third-line therapies. Table 2 is a review of the results of current HPV therapies.^{9,13-23,27-42} The rationale for the best third-line therapy is lacking. There is not conclusive data to allow clinicians to make informed decisions about which therapy is best. Until there is more evidence, third-line therapies should be tailored to meet the needs of both the patient and physician. These therapies include, but are not limited to, topical and intralesional immunostimulators, chemotherapeutics, laser ablation, and surgical removal. Regardless of the treatment chosen, the education of the patient about viral etiology and treatment expectations is imperative.

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