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THE EFFICACY AND ACCEPTABILITY OF THE BIFURCATED NEEDLE TECHNIQUE

A Summary of Studies Conducted in India

Prior to the introduction in India of the bifurcated needle (multiple puncture technique), comparative studies of the needle and the rotary lancet were conducted by the National Institute of Communicable Diseases (NICD) and the Directorate General of Health Services in New Delhi in order to determine the relative efficacy of each method. In addition, a study of the acceptability of vaccination employing the bifurcated needle was performed by the Central Health Education Bureau in a village, Najafgarh, about 20 miles from Delhi.

With the permission of the Ministry of Health, Family Planning and Urban Development, a summary of the main findings of these studies has been prepared.

I. Relative efficacy of the two techniques

Materials and methods

The vaccine used in experiments was obtained from the State Vaccine Institute in Patwadangar. Its potency according to tests done at NICD was 2.99×10^8 p.f.u. per ml. The vaccine was reconstituted with 40 per cent. glycerine buffer nitrate solution and diluted to obtain three concentrations of vaccine as follows: 1×10^8, 5×10^7 and 1×10^7 p.f.u./ml. After preparation, the vaccine was preserved constantly at 20°C.

Vaccinations with vaccines of these potencies were performed by trained vaccinators as follows:

The bifurcated needle was dipped into the vaccine and 15 punctures were made on the forearm; a second insertion was made in the same manner at a site about one inch away from the first.

The rotary lancet was dipped into the vaccine and two drops were placed one inch apart on the skin in the middle of the forearm. Introduction of the virus at each site was performed by rotation of the rotary lancet through one complete circle.

The persons selected for study consisted of a group of 642 schoolchildren, all with a history of vaccination or revaccination during the last three years and a second group of 26 children aged two months to two years who had never been successfully vaccinated.

The first group of 642 schoolchildren was divided randomly into nine subgroups. In each of three subgroups (A, B, C), vaccine of one of the three levels of potency was administered by both techniques to every individual. In the remaining six subgroups (D, E, F, G, H, I), vaccine of one of the three levels of potency was administered by only one technique of vaccination in each child. The group of 26 unvaccinated children was divided randomly into three subgroups and vaccines of different potencies were administered by both techniques to every child.

The vaccination sites were examined after seven days by two independent readers who had no knowledge as to which technique was used and the results were classified according to WHO recommendations.

Results

The results obtained among 642 revaccinated schoolchildren indicate that the multiple puncture technique induced a consistently higher proportion of major reactions in all groups (Tables 1 and 2). The reasons for the differences in the frequency of reactions between the two principal study groups (Table 1 vs. Table 2) are unknown.

TABLE 1. RESULTS OF SIMULTANEOUS REVACCINATION OF A GROUP OF SCHOOLCHILDREN WITH THE BIFURCATED NEEDLE AND THE ROTARY LANCET

Subgroup	Vaccine potency (p.f.u./ml)	No. of children revaccinated	Rotary lancet		Bifurcated needle	
			No. of major reactions	%	No. of major reactions	%
A	1×10^8	84	22	26	47	56
B	5×10^7	82	10	12	29	35
C	1×10^7	81	10	12	26	32

TABLE 2. RESULTS OF REVACCINATION AMONG SEPARATE GROUPS VACCINATED WITH THE ROTARY LANCET OR THE BIFURCATED NEEDLE

Vaccine potency (p.f.u./ml)	Rotary lancet				Bifurcated needle			
	Subgroup	No. of children revaccinated	No. of major reactions	%	Subgroup	No. of children revaccinated	No. of major reactions	%
1×10^8	D	69	31	45	E	63	44	70
5×10^7	F	69	17	25	G	64	38	59
1×10^7	H	63	15	24	I	69	36	52

From both studies it is also clear that the percentage of major reactions diminished with the use of vaccines of progressively lower potencies.

Although the numbers are small, the bifurcated needle technique also proved to be superior to the rotary lancet among children given primary vaccination, especially when vaccine of lower potency was used (Table 3).

TABLE 3. RESULTS OF PRIMARY VACCINATION WITH BOTH TECHNIQUES OF CHILDREN AGED TWO MONTHS TO TWO YEARS

Subgroup	Vaccine potency (p.f.u./ml)	No. of children vaccinated	Rotary lancet		Bifurcated needle	
			No. of major reactions	%	No. of major reactions	%
1	1×10^8	9	9	100	9	100
2	5×10^7	9	6	67	7	78
3	1×10^7	8	2	25	4	50

These data lead to the following conclusions:

1. A much higher proportion of successful takes is obtained with the bifurcated needle technique than with the rotary lancet technique.

2. It is necessary to use a vaccine of high potency (not below 1×10^8 p.f.u./ml) to obtain satisfactory results both in revaccinees as well as in primary vaccinees.

II. Acceptability of the two techniques

A study to determine the acceptability of the bifurcated needle technique in village populations was undertaken by the Central Health Education Bureau in co-operation with the Rural Health and Training Centre, Najafgarh.

Material and methods

For the study, five villages in Najafgarh block were selected, taking into account the distance from the Health Centre, size, approachability and basic socio-economic conditions. The population of the selected villages according to the 1961 census was 4741, from which a sample of 2071 persons in 206 families was finally selected for study.

A visit was paid during the morning by vaccinators administering vaccine by the multiple puncture technique. The vaccinators avoided any explanation and did not attempt to force the persons concerned to accept vaccination. The vaccinators were accompanied by members of the study team who acted as objective observers. During a second visit, seven days later, take rates were determined and opinions of the bifurcated needle technique were solicited.

Results

During the first visit, only 691 persons out of 2071 were at home. From these, 82 (about 12 per cent.) were children below four years of age who had never been vaccinated previously. The remaining 609 persons were of various age-groups.

During the second visit, 74 out of 82 persons given primary vaccination were examined. All developed major reactions (100 per cent. take rate). Among 87 of the 149 revaccinees who were examined, major reactions were observed in 69 (79 per cent.).

One of the main findings of this detailed and thorough study was the fact that the acceptance of vaccination did not depend on the vaccination technique used. The people at the time of vaccination were not interested by which technique the vaccination was performed and, surprisingly, few realized that the technique applied was different from the customary rotary lancet method.

It is noted, parenthetically, that there was considerable difficulty in reaching an acceptable proportion of the population of a village during a single visit, especially in the morning hours. In the age-group below one year, the main reason for avoiding the administration of vaccine was the opinion of the mother that the child was too young to be vaccinated. Among older people the reasons for refusals were fear of incapacitating after-effects of vaccination, a belief that older people are not so vulnerable to smallpox, and the opinion that there is no need for protection in the absence of an outbreak.