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Use of standardized visual aids improves informed consent for appendectomy in children: A randomized control trial

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ABSTRACT

Background: Obtaining informed consent for surgical procedures is often compromised by patient and family educational background, complexity of the forms, and language barriers. We developed and tested a visual aid in order to improve the informed consent process for families of children with appendicitis.
Methods: Families were randomized to receive either a standard surgical consent or a standard consent plus visual aid. Univariate and multivariate analyses were performed to assess the effectiveness of adding the visual aid to the consent procedure.
Results: Parents in both cohorts were similar in age, gender and education level ($p > 0.05$). On multivariate analysis, visual consent had the strongest influence on parent/guardian comprehension (OR 4.0; 95%CI 2.2–7.2; $p < 0.01$), followed by post-secondary education (OR 2.7; 95%CI 1.5–4.9; $p < 0.01$), and use of external resources to look up appendicitis (OR 2.0; 95%CI 1.1–3.6; $p = 0.02$).
Conclusion: Visual aids improve understanding and retention of information given during the informed consent process of children with appendicitis.

Introduction

Informed consent is the cornerstone of ethical surgical practice and ensures that patients and their families fully understand the nature of their condition, the risks and benefits of the proposed procedure, and alternative treatments.[1] Prior studies have raised concerns regarding the effectiveness and execution of the contemporary consent process.[2] Specifically, physician-patient communication during the consent process can be hindered by language, educational, and/or socio-cultural barriers.[3] More than one third of the adult population in the United States have limited health literacy that may affect their ability to obtain and process health-related information.[4,5] Engel et al. found that 78% of patients failed to understand emergency room discharge instructions and 80% of patients with comprehension deficits did not recognize their difficulty with comprehension.[4] Informed consent is not only an ethical imperative; enhancing patient comprehension has been shown to correlate with greater satisfaction, improved outcomes and lower postoperative complications.[6–9]

The contemporary consent process consists of an extremely detailed legal document combined with an interactive discussion between the surgeon and the patient. Studies of this process have consistently shown that patient consent forms are written at levels which exceed the average patients' reading level.[10–13] A study by Williams et al. which utilized the Functional Health Literacy in Adults instrument to assess 2659 patients at two public hospitals, revealed that 60% were unable to comprehend a standard informed consent document.[14] . Santavirta et al. found that 37% could not name any relevant complication after undergoing informed consent for hip replacement, a number which was not changed by intensive patient education prior to surgery.[19] Hutson et al. showed that patients tend to recall the expected benefits of surgery more frequently than the potential risks.[20] While adjuncts to the consent such as educational brochures and pamphlets improve patient satisfaction with the consent process, they may not improve comprehension due to limited health literacy as well as other educational and language barriers.[21,22] As a result of these findings, many investigators have sought more effective ways to improve the consent process.[2,23–25]

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Patient preference for visual aids has been well described. Prior studies have shown that pictograms improve medication understanding and consequently medication adherence.[26–28] A randomized controlled trial of 225 low-literacy patients found that patients educated with pictograms were more likely to use eye drops as prescribed.[29] Similarly, Leong et al. who performed a randomized crossover trial of 30 patients on the medical wards of an urban, tertiary care center, found 77% of participants reported that pictograms helped them understand medication instructions, 67% of participants preferred pictograms, and 93% felt pictograms should be used on all medication labels.[30] These data, however, relate to medication adherence, the data for other areas is lacking. In this study, we describe the use of a novel visual aid (Fig. 1) to supplement the standard consent process as a means to improve the informed consent process for the families of children undergoing appendectomy for acute appendicitis.

Material and methods

Children with acute appendicitis who presented to the emergency department at a tertiary care children's hospital or one of its two satellite campuses were randomized to either the standard consent procedure (written consent plus surgeon explanation) or standard consent plus visual aid. The study took place over a three-month period between August 2017 and November 2017 and was approved by the Baylor College of Medicine IRB (H-41621). No patients during this time underwent non-operative treatment of acute appendicitis. Children undergoing interval appendectomies or incidental appendectomies as part of a broader procedure were excluded.

This was a parallel trial. The primary outcome was overall score on the knowledge-based assessment. Secondary outcomes were the effect of post-secondary education, use of external resources and patient reported comprehension on the knowledge-based assessment scores. Randomization was computer generated on a 1:1 ratio and placed in sealed envelopes. Patients were assigned to either a standard consent or a standard consent plus visual aid. A sample size of 71 per arm was determined in order to power the study to detect a 1-point difference on the knowledge-based assessment with an $\alpha = 0.05$. The visual aid consisted of illustrations highlighting the cause of appendicitis, its treatment and complications (Fig. 1). A standardized script was developed to ensure that all parents/guardians were receiving the same verbal information regardless of the group they were randomized to. During the first 24-h after surgery parents/guardians were offered the opportunity to take a knowledge-based test evaluating the effectiveness of the surgical consent. A detailed cover sheet describing the purpose of the study, potential benefits and risks was provided. Parents/guardians were blinded to the different methods of consents being administered. If the parent/guardian assented to participate, a self-administered survey and knowledge-based assessment was provided in either English or Spanish. The survey included questions about parental/guardian age, educational level, relationship to the patient, use of external resources to look up their child's diagnosis or treatment, and an appraisal of the consent process. To evaluate comprehension and retention, the survey also included four multiple-choice questions about the etiology of appendicitis, the planned intervention and potential complications after surgery (Fig. 2).

Parent/guardian self-reported level of understanding of their child's condition and the planned procedure was collected using a 5-point Likert scale and categorized into two groups: High level of understanding[4,5] vs. low level of understanding[1–3] for analysis. Parent/guardian education was collected as: professional or graduate degree, college degree, vocational school (or some college), high school diploma/GED or did not finish high school. These responses were then grouped into two categories: post-secondary education vs. no post-secondary education for analysis. Descriptive statistics were used to summarize attributes. In the univariate analysis, Chi-Square and Fisher's exact tests were used to evaluate the categorical data which was then reported as frequencies and proportions, while Wilcoxon rank-sum tests or students t-tests were used to evaluate the continuous data. Bonferroni corrected p-values, to adjust for multiple comparisons, were calculated for the knowledge-based assessment scores. A multivariate ordinal logistic model was applied to study the independent contributions of the visual consent, parental/guardian education and the use of external resources. Variables were selected a-priori for inclusion in the

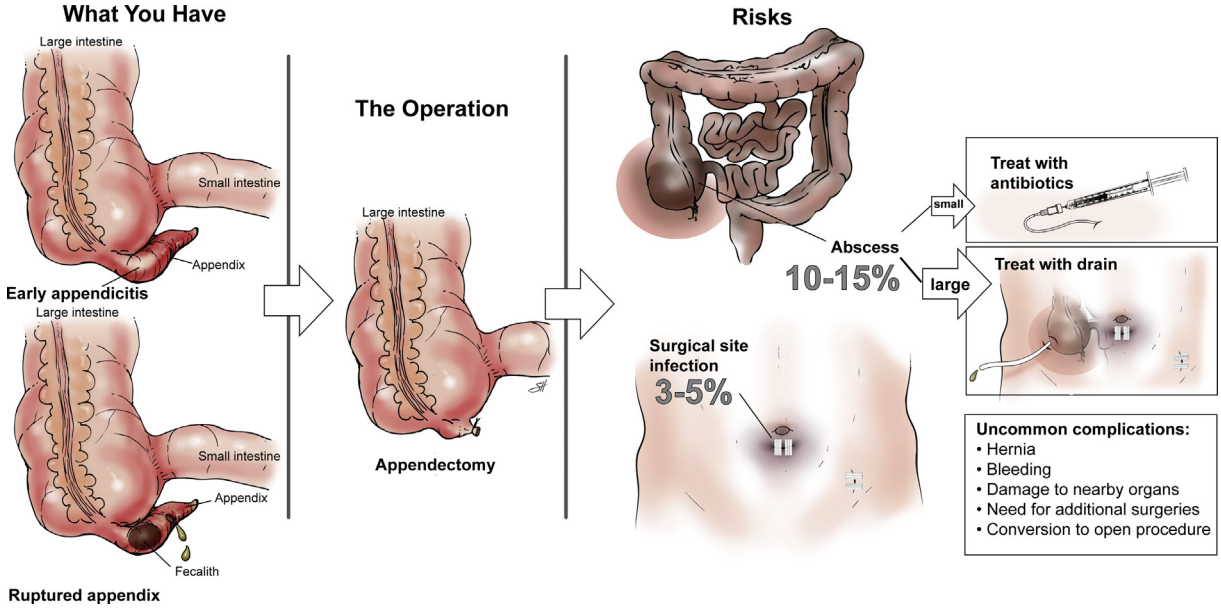

Fig. 1. – Visual Consent Aid © Baylor College of Medicine Department of Surgery.