

ORIGINAL ARTICLE

Retrospective surveillance of intussusception in pediatric hospitals in Havana: a necessary step before the introduction of rotavirus vaccine

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ABSTRACT

Background and Objectives: Intussusception (IS) is a common cause of bowel obstruction in children and has attracted increased attention since it was linked with the first rotavirus vaccine, Rotashield®, although many cases of intussusception self-resolve and could be fatal if not treated promptly. This study aims to provide information on clinical and epidemiology characteristics of IS among children aged < 24 months before rotavirus vaccine introduction. **Methods:** This is a hospital-based, retrospective review of hospital records from January 2011 to December 2020, at two largest pediatric hospitals in Havana, Cuba. **Results:** A total of 147 children aged less than 24 months diagnosed with intussusception were included. Most cases occurred under 1 year of age and the male was predominant. The predominant symptoms were vomiting (47.2%), irritability (31.7%), “currant jelly” bloody stool (42.5%) and abdominal pain (27.02%). A total of 69 patients were treated surgically using major manual reduction of intussusception. The postoperative complications were 8.8% and surgical site infection was the most frequent complication. None deaths were reported from both hospitals. **Conclusion:** Efforts should be made to complete a large-scale baseline surveillance of intussusception around the country before the introduction of rotavirus vaccine.

Key words: intussusception, children, age, rotavirus vaccine

INTRODUCTION

Intussusception (IS) is a condition in which the intestine folds in on itself and is the most common cause of bowel obstruction in infants and involves the ileum invaginating through the ileocecal valve into the cecum. As the bowel intussuscepts, it pulls along its blood supply. If the intussusception is not relieved, the vascular supply of the bowel may be compromised, resulting in intestinal ischemia and possibly perforation.^[1] Although many cases of intussusception

self-resolve, others can be fatal if not treated promptly.^[2]

Treatment for IS includes reduction by air, hydrostatic enema, or surgery.^[3] IS is most likely to occur naturally in infants, between 4 and 10 months of age.^[2] The mean incidence is 74 cases per 100,000 infants < 1 year of age (range: 9–328), but is variable across geographic regions, most notably with higher rates in parts of Asia.^[1]


IS has attracted increased attention since it was linked with the first rotavirus vaccine, Rotashield® (RRV-TV) (Wyeth).^[4] Currently, four oral rotavirus vaccines:

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Rotarix® (RV1), Rota Teq® (RV5), Rotavac® or Rotasiil® are used in various parts of the world in routine immunization program and prevent episodes of rotavirus diarrhea and no increased risk of serious adverse events, including IS.^[5,6] Due to the benefit of RV vaccination that far outweighs this risk, since 2009, World Health Organization (WHO) has recommended that rotavirus vaccine should be used in all countries.^[7]

Considering the real-world evidence accumulated since the launch of the globally available RV vaccines and the high vaccine coverage in some regions, the increased risk of IS following RV vaccination does not seem to translate into an overall long-term increase of IS in countries with RV vaccination included in their national immunization programs.^[8]

National monitoring of intussusception prior to the introduction of Rotavirus vaccines has a crucial role in providing important background data to monitor the safety of these vaccines.^[3,9–11]

Rotavirus vaccine have yet to be introduced in Cuba, and efforts are being made to accomplish this objective in the next years.^[12] In Cuba, the insufficient report^[13–15] do not allow for the establishment of consistent baseline rates for IS and that could estimate the additional number of cases that may be associated following immunization with a rotavirus vaccine in the future. This study's aim was to provide information on clinical and epidemiology characteristics of IS among children aged < 24 months, in Havana, Cuba before the introduction of rotavirus vaccine.

MATERIAL AND METHODS

Study design and participating hospitals

This study is a hospital-based, retrospective review of hospital records from January 2011 to December 2020, at two largest paediatric hospitals in Havana, Cuba. The criteria for hospitals to participate in this study included the ability to diagnose and manage cases of IS (availability of paediatric surgeon, radiologist, equipment, and facilities).

Juan Manuel Márquez Paediatric Hospital (JMMH) is a 337-bedded government paediatric referral hospital. The hospital serves a population of approximately 420 000 children from neighbouring municipalities: Marianao, Playa, La Lisa and western province of Artemisa. The Havana Centre Paediatric Hospital (HCPH) is a 260-bedded government paediatric referral and performing paediatric surgeries from municipalities Centro Habana, Plaza, Habana Vieja, Habana del Este and Mayabeque province. More than 50% of Havana population seeks service from these hospitals. The study was discussed by research committee of both hospitals.

Case definition

We selected cases of IS using the case definition developed by the Cuban Guidelines of Good practices of Paediatric Surgery,^[16] which is in consensus with the level 1 diagnostic certainty for intussusception as per Brighton collaboration criteria. (Brighton Collaboration Working Group).^[17] Diagnostic certainty as per level 1 Brighton collaboration criteria are the confirmation of intussusception during surgery and/or by specific radiologic findings (if reduced by pneumatic/hydrostatic/ contrast enema) or at autopsy. Children aged < 24 months who met the criteria of intussusception case were included.

Retrospective data collection and analysis

This study used data on admissions from January 2011 to December 2020 of both hospitals with a discharge diagnosis of IS (code K56.1) according to the International Classification of Disease, version 10 [ICD-10] in children aged < 24 months.^[18]

The medical staff reviewed IS cases admitted on surveying paediatric inpatient wards, surgical theatre and admission logs, at the hospital. The revision was coordinated with the hospital paediatric surgeons and radiologists.

The surveillance staff completed a brief study questionnaire (epidemiological form) with all information recovered from each notified case. The questionnaire was validated previously.^[14] Data were entered into an electronic database and checked for accuracy. This process (data extraction and entry) was performed by the same investigator.

The information was described by hospitals. Frequencies were calculated by year, hospital, age group, sex, clinical symptoms or signs, diagnostic and treatment. To examine potential seasonal variation of intussusception cases, the number of cases in both hospitals was plotted by year and month of hospitalization. The proportions and frequency tables were used to summarize categorical variables. Chi-square (χ^2) and Fisher's exact tests were used to compare the categorical variables between both hospitals. The level of significance was considered at 0.05 (5%). The statistical analysis was performed using statistical package R version 4.2.0 for Windows (R Core Team (2022). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. <https://www.R-project.org>)

RESULTS

Between January 2011 and December 2020, a total of 147 children aged less than 24 months, diagnosed with

intussusception were admitted to the two hospitals, 63 (42.85%) from HCPH and 84 (57.14%) from JMMH. Many cases occurred under 1 year of age; the peak age incidence was in the age group of 4–5 months (Figure 1). Among confirmed cases, ninety-four (63.94%) were males and 53 (36.05%) females at two hospitals in Havana. The male was predominant in both hospitals.

In our study, a potential increase of intussusception cases was detected during April–May and June for both hospitals (Figure 2). The proportion of patients with IS managed in the surgical wards of JMMH and HCPH, was in correspondence with municipality where each child live in Havana (data not shown). Both hospitals offered medical assistance to children from Artemisa (27 cases) and Mayabeque (10 cases) respectively, provinces very near from Havana. In addition, four cases coming from Matanzas, Camagüey, Granma and Santiago de Cuba indistinctly arrived to hospital and were hospitalized.

The most common symptoms observed were vomits (70, 47.2%), irritability (47, 31.7%), bloody stool “currant jelly” (63, 42.5%) and abdominal pain (40, 27.02%). The proportion of children with vomits, and blood in stools, was higher in children admitted at HCPH, in contrast the abdominal pain was more common among children at JMMH.

Overall, the irritability or intermittent crying occurred recurrently at HCPH (31 *vs.* 16) (Table 1). The fever was observed less frequently. Eleven patients present alterations in the state of consciousness, which translates as lethargy.

None cases of abdominal distension were recollected between of two hospitals. In the present investigation, generally the time between the onsets of symptoms and arrived to the hospital does not exceed 24 hours, and a minority of cases arrived to hospital within 3 or more days of onset of clinical picture.

Ultrasonography and plain abdominal radiography were diagnostic methods more informed. At HCPH, abdominal ultrasound was used to confirm diagnosis in all the patients and thirty cases by plain abdominal radiography. Twelve children were diagnosed using plain abdominal radiography and the rest with ultrasonography at JMMH.

A total of 69 patients were treated surgically using major manual reduction of intussusception (Table 2). Six children required bowel intestinal resection with anastomosis, three for each hospital. Of the 69 patients, 4 of HCPH and 12 of JMMH requiring a secondary operative intervention following a primary surgery.

Forty-three children were successfully managed non-surgical reduction in HCPH, and the frequency of these reduction (pneumatic and hydrostatic) is shown in table 2. Among 22 cases managed non-surgically, only one case was treated by reduction with barium contrast at JMMH.

Twenty-six children who initially underwent non-surgical procedures required surgical management following failure of such procedures.

The postoperative complications were recorded in 13 (8.8%) patients. Of these, surgical site infection was the most frequent accounting for 6 cases of both hospital (4 cases of HCPH and 2 of JMMH). None deaths were reported from both hospitals.

The length of hospital stay ranged from 1 day to 18 days with a median of 4.6 days, those patients underwent surgical intervention or with post-operative complications had longer hospital stay. The hospital stay for intussusception cases was not different between both hospitals.

DISCUSSION

WHO recommends monitoring the risk of IS for countries introducing rotavirus vaccine.^[1,2] The ability to assess a risk of it after vaccination will depend on the availability of information concerning the background rates of IS in the population of interest. There is few studies in Cuba about it, and are reports of cases in surgical unit of any hospital and is not reflect of the global incidence of country.^[14–16] The aim of the present study was to retrospectively describe intussusception data among children < 2 years of age at two large hospitals in La Havana province, Cuba.

Most cases of IS occurred in infants between 4 and 9 months of age. This finding is similar to previous reports in the region of the Americas with 63%, 54% in Europe and 35% in the Pacific region where more than $\geq 80\%$ of hospital admissions due to IS occur in the first year of life.^[2] The previous study in Cuba reported the occurrence of IS around the age of 6 months ranged from 47.1% to 55.9%.^[13–15] Our study evidenced that the occurrence of IS was very low in the first two months when rotavirus vaccination should have been administered following WHO’s recommendation.

The data recollected were restricted to children aged < 24 months and those who were given a primary diagnosis of intussusception, since this is the target age group for rotavirus vaccines and is hence of primary interest. Rotavirus vaccination could prevent a large proportion of intussusception cases associated with

Table 1: Clinical presentation of intussusception in children aged < 24 months, at two hospitals in Havana, *n* (%)

Clinical symptoms/signs	HCPH (<i>N</i> = 63)	JMMH (<i>N</i> = 84)	Total <i>N</i> = 147
Vomits	39 (56.5)	31 (36.5)	70 (47.3)
Fever	10 (14.5)	11 (12.9)	21 (14.2)
Diarrhoea	13 (18.8)	12 (14.1)	25 (16.9)
Bloody stool	34 (49.3)	29 (34.1)	63 (42.6)
Lethargy	7(10.1)	4 (4.7)	11 (7.4)
Abdominal pain	29 (42.0)	11 (12.9)	40 (27.0)
Irritability	31 (44.9)	16 (18.8)	47 (31.8)

HCPH: Havana Centre Paediatric Hospital; JMMH: Juan Manuel Márquez Paediatric Hospital

Table 2: Distribution of patients according to type of procedure surgical at two hospitals in Havana, *n* (%)

Type of treatment	HCPH	JMMH	Total
Non-surgical			
pneumatic reduction	23 (36.5)	0	23 (15.6)
hydrostatic reduction	15 (23.8)	21 (25)	36 (24.5)
barium reduction	5 (7.9)	1 (1.2)	6 (4.1)
Total	43 (68.3)	22 (26.2)	65 (44.2)
Surgical			
Manual reduction	26 (41.3)	43 (50.6)	69 (46.9)
Bowel resection and anastomosis	3 (4.8)	3 (3.6)	6 (4.1)
Cecopexy	6 (9.5)	3 (3.6)	9 (6.1)
Appendectomy	1 (1.6)	7 (8.2)	8 (9.8)
Two or more procedure	4 (6.3)	12 (14.1)	16 (19.7)
Total	40 (63.5)	68 (80)	81 (55.1)

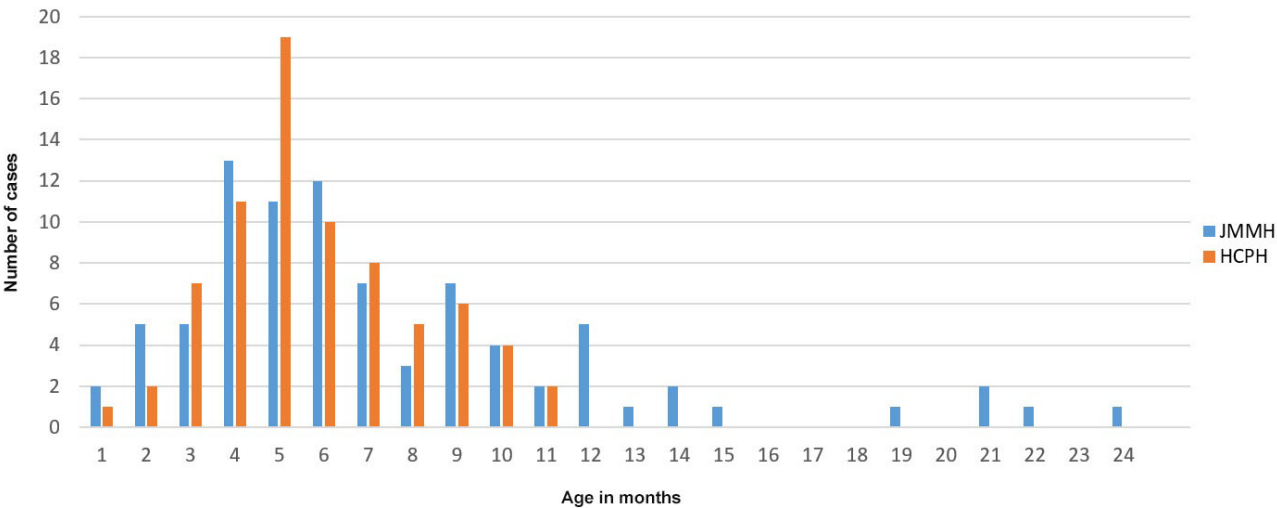


Figure 1. Age distribution of intussusception in children \leq 24 months old, at two hospital in Havana, 2011-2020. HCPH: Havana Centre Paediatric Hospital; JMMH: Juan Manuel Márquez Paediatric Hospital

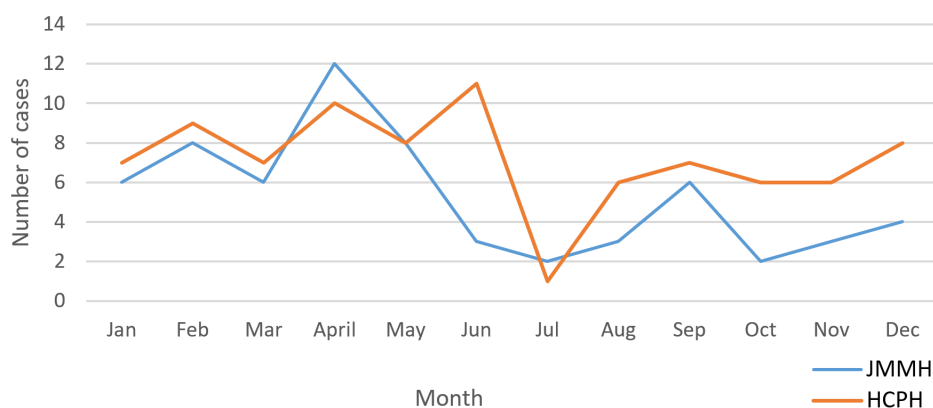


Figure 2. Monthly distribution of intussusception in children aged < 24 months, Havana, 2011-2020. HCPH: Havana Centre Paediatric Hospital; JMMH: Juan Manuel Márquez Paediatric Hospital

rotavirus infection since most cases occur currently in children old enough to be vaccinated.

Consistent with previous research^[3,11,19–23], the intussusception was more frequent in males (63.4% HCPH and 64.2% HJMM). The explanation for this is unclear, which suggests the higher density of intestinal Peyer's patches in males. Previous research explain that sex hormones are linked with the immune response and with intestinal motility, which may explain the gender difference (male predominance of intussusception).^[9]

There were two peaks: April-May and June in 10 years, despite of it is not possible to describe a seasonal pattern, this observation was consistent to report from countries in the Americas^[22] Europe^[23], Asia^[9,11,19,20] and Africa^[21,24]. Some authors reports that intussusception is more common during the dry season and documents it with period of higher incidence of gastroenteritis.^[24] In Cuba, gastroenteritis showed a seasonal peak in the months of May and June (wet seasons), so the morbidity diminished to minimal values during November to December. However, the highest rate of rotavirus positivity is found in winter.^[25] In our investigation, the number of cases with diagnosis of intussusception presenting gastroenteritis caused by rotavirus was not observed as an increase.

We could observe an association within presence of symptom or signs of viral illness such as upper respiratory diseases and diarrheal previously to begin with the intussusception. This information was obtained from medical records, but there could be a bias in this data due to the fact that it is collected from a secondary source, which is a limitation. This study is unlike other studies where the mother can be asked about the history of presenting some of these diseases before.

The classic triad of vomiting, passage of blood through the rectum and abdominal pain was documented in 23 (15.6%) of 147 children, that which is same those reported from other researchers in developing countries.^[3,11,20–22]

In this study, we use the practical and clinical criteria of intussusception presented in The Cuban Clinical Practice Guideline for Intussusception. These guidelines were approved by consensus at the III National Symposium of Paediatric Surgery in Varadero, 2019^[16] and each component is corresponding with the definition of Brighton Collaboration Working Group.^[17] There is a risk of developing IS following rotavirus vaccine.^[4] Therefore, it will be interesting the validation of the internationally standardized criteria for defining IS in infants, who could be participating in clinical trials once rotavirus vaccine being included in Cuba.

The treatment of intussusception has evolved from primarily operative management to the preference for non-operative reduction with either air or barium contrast. Non-surgical reductions of intussusception had been shown to decrease length of hospitalization, shorten recovery, and reduce the risk of complications associated with major abdominal surgery.^[14] However, in developing countries the treatment of intussusception is predominantly surgical. The facilities and technical expertise necessary to perform safe and effective enema non-surgical reduction are frequently unavailable outside major city hospitals.^[20–22]

The success rate of hydrostatic or air enema therapy varied widely between institutions^[20–22], which may reflect differing expertise in this technique. In this study, air enema was carried out successful (23 of 43 cases) at HCPH. The study confirms previous findings of the useful of non- surgical interventions in the management

of intussusception using air reduction respect to hydrostatic enema therapy (barium and saline).^[13–15,26]

In comparison to HCPH, most of the surgical interventions were performed at JMMH. This is agreement with a previous report in the same hospital.^[14] This Hospital offers paediatric surgery service for children from Artemisa province, rural area located a considerable distance from the hospital. Then, the time of duration of symptoms (between the beginning of the symptoms and arrival to hospital) could be prolonged till their access to health care facilities.

Surgery still plays an important role in patients with complicated intussusception, duration of symptoms, recurrent intussusception or in those in whom attempts at hydrostatic or air reduction have failed. Cuba continues promoting the management of intussusception for non-surgical reduction because there are facilities and qualified personnel. The late presentation of a significant proportion of patients in developing countries may render them unsuitable for enema reduction because of the increased risk of perforation and sepsis, even if these facilities are available.^[21]

Srinivasan *et al.* reported a delay in intussusception management either due to delay in seeking medical attention or time-consuming referral process through primary or secondary to tertiary care centres in the public health system may have potentially influenced the severity and duration of illness of children.^[20]

Both are large children's hospitals (tertiary health care centres) that have as benefit to shorter length of stay than patients attending hospitals with small paediatric case-loads. This study shown that the length of hospital stay was extended in those patients that had a surgical management, consistently with studies which described a significant association between hospital size and the likelihood of a patient with intussusception receiving surgical treatment.^[19–22]

Baseline intussusception surveillance is needed in sites where trials of rotavirus vaccines are planned, and post-licensure intussusception surveillance may also be required by some licensing agencies.

In conclusion, this study provides epidemiological and clinical data on intussusception among children < 2 years of age in Havana, which is important to estimate the incidence rate for intussusception in Cuban children before the introduction of rotavirus vaccine. The data collected could facilitate the monitoring on any potential risk of IS as an adverse event associated with the vaccine post-approval. Efforts should be made to complete a large-scale baseline surveillance of IS around the country to promote the rotavirus vaccine introduction. The data

collected were limited to the register availability. It is important that all information to collect in the history is available, which will help to estimat the risk of intussusception following vaccination.

DECLARATIONS

Author contribution

Pérez NL conceptualized the study and participated in the process of designing the study with Blanco NA and González IPL, Hernández MJF, Gámez-Fonts LN, Ortega EM, González IPL, and González EC were involved to acquisition, analysis and interpretation of data, and Sosa MMM performed the statistical analysis. Blanco NA drafted the original draft, and González IPL, Sosa MMM and Pérez NL revised the manuscript. All authors read and approved the final manuscript. All authors had full access to all the data in the study and accept the responsibility to submit the data for publication. Blanco NA is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs. Ortega EM and Hernández MJF are joint first authors.

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Informed consent and ethical approval

There are Collaboration Agreements for Research between Finlay Vaccine Institute and Tropical Medicine Institute "Pedro Kouri", Havana Centre Paediatric Hospital and "Juan Manuel Márquez" Paediatric Hospital. The agreement propose that research protocols will be sending and approving by Scientific Council of Finlay Vaccine Institute. The study was approved by the Research Ethical Committee of each hospital. We performed a retrospective study and collected the information about each study participants of both hospitals.

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Conflicts of interest

There is no conflict of interest with any financial support.

Data sharing statement

No additional data is available.

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