

INTUSSUSCEPTION RATES BEFORE AND AFTER THE INTRODUCTION OF ROTARIX: A SINGLE-CENTRE OBSERVATIONAL STUDY.

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Rotavirus gastroenteritis currently represents one of the leading cause of hospitalization and death in children aged younger than 5 years¹, especially in poor countries², where vaccination represents the only feasible prevention. Although current rotavirus vaccines were not associated with an increased risk of intussusception before marketing authorization, recent post-marketing surveillance data from international settings have observed a small increased risk of intussusceptions after monovalent rotavirus vaccination.

We investigated the rate of intussusception in a cohort of infants (0-12 months of age) living in the area of Messina (North-East of Sicily; 1.135 km²; including the municipalities of: Messina, Villafranca, Roccalumera, Taormina, Milazzo, Lipari, Barcellona PG, Patti, Mistretta and Sant'Agata), before and after the introduction of free Rotarix vaccination in Sicily.

Throughout the study period (2012-2016), the rate of intussusception (using ICD-9-CM code 560.0) at the Pediatric Department of the A.O.U. Policlinico G. Martino, was 95/61.338 (0,15%), including all hospital and emergency department visits of children. All intussusception cases were stratified according to the common classification (small-bowel intestine n=66, 70%; ileocolic n=29, 30%) and sex (males=64, 67%; females=31, 33%). The rate of intussusceptions estimated only in infants (0-12 months of age), was 1,74/10.000 before vaccination program introduction (2012) and had no linear trend over the observed vaccination period (2013-2016).

Since March 2014, as a part of a multicenter study project of active pharmacovigilance coordinated by the Italian National Institute of Health, all parents were asked on their child vaccination status, and we found 34 intussusceptions, 7 (20%) of which occurred in infants, with only 1 Adverse Event due to Rotarix exposure (first dose). Throughout the 4 years of observation (2013-2016), the local health authority (ASP Messina) administered 8719 doses of Rotarix in the area of Messina, with 2 intussusceptions as Adverse Drug Reactions (ADRs), one of which recorded from our study. According to the local health authority data, 4 years after the introduction of free Rotarix vaccine in Sicily, the rate of complete vaccination is not equally spread in the Messina area ranging from 0% to 86% (depending on the municipality), with an average coverage of first dose vaccination in 2016 newborns of 38%. Regarding the full cycle of vaccination (first and second dose) the area of Messina shows the lowest rate of coverage as compared to the vaccination records in Sicily (13% vs 37%). The reasons for this poor vaccination rate can be found in: a) underestimation of Rotavirus gastroenteritis severity; b) high awareness among parents; c) missing the recommended time-period for vaccination.

Our results indicate that the rate of intussusception in the Messina area is low because of a poor participation to the vaccination program, being the coverage lower than 45%, as recommended by

the national health authority. Furthermore, our data suggest the need of efforts, by local authorities aimed at implementing and promoting the culture of vaccination.

References

1. Liu J, Platts-Mills JA, et al. Use of quantitative molecular diagnostic methods to identify causes of diarrhoea in children: a reanalysis of the GEMS case-control study. *Lancet*. 2016 Sep 24;388(10051):1291-301.
2. Santosham M, Steele D. Rotavirus Vaccines - A New Hope. *N Engl J Med*. 2017 Mar 23;376(12):1170-1172.
3. Costantino C, Amodio E, Vitale F. Impact on rotavirus gastro-enteritis hospitalisation during the first year of universal vaccination in Sicily. *PaediatrInt Child Health*. 2015 May 11:2046905515Y0000000007.