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Refractory/therapy-resistant/intractable constipation in children

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ABSTRACT

Introduction A better understanding of key concepts is required to properly characterise intractable constipation (IC). We aimed to determine how IC is defined by Latin and Ibero-American paediatric gastroenterologists.

Methods A questionnaire was administered to evaluate concepts supporting the definition and use of a unified term for IC. The collected data were analysed using univariate and bivariate analyses. ORs with their corresponding 95% CIs were calculated, p values <0.05 were statistically significant.

Results A total of 429 paediatric gastroenterologists participated: 45.7% Latin American Society for Pediatric Gastroenterology, Hepatology and Nutrition (LASPGHAN) members (group 1), 16.3% Ibero-American LASPGHAN members (group 2) and 38.0% non-LASPGHAN affiliates (group 3). Most respondents considered lower bowel frequency despite receiving 'optimal medical treatment' (94.6%), with 51.0% indicating a period of 2–3 months; defined 'prior treatment failure' as the use of two laxatives (51.7%); selecting the tertiary level care prior to diagnosis (43.1%); wished to include the term 'optimal medical treatment' for diagnostic criteria (93.0%); believed follow-up should be carried out by a paediatrician/specialist (86.7%) and preferred the term refractory constipation (86.7%). When comparing group 1 versus group 2, the Spanish group preferred the term 'treatment-resistant constipation' (OR=1.96; 95% CI 1.08 to 3.55; p=0.0157).

Conclusions Latin and Ibero-American paediatric gastroenterologists prefer replacing the term 'IC' with 'refractory/treatment-resistant constipation' defined as a form of paediatric FC characterised by the persistence of clinically relevant symptoms despite optimal conventional medical treatment, appropriately prescribed, supervised and adhered to for a minimum period of 2–3 months, after structural, neurological and metabolic organic causes have been excluded.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Therapy-resistant constipation is a significant problem in clinical practice and until recently there was no international consensus for the definition. It is imperative to have a definition for the Latin and Ibero-American region where the resources are not equally distributed.

WHAT THIS STUDY ADDS

⇒ Latin and Ibero-American gastroenterologists recommend replacing the term intractable constipation with refractory/treatment-resistant constipation and emphasise management at the secondary level of care. They support maintaining 'optimal medical treatment' criteria, defining therapeutic failure within 2–3 months as the need for two laxatives, multiple enemas or medications, with follow-up by a paediatrician or specialist.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Findings of this study show that the definition provided by the international consensus is agreeable to Latin and Ibero-American paediatric gastroenterologists. The definition can be used in clinical practice, research and policy-making in the region.

INTRODUCTION

The worldwide prevalence of functional constipation (FC) in school-aged children and adolescents according to the Rome IV Criteria is 12.0% (95% CI 11.0% to 15.0%, I^2=92.0%).[1] Approximately one-quarter of children with FC continue to experience symptoms into adulthood; identified risk factors include older age at onset, a longer delay between symptom onset and the first outpatient visit, and a lower frequency of defecation at study entry.[2]

Intractable constipation (IC) is defined by the National Institute for Health and Care Excellence, as constipation that does not respond to optimal and sustained medical treatment and according to the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), as constipation that does not respond to optimal conventional treatment for at least 3 months. However, the current Rome IV Criteria do not consider IC[3–5] and a systematic review fails to provide an explicit definition of treatment-resistant constipation

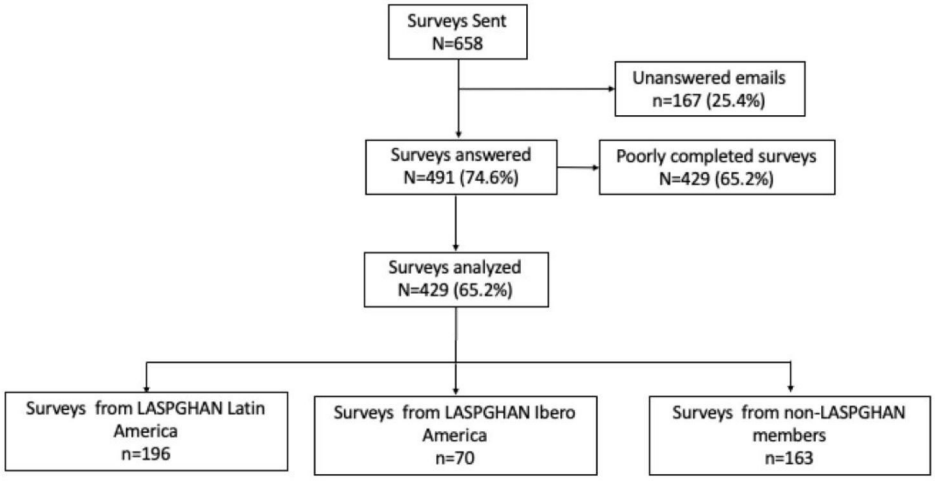

Figure 1 Population flow chart. LASPGHAN, Latin American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

in children.[6] Another study, when evaluating the efficacy and safety of treatments used for IC in children, is unable to draw solid conclusions.[7] For this reason, a group of paediatric gastroenterologists from the ESPGHAN and NASPGHAN propose a protocol to update the treatment guidelines for FC.[8]

A recent cross-sectional survey of general paediatricians, paediatric gastroenterologists and researchers using an online questionnaire proposes the term 'treatment resistant constipation' for IC. This is defined as constipation that does not respond to the maximum dose of at least two laxatives from different classes for a minimum of 3 months, with good adherence and follow-up at a secondary or tertiary care centre.[9] Currently, the term IC presents a significant conceptual gap due to the lack of clarity regarding the transition point between chronic constipation and this more complex condition. Furthermore, the absence of a complete and unified definition limits homogeneity across clinical studies and hinders the standardisation of diagnostic and therapeutic approaches.

The position of the members of the Latin American Society for Pediatric Gastroenterology, Hepatology and Nutrition (LASPGHAN) on this topic is unknown. Therefore, the present study seeks to involve paediatric gastroenterologists belonging to this society in order to reach a consensus on a definition of the term IC and to explore its possible associations. A more precise understanding of these aspects will optimise the therapeutic approach to IC, improving the quality of life of paediatric patients and their caregivers, and contributing to a significant reduction in the associated costs within healthcare systems.

METHODS

The questionnaire developed by Gordon *et al*[9] was used to collect data. It consisted of seven questions; it aimed to evaluate key concepts for defining and using a unified term for IC. This questionnaire was previously translated to Spanish using the translation and back-translation method, to ensure semantic and conceptual equivalence between the original and translated versions, while preserving the intent of the items, scientific terminology and clarity of the content. It was subsequently converted to Google Forms and sent to the email addresses of Latin American and Ibero-American paediatric gastroenterologists registered in the LASPGHAN database as of 31 January 2024, as well as to a group of non-LASPGHAN affiliated paediatric gastroenterologists. All participants were Spanish-speaking. Consequently, we were able to include broad and diverse representation of expert professionals active in the field.

Statistical analysis was performed using Stata V.16 software. Descriptive and analytical statistical tests were applied according to the nature of the variables. Fisher's exact test was used when appropriate, along with two-tailed Student's t-test and the χ^2 test. A multiple logistic regression model was developed to identify potential associations and predictive factors. To evaluate possible risk factors, univariate and bivariate analyses were conducted with calculation of ORs and their corresponding 95% CIs. P values <0.05 were considered statistically significant.

RESULTS

A total of 658 Latin American and Ibero-American paediatric gastroenterologists were invited to participate, of whom 491 (74.6%) responses were received. Figure 1 depicts the response rates of the participants.

General analysis

The majority of the paediatric gastroenterologists surveyed were affiliated with LASPGHAN Latin America (45.7%), and Argentina had the highest representation (29.6%) (table 1).

Regarding the seven questions aimed to reach a consensus on the most suitable definition of IC, 94.6% of participants considered the duration of constipation key for a diagnosis. Among these respondents, the option of 2–3 months was selected by more than

half (51.0%). Furthermore, 51.7% of respondents defined the criterion of 'prior therapeutic failure' as the concurrent administration of two laxative agents without an adequate response. With respect to the level of care required before establishing the diagnosis, 43.1% considered that these paediatric patients should be managed at the tertiary level (specialised care units).

When asked whether the concept of 'optimal medical treatment' should be included within the diagnostic criteria, 93.0% agreed. And for the monitoring of this treatment, 86.7% considered that this should be carried out by a paediatrician or a specialist. The participants were divided almost equally with regard to the most appropriate terminology where 44.9% to 'refractory constipation' followed by 38.2% to 'treatment-resistant constipation' (table 1).

Table 1 General analysis of knowledge about IC among Latin American and Ibero-American gastropediatricians (N=429)

Membership	Number (%)
LASPGHAN Latin America (Argentina, Chile, Colombia, Ecuador, Costa Rica, El Salvador, Mexico, Peru, Nicaragua, Panama, Paraguay, Honduras)	196 (45.7)
LASPGHAN Ibero-America (Spain)	70 (16.3)
Non-members LASPGHAN	163 (38.0)
Continent	
Latin America	353 (82.3)
Ibero-America	76 (17.7)
Do you take into account the duration during which the child does not have bowel movements despite receiving 'optimal medical treatment'?	
No	23 (5.4)
Yes	406 (94.6)
How long is necessary to consider 'optimal medical treatment' in order to diagnose intractable constipation?	
Less than 1 month	70 (17.2)
2–3 months	207 (51.0)
4–6 months	97 (23.9)
More than 6 months	32 (7.9)
Which of the following could be considered 'prior treatment failure'?	
Use of two laxative agents	222 (51.7)
Other	207 (48.3)
At which level of care should the child be managed before being diagnosed with intractable constipation?	
Primary (community)	80 (18.6)
Secondary (hospital)	164 (38.2)
Tertiary (specialised care units)	185 (43.1)
Should 'optimal medical treatment' be included in the diagnostic criteria for intractable constipation?	
No	30 (7.0)
Yes	399 (93.0)
Who should assess adherence to 'optimal medical treatment'?	
The parents	40 (9.3)
The child	1 (0.2)
The general practitioner or family doctor	16 (3.7)
The paediatrician or specialist	372 (86.7)
What would be the most appropriate term to define 'intractable constipation'?	
Refractory constipation	240 (44.9)
Treatment-resistant constipation	164 (38.2)
Intractable constipation	21 (4.9)
Other	2 (0.5)

IC, intractable constipation; LASPGHAN, Latin American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

Table 2 Comparative analysis of LASPGHAN Latin America, LASPGHAN Ibero-America and non-LASPGHAN members (N=429)

	LASPGHAN Latin America **n=196**	LASPGHAN Ibero-America n=70	Non-LASPGHAN members **n=163**	**P value**
1. Do you take into account the duration during which the child does not have bowel movements despite receiving 'optimal medical treatment'?				
No	10 (5.1)	2 (2.9)	11 (6.8)	0.47
Yes	186 (94.9)	68 (97.1)	152 (93.2)	
2. How long is necessary to consider 'optimal medical treatment' in order to diagnose intractable constipation?				
	(n=186)	(n=68)	(n=152)	
Less than 1 month	28 (15.1)	16 (23.5)	26 (17.1)	0.28
2–3 months	104 (55.9)	32 (47.1)	71 (46.7)	0.18
4–6 months	44 (23.7)	13 (19.1)	40 (26.3)	0.50
More than 6 months	10 (5.4)	7 (10.3)	15 (9.9)	0.22
3. Which of the following could be considered 'prior treatment failure'?				
Use of two laxative agents	103 (52.6)	39 (55.7)	80 (49.1)	0.62
Other	93 (47.4)	31 (44.3)	83 (50.9)	
4. At which level of care should the child be managed before being diagnosed with intractable constipation?				
Primary	36 (18.4)	18 (25.7)	26 (15.9)	0.21
Secondary	64 (32.6)	25 (35.7)	75 (46.0)	0.03
Tertiary	96 (49.0)	27 (38.6)	62 (38.0)	0.08
5. Should 'optimal medical treatment' be included in the diagnostic criteria for intractable constipation?				
No	11 (5.6)	5 (7.1)	14 (8.6)	0.54
Yes	185 (94.4)	65 (92.9)	149 (91.4)	
6. Who should assess adherence to 'optimal medical treatment'?				
The parents	19 (9.7)	4 (5.7)	17 (10.4)	0.51
The child	1 (0.5)	0 (0.0)	0 (0.0)	0.55
The general practitioner or family doctor	5 (2.5)	3 (4.3)	8 (4.9)	0.48
The paediatrician or specialist	171 (87.2)	63 (90.0)	138 (84.7)	0.52
7. What would be the most appropriate term to define 'intractable constipation'?				
Refractory constipation	116 (59.2)	35 (50.0)	89 (54.6)	0.37
Treatment-resistant constipation	66 (33.7)	35 (50.0)	63 (38.6)	0.05
Intractable constipation	13 (6.6)	0 (0.0)	8 (4.9)	0.08
Other	1 (0.5)	0 (0.0)	1 (0.6)	0.81

LASPGHAN, Latin American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

Comparative analysis

LASPGHAN Latin America versus LASPGHAN Ibero-America versus non-members of LASPGHAN

When comparing the three groups, it was observed that paediatric gastroenterologists not affiliated with LASPGHAN were more likely to manage children at the secondary level of care before establishing a diagnosis (p=0.03), compared with the tertiary or primary levels (table 2). These results were confirmed by a comparative subanalysis between LASPGHAN Latin America members and non-LASPGHAN members (OR=1.75; 95%CI 1.11 to 2.76; p=0.0097) (online supplemental table 1). LASPGHAN Ibero-American paediatric gastroenterologists showed a tendency to prefer the term 'treatment-resistant' over 'intractable' (p=0.05) (table 2). This trend was confirmed through a comparative subanalysis between LASPGHAN Latin American members and LASPGHAN Ibero-American members (OR=1.96; 95%CI 1.08 to 3.55; p=0.0157) (online supplemental table 2).

LASPGHAN Latin America versus non-LASPGHAN members

Without statistically significant differences, both groups considered 2–3 months of constipation duration as a diagnostic criterion for IC. LASPGHAN Latin American members more frequently defined therapeutic failure as lack of response to two laxatives (52.6% vs 49.1%), while non-affiliated participants favoured other criteria. Both

Figure 2 What is known, what is new and what the future is. FINDERS, Functional International Digestive Epidemiological Research Survey.

groups agreed that optimal treatment assessment should be part of the diagnostic process, performed by a paediatrician or a specialist (87.2% vs 84.7%), and preferred the term 'refractory constipation' (59.2% vs 54.6%) (online supplemental table 1).

LASPGHAN Latin America versus LASPGHAN Ibero-America

Without statistically significant differences, both groups considered 2–3 months as the most frequent time frame (55.9% vs 47.1%). Neither group considered lack of response to two laxatives as the main criterion for therapeutic failure. Both agreed on tertiary-level diagnosis (49.0% vs 38.6%) and that optimal treatment evaluation should be performed by a paediatrician or specialist (87.2% vs 90.0%) (online supplemental table 2).

LASPGHAN Ibero-America versus non-LASPGHAN members

Finally, without statistically significant differences, both groups identified 2–3 months as the key diagnostic timeframe (47.1% vs 46.7%). Non-LASPGHAN professionals more frequently cited two laxatives as therapeutic failure criterion (49.1%) and favoured secondary-level care diagnosis (46.0% vs 35.7%). Both groups agreed that optimal treatment evaluation should be the responsibility of a paediatrician or specialist (90.0% vs 84.7%) and preferred 'refractory constipation' (50.0% vs 54.6%) (online supplemental table 3).

DISCUSSION

Constipation poorly responding to optimal medical management is a significant clinical problem in paediatric practice.[2 10] In 2014, the NASPGHAN and ESPGHAN societies introduced the term IC for the first time in their evidence-based recommendations, to describe patients with FC who do not show clinical improvement and exhibit a persistent course over time.[11] The only established characteristic of this condition was the lack of response to optimal conventional medical treatment for at least 3 months.[6 11] However, these guidelines do not clearly specify what is considered 'optimal conventional treatment,' nor do they provide a specific algorithm for the diagnosis and management of IC.[6] Instead, they emphasise that, to establish the diagnosis, it is essential to first rule out organic pathologies, such as Hirschsprung disease (by biopsy and anorectal manometry), anatomical malformations (through barium enema), and spinal malformations (by MRI).[11]

Due to the lack of resolution and considering the high prevalence of this condition, Gordon *et al*[9] proposed in 2024, through a consensus developed by a panel of experts including general practitioners, general paediatricians, paediatric gastroenterologists and researchers, a more precise definition for IC. This proposal established a unified term for its designation, a specific timeframe for diagnosis, a consensus definition of therapeutic failure, the appropriate clinical setting for evaluation, and the professionals responsible for assessing treatment adherence, using a seven-question questionnaire.[8 9] This process resulted in a guiding conclusion regarding what could be considered IC. In this study, we sought to expand the scope of the original research by using the same questionnaire[9] and incorporating the participation of paediatric gastroenterologists affiliated with LASPGHAN Latin America and LASPGHAN Ibero-America, with the aim of strengthening consensus and clinical applicability in these Spanish-speaking regions. The novelty of this study lies in exploring potential associations among LASPGHAN Latin American, LASPGHAN Ibero-American, and non-LASPGHAN affiliated paediatric gastroenterologists, in order to identify similarities and differences in their perspectives and clinical approaches.

When these results were compared —excluding the latter response—with those obtained by professionals in the study by Gordon *et al*[9] a similar level of concordance was observed. However, Gordon *et al*[9] did not specify who should perform the treatment evaluation, instead, they emphasised how the evaluation should be conducted, relying on a detailed patient medical history. It is of great academic and pragmatic benefit that such an independent research exercise has confirmed convergence of thought on this vital definition for both clinical and research practice. It is suggested that this would support its use and potential future endorsement by societies such as Rome.

Unlike the previous study, this sample included general paediatric gastroenterologists not affiliated with a professional society. This subset who mostly identified other types of treatments as criteria for defining therapeutic failure. These non-LASPGHAN affiliated paediatric gastroenterologists, who may base their decisions on personal experience, available resources, or local contextual factors rather than on standardised guidelines.[12] This heterogeneity has been documented in multiple studies, which report significant differences in the management of paediatric FC among professionals and hospital centres, even within the same country.[13] The observed variability highlights the need to unify diagnostic and therapeutic criteria and to strengthen the implementation of evidence-based guidelines, such as those recommending the use of polyethylene glycol as the first-line treatment for paediatric FC.[14] This gap has recently been emphasised by Kilgore *et al*[15] who point out that IC cannot be defined solely by symptom duration, instead of the lack of response to truly optimal medical treatment, including osmotic laxatives at adequate doses, for a sufficient period of time, and with systematic assessment of adherence, before classifying a patient as refractory.

Regarding the most appropriate term to designate the condition, there is an interesting discordance. The LASPGHAN Ibero-American paediatric gastroenterologists and the study conducted by Gordon *et al*[9] showed a preference for the term 'treatment-resistant' in contrast to LASPGHAN Latin American specialists, who favoured 'refractory.' This difference highlights conceptual and semantic variability surrounding difficult-to-manage FC.

Although both terms are often used interchangeably in the literature, each conveys distinct clinical nuances related to therapeutic response and disease severity.[6] The use of the terms 'resistant' and 'refractory' entails subtle but relevant differences in both their linguistic definitions and medical application. According to the Royal Spanish Academy (RAE), 'resistant' is defined as something that 'offers great force or difficulty against something' or 'withstands the action of an agent without being altered or destroyed,' whereas 'refractory' is described, among other meanings, as something that 'does not respond to treatment'.[16] While the former tend to prefer 'refractory' and the latter 'treatment-resistant,' this discrepancy reflects variations in clinical interpretation and levels of healthcare complexity. In addition, the study by Gordon *et al*[9] included professionals from different specialties beyond paediatric gastroenterology, which may have contributed to the heterogeneity of some responses. However, we acknowledge practically a move to a single term may be preferable.

Based on these findings, we propose that IC should be defined as

'a form of paediatric FC characterised by the persistence of clinically relevant symptoms despite optimal conventional medical treatment, appropriately prescribed, supervised and adhered to for a minimum period of 2–3 months, after structural, neurological and metabolic organic causes have been excluded, in accordance with established international guidelines' (figure 2).

The exclusion of structural, neurological and metabolic organic causes is a fundamental step in the evaluation of paediatric IC. Although the present study was not designed to establish a detailed diagnostic protocol, this process should be carried out in accordance with established international guidelines, such as those from ESPGHAN and NASPGHAN, which provide structured approaches based on clinical assessment and complementary investigations.[4 8 11 12]

This proposal is consistent with the approach advocated by recent consensus statements, such as the *Società Italiana di Gastroenterologia, Epatologia e Nutrizione Pediatrica* position paper, which emphasise the need for flexible, operational definitions based on therapeutic response, clinical context and underlying pathophysiology rather than on rigid, exclusively time-based criteria.[5]

Agreement on a name for the condition was not fully consensus, with Latin Ibero-Americans agreeing with Gordon *et al* that 'treatment resistant' should be used. While Latin American responders did not agree and so it is difficult to fully support this term, there is consensus that the designation 'IC' should no longer be used, given its imprecision and lack of conceptual support in current clinical practice.

This study has several limitations. First, the use of a questionnaire-based design reflects self-reported opinions, which may not fully represent real-world decision-making. Second, participation was voluntary, introducing a potential selection bias, as clinicians with greater interest or expertise in the topic may have been more likely to respond. Additionally, the study did not collect sociodemographic information on participants', which could influence their perspectives and limit more in-depth subgroup analyses. Furthermore, although the study intentionally focused on paediatric gastroenterologists to provide a specialised perspective, the exclusion of general paediatricians may limit the broader applicability of the findings across all levels of care. Finally, therapeutic decisions following the diagnosis of IC were not evaluated. While the study focused on conceptual definitions and diagnostic criteria, it did not address management strategies after diagnosis or the need for referral to specialised care, which are clinically relevant aspects that should be explored in future research.

CONCLUSIONS

This group of Latin American and Ibero-American paediatric gastroenterologists mainly prefers changing the term 'IC' to 'refractory/treatment-resistant constipation.' This is defined as 'a form of paediatric FC characterised by the persistence of clinically relevant symptoms despite optimal conventional medical treatment, appropriately prescribed, supervised and adhered to for a minimum period of 2–3 months, after structural, neurological and metabolic organic causes have been excluded'.

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