International Journal of Pediatric Otorhinolaryngology 78 (2014) 2258–2261

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

Pediatric otoplasty and informed consent: Do information handouts improve parental risk recall?

Emily Papsin [a], Rebecca Haworth [b], Jill M. Chorney [b], Michael Bezuhly [c], Paul Hong [c,d,*]

[a] Department of Neuroscience, Dalhousie University, Halifax, Nova Scotia, Canada
[b] Department of Anesthesia, Pain Management and Perioperative Medicine, Dalhousie University, Halifax, Nova Scotia, Canada
[c] IWK Health Centre, Dalhousie Pediatric Craniofacial Group, Department of Surgery, Dalhousie University, Halifax, Nova Scotia, Canada
[d] School of Human Communication Disorders, Dalhousie University, Halifax, Nova Scotia, Canada

ARTICLE INFO

Article history:
Received 6 October 2014
Received in revised form 14 October 2014
Accepted 16 October 2014
Available online 25 October 2014

Keywords:
Informed consent
Information handouts
Otoplasty
Complications
Risks

ABSTRACT

Background: The elective nature of pediatric otoplasty requires that parents are well educated regarding the risks involved. Simple educational tools have been found to enhance risk recall in some surgical procedures.
Objective: To assess the effectiveness of information handouts in improving parental risk recall.
Methods: Fifty caregivers were randomly assigned to receive traditional oral dialog of the surgical risks, or to receive oral discussion and a written handout outlining the risks of otoplasty. Twelve to 14 days after the consultation, parents were contacted for assessment of risk recall.
Results: Overall risk recall was 48% (3.4 of 7 risks recalled). Bleeding (82%) was the most commonly recalled risk, while cartilage necrosis/deformation (14%) was the least recalled risk. Mean risk recall was higher in the group that received written information (3.9 of 7 risks) compared to the group that received only oral discussion (2.8 of 7 risks) ($p = 0.003$). No child or parental variables were significantly related to higher risk recall on multivariable analysis.
Conclusion: Caregiver risk recall in pediatric otoplasty was improved with the addition of written information provided during the informed consent process. As the consent process serves a vital role in pediatric otolaryngology, the use of supplementary educational materials should be further studied.

1. Introduction

The fundamental basis of any good doctor–patient relationship depends upon the level of trust a patient is willing to place in the doctor. In pediatric medicine, this situation is complicated since parents or caregivers are acting on behalf of their child and often make proxy decisions [1]. Matters are made more complex when elective surgical procedures are being considered, which may not be paramount to a child's survival. Otoplasty is a procedure that is commonly performed in pediatric otolaryngology. Although otoplasty procedures are elective and usually well tolerated, they still place children at risk [2].

Since many patients who undergo otoplasty are early school-aged and therefore are unable to give their own consent, parents are usually in a position where they make or help their children make a decision that could impact them significantly. Moreover, there are instances where the primary indication for surgery is anticipated parental concern, and the child themselves has no real issue with the appearance of their ears [3]. Therefore, the decision to proceed with otoplasty and its informed consent process is crucial.

It has been noted that simply informing patients and their families of the risks involved in a surgical procedure does not necessarily constitute adequate informed consent [4]. Moreover, even after undergoing a detailed informed consent process, patients and proxy decision-makers have demonstrated poor recall of the risks discussed during the surgical consultation visit [5,6].

Sophisticated educational interventions, such as decision aids, have helped patients better understand the informed consent process [7]. They can result in improved health outcomes and quality of care, along with higher satisfaction [7,8]. Even straightforward educational tools, such as information handouts or pamphlets outlining the potential complications of a medical

* Corresponding author at: IWK Health Centre, 5850/5980 University Avenue, PO Box 9700, Halifax, Nova Scotia B3K 6R8, Canada. Tel.: +1 902 470 0841; fax: +1 902 470 8929.
E-mail address: Paul.Hong@iwk.nshealth.ca (P. Hong).

http://dx.doi.org/10.1016/j.ijporl.2014.10.028
0165-5876/

or surgical procedure, have been found to increase patients' comprehension and risk recall [5,9].

The objective of this study was to determine the effectiveness of a simple educational intervention, in the form of an information handout, in enhancing caregiver understanding and retention of surgical risks. Specifically, the level of risk recall after pediatric otoplasty consultation was compared between parents who received traditional oral dialog of the surgical risks and those receiving an oral discussion and a written handout outlining the risks.

2. Methods

Local Institutional Review Board approval was obtained for this study.

A priori sample size calculation found 50 participants to be sufficient and therefore children and their caregivers were consecutively enrolled until the sample size was reached. The parents were all able to fluently communicate in English and no other surgical procedures were discussed at the consultation visit.

A standard surgical consultation, which included a detailed discussion of the potential risks of otoplasty, was carried out by the senior author. Seven specific potential complications were discussed with each participant in a standard fashion following a premade script to ensure consistency. The complications discussed included: pain and numbness, unexpected or poor cosmetic result, excessive scarring, asymmetry, bleeding, infection, and ear cartilage necrosis/deformation. Equal emphasis was placed on each complication and all parents were given an opportunity to ask questions at the end of the visit.

After the surgical consultation, the senior author informed the parents that there was a research study in progress involving the caregivers of children considering otoplasty. Parents were asked whether or not it would be okay for a research assistant to call them at home to further discuss their involvement in the study. If agreeable, the caregiver was randomly assigned to either the control or the study group. Randomization was carried out using an online Research Randomizer program [10]. The study group received a handout with a list of the possible complications alongside a brief description of each complication (Table 1). The handout was given before the child and parent(s) left the clinic. The control group did not receive the written handout; all subjects were otherwise treated equally. No other information regarding the study was provided at this time.

All participants received a phone call from a research assistant 12–14 days after the initial consultation. The research assistant described the study and asked the parents if they were willing to further participate. Upon receiving verbal consent, the research assistant asked the caregiver to repeat all of the risks discussed at the consultation visit that they could recall. The number of risks recalled, as well as the specific risks recalled, were documented. A description of a risk was counted as a risk recalled (i.e., the parent did not have to specifically name the risk). There was no prompting and the research assistant was blinded to the randomization assignments. The researcher also asked some demographic questions regarding parent and child age, parental employment status, previous medical/surgical experience for their child, occupation and income. All of the answers were recorded on a standard set form.

Statistical analysis was performed with SPSS Statistics Version 17 (IBM Corp., Armonk, NY). Mean risk recall were compared between groups using two-tailed *t*-test. Specific risks recalled were compared between groups using chi-squared tests. Independent sample *t*-tests and chi-squared tests were used to determine if the control and study groups differed at baseline.

Table 1
Otoplasty handout given to the study group caregivers.

Otoplasty handout

Otoplasty is a surgical procedure that corrects ears that stick out too much. The risks of this procedure includes:

- Pain and numbness: there will be some temporary discomfort and numbness. Medications will be prescribed to help with pain
- Unexpected or poor result: the ears may not look like how you expected them to look. Very rarely, the ears may stick out again even after the operation
- Scarring: scarring can occur where the skin was cut. This is usually minimal and not noticeable
- Asymmetry: sometimes the ears may not look same on both sides. Rarely, one ear can appear to stick out more
- Bleeding: bleeding can occur but is rare
- Infection: infection can occur inside the ear and on the skin
- Ear cartilage loss: very rarely, ear cartilage (firm structure under the skin forming the ear shape) can change due to a severe infection. Most patients will report severe pain when this happens

3. Results

3.1. Patient characteristics

Fifty-four consecutive children and their parents or legal guardians undergoing otoplasty consultations were asked to participate in the current study. Two parents refused to participate and two others were lost to follow-up. Hence, 50 children and their caregivers were prospectively enrolled and completed the study. When two parents were present at the surgical consultation visit, only one of them who was available to take the phone call was asked to participate. This was mostly the caregiver who answered the phone call initially. There were 25 subjects in both the study and control groups. The average length of follow-up was 13.5 days for the study group and 12.9 days for the control group.

A summary of the relevant demographic data obtained from the subject pool is shown in Table 2. With respect to the demographic variables, there were no significant differences between the study and control groups.

3.2. Study group and control group outcomes

Overall risk recall for both the control and study group participants was 48% (168 of 350 risks recalled). The mean level of actual risk recall was 3.4 risks (SD 1.2) of 7 potential complications. Overall, bleeding (82%), infection (68%), and pain (66%) were the most frequently recalled potential complications. The least frequently recalled risk was ear cartilage loss/necrosis (14%). No caregiver was able to recall all 7 risks; all caregivers recalled at least 1 risk (range 1–5).

Table 2
Participant demographic data.

Demographics	Study group	Control group	*p* value
Parent age (years)			0.205
Mean	35.2	33.4	
Range	26–43	28–41	
Child age (years)			0.106
Mean	7.1	6.3	
Range	26–43	28–41	
Parent gender			0.508
Male	7 (28)	5 (20)	
Female	18 (72)	20 (80)	

p values: independent samples *t*-test used for parent and child age; chi-squared test used for parent gender.
Gender data is presented in absolute numbers and percentages in parentheses. Note that not all participants answered the gender question.