

**Evaluation of One Day Discharge After
Laparoscopic Appendectomy for Uncomplicated
Appendicitis in Children.**

NCT05095987

12.07.2022

Study Protocol and Statistical Analysis Plan

Objectives: Laparoscopic appendectomy is one of the most common emergency interventions in pediatric surgery. Over the last decade a protocol for one day discharge after laparoscopic appendectomy was established. The aim of this study is to determine the safety, which is evaluated using rates of complication, readmissions and return into operating room. Additionally, parental satisfaction is investigated for discharge to home within 24 hours after laparoscopic appendectomy for uncomplicated AA.

Primary outcome measures are the safety of laparoscopic appendectomy due to uncomplicated AA and discharge within 24 hours and parental satisfaction.

Secondary outcome measures include the rate of readmission and return to operating room, the complication rate and cost reduction.

Inclusion Criteria: Patients of both genders, between 6 to 17 years of age, who undergo laparoscopic appendectomy and are discharged within 24 hours after surgery.

Exclusion Criteria: Patients younger than 6 and older than 17 years of age, operated due to complicated AA; patients with prolonged hospital stay, more than 24 hours after surgical treatment for any reason – surgeon choice, intraoperative complications, additional pathology; patients undergoing conventional open operating technique for AA.

Type of study: Single-center prospective non-randomized cohort study.

Place of study: All patients included are operated by three surgeons at the Department of Pediatric surgery, University Hospital of Split in Croatia.

Description: In this prospective cohort single center study, patients presenting with the clinical picture of AA to the surgical emergency admission of the University Hospital of Split go through the diagnostical algorithm and are evaluated using the AIR score. Intraoperative decision of inclusion is made by the surgeon and parents are informed about possibility of participation in this study postoperatively. Before discharge the parents are counselled about pain management and home childcare. The two-page questionnaire is handed to the parents with instruction of use. The questionnaire is designed to investigate on possible changes in behavior and the pain level of the child by using visual analogue scale (VAS) measuring from 0 to 10. With this questionnaire, homebased pain management is recorded. Parents return to the outpatient check-up on 7th postoperative day and hand in the filled-out questionnaires. Complication is defined as any postsurgical condition requiring emergency visit, readmission, or return to operating room. Patients are evaluated for surgical related complications using the Clavien-Dindo classification.

Methods: The data is collected from the study protocol which is completed from the medical history data and operative list. Additionally, a two-page questionnaire is handed out to the parents which they fill out immediately after discharge, every postoperative day until the first outpatient control appointment and directly before the appointment. The corresponding data is obtained by revising the study protocols and medical records. The data is analyzed using the Microsoft Excel for Windows Version 11.0 (Microsoft Corporation) and SPSS 24.0 (IBM Corp, Armonk, NY) software programs. Statistical methods used are median with IQR, and percentage of total.

Ethical approval: All procedures performed in studies involving human participants are in accordance with ethical standards of the institution and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Authors declare that the research is conducted according to the principles of the World Medical Association Declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects”. Patients are informed in detail and informed consent is obtained from the parents or legal guardians of the patients to use the data. The study protocol is approved by the Ethics Review Board of University Hospital of Split with reference Number 2181-147/01/06/M.S.-21-02.

Evaluation of the discharge of children from hospital treatment to home care operated on for acute appendicitis Protocol number _____

CLINICAL AND DEMOGRAPHIC DATA

Datum _____ MB _____
Name and Surname _____; Age _____; Sex M / F;
Height _____ cm; Weight _____ kg; Duration of Symptoms _____ h;
Body Temperature _____ °C; Duration of surgery _____ min;
Operation Starting Time _____ h; Exact discharge time (date and hour) _____

LABORATORY AND RADIOLOGIC REPORTS

Leukocytes _____ x10⁹/L CRP _____ mg/L Neutrophils _____ %

ULTRASOUND:

INTRAOPERATIVE REPORT

Medical report: a) catarrhal b) phlegmonous c) gangrenous

d) perforated – local peritonitis e) perforated – diffuse peritonitis

f) without pathological findings g) other _____

Appendiceal Base Management:

a) polymeric clip b) endoscopic loop c) harmonic scalpel (Gupta) ULTRACISION / LOTUS

INTRAOPERATIVE COMPLICATIONS:

EARLY POSTOPERATIVE COMPLICATIONS:

PATHOLOGICAL REPORT

a) catarrhal b) phlegmonous c) gangrenous d) without pathological findings

AIR SCORE		
Vomiting	1	
Pain in the RLQ	1	
Rebound tenderness 1 – light; 2 – medium; 3 – strong	0 - 3	
Elevated Body Temperature > 38.5 °C	1	
Neutrophils: 0 ≤70%; 1 70 – 84%; 2 ≥85%	0 - 2	
Leukocytes: 0 ≤10; 1 10 – 14.9; 2 ≥15	0 - 2	
CRP: 0 ≤10; 1 10 – 49; 2 ≥50	0 - 2	
AIR SCORE	12	

KOMPLICATION:

SATISFACTION ON DISCHARGE: 1 / 2 / 3

SATISFACTION AT FIRST POSTOPERATIVE APPOINTMENT: 1 / 2 / 3

SURGEON _____

CHILD'S NAME: DATE & HOUR OF SURGERY: PROTOCOL NUMBER:
PARENTS' NAME: DATE & HOUR OF DISCHARGE: ORDERING PEDIATRIC SURGEON:

**SATISFACTION OF PARENTS ABOUT DISMISSAL WITHIN 24 HOURS
FROM SURGICAL TREATMENT OF CHILD DUE TO ACUTE
INFLAMMATION OF APPENDIX
(TO BE COMPLETED ON DAY OF DISCHARGE)**

Immediately after the surgery and getting detailed information about the past procedure from the pediatric surgeon, how did you feel about being discharged to home care within 24 hours?

1. Angry about the child's short hospital stay, unhappy, very nervous and scared, completely unprepared.
2. Moderately nervous and unprepared and averagely satisfied.
3. Good, lucky, prepared, maximally satisfied.

Comment:

**PARENTAL MEASUREMENT OF POSTOPERATIVE PAIN AT HOME
(To be completed at home until the first outpatient check-up)**

Children sometimes have behavioural changes when recovering from surgical treatment. The attached questionnaire consists of a list of behavioural changes that your child may or may not show during recovery in home care. Please answer yes or no for each symptom:

- | | |
|---|----------|
| 1. Complains and ask for more than usual | YES / NO |
| 2. Cries more than usual | YES / NO |
| 3. Plays less than usual | YES / NO |
| 4. Does not do things he/she usually does | YES / NO |
| 5. Seems more worried than usual | YES / NO |
| 6. Quieter than usual | YES / NO |
| 7. Has less energy than usual | YES / NO |
| 8. Refuses to eat (more than usual) | YES / NO |
| 9. Eats less than usual | YES / NO |
| 10. Holds on to the painful part of the body | YES / NO |
| 11. Is careful not to hit the painful part of the body | YES / NO |
| 12. Moans, sighs, and painfully whines more than usual | YES / NO |
| 13. Redder in the face than usual | YES / NO |
| 14. Wants to be close to you more than usual without separating | YES / NO |
| 15. Agrees to take medication without discussion or refusal | YES / NO |

Additional comments on the child's condition and behaviour:











































POSTOPERATIVE PAIN I (CHILD INFORMATION)

Weight: _____ kg; Height: _____ cm; Sex: M / F; Allergies to medication: _____

What does your child normally take for pain or fever? _____

POSTOPERATIVE PAIN II (HOME CARE AND THERAPY)

Please indicate by postoperative day how you alleviated pain and lowered your child's temperature and how often per day (indicate the name of the drug, the amount of one dose and how many times a day she/he received the drug) and the child's pain rating on the same days. up to 10; (0-without pain; 10-unbearable intense pain)

I. P.O. day: _____	Child's rating:						
		0	2	4	6	8	10
II. P.O. day: _____	Child's rating:						
		0	2	4	6	8	10
III. P.O. day: _____	Child's rating:						
		0	2	4	6	8	10
IV. P.O. day: _____	Child's rating:						
		0	2	4	6	8	10
V. P.O. day: _____	Child's rating:						
		0	2	4	6	8	10
VI. P.O. day: _____	Child's rating:						
		0	2	4	6	8	10
VII. P.O. day: _____	Child's rating:						
		0	2	4	6	8	10

Comment: _____

PARENTAL ASSESSMENT AND SATISFACTION ONE WEEK AFTER SURGICAL TREATMENT AND RELEASE WITHIN 24 HOURS OF SURGERY

(Fill in just before coming to the outpatient check-up and take the above with you and hand it over to the attending physician)

Looking back at it how do you feel and what do you think now about the child being discharged from hospital within 24 hours of surgery?

1. I think it was a good choice and the best thing that could be done.
2. I am not sure if it was a good choice and the best thing that could be done.
3. I think it was a bad decision releasing the child from hospital this early and that he has this condition/disease again. I would like her/him to be discharged to home care later and to stay in the hospital longer.

Parents' comments on this type of discharge: _____
