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Original Article

An Educational Video Improves Consent in Pediatric Lumbar Puncture: A Randomized Control Trial

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ABSTRACT

Background: Lumbar puncture is a low-risk procedure performed on pediatric patients for a variety of indications. Parents give consent to this procedure but are often left with concerns. There are no published studies on the nature of the concerns of parents in North America and no studies examining a process to improve pediatric lumbar puncture consent. Here we identify parent concerns with lumbar puncture and determine the utility of an adjunctive educational video.
Methods: Seventy-two patient-parent dyads were enrolled in a randomized control trial to receive standard consent with or without an educational video. A survey was provided to determine parent self-rated understanding of the procedure, their perception of its safety, their perception of the painfulness, and their overall comfort with their child undergoing lumbar puncture. In addition, demographic characteristics and qualitative information about parent concerns were collected.
Trial registration: NCT03677219.
Results: The video resulted in significantly greater parent understanding of the procedure ($P = 0.015$) and perception of its safety ($P = 0.021$) compared with controls. Parent comfort with the procedure increased after viewing the video ($P = 0.002$). Parents' top three concerns were pain, infection, and neurological injury.
Conclusions: Parent concerns in pediatric lumbar puncture include pain, infection, and neurological injury, and viewing an educational video improved parent perception of understanding and safety compared with controls. In addition, there was reduced variability of responses in those who viewed the video. Thus a short educational video on a handheld device is an effective means to address parent concerns and standardize the process of pediatric lumbar puncture consent.

Introduction

Lumbar puncture is a safe procedure commonly performed in children. However, it can cause a high level of anxiety for patients and their parents. In neurology patients, lumbar puncture is frequently used to investigate pathology such as seizures, demyelination, and developmental delay. In these nonemergency contexts, parents may be worried that the risks of the procedure do not justify the diagnostic benefit. The most prominent concerns for parents are infection or neurological injury,[1,2] although these risks are extremely low, and the most frequent side effect is headache.[3,4] These worries reflect an opportunity to improve the consent process to adequately educate parents about the nature of the procedure and the risks involved. The success of informed consent is critical to the physician-patient relationship and is dependent on the nature of the treatment or procedure, the communication skills

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of the physician, and the education and context of the parent.[5,6] The variability of these factors can contribute to inadequacy of informed consent[7] and imperfect comprehension of information by patients and parents.[8]

Systematic reviews in the surgical realm suggest that multimedia or video presentations are effective at increasing patient comprehension and satisfaction during the surgical consent process.[9,10] In addition, videos have been used in the process of obtaining consent from patients for clinical trials and have been proved to be effective for nearly 40 years.[11,12] Given published reports of parental anxiety and misunderstanding of lumbar puncture, it might be that readily available technology (such as tablet computers) could improve lumbar puncture consent. There have not yet been any published studies on the effect of a video to improve the informed consent process in pediatric lumbar puncture. A study of adult lumbar puncture consent used an animated video to replace consent discussions and resulted in improved patient scores before and after viewing, although the authors did not show a difference between patients undergoing video consent and traditional consent.[13] The current study builds on this by using both animations and live footage to augment the consent discussion, rather than replace it. In this study we endeavor to understand for the first time the concerns of a diverse North American parent group and test whether the lumbar puncture consent process is improved with an educational video, using handheld technology.

Methods

This study is a prospective randomized control study examining a method to improve informed consent in lumbar puncture. The study was conducted at British Columbia Children's Hospital in the Pediatric Neurology Division from January 2015 to May 2017. This division performs approximately 250 to 300 lumbar punctures per year.

Survey design

Surveys were designed to be short, clear, and easy to read (approximately fifth grade reading level) (Supplemental Figure 1). A Likert scale (1 to 10) was used to gauge parent impressions on four key questions: their *understanding* of the procedure, their perception of its *safety*, their perception of the *painfulness*, and their overall *comfort* with their child undergoing lumbar puncture. In addition, the following information was collected: year and month of patient birth, reason for lumbar puncture, whether they consented to lumbar puncture, language spoken at home, any acquaintances with a history of either lumbar puncture or epidural anesthetic, areas to fill in their concerns and list possible improvements to the consent processes, as well as the initials of the physician performing the consent discussion. The four key questions and pertinent demographic information questions were developed by surveying pediatric neurology physicians and surveys were validated by four expert clinicians (two pediatric neurologists, two pediatric metabolic specialists) using the Content Validity Index, rating each element of the questionnaire from one (not relevant) to four (highly relevant), with an average item-Content Validity Index of 90%. Of the 10 survey questions, seven had an excellent Content Validity Index kappa (>0.74), two were good (0.6 to 0.74), and one was bad (<0.4), resulting in the removal of that question. The duration of the consent discussion from onset of the explanation to the parent signing consent for lumbar puncture, rounded to the nearest five minutes, was estimated by the consenting physician.

Sample size

Using a minimum clinically important difference of two points on the Likert scale, an alpha of 0.05 (two-tailed), and a power of 0.80, the sample size was 72 pediatric neurology lumbar puncture cases (36 patients in each arm of the study).

Subjects

British Columbia Children's Hospital serves the entire province, and also serves the Yukon, with a total population of children aged zero to 14 years of 697,900.[14] The pediatric neurology service cares for a culturally and ethnically diverse patient population representative of a large North American city. Parents were approached in the following locations: outpatient clinic, inpatient neurology ward, outpatient medical day unit, and outpatient day surgery. Patients underwent lumbar puncture with conscious sedation, or with general anesthetic, depending on the circumstances. Recruitment was in a nonconsecutive manner by participating residents and staff physicians. Inclusion criteria were patient aged less than 17 years, parent present for consent, patient under the care of the neurology team, and consenting physician able to communicate with parent directly or through a translator. Exclusion criteria included patients with emergency indications for lumbar puncture, parents unable to communicate in English if no translator was available, and consent not performed in person (over the phone). The survey was translated from English by a translator when necessary.

Study enrollment

After a formal consent conversation and signature of consent, parents were asked by the physician if they would participate in the study by filling out a questionnaire about their concerns. If they agreed they consented to the study and were given privacy to answer the survey.

While outside the room, the physician opened an opaque sealed envelope to determine if the parents were randomized to view the two-minute educational video. If they were, the video was offered on an iPad mini, and if the parents viewed it a second follow-up survey was administered. If the parents chose not to view the video, their reason was recorded.

Blinding

Both the physician and parents were unaware of their group throughout the consent discussion, consent itself, and initial survey. Parents were unaware there was a possibility of viewing a video. There was allocation concealment. The analysis of results was not blinded.

Randomization

A random number generator was used to construct a set of sequentially numbered envelopes resulting in 36 controls and 36 video subjects. The envelopes containing allocation were opaque, sealed, and equal weight, and these envelopes were contained in a larger sealed envelope. The random sequence was generated by the lead author.

Ethics

The study, including the blinded nature of the video, was approved by the British Columbia Children's Hospital ethics review board.

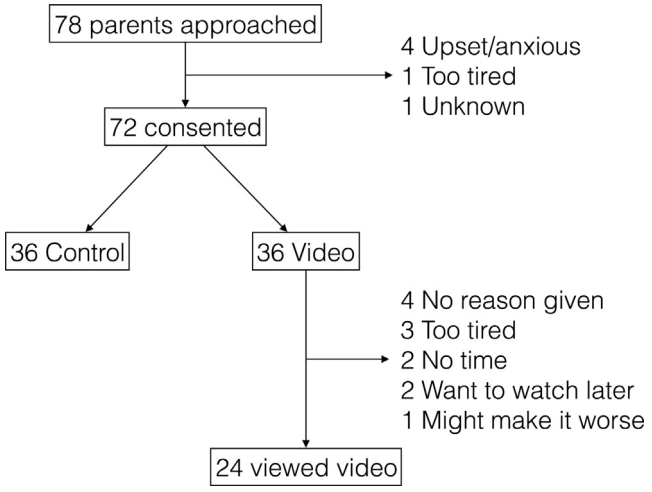

FIGURE 1. Study participants (all parents consented to lumbar puncture).

Video

The video was generated using a video of an infant lumbar puncture combined with animations of the anatomy involved (Supplemental Figure 2). The video was designed to show parents the positioning, landmarking, needle size, and other specific details of the procedure. At the moment of needle insertion, the video cut to an animation demonstrating the layers penetrated and the parting of the cauda equina. The duration of the video was 2 minutes 11 seconds. It was developed and narrated by M.D.

Outcome

The outcome of interest was change in parent rating of their understanding, perception of safety, pain, and comfort with their child undergoing the procedure, compared with the control arm.

Analysis

Initial (postconsent) survey

The response to the initial survey for both the control and video groups was compared on the four core survey questions measured by Likert scale 1 to 10 by Wilcoxon rank sum test and Fisher exact test using STATA 15 software to ensure the randomization effectively produced two statistically similar groups. Relationships between variables were determined by calculating the Spearman coefficient of correlation.

Second survey (primary outcome)

Comparison between the controls and those randomized to watch the video (post–video survey) was performed on the four core survey questions measured by Likert scale 1 to 10. Results were expressed as medians and interquartile range (seventy-fifth percentile minus twenty-fifth percentile). Comparisons were by Wilcoxon rank sum test. Analysis was by intention to treat. In addition, Wilcoxon matched-pairs sign test was conducted to determine whether within subjects there was a significant difference in the Likert scale scores after watching the video.

The two qualitative questions at the end of each survey were grouped by answer type.

Results

Seventy-eight parents were approached for participation in the study, and seventy-two consented (Fig 1). Twenty-three physicians participated. All parents consented to lumbar puncture. The demographics of the groups are summarized in Table 1. The most common indication for lumbar puncture was as part of seizure evaluation, followed by inflammatory diseases. A female guardian provided consent in 65% of cases, a male guardian in 16%, and the gender of the guardian was not available in 18%. There were no significant differences in responses comparing female or male guardians.

Of the 36 parents randomized to view the video, 24 (67%) chose to watch (Fig 1). Reasons provided for declining the video included "too tired" (25%), typically during an overnight admission; "no time" for two parents (17%); two parents (17%) wished to wait until their spouse was present; one parent (8%) was concerned viewing the video would worsen their anxiety; and four parents (33%) gave no reason. There was no significant difference in any of the demographic characteristics or initial survey responses comparing those who chose to watch the video and those who did not.

Comparison of the 24 parents who viewed the video with the 36 in the control group is summarized in Table 2 and Fig 2. Parent self-rated understanding and perception of safety was significantly higher in parents who viewed the video compared with controls. For each 1-point increase in parent understanding, their perception of safety increased 0.88 points, and for each 1-point increase in their perception of safety, their comfort increased by 1.2 and their perception of pain decreased by 1.1. Comparison of responses before and after viewing the video revealed significant

TABLE 1.
Baseline Characteristics of Control and Video Group

	Control Group	Video Group
Demographic information		
Age of child (mean years, 95% CI)	6.3 (4.3-8.3)	5.3 (3.2-7.3)
Time to consent (mean minutes, 95% CI)	13.8 (−8.3 to 76.4)	16.8 (11.5-22.1)
Respondent guardian female (%)	24/28 (86)	23/31 (74)
English spoken at home (%)	30/36 (83)	29/36 (81)
Someone they know with lumbar puncture (%)	7/31 (23)	9/32 (28)
Someone they know with an epidural (%)	9/22 (35)	15/23 (65)
Indication for lumbar puncture (%)		
Seizures	12 (33)	8 (22)
Inflammation	9 (25)	5 (14)
Abnormal development	2 (6)	5 (14)
Movement disorder	4 (11)	6 (17)
Headache	3 (8)	4 (11)
Abnormal neurologic examination	4 (11)	3 (8)
Infection	0 (0)	1 (3)
Genetic	0 (0)	2 (6)
Miscellaneous	1 (3)	1 (3)
Postconsent (/10) (medians, IQR)		
Understanding	9 (2)	9 (2)
Safety	8 (3)	8 (1)
Pain	5 (6)	5 (4)
Comfort	7 (2.5)	6.5 (4)

Abbreviations:
CI = Confidence interval
IQR = Interquartile range

TABLE 2.
Effect of Video, Controls versus Post-Video

Medians, IQR	Control, Median (IQR)	Video, Median (IQR)	*P* Value
Understanding	9 (2)	10 (1)	0.029
Safety	8 (3)	9 (1)	0.023
Pain	5 (6)	4 (5)	0.16
Comfort	7 (2.5)	8 (3)	0.19

Abbreviation:
IQR = Intrerquartile range

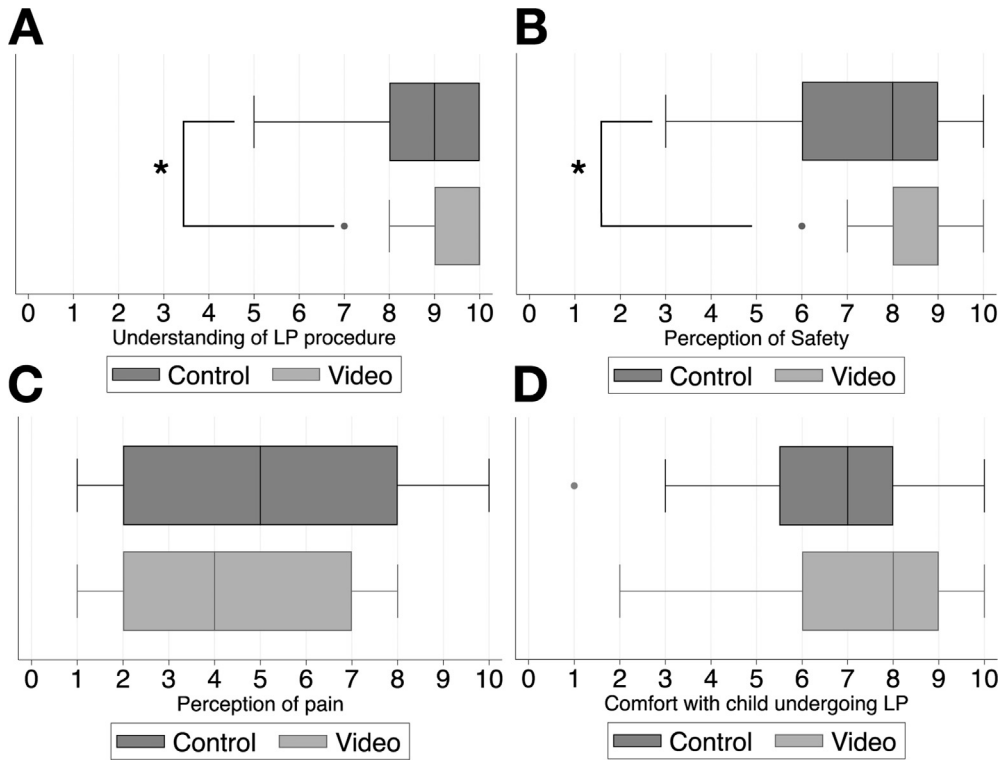

FIGURE 2. Box-whisker plots of parent Likert rating comparing the control group to the video group postvideo. (A): Self-rated understanding of lumbar puncture procedure. (B) Perceived safety of lumbar puncture procedure. (C) Perceived pain of lumbar puncture procedure. (D) Overall comfort with child undergoing lumbar puncture procedure. *P value < 0.05, Wilcoxon rank sum test. Dot shows outlying data point.

improvements in self-rated understanding, safety, and comfort (Table 3 and Fig 3).

There were significant correlations between the four response variables. After viewing the video, comfort with their child undergoing the procedure was significantly correlated with their perception of safety (0.76, $P < 0.001$) and understanding (0.44, $P = 0.04$), and inversely correlated with their perception of pain (-0.52, $P = 0.01$) (Fig 4).

There was significantly less variability in the responses of the video group for understanding compared with the control group (two-tailed F-test, $P = 0.03$).

Sixty-seven of seventy-two (93%) parents provided a response to the question, "what are your concerns about the procedure?" (Fig 5) demonstrating pain, infection, and permanent neurological injury as the most common concerns after the standard consent discussion. Twenty-two of the twenty-four parents (92%) who viewed the video stated it was helpful; two (8%) were unanswered.

Discussion

This study is the first to characterize parent perceptions of pediatric lumbar puncture immediately following the consent process in a diverse North American parent group. The top three concerns were pain, infection, and neurological injury. Viewing a two-minute educational video with live footage and animations following the consent discussion resulted in significantly higher self-rated parent understanding of the procedure and perception of safety compared with controls, and there was less variability of parent responses compared with controls.

Consent for lumbar puncture is obtained by individuals with variable experience, from senior medical students and junior residents to senior faculty. In a survey of medical residents obtaining consent for lumbar puncture, many acknowledged they are not comfortable with the key elements of informed consent.[15] A tool such as a two-minute video can ensure that parents receive the key information in a standardized fashion that is informative and uses clear, neutral terms.

There are some notable differences in parent attitudes toward lumbar puncture compared with previous studies from outside North America, which have focused on high refusal rates.[1,2] All parents involved in the present study consented to lumbar puncture, even those who rated their comfort with the procedure as one out of 10. Parents' comfort with lumbar puncture correlated most strongly with their perception of safety, and their greatest concern was pain. This is in contrast to previous studies where the most common reason for refusal was concern about paralysis.[1,2,16,17] The greater rate of consent and less common concern about paralysis in the present study may be due to a high level of trust in the health care system and its practitioners. Another important difference in our population is that the indication for lumbar puncture was most commonly as part of new-onset seizure investigations, followed by inflammatory diseases. This finding is in contrast to other studies, where the most common indication is meningitis or febrile seizure.[1,2] It is possible in emergency situations that perceptions about lumbar puncture may be affected by the acuity of their child's

TABLE 3.
Effect of Video, Paired Test

Medians, IQR	Video Group, PreVideo, Median (IQR)	Video Group, PostVideo, Median (IQR)	P Value
Understanding	9 (2)	10 (1)	0.01
Safety	8 (1)	9 (1)	0.003
Pain	5 (4)	4 (5)	0.72
Comfort	6.5 (4)	8 (3)	<0.001

Abbreviation:
IQR = Intrerquartile range

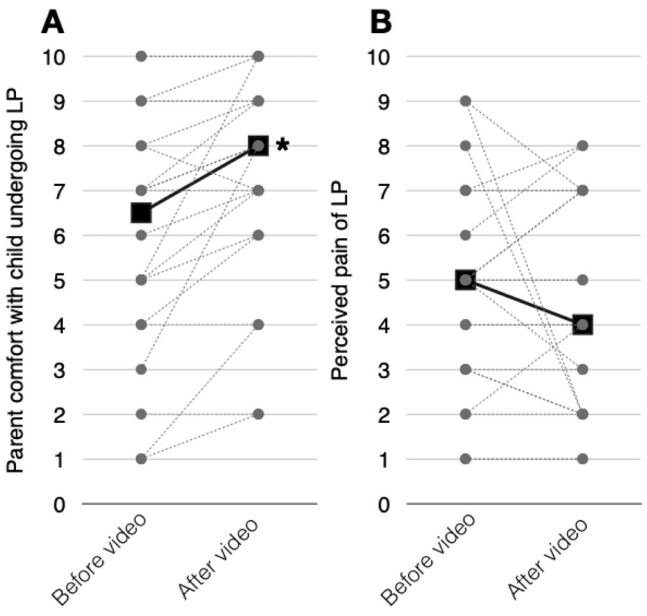

FIGURE 3. Paired comparisons before and after viewing educational video. (A) Comfort with child undergoing lumbar puncture procedure. (B) Perceived pain. Prevideo, after standard consent discussion by physician; gray circles, individual parent response; dotted line, connecting individual parent responses before and after viewing the video; black squares, median values before and after viewing the video; heavy line, connection of median parent responses before and after viewing the video. $^{*}P < 0.05$, Wilcoxon signed rank sum test.

illness and may be differently amenable to further education with a video. The gender of parents in our study was similar to the pediatric literature, which shows a female preponderance, and our sample of male guardians was too small to determine if there are differences in male guardian versus female guardian perceptions of lumbar puncture.[18]

The mixture of live and animated content in the educational video was designed to provide insight into the visual experience of lumbar puncture, as well as educate about the relevant anatomy. In contrast, a recent study of consent in lumbar puncture used a four-minute cartoon video to either augment or replace the consent processes for adults. The authors found improved scores on all six of the metrics they used comparing before and after the video,[13] although there was no difference in patients randomized to see the video versus those who underwent traditional consent. The significant difference between video and control groups in our study may be in part because of the combination of live action and animation; several parents emphasized in their feedback that actually seeing the procedure was helpful.

Limitations

In the formatting of the questionnaire, the Likert scales ranged from 1 to 10, and in three of the scales a score of "10" was associated with a positive feeling (high level of comfort, high level of safety, high level of understanding), but for the pain scale this was reversed, "10" was a high degree of pain, and "1" was the lowest. Although this seemed intuitive in the study design, we suspect a minority of parents may have failed to appreciate this reversal. This is supported by the high variability and interquartile range of the pain scores relative to the three other measures (Figs 2 and 3). Parent-rated understanding of the procedure may be different than their actual understanding as measured by a test of recall; however, in the setting of this study the procedure is frequently performed minutes to days after the consent discussion, too short a time to test parent recall. Finally, it is not clear how applicable our results would be to other parent populations, such as those whose children are undergoing an emergency lumbar puncture to rule out meningitis, although it may be inferred that they would receive similar benefit.

Conclusions and future directions

This study describes pain, neurological injury, and infection as the leading concerns of North American parents in lumbar puncture and demonstrates that an educational video including footage of a pediatric lumbar puncture and explanatory animations viewed on a handheld device can significantly improve parent-perceived understanding and safety of the procedure compared with consent discussion alone. The qualitative portion of the study revealed that the most frequent concern for parents was the pain of the procedure; however, parents may not voice concern about pain during the consent discussion, thus consent in lumbar puncture should include the strategies that will be used to address pain during the procedure as well as after. Furthermore, some parents wanted statistics about side effects, and a standardized handout would ensure the same correct information is disseminated, regardless of the experience of the person obtaining consent.

The group of parents who viewed the video rated the procedure as significantly safer than the parents who did not. Improved parent perception of lumbar puncture safety is correlated with

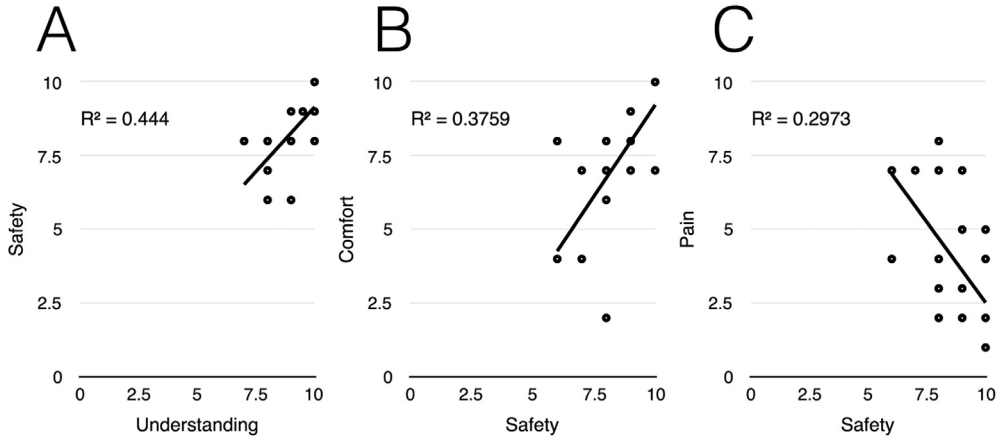

FIGURE 4. Postvideo relationships between understanding and safety and safety with comfort and pain perception, Likert scale 1 to 10. (A) Perceived safety versus perceived understanding. (B) Comfort with child undergoing procedure versus perceived safety of the procedure. (C) Perceived pain of the procedure versus perceived safety of the procedure.

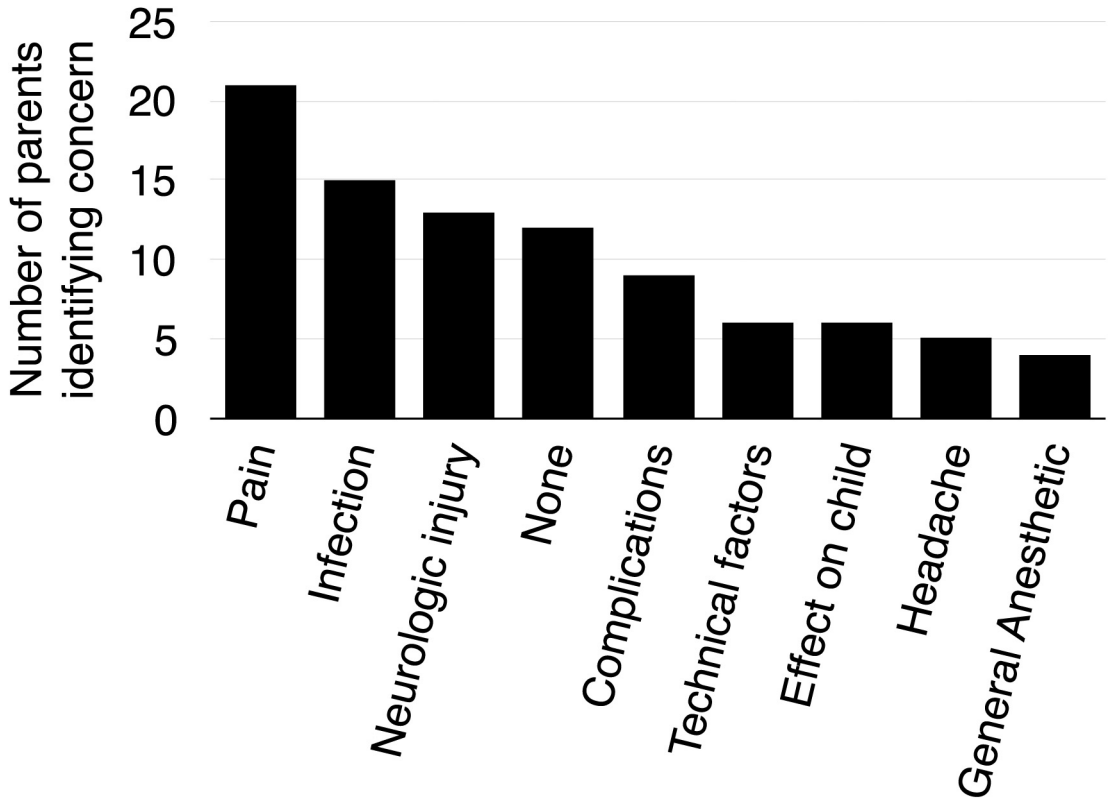

FIGURE 5. Parent concerns with lumbar puncture. Parents were provided with a blank space to write their concerns, which were often multiple, and results were categorized and tabulated.

decreased perception of pain and increased comfort with their child undergoing lumbar puncture. A short educational video on a handheld device helps to standardize parent perceptions and is an effective communication tool for physicians when obtaining consent from parents for pediatric lumbar puncture.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pediatrneurol.2019.04.014.

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