Validation of clinical case definition of acute intussusception in infants in Viet Nam and Australia

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Objective To test the sensitivity and specificity of a clinical case definition of acute intussusception in infants to assist health-care workers in settings where diagnostic facilities are not available.

Methods Prospective studies were conducted at a major paediatric hospital in Viet Nam (the National Hospital of Pediatrics, Hanoi) from November 2002 to December 2003 and in Australia (the Royal Children’s Hospital, Melbourne) from March 2002 to March 2004 using a clinical case definition of intussusception. Diagnosis of intussusception was confirmed by air enema or surgery and validated in a subset of participants by an independent clinician who was blinded to the participant’s status. Sensitivity of the definition was evaluated in 584 infants aged < 2 years with suspected intussusception (533 infants in Hanoi; 51 in Melbourne). Specificity was evaluated in 638 infants aged < 2 years presenting with clinical features consistent with intussusception but for whom another diagnosis was established (234 infants in Hanoi; 404 in Melbourne).

Findings In both locations the definition was sensitive (96% sensitivity in Hanoi; 98% in Melbourne) and specific (95% specificity in Hanoi; 87% in Melbourne) for intussusception among infants with sufficient data to allow classification (449/533 in Hanoi; 50/51 in Melbourne). Reanalysis of patients with missing data suggests that modifying minor criteria would increase the applicability of the definition while maintaining good sensitivity (96–97%) and specificity (83–89%).

Conclusion The clinical case definition was sensitive and specific for the diagnosis of acute intussusception in infants in both a developing country and a developed country but minor modifications would enable it to be used more widely.


Introduction

The withdrawal of the first rotavirus vaccine to be licensed in the United States (RotaShield, Wyeth–Lederle Vaccines, Philadelphia, PA, United States), due to an unexpected association with intussusception, resulted in a major setback in the effort to reduce the global burden of rotavirus gastroenteritis. Although the risk of intussusception following immunization with RotaShield is low, it has posed a major challenge to the future development of a safe and effective vaccine. Large-scale clinical trials are now required to detect a risk of intussusception of < 1 in 10 000. 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.

Intussusception is the invagination of the bowel by a more proximal segment. The intussusception can be propelled distally by peristalsis, resulting in intestinal obstruction and vascular compromise of the intestine. Prompt identification and reduction by air enema or hydrostatic enema or by surgery is vital to minimize the morbidity and mortality that may be associated with this condition. To assist in the early recognition of infants with intussusception a clinical case definition for the diagnosis of acute intussusception in infants and young children was developed by WHO and the Brighton Collaboration. The aim of the clinical case definition was to provide practical clinical criteria that will identify the majority of children with intussusception presenting at a variety of health-care settings. The clinical case definition that was developed showed promise (sensitivity = 97%; specificity = 87–91%) in a retrospective study in a tertiary care hospital in Australia. The aim of this study was to validate the clinical case definition for intussusception by assessing the performance of the criteria prospectively in parallel studies in a developed country and in a developing country where there is a high incidence of intussusception. Each component of the definition was analysed to assess the reliability of individual symptoms and signs as well as groups of symptoms and signs to assess the sensitivity and specificity of the definition.

Methods

Prospective studies were performed at the National Hospital of Pediatrics in Hanoi, Viet Nam, during a 14-month period.
period (1 November 2002–31 December 2003) and the Royal Children’s Hospital in Melbourne, Australia, over a 24-month period (19 March 2002–18 March 2004). The study was approved by the Ethics Committee of the Ministry of Health, Viet Nam, and the Ethics in Human Research Committee of the Royal Children’s Hospital, Melbourne. Free and informed consent was obtained from each child’s legal guardian.

The sensitivity of the clinical case definition was evaluated in infants aged < 2 years presenting to the hospitals. Medical staff completed a standardized questionnaire (in English or Vietnamese) that reviewed the symptoms and signs described in the clinical case definition. A diagnostic procedure was then performed to confirm or exclude intussusception. Only patients with the diagnosis of primary idiopathic intussusception confirmed by air enema or surgery were included in the calculation of sensitivity. Validation of cases of intussusception diagnosed by air enema was conducted by an independent radiologist (MdC) blinded to the infant’s status who reviewed radiographs of the air enema examination from before and after air reduction. Surgical notes for all patients diagnosed with intussusception at surgery were reviewed by an independent observer to confirm the diagnosis.

The specificity of the definition was assessed in patients with symptoms and signs that may occur in intussusception but for whom an alternative diagnosis was established (non-intussusception control group).

The non-intussusception control group included infants aged < 2 years presenting to the hospitals with one or more of the following symptoms or signs: vomiting without respiratory symptoms, abdominal pain, rectal bleeding, bowel obstruction or abdominal mass. At the hospital in Melbourne, eligible patients were recruited over a 2-week period once every 2 months from 14 October 2002 to 3 August 2003 (a total of 12 weeks) to avoid a seasonal bias. Similarly, at the hospital in Hanoi patients were recruited at regular intervals from 16 January 2003 to 31 December 2003 (a total of 9.5 weeks). The doctor who treated the patients in the non-intussusception control group completed the same standardized questionnaire used for the intussusception cases.

Individual symptoms and signs and groups of clinical features within the clinical case definition were assessed for sensitivity and specificity in both groups of infants: those diagnosed with intussusception and the non-intussusception control group. The infant’s condition was then categorized as probable intussusception, possible or negative for intussusception according to the level of diagnostic certainty as defined by the clinical case definition (Box 1). Some infants could not be categorized by the definition because data were missing. A patient’s status was defined as inconclusive if data were missing and the category of diagnostic certainty judged by the clinical case definition was different when the missing value (or values) was assumed to be positive compared with when the missing value was assumed to be negative. Secondary analyses were performed to establish a range of sensitivity results for the case definition by changing the assumptions about the missing data.

For patients in the control group it was considered unethical to perform a rectal examination if it was not clinically indicated. Therefore, an additional analysis of specificity was performed for patients in this group using all of the elements of the clinical case definition except those dependent on conducting a rectal examination (rectal mass, blood on rectal examination and intestinal prolapse if not visible on external examination). In order to identify the effect of making changes to the definition to improve sensitivity without compromising specificity, we also measured the effect of removing specific criteria from the case definition (criteria that either performed less well or were incompletely recorded).

The frequency of symptoms and signs between study sites was compared using the χ² test. Sensitivity was calculated using all infants diagnosed as having intussusception at the study site and in the subset of infants with intussusception confirmed by the independent observer.

**Findings**

**Assessment of sensitivity**

During the 14-month study in Hanoi we assessed 533 children aged < 2 years with primary idiopathic intussusception confirmed by air enema or surgery. This contrasts with the 51 cases of intussusception diagnosed in Melbourne during a 24-month study. At both sites a male predominance was observed, and the median age of infants with intussusception was similar (Table 1).

Independent confirmation of the diagnosis of intussusception by radiological evaluation and/or review of surgical notes was possible for 446 of 533 infants (84%) seen at the hospital in Hanoi and for 34 of 51 infants (67%) seen in Melbourne (Table 2). Abdominal pain was the most common symptom reported among cases, occurring in ≅ 94% of infants with intussusception presenting at both hospitals (533/533 infants in Hanoi; 48/51 in Melbourne) (Table 3). An abdominal mass detected on clinical examination was reported in 82% (436/532) of infants at the hospital in Hanoi compared with only 55% (28/51) at the hospital in Melbourne (P < 0.004). In Melbourne, lethargy and pallor were frequently observed on clinical examination of infants, however these two clinical features were not consistently reported in infants presenting in Hanoi (P < 0.004). Ultrasound examination was shown to be sensitive at correctly identifying intussusception in ≅ 97% of infants who were subsequently diagnosed with intussusception by air enema or surgery at both hospitals (463/477 infants in Hanoi; 24/24 in Melbourne).

Sensitivity was initially calculated for patients for whom there was sufficient data to allow a classification to be made in strict accordance with the clinical case definition (Box 1). This calculation identified a sensitivity of 98% at the hospital in Melbourne (49/50 assessable cases) and 96% at the hospital in Hanoi (433/449 assessable cases) (Table 4). However, one case in Melbourne (2%) and 84 cases in Hanoi (16%) could not be classified because a plain abdominal X-ray, rectal examination or both were not performed and thus the requirements of the definition could not be met; these cases were defined as inconclusive (Table 4). Inconclusive cases were less likely to be classified as positive for the major criterion of evidence of gastrointestinal bleeding (172 cases) compared with patients classified as probable (308/422 cases). Analysis of sensitivity for patients in the inconclusive group was performed by assuming that the missing value was either positive or negative (Table 4). Using this method, the
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Clinical case definition of intussusception

Box 1. Clinical case criteria for the diagnosis of acute intussusception in infants and young children

**Level 1 of diagnostic certainty**

**Surgical criteria:**
The demonstration of invagination of the intestine at surgery;
and/or

**Radiological criteria:**
The demonstration of invagination of the intestine by either air or liquid contrast enema;
and/or

The demonstration of an intra-abdominal mass by abdominal ultrasound with specific characteristic features that is proven to be reduced by hydrostatic enema on post-reduction ultrasound.
and/or

**Autopsy criteria:**
The demonstration of invagination of the intestine.

**Level 2 of diagnostic certainty**

**Clinical criteria:**
Two major criteria (see table for major and minor criteria for diagnosis below);

**or**

One major criterion and three minor criteria (see table for major and minor criteria for diagnosis below).

**Level 3 of diagnostic certainty**

**Clinical criteria:**
Four or more minor criteria (see minor criteria for diagnosis below).

**Any level of diagnostic certainty**

In the absence of surgical criteria with the definitive demonstration of an alternative cause of bowel obstruction or intestinal infarction at surgery (e.g., volvulus or congenital pyloric stenosis).

**Major and minor criteria used in the case definition for the diagnosis of intussusception**

**Major criteria**

1. Evidence of intestinal obstruction:
   - History of bile-stained vomiting, and either
   - Examination findings of acute abdominal distension and abnormal or absent bowel sounds; or
   - Plain abdominal radiograph showing fluid levels and dilated bowel loops.

2. Features of intestinal invagination
   - One or more of the following:
     - Abdominal mass;
     - Rectal mass;
     - Intestinal prolapse;
     - Plain abdominal radiograph showing a visible intussusceptum or soft tissue mass;
     - Abdominal ultrasound showing a visible intussusceptum or soft tissue mass;
     - Abdominal CT scan showing a visible intussusceptum or soft tissue mass.

3. Evidence of intestinal vascular compromise or venous congestion:
   - Passage of blood per rectum; or
   - Passage of a stool containing “red currant jelly” material; or
   - Blood detected on rectal examination.

**Minor criteria**

- Predisposing factors: age <1 year and male sex;
- Abdominal pain;
- Vomiting;
- Lethargy;

- Pallor;
- Hypovolemic shock;
- Plain abdominal radiograph showing an abnormal but non-specific bowel gas pattern.

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**Assessment of specificity**

In the specificity arm of the study, 404 patients in Melbourne and 234 patients in Hanoi were enrolled. These patients presented with symptoms and signs consistent with intussusception but had an alternative diagnosis established, including gastroenteritis (186 infants in Hanoi; 213 in Melbourne), other infections (23 in Hanoi; 101 in Melbourne), and non-infectious gastrointestinal disorders (5 in Hanoi; 43 in Melbourne). For a significant proportion of control infants, rectal examination or plain abdominal radiograph were not considered clinically indicated, and therefore they were not ethically justified. These patients were classified as “inconclusive” according to the clinical case definition. Sensitivity of the clinical case definition ranged from 81–97% in Hanoi and 96–98% in Melbourne. A subanalysis was performed using only those patients for whom the diagnosis of intussusception had been confirmed by an independent radiologist or medical observer or both. No difference in sensitivity was observed among this subgroup.
the definition using the same methods as in the sensitivity analysis (Table 4). Data for control patients were reanalysed, omitting data from the rectal examination from major criteria 2 and 3 (Table 4) irrespective of the result. The specificity of the clinical case definition in correctly identifying non-intussusception controls was 95% in Hanoi (223/234) and 87% in Melbourne (352/404). Only 11 controls (2%) were defined as having probable intussusception according to the case definition in a combined analysis using data from both sites (2 in Hanoi; 9 in Melbourne).

**Changes to the clinical case definition**

Due to the reluctance of medical staff and families to have a rectal examination performed in infants, we reanalysed data from patients classified as having intussusception but omitted the results of the rectal examination from major criteria 2 and 3 using the same approach as in the specificity arm of the study. This resulted in a small reduction in sensitivity at both sites.

Because radiological facilities may not be available in some primary care centres we also reassessed data from the sensitivity and specificity arms of the study, omitting any contribution made to the definition by a radiological examination (major criteria 1 and 2 and minor criterion). When non-specific X-ray changes (minor criterion) were excluded from the definition, and the definition was changed to include only two or more minor criteria, sensitivity remained at 96–97% but specificity fell (85% in Hanoi; 65% in Melbourne).

Due to the disparity between sites in reports of lethargy occurring in patients, the analysis was repeated, omitting both lethargy (minor criterion) and non-specific X-ray changes from the criteria and changing the definition to include only two or more minor criteria. Again, sensitivity remained at 96–97% and specificity was reduced but not as dramatically as when only X-rays were omitted (89% in Hanoi; 83% in Melbourne).

**Discussion**

The clinical case definition for acute intussusception in infants was found to be both sensitive and specific for diagnosing intussusception in Hanoi and Melbourne. An important strength of this prospective study is our adherence to strict criteria for diagnosis and the validation of the diagnosis in a high proportion of patients by an independent radiologist who was blinded to the patient’s status. The study confirms previous findings of a retrospective validation study performed at a tertiary care paediatric hospital in Australia. The definition has already been used successfully in clinical trials of a rotavirus vaccine in which more than 65,000 infants in Latin America and Asia participated.

Since untreated intussusception may result in death, a primary goal of this clinical case definition was to identify the majority of infants with intussusception. However, intussusception may have a wide range of clinical presentations — from lethargy to haemodynamic shock — and it is unrealistic to expect a clinical case definition to identify all patients. Improving the sensitivity of a clinical case definition often comes at the expense of specificity. Although intussusception is the most common cause of intestinal obstruction in infants, it is still far less common than gastroenteritis, particularly in developing countries. Interestingly, the specificity of the definition in Viet Nam (95%) was higher than in Australia (87%), suggesting that the definition performs well in a country with a high burden of gastroenteritis and intussusception. However, there is a significant disparity in the number of patients presenting with gastroenteritis compared with those diagnosed with intussusception. Even with a specificity of 95%, the definition should be aiming to identify patients at high risk of intussusception and should not replace clinical judgement in determining which patients should undergo further investigations to diagnose or exclude intussusception.

One of the difficulties we encountered was defining the appropriate method for assessing the subset of intussusception cases and controls who had data missing from components of the definition. The missing data were mainly the result of the reluctance of medical staff and families to have a rectal examination or an erect and supine abdominal radiograph performed if not clinically indicated. These omissions were considered to be valid, in light of the ethical issues they raised, if medical staff considered the investigations to be inappropriate or that they would pose

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intussusception cases</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hanoi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of infants</td>
<td>533</td>
<td>234</td>
</tr>
<tr>
<td>Median age (months)</td>
<td>9.3</td>
<td>11.3</td>
</tr>
<tr>
<td>Sex (% male)</td>
<td>65</td>
<td>59</td>
</tr>
<tr>
<td>Melbourne</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of infants</td>
<td>51</td>
<td>404</td>
</tr>
<tr>
<td>Median age (months)</td>
<td>8.4</td>
<td>10.3</td>
</tr>
<tr>
<td>Sex (% male)</td>
<td>69</td>
<td>56</td>
</tr>
</tbody>
</table>

Table 2. Confirmation of intussusception by an independent radiologist blinded to child’s status or by surgery, Hanoi and Melbourne, 2002–04

<table>
<thead>
<tr>
<th>Confirmation of intussusception</th>
<th>Hanoi (n = 533)</th>
<th>Melbourne (n = 51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intussusception confirmed by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiologist</td>
<td>409 (77)%</td>
<td>30 (59)</td>
</tr>
<tr>
<td>Surgery</td>
<td>37 (7)</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Total no. confirmed</td>
<td>446 (84)</td>
<td>34 (67)</td>
</tr>
<tr>
<td>Possible intussusception confirmed by radiologist</td>
<td>22 (4)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Intussusception not confirmed by radiologist</td>
<td>36 (7)</td>
<td>6 (12)</td>
</tr>
<tr>
<td>No X-ray available or poor quality film</td>
<td>29 (5)</td>
<td>9 (18)</td>
</tr>
</tbody>
</table>

* Values in parentheses are percentages.
Table 3. Sensitivity and specificity of each component of the clinical case definition for intussusception, Hanoi and Melbourne, 2002–04

<table>
<thead>
<tr>
<th>Component</th>
<th>Sensitivity(^a)</th>
<th>Specificity(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major criterion 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomit, bile-stained</td>
<td>159/530 (30)</td>
<td>212/233 (91)</td>
</tr>
<tr>
<td>Abdominal distension</td>
<td>91/533 (17)</td>
<td>194/234 (83)</td>
</tr>
<tr>
<td>Nil or abnormal bowel sounds</td>
<td>360/507 (71(^c))</td>
<td>126/234 (54)</td>
</tr>
<tr>
<td>Intestinal obstruction on plain abdominal X-ray</td>
<td>27/54 (50)</td>
<td>1/2 (50)</td>
</tr>
<tr>
<td>Combined(^d)</td>
<td>52/437 (12)</td>
<td>230/233 (99)</td>
</tr>
<tr>
<td><strong>Major criterion 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal mass</td>
<td>436/532 (82(^c))</td>
<td>234/234 (100)</td>
</tr>
<tr>
<td>Rectal mass</td>
<td>5/476 (1)</td>
<td>73/73 (100)</td>
</tr>
<tr>
<td>Rectal prolapse</td>
<td>0/532 (0)</td>
<td>234/234 (100)</td>
</tr>
<tr>
<td>Intussusception mass on plain abdominal X-ray</td>
<td>14/54 (26)</td>
<td>2/2 (100)</td>
</tr>
<tr>
<td>Intussusception mass on ultrasound(^e)</td>
<td>463/477 (97)</td>
<td>–</td>
</tr>
<tr>
<td>Combined(^d)</td>
<td>511/517 (99)</td>
<td>73/73 (100)</td>
</tr>
<tr>
<td><strong>Major criterion 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectal bleeding</td>
<td>251/533 (47)</td>
<td>213/234 (91)</td>
</tr>
<tr>
<td>Redcurrant jelly stool</td>
<td>74/491 (15)</td>
<td>73/73 (100)</td>
</tr>
<tr>
<td>Blood on rectal examination</td>
<td>261/474 (55)</td>
<td>154/177 (87)</td>
</tr>
<tr>
<td>Combined(^d)</td>
<td>309/510 (61)</td>
<td>154/177 (87)</td>
</tr>
<tr>
<td><strong>Minor criteria</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &lt; 1 year and male sex</td>
<td>237/533 (44)</td>
<td>154/234 (66)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>533/533 (100)</td>
<td>192/234 (82)</td>
</tr>
<tr>
<td>Vomiting, nonspecific</td>
<td>325/533 (61)</td>
<td>35/234 (15)</td>
</tr>
<tr>
<td>Pallor</td>
<td>277/533 (52(^c))</td>
<td>218/234 (93)</td>
</tr>
<tr>
<td>Lethargy</td>
<td>203/533 (38(^c))</td>
<td>211/234 (90)</td>
</tr>
<tr>
<td>Haemodynamic shock</td>
<td>5/533 (1(^c))</td>
<td>234/234 (100)</td>
</tr>
<tr>
<td>Nonspecific, abnormal bowel gas pattern on plain abdominal X-ray</td>
<td>4/54 (7)</td>
<td>2/2 (100)</td>
</tr>
<tr>
<td>At least 2 minor criteria</td>
<td>515/533 (97)</td>
<td>125/234 (53)</td>
</tr>
<tr>
<td>At least 3 minor criteria</td>
<td>382/533 (72)</td>
<td>206/234 (88)</td>
</tr>
</tbody>
</table>

\(^a\) Sensitivity is the number (%) of patients with intussusception who had the sign or the symptom.
\(^b\) Specificity is the number (%) of control patients without the sign or the symptom.
\(^c\) \(P < 0.004\) using \(\chi^2\) test to compare Viet Nam to Australia.
\(^d\) Statistic uses all infants for whom sufficient data were available to make a conclusive classification.
\(^e\) Ultrasound was not performed on control infants in Viet Nam.

It is challenging to develop a practical clinical case definition for intussusception that is suitable for use in a range of health-care settings. We identified a marked difference between the frequency of reports of lethargy and pallor in Viet Nam and Australia, although most of the other clinical features were consistently reported at both sites (Table 3).\(^{11,13}\) The clinical case definition includes the use of basic radiology, however not all health centres may be able to perform an abdominal X-ray. To investigate the sensitivity of the definition in the absence of any radiological facilities we reanalysed the data to exclude the need for an X-ray or ultrasound. When the criterion for non-specific X-ray changes was excluded and the definition was relaxed to include only two or more minor criteria, sensitivity remained at 96–97% at the expense of specificity (85% in Hanoi; 65% in Melbourne). However, if both the non-specific X-ray changes and lethargy were excluded and the definition was relaxed to include only two or more minor criteria, a greater proportion of cases were able to be assessed. Under these conditions, the sensitivity of the definition remained 96–97% and the specificity was 83–89%. This suggests that exclusion of these two features will improve applicability and increase the reliability of the definition.

**Conclusion**
The clinical case definition for the diagnosis of acute intussusception in infants...
and young children has been shown to be sensitive and specific in prospective studies in both a developing country and a developed country. Modification of the minor criteria of the definition may be associated with improved compliance by staff and may also increase the reliability of the definition. The aim of this clinical case definition is to enable infants with intussusception who are participants in clinical trials of rotavirus vaccine to be assessed as well as those presenting to a range of health-care settings where diagnostic facilities may be limited.

Acknowledgements
We would like to acknowledge the support and guidance of Dr Duncan Steele and Dr Bernard Ivanoff at the Department of Vaccines and Biologicals, WHO, Geneva. We would also like to acknowledge the help of the staff at the Departments of Surgery, Medical Imaging/Radiology and Emergency Medicine at the National Hospital of Pediatrics in Hanoi and the Royal Children’s Hospital in Melbourne.

Résumé
Validation de la définition du cas clinique d’invagination intestinale aiguë chez le nourrisson au Viet Nam et en Australie
Objectif Évaluer la sensibilité et la spécificité d’une définition du cas clinique d’invagination intestinale aiguë chez le nourrisson afin d’aider les soignants lorsquels les moyens de diagnostic font défaut. 
Méthodes Des études prospectives ont été menées dans un grand hôpital pédiatrique du Viet Nam (Hôpital national de pédiatrie de Hanoi) de novembre 2002 à décembre 2003, ainsi qu’en Australie (le Royal Children’s Hospital de Melbourne) de mars 2002 à mars 2004, en se servant d’une définition du cas clinique d’invagination intestinale. Le diagnostic d’invagination a été confirmé par lavement à l’air ou intervention chirurgicale et validé dans un sous-ensemble de participants par un clinicien indépendant qui ne connaissait pas l’état des patients. On a évalué la sensibilité de la définition sur 584 nourrissons âgés de moins de 2 ans avec suspicion d’invagination (533 à Hanoi et 51 à Melbourne) et sa spécificité sur 638 nourrissons également âgés de moins de 2 ans, qui présentaient des signes cliniques évoquant une invagination intestinale mais pour lesquels un diagnostic différent avait été posé (234 à Hanoi et 404 à Melbourne).

Résultats Dans les deux établissements, la définition utilisée s’est révélée sensible (sensibilité de 96 % à Hanoi et de 98 % à Melbourne) et spécifique (spécificité de 95 % à Hanoi et de 87 % à Melbourne) pour le diagnostic d’une invagination chez les nourrissons au sujet desquels les données étaient suffisantes pour permettre un classement (449/533 à Hanoi; 50/51 à Melbourne). Une réanalyse des cas pour lesquels on manquait de données permet de penser qu’en modifiant certains critères mineurs on étendrait le champ d’application de la définition tout en lui conservant une bonne sensibilité (96 - 97 %) et une bonne spécificité (83 - 89 %).

Conclusion Cette définition du cas clinique s’est révélée à la fois sensible et spécifique pour le diagnostic de l’invagination intestinale aiguë chez le nourrisson aussi bien dans un pays en développement que dans un pays développé, mais on pourrait l’utiliser plus largement moyennant quelques modifications mineures.

Resumen
Validación de la definición clínica de caso de invaginación intestinal aguda en lactantes en Viet Nam y Australia
Objetivo Determinar la sensibilidad y la especificidad de una definición clínica de caso de invaginación intestinal aguda en los lactantes para ayudar a los profesionales sanitarios que trabajan en entornos que carecen de servicios diagnósticos.

Métodos Utilizando una determinada definición clínica de caso de invaginación intestinal, se realizaron estudios prospectivos en un importante hospital pediátrico de Viet Nam (Hospital Nacional de Pediatría, Hanoi) entre noviembre de 2002 y diciembre de 2003,
y en Australia (Royal Children’s Hospital, Melbourne) entre marzo de 2002 y marzo de 2004. El diagnóstico de invaginación intestinal fue confirmado mediante examen de aire o cirugía y validado en un subconjunto de pacientes por un médico independiente que desconocía la situación del participante. Se evaluó la sensibilidad de la definición en 584 niños menores de 2 años con presunta invaginación intestinal (533 niños en Hanoi; 51 en Melbourne). La especificidad se evaluó en 638 niños menores de 2 años que presentaban signos clínicos compatibles con invaginación intestinal pero con otro tipo de diagnóstico (234 niños en Hanoi; 404 en Melbourne).

**Resultados** En los dos lugares estudiados, la definición utilizada fue sensible (sensibilidad del 96% en Hanoi, y del 98% en Melbourne) y especifica (especificidad del 95% en Hanoi, y del 87% en Melbourne) para la invaginación intestinal entre los lactantes con datos suficientes para poder clasificarlos (449/533 en Hanoi; 50/51 en Melbourne). El reanálisis de los pacientes sobre los que faltaban datos parece indicar que la modificación de algunos criterios secundarios ampliaría la aplicabilidad de la definición sin influir apenas en la sensibilidad (96% - 97%) y la especificidad (83% - 89%).

**Conclusion** La definición clínica de caso de invaginación intestinal aguda en lactantes se reveló sensible y específica tanto en un país en desarrollo como en un país desarrollado, pero la introducción de ligera modificaciones permitiría aplicarla de forma más amplia.

**References**


