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**Immunogenicity and reactogenicity of 2-doses of live attenuated varicella (Oka strain) vaccine in Indian children**

Monjori Mitra, Choudhary J, Basu S, Halder P, Poddar S, Bahrus KG and Jayan S  
Institute of Child Health, India

**P**roblem Statement: Incomplete prevention of varicella outbreaks, despite effective single dose varicella vaccination has led United States adopting 2-dose regimen as per CDC surveillance data, with the objective to further decrease varicella morbidity & outbreaks. Subsequently, Indian Academy of Paediatrics also recommended 2-dose schedule since 2011. A 3-month interval 2 dose regimen has demonstrated better effectiveness & less breakthrough infections as compared to 4-6 year interval regimen. Coverage of varicella vaccination is limited in India due to its absence in National immunization program. This study aims to evaluate the 2-dose regimen with 3 months interval in Indian children to explore possible benefits. Methodology: This prospective, single arm study included children of 1-12 years old without prior history of varicella infection or vaccination, who were administered 2 doses of live attenuated varicella (Oka strain) vaccine, 3 months apart. The anti-varicella antibody (anti-VZV) titres were measured using validated ELISA assay at baseline, and 28 days after 1st and 2nd dose of vaccination. The mean GMT

and sero-conversion rates (defined as anti-VZV > 10 mIU/ml or multi-fold rise in titres) were determined. Safety assessment included monitoring of solicited and unsolicited vaccine related adverse events. Findings: The mean age of completers (n=279) was 4.45±2.89 years (51.8% males). Amongst baseline sero-negative subjects (anti-VZV < 10 mIU/ml), 99.3% and 100% subjects achieved successful sero-conversion after 1st and 2nd dose respectively. The GMTs achieved were 97.74 mIU/ml (85.94-109.55, p<0.001) and 772.27 mIU/ml (756.89-787.66, p<0.001), respectively, indicating significant increase in GMT after second dose from that of first dose. Adverse events were reported in 21.3% subjects, (including 5 serious events, unrelated to vaccine). All events were mild in nature, with pain (32.5%), redness (19.2%) and fever (9.2%) being most common. Conclusion: Two dose varicella vaccine regimens with 3 months interval demonstrated high immunogenicity with better tolerability in Indian children and can be an effective regimen.

**Biography**

Monjori Mitra is an award winning pediatrician, academician, researcher, author, editor, clinical investigator and office bearer of Indian Academy of Paediatrics. She serves As Associate Professor of paediatric medicine in the esteemed Institute of Child Health, Kolkata. Her area of expertise is paediatric vaccinology and nutrition. She carries a rich clinical experience of more than 20 years in pediatric medicine. She has served in the capacity of executive member of Indian Pediatric Society. She has been advisor to the editorial board of Indian Journal of Practical Pediatrics and Indian Pediatrics. She has been honorary speaker at various international and national conferences and forums. She has authored various articles, journals and books on vaccines, vaccinology, and pediatric diseases with various national and international publications in indexed journals. She has been the Principal investigator for a number of clinical trials conducted in pediatric population across several therapeutic areas.

monjorimr@gmail.com

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