

Patient centred outcomes following non-operative treatment or appendicectomy for uncomplicated acute appendicitis in children

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Abstract

Whilst non-operative treatment has emerged as an alternative to surgery for the treatment of uncomplicated acute appendicitis in children, comparative patient centred outcomes are not well documented. We investigated these in a feasibility randomised trial. Of 57 randomised participants, data were available for 26. Compared to appendicectomy, children allocated to non-operative treatment reported higher short term quality of life scores, shorter duration of requiring analgesia, more rapid return to normal activities and shorter parental absence from work. These preliminary data suggest differences exist in recovery profile and quality of life between these treatments that are important to measure in a larger RCT.

Trial registration ISRCTN15830435.

Treatment of appendicitis in children has traditionally been by appendicectomy. Over recent years there has been increasing interest in the use of non-operative treatment as an alternative to appendicectomy^{1,2} but comparative outcomes of these two different treatment modalities are poorly understood. Previous reports have tended to focus on outcomes most relevant to surgeons such as surgical complications and other treatments required rather than considering a full range of outcomes that we know are important to patients and families.³ Here we report a number of patient centred outcomes including health related quality of life (HRQoL) in data arising from a feasibility randomised controlled trial.

A feasibility RCT comparing appendicectomy and non-operative treatment in children with suspected uncomplicated acute appendicitis was undertaken in three United Kingdom centres over a 12 month period beginning March 2017. Full details of the methodology, key clinical findings and feasibility findings of the trial have been previously reported.⁴ To understand patient centred markers of recovery we used parent completed diary cards following hospital discharge to record duration of analgesia use, time taken to return to normal and full activities and duration of parental absence from work. We used the CHU-9D tool⁵ to measure HRQoL during the trial period. Since this was a feasibility trial, we report descriptive data without formal statistical analyses. Data are reported on an intention to treat basis as per trial allocation.

Patients and families were involved in the design of the trial, development of patient and family facing materials and defining outcomes to be measured.

A total of 57 participants were enrolled in the trial of whom 28 were allocated to appendicectomy and 29 to non-operative treatment. Data relating to early post-discharge recovery were available for 26 participants - 15 in the appendicectomy arm and 11 in the non-operative treatment arm. The proportion of participants taking analgesia was generally lower for each day following discharge in the non-operative treatment arm than the appendicectomy arm. Following non-operative treatment participants were able to return to normal or full activities earlier than those in the appendicectomy arm. Fewer than half of participants in the appendicectomy reported being able to participate in full activities by two weeks following discharge. Parents of participants in the non-operative treatment arm were able to return to work earlier than those in the appendicectomy arm. Health related quality of life assessed using the CHU-9D tool at enrolment, hospital discharge and further time points during the six month follow up period is shown in Figure 1.

Whilst we acknowledge a relatively small sample size and incomplete data, our observation of an apparent difference in early post-discharge recovery profile between participants allocated to appendicectomy or non-operative treatment is an important finding with relevance for both clinical practice and future research. Avoidance of general anaesthesia, trauma of surgery and lack of exposure to operative/ post-operative complications are viewed as potential benefits of non-operative treatment over surgery by patients and parents. Our data suggest there may be additional benefits to non-operative treatment over surgery in terms of more rapid return to baseline activity status and societal benefits with fewer days of parental work absence. Patients and parents may wish to consider these as well as more direct clinical outcomes when considering choice of treatment. Furthermore, there appear to be short term differences in HRQoL between treatment arms which may be clinically meaningful and will inform design of future cost-utility analyses.

Overall our data emphasise the importance of measuring a full range of outcomes including these patient centred outcomes in future research and provide greater insights into short term differences in outcomes between treatment arms.

Table 1: Profile of post-discharge recovery in each treatment arm

Day following discharge	Analgesia used		Able to do normal activities		Able to do full activities		Parental work absence	
	NOT	APP	NOT	APP	NOT	APP	NOT	APP
0	27	80	82	7	36	0	36	67
1	27	73	91	7	36	7	36	53
2	18	60	91	33	45	7	9	40
3	18	60	91	47	54	13	9	40
4	27	40	100	53	73	20	9	40
5	20	47	90	67	80	20	10	27
6	20	20	90	73	80	20	10	27
7	20	27	100	80	90	20	20	27
8	10	13	100	80	80	27	10	20
9	10	13	100	87	90	33	0	20
10	10	7	80	93	70	40	0	13
11	10	7	90	93	90	40	0	13
12	10	13	90	87	90	40	0	7
13	0	7	90	87	90	47	0	7
14	0	13	70	87	70	47	0	20

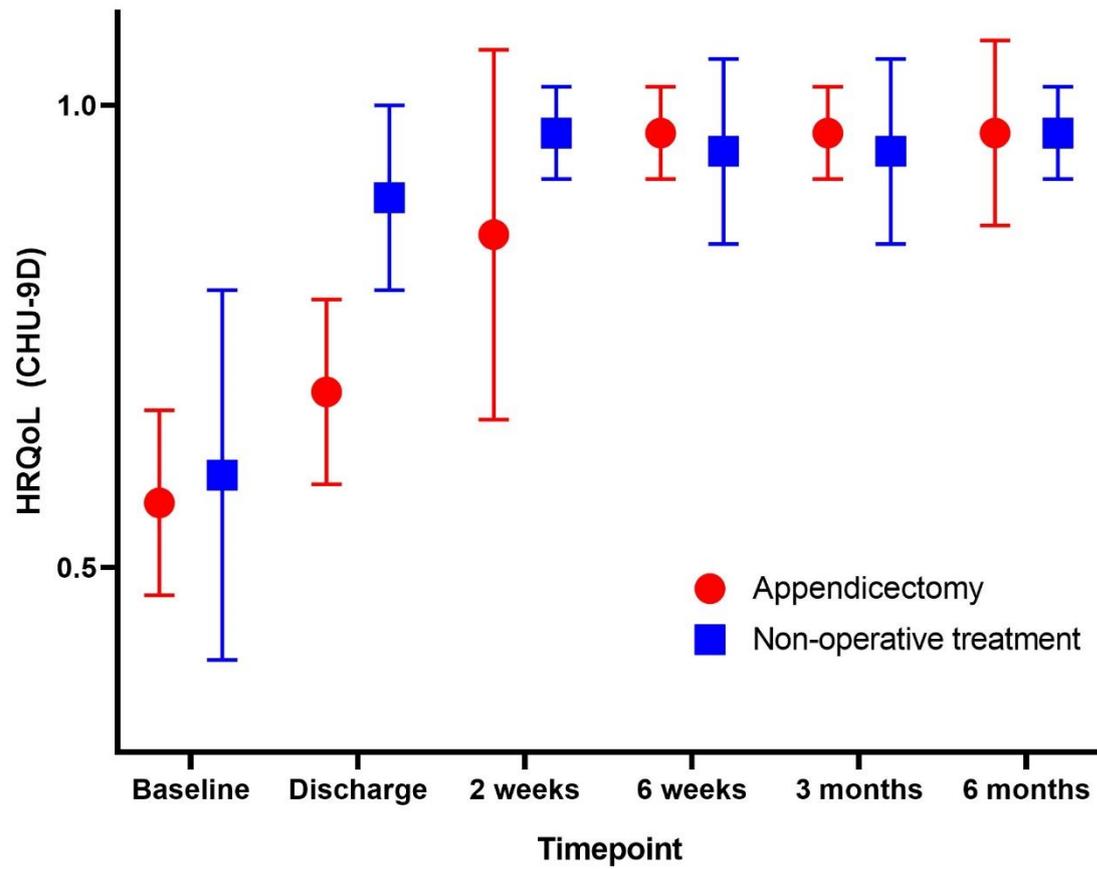
Data are percentage of participants reporting data on each day. For all outcomes, n=15 for APP arm and n=11 for NOT arm for days 0-4 and n=10 for days 5-14.

NOT – non-operative treatment arm; APP – appendicectomy arm

Figure 1: Health related quality of life (CHU-9D) during the trial.

Data are mean with standard deviation

HRQoL is scored on a scale from 0 (dead) to 1 (perfect health)



References

1. Georgiou R, Eaton S, Stanton MP, et al. Efficacy and Safety of Nonoperative Treatment for Acute Appendicitis: A Meta-analysis. *Pediatrics* 2017;139(3) doi: 10.1542/peds.2016-3003
2. Minneci PC, Hade EM, Lawrence AE, et al. Association of Nonoperative Management Using Antibiotic Therapy vs Laparoscopic Appendectomy With Treatment Success and Disability Days in Children With Uncomplicated Appendicitis. *JAMA* 2020;324(6):581. doi: 10.1001/jama.2020.10888
3. Sherratt FC, Allin BSR, Kirkham JJ, et al. Core outcome set for uncomplicated acute appendicitis in children and young people. *Br J Surg* 2020 doi: 10.1002/bjs.11508 [published Online First: 2020/03/18]
4. Hall NJ, Eaton S, Sherratt FC, et al. CONservative TReatment of Appendicitis in Children: a randomised controlled feasibility Trial (CONTRACT). *Archives of Disease in Childhood* 2021:archdischild-2020-320746. doi: 10.1136/archdischild-2020-320746
5. Stevens KJ. Assessing the performance of a new generic measure of health related quality of life for children and refining it for use in health state valuation. *Applied Health Economics and Health Policy* 2011;9:157-69.