SHORT COMMUNICATION

A Preventive Approach to Impetigo of Treaty Indians Using Staphylococcus Polyvalent Somatic Antigen Vaccine

H. DILLENBERG, M.D.* and M. P. D. WALDRON, M.D.,†
Regina, Sask.

ABSTRACT

In a controlled study, Greenberg's staphylococcal polyvalent somatic antigen vaccine was administered to 190 Indian volunteers of a reserve in Saskatchewan in an attempt to reduce the incidence of impetigo. An intradermal skin test dose of 0.1 ml. was given initially. Reactors were forthwith placed in a separate category, otherwise this test injection was followed by intramuscular injection of 0.25 ml. of the vaccine, repeated a second time after six weeks. One hundred and sixty-nine controls received "placebo vaccine". Four months later the number of cases of impetigo in the vaccinated group had been reduced from 55 to 16. There was no reduction in the control group. The preventive effect waned after five months. The results of this field trial are considered encouraging.

IMPETIGO is common among the Treaty Indians of Saskatchewan. The low standard of living in dirty, crowded and ill-ventilated homes; the shortage of clothes, bedding and common household utensils; in winter, the difficulty of bathing and washing of clothes; the resulting infestation with mites, lice, fleas and bugs; and a common lack of variety in nutrition and the apathy of the Indians in accepting and utilizing modern health education, all these are precipitating factors for impetigo as well as formidable obstacles in its prevention.

Where health education can be brought to bear, as in boarding schools, cleanliness and nutrition are of course adequate. Contact of the students, during holidays and over the week-end, with their home offsets this gain quickly.

The nurses of the Indian Health Services can do little. Use of antiseptics by Indians cannot be relied upon. Even drugs are rarely taken as they should be. Unless the standards of living and of health education on the Reservations can be raised in patient and relentless pursuit, the prevention of dirt-borne dermatitis via environmental decontamination seems hopeless.

However, there has been decided progress in the prevention of killer-diseases via immunization of the Indians. Smallpox, poliomyelitis, diphtheria, tetanus and pertussis have been effectively reduced, and the immunization campaigns of the Indian Health Services have met with increasing favourable response in Saskatchewan. A slow realization seems to have developed that the "White Man's" needles can be useful. Here, then, seemed to be a chance for the preventive approach to impetigo via immunization against *Staphylococcus aureus*.

Unquestionably, there has been a return to vaccines in the therapy of recurrent staphylococcal dermatitis. The Provincial Laboratories in Regina have issued, since 1957, a steady monthly supply of their home-made polyvalent staphylococcal vaccine with toxoid. More than 1800 patients have been treated with this preparation, and over 700 medical reports indicate its beneficial effect in approximately 90% of treated patients.[1] Used in families with staphylococcal chain-infections, this vaccine has proved a useful preventive agent. But it has to be administered in a series of nine injections with intervals of three to four days and is hardly suitable for mass immunizations.

The authors have followed with interest the development and trials of Greenberg's somatic antigen,[2] a carefully conceived and prepared vaccine, which can be given in two or three "double-barrelled" injections with four-week intervals. It would therefore lend itself to mass immunizations.

When the report on trials with this antigen sounded encouraging[3, 4] and when, in several small studies by one of the authors (H.D.), its paucity of side effects and its efficacy seemed evident, plans were made to use it in a field trial among the impetigo-ridden residents of the large Beardy's Reservation near Duck Lake in Saskatchewan. Dr. T. J. Orford, Regional Superintendent of the Indian Health Services in Saskatchewan, very kindly permitted use of the vaccination on the basis of voluntary participation of the Indians and the full agreement by the Chief and his Councillors on the Reservation. Dr. Greenberg supplied the vaccine and a placebo for a controlled and blind study of a hoped-for number of 300 volunteers, 150 to be given the vaccine and 150 the placebo.

Presented in synopsis to the National Advisory Committee on Epidemiology, Ottawa, December 4, 1962.

*Provincial Epidemiologist, Department of Public Health, Regina, Sask.
†Zone-Superintendent, Indian and Northern Health Services, Prince Albert, Sask.

SETTING, MATERIALS AND METHOD

Beardy's Reserve, housing a band of approximately 500 Cree-Indians, lies five miles west of the town of Duck Lake. Most homes are hidden in the bush and are mere shacks. There is an abundance of children. About half of the children go to the elementary day-school in the centre of the Reservation; the others go to St. Michael's Mission at Duck Lake, where the Catholic Oblate Order maintains a boarding school for Grades 1 to 10. These students return only on week-ends to the Reservation. They are well looked after by the Mission staff, with a clean-up campaign on Sunday nights when they return from their week-ends. Nevertheless, approximately one-fourth of the students suffered from varying degrees of impetigo and boils, which caused much work and frustration for the Sister in the school dispensary. On the Beardy's Reservation proper, approximately one-fifth of the residents had impetigo on November 22, when the vaccination program started. The study was divided into two parts—Part A involving the students at St. Michael's Mission School on November 21, 1961, and Part B, the volunteers at the Reserve on November 22, 1961.

The volunteers in both groups were examined for boils and impetigo. Existing lesions were swabbed for culture and a description of the extent of the eruptions was recorded. They were then given alternately a 0.1-ml. intradermal skin test dose of either vaccine or placebo. Thirty minutes later, the skin tests were read and a decision was made whether to carry on with vaccine in the vaccine-tested persons who showed a wheal. This step was necessary, as the authors were unable to stay several days and await any delayed reactions for which medical help might be requested. Should such a delayed anaphylactic reaction happen, the trust of the Indians might be shattered. Hence, vaccine-tested volunteers with wheals were shunted to the group then receiving placebo and thus formed an "intermediate group", to be considered separately in the final assessment. The skin test was followed by administration of 0.25 ml. of either vaccine or placebo intramuscularly. The switch from 0.5 ml. intramuscularly, as suggested by Greenberg, to 0.25 ml. intramuscularly was conditioned by the unexpectedly large number of volunteers, for which number the initial supplies were inadequate.

St. Michael's School was revisited on November 22 to assess the occurrence of local or systemic reactions. On the Reservation this was not possible since the Indians would come for "needles" but not for a mere inspection. Here, the nurse enquired in the ensuing weeks after symptoms and made observations.

On January 10 and 11, 1962, the procedure with both groups was repeated. There were seven drop-outs at St. Michael's and over 30 at the Reservation. They were stricken from the register. On March 31, 1962, the first re-examination took place. The vaccinees were examined where they reported. The records of the Sister at St. Michael's dispensary and of the public health nurse at the Reservation were checked for pertinent entries and the records of the medical clinic at Rosthern, 20 miles to the south, were consulted for entries on Indians of Beardy's Reserve with impetigo and boils.

On May 14, 1962, "Treaty Day", a second check-up by the public health nurse was made, and in the first week of August 1962 the public health nurse checked again and reviewed her files. By that time many families had left for the beet harvest in Alberta and the students at St. Michael's were on holidays. Hence, assessment can be reported only to May 14, four months following the completed course.

RESULTS

There were three categories of volunteers: (1) those who had received placebo only; (2) an "intermediate group" who received a skin test with vaccine and then an intramuscular injection of placebo; and (3) those who had received vaccine only.

TABLE I.

	No. of volunteers	*No. with dermatitis on Nov. 21*	*No. healed by March 31*	*No. of new cases by March 31*	*No. of new cases by May 14*
		St. Michael's School			
Placebo group...	98	11	7	7	4
Intermediate group.....	18	5	5	2	1
Vaccine group...	118	41	36	7	3
Total.....	234				
		Beardy's Reservation			
Placebo group...	71	11	4	4	3
Intermediate group.....	82	17	13	3	6
Vaccine group...	72	14	13	3	2
Total.....	225				

Since both groups, the students at St. Michael's and the residents of Beardy's Reservation, shared many of the predisposing factors in their homes on the Reservation, combining the numbers for a further comparison appears justified.

The impression of the Sister at St. Michael's dispensary, of the public health nurse on the Reservation, and of the physicians at Rosthern, was that there had been a reduction in the incidence of boils and impetigo in early 1962. All swabs taken from lesions on November 21 and 22, 1961, showed a growth of *Staphylococcus aureus* upon culture. However, in over one-third a mixed flora

TABLE II.—TOTAL PARTICIPATION IN THE STUDY

	No. of volunteers	*No. with dermatitis on Nov. 21*	*No. healed by March 31*	*No. of new cases by March 31*	*No. of new cases by May 14*
Placebo group ..	169	22	11	11	7 (11 + 7 = 18)
Intermediate group.....	100	22	18	5	7 (5 + 7 = 12)
Vaccine group...	190	55	49	10	5 (10 + 5 = 15)
Total.....	459	99	78	26	19

of *Staphylococcus aureus* and beta-hemolytic streptococci or of *Staphylococcus aureus* and coliform organisms was isolated.

Swab specimens from the persisting lesions on March 31, 1962, at St. Michael's School grew *Staphylococcus aureus* in three of four cultures in the placebo group and in two of five cultures in the vaccine group. The fourth placebo group volunteer had beta-hemolytic streptococci and the three other vaccine volunteers a mixture of beta-hemolytic streptococci and *Proteus vulgaris.*

There were no constitutional side effects and no immediate or delayed anaphylactic reactions following the injections of either vaccine or placebo. The nature of the latter was not known to the authors, although they had to insist upon knowing which ampoules contained the vaccine for reason of the above-mentioned precautions. Local reactions that occurred within 30 minutes were erythema or an edematous reddish swelling of the skin around the injection site; the diameters ranged from 5 to over 20 mm. and many true wheals were seen. There was rarely a complaint of pain following the injection. Erythema and swelling decreased within 24 hours, and no skin rash was observed during the study .

The number in the "intermediate group" on Beardy's Reservation was considerably higher than at St. Michael's School. The authors felt obliged to use the greatest caution here, for reasons already stated. Even when mild erythema was observed after the vaccine skin test, the volunteer was placed in the intermediate group. It was felt that this precaution was owed to all parties concerned, even if the figures of the controlled study would be reduced thereby.

DISCUSSION AND CONCLUSIONS

This study was conducted under field conditions and may not have been as carefully controlled as the analytic mind would like it to have been. Nevertheless, certain observations may be accepted. There was a reduction of impetigo by March 31, 1962: the 99 cases of November 21 and 22, 1961, had decreased to 47 cases by March 31. This reduction was drastic in the "intermediate" and the "vaccine" groups in which only 10 of the original 77 impetigo cases were still showing lesions on March 31, while this was true of 11, or half of the original 22 cases in the "placebo group", on March 31.*

This indicates a considerable curative effect of the vaccine with success in close to 90% of the vaccine group and nearly 82% in the "intermediate group". If the small numbers were not insufficient for analysis, one would even be tempted to think that the greater "antigenic mass" in the "vaccine group" reflected itself in these figures but that, notwithstanding the small dose of vaccine, the skin tests with it had a marked effect already. The results on May 14 indicate that by this time the protective effect was waning, although relatively fewer new cases (7.9% of 190) appeared in the "vaccine group" than in the "placebo group" (10.5% of 169) or the "intermediate group (12% of 100). A booster dose might be in order at this stage to obtain more convincing statistics of the preventive ability of the vaccine.

With the strict precautions taken, the side effects of the vaccine were of a harmless nature in this study, confirming the previous experiences of one of the authors (H.D.).

The result of this venture appears encouraging and invites future studies. Clearly some additional measure is necessary in the prevention of the dirt-borne dermatitis of Treaty Indians until the slow progress of health education has resulted in a higher level of hygiene on the Reservations, and the use of anti-staphylococcal immunizing agents, such as Greenberg's somatic antigen vaccine, seems to be one such promising measure.

SUMMARY

A trial of Greenberg's staphylococcus somatic antigen vaccine in Treaty Indians of Saskatchewan resulted in a useful reduction in the incidence of impetigo and boils in the "vaccinated group" of a placebo-controlled study. No significant decrease in the incidence of skin infections was found in the "placebo group" four months after the "placebo" vaccinations. There were no side effects from the somatic antigen, and its mode of administration was found to be suitable for immunization of larger groups of persons. More booster doses are needed to enhance the preventive efficacy of the antigen.

The authors wish to thank Dr. Greenberg for supplies of vaccine and placebo, the public health nurses of the Prince Albert Indian Health Zone for unwavering and warm-hearted support, the Chief of Beardy's Reserve, Mr. Ambrose Gamble, for his confidence and great help, Miss P. Ford for typing this report, and Dr. W. Harding le Riche for his guidance and advice in completing the paper.

REFERENCES

1. DILLENBERG, H.: *Canad. J. Public Health,* 53: 248, 1962.
2. GREENBERG, L. AND COOPER, M. Y.: *Canad. Med. Ass. J.,* 83: 143, 1960.
3. GREENBERG, L., COOPER, M. Y. AND HEALY, G. M.: *Ibid.,* 84: 945, 1961.
4. GREENBERG, L. AND LE RICHE, W. H.: *Canad. J. Public Health,* 52: 479, 1961.

*Dr. W. Harding le Riche, Professor and Head, Department of Epidemiology and Biometrics, School of Hygiene, University of Toronto, kindly analyzed Table II statistically. He confirmed the data for the curative effect of the somatic antigen as highly significant, whereas the preventive effects were not significant.