

REVERSAL OF NEGATIVE LEPROMIN REACTIONS
FOLLOWING USE OF
TUBERCULOSIS VACCINE IRRADIATED¹

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A substantial change has taken place in recent years in the approach to the prevention of leprosy through antituberculosis vaccination. Since 1939 efforts have been made to start trials of BCG vaccine on humans as a prophylactic measure against malign leprosy. The third Pan-American Conference on Leprosy held in Buenos Aires in 1951, in connection with a subject of its agenda, "Actual Status of Antileprosy Campaigns," suggested the possibility of including BCG vaccination as a prophylactic measure.

After that time numerous studies were conducted, and at the Sixth International Congress of Leprology held in Madrid in 1953 no less than 18 of the papers offered dealt, in one way or another, with the effects of BCG vaccination, several of them with respect to prophylaxis. The report of the Committee on Epidemiology and Control stressed "the promising results which have recently been obtained with the lepromin reaction induced by B.C.G."²

Those of us who were interested wanted to conduct a study on the use of BCG in the areas of the highest morbidity in this country. In May 1953, at a meeting of the Argentine Society of Leprology, we announced the beginning of our study although we had the serious obstacle of the short space of time that BCG can be used after manufacture. At about the same time we were offered³ a new vaccine which had the advantage of being stable for a long period of time, thus facilitating large-scale trials.

MATERIAL AND METHOD

Characteristics of the vaccine.—This vaccine was prepared from cultures of a virulent human strain of *Mycobacterium tuberculosis*, No. 199RB (1, 2), inactivated by ultraviolet irradiation. Each cubic centimeter con-

¹ Paper presented during the session held by the Argentine Society of Leprology on November 18, 1956.

² A footnote to that report reads, "The General Council of the Congress proposed that [a certain] sentence be struck out, holding that the use of B.C.G. is still in the experimental stage and that as yet there is no adequate evidence to justify the indicated view that it is an established measure of prophylaxis. The final plenary session, however, voted for the retention of the statement."

³ By Dr. E. H. Payne, of Parke, Davis and Company, Detroit, Mich.

tains bacilli equivalent to 1 mgm. in semi-moist weight. It was supplied in 20 cc. vials and can be stored for a year or more without loss of potency.

Technique of inoculation.—Inoculations were made intramuscularly, the dosage being 0.5 cc. for infants and children up to six years old, and 1.0 cc. for older persons. Subcutaneous injections were also given without inconvenience. This dose was repeated at 15-day intervals to complete three inoculations. No preliminary tuberculin testing before administration of the tuberculosis vaccine was found necessary.

Vaccinations performed.—From the time this study was begun, in August 1955, until this report was prepared a total of 72 subjects, all lepromin negative before the vaccination, were treated and retested; and 50 of them are dealt with in this report. Among these 50 individuals there were 4 who were under six years of age. Of the adults, 6 had received two series of oral BCG vaccination in doses of 800 mgm. but had remained Mitsuda negative. Three weeks after the third dose of irradiated vaccine, the lepromin test was repeated.

RESULTS

The results of the post-vaccination lepromin tests are shown in Table 1. It will be seen that there was lepromin reversal—i.e., conversion from negative to positive Mitsuda reactivity—in 78 per cent of the entire group. All of the individuals who previously had received BCG without converting now became positive, but their number is too small to be of significance.

TABLE 1.—Lepromin conversion after treatment with irradiated tuberculosis vaccine in 50 lepromin-negative leprosy contacts, of which 6 had previously received BCG vaccination.

Group	No. of cases	48 hours			4 weeks		
		No. read	Positive	Negative	No. read	Positive	Negative
Not BCG vaccinated	44	29	13 (45%)	16 (55%)	44	33 (75%)	11 (25%) ^a
BCG vaccinated	6	4	1 (25%)	3 (75%)	6	6 (100%)	0 (0%) ^b
Total	50	33	14 (42%)	19 (58%)	50	39 (78%)	11 (22%)

^a Index of positivation: 75 per cent

^b Index of positivation: 100 per cent

The 11 individuals who had remained lepromin negative (Table 1) received another course of three inoculations of the irradiated vaccine. The results were as follows: (a) Of 6 individuals whose 48-hour reactions were read, 4 (66.7%) were positive, the other two negative. (b) of the entire group, 8 (73%) gave positive late reactions, while only 3 remained negative.

Thus there was a total of 47 reversals, or 94 per cent. This percentage favors the irradiated tuberculosis vaccine, since in our study with BCG, following three vaccinations, our total reversals were 75 per cent.

TOLERANCE

In general, tolerance for the tuberculosis vaccine was good although we observed some reactions that should be reported. In 4 cases, i.e., 8 per cent of the total, there was local inflammation with some congestion and erythema with varying degrees of pain. This reaction appeared about 48 hours after the injection, lasted for several days, and then disappeared without sequelae. This happened in one individual after the first injection, and in three individuals after each injection.

One of these individuals also had some general symptoms, including some fever and malaise. It may be of interest that this individual had previously received BCG on two different occasions.

SUMMARY AND CONCLUSIONS

Fifty healthy, lepromin-negative individuals living with leprosy were vaccinated with Tuberculosis Vaccine, Irradiated. In 47 of them the lepromin reaction became positive after one or two courses of the vaccine.

We believe that Tuberculosis Vaccine, Irradiated, may prove to be of value because it changes Mitsuda-negative individuals to positive reactors.

RESUMEN Y CONCLUSIONES

A 50 sujetos sanos y negativos a la lepromina, que vivían con leproso, se les vacunó con Vacuna Anti-Tuberculosa, Irradiada. En 47 de ellos la reacción a la lepromina se volvió positiva al cabo de una o dos series de la vacuna.

Opinan los AA. que la Vacuna Anti-Tuberculosa, Irradiada, puede resultar de valor porque vira a positivos a los sujetos negativos a la Mitsuda.

REFERENCES

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