

Abdominal manipulation and other cultural risk factors associated with complication of acute appendicitis in pediatric patients

Manipulación abdominal y otros factores de riesgo culturales asociados a complicación de apendicitis aguda en pacientes pediátricos

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What do we know about the subject matter of this study?

Delayed diagnosis and treatment of acute appendicitis is a known risk factor for its complication. There is limited knowledge of “empacho” and its respective treatment as a risk factor for the complication of acute appendicitis.

What does this study contribute to what is already known?

Sociocultural beliefs, such as “empacho”, abdominal manipulation, and intake of home remedies are risk factors for the complication of an established picture of acute appendicitis.

Abstract

In children, acute appendicitis (AA) is usually mistaken for *empacho*, which, according to popular belief, is caused by the ingestion of undercooked or cold food causing gastrointestinal symptoms. The empirical treatment is abdominal manipulation, consisting of massages with different maneuvers on the abdominal wall, accompanied by home remedies. The effect of these therapies in the presence of AA is unknown. **Objective:** To determine the association between abdominal manipulation and complicated AA in pediatric patients. **Patients and Method:** Case-control study in a pediatric population under 18 years of age, with acute abdomen symptoms, who underwent surgery for AA, in a tertiary health institution in Honduras. Cases were defined as patients with complicated AA and controls as those with simple AA. A binary logistic regression model was used to determine the risk factors associated with complications of AA. **Results:** Sixty-two pediatric patients were analyzed (31 cases and 31 controls) with a median age of 11 years. 58.1% were from an urban area. 77.4% of the

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cases and 9.7% of controls had a history of abdominal manipulation. The most frequent initial symptom was abdominal pain. In the univariate analysis, male sex, prolonged evolution time, use of home remedies, leukocytosis $> 20,000/\text{mm}^3$, and abdominal manipulation were risk factors for complicated AA. In the multivariate model, abdominal manipulation was the main risk factor (OR 15.94 [3.40-74.59]). **Conclusion:** Cultural beliefs such as *empacho* and its respective treatments such as abdominal manipulation and use of home remedies are risk factors for the complication of an established AA case, as well as contributing to the delay in diagnosis.

Introduction

Acute appendicitis (AA) is the main surgical emergency, particularly in children¹. AA is the inflammation of the vermiform appendix, a blind-ended pouch-like extension². The pathophysiology of AA consists in the obstruction of the proximal lumen of the appendix, generally by a fecalith, which triggers an accumulation of mucous secretions, with an increase in intraluminal pressure that collapses the venous system and causes thrombosis, and subsequently ischemia of the appendiceal mucosa. If the obstruction persists, the progressive increase of the intraluminal pressure causes venous infarcts, necrosis of the wall, and finally appendiceal perforation³⁻⁶.

The clinical picture is quite variable in pediatric patients, but it usually begins with epigastric pain that later migrates to the right iliac fossa, usually accompanied by fever⁷. Additional and variable symptoms include nausea, vomiting, anorexia, and diarrhea⁸.

At an early age, a delayed diagnosis is common in children, with a complication rate of 57% in preschool patients⁹. The lack of knowledge of this pathology by the general population added to the atypical and non-specific presentation at an early age, cause that this clinical picture is confused by parents/caregivers with *empacho*ⁱ and they decide to initiate treatment at home or go to a therapist called *sobador*^{ii 10-13}.

Empacho, a syndrome of cultural affiliation in some rural areas recognized throughout Latin America, is believed to be secondary to intestinal indigestion¹⁴, occurs most frequently in infants or young children, and is a disease in children that is mainly caused by the ingestion of undercooked or cold food^{15,16}. As a general rule, the diagnosis is domestic, where parents/caregivers are who recognize the main clinical characteristics which are similar to those of AA such as abdominal pain, nausea, vomiting, diarrhea, or constipation; sometimes fever and general malaise are usually present¹⁷.

The first curative remedies are home remedies and

i Indigestion.

ii Cen. Am., Ecu., U.S., Mex, Peru, and Chile. Person who treats bone dislocations and performs healing massages.

include religious rituals, massages, special maneuvers, laxatives, and/or medicinal herbs¹². In Latin America, the treatment of *empacho* consists of abdominal and dorsal-lumbar massage including rubbing, skin stretching, and sustained pressure on the abdominal wall¹⁸, and many therapists use grease and oil-based products to facilitate the maneuvers^{13,19}. All this is also accompanied by the intake of herbal infusions and/or laxatives that help to improve the gastrointestinal picture²⁰.

These maneuvers applied in an already established case of AA could delay the diagnosis, accelerate the pathophysiological process, and modify the clinical picture, making its diagnosis more difficult and consequently resulting in the different complications of AA. Multiple studies have established the risk factors for complicated AA, but there is limited literature on sociocultural beliefs, in this case on *empacho* and its respective treatment, as a risk factor for the complication of AA. The objective of this study is to determine the association between abdominal manipulation and complicated AA in a pediatric population.

Patients and Method

Observational, analytical, retrospective, case-control study. We analyzed a sample of pediatric patients, who underwent surgery due to AA, both simple and complicated, identified in the pediatric surgery ward of the *Hospital Nacional Dr. Mario Catarino Rivas*, a second-level care hospital of major importance in the northwestern area of Honduras.

Inclusion criteria were all patients under 18 years of age, with clinical symptoms of acute abdomen on admission, and who had undergone surgery for AA. All patients were considered as cases when at least one of the following complications was evidenced during surgery: gangrenous appendicitis, cecal appendix perforation, plastron appendicitis, and/or intra-abdominal abscess, and all patients were classified as controls if no complication was identified during surgery and the diagnosis of simple AA was recorded in the post-operative note. Pre-surgical patients, patients with un-

derlying comorbidities, operated patients diagnosed with acute abdomen other than AA, and patients with non-surgical acute abdomen were excluded.

A non-probabilistic sampling method was used due to the lack of knowledge of the total universe of patients with AA in the pediatric population. Using a consecutive recruitment method, 31 pediatric patients were included in the case and the control groups in an unpaired 1:1 ratio, according to compliance with the selection criteria and consent to participate in the study.

The patients were recruited in two steps as follows: 1) Review of clinical records after surgery of the patients, where the diagnosis of AA was confirmed and classified as simple or complicated AA according to the surgery findings recorded in the post-operative note; and 2) Direct interview with the patient and family or responsible person by three authors (DA, JO, and RC).

The variables to be studied were collected using a form with content validation by experts. The data obtained from the clinical record were the symptoms recorded on admission (abdominal pain, fever, nausea, vomiting, etc.) and the evolution time of pain and its intensity. Sociodemographic variables such as age, sex, zoning (rural and urban), and laboratory tests (blood count, C-reactive protein, urine test) were considered. In addition, by direct interview with the patient and/or responsible persons, it was considered exposure to possible risk factors such as the parents/guardians' schooling (no schooling, primary, secondary, and higher education), history of abdominal manipulation, time between the onset of pain and abdominal manipulation, clinical picture before and after abdominal manipulation (symptoms, signs, evolution time and intensity of pain), the person performing the manipulation (family or private), and self-medication (analgesics, antispasmodics, home remedies such as teas, oils, infusions).

The postoperative diagnosis, surgical findings, and pain intensity were studied and quantified by applying scales according to age, using the Wong-Baker pain scale in patients aged 3-10 years²¹, and in patients older than 10 years, an analogous numerical pain scale. The statistical analysis was performed using the IBM SPSS version 25.0 Statistical Package (license in force).

Statistical Analysis

Descriptive statistics were used to characterize the sample under study, frequencies and percentages were obtained for categorical variables, and an analysis of measures of central tendency, dispersion, and summary measures were performed for continuous variables. Mann-Whitney U, Chi-square, or Fisher's exact test were used to compare groups, as appropriate after evaluation by the Shapiro-Wilk normality test. Chi-

square and Cramer's V test of independence were used to statistically test an association between variables and to quantify the intensity of such association, respectively.

Odds ratios (OR) were calculated by univariate binary logistic regression analysis and their respective 95% confidence intervals, to assess the risks associated with complicated AA. The reference value used for the OR was 1. The Breslow-Day test was used to assess homogeneity in the different strata of the ORs. To determine a conditional association in the presence of a confounder, the Cochran-Mantel-Haenszel test was performed. Significant variables (p -value < 0.05) in the univariate analysis were candidates for multivariate logistic regression analysis (using the Enter method) to control for all possible confounders. The Nagelkerke's R^2 value and the Hosmer-Lemeshow test were considered for the choice of the final model. Finally, the alpha value for statistical significance was set as $p < 0.05$.

A post hoc power analysis of the OR obtained in logistic regression was performed for the variables of interest between complicated AA and abdominal manipulation. The calculated post hoc power was $> 90\%$ with an alpha of 0.05.

Ethical Aspects

The study protocol was approved by the institutional ethics committee of the *Universidad Nacional Autónoma de Honduras* N° 014-09. After approval of the project, patients were actively recruited, with the authorization of parents/guardians by signing an informed consent form and the assent of the pediatric patient before enrollment.

Results

Clinical and sociodemographic characteristics

70 patients who met the selection criteria were recruited. 8 patients were excluded because they did not present all the required information, 6 from the case group and 2 from the control group, resulting in a final sample of 62 patients composed of 31 patients with complicated AA (cases) and 31 patients with simple AA (controls).

The median age was 11 years [IQR 7.0 - 14 years] in both groups, with a range of 3 - 17 years. The age group with the highest prevalence was 12 - 14 years, representing 35.5% of the entire sample. 61.3% of the patients were male. There was no significant difference in the median age between the two groups ($U = 466$ $p = 0.838$). More than half of the population (58.1%) came from urban areas of the country. 53.2% of the parents/guardians of the patients had an elementary school level, and only 6.5% had a university degree.

100% of the patients with parents/guardians with a university degree had a complication (Table 1).

The most frequent initial symptoms in both groups were abdominal pain (88.7%), vomiting (4.8%), and fever (3.2%). Regarding the time between the onset of symptoms and hospitalization, a significant difference was reported in patients who presented any complication, with a median of 48 hours [IQR 38 - 96 hours] compared with controls with a median of 24 hours [IQR 24 - 48 hours] ($U = 236.5$; $p = 0.001$). Likewise, a significant difference was observed in the initial intensity of pain before hospitalization, with cases having a median of 6 points [IQR 5 - 7 points] on the analog pain scale, compared with controls with a median of 8 points [IQR 6 - 9 points] ($U = 630$; $p = 0.016$).

Both the case and control groups presented history of abdominal manipulation in 77.4% (24/31) and 9.7% (3/31), respectively. The median time between the onset of symptoms and abdominal manipulation was 24 hours [IQR 15 - 48 hours] in both groups. Of the patients who underwent abdominal manipulation, in 74.1% (20/27) of them, it was performed by a family member, and 17 of these patients suffered at least one complication. 7 patients underwent abdominal manipulation by a *sobador* or therapist and all of them presented a complication.

Among the cases that had history of abdominal manipulation, they showed a deterioration of the clinical picture with increased pain intensity, generalization of pain, and the appearance of new symptoms such as constipation (27.4%) and diarrhea (25.8%) (Figure 1). However, at the time of hospitalization, there was no significant difference in pain intensity between the two groups ($U = 429$; $p = 0.576$).

On admission, 91.9% of patients had pain on palpation at McBurney's point and 95.2% showed Blumberg's sign. 32.3% of cases reported leukocytosis higher than 20,000/mm³ compared with 9.7% of controls. 12.9% of the cases reported a C-reactive protein level higher than 80 mg/L, compared with controls who no one presented an increase higher than these values (normal range < 6mg/dl). Only 3 patients had a urine test, which showed non-pathological findings (Table 1).

Among the most frequent complications observed in the postoperative period were cecal perforation (32.3%), gangrenous appendicitis (8.1%), and intra-abdominal abscess (8.1%) (Table 1). 16.1% of cases reported more than two complications at the same time (5/31). All patients (5/5) with two or more complications underwent abdominal manipulation. Table 2 shows the characteristics of the 5 cases with 2 or more complications. A statistically significant association was observed between the history of abdominal manipulation and complicated AA ($\chi^2 = 28.93$; $p < 0.001$) and

the intensity of the relationship between these variables is strong (Cramer's V index = 0.683; $p < 0.001$).

The univariate analysis reported that the risk factors for the development of complicated AA were male sex (OR 3.07 [95% CI 1.05 - 8.93]), every hour between symptoms onset and hospitalization (OR 1.03 [95% CI 1.01 - 1.05]), use of home remedies (OR 5.89 [95% CI 1.46 - 23.73]), leukocytosis > 20,000/mm³ at admission (OR 4.44 [95% CI 1.08 - 18.18], and abdominal manipulation (OR 32.00 [95% CI 2.22 - 137.50]) (Table 3).

In a sub-analysis by strata, the results of the test to assess homogeneity between both sexes were not significant for complicated AA (Breslow-Day test, $p = 0.06$). The time of evolution between symptom onset and hospitalization (> 48 hours) was not significant, suggesting that the association between abdominal manipulation and complicated AA exists despite a prolonged time of evolution (Breslow-Day test, $p = 0.67$).

Abdominal manipulation persisted as a risk factor for complicated AA in the multivariate analysis, once adjusted for significant variables in the univariate analysis (OR 15.94 [3.40-74.59]) (Table 3).

Discussion

The main finding of this study was to establish the relationship between history of abdominal manipulation and complicated acute appendicitis. Different risk factors for the development of complicated appendicitis, such as the implementation of cultural practices including abdominal manipulation and home remedies intake, were also analyzed.

These cultural practices are frequently used in people with abdominal pain, often being AA. AA is the most frequent cause of acute surgical abdomen in the pediatric population. It is estimated to account for 1-8% of children presenting to the emergency department with abdominal pain²². Approximately 30-74% of children present with complicated AA, with rates ranging from 69-93% for patients aged 2-5 years to 100% for 1-year-olds^{23,24}. This contrasts with what was found in our study, where the age group with the highest frequency of complications was 7-12 years.

Among the most studied risk factors for the complication of AA is the prolonged time between the onset of symptoms and surgical intervention. This usually occurs due to the diagnostic delay as a consequence of the insidious clinical presentation of AA in children^{4,25,26}. The prevalence of perforation is 7% when symptoms are present in less than 24 h, and increases exponentially to 98% when symptoms are present for more than 48 h²⁷. In contrast to what has been described, in this study, 51.6% of the cases had a clinical evolution of less than 48 hours, which suggests the

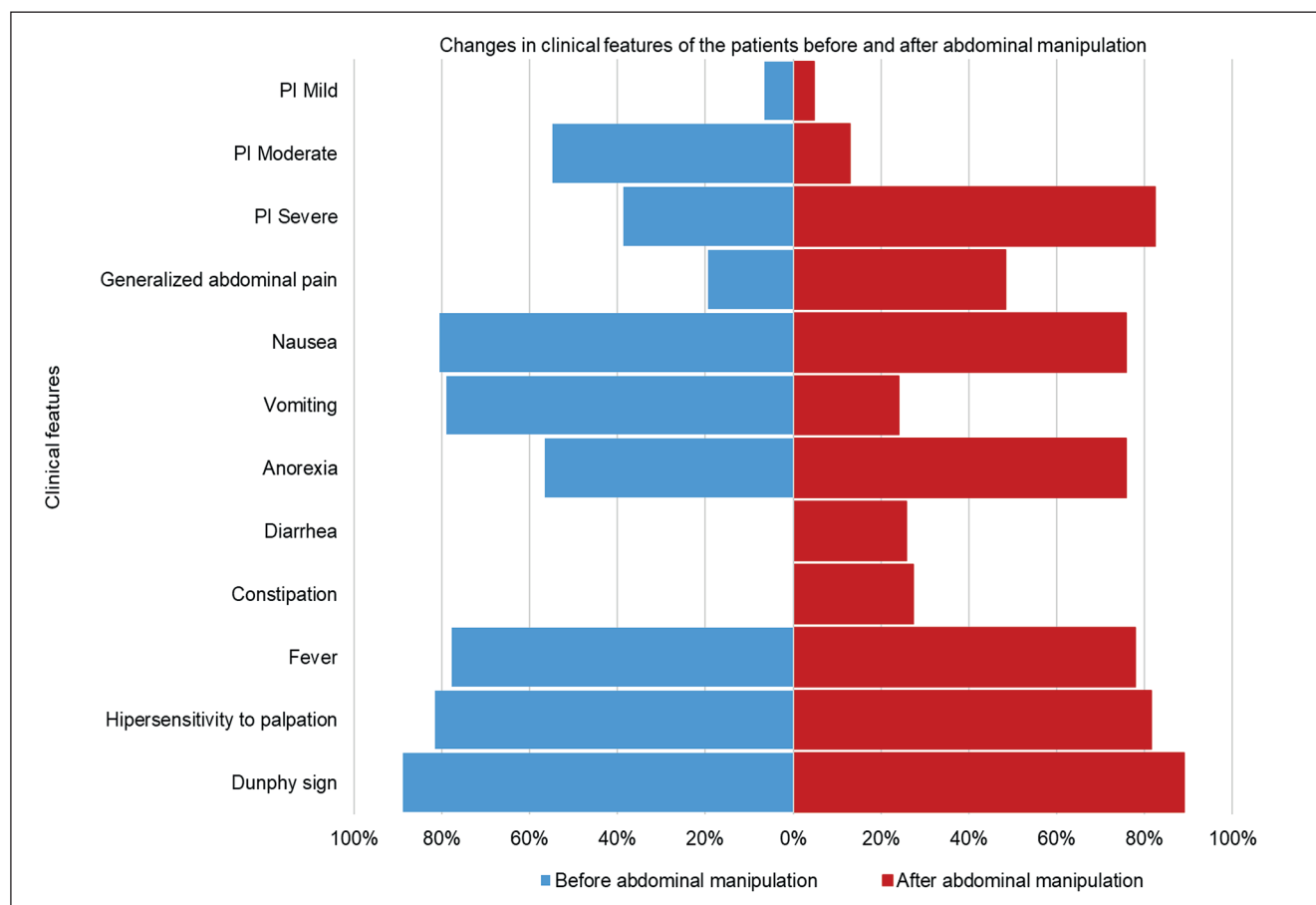


Figure 1. Changes in clinical features of the 27 patients before and after abdominal manipulation. Increased pain intensity, generalization of abdominal pain and the appearance of new symptoms such as constipation and diarrhea were the most significant findings after abdominal manipulation. Abbreviations: PI; Pain intensity.

existence of another risk factor that could contribute to the complication.

One of the most frequent causes of diagnostic delay in Latin America is sociocultural beliefs, such as *empacho* and its respective treatment. A case series study of AA complicated due to history of abdominal manipulation proposes the possibility of an increased risk of the complication of AA due to external factors, such as abdominal manipulation¹⁰.

A study conducted by Rodriguez-Herrera G. describes that 18.42% of the patients studied had a history of abdominal manipulation and states that this does not affect the real evolution of AA but delays early medical consultation since it is expected to be “cured” by traditional treatment²⁸. However, this study establishes that abdominal manipulation is the most influential factor for the complication of an established AA, increasing the risk up to 16 times more in those who underwent manipulation.

Multiple studies have established self-medication as a risk factor for the development of complicated

AA^{29,30}. In this study, the use of analgesics and anti-spasmodics was not determinant for the complication of AA. However, the intake of home remedies such as teas, herbal infusions, and/or oils as part of the empirical treatment of *empacho* significantly increased the risk in the univariate analysis.

This empirical treatment could accelerate the pathophysiological process of an already established AA. The repeated extrinsic application of pressure to the abdomen could increase intra-abdominal pressure, thus increasing intracecal pressure, and contributing to vascular collapse, resulting in an ischemic state that leads to perforation of the appendix in a shorter evolution time.

In the same way, abdominal manipulation or “*so-bada*”ⁱⁱⁱ not only increases the risk of the complication of AA but also contributes to the change in the clinical picture. Due to the perforation of the appendix, the picture progresses on many occasions to generalized peritonitis⁶.

iii Abdominal massage.

Table 1. Sociodemographic and clinical features of the 62 patients under study

Variable	Total n = 62 (%)	Complicated n = 31 (%)	Uncomplicated n = 31 (%)	P-value ^a
<i>Age groups in years, median^b</i>	11 [IQR, 7-14]	11 [IQR, 6-13]	11 [IQR, 7-14]	0.838
1-6	13 (21.0%)	7 (22.6%)	6 (6.0%)	
7-12	25 (40.3%)	14 (45.2%)	11 (35.5%)	
13-18	25 (38.7%)	10 (32.3%)	14 (45.2%)	
<i>Sex</i>				0.037
Male	38 (61.3%)	23 (74.2%)	15 (48.4%)	
Female	24 (38.7%)	8 (25.8%)	16 (51.6%)	
<i>Place of residence</i>				0.99
Urban	36 (58.1%)	18 (58.1%)	18 (58.1%)	
Rural	26 (41.9%)	13 (41.9%)	13 (41.9%)	
<i>Schooling of the person in charge</i>				0.03
No schooling	4 (6.5%)	3 (9.7%)	1 (3.2%)	
Primary	33 (53.2%)	17 (54.8%)	16 (51.6%)	
Secondary	21 (33.9%)	7 (22.6%)	14 (45.2%)	
College	4 (6.5%)	4 (12.9%)	0 (0.0%)	
<i>Time of evolution, median^b</i>	44 [IQR, 24 - 72]	48 [IQR, 28 - 96]	24 [IQR, 24 - 48]	0.001
<i>Initial symptom</i>				0.343
Abdominal pain	55 (88.7%)	26 (83.9%)	29 (93.5%)	
Vomiting	3 (4.8%)	2 (6.5%)	1 (3.2%)	
Fever	2 (3.2%)	1 (6.5%)	1 (3.2%)	
Anorexia	1 (1.6%)	1 (3.2%)	0 (0.0%)	
Nausea	1 (1.6%)	0 (0.0%)	1 (3.2%)	
<i>Initial pain intensity, median^c</i>	7 [IQR, 5-8]	6 [IQR, 5-7]	8 [IQR, 6-9]	0.016
Mild	4 (6.5%)	2 (6.5%)	2 (6.5%)	0.02
Moderate	34 (54.8%)	22 (71.0%)	12 (38.7%)	
Severe	24 (38.7%)	7 (22.6%)	17 (54.1%)	
<i>Pain intensity at admission, median^c</i>	9 [IQR, 8 - 10]	10 [IQR, 8 - 10]	9 [IQR, 8 - 10]	0.576
Mild	3 (4.8%)	2 (6.5%)	1 (3.2%)	0.60
Moderate	8 (12.9%)	5 (16.1%)	3 (9.7%)	
Severe	51 (82.3%)	24 (77.4%)	27 (87.1%)	
<i>Abdominal manipulation</i>				< 0.001
Yes	27 (43.5%)	24 (77.4%)	3 (9.7%)	
No	35 (56.5%)	7 (22.6%)	28 (90.3%)	
<i>Self-medication</i>				
Analgesic	12 (19.4)	6 (19.4%)	6 (19.4%)	0.439
Antispasmodic	6 (9.7%)	2 (6.5)	4 (12.9)	0.708
Antibiotics	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA
Home remedies	15 (24.2%)	12 (38.7%)	3 (9.7%)	0.001
<i>White blood cell (WBC) count</i>				
< 10,000/mm ³	5 (8.1%)	4 (12.9%)	1 (3.2%)	0.032
10-15,000/mm ³	17 (27.4%)	5 (16.1%)	12 (38.7%)	
15-20,000/mm ³	27 (43.5%)	12 (38.7%)	15 (48.4%)	
> 20,000/mm ³	13 (21%)	10 (32.3%)	3 (9.7%)	
<i>C-reactive protein level</i>				0.07
< 80 mg/L	1 (1.6%)	0 (0.0%)	1 (3.6%)	
> 80 mg/L	4 (6.5%)	4 (12.9%)	0 (0.0%)	
<i>Complications</i>				
Gangrenous appendicitis	5 (8.1%)	5 (16.1%)	0 (0.0%)	
Appendicular plastron	5 (8.1%)	5 (16.1%)	0 (0.0%)	
Intra-abdominal abscess	5 (8.1%)	5 (16.1%)	0 (0.0%)	
Cecal appendix perforation	20 (32.3%)	20 (64.5%)	0 (0.0%)	
Generalized peritonitis	2 (3.2%)	2 (6.5%)	0 (0.0%)	

^aChi-square test, Mann-Whitney U test, Fisher's Exact Test, as required. ^bTime between symptom onset and hospitalization. ^cAnalog pain scale (1-10 points).

Table 2. Characteristics of patients with two or more complications in the case group

Case No.	Age	Sex	Evolution time ^a	Abdominal manipulation	Associated complications
Case 1	6 years	Man	72 hours	Yes	Cecal appendix perforation, generalized peritonitis.
Case 2	10 years	Man	168 hours	Yes	Cecal appendix perforation, intra-abdominal abscess.
Case 3	10 years	Woman	48 hours	Yes	Cecal appendix perforation, appendicular plastron.
Case 4	14 years	Woman	72 hours	Yes	Cecal appendix perforation, appendicular plastron, intra-abdominal abscess
Case 5	15 years	Woman	72 hours	Yes	Cecal appendix perforation, generalized peritonitis.

^aTime of evolution between the onset of abdominal pain and hospitalization.

Table 3. Risk factors for complicated acute appendicitis in univariate analysis and multivariate model by binary logistic regression

Variable	Unadjusted OR (CI, 95%)	p-value ^c	Adjusted OR (CI, 95%)	p-value ^c
Male (vs. female)	3.07 (1.05-8.93)	0.04	2.74 (0.57-13.11)	0.22
Age ^a	0.99 (0.87-1.13)	0.92	-	-
Time of evolution ^b	1.03 (1.01 - 1.05)	0.003	1.02 (0.99-1.05)	0.09
WBC on admission	5.89 (1.46 - 23.73)	0.003	-	-
> 20,000/mm ³ (vs. < 20,000)	4.44 (1.08-18.18)	0.03	2.90 (0.40-20.95)	0.28
Abdominal manipulation	32.00 (2.22 - 137.5)	0.001	15.94 (3.40-74.59)	< 0.001

Abbreviations OR, odds ratio; CI, confidence interval. Final model adjusted for significant risk factors in the univariate analysis. The use of home remedies was excluded from the final model because it was considered a confounding factor (Mantel-Haenszel test; $p > 0.05$). ^aFor each year of age of life. ^bTime in hours between symptom onset and hospitalization. ^cWald's χ^2 test.

Diarrhea associated with generalized abdominal pain and fever in an AA may mimic gastroenteritis. Gastroenteritis is the most common misdiagnosis; in fact, diarrhea may be present in 33 - 41% of patients with AA³¹. In this study, notable changes in the clinical picture were increased pain intensity following manipulation and the occurrence of diarrhea and constipation in some patients. This change in the clinical picture contributes to the delay in diagnosis and timely medical treatment, increasing the risk of complications.

Our results should be evaluated given their limitations due to their retrospective nature and the information collected is limited to what is recorded in the clinical records. Likewise, there is a risk of recall bias due to the collection of information by direct interview. The sample size in this study is small, which influences the reliability of the confidence intervals observed for some variables in the logistic regression model. However, this limitation was balanced by a post hoc sensitivity analysis. The study was performed in a hospital with limited resources, in which the diagnosis of acute appendicitis is made by a specialist in pediatric surgery through clinical practice, often without the

support of imaging studies, so these studies were not considered. The type of maneuvers performed by the family member or therapist was not taken into consideration, since these could be different for each patient, nor the number of times these maneuvers were performed. However, it should be noted that our results evidence the risks of abdominal manipulation and the ingestion of home remedies as empirical treatments for acute appendicitis. Large-scale prospective studies are recommended to explore and understand the underlying mechanisms of this phenomenon.

Conclusion

Cultural beliefs such as *empacho* and their respective treatments such as abdominal manipulation and the ingestion of home remedies are risk factors for the complication of an established picture of AA as well as contributing to the prolongation of the time of evolution and diagnostic delay. Therefore, it is recommended that medical personnel consider the history of abdominal manipulation in those pediatric patients with acute abdominal pain.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/

or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

Financial Disclosure

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