

Abstract

Objectives: 1) To examine the usability and feasibility of a decision aid prototype for pediatric obstructive sleep apnea (OSA) on parents' level of decisional conflict and perception of involvement in the shared decision-making process. 2) To estimate parameters for a future randomized controlled trial.

Design: Multicenter randomized pilot trial.

Methods: Ninety-nine parents of children (< 6 years) undergoing consultation for adenotonsillectomy for SDB were prospectively enrolled. Families were randomly assigned to receive the decision aid prototype (DA) or follow standard care procedures. The DA was developed in accordance with the International Patient Decision Aids Standards guideline. All consultations were video-recorded and coded with the OPTION instrument. Following the consultation parents completed the Decisional Conflict Scale (DCS) and Shared Decision-Making Questionnaire (SDM-Q-9) while otolaryngologists completed the physician version (SDM-Q-Doc). A subset of parents and surgeons were interviewed to assess the usability of the DA.

Results: Overall, 33.3% of parents had clinically significant decision conflict. A negative correlation between DCS and SDM-Q-9 was observed ($p < 0.001$), but total median DCS and SDM-Q-Doc scores were not correlated. In parents receiving the DA, the mean total OPTION score was 13.83 out of 40 (SD 5.24), compared to 11.95 (SD 5.21) in those not receiving the DA ($p = 0.11$). Similarly, the DCS ($p = 0.775$), SDM-Q-9 ($p = 0.845$), and SDM-Q-Doc ($p = 0.369$) scores were not impacted by the use of the DA. Interviews showed that parents found the DA helpful but wanted more time to read and contemplate the information. Both parents and surgeons indicated that direction on how to use the DA would be beneficial.

Conclusions: There were no significant differences in the decisional conflict or shared decision-making with the use of a paper-based DA for pediatric OSA. However, the need for improvement in SDM techniques was suggested from the results in both groups. Future studies training otolaryngologists on effective SDM techniques and how to appropriately utilize decision aids may improve SDM for pediatric OSA.

Introduction

- *Shared decision-making* (SDM) has been defined as "an approach to medical decisions in which patients and clinicians work together to reach a mutually agreed upon decision that is consistent with the best available evidence, as well as patients' preferences."^{1,2}
- *Decision aids* are evidence-based, practical tools to provide decision support.
 - Help patients/families (and providers) become involved in decision-making by providing precise information about the options and outcomes of treatments, clarifying personal values with respect to the intervention that is being considered, and providing guidance in the steps of decision-making.^{3,4}
 - Supplement the traditional informed consent counseling from healthcare providers, but also provide accessibility outside the formal consultation time.
 - Improve patient knowledge and lead to less decisional conflict and greater concordance between patient values and the chosen option.³
 - May also improve health outcomes by better preparing patients and families to manage the demands of surgery (e.g., postoperative pain, infection).
 - Can relay clinical practice guidelines or other evidence-based care recommendations^{4,5} potentially saving costs by reducing non-evidence based procedures.
 - No comprehensive decision aid exists within otolaryngology.⁴

Primary objective: Assess the usability and feasibility of the decision aid prototype in preparation for a future randomized controlled trial.

Methods

- Prospective randomized pilot study performed at:
 - IWK Health Centre (Halifax, Nova Scotia, Canada)
 - Primary Children's Hospital (Salt Lake City, Utah, United States).
- Research Ethics Board approval was obtained at both sites.
- Participants were parents considering adenotonsillectomy for their children (<6 years of age) presenting with sleep disordered breathing. Caregivers who did not have the decision-making authority or not fluent in English were excluded.
- Surgeon participants consisted of seven fellowship-trained pediatric otolaryngologists (two in Halifax and five in Salt Lake City).
- Parents were blinded and randomized to either receive the decision aid prototype during the visit (study group) or undergo the usual surgical consultation (control group).
- All interactions were video-recorded using dual mounted cameras.

Outcome Measures

- 1) After consultation, parents completed the following measures:
 - Decisional Conflict Scale (DCS), validated to assess uncertainty about medical decisions.
 - Shared Decision-Making Questionnaire-Parent Version (SDM-Q-9), validated to assess perceptions of involvement in decision-making.
- 2) Surgeons completed Shared Decision-Making Questionnaire-Physician Version (SDM-Q-Doc).
- 3) Video-recordings were coded with the OPTION instrument. The OPTION measures the extent to which clinicians involve their patients (or parents in this study) in medical decision-making.
- 4) Study group parents asked to provide general feedback and to recommend any changes in the decision aid. A subset of the surgeons completed a semi-structured interview to assess the usability and feasibility of the decision aid.

Decision Aid Content

The two-page decision aid prototype (available on request) contained:

- Information about pediatric sleep disordered breathing and the two most common treatment options (surgery and watchful waiting) with their risks and benefits.
- Visual reinforcements complemented the numerical risk information and a values clarification exercise was included.

Data Analysis

- SPSS Statistics for Windows Version 17.0 (SPSS Inc, an IBM Company, Chicago, Illinois).
- Non-parametric or parametric tests for non-normally or normally distributed data.
- Spearman's ρ correlations were used to examine the relation between shared decision-making (SDM-Q-9 and SDM-Q-Doc) and level of decisional conflict (DCS).

Results

Participants

- 100 parents were enrolled (70 from Salt Lake City and 30 from Halifax); one participant did not complete the study.
- Fifty-one parents randomized to receive the decision aid; 48 parents to the control group (Table 1).
- Small to moderate effect size of 0.36 was noted (Cohen's d calculation, to estimate the sample size for a future randomized controlled trial).

Study Group and Control Group

- Clinically significant decisional conflict - 33 (33.3%) of all parents.
 - Study group: 15 (29.4%)
 - Control group: 18 (37.5%) ($p = 0.394$).
- Total median DCS score was significantly negatively correlated to total median SDM-Q-9 score (Spearman's ρ , -0.710; $p < 0.001$) but not to median SDM-Q-Doc scores (Spearman's ρ , -0.162; $p = 0.112$), and total median SDM-Q-9 and SDM-Q-Doc scores (Spearman's ρ , 0.161; $p = 0.115$).

Study Group versus Control Group (Table 2)

- No significant differences in baseline characteristics between control/study group.
- No difference in total median DCS, SDM-Q-9, or median SDM-Q-Doc scores between control and study groups.

Decision Aid Feedback

Parents

- Majority (91.2%) did not suggest any specific changes to the decision aid.
- Nine parents provided suggestions:
 - Not having adequate time to read over and consider the content of the decision aid (4 parents).
 - The surgeon did not really use the decision aid during the visit (1 parent).
 - Would have appreciated more time during the consultation to go over the information in the decision aid before deciding on whether to proceed with surgery or would have made a discussion of risks and benefits easier (2 parents).
 - Three parents reported that their decision was already made (to proceed with surgery) before the surgical consultation.
 - One parent felt the decision aid seemed to prefer the surgical option.
 - One parent reported that the surgeon's opinion and test results mostly influenced the decision rather than the decision aid itself.

Surgeons

- Three of seven surgeons participated in the decision aid feedback interviews.
- Positives:
 - Decision aid easy to read, visually appealing, presented information clearly.
 - Consultation time not lengthened and the tool did not make communication more difficult during the visit.
 - Facilitated the review of risks and benefits and the visual component was helpful for the parent.
- Concerns:
 - Patients/parents not having enough time to read and contemplate the information contained in the decision aid during the consultation.
 - Surgical risks section may not be applicable to certain situations (e.g., intracapsular tonsillectomy may have different rates of bleeding and pain; different sites may have different complication rates).
 - Surgeons wanted to know how beneficial the decision aid was from the patients'/parents' perspective.

Table 1. Participants baseline information.

	Participants	
	Parent	Child
Age Mean year	Mother: 33.7 (range 22-49, SD 6.4) Father: 35.2 years (range 24-48, SD 5.7)	3.9 (range 1-7, SD 1.6)
Sex N(%)	Mother: 83 (83.8%) Father: 14 (14.1%) Foster parent: 2 (2.0%)	Girls: 48 (48.5%) Boys: 51 (51.5%)
Marital Status N(%)	Married or common-law: 81 (81.8%) Not married: 18 (18.2%)	
Parent Education N(%)	High school or less: 36 (36.4%) College/undergraduate: 48 (48.5%) Graduate degree or higher: 15 (15.2%)	
Family Income N(%)	Less than \$20,000 per year: 12 (12.1%) \$21,000 to \$50,000 per year: 18 (18.2%) \$51,000 to \$100,000 per year: 32 (32.3%) More than \$100,000 per year: 30 (30.3%) Prefer not to answer: 7 (7.1%)	
Previous Surgery* N(%)	Yes: 23 (23.2%) No: 76 (76.8%)	

SD-standard deviation; *previous surgery for any child in the family

Table 2. Outcome measure results by randomization.

	Control Group (N=48)	Study Group (N=51)	Mann-Whitney U (Z Score)
Total DCS (IQR, SE)	6.25 (0-26.6, 2.03)	12.50 (0-25, 1.75)	1184.00, $p = 0.775$ (-0.286)
SDM-Q-9 (IQR, SE)	90.74 (74.1-100, 1.92)	88.89 (83.3-100, 1.84)	1173.00, $p = 0.845$ (-0.195)
SDM-Q-Doc (IQR, SE)	83.33 (77.8-96.3, 1.61)	83.33 (77.8-92.6, 1.26)	1072.50, $p = 0.369$ (-0.898)
OPTION* (Range, SD)	11.95 (9-15, 5.21)	13.83 (9-18, 5.24)	729.00, $p = 0.111$ (-1.594)

IQR-interquartile range; SE-standard error; *control group N=38 and study group N=48

Conclusions

One-third of the parents in our study had clinically significant decisional conflict. No significant differences in the decisional conflict or shared decision-making with the use of a paper-based DA for pediatric OSA. However, a pilot or feasibility study should not be used to determine effectiveness of intervention as the primary goal of a pilot study is to get parameters for a randomized trial. Video analysis showed that the decision aid was not often used extensively during the clinical encounter. Therefore, the need for improvement in SDM techniques was suggested from the results in both groups. Future studies training otolaryngologists on effective SDM techniques and how to appropriately utilize decision aids may improve SDM for pediatric OSA.

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