COMPARISON OF IMPACT OF ONLINE VIDEO AND CONVENTIONAL CONSENT ON PARENTAL ANXIETY, SATISFACTION AND COMPREHENSION OF INFORMED CONSENT IN PEDIATRIC SURGICAL PROCEDURES

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DECLARATION

I hereby declare that the thesis titled "**Comparison of impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures**" embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled "**Comparison of impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures**" is the bonafide work of Dr Tanmay Motiwala carried out under our guidance and supervision, in the Department of Pediatric Surgery, All India Institute of Medical Sciences, Jodhpur.

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Dedicated to all the kids whose suffering and endurance of pain inspires me to strive and make this world a better place for them

List of Abbreviations

RCT: Randomized Control Trial

CTRI: Clinical Trial Registry- India

STAI: State Trait Anxiety Inventory

IEC: Institutional Ethical Committee

IQR: Inter Quartile Range

SD: Standard Deviation

SNOSE: Sequentially Numbered Sealed Opaque Envelope

InSCED: Indian Standard Classification of Education

VT: Video Tool

Non VT: Non Video Tool

PUV: Posterior urethral valves

ARM: Anorectal malformation

HD: Hirschsprung's Disease

KBT: Knowledge based test

SUMMARY

Introduction

Informed consent is an integral part of the surgical process, as it helps parents and guardians fully understand the risks, benefits, and alternatives to a particular procedure. Various methods have been developed over time to improve parental understanding, decrease anxiety and increase parental satisfaction. However, there is scanty literature available regarding the use of multimedia tools in pediatric patients in the process of taking informed consent. Over the last few years, with the internet boom and the availability of open platforms like Google™ and Youtube™, parents tend to look up to these sources for information. We, therefore, planned to investigate the role of ad-lib access to an online video on informed consent for pediatric surgical procedures in terms of parental knowledge, anxiety, and satisfaction, compared to the conventional process.

Objectives

The objective of this study was to compare the impact of online video and conventional consenting on parental anxiety, satisfaction, and comprehension of informed consent in pediatric surgical procedures.

Methods

The study commenced after the approval by institutional ethical committee and clinical trials registration. Patients meeting the inclusion criteria were included in this randomized controlled trial which included a video tool group and conventional consent group. Novel videos were created using Microsoft PowerPoint and were edited using iMovie software. The videos were developed separately for each disease under study. The videos were then uploaded on google drive, and the pertinent links were shared with the parents at the time of consenting. A total of 90 patients were randomized into video tool group and conventional consent group and consent was taken according to the assigned group. The respondents were asked to complete the State Trait Anxiety Inventory (STAI) questionnaire, a five-question knowledge based test, Likert based questionnaire to assess overall effectiveness in both the groups and Spencer satisfaction questionnaire survey. Scores of the video tool group and conventional consent group were statistically compared.

Results

During the study period, 90 patients were randomized into video tool group (45) and conventional consent group (45). There was a statistically significant difference between the means of percentage fall in STAI scores between the VT (47.44 ± 9.10) and Non VT (27.43 ± 12.35) groups (p= 0.04). The video tool group showed improved comprehension as compared to conventional consent group for all the five questions of knowledge based test ($p<0.05$). There was no difference between the satisfaction scores of both the groups. (p=0.82).

Majority of respondents in the video tool group agreed that they felt better informed after watching the video than after verbal consultation, would recommend the video to other parents, support the concept of medical information videos and had watched the video more than once. All respondents in the conventional consent group wished to have online videos with the same information.

Conclusion

Providing online informative videos to the parents at the time of consent can help decrease parental anxiety, improve comprehension and is associated with good overall satisfaction of the parents. These standard videos with ad-lib access can become a new norm in the future for informed consent.

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INTRODUCTION

Introduction

Informed consent is an essential component of medical ethics. It is an integral part of the surgical process, as it helps parents and guardians fully understand the risks, benefits, and alternatives to a particular procedure. It is based on the principle of autonomy, meaning that patients or their legal guardians have the right to decide about their healthcare. The term “informed consent” was first coined in 1957 (1). The term “informed” implies that the person giving consent understands the need for surgery, alternatives, risks and benefits, expected outcome, possible complications, and technical aspects of the procedure itself (2).

In pediatric population, it is the parents or the legal guardian who provides informed consent for any surgical procedure. As it is the role of parents to safeguard their child's interests and safety, they must understand the risks, benefits and possible outcomes of the procedure their child is undergoing. But the parents of a child undergoing surgery usually become apprehensive and anxious when informed about the need for surgery. This is further aggravated by their lack of knowledge and comprehension about the disease in concern, surgical procedure, and informed consent process (3–5). The fact that their child needs surgery may lead to an emotional predicament which further impedes the reception of information by the parents during the consent process (6).

Informed consent is not just a formality but an ongoing process that begins before the procedure and continues throughout the patient's care. Legal obligation of the consent ends once the consent is obtained. However, the parental perception of the information is frequently ignored. It is essential for parents and guardians to ask questions and fully understand the implications of the proposed procedure before giving their consent. A few studies suggest that less than one-third of persons signing an informed consent actually demonstrate at least adequate understanding of the procedure, including its risks and benefits (7,8).

The consent is obtained by either the surgeon or the assistant involved in the case. Due to heavy workload, there may be limited interaction between the parents and the doctor, which leads to flooding of information for the parents in a short span of time. There are times when the consent is taken by a junior in the surgical team who may

not have much experience in taking consent and about the surgical procedure as well. This can lead to poor transfer of information from the doctor to the patient, which can have significant implications on parents' expectations about the surgery and post-operative outcomes. It is essential to understand that most claims of malpractices are due to communication failures instead of failures in the treatment (1). Despite the importance of consent-taking process to the provision of safety, high-quality, patient-centred health care in clinical practice, it is often inadequate (9,10).

Another problem with the method of conventional consenting is the loss of information by the parents. A study showed that 40 to 80% of the information given by doctors is immediately forgotten. The higher the amount of information, the lower the proportion of data remembered (11). The anxiety of parents, presence of single parents at the time of consenting and their apprehension can further add to the gaps in the process of understanding of parents about the surgical procedure. An unanswered question, data forgotten after the consultation or informing about indication of surgery, generates anxiety in parents and can possibly impact their children (4). Therefore, it is logical to think that improving the quality of preoperative information at the time of consulting can help to decrease the anxiety of parents and children (12,13).

In the modern era, with access to tonnes of information that is freely available online. The parents often search on the web, read about it, and expect detailed information from the doctor. They also have many queries for which they would like to seek answers from the doctor. In addition, the parents often want to discuss the whole process with their family and friends to seek help in the decision-making process. Due to the paucity of information that the parents actually retain, this process also gets impeded.

While explaining the various aspects of surgery, parents may feel anxious, desire to seek more answers to their doubts and may even show a lack of comprehension. Previous studies have shown the sources of anxiety during the consent process and ways to alleviate it (3). This highlights the need for recognising the need for a patient-centred consent process and evaluation of perception of the given information to parents.

With the increase in literacy of parents and awareness on the part of doctors about the process of consenting, multiple adjuncts have been developed in association with consent process to improve understanding, decrease anxiety, and improve patient satisfaction. These adjuncts include written information such as informational leaflets or pamphlets, audio-visual or multimedia tools such as interactive computer programs, videos, individual teaching sessions, and test/feedback techniques (14–16). These tools employ a combination of audio and visual information. A few studies have shown these methods to improve patient comprehension and increase patient satisfaction.

Recently, Paton et al. showed that a multimedia teaching tool can decrease parental anxiety for infants undergoing pyloromyotomy (17). A few Randomized controlled trials (RCTs) in adults suggest better comprehension among patients where video tool-assisted informed consent was taken before surgery (18–20).

However, there is scanty literature available regarding the use of multimedia tools in pediatric patients in the process of taking informed consent. Over the last few years, with the internet boom and the availability of open platforms like Google™ and Youtube™, parents tend to look up to these sources for information. By using online video tools, parents can review consent materials at their own pace, pause the video to ask questions and revisit the information as needed. It has also been seen in Indian scenario that the parents like to discuss various aspects of the surgery with their family or friends. But due to a lack of retention or comprehension of the information, they may not be able to discuss it with them. This gave us the idea to have a tool that is video based and can be freely accessed by the parents online with ad-lib access.

RATIONALE FOR THIS STUDY:

We identified a deficiency in the available scientific literature on the use of video tool to explain the surgical procedure to parents of children undergoing surgery and its impact on parental anxiety, satisfaction and comprehension during the process of giving consent. We, therefore, plan to investigate the role of ad-lib access to an online video on informed consent for pediatric surgical procedures in terms of parental knowledge, anxiety, and satisfaction, compared to the conventional process of on spot consenting.

REVIEW OF LITERATURE

Review of Literature

Informed Consent

The term informed consent was first coined in 1957 (1). Informed consent is "voluntary authorisation by a patient or research participant, with full comprehension of the risks involved for diagnostic or investigative procedures and medical and surgical treatment " (21). Various societies have come up with multiple guidelines over time, and the process of informed consent has been ever-evolving with the patient-centric approach. For consent to be informed, doctor must have discussed the diagnosis, treatment options, and an explanation of the procedure, including risks, benefits of the procedure and other alternatives (7,22). Failure to obtain adequate informed consent compromises patient safety and autonomy and legally may constitute negligence (23–26). Despite the clinical importance of informed consent medicolegally, informed consent process in clinical practice is inadequate (9,10).

In pediatric patients, it is the parents or the legal guardians who provide consent in surrogate for their children (2). As a medical or surgical fraternity communicating with the parents or the caregivers, it is essential to appreciate the complexity of how decisions are made by parents and surrogates. A recent literature review of 55 research articles on the treatment decision-making process noted that decisions are influenced by provider relationships, previous knowledge, and changes in a child's health status, emotions, and faith (27). Studies have shown that parental coping mechanisms and their perceptions of undue external influence by clinicians or family members on decision-making may result in hostile and uncertain feelings about treatment goals for their seriously ill children (5). These factors make the process of informed consent in pediatric patients way more critical as well as more complicated at the same time. Historically and legally, medical decision-making in children has centred on the best-interest standard, which directs the surrogate to maximise benefits and minimise harm to the minor and sets a threshold for intervention in cases of abuse and neglect (28). Shared, family-centred decision-making is an increasingly used process in the pediatric medical decision-making (29). This process depends on collaborative communication and exchange of information between the medical team and family. Therefore, the medical team needs to discuss the patient's disease process and the risks and benefits of treatment options in an easily understandable and

comprehensive format with the aid of various tools that may facilitate easy understanding by the parents.

Problems in the process of conventional informed consent

Previous studies have identified that patient comprehension of the critical elements of informed consent is poor (30,31). A study by Williams et al., which utilised the Functional Health Literacy in Adults instrument to assess 2,659 patients at two public hospitals, revealed that 60% could not comprehend a standard informed consent document (32). Hutson et al. showed that patients tend to recall the expected benefits of surgery more frequently than the potential risks (33). Santavirta et al. found that 37% could not name any relevant complication after undergoing informed consent for hip replacement. This number was not changed by intensive patient education before surgery (34). Many consent forms do not contain the key elements of informed consent or are written in a language too complex for many patients to understand (35–37). Physicians receive little training in how to conduct informed consent discussions. Various other factors that may affect the process of informed consent include misunderstandings about consent requirements and goals, differing legal standards for informed consent disclosure, and the time pressures and competing demands of the clinical medicine (38,39). A study revealed that less than one-third of persons signing an informed consent actually demonstrated at least adequate understanding of the procedure, including its risks and benefits (8). Merz et al., in a study of informed consent litigation, noted that there was no consistency in the verbal expressions used by physicians to categorise risk (40). Studies of the comprehension of health education hand-outs show that, typically, only half the recipients can comprehend health education materials (41). Studies of readability suggest that the existing forms for informed consent are often too complex and challenging for the average person to understand (41–43).

While explaining the various aspects of the surgery, parents may feel anxious, desire to seek more answers to their doubts and may even show a lack of comprehension. The young age of the patient, need for surgery (emergency or elective), and possible complications due to young age may further make parents more anxious. Previous studies have shown the sources of anxiety during the consent process and ways to alleviate it (3). To summarise, the literature search reveals that the fundamental

problem lies primarily along the domains of anxiety of parents and comprehension of the information provided to them, which may be due to various factors.

With so many flaws being highlighted by so many studies over time, various researchers have sought alternative methods to improve the informed consent process.

Alternative consent procedures in pediatric patients

The literature suggests that using online video and other multimedia tools can positively impact parental anxiety, satisfaction, and comprehension of informed consent in pediatric surgical procedures. However, the effectiveness of these tools may vary depending on the specific procedure and the population being studied.

JA Friedlander et al. (2010) evaluated the adequacy of pediatric informed consent and its augmentation by a supplemental computer-based module in pediatric endoscopy in 2010 in 148 children by an RCT. They observed that the ability to achieve informed consent, as measured by the new instrument developed by them, was 10% in the control form-based consent group and 33% in the electronic-assisted consent group ($P<0.0001$). However, this multimedia tool-based informed consent did not alter secondary outcome measures of subject satisfaction or anxiety (44).

CJ Chantry et al. (2010) studied if videotapes about neonatal circumcision would be superior to the traditional physician-based informed consent for maternal knowledge, satisfaction and perception of provider bias in 2010 in 304 mothers interested in or undecided about circumcision of their neonate and found that composite knowledge ($p = 0.78$) or satisfaction ($p = 0.16$) did not differ between the groups and concluded that there was no difference in maternal knowledge between "Video-plus' and traditional informed consent in their study setting (45).

Spencer SP et al. (2015) studied whether the use of multimedia tools in taking consent for ketamine sedation for fractures in the emergency department improved parental satisfaction and comprehension as compared to standard practice in 2015 by a Randomised Prospective Study and observed that Multimedia presentation improved parental understanding of Ketamine sedation. In contrast, parental satisfaction with the informed consent process remained unchanged(46).

Ji Let al (2015) studied the effect of draw MD APP in 108 children between 4 - 12 years of age scheduled for tonsillectomy and strabismus surgeries in 2015 (drawMD APP is a visible health product including Arm, Central Line Chest Tube, Intubation, Spinal Epidural, Surface Anatomy, Heart, Cardiomyopathy Values, and Abdominal Cavity and the app facilitated drawing for patient with sketching tools, text annotations and condition- or procedure-specific stamps with a hypothesis that visuals create a memorable experience by simplifying complex information right in front of the parents' eyes), they observed that drawMD APP-guided pre-operative education was effective in the reduction of parental pre-operative anxiety and improved parents' satisfaction, but had no influence on children (3).

EH Rosenfeld et al. (2018) studied the role of using standardised visual aids in improving the informed consent for appendectomy in children by an RCT involving 160 individuals (76 in the visual consent cohort and 84 in the normal consent cohort) in 2018. They observed that visual consent had the strongest influence on parent/guardian comprehension ($p < 0.01$) and thus aids in improving understanding and retention of information given during the informed consent process of children with appendicitis (47).

Paton EA et al. (2018) studied the impact of multimedia teaching tools on parental anxiety and knowledge during the informed consent process in 2018, a time-interrupted series design in 31 children, with 17 in the conventional consent group and 14 in the multimedia tool-based consent group. They observed that there was a significant decrease in anxiety noted with the use of the multimedia teaching tools ($p = 0.046$) but no significant difference in knowledge ($P = 0.84$) (17).

Book F et al. did a randomized controlled trial on the effect of access to an online video on caregivers' consent process, knowledge, and anxiety with children scheduled for inguinal hernia repair in 50 patients. They found that preoperatively providing access to an online consent video regarding inguinal hernia repair reduces anxiety ($P =0.026$) and enhances knowledge ($P = 0.016$) without altering satisfaction level. Adjunct online videos are helpful to improve the consent process (2).

The literature search revealed scanty articles on the effect of various multimedia tools on the process of informed consent in pediatric patients. The above results also show

inconsistency among multiple studies. Therefore, we planned to investigate the role of ad-lib access to an online video on informed consent for pediatric surgical procedures in terms of parental knowledge, anxiety, and satisfaction and compare it with the process of conventional consenting.

AIMS AND OBJECTIVES

Aims and Objectives:

Aim:

To compare the impact of online video and conventional consenting on parental anxiety, satisfaction, and comprehension of informed consent in pediatric surgical procedures.

Objectives:

1. To evaluate the parental comprehension, anxiety and satisfaction regarding the informed consent obtained by conventional method.
2. To evaluate the parental comprehension, anxiety and satisfaction regarding the informed consent obtained using online video.
3. To compare the parental comprehension, anxiety and satisfaction regarding the informed consent obtained by a conventional method with that obtained by online video.

MATERIALS AND METHODS

Materials and Methods

Study Design

The study was a hospital-based Randomized Control Trial.

Registered in Clinical Trial Registry- India (CTRI) with registration number- CTRI/2021/07/034680

Study Setting

The study was carried out in the Department of Pediatric Surgery, AIIMS Jodhpur.

Study Duration: 21 months

Sample Size:

Book F et al. found lower anxiety scores in the video intervention group (50 +/- 10) compared to the control group (58 +/- 11). Considering this for calculation, a sample size of 45 was calculated as required per group at a 95% Confidence interval, 90% power and 20% contingency (2). A total of 90 patients were enrolled during the designated study period.

Inclusion criteria:

All patients less than 18 years admitted to the Pediatric Surgery department of AIIMS Jodhpur for undergoing surgeries under the following groups-

Neonatal surgery:

1. Anorectal malformations.

2. Hirschsprung disease.

3. Meningomyelocele.

4. Congenital diaphragmatic hernia.

5. Tracheoesophageal fistula

6. Bowel atresia

Genitourinary surgeries:

1. Posterior urethral valves.

2. Inguinal hernia.

3. Undescended testis.

4. Hydrocoele.

Exclusion criteria-

1. Patients less than 18 years undergoing surgeries for conditions other than the above mentioned conditions.
2. Parents/Legal guardians not consenting for the study.
3. Do not have access to the internet with online video viewing capabilities.

4. Unable to understand Hindi or English (as judged by the participants themselves).

Index Case- Any patient undergoing surgeries for conditions mentioned above in the inclusion criteria in the Department of Pediatric Surgery, AIIMS Jodhpur.

Baseline Data Recording-

- Patient demographics
- Proposed surgery
- Followed by the administration of pre-consent State Trait Anxiety Inventory (STAI), taking the consent and post-consent STAI, Knowledge and Likert questionnaire.

Study Population-

The patients and controls were recruited as per inclusion and exclusion criteria from In-patient Department of Pediatric Surgery, All India Institute of Medical Sciences, Jodhpur. Informed consent was obtained from all subjects. The study protocol fulfilled the ethical consideration according to Helsinki declaration and commenced after the Institutional Ethics Committee (IEC) approval.

Data Management-

All data were entered in Microsoft Excel and analysed using statistics analysing software (IBM Corp. released 2015. IBM SPSS Statistics for Windows, version 23.0. Armonk, NY: IBM Corp.)

Statistical analysis-

- All nominal data, like gender, were described using percentages and analysed using the Chi-square test or Fischer Exact Test.
- All Ordinal data like STAI scores were described using Median (IQR) and analysed using the Mann-Whitney U test.
- All continuous data like age was described using mean (SD) and analysed using an Independent sample t-test.

- “P-value” of less than 0.05 was considered statistically significant.

PROCEDURE-

Novel videos were created using Microsoft PowerPoint and were edited using iMovie software. The videos were developed separately for each disease under study. The videos were then uploaded on google drive, and the pertinent links were shared with parents at the time of consenting.

Video tool-

Below (Figure 1-5) are screenshots of the video used to provide patient information at the time of consent.

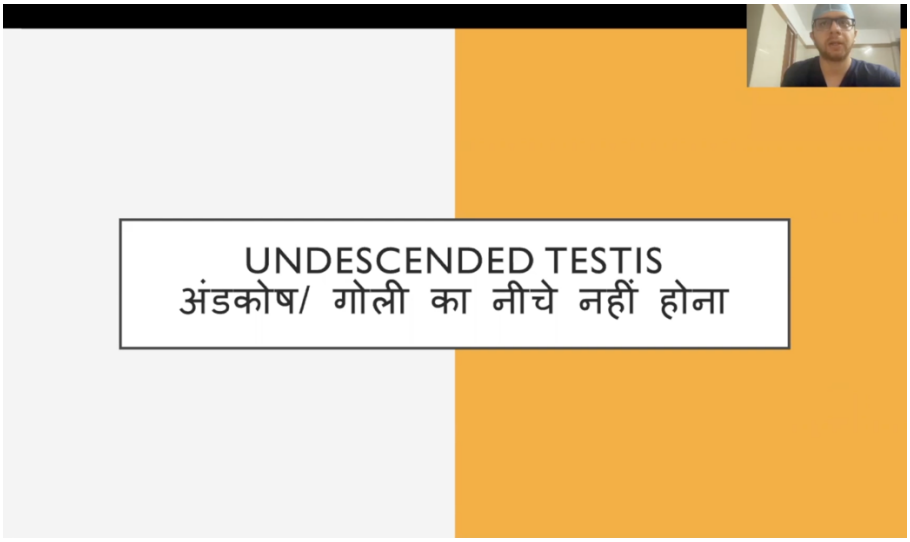

Figure 1

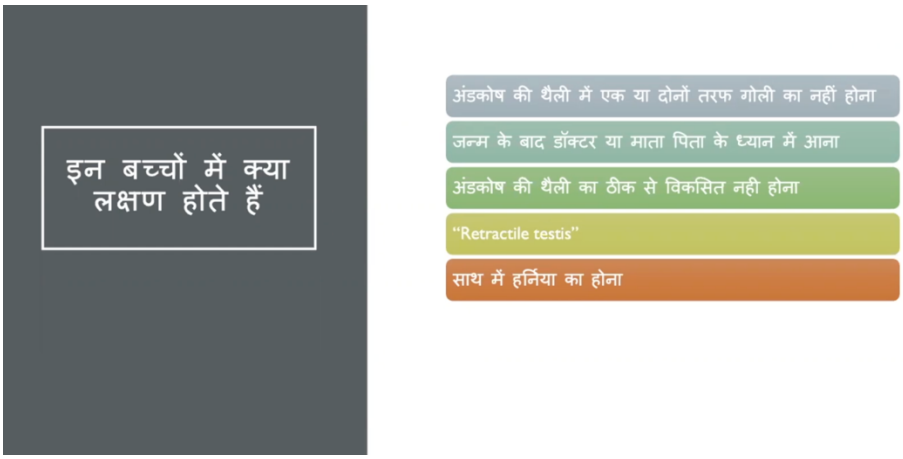

Figure 2

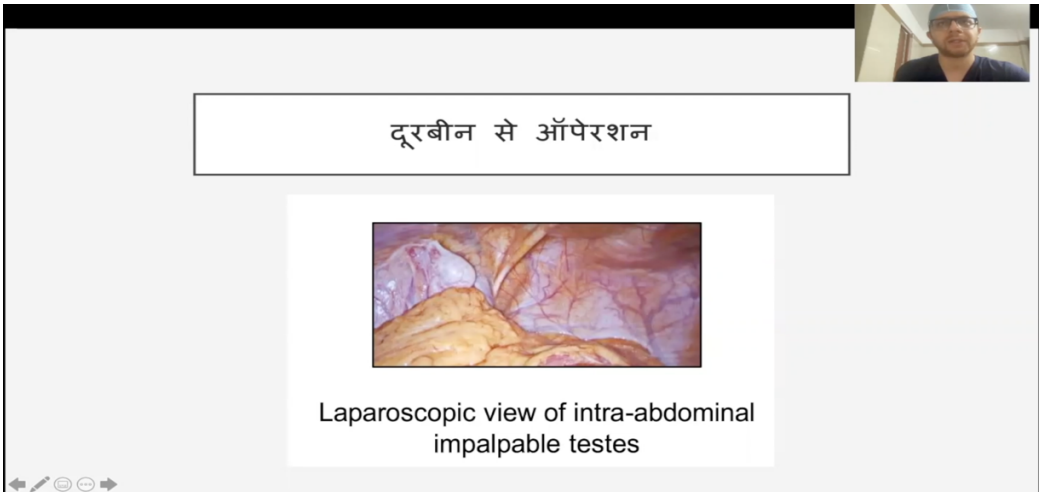

Figure 3

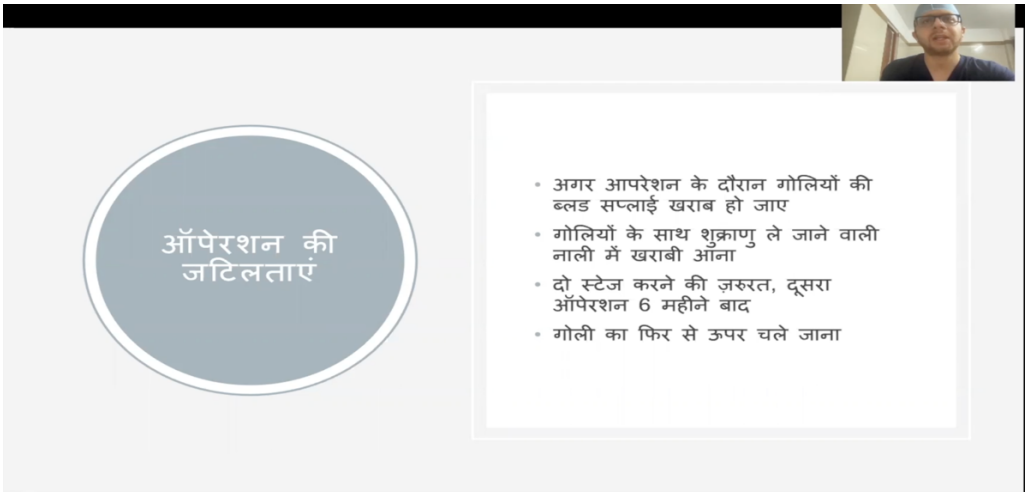

Figure 4

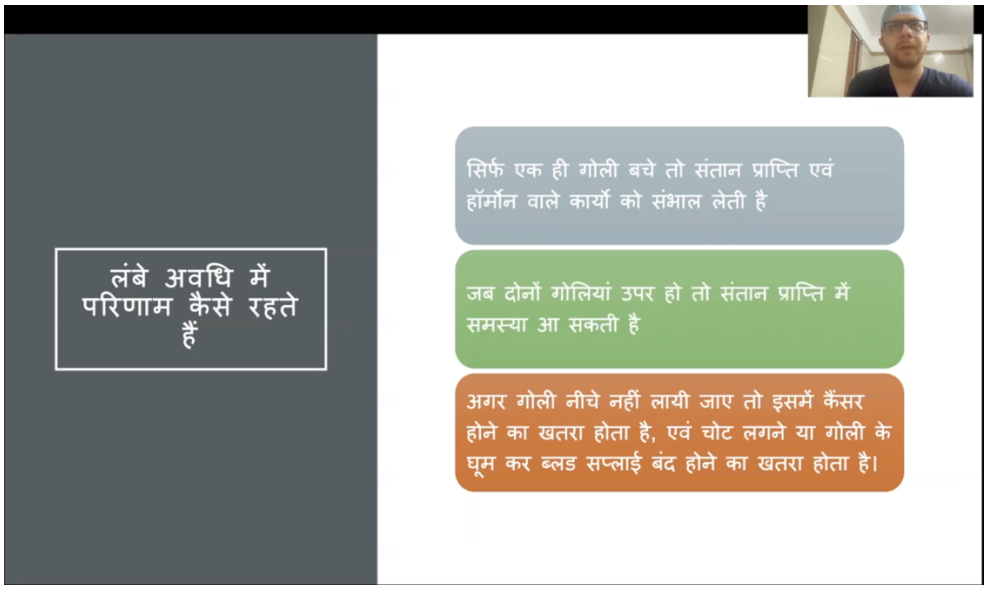
लंबे अवधि में परिणाम कैसे रहते हैं
सिर्फ एक ही गोली बचे तो संतान प्राप्ति एवं हॉर्मोन वाले कार्यो को संभाल लेती है
जब दोनों गोलियां उपर हो तो संतान प्राप्ति में समस्या आ सकती है
अगर गोली नीचे नहीं लायी जाए तो इसमें कैंसर होने का खतरा होता है, एवं चोट लगने या गोली के घूम कर ब्लड सप्लाई बंद होने का खतरा होता है।

Figure 5

Parental anxiety-

Parental anxiety was measured using State-Trait Anxiety Inventory (STAI) tool. This tool is a standard and validated tool used very commonly to measure the participant's state (situational) and trait (baseline) anxiety using 4 points Likert-type scale with scores varying from 1 to 4. Two forms were used in this study: STAI AD Form Y-1, comprising a 20-item questionnaire that assesses the parent's anxiety at a point in time. This form will be referred to as a state questionnaire. The second form was STAI AD Form Y-2 which assesses parents' baseline or trait anxiety. This form will be referred to as trait questionnaire in our study.

STAI tool employs a mix of positive or anxiety-absent characteristics ("I feel at ease") along with negative traits ("I feel frightened"). Each question has a response with a score varying from 1 to 4. The scores, therefore, range from 20 (indicating low or absent anxiety) to 80 (indicating high anxiety). A scoring key that was provided along with the licensed questionnaire was used. Persons scoring 75th centile or higher were considered to have high anxiety (48). STAI scores are commonly classified as "no or low anxiety" (20-37), "moderate anxiety" (38-44), and "high anxiety" (45-80) (49). The STAI tool is copyright material. 180 copies of the tool were purchased at the study's beginning from Mind Garden, Inc. (50).

Knowledge based test (KBT)-

A knowledge based test was designed individualised to each disease under consideration in this study. This test included five questions related to the patient's disease, surgery planned, complication, and the duration of stay. Each correct answer was given a score of +1, and a wrong answer was a 0 score. An example of the questionnaire is shown below:

DISEASE SUBJECT UNDER STUDY-UNDESCENDED TESTIS	
By what age do the testicles normally descend in the scrotum? 1. Before birth 2. At 1 month of age 3. Between 1-6 months of age 4. I don't know	**टेस्टिकल्स आमतौर पर स्क्रोटम में किस उम्र में उतरते हैं?** 1. जन्म से पहले 2. 1 महीने की उम्र में 3. 1-6 महीने की आयु के बीच 4. मुझे नहीं पता
What do you think will happen if the child is not operated for undescended testis? 1. Nothing 2. Can result in Cancer 3. It will descend on its own in adulthood 4. I don't know	**अगर बच्चे को अवांछित टेस्टिस के लिए** ऑपरेशन **नहीं किया जाता है तो क्या होगा?** 1. कुछ भी नहीं होगा 2. कैंसर का कारण बन सकता है 3. यह वयस्कता में अपने आप पर उतर जाएगा 4. मुझे नहीं पता
What do you think are the common complications of the surgery planned for your child? 1. Infection and Bleeding 2. Testicular trauma 3. Infertility 4. I don't know	**आपके बच्चे के लिए शल्य चिकित्सा की सामान्य जटिलता क्या हैं?** 1. संक्रमण और रक्तस्राव 2. गोली में चोट लगने की सम्भावना 3. बांझपन 4. मुझे नहीं पता
What do you think will be considered if grossly non-functional testis is noted intraoperatively? 1. Surgical removal of testis (Orchiectomy) 2. Giving medications to reestablish the function of testis 3. No intervention required 4. I don't know	**सर्जरी के दौरान कोई** ख़राब **टेस्टिस मौजूद होने पर क्या** किया जाता **है?** **1.** टेस्टिस (ऑरिटेक्टोमी) को सर्जरी द्वारा हटा दिया जाता है 2. टेस्टिस के कार्य को पुन: स्थापित करने के लिए दवाएं देना 3. कोई हस्तक्षेप की आवश्यकता नहीं है 4. मुझे नहीं पता
What do you think in days is the expected duration of hospital stay after surgery in an uncomplicated case of Undescended Testis? 1. 1-3 days 2. 7-10 days 3. 15days 4. I don't know	इस **सर्जरी के बाद अस्पताल में रहने की अपेक्षित अवधि क्या है?** 1. 1-3 दिन 2. 7-10 दिन 3. 15 दिनों के 4. मुझे नहीं पता

Spencer Satisfaction score:

A satisfaction score based on Spencer et al. (46) was used to assess the parents' satisfaction with the entire consent process for both groups. Permission to use the questionnaire and to translate it into Hindi was sought from the author. The questionnaire consists of various questions which have responses based on the Likert scale, and it varies from a score of 1 to 4. Few of its questions are peculiar to the group where video tool is used, and few are for a group where conventional consent is taken. The scores for each question were analysed separately for both groups. Some of the questions in the questionnaire are shown below-

Satisfaction questionnaire

Please choose one number from 1 to 4 for each question. The numbers represent:

1= strongly agree; 2=agree; 3= disagree; 4=strongly disagree

	1	2	3	4
1. I was fully involved in decision-making.				
2. I was given opportunity to ask questions.				
3. I know I had the right to refuse surgery.				
4. I had enough time to make a decision.				
5. I felt pressured to make a decision.				
6. I believe to have enough information, to make a decision.				
7. I understand the procedure of inguinal hernia repair.				
8. I understand, why my child needs the surgery.				
9. I understand, why the inguinal hernia needs to be surgically removed.				
10. I believe the surgery helps my child.				
11. I trust the surgeon to do the right thing for my child.				
12. I was satisfied with the way information was presented to me.				
13. I believe, the surgeon had enough time for me.				
14. Should my child have an inguinal hernia again, I would make the same decision.				
15. The doctor answered all my questions.				
16. I searched for information in the internet on my own.				

Workflow:

Parents of the patients getting admitted under the department of Pediatric Surgery, AIIMS Jodhpur, that fulfilled the inclusion criteria were detailed about study, and informed consent was taken for their participation in the study.

Randomization was done using sequentially numbered, opaque sealed envelope (SNOSE) method. Computer-generated random numbers were used on a 1:1 ratio and placed in sealed envelopes. Patients were randomized into two groups- a video tool based group and a conventional consent group. Based on the allocation of the group, parents were either administered a traditional standard surgical consent method wherein surgical resident of the operating team explained the diagnosis of patient, surgery planned, treatment alternatives, if any, that were available, possible complications of the surgery, risks and benefits and also addressed queries of the parents. Or the standard surgical consent was aided with a video tool, and a freely accessible link to the video was given along with it based on the group allocation.

On the first encounter with parents or legal guardians of patients fulfilling the inclusion criteria, resident sought the demographic details of the patient and their guardian like age, sex, relation with patient, educational status of parents and diagnosis of the patient. Educational level was documented as per the Indian Standard Classification on Education (InSCED) developed by the Ministry of Human resource development, Government of India. The parents were then administered STAI questionnaire (both State-Y1 and trait-Y2 forms), after which the resident doctor duly explained the surgery with or without the aid of a video tool based on the randomization. Informed consent was taken from the parents, and STAI Y1 form was re-administered to evaluate their state of anxiety post-consent. A knowledge based test specific to the disease and a Likert-based questionnaire about their overall experience with the consent process was administered, and the results were analysed.

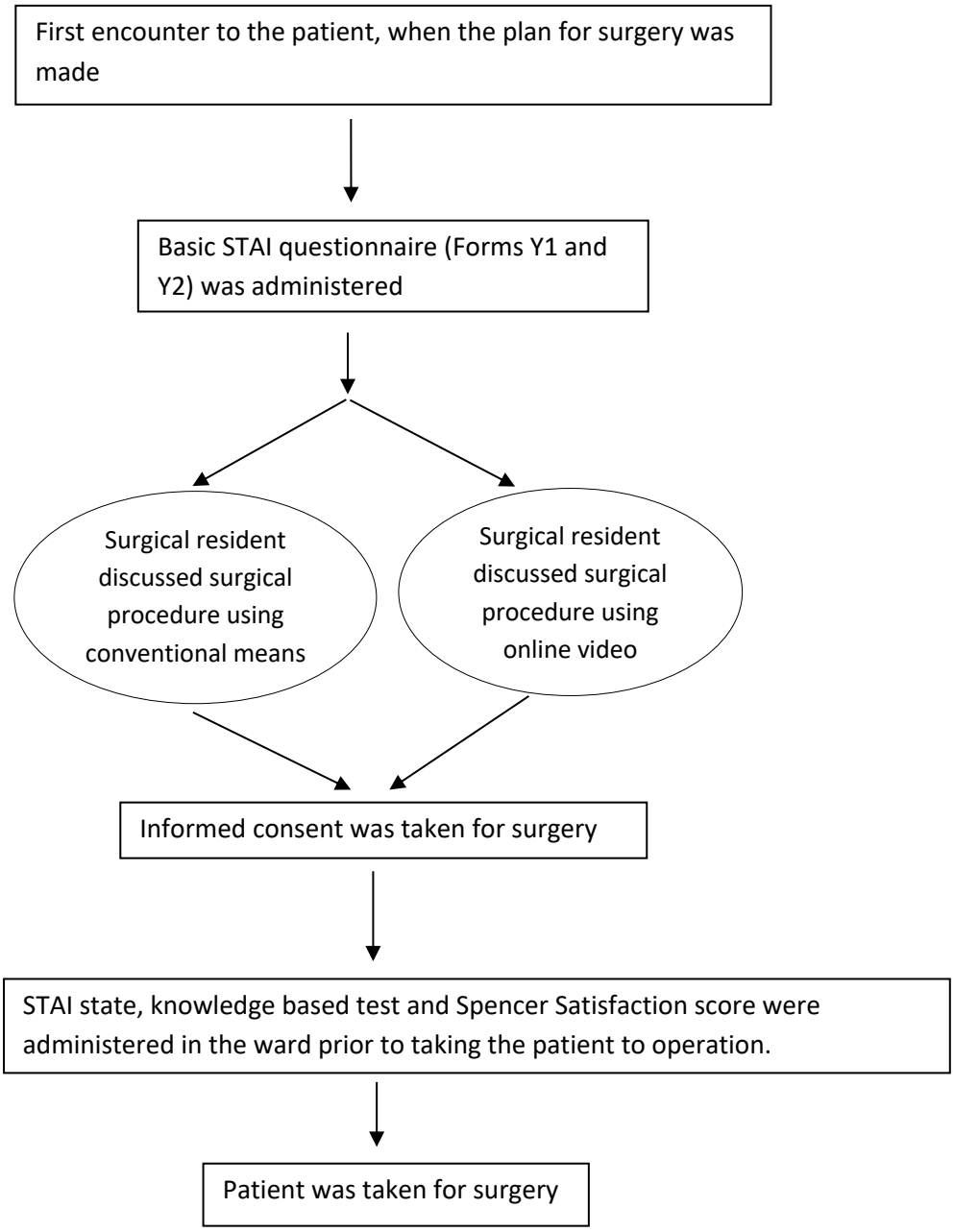

Figure 6: Summary of the workflow

Ethical Consideration:

The study was done only in patients with parents who had given consent to be included. The study commenced after due approval by the IEC (Institutional Ethical Committee) and CTRI registration. Neither the patients' names nor their identity has been disclosed anywhere in the thesis. Study fulfilled the Declaration of Helsinki and ICMR guidelines for biomedical research.

RESULTS

Results

We analysed demographic data of the patients and parents, which included age and sex of the patient, relation of attendant to the patient and educational status of attendant. Using STAI questionnaire, the pre-operative patient's anxiety was assessed and compared between the video tool (VT) and conventional consent (Non VT) groups. First administration of the questionnaire included both the state and trait sets of questions (Pre consent anxiety assessment- Y1, Y2). It was followed by a state questionnaire again (Y1 form) after the consent based on VT or non VT group. Parents' knowledge about the surgical procedure was assessed by a knowledge based test and compared between the two groups. And satisfaction of the parents with informed consent process was evaluated between the two groups using the Spencer satisfaction score.

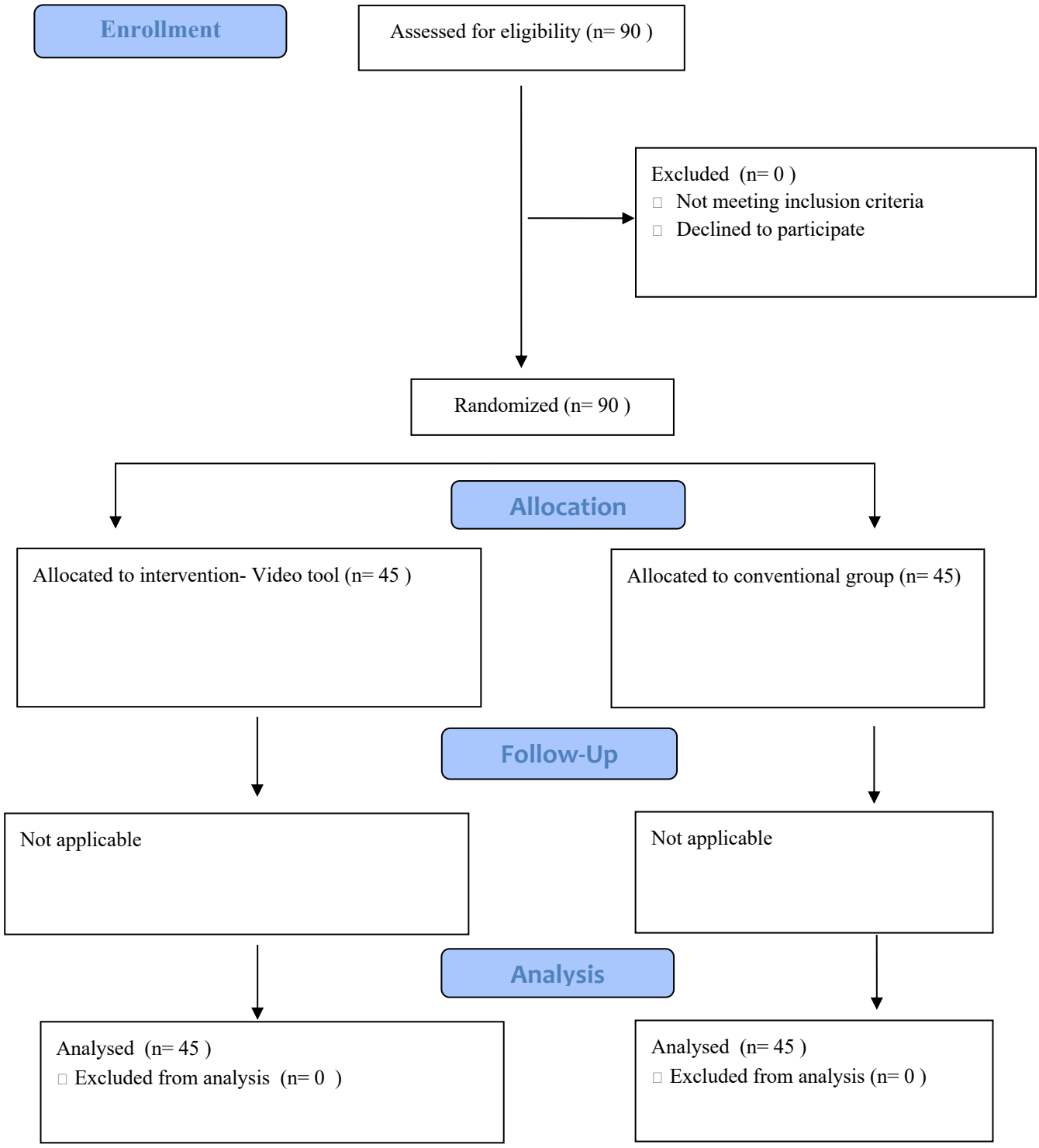

Figure 7: Consort diagram for Randomized control trial

1. Demographics:

Table 1: Central tendency of age group of patients

Median	3
Interquartile range (IQR) (Q3-Q1)	7-1

Median age of the children who underwent procedures was three years. Interquartile range (Q3-Q1) was 7-1.

Table 2: Frequency distribution of age group of patients

Age groups	Frequency	(%)
≤ 4 years	54	60
5 to 8 years	17	18.9
>8 years	19	21.1

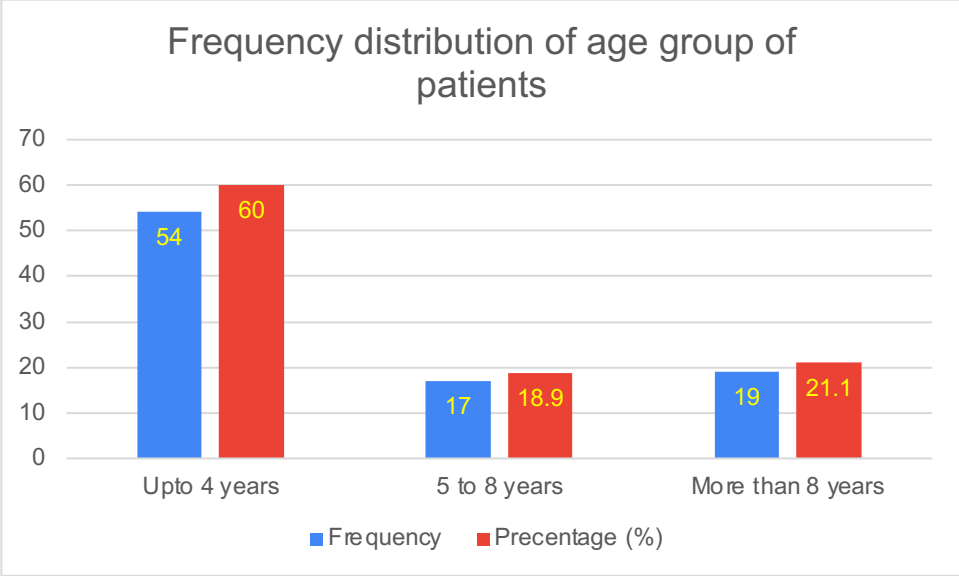

Figure 8: Frequency distribution of age group of patients

Majority of the patients, i.e., 54 (60%) of patients belonged to age group up to 4 years, followed by 17 (18.9%) belonging to age group 5 to 8 years and then 19 (21.1%) patients belonging to more than 8 years group.

Table 3: Comparison of age group-wise distribution of patients between the two groups.

Age group	Randomised group (VT) n(%)	Randomised group (Non VT) n(%)
Up to 4 years	29 (64.4)	25 (55.6)
5-8 Years	7 (15.6)	10 (22.2)
More than 8	9 (20)	10 (22.2)

Chi-Square value = 0.87, P value = 0.645 (Not significant)

Among the patients on which VT was used, majority of the patients, i.e., 29 (53.7%), were found to be in the age group up to 4 years, and in the non-VT group, majority of patients, i.e., 23 (55.6%) were also in the age group up to 4 years.

The comparison of distribution of ages group between two groups was found to be statistically non-significant (p= 0.645).

Therefore, the randomisation was free of age as a confounding factor and ensured a better comparison between the two groups.

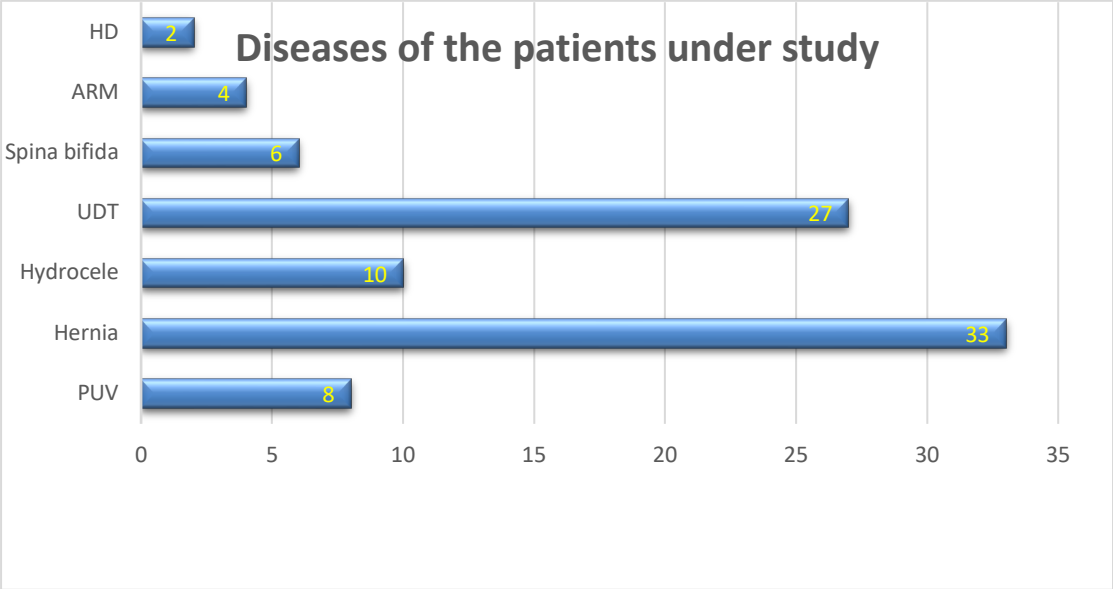

Figure 9: Bar diagram representing the frequency distribution of the diseases

Most of the cases were of Inguinal hernia (33) followed by Undescended testis (27), Hydrocele (10), Posterior urethral valves (PUV) (8), Spina bifida (6), Anorectal malformation (ARM) (4) and Hirschsprung's disease (HD) (2).

Table 4: Comparison of diseases frequency between the two groups

Disease	**VT group**	**Non VT group**
PUV	4	4
Hernia	16	17
Hydrocele	6	4
Undescended testis	13	14
Spina bifida	3	3
Anorectal malformation	2	2
Hirschsprung's disease	1	1

The mean (±SD) of the two groups was compared (VT- 6.43 ±5.80 vs Non VT- 6.43 ±6.35) using unpaired student t test and the difference was **statistically non significant (P value- 0.55)**.

Table 5: Frequency distribution of gender of patients

Gender	Frequency	(%)
Male	78	86.7
Female	12	13.3

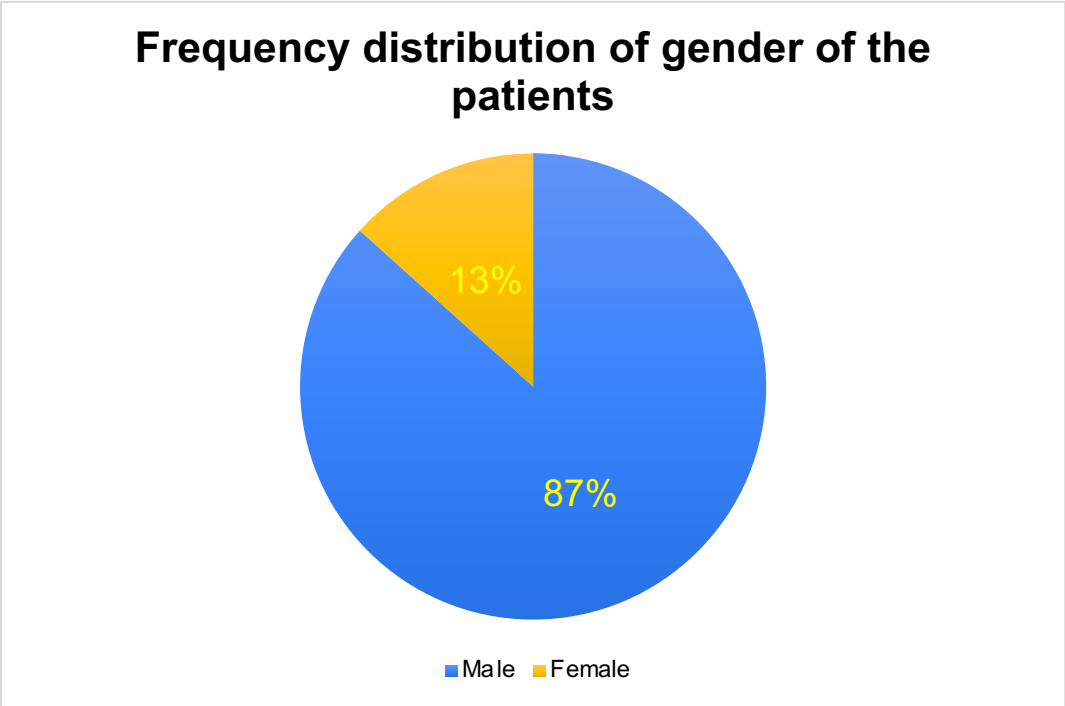

Figure 10: Frequency distribution of gender of patients

Majority of patients, i.e., 78 (86.7%), were males, and 12 (13.3%) were females.

Table 6: Frequency distribution of the consenting person

Consent (parents)	Frequency	Percentage (%)
Mother	4	4.4
Father	82	91.1
Both	4	4.4

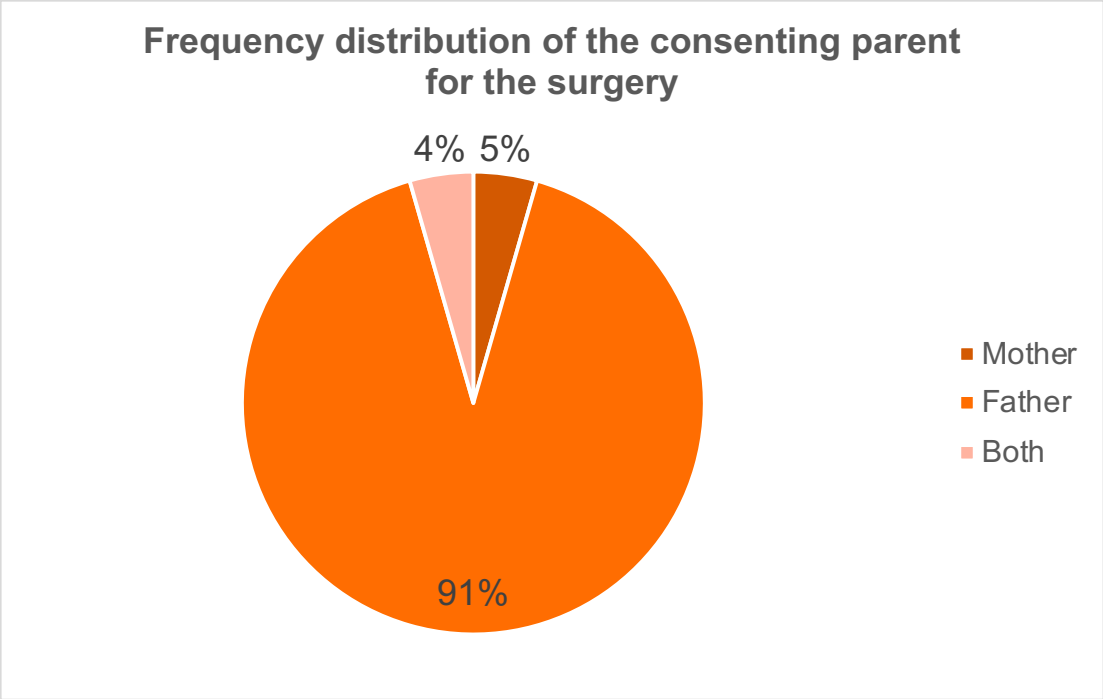

Figure 11: Frequency distribution of the consenting parent for the surgery

In our study, either or both parents were available to give informed consent in all the cases. Out of this, fathers were the consenting person in 82 (91.1%), mothers in 4 (4.4%) and both were available to give consent in only 4 (4.4%) cases.

Table 7: Comparison of consenting respondents between the two groups

Sex of parent	Randomised group (VT) n(%)	Randomised group (No VT) n(%)
Father	40 (88.9)	42 (93.3)
Mother	3 (6.7)	1 (2.2)
Both	2 (4.4)	2 (4.4)

Chi-square- 1.049, P value- 0.592 (Non-significant)

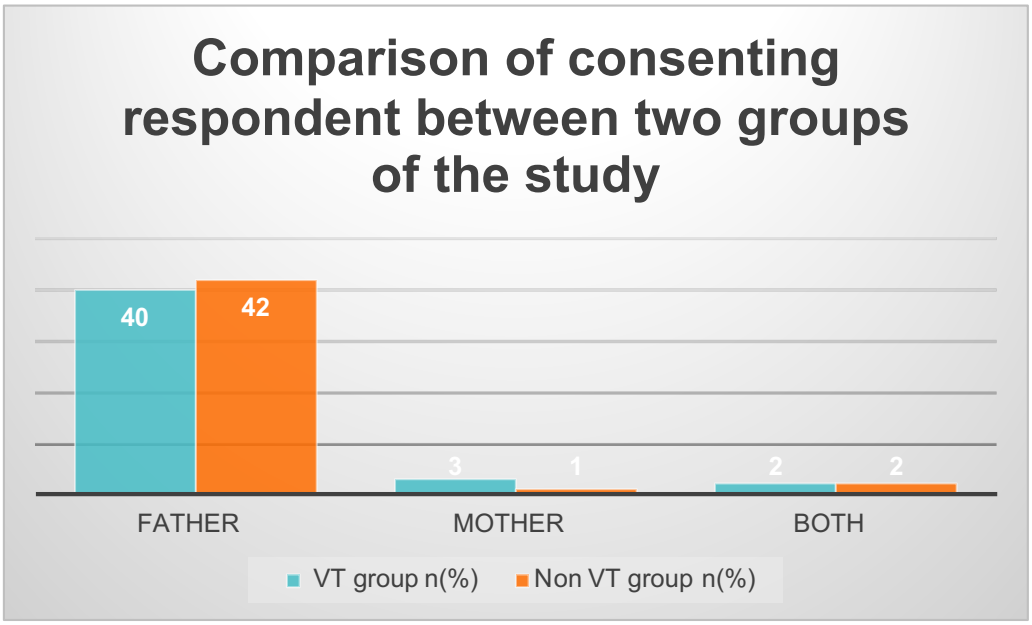

Figure 12: Comparison of consenting respondents between two groups of study

Fathers were the respondents in the majority of cases in both the groups (VT vs Non VT)- 40 (88.9) vs 42 (93.3). This distribution of respondents between the two groups showed no statistically significant difference (p= 0.592).

Table 8: Frequency distribution of educational status of parents as per Govt. of India

Education	Frequency	Percentage
Pre Primary	7	7.8
Primary	4	4.4
Upper Primary	8	8.9
Secondary	12	13.3
Senior Secondary	13	14.4
Undergraduate	11	12.2
Post Graduate	11	12.2
M.Phil	4	4.4
Diploma	13	14.4
Post Graduate Diploma including advanced diploma	3	3.3
Integrated	1	1.1
In Service Training	3	3.3

Diploma and secondary education were the most common educational qualification which was there in 13 (14.4%) consenting parents respectively.

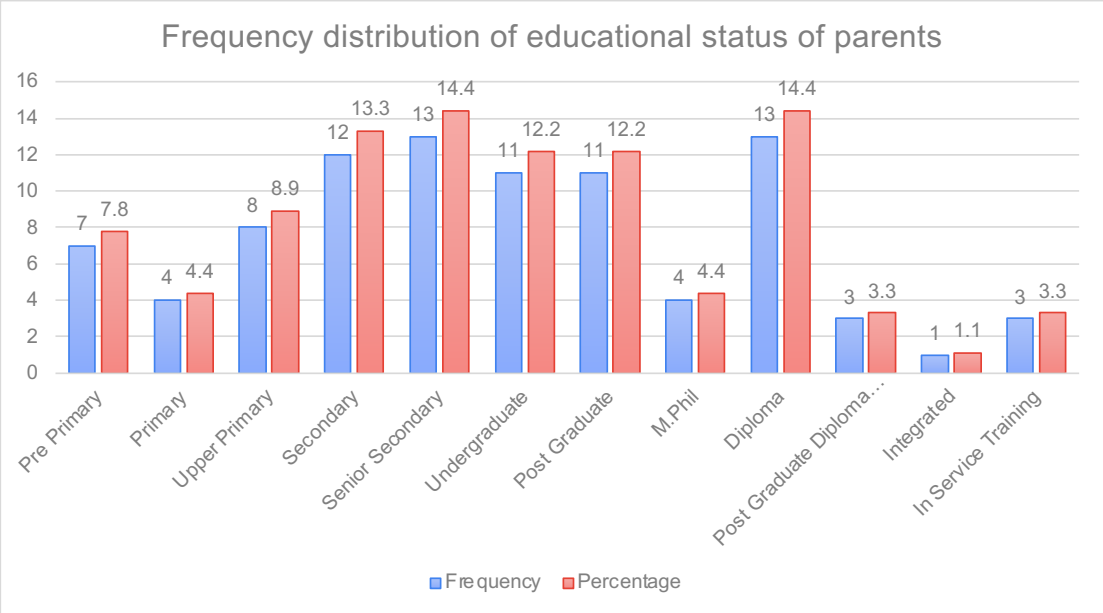

Figure 13: Frequency distribution of educational status of parents as per Govt. of India

Table 9: Frequency distribution of educational status as per govt. of India subcategorised

Education of parents	Frequency	(%)
Primary	11	12.2
Secondary	20	22.2
Higher Secondary	12	14.4
Graduation	27	30.0
Post-Graduation	19	21.1

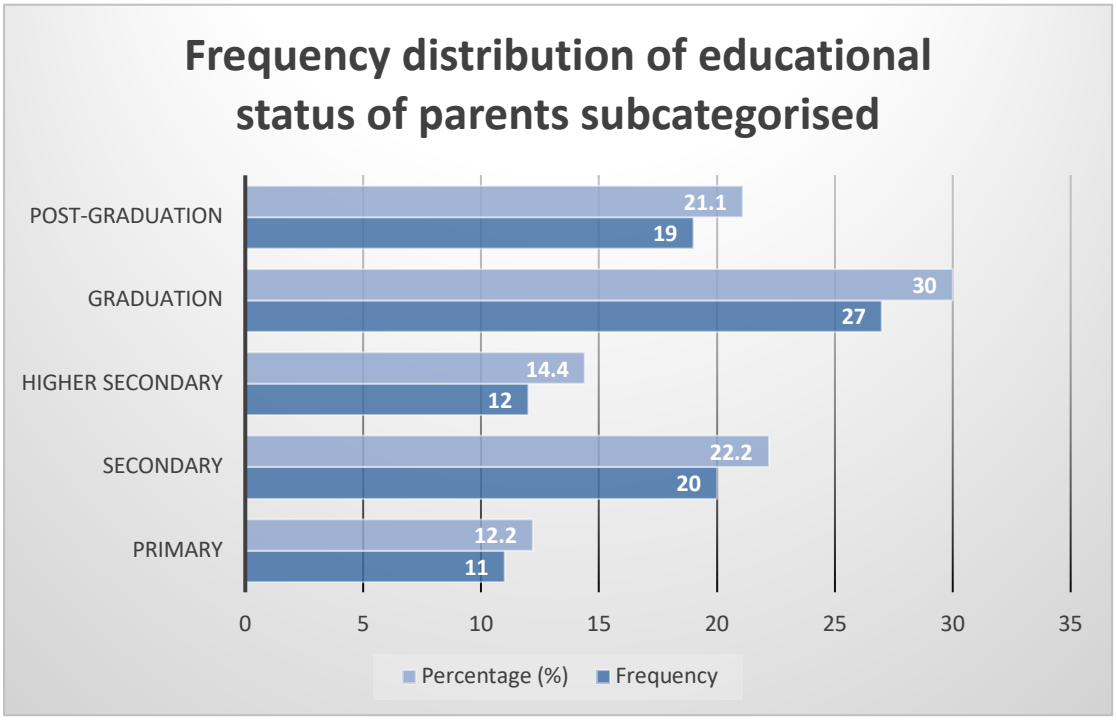

Figure 14: Frequency distribution of educational status- subcategorised

The educational status was further subcategorised for the ease of comparison between the two groups. Based on the subcategorisation, most of the parents were graduated 27 (30%), followed by secondary education 20 (22.2%), post-graduation 19 (21.1%) and higher secondary 12 (14.4%). Only 11 (12.2%) patients had up to primary education. When both parents were present for consenting, a higher education level among the two was considered.

Table 10: Comparison of educational status of consenting respondent between two groups

Education of parents	VT group	Non VT group
Primary	5(11.1)	6(13.3)
Secondary	8(17.8)	12(26.7)
Higher Secondary	9(20.0)	4(8.9)
Graduation	12(26.7)	15(33.3)
Post-Graduation	11(24.4)	8(17.8)

Chi-Square- 3.62, P value- 0.460

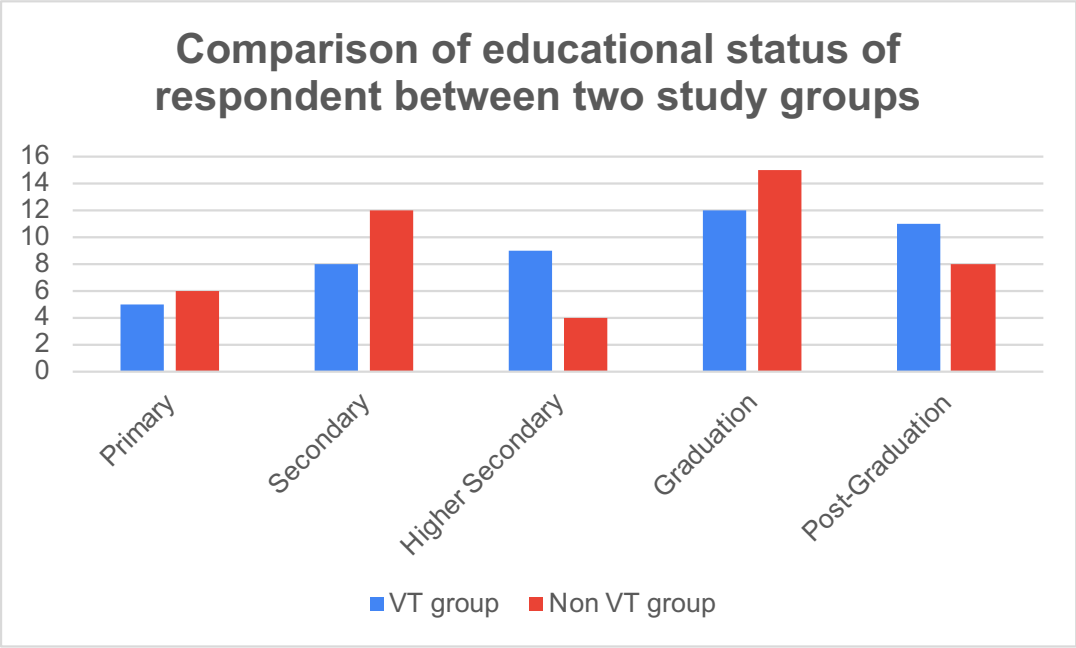

Figure 15: Comparison of educational status of consenting respondent between two study groups

2. Anxiety scores based on STAI Questionnaire:

Pre-consent anxiety assessment:

Table 11: STAI Y1 form (pre-consent state anxiety):

Mean	55.5
Standard Deviation	9.54
Range	26-70

The mean (±SD) value of overall pre consent state anxiety (Y1) was 55.5 (±9.54) with a range of 26-70.

Table 12: STAI Y2 form (pre-consent trait anxiety):

Mean	34.96
Standard Deviation	5.36
Range	23-54

The mean (±SD) value of overall pre-consent trait anxiety (Y2) was 34.96 (±5.36) with a range of 23-54

Table 13: STAI Y1 form (post consent state anxiety):

Mean	34.04
Standard Deviation	7.74
Range	20-51

The mean (±SD) value of overall post-consent state anxiety (Y1) was 34.04 (±7.74) with a range of 20-51

Table 14: Comparison of STAI scores between the VT and Non VT groups:

Variable	VT group (Mean±SD)	Non VT group (Mean±SD)	P Value
STAI Y1 pre consent score total	55.75 ± 9.26	55.24 ± 9.90	0.65
STAI Y2 pre consent total score	34.62 ± 5.83	35.31 ± 4.89	0.24
STAI Y1 post consent total score	28.66 ± 3.72	39.42 ± 6.94	<0.0001
Percentage fall in STAI Y1 score	47.44 ± 9.10	27.43 ± 12.35	0.04

The mean value of pre-consent state anxiety (Y1) total score in the VT group was 55.75 ± 9.26, whereas, in the Non VT group, it was 55.24 ± 9.90. The difference between the means was statistically non-significant (p= 0.65).

The mean value of pre-consent trait anxiety (Y2) total score in the VT group was 34.62 ± 5.83, whereas, in the Non VT group, it was 35.31± 4.89. The difference between the means was statistically non-significant (p= 0.24).

The mean value of total post-consent state anxiety (Y1) score in the VT group was 28.66 ± 3.72, whereas, in the Non VT group, it was 39.42±6.94. **The difference between the means was statistically significant (p< 0.0001). This shows that the post-consent state anxiety in the VT group was significantly lower than in the Non VT group.**

The mean value of percentage fall in STAI Y1 scores in the VT group was 47.44 ± 9.10, whereas, in the Non VT group, it was 27.43 ± 12.35. **The difference between the means of percentage fall in STAI Y1 scores between the VT and Non VT groups was significant (p= 0.04). This shows that the percentage fall in STAI Y1 scores in the VT group was significantly higher than in the Non VT group.**

3. Parental comprehension based on Knowledge based tests (KBT):

Table 15: Overall results of knowledge-based test:

Variable	Correct n (%)	Wrong n (%)
KBT Q1	65(72.2)	25 (27.8)
KBT Q2	68(75.6)	22(24.4)
KBT Q3	60(66.7)	30(33.3)
KBT Q4	54(60.0)	36(40.0)
KBT Q5	61(67.8)	29(32.2)

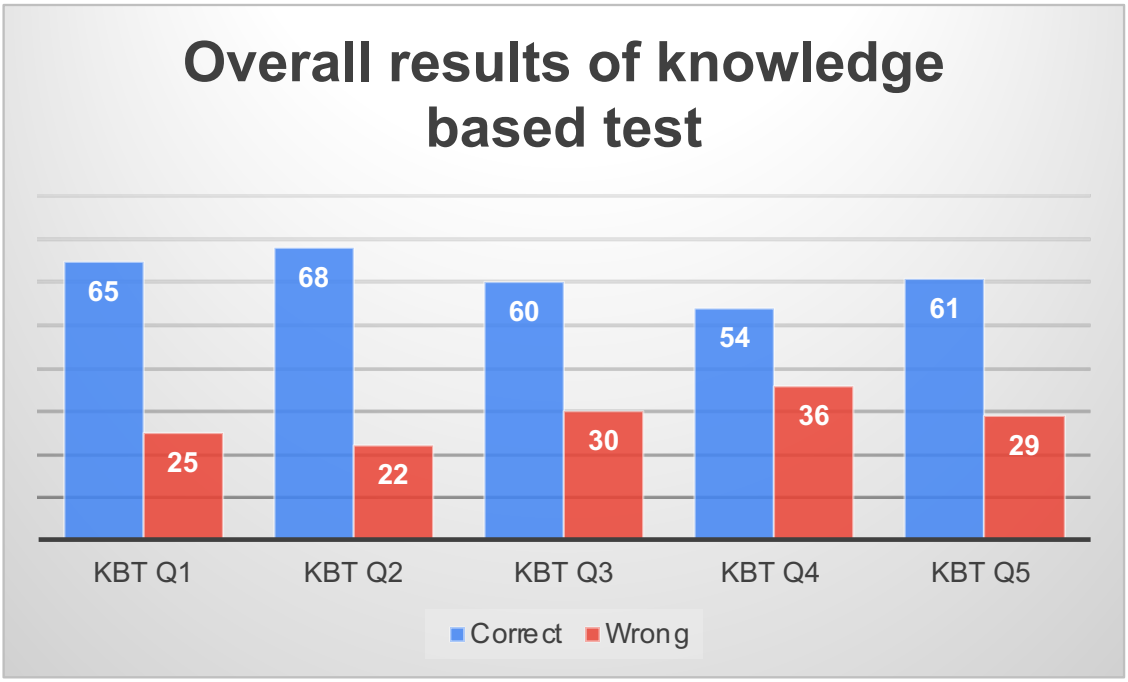

Figure 16: Overall results of knowledge-based test by both study groups

The questions (total five questions) in the KBT were answered correctly by 72.2%, 75.6%, 66.7%, 60% and 67.8% of the respondents, respectively.

Table 16: Comparison of results of knowledge-based test between both study groups

KBT Q1	**Randomised group (VT) n(%)**	**Randomised group (No VT) n(%)**	**Chi Square Value**	**P Value**
Correct	41(91.1)	24(53.3)	16.006	<0.0001
Wrong	4(8.9)	21(46.7)		
KBT Q2				
Correct	39(86.7)	29(64.4)	6.012	0.014
Wrong	6(13.3)	16(35.6)		
KBT Q3				
Correct	37(82.2)	23(51.1)	9.80	0.002
Wrong	8(17.8)	22(48.9)		
KBT Q4				
Correct	35(77.8)	19(42.2)	11.85	0.001
Wrong	10(22.2)	26(57.8)		
KBT Q5				
Correct	36(80.0)	25(55.6)	6.16	0.013
Wrong	9(20.0)	20(44.4)		

41(91.1%) respondents in the VT group answered first question (KBT Q1) correctly, while only 24 (53.3%) respondents in the non-VT group responded to the question correctly; this difference was **statistically significant** (p= <0.0001).

39 (86.7%) respondents in the VT group answered second question (KBT Q2) correctly, while only 29 (64.4 %) respondents in the non-VT group answered the question correctly; this difference was **statistically significant** (p= 0.014).

37 (82.2%) respondents in the VT group answered third question (KBT Q3) correctly, while only 23 (51.1%) respondents in the non-VT group answered the question correctly; this difference was **statistically significant** (p= 0.002).

35 (77.8%) respondents in the VT group answered fourth question (KBT Q4) correctly, while only 19 (42.2%) respondents in the non-VT group answered the question correctly; this difference was **statistically significant** (p= 0.001).

36 (80%) respondents in the VT group answered fifth question (KBT Q5) correctly, while only 25 (55.6%) respondents in the non-VT group answered the question correctly; this difference was **statistically significant** (p= 0.013).

Table 17: Comparison of overall experience of the respondent regarding the effectiveness of information given between both the study groups

	VT group n (%)	**Non VT group n (%)**
Very effective	34(75.6)	7(15.6)
Effective	10(22.2)	24(53.3)
Moderately effective	1(2.2)	14(31.1)

Chi-Square- 34.81, P value- <0.0001

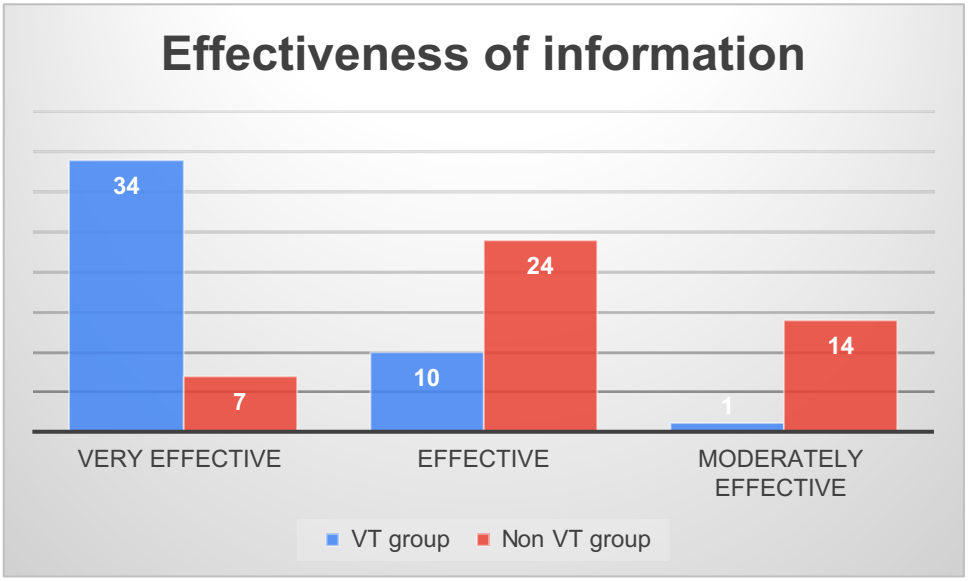

Figure 17: Comparison of the overall experience of respondent regarding the effectiveness of information given between both the study groups.

34 respondents (75.6%) in the VT group found the overall experience very effective, while only 7 (15.6%) respondents found it very effective in the Non VT group. **This difference was found to be statistically significant (p= <0.0001).** Majority (53.3%) of the respondents in the Non VT group found it effective.

Table 18: Comparison of respondents' overall experience regarding understanding disease pathology between both the study groups

	VT group n(%)	Non VT group n(%)
Completely understood	29(64.4)	9(20.0)
Understood	14(31.1)	24(53.3)
Somewhat understood	2(4.4)	12(26.7)

Chi-square- 20.30, P value- <0.0001

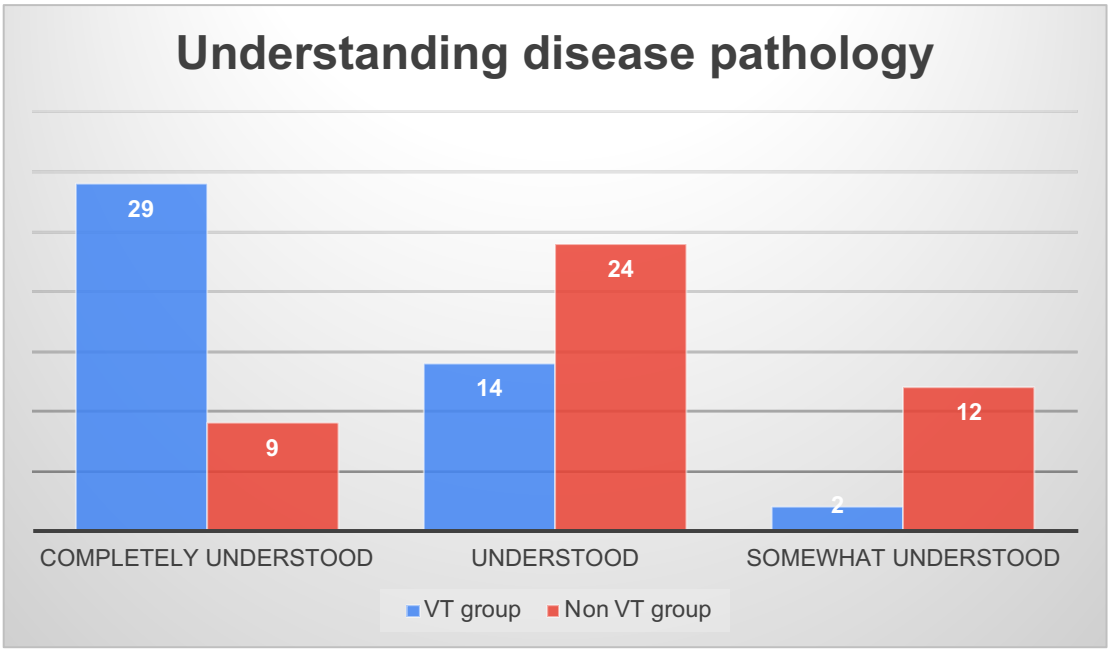

Figure 18: Comparison of respondents' overall experience regarding understanding disease pathology between both the study groups.

29 respondents (64.4%) in the VT group completely understood disease pathology, while only 9 (20 %) respondents in the Non VT group completely understood disease pathology. **This difference was found to be statistically significant (p= <0.0001).**

Table 19: Comparison of respondents' overall experience regarding understanding details of surgery planned between both the study groups.

	VT group n(%)	Non VT group n(%)
Completely understood	29(64.4)	8(17.8)
Understood	15(33.3)	17(37.8)
Somewhat understood	1(2.2)	20(44.4)

Chi-Square- 29.23, P value- <0.0001

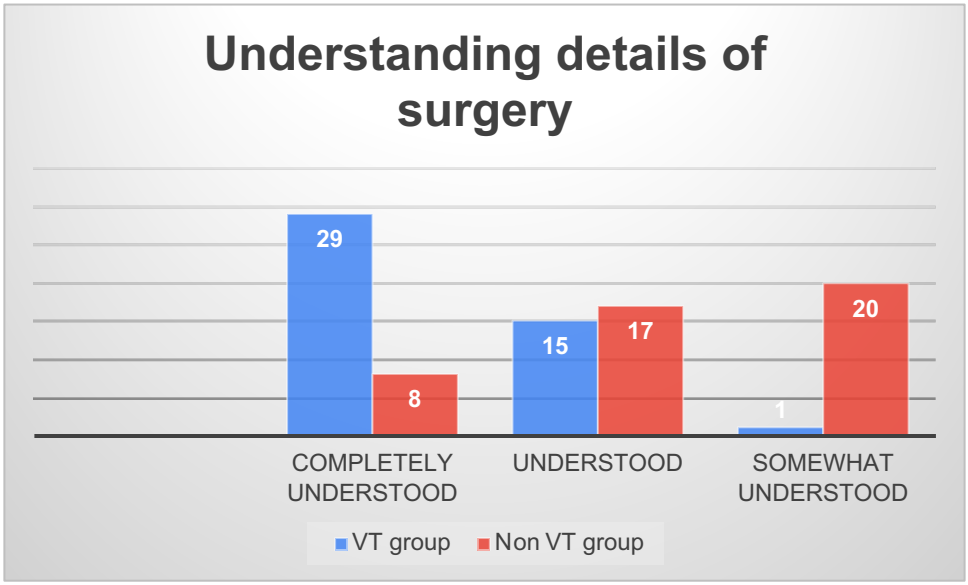

Figure 19: Comparison of the respondent's overall experience regarding the details of surgery planned between both the study groups.

29 respondents (64.4%) in the VT group completely understood the details of the surgery planned, while only 8 (17.8 %) respondents in the Non VT group completely understood the details of the surgery planned. **This difference was found to be statistically significant (p= <0.0001).**

Table 20: Comparison of overall experience of respondent regarding the understanding of post-operative complications between both the study groups.

	VT group n(%)	**Non VT group n(%)**
Completely understood	31 (68.9)	15(33.3)
Understood	12 (26.7)	20 (44.4)
Somewhat understood	2 (4.4)	10 (22.2)

Chi-Square- 12.9, P value- <0.001

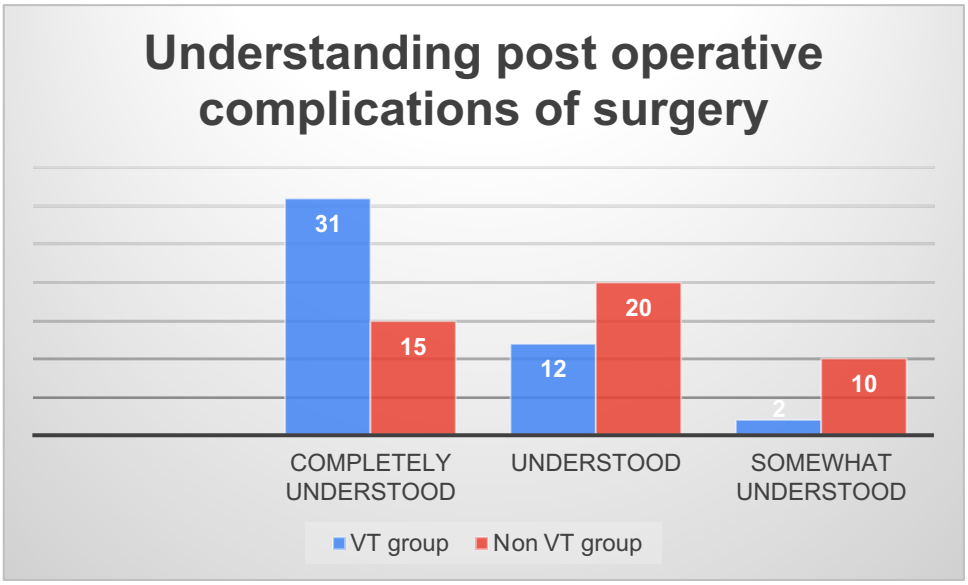

Figure 20: Comparison of overall experience of respondent regarding the understanding of post-operative complications between both the study groups.

31 respondents (68.9%) in the VT group completely understood post-operative complications of the surgery, while only 15 (33.3%) respondents in the Non VT group completely understood post-operative complications of the surgery. **This difference was found to be statistically significant (p= <0.001).**

4. Patient satisfaction based on the modified Spencer Satisfaction score

Table 21: Comparison of overall satisfaction scores of both groups.

Variable	VT group (Mean±SD)	Non VT group (Mean±SD)	P Value
Spencer scale	19.33 ± 1.53	19.48 ± 1.48	0.82

The mean score (±SD) of the 15 questions of Spencer scale for the VT group was 19.33 (± 1.53) while it was 19.48 (± 1.48) for the Non VT group, and **the difference between the two groups was found statistically non-significant** (p=0.82).

Table 22: Analysis of responses to questions asked specifically to the VT group only (based on Spencer's Satisfaction score).

	Strongly agree n(%)	**Agree**	**Disagree**	**Strongly Disagree**
Better informed after Video than verbal	41(91.1)	4(8.8)		
Recommend video to other parents	45(100)			
Video helped to ask more questions	41(91.1)	4(8.8)		
Had opportunity to ask questions to doc	45(100)			
Support concept of medical info videos	42(93.3)	3(6.6)		
Liked content of video	42(93.3)	3(6.6)		
I watched the video more than once	39(86.6)	3(6.6)		3(6.6)

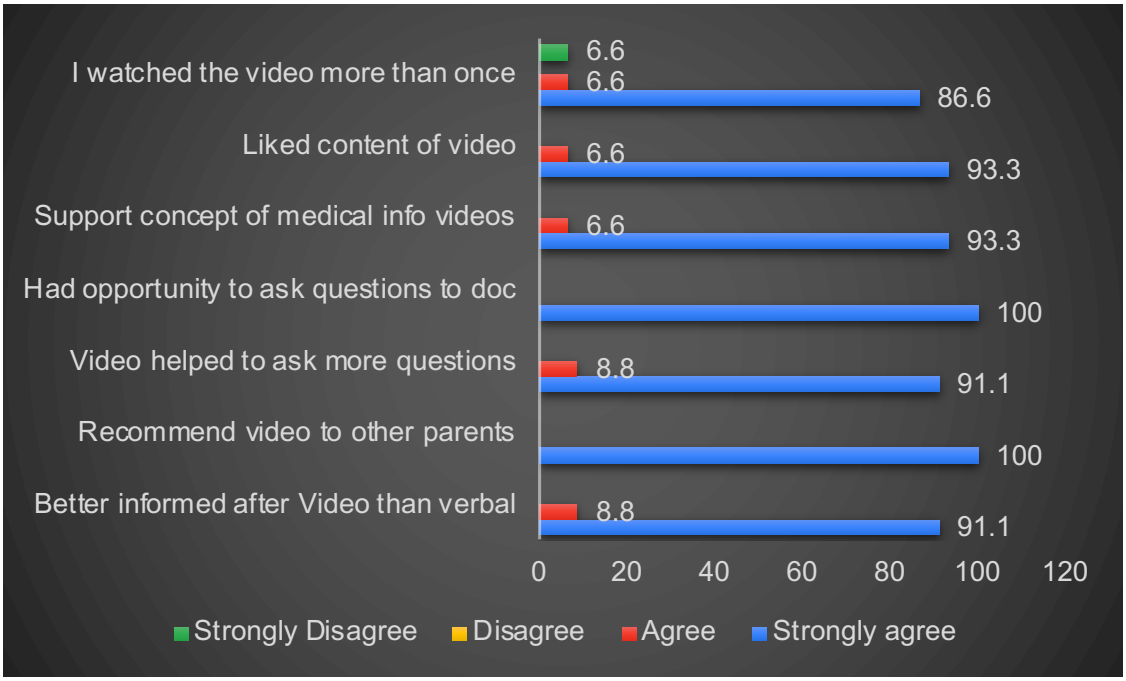

Figure 21: Analysis of responses to questions asked specifically to the VT group only (based on Spencer Satisfaction score) (Values represented are in %)

41 respondents (91.1%) strongly agreed that they felt better informed after watching the video than after verbal consultation.

All (100%) respondents strongly agreed that they would recommend the video to other parents.

41 (91.1%) respondents strongly agreed that the video reminded them to ask more questions to the doctor.

All (100%) of the respondents strongly agreed that they had the opportunity to ask questions to the doctor.

42 (93.3%) respondents strongly agreed that they, in general, support the concept of medical information videos.

42 (93.3%) respondents strongly agreed that they liked the video content they had seen.

39 (86.6%) respondents strongly agreed that they had watched the video more than once. 3 (6.6%) respondents who disagreed with it felt that they did not feel the need to watch the video again.

Table 23: Analysis of responses to questions asked specifically to Non VT group only (based on Spencer Satisfaction score).

	Strongly agree	Agree	Disagree	Strongly Disagree
I wish I had online video with same information	45(100)			
I searched internet for more information	40(88.8)			5(11.1)

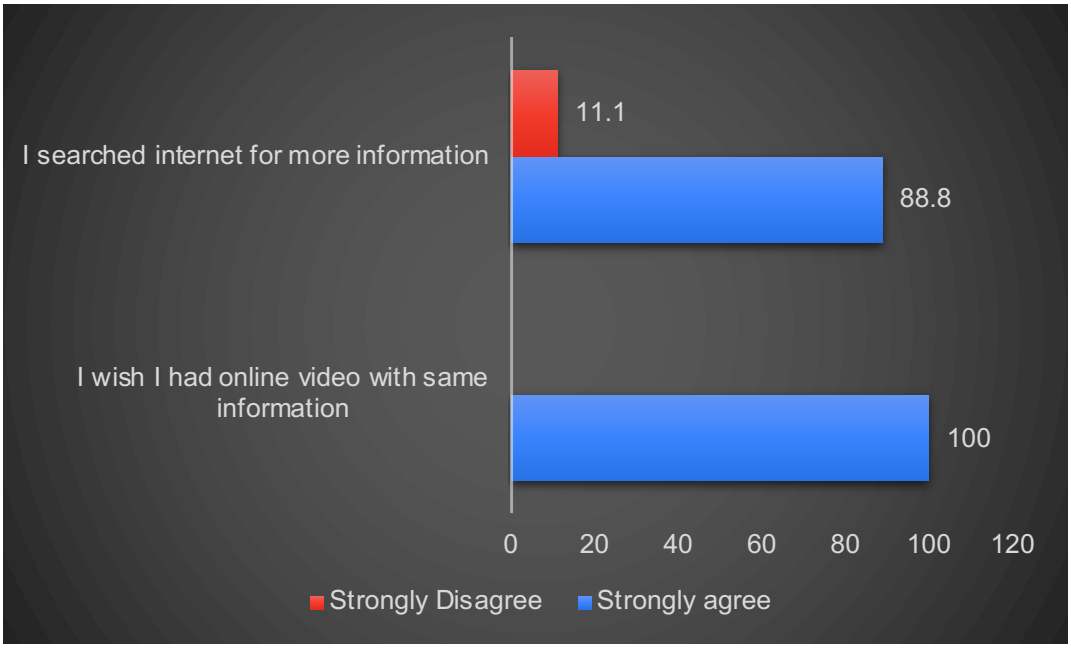

Figure 22: Analysis of responses to questions asked specifically to Non VT group only (based on Spencer Satisfaction score) (Values represented are in %)

All (100%) respondents strongly agreed that they wished to have online videos with the same information.

40 respondents (88.8%) strongly agreed that they searched the internet for more information.

DISCUSSION

Discussion

Informed consent is an essential part of surgical process, as it helps ensure that parents and guardians fully understand the risks, benefits, and alternatives to a particular procedure. For informed consent to be valid, it must be given voluntarily by a patient (or their surrogate) who understands the information provided, retains that information long enough to make an informed decision, and weighs benefits against the risks of the procedure (27).

The contemporary consent process is frequently inconsistent, and comprehension by parents may vary based on various educational and language backgrounds (51). The young age of the patient, need for surgery (emergency or elective), and possible complications due to young age may make the parents more anxious. Previous studies have shown the sources of anxiety during consent process and ways to alleviate it (3). Our literature search revealed problems with conventional informed consent, which could be majorly divided into domains of comprehension of the information by the parents, alleviation of parents' anxiety related to the surgery and the overall satisfaction of the parents with the process of informed consent. Therefore we planned to compare the impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures.

We included 90 patients in our study. The median age of the children who underwent procedures was three years. Interquartile range (Q3-Q1) was 7-1. Most of the cases were of inguinal hernia (33) followed by undescended testis (27), hydrocele (10), posterior urethral valves (PUV) (8), spina bifida (6), anorectal malformation (ARM) (4) and Hirschsprung disease (HD) (2). Previous similar published studies in the similar domain in pediatric surgical patients included mainly single disease condition (2,17). There was no significant difference between the distribution of diseases between both the groups in our study (p=0.55). Our study had most patients under the age of four in both groups (VT vs Non VT- 64.4% vs 55.6%). There was no significant difference between the distribution of various age groups of patients between the two groups (p=0.645). This suggests that age was not a confounding factor, and both groups were comparable. The predominant age group being less than four years can be attributed to the conditions included in our study.

One of the critical factors in understanding informed consent is the educational status of parents (or legal guardians). In our study, Diploma and secondary education were the most common educational qualifications, which was there in 13 (14.4%) parents. On comparison of educational status of the consenting respondent between (Table 9) the two groups, there was no significant difference (p-0.46). This implies that both the groups (VT and Non VT) were comparable in terms of educational status of the parents. Various studies show differences in the educational status of consenting respondents, which can be attributed to the variability in geographical location and literacy rates in those areas.

In our study, fathers were the consenting respondent in majority of cases in both the groups (VT vs Non VT)- 40 (88.9%) vs 42 (93.3%). This distribution of respondents between the two groups showed no statistically significant difference (p= 0.592), which suggests that both groups were comparable in terms of consenting respondents. Both parents were consenting respondents in only 4.4% of cases in both groups. Either of the parents was available to give consent in all the cases. Ayenew et al., in their study of 194 patients, found that 54.1% of respondents were mothers and 45.9% were fathers (52). In the study by Rosenfeld et al., which included 76 respondents, 87% were mothers, and 12% were fathers (47). Our data highlights the patriarchal nature in decision-making in our country.

Reducing patient anxiety is one of the core principles during the process of informed consent during preoperative consultation. Pre-operative parental anxiety may cause increased anxiety in children during the perioperative period (5,53). The anxiety of parents, presence of single parents at the time of consenting and their apprehension can further add to the gaps in the process of understanding of parents about the surgical procedure. An unanswered question, data forgotten after the consultation or simply knowing that surgery is needed, generates anxiety in parents and can possibly impact their children (4). Therefore, it is logical to think that improving the quality of preoperative information at the time of consulting can help to decrease the anxiety of parents and children (12,13).

Our study found that overall state anxiety (both groups included) was 55.5 (±9.54). This shows the state of anxiety among parents before the surgery of their children, which, in turn, further highlights the need for a structured informed consent procedure. The overall state of anxiety after consent (both the groups included) was 34.04 (±7.74). On evaluating the anxiety scores (Y1 and Y2) separately between the two groups, we found no significant difference between the pre-consent state anxiety (Y1) scores and trait anxiety (Y2) scores (P values were 0.65 and 0.24). However, we found a statistically significant difference between the post-consent state anxiety (Y1) scores between the VT group and Non VT group (28.66 ± 3.72 vs 39.42 ± 6.94, $p<0.0001$). We also found that the difference between the means of percentage fall in STAI Y1 (Pre and post-consent) scores between VT and Non VT groups was significant ($p= 0.04$). Our findings suggest that the video tool was more effective in decreasing parental anxiety than the conventional method.

Pomicino et al. also found that average levels of parental anxiety before surgery in Pediatric Cardiac Surgery and Pediatric Urology units were 53.64 ± 13.95 and 51.42± 11.74, respectively, which is similar to our findings. Book et al. also found similar anxiety values and significantly decreased anxiety levels in the intervention group measured using STAI (2). Paton et al. also found a substantial reduction in anxiety levels in the multimedia intervention group (17). Our study corroborates the findings of these studies. The anxiety levels in abovementioned studies measured using the STAI questionnaire were also relatable. This highlights the impact of VT in decreasing parental anxiety.

Previous studies have identified that patient comprehension of the critical elements of informed consent is poor (30,31). A study by Williams et al. revealed that 60% could not comprehend a standard informed consent document (32). Hutson et al. showed that patients tend to recall the expected benefits of surgery more frequently than the potential risks (33). Santavirta et al. found that 37% could not name any relevant complication after undergoing informed consent for hip replacement, (34). Another study revealed that less than one-third of persons signing an informed consent actually demonstrated at least adequate understanding of the procedure, including its risks and benefits (8).

In our study, overall, the questions (total of five questions) in the Knowledge-based test (KBT) were answered correctly by 72.2%, 75.6%, 66.7%, 60% and 67.8% of the respondents, respectively. On comparing the response to KBTs between the two groups, 41(91.1%) respondents in the VT group answered first question (KBT Q1) correctly. In contrast, only 24 (53.3%) respondents in the non-VT group responded to the question correctly, which was statistically significant (p= <0.0001). Similarly, we found a statistically significant difference between respondents giving correct answers in the VT group and the Non VT group in other four questions. Our study suggests improved comprehension in the group where VT was used compared to the conventional consent group. Book et al. also showed better comprehension in the intervention group where a video tool was used (2). However, Paton et al. found no improvement in knowledge in the group with the multimedia intervention (17). The discrepancy may be due to the method used. We believe that video tool is better at improving comprehension among parents over other multimedia tools.

We also found a significant difference between the VT and Non VT groups in terms of respondents' overall experience regarding the effectiveness of overall information provided, understanding of the disease pathology, details of surgery planned and understanding of postoperative complications (p< 0.0001 in all the instances). These findings suggest that patients perceive video tool better than the conventional method, which is associated with an overall better experience.

Patient satisfaction is an important parameter to measure the quality of the consent process. After all, if the parents are not satisfied, process of informed consent can potentially affect their anxiety levels and comprehension as well as, eventually, overall outcome of the procedure. In our study, we used Spencer satisfaction score to compare the overall satisfaction between the two groups and did not find any statistically significant difference (p=0.82). Five questions were meant specifically for the VT group, and two were meant specifically for the Non VT group only. We analysed the responses to these questions separately.

Amongst the questions asked specifically to the VT group. 91.1% of respondents strongly agreed that they felt better informed after watching the video than after

verbal consultation. This finding probably suggests the parents have overall better comprehension with information videos. All (100%) respondents strongly agreed that they would recommend the video to other parents. 91.1% of respondents strongly agreed that the video reminded them to ask more questions to the doctor. We believe this may be due to parents getting adequate time to process the information at a pace they can understand. All (100%) of the respondents strongly agreed that they had the opportunity to ask questions to the doctor. 93.3% of respondents strongly agreed that they generally support the concept of medical information videos, and 93.3% strongly agreed that they liked the content of the video they had seen. We believe that the overall strongly positive response of the respondents of the VT group may have been amplified due to the overall change in the habits of the people in the country where there has been a boom of platforms like Youtube™ where such information videos are freely available.

86.6% of respondents strongly agreed that they had watched the video more than once. 3 (6.6%) respondents who disagreed with it felt that they did not feel the need to watch the video again. Paton et al. used multimedia tools only once during the consent (17). We believe that the ability of parents to have a video that can be accessed multiple times, shared with relatives and watched at a comfortable pace may have facilitated the decrease in anxiety scores, improved comprehension and parental satisfaction. Such videos also ensure that the information stays uniform and standard information is passed to all the patients.

Amongst the questions specifically asked to Non VT group. All (100%) respondents strongly agreed that they wished to have online videos with the same information. 88.8% of respondents strongly agreed that they searched the internet for more information. These findings further support our conclusions mentioned above.

Limitations of the study:

In this study, we have focussed mainly on commonly performed surgeries. We believe that in future, we may be able to make such standard videos for other complex procedures as well. Although in our study, the parents did not ask any significant leading questions after watching the videos, which were not included in the video, there may be such instances in practice for some doctors. We recommend noting frequently asked questions and adding them to the videos later.

CONCLUSION

Conclusion

Providing online informative videos to the parents at the time of consent can help decrease parental anxiety, improve comprehension and is associated with good overall satisfaction of the parents. These standard videos with ad-lib access can become a new norm in the future for informed consent.

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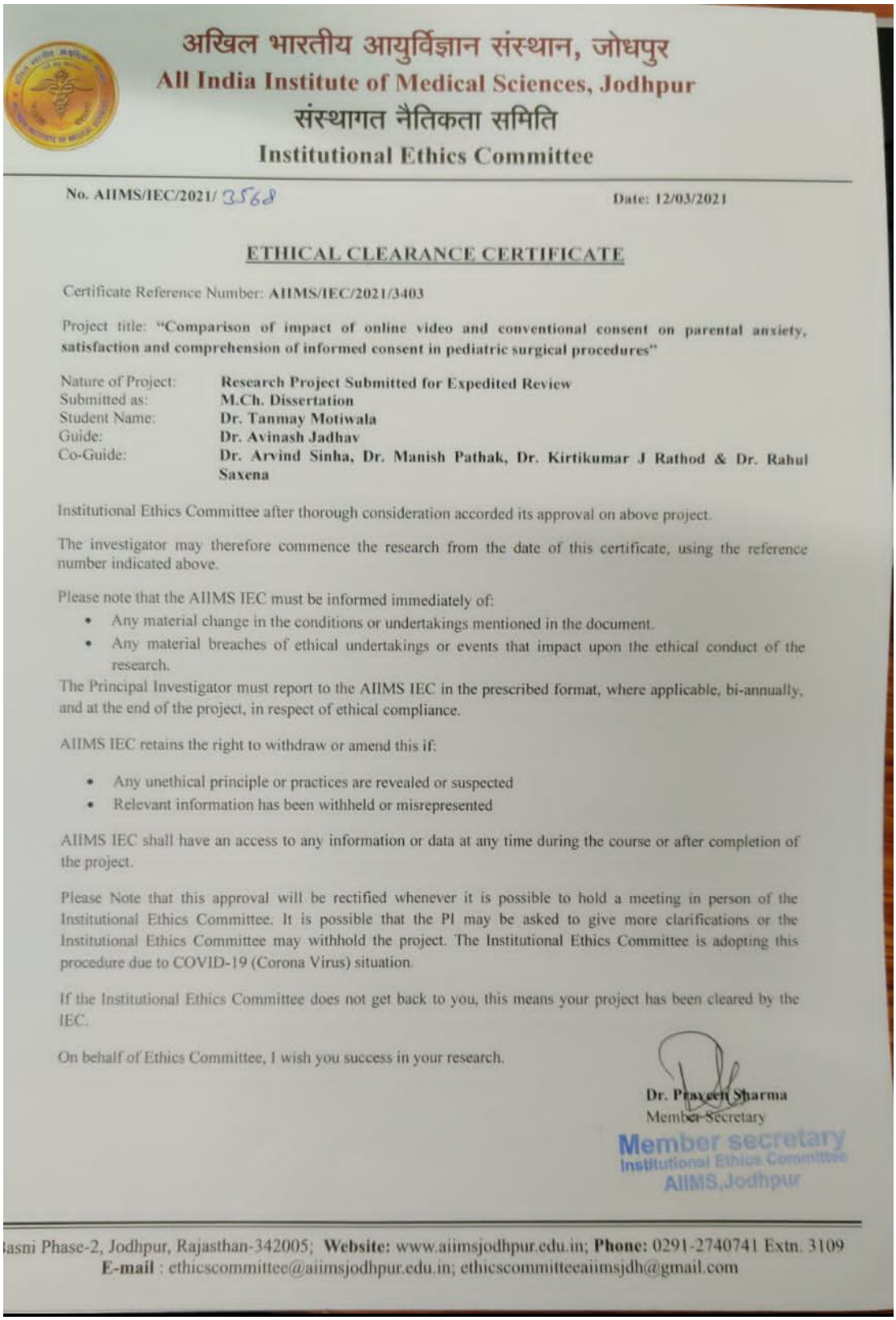
ANNEXURES

Annexure 1: Institutional Ethical committee clearance



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/ 3568 Date: 12/03/2021

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3403**

Project title: **"Comparison of impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.Ch. Dissertation**
Student Name:	**Dr. Tanmay Motiwala**
Guide:	**Dr. Avinash Jadhav**
Co-Guide:	**Dr. Arvind Sinha, Dr. Manish Pathak, Dr. Kirtikumar J Rathod & Dr. Rahul Saxena**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Jasni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
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Annexure 2: Informed Consent Form (English)

All India Institute of Medical Sciences
Jodhpur, Rajasthan

Informed Consent Form

Title of the project : Comparison of impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures

Name of the Principal Investigator : Dr. Tanmay Motiwala Tel. No. 7000445921

Patient/Volunteer Identification No. _____

I, _____parent of _____ R/o _____

give my full, free, voluntary consent to be a part of the study "Comparison of impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from AIIMS Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my records.

Date : _____

Place : _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date : _____ _____

Place : _____ Signature of Principal Investigator

1. Witness 1 2. Witness 2

Name: _____ Name: _____

Address: _____ Address: _____

Annexure 3: Informed Consent Form (Hindi)

अखिल भारतीय आयुर्विज्ञान संस्थान ,जोधपुर, राजस्थान

शीर्षक: ऑनलाइन वीडियो के प्रभाव और पारंपरिक सूचित सहमति की सहमति का बाल चिकित्सा प्रक्रियाओं में पैतृक चिंता, संतुष्टि और समझने में पर प्रभाव की तुलना

माता पिता-सूचित सहमति फॉर्म

एमसीएच छात्र का नाम – डॉ तन्मय मोतीवाला टेलीफोन नंबर : 7000445921

रोगी की पहचान संख्या: _____

मैं,_____ के माता/पिता

_____के निवासी,

इस अध्ययन " ऑनलाइन वीडियो के प्रभाव और पारंपरिक सूचित सहमति की सहमति का बाल चिकित्सा प्रक्रियाओं में पैतृक चिंता, संतुष्टि और समझने में पर प्रभाव की तुलना" में अपने बच्चे की भागीदारी के लिए अपनी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति देता हूं। इस अध्ययन की प्रक्रिया और प्रकृति को डॉक्टर ने मुझे अपनी भाषा में मेरी पूर्ण संतुष्टि के लिए समझाया है। मैं पुष्टि करता हूं कि मुझे सवाल पूछने का अवसर मिला है। मैं समझता हूं कि मेरे बच्चे की भागीदारी स्वैच्छिक है और मुझे किसी भी कारण के बिना किसी भी समय अध्ययन से बाहर निकलने का अधिकार है।

मैं समझता हूं कि मेरे बच्चे और मेरे बच्चे के किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एम्स जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों द्वारा देखा जा सकता है। मैं इन व्यक्तियों को अपने बच्चे के रिकॉर्ड तक पहुंचने की अनुमति देता हूं।

दिनांक :_____

स्थान :_____

हस्ताक्षर _____

यह प्रमाणित करने के लिए कि उपर्युक्त सहमति मेरी उपस्थिति में प्राप्त की गई है।

एमसीएच छात्र का हस्ताक्षर _____

गवाह 1 गवाह 2

_____ _____

Annexure 4: Patient Information Sheet (English)

All India Institute of Medical Sciences
Jodhpur,Rajasthan

Participant information sheet

Patient name:

Patient id:

Title of study: "Comparison of impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures"

Study design: Randomised Control Study

Benefits of the study to the patients: No monetary benefits

Plays a role in increasing the orientation of the parents towards the procedure planned thus reducing their anxiety and increasing the optimal patient care.

Any potential risks to the participants: none

Details of the candidate with phone number:

Dr. Tanmay Motiwala

MCh Paediatric Surgery

AIIMS Jodhpur

7000445921

Annexure 5: Patient Information Sheet (Hindi)

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस
जोधपुर, राजस्थान

प्रतिभागी सूचना पत्रक

रोगी का नाम: .....
रोगी आईडी:.....

अध्ययन का शीर्षकब" : ऑनलाइन वीडियो के प्रभाव और पारंपरिक सूचित सहमति की सहमति का बाल चिकित्सा प्रक्रियाओं में पैतृक चिंता, संतुष्टि और समझने में पर प्रभाव की तुलना"

आपको कोई मौद्रिक लाभ नहीं दिया जाएगा।

यह अध्ययन माता पिता में शल्य क्रिया से सम्भंदित चिंता कम करने में और मरीज़ की सेवा बढ़ाने में मदत कर सकता है । प्रतिभागियों को कोई संभावित जोखिम नहीं है ।

फोन नंबर के साथ उम्मीदवार का विवरण :
डॉ तन्मय मोतीवाला
एमसीएच बाल चिकित्सा सर्जरीविभाग
एम्स जोधपुर
7000445921

Annexure 6: CTRI Registration

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PDF of Trial
CTRI Website URL - http://ctri.nic.in

Clinical Trial Details (PDF Generation Date :- Mon, 09 Jan 2023 13:01:48 GMT)

CTRI Number	CTRI/2021/07/034680 [Registered on: 08/07/2021] - **Trial Registered Prospectively**
Last Modified On	07/07/2021
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Behavioral
Study Design	Randomized, Parallel Group Trial
Public Title of Study	To compare online video and conventional consenting methods of informed consent in pediatric surgical procedures
Scientific Title of Study	Comparison of impact of online video and conventional consent on parental anxiety, satisfaction and comprehension of informed consent in pediatric surgical procedures

Annexure 7: STAI Questionnaire and license to use it

State-Trait Anxiety Inventory for Adults™ (Short Form)

Instrument and Scoring Key

Developed by Charles D. Spielberger

in collaboration with R.L. Gorsuch, R. Lushene, P.R. Vagg, and G.A. Jacobs

Published by Mind Garden, Inc.

info@mindgarden.com www.mindgarden.com

Important Note to Licensee

www.mindgarden.com

To Whom It May Concern,

The above-named person has made a license purchase from Mind Garden, Inc. and has permission to administer the following copyrighted instrument up to that quantity purchased:

State-Trait Anxiety Inventory for Adults

The four sample items only from this instrument as specified below may be included in your thesis or dissertation. Any other use must receive prior written permission from Mind Garden. The entire instrument may not be included or reproduced at any time in any other published material.

Citation of the instrument must include the applicable copyright statement listed below.
Sample Items:

I feel at ease
I feel upset
I lack self-confidence I am a steady person

Sincerely,

Robert Most
Mind Garden, Inc. www.mindgarden.com

State-Trait Anxiety Inventory for Adults Instrument (Adult Form) and Scoring Guide

English and Hindi versions Developed by Charles D. Spielberger

in collaboration with R.L. Gorsuch, R. Lushene, P.R. Vagg, and G.A. Jacobs

Published by Mind Garden, Inc.

info@mindgarden.com www.mindgarden.com

Annexure 8: Indian Standard Classification of Education

Developed by Government of India, Ministry of Human resource development department of higher education, New Delhi in 2014

First digit code	Description
A	**Pre-primary**
B	**Primary**
C	**Upper Primary**
D	**Secondary**
E	**Senior Secondary**
F	**Undergraduate**
G	**Post Graduate**
H	**M.Phil**
I	**Ph.D**
J	**Diploma**
K	**Post graduate diploma including advanced diploma**
L	**Integrated**
M	**Certificate**
N	**In sevice training**
O	**Adult education**
X	**Education n.e.c**

Annexure 9: Likert scale to assess the overall experience of the parents with the method of consent adopted in the study

DEPARTMENT OF PEDIATRIC SURGERY

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR, 324005

LIKERT SCALE TO ASSESS THE COMPREHENSION OF THE PARENTS

1. Rate the overall effectiveness of the the information given to you about the surgery of your child?

Very effective Effective Moderately effective Somewhat effective Ineffective

2.How well did you understand about the disease pathology of the patient explained by the resident?

Completely understood Understood Somewhat understood Couldnot understand mostly Couldnot understand

3. How well did you understand about the surgery planned for your child explained by the resident?

Completely understood Understood Somewhat understood Couldnot understand mostly Couldnot understand

4. How well did you understand about the post-operative complications that your child may encounter explained by the resident?

Completely understood Understood Somewhat understood Couldnot understand mostly Couldnot understand

Annexure 10: Satisfaction score given by Spencer et al

Satisfaction questionnaire

Please choose one number from 1 to 4 for each question. The numbers represent:

1= strongly agree; 2=agree; 3= disagree; 4=strongly disagree

	1	2	3	4
1. I was fully involved in decision-making.				
2. I was given opportunity to ask questions.				
3. I know I had the right to refuse surgery.				
4. I had enough time to make a decision.				
5. I felt pressured to make a decision.				
6. I believe to have enough information, to make a decision.				
7. I understand the procedure of inguinal hernia repair.				
8. I understand, why my child needs the surgery.				
9. I understand, why the inguinal hernia needs to be surgically removed.				
10. I believe the surgery helps my child.				
11. I trust the surgeon to do the right thing for my child.				
12. I was satisfied with the way information was presented to me.				
13. I believe, the surgeon had enough time for me.				
14. Should my child have an inguinal hernia again, I would make the same decision.				
15. The doctor answered all my questions.				
16. I searched for information in the internet on my own.				
17. I feel save.				

Video group: Only answer these questions, if you have watched the video

	1	2	3	4
18. I believe to be better informed after watching the video compared to only verbal consultation.				
19. I would recommend the video to other parents.				
20. The video reminded me to ask the doctor more questions.				
21. I had the opportunity to ask the doctor more questions.				
22. In general, I support the concept of medical information videos.				
23. I liked the content of the video I have seen.				
24. I have watched the video more than once.				

Control group: Only answer these questions, if you have NOT watched the video

	1	2	3	4
27. I desired an online video with more information about the medical procedure.				
28. I searched the internet for more information.				

Annexure 11: Permission to use Spencer satisfaction questionnaire

Spencer, Sandra <Sandra.Spencer@nationwidechildrens.org> Wed, Dec 9, 2020, 8:09 PM
to me

Dr. Motiwala:

I apologize for the delayed response.

Please feel free to utilize the questionnaire. I hope it will be a great resource to you and your team. We would appreciate the acknowledgement.

Also, please keep me updated on how your project progresses. I would be interested to see the results. Interestingly, we just had this translated into Spanish, Somali, and Nepali (our largest language needs). We have native speakers lined up to do the recording.

Please let me know how I can be of additional assistance! Happy to help or collaborate in any way that I can.

Thank you and good luck!

Sandra

Sandra P. Spencer, MD
Associate Professor of Clinical Pediatrics
Director of Quality Improvement, Emergency Medicine
Co-Medical Director, NCH Clinical Pathways Program
Co-Program Director, NCH Pediatric Quality and Safety Fellowship
Division of Pediatric Emergency Medicine
Nationwide Children's Hospital
Sandra.Spencer@nationwidechildrens.org