

# Effects of intraperitoneal bupivacaine injection in laparoscopic appendectomy in children on post-operative pain: A controlled randomized double-blinded study

✉ Ergun Ergün, M.D.,<sup>1</sup> ✉ Anar Gurbanov, M.D.,<sup>1</sup> ✉ Gülnur Göllü, M.D.,<sup>1</sup> ✉ Ufuk Ateş, M.D.,<sup>1</sup>  
✉ Meltem Bingöl Koloğlu, M.D.,<sup>1</sup> ✉ Ahmet Murat Çakmak, M.D.,<sup>1</sup> ✉ Özlem Selvi Can, M.D.<sup>2</sup>

<sup>1</sup>Department of Pediatric Surgery, Ankara University Faculty of Medicine, Ankara-Türkiye

<sup>2</sup>Department of Anesthesiology and Reanimation, Ankara University Faculty of Medicine, Ankara-Türkiye

## ABSTRACT

**BACKGROUND:** The aim of this study is to determine the effects of local anesthetics administered intraperitoneally in laparoscopic appendectomy.

**METHODS:** Patients who underwent laparoscopic appendectomy due to acute appendicitis were enrolled in the study. The children were divided into two groups. Intraperitoneal bupivacaine injection to appendectomy site and subdiaphragmatic area was performed after resection of appendix and aspiration of intraperitoneal reactive fluid in Group 1 while Group 2 did not receive this therapy. The children were questioned by a nurse at postoperative 1<sup>st</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> h. Pain scores (PS) (abdominal), abdominal wall incisional pain (IP), shoulder pain (SP), and first need for analgesics were recorded.

**RESULTS:** One hundred and twenty children were enrolled to the study. There was no significant difference in PS values and IP values between the two groups ( $p>0.05$ ). SP values at 12<sup>th</sup> and 24<sup>th</sup> h were significantly lower in Group 1 ( $p<0.05$ ). There was a statistically significant reduce in analgesic need in Group 1 ( $p=0.007$ ).

**CONCLUSION:** Intraperitoneal bupivacaine instillation to surgery site and subdiaphragmatic area seems to reduce the SP post-operative and also reduce post-operative analgesic need. More meaningful results can be obtained with an increase in the number of patients.

**Keywords:** Bupivacaine; child; laparoscopy; pain.

## INTRODUCTION

Acute appendicitis (AA) is a common surgical emergency among children.<sup>[1]</sup> In recent years, laparoscopic appendectomy has become a standard therapeutic procedure for AA in many hospitals.<sup>[2,3]</sup> Laparoscopic appendectomy has been associated with shorter hospital stays, decreased scarring and decreased post-operative pain.<sup>[4]</sup> However, laparoscopy is not a pain-free procedure and the management of postlaparoscopy pain remains to be a major concern.<sup>[5]</sup> The origin of pain after laparoscopic appendectomy is multifactorial, with pain arising from the incision sites, the pneumoperi-

toneum, diaphragmatic stretching with phrenic nerve neuropathia, and direct tissue injury.<sup>[6]</sup> Different methods have been tried to reduce pain after laparoscopic appendectomy in children.<sup>[7,8]</sup> Recently, local anesthetic solutions have been injected into the peritoneal cavity to reduce peritoneal pain.<sup>[9]</sup> Primary aim of this study was to compare pain scores (PS) of children who were applied local anesthetics intraperitoneally and not in laparoscopic appendectomy. As secondary outcome, it was aimed to investigate the effects of intraperitoneal regional and subdiaphragmatic bupivacaine injection on incisional pain (IP), shoulder pain (SP), and post-operative analgesic need.

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Address for correspondence: Özlem Selvi Can, M.D.

Ankara Üniversitesi Tıp Fakültesi, Anesteziyoloji ve Reanimasyon Anabilim Dalı, Ankara, Türkiye

Tel: +90 312 - 508 23 96 E-mail: ozlemcan@gmail.com

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## MATERIALS AND METHODS

The study was performed in adherence to the Declaration of Helsinki and was approved by the ethical committee of Ankara University (No:İ3-96-19). Consecutive patients who underwent laparoscopic appendectomy due to AA between January 2018 and January 2020 were planned to be enrolled in the study. The children were divided into two groups according to random numbers table. Written informed consent was obtained from all of the children and/or their parents. Sociodemographic data were recorded.

Exclusion criteria were as follows: Patients with ASA 2 and above, children/parents who refused to join the study, children under 4 years, children with allergies to at least one of the drugs to be used in the study, children with comorbid disease (diabetes insipidus, diabetes mellitus, hepatic failure, renal failure, cardiac anomaly, or cardiac failure), children with chronic pain, BMI >35, children with cognitive impairment, children with history of the previous abdominal surgery, and children with perforated appendicitis.

### Anesthetical Approach

All children were administered 0.01 mg/kg (intravenous [IV]) or 0.3 mg/kg (oral) midazolam before taken to the operation theatre. Anesthesia was induced with lidocaine 1 mg/kg and propofol 2–3 mg/kg. Then, 1 mg/kg rocuronium was administered and 90–120 s later children were intubated. To ensure the depth of anesthesia, 0.5–1 mcg/kg remifentanyl was administered considering the normotensive status of the patients. After induction, 0.1–0.15 mg/kg ondansetron was administered. Sevoflurane was administered as minimum alveolar concentration 1.3 with 40% oxygen and 60% nitric oxide for maintenance of anesthesia. During the surgery, 15 mg/kg paracetamol was administered to each patient. None of the children has received caudal anesthesia.

### Surgical Drug Administration

All patients underwent laparoscopic appendectomy. CO<sub>2</sub> insufflation pressures are shown in Table 1. Preincisional bupivacaine (0.25%) injection was routine in both groups. Intraperitoneal bupivacaine (0.125%–0.5 cc/kg) injection to appendectomy site and subdiaphragmatic area was performed after resection of appendix and aspiration of intraperitoneal reactive fluid in Group 1 while Group 2 did not receive this therapy. The total dose including incisional injection of bupivacaine to be used was calculated by at least two clinicians separately for each patient to prevent overdose.

### Post-operative Course

All children began feeding at post-operative 6<sup>th</sup> h and they were encouraged to walk and mobilize. The children were questioned by a nurse who was blind to the study groups at postoperative 1<sup>st</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> h. PS (abdominal), abdominal wall IP, and SP were recorded for each of these

**Table 1.** CO<sub>2</sub> insufflation pressures by age

Age (years)	4–8	8–18
CO <sub>2</sub> insufflation pressures	<12 mmHg	<14 mmHg

visits. In addition, patients' first need for analgesics was also recorded.

### Pain Assessment Scales

Verbal rating scale and visual analog scale both with scores ranging from 0 (no pain) to 10 (worst possible pain) were used to scale the pain levels. SP was questioned through “yes/no” questions since SP seems difficult to scale by most of the children. None of the children were given any analgesics until the PS was 5 or more. Paracetamol (10 mg/kg) was introduced intravenously in case of the PS was 5 or more in any of the scales. PS of the patients who were given paracetamol were evaluated again 1 h later and 1 mg/kg contramal IV was planned for children if the score was still equals or above 5.

### Statistical Method

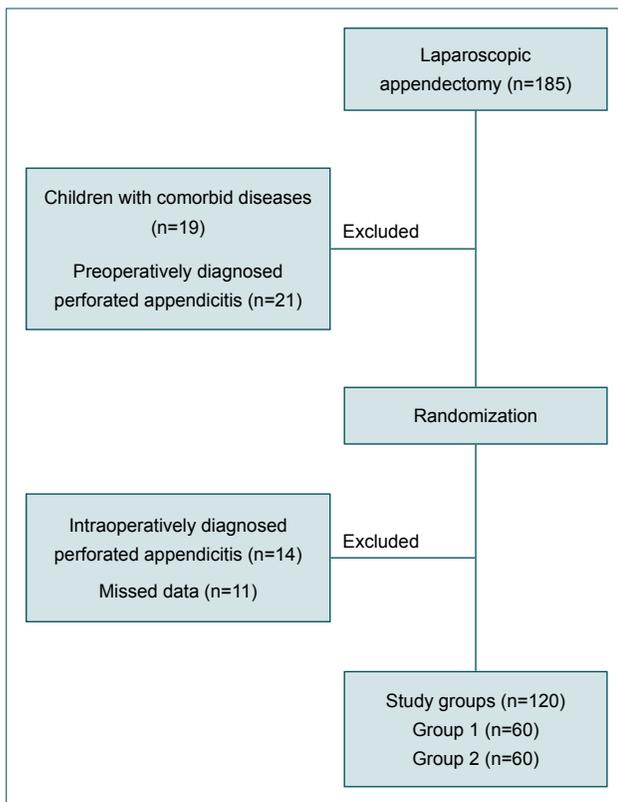
SPSS program (IBM SPSS Statistics 22, Chicago) was used for statistics. Continuous data were reported as mean±SD. Categorical data were summarized as frequencies and percentages. Mann–Whitney test was used for quantitative data and Chi-square test was used for qualitative data for statistical analysis. In all tests, results were considered statistically significant if  $p \leq 0.05$ .

## RESULTS

One hundred and twenty children were enrolled to the study. During the study period, children with comorbid diseases (n=19) and pre-operative diagnosis of perforated appendicitis (n=21) and children under 4 years (n=7) were not included at first place. However, children who were diagnosed as perforated appendicitis intraoperatively and children whose data were missing were excluded after randomization and consecutive patients were replaced (n=14 and n=11, respectively). Study was carried on until 60 cases for each group were obtained (Fig. 1). There were no significant differences between the groups with respect to sex, age, weight, height, and operation time (Table 2). No conversion to open surgery was necessary for any patient. No intraoperative complications were recorded.

There was no statistically significant difference in PS values between the two groups at any hour ( $p > 0.05$ ). There was no statistically significant difference in IP values between the two groups at any hour ( $p > 0.05$ ). SP values at 12<sup>th</sup> and 24<sup>th</sup> h were significantly lower in Group 1 ( $p < 0.05$ ).

Five patients in Group 1 and 16 patients in Group 2 needed analgesics within 24 h. There was a statistically significant re-



**Figure 1.** Flow chart of the patients.

duce in analgesic need in Group 1 ( $p=0.007$ ). The hour of analgesic need though did not differ significantly between groups. Group 1 needed within  $9.6\pm 6.1$  h while Group 2 within  $8.6\pm 5.5$  h (Table 3).

No post-operative complications occurred due to the surgery or the medication used.

## DISCUSSION

SP at the post-operative 12 and 24<sup>th</sup> h was reduced significantly in Group 1. Also less children in Group 1 needed analgesics in the post-operative course.

Laparoscopic surgery has some proven advantages over open surgery in adults and children such as low length of hospital stay, less post-operative wound infections, faster recovery, and better cosmetic results. Post-operative pain and analgesic need after laparoscopic appendectomy also significantly lower than the open approach.<sup>[10-13]</sup>

Although the pain after laparoscopy is less, the procedure is not completely painless and pain continues to be the most common complaint in the early post-operative period.<sup>[14]</sup> Apart from abdominal and IP, SP which has not been encountered in open surgery may be problematic for patients underwent laparoscopic surgery.<sup>[15]</sup>

Different methods have been used in the adult population to

**Table 2.** Patient characteristics and operative data

Characteristic value	Group 1	Group 2	p-value
Number	60	60	
Sex (male/female)	36/24	33/27	0.356
Age (years)	$10.8\pm 3.3$	$11.5\pm 3.7$	0.543
Weight (kg)	$39.7\pm 14.4$	$46.5\pm 21.1$	0.077
Height (cm)	$146.5\pm 17.3$	$149.1\pm 21.9$	0.368
Operation time (min)	$39.9\pm 13.1$	$37.3\pm 12.7$	0.273
Intraoperative complication	0	0	

**Table 3.** Postoperative findings

Characteristic value	Group 1	Group 2	p-value
PS1	$2.9\pm 0.9$	$3.4\pm 1.1$	0.11
PS6	$2.6\pm 1.0$	$2.9\pm 1.4$	0.62
PS12	$2.1\pm 1.2$	$2.5\pm 1.4$	0.09
PS24	$1.5\pm 0.9$	$2.0\pm 1.3$	0.09
IP1	81.7%	81.7%	1
IP6	70%	66.7%	0.84
IP12	58.3%	58.3%	1
IP24	36.7%	36.7%	1
SP1	31.7%	36.7%	0.70
SP6	36.7%	41.7%	0.70
SP12	10.0%	26.7%	0.03
SP24	6.7%	18.3%	0.04
Analgesic need (n)	5	16	0.007
Analgesic need (ho-urs)	$9.6\pm 6.1$	$8.6\pm 5.5$	0.73

PS: Pain scores; IP: Abdominal wall incisional pain; SP: Shoulder pain.

reduce the intensity of pain after minimally invasive surgery, including a low-pressure pneumoperitoneum, periportal anesthetic infiltration, saline washout, and intraperitoneal instillation of local anesthetics.<sup>[16,17]</sup> However, studies performed among children are limited.<sup>[18,19]</sup>

PSs of the children in both groups were statistically similar even though a slight reduce was observed in Group 1. The results were similar with the study of Hamill et al.<sup>[18]</sup> who concluded that intraperitoneal local anesthetic injection did not result decreasing the PSs in children underwent laparoscopic surgery after a well-designed randomized controlled study with 175 patients. They injected local anesthetic after the procedure was completed and to only surgical site and pelvis. On the other hand, Basha et al.<sup>[19]</sup> showed that intraperitoneal injection of bupivacaine significantly reduced post-operative pain and improved hemodynamics of patients. They instilled the local anesthetic all over the peritoneal cavity in the beginning of the surgery. In the present study, local anesthetic injected

after the surgical procedure completed to the surgical site and subdiaphragmatic area. The authors think applying bupivacaine in the beginning of the surgery may have the risk of aspiration of the anesthetic fluid and mislead the results. Furthermore, in the present study, subdiaphragmatic injection was also performed to possibly prevent SP due to diaphragmatic irritation with CO<sub>2</sub> insufflation. SP rates among two groups were statistically significant at 12<sup>th</sup> and 24<sup>th</sup> h (p=0.03 and 0.04, respectively) although no difference was observed at first and 6<sup>th</sup> h. Even though the PS were similar at 1<sup>st</sup> h, late difference in SP rate may be indicating a possible benefit of subdiaphragmatic injection, which was not mentioned in the study of Hamill et al.<sup>[18]</sup> Reducing SP which has already been accepted as a pitfall of laparoscopic surgery may lead better mobilization, increased quality of life and quicker recovery period in these children.<sup>[20]</sup> It has been shown that carbon dioxide irritates the abdominal and diaphragmatic nerves chemically and the mechanical effect of residual gas (also calling visceral ligament traction) is effective in the development of SP.<sup>[21,22]</sup> Various approaches have been presented in the literature to prevent or reduce SP after laparoscopic surgery. For this purpose, warmed and humidified CO<sub>2</sub> insufflation, intraperitoneal local anesthetic injection, subdiaphragmatic intraperitoneal local anesthesia, oral pregabalin, piroxicam patch, and meridian acupressure therapy were used.<sup>[23–26]</sup> The present study may contribute to the studies on preventing SP in children since many of these studies were in adult population and data on children are quite rare.

Post-operative IPs were similar in both groups at any hours. This result may be expected since the difference in two groups was intraperitoneal local anesthetic injection and it may not be expected to effect to trocar sites. Even so two groups were compared in terms of IP to reveal any difference in children regarding pain perceptions. Trocar site local anesthesia is routine in the clinic for many years since it has been proven to reduce pain such as in the study of Hasaniya et al.<sup>[27]</sup> being showed that peri incisional insertion of local anesthesia at the trocar sites in laparoscopic cholecystectomy significantly reduces post-operative pain.

Another outcome of the study was that intraperitoneal local anesthetic infiltration significantly reduced the need for postoperative analgesics in children. Even though the PSs were statistically similar, slight decrease in Group 1 brought the difference between two groups regarding analgesic need. The children whose PS were 5 or above were administered parenteral paracetamol (10 mg/kg). There were five children who required paracetamol in Group 1 while there were 16 in Group 2 (p=0.007). None of the children in the present study required opioid analgesic but the usage of opioids are not very rare in the literature. Liu reported children required opioid analgesics and not with very low rates (34%).<sup>[3]</sup> Even though there was not statistical data, the authors believe that low CO<sub>2</sub> pressures, short operative time and intraoperative effective analgesia could be effective in not needing opioids in the study group.

Not measuring plasma levels of local anesthetics may be a limitation of the study even though the doses were calculated for each child separately. Another limitation was excluding children after randomization since (1) the perforated appendicitis could not be diagnosed in 14 children and (2) the study team missed data of 11 children. The aim of excluding children with perforated appendicitis was to keep a standardized protocol. Although the evaluation of PS may be performed depending on the children, parents or medical staff; we thought that blinded nurses would be better in terms of objectivity but even though all of the nurses were blind to the study, it was not possible to evaluate every child by same nurses due to their working schedule. An interesting limitation was that the children well responded to questions on their PS levels but when it came to questions on SP they could only answer “yes or no” and we could not evaluate SP as we could the PS.

## Conclusion

Intraperitoneal bupivacaine instillation to surgery site and subdiaphragmatic area seems not to affect PS and IP in children postoperatively. However, it seems to reduce the SP at postoperative 12<sup>th</sup> and 24<sup>th</sup> h and also reduce postoperative analgesic need. More meaningful results can be obtained with an increase in the number of patients.

**Ethics Committee Approval:** This study was approved by the Ankara University Faculty of Medicine Human Research Ethics Committee (Date: 12.09.2019, Decision No: İ3-96-19).

**Peer-review:** Internally peer-reviewed.

**Authorship Contributions:** Concept: U.A., Ö.S.C.; Design: E.E., Ö.S.C.; Supervision: G.G., M.B.K.; Materials: A.G., E.E.; Data: A.G., E.E.; Analysis: M.C., D.S.C.; Literature search: E.E., U.A., G.G.; Writing: A.G., E.E., Ö.S.C.; Critical revision: E.E., Ö.S.C., A.M.Ç.

**Conflict of Interest:** None declared.

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## ORIJİNAL ÇALIŞMA - ÖZ

### Çocuklarda laparoskopik apendektomilerde intraperitoneal bupivakain enjeksiyonunun ameliyat sonrası ağrı üzerine etkileri: Kontrollü randomize çift kör çalışma

Dr. Ergun Ergün,<sup>1</sup> Dr. Anar Gurbanov,<sup>1</sup> Dr. Gülnur Göllü,<sup>1</sup> Dr. Ufuk Ateş,<sup>1</sup> Dr. Meltem Bingöl Koloğlu,<sup>1</sup> Dr. Ahmet Murat Çakmak,<sup>1</sup> Dr. Özlem Selvi Can<sup>2</sup>

<sup>1</sup>Ankara Üniversitesi Tıp Fakültesi, Çocuk Cerrahisi Anabilim Dalı, Ankara

<sup>2</sup>Ankara Üniversitesi Tıp Fakültesi, Anesteziyoloji ve Reanimasyon Anabilim Dalı, Ankara

**AMAÇ:** Çalışmanın amacı, laparoskopik apendektomilerde intraperitoneal olarak uygulanan lokal anestetiklerin etkilerini belirlemektir.

**GEREÇ VE YÖNTEM:** Akut apandisit nedeniyle laparoskopik apendektomi yapılan hastalar çalışmaya alındı. Çocuklar iki gruba ayrıldı. Grup 1'de apendiks rezeksiyonu ve intraperitoneal reaktif sıvının aspirasyonundan sonra apendektomi lojuna ve subdiyafragmatik bölgeye intraperitoneal bupivakain enjeksiyonu yapıldı. Grup 2'de ise bu uygulama yapılmadı. Çocuklar ameliyat sonrası 1., 6., 12. ve 24. saatlerde hemşire tarafından sorgulandı. Ağrı skorları (karın), karın duvarı kesi ağrısı, omuz ağrısı ve ilk analjezik ihtiyacı kaydedildi.

**BULGULAR:** Çalışmaya 120 çocuk katıldı. Ağrı skor değerleri ve kesi yeri ağrı değerleri açısından iki grup arasında anlamlı fark yoktu ( $p>0.05$ ). 12. ve 24. saat omuz ağrısı değerleri Grup 1'de anlamlı olarak düşüktü ( $p<0.05$ ). Grup 1'de analjezik ihtiyacı istatistiksel olarak anlamlı derecede düşüktü ( $p=0.007$ ).

**TARTIŞMA:** Bupivakainin cerrahi bölgeye ve subdiyafragmatik bölgeye intraperitoneal olarak enjekte edilmesi, ameliyat sonrası omuz ağrısını ve ameliyat sonrası analjezik ihtiyacını azalttığı görülmektedir. Hasta sayısının artması ile daha anlamlı sonuçlar elde edilebilir.

**Anahtar sözcükler:** Ağrı; bupivakain; çocuk; laparoskopi.

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