ACTIVE OBSERVATION VERSUS INTERVAL APPENDICECTOMY FOLLOWING SUCCESSFUL NON-OPERATIVE TREATMENT OF APPENDIX MASS IN CHILDREN: A RANDOMISED **CONTROLLED EVALUATION**

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Aims: Initial successful conservative treatment of appendix mass in children is a common scenario. Systematic review (retrospective series only) suggested equipoise between the risk of recurrent appendicitis (20%) and complications of interval appendicectomy (IA). We aimed to conduct the first multi-centre randomised-controlled evaluation of IA (2-3 months following initial successful treatment) vs. active observation (AO, 3 monthly review for 1 year) in children with non-operatively treated appendix mass.

Methods: Ethically approved, international, multicentre randomised controlled-evaluation of children (3-15yrs) with appendix mass successfully treated without surgery or percutaneous drainage. Online randomisation was performed, with minimisation for age, gender, centre and presence of sonographic faecolith. Primary AO outcome was incidence of recurrent acute appendicitis (histological acute inflammation or recurrent appendix mass). Primary IA outcome was significant appendicectomyrelated complication. Patients were followed for 1 year following enrolment. Data are median (range) or incidence and were analysed on an intention-to-treat basis. ISRCTN number: 93815412.

Results: Full enrolment was achieved - 106 children, 52 male, median age 8 years (range 3-15). Fifty-two allocated to IA, 54 to AO. Significant complications occurred in 3/52 (6%) IA patients - wound infection (n=2), bowel resection after port-site hernia (n=1). Six of 52 (12%) AO children underwent appendicectomy within 1 year for histologically-confirmed acute appendicitis. A further 6/52 (12%) had appendicectomy for acute or chronic abdominal pain without acute inflammation on histology. Three further AO children had hospital admissions for abdominal pain (no appendicectomy). Duration of hospitalisation is shown in the Table. No carcinoid tumours were detected.

Conclusions: More than 3/4 patients under AO did not require appendicectomy within one year. IA had a low risk (6%) of complications, with unplanned re-operation in 1 child (2%). Both IA and AO carry risks of further surgery and hospitalisation. These prospective data will help inform decisionmaking in this group of children.

<u>Table: Duration of hospital stay during 1 year follow-up for each treatment group</u>		
	IA (n=51)	AO (n=52)
Scheduled hospitalisation for	n=37, 31.5 hrs (10.0-	n=1, 32.8hrs
planned procedure	73.3)	
Unscheduled hospitalisation	n=3, 8 days (7.3-10.0)	n=15, 2.1 days
	-	(0.7-8.9)
Overall duration of hospitalisation	31.5 hrs (0.0-239.3)	0 hrs (0-248.9)

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