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Successful Treatment of Early Presenting Intussusception With a Single Dose of Corticosteroid: A Prospective Randomized Controlled Trial

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ABSTRACT

Introduction: To evaluate and compare the success rates of follow-up versus a single dose of corticosteroid (methylprednisolone) treatment in early-diagnosed intussusception cases to achieve resolution without the need for hydrostatic or pneumatic reduction and surgery.

Methods: This study was conducted as a prospective randomized controlled trial. Patients aged 0–4 years, admitted to the Pediatric Emergency Department with a history of symptoms less than 24 h diagnosed with intussusception by ultrasound were randomly assigned to two groups. The treatment group received a single intravenous dose of 1 mg/kg methylprednisolone, while the control group was followed without medication. Follow-up ultrasound was performed at a median of 4 h.

Results: The study included 60 patients in the steroid treatment group and 32 patients in the control group, with male-to-female ratio of 47:45 and a mean age of 28.3 ± 12.0 months. Ileoileal intussusceptions were more common in the control group (19/32, 59.4 %), while ileocolic intussusceptions were more frequent in the treatment group (22/60, 36.7 %) ($p = 0.023$). Steroid treatment was successful in 49 of 60 cases (81.7 %), whereas follow-up was successful in 18 of 32 cases (56.3 %). Overall, steroid treatment was significantly more successful ($p = 0.009$). For ileocolic intussusceptions, steroid treatment was successful in 17 of 22 cases (77.3 %), compared to 2 of 9 cases (22.2 %) in the control group ($p = 0.012$).

Conclusions: Single-dose steroid treatment is particularly effective for ileocolic intussusceptions presenting within 24 h. Steroid treatment may also be considered for unresolved ileoileal intussusception cases after initial follow-up.

The clinical trial registration number is NCT05640375 (clinicaltrials.gov).

1. Introduction

Intussusception refers to a pediatric emergency primarily affecting children younger than 4 years old, characterized by the invagination of a proximal intestinal segment (intussusceptum) into a distal segment (intussuscipiens) [1,2]. Ultrasound is the primary diagnostic tool. The majority of ileoileal and jejunal intussusceptions resolve spontaneously with observation, whereas ileocolic intussusceptions usually require hydrostatic or pneumatic reduction, or surgical intervention [1,3].

Previous literature [4–6] suggests that methylprednisolone, a synthetic glucocorticoid, may promote the spontaneous resolution of intussusceptions by mitigating inflammation and edema. This study seeks to assess the effectiveness of a single dose of methylprednisolone compared to a 4 h of observation regimen for the management of early-diagnosed intussusception cases, aiming to reduce the need for more invasive interventions.

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2. Methods

This prospective randomized controlled study involved patients aged 0–4 years, who presented with symptoms for less than 24 h and were diagnosed with intussusception via ultrasound in the Pediatric Emergency Department of our hospital.

Exclusion criteria encompassed patients with widespread abdominal tenderness and guarding, decreased intestinal blood flow on ultrasound, pneumoperitoneum on abdominal radiography, or other urgent surgical intervention indications. Each case was managed according to its specific needs. The study was approved by the … Clinical Research Ethics Committee (Project no: KA19/337) and the … Medicine and Medical Device Agency (Project no: 19-AKD-188). The clinical trial registration number of this study is NCT05640375 (clinicaltrials.gov).

After intussusception was diagnosed via ultrasound in the pediatric emergency unit, the consulting pediatric surgeon provided information about the study to the parents or guardians. Written informed consent was obtained from those who agreed to participate. Following consent, a parent or guardian selected an envelope to assign the patient to either the treatment or control group. A piece of paper with the letter 'T' (the first letter of the word 'follow-up' in our language) written on it for the control group and a piece of paper with the letter 'S' written on it for the steroid group were placed in a white envelope. The envelopes and the papers inside were kept and were not changed throughout the study. After the families were informed about both groups and agreed to participate, one of the envelopes was chosen and the study group was determined in this way. Patients in the corticosteroid treatment group received a single intravenous dose of methylprednisolone (1 mg/kg), while those in the control group received no medication. All patients were monitored without enteral feeding, and IV hydration was administered, with abdominal re-examinations every 2 h. Antibiotic treatment was not given unless there was concurrent infection. Analgesics were not given as the abdominal examination findings were monitored. After 4 h which was the time period we used for observation of ileoileal intussusception cases before the study, a follow-up ultrasound was performed to assess the efficacy of the 4 h of observation or corticosteroid treatment. If intussusception resolved, we gradually started oral feeding and observed the patients for 2 h after completion of oral feeding. If intussusception persisted, standard initial treatment involved hydrostatic reduction, and if this failed, surgical intervention was implemented.

A biostatistician determined the required sample size to be a total of 120 patients, 60 patients per group by the one-way hypothesis of "Significance Test of the Difference Between Two Rates", which would provide 80 % test power at a 95 % confidence level, with $p_1 = 0.80$ and $p_2 = 0.95$. An interim analysis was done after the steroid group reached to the targeted number at which we found significant differences favoring steroid treatment and therefore, the study was terminated. The collected data included age, symptoms, duration of symptoms, initial and follow-up ultrasound findings, length of intussusception, mesenteric lymphadenopathy (LAP), hospitalization data, and interventions for unresolved cases, as gathered by the pediatric surgeon or emergency department physicians.

Statistical analysis was conducted using IBM SPSS Statistics Version 11.0 (IBM Corp., Chicago, IL, USA). Categorical variables were reported as numbers and percentages, while numerical data were presented as means ± standard deviations. Continuous variables were compared using the t-test for parametric data and the Mann–Whitney U test for non-parametric data. Categorical variables were analyzed using Pearson's chi-square test or Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

3. Results

The study was conducted from March 2020 to December 2023. The control group comprised 32 patients and the steroid group 60, due to interim analysis which revealed significant differences favoring steroid treatment. All cases were presenting for the first time, except for one case in the control group, who developed intussusception 18 months earlier and was successfully treated with hydrostatic reduction.

The study population had a male-to-female ratio of 47:45, with a mean age of 28.3 ± 12.0 months. There were no significant differences in age or gender between the treatment and control groups (Table 1). The primary symptoms included vomiting (46/92, 50.0 %) and abdominal pain (39/92, 41.3 %), with similar symptom distributions across groups (Table 2). The duration of symptoms, as well as the location and length of the invaginated segment, were comparable in both groups (Tables 1 and 2). When the quadrants where intussusception was seen according to ultrasound were examined, 40 % (34/85) were seen in the right lower quadrant, 16 % (15/85) in the left lower quadrant, 15 % (14/85) in the right upper quadrant, 14 % (13/85) in the left upper quadrant, and 10 % (9/85) in the midline. There was no significant difference between the two groups in this respect ($p = 0.755$).

Ileoileal intussusceptions were more common in the control group (19/32, 59.4 %), whereas ileocolic intussusceptions were more prevalent in the steroid group (22/60, 36.7 %) ($p = 0.023$). Follow-up ultrasounds were performed at a median of 4 h (range: 3–5 h). The steroid treatment demonstrated an 81.7 % (49 out of 60) success rate, compared to 56.3 % (18 out of 32) in the control group ($p = 0.009$). Ileocolic intussusceptions resolved in 77.3 % (17 out of 22) of cases of steroid treatment and in 22.2 % (2 out of 9) of the control group ($p = 0.012$) (Table 2, Fig. 1).

In the control group, there was no statistically significant difference in the length of the intussusception between resolved and unresolved cases ($p = 0.286$). Specifically, the length of intussusception in resolved cases was 24 mm (range: 10–50 mm), compared to 32.5 mm (range: 14–70 mm) in unresolved cases. Conversely, in the steroid treatment group, resolved cases had a significantly shorter intussusception length compared to unresolved cases ($p < 0.001$). The length of intussusception in resolved cases was 21 mm (range: 13–50 mm), while in unresolved cases, it was 40 mm (range: 25–60 mm).

Overall, 33.7 % (31 out of 92) of cases required hospitalization, with 56.3 % (18 out of 32) of the control group being hospitalized compared to 21.7 % (13 out of 60) of the steroid treatment group ($p = 0.002$).

Recurrence occurred within 2 weeks in 6 patients (12.2 %) who were successfully treated with steroid therapy and in 3 patients (27.3 %) who failed steroid therapy and were treated with hydrostatic reduction or surgery ($p = 0.345$). Among the follow-up patients, recurrence occurred in 1 patient (7.1 %) who continued to have intussusception.

Two patients from the control group and one patient from the steroid group required surgical intervention due to failure of hydrostatic reduction, and only manual reduction was performed. No complications or adverse events occurred, and no patients were excluded from the study.

4. Discussion

Management options for intussusception are not without risks. Pneumatic reduction carries a 0.8 % risk of intestinal perforation [7]. Additionally, complications such as fever from bacterial translocation and septicemia have been reported [8]. Additionally, fluoroscopy exposes patients to radiation. The psychological stress

Table 1
Demographic and clinical characteristics.

	Steroid Group (n = 60)	Control Group (n = 32)	*p*-value	Total
Age	28.3 ± 12.0 months	31.4 ± 10.2 months	0.224	29.4 ± 11.5 months
Period of symptoms	12 h (1–24 h)	12 h (1–24 h)	0.390	12 h (1–24 h)
Length of invaginated segment	25 mm (13–60 mm)	25 mm (10–70 mm)	0.846	25 mm (10–70 mm)
Length of LAP	13 mm (5–26 mm)	10 mm (5–24 mm)	0.131	13 mm (5–26 mm)

Length of LAP: Length of the longest axis of lymphadenopathy reported on ultrasound (mm).

Table 2
Symptom distribution and US findings.

	Steroid Group (n = 60)	Control Group (n = 32)	Total (n = 92)	*p*-value
Symptoms				
Vomiting	80.0 % (48/60)	71.9 % (23/32)	77.2 % (71/92)	$p = 0.377$
Abdominal pain	53.3 % (32/60)	65.6 % (21/32)	57.6 % (53/92)	$p = 0.256$
Diarrhea	18.3 % (11/60)	31.3 % (10/32)	22.8 % (21/92)	$p = 0.160$
Fever	16.7 % (10/60)	18.8 % (6/32)	17.4 % (16/92)	$p = 0.802$
Irritability[a]	8.3 % (5/60)	0.0 % (0/32)	5.4 % (5/92)	
US findings – intussusception type				**$p = 0.023$**
Ileocolic	**36.7 % (22/60)**	28.1 % (9/32)	33.7 % (31/92)	
Ileoileal	28.3 % (17/60)	**59.4 % (19/32)**	39.1 % (36/92)	
Others (colocolic, jejunal)	11.7 % (7/60)	3.1 % (1/32)	8.7 % (8/92)	
Unknown (not documented)	23.3 % (14/60)	9.4 % (3/32)	18.5 % (17/92)	
US findings –Mesenteric LAP	43.3 % (26/60)	46.9 % (16/32)	44.6 % (41/92)	$p = 0.745$
US findings – free fluid	11.7 % (7/60)	18.8 % (6/32)	14.1 % (13/92)	$p = 0.353$
Overall success	**81.7 % (49/60)**	**56.3 % (18/32)**		**$p = 0.009$**
Ileocolic intussusception	**77.3 % (17/22)**	**22.2 % (2/9)**		**$p = 0.012$**
Ileoileal intussusception	**100.0 % (17/17)**	**63.2 % (12/19)**		**$p = 0.008$**
Others (colocolic, jejunal)	71.4 % (5/7)	100.0 % (1/1)		$p = 1.000$
Segment unreported	71.4 % (10/14)	100.0 % (3/3)		$p = 0.541$

Ratios with statistical significance are shown in bold.
[a] Statistical analysis could not be made.

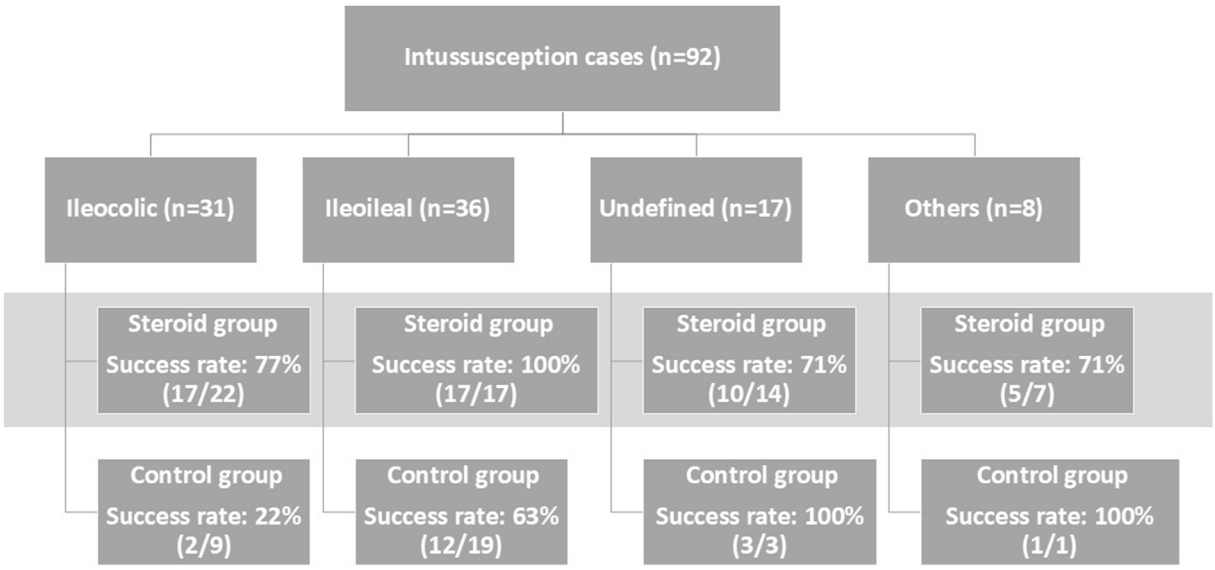

Fig. 1. Distribution of patients and summary of treatment response results.

and abdominal discomfort experienced by infants and children are significant but unquantified drawbacks. Surgery presents its own challenges, including scarring, an increased risk of adhesive intestinal obstruction, anesthesia-related complications, bleeding, and infection. If possible, it would be preferable to protect patients from these.

Corticosteroids are typically used to reduce inflammation and edema at acute conditions such as allergic reactions, asthma, laryngitis, airway edema, and post-bronchoscopy or extubation as a single dose (1 mg/kg). Although chronic and high-dose steroid therapy is associated with various side effects, low-dose (1 mg/kg) regimens are generally considered safe [9]. Steroids also have been used in gastrointestinal disease as well, especially in Henoch Schönlein Purpura and intussusception in this entity. Sönmez et al. reported the resolution of intussusception in a patient receiving steroid treatment for Henoch-Schönlein purpura (HSP) during

laparoscopy, with three out of four HSP patients experiencing resolution solely with steroids [4]. Lopez et al. also observed the resolution of recurrent intussusception linked to lymphoid hyperplasia following steroid treatment [5]. Similarly, Shteyer et al. documented the resolution of recurrent intussusception associated with lymphoid hyperplasia after steroid therapy [6]. While some studies suggest that combining steroid therapy with hydrostatic or pneumatic reduction may reduce recurrence compared to either treatment alone [10,11], another research has found no significant difference [12]. In fact, these reports are case reports, case series, and studies with a small number of patients and provide limited evidence. Nevertheless, these studies have shown the effect of steroid treatment in the treatment of intussusception and have led us to conduct further studies.

Idiopathic intussusceptions constitute approximately 95 % of all intussusception cases [13], with thickening of the Peyer's plaques (lymphoid tissue within the intestinal wall) due to infection as an important contributing factor [13,14]. The increased incidence of intussusception following rotavirus vaccination also supports this theory [14]. We think that corticosteroids, with their anti-inflammatory properties, alleviate Peyer's patch thickening [5,6,10–12] and reduce edema in the invaginated segment, thereby promoting spontaneous resolution of the intussusception. The antiedema effect may also explain why steroid treatment is more successful in short segments of ileocolic intussusception. The decrease in edema due to steroid treatment facilitates the reduction of intussusception. From a mechanical point of view; the shorter the intussusceptum, the higher the expectation of reduction. Consequently, steroid administration could potentially eliminate the need for hydrostatic or pneumatic reduction, even surgery. However, it is important to note that corticosteroid treatment should be avoided in cases where ultrasound reveals pathologically enlarged mesenteric lymphadenopathy, due to concerns about possible lymphoma.

It should also be noted that observation was successful in approximately two-thirds of the ileoileal intussusception cases, in all of the three cases in which ultrasonography could not distinguish ileocolic from ileoileal, and in one case of colocolic intussusception (based on ultrasound findings). As expected, the success rate with observation was low only in the ileocolic intussusception type.

Despite the risks of circulatory compromise in the invaginated segment due to delayed treatment, existing literature indicates that this risk becomes substantial only after a 48-h symptom duration [14]. Our review of cases over the past decade reveals that 80 % of our patients were diagnosed within 24 h of symptom onset [2]. To avoid complications while waiting for treatment outcomes, we included only cases with symptom durations of less than 24 h.

In a previous study, we observed that 44 % of cases initially diagnosed as ileoileal based on ultrasound findings were identified as colonic intussusceptions during hydrostatic reduction [2]. Similarly, 23 % of cases initially diagnosed as ileocolic based on ultrasound showed contrast material passing into the ileum without pausing in the colon during reduction [2]. This finding aligns with the 22.2 % resolution rate of ileocolic intussusception observed with 4 h of observation alone. These results suggest that ultrasound findings may not always accurately differentiate between ileocolic and ileoileal intussusception. Therefore, we included all types of intussusceptions diagnosed in our study, as ileoileal intussusceptions could be ileocolic and may require treatment. We think that for patients diagnosed with ileoileal intussusception on ultrasound, steroid treatment may be considered if spontaneous resolution does not occur, given the potential for diagnostic error.

Despite the higher prevalence of ileoileal intussusceptions in the control group and a greater number of ileocolic cases in the steroid group, the superior success rate of steroid therapy over control group in both the overall study population and subgroups indicates that this treatment approach may be more effective. Our findings revealed that a majority of patients in the treatment group and nearly half of those in the control group did not require hospitalization, as their intussusceptions resolved promptly. After a follow-up ultrasound examination, patients with resolved intussusceptions were gradually introduced to enteral feeding and they responded well. Consequently, hospitalization was unnecessary, and these patients were discharged without requiring readmission to the emergency department.

In patients treated with steroid treatment, 12.2 % experienced early recurrence (within 14 days). In a previous study that reported clinical features of intussusception, we reported that we observed early recurrence (within 2 weeks) in 22 of our 209 intussusception patients (10.5 %) (2). In the literature, this rate is given as 9.4–10.5 % (2). Since the recurrence rate after steroid treatment is slightly higher than in the literature, we think that it would be good to provide detailed information to the families and even to call these patients for a control examination a few days later and have a control ultrasound.

This study has several limitations. First, the reliance on ultrasound alone for differentiating between ileocolic and ileoileal intussusception may lead to diagnostic inaccuracies and treatment discrepancies. Second, our study focused exclusively on patients presenting within 24 h of symptom onset. Future researches should consider extending the symptom duration window to 48 h, as existing literature suggests this may be associated with lower complication rates. Larger studies with extended symptom duration limits are necessary. Third, there is a difference in numbers between the steroid group and the follow-up group. Unfortunately, we do not have an explanation for this difference. In the next study, we plan to choose another randomization method.

5. Conclusion

For cases of early-diagnosed ileo-ileal intussusception without complications and with symptom duration less than 24 h, 4 h of observation remains to be the preferred approach. Regarding ileocolic intussusceptions with symptom durations less than 24 h, especially if the invaginated segment is short, single-dose methylprednisolone treatment may be effective in reducing both the need for invasive interventions and hospitalization. We also recommend exploring single-dose steroid treatment for ileoileal intussusceptions that do not respond to initial observation. Further research is needed to validate these findings and refine treatment protocols.

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Conflict of interest

The authors declare no conflicts of interest regarding this article.

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