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## Randomized, Single-blinded Trial of Laparoscopic Versus Open Appendectomy in Children

### Effects on Postoperative Analgesia

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**Background:** The benefit of laparoscopy to patients has been clearly established in adults undergoing cholecystectomy. Results are less clear for appendectomy. The current study was undertaken to compare the respective 3-day postoperative periods after laparoscopic and open appendectomy in children.

**Methods:** Sixty-three children (aged 8-15 yr) scheduled for appendectomy were randomly assigned to two groups: open and laparoscopic. Postoperative evaluation included delay of postoperative recovery (walking and feeding), pain assessment by visual analog scale during the 3 subsequent days, amount of nalbuphine administered *via* a patient-controlled analgesia system during the first 48 h and responses by children, parents, and nurses on the overall quality of analgesia.

**Results:** There was no difference between groups for demographic data (particularly macroscopic aspect of appendix), analgesia, sedation, delay before eating and walking, incidence of urinary retention, nausea, vomiting. Operative time was longer ( $P \leq 0.05$ ) in the laparoscopic group ( $54 \pm 17$  min) than in the open group ( $39 \pm 18$  min). Thirty five percent of the children had pain at the shoulder in the LAP group *versus* ten percent in the open group ( $P \leq 0.05$ ).

**Conclusions:** Laparoscopy did not improve analgesia and postoperative recovery after appendectomy in children. (Key words: Analgesics, opioid: nalbuphine. Anesthesia: pediatric. Anesthetic techniques: patient-controlled analgesia. Pain:

postoperative. Surgery techniques: appendectomy; laparoscopy.)

SINCE 1971, when Gans and Berci<sup>1</sup> demonstrated the feasibility of laparoscopy in children, an increase in the use of laparoscopic surgery has occurred.<sup>2</sup> Appendectomy is the most frequent indication for laparoscopy in children. The benefits of laparoscopy in adults undergoing cholecystectomy<sup>3-5</sup> include decreased pain and ileus after surgery, lower analgesic requirement, faster onset of feeding, and shortened hospital stays and convalescence. Results are less clear for those undergoing appendectomy<sup>6-7</sup> and have been mostly reported in adults<sup>8-10</sup> with often nonhomogeneous groups and inadequate treatment for pain. The aim of this study was to compare the quality of the postoperative periods during the first 3 days after laparoscopic or open appendectomy in children.

### Material and Methods

The study was conducted over 18 months, using a randomized blinded prospective design and was approved by the Regional Ethical Human Studies Committee. Written informed consent was obtained from patients' parents.

#### Patients

Children, ASA physical status 1 or 2, aged 8-15 yr, with clinical signs of appendicitis and scheduled for appendectomy were enrolled. Children with neurologic disease or who appeared uncooperative or weighed less than 20 kg were not included in the study. During the preoperative visit, children and their parents were instructed in the use of patient-controlled analgesia (PCA). It was stressed to the parents that only the patient must activate the PCA device. The visual analog

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pain scale (VAS) also was explained. In the operating room, children were randomly assigned to open or laparoscopic appendectomy. A blinded procedure was introduced: children, parents, and nurses did not know during the study if laparoscopic or open appendectomy was performed. They were informed as to the type of procedure only after the end of the study.

#### Anesthetic Management

Premedication consisted in  $1.5 \text{ mg} \cdot \text{kg}^{-1}$  oral hydroxyzine 1 h before surgery. Ten micrograms per kilogram of atropine were administered intravenously, immediately before induction of anesthesia. Induction was performed with  $3\text{--}5 \text{ mg} \cdot \text{kg}^{-1}$  propofol and  $0.1 \text{ mg} \cdot \text{kg}^{-1}$  dextromoramide. Tracheal intubation was facilitated by  $0.5 \text{ mg} \cdot \text{kg}^{-1}$  intravenous atracurium and anesthesia was maintained with isoflurane 1% in oxygen/nitrous oxide (fractional inspired oxygen tension = 0.5) and additional intravenous boluses of dextromoramide as required to maintain stable heart rate and arterial pressure. In the laparoscopic group, an atracurium infusion was used to maintain muscular relaxation until the appendix was removed. Controlled ventilation was adjusted to maintain normocapnia. Noninvasive arterial blood pressure, electrocardiogram, end tidal carbon dioxide, arterial oxygen saturation, and nasopharyngeal temperature were monitored throughout surgery. After induction of anesthesia, a nasogastric tube was introduced to empty the stomach, which was removed at the end of the surgery. Intraoperative hydration consisted of  $5 \text{ ml} \cdot \text{kg}^{-1} \cdot \text{h}^{-1}$  (5% dextrose, 0.4% NaCl, 0.15% KCl).

#### Surgery

Three surgeons performed laparoscopic appendectomy. Care was taken to ensure that the intraabdominal pressure did not exceed 12 cm  $\text{H}_2\text{O}$  during laparoscopy. The technique was guided by videoendoscopy. Two incisions were made in the right and left lower quadrants for additional trocars. After the appendix was identified, its tip was grasped and divided at the base of the appendix. A 3.5 endoloop ligature (coated vicryl, Ethicon) was then introduced and secured around the base of the appendix.

In the open group, appendectomy was performed through McBurney's incision.<sup>11</sup>

The area of skin disinfected and the surgical dressings were identical for all children.

#### Patient-controlled Analgesia

A first intravenous dose ( $25 \text{ mg} \cdot \text{kg}^{-1}$ ) of propacetamol was given in the recovery room just before extubation. When children were completely awake and able to answer questions, they were transported to the surgical ward. During the ensuing 48 h, children received every 6 h,  $25 \text{ mg} \cdot \text{kg}^{-1}$  intravenous propacetamol, and for the next 24 h  $12.5 \text{ mg} \cdot \text{kg}^{-1}$  oral paracetamol. Two hours after extubation, children received an intravenous loading dose ( $0.2 \text{ mg} \cdot \text{kg}^{-1}$ ) of nalbuphine. When analgesia was insufficient, children were able to self-administer intravenous boluses ( $25 \mu\text{g} \cdot \text{kg}^{-1}$ ) of nalbuphine with a PCA system (Lifecare 4200, Abbott; lockout interval 10 min; maximal dose,  $0.2 \text{ mg} \cdot \text{kg}^{-1}/4 \text{ h}$ ). Programming of the PCA systems was performed by one of the authors.

A continuous infusion (5% dextrose, 0.4% NaCl, 0.15% KCl) was maintained at the rate of  $83 \text{ ml} \cdot \text{h}^{-1} \cdot \text{m}^{-2}$  until recovery of normal feeding, after which the infusion rate was maintained at a minimal rate of  $50 \text{ ml} \cdot \text{h}^{-1}$  to prevent catheter obstruction. An antireflux valve was incorporated into the intravenous catheter to prevent the possible accumulation of nalbuphine in the maintenance intravenous fluid tubing, if blockage of the cannula occurred. No other opioid was administered to the children.

#### Pain and Postoperative Recovery Evaluation

Pain was rated by the children every 3 h (except when the child was asleep) for 72 h using a 10-cm VAS scale. The first pain assessment was made 2 h after recovery from anesthesia. Shoulder pain also was recorded. The amount of nalbuphine used during the first and the second days of the study was recorded as well as the number of PCA requests.

Sedation was rated by nurses every 3 h using a categorical scale: 0 = completely awake, 1 = awake but drowsy, 2 = asleep. The first sedation and pain evaluation were performed simultaneously. Delay before normal feeding and walking, side effects such as nausea, vomiting, and urinary retention requiring bladder catheterization were recorded.

#### Poststudy Evaluation

Standardized written questionnaires were given at the end of the study to children, their parents, and nurses to evaluate the overall quality of analgesia over 3 days. The question was: "Do you find pain treatment during the first postoperative hours as poor, good or very good." Furthermore, nurses commented on whether

Table 1. Demograph

Sex ratio (M/F)
Age (yr)
Weight (kg)
Duration
Surgery (min)
Anesthesia (min)
Dextromoramide dose
Delay before nalbuph

All values, except sex/r

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Table 1. Demographic Data

	Laparoscopic (n = 32)	Open (n = 31)
Sex ratio (M/F)	18/14	16/15
Age (yr)	10.9 ± 1.6	11.3 ± 1.7
Weight (kg)	38 ± 10	39 ± 11
Duration		
Surgery (min)	54 ± 17	39 ± 18*
Anesthesia (min)	95 ± 26	75 ± 25†
Dextromoramide dose (mg)	2.4 ± 0.9	2.4 ± 1
Delay before nalbuphine (min)	180 ± 30	172 ± 29

All values, except sex/ratio, are mean ± SD.

\*  $P \leq 0.001$  between groups, Student's  $t$  test.

†  $P \leq 0.01$  between groups, Student's  $t$  test.

or not the PCA system was easy to use and if it was suited to the child.

Statistical analysis was performed using chi-square analysis for categorical data, Student's  $t$  test for unpaired parametric data, Kruskal-Wallis analysis, followed by Mann-Whitney  $U$  test for nonparametric data as indicated. Parametric values were expressed as mean ± SD. Nonparametric data such VAS or PCA nalbuphine use were expressed by median values and interquartile range (25–75%). All test hypotheses were two-sided.  $P$  values less or equal to 0.05 were considered as significant in surgery comparisons. The nalbuphine consumption administered *via* a PCA device, during the first postoperative day after appendicular abscess and vesicoureteral reflux surgery in children was evaluated in a preliminary study. The results of this study allowed us to conclude that it was necessary to have 31 children in each group to detect a difference of 30% for nalbuphine PCA consumption with a type I error of 0.05 and a type II error of 0.2.

## Results

### Demographics

A total of 63 children entered the study. Both the laparoscopic (n = 32) and open (n = 31) groups were identical for demographic data, peroperative dose of opioid analgesic, delay between the last dextromoramide dose and the nalbuphine loading dose (table 1). There was no difference for macroscopic aspect of appendix between the laparoscopic (normal: n = 5, inflamed: n = 24, abscessed: n = 3) and open (normal: n = 4, inflamed: n = 23, abscessed: n = 4) groups.

Operative and anesthesia times (table 1) were significantly longer in the laparoscopic group than in the open group. Operative mortality was absent and overall morbidity was minor (nausea, vomiting). There was no occurrence of wound infection. No patient in the laparoscopic group required conversion to open operation.

### Patient-controlled Analgesia

Patient-controlled analgesia data were missing for four patients in the laparoscopic group. The PCA nalbuphine dose (median, interquartile range 25–75%) was not different between both groups during the first day (414 [218–773]  $\mu\text{g/kg}$  in the open group *vs.* 562 [419–734]  $\mu\text{g/kg}$  in the laparoscopic group) as well as during the second day (267 [50–577]  $\mu\text{g/kg}$  in the open group *vs.* 220 [81–407]  $\mu\text{g/kg}$  in the laparoscopic group).

### Visual Analog Scale

Visual analog pain scale (fig. 1) during the 72 postoperative h indicated no difference between groups. Percentage of children with a VAS score greater than 3 was not different between the open and laparoscopic groups.

### Pain Shoulder

Thirty-five percent of the children reported shoulder pain in the laparoscopic group *versus* ten percent in the open group ( $P \leq 0.05$ ).

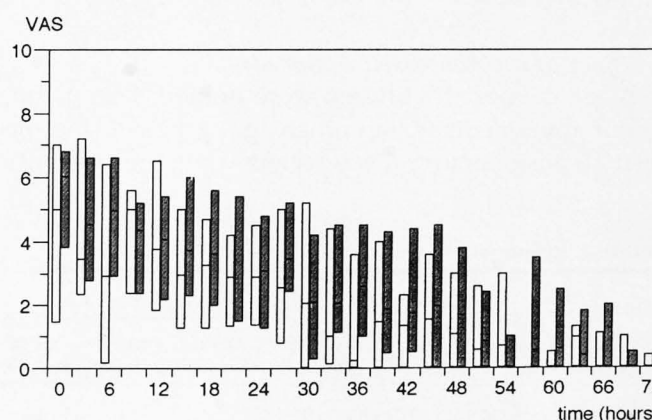


Fig. 1. Visual analog pain scores during the first 72 postoperative h after laparoscopic ■ (n = 32) or open □ (n = 31) appendectomy in children. Data are medians and interquartile ranges (25–75%). \*Laparoscopic *versus* open appendectomy, Mann-Whitney  $U$ ,  $P < 0.005$ .

### Responses to Questionnaire

There were 11 missing responses (children:  $n = 3$ , parents:  $n = 4$ , nurses:  $n = 4$ ) among the 189 questionnaires (5.8%). No difference was observed between groups in responses to questionnaires (table 2). Responses of parents, nurses, and children to questionnaires were not statistically significant. Analgesia was equally assessed by the children and their parents or the nurses, respectively, in 46% and 52% of the cases. Seventeen percent of the children rated their analgesia as less than did their parents whereas ten percent of the children rated analgesia as less than did the nurses. Nurses described PCA use as easy for 97% (laparoscopic group) and 93% (open group) of the children.

### Postoperative Recovery

Delays of regular feeding (h, medians, interquartile) were not different between open (24 [22–36]) and laparoscopic (24 [22–30]) groups. There were three missing data in the laparoscopic group and two in the open group for delay of walking, which (h, medians, interquartile) was not different between open (30 [24–48]) and laparoscopic (24 [21–41]) groups (table 3).

### Adverse Events

Sedation scores were different ( $P \leq 0.05$ ) only at the third postoperative hour: the number of children considered by the nurses as sleepy, was greater in the open group than in the laparoscopic group.

The incidence of nausea, vomiting (laparoscopic group 41%, open group 32%) was not different nor was the incidence of urinary retention different (open group 6%, laparoscopic group 3%).

### Effect of an Abscessed Appendix

When data of all children were pooled, PCA nalbuphine use (medians, interquartile,  $\mu\text{g/kg}$ ) during the first 48 postoperative h was greater when the appendix

Table 2. Responses to Questionnaires

	Laparoscopic			Open		
	Child (n = 33)	Parents (n = 31)	Nurse (n = 31)	Child (n = 28)	Parents (n = 28)	Nurse (n = 28)
Analgesia						
Very good	2	10	6	2	11	14
Good	24	18	20	23	15	12
Poor	6	3	5	3	2	2

Values are number of children. Differences between laparoscopic and open groups were not significant (chi-square).

Table 3. Delay of Walking According to the Technical Procedure or Macroscopic Appearance of Appendix

Laparoscopic group (n = 29)	24 (21–41)
Open group (n = 29)	30 (24–48)
Macroscopic appearance of appendix	
Normal (n = 9)	29 (13–39)
Inflammatory (n = 43)	24 (24–43)
Abscessed (n = 6)	48 (36–50)*

Data are median and interquartile range (25–75%) and are expressed in hours.

\*  $P \leq 0.02$  difference between abscessed and normal or inflamed appendix (Kruskal-Wallis analysis followed by Mann-Whitney U test).

was abscessed (1390 [1072–1631]) than when appendix was normal (568 [357–1001]) or inflamed (756 [300–1040];  $P \leq 0.05$ ). If the nalbuphine use is compared during each postoperative day, this difference was observed only during the second postoperative day. However, PCA nalbuphine use ( $\mu\text{g/kg}$ ) during the first postoperative day was greater when the appendix was abscessed (573 [493–577]) than when it was normal (73 [0–402]) or inflamed (204 [66–403];  $P \leq 0.02$ ).

Delay of walking was greater ( $P \leq 0.02$ ) when appendix was abscessed (48 [36–50]) than when it was normal (29 [24–43]) or inflamed (24 [24–43]). When the appendix was abscessed, children (laparoscopic:  $n = 3$ , open:  $n = 4$ ) received intravenous antibiotics in the hospital for 5 days. All the other children (89%) were discharged from the hospital at the 72nd h immediately at the end of the study.

### Discussion

In contrast to earlier studies, these results suggest that laparoscopic appendectomy does not offer any obvious advantage over the traditional open technique with regard to postoperative pain or recovery. Several reasons may account for our results.

First, none of the previous studies<sup>6,8,10,12</sup> were randomized and moreover none were blinded. Selection for open or laparoscopic appendectomy was made by surgeon availability<sup>6,8,10,12</sup> or open appendectomy was performed in case of failure of laparoscopy.<sup>7</sup> Consequently, groups were not always comparable.<sup>6,10</sup> Second, perforated appendicitis was more frequent in the conventionally treated group of Tate *et al.*<sup>10</sup> Thus, their postoperative course was likely affected by the more severe pathology and altered treatment. Third, a majority of previous studies involved adults.<sup>10,12</sup> The study

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by Ure *et al.*<sup>7</sup> is the only one to include exclusively children and adolescents.

In previous studies,<sup>8-10</sup> pain evaluation was based on intramuscular analgesic requirements as judged by nurses. Furthermore, analgesia was not standardized for all patients.<sup>9</sup> Requirements for analgesia are less after laparoscopic appendectomy in the nonrandomized prospective evaluation of Mc Anena *et al.*<sup>8</sup> However, the infiltration of the abdominal wound with local anesthetic in the laparoscopic group and the greater incidence of wound abscess in the open group may explain the better results for laparoscopy.

Visual analog pain scale is the best validated pain score reported in children older than 5 yr.<sup>13</sup> Ure *et al.*<sup>7</sup> failed to observe any difference after laparoscopic or open appendectomy. We observed a similar evolution of pain over the 72 postoperative h: pain was maximal during the first day and then quickly decreased. However, patients were not randomized in Ure's study. Appendectomy was first performed by laparoscopy (77% of the patients) and when a problem occurred, laparotomy was performed (21% of the patients).

Children were able to resume normal diet and activity quickly in both groups. Delay of feeding, *i.e.*, until patient tolerated a regular diet, was identical to previous studies<sup>7</sup> where feeding was possible after the second postoperative day in 75% of the cases. Reintroduction of normal diet and activity occurs earlier after laparoscopic than open appendectomy in a few studies<sup>10</sup> but the absence of a blinded study design is a limitation of study design.

The delay of walking is probably related to pain and is one element limiting discharge.<sup>7-8</sup> Several authors<sup>6,8</sup> have demonstrated in nonblinded studies that laparoscopy shortens hospital stays after appendectomy. The decision to discharge depends on several parameters including pain, nausea, or vomiting, the ability to ambulate, and feeding, and may be influenced if the same physician both performs the appendectomy and makes the decision to discharge the patient. Patients were discharged home in 3 days at the end of the study except in case of appendiceal abscess. In these children, intravenous antibiotics were given for 5 days and their hospital stay was prolonged. This length of hospital stay was in the range of previous results.<sup>9</sup> However, we did not assess the impact of laparoscopy on the length of hospital stay. Consequently, we were not able to determine if the laparoscopic technique allowed early discharge and return to full activity.

Although duration of surgery was greater in the laparoscopic group, children in both groups received the same amount of dextromoramide. This may explain why children were more sedated in the open group 3 h after the end of the surgery than in the laparoscopic group.

Recovery was slower for boys than girls. Interestingly, among the six children with abscessed appendix, only one was female and five were male. However, the number of children with abscessed appendix is too small to perform statistical analysis concerning this specific point.

In conclusion, laparoscopic appendectomy does not improve postoperative recovery in children between 8 and 15 yr. Specifically, analgesia evaluated through VAS and analgesic requests is not modified when compared with that after conventional surgical treatment. Delays for eating and walking are not different. Consequently, the improvement of the postoperative period is not a valid argument in the decision to perform laparoscopic or open appendectomy.

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## Laryngeal A Prospective

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**Background:** A prospective study was conducted to determine the rate of skill acquisition in pediatric anesthesiology. The aim was to provide information on the training required to achieve proficiency.

**Methods:** Eight anesthesiologists with no previous training with a video recording of airway were observed. Each (600 patients in total) followed the manufacturer's guidelines for laryngoscopy. The manufacturer's recommended protocol for intubation was achieved with a propofol or isoflurane and either as clinically indicated. The intubation was documented during recovery phases of anesthesia. The consultant's training was initiated.

**Results:** The total of 121 children, fifty-five children had two problems. Of the problems, the problem rate was 31.5%. The problem rate was 62% from 62% to 2% for problems, and 39% for problems.

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