Title: Postoperative Activity Restrictions in Children (PARC)

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SUMMARY

BACKGROUND: Currently, there are no evidence-based guidelines for postoperative activity restrictions in routine pediatric surgery. Recent studies suggest that patients may return to normal activity earlier than previously thought. We aim to compare time to full activity and post-operative outcomes. This study will describe family preferences for self-directed activity restrictions (SDAR) and physician directed activity restrictions (PDAR) following routine surgeries.

STUDY DESIGN: Single institution, prospective clinical trial (NCT04145895). Patients who present for a routine inguinal hernia repair or laparoscopic appendectomy for uncomplicated appendicitis are eligible for participation. Participating families will choose to enroll in either the control (PDAR) or experimental (SDAR) groups. The PDAR patients are restricted from full activity for two weeks post-operatively. For SDAR, patients are instructed to return to full activity when pain is improving and the family feels comfortable. At 4-6 weeks postoperatively, caregivers will complete a survey to assess time to resume full activity, time to return to school and work, surgical complications, and patient and caregiver satisfaction.

BACKGROUND AND SIGNIFICANCE

Postoperative activity restrictions (PAR) serve to minimize the risk of complications and prevent stress on the operative site following abdominal surgery. By minimizing intra-abdominal pressure, PAR are used to prevent the breakdown of the surgical repair and closure.[1] Commonly restricted activities include heavy lifting, exercise, and strenuous activity. As children are highly active by nature, limiting physical activity is difficult.[2] Pediatric surgeons may restrict time to return to school or extracurricular activities. However, these restrictions create a societal burden through school absences and missed work days. Additionally, PAR can negatively impact a child's psychosocial well-being and cause undue family stress.[2]

PAR are physician-dependent as evidence-based guidelines for restrictions following routine pediatric surgery are not established. Recent studies demonstrate considerable variability in surgeons' recommendations following laparoscopic appendectomy and inguinal hernia repair in children.[1] The lack of consensus amongst physicians may be attributed to the corresponding lack of evidence in this area.[3] A 2020 survey on surgeon recommendations for postoperative activity found that only 23.8% of respondents indicated that their recommendations were based on evidence in the literature.[4] More than half of the respondents indicated that they followed practices learned in training, and 50.7% indicated that recommendations had been developed from previous experience.[4] Others propose the use of self-directed activity restrictions (SDAR) following routine pediatric surgery.[2] Proponents of SDAR suggest patients may safely return to normal activity earlier than previously thought. Additional benefits include greater patient and family satisfaction and quality of life.

Prospective investigation is needed to develop evidence-based guidelines for PAR in the pediatric population. We conducted a single institution, prospective clinical trial (NCT04145895) to compare length of time to full activity, as well as, post-operative outcomes of SDAR and physician directed activity restrictions (PDAR) in children following inguinal hernia repair and laparoscopic appendectomy. Further, we aimed to describe the preference of families for SDAR or PDAR, patient and caregiver satisfaction, and parental time of work. This paper reports the preliminary results of this study.

METHODS

Participants

This study was approved by the Beaumont Institutional Review Board (2019-224). Patients who presented to Beaumont Royal Oak and Beaumont Troy for a routine inguinal hernia repair (ages 2-13 years) or laparoscopic appendectomy for uncomplicated appendicitis (ages 0-17 years) were eligible for participation. Patients meeting eligibility criteria (**Figure 1**) were identified by the pediatric surgeons, including the Primary Investigator (P.B.), and were provided with an information sheet detailing the study, which served as consent for participation. Parents and patients who elected to participate then chose to enroll in the control group (PDAR) or experimental group (SDAR). The PDAR instructions detailed that patients are restricted from full, normal activity for 2 weeks after their procedure. The SDAR instructions specified that they may return to full activity when their pain is improving and the parent, or guardian, feels comfortable advancing their activity. Enrollment is still accruing for this study.

Figure 1. Patient eligibility criteria

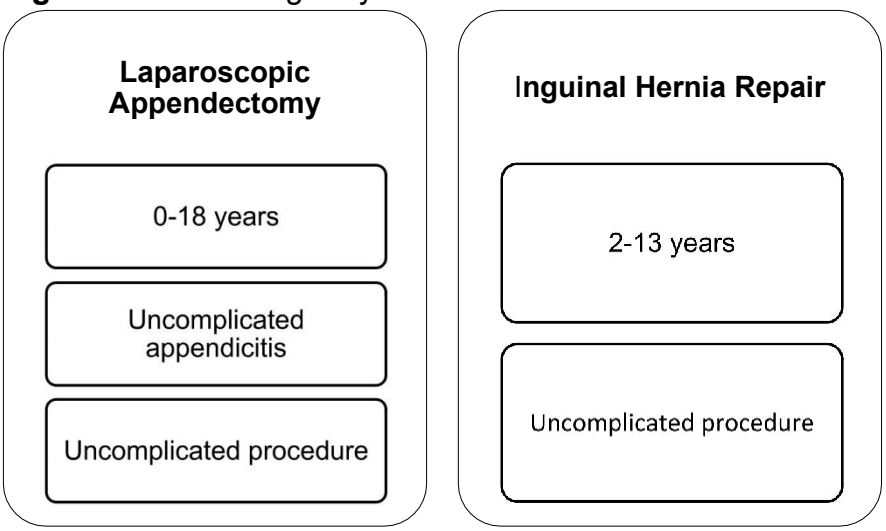

Figure 1. Patient eligibility criteria for participation in the clinical trial.

Data Collection

Baseline characteristics, comorbidities, surgical complications, length of stay, and pain medications will be obtained for each participant from the time of surgery. At 4-6 weeks postoperatively, parents or guardians will be asked to complete a survey at their follow-up appointment or online using Research Electronic Data Capture (REDCap). The survey includes assessments of the time taken to return to school and work, return to full activity, surgical complications, and patient and caregiver satisfaction (**Figure 2**).

Figure 2. Postoperative Survey

Your Child's Experience Postoperatively	
For how long was your child on pain medications following the procedure?	⎦ 1-2 days ⎦ 3-4 days ⎦ 4-7 days ⎦ >1 week
How many days following the procedure did your child return to school, daycare, summer camp, or summer school?	
Approximately how many days after surgery did your child return to full activity (sports, gym, dance, outdoor play, etc.)?	
Did your child's wound have any oozing or bleeding following discharge from the hospital?	⎦ None ⎦ Mild (slight drainage) ⎦ Moderate (drainage with blood) ⎦ Severe (oozing with blood)
If you answered mild, moderate, or severe to the previous question, when did this occur?	
If you answered mild, moderate or severe to the previous question, did this require any treatment by your surgical team?	
Did your child experience any postoperative complications?	⎦ No ⎦ Yes
If you answered yes to the previous question, please specify:	
After resuming full activity, did your child experience an increase in pain?	⎦ No ⎦ Yes
If you answered yes to the previous question, did they require any medication for the pain?	⎦ No ⎦ Yes
How compliant was your child with their postoperative instructions?	⎦ Compliant ⎦ Partially compliant ⎦ Not compliant

How would you describe your child's overall satisfaction following the procedure?	⎦ Very satisfied ⎦ Satisfied ⎦ Neither satisfied or dissatisfied ⎦ Dissatisfied ⎦ Very dissatisfied
Your Experience Postoperatively	
What is your relationship to the child?	⎦ Mother ⎦ Father ⎦ Grandparent ⎦ Legal Guardian ⎦ Other
Did you or another caregiver take time off work to care for your child following their procedure?	⎦ Yes ⎦ No
Did you have to find additional childcare for your child following their procedure?	⎦ Yes ⎦ No
How would you describe your overall satisfaction following your child's procedure?	⎦ Very satisfied ⎦ Satisfied ⎦ Neither satisfied or dissatisfied ⎦ Dissatisfied ⎦ Very dissatisfied
Were you satisfied with the instructions detailed in your discharge guidelines?	⎦ Very satisfied ⎦ Satisfied ⎦ Neither satisfied or dissatisfied ⎦ Dissatisfied ⎦ Very dissatisfied
If your followed physician-directed instructions, did you follow the recommendations strictly?	⎦ Yes ⎦ No ⎦ Somewhat
If you chose self-directed instructions, did you feel comfortable determining when your child was able to resume full activity?	⎦ I felt comfortable ⎦ I had some concerns ⎦ I did not feel comfortable ⎦

Figure 2. Postoperative survey provided to patients 4-6 weeks following their procedure. Patients were able to complete the survey at their postoperative visit or online via REDCap.
⎦

Objectives

The primary outcome of this study is length of time to full activity.
Secondary outcomes will evaluate patient preference to PDAR and SDAR based on choice of study arm and the impact of restriction type on number of parental days off work.
Clinical complications will also be tracked. Patient satisfaction will be defined as a cumulative score of three satisfaction factors (child, parent, and satisfaction with discharge guidelines).

Statistical Analysis

Continuous data will be presented as mean (SD) or median (IQR) depending on distribution, and analyzed using unpaired t tests or Mann Whitney ranked sum tests. Categorical data will be presented as number (%) and will be analyzed using Chi Square or Fisher's exact test depending on frequencies P values <.05 will be considered significant.

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