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SIMULTANEOUS BCG AND SMALLPOX VACCINATION ON NEWBORN INFANTS

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Telah dikemukakan anggapan-anggapan yang terdapat dewasa ini tentang vaksinasi BCG dan cacar secara simultan.

Telah dilakukan vaksinasi BCG dan cacar secara simultan pada 729 neonati dengan freeze dried Smallpox vaccine buatan dari Bio Farma dan freeze dried BCG vaccine Tokyo.

Pencacaran dilakukan secara multiple puncture dan bifurcated needle dengan suntikan BCG dengan jarum dan spuit khusus intracutan dengan dosis 0,1 ml. Tuberkulin test dilakukan dengan PPD dari Kopenhagen dengan kekuatan 2 TU 9 minggu setelah vaksinasi.

Dari 741 bayi yang diikut sertakan dalam survey, 12 menolak, 3 bayi tidak dapat dilakukan pemeriksaan pertama, 35 bayi belum diperiksa, pemeriksaan pertama telah dilakukan pada 691 bayi. Dari 406 bayi yang seharusnya sudah diperiksa untuk pemeriksaan kedua, 23 dapat dilakukan karena tidak dapat dijumpai atau meninggal.

Telah dikemukakan bahwa pencatatan alamat yang jelas dan lengkap serta kesungguhan dalam melakukan home visits sangat penting untuk berhasilnya penyelidikan semacam ini.

Dari hasil-hasil yang didapatkan sampai sekarang telah dapat diambil kesimpulan sementara, bahwa vaksinasi BCG dan cacar secara simultan memberikan hasil yang memuaskan, juga bila dibandingkan dengan hasil-hasil penyelidikan diluar negeri take pada pencacaran 99.4 per cent, test tuberkulin dengan PPD 2 TU 9 minggu setelah vaksinasi memberikan indurasi lebih dari 5 mm pada 99.75 per cent dan tidak menimbulkan komplikasi-komplikasi.

Pelaksanaan vaksinasi BCG dan cacar dapat dilakukan oleh tenaga paramedis yang telah mendapat latihan khusus dan diawasi oleh dokter yang kompeten.

Dianjurkan untuk melakukan follow up pada bayi-bayi yang diikut sertakan dalam survey ini.

There are conflicting opinions as regard the effect of simultaneous BCG and Smallpox vaccination. Frequently it is held that simultaneous application of the two vaccines should be avoided, it being thought that the responses to the vaccination, would be adversely affected and complications arise. In some countries this opinion is reflected in the legislation and instructions relating to vaccination, which prescribe that there should be a certain interval between BCG vaccination and vaccination against Smallpox. This belief has so far not been proved or disproved by large scale strictly controlled studies.

Considering that many countries are at present planning to conduct immunization campaigns against a number of diseases, it would be useful to make a thorough investigation to determine whether combined BCG-Smallpox immunization programmes would result in satisfactory responses to both vaccinations without causing complications. Clearly such combined immunization programmes would permit great savings in staff, time and money as compared to separate programmes.

BCG vaccination on newborn infants in many countries has been done for quite a long time with good results as for example in Russia and Chechoslovakia BCG vaccination on newborn infants is compulsory (Cervenka

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et al, 1966). Vaccination against Smallpox on newborn infants in Indonesia has been proved to be an acceptable procedure. Now the question is, whether those two vaccinations could be given simultaneously with the consideration that they would give sufficient immunity for the corresponding diseases without causing undesirable complications compared with the separate procedure.

MATERIALS AND METHODS

Study population: The study population was newborn infants born in the following maternity wards or hospitals in Bandung city, Indonesia, during the period from May 1970 to May 1971 :

1. Department of Obstetrics and Gynecology, Central General Hospital "Dr. Hasan Sadikin".
2. Maternity Clinic "Sariningsih"
3. Maternity Clinic of the Health Center Andir.

Only the normal and healthy newborn infants with the birthweight more than 2.500 grams and the age not more than 28 days was given the vaccination. Vaccination was given with the mother's consent.

Technic of vaccination and vaccine products employed:

BCG vaccination: Freeze dried vaccine with Batch No. 11280 G prepared by the BCG Laboratory, Tokyo was used in this study. 0.1 ml of the reconstituted vaccine injected strict intracutaneously on the right shoulder using special syringe and physical needle for BCG.

Smallpox vaccination: Immediately after BCG injection, the same person does the Smallpox vaccination by multiple-pressure method using befurcated needle on the left shoulder. Smallpox vaccine used in this survey was in freeze dried form with Batch No. 1687, 1698, 2027, and 2451 prepared by P.N. Bio Farma, Bandung, Indonesia. These Batch numbers had been tested by WHO Central Laboratory.

Tuberculin testing: Mantoux test was done nine weeks after vaccination with PPD Tuberculin, RT 23 with Tween 80. The reaction was examined 48 or 72 hours afterwards.

Folow-up scheme: One week after vaccination the parents were asked to return their babies for examination. Reaction to Smallpox vaccination was observed and noted, the temperature was taken. Nine weeks after vaccination the second examination was performed, during which the cicatrix of Smallpox, the lesion at the site of BCG injection as well as the nutritional- and the general state of the child were noted. The parents were asked for a history of possible Encephalitis post vaccinalis. After the completion of the examination, Tuberculin testing was done and the result was read at the third examination 48 or 72 hours afterwards. If the parents did not bring their child for the first, second and third examination, homevisits were made in the afternoon of the same- or the next day.

Personnel : Four midwives and four nurses had been trained by a WHO expert to do the task. Each of them has done more than 200 vaccinations on schoolchildren and newborn infants before they began with this study. Administrative works done by a secretary and the whole survey supervised by the authors.

RESULTS

Included in this survey were 1.585 newborn infants, of which the parents of 22 refused the vaccination. Vaccination was done on 1.563 newborn infants. For several reasons 10 infants were not given the first follow-up examination, 66 failed to be examined on the second- and third examination. Four infants refused to be Tuberculin tested and 17 died before the age of 9 weeks.

Table 1. Number of infants asked to be vaccinated, the refusals and vacinated.

Number of infants asked to be vaccinated	Number of refusals	Number vaccinated
1.585	22	1.563

Table 2. Reasons for refusals

Reasons	Number of infants	Percentages
No clear reason	14	63.6
Grandmother's objection	2	0.9
Afraid of becoming ill	6	35.5
Total	22	100.0

Table 3 shows the reasons for the loss of infants at 9 weeks follow-up examination.

Table 3. Number of infants lost at 9 weeks follow-up examination by reasons.

Reasons	Number	Percentage
Moving of the family	53	54
Could not be located	24	24.5
Died before the age of 9 weeks	17	17.35
Refused to be Tuberculin tested	4	4.15
Total	98	100.00

Table 4 shows causes of death, age and sex of the 17 infants who died before the age of 9 weeks.

Table 4. Causes of death, by age and sex of the 17 infants who died before the age of 9 weeks.

No.	Reg. No.	Sex	Age (days)	Causes of death
1	0095	M	34	Bronchopneumonia
2.	0132	M	47	Fever, the cause was not known
3.	0341	M	12	Enteritis and dehydration
4.	0654	M	16	Enteritis and dehydration
5.	0690	M	10	Bronchopneumonia
6.	0693	M	17	Enteritis and dehydration
7.	0708	F	8	Tetanus neonatorum
8.	0750	F	62	Not known
9	0770	F	11	Enteritis and dehydration
10	0928	F	24	Bronchopneumonia
11	1387	F	64	Enteritis and dehydration
12	1405	M	50	Not known
13	1406	M	28	Not known
14	1860	M	38	Bronchopneumonia
15	2266	M	52	Invagination
16	2480	M	12	Not known
17	2484	M	36	Bronchopneumonia

Follow-up examination one week after vaccination:

a. General reaction.

Table 5. General reaction of the infants one week after vaccination.

Type of reaction	Number of infants	Percentage
mild	1.107	71.3
moderate	446	28.7
severe	–	–
Total	1.553	100.0

b. Body temperature.

Table 6. Body temperatures one week after vaccination.

Temperature (centigrade)	Number of infants	Percentage
36.0 – 36.4	377	24.24
36.5 – 36.9	844	54.44
37.0 – 37.4	322	20.67
37.5 – 37.9	8	0.52
38.0 – 38.5	2	0.13
Total	1.553	100.00

Smallpox vaccination.

Table 7. Results of Smallpox vaccination at one week.

Vesiculation	Number of infants	Percentage
present	1.480	95.5
absent	73	4.5
Total	1.553	100.0

Follow-up examination at 9 weeks after vaccination:

a. General condition.

Table 8. General condition of the infants 9 weeks after vaccination

Appearance	Number of infants	Percentage
looked good and fairly good	1.370	93.5
looked sick	95	6.5
Total	1.465	100.0

b. Nutritional state.

Table 9. Nutritional state of the infants 9 weeks after vaccination

Nutritional state	Number of infants	Percentage
good and fairly good	1.425	97.5
undernourished	40	2.5
Total	1.465	100.0

c. Cicatrix of Smallpox vaccination.

Table 10. Cicatriees of Smallpox vaccination 9 weeks after vaccination

Cicatrix	Number of infants	Percentage
present	1.420	97.0
absent	45	3.0
Total	1.465	100.0

It should be noted that the infants who showed "no take" at one week examination, the vaccination repeated.

d. BCG lesions.

Table 11. Frequency distribution by size of

Diameter of lesion (mm)	Number of infants	Percentage
No lesion	1	0.07
1	2	0.14
2	25	1.05
3	172	11.75
4	405	27.62
5	656	44.65
6	151	11.12
7	29	1.98
8	21	1.41
9	2	0.14
10	1	0.17
Total	1.465	100.00

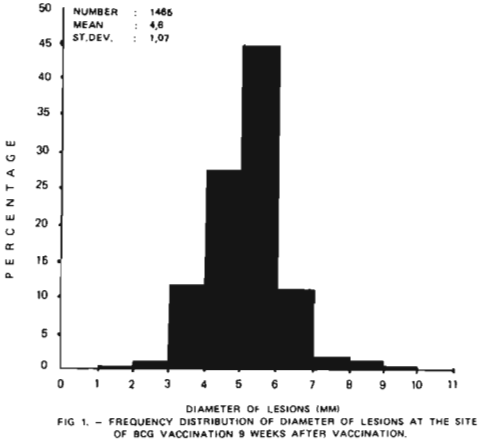

FIG 1. – FREQUENCY DISTRIBUTION OF DIAMETER OF LESIONS AT THE SITE OF BCG VACCINATION 9 WEEKS AFTER VACCINATION.

Table 2. Reasons for refusals

Reasons	Number of infants	Percentages
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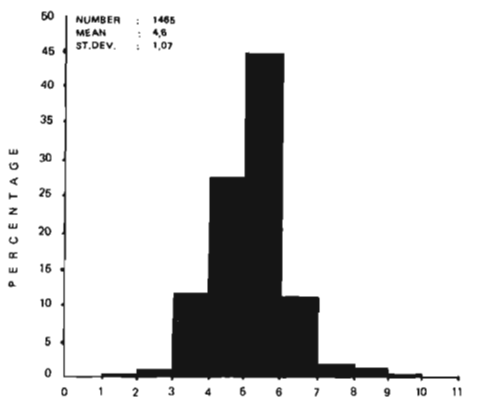

FIG 1. – FREQUENCY DISTRIBUTION OF DIAMETER OF LESIONS AT THE SITE OF BCG VACCINATION 9 WEEKS AFTER VACCINATION.

e. Mantoux reaction.

Table 12. Frequency distribution by size of Tuberculin indurations 9 weeks after vaccination tested with 2 TU PPD Tuberculin RT 23 with Tween 80

Diameter of induration (mm)	Number of infants	Percentage
0 – 1	9	0.61
2 – 3	22	1.50
4 – 5	51	3.45
6 – 7	248	16.90
8 – 9	319	21.80
10 – 11	403	27.50
12 – 13	208	14.20
14 – 15	94	6.40
16 – 17	57	3.85
18 – 19	33	2.25
20 – 21	8	0.55
22 – 23	2	0.14
24 – 25	10	0.77
26 – 27	1	0.08
Total	1.465	100.00

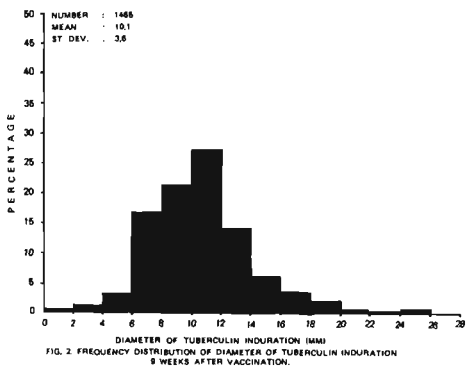

FIG. 2. FREQUENCY DISTRIBUTION OF DIAMETER OF TUBERCULIN INDURATION 9 WEEKS AFTER VACCINATION.

DISCUSSION

Out of 1.585 infants the parents of 22 refused to have their babies vaccinated. Their reasons were not clear. Some said that the grandmother would not allow it, while others were afraid their babies would become ill. Actually the number of the refusals was lower than expected.

About 50 per cent of the vaccinated infants did not come to the office for the first follow-up examination, and more than 75 per cent failed to come for the second- and third examination. Most of the reasons were :

1. They forgot to do it.
2. They thought it was not very important.
3. Their belief that a baby should not be taken outside the house before the age of 40 days.
4. They could not afford transportation cost.

It is clear from these findings that in conducting such a study, necessary steps should be taken to overcome the handicaps such as:

1. To stress to the personnel the importance of homevisits.
2. To allocate a budget for homevisit transpostation cost.
3. A clear and complete adress of the parents should be noted at the time of vaccination.

Smallpox vaccination: Regarding the criterion for a successful Smallpox vaccination the authors refered to the Report of the WHO expert Committee on Smallpox in WHO Tech. Rep. Series No. 283:20 (1964): "A successful primary vaccination is one which, on examination after one week, shows a typical Jennerian vesicle". In this study the typical vesiculation were present in 1.480 out of 1.553 infants one week anter vaccination (95.5 per cent). This figure was indeed a good result, and that is true when compared for instance with the figure obtained by Lin, N.T. et al in 1965 (75.7 per cent). This better result might be due to the difference of the vaccination method. In this study multiple-pressure method was used instead of scratching method used Lin, H.T. et al.

Constitutional symptoms and signs observed one week after vaccination were mild in 1.107 infants (71.3 per cent), moderate in 446 infants (28.7 per cent) and none of them showed a severe reaction. Body temperatures varied from 36.0 to 38.5 C. No complications were observed.

BCG vaccination: Diameter of the BCG lesions 9 weeks after vaccination varied from 0 to 10 mm with a mean of 4.6 mm. Most of the lesions were covered by scabs and only 4 babies had open ulcers with the diameter from 2 to 5 mm.

Regarding the criteria of BCG complications, Ustvedt in the Conference on European BCG Programmes, suggested:

a. Reaction at the site of BCG injection.
"It seems reasonable, however, to fix the limit for a strong local reaction at 10 mm, and to disregard the cases where there is only induration, and no ulcer or scab. The few cases where a real abscess is found at the site of vaccination must, of course, be included in the term strong local reaction".

b. Glandular enlargement.
"In connection with BCG vaccination it seems reasonable to classify as complications only the cases where the enlargement of the glands reaches such a degree that it is disagreeable, and the cases where suppuration takes place, perhaps also the cases where glands are enlarged which do not belong to the strictly regional lymphglands".

Refering to the above criteria, there was no strong reaction or complication observed in this study.

Regarding the immunity after BCG vaccination, Lydia B. Edwards et al (1953) wrote: "BCG induced allergy as commonly used as an index of the immunity to TBC presumably engendered by vaccination. If the vaccinated person develops a Tuberculin reaction exceeding a specified size to a specified dose of Tuberculin, the vaccination is considered successful; if not the vaccination is regarded as a failure because sufficient allergy was not induced". The results of Tuberculin testing with 2 TU PPD Tuberculin, RT 23 with Tween 80, 9 weeks after vaccination are shown in Table 12 and Figure 2. The diameter of indurations varied from 0 to 27 mm with a mean of 10.1 mm. What is the diameter of Tuberculin induration that can be regarded as positive (when sufficient allergy is induced)? This question is difficult to answer. The logical way to evaluate this, is to make a controlled study. A group of children with the same criteria as study population should be used as controlled group. After 9 weeks the same Tuberculin testing should be performed on both groups and then compared the Tuberculin induration obtained between the two groups; unfortunately we could not effect such a study. We only can compare our results with the results obtained by other authors. Most of the authors regarded the diameter of Tuberculin induration of 6 mm and more as positive (Cervenka et al, Lin, H.T. et al). If the same limit is used in this study we get the positive result in 1.383 out of 1.465 infants (94.4 per cent). This figure is higher than the figure obtained by Cervenka et al (84.6 per cent) for Danish vaccine and 82.5 per cent for Swedish vaccine) and almost the same with the figure obtained by Moodie et al in Hongkong, 1962 (94.8 per cent) (as cited by Lin, H.T. et al).

One might ask, whether simultaneous vaccination might worsen the general condition of the infants and so indirectly increase the susceptibillity and lower the general resistance to the common disease during early infancy. The best way to answer this, of course, is with a controlled group study, and as we said before, we could not effect it here. To give some impression about this problem, the general condition and nutritional state of the infants were noted at the second examination. It can be seen from Table 8 and 9 that there were only 95 out of 1.465 infants were looked sick (6.5 per cent), and 40 out of 1.465 infants were undernourished (2.5 per cent). These figures were not much different from those of the Health Center.

As it can be seen from Table 4, there were 17 infants who died before the age of 9 weeks. To find out the causes of death we tried to ask the parents, the doctors who treated them, and the hospital where they were admitted. On 5 infants the causes of death were not clear, 5 died of Bronchopneumonia, 5 of Enteritis and dehydration, 1 of Tetanus neonatorum, and 1 of Invagination. It is the

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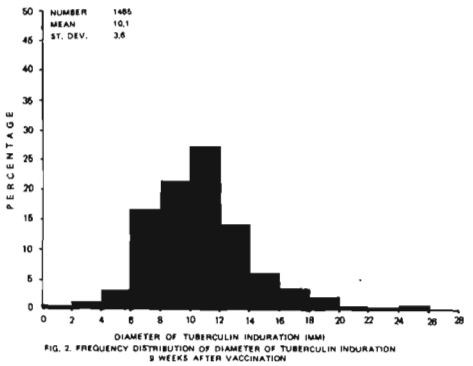

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authors opinion that these causes of death are not related to the vaccination.

One might ask whether BCG and Smallpox vaccination should be given by two persons or could these two vaccination be done by one person only. This study did not try to evaluate these two possibillities. In this study BCG and Smallpox vaccination were done by one person, and the results were favourable. For practical purposes this "one-person-for-two vaccination method" would be more practical.

BCG and Smallpox vaccination should be successful if done by adequately trained paramedical personnel, midwives and/or nurses, under the continuous supervision of a competent and dedicated officer.

SUMMARY AND CONCLUSION

Conflicting opinions have been put forward about simultaneous BCG and Smallpox vaccination. Parents of 1.585 newborn infants born in the Obstetrics and Gynecology Department of the Central General Hospital "Dr. Hasan Sadikin", Maternity Clinic "Sariningsih" and Maternity Clinic of the Health Center "Andir", all in Bandung city, were asked to have their babies simultanously vaccinated. Parents of 22 of these infants refused. Their reasons were: not clear, afraid of becoming ill, and grandmother would not allow it.

Follow-up examinations were done at 1 week and 9 weeks after examination on 1.563 vaccinated infants. At the second examination Mantoux test with 2 TU PPD Tuberculin, RT 23 with Tween 80, were performed and the results were read 48 or 72 hours afterwards (third visit). 98 infants were lost during the entire follow-up scheme period: 10 at the first examination, 88 at the second and third examination. Reasons for the loss of the infants were: moving of the family 53; their home could not be located on homevisit 24; died before the age of 9 weeks 17; refused to be Tuberculin tested 4.

Smallpox vaccination: Vesiculations were present one week after vaccination in 1.480 out of 1.553 vaccinated infants (95.5 per cent). Constitutional symptoms were mild in 1.107 infants (71.3 per cent), moderate in 446 (18.7 per cent) and none of them showed severe reactions. Temperatures varied from 36.0 to 38.5 C.

BCG vaccination: Diameter of Tuberculin indurations 9 weeks after vaccination as tested with 2 TU PPD Tuberculin, RT 23 with Tween 80, varied from 0 to 27 mm with a mean of 10.1 mm. Diameter of 6 mm and more was found in 1.383 out of 1.465 infants (94.4 per cent).

Complications: No complications either from Smallpox or from BCG vaccination were observed.

The discussion has stressed the importance of homevisits and related factors.

Opinions of some famous authors have been cited regarding the criteria of a successful vaccinations as well as its complications. Referring to these opinions, which are generally accepted, simultaneous BCG and Smallpox vaccination in this study had satisfactory results without causing any complication.

The authors have tried to give the impression that simultaneous BCG and Smallpox vaccination did not increase the susceptibillity or lower the general resistance against the common diseases during early infancy.

It has been suggested that further follow-up and observation of the vaccinated children is very important to get better evaluation of the efficacy of the vaccination in the community, so that it might be used as a fundamental basis for the policy of the TBC and Smallpox Control Programmes in the future.

The authors are of the opinion that BCG and Smallpox vaccination can be done by paramedical personnel, if they are adequately trained and supervised by a competent and dedicated officer. One person for the two vaccinations would be more practical and efficient.

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