Ultrasound and Plantar Warts: A Double Blind Study

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During the past ten years, ultrasound has become an increasingly popular method of treating plantar warts. Several authors[1-3] have reported similar results with this mode of treatment. These investigators, using essentially the same technique, recorded an 80 to 87 per cent cure. Their statistics compare favorably with the 85.3 per cent cure recorded by Barr and Coles.[4]

Cherup *et al*[1] mention the use of five patients as a control group. There was no improvement following a series of simulated treatments. The authors then concluded they had "eliminated the possibility of improvement by psychic effect." No mention is made of the method utilized to ensure control of the trial group. Kent,[2] in reporting on 1000 cases, "felt that controls could serve no useful purpose under the limitations imposed by this type of study." Other clinicians, including Rowe and Gray[3] and Benson,[5] make no mention of using controls to verify the effectiveness of ultrasound in the treatment of warts.

Prestudy

Certain questions were left unanswered by these studies; therefore, it was decided to investigate the problem in more depth. First, it was felt that we should become proficient in the treatment regimen. A prestudy was instituted to train personnel, perfect the technique, and evaluate the efficiency of the ultrasonic generators.

A method of irradiating warts with ultrasound, as advocated by Benson,[5] was adopted. The ultrasound technique used was 0.6 watts per square cm, given by direct contact, continuously for 15 minutes. Treatments were administered once a week. After a base line of an 83 per cent patient cure was established, attempts were made to influence this rate by varying the intensity of the sound and/or the duration or frequency of the treatment. No correlation between the three factors could be found which would materially alter the success factor.

The inability to change the cure rate led us to question the value of ultrasound as a curative agent for warts. Further questions were posed by the theories of spontaneous remission of warts[4] and the psychotherapeutic[6] effects of wart treatment.

Present Study

A double blind study was organized to determine the effectiveness of ultrasound on fresh plantar warts. The study was conducted under the direction of the chief of the Orthopaedic Surgery Service.

The following criteria were established for admitting patients to the study:

1. Simple plantar warts, time of onset up to six months.
2. A negative history of medical or home cure treatment.
3. No evidence of spontaneous tissue death; i.e., excessive dryness or black spots.
4. Patients must have had no affiliation or parental association with the hospital.

The Chiefs of the Orthopedic and Dermatology Services were responsible for accurate diagnosis of the lesions, as well as determining final results. Each patient was interviewed prior to treatment by the Chief of Physical Therapy. Data were recorded concerning the patient's age, and the age, size, and location of the wart. The etiology of warts was explained to the patient and/or his parents, and an explanation of the treatment program was given. All patients were told that our experience indicated that the wart would probably be resolved in six to eight weeks, and that they had an 85 per cent chance of the treatment being effective.

The patient's record was then given to a specifically designated physical therapy officer or her assistant, who assigned a control number to the patient's record. This control number, taken from a sheet of random numbers, was used to classify the patient as to placebo or control group.

The treatment consisted of having the patient soak the foot for ten minutes in tepid water, followed by swabbing the area with hydrogen peroxide, and then shaving the callus from the wart. Ultrasound was then administered. Patients with multiple warts had each lesion treated. All treatments were given weekly by the same therapy technician, using a Medcosonolator® ultrasound generator. Ultrasound was applied through the contact method, using Aquasonic® transmission gel as the coupling agent. Dosage for the sound treatment was 0.8 watts per square cm, administered for a 12 minute period.

Following preparation of the patient for ultrasound by the therapy technician, the control therapist or control technician was called to turn on the ultrasound machine, whose control surface was screened from the patient's and therapy technician's view. The power and automatic timer were set the same for each patient. For the patients receiving placebo treatments, power to the machine was not engaged.

When the therapy technician administering the treatment noted a clearing of the wart, the area was examined by the Chief of Physical Therapy, using a magnifying glass. Criteria established for a cure called for epithelial lines to be intact, with no evidence of foreign tissue present. All questionable cases were reviewed by the Chief of the Orthopaedic or Dermatology Service. A follow-up examination was conducted on all available patients three months after the conclusion of the study.

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TABLE I

RESULTS OF TREATMENT IN STUDY PATIENTS

	Number Patients	Number Warts	Ave. Age	Age Range	Cure Rate By Patient	Ave. Rx Weeks	Ave. Elapsed Wks. to Wart Removel	Range Rx Wks.
Placebo	15	18	11 yrs	8-18 yrs	86.6%	9.7	11.0	3 to 18 Weeks
Control	17	21	11.7 yrs	3-33 yrs	82.3%	7.6	8.3	2 to 17 Weeks

The patient's treatment was summarized by the Chief of Physical Therapy. The information was then given to the control therapist, who recorded the data. Only the control physical therapist or her assistant, the control technician, knew the actual designation of the patient's grouping, from the start to the end of treatment and the entire study.

Results

Thirty-two patients were included in the study conducted from November 1970 through August 1971. Thirteen of 15 patients (86.6 per cent) who received placebo ultrasound treatments had their warts cured. Patients in the control (actual treatment) group attained a cure rate of 82.3 per cent, with three failures in 17 patients (Table I).

In the placebo group, three patients had two warts; the rest had single lesions. One patient in the control group had three warts, while two patients had two warts. One patient with two lesions in the control group was not cured; all other multiple lesions were resolved.

Two patients in the study were over age 20. Both were in the control group. One, a female, 26 years of age did not have her wart cured. The other, a 33 year old male, had 17 treatments, prior to discharge with the wart removed.

The difference in the average treatment weeks and average weeks to wart removal may be somewhat misleading. This factor accounts for the patients who missed their regular scheduled treatment, thus receiving less treatments than total administrative weeks until the wart was resolved.

Both study groups averaged more treatment weeks and elapsed weeks until final removal of the wart than did the prestudy group. This may have been due to a hesitancy on the part of the examiner to declare the area free of foreign tissue on the study patients. There was also a significant difference within the study groups in the treatment and total elapsed weeks. The difference found within the study was greater than that of the controlled and prestudy groups.

Results of the follow-up investigation revealed the former wart site to be free of foreign tissue on all patients who had obtained a cure. Six patients from each group were reexamined. The period from the last treatment until the examination ranged from 4.5 to 10 months for both groups. One patient in the control group was discharged as a failure; however, his wart had disappeared when he was examined five months later.

TABLE II

COMPARATIVE EFFECTS ON WARTS IN PRESTUDY AND STUDY GROUPS

Group	No. Warts	No. Failures	Cure Rate	Ave. Wks. Wart Rxed
Prestudy	131	13	90%	6.4
Placebo	18	2	88%	9.2
Control	21	4	81%	7.2

Discussion

Plantar warts are a malady of the young. Rasmussen[7] stated that 75 per cent of those with plantar warts were under 20 years of age. Barr and Coles,[4] in their survey of 1,890 patients, found 63.7 per cent to be 10 to 14 years of age, and 90 per cent to be 5 to 20 years. In addition, they noted a 20 per cent spontaneous resolution of plantar warts, especially during the first 12 months duration.

Young patients are more susceptible to psychological influence on warts, as witnessed by the number of bizarre remedies they try. Montgomery[6] writes, "All psychotherapeutic methods are more effective with the young." Anderson and Shirreff[8] treated 192 cases of plantar warts with formalin soaks, or plain water, or inert tablets by mouth. They reported over a 60 per cent cure with each group, but they noted that the rate of response diminished with age.

In our pre-study group, a 90 per cent cure was recorded for 131 plantar warts of one to six months duration. During the study phase, an 88 per cent cure was attained in the placebo group, while 81 per cent of the warts were cured in the control group (Table II). These results are compatible with the 80 to 87 per cent cure recorded by others,[1-3] but they do not equal the 93.3 per cent cure in the 14 cases recorded Cherup *et al.*[1]

There appears no plausible explanation for the longer time required to remove the warts by placebo treatments. However, Kent,[2] reporting on over 500 patients, had an average treatment time of 12.6 weeks, which is 1.6 weeks longer than we noted for the placebo group.

The cure response noted in this study for the placebo ultrasound treatments may well be due to the psychotherapeutic response mentioned by Montgomery.[6] There is also the possibility that soaking the foot, swabbing the area with hydrogen peroxide, along with shaving the wart, may have influenced the final results. In either case, evidence indicates that ultrasound certainly appears to lack therapeutic value in the treatment of plantar warts from onset to six months duration.

Summary

A double blind study was made to evaluate the effectiveness of ultrasound in the treatment of plantar warts up to

six months of age. Of the 32 patients in the study, 15 were given placebo ultrasound treatments with 86.6 per cent cure. Seventeen patients in the control group received regular ultrasound therapy with 82.3 per cent effectiveness. Patients averaged 11 to 12 years of age in both groups. Our interpretation of the study is that ultrasound is of no benefit in the treatment of plantar warts from onset to six months.

References

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