USE OF THE BIFURCATED NEEDLE FOR BCG VACCINATION OF NEWBORNS[1, 2]

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It has been suggested that the bifurcated needle technique used successfully against smallpox might be gainfully employed in BCG vaccination of newborns against tuberculosis. The two Chilean studies described here were conducted in order to assess its potential in this regard and to reexamine the previously reported technical difficulties involved.

Introduction

The bifurcated needle affords a simple means of vaccination that has been used successfully against smallpox (*1, 2*). Indeed, the simplicity of this technique is regarded as one of the factors which contributed significantly to smallpox eradication on the Asian Continent.

Shortly before completing the massive phase of smallpox vaccination in Asia and in some African countries, the idea arose of employing the existing organization of mobile vaccination teams to conduct a campaign against tuberculosis using the same bifurcated needle technique. This would eliminate the need for retraining personnel in new vaccination techniques and procedures.

Before deciding to use the bifurcated needle for BCG vaccination, however, it was judged essential to compare its technical efficacy with that of the intradermal technique—the best of the currently available methods. The comparison was made by various investigators on the basis of tuberculin sensitivity and vaccinal skin lesions.

Studies were made of children in India (*3*), Cameroon (*4*), The Central African Republic (*5*), Tanzania (*6*), and Mexico (*7*). In no case, even with BCG vaccine concentrations of 160 mg per ml, did the effectiveness of the bifurcated needle technique match that of the intradermal method. At best, it was estimated that the actual BCG vaccine dose which penetrated the subjects was only one-third of the intradermally injected dose. Furthermore, the results were observed to vary significantly from one subject to the next, a circumstance appreciably reducing the reliability of the method.

If the technical efficacy of bifurcated needle vaccination could be improved to a point where half of the standard intradermal dose penetrated the subject, and if variations introduced by different vaccinators could be reduced, this would then be the ideal method for BCG vaccination of the newborn. In fact, it has been recommended for some time that the dose administered to newborns and infants should be half the standard dose in order to avoid local complications such as abscesses and satellite adenopathies (*8*).

Therefore, two consecutive studies were

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designed and carried out in order to further test the effectiveness of the bifurcated needle in BCG vaccination of the newborn. This article presents the results of those studies.

Study I

Materials and Methods

The first study was performed in 1975 in the maternity wards of the Barros Luco, San Borja, and Salvador hospitals in Santiago, Chile. A total of 895 newborns were vaccinated with either the intradermal or the bifurcated needle technique without any prior tuberculin testing.

The vaccines employed were as follows:

a) Freeze-dried BCG vaccine from Japan at a concentration of 80 mg per 1.0 ml. This was administered with the bifurcated needle technique. Since each ampule contained 80 mg of vaccine, 1.0 ml of diluent was added to achieve the required concentration.

b) An international reference preparation of BCG vaccine was furnished by the Serum Institute of Copenhagen, Denmark. This was administered by the intradermal route and was used in two concentrations, the standard dose and half the standard dose.

The vaccines were evaluated at the Chilean Bacteriological Institute. It was found that the number of viable particles per ml in samples taken at the time of vaccination did not vary significantly from the viability indicated by the producing laboratories. This was taken to indicate that the products had been properly preserved and transported.

The intradermal vaccination, administered with an Omega Syringe, introduced 0.1 ml of vaccine at standard or half-standard strength into the outer face of the left arm, 2 cm below the top of the shoulder, in accord with WHO standards (*9*).

The multiple puncture vaccination was administered after introducing the bifurcated needle into the vaccine vial in such a way that, on withdrawal, a droplet of vaccine remained on the prong fork. Nine vertical punctures were then made in the skin of the subject's arm at the same site used for the intradermal injections. The bifurcated needles were sterilized with dry heat. Figure 1 shows this vaccination procedure.

The vaccinations were administered by two midwives with many years' experience in giving intradermal vaccinations, six nursing auxiliaries who had previously administered smallpox vaccinations with the bifurcated needle, and two nurses skilled at applying and reading the tuberculin test.

The vaccination schedule for the study was established by random selection of the hospitals and the days for vaccination with the bifurcated needle, the standard intradermal dose, and the half-standard intradermal dose.

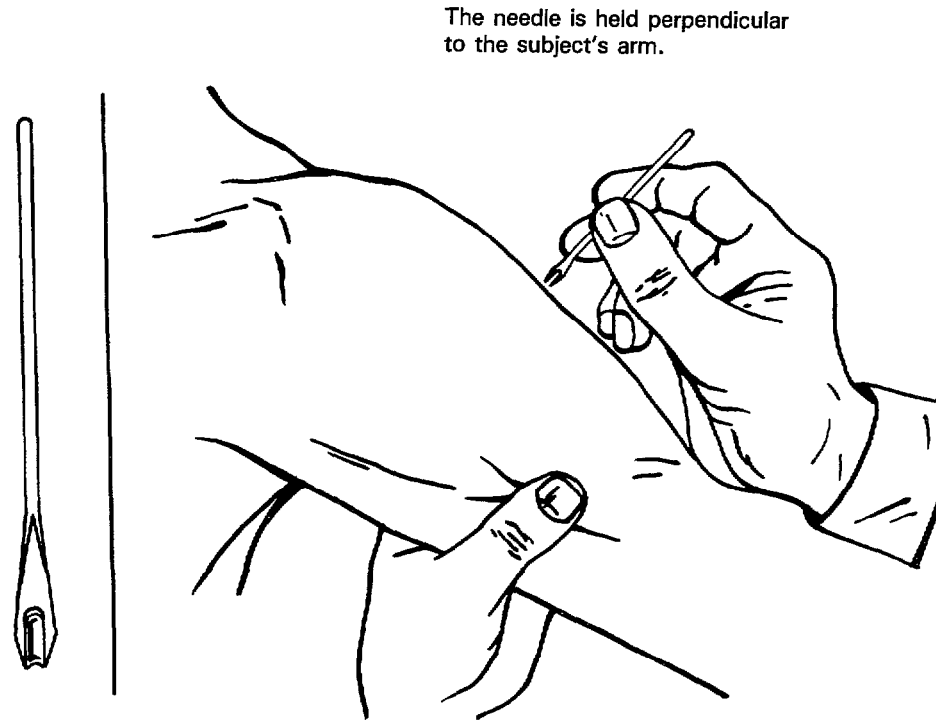
Post-vaccinal evaluation was accomplished by means of a tuberculin test administered five months after vaccination. This test employed 2 tuberculin units of PPD RT 23 with polysorbate 80 (tween 80).

Results

The results of the study were analyzed with the assistance of the Departments of Biostatistics and Public Health of the University of Chile.

Table 1 gives the principal results. A total of 895 newborns were vaccinated, 582 with the bifurcated needle, 169 with the standard intradermal dose, and 144 with half the standard intradermal dose. Those receiving the standard intradermal dose exhibited a tuberculin reaction five months after vaccination whose average induration was 7.6 mm. Those injected with half this dose exhibited an average tuberculin reaction of 6.3 mm. Thus, reducing the standard dose by half prompted an average reduction of only 1.3 mm in the induced tuberculin

Figure 1. Vaccination with the bifurcated needle.



Source: World Health Organization, Document WHO/SE/68.2 Rev. 1.

sensitivity. This finding agrees with other published observations (*10*).

On the other hand, the average tuberculin sensitivity shown by those subjects vaccinated with the bifurcated needle was only 4.9 mm, indicating that the amount of vaccine inoculated by this method was approximately one-tenth the standard dose. When the results obtained with the bifurcated needle were compared with those obtained by injecting half the standard dose, the difference was found to be significant. It was therefore concluded that the vaccine concentration was too weak, or else the number of punctures made was insufficient to achieve the desired effect.

Table 2 shows the average results achieved by each vaccinator participating in the experiment in terms of tuberculin sensitivity. The multiple puncture (bifurcated needle) inoculations were administered by six vaccinators in order to test the consisten-

Table 1. Tuberculin reactions observed in Study I, five months after BCG vaccination of newborns.

Vaccination technique	No. of newborn subjects	Post-vaccinal tuberculin reaction	
		Average induration (mm)	Standard deviation
Intradermal, standard dose	169	7.6	4.6
Intradermal, 1/2 standard dose	144	6.3	4.6
Bifurcated needle	582	4.9	3.8
Total	895	—	—

cy of the method. It was felt that if several individuals could obtain virtually identical results, this would indicate that the technique could be applied easily with a minimum of variability. An overall statistical analysis was therefore made of differences in the results obtained by each of the six vaccinators using the bifurcated needle. This analysis found that none of the observed differences were statistically significant. Contrary to the results of previous research on schoolchildren, this supports the conclusion that variations introduced by individual vaccinators in the present study were within acceptable limits and would not constitute grounds for objection to the use of this technique.

On the other hand, it is interesting to note that statistically significant differences were observed in the results obtained by the

Table 2. Tuberculin reactions observed in Study I, broken down according to the individual workers administering vaccine.

Vaccination technique	No. of newborn subjects	Post-vaccinal tuberculin reaction	
		Average induration (mm)	Standard deviation
Intradermal, standard dose			
Vaccinator 1	86	6.6	4.1
Vaccinator 2	83	8.3	4.7
Intradermal, 1/2 standard dose			
Vaccinator 1	90	6.6	4.8
Vaccinator 2	54	5.6	4.3
Bifurcated needle			
Vaccinator 1	100	5.3	3.9
Vaccinator 2	93	5.0	3.5
Vaccinator 3	143	4.7	3.5
Vaccinator 4	87	5.0	4.4
Vaccinator 5	75	4.9	3.7
Vaccinator 6	84	4.3	4.2

Table 3. Tuberculin reactions observed in Study II, five months after BCG vaccination of newborns.

Vaccination technique	No. of newborns studied	Post-vaccinal tuberculin reaction	
		Average induration (mm)	Standard deviation
Intradermal, standard dose	74	7.0	4.6
Intradermal, 1/2 standard dose	62	6.1	4.4
Bifurcated needle	175	4.1	4.2
Total	311	—	—

two vaccinators using the intradermal method—both of whom were experienced in the use of the technique.

No complications were observed in connection with any of the methods employed.

Study II

Because of the poor results obtained from the first study—in terms of the efficacy of the bifurcated needle for BCG vaccination—it was decided to conduct a second study in which two modifications were introduced. Specifically, a vaccine concentration of 160 mg per ml was selected (0.5 ml of diluent in an ampule containing 80 mg of dry BCG powder), and the number of needle punctures was increased from nine to fifteen. No modifications were made in the doses used with the intradermal method.

Table 3 shows the principal data obtained from this study, which was completed in 1976 and which involved vaccination of 311 newborns. Despite the use of double-strength vaccine and the increased number of skin punctures, the relationships between the results obtained with the three different procedures remained essentially the same as those obtained in the first study. In this case, however, it could be estimated that the average amount of vaccine introduced into the subject with the bifurcated needle was even less than one-tenth of the standard intradermal dose.

Discussion and Conclusions

Most Latin American countries have established appropriate BCG vaccination policies. Nevertheless, for a variety of reasons it has not been possible to achieve effective BCG coverage, so that the present vaccination coverage of children under one year of age in Latin America is only about 25 per cent (*11*). One of the reasons for this poor coverage is the difficulty of training personnel to administer vaccine by the intradermal method.

Multiple puncture vaccination with a bifurcated needle can be performed by personnel with only basic preparation and a minimum of training; hence the interest in continued investigation of the technical capabilities of this method.

The main problem which emerges from these studies is that the dose of vaccine actually penetrating the subject is insufficient. Specifically, it appears that a vaccine concentration of 160 mg per ml was insufficient to permit the bifurcated needle procedure to approximate the efficacy of the intradermal technique. It would not seem possible to further increase this vaccine concentration. On the other hand, it might be feasible to enlarge the fork of the needle so as to withdraw a larger dose of vaccine. Another possibility would be to administer the vaccine at two different sites on the arm.

In conclusion, the bifurcated needle technique cannot yet be recommended for BCG vaccination of newborns. Nevertheless, its evident functional advantages make it worthwhile to continue exploring the technical possibilities of this method.

SUMMARY

The bifurcated needle vaccination method used successfully against smallpox is a relatively simple technique that can be administered by personnel with only basic preparation and a minimum of training. This fact suggests that it could prove useful in campaigns of BCG vaccination against tuberculosis—especially for vaccination of newborns. With this end in mind, two studies were carried out in Santiago, Chile, to examine previously reported difficulties with the method and to assess its potential as an alternative to the best current method, that of intradermal inoculation.

These studies indicated that previously reported variations in the results achieved by different vaccinators could be markedly reduced. However, they also found that the bifurcated needle method did not cause a sufficiently large dose of vaccine to enter the subject—even when fifteen needle strokes and a highly concentrated vaccine (160 mg per ml) were employed. It was thus concluded that although modification of the needle or other changes might ultimately yield satisfactory results, the bifurcated needle technique cannot yet be recommended for BCG vaccination of newborns.

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