DEVELOPMENT OF TOOL TO MEASURE PREOPERATIVE PARENTAL ANXIETY FOR PARENTS OF CHILDREN ADMITTED FOR SURGERY IN PAEDIATRIC WARD AT AIIMS, JODHPUR.

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Master of Science in Nursing

(Paediatric Nursing)

by

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DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled “DEVELOPMENT OF TOOL TO MEASURE PREOPERATIVE PARENTAL ANXIETY FOR PARENTS OF CHILDREN ADMITTED FOR SURGERY IN PAEDIATRIC WARD AT AIIMS, JODHPUR” has been prepared by me under the guidance of Dr. Mukesh Chandra Sharma, Associate Professor, College of Nursing, AIIMS, Jodhpur, Mrs. Remiya Mohan, Assistant Professor, College of Nursing, AIIMS, Jodhpur, Dr. Kirtikumar Rathod, Associate Professor, Dept. of Paediatric Surgery, AIIMS, Jodhpur and Dr. Tanu Gupta, Clinical Psychologist, Dept. of Psychiatry, AIIMS, Jodhpur. No part of this thesis has formed the basis for the award of any degree previously.

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CERTIFICATE BY THE GUIDE

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Ms. Theresa Jose

Date

LIST OF ABBREVIATIONS USED

ABBREVIATION	FULL FORM
AIIMS	ALL INDIA INSTITUTE OF MEDICAL SCIENCES
APAIS	The Amsterdam Preoperative Anxiety and Information Scale
χ^2	Chi-square
df	Degree of freedom
f	Frequency
HAM-A	Hamilton Anxiety Rating Scale
p	Level of significance
N	Number of subjects
PPAS	Preoperative Parental Anxiety Scale
SCAS	Spence Children's Anxiety Scale
SD	Standard deviation
STAI	State Trait Anxiety Inventory

ABSTRACT

Introduction: Surgery in paediatric patients is a kind of distressful experience for both the child and the family which is usually accompanied by preoperative anxiety due to the illness, hospitalization, fear of anaesthesia and the procedure itself. Due to the potential changes in various aspects of parental life, like change in their natural needs and socioeconomic issues, stress and anxiety would be higher for the parents of a hospitalized child. The preoperative parental anxiety shows a significant impact on the child, family functioning as well as on the parents themselves in terms of physical and psychological aspects. Therefore proper reliable and valid tools are very much necessary for the measurement of the preoperative parental anxiety. The objective of the present study was to develop a tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward.

Methods: A methodological study design was used for the development and validation of Preoperative Parental Anxiety Scale (PPAS). The development of the tool carried out in three phases, item development, scale development and scale evaluation. The items for the PPAS were generated through extensive literature review and Focussed Group Discussions and a content validation was done through the use of modified Delphi process, which yielded the tool with 28 items in 5 different domains. The PPAS was administered to 100 parents of children admitted for surgery in paediatric ward at AIIMS, Jodhpur. The reliability was tested with Cronbach's alpha. The construct validity of the tool was checked with the exploratory factor analysis

while the concurrent validity was examined using Hamilton Anxiety Rating Scale (HAM-A).

Results: The results of this study of PPAS suggest that it is a valid and highly reliable tool to measure the preoperative parental anxiety. In the 100 subjects, the reliability of PPAS was excellent with Cronbach's alpha of 0.938. The mean score of each item ranged from 0.18-2.81, with a SD of 0.5-1.269. The Mean Inter Item Correlation (MIIC) was 0.358. The concurrent validity when checked with the standardised tool HAM-A; showed a good correlation with Pearson correlation coefficient, r = 0.885. Principal Component Analysis had generated 7 factors with Eigenvalue of more than 1.00.

Conclusion: Preoperative Parental Anxiety Scale (PPAS) is a feasible and a highly reliable and valid tool to measure the preoperative parental anxiety among parents of children admitted for surgery. It accords towards the need for further more research into the measurement of the parental anxiety. Therefore physicians and nurses should pay attention to identify the areas of parental anxiety to provide high quality paediatric health care services for both children and their caregivers.

Keywords: **Tool development, Preoperative, Parents, Anxiety, Surgery**

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CHAPTER-I
INTRODUCTION

INTRODUCTION

“Anxiety in a person’s heart weighs him down, but an encouraging word brings him joy” (Proverbs. 12:25)

BACKGROUND OF THE STUDY

Lakhs of paediatric surgeries are taking place every year and among these children, preoperative anxiety is very much significant. A scheduled surgical operation in the child is really a stressful procedure not only for the child but also for the whole family. Surgery in paediatric patients is an unpleasant and potentially stressful situation which is usually followed by preoperative anxiety due to the child’s illness, hospitalization, fear of anaesthesia and the surgery itself.[1] Apart from this, preoperative period seems to be a period of uncertainty for most of the parents and most of the times detailed provision of information about surgery and complications might be lacking and this lacking knowledge could also trigger the parental anxiety.[2] Due to the potential changes in various aspects of parental life, like change in their natural needs and socioeconomic issues, anxiety would be higher for the parents of a hospitalized child.

Bevan et al.[3] reported that anxiety of relatives is a factor of great importance and influence on the preoperative anxiety levels of children and effectively contributes to the development of behavioural changes in postoperative paediatric patients.

Parental anxiety may affect the child in many ways like transfer of stress to the child which would pose negative outcomes in children at various times including both pre and post-operative period as well as during the entire

period of hospitalization specially for younger children.[4] Also, it is well established that preoperative anxiety in children may lead to negative postoperative responses, including longer hospitalization period, more pain, and long-term behavioural problems like anxiety, feeding issues, nocturnal fears, shyness, sleep disorders, bed-wetting and aggression.[5]

According to Scrimin et al.[6] children depend on parents for guidance and support in order to cope with the stressful situations, due to which parents play an important role when they undergo surgery.

Parents of hospitalized children would have a feeling of discomfort, fear, helplessness etc.[2] Many studies have shown that anxiety and depression in parents of sick and disabled children is much higher than that of parents of healthy children.[7] This would be greater when they have to prepare their child for surgery as well as during postoperative days.

When parents are stressed and exhibits higher levels of anxiety, the effectiveness of supporting their child may decline as they would also be emotionally involved in the event.[8] Also when they become stressed they face difficulties in accepting the role of caregiver, fully in the management of their sick child[9] and there would be communication issues in between the health professionals and parents, which would indirectly affect the child care.[10]

Halstorme and Elander[11] states in their research that parents of hospitalized children are also in need of support and a feeling of security. Therefore, proper psychological preparation of parents and children should be done and is essential before the surgical procedure[4] Nowadays, in the field of Paediatrics, due to the emergence of the concept of family-centred care, the

parents stay with the child during the period of hospitalization and are also encouraged to participate in the care of their child.

Many preoperative preparation programmes were developed for the reduction of preoperative parental and child anxiety in the healthcare settings. Also several other interventions like parental presence during induction of anaesthesia, play therapy, maintenance of good rapport between parents, children and health care staff, etc. found to be beneficial in reducing the surgical anxiety of both parents and children.[12]

NEED OF THE STUDY

Acute situational anxiety is a kind of subjective feeling regarding an unpleasant, fearful emotion or uneasiness which might be due to the immediate situation that can be mainly found in the hospital settings especially during the preoperative period. This preoperative parental anxiety might be mostly due to fear of possible complications, disability or death of the child, lack of knowledge, financial concerns, condition of child after surgery,etc.[13] The main stress points for parents during these period would be the admission time, preoperative investigations and also taking the child to the waiting area.[14]

The estimated incidence of preoperative anxiety ranges from 11% to 80% in adult patients. Robyn et al.[15] reported that about 51%, 24% and 26% of parents of children hospitalized in the PICU had symptoms indicative of major depression, severe anxiety and significant decisional conflict respectively. Certain study findings revealed that the overall prevalence of parental anxiety

was 74.2% among parents of children undergoing surgery regardless of the diagnosis of the child, when measured using STAI scale.[16]

Preoperative anxiety can lead to various physiological as well as cognitive symptoms. Caring at night, worries about the condition of the child, etc. would lead to sleep disturbances in both parents and children[7]. Also the parental psychological responses could vary individually and would interfere with their normal functioning.[17] The preoperative parental anxiety showed a significant impact on the child, family functioning as well as on the parents themselves in terms of physical and psychological aspects. Therefore proper reliable and valid tools are required to measure the preoperative anxiety.[18]

Many instruments had been developed in order to measure the preoperative anxiety level of patients. Most commonly used one is Spielberger's State-Trait Anxiety Inventory (STAI).[19,20] The state anxiety is considered as an emotional response to uncertainty of a potential threat. But this will be different for different groups or situations. For example, pregnant women and parents with new born may suffer anticipatory anxiety around what the future will hold for their infants. In contrast, the anxiety-related circumstance for critically ill and respiratory patients may be more immediate and physical in nature.[21]

Other instruments included the Amsterdam Preoperative Anxiety and Information Scale (APAIS), the Hospital Anxiety and Depression Scale (HADS) and the Hamilton Anxiety rating Scale (HAM-A). However these instruments possess questions that are generalized in nature that is not specific towards the preoperative parental anxiety.

As researcher could not find a clinically applicable instrument in the literature

which is specific for the assessment of preoperative parental anxiety, this study aimed to develop an instrument satisfying the mentioned condition.

AIM

The study aims to develop and test tool to measure preoperative parental anxiety for parents of children admitted for surgery.

STATEMENT OF PROBLEM

Development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur.

OBJECTIVES

1. To develop a tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward.
2. To test the psychometric properties of the tool in terms of reliability and validity.

ASSUMPTIONS

1. Parents are having anxiety before surgery of their children.
2. A proper and systematically designed approach is required for developing the tool.
3. Systematically developed tool shows different psychometric properties.
4. Prepared preoperative tool will be consistent with other standardized anxiety measurement tools.

HYPOTHESES

In order to determine the concurrent validity the following hypotheses were formulated:

- H_0 : There is no significant difference between the mean anxiety scores of both PPAS and HAM-A.
- H_1 : There is significant difference between the mean anxiety scores of both PPAS and HAM-A.

OPERATIONAL DEFINITIONS

1. **Tool :** Tool is the means by which data can be collected to measure preoperative parental anxiety.
2. **Measure:** It means to estimate the preoperative parental anxiety.
3. **Preoperative:** The time period between the admission in the ward for surgery and before going for the surgical procedure.
4. **Parental anxiety:** An emotion characterized by feelings of tension, worried thoughts and physical changes of parent in response to child's surgery such as surgery itself, anaesthesia, preoperative fasting, postoperative pain, treatment.
5. **Parents of children**: Both mother and father of children admitted for surgery in Paediatric surgery ward.
6. **Surgery**: It includes any surgery under general anaesthesia.

DELIMITATION

Study was delimited to parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur.

CHAPTER-II
REVIEW
OF LITERATURE

REVIEW OF LITERATURE

The review of literature was carried out in order to explore the factors affecting the anxiety of the parents due to the surgery of their child. The review had been conducted from various journals, articles and other previous studies using the electronic databases Pubmed, MEDLINE, CINAHL, Cochrane Library and Google Scholar. The studies that were not in English language were also taken into consideration whose English version was available. The areas under focus in this review were the preoperative parental anxiety in terms of factors affecting as well as the impact of parental anxiety. The BOOLEAN Operators, *AND/ OR* was used for the review, using the following:

- Parental anxiety AND child's surgery
- Parental anxiety AND child's anxiety
- Preoperative anxiety AND Parents OR Child
- Parental anxiety AND anaesthesia
- Parents AND preoperative period
- Parents AND anxiety AND post-operative outcome

Inclusion and exclusion criteria

The review focussed mainly on the studies containing information related to preoperative period anxiety of the parents. The studies which suggested about factors affecting the preoperative parental anxiety, impact of parental anxiety on child as well as family, the various tools used to assess the anxiety level and the measures to overcome the parental anxiety were included. Also those studies published in between the year 1971 to 2020 were considered for the review.

The strategy for search consisted of MeSH and non-MeSH index terms to make sure that all materials was included. Studies related to the assessment of anxiety other than during the preoperative period and those studies whose full text was not available were excluded. The selection of articles for review were given in the form of PRISMA flow diagram (1009)[22] as shown in figure 1.

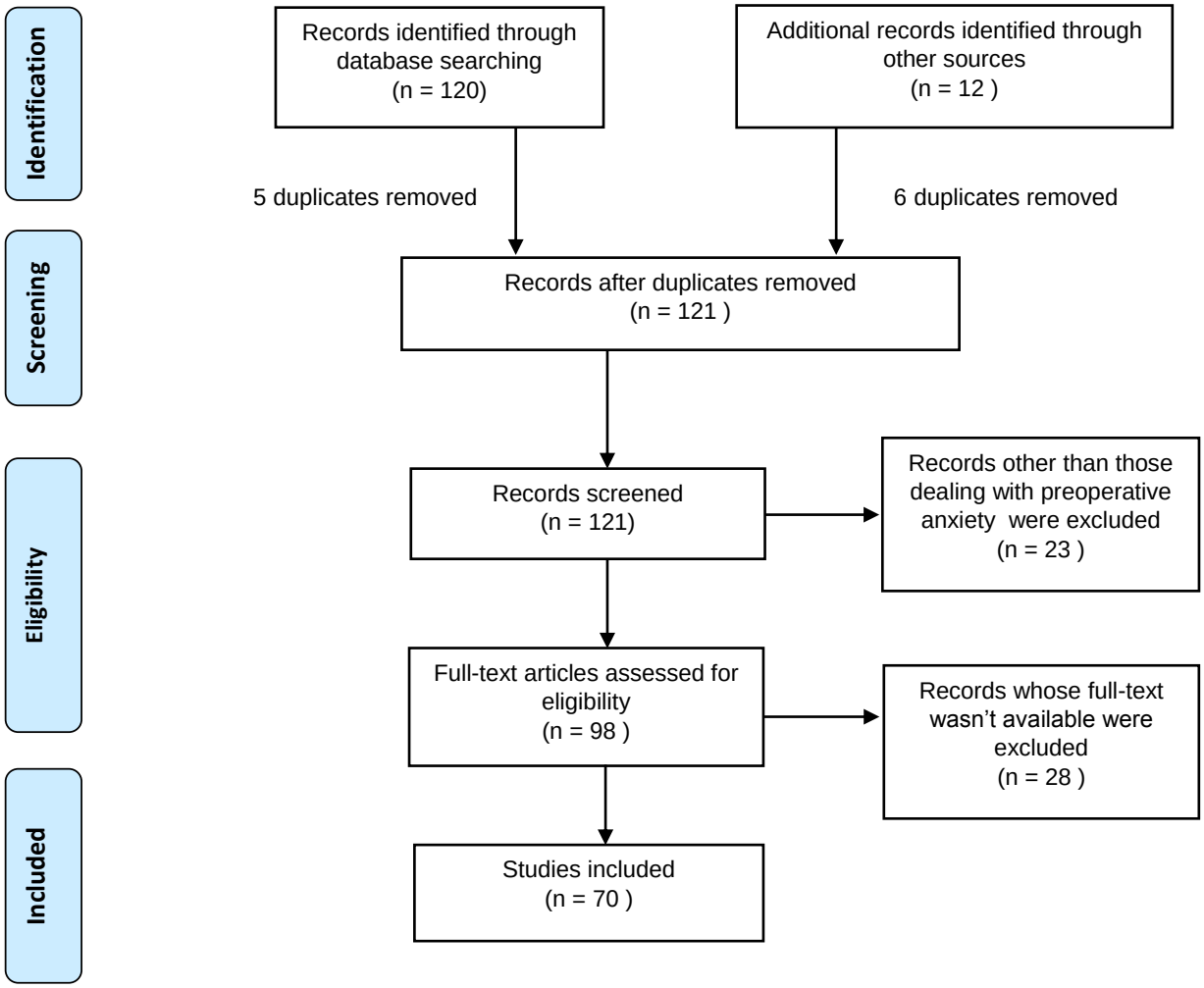

Fig 1: PRISMA flow diagram for the article selection under review

This review has been categorized into following sections:

I. Factors affecting the parental anxiety regarding their child's surgery

II. Tool development and validation studies related to anxiety

I. Factors affecting the parental anxiety regarding their child's surgery

Shirley et al.[23] conducted an investigation to measure the anxiety levels in 100 parents of children scheduled for elective surgery at the Royal Aberdeen Children's Hospital utilizing Leeds scale for self-assessment of anxiety. The results showed that forty-two per cent of parents were significantly anxious about the surgical procedure, anaesthesia, postoperative pain and treatment, and hospitalisation by large, out of which mothers being more anxious. The findings demonstrated that all parents, whether recognized as anxious or not, agreed on factors likely to lower anxiety: pre-operative information from staff, having an option to accompany their child to the operating theatre and being available at induction of anaesthesia.

A study conducted by **Thompson et al.**[24] expected to identify the occurrence and explicit sources of anxiety in hundred parents of children under thirteen years of age admitted to hospital for elective surgical procedure, to isolate factors associated with expanded anxiety and to identify useful ameliorative measures**.** The outcomes indicated that surgery, anaesthesia, pre-operative fasting, postoperative treatment, postoperative pain and hospitalisation are the major considerations that are impacting the parental anxiety before surgery of their child.

Charana et al.[1] led a study to survey the effect of specific demographic qualities in parent's and children's preoperative anxiety among 128 Greek-speaking children (1–14 years of age) who needed to go through minor surgery in a University General Hospital using STAI and socio- demographic questionnaire for parents and modified-YPAS for children. The results uncovered that the major indicators associated with the parental anxiety were

child's age, gender, area of residence, being a mother, single child, premedication and education level.

A descriptive study done by **Laura et al.**[25] to research on pre and postoperative anxiety levels in parents of surgical patients on a day before and after surgery and to identify factors that affect parental anxiety among one hundred and one parents of children undergoing surgery at a healthcare facility in Italy, utilizing an Italian version of the State-Trait Anxiety Inventory Form Y questionnaire. Findings suggested that mothers were more anxious than fathers and passing of information regarding pre and post-surgery nutrition, pain management, anaesthesia tend to reduce parental anxiety levels while that of possible complications increased parental anxiety.

ANXIETY

In general, anxiety can be defined as an emotion characterized by feelings of tension, worried thoughts and physical changes like raised blood pressure.[26] It could be considered as a universal emotion which could be enhanced by real or perceived threats.[27-30] Preoperative anxiety could be related with the feelings of apprehension, fear and worry during the period before the surgery. Preoperative period is very stressful for both parents as well as children due to which various behavioural and physiological alterations could be seen in them.[2,30]

1. FACTORS RESPONSIBLE FOR PREOPERATIVE PARENTAL ANXIETY:

The review findings showed that the considerable factors affecting the anxiety level of the parent during preoperative period were the type of surgery, type of

anaesthesia, preoperative information accessibility, pre-operative fasting, fear of postoperative pain and treatment, fear of death and previous history of surgery in general, out of which mothers being more anxious. Review findings also revealed that the other factors like concern about the family, intraoperative and postoperative pain of the child, chances of disability, fear of both anaesthetic and surgical complications, fear of surgical mistakes, fear of not awakening after the general anaesthesia, fear of economic loss due to the treatment costs, fear of loss of one's normal social life and fear of blood transfusion requirement, cosmetic problems the child might face after surgery[10,23] as well as the length of hospital stay after surgery[31] also influence the level of parental anxiety during preoperative period. Additional factors also involve the social contacts of the parents,[6] parental perception of the external locus of control of child's health,[6,32,33] parental separation[34] and period of recovery.[35] Evidences also suggested that the major predictors associated with parental anxiety in terms of specific demographic characteristics were child's gender[31] and age, gender of the parent, area of residence, socio-economic status, being a mother, single child and education level, spirituality and occupation. Other factors responsible for anxiety levels of parents were the psychological features like low self-efficacy, poor coping mechanisms[16] and the anxiety of the child itself.

Type of Surgery

The type of surgery or severity of the surgery described as major or minor or day surgery could be considered as a factor that could make the parents anxious during the preoperative period. Parents found to be more anxious

when their child's surgery was a major one as compared to day surgery.[6] Also a large proportion of parents (42%) were anxious to the point of illness.[23]

As per **Salgado et al.** [36] parental anxiety was reported to be higher for paediatric cardiologic and urologic surgeries than other systems.

Anaesthesia

Fear of surgery and anaesthesia was reported to be one of the factors causing increased parental anxiety.[37]

Parental presence during the induction of anaesthesia: Study finding[38] revealed that anxiety would be higher in those mothers who had shown an increased desire to be present during the induction of anaesthesia of their child. For some parents, observing their child falling asleep could elicit the anxiety levels in them if they were allowed to be present during induction of anaesthesia.[2,39]

In contrast, other study findings [40-43] suggested that parental presence during induction of anaesthesia seemed to reduce both child and parental anxiety.

Type of anaesthesia: Anxiety is higher for general anaesthesia (89%) than that with spinal (6.9%) and local (3.5%).[16]

Preoperative Information Accessibility

Anxiety is higher if preoperative information is not available (56%) i.e. lack of information could also be a factor affecting preoperative parental anxiety.[2] Also, preoperative information enhances the parental cooperation with the staff and could help them to control their anxiety levels.[42-45] Parents

expressed a high desire for preoperative information[43,44] among whom mothers tend to be having more information seeking behaviour [13,45]

In contrast to this, certain other studies[16,23,24,46] showed that there is no significant difference between the levels of anxiety before and after the provision of anaesthetic information. Some studies suggested that preoperative information doesn't increase the anxiety level[4,41] while other study also adds that it even won't decrease the level of anxiety.[4] Also in case of parents who are showing distress, the ability to take up information would be less.[10]

Fear of Death

The parents of children undergoing surgery tend to have fear regarding the death of their child or hospitalization of their child in ICU's.[36] According to **Ayenew et al.**[16] majority of the parents expressed a fear of the death of their child (80%).

Previous Experience of Surgery

One study finding[47] reported that parents with a prior experience of more than ten years of a surgery under anaesthesia seemed to have decreased levels of anxiety while those with less than ten years of surgical experience showed higher levels of anxiety. Literature also suggests that the previous surgical or anaesthetic exposure revealed to lower the anxiety level in preoperative period by reducing the misunderstandings and fear of unknown.[48,49]

There is a study[50] which suggested that previous experience of surgery would relate to higher anxiety level if they had already undergone stressful events ever during previous surgery.

But in contrast to this many other literature findings [13,51,52] revealed that there is no effect of previous experience to anaesthesia on preoperative anxiety. There is also suggestion that maternal experience of a previous surgery doesn't have a significant association with the maternal anxiety in predicting the level of anxiety.[45]

Fear of Postoperative Pain Of The Child

About 86% of the parents had a fear of the postoperative pain of their child and the fear being higher regarding the first 24 hours of surgery.[52] This is in support with several other studies from the literature.[13,16,23,24]

Parental Separation

Parental separation is another factor that is associated with the anaesthesia related anxiety for both child and the parents and is more significant with maternal separation.[34]

Postoperative Treatment

Certain study findings[23,24] suggested that parents were highly anxious about the post-surgical treatment of their child.

Recovery

In another study[35] the author claimed that parental anxiety decreased from preoperative to postoperative period but the level remained to be higher showing that parents seem to be anxious about the recovery of their child.

Parental Perception About External Locus of Control Of Health

In a study conducted by **Scrimin et al.** [6] it was found that the parental external locus of control of their child's health was related to decreased anxiety levels. This was in contrast with the other literature findings[32,33] which proposed that external locus of control of health is associated with increased levels of

parental stress which might be because of the fact that the during hospitalization, parents rely on the healthcare staff for the care and health related activities of their child than their own efforts.

Child's Anxiety on Parents

There were many other studies from the literature that reported that child's anxiety and parental anxiety are directly correlated to each other. The child's anxiety could increase the parental anxiety and vice-versa.[16,23,24,30,53-56] According to **Kain et al.**[54] small children in between the age of one to five years tend to show high preoperative anxiety.

Social Contacts

Anxiety could also be associated with the number of social contacts of the parents in terms of friends and relatives. The parents with higher anxiety expressed their need for the support from their family and peers.[6] According to **Shirley et al.**[23] less than sixty percent of the parents had a fear about the loss of one's social life.

Specific Demographic Characteristics

Gender of the parents: Several studies were suggestive of the fact that mothers seemed to show higher anxiety levels than fathers. Also they were about four times more anxious in comparison with fathers.[1,16,23,34,57,58] There is another study[45] which reported that mothers appear to be highly anxious for their child's surgery comparing to women undergoing surgery themselves.

Gender of the child: The maternal anxiety was not associated with the gender of the child during induction of anaesthesia as per some studies[13,45,59] while in a study conducted by **Charana et al.**[1] it was concluded that parental anxiety is higher if the child undergoing surgery is female.

Age of the parents: The parental age is not directly proportional to the higher levels of anxiety which could be explained by the fact that as the parental age increases, better would be the coping abilities.[6,45]

Age of the child: Parents especially mothers seemed to be more anxious if their child is of younger age[45,55] and is more if the age is less than a year and is in between ten to eighteen years.[16,60-62] Similar finding was reported by **Charana et al.**[1] in their study suggesting that parental anxiety would be high if the child's age is less than 5 years.

This was in contrast with the findings of other studies[13,25] in which they couldn't find any association between maternal anxiety and child's age.

Parental education: According to **Scrimin et al.**[6] levels of anxiety in parents was associated with the years of their education. Well educated parents tend to show fewer acute stress symptoms than those with less education and the coping abilities of the former being better when comparing with the latter.

But these findings were in divergence with the other literature findings[45,63] which revealed that higher education level is associated with higher levels of stress.

While other studies[13,64] suggests that there is no association between maternal education level and anxiety level.

There is another study[1] which reported that either higher or lower level of education, parental anxiety tends to be higher always during preoperative period; former one due to detailed knowledge of surgical risks while latter due to lack of knowledge.

Spirituality: In a study conducted by **Tabrizi et al.**[12] it was reported that the maternal spiritual beliefs helped in relieving the parental anxiety levels. There is also a study[65] evidence that spirituality was related to good levels of self-esteem which could thereby lead to decreased levels of anxiety.

Area of residence: There are many study findings[1,30,66] which revealed that those families residing in urban areas tend to have lower level of anxiety than rural residents.

According to **Ayenew et al.**[16] majority of the parents expressed about their concern for other family members due to child's hospitalization, fear of death of their child, intraoperative and postoperative pain that their child would have to suffer, the future condition of their child, chances of disability of their child, complications related to surgery and anaesthesia. One-half of the parents had a fear of economic loss, the requirement for blood transfusion of the child during surgery, a cosmetic problems that might arise after surgery.

According to **Shirley et al.**[23] more than 70% of the parents had a fear of the anaesthetic complications while about 79% of the parents were more worried about the surgical complications. Parents also expressed a fear regarding the chances of surgical or medical mistakes (57%).

2. **PERIOD OF PREOPERATIVE PARENTAL ANXIETY**: The main stress points for parents during these period would be the admission time, preoperative investigations and also taking the child to the waiting area.[14,67]

3. IMPACT OF PREOPERATIVE PARENTAL ANXIETY:

The impact of preoperative parental anxiety could be identified in terms of what or who is being affected with it. Therefore, the impact was categorized under the following headings:

Impact on parent itself: The change in established parenting role, demand for an adaptation to the new hospital environment, feeling of helplessness in caring their child, difference in perception of parenting role by the staff and the parents themselves, behavioural change in learning the role of staff in caring the child were found to be the major effects of hospitalization of the child on parents.[14,68] The impact could be both physical, psychological, social and financial.

The physical impacts consist of fatigue, insomnia, palpitation, restlessness, poor appetite, changes in elimination habit, etc. and the psychological impacts include feeling of anger, boredom, anonymity, lack of privacy, deperso-nalization during these period. Disruptions in family functioning and other social relationships would be included in the social impact while inability to go for job or loss of job and increased costs of child care leading to the economic crisis of the family were the major financial impact factors on the parents.

Impact on ill child: The parental anxiety and other demographic features of the child showed significant impact on the anxiety of the child in terms of postoperative outcomes including longer hospitalization period, more pain, and long-term behavioural changes such as initial aloofness to the parents followed by showing dependency and negative behaviour like hyperactivity,

temper tantrums, regression in newly learned skills, emotional coldness, anger etc.[5,54,69]

Impact on children in the home: Parents often felt that the children at home were being neglected especially the younger ones as the parents, mostly mothers were involved in caring the sick child at hospital.[41] Also, siblings at home might develop a feeling of anger, loneliness, fear, resentment and jealousy towards the ill child.

Impact on other family members: Parents often complaints of the pending household works,[18,70] inability to take care of other family members and also the disruption in normal family functioning in terms of social, economic and spiritual functioning.

II. Tool development and validation studies related to anxiety

Maier et al.[69] conducted a study to test the validity and reliability of the Hamilton Anxiety Scale (HAM-A) in two unique samples with anxiety disorders [N=97] and with depressive disorders [N=101]. The reliability and the concurrent validity of the HAM-A and its subscales was ended up being adequate while the internal validity was found to be deficient upon being tested by latent structure analysis.

Meyer et al.[70] conducted a study to develop the Penn State Worry Questionnaire (PSWQ) among 1,580 college students consisting of sixteen items using factor analysis. The findings revealed that the questionnaire had high internal consistency and good test–retest reliability.

Maaike et al.[71] directed a research study to examine the psychometric properties of the parent version of the Spence Children's Anxiety Scale (SCAS-P) in which 484 parents of anxiety disordered children and 261 parents in a normal control group were taken on interest. Results of factor analysis upheld for six intercorrelated factors, that corresponded with the child self-report just as with the order of anxiety disorders by DSM-IV. The reliability and validity of the subscales were found to be satisfactory to excellent. The SCAS-P is recommended as a screening instrument for normal children and as an indicative instrument in clinical settings.

Wan et al.[72] conducted a study to develop and evaluate the Parenting to Reduce Child Anxiety and Depression Scale (PaRCADS) as a measure to assess parenting against a bunch of evidence-based parenting guidelines for the anticipation and prevention of child anxiety and depressive problems. In the 1st study, 355 parents and their children of 8–11 years old across Australia completed the PaRCADS and measures of parenting, general family functioning, child anxiety and depressive symptoms, and parent and child health-related quality of life. In 2nd study, six subject-experts independently evaluated the PaRCADS items. Findings involved removal of four items to yield a 79-item, 10-subscale PaRCADS. The reliability ranged from .74 to .94 and convergent validity was indicated by moderate to strong correlations with other parenting and family functioning measures while discriminant validity was supported by small to moderate correlations with a measure of parents' health-related quality of life. Results uncovered that the PaRCADS demonstrated adequate psychometric properties due to which it can be used as a measure of parenting risk and protective factors for child anxiety and

depression for intervention and evaluative purposes in preventive programs and research.

Amanda et al.[73] in a study to develop and validate Anxiety Symptoms Questionnaire [ASQ] to improve assessment of anxiety symptoms in a clinical setting examined the reliability and validity of the ASQ in 240 patients with anxiety disorders and/or depression, 111 non-clinical control subjects and 487 college students using Factor analysis, Pearson's correlation coefficients and logistic regression. The findings revealed that it is a reliable and valid self-rated anxiety criteria that can be used for screening and assessing anxiety symptoms in psychiatric as well as college settings.

Zigmond et al.[74] in a study to develop a self-rated Hospital Anxiety and Depression Scale to detect the states of anxiety and depression in the hospital outpatient setting among one hundred adults between the ages of 16 and 65 who suffered from a wide range of illnesses and complaints. The correlations ranged from +0.76 to +0.41 and the significance was $P < 0.01$ for the anxiety items. The findings suggested that HAD can be used as a reliable and valid tool for screening of clinically significant anxiety and depression in patients attending a general medical clinic.

Linda et al.[75] conducted a research to develop a shortened state anxiety scale from the 20-item Spielberger State Anxiety Inventory among two-hundred ventilated patients from nine ICUs in the urban Midwest. A 6-item scale was developed using exploratory factor analysis techniques with 66.66 percent of the variance and a correlation of 0.92. The investigation discoveries recommended that the shortened scale indicated a large number

of the desirable properties of the full-length version and extra exploration is needed to additionally validate this shortened scale.

Houtman et al.[76] conducted a study to validate and test the reproducibility of the anxiety thermometer which is either a continuous or a 10-point Likert-type scale on which subjects were asked to rate their anxiety feelings at a particular moment. The State-Trait Anxiety Inventory (STAI) A-State scale was used as a validation criterion and test-retest correlation coefficient was calculated to test the reproducibility of the thermometer. The findings revealed that the validity and reproducibility of the anxiety thermometer is fair with correlation coefficients between 0.60 and 0.78.

Yeseul et al.[77] conducted a study to evaluate the psychometric properties of the Korean Anxiety Screening Assessment (K-ANX) developed for screening anxiety disorders among 613 subjects. The reliability was checked using Cronbach's alpha, item-total correlation, and test information curve and validity by using focus group interviews, factor analysis, correlational analysis and item characteristics based on item response theory (IRT). The results revealed that the K-ANX has a higher sensitivity (0.795) and specificity (0.937) when compared with the Beck Anxiety Inventory (BAI) and Generalized Anxiety Disorder 7-item scale (GAD-7).

Standard tools available to measure anxiety

Even though different instruments were available to measure anxiety level of parents, STAI was used widely. The state anxiety is considered as an emotional response to uncertainty of a potential threat. But this will be different for different groups or situations. For example, pregnant women and

parents with new born may suffer anticipatory anxiety around what the future will hold for their infants. In contrast, the anxiety-related circumstance for critically ill and respiratory patients may be more immediate and physical in nature.[14]

Various studies revealed the use of different scales of measurement of parental anxiety, out of which a few are described below. The findings were summarised in Appendix-XV.

State-Trait Anxiety Inventory (STAI): Being published first in 1970 by Charles Spielberger et al. it had undergone a revision in 1983, changing it from STAI-X to STAI-Y. This is a self-reported 4-point questionnaire, ranging from 1-4, which consisted of 2 subscales assessing both state (situational) as well as the trait anxiety with 20 items in each subscales having a score of 20-80. The STAI form Y-1 had points 1 (not at all), 2 (somewhat), 3 (moderately), 4 (very much so) while the STAI form Y-2 comprised of 1 (almost never), 2 (sometimes), 3 (often), 4 (almost always). The time required for execution would be 10-30 minutes in paper and pencil administration and is available in almost 48 languages.[78]

Hospital Anxiety And Depression Scale-Anxiety (HADS-A): HADS was developed by Zigmond and Snaith in 1983. This is an either self or interviewer administered 14 itemed tool developed for assessing the generalized symptoms of anxiety and depression with 7 items each, in terms of tension, fear, worry, panic, difficulties in relaxing and restlessness on a 4- point scale, ranging from 0-3. Different responses are used for rating each point depending upon the items being assessed like not at all, from time to time, a lot of the time, most of the time (tension), not at all, a little but doesn't worry

me, yes but not too badly, very definitely and quite badly (frightened feeling), only occasionally, from time to time but not too often, a lot of the time, a great deal of time (worrying thoughts), definitely, usually, not often, not at all (relaxed), not at all, occasionally, quite often, very often (butterflies in stomach), not at all, not very much, quite a lot, very much indeed (restless) and not at all, not very often, quite often, very often indeed(panic feelings) with a score of 0 to 3 in respective order for each. The time required for completion would be about 3-5 minutes in paper and pencil administration and was translated in different languages.[78]

Hamilton Anxiety Rating Scale (HAM-A): This is a clinician rated 5-point rating scale developed by M. Hamilton in 1959 which is used to assess the severity of anxiety symptoms consisting of 14 items with a range of 0-4 (not present, mild, moderate, severe, very severe) that measures psychic and somatic anxiety. The time required for administration would be about 10-20 minutes and has been translated in different languages. [78-80]

Beck Anxiety Inventory (BAI): It is a 4-point Likert scale developed by Aaron T. Beck, MD in order to measure anxiety regarding the somatic symptoms and to screen from depression with a range of 0-3 (not at all, mildly but it didn't bother me much, moderately- it wasn't pleasant at times, severely- it bothered me a lot). The time required for administration would be about 5-10 minutes. Different language translations were available. [78,81-83]

Zung Anxiety Rating Scale (SAS): It is a self- reported norm referenced 4-point rating scale developed by William W.K. Zung M.D to measure the levels of anxiety in terms of cognitive, autonomic, motor and central nervous system

symptoms. The scale ranges from 1-4 (a little of the time, some of the time, good part of the time, most of the time) with a score between 20 to 80.[84,85]

The Amsterdam Preoperative Anxiety and Information Scale (APAIS): This tool was developed in 1996 by Moerman N et al.[20] which consists of two subscales on anxiety and need for information with a total of 6 items that were been rated on a 5-point rating scale ranging from 1-5 (not at all, somewhat, moderate, moderately high, extremely).[86,87]

Spence Children's Anxiety Scale (SCAS): Being published in 1998 by Susan H. Spence, SCAS was a self-reported 4 point scale with 44 items divided in six subscales of panic disorder, agoraphobia, generalised anxiety disorder, obsessive compulsive disorder, separation anxiety disorder and specific phobias (fear of physical injury). The child version comprised of the use of all 44 items while the parent version excluded the 6 positive items making it into 38 itemed scale with the score ranging from 0-3 (never, sometimes, often, always). It is available in various languages including Italian, Turkish, Hindi, etc. and the time for administration would be about 5-10 min.[88]

PaRCADS: This scale was developed by Wan Hua et al. which consisted of 83 items originally with 10 domains. It used the terms like almost never, rarely, sometimes, often, almost always for rating. It had a moderate to strong convergent validity with other parenting and family functioning measures along with reliability ranging from 0.74-0.94.[72]

Anxiety Symptoms Questionnaire (ASQ): It is a 17 itemed scale developed by Amanda et al. which assess the intensity and frequency of anxiety symptoms during the past one week for an individual. This 10 point Likert

scale ranges from 0-10 for intensity and frequency each with a total score of 340. The time required for administration is about 10 minutes.[73]

Mood and Anxiety Symptom Questionnaire (MASQ): MASQ is a 90 itemed questionnaire developed originally by Watson and Clark under 3 major domains of general distress, anxiety arousal and anhedonic depression. This 5 point scale ranging from 1-5 (not at all, a little bit, moderately, quite a bit, extremely) had been translated into various languages and the shorter versions of 62 and 26 items were also available. For the short version of 30 items, the time required for administration is 10 minutes.[89]

Perceived stress scale (PSS): This scale was developed by Sheldon Cohen. It is an instrument which measure the perception of stress towards the stressful life situations in one's life. It consisted of 10 items on a 5 point Likert scale ranging from 0-4 (never, almost never, sometimes, fairly often, very often) with the score in between 0 to 40. Being translated in different languages including Hindi, it requires about 5-10 minutes for the completion of questionnaire.[90,91]

Depression Anxiety Stress-Scale (DASS): The original version was developed by Lovibond which consisted of 42 items was later shortened into 21 items. DASS 21 contained 3 domains of depression, anxiety and stress with 7 items in each domain. It is a 4 point Likert scale ranging from 0-3 (Did not apply to me at all, applied to me to some degree, or some of the time, applied to me to a considerable degree or a good part of time, applied to me very much or most of the time) with a score of 0-126. The scale is a widely used measure for assessing the symptoms of depression, anxiety and stress

in non-clinical as well as clinical settings. Translations were available in different languages including Hindi.[92]

GAD 7: This scale was originally developed by Spitzer et al. in 2006 which is used as severity indicating and screening scale for generalized anxiety disorder. This 7 item Likert scale ranges from 0-3 (not at all, several days, more than half the days, nearly every day) with a total score of up to 21. It had a specificity of 82% and a sensitivity of 89% for a threshold score of 10.[93]

Various terminologies used in standardized tools to denote anxiety and stress:

STAI used the wordings like feel tense, strained, at ease, upset, worrying, frightened, nervous, jittery, indecisive, confused, steady, relaxed, content, comfortable, secure, calm, pleasant, nervous, restless, satisfied, difficulties, disturbing thoughts, feel inadequate, unimportant thoughts, disappointments, steady, state of tension or turmoil to denote anxiety.

HADS contain terminologies such as tense or wound up, enjoy, frightened, feeling of, Worrying thoughts, at ease, feel relaxed, slowed down, feeling like 'butterflies' in the stomach, lost interest, restless, feelings of panic.

HAM-A included terms like worries, anticipation, fearful anticipation, irritability, tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax, being left alone, difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors, difficulty in concentration, poor memory, loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing, pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice,

increased muscular tone, tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation, tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat, pressure or constriction in chest, choking feelings, sighing, dyspnea, difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, looseness of bowels, loss of weight, constipation, frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair, fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing.

BAI used the terminologies of numbness or tingling, feeling hot, wobbliness in legs, unable to relax, fear of worst happening, dizzy or lightheaded, heart pounding/ racing, unsteady terrified or afraid, nervous, feeling of choking, hands trembling, shaky/ unsteady, fear of losing control, difficulty in breathing, fear, scared, indigestion, faint, face flushed to indicate anxiety.

SAS contain wordings such as feel, nervous, anxious, afraid, get upset easily, feel panicky, falling apart, shake and tremble, bothered, headaches, neck and back pain, weak, tired easily, heart beating fast, dizzy spells, fainting spells or feel like it, numbness and tingling, stomach aches or indigestion, empty my bladder often, dry and warm, hot and blushes, fall asleep, good night's rest, nightmares for denoting anxiety.

APAIS used the expressions like worried, anesthetic, continually, as much as possible, procedure for assessing the preoperative anxiety and information scale.

SCAS included terminologies like worry, scared, afraid, suddenly feel, trouble, can't seem to get, something bad, tremble or shake, heart beats really fast, funny feeling in stomach, heart starts to beat too quickly for no reason and get bothered in their English version while the Hindi version used the words like चिंता, भय, दिक्कत, डर, ठीक नहीं, अनर्थ, सांस नहीं ले पा रही हूं, जांचना पड़ता, घबराहट, परेशानी, धड़कन तेज, कांपना या धरधराने लगता हूं, कुछ बुरा न हो जाए, समस्या.

PaRCADS used the words like upset, feel angry, giving up on tasks, feels discouraged, something is bothering, anxious, struggling with problems, face situations, manage, strategies to calming, stress, seeking help, dealing with problems.

ASQ itself used the expressions such as anxiety, nervousness, worrying, irritability, muscle tension or tightness, trouble relaxing, trouble falling or staying asleep, fatigue or lack of energy, problems with concentration or attention, trouble remembering things, shortness of breath, chest tightness or pain, pounding/skipping/racing heartbeat, stomach upset, nausea, constipation, diarrhoea or irritable bowels, dizziness, light headedness, headaches, trembling or shakiness, numbness, tingling, excessive sweating, flushing or frequent urination, feeling restless, keyed up, or on edge, anticipating or fearing something bad might happen, trouble functioning at home, work, or socially due to anxiety for assessing the anxiety symptoms.

MASQ contained terms of felt afraid, startled easy, felt confused, felt sad, alert, felt discouraged, nauseous, felt like crying, diarrhoea, felt worthless, felt nervous, depressed, irritable, faint, felt uneasy, felt really bored, felt hopeless, blamed myself, numbness or tingling, afraid I was going to lose control, felt

dissatisfied, trouble remembering things, felt like I didn't need much sleep, nothing was very enjoyable, something awful will happen, did not have much of an appetite, pessimistic, pain in my chest, failure, hot or cold spells, restless, trouble falling asleep, trouble staying asleep, dizzy or lightheaded, unattractive, short of breath, sluggish or tired, shaky, unable to relax, choking, unable to laugh easily, upset stomach, felt inferior, lump in my throat, slowed down, dry mouth, muscles twitched or trembled, muscles were tense or sore, trouble making decisions, going crazy, afraid, disappointed, worried, heart was racing or pounding, trouble concentrating, tense or "high strung", trembling or shaking, trouble paying attention, urinate frequently, trouble swallowing, tired or fatigued.

PSS used the phrases like upset, felt, unable to control, nervous, stressed, confident, cope, irritations, angered, difficulty, piling up, overcome to indicate stress in their English version while the Hindi version used the words like अप्रत्याशित, परेशान, नियंत्रित, घबराहट, तनाव, समस्याओं, आत्मविश्वास, निपटा, चिड़चिड़ाहट, नियंत्रण के बाहर, गुस्सा, मुसीबत.

DASS 21 English version contained terminologies like found it hard, aware of, dryness of my mouth, couldn't seem to, experience, positive feeling at all, breathing difficulty, excessively rapid breathing, breathlessness in the absence of physical exertion, difficult to, work up, initiative to do things, tended to, over-react, trembling, worried, nothing to look forward to, agitated, difficult to relax, down-hearted and blue, intolerant, close to panic, unable, enthusiastic, worth much, aware, sense of heart rate increase, heart missing a beat, scared, meaningless while that of Hindi version consisted of expressions like क्षीणता, कमी, मुंह सुखना, सकारात्मक भाव, अनुभव, सांस लेने में तकलीफ, सांस

का फूलना, दिक्कत, कांपना, घबरा, चिंतित, बेवकूफी, दोषी, घबराया, मुश्किल, उदास और दुखी, आतंकित, असमर्थ, भावुक, दिल की धड़कन को महसूस, तेज गति से धड़कन या कभी रुक जाना, डर, जीवन सार्थक नहीं to denote the construct.

GAD-7 included the terms such as feeling, nervous, anxious or on edge, control, worrying too much, trouble relaxing, restless, hard to sit still, becoming easily annoyed, irritable, afraid.

Common Terminologies

The terminologies used in common in the English version of the above standardised tools by various researchers were feel tensed, upset, worrying, nervous, restless, frightened, irritability, trembling, shaky, inability to relax, difficulty in falling asleep, fatigue, nightmare, difficulty in concentration, loss of interest, pains, hot and cold flushes, palpitations, chest pain, muscle tightness, fainting, dizziness, light headedness, constipation, nausea, flushing, hand tremors, numbness or tingling, afraid, terrified, scared, fear, anxious, falling apart, tired, weak, bothered, heart beating fast, feel angry, shortness of breath, chest tightness, excessive sweating, flushing or frequent urination, trouble functioning, felt confused, felt really bored, disappointed, stressed, dry mouth, fearing something bad might happen, while that of the Hindi version consisted of सांस लेने में तकलीफ, दिक्कत, कांपना, घबरा, चिंतित, तेज गति से धड़कन, डर, परेशान, चिंता, भय to denote the anxiety.

CHAPTER-III
RESEARCH METHODOLOGY

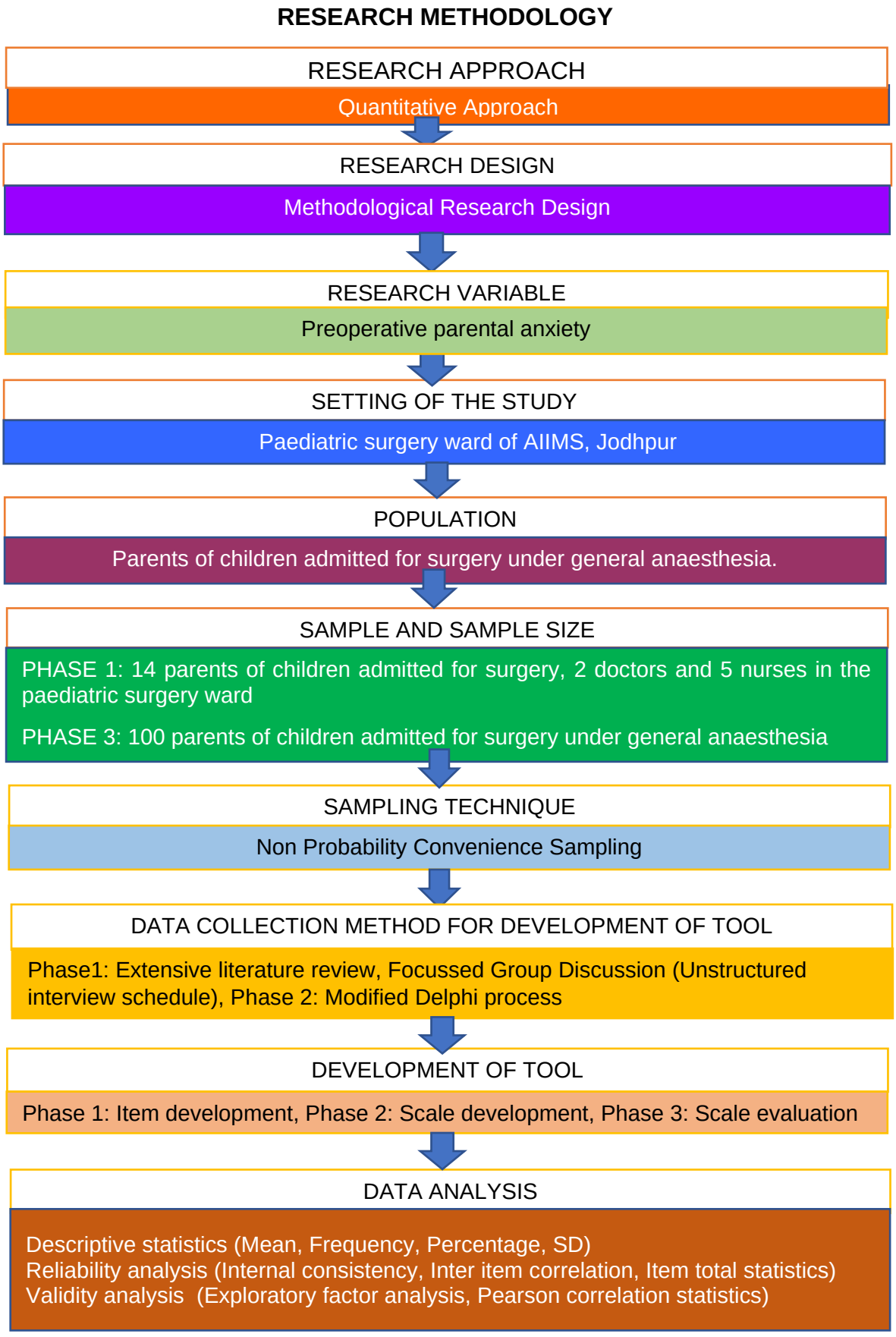

Fig 2: Diagrammatic representation of research methodology

RESEARCH METHODOLOGY

Research methodology could actually be considered as a systematic, organized and structured way to get solutions to the research problem. It includes all the steps, strategies, procedures and the entire course of action for undertaking the research study. This chapter deals with the research methodology adopted for 'Development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur'. It gives a detailed description of the research design, variables, setting, population, sampling technique, sample and sample size, inclusion and exclusion criteria for samples, ethical consideration, method of data collection and steps of tool development.

RESEARCH APPROACH

Quantitative research approach was used in the current study. It is the systematic and empirical investigation of observable phenomena in terms of statistical or computational methods.

RESEARCH DESIGN

Research design refers to the entire framework or blueprint of the process chosen by the researcher in order to carry out a particular study. In the present study, the research design used was methodological research design. Methodological research design is the process used for the development of a reliable and valid instrument for the purpose of measurement of particular constructs under investigation. It is focussed to develop or refine methods of obtaining, organizing or analysing the data.

RESEARCH VARIABLE

In the present study, the research variable is preoperative parental anxiety. The socio-demographic variables include parent, gender of child, age of parent and child, religion, area of residence, education and occupation of parent, socioeconomic status, type of family, number of children, birth order of the child admitted for surgery, previous experience of hospitalization and previous experience of surgery.

STUDY SETTING

Appropriate selection of the study setting is an essential factor while conducting a research as it would pose a major influence in data collection. The study setting is the physical location or environment where the study actually takes place. This study was conducted in Paediatric surgery ward at AIIMS, Jodhpur. The Head of the Department of Paediatric Surgery is Dr. Arvind Sinha. The Paediatric Surgery ward is located on the second floor D-Block of IPD building in AIIMS, Jodhpur, with a bed strength of 31 including 3 beds reserved for neonatal unit. Both preoperative as well as postoperative paediatric cases were admitted here.

POPULATION

Population refers to the overall cases that fulfils a designated sets of criteria for a given study. By defining the study population, it is possible to identify the group in which results could be generalized. In this study, the study population comprised of all the parents of children admitted for surgery under general anaesthesia.

SAMPLE AND SAMPLE SIZE:

Sample is the subset of a population that were chosen from the entire study population, fulfilling the sampling criteria from whom the actual data would be collected.

In the item development phase (phase 1), in order to develop the items**,** 2 doctors and 5 nurses in the paediatric surgery ward and 14 parents of children admitted for surgery under general anaesthesia in Paediatric surgery ward at AIIMS Jodhpur were selected for Focussed Group Discussion. The recommended number of members in a focussed group is about 6-12. [94-96] For the administration of the tool, a sample size of 200-300 subjects is recommended so that factor analysis could be done.[97] But, since sampling inadequacy was present due to COVID-19 pandemic, in the scale evaluation phase (phase 3), 100 parents of children admitted for surgery under general anaesthesia in Paediatric surgery ward at AIIMS Jodhpur were only selected.

INCLUSION CRITERIA:

In the item development phase (phase 1), for the purpose of item development, parents who speaks Hindi and doctors and nurses working in the paediatric surgery ward for a duration of not less than 1 year and those who were willing to participate in the study were included.

In the scale evaluation phase (phase 3), for the purpose of scale evaluation**,** parents who can read Hindi and those parents who were willing to participate in study during the period of data collection were included.

EXCLUSION CRITERIA:

In the item development phase (phase 1), in order to develop item**,** the exclusion criteria involved any emergency surgery, delayed growth of the child and illiterate parents and the doctors and nurses with an experience of less than 1 year in the paediatric surgery ward.

In the scale evaluation phase (phase 3), in order to evaluate the scale**,** parents of children having any emergency surgery, delayed growth of the child and illiterate were excluded from the study.

SAMPLING TECHNIQUE

Non – probability convenience sampling was used in this study in which the most readily available parents, doctors and nurses were selected as the study subjects. Convenience sampling is a sub type of non-probability sampling that involves selection of those subjects from the population as per the readily availability of the subjects and the convenience of the researcher.

DATA COLLECTION METHOD FOR DEVELOPMENT OF TOOL:

In the item development phase (phase 1), in order to develop item**,** an extensive review of literature and Focussed Group Discussions (FGDs) were carried out. Literature review conducted from various journals and databases. FGDs were carried out among 2 doctors and 5 nurses in the paediatric surgery ward and 14 parents of children admitted for surgery under general anaesthesia through an unstructured face-to-face group interview of about 40-45 minutes duration and the responses were noted.

The discussion initiated with the question that “what comes to your mind when you think about your child’s surgery” for parents and “according to you, what makes the parents more anxious about their child’s surgery?” for the nurses and doctors, which was then proceeded over the responses.

In the scale development phase (phase 2), in order to develop the scale, two rounds of modified Delphi process with 10 experts were conducted.

DEVELOPMENT OF TOOL

According to **Godfred et al.**[97] there are three phases of tool development viz; item development, scale development and scale evaluation that involved various steps. **Cheong et al.**[98] in their study to develop a valid and reliable scale that measures the healthy life styles among young adults also followed different steps of tool development. Phase 1 (item development phase) consisted of identification of the domains of preoperative parental anxiety and item pool generation and phase 2 (scale development) involved 3 steps such as selection of the measurement scale, expert review of the initial item pool and revision and inclusion of items. While phase 3 (scale evaluation) comprised of 3 steps like administration of the items to the subjects, evaluation of the items and optimization of tool length. The phases were summarized in the following manner in fig 2:

PHASES OF TOOL DEVELOPMENT

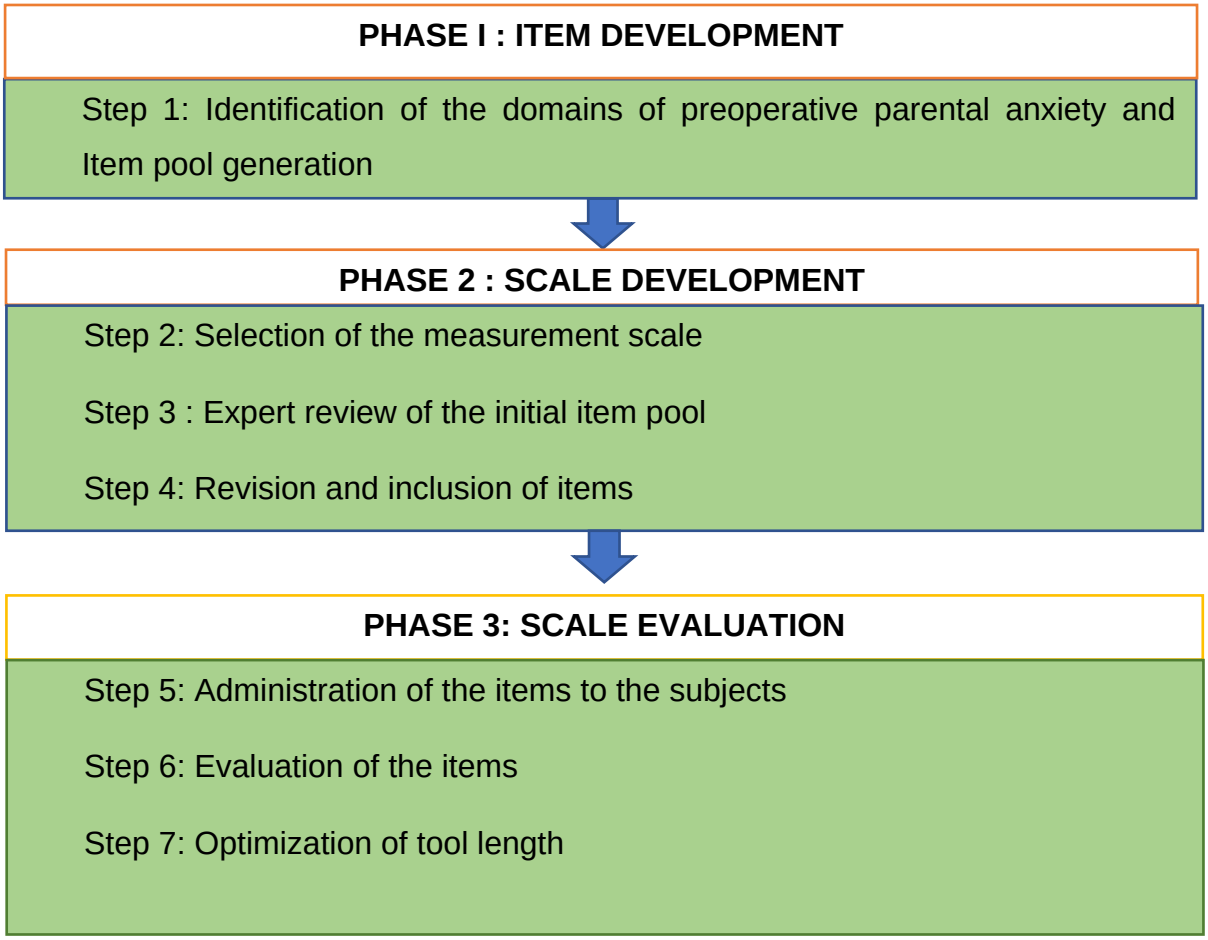

Fig 3: Phases of tool development

PHASE I : ITEM DEVELOPMENT

Step 1: Identification of the domains of preoperative parental anxiety and item pool generation

A. Identification of the domains

Review of literature from scientific databases carried out to identify factors that affect the parental anxiety. Focussed Group Discussion (FGD) had been conducted among 14 parents of children admitted for surgery under general anaesthesia, 2 doctors and 5 nurses in the paediatric surgery ward satisfying

the inclusion criteria regarding the factors that they have considered as to be responsible for preoperative parental anxiety.

a) Extensive review of literature

For the identification of the domains, an extensive review had been conducted from various journals, articles and other previous studies using the electronic databases like Pubmed, MEDLINE, CINAHL, Cochrane Library and Google Scholar.[23-93] The studies based on factors affecting the preoperative parental anxiety, impact of parental anxiety on child as well as family, the various tools for assessment of anxiety level were included in the review. Based on the PRISMA guidelines, after the identification of the records related to the topic of interest, it was then screened for duplicates and those which were eligible was considered for review (Fig 1), as described earlier in Chapter 2.

b) Focussed Group Discussion

A Focussed Group Discussion (FGD) is the platform to collect and gather information from people of similar experience or background through the discussion of a common topic of interest. It is a type of qualitative research where the subjects were allowed to express about their perceptions, beliefs or opinion about the topic of discussion. This is basically moderated by a facilitator and would consist of about 6-12 people. The facilitator introduces the topic for discussion and helps the members to actively participate in the natural discussion amongst themselves. FGD's are a best way to explore the ideas and opinions of subjects within the group and a means to provide insight regarding the various agreements or disagreements regarding a particular topic. The group discussion and composition should be carefully

planned to create a non-threatening environment, so that subjects could feel free to express themselves and provide honest opinions. Subjects should also be actively encouraged to express their opinions as well as to respond to other members and questions given by the facilitator in order to get an in depth content.[94-96] The following were the objectives of FGD:

- To gain insight regarding factors affecting preoperative anxiety among parents of children admitted for surgery
- To use the insights from this FGD for item pool generation in order to develop the Preoperative Parental Anxiety Scale.

Methodology for FGD

Two FGDs, one for parents and one for the staff, conducted on 5th October 2020 in the Paediatric Surgery Ward of AIIMS, Jodhpur. A total of 8 parents of children admitted for surgery in the Paediatric Surgery Ward participated in the FGD for parents while 5 nurses and 2 doctors working in the Paediatric Surgery Ward participated together in the FGD for the staff. The nurses and doctors were considered for the discussion as they have marked interaction with the parents and children admitted for surgery. All sessions conducted after obtaining the informed written consent from the parents and a verbal consent from the staff. All the FGDs were of about 40-45 minutes duration and the responses were noted. The discussion carried out around the factors affecting preoperative anxiety among parents of children admitted for surgery, and initiated with the question like “what comes to your mind when you think about your child’s surgery” for parents and “according to you, what makes the parents more anxious about their child’s surgery?” for the nurses and doctors,

which was then proceeded over the responses. An initial pool of items generated from the themes derived from these FGDs which were then combined with the items obtained through extensive review of literature. Later, an additional FGD was conducted on 7th October 2020 at the same setting for 6 parents in order to confirm the agreement with the pool of items obtained from the previous Focussed Group Discussions and review of literature.

Thematic Analysis

This section presents the findings of the FGDs about the factors affecting the preoperative parental anxiety among parents of children admitted for surgery. The information in this section represents the researcher's interpretation on the basis of the notes made upon the FGDs.

Factors Affecting The Preoperative Parental Anxiety

i. Outcome of the surgery

Most of the parents have shown concern regarding the outcome of the surgery and about the condition of the child after surgery. Some parents expressed about the success and survival rate after the surgery while the other concerns were in terms of duration of recovery. Similar response was elicited from the side of staff also.

Illustrative quotations from the group:

"From my experience, parents were mostly worried about the condition of their child after surgery and also about the recovery period. Mostly they were tensed about the final result of the operation, about how soon the child will recover, etc.." (staff)

“Operation ke baad mera bacche ko kya hoga..baccha swasth hoga ya nahi.. aur kitne din me thik hoga..bhagwan ki kripa se sab thik hona chahiye” (What will happen to my child after operation..child will be healthy or not..when he will recover..by god’s grace everything should go well) (mother)

“Operation ke baad bacche ki condition kya hogi.. jaldi thik hoga ya nhi” (After operation, what will be the condition of the child..he will recover soon or not) (father)

ii. Anaesthesia

Some parents were concerned about the waking up from general anaesthesia. Doctors also expressed that many times parents asked them regarding time taken for the child to regain consciousness.

Illustrative quotations from the group:

“I had many experiences that parents were asking regarding the time taken for the child to regain consciousness…mostly they were not able to understand the general anaesthesia in detail but still they know that bacche ko behosh krte h..” (They know that child will be given with anaesthesia) (staff)

“Doctor saab ne bataya ki bacche ko behosh krna padega operation se phle.. zyada mujhe ni pata..baccha kitne der me vaapas hosh me aayega madam..?” (Doctor said that before operation, anaesthesia will be given to the child..I don’t know much..in how much time will the child be back to consciousness, madam?) (parent)

iii. Postoperative period

Most of the parents discussed about pain for their child during postoperative period as well as the length of hospital stay. The nursing staff also discussed regarding the parental concern regarding postoperative pain and postoperative diet that could be given for the child. Some added about the postoperative care of their child.

Illustrative quotations from the group:

“Parents usually get tensed about how much pain their child needs to suffer after surgery and for how long.. ” (staff)

“I have seen that parents, mostly mothers asked me about what food they should give their child after surgery.. they were also confused regarding how much time their child should be kept on NPO after surgery.. they might say child had not eaten anything since night before operation and how long they should be kept so..?.” (staff)

“Parents were also not clear about how they should do wound care after surgery especially in case of colostomy patients…when they should be able to bath the child.. or is there any problem if the dressing gets wet etc.. they were not confident enough in performing things at first.. after some time it becomes ok for them..” (staff)

“Madam operation ke baad mere bacche ko kitna dard hoga..aur kitne din tak hamey hospital me rehna padega..?” (Madam, after operation how much pain will be there for my child? For how many days should we have to remain in the hospital..?) (parent)

iv. **Preparation for surgery**

Mothers discussed their concern about keeping the child NPO before surgery. Staff also agreed with the same. Some parents discussed that even the entire preoperative preparation like procedures, fasting makes them anxious.

Illustrative quotations from the group:

“I have seen that parents won’t get easily convinced with idea of keeping the child NPO before surgery. They may ask you that what if the child is given little chai or biscuit before surgery.. they have a fear that their child may faint if they don’t eat anything for long..” (staff)

“Kab tak baccha bhukha rahega..kuch to kha sakta hai na...chai, biscuit vagera..?” (For how long does the child will be kept without taking food..does some snacks like tea or biscuit, can be given..?) (parent)

v. Family

Parents of nuclear family discussed their worry about the care of the healthy child at home as they were involved in the care of sick child. Few parents discussed about their concern about household responsibilities.

Illustrative quotations from the group:

“Aaj kal ghar ke saare kaam krne k liye mushkil ho rha h..ghar me chota baccha bhi h..uski chinta ho rhi h mujhe..” (Nowadays it’s getting difficult to perform household responsibilities..small kids are there at home..I worry about them) (parent)

“Humare ghar m chote bacche ko dekhne k liye sasural me log h..mujhey zyadatar parvah iski vajah se hi h..iska kya hoga..” (In our home, in-laws will

take care of smaller kids..mostly my concern is about this child, what will happen to him) (parent)

vi. Surgery related

Most of the parents discussed about their tension regarding the surgical procedure itself, the chances of any mistakes, complications of surgery and chances of death during surgery. Two parents also added about their concern regarding scar formation after surgery especially for girl child and also regarding chances of injury to adjacent organs. Nursing staff and doctors also had similar opinion.

Illustrative quotations from the group:

“Bacche ke operation k baare m soch k tension ho rhi h mujhe..kya hoga iska..operation ka koyi nuksaan nahi hona chahiye..bhagwan ki kripa se koi galti nahi honi chahiye..operation ke samay iski jaan ki bhi parva h mereko..iska kya hoga..” (By thinking about child’s operation, I’m getting tensed..what will happen to him..there should not be any problem related to operation..by god’s grace, there shouldn’t be any mistakes..I’m concerned about the life of my child, during operation..what will happen to him) (parent)

“Meri zyada chinta iski operation ki vajah se hi h..kya zyada nishaan padega kya..ladki bhi h..shaadi bhi honi h..” (Most of my tension is due to this operation of my child..whether there will be more scar formation..this is a girl child and marriage also has to be done) (parent)

“Madam, kya is operation se doosre organ ko kuch problem to ni hoga na..?” (Madam, does any other adjacent organs will be injured by this operation..?) (parent)

“Mostly I have seen parents getting tensed about the operation itself. Because for them it is really stressful that they have to make their child undergo surgery.. that is also a reason that village people go for local traditional treatments.. they might fear that their child may die during operation. Parents were tensed about complications of surgery also or whether it would cure permanently or not..” (staff)

vii. Financial related

Parents mainly fathers discussed about the expenditure for surgery and treatment of their child. The fathers who were mostly daily labourers, worried about their inability to go for work due to the hospitalization of their child for surgery and the previously working mothers had resigned from their job for the treatment of the child.

Illustrative quotations from the group:

“Bache ke operation aur ilaj k liye bahut zyada kharcha kiya hmne..phle doosre private hospital me dikhaya..abhi to utna nhi dena pad rha h..lekin iski bharti ki vajah se mujhe naukari jaane m bhi dikkat ho rhi h..” (We have spent a lot of money on child’s treatment and operation..earlier we had consulted in a private hospital..currently that much amount is not getting spent as earlier..but, due to hospital admission of my child, I’m not able to go for work) (parent)

“Phle me bhi kaam krti thi..abhi iske ilaj k liye meine kaam ko chod diya..ab to sirf iske papa job k liye jaate h..” (Earlier I also used to go to work..due to his treatment, I had to leave the job..currently only his father goes for work) (parent)

“Hum majdoori ka kaam karte h..abhi kaam k liye jaa bhi ni paa rhe h..pata ni kya hoga..bs jaldi thik hona chahiye sab..” (We used to do labour work..currently not able to go for work..don’t know what will happen.. everything should be fine soon) (parent)

viii. Quality of life

Parents showed their concern regarding future of their child after surgery, marriage and chances of recurrence. Nursing staff pointed out that the parents were more concerned about quality of life of the child after the surgery, physical rehabilitation, chances of disability and marriage issues for their child.

Illustrative quotations from the group:

“Usually parents, especially mothers ask you frequently regarding the quality of life of their child after surgery. They want to know whether it is a permanent cure or not, or is there any chances of recurrence is there.. whether their child would be able to maintain normal life like other children.. they also would be tensed about chances of disability after operation” (staff)

“Mothers are also concerned about their child’s marriage especially in case of child with hypospadiasis and bladder extrophy severe cases for their sons..” (staff)

“Aage iska kya haal hoga..chhoti h ye ..kya operation ki vajah se kuch aur nuksaan to nahi hoga na..? aur ye dikkat dobara nhi hona chahiye ..is operation se sab kuch thik hona chahiye..” (She is small now, what will be her condition in future..will there be any more problem due to this operation..?

This problem should not arise again..everything should go well after this operation) (parent)

“Ladka h.. kal jab iski shaadi hogi tab kuch dikkat to nhi hoga na..?” (He is a male child, in future will there be any problem at the time of his marriage?) (mother of child with bladder extrophy)

ix. Physical symptoms

Many parents complained about headache and interrupted sleep. One parent insisted about feeling of tiredness. Nursing staff suggested about their experience regarding parents complaining about sleep disturbances.

Illustrative quotations from the group:

“I have experienced with parents complaining about sleep problems only and other symptoms of anxiety like palpitations and all had not seen.. may be because of the hospital environment…” (staff)

“Mujhe kabhi kabhi sir me dard hota h.. neend nhi aa pati h..bar bar jagna padta h beech beech me..aur kuch dikkat nahi h..” (Sometimes I have headache..I’m not able to sleep..frequently I have to arise in between the sleep..there is no other problem) (parent)

“Mujhe aise koyi problems ni h..” (I donot have such kind of problems) (parent)

“Mereko kabhi kabar tiredness feel hoti h..” (Sometimes, I feel tiredness) (parent)

x. Psychological symptoms

Some parents expressed about their loss of interest in selfcare activities like grooming, bathing in comparison with the previous life and also regarding occurrence of bad dreams during sleep.

Illustrative quotations from the group:

“Hamey aaj kal time nhi mil paata h..nahane dhone ka bhi..pura time bacche ka khayal rakhne me nikal jaata h..” (Nowadays, we don’t get enough time, even for bathing and washing too..entire time goes on taking care of the child) (parent)

“Mujhe kabhi kabhi ajeeb sapna bhi aata h..baad me so ni paate h..” (Sometimes I have bad dreams during sleep..after that I won’t be able to sleep) (parent)

xi. Demographic aspects

According to the staff, mothers seemed to be more anxious than fathers and also anxiety is more if the child is male or if age is more than 3 years. Also, anxiety was higher if it is their first child and parents were having good education. Parents’ opinion also suggested the same. In addition, some parents who were having good faith in God and following the religion expressed that they trust in God and that makes them relaxed at times of stress. Also, those from the joint family seemed to be worried less about the family than that of nuclear family.

Illustrative quotations from the group:

“Mothers seem to be tensed more than fathers as mostly child is having mother at bedside. I have also seen that more educated parents are more stressed as they have more and more doubts.. also if the age of the child is more than 3 years and it is male child, family become more anxious than that of younger children specially in case of new born surgeries..” (staff)

“I have experienced that parents show more concern and worry if the problem is for their male child and if it is older child.. and also if it is their first child..” (staff)

“Mujhe itna zyada tension nhi h..sab bhagawaan dekh lenge..” (I don’t have much tension..God will take care of everything)..” (parent)

Summary of FGD

This section presents the several insights obtained from the FGDs regarding the factors affecting the preoperative parental anxiety among parents of children admitted for surgery.

The parents were mostly anxious regarding the outcome of the surgery, the condition of their child after surgery and the surgical procedure itself. Other factors identified included the anaesthesia, preparation for surgery, postoperative period in terms of pain, diet. They also expressed their concern about care of other family members, financial issues, quality of life after surgery. The physical symptoms included headache and sleep disturbances while psychological symptoms like loss of interest in self-care and occurrence of bad dreams were suggested by a few. The summary of FGDs were illustrated in table 1:

Table 1: Summary of FGD

MAIN THEMES	SUB THEMES
1. Outcome of the surgery	• Outcome of the surgery • Condition of the child after surgery • Success • Survival rate after surgery • Recovery
2. Anaesthesia	• Waking up from general anaesthesia
3. Postoperative period	• Postoperative pain • Length of hospital stay • Postoperative diet • Postoperative care
4. Preparation for surgery	• Preoperative NPO status • Preoperative tests and procedures
5. Family	• Caring other healthy child due to more time devoted for ill child • Household responsibilities
6. Surgery related	• Surgical procedure itself • Chances of any mistakes • Complications • Death during surgery • Cosmetic problems • Chances of injury to adjacent organs
7. Financial related	• Expenditure for surgery and treatment • Inability to go for work
8. Quality of life	• Future of their child after surgery • Marriage • Chances of recurrence • Physical rehabilitation • Chances of disability
9. Physical symptoms	• Headache • Interrupted sleep • Tiredness
10. Psychological symptoms	• Loss of interest in selfcare activities • Occurrence of bad dreams during sleep
11. Demographic aspects	• Mothers • Age of child • Birth order (1st child) • Education of parents • Spirituality • Nuclear family

B. ITEM POOL GENERATION

An initial pool of items generated based on the content that were identified through deductive and inductive methods via literature reviews and FGDs respectively. These items classified into different domains. The items

generated from literature reviews and FGDs were summarised in domain wise in the following manner in table 2:

Table 2: Summary of item pool generation

MAIN DOMAINS	SUB DOMAINS
1. Outcome of the surgery	1. Outcome of the surgery 2. condition of the child after surgery 3. success 4. survival rate after surgery 5. recovery
2. Anaesthesia	6. waking up from general anaesthesia
3. Postoperative period	7. Postoperative pain 8. length of hospital stay 9. postoperative diet 10. postoperative care
4. Preparation for surgery	11. Preoperative NPO status 12. Preoperative tests and procedures 13. Preoperative accessibility to information
5. Family	14. caring other healthy child due to more time devoted for ill child 15. household responsibilities
6. Surgery related	16. surgical procedure itself 17. type of surgery 18. intraoperative pain 19. requirement of blood 20. chances of any mistakes 21. complications 22. death during surgery 23. cosmetic problems 24. chances of injury to adjacent organs
7. Financial related	25. expenditure for surgery and treatment 26. economic loss due to surgery and treatment
8. Quality of life	27. future of their child after surgery 28. marriage 29. chances of recurrence 30. physical rehabilitation 31. chances of disability
9. Physical symptoms	32. headache 33. interrupted sleep 34. tiredness 35. poor appetite
10. Psychological symptoms	36. loss of interest in selfcare activities 37. occurrence of bad dreams during sleep 38. feeling of boredom 39. anger outbursts 40. inability to concentrate on activities 41. frequent occurrence of worrying thoughts 42. loss of interest in social life
11.Previous experience	43. Previous experience of hospitalization 44. Previous experience of surgery
12.Child's anxiety	45. Child's anxiety

PHASE 2 : SCALE DEVELOPMENT

Step 2: Selection of the measurement scale

This step involves the selection of measurement scale for the tool under development. For this purpose, review of different tools for assessing the anxiety levels were identified through extensive review of tool development studies as mentioned in Chapter 3.[69-93] A 4-point Likert rating scale selected for recording participant responses. The scores that were assigned to each response anchor to the Likert rating scale as follows:

0: Never 1: Sometimes 2: Fairly Often 3: Always

Step 3 : Expert review of the initial item pool

The third step involved the review of initial pool of items by the expert panel through the modified Delphi process. The Delphi process is basically a forecasting process or a series of rounds that could be used for the purpose of achievement of group consensus.[99] Also we could consider the Delphi as a structured way of communication that could be used to facilitate learning instead of a forced consensus.[100] This approach was initially developed in the 1950-'60 period by Norman Dalkey et al. in order to attain an opinion consensus from experts.[101] The basic principles of a classic Delphi process involves anonymity, iteration, controlled feedback and statistical aggregation of responses.[102] Still, modifications could be made in the Delphi by the researcher as per convenience of the study.[103]

The number of rounds for Delphi depends upon the previous knowledge about the topic as well as the achievement of group consensus.[99,104] Usually it involves 2-3 rounds but when the items were already prepared by the

researcher, two rounds were considered as essential.[105-107] The present study consisted of two rounds of Delphi process for the content validation of the tool.

Rationale for Delphi

Since this study involves the development of a scale measuring preoperative parental anxiety, it requires the suggestions and opinions from a group of experts with good expertise in the field rather than solitary remarks; for which Delphi could be considered as an effective means of group interaction. Also, since the Delphi is flexible and heterogenous in nature in the present study, it could help in eliciting an extensive impression on the topic under study.[108]

Modifications

a. The face-to-face feedback in classic Delphi[109] was replaced with the non-face to face method through the use of electronic mail.
b. Since the initial pool of items were already prepared by the researcher, the first round of unstructured open ended questionnaire feedback similar to that of a classic Delphi process [99] was omitted.

Stages of Delphi

Fig 4: Stages of Delphi process

1. Identification and selection of experts

The proper accomplishment of Delphi process depends mainly on the expert panel. Therefore careful selection of experts should be made.[99] An expert is considered as a person who possess expertise and knowledge in the field under study, who has time and willingness to participate as well as the one with effective communication skills.[110] Willingness and commitment are essential factors since the process involves multiple rounds before attaining consensus.[103]

Panel structure: The experts were selected from the field of Paediatric nursing, Paediatric surgery, Clinical and child psychology, Psychiatry and Anaesthesiology and Critical care, thereby maintaining the heterogenicity of the group. The selection of experts was done through purposive sampling

technique[111] as they were selected for a purpose of application of their knowledge and expertise towards the topic.[112]

Panel size: The number of panel members could vary from ten to more than thousand.[113] Many other studies also reveal the inclusion of about twelve to fifteen panel members in Delphi process.[114,115] The Delphi panel for the present study consisted of 10 experts out of which 4 were from the field of Paediatric nursing, 4 from the Department of Clinical and Child Psychology, 1 each from the Department of Psychiatry and Department of Anaesthesiology and Critical care.

2. Sending invitation to the experts

Since the panel members were present over different parts of India, the main means of invitation was via email, even though personal contact was also used as a means of communication. The initial contact with the selected experts were made through mail in which a request letter was sent inviting them for the Delphi method along with the study title. Request letter was sent to 30 experts out of which 21 had given the consent for participation. For those experts within the Institute, the correspondence was obtained through personal contact.

3. First Delphi round

Once the confirmation mail was obtained, another email was sent to the experts consisting of the brief study methodology, preliminary draft of the tool and the evaluation criteria for validation of the tool, notifying them regarding the return of their suggestions to the same email id. The panel members for the first round were considered as significant since it guides the further

rounds.[115,116] The evaluation criteria for validation of the draft consisted of a 3 point Likert scale of 1 = irrelevant, 2 = need modification and 3 = highly relevant, along with a column for remarks and suggestions, for the relevancy and appropriateness of the items. The validators were asked to go through the draft and to provide their suggestions upon the initial draft in the Likert scale. Out of 21 experts to whom the draft was sent, 10 experts completed the first round. The first round was completed in three weeks.

4. Analysis of first Delphi round results

Once the responses were obtained, the interpretation of the first round was done. For the Section A, the main suggestion was to keep the age of child and parents as open ended rather than forming the categories earlier. Other suggestions included regarding the relevance of socioeconomic status and previous experience of hospitalization in terms of good, bad or worst. For Section B, the major areas of suggestions included previous experience of hospitalization and surgery, merging of domains, emotional components within certain items as well as rephrasing of the sentences. The items regarding the preoperative information, psychological symptoms like experience of bad dreams during sleep, feeling of boredom, anger out bursts and loss of interest in social life were considered as irrelevant by one validator. Out of the initial 16 items in Section A, 6 items were considered as highly relevant by all validators (100%), 5 need modification and 5 as not relevant by one validator. Also out of the initial 45 items in Section B, 12 items were considered as highly relevant by all experts (100% agreement), 28 items requiring modification and 5 items were considered as irrelevant by one validator.

Anonymity of the validators was maintained throughout the process.[102]

First modification of tool

After the interpretation of expert suggestions from the first Delphi round, first modification was made in the initial draft of tool with 45 items. Items were reviewed and revised. Further, the revised items were rearranged by assigning them to appropriate categories.

Domain modification

Since many items in different previous domains were overlapped as well as had similar meaning, the previous domains 'outcome of the surgery, anaesthesia, postoperative period, preparation for surgery, surgery related and quality of life' were merged and modified into main domain 'surgery and surgery related procedures'. The previous domains of 'physical symptoms and psychological symptoms' were merged as sub domains of the main domain 'personal symptoms'. The other main domains child's anxiety, financial related and previous experience of surgery and hospitalization were retained as such.

Item removal : 3 items from surgery related domain (Items 10, 11, 12) and 2 items from psychological symptoms (Items 41 and 42) were removed. (Table 3)

Item modification

The 9 items in the domains 'outcome of the surgery, surgery related and quality of life' were merged and modified (old items 14, 15, 20, 22, 23, 32 and 33 were merged as a new item 10 and old items 24 and 25 as new item 12). The initial 2 items (items 1 and 2) in the previous domain 'family related' were

merged into new item 20 and renamed as domain of ‘family responsibilities’. The other items that were merged included 2 items from ‘physical symptoms’ (old items 35 and 36 merged to be a new item 23). Also, other 2 items from the domain ‘financial related’ (Items 3 and 4) were merged into new item 21. Apart from this, other modifications were the reframing of sentences of old items 13, 26, 29, 34, 38 and 39. (Table 3)

The new domains were previous experience (2 items), surgery and surgery related procedures (16 items), child’s anxiety (1 item), family responsibilities (1 item), financial concerns related to child’s surgery and treatment (1item), personal symptoms (9 items). The revision of the initial draft was made in the manner as given in Table 3.

5. Second Delphi Round

Invitations for the second round was sent to only those who had completed the first round and a feedback of first round was also sent along with the modified tool. The feedback of first round was given in tabular form consisting of the compilation of all responses by maintaining the anonymity along with the percentage of agreement of validators regarding the items in first round and the final opinion of the validator regarding the suggestions from first round in terms of the question “Do you want any modification in the given suggestions from first round?” for which they were asked to answer in the form of Yes/ No, if no then why/ Can’t say. The experts were allowed to adjust their answers in this round, based on how they interpret the "group response" that was provided to them. Apart from this, the evaluation criteria used in first round of Delphi was also given for evaluating the modified draft. Out of the 10

experts to whom the feedback of first round was sent, 7 experts completed the second round. It took 2 weeks to complete the second round.

6. Analysis of Delphi Round 2 Results

After obtaining the responses from the validators, interpretation of second round was done. For the Section A, the suggestion to keep the age of child and parents as open ended rather than forming the categories earlier were accepted by the validators and no other suggestions was made. For Section B, the suggestion regarding removal of items 10, 11, 12, 41 and 42 from initial draft were accepted by the validators along with merging of items and other than that, removal of domain ‘previous experience’ was a newer suggestion. The necessary modifications were made accordingly in the further step (Table 3).

Table 3: Summary of the modification of tool

Old items	Items after first modification	Items after second modification
1. I'm concerned about caring other healthy child due to more time devoted for ill child 2. I'm concerned about household responsibilities due to more time devoted for ill child	20. I feel stressed about household responsibilities specially caring other healthy child/children due to more time given for the ill child **(1 and 2 merged)**	18. I feel stressed about household responsibilities specially caring other healthy child/children due to more time given for the ill child
3. I feel tensed about hospital expenditure for my child's surgery 4. I have a fear of economic loss due to treatment cost of my child	21. I have a fear of economic loss due to surgery and treatment cost of my child **(3 and 4 merged)**	19. I have a fear of expenses due to surgery and treatment cost of my child
Attempt the following if you have any previous experience of hospitalization or surgery: 5. I feel stressed about my child's condition by thinking about the previous experience of the child's hospitalization 6. I feel tensed about my child's condition by thinking about the previous experience of child's surgery.	Attempt the following if you have any previous experience of hospitalization or surgery: 1. I feel tense about my child's condition by thinking about the previous experience of the child's hospitalization 2. I feel tense about my child's condition by thinking about the previous experience of child's surgery.	**Removed** **Removed**
7. I feel tensed on seeing the anxiety of my child	19. I feel tensed on seeing the anxiety of my child	17. I feel tensed on seeing the anxiety of my child
8. I have a fear regarding my child's surgical procedure itself 9. I get upset regarding type of surgery to be performed in my child	6. I have a fear regarding my child's surgical procedure especially the duration of surgery 7. I get upset regarding type of surgery to be performed in my child	4. I have a fear regarding my child's surgical procedure especially the duration of surgery 5. I get upset regarding type of surgery to be performed in my child

10. I worry about the intraoperative pain of my child 11. I'm fearful of the blood transfusion requirement for my child during surgery 12. I'm scared of the surgical errors during my child's surgery 13. I'm afraid of the death of child/ life of my child during surgery. 14. I'm frightened about the complications of my child's surgery like injury to other organs. 15. I worry about the cosmetic problems for my child after surgery.	**Removed** **Removed** **Removed** 8. I am scared if something will happen to my child during surgery **(rephrased)** 10. I'm scared about the complications in my child following surgery **(14, 15, 20, 22, 23,32,33 merged)** **See 10**	6. I am scared if something will happen to my child during surgery 8. I'm scared about the complications in my child following surgery
16. I feel tensed about keeping the child NPO before surgery. 17. I feel scared about the preoperative investigations and procedures of my child. 18. I feel stressed whenever I get preoperative information related to surgery of my child.	3. I feel tense about keeping the child NPO before surgery. 4. I feel scared about the preoperative investigations and procedures in my child. 5. I feel stressed whenever I get preoperative information related to surgery of my child.	1. I feel tense about keeping the child NPO before surgery. 2. I feel scared about the preoperative investigations and procedures in my child. 3. I feel stressed whenever I get preoperative information related to surgery of my child.
19. I feel stressed about the inability of my child to wake up from anaesthesia.	9. I feel stressed about the inability of my child to wake up from anaesthesia.	7. I feel stressed about the inability of my child to wake up from anaesthesia.
20. I have a fear regarding outcome of surgery of my child. 21. I'm scared about the condition of my child after surgery. 22. I'm worried about the percentage of success of surgery of my child. 23. I feel tensed about the survival rate of my child after surgery.	**See 10** 11. I'm scared about the condition of my child after surgery. **See 10** **See 10**	9. I'm scared about the condition of my child after surgery.

24. I fear about the recovery of my child after surgery 25. I'm tensed about the duration of recovery of child after surgery	12. I fear about the recovery, especially about the duration of recovery of my child after surgery **(24 and 25 merged)** **See 12**	10. I fear about the recovery, especially about the duration of recovery of my child after surgery
26. I worry about the postoperative pain of my child 27. I'm tensed about the length of hospital stay after surgery of my child 28. I worry about the postoperative diet of my child 29. I'm afraid of the postoperative care of my child especially wound care and colostomy	13. I'm worried about the immediate postoperative pain of my child **(rephrased)** 14. I'm tensed about the length of hospital stay after surgery of my child 15. I worry about the postoperative diet of my child 16. I'm worried about the postoperative care of my child especially wound care. **(rephrased)**	11. I'm worried about the immediate postoperative pain of my child 12. I'm tensed about the length of hospital stay after surgery of my child 13. I worry about the postoperative diet of my child 14. I'm worried about the postoperative care of my child especially wound care.
30. I feel stressed about the future of my child after surgery 31. I have a fear about the recurrence of the same condition for my child even after surgery 32. I feel worried about the physical rehabilitation of my child after surgery 33. I'm scared about the disability of my child after surgery	17. I feel stressed about the future of my child after surgery 18. I have a fear about the recurrence of the same problem in my child even after surgery **See 10** **See 10**	15. I feel stressed about the future of my child after surgery 16. I have a fear about the recurrence of the same problem in my child even after surgery
The following physical symptoms are present in me or not: 34. I'm having headache whenever I think about the surgery of my child. 35. I'm having deprivation of sleep due to tension regarding surgery of my child.	Whenever caring for my child, I feel/experience the following: 22. I'm having headache/ any other body pain whenever I think about the surgery of my child. **(rephrased)** 23. I'm having sleeping difficulty during night by thinking about the surgery of	Whenever caring for my child, I feel/experience the following: 20. I'm having headache/ any other body pain whenever I think about the surgery of my child. 21. I'm having sleeping difficulty during night by thinking about the surgery of my child.

	my child. **(35 and 36 merged)**	
36. I'm having interrupted sleep during night by thinking about the surgery of my child	**See 23**	
37. I'm always having a feeling of tiredness throughout the day during these days in the hospital	24. I'm always having a feeling of tiredness throughout the day during these days in the hospital	22. I'm always having a feeling of tiredness throughout the day during these days in the hospital
38. I'm having poor appetite during these days due to frequent thought about my child's condition	25. I don't feel like eating during these days due to frequent thought about my child's condition (**rephrased)**	23. I don't feel like eating during these days due to frequent thought about my child's condition
39. I feel loss of interest in selfcare activities	26. I don't feel like spending time on myself ever since this issue of surgery has come up **(rephrased)**	24. I don't feel like spending time on myself ever since this issue of surgery has come up
40. I have experienced bad dreams during sleep about my child's condition.	27. I have experienced bad dreams during sleep about my child's condition.	25. I have experienced bad dreams during sleep about my child's condition.
41. I have a feeling of boredom in the hospital	**Removed**	
42. I have sudden anger outbursts towards others	**Removed**	
43. I feel inability to concentrate on activities	28. I feel inability to concentrate on activities	26. I feel inability to concentrate on activities
44. I have frequent occurrence of worrying thoughts about my child's condition.	29. I have frequent occurrence of worrying thoughts about my child's condition.	27. I have frequent occurrence of worrying thoughts about my child's condition.
45. I feel loss of interest in social	30. I feel loss of interest in social life	28. I feel loss of interest in social life

CONTENT VALIDITY

Content validity is the degree to which an instrument has an adequate and appropriate items for the construct under measurement[117-121] Among the various approaches for identifying the content validity, the most recommended one is in terms of expert review upon the relevance of items with the construct. Also, among the nursing research studies, the commonly used measure of content validity is content validity index (CVI). CVI calculated using two forms, namely CVI for item (I-CVI) and CVI for scale (S-CVI). [117-121]

CONTENT VALIDITY INDEX (CVI)

Based on the responses of the experts in second round on the three point Likert scale, validity of each item assessed and a content validity index computed. Prior to the estimation of CVI, the responses of the validators were re-coded as, 0 for those items which were in the category of 'need modification and irrelevant' (relevance scale of 1 & 2) and 1 for those 'highly relevant' items on the Likert scale (relevance scale of 3).[118]

I-CVI (item-level content validity index) is the proportion of content experts giving the item as relevant and could be calculated using the formula: I-CVI = (agreed items) / (number of experts) while S-CVI/Ave (scale-level content validity index based on the average method) is the average of the I-CVI scores for all items on the scale or the average of proportion relevance judged by all experts which is calculated as S-CVI/Ave = (sum of I-CVI scores) /(number of item).[122] The acceptable cut-off score for CVI for at least 9 experts should be at least 0.78. [118,119] As per the calculation, the S-CVI/ Ave and S-CVI/ UA were 0.98 and 0.8 respectively.

Step 4: Revision and inclusion of items

Second Modification of the tool

From the first modified tool, the items 14 and 16 in Section A and items 1 and 2 in Section B were removed, thus making the final tool consisting of 14 items in section A and 28 items in Section B (Table 3). After 2nd modification, the tool consists of 5 domains with 28 items, namely, surgery and surgery related procedures (16 items), child's anxiety (1 item), family responsibilities (1 item), financial concerns related to child's surgery and treatment (1item), personal symptoms (9 items). (Appendix- VIII)

Translation to Hindi language

Once the modification carried out, the revised tool in English translated into Hindi language. (Appendix-X) The language validity of the tool in Hindi was obtained from the expert from this field. (Appendix-XII)

Pilot testing of the tool

After getting the language validation in Hindi from the expert, pilot study was conducted among 20% of the total estimated sample of parents of children admitted for surgery under general anaesthesia i.e. among 20 parents including both mother and father satisfying the inclusion criteria using non–probability convenience sampling technique. The main objectives were

- to try out the tool for assessing the feasibility of scale;
- to determine the time that is required to complete the tool;
- to examine the placement and composition of the items;
- to determine the understanding and language clarity of tool

Duration of data collection: Data were collected from 27/11/2020 to 02/12/2020.

Procedure of data collection for testing of the tool

Prior to pilot study, a self-introduction was given to the subjects (parents) and they were assured of maintaining the confidentiality of their responses. After obtaining the consent from the study subjects (parents), the self-reported PPAS consisting of 28 items administered to 20 parents including both mother and father of children admitted for surgery in the study setting. The approximate time taken by each parent to complete the questionnaire was about 10-12 minutes. The tool found to be feasible with proper understanding and language clarity for the parents.

PHASE 3: SCALE EVALUATION

Step 5: Administration of the items to the subjects

The final modified draft of tool consisting of 28 items, that were evolved through literature review, content validation by experts, and the pilot study, was then administered to 100 parents of children admitted for surgery under general anaesthesia in Paediatric surgery ward at AIIMS, Jodhpur, in order to test the validity and reliability.

Method of Data Collection

Researcher has taken the ethical approval for the current study from the institutional ethical committee. The process of data collection explained to the subjects (parents) and a written informed consent obtained from them. Confidentiality regarding the data was assured so as to get cooperation

throughout the procedure of data collection. Data were collected with a self-report method using Preoperative Parental Anxiety Scale (PPAS) in Hindi language and only from those who fulfil the inclusion criteria and those who were willing to participate in the study. Parents were asked to fill the 4-point Likert scale of PPAS, ranging from 0–3, with their responses towards the items provided in terms of never, sometimes, fairly often and always. The method of administration was pen and paper method. Confidentiality and anonymity of the responses maintained throughout the study.

Step 6: Evaluation of the items

Reliability of the tool refers to the degree to which an instrument yields consistent results. Internal consistency of tool was calculated using Cronbach's alpha which estimates the extent to which different items would reliably measure the critical attribute. Values of 0.80 or higher were considered especially desirable, i.e., the degree to which the set of items in the scale co-vary, relative to their sum score. The Cronbach's alpha value for the entire 28 items of PPAS was 0.938 (Table 5) which was found to be excellent.

Construct validity indicates the extent to which a measurement method accurately represents a construct and produces an observation, distinct from that which is produced by a measure of another construct. Construct validity of the tool was assessed by exploratory factor analysis. The appropriateness of PPAS for factor analysis was determined through the Kaiser-Meyer-Olkin (KMO) test and Bartlett test of sphericity. Since the KMO value came out as 0.832 and the Bartlett test of sphericity showed an approximate $\chi 2$ value of

2090.693 (p =0.000), the items in PPAS was found to be suitable for factor analysis. The Principal Component Analysis had yielded 7 factors with an Eigenvalue more than 1.00, accounting for more than 60% of variance.

Criterion validity of the tool was assessed by concurrent validity. It refers to the extent to which the results of a particular measurement or test, correspond to those of a previously established measurement for the same construct. This was checked by concurrent validity using the standardised tool 'Hamilton Anxiety Rating Scale' (HAM-A), which was available in the Public domain for free to use (Appendix-XI). HAM-A had an inter-rater reliability of 0.74.[69] The results were used for optimization of tool length.

Step 7: Optimization of tool length

As per the DeVille's guidelines of scale development process, the final tool with 28 items were prepared after checking of the validity and reliability.[98] The score on PPAS ranged from 0 to 84.

ETHICAL CONSIDERATION

Ethical clearance was obtained from the institutional ethical committee of the institution with reference number: AIIMS/IEC/2020-21/3025 (Appendix-I). Informed written consent was taken from the study subjects after giving proper explanation of the purpose of the study (Appendix-IV & V). Confidentiality and anonymity of the subjects and the data collected were maintained throughout the study.

PLAN FOR DATA ANALYSIS

Statistical analysis was performed using the Statistical Package for Social Sciences Programme version 26 (SPSS- 26). Descriptive statistics such as

frequency, percentage, mean and standard deviation were used to find out the characteristics of the study subjects.

Content validity and face validity of the tool were analysed by expert's opinion, and content validity index was also calculated for content validity. Construct validity of the tool was assessed by exploratory factor analysis. While criterion validity of the tool was assessed by concurrent validity using the standardised tool 'Hamilton Anxiety Rating Scale' (HAM-A). The reliability was assessed with internal consistency of tool using Cronbach's alpha which estimates the extent to which different items will reliably measure the critical attribute. The item total statistics as well as inter item correlation was calculated.

SUMMARY

This chapter dealt with Research Methodology. Quantitative research approach and methodological research design was used in this study. Study was conducted in Paediatric surgery ward at AIIMS Jodhpur, Rajasthan. Data were collected from those 100 parents who were selected using non-probability convenience sampling technique, using the self-reported Preoperative Parental Anxiety Scale (PPAS). Collected data were entered into master sheet and SPSS 26 version was used for the statistical analysis. The next chapter deals with the Analysis, Interpretation and Discussion.

CHAPTER-IV

ANALYSIS, INTERPRETATION AND DISCUSSION

ANALYSIS, INTERPRETATION AND DISCUSSION

Data analysis and interpretation were done in accordance with the study objectives. Data were analysed using the Statistical Package for Social Sciences Programme version 26 (SPSS- 26). Descriptive statistics were used to find out the study subjects' characteristics in terms of frequency, percentage, mean and standard deviation. Content validity was estimated from the content validity index (CVI) while criterion validity was assessed by concurrent validity using the standardised tool 'Hamilton Anxiety Rating Scale' (HAM-A). Factor analysis was done to test the dimensionality. The reliability was assessed with internal consistency of tool using Cronbach's alpha.

The presentation of data organized and arranged in the following sections:

SECTION A: Description of socio-demographic variables of parents of children admitted for surgery

SECTION B: Reliability analysis for the Preoperative Parental Anxiety Scale (PPAS)

SECTION C: Validity analysis for the Preoperative Parental Anxiety Scale (PPAS)

SECTION A: Description of socio-demographic variables of parents of children admitted for surgery

Table 4: The frequency and percentage distribution of socio-demographic variables of parents of children admitted for surgery

(N = 100)

Socio- demographic variables	f (%)
Parent:	
Father	50 (50)
Mother	50 (50)
Gender of the child:	
Boy	28 (56)
Girl	22 (44)
Age of the parent: (in completed years)	
20-30	37 (37)
30-40	53 (53)
>/= 40	10 (10)
Mean +/- SD	31.41 +/- 5.605
Age of the child:	
<1 year	09 (18)
1-6 years	21 (42)
6-12 years	16 (32)
12-18 years	04 (8)
Mean +/- SD	5.64 +/- 4.15
Religion	
Hindu	82 (82)
Muslim	18 (18)
Area of residence	
Rural	36 (36)
Urban	64 (64)
Education of the parent	
Below 10^{th} class	27 (27)
10^{th} pass	20 (20)
12^{th} pass	22 (22)
Graduate and above	31 (31)
Occupation of the parent	
Gov job	11 (11)
Private job	23 (23)
Own business	17 (17)
Farmer	08 (8)
Daily wage worker	02 (2)
Homemaker	39 (39)
Socioeconomic status:	
Upper Middle (II)	18 (18)
Lower Middle (III)	50 (50)
Upper Lower (IV)	32 (32)

Type of family:	
Nuclear	36 (36)
Joint	64 (64)
No of children:	
1	30 (30)
2	58 (58)
3	08 (8)
4 and above	04 (4)
Birth order of the child admitted for surgery	
1	58 (58)
2	36 (36)
3	04 (4)
4 and above	02 (2)
Previous history of hospitalization for your child	
Yes	18 (18)
No	82 (82)
Previous history of surgery for your child	
Yes	02 (2)
No	98 (98)

Table 4 depicts the frequency and percentage distribution of socio-demographic variables of parents of children admitted for surgery. There were total of 100 study subjects, out of which half were fathers and the other half were mothers. 56% of the children were boys while girls constituted 44%. 53% of the parents were in the age group of 30 to 40 years while only 10% were more than 40 years of age. The mean age of the parents was 31.41 years with a SD of 5.605. Among children, 42% were in between the age group of 1-6 years while only 8% were adolescents within the age group of 12-18 years. The mean age of the children was 5.64 years with a SD of 4.15. 82% of the study subjects were Hindu by religion while the remaining were Muslims. 64% of the study subjects were urban residents. 31% of the study subjects were graduates while 20% had completed their 10^{th} class. 39% of the study subjects were homemakers while 2% were daily wage workers. 50%

study subjects belonged to lower middle class. More than half of the study subjects i.e. 64% were from joint family. About 58% of the study subjects had 2 children while only 4% had 4 and more children. 58% of the study subjects were having the surgery for their 1st child. Majority of the study subjects didn't have a previous history of hospitalization for their child (82%). Also about 98% of the study subjects didn't had a previous surgical history for their child.

SECTION B: Reliability analysis for the Preoperative Parental Anxiety Scale (PPAS)

Table 5: Internal consistency of the Preoperative Parental Anxiety Scale (PPAS) using Cronbach's Alpha

Number of Items	Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items
28	.938	.940

Table 5 shows the internal consistency of the Preoperative Parental Anxiety Scale (PPAS) using Cronbach's Alpha.

The Cronbach's alpha was calculated to find out the internal consistency of the tool. The Cronbach's alpha value was 0.938 for the entire 28 items (Table 5) which was found to be excellent.

Table 6: Mean and standard deviation of each item of Preoperative Parental Anxiety Scale (PPAS)

	Mean	SD	N
Item 1	1.62	.993	100
item 2	1.80	.899	100
item 3	2.03	.784	100
item 4	2.45	.880	100
item 5	2.35	.730	100
item 6	2.81	.598	100
item 7	1.54	1.019	100
item 8	2.54	.673	100
item 9	2.66	.699	100
item 10	2.10	.759	100
item 11	1.67	.792	100
item 12	1.16	1.117	100
item 13	.89	.984	100
item 14	1.46	.958	100
item 15	2.45	.730	100
Item 16	2.05	.821	100
item 17	1.65	1.077	100
item 18	1.23	1.196	100
item 19	1.37	1.269	100
item 20	1.53	1.010	100
item 21	2.03	.926	100
item 22	.83	.965	100
item 23	1.69	.992	100
item 24	1.40	1.064	100
item 25	.18	.500	100
item 26	.54	.758	100
item 27	1.57	1.027	100
item 28	.47	.810	100

Table 6 describes the Mean and standard deviation of the Preoperative Parental Anxiety Scale (PPAS). Out of 100 study subjects, the mean score of each item ranged from 0.18-2.81, with a SD of 0.5-1.269. Of the 28 items of the PPAS, the highest and lowest mean score on the 4-point Likert scale was for the items 6 and 25 respectively. (Table 6).

Table 7: Inter-item correlation matrix for Preoperative Parental Anxiety Scale (PPAS)

	Item 1	item 2	item 3	item 4	item 5	item 6	item 7	item 8	item 9	item 10	item 11	item 12	item 13	item 14	item 15	item 16	item 17	item 18	item 19	item 20	item 21	item 22	item 23	item 24	item 25	item 26	item 27	item 28
item 1	1.000																											
Item 2	.627	1.000																										
item 3	.456	.596	1.000																									
item 4	.440	.421	.390	1.000																								
item 5	.408	.462	.334	.428	1.000																							
item 6	.252	.267	.378	.375	.524	1.000																						
item 7	.424	.527	.447	.346	.286	.270	1.000																					
item 8	.340	.548	.600	.438	.413	.634	.454	1.000																				
item 9	.161	.180	.424	.399	.255	.665	.189	.609	1.000																			
item 10	.346	.385	.623	.431	.429	.554	.452	.665	.521	1.000																		
item 11	.494	.573	.358	.461	.429	.399	.373	.413	.288	.408	1.000																	
item 12	.219	.384	.364	.070	.116	.107	.429	.341	.057	.315	.471	1.000																
item 13	.536	.546	.397	.373	.336	.187	.523	.304	.136	.326	.809	.522	1.000															
item 14	.642	.577	.385	.303	.389	.225	.581	.300	.070	.395	.588	.516	.612	1.000														
item 15	.461	.508	.488	.468	.517	.499	.458	.570	.322	.502	.452	.208	.449	.582	1.000													

item 16	.234	.274	.437	.374	.173	.184	-.045	.462	.171	.413	.367	.311	.219	.112	.249	1.000												
item 17	.441	.428	.395	.317	.337	.257	.303	.361	.203	.427	.574	.442	.536	.569	.382	.374	1.000											
item 18	.219	.222	.154	.083	.254	.146	.220	.183	.070	.308	.251	.343	.185	.383	.216	.029	.361	1.000										
item 19	.153	.190	.202	.112	.121	.134	.195	.284	.109	.213	.304	.564	.260	.258	.135	.224	.192	.629	1.000									
item 20	.515	.563	.605	.365	.198	.269	.455	.511	.258	.484	.423	.524	.497	.456	.427	.394	.358	.182	.326	1.000								
item 21	.584	.517	.583	.429	.134	.375	.486	.573	.406	.542	.441	.396	.370	.485	.503	.410	.355	.240	.231	.739	1.000							
item 22	.238	.380	.260	.150	-.101	.049	.423	.298	.123	.175	.455	.429	.502	.413	.296	.087	.185	.244	.267	.353	.458	1.000						
item 23	.423	.372	.505	.323	.235	.240	.397	.405	.342	.498	.537	.529	.544	.502	.460	.342	.427	.291	.309	.489	.582	.536	1.000					
item 24	.394	.497	.494	.237	.286	.359	.488	.471	.307	.488	.626	.702	.564	.611	.429	.278	.573	.467	.496	.497	.562	.530	.693	1.000				
item 25	.160	.193	.141	.112	-.091	.048	.342	.068	.061	.138	.228	.129	.246	.310	.191	-.071	.381	.234	-.026	.049	.163	.483	.154	.224	1.000			
item 26	.504	.442	.278	.313	.258	.140	.560	.195	.026	.327	.435	.446	.555	.656	.433	.070	.531	.341	.126	.375	.423	.431	.534	.556	.514	1.000		
item 27	.482	.507	.442	.127	.405	.244	.523	.281	.118	.354	.395	.307	.522	.614	.557	.038	.401	.237	.085	.514	.406	.313	.393	.464	.290	.600	1.000	.
item 28	.400	.214	.248	.310	.129	.103	.522	.067	.000	.252	.323	.184	.446	.565	.339	-.005	.515	.284	-.004	.199	.345	.271	.334	.354	.512	.702	.427	1.000

Table 7 depicts the Inter-item correlation matrix for Preoperative Parental Anxiety Scale (PPAS). The inter item correlation of PPAS was found to be in between -0.101 to 0.809. (Table 7).

Table 8: Summary item statistics of the Preoperative Parental Anxiety Scale (PPAS)

	Mean	Minimum	Maximum	Range	Maximum/ Minimum	Variance	Number of Items
Item Means	1.645	.180	2.810	2.630	15.611	.454	28
Item Variances	.831	.250	1.609	1.359	6.434	.105	28
Inter-Item Correlations	.358	-.101	.809	.910	-7.995	.027	28

Table 8 shows the summary of item statistics of the Preoperative Parental Anxiety Scale (PPAS). The Mean Inter Item Correlation (MIIC) was 0.358 with a mean item variance of 0.831 (Table 8).

Table 9: Item-total statistics of the Preoperative Parental Anxiety Scale (PPAS)

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
item 1	44.45	223.341	.632	.935
item 2	44.27	223.835	.685	.934
item 3	44.04	227.049	.652	.935
item 4	43.62	229.268	.489	.937
item 5	43.72	232.628	.445	.937
item 6	43.26	234.578	.444	.937
item 7	44.53	222.736	.634	.935
item 8	43.53	229.726	.632	.935
item 9	43.41	234.911	.358	.938
item 10	43.97	227.767	.643	.935
item 11	44.40	225.313	.721	.934
item 12	44.91	222.083	.593	.936
item 13	45.18	221.543	.702	.934
item 14	44.61	221.008	.743	.934
item 15	43.62	228.177	.651	.935
item 16	44.02	233.373	.360	.938
item 17	44.42	221.600	.634	.935
item 18	44.84	226.600	.418	.938
item 19	44.70	226.778	.384	.939
item 20	44.54	221.847	.672	.934
item 21	44.04	222.726	.705	.934
item 22	45.24	227.578	.501	.937
item 23	44.38	221.592	.694	.934
item 24	44.67	217.395	.783	.933
item 25	45.89	238.018	.312	.938
item 26	45.53	227.484	.657	.935
item 27	44.50	223.626	.599	.935
item 28	45.60	230.646	.479	.937

Table 9 represents the Item-total statistics of the Preoperative Parental Anxiety Scale (PPAS). Since the value of Cronbach's alpha didn't show any increase upon the deletion of items, it shows that all the items were significantly reliable and all could be retained. (Table 9).

Table 10: Scale statistics of the Preoperative Parental Anxiety Scale (PPAS)

Mean ± SD	Variance	Number of Items
46.07 ± 15.591	243.076	28

Table 10 summarizes the Scale statistics of the Preoperative Parental Anxiety Scale (PPAS). The mean preoperative anxiety score of the parents of children admitted for surgery were 46.07 and the SD was 15.591 with a variance of 243.076, showing a moderate level of preoperative parental anxiety as per PPAS (Table 10).

SECTION C: Validity analysis for the Preoperative Parental Anxiety Scale (PPAS)

Part I: Determination of construct validity using exploratory factor analysis

Table 11: KMO and Bartlett's Test of sphericity for PPAS

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.832
Bartlett's Test of Sphericity	**Approx. Chi-Square**	2090.693
	df	378
	Level of Significance	.000

Table 11 represents the KMO and Bartlett's Test of sphericity for appropriateness of PPAS for factor analysis. The appropriateness of PPAS was determined through the Kaiser-Meyer-Olkin (KMO) test and Bartlett test of sphericity. KMO value of more than or equal to 0.80 was considered to be suitable for factor analysis. KMO value for PPAS was found to be 0.832 and the Bartlett test of sphericity yielded an approximate $\chi 2$ value of 2090.693 ($p = 0.000$), making the items appropriate for factor analysis. [117,122]

Table 12: Extraction Communality of items through Principal Component Analysis.

	Initial	Extraction
item1	1.000	.662
item2	1.000	.687
item3	1.000	.692
item4	1.000	.585
item5	1.000	.844
item6	1.000	.789
item7	1.000	.687
item8	1.000	.784
item9	1.000	.782
item10	1.000	.721
item11	1.000	.885
item12	1.000	.750
item13	1.000	.837
item14	1.000	.773
item15	1.000	.632
item16	1.000	.825
item17	1.000	.742
item18	1.000	.799
item19	1.000	.781
item20	1.000	.783
item21	1.000	.788
item22	1.000	.811
item23	1.000	.619
item24	1.000	.788
item25	1.000	.728
item26	1.000	.776
item27	1.000	.695
item28	1.000	.802

Table 12 shows the Extraction Communality of items of PPAS through Principal Component Analysis. To find out the extraction communality of each item of the tool, Principal Component Analysis method was instituted. The initial communality of each item was assumed to be 1 (100%). For the PPAS, extraction communality of the items was in between 0.585 to 0.885 (Table 12). Average communality of items should be more than 0.5 and here for PPAS, it was found to be 0.751 which implies data was considered as appropriate for factor analysis.

Table 13: Total variance of the items extracted through Principal Component Analysis

	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
Item	**Total**	**% of Variance**	**Cumulative %**	**Total**	**% of Variance**	**Cumulative %**	**Total**	**% of Variance**	**Cumulative %**
1	11.109	39.677	39.677	11.109	39.677	39.677	4.995	17.839	17.839
2	2.873	10.262	49.939	2.873	10.262	49.939	3.825	13.662	31.502
3	2.012	7.187	57.126	2.012	7.187	57.126	3.025	10.805	42.306
4	1.450	5.180	62.306	1.450	5.180	62.306	2.807	10.026	52.332
5	1.413	5.045	67.351	1.413	5.045	67.351	2.608	9.315	61.647
6	1.180	4.214	71.565	1.180	4.214	71.565	2.102	7.507	69.154
7	1.010	3.606	75.171	1.010	3.606	75.171	1.685	6.017	75.171
8	.854	3.050	78.222						
9	.748	2.671	80.893						
10	.668	2.387	83.280						
11	.606	2.166	85.446						
12	.508	1.815	87.261						
13	.464	1.658	88.919						
14	.395	1.410	90.329						
15	.371	1.326	91.656						
16	.320	1.142	92.797						
17	.306	1.092	93.889						
18	.285	1.017	94.906						
19	.230	.822	95.727						

Table 13: Total variance of the items extracted through Principal Component Analysis

Item	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
20	.208	.741	96.468						
21	.193	.689	97.158						
22	.179	.639	97.797						
23	.145	.517	98.313						
24	.124	.443	98.757						
25	.104	.371	99.128						
26	.099	.352	99.480						
27	.088	.314	99.794						
28	.058	.206	100.000						

Table 13 shows the Total variance of the items extracted through Principal Component Analysis.

Factor extraction condenses the items into smaller number of items and is used to identify the number of underlying dimensions. Principal Component Analysis method was used for the extraction of factors of PPAS. PCA had generated 7 factors. The Eigenvalue of all the 7 factors were above 1.00. For the number of factors extracted from Principal Component Analysis to be meaningful, it should account for at least 60% of the total variance.[117,120,122] Here the Principal Component Analysis had showed that the first four factors account for 62.3% of the total variance and the remaining 3 factors contribute to 3% or more to the total variance.

Fig 5: Scree plot for the seven factor structure of the PPAS

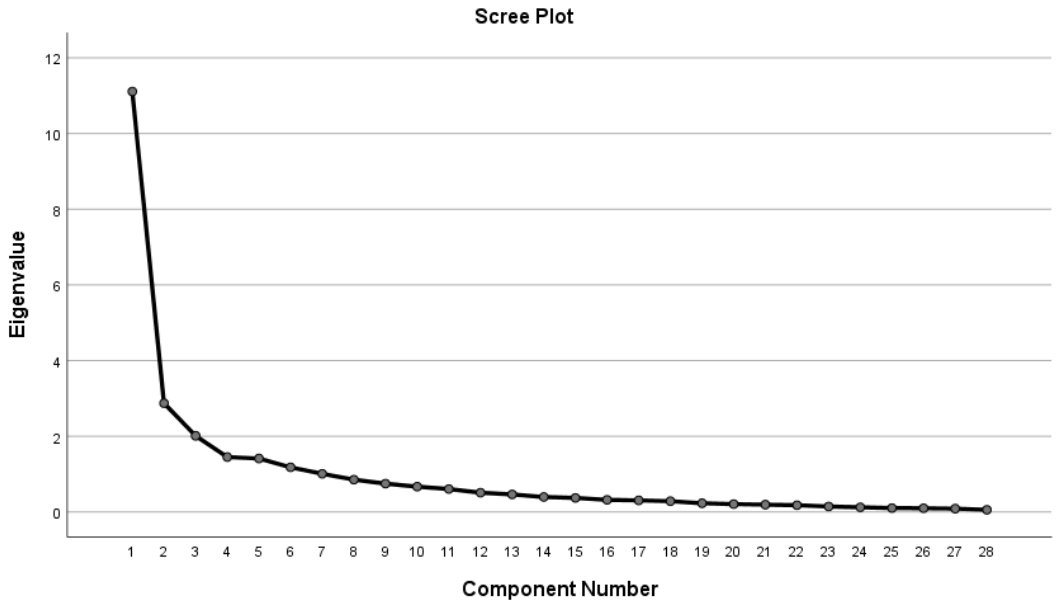

Fig 5 illustrates the scree plot for the seven factor structure of the PPAS. Since there is a considerable discontinuity after 7th component with eigenvalue of less than 1.00, seven factors could be extracted.

Table 14: Rotated Component Matrix of the items extracted through Principal Component Analysis

	Component						
	1	**2**	**3**	**4**	**5**	**6**	**7**
item1	.660						
item2	.690				.371		
item3	.555	.431				.409	
item4		.452			.325	.382	
item5	.365	.422			.371		
item6		.847					
item7	.638		.329				
item8	.344	.734					
item9		.868					
item10	.322	.647				.320	
item11					.802		
item12	.304			.644	.312		.314
item13	.429				.735		
item14	.612		.414		.368		
item15	.539	.477					
item16						.860	
item17			.543		.361	.394	
item18			.324	.800			
item19				.853			
item20	.685					.410	
item21	.566	.366				.422	.329
item22					.346		.718
item23	.327			.323	.322		.326
item24	.338			.581	.357		
item25			.780				.309
item26	.465		.676				
item27	.738						
item28			.837				

Table 14 depicts the Rotated Component Matrix of PPAS through Varimax rotation. Once the factors were extracted through Principal Component Analysis, factor rotation was done with Varimax with Kaiser Normalization.

The first factor had an initial acceptable loadings of 17 items from which 10 items [(items 1,2,3,7,14,15,20,21,23,27), (range, 0.327 - 0.738)] were retained and accounted for 39.67% of variance with an Eigenvalue of 11.109. The second factor evidenced an initial acceptable loadings of 9 items from which 6 items [(items 4,5,6,8,9,10), (range, 0.422 – 0.868)] were retained and accounted for 10.26% of variance with an Eigenvalue of 2.87. The third factor had loaded with 7 items initially, from which 4 items [(items 17,25,26,28), (range, 0.543 – 0.837)] were retained and accounted for 7.187% of variance with an Eigenvalue of 2.012. The fourth factor evidenced acceptable loadings from 4 items [(items 12,18,19,24), (range, 0.581 – 0.853)] and accounted for 5.18% of variance with an Eigenvalue of 1.45. The fifth factor had initial acceptable loadings from 11 items, out of which 2 items were retained [(items 11,13), (range, 0.735 – 0.802)] and accounted for 5.045% of variance with an Eigenvalue of 1.413. The factor 6 was initially loaded with 7 items from which retention of 1 item [(item 16), (factor loading = 0.860)] was made and accounted for 4.214% of variance with an Eigenvalue of 1.18. The seventh factor had an initial acceptable loadings from 5 items from which only 1 item retained. [(item 22), (factor loading = 0.718)] and accounted for 3.6% of variance with an Eigenvalue of 1.010.

A factor loading of more than 0.3 was considered as the criteria for acceptable loading.[123] Also, the items were retained within the factor in which they had higher factor loadings[117,122]

Part II: Determination of criterion validity through concurrent validity

Criterion validity of the tool was assessed by concurrent validity. This was checked by concurrent validity using the standardised tool 'Hamilton Anxiety Rating Scale" (HAM-A- English version) by interviewing the study subjects by asking questions in Hindi. HAM-A had an inter-rater reliability of 0.74[69]

Pearson correlation statistics was used to estimate the correlation between the mean anxiety scores of both PPAS and HAM-A among 20 study subjects. The hypothesis for correlation analysis were given below:

- H_0 : There is no significant difference between the mean anxiety scores of both PPAS and HAM-A.
- H_1 : There is significant difference between the mean anxiety scores of both PPAS and HAM-A.

Table 15: The Pearson correlations between the mean anxiety scores of both PPAS and HAM-A (N=20)

	Mean	**SD**	**Pearson Correlation Coefficient, r**
PPAS	44.75	14.732	0.885*
HAM-A	9.70	4.802	0.885*
N	20		

*. Correlation is significant at the 0.01 level (2- tailed)

Table 15 represents the Pearson correlation between the mean anxiety scores of both PPAS and HAM-A. Since PPAS and HAM-A was found to be positively correlated (r = 0.885), the null hypothesis could be accepted which implies that there is no significant difference between the mean anxiety scores of both PPAS and HAM-A. Thus, the PPAS found to have good concurrent validity upon measuring the construct under topic of study when compared with a standardized tool HAM-A.

DISCUSSION

Surgery in paediatric patients is a kind of distressful experience for both the child and the family. The anxiety would be higher for the parents of a hospitalized child. The preoperative parental anxiety shows a significant impact on the child, family functioning as well as on the parents themselves in terms of physical and psychological aspects.

The present study has been conducted for the development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur among 100 study subjects (parents). The Preoperative Parental Anxiety Scale (PPAS) developed in three phases of item development, scale development and scale evaluation through seven steps. Similar methodology was used in other studies from the literature.[97,98] The final tool consists of 28 items, which were developed through extensive literature review, FGDs and Delphi process.

Literature revealed that the major factors responsible for the parental anxiety during the preoperative period of their child's surgery were family concerns, postoperative pain of the child, chances of disability, fear of both anaesthetic and surgical complications, fear of surgical mistakes, fear of not awakening after the general anaesthesia, fear of economic loss due to the treatment costs, fear of loss of one's normal social life as well as the length of hospital stay[10,23] Evidences also suggested that the major predictors associated with parental anxiety in terms of specific demographic characteristics were child's gender[31] and age, gender of the parent, area of residence, socio-economic status, being a mother, single child and education level, spirituality and

occupation. Additional factors also involve the social contacts of the parents,[6] parental perception of the external locus of control of child's health,[6,32,33] parental separation[34] and period of recovery.[35]

The number of fathers and mothers participated in the study were equal (50% each). 53% of the parents were in the age group of 30 to 40 years and the mean age of parents were 31.41 years and a SD of 5.605. 56% of the children were boys. Among children, 42% were in between the age group of 1-6 years and the mean age of the children was 5.64 years with a SD of 4.15. 64% of the study subjects were urban residents and 31% of the study subjects were graduates. Majority of the study subjects didn't have a previous history of hospitalization for their child (82%). Also about 98% of the study subjects didn't had a previous surgical history for their child.

The results of this study of PPAS suggest that it is a comprehensible and well organized tool with good practicability. The S-CVI/ Ave and S-CVI/ UA were 0.98 and 0.8 respectively, which was good.

PPAS demonstrated excellent reliability as measured by internal consistency with Cronbach's alpha of 0.938. This result is comparable with the anxiety measures of other tools like HADS, STAI, BAI and SCAS-P.[74,78,88] In a similar study, the internal consistency was strong with Cronbach's alpha of 0.94 for Anxiety Symptoms Questionnaire developed by **Amanda et al.**[73]

The mean score of each item ranged from 0.18-2.81, with a SD of 0.5-1.269. The Mean Inter Item Correlation (MIIC) was 0.358, which was acceptable as it is more than 0.015.

The concurrent validity when checked with the standardised tool 'Hamilton Anxiety Rating Scale' (HAM-A) showed a strong correlation with Pearson correlation coefficient of 0.885. Similar result was identified when ASQ was compared with HAM-A (0.58-0.75).[73] In another study, the Pearson correlation of APAIS anxiety subscale has shown significant correlation with the anxiety scores of other tools STAI and HADS.[124]

It takes about 10-12 minutes to complete PPAS which is similar to the other studies.[73,85,125]

KMO and Bartlett tests revealed that the items were appropriate for factor analysis as the value came to be 0.832 and an approximate $\chi 2$ value of 2090.693 ($p = 0.000$) respectively.[123] Also, since the average communality of items for PPAS was found to be 0.751 it was found to be suitable for factor analysis as the cut-off point is >0.5. Principal Component Analysis had generated 7 factors with Eigenvalue of more than 1.00. Also, the first four factors account for 62.3% of the total variance and the remaining 3 factors contribute to 3% or more to the total variance . All the items with a factor loading of 0.30 or more were retained within the factor in which they had higher factor loadings[123] which showed that PPAS has a good construct validity. The amount of total variance for the seven factors of PPAS is 75.17% which is consistent with the previous studies.[117,122,124]

As there is no clinically applicable instrument in the literature which is specific for the assessment of preoperative parental anxiety, this study was aimed to develop the Preoperative Parental Anxiety Scale (PPAS). In comparison with the already available tools to measure the anxiety, PPAS is

mainly designed to measure the preoperative parental anxiety. Also, it's consistently reliable correlation with the HAM-A which was used as a gold standard for concurrent validity assessment, makes it a tool with good clinical application. Thus the findings suggest that PPAS is a valid and highly reliable tool to measure the preoperative parental anxiety.

The major study findings were catalogued as follows:

- PPAS was found to be comprehensible and well organized with good practicability.
- The S-CVI/ Ave and S-CVI/ UA were 0.98 and 0.8 respectively.
- The reliability of PPAS was assessed with internal consistency using Cronbach's alpha and was estimated to be 0.938.
- The concurrent validity was found to be good when checked with the standardised tool ''Hamilton Anxiety Rating Scale' (HAM-A).
- The mean score of each item ranged from 0.18-2.81, with a SD of 0.5-1.269.
- The Mean Inter Item Correlation (MIIC) was 0.358 with a mean item variance of 0.831.
- Average communality of items for PPAS was found to be 0.751.
- Principal Component Analysis had generated 7 factors with Eigenvalue of more than 1.00. Also, the first four factors account for 62.3% of the total variance and the remaining 3 factors contribute to 3% or more to the total variance.

CHAPTER-V

SUMMARY CONCLUSION AND RECOMMENDATION

SUMMARY CONCLUSION AND RECOMMENDATION

This chapter provides a brief account about the present study consisting of brief description about the study methodology, strengths and limitations, implication of the study in nursing and recommendation for future research.

A quantitative methodological research design study was conducted for the development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur. The main objectives of the study were:

1. To develop a tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward.
2. To test the psychometric properties of the tool in terms of reliability and validity.

The study samples for the item development phase (phase 1) were 2 doctors and 5 nurses in the paediatric surgery ward and 14 parents of children admitted for surgery under general anaesthesia in Paediatric surgery ward at AIIMS Jodhpur while the samples for the scale evaluation phase (phase 3) were 100 parents of children admitted for surgery under general anaesthesia in Paediatric surgery ward at AIIMS Jodhpur. Non – probability convenience sampling was used in this study in which the most readily available parents, doctors and nurses were selected as study participants.

Data collection methods for development of tool were extensive literature review and FGDs in the item development phase (phase 1) and Delphi process in the scale development phase (phase 2).

The pilot testing of PPAS with 28 items to 20 study subjects showed that approximate time taken by each parent to complete the questionnaire was about 10-12 minutes. The tool was found to be feasible with proper understanding and language clarity for the parents. The administration of tool was taken place from Nov 2020 to DEC 2020 and the statistical analysis was done using SPSS version 26.

Strength of the study

- This tool is first of its kind that particularly meant for measuring preoperative parental anxiety.
- The PPAS was found to have good practicability in paediatric surgery settings.

Limitations of the study

- Research findings cannot be generalized as only single setting was selected for conducting the study.
- All children within the paediatric age group were included and not a particular age category.
- Only surgery under GA was considered.
- System wise surgery specifications was not made.
- Due to COVID 19 pandemic situation, sampling inadequacy was present for the testing of the tool.

IMPLICATIONS IN NURSING

Nursing is considered as an oldest of art and youngest of science. There is always a great emphasis on changing and advancing the nursing knowledge

through continuing education and research which in terms were oriented towards the provision of best and better quality care to the patients. The findings of the present study have implication in nursing practice, education, administration and research.

a) **Nursing practice:**

Now-a-days, Paediatric nursing is mainly focussed upon the quality improvement in the provision of care to children as well as their family. Parents being the caregivers would be subjected for extreme anxiety whenever caring for their child. Therefore, nurses should be encouraged to identify the areas of parental anxiety for the formulation of interventions to reduce parental anxiety specific to the preoperative period.

b) **Nursing education:**

The dual role nurse educator is a newly emerging concept. Nurse educators could have a great opportunity to identify the areas of lacking of knowledge and skills in the similar anxiety measurement scales and their implementation along with the training of student nurses in this field along with the identification and exploration of innovative ways to reduce preoperative parental anxiety.

c) **Nursing administration:**

The role of nurse administrators and supervisors were in a changing process due to the increasing opportunities and responsibilities towards patients and subordinates. The nurse administrator should co-ordinate with other health care team members in the improvement of quality of life of parents and children. They should focus on implementing various strategies and

measures for the assessment of preoperative parental as well as child's anxiety in the clinical settings under their supervision.

d) **Nursing research:**

One of the major aims of nursing research is to refine and expand the existing body of knowledge. Similar methodological researches should be done to improve the knowledge as well as in developing newer specific tools to measure anxiety along with the testing of its psychometric properties.

RECOMMENDATIONS

On the basis of the present study findings, it is recommended that:

- A study can be repeated on a large sample and in a different setting so that findings of psychometric validation can be more generalized in the population.
- Inter-rater as well as test retest reliability can be assessed.
- Convergent validity as well as discriminant validity of the tool can be assessed.
- A multi-centre study can be done for parents of children admitted for surgery for different age groups as well as for different surgeries.
- A comparative study can be done to assess the levels of preoperative parental anxiety with the existing anxiety assessment scales.
- A study can be conducted for seeking the interventions for reducing the preoperative parental anxiety based upon the anxiety level identified.

CONCLUSION

In conclusion, the result of this study has shown that Preoperative Parental Anxiety Scale (PPAS) is a feasible and a highly reliable and valid tool to measure the preoperative parental anxiety among parents of children admitted for surgery. It accords towards the need for further more research into the measurement of the parental anxiety. Therefore physicians and nurses should pay attention to identify the areas of parental anxiety to provide high quality paediatric health care services for both children and their caregivers.

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APPENDICES

Appendix-I

ETHICAL CLEARANCE CERTIFICATE

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

No. AIIMS/IEC/2020/3107 **Date: 01/06/2020**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2020-21/3025**

Project title: **"Development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS Jodhpur"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**Student Research Project, as a part of Academic Programme**
Investigator:	**Theresa Jose**
Supervisor:	**Mr. Mukesh Chandra Sharma**
Co-Supervisor:	**Dr. Tanu Gupta, Mrs. Remiya Mohan & Dr. Kirti Kumar Rathod**

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

Appendix-II

LIST OF EXPERTS FOR DELPHI PROCESS

NAME	NAME
Dr. Poonam Joshi Associate Professor Paediatric Nursing CON, AIIMS, DELHI	**Dr. Rachna Bhargava** Additional Professor Dept of Psychiatry and NDDTC AIIMS, DELHI
Mrs. Rupinder Deol Assistant Professor Paediatric Nursing AIIMS, Rishikesh	**Dr. Renu Sharma** Child Psychologist Dept of Psychiatry AIIMS, DELHI
Dr. Theresa Leonilda Mendonca Vice Principal/Professor Laxmi Memorial College of Nursing AJ Towers, Balmatta, Mangalore, 575002	**Haleemunissa S** Child psychologist Dept of Psychiatry AIIMS, Jodhpur
Dr. Prabudh Goel Associate Professor Dept of Paediatric Surgery AIIMS, Delhi	**Dr. Naresh Nebhinani** Additional Professor Department of Psychiatry AIIMS, Jodhpur
Dr. Bharat Paliwal Associate Professor Dept of Anaesthesiology and critical care AIIMS, Jodhpur	**Mrs. Mamta** Assistant professor CON, AIIMS, Jodhpur

Appendix-III

LETTER REQUESTING EXPERTS FOR CONTENT VALIDITY

A LETTER REQUESTING EXPERTS FOR CONTENT VALIDITY

Expert opinion on validity of preliminary draft of tool to measure preoperative parental anxiety for parents of children admitted for surgery in paediatric ward of AIIMS, Jodhpur, under Delphi technique

From
Theresa Jose
M.Sc. Nursing (Batch 2019)
College of Nursing, AIIMS, Jodhpur

To

_____

Subject: Expert opinion on validity of preliminary draft of under 2- 3 rounds of Delphi technique

Respected Sir/Madam

I, Theresa Jose, M.Sc. Nursing (Batch 2019) student of College of Nursing, AIIMS, Jodhpur have undertaken the following topic for research project: "Development of Tool To Measure Preoperative Parental Anxiety For Parents of Children Admitted For Surgery In Paediatric Ward At AIIMS, Jodhpur" under the supervision of Dr. Mukesh Chandra Sharma, Associate Professor, Paediatric Nursing, AIIMS, Jodhpur.

Objective of the study is

1. To develop a tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward.

I request you to kindly validate my research tool for appropriateness and relevancy and give your opinion for any modification and improvement needed.. Your esteemed opinion and critical comments will provide the required direction and contribute immensely to the quality and content of my research.

Looking forward for your expert guidance and suggestions.
Thanking you in anticipation
Yours sincerely
Theresa
Theresa Jose
M.Sc. Nursing (Batch 2019)
College of Nursing, AIIMS, Jodhpur

forwarded for validation

GUIDE/SUPERVISOR
Dr. Mukesh Chandra Sharma
Associate Professor
College of Nursing, AIIMS, Jodhpur

CO-GUIDE	CO-GUIDE	CO-GUIDE
Mrs. Remiya Mohan	Dr. Kirtikumar Rathod	Dr. Tanu Gupta
Lecturer	Associate Professor	Clinical Psychologist
College of Nursing	Dept. of Paediatric Surgery	Dept. of Psychiatry
AIIMS, Jodhpur	AIIMS, Jodhpur	AIIMS, Jodhpur

Enclosure:

- Brief methodology
- Preliminary draft (English/ Hindi)
- Evaluation criteria checklist for validation tool
- Certificate of validation

Appendix-IV

Informed Consent Form

Title of the research study: "Development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur".

Name of the Investigator: Theresa Jose (M.Sc. Nursing)

Subject Identification No:

I, _____S/o__or W/o _____R/o _____ give my full, free, voluntary consent to be a part of the study "Development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward", 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 may be looked at by responsible individual from All India Institute of Medical Sciences Jodhpur, Rajasthan. 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 PG Student

1. Witness 1 2. Witness 2

Signature Signature

Name: _____ Name: _____

Address: _____ Address: _____

Appendix-V

सूचित सहमति प्रपत्र

परियोजना का शीर्षक: " **एम्स जोधपुर में बाल चिकित्सा वार्ड में सर्जरी के लिए भर्ती बच्चों के माता-पिता की सर्जरी से पूर्व चिंता को मापने के लिए उपकरण का विकास "।**

अन्वेषक का नाम: **तेरेसा जोस**

पहचान संख्या :_____

मैं_____**पुत्र/पत्नी**_____,**निवासी**_____ :
" एम्स जोधपुर में बाल चिकित्सा वार्ड में सर्जरी के लिए भर्ती बच्चों के माता-पिता की पूर्व शल्य चिकित्सा चिंता को मापने के लिए उपकरण का विकास " नामक अध्ययन जिसकी प्रक्रिया और प्रकृति मुझे मेरी अपनी भाषा में पूर्ण संतुष्टि के साथ समझा दी गयी है, मैं भाग लेने के लिए अपनी पूर्ण, स्वतंत्र एवं स्वेच्छिक सहमति देता /देती हूँ । मैं पुष्टि करता/ करती हूँ कि मुझे सवाल पूछने का अवसर दिया गया है।

मैं समझता/ समझती हूँ कि मेरी भागीदारी स्वैच्छिक है और मैं अपने इस अधिकार से अवगत हूँ कि मैं किसी भी समय बिना कोई कारण दिए इस अध्ययन से अपना नाम वापस ले सकता /सकती हूँ।

मैं समझता/समझती हूँ कि मेरे बारे में एकत्र जानकारी एम्स जोधपुर के किसी भी जिम्मेदार व्यक्ति द्वारा या नियामक अधिकारियों द्वारा देखी जा सकती है। मैं उपरोक्त व्यक्तियों को मेरे द्वारा दी गई जानकारी देखने की अनुमति देता/ देती हूँ।

दिनांक: _____

स्थान: _____ **हस्ताक्षर**

यह प्रमाणित है कि उपरोक्त सहमति मेरी उपस्थिति में प्राप्त की गयी है।

दिनांक: _____

स्थान: _____ **हस्ताक्षर अन्वेषक**

1.**साक्षी**-1
नाम:_____
पता:_____
हस्ताक्षर:----------

2. **साक्षी**-2
नाम:_____
पता:_____
हस्ताक्षर:----------

Appendix-VI

Participant Information Sheet

Part 1:

1. Purpose of the research study: Development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur.

2. Study procedure to be followed: The study will proceed through three phases involving item development, scale development and scale evaluation respectively.

3. Benefits from the study: The study will help in developing the tool specific for measuring preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur.

4. Risk of the study: None

5. Complication of the study: None

6. Confidentiality: Data collected from the participants shall not be allowed shared with anyone except the study investigator.

7. Rights of the participants: Participants would have the freedom to share their data and to continue or leave the study if they desire so at any point of time.

Participant Signature:

Participant Name:

Part 2:

Investigator's word

I have explained the purpose, procedure, benefits, and harms of the study in details to the participants. All the information regarding study has been disclosed and enough opportunity for asking questions regarding the study was given to study participant.

Principal Investigator Signature	Witness signature
Name:	Name:
Date:	Date:

Appendix-VII

प्रतिभागी सूचना पत्र

भाग 1:

1. **शोध अध्ययन का उद्देश्य**: " **एम्स जोधपुर में बाल चिकित्सा वार्ड में सर्जरी के लिए भर्ती बच्चों के माता-पिता की सर्जरी से पूर्व चिंता को मापने के लिए उपकरण का विकास** " ।

2. **अध्ययन की प्रक्रिया का पालन किया जाएगा**: **अध्ययन क्रमशः तीन चरणों में आगे बढ़ेगा जिसमें आइटम विकास, स्केल विकास और स्केल मूल्यांकन शामिल हैं।**

3. **अध्ययन से लाभ**: **यह अध्ययन एम्स जोधपुर में बाल चिकित्सा वार्ड में सर्जरी के लिए भर्ती बच्चों के माता-पिता के लिए सर्जरी से पूर्व चिंता को मापने के लिए विशेष उपकरण विकसित करने में मदद करेगा।**

4. **अध्ययन का जोखिम**: **कोई नहीं**

5. **अध्ययन की जटिलता**: **कोई नहीं**

6. **गोपनीयता**: **प्रतिभागियों से एकत्र किए गए डेटा को अध्ययन अन्वेषक को छोड़कर किसी के साथ साझा करने की अनुमति नहीं दी जाएगी।**

7. **प्रतिभागियों के अधिकार**: **प्रतिभागियों को अपने डेटा को साझा करने और किसी भी समय यदि वे चाहें तो अध्ययन जारी रखने या छोड़ने की स्वतंत्रता होगी।**

प्रतिभागी हस्ताक्षर:

भाग लेने वाले का नाम:

भाग 2:

अन्वेषक का शब्द

मैंने प्रतिभागियों को विवरण में अध्ययन के उद्देश्य, प्रक्रिया, लाभ और हानि के बारे में बताया है। अध्ययन के बारे में सभी जानकारी का खुलासा किया गया है और अध्ययन के बारे में सवाल पूछने के लिए पर्याप्त अवसर अध्ययन प्रतिभागी को दिया गया था।

प्रधान अन्वेषक हस्ताक्षर **साक्षी हस्ताक्षर**

नाम **नाम**:

दिनांक: **दिनांक**:

Appendix-VIII

BLUE PRINT OF SCALE

S.N.	New domains		Items included
1.	**Surgery and surgery related procedures (16)**	Concerns of the parents related to • preparation for surgery of the child (3) • surgery of the child (3) • anaesthesia of the child (1) • outcome of the child's surgery (3) • postoperative period of the child (4) • quality of life of the child after surgery (2)	1-16
2.	**Child's anxiety (1)**	Effect of child's anxiety on parental anxiety (1)	17
3.	**Family responsibilities (1)**	Concerns of the parents about the family and house hold responsibilities due to child's surgery (1)	18
4.	**Financial concerns related to child's surgery and treatment (1)**	Financial concerns of the parents related to child's surgery and treatment (1)	19
5.	**Personal symptoms (9)**	Physical symptoms experienced by parents (4) Psychological symptoms experienced by parents (5)	20,21,22,23,24, 25,26,27, 28

Min. Score= 0 Max. Score= 84

Category	Scoring	% of Score
Mild	<28	<33.3%
Moderate	28-56	33.3%-66.66%
Severe	56-84	>66.66%

Appendix-IX

TOOLS FOR DATA COLLECTION

SECTION–A: SOCIO-DEMOGRAPHIC VARIABLES (ENGLISH)

<u>INSTRUCTIONS:</u> Please provide the following information. All the information will be kept confidential.

1. Parent: a) Father b) Mother
2. Gender of the child: a) Boy b) Girl
3. Age of the parent:
4. Age of the child:
5. Religion: a) Hindu b) Muslim c) Christian d) Sikh e) Others
6. Area of residence: a) Rural b) Urban
7. Education of the parent (whichever applicable) : a) Below 10^{th} class b) 10^{th} pass c) 12^{th} pass d) Graduate and above
8. Occupation of the parent (whichever applicable): a) Gov job b) Private job c) Own business d) farmer e) Daily wage worker f) Homemaker g) Unemployed
9. Socioeconomic status:

a. Occupation of the head of the family

Sl no	Occupation of the head of the family	Score
1	Legislators, Senior Officials & Managers	10
2	Professionals	9
3	Technicians and Associate Professionals	8
	Clerks	
4	Skilled Workers and Shop & Market Sales	7
5	Workers	6
6	Skilled Agricultural & Fishery Workers	5
7	Craft & Related Trade Workers	4
8	Plant & Machine Operators and Assemblers	3
9	Elementary Occupation	2
10	Unemployed	1

b. Education of the head of the family

Sl no	Education of the head of the family	Score
1	Profession or Honours	7
2	Graduate	6
3	Intermediate or diploma	5
4	High school certificate	4
5	Middle school certificate	3
6	Primary school certificate	2
7	Illiterate	1

c. Total monthly income of the family

Sl no	Updated Monthly Family Income in Rupees (2020)	Score
1	≥ 199,862	12
2	99,931–199,861	10
3	74,755 –99,930	6
4	49,962–74,755	4
5	29,973– 49,961	3
6	10,002–29,972	2
7	≤ 10,001	1

Kuppuswamy's socio-economic status scale 2020

Sl no	Score	Score Socioeconomic Class
1	**26-29**	**Upper (I)**
2	**16-25**	**Upper Middle (II)**
3	**11-15**	**Lower Middle (III)**
4	**5-10**	**Upper Lower (IV)**
5	**<5**	**Lower (V)**

10. Type of family: a) Nuclear b) Joint
11. No of children: a) 1 b) 2 c) 3 d) 4 and above
12. Birth order of the child admitted for surgery: a) 1 b) 2 c) 3 d) 4 and above
13. Do you have any previous history of hospitalization for your child?
    (a) Yes (b) No
14. Do you have any previous history of surgery for your child?
    (a) Yes (b) No

(SECTION-B)

PREOPERATIVE PARENTAL ANXIETY SCALE (PPAS) - ENGLISH

INSTRUCTIONS: Following scale consists of statements based on the preoperative parental anxiety. Please provide answer in terms of never, sometimes, fairly often and always. There is no right and wrong answer. All the information will be kept confidential.

ITEMS	Never 0	Sometimes 1	Fairly Often 2	Always 3
1. I feel tense about keeping the child NPO before surgery. 2. I feel scared about the preoperative investigations and procedures in my child. 3. I feel stressed whenever I get preoperative information related to surgery of my child.				
4. I have a fear regarding my child's surgical procedure especially the duration of surgery 5. I get upset regarding type of surgery to be performed in my child 6. I am scared if something will happen to my child during surgery				
7. I feel stressed about the inability of my child to wake up from anaesthesia.				
8. I'm scared about the complications in my child following surgery 9. I'm scared about the condition of my child after surgery. 10. I fear about the recovery, especially about the duration of recovery of my child after surgery				
11. I'm worried about the immediate postoperative pain of my child 12. I'm tensed about the length of hospital stay after surgery of my child 13. I worry about the postoperative diet of my child 14. I'm worried about the postoperative care of my child especially wound care.				
15. I feel stressed about the future of my child after surgery 16. I have a fear about the recurrence of the same problem in my child even after surgery				
17. I feel tensed on seeing the anxiety of my child				
18. I feel stressed about household responsibilities specially caring other healthy child/children due to more time given for the ill child				
19. I have a fear of expenses due to surgery and treatment cost of my child				
Whenever caring for my child, I feel/experience the following: 20. I'm having headache/ any other body pain whenever I think about the surgery of my child. 21. I'm having sleeping difficulty during night by thinking about the surgery of my child. 22. I'm always having a feeling of tiredness throughout the				

day during these days in the hospital 23. I don't feel like eating during these days due to frequent thought about my child's condition				
24. I don't feel like spending time on myself ever since this issue of surgery has come up 25. I have experienced bad dreams during sleep about my child's condition. 26. I feel inability to concentrate on activities 27. I have frequent occurrence of worrying thoughts about my child's condition. 28. I feel loss of interest in social life				

Appendix-X

अनुबंध **X**

डेटा संकलन के लिए उपकरण

अनुभाग– A : सामाजिक जनसांख्यिकीय चर (हिन्दी)

निर्देश : कृप्या निम्नलिखित जानकारी प्रदान करें। सभी जानकारी को गोपनीय रखा जाएगा।

1. ज्नक : a) पिता b) माता
2. बच्चे का लिंग : a) लड़का b) लड़की
3. माता/पिता की आयु : .....
4. बच्चे की आयु : .....
5. धर्म : a) हिन्दु b) मुस्लिम c) ईसाई d) सिख e) अन्य
6. निवास का क्षेत्र : a) ग्रामीण b) शहरी
7. माता/पिता की शिक्षा :

(जो भी लागू हो) : a) 10 वीं कक्षा से नीचे b) 10 वीं पास c) 12 वीं पास

d) स्नात्तक और उससे अधिक

8. माता/पिता का व्यवसाय :

(जो भी लागू हो) : a) सरकारी नौकरी b) निजी नौकरी c) अपना व्यापार d) किसान e) दैनिक मजदूर f) गृहिणी g) बेरोजगार

9. सामाजिक आर्थिक स्थिति

a) परिवार के मुखिया का व्यवसाय

क्रम संख्या	परिवार के मुखिया का व्यवसाय	स्कोर
1	विधायक, वरिष्ठ अधिकारी और मैनेजर	10
2	व्यवसायी	9
3	तकनीशियन और एसोसिएट पेशेवर	8
4	क्लर्क	7
5	पेशेवर श्रमिक और दुकार एंव बाजार बिक्री कार्यकर्ता	6
6	पेशेवर खेती–बाड़ी एंव मत्स्य श्रमिक	5
7	शिल्प एंव व्यापार संबंधित कार्यकर्ता	4
8	कारखाना एंव मशीन ऑपरेटर और संयोजनकर्ता	3
9	सामान्य व्यवसाय	2
10	बेरोजगार	1

b) परिवार के मुखिया की शिक्षा

क्रम संख्या	परिवार के मुखिया का व्यवसाय	स्कोर
1	पेशेवर या ऑनर्स	7

2	स्नात्तक	6
3	इंटरमीडिएट या डिप्लामा	5
4	उच्च शिक्षा का प्रमाण–पत्र	4
5	मध्यवर्ती शिक्षा का प्रमाण–पत्र	3
6	प्राथमिक शिक्षा का प्रमाण–पत्र	2
7	निरक्षर	1

c) परिवार की कुल मासिक आय

क्रम संख्या	रूपयो (2020) में पारिवारिक मासिक आय का अपडेट	स्कोर
1	≥ 199,862	12
2	99,931 – 199,861	10
3	74,755 – 99,930	6
4	49,962 – 74,755	4
5	29,973 – 49,961	3
6	10,002 – 29,972	2
7	≤ 10,001	1

कुप्पुस्वामी की सामाजिक–आर्थिक स्थिति का स्केल 2020

क्रम संख्या	स्कोर	स्कोर सामाजिक–आर्थिक श्रेणी
1	26 – 29	उच्च वर्ग (I)
2	16 – 25	उच्च–मध्य मवर्ग (II)
3	11 – 15	निम्न–मध्य वर्ग (III)
4	5 – 10	उच्च–निम्न वर्ग (IV)
5	< 5	निम्न वर्ग (V)

10. पारिवारिक स्थिति : a) एकल परिवार b) सयुक्त परिवार

11. बच्चो की संख्या : a) 1 b) 2 c) 3 d) 4 और उससे अधिक

12. सर्जरी के लिए भर्ती हुए बच्चे का जन्म क्रम : a) 1 b) 2 c) 3 d) 4 और उससे अधिक

13. क्या आपके बच्चे का अस्पताल में भर्ती होने से पहले का पिछलहै ? a) हाँ b) नहीं

14. क्या आपके बच्चे की पहले कभी सर्जरी हुई है ? a) हाँ b) नहीं

(खंड बी)

ऑपरेशन से पूर्व माता–पिता की चिंता का स्केल

(हिन्दी)

निर्देश : निम्नलिखित स्केल में माता–पिता की चिंता के आधार पर विवरण शामिल होते है। कृप्या कभी नहीं, कभीकभार, कई बार और हमेश के संदर्भ में जवाब प्रदान करें। यहाँ कोई भी सही और गलत जवाब नहीं है। सभी जानकारी को गोपनीय रखा जाएगा।

क्रम संख्या	सवाल	कभी नहीं	कभीकभार	कई बार	हमेशा
1	मैं सर्जरी से पहले बच्चे को भूखा रखने के बारे में चिंता महसूस करता/ती हूँ।				
2	मुझे अपने बच्चे के लिए ऑपरेशन से पूर्व जांचों और प्रक्रियाओं के लिए डर लगता है।				
3	मुझे जब कभी अपने बच्चे की सर्जरी से संबंधित ऑपरेशन से पूर्व सूचना मिलती है तो मुझे तनाव महसूस होता है।				
4	मुझे अपने बच्चे की सर्जिकल प्रक्रिया खासकर सर्जरी की अवधि के बारे में डर है।				
5	मुझे अपने बच्चे में होने वाली सर्जरी के प्रकार से परेशान हूँ।				
6	मुझे डर है, अगर सर्जरी के दौरान मेरे बच्चे को कुछ हो जाएगा।				
7	मैं अपने बच्चे के होश में ना आ पाने की स्थिति के बारे में तनाव महसूस करती/ता हूँ।				
8	मैं सर्जरी के बाद अपने बच्चे के मुश्किल स्थिति मे आने के बारे में डरती/ता हूँ।				
9	मैं सर्जरी के बाद अपने बच्चे की स्थिति को लेकर डर गया/गई हूँ।				
10	मुझे सर्जरी के बाद मेरे बच्चे के ठीक होने की अवधि के बारे में डर है।				

क्रम संख्या	सवाल	कभी नहीं	कभीकभार	कई बार	हमेशा
11	मैं अपने बच्चे के ऑपरेशन के तुंरत बाद होने वाले दर्द के लिए चिंतित हूँ।				
12	मैं अपने बच्चे की सर्जरी के बाद अस्पताल में रहने की लंबी अवधि के लिए परेशान हूँ।				
13	मुझे अपने बच्चे को ऑपरेशन के बाद दिये जाने वाले आहार की चिंता है।				
14	मैं अपने बच्चे की सर्जरी के बाद की देखभाल, खास कर घाव की देखभाल के लिए चिंतित हूँ।				
15	मैं सर्जरी के बाद अपने बच्चे के भविष्य के लिए चिंता महसूस करती/ता हूँ।				
16	मुझे सर्जरी के बाद भी अपने बच्चे में वही समस्या फिर से हो जाने का डर है।				
17	अपने बच्चे की घबराहट को देखकर मुझे चिंता महसूस होती है।				
18	मैं बीमार बच्चे को अधिक समय दिए जाने के कारण घरेलू जिम्मेदारियों, विशेष रूप से अन्य स्वस्थ बच्चे/बच्चों की देखभाल करने के लिए थकान महसूस करता/ती हूँ।				
19	मैं अपने बच्चे की सर्जरी केलिए अस्पताल के खर्च के बारे में तनाव महसूस करता/ती हूँ।				
	जब भी मैं अपने बच्चे की देखभाल करता/ती हूँ, मुझे निम्नलिखित का अनुभव होता है :–				
20	मैं जब कभी अपने बच्चे की सर्जरी के बारे में सोचता/ती हूँ, तो मुझे सिरदर्द/शरीर में दर्द होता है				
21	मुझे अपने बच्चे की सर्जरी के बारे में सोचकर रात के समय सोने में तकलीफ होती है।				
22	मुझे इन दिनों के दौरान हमेशा अस्पताल में दिन भर थकान महसूस होती है।				
23	मेरा अपने बच्चे की स्थिति के बारे में अक्सर सोचने के कारण इन दिनों के दौरान खाने का मन नहीं करता है।				

क्रम संख्या	सवाल	कभी नहीं	कभीकभार	कई बार	हमेशा
24	मुझे खुद पर समय बिताने का मन नहीं करता, जब से सर्जरी का मामला सामने आया है।				
25	मैंने अपने बच्चे की स्थिति के बारे में नींद के समय बुरे सपने देखे हैं।				
26	मैं गतिविधियों पर ध्यान केंद्रित करने में असमर्थता महसूस करता/ती हूँ।				
27	मुझे अपने बच्चे की स्थिति के बारे में चिंता का ख्याल आता है।				
28	मै सामाजिक जीवन में रुचि की कमी महसूस करता/ती हूँ।				

Appendix-XI

Tool for data collection- HAM-A

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 Anxious mood [0] [1] [2] [3] [4]

Worries, anticipation of the worst, fearful anticipation, irritability.

2 Tension [0] [1] [2] [3] [4]

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 Fears [0] [1] [2] [3] [4]

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 Insomnia [0] [1] [2] [3] [4]

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 Intellectual [0] [1] [2] [3] [4]

Difficulty in concentration, poor memory.

6 Depressed mood [0] [1] [2] [3] [4]

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 Somatic (muscular) [0] [1] [2] [3] [4]

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 Somatic (sensory) [0] [1] [2] [3] [4]

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 Cardiovascular symptoms [0] [1] [2] [3] [4]

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 Respiratory symptoms [0] [1] [2] [3] [4]

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 Gastrointestinal symptoms [0] [1] [2] [3] [4]

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 Genitourinary symptoms [0] [1] [2] [3] [4]

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 Autonomic symptoms [0] [1] [2] [3] [4]

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 Behavior at interview [0] [1] [2] [3] [4]

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

Appendix-XII

CERTIFICATE FOR LANGUAGE VALIDITY OF TOOL (HINDI)

COLLEGE OF NURSING

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

RESEARCH PROJECT

CERTIFICATE OF LANGUAGE VALIDITY OF THE TOOL(HINDI)

I, Dr. / Mr./ Mrs. ..... Gajendra Verma ..... hereby certify that the tool for data collection of the research project titled "**Development of tool to measure preoperative parental anxiety for parents of children admitted for surgery in Paediatric ward at AIIMS, Jodhpur**" prepared by Theresa Jose is found to be valid and up to date.

Place: Sojat City

Date: 4/12/2020

Signature & Seal of Validator

सहायक आचार्य
राजकीय महाविद्यालय
सोजत सिटी

Appendix-XIII

CODING SHEET FOR PERSONAL VARIABLES

S.No	Category	Range	coding
1.	Parent	Father	1
		Mother	2
2.	Gender of child	Boy	1
		Girl	2
3.	Age of the parent	20-30 years	1
		30-40 years	2
		>40 years	3
4.	Age of the child	<1 year	1
		1-6 years	2
		6-12 years	3
		12-18 years	4
5.	Religion	Hindu	1
		Muslim	2
		Christian	3
		Sikh	4
		Others	5
6	Area of residence	Rural	1
		Urban	2
7	Education of the parent	Below 10th class	1
		10th pass	2
		12th pass	3
		Graduate and bove	4
8	Occupation of the parent	Gov job	
		Private job	1
		Own business	2
		Farmer	3
		Daily wage worker	4
		Homemaker	5
		Unemployed	6
			7
9	Socioeconomic status	Upper	
		Upper Middle	1
		Lower Middle	2
		Upper Lower	3
		Lower	4
			5

10	Type of family:	Nuclear Joint	1 2
11	No of children:	1 2 3 4 and above	1 2 3 4
12	Birth order of the child admitted for surgery	1 2 3 4 and above	1 2 3 4
13	Previous history of hospitalization for your child	Yes No	1 2
14	Previous history of surgery for your child	Yes No	1 2

Appendix-XIV

MASTER DATA SHEET

item	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
sample																												
1	3	2	2	3	3	3	3	2	2	2	1	0	0	3	3	1	3	3	0	1	2	1	1	1	2	2	2	3
2	3	3	2	3	3	3	3	3	2	3	2	1	2	3	3	2	3	3	0	2	3	1	2	2	0	2	3	3
3	3	3	3	3	3	3	2	3	3	3	2	3	2	2	3	3	2	2	3	3	3	2	3	3	0	3	3	0
4	2	3	2	3	3	3	2	2	2	2	2	3	1	2	3	2	2	2	3	3	2	1	3	2	0	1	3	0
5	3	3	1	3	3	2	2	2	1	0	3	3	3	3	2	2	3	1	3	1	1	1	1	1	0	1	1	1
6	3	3	3	1	3	3	1	3	1	3	2	3	1	3	3	3	2	3	3	3	3	1	2	3	0	1	3	0
7	2	2	2	2	3	3	2	3	3	3	3	3	1	2	2	2	3	3	3	3	2	1	2	2	0	0	1	0
8	3	3	3	3	3	3	2	3	3	3	3	3	2	2	3	3	3	3	3	3	3	2	3	3	1	2	2	0
9	2	2	3	3	2	3	1	3	3	2	3	1	2	1	2	3	2	0	2	3	3	2	1	2	0	0	1	1
10	3	3	3	3	2	3	2	3	3	2	3	2	2	2	3	3	3	1	1	3	3	1	2	3	0	0	3	0
11	1	1	2	3	2	3	2	3	3	2	1	1	0	1	2	1	0	0	0	2	2	1	2	1	0	0	0	0
12	3	3	3	3	3	3	3	3	3	3	2	2	2	2	3	2	2	0	0	3	3	2	3	2	0	1	2	0
13	0	1	1	2	2	2	0	2	2	1	1	0	0	0	2	1	0	0	0	0	1	0	1	0	0	0	0	0
14	2	2	3	3	3	3	1	3	3	2	2	0	1	1	3	3	1	0	0	1	2	1	2	1	0	0	1	0
15	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	0	0	3	3	0	3	2	0	2	3	1
16	1	2	2	3	3	3	1	2	3	1	1	1	0	1	2	2	2	0	0	2	2	0	0	1	0	0	2	0
17	2	2	3	3	3	3	3	3	3	3	2	3	2	2	3	3	3	2	2	3	3	0	3	3	0	2	3	2
18	1	2	2	3	3	3	2	3	3	3	2	1	0	1	2	3	2	3	2	0	2	0	2	2	0	0	0	0
19	1	1	1	2	2	3	0	2	3	1	1	0	0	1	2	1	1	3	3	0	1	0	1	1	0	0	1	0
20	2	3	2	3	2	3	1	2	3	2	2	1	2	2	3	1	2	3	3	3	2	1	2	2	0	1	1	1
21	1	1	2	1	2	3	1	3	3	2	1	1	0	0	1	1	1	2	3	1	1	0	2	1	0	0	1	0
22	1	2	2	1	2	3	1	3	3	2	1	1	0	0	2	2	1	3	3	2	3	2	1	2	1	0	3	0
23	0	0	1	3	2	3	0	2	2	2	1	0	0	0	2	3	1	0	0	0	0	0	1	0	0	0	0	0
24	0	1	2	3	2	2	0	2	3	2	1	1	0	0	1	3	1	1	0	2	2	0	1	0	0	0	0	0

25	1	2	2	3	2	3	2	3	2	2	1	0	0	1	3	2	0	0	2	2	2	0	0	0	0	0	1	0
26	2	2	3	3	3	3	2	3	3	3	2	1	2	2	3	3	2	0	2	3	2	1	2	1	0	0	3	1
27	3	3	3	3	3	3	2	3	3	3	2	1	2	2	3	2	2	0	0	3	3	0	2	2	0	0	2	0
28	2	3	3	3	3	3	1	3	3	2	1	0	0	0	2	2	1	0	0	0	1	0	0	1	0	0	1	0
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54	2	2	1	2	2	3	2	3	3	2	2	1	1	1	3	2	0	0	0	2	3	3	3	2	0	1	2	0
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61	0	1	1	2	2	2	0	2	2	1	1	0	0	0	2	1	0	0	0	0	1	0	1	0	0	0	0	0
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66	1	2	2	3	3	3	2	3	3	3	2	1	0	1	2	3	2	1	2	0	2	0	2	2	0	0	0	0
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68	3	1	2	3	3	3	0	2	3	2	2	0	1	2	3	2	3	2	0	1	2	0	3	2	0	1	2	1
69	0	1	1	1	3	3	2	3	3	3	2	3	2	2	3	1	3	3	3	0	0	1	1	3	0	0	0	0
70	0	3	3	2	3	3	2	3	3	3	3	3	3	3	3	2	3	3	3	1	0	3	3	3	1	1	3	0
71	0	0	1	0	1	0	1	0	0	0	0	1	0	0	1	1	0	1	1	0	0	0	2	0	0	0	2	0
72	1	1	3	1	3	3	2	3	3	2	0	1	0	1	3	2	1	1	1	2	1	0	2	1	0	0	3	0
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74	1	1	1	3	3	3	1	3	3	2	1	0	0	1	2	1	3	2	2	1	1	0	1	1	0	1	2	0
75	1	1	1	0	2	3	1	2	3	1	1	1	0	2	1	1	1	1	1	0	1	0	0	2	0	0	2	0
76	2	2	2	2	2	3	2	3	3	2	2	1	0	3	2	2	2	1	1	2	2	0	1	2	0	1	2	0
77	0	0	1	1	2	3	0	2	2	1	1	0	0	0	3	2	1	0	0	0	1	0	0	0	0	0	1	0
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79	1	2	2	1	2	3	3	2	2	2	1	0	0	1	1	1	1	0	0	1	2	1	1	0	0	0	2	0
80	2	1	2	2	1	3	3	2	3	2	2	0	2	1	2	1	2	1	0	1	2	1	1	0	2	2	2	2
81	2	2	1	3	3	3	2	3	3	2	2	1	1	2	3	2	0	3	3	2	3	3	3	2	0	1	2	0
82	1	1	2	2	1	3	1	3	3	2	1	3	0	1	2	3	2	1	3	2	3	1	2	2	0	0	0	0
83	1	2	2	3	3	3	2	3	3	3	2	1	0	1	2	3	2	1	2	0	2	0	2	2	0	0	0	0
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85	2	1	1	3	3	3	2	2	3	2	2	1	1	1	2	1	0	2	3	1	1	0	0	1	0	0	2	0
86	3	1	2	3	3	3	0	2	3	2	2	0	1	2	3	2	3	1	2	1	2	0	3	2	0	1	2	1

87	1	1	2	2	1	3	1	3	3	2	1	3	0	1	2	3	2	2	3	2	3	1	2	2	0	0	0	0
88	2	3	3	3	2	3	2	3	3	2	3	2	2	2	3	3	3	3	3	2	3	3	3	3	1	1	2	1
89	1	2	2	3	2	3	2	3	2	2	1	0	0	1	3	2	0	0	2	2	2	0	0	0	0	0	1	0
90	2	2	3	3	3	3	2	3	3	3	2	1	2	2	3	3	2	0	2	3	2	1	2	1	0	0	3	1
91	0	2	2	2	2	3	1	3	3	2	1	0	0	1	3	2	1	1	0	1	1	0	1	0	0	0	2	0
92	1	2	2	3	3	3	2	3	3	2	2	0	2	1	3	2	2	0	0	2	2	1	1	1	0	0	2	0
93	1	2	2	3	2	3	2	2	2	2	1	0	0	1	3	2	0	0	2	2	2	0	0	1	0	0	1	0
94	3	2	2	3	2	3	3	3	3	2	2	2	2	2	3	2	1	0	1	2	3	2	3	2	0	1	2	1
95	1	1	3	1	3	3	2	3	3	2	0	1	0	1	3	1	1	1	1	1	2	1	1	0	0	0	2	0
96	2	3	3	3	3	3	1	3	3	2	1	0	0	0	2	2	1	2	1	0	1	0	0	1	0	0	1	0
97	1	0	1	3	2	3	0	2	2	2	1	0	0	0	2	3	1	0	0	0	1	0	1	0	0	0	0	0
98	2	1	2	3	2	3	0	2	3	3	1	1	0	1	1	3	2	0	0	2	2	0	1	0	0	0	1	0
99	3	2	2	3	1	2	3	3	3	2	0	0	0	1	3	1	1	2	2	2	3	1	1	0	0	0	1	0
100	3	3	3	3	3	3	3	3	3	3	2	1	2	2	3	2	2	2	2	3	3	0	2	2	0	0	2	0

Appendix-XV

COMPARISON OF VARIOUS TOOLS TO MEASURE ANXIETY

Name of the tool	Major domains	No of items	Min score	Max score	Reliability	Validity	Interpretation	Samples used	Terminologies used	Terminologies in Common
STAI	State anxiety Trait anxiety	20 20	20 20	80 80	Test retest reliability = 0.65-0.75 Internal consistency[1][9] = 0.86-0.95	Reported as supported by studies[126]	Higher scores suggest greater anxiety levels.	parents of children undergoing surgical operation (n = 203)[16]	Feel tense, strained, at ease, upset, worrying, frightened, nervous, jittery, indecisive, confused, steady, relaxed, content, comfortable, secure, calm, pleasant, nervous, restless, satisfied, difficulties, disturbing thoughts, feel inadequate, unimportant thoughts, disappointments, steady, state of tension or turmoil.	Feel tensed, upset, worrying, nervous, restless, frightened, irritability, trembling, shaky, inability to relax, difficulty in falling asleep, fatigue, nightmare, difficulty in concentration, loss of interest, pains, hot and cold flushes, palpitation, chest pain, muscle tightness,
HADS	Anxiety Depression	7 7	0 0	21 21	Internal consistency[7][8] =0.84-0.90	supported by studies[127]	0-7: normal / no anxiety 8-10: mild 11-14: moderate 12-21: severe	Primary family caregivers of palliative care patients (n = 106)[97]	tense or 'wound up', enjoy, frightened, feeling of, Worrying thoughts, at ease, feel relaxed, slowed down, feeling like 'butterflies' in the stomach, lost interest, restless, feelings of panic.	
HAM-A	Psychic anxiety Somatic anxiety	14	0	56	Inter-rater reliability[69]=0.74	-	<17: mild severity 18-24: mild to moderate severity 25-30: moderate to severe	Mothers of paediatric patients on mechanical ventilation (n=64)[80]	Worries, anticipation, fearful anticipation, irritability, tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax, being left alone, Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors, Difficulty in concentration, poor memory, Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing, Pains and aches, twitching, stiffness, myoclonic jerks, grinding ofteeth, unsteady voice,	

									increased muscular tone, Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation, Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat, Pressure or constriction in chest, choking feelings, sighing, dyspnea, Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, looseness of bowels, loss of weight, constipation, Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair, Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing.	fainting, dizziness, light headednes s, constipatio n, nausea, flushing, hand tremors, numbness or tingling, afraid, terrified, scared, fear, anxious, falling apart, tired, weak, bothered, heart beating fast, feel angry, shortness of breath, chest tightness, excessive sweating, flushing or frequent urination, trouble functioning ,felt
BAI	Somatic symptoms of anxiety	21	0	63	Internal consistency(78)= 0.90-0.94	Good converge nce with HAM-A (r = 0.51), STAI (r = 0.47-0.58).[78]	0-9: normal / no anxiety 10-18: mild to moderate 19-29: moderate to severe 30-63: severe anxiety	validation study of the Portuguese version of the BAI (n = 1160)[83]	Numbness or tingling, feeling hot, wobbliness in legs, unable to relax, fear of worst happening, dizzy or lightheaded , heart pounding/ racing, unsteady terrified or afraid, nervous, feeling of choking, hands trembling, shaky/ unsteady, fear of losing control, difficulty in breathing, fear, scared, indigestion, faint, face flushed	
SAS	Cognitive, autonomic, motor and central nervous system symptoms	20	20	80	Cronbach's alpha = 0.83[84]	Concurre nt validity of 0.30 with Taylor Manifest Anxiety	20-44: Normal 45-59: mild to moderate 60-74: marked to severe 75 and above: extreme anxiety	sample primarily composed of undergraduate psychology students at a regional Australian	Feel, nervous, anxious, afraid, get upset easily, feel panicky, falling apart, shake and tremble, bothered, headaches, neck and back pain, weak, tired easily, heart beating fast, dizzy spells, fainting spells or feel like it, numbness and tingling, stomach aches	

						Scale.[85]	levels	university (n=210), complimented by a small clinical sample (n=141)[85]	or indigestion, empty my bladder often, dry and warm, hot and blushes, fall asleep, good night's rest, nightmares.	confused, felt really bored, disappointed, stressed, dry mouth, fearing something bad might happen.
APAIS	Anxiety (4) Need for information (2)	6 (4+2)	4 2	20 10	Test retest reliability for anxiety (r= 0.92) and need for information (r=0.62)[86,87]	Good convergence with STAI (r = 0.74)	Higher values are suggestive of higher anxiety and higher need for information.	measured the preoperative anxiety of adult Turkish patients undergoing surgery (n=210)[86]	Worried, anaesthetic, continually, as much as possible, procedure	
SCAS	Panic/agora phobia Social phobia Separation anxiety Generalised anxiety OCD Fear of physical injury	44	0	132	Test retest reliability = 0.61-0.82 Internal consistency = 0.87-0.94	Strong correlations with SCARED (r= 0.85-0.89)[88]		484 parents of anxiety disordered children aged from 6 to 18 years and 261 parents in a normal control group.	Worry, scared, afraid, suddenly feel, trouble, can't seem to get, something bad, tremble or shake, heart beats really fast, funny feeling in stomach, heart starts to beat too quickly for no reason, get bothered.	
SACS-P	do	38 (Excluding positive items)	0	114	Test retest reliability = 0.53-0.88 Cronbach's alpha = 0.89	Good convergence with CBCL-internalizing)				
PaRCAD	10 domains	83	-	-	Reliability =	Moderate	Higher score	355 parents of	Upset, feel angry, giving up on tasks,	

S	(Relationship with your child, Involvement in child's life, Child's relationships with others, Rules and Consequence for child, Health habits,Home environment Managing Emotions, Setting goals and dealing with problems, Dealing with negative emotions, Getting help when needed)				0.74-0.94[72]	to strong convergent validity with other parenting and family functioning measures. (P-CRPBI: AcceptanceParent report of the Children's Report of Parent Behaviour Inventory - Acceptance subscale, P-PCS: Parent report of the Psychological Control Scale)	on the scale was associated with lesser anxiety and depressive symptoms and better health-related quality of life in the child.	children aged 8-11 years in Australia	feels discouraged, something is bothering, anxious, struggling with problems, face situations, manage, strategies to calming, stress, seeking help, dealing with problems.	
ASQ	Anxiety	17	0	340	Cronbach's alpha = 0.94-	In patients	-	240 outpatients with generalised	Anxiety, nervousness, worrying, irritability, muscle tension or tightness,	

	Frequency and intensity				0.96[73]	with an anxiety disorder, the correlation with HAM-A was most significant among those with panic disorder (r=0.80), followed by those with GAD (r=0.61) and SAD (r=0.48)		anxiety disorder, social anxiety disorder, panic disorder or major depressive disorder	trouble relaxing, trouble falling or staying asleep, fatigue or lack of energy, problems with concentration or attention, trouble remembering things, shortness of breath, chest tightness or pain, pounding/skipping/racing heartbeat, stomach upset, nausea, constipation, diarrhoea or irritable bowels, dizziness, light headedness, headaches, trembling or shakiness, numbness, tingling, excessive sweating, flushing or frequent urination, feeling restless, keyed up, or on edge, anticipating or fearing something bad might happen, trouble functioning at home, work, or socially due to anxiety.	
MASQ	general distress anxious arousal anhedonic depression,	90 (original)	-	-	Internal consistency is more than 0.87.[89]	Had significant correlation with RCMAS (r = 0.633) Not showed significant correlation with ASQ.[89]	Greater levels of symptomatology was seen with higher scores.	136 young people with specialist reference	Felt afraid, startled easy, felt confused, felt sad, alert, felt discouraged, nauseous, felt like crying, diarrhea, felt worthless, felt nervous, depressed, irritable, faint, felt uneasy, felt really bored, felt hopeless, blamed myself, numbness or tingling, numbness or tingling, afraid i was going to lose control, felt dissatisfied, trouble remembering things, felt like i didn't need much sleep, nothing was very enjoyable, something awful will happen, did not have much of an appetite, pessimistic, pain in my chest, failure, hot or cold spells, restless, trouble falling asleep, trouble staying asleep,	

									dizzy or lightheaded, unattractive, short of breath, sluggish or tired, shaky, unable to relax, choking, unable to laugh easily, upset stomach, felt inferior, lump in my throat, slowed down, dry mouth, muscles twitched or trembled, muscles were tense or sore, trouble making decisions, going crazy, afraid, disappointed, worried, heart was racing or pounding, trouble concentrating, tense or "high strung", trembling or shaking, trouble paying attention, urinate frequently, trouble swallowing, tired or fatigued.	
Percieved stress scale	Stress	10	0	40	Cronbach's alpha= 0.731[90]	moderate concurrent criterion validity (r= 0.39)	PSS scores are made by reversing the responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) to the four positively stated items (items 4, 5, 7, & 8) and then summing up all items.	480 adult subjects aged 25--65 years in an urban area of North East Delhi [91]	Upset, felt, unable to control, nervous, stressed, confident, cope, irritations, angered, difficulty, piling up, overcome	
DASS 21	Depression Anxiety Stress	Total = 21 7 7 7	0	126	Cronbach's alpha= 0.990[92]	Construct validity of anxiety with HADS = 0.834	For anxiety: Normal = 0-7 Mild = 8-9 Moderate = 10-14 Severe = 15-19 Extremely severe = 20+ Since DASS 21 is a short version of original DASS 42 scale the summed	111 oral cancer and 56 oral potentially malignant disorders patients	Found it hard, aware of, dryness of my mouth, couldn't seem to, experience, positive feeling at all, breathing difficulty, excessively rapid breathing, breathlessness in the absence of physical exertion, difficult to, work up, initiative to do things, tended to, over-react, trembling, worried, nothing to look forward to, agitated, difficult to relax, down-hearted and blue, intolerant, close to panic, unable, enthusiastic, worth much, aware, sense	

							numbers in each sub-scale should be multiplied by 2 before the interpretation of scores.		of heart rate increase, heart missing a beat, scared, meaningless.	
GAD 7	Generalized anxiety	7	0	21	internal consistency = 0.89	Good positive correlation with BAI (r = 0.69)[93]	mild anxiety = 0 to 4 moderate anxiety = 5 to 9 moderately severe anxiety = 10 to 14 severe anxiety = 15 to 21	536 patients under treatment for anxiety and related disorders[93]	Feeling, nervous, anxious or on edge, control, worrying too much, trouble relaxing, restless, hard to sit still, becoming easily annoyed, irritable, afraid.	