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# Retrospective surveillance for intussusception in children aged less than five years at two tertiary care centers in India



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#### ABSTRACT

*Background:* A rotavirus vaccine could soon become part of India's national immunization program. However the occurrence of intussusception due to rotavirus vaccine is a potential safety concern. This surveillance aimed at the collection of baseline data on childhood intussusception which would facilitate the monitoring of intussusception cases after the introduction of rotavirus vaccines.

Methods: We retrospectively reviewed medical records of confirmed intussusception cases in children under the age of five, treated during 2007–2012 at two tertiary care hospitals attached to medical schools in India. Demographic, clinical, diagnostic and treatment practices data were obtained from hospital records

Results: Over a five to six year observation period, we identified 187 confirmed cases of intussusception, of which 75% were males. The median age of intussusception was 8 months, and we observed a possible trend in the distribution of cases with the highest number of cases being reported in the month of April and lowest in the month of October. The most common diagnostic methods used were ultrasonography and abdominal radiography with most cases being treated surgically (71%). The median length of hospital stay was 8 days (range 1–40) and mean was 10.2 days. Records of any fatality due to intussusception were not found during the review of the records.

Conclusions: This analysis provides an estimate of the baseline data of childhood intussusception prior to the introduction of the rotavirus vaccination as a part of routine immunization in India. A prospective surveillance system using a standardized case definition is needed in order to better examine the incidence of intussusception in developing countries.

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#### 1. Introduction

Intussusception is characterized by a sudden onset of abdominal pain, vomiting, rectal bleeding, and the presence of a palpable abdominal mass. These signs and symptoms are caused by bowel obstruction due to invagination of a segment of intestine into the adjoining intestinal lumen. The condition is diagnosed by ultrasonography, radiology or surgery, and is usually treated by air or hydrostatic reduction enema under radiologic or ultrasound guidance.

However, surgery may be required in some cases, and approximately 10% of patients with intussusception undergo an intestinal

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resection due to a vascular injury to the intestine. Intussusception primarily affects children, with the peak incidence reported between 4 and 10 months of age [1]. The background incidence and case fatality vary widely by region, and deaths from intussusception are more common in developing than in industrialized countries [2].

As per Global Enteric Multicenter Study (GEMS) conducted in low income countries, the estimated incidence of moderate-to-severe diarrhea is highest in India [3]. Worldwide in 2008, diarrhea attributable to rotavirus infection resulted in 453,000 deaths (95% CI 420,000–494,000) in children younger than 5 years; 37% of deaths attributable to diarrhea and 5% of all deaths in children younger than 5 years. Five countries accounted for more than half of all deaths attributable to rotavirus infection: Democratic Republic of the Congo, Ethiopia, India, Nigeria, and Pakistan; India alone accounted for 22% of deaths (98,621 deaths) [4] .One of the safety concern for rotavirus vaccines as they are introduced in routine childhood immunization programs is the occurrence of

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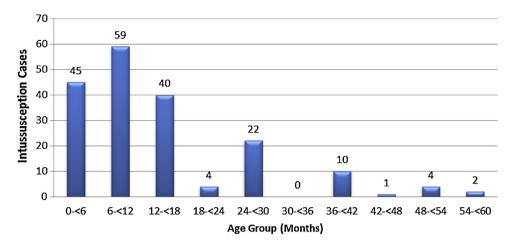


Fig. 1. Age distribution of intussusception cases in children aged less than 5 years

intussusception, a serious intestinal condition that occurs naturally in infancy at a relative low frequency [5]. An earlier vaccine (Rotashield®, Wyeth Vaccines, USA) based on a different (rhesus) strain than the current WHO recommended vaccines was found to be associated with an increased risk of intussusception [6]. For the current vaccines, large clinical trials did not find an increased risk of intussusception at a level similar to that seen with the previous rhesus vaccine [7,8].

As in many other emerging economies, sufficient background data on incidence and epidemiology of intussusception is unavailable in India. At present there are three rotavirus vaccines under development in India by local Indian manufacturers and since all three of them may ultimately be used as a part of public health system in India and intended for a widespread global use by the virtue of a WHO pre-qualification, there is an urgent need to generate baseline data related to intussusception from India. In light of this, we undertook a retrospective surveillance at two tertiary care centers in India to collect local data on the baseline characteristics and epidemiology of intussusception to support post introduction safety monitoring.

## 2. Method

#### 2.1. Study area and participating hospitals

This retrospective hospital-based analysis reviewed cases of intussusception documented in the medical records during the years 2007–2012, at two centers attached to Medical Schools in India. From southern India, Kasturba Medical College (KMC), Manipal (2007–2011), and from north-central India CSM Medical University (CSMMU), Lucknow (2007–2012) were involved in this study. Necessary permission was obtained at each of the hospitals to facilitate the review of patient medical records by the local study teams. Patient confidentiality was respected during the compilation and analysis of the data.

#### 2.2. Case definition and data sources

Surveillance to identify cases of intussusception was planned for at least five complete years. Children ≤60 months of age with confirmed diagnosis of intussusception, using the case definition developed by the Brighton Collaboration Working Group, from January 2007 through December 2012 were eligible for inclusion in the database. [9].

Patients at Level 1 of diagnostic certainty were defined as confirmed cases. Level 1 requires one of the following: demonstration

of invagination of the intestine at surgery and/or by either air or liquid-contrast enema, presence of intra-abdominal mass on ultra-sonography, and/or the demonstration of invagination at autopsy. Cases diagnosed using a combination of clinical symptoms and signs according to Levels 2 and 3 of diagnostic certainty are defined as probable. Suspected cases are patients with a diagnosis of intus-susception for whom the available information prevents from determining the level of diagnostic certainty. Data for each identified case was collected by reviewing admission and discharge logs, case history records, ultrasonography, radiology logs, and surgery reports from the respective hospitals.

#### 2.3. Data collection and analysis

For this study, baseline data of confirmed cases of intussusception only was collected. For each identified child, information on demographics, admission and discharge dates, clinical signs and symptoms and their duration, as well as diagnostic and treatment procedures performed was extracted, recorded on pre-developed case record forms and then entered into an MS Excel database. Symptoms and signs were recorded as positive or negative only if the presence or absence of the symptom or sign was documented by the medical and/or nursing staff in the patient's records. The data was pooled and analyzed according to age, sex, clinical signs, year and month of hospitalization, and diagnostic and treatment-related characteristics.

### 3. Results

During the surveillance, we identified 187 confirmed cases of intussusception in children less than 60 months (5 years) of age. The median age of diagnosis was 8 months (range 1.5–60). The majority of cases diagnosed were below the age of 12 months (55.6%) with the highest number of cases in the age group of 6–11 months (31.6%) (Fig. 1).

We identified a male–female ratio of 3.1:1, with males accounting for 75% and females 25% of confirmed intussusception cases.

We found the highest numbers of cases of intussusception in the month of April and lowest numbers in the month of September (Fig. 2).

The study observed that the most frequent symptoms were recurrent vomiting (51.3%) and abdominal pain (47%). Other symptoms recorded include: blood in stool (18.7%), abdominal distension (12.3%), excessive crying (13.4%) and fever (6.4%). We documented the classic triad of vomiting, passage of blood through the rectum and abdominal pain in 18.7% of children.

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