INTRAMUSCULAR INJECTION AS A PROVOKING FACTOR FOR PARALYSIS IN ACUTE POLIOMYELITIS A CASE CONTROL STUDY

N. Deivanayagam
K. Nedunchelian
S. Shaffi Ahamed
T.P. Ashok
N. Mala
S.R. Ratnam

ABSTRACT

In order to identify the role of intramuscular injection (IM) as a provoking factor for poliomyelitis, a case control study as done at the Institute of Child Health, Madras from May 1988 to May 1989. The case was defined as acute poliomyelitis if he had acute asymmetric flaccid paralysis of lower motor neurone type without objective sensory disturbance following a short episode of fever. Controls were taken from children attending outpatient department for fever. Two controls matched for aged and sex were recruited for each case. Recruitment, data collection and clinical examination were done by a single pediatrician. IM injection received within 30 days prior to onset of paralysis or illness was considered to be the risk factor.

The total number of cases and controls recruited were 257 and 515, respectively. Among cases, 172 (66.9%) out of 257 and among controls 252 (48.9%) out of 515, received IM injection within one month earlier to onset of paralysis or illness. The overall risk of paralysis, estimated for IM injection, was increased [odds ratio (OR) 2.1 (95% CI, 1.5-3.0)]. The maximum risk for paralysis was observed to be 2 weeks preceding the illness; the ORs for <7 days was 2.2 (95% CI, 1.6-3.2) and for 7-13 days 3.2 (95% CI, 1.8 to 5.8). The risk of paralysis associated with IM injection was similar for unimmunized and immunized cases (OR 2.4 and 2.2). Multiple injections were not associated with a higher risk of developing paralysis. Other factors observed to be risk for poliomyelitis included maternal illiteracy, OR 2.1 (95% CI, 1.4-2.9) and an unsafe way of excreta disposal, OR 1.5 (95% CI, 1.1-2.2). We conclude that IM injections should be avoided for children with fever of undetermined or viral origin.

Key words: *Acute poliomyelitis; Intramuscular injection.*

India is in the process of controlling poliomyelitis and aiming at eradication. Apart from immunization coverage, there is a need to search for and avoid other factors contributing to acute poliomyelitis. One of the important factors incriminated to provoke paralysis when the child is incubating poliovirus, is intramuscular (IM) injection(1-3). It is common practice to give either an antipyretic or an antibiotic as injection for patients seeking advise for fever. There have been descriptive studies in Indian literature stating history of IM injections, ranging from 42 to 70%, prior to the onset of paralysis(4-6). However, these studies do not link the causal association and the magnitude of risk. This study was part of a large study on different aspects related to control of poliomyelitis. The objective was to find out the role of IM injection as a provoking factor if given within one month prior to onset of illness and other factors contributing to occurrence of acute poliomyelitis.

From the Clinical Epidemiology Unit, Madras Medical College and Advanced Center for Clinical Epidemiological Research and Training, Institute of Child Health, Madras.

Reprint requests: Dr. N. Deivanayagam, CEU/ ACCERT, Institute of Child Health, Hall's Road, Egmore, Madras 600 008.

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Material and Methods

All children, under 5 years with acute poliomyelitis, admitted at the Institute of Child Health, Madras during May 1988 to May 1989 were studied. The case was defined as suffering from acute poliomyelitis if he had acute asymmetric flaccid paralysis of lower motor neurone type without objective sensory disturbances following a short episode of fever(7). Controls were children selected at random from outpatients attending the hospital for upper respiratory tract infection or probable viral fevers. Two controls, age and sex matched were recruited for each case. Age of the controls was exactly matched for the cases less than 12 months, ±1 month for 12-23 months and ±2 months for cases older than 23 months. For all the cases and controls, demographic data and symptoms were elicited.

Details of injection including the date, number and site of injections were elicited. Nature of medicine was ascertained and confirmed wherever the prescription was available. Data collection and clinical examination was done by a single pediatrician throughout the study. IM injection received within 30 days prior to onset of paralysis or illness was considered to be a risk factor. Drinking water from corporation tap was considered as protected water supply and the rest as unprotected (well, river, pond). Using flush type of lavatory was considered as a safe way of excreta disposal and others as unsafe (dry lavatory and open air defection).

Statistical Methods

Odds Ratio (OR) and 95% Confidence Interval (CI) was arrived at for IM injection and for other factors by univariate analysis. Mantel Haenzel (MH) test was used for controlling age and immunization status. The factors like parents' literacy, water source, excreta disposal, immunization status and IM injection were included to effect adjustment for confounding. Logistic regression analysis by SPSS PC+ was used to assess the risk contributed by individual factors.

Results

Total number of cases and controls recruited were 257 and 515, respectively. The distribution of cases and controls among various age groups is shown in *Table I.* A total of 32% of cases were under 12 months and 78.6% were under 24 months of age. Among cases, 172 (66.9%) out of 257 and among controls 252 (48.9%) out of 515 received IM injection within one month earlier to onset of paralysis or illness. The overall risk estimated for IM injection for paralysis was 2.1 (95% CI, 1.5-3.0). After controlling for age by Mantel Haenszel test, the higher exposure rate of IM injection was significant for cases ($p<0.001$). The risk of paralysis associated with IM injection in relation to time period prior to paralysis is shown in *Table II.* There was maximum risk for paralysis if the child received IM injection between 7 and 13 days prior to illness. There was no dose response relationship between the number of injections and the risk of paralysis. Odds ratios estimated for those who received one, 2-5, and more than 5 injections are 2.9 (95% CI, 2.0-4.3), 2.1 (95% CI, 1.4-3.1) and 1 (95% CI, 0.4-2.5), respectively. Multiple injections were not associated with more risk.

There was statistically significant difference in the risk of paralysis in relation to immunization status 0, 1, 2 or 3 doses, ($p<0.001$). Among cases, the upper limb involvement was 11.6 and 10.5% among

TABLE I—*Age Distribution and IM Injection Status*

Age (mo)	Cases (n=257)				Controls (n=515)			
	IM injection		No. injection		IM injection		No. injection	
	n	(%)	n	(%)	n	(%)	n	(%)
2– 5	16	(9.3)	4	(4.7)	30	(11.9)	15	(5.7)
6–11	42	(24.4)	20	(23.5)	59	(23.4)	63	(23.9)
12–17	55	(32.0)	29	(34.1)	87	(34.5)	74	(28.1)
18–23	21	(12.2)	15	(17.7)	38	(15.1)	34	(12.9)
24–35	25	(14.5)	14	(16.5)	28	(11.1)	49	(18.6)
>35	13	(7.6)	3	(3.5)	10	(4.0)	28	(10.7)
Total	172		85		252		263	

χ^2 = 21.93, p<0.001; Mantel Haenszel OR 2.4 (95% CI 1.8–3.2).

TABLE II—*Risk of Paralysis Associated with IM Injection in Relation to Time Prior to Paralysis.*

Time period (days)	Cases*	Controls*	OR	(95% CI)
No injection	85	263	1.00	
< 7*	111	153	2.20	(1.6–3.2)
7–13*	31	30	3.20	(1.8–5.8)
14–20*†	27	59	1.40	(0.8–2.4)
21–29†	3	10	0.93	(0.3–3.5)

* χ^2 = 7.22, p=0.03.
† taken together as single value for statistical significance.

those who received and did not receive IM injection respectively. The lower limb involvement was 97.7% among both who received and not received injections. An association between the limb injected and limb paralysed was observed, right lower limb 16/38 (42%), left lower limb 15/45 (33%) and both lower limbs 28/69 (41%).

Table III shows the crude ORs for risk factors for paralysis. By univariate analysis the factors associated with paralysis were unimmunized child, OR 14.2 (95% CI, 9.0-22.5); unsafe excreta disposal, OR 2.4 (95% CI, 1.8-3.3); unprotected water supply, OR 1.9 (95% CI, 1.4-2.6); and parental illiteracy, OR 1.8 (95% CI, 1.3-2.5). After adjusting by logistic regression, the risks observed were, unimmunized child, OR 5.3 (95% CI, 3.9-7.8); IM injection, OR 1.9 (95% CI, 1.3-2.7) and maternal illiteracy, OR 2.1 (95% CI, 1.4-2.9).

Discussion

Intramuscular injections during the

TABLE III–*Risk Factors for Acute Paralytic Poliomyelitis*

	Cases		Controls		Crude OR*	Adjusted OR
	n=257	(%)	n=515	(%)	(95% CI)	(95% CI)
IM injection						
No	85	(33.1)	263	(51.1)	1	
Yes	172	(66.9)	252	(48.9)	2.1 (1.5–2.9)	1.9 (1.3–2.7)
Immunization status						
3doses	75	(40.1)	380	(90.5)	1	
0 doses	112	(59.9)	40	(9.5)	14.2 (9.0–22.5)	5.3 (3.9–7.8)
Water source						
Protected	79	(30.7)	235	(45.6)	1	
Unprotected	178	(69.3)	280	(54.4)	1.9 (1.4–2.6)	–
Excreta Disposal						
Safe	92	(35.8)	296	(57.5)	1	
Unsafe	165	(64.2)	219	(42.5)	2.4 (1.8–3.3)	1.5 (1.1–2.2)
Mother's literacy						
Literate	162	(63.0)	337	(65.4)	1	
Illiterate	95	(37.0)	178	(34.6)	1.1 (0.8–1.5)	2.1 (1.4–2.9)
Father's literacy						
Literate	164	(63.8)	391	(75.9)	1	
Illiterate	93	(36.2)	124	(24.1)	1.8 (1.3–2.5)	–

* OR = odds ratio.

incubation period or immediately prior to onset of poliomyelitis, has been incriminated as provoking factor for paralysis. Provocative poliomyelitis was first recognized, in 1950 after mass use of DPT vaccine, in UK and Australia(8). In developing countries like India it is a common practice that injections are demanded by parents or given by general practitioners when actually there is no need.

The present study shows that a child who received IM injection during the "risk period" was two times at-risk to develop paralysis. This is similar to the report of findings by others(9-11) who reported a relative risk varying from 1.5–2.5. However, Guyer *et al.* reported the risk to be as high as 16.8(12). The high risk in that study was probably due to the bias in the selection of controls who had been free from all

illnesses. The risk of paralysis by IM injection in the present study was similar in all age groups. The risk for developing paralysis after IM injection was the same irrespective of the child's immunization status for OPV. This finding reinforces our earlier observation of similar proportion of cases of poliomyelitis who received IM injection among immunized, partially immunized and unimmunized children(13).

Risk of paralysis has been reported with IM injection given at any time within one month earlier to onset of illness(12). Our finding confirms this. Korns *et al.* observed a uniformly two-fold difference for each week interval upto 2 months earlier to onset of illness(9). The higher risk when IM injection was given between 7 to 13 days earlier to onset of paralysis as seen in this study is also previously reported(14). Guyer *et al.* also reported a relative risk of 32 for the period of 8-14 days prior to the onset of disease as the highest risk period(12). The high risk could be explained by the fact that this period corresponds to the incubation period and the hyperemia induced by the injection possibly allows the virus to get localized in the corresponding segment of the spinal cord. It is reported that children who received multiple injections are twice at risk to develop paralysis compared to those who received single injection(12). However, we did not find any such relation.

Apart from IM injection during the month preceding paralysis, non-immunization, unsafe excreta disposal and maternal illiteracy were risk factors for paralysis. Coverage of all eligible children with OPV has been stressed by many studies. We conclude that IM injections should be avoided in children with fever of undetermined or viral origin to avoid precipitating attacks of paralytic poliomyelitis.

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NOTES AND NEWS

GROUP ON CHILDHOOD DISABILITY

A Group on Childhood Disability has been formed under the aegis of the IAP. This is a multidisciplinary group which will be working for the welfare of disabled children of the country. The aim of this group is to collect information from all over the world regarding their prevalence management and rehabilitation of these children. Educating the parents will also be one of the aims of this group.

Membership fee :

1. Ordinary member	–	Rs. 100/- per year or Rs. 1000/- life membership
2. Associate member (for non-Pediatrician)	–	Rs. 50/- per year or Rs. 500/- life membership

Members interested in the total welfare of disabled children are requested to apply for the membership of this group to:

Dr. S.D. Singh,
Professor and Head,
Department of Pediatrics,
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