

- [Intussusception in southern India: comparison of retrospective analysis and active surveillance.](#)

Jehangir S.Vaccine. 2014.[1 comment](#)

[Jacob Puliye12014 Aug 12 08:51 a.m.](#)edited

I congratulate the authors of this analysis. However their analysis begs more questions than it answers.

They found that there were 581 cases of ultrasound diagnosed intussusception per 100,000 child years, during the Rotavirus trial, which works out to be 1 intussusception in every 172 children, each year, or 1 intussusception for every 86 children who were followed up for 2 years in the study (approximately - not counting 6 weeks before vaccination).

Bhandari et al [Bhandari N, 2014](#) have reported that 40 babies have to be vaccinated to prevent one severe rotavirus gastroenteritis episode (NNT = 40) in the 2 year of study.

The analysis by Jehangir et al [Jehangir S, 2014](#) of data from the Rotavirus vaccine trial showed that 1 in every 86 babies in the trial: 1) developed symptoms and signs of intussusception confirmed by a study pediatrician (namely pass blood in stools, or have continuous vomiting, abdominal distension or abdominal lump) and 2) had the diagnosis of intussusception confirmed on ultra sound.

About half the cases resolved spontaneously. In field conditions, the other half will need urgent radiographic reduction or surgery and if these are not available (in remote villages where the vaccine will be administered), mortality is near 100%

Jehangir and colleagues report intussusception in the study sample, without differentiating the babies who received the study drug (rotavirus vaccine) from those who received placebo. This differentiation is crucial because the rate of intussusception in the controls can be assumed to be the natural rate of intussusception using the surveillance methods described in the study.

As the study has now been analysed after unmasking the vaccine recipients, this data on how many among the trial drug recipients and how many among the placebo recipients developed (ultrasound proven)intussusception, should be provided on the PubMed Commons. From this we can determine the NNT for intussusception (numbers of babies that need to be vaccinated to cause intussusception in 1 child) The authors need to publish data on the number of ultrasound diagnosed intussusception per 100,000 child years among those who received rotavirus vaccine and the corresponding figure for placebo recipients.

Instead of this comparison, the authors do a retrospective analysis of data on intussusception treated at their tertiary referral hospital, between 1 January 2010 and 31 August 2013.

Only babies who had intussusception that needed surgical or radiological treatment and which was confirmed on ultrasound examination, were included.

Thus only cases qualifying as intussusception at Level 1 diagnostic certainty, were included and all those whose intussusception resolved spontaneously (without medical intervention) were excluded from the retrospective study.

Under these circumstances it is meaningless to assert that all the babies selected for analysis in the retrospective study needed some intervention but only about 44% of those that were identified in the rotavirus vaccine-trial-active-surveillance, needed intervention.

The authors then go on to conclude that, as 56% of babies with ultrasound diagnosed intussusception in the vaccine trial recovered spontaneously, active surveillance is not a good method to detect adverse events following immunization, and that sentinel hospital based surveillance (for post marketing surveillance after rotavirus vaccine introduction) was better.

The rationale for this conclusion is difficult to fathom. Children who come to tertiary centers (and sentinel surveillance hospitals) with intussusception usually survive. It is the babies in remote areas, far away from roads and transport who die untreated and undiagnosed after intussusception.

The sentinel surveillance will have no record of these cases of intussusception or deaths. Their deaths will not even be counted using the WHO recommended strategy of sentinel hospital based surveillance. That is the big tragedy.