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A randomized trial of pneumatic reduction versus hydrostatic reduction for intussusception in pediatric patients☆,☆☆,★

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ABSTRACT

Objectives: Data of randomly controlled trials comparing the hydrostatic and pneumatic reduction for intussusception in pediatric patients as initial therapy are lacking. The aim of this study was to conduct a randomly controlled trial to compare the effectiveness and safety of the hydrostatic and pneumatic reduction techniques.
Study design: All intussusception patients who visited West China Hospital of Sichuan University from January 2014 to December 2015 were enrolled in this study in which they underwent pneumatic reduction or hydrostatic reduction. Patients were randomized into ultrasound-guided hydrostatic or X-ray-guided pneumatic reduction group. The data collected includes demographic data, symptoms, signs, and investigations. The primary outcome of the study was the success rate of reduction. And the secondary outcomes of the study were the rates of intestinal perforations and recurrence.
Results: A total of 124 children with intussusception who had met the inclusion criteria were enrolled. The overall success rate of this study was 90.32%. Univariable analysis showed that the success rate of hydrostatic reduction with normal saline (96.77%) was significantly higher than that of pneumatic reduction with air (83.87%) ($p = 0.015$). Perforation after reduction was found in only one of the pneumatic reduction group. The recurrence rate of intussusception in the hydrostatic reduction group was 4.84% compared with 3.23% of pneumatic reduction group.
Conclusion: Our study found that ultrasound-guided hydrostatic reduction is a simple, safe and effective nonoperative treatment for pediatric patients suffering from intussusceptions, and should be firstly adopted in the treatment of qualified patients.
Level of evidence: Therapeutic study
Type of study: Prospective study

Intussusception is a common abdominal emergency in infancy and childhood with an incidence of one to four in 2000 [1]. Delayed diagnosis and treatment may lead to bowel necrosis or even death. There are mainly two kinds of intussusception which are idiopathic and secondary to a pathologic lead point. Most of the cases are idiopathic, which means there is no obvious cause other than lymphoid hyperplasia of the terminal ileum, but in some cases invagination is secondarily induced by an identifiable cause (pathological lead point; PLP).

Currently, treatment modalities for intussusception include both non-operative and operative procedures. A non-operative procedure will likely be performed if no contraindications are present, which include: signs of peritonitis, perforation and a hemodynamically unstable patient in spite of adequate resuscitation [2–5]. Operative procedures will be given when non-operative treatment is contraindicated or has failed. The reported success rate of non-operative reduction in the literature ranged from 46% to 94% [6]. The non-operative reduction procedure can be performed with a hydrostatic or pneumatic pressure enema under ultrasound or fluoroscopy. Pneumatic reduction under fluoroscopic monitoring has gained increasing acceptance. Compared with barium reduction, pneumatic reduction using air in the treatment of intussusception is an alternative method that is very effective and has additional advantages including less radiation, lower cost and decreased risk of perforations [7]. However, the use of the pneumatic reduction technique under fluoroscopy will expose children with intussusception

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to radiation. An alternative technique is ultrasound-guided hydrostatic reduction with normal saline which can avoid radiation. Both the latter methods are reported to have success rates of 80–90% and are clearly superior to the barium technique [8].

Controversy relating to the search for the optimal reduction technique aiming to maximize success rates while minimizing mortality and morbidity rates persists though. As pneumatic reduction and hydrostatic reduction have not been compared with randomly controlled trials, we therefore conducted a randomly controlled trial to compare the effectiveness and safety of the hydrostatic reduction with ultrasound monitoring and pneumatic reduction with fluoroscopic monitoring.

1. Methods

This open-label, randomly controlled trial was approved by the Institutional Review Board and Ethical Committee at the West China Hospital of Sichuan University in China. Candidates for inclusion in the study were children from 0 to 18 who were diagnosed with intussusception and visited the hospital emergency during the period from January 2014 to December 2015, but we excluded the patients who had contraindications for a non-operative reduction, which included peritonitis, perforation signs, and non-responsive shock that required surgery.

All patients meeting study criteria were eligible for the study and were approached for informed consent. The data collected included demographic data (sex, age, and bodyweight), symptoms (vomiting, abdominal pain, rectal bleeding, diarrhea, distention, constipation, and duration of symptoms), signs (temperature, palpable mass, and location of the mass), investigations (white blood cell counts, neutrophils, electrolytes, and ultrasound findings) and the cases of intestinal perforations and recurrence. The diagnosis of intussusception was determined by an ultrasound conducted by an experienced examiner according to the clinical definition for the diagnosis of acute intussusception [9].

After written informed consent had been obtained, an investigator at the West China Hospital of Sichuan University performed computerized randomization on a central server. An independent data manager designed the randomization table. The patients were randomly allocated by the research pharmacy staff using computer-generated stratified randomization codes to the pneumatic group or the hydrostatic group. Based on the methods of reduction used for treatment, the patients were grouped as either the pneumatic reduction group or the hydrostatic reduction group, in which air reduction represented pneumatic reduction and normal saline reduction represented hydrostatic reduction respectively. These procedures were performed in well-hydrated children with stable vital signs.

Both of the standard techniques of reduction are composed of three repeated 3-min procedures. Hydrostatic reduction was performed by a pediatric surgeon using ultrasound guidance and pneumatic reduction was performed by a radiologist in the company of a pediatric surgeon using fluoroscopic guidance. A Foley catheter was inserted via the anus of the patient and the buttock was taped to prevent air or normal saline leakage. For the pneumatic reduction method under fluoroscopic monitoring with a Sonialvision Safire, all patients received pressure from 80 to 120 mmHg. For the hydrostatic reduction method, the reduction of the intussusception was studied using the guidance of ultrasonography by using a 5–10 MHz transducer and all patients received continuous pressure from 74 to 88 mmHg with the assistance of the balloon (Fig. 1). Sedation drugs were given according to the hospital sedation guidelines.

1.1. Primary and secondary outcome

The primary clinical outcome of the study was the success of non-operative reduction. The success of reduction was determined by the disappearance of intussusception and the visualization of the normal saline or air from the cecum to the ileum through the ileocecal valve or normal saline or air-distended ileum and the disappearance of intussusception after reduction by ultrasound examination. Whichever method of reduction was adopted, ultrasound was performed again to confirm the success of the reduction. The secondary clinical outcomes of the study were the rate of intestinal perforation during reduction and recurrence after reduction.

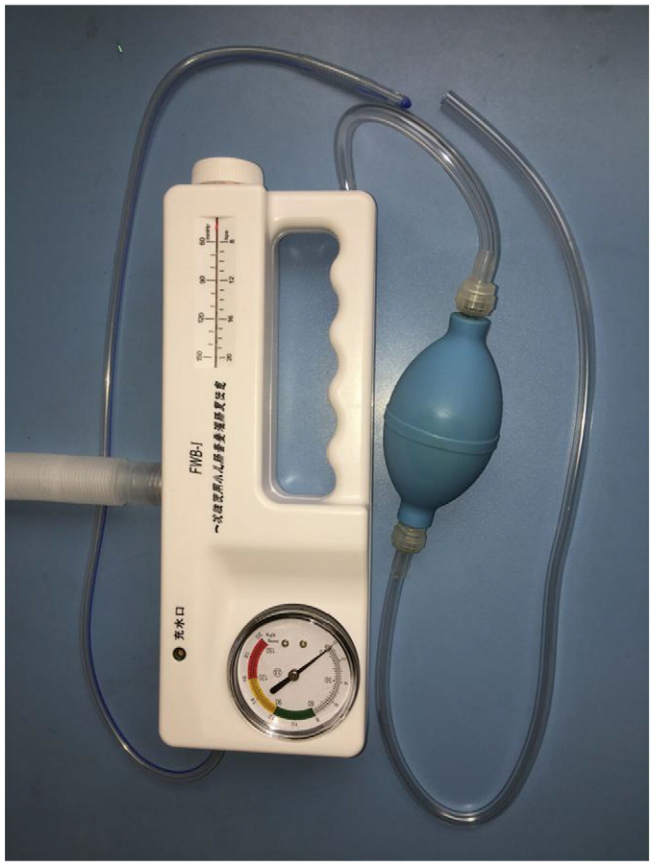

Fig. 1. Photo of the apparatus of hydrostatic reduction.

1.2. Statistical analyses

Data collection was performed on a standardized, computerized, secured case-record form accessible online and was controlled by an independent data-management center. All statistical analysis was performed with the use of SPSS Statistics for Windows, version 23.0 (SPSS). The categorical descriptive data were reported as counts (N) and percentage (%). The categorical univariate analysis was done by Fisher's exact test. The numerical descriptive data were reported as mean and standard deviation. The data was analyzed using the $\chi 2$ and the Student t test. The statistical significance level was set as two-tailed with P-value <0.05.

2. Results

A total of 147 episodes of intussusception were identified among patients who visited the West China Hospital of Sichuan University. The baseline characteristics of all the patients are shown in Table 1. Median follow-up time was 12 months, however the parents of 12 patients refused to participate in the study and the data of 5 patients is missing. Six patients were excluded due to the contraindications after the diagnosis. One hundred and twenty four episodes were included in this study (Fig. 2). The male to female ratio was 2:1. The median age of the patient was 21.50 months with a mean weight of 12.46 kg. The most

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