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Author(s)	Konno, Tasuke; Yamaguchi, Yoshiko; Minegishi, Masayoshi et al.
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# A CLINICAL TRIAL OF LIVE ATTENUATED VARICELLA VACCINE (BIKEN) IN CHILDREN WITH MALIGNANT DISEASES

TASUKE KONNO, YOSHIKO YAMAGUCHI,  
MASAYOSHI MINEGISHI, YOICHI GOTO and  
SHIGERE TSUCHIYA

Department of Pediatrics, Tohoku University School of Medicine, Sendai, Miyagi, 980 Japan

The live attenuated varicella vaccine (Biken) derived from the Oka strain was used for immunization of childhood cancer patients in remission but on chemotherapy. Thirty nine patients were immunized without any severe adverse effects but 6 recipients had a small number of vesicles. Seroresponses were observed in 90% of recipients examined. During the follow-up period 6 leukemia recipients were suffered from natural varicella in family or community contacts. No vaccinee developed herpes-zoster during this study period.

Varicella has been known to be more severe in children with malignant diseases (Feldman et al., 1975). The successful development of a live attenuated vaccine by Takahashi et al. has made the most significant advance in prevention of varicella (Takahashi et al., 1975; Asano et al., 1975; Izawa et al., 1977). In this study a clinical trial of the live varicella vaccine (Biken) was carried out in children with cancer.

## VACCINE

The vaccine used in this study was supplied as a lyophilized preparation by Dr. Takahashi, Research Institute for Microbial Diseases, Osaka University, Osaka. The dose of vaccine was 0.5 ml and administered subcutaneously.

## VACCINEE

The live vaccine was given to 39 patients consisting of 30 with acute leukemia, 3 with chronic leukemia, 4 with neuroblastoma, and 2 with rhabdomyosarcoma. Their status of malig-

nancy was in remission in all but 3 patients who received the vaccine because of occurrence of varicella in the hospital ward. All recipients were on chemotherapy. Their age ranged from 3 months to 10 years with a mean of 3.3 years.

## FOLLOW-UP OBSERVATION

As shown in Table 1 the observation period after immunization ranged from 6 months to

TABLE 1. *Follow-up periods after immunization*

Follow-up period	Living	Died
>6 years	2	
5-6	2	
4-5	3	2
3-4	4	1
2-3	3	3
1-2	4	6
<1	3	6
	21	18

TABLE 2. *Varicella in leukemia patients after immunization*

Patient	Immunization			Onset of varicella (interval <sup>b</sup> , month)
	Date (age)	Status	Serologic response <sup>a</sup>	
W. S.	Nov. 21, '77 (4)	6 months in remission	<2/2	Jul. 1, '79 (19)
I. A.	Nov. 29, '77 (4)	6 months in remission	<2/<2	Jan. 4, '80 (25)
K. K.	Jan. 17, '78 (3)	6 months in remission	<2/16	Jul. 4, '79 (17)
W. K.	Jan. 18, '80 (3)	soon after "induction"	<2/32	Apr. 30, '81 (15)
S. M.	Apr. 18, '81 (2)	soon after "induction"	—	Jan. 22, '82 (9)
K. T.	Feb. 17, '82 (4)	20 months in remission	—	Apr. 5, '83 (14)

<sup>a</sup> IAHA titers, Pre-/Post-immunization.<sup>b</sup> Between immunization and onset of varicella.

more than 6 years among the living recipients and from 2 months to 4 years among the dead recipients.

#### OCCURRENCE OF VARICELLA AFTER IMMUNIZATION

During the follow-up periods 6 patients with acute leukemia developed varicella in contact to natural varicella 9 to 25 months after immunization (Table 2). Three (E.S., I.A., K.K.) of them received the vaccine of the same lot which was supplied in 1977. It seemed to be related to either low dose or viability of vaccine administered. Two (W.K., S.M.) were vaccinated soon after remission induction therapy for leukemia. The time for vaccination seemed to be inappropriate in these patients. The patient, K.T., received vaccine in a state of complete remission and was suffered

from varicella 14 months later. However, varicella in those 6 patients was mild and lasted only a few days.

#### SERORESPONSE

The immune adherence hemagglutination (IAHA) assays (Yamada et al., 1979) were carried out on serum specimens collected before and 2 to 4 weeks after vaccination. Out of 20 recipients examined 18 showed significant rise of antibodies against varicella.

#### CONCLUSION

Based on the above observation it may be concluded that the live attenuated varicella vaccine (Biken) can be used effectively in prevention for patients with malignant diseases without any severe adverse effects.

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