Protective Plastic Film Dressing in Smallpox Vaccination

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A DRESSING on the site immediately after smallpox vaccination frequently is of value. If the vaccinated person has eczema, a dressing will reduce the risk of secondary lesions. A dressing will also prevent secondary inoculation from vaccinated hospital personnel to patients. Moreover, many vaccinators regularly cover the vaccination site although there is no strict medical requirement for doing so.

Gauze pads applied on the vaccination site after the vaccine has dried seem to be the most common type of dressing. The pads usually are not removed until the patient sees the physician again, at which time a pustule commonly has developed. Removing the gauze pad then can be difficult. Also, secondary pustules often develop as a result of skin reactions to the adhesive tape.

Therefore a dressing without the disadvantages of gauze pads is desirable. An aerosol of plastic in a solvent which dries and forms a thin film almost instantly after application offers several advantages, especially during mass vaccination programs.

This study was undertaken to investigate the advantages of a commercially available plastic aerosol, Nobecutan (*A*), or Rezifilm, as it is known in the United States, as a dressing for vaccination sites. The plastic dressing was compared to the traditional gauze pad, and special attention was given to the possibility that the plastic might affect the vaccine and thus influence the number of positive vaccination results.

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Method

The plastic material in the aerosol is a metacryl dissolved in ethylacetate and when dry is resistant to mechanical wear. According to the manufacturer, the film is permeable by water vapors. Therefore evaporation from the normal skin is unaffected. The dressing, however, is impermeable to water. The film, which can be removed instantly by using a special solvent or an alcohol-ether mixture, normally remains on the skin 2–4 days after which it is gradually shed. The aerosol solution also contains an antiseptic compound, tetramethylthiuramdisulfide, which is strongly antibactericidal and antifungal (*1*). The plastic is sprayed from an aerosol package to the desired site.

The 751 persons in this study were vaccinated during 1966 and 1967, and most of them were participants in the regular smallpox vaccination program of the staff at the Hospital for Infectious Diseases in Stockholm. In addition, a mass vaccination campaign was conducted among the personnel at the National Institute of Public Health in Stockholm.

Vaccinees included males and females in different age groups. The majority were younger females. The vaccinees were not classi-

fied by age or sex because these factors were not considered likely to influence the subject of this study, that is, the effect of the covering on the result of the vaccination.

The standard inoculum, an egg vaccine manufactured by the National Bacteriological Laboratory in Stockholm, had a titer of about $10^{7.4}$ $TCID_{50}$ per milliliter (*2*). A more potent vaccine, which had a titer about $10^{8.1}$ $TCID_{50}$ per milliliter, was used to revaccinate persons who had reacted positively to vaccination within the past 5 years. If no positive result was obtained from two inoculations with the standard vaccine, the more potent vaccine was used subsequently.

Only 67 persons were given the standard vaccine, and except for a slightly higher percentage of positive results they did not differ from the group inoculated with the more potent vaccine. To achieve maximum uniformity among the participants, only the 684 persons initially vaccinated with the more potent vaccine were included in this study.

I vaccinated all the participants by using the multiple pressure technique. The initial vaccination was performed on the back of the upper part of the left arm. Subsequent revaccinations were alternated between the right and the left arms.

The aerosol was applied before the vaccine had dried. The spray was pointed directly at the vaccination site. The gauze pad dressing was applied on the site after the vaccine had dried, which took 3–5 minutes.

The results were read 4–8 days afterward. A reaction was considered positive only if a crusta was observed. All cases of papules or infiltration of the inoculated site were deemed negative, and the persons were revaccinated.

The investigation was divided into three phases. In the first phase the aerosol spray and the gauze pad were applied to alternate vaccinees. In this phase the dressing of the site was known when 237 vaccinations were performed.

In the second phase, which involved 371 vaccinees, all persons born on odd numbered days were sprayed with the aerosol, and those born on even numbered days had gauze pads applied. During the second and third phase the intended treatment of the inoculation site was unknown when the vaccination was given. In the second phase the size of the crusta was recorded when the vaccination result was read.

In the third phase, 76 employees of the National Institute of Public Health in Stockholm participated in a mass vaccination program on a voluntary basis.

For all revaccinations of persons with negative reactions, treatment of the site was altered so that persons who had been sprayed with the aerosol or had the gauze pad applied on the previous vaccination received the other form of dressing.

Results

The percentage of positive results for all vaccines was 89 percent for the group whose vaccination sites were sprayed with the aerosol and 84 percent for the group whose vaccination sites were dressed with a gauze pad (table 1). In none of the three phases did the application of the plastic film exert a negative effect on the number of positive results.

Indeed, a slightly larger number of positive results was found in the group given the aerosol dressing. However, this difference was not statistically significant in any of the three phases of the investigation or in the entire study.

The sizes of the vaccination crustae were measured in phase two of the investigation

Table 1. Results after smallpox vaccination, by type of dressing

Phase of investigation	Number of vaccinees	Plastic film				Gauze pad			
		Positive		Negative		Positive		Negative	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
1	237	106	88	15	12	94	81	22	19
2	371	188	88	25	12	137	87	21	13
3	76	32	---	1	---	34	79	9	21
Total	684	326	89	41	11	265	84	52	16

Table 2. Distribution of size of smallpox vaccination crustae in phase 2, by type of dressing

Size of crusta (millimeters)	Plastic film		Gauze pad	
	Number	Percent	Number	Percent
1–2	69	38	48	35
3–4	58	32	47	34
5–6	32	18	29	21
7–8	12	7	8	6
>8	9	5	6	4
Total	180	100	138	100

(table 2) and compared by type of dressing applied. No appreciable difference due to the type of dressing applied was noted. The outcome of revaccinations of primarily negative vaccinees was also unaffected by the type of dressing applied (table 3).

Comments

The number of positive reactions among the vaccinees was about the same as reported earlier in a similar study (*3*). Differences in vaccination technique and the immunological status of vaccinees make comparisons with the observations in this study and those of other authors difficult.

Although I read all the results in this study, I believe there is no appreciable bias in the readings. The majority of the positive reactions were typical, with a pustule and induration of the vaccination site. Most of the negative reactions were easily classified because no evidence of vaccination could be detected at the site. When there was no typical crusta, the vaccination was deemed negative.

These vaccination trials clearly showed that the use of plastic film is of great value if the vaccination site is to be dressed. Immediate application obviates waiting until the vaccine has dried, and knowing they can bathe as usual comforts many vaccinees. The bactericidal and fungicidal properties of the film may help to prevent secondary infections in the vaccination wound. However, this possibility was not experimentally investigated.

Throughout the investigation the aerosol was used as a dressing when pustules developed. This prevented secondary pustules in reaction sites of persons hypersensitive to adhesive tape applied to gauze pad bandages. Only one of 367 vaccinated persons who received the aerosol was hypersensitive to the plastic. A rash without papules developed within 24 hours but disappeared within 1 day without treatment. This person had a history of hypersensitivity to many other substances, including adhesive tape.

Summary

The objective of this study was to determine the merits of a plastic aerosol, Nobecutan, or Rezifilm as it is known in the United States, as a dressing for smallpox vaccination sites. The aerosol, which dried as a protective film, was compared with the traditional gauze pad dressing, and special interest was given to the possible effect of the plastic on the number of positive vaccination results.

The percentage of positive results for all 684 vaccinees was 87 percent for 367 persons whose vaccination sites were sprayed with the aerosol and 80 percent for 317 persons whose vaccination sites were dressed with a gauze pad. Application of the plastic film did not exert a negative effect on the number of positive results.

From a practical point of view, the plastic

Table 3. Results of revaccination of persons with negative reactions, by type of dressing

Revaccination number	Number of persons revaccinated	Plastic film			Gauze pad		
		Positive	Negative	Percent negative	Positive	Negative	Percent negative
1	51	3	23	88	9	16	64
2	37	14	8	36	10	5	33
3	12	4	4	----	2	2	----
4	4	2	1	----	1	----	----

film offered several advantages over the gauze pad dressing, including prevention of secondary pustules on persons sensitive to adhesive tape.

REFERENCES

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(*2*) Espmark, Å. J.: Tissue culture end-point titrations as a routine potency test for smallpox vaccine. Arch Ges Virusforsch 15: 35–49 (1964).

(*3*) Rylander, R.: Smittkoppsvaccinering av sjukhuspersonal. (Smallpox vaccination of hospital personnel.) Svenska Läkartidn 59: 3793–3800 (1962).

SUPPLY REFERENCE

(*A*) AB Bofors Nobel-Pharma, Mölndal, Sweden.

Revocation of Licenses for Normal Human Plasma

Manufacturers holding licenses for normal human plasma have been requested not to sell or ship it in interstate or foreign commerce. In a statement to these manufacturers, the director of the Division of Biologics Standards, National Institutes of Health, Public Health Service, cited persuasive evidence that "combined treatment of normal human plasma with ultraviolet irradiation and storage at 30–32° C. for 6 months under closely controlled commercial supervision does not eliminate the risk of hepatitis." In a 3-year controlled study, 10 percent of the patients receiving the plasma (which was treated and stored as described) became ill within 6 months.

The evidence cited appeared in a report entitled "A Controlled Study of the Safety of Pooled Plasma Stored in the Liquid State at 30-32° C. for Six Months," by A. G. Redeker, C. E. Hopkins, B. Jackson, and P. Peck, and a statement of the Committee on Plasma and Plasma Substitutes of the National Research Council in the March–April 1968 issue of *Transfusion.*

The director's statement concluded that "unless data are made available which refute substantially the conclusions necessarily drawn from the cited papers, appropriate steps will be taken on June 15, 1968, to revoke all presently issued licenses for normal human plasma."