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Comparative Studies of Smallpox Vaccination by the Bifurcated Needle and Rotary Lancet Techniques

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Comparisons were made in groups of schoolchildren in New Delhi of the rotary lancet and bifurcated needle techniques for primary vaccination and revaccination against smallpox. Vaccines of 3 different titres were employed in the tests. The results indicate that the bifurcated needle technique is superior to the rotary lancet technique for both primary vaccination and revaccination, the percentage of major reactions in revaccinations in which the bifurcated needle technique was used being significantly higher, irrespective of the vaccine dilution. However, the proportion of major reactions decreased gradually in both techniques with the greater dilution of the vaccine.

It was shown that when a fully potent vaccine is used there is no advantage in making 2 insertions by the bifurcated needle technique but that when the rotary lancet technique is employed and when the vaccine is not fully potent there is a significant improvement in the successful take rate when 2 insertions are given. In areas where storage facilities for vaccines in the field are not ideal and the full potency of vaccines is doubtful, the use of the bifurcated needle technique with 2 insertions seems to be the method of choice.

The use of bifurcated needles for carrying out smallpox vaccinations has been favourably commented upon by many authorities. In India, because of considerable variations in temperatures and poor facilities for refrigeration, or even none, in most rural areas, there are problems in maintaining the desired level of potency in smallpox vaccines. Some workers therefore fear that the small amount of vaccine (0.0017 ml–0.0029 ml) that is picked up by a bifurcated needle may not produce the desired percentage of takes when the vaccine used in the field is likely to be substandard. However, one of the arguments advanced in favour of the bifurcated needle technique is that although the quantity of vaccine delivered is small, most of the virus particles are placed on, or at, the Malphigian layer of the skin, thereby facilitating the multiplication of the virus. This apparently is not so in the rotary lancet technique.

Consequently, it was decided that the National Institute of Communicable Diseases, India, would carry out a comparative study in Delhi, using the bifurcated needle (multiple-puncture vaccination) and the conventional rotary lancet methods and taking into account only the reactogenicity as an indication of successful vaccination. This communication presents the results of the study.[7]

MATERIAL

For primary vaccination, 26 previously unvaccinated children aged 2 months to 2 years in the village of Burari near Delhi (Delhi Municipal Corporation area) were selected; for the revaccina-

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[7] Only the efficacy studies are reported here. The acceptability studies were carried out by another organization and the results will be reported separately.

tion, 642 children in the 1st–11th classes of a public school in New Delhi were selected. These children had been vaccinated or revaccinated 1–3 years previously.

METHODS

National Reference Smallpox Vaccine (batch FD-25 II/66) obtained from the State Vaccine Institute, Patwadangar, Uttar Pradesh, India, was tested on the chorioallantoic membrane of 12-day-old chick embryos by the method advocated by Westwood, Philipps & Boulter (1957). The average potency titre, based on 50 determinations, was found to be 2.99×10^8 pock-forming units/ml. The contents of a number of ampoules of freeze-dried vaccine were reconstituted in 40% glycerol citrate buffer solution in order to produce graded titres of the vaccine: 1.0×10^8 ml, 5.0×10^7 ml and 1.0×10^7 ml.

Small quantities of the vaccines were stored in a deep-freeze cabinet at −20°C immediately after being reconstituted so that their titres could be determined before the vaccinations were carried out. The remaining vaccine was placed in sterile screw-capped bottles and taken to the vaccination site on ice in vacuum flasks. The vaccines of graded titres were used in the vaccination trials and the bottles were then returned to the Institute in vacuum flasks containing ice and were stored in a deep-freeze cabinet at −20°C. The vaccines were tested for potency on the chorioallantoic membrane of 12-day-old chick embryos 7 hours later. A fall in potency of one-half log was noted in each dilution of vaccine.

The study consisted of 3 parts:

(1) Three groups of previously vaccinated children numbering 81, 82 and 84 were drawn from the 5th–11th classes. Each child was revaccinated with both the bifurcated needle and rotary lancet techniques (a single insertion by each method) and for each group a vaccine of different titre was used.

(2) Three other groups of previously vaccinated children drawn from the nursery class to the 5th class were each divided into 2 subgroups containing 63–69 children each. Vaccines of 3 different titres were used for each main group while different vaccination techniques were used in the subgroups.

(3) Three groups of unvaccinated children, each consisting of 8 or 9 children from the village of Burari, were given primary vaccinations with both techniques. Every child received a single insertion by each technique and vaccines of different titres were used for each group. In addition, a group of 12 persons was "vaccinated" with a placebo by both the techniques under study.

Design of experiment for part 1

Children from the 5th to the 11th classes were specially allotted to 3 groups, i.e., the first child on the class register being allotted to the first group, the second child to the second group and the third child to the third group, etc.; thus all the children were allocated to 3 groups of 81, 82 and 84, respectively.

Design of experiment for part 2

In this part of the study, 3 groups, each with 2 subgroups, were set up from some of the children in the nursery class to the 5th class who were also allotted to each group serially. All the classes were equally represented in all 6 subgroups.

Design of experiment for part 3

Altogether, 26 children included in this study were allotted to each group equally by random sampling.

Methods of vaccination

Vaccinations by the 2 techniques were performed by vaccinators from the New Delhi Municipal Committee using National Reference Smallpox Vaccine. For the rotary lancet technique, the conventional method of vaccination was employed in which the spatular end of a lancet was dipped into vaccine and 2 drops were placed 1 in (2.5 cm) apart in the middle third of the forearm. The needle end of the lancet was then applied and rotated through a complete circle in each drop. In the bifurcated needle technique the needle was dipped into vaccine and 15 strokes were made in each of 2 sites 1 in (2.5 cm) apart. For parts 1 and 3 of the study, in which the vaccinations with both techniques were performed on the same individual (with a single insertion by each technique), the minimum distance between the 2 insertions was 2½ in (6 cm) or more. In primary vaccinations 15 strokes were made for each insertion with the bifurcated needle.

Altogether, 1000 bifurcated needles and 6 rotary lancets were received from the Deputy Director General of Health Services (Smallpox), Delhi. The needles were sterilized in boiling water for 15–20 minutes, whereas the rotary lancets after an initial boiling for 15–20 minutes were then flamed over a spirit lamp and cooled for 2 minutes before the next vaccination was performed.

Inspections of revaccinations were made independently by 2 readers on the seventh day, and their observations were recorded as recommended by the

WHO Scientific Group on Smallpox Eradication (1968). The interpretation of results obtained following primary vaccinations did not present any problem because of the development of the easily recognizable Jennerian vesicle. In revaccinated individuals a response was regarded as a " major reaction" if a typical Jennerian vesicle or vesicular or pustular lesion, or a definite area of palpable induration or congestion surrounding a scab or an ulcer was present. Any other response to vaccination was considered as an equivocal reaction. Readings of the response to vaccination were recorded without knowledge of the technique used.

RESULTS AND DISCUSSION

Table 1 shows the successes obtained in revaccinations using the 2 techniques and it is clear that the percentage of successful takes from the bifurcated needle technique is higher than from the rotary lancet technique for each of the 3 titres of vaccine. However, in group A in which a vaccine titre of 1×10^8/ml was used, a higher proportion of successful takes was noted as compared with groups B and C in which the titre of the vaccine was 5×10^7/ml, and 1×10^7/ml, respectively. Thus a low titre of vaccine probably affected the take rate in revaccinations.

Table 2 shows the take rate for revaccinations carried out by the 2 techniques in different individuals. From Table 2, it may be seen that the proportion of successful takes was higher with the bifurcated needle technique than with the rotary lancet technique for all the titres of vaccine used in the trials. However, when these results were compared with the corresponding results for individuals in whom both techniques had been used (see Table 1), the take rate was also significantly higher in this group, irrespective of the titre of the vaccine and the technique employed.

An attempt was made to correlate the number of insertions in revaccination by different techniques and the take rate; these results are set out in Table 3. This observation was limited to the second group in which individuals were vaccinated by a single technique. It is apparent that with the bifurcated needle technique, the proportion of individuals showing successful takes at both sites of vaccine insertion was higher than when the lancet technique was used. The take rates gradually decreased when vaccines of lower titre were employed.

The over-all percentage of takes that would have been recorded if a single insertion only had been administered was calculated. It is apparent that when fully potent vaccine is used there is little advantage in making 2 insertions with a bifurcated needle. However, when a vaccine of lower titre or a rotary lancet is used, 2 insertions lead to a significant improvement in the take rate. In countries where refrigerated storage facilities are available under field conditions, the bifurcated needle technique with a single insertion is satisfactory. However, where storage facilities are inadequate and the full potency of vaccines cannot be maintained, 2 inser-

TABLE 1

COMPARISON OF SUCCESSFUL TAKE RATES FOR BIFURCATED NEEDLE AND ROTARY LANCET TECHNIQUES IN REVACCINEES APPLIED TO THE SAME PERSONS [a]

Group	Titre of vaccine (pock-forming units/ml)	Technique employed	Total no. of revaccinations	No. of persons showing successful takes	Percentage of successful takes
A	1×10^8	Rotary lancet	84	22	26.2
		Bifurcated needle	84	47	56.0
B	5×10^7	Rotary lancet	82	10	12.2
		Bifurcated needle	82	29	35.4
C	1×10^7	Rotary lancet	81	10	12.3
		Bifurcated needle	81	26	32.1

[a] Single insertion by each technique.

TABLE 2

COMPARISON OF SUCCESSFUL TAKE RATES FOR BIFURCATED NEEDLE AND ROTARY LANCET TECHNIQUES IN REVACCINEES APPLIED TO DIFFERENT PERSONS

Group	Titre of vaccine (pock-forming units/ml)	Technique employed	Total no. of revaccinations	No. of persons showing successful takes	Percentage of successful takes
A	1×10^8	Rotary lancet	69	31	44.9
		Bifurcated needle	63	44	69.8
B	5×10^7	Rotary lancet	67	17	25.4
		Bifurcated needle	64	38	59.4
C	1×10^7	Rotary lancet	63	15	23.8
		Bifurcated needle	69	36	52.2

tions with a bifurcated needle appear to be the method of choice.

Take rates in primary vaccination using the 2 techniques vaccines of different titres are shown in Table 4. It may be seen from this table that the take rate was 100%, irrespective of the technique used, when the titre of the vaccine was 1×10^8/ml. With vaccines of lower titre the take rate was higher with the bifurcated needle technique than with the rotary lancet technique. However, the number of children included in this study was small and therefore definite conclusions cannot be drawn.

Results of placebo revaccinations

Altogether, 12 persons in each group were "revaccinated" with the vaccine diluent only, using both techniques. On the seventh day no signs were observed in persons "vaccinated" by the bifurcated needle technique while in those "vaccinated" by the rotary lancet technique, very faint signs were observed.

CONCLUSIONS

(1) With undiluted vaccine, the bifurcated needle technique gave a significantly higher take rate,

TABLE 3

DISTRIBUTION OF SUCCESSFUL TAKES IN REVACCINATION ACCORDING TO THE NUMBER OF INSERTIONS WITH VACCINES OF 3 DIFFERENT TITRES

Group	Titre of vaccine (pock-forming units/ml)	Technique employed	Total no. of successful takes	Persons with takes from 1 insertion		Persons with takes from both insertions		Percentage of persons with takes if insertion had been made	Percentage improvement
				Number	% (x)	Number	% (y)	$\left(z;\text{i.e., } y+\frac{x}{2}\right)$	$\left(\frac{z-y}{y} \times 100\right)$
A	1×10^8	Rotary lancet	31	10	32.3	21	67.7	83.9	23.9
		Bifurcated needle	44	3	6.8	41	93.2	96.6	3.6
B	5×10^7	Rotary lancet	17	6	35.3	11	64.7	82.4	27.4
		Bifurcated needle	38	10	26.3	28	73.7	86.9	17.9
C	1×10^7	Rotary lancet	15	10	66.7	5	33.3	66.7	100.0
		Bifurcated needle	36	14	38.9	22	61.1	80.6	31.9

TABLE 4

COMPARISON OF SUCCESSFUL TAKE RATES IN PRIMARY VACCINEES RESULTING FROM BOTH THE BIFURCATED NEEDLE AND ROTARY LANCET TECHNIQUES APPLIED TO THE SAME PERSONS

Group	Titre of vaccine (pock-forming units/ml)	Technique	Total primary vaccinations by single insertion	No. of children with successful takes	Percentage of successful takes
A	1×10^8	Rotary lancet	9	9	100.00
		Bifurcated needle	9	9	100.00
B	5×10^7	Rotary lancet	9	6	66.7
		Bifurcated needle	9	7	77.8
C	1×10^7	Rotary lancet	8	2	25.0
		Bifurcated needle	8	4	50.0

namely, 56.0% as compared with 26.2% by the rotary lancet technique. The proportion of major reactions produced by both techniques gradually decreased when vaccines of lower titre were used.

(2) When undiluted vaccine was used, the proportion of individuals showing a major reaction from both insertions of the bifurcated needle technique was 69.8% as compared with 44.9% with the rotary lancet technique. When vaccines of lower titre were used there was a gradual decrease in the take rate produced by both techniques although the bifurcated needle technique showed a higher take rate at all titres as compared with the rotary lancet technique.

(3) With a fully potent vaccine, there is little advantage in giving 2 insertions with a bifurcated needle but a significant improvement of 23.9% was observed when 2 insertions of a rotary lancet were employed. Similarly, with a weak vaccine, the improvement in the take rate from 2 insertions varied from 17.9%–31.9% with the bifurcated needle technique to 27.4%–100% with the rotary lancet technique. In areas where storage facilities for vaccine are inadequate, and particularly in rural field conditions where the potency of vaccines is likely to be slightly reduced, the use of 2 insertions with the bifurcated needle technique should be seriously considered.

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RÉSUMÉ

VACCINATION ANTIVARIOLIQUE: ÉTUDE COMPARATIVE DES TECHNIQUES UTILISANT L'AIGUILLE BIFURQUÉE OU LA LANCETTE ROTATIVE

On a recherché et comparé les avantages respectifs de l'emploi de l'aiguille bifurquée ou de la lancette rotative pour la primo-vaccination et la revaccination antivarioliques chez des écoliers de New Delhi (Inde). Trois préparations de vaccin ont été utilisées dont les titres, exprimés en unités formatrices de vésicule, étaient de 1×10^8/ml, 5×10^7/ml et 1×10^7/ml.

Dans un premier temps, trois groupes de 81, 82 et 84 enfants déjà immunisés ont été revaccinés simultanément par les deux techniques, un vaccin de titre différent étant utilisé dans chaque groupe. Des taux de prise nettement plus élevés ont été observés après emploi de l'aiguille bifurquée, indépendamment du titre du vaccin.

On a ensuite revacciné trois autres groupes d'enfants

en utilisant pour chaque groupe un vaccin de titre différent, la moitié des sujets, dans chaque série, étant vaccinés au moyen soit de l'aiguille bifurquée soit de la lancette rotative. Ici encore, l'aiguille bifurquée a fait preuve d'une nette supériorité sur l'autre instrument.

Enfin, on a procédé à la primo-vaccination, simultanément par les deux techniques, d'enfants répartis en trois groupes recevant chacun un vaccin de titre différent. Avec la préparation titrant 1×10^8 unités/ml, le taux de prise a été de 100%, quelle qu'ait été la technique utilisée. Avec les vaccins de titre inférieur, l'aiguille bifurquée a donné de meilleurs résultats que la lancette rotative.

Ces données confirment des observations antérieures. Il apparaît par ailleurs que si l'on utilise un vaccin très actif, il n'y a guère de profit à pratiquer deux inoculations à l'aide de l'aiguille bifurquée. Par contre, cette pratique améliore nettement les taux de prise en cas d'emploi d'un vaccin de titre faible. Elle est aussi la technique de choix lorsque les conditions locales de conservation du vaccin sont peu satisfaisantes.

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