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

Julie E Bines,[a] Nguyen Thanh Liem,[b] Frances Justice,[a] Tran Ngoc Son,[b] John B Carlin,[c] Margaret de Campo,[d] Kris Jamsen,[c] Kim Mulholland,[e] Peter Barnett,[f] & Graeme L Barnes[a]

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 used 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.

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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.[1–3] 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.[2] Large-scale clinical trials are now required to detect a risk of intussusception of < 1 in 10 000.[4–6] 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.[7] The aim of the clinical case definition is 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.[8] 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

[a] Murdoch Children's Research Institute, Melbourne, Australia. Correspondence to Dr Bines (email: julie.bines@rch.org.au).
[b] Department of Surgery, National Hospital for Paediatrics, Hanoi, Viet Nam.
[c] Clinical Epidemiology and Biostatistics Unit, Murdoch Children's Research Institute, Melbourne, Australia.
[d] Department of Medical Imaging, Monash Medical Centre, Clayton, Australia.
[e] Centre for International Child Health, Department of Paediatrics, University of Melbourne, Australia.
[f] Department of Emergency Medicine, Royal Children's Hospital, Melbourne, Australia.

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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 χ^2 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 (1/72 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

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

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;

or

The demonstration of an intra-abdominal mass by abdominal ultrasound with specific characteristic features[b] 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[c] 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:*
   - i. History of bile-stained vomiting;
     and either
   - ii. Examination findings of acute abdominal distension and abnormal or absent bowel sounds;
     or
   - iii. Plain abdominal radiograph showing fluid levels and dilated bowel loops.

2. *Features of intestinal invagination*

   One or more of the following:
   - i. abdominal mass;
   - ii. rectal mass;
   - iii. intestinal prolapse;
   - iv. plain abdominal radiograph showing a visible intussusceptum or soft tissue mass;
   - v. abdominal ultrasound showing a visible intussusceptum or soft tissue mass;
   - vi. abdominal CT scan showing a visible intussusceptum or soft tissue mass.

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

Minor criteria

i. Predisposing factors: age <1 year and male sex;
ii. Abdominal pain;
iii. Vomiting;[d]
iv. Lethargy;[e]
v. Pallor;[e]
vi. Hypovolemic shock;
vii. Plain abdominal radiograph showing an abnormal but non-specific bowel gas pattern.

[a] Source: *Ref. 7* reproduced with permission from Elsevier.
[b] Target sign or doughnut sign on transverse section and a pseudo-kidney or sandwich sign on longitudinal section.
[c] If one major criterion is the passage of blood per rectum that is mixed in a diarrhoeal stool, consideration should be given to infectious causes (e.g., *E. coli*, shigella, or amoebiasis). In such cases two major criteria should be met.
[d] If the vomiting is bile-stained, it cannot be counted twice as a major and minor criterion.
[e] Lethargy and pallor typically occur intermittently in association with acute spasms of abdominal pain. In patients with severe or prolonged intussusception, lethargy and pallor may become a constant feature associated with a deterioration in cardiovascular status and impending hypovolemic shock.

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.

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 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).

Table 1. **Characteristics of infants with intussusception and non-intussusception control group, Hanoi and Melbourne, 2002–04**

Characteristics	Intussusception cases	Control group
Hanoi		
No. of infants	533	234
Median age (months)	9.3	11.3
Sex (% male)	65	59
Melbourne		
No. of infants	51	404
Median age (months)	8.4	10.3
Sex (% male)	69	56

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 nonspecific 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.[8] 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.[9]

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.[10–13] 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.[14–16] 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 2. **Confirmation of intussusception by an independent radiologist blinded to child's status or by surgery, Hanoi and Melbourne, 2002–04**

Confirmation of intussusception	Hanoi (*n* = 533)	Melbourne (*n* = 51)
Intussusception confirmed by:		
Radiologist	409 (77)[a]	30 (59)
Surgery	37 (7)	4 (8)
Total no. confirmed	446 (84)	34 (67)
Possible intussusception confirmed by radiologist	22 (4)	2 (4)
Intussusception not confirmed by radiologist	36 (7)	6 (12)
No X-ray available or poor quality film	29 (5)	9 (18)

[a] 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**

Component	Sensitivity[a]		Specificity[b]	
	Hanoi (*n* = 533)	Melbourne (*n* = 51)	Hanoi (*n* = 234)	Melbourne (*n* = 404)
Major criterion 1				
Vomit, bile-stained	159/530 (30)	16/51 (31)	212/233 (91)	392/404 (97)
Abdominal distension	91/533 (17)	16/51 (31)	194/234 (83)	383/403 (95)
Nil or abnormal bowel sounds	360/507 (71)[c]	13/42 (31)	126/234 (54)	348/382 (91)
Intestinal obstruction on plain abdominal X-ray	27/54 (50)	11/37 (30)	1/2 (50)	23/24 (96)
Combined[d]	52/437 (12)	9/48 (19)	230/233 (99)	403/404 (99)
Major criterion 2				
Abdominal mass	436/532 (82)[c]	28/51 (55)	234/234 (100)	395/403 (98)
Rectal mass	5/476 (1)	3/31 (10)	73/73 (100)	45/45 (100)
Rectal prolapse	0/532 (0)	0/49 (0)	234/234 (100)	266/266 (100)
Intussusception mass on plain abdominal X-ray	14/54 (26)	15/37 (41)	2/2 (100)	24/24 (100)
Intussusception mass on ultrasound[e]	463/477 (97)	24/24 (100)	–	4/4 (100)
Combined[d]	511/517 (99)	45/45 (100)	73/73 (100)	42/50 (84)
Major criterion 3				
Rectal bleeding	251/533 (47)	22/51 (43)	213/234 (91)	392/404 (97)
Redcurrant jelly stool	74/491 (15)	7/47 (15)	213/234 (91)	404/404 (100)
Blood on rectal examination	261/474 (55)	13/25 (52)	159/177 (90)	55/56 (98)
Combined[d]	309/510 (61)	26/37 (70)	154/177 (87)	53/67 (79)
Minor criteria				
Age < 1 year and male sex	237/533 (44)	27/51 (53)	154/234 (66)	259/404 (64)
Abdominal pain	533/533 (100)	48/51 (94)	192/234 (82)	326/402 (81)
Vomiting, nonspecific	325/533 (61)	31/51 (61)	35/234 (15)	93/404 (23)
Pallor	277/533 (52)[c]	39/50 (78)	218/234 (93)	299/404 (74)
Lethargy	203/533 (38)[c]	49/51 (96)	211/234 (90)	206/404 (51)
Haemodynamic shock	5/533 (1)[c]	11/51 (22)	234/234 (100)	395/399 (99)
Nonspecific, abnormal bowel gas pattern on plain abdominal X-ray	4/54 (7)	10/37 (27)	2/2 (100)	17/24 (71)
At least 2 minor criteria	515/533 (97)	51/51 (100)	125/234 (53)	113/404 (28)
At least 3 minor criteria	382/533 (72)	49/51 (96)	206/234 (88)	270/404 (67)

[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 χ^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.

an unnecessary risk. One approach to interpreting the sensitivity data would have been to exclude from the analysis all patients with missing data. However, this could have biased the results. By including data from patients with a missing value (or values) and reanalysing the data by assuming the missing component was positive or negative, the sensitivity of the test could be expressed as a range. Because staff did not perform rectal examinations in control infants, we attempted to minimize potential bias by excluding data from the rectal examination irrespective of the result in the specificity analysis.

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. ■

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Table 4. **Classification of intussusception cases and controls according to the clinical case definition, Hanoi and Melbourne, 2002–04**

	Primary analysis		Reanalysis assigning inconclusive cases	
	Cases	Controls	Assuming missing value is positive	Assuming missing value is negative
Hanoi				
Probable	433 (81)[a]	2 (1)	517 (97)	433 (81)
Possible	0	3 (1)	0	0
Negative	16 (3)	145 (65)	16 (3)	100 (19)
Inconclusive[b]	84 (16)	84 (36)	0	0
Total	**533**	**234**	**533**	**533**
Melbourne				
Probable	49 (96)	9 (2)	50 (98)	49 (96)
Possible	0	1 (1)	0	1 (2)
Negative	1 (2)	57 (14)	1 (2)	1 (2)
Inconclusive[b]	1 (2)	337 (83)	0	0
Total	**51**	**404**	**51**	**51**

[a] Values in parentheses are percentages.
[b] These cases were designated as inconclusive or unable to be defined by the clinical case definition owing to missing data.

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Résumé

Validation de la définition du cas clinique d'invagination intestinale aiguë chez le nourrisson au Viet Nam et en Australie

Objectif Evaluer la sensibilité et la spécificité d'une définition du cas clinique d'invagination intestinale aiguë chez le nourrisson afin d'aider les soignants lorsque 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 enema 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 específica (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%).

Conclusión 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 ligeras modificaciones permitiría aplicarla de forma más amplia.

ملخص

توثيق مصداقية تعريف الحالات السريرية (الإكلينيكية) للانغلاف الحاد لدى الرُّضَّع في فيتنام وأستراليا

الهدف: اختبار مدى حساسية ونوعية تعريف الحالات السريرية للانغلاف الحاد لدى الرُّضَّع لمساعدة العاملين الصحيِّين في المواقع التي لا تـتوافر فيها الوسائل التشخيصية.

الطريقة: أجريت دراسات استقبالية في إحدى المستشفيات الكبيرة للأطفال في فيتنام (المستشفى الوطني للأطفال في هانوي) في الفترة بين تشرين الثاني/نوفمبر 2002، وكانون الأول/ديسمبر 2003، والمستشفى الملكي للأطفال في ملبورن في الفترة بين آذار/مارس 2002، وآذار/مارس 2004، باستخدام تعريف الحالات السريرية للانغلاف. وقد تأكَّد تشخيص الانغلاف بالحقنة الشرجية الهوائية أو بالجراحة، وقام أطباء سريريون مستقلون بالتأكُّد من الحالات لدى مجموعة من المشمولين بالدراسة دون أن يعرفوا شيئاً عن حالاتهم. وقد تم تقيـيم حساسية تعريف الحالات السريرية للانغلاف لدى 584 رضيعاً ممن تقل أعمارهم عن سنتين وكان يشك لديهم بوجود الانغلاف (533 رضيعاً في هانوي و51 في ملبورن). كما تم تقيـيم نوعية تعريف الحالات السريرية للانغلاف لدى 638 رضيعاً ممن تقل أعمارهم عن سنتين ولديهم ملامح سريرية تـتماشى مع الانغلاف، إلا أنهم قد شخّصوا تشخيصاً مختلفاً (234 رضيعاً في هانوي و404 في ملبورن).

الموجودات: كان تعريف الحالات السريرية للانغلاف لدى الرُّضَّع في كلا الموقعين يتمتع بالحساسية (96% في هانوي و98% في ملبورن) والنوعية (95% في هانوي و87% في ملبورن) مع توافر معطيات كافية تسمح بالتصنيف (449 من بين 533 رضيعاً في هانوي، و50 من بين 51 في ملبورن). إن إعادة تحليل حالات المرضى الذين يفتقدون المعطيات يشير إلى أن معطيات معدَّلة قليلة قد تزيد من قابلية تطبيق تعريف الحالات السريرية للانغلاف مع المحافظة على الحساسية الجيدة (96 – 97%) والنوعية الجيدة (83 – 89%).

الاستنتاج: لقد تمتع تعريف الحالات السريرية لتشخيص الانغلاف الحاد لدى الرُّضَّع في كلٍّ من البلدان المتقدِّمة والنامية بكلٍّ من الحساسية النوعية، إلا أن تعديلات قليلة عليه قد تجعله أكثر انتشاراً.

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