Predictive factors for anxiety during blood sampling and insertion of peripheral intravenous catheters in paediatric patients in Spain.

ABSTRACT

Introduction

Invasive procedures for diagnosis purposes such as venepuncture and peripheral venous catheter insertion are painful procedures that cause great stress for paediatric patients. The

objective of this study is to find out the factors that have an impact on the level of anxiety experienced by children undertaken these procedures.

Design and methods

Prospective study, 359 children between 2 and 15 years old were included, treated in a tertiary reference hospital in the region of Navarra (Spain). The impact of the variables recorded was analysed using a regressive analysis, the Wong-Baker and FLACC scales were used to measure the level of pain and the PACBIS scale to measure the level of stress and anxiety.

Results

The average age of the participants was 7.93 years (SD: 4.04), with 51.8% (n = 186) boys and 48.2% (n = 173) girls. The mean value of pain recorded was 4.43 (SD:3.10). 45.7% (n = 123) of the venepuncture techniques was associated with minimum level of anxiety, including 11.1% of intravenous catheterization. Variables determining the anxiety has been detected such as age, sex, level of pain, parental conduct and time spent on the procedure.

Conclusions

Paediatric patients experience high levels of anxiety when undergoing painful procedures which are conditioned by multifactorial reasons. The increase in stress is directly related to the older age (>6 years old) of the patient, and statistically significant by the female gender, the longer duration of the technique and the parental block.

Practice implications

Healthcare professionals should work on some of the variables and apply measures aimed to mitigate anxiety levels. For example, reducing the duration of the procedure, training parents, and distracting techniques.

Keywords

Paediatrics, anxiety, pain, risk factors, venipuncture, peripheral venous catheter

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INTRODUCTION

The paediatric population has a high rate of suffering accidents and diseases; the prevalence increases especially in children below 5 years old. Long-term diseases affect around 10 -12% of children and teenagers worldwide (Wolfe et al. 2013), increasing the risk of developing psychological disorders such as anxiety and depression (Cohen et al. 2017). These alterations in children´s health is frequently accompanied by other side effects such as pain.

In paediatric emergency departments, pain represents up to 78% of the visits, either from acute causes such as injuries and trauma, or exacerbations of chronic diseases (Krauss et al. 2016). These visits to emergency departments and hospitalization usually involve invasive procedures, needed for a diagnostic or therapeutic purpose, increasing levels of pain and anxiety in children (Krauss et al., 2016; Toledo del Castillo et al., 2019). The most feared and stressful diagnostic procedures for children are intravenous catheterizations, venous punctures, insertion of urine catheters and wound sutures (Ali et al. 2016; Bradford et al., 2019), raising their anxiety levels (Eijlers et al., 2019; Ploghaus et al., 2001).

Pain and anxiety are conditioned by psychological and environmental factors, affecting the perception of everyone. These factors involve the age, sex, cognitive level, and environment, as well as the culture and behaviour of the parents or healthcare professionals attending the child (Gancedo, 2009). Within all these factors, the role of the parents is crucial.

As referents of the children, the parents´ attitude can influence the child's perception or experience of the situation, increasing or decreasing their anxiety and pain (Karlsson et al. 2014).

The proactive attitude of the parents will depend on their levels of anxiety.

Sometimes healthcare professionals establish strategies to manage their anxiety such as offering to leave the examination room if the parents' behaviour is conditioning the peacefulness of the child. (Krauss et al., 2016; Svendsen et al. 2016).

The level of anxiety perceived by parents and experienced by paediatric patients can also cause distress in healthcare professionals (Ali et al., 2016), conditioning their performance and the development of the technique or procedure.

Over the last several decades, pain mitigation strategies have been assessed for puncture techniques, including interventions such as pharmacological, physical, procedural, psychological and other techniques (Ballard et al, 2018; Birnie et al. 2018; Taddio et al., 2010).

Studies that focus their analysis on the implementation of distraction methods such as Virtual Reality (VR), have shown clear benefits. Such as a decrease in the anxiety and pain of the paediatric patient undergoing a painful procedure; as well as decreasing anxiety levels in their parents and nursing professionals performing the technique (Álvarez García et al. 2017, p.; Martín -Valbuena et al., 2018; Toledo del Castillo et al., 2019).

However, according to various investigations, health professionals at the emergency departments and primary care centres do not routinely implement or evaluate this type of measure (Benini et al., 2019, p.45; Rodríguez et al. 2016) perhaps because of the uncertainty about its effectiveness, time commitment or potential costs (Rodríguez et al. 2016).

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Anxiety has an important repercussion on the evolution of patients. It influences their comfort levels during their stay. This is associated with adverse events such as escape attempts (Chorney & Kain, 2009), nutritional alterations, metabolic and sleep patterns (Kain et al., 2006) and even manifestation of post-traumatic stress symptoms (Meentken et al. 2017).

However, available literature shows that the assessment and management of pain and anxiety during the performance of procedures in the paediatric population is often not adequately conducted (Ali et al., 2016; Hedén Von Essen & Ljungman, 2020), being the lack of time or the lack of knowledge of coping strategies, the main barriers identified (Spanos et al., 2008). Improving the knowledge about the main predictors of the level of anxiety experienced by the paediatric patient during an invasive technique will allow us to improve our clinical practice and quality of care. Therefore, the aim of this study is to determine the conditioning factors of the variability of anxiety levels in children who undergo an invasive procedure such as venepuncture.

DESIGN AND METHODS

A prospective observational study was carried out in a tertiary reference hospital for the Autonomous Community of Navarre, within the "Complejo Hospitalario de Navarra (CHN)" Hospitals, in Spain.

Population sample

The population recruited for this study consisted of 359 children who attended the paediatric emergency service or the outpatient paediatric blood extraction laboratory at the Principe de Viana Specialist Center, within "Complejo Hospitalario de Navarra (CHN)" Hospitals.

The main inclusion criteria for the study were: ages from 2 to 15 years old, undergoing a venipuncture or vascular access procedure with a peripheral venous catheter, a situation that doesn´t involve any vital risk, and acceptance of participation in the study by their legal guardians. Exclusion criteria were: children with structural impairment in facial or visual functional area, or acute patients with a triage result of level 1 (vital emergency).

The selection of the participants was made by consecutive sampling, calculated with the Epitable software establishing as criteria a type I error (α) of 0.05, a power of 80% (error β= 0,20) and a minimum difference (Δ) in adequacy of detectable pain management of 0.30.

Variables and measurement instruments

The variables collected were: age, sex, diagnostic suspicion, severity of the triage process, type of companion, type of puncture technique, number of punctures, time of technique and level of pain. The first puncture attempt was selected to reduce variability in user condition.

Pain in children was measured with a visual analogue scale with facial drawings, the Wong-Baker Faces Pain Scale (Naegeli et al. 2018, p.499). It consists of six face drawings with a score of 0, 2,

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4, 6, 8, 10, and a range from a smiling face for no pain (0 points) to a tearful face for the highest possible pain (10 points).

The FLACC standardized scale (Face, Leg, Activity, Cry and Consolability) (Manworren & Hynan, 2003; Hummel, 2017) was used to measure pain in younger children or non-collaborative patients. The scores on these scales were interpreted as: 0 = relaxed and comfortable, 1-3 = mild discomfort, 4-6 = moderate pain, 7-10 = severe discomfort/pain. Both scales are used frequently in the hospital setting due to the simplicity and speed of the evaluation and psychometric references show a good level of validity and specificity (Obrecht JA et al, 2014, p.97).

PACBIS scale (Perioperative Adult and Child Behavioural Interaction Scale) was used to measure levels of anxiety, a method selected for its great validity and high level of specificity in the detection of stress in paediatric patients (Sadhasivam et al., 2010). This scale contains four dimensions: an individual assessment of 0-2 where the values have been coded as: 0 or without anxiety and 1 & 2 as moderate or severe anxiety respectively. Each of the dimensions includes the most characteristic observable behaviours in the child or parents. The child´s levels of anxiety and coping capacity is measured by the Child Distress Subscale and the Child Coping Subscale while the parent's behaviour is measured by the Parent's Behaviour Subscale, being valued as reactive or blocked (Negative Parent) or, proactive or collaborative (Positive Parent).

The PACBIS (Sadhasivam et al, 2009, p.823) assesses the conduct / behavior of children and parents in real time. Thus, it is a child-adult behavioral interaction scale that allows the behaviors, responses and interactions between children and their parents to be identified in real time. This scale has shown excellent intra-observer reliability (kappa index 0.62 - 0.94) and excellent correlation with other instruments that evaluate the same constructs.

Data collection procedure

All data related to the assessment of the patient was collected by two nurses from each of the services, by observing and recording variables and not interfering during the procedure. Data registration was carried out immediately after the procedure. At the beginning of the study the research team explained in detail the use of the scales and the data collection procedure, ensuring consistent and systematic data collection.

Analysis of data

In the first instance a descriptive analysis of the variables was carried out, using the mean and standard deviation (SD) for quantitative variables and the frequency and percentage for qualitative variables.

Subsequently, a multivariable logistic regression analysis was performed. In order to choose the best explanatory model for the dependent variable "anxiety", the stepwise selection method was used with the independent variable "parental attitude" and the control variable “level of pain”. According to this method, starting from the null model and using the likelihood ratio, the significant variables, at the significance level of 0.05, have been progressively included in the regression model, while those that lost their significance were excluded, at a level 0.10 (Neter et al. 1996, p.39). All analyses have been carried out using the SPSS 25 statistical program.

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Ethical considerations

The clinical study was approved by the Clinical Research Ethics Committee of the Navarra Health Department. The patient's legal guardians received information from the clinical study and freely agreed to participate, signing the corresponding informed consent. The written consent was signed by the parent, and the verbal consent was obtained from the paediatric patient involved in the study.

RESULTS

The average age of the participants was 7.93 years (SD: 4.04), with 51.8% (n=186) boys and 48.2% (n=173) girls. In 73.5% (n=274) of the cases the procedure was a venepuncture and 26.5% (n=95) canalization of a peripheral venous catheter. All patients were accompanied by a parent, with the patient's mother or father being the main companion.

Patients from 6 years onwards registered a higher experience of anxiety (table 2) and all the children aged 15 experienced a situation of stress and anxiety (p = 0.005).

Regarding the sex of the paediatric patients, 82.8% (n=154) of the boys and 85% (n=147) of the girls reported having some level of anxiety during the procedure (p = 0.339).

The average amount of time needed for the procedure was 2 minutes 15 seconds (SD: 4.04), ranging from 10 seconds for the fastest procedure to 11 minutes. The duration of the technique detected that 83.35% (n=227) of the total venepuncture were performed in less than 2 minutes.

Lower anxiety levels were observed in procedures with a shorter duration range, especially below 2 minutes; 30% (n=108) of the procedures were performed in less than 1 minute and 18.9% (n=68) of the procedures had a duration between 1 and 2 minutes (p = 0.000) (table 1).

The average value of pain was 4.43 (SD: 3.10), with 7% (n=25) of the children expressing absence of pain.

The 35.7% (n=76) of the children manifested mild pain and 34.7% moderate pain (n=74). The highest level of pain, interpreted as severe pain, was reflected in 21.6% (n=46) (p = 0.000) of the paediatric patients.

Pain values show that 64% (n=138) of the patients presented a medium to moderate level of pain, with an average objective value greater than 5 on the Wong-Backer/ FLACC scale.

The results obtained with the Wong-Backer scale showed a high level of pain, 11.5% (n=37) of boys and 16.2% (n=62) of girls experienced maximum pain levels identified as 10/10 (graph 1).

This scale also reported pain levels considered as mild, the identification of a low pain level in correlation to pain of 1/10 and 2/10 in 12.8% (n=89) of boys and 7.3% (n=26) of girls. Similar results were obtained with the assessment from the FLACC scale (graph 2), where 26.9%, (n=53) of boys and 32.4% (n=71) of girls reported experiencing a minimum level of anxiety in correlation to low levels of pain.

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About pain, 45.7% (n=123) of the venepuncture reported a minimum level of pain for the patients. While for the intravenous catheterization procedures performed 11.1% (n=85) reported the minimum level of anxiety (p = 0.000) (table 1).

Focusing on the analysis of results in the anxiety levels, variations were observed in the level of anxiety according to the range of age analysed (Table 2).

Patients aged 3 and 4 years old presented anxiety rates oscillated between 60.6% (n=20) and 67.6% (n=23) while 100% of the patients aged 15 expressed experiencing anxiety over the procedure.

Overall, the level of anxiety experienced by the child and evaluated with the subscale "Child Distress" found that 56.8% (n=255) of paediatric patients did not present anxiety during the procedure while 43.2% (n=155) experienced some level of anxiety.

In relation to parents' attitude, evaluated with the “Negative Parent and Positive Parent” Subscale, it was observed that 88.9% (n=319) presented positive behaviour, while 11.1% (n=40) presented a behaviour interpreted as lack of adaptation or stress during the procedure. Within this 11.1% (n=40), the 80% (n=32) of the relatives presented a high reaction or blocking response to the procedure, showing an elevated anxiety response in the child (graph 3).

Analysing the results obtained from the multivariate logistic regression; four predictive variables have been appreciated to be possible conditioning factors on the child's anxiety.

These are age, sex, level of pain and parental behaviour, the latter being the most influential variable in children's anxiety.

Therefore, the regression analysis demonstrates that parents' attitude or lack of adaptation was associated with children's anxiety ($p < 0.01$), in such a way that those children had an “advantage” (odds) to develop anxiety 7 times (odds ratio) higher than children whose parents developed an attitude of adaptation during the procedure (95% CI 2,599-19,312). With less intensity, the “advantage” (odds) of developing anxiety also occurred in girls compared to boys (1.8 times higher). As pain increased in the procedure (for each point of more pain in the procedure, there was an “advantage” of 1,3). However, the “advantage” of developing anxiety decreased by 0.8 as age increased.

DISCUSSION

The aim of this study was to determine the factors that could affect the level of anxiety in children undergoing an invasive procedure such as venepuncture. The results indicated that a high percentage (43.2%) of the recruited paediatric patients experienced anxiety during the puncture procedure. The factors which influence the level of anxiety were: parents' attitude during the procedure and sex and the level of pain experienced by the patient (Kleidon et al, 2020). Another factor, the age (Lee et al., 2020) has a clear influence but life is random, considering it a marker factor for assessing the level of anxiety but without statistically significant findings after regression analysis.

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Focusing on the anxiety level of the children's parents, it was observed that 11.1% presented a reactive or blocking attitude to face the situation during the performance of the procedure (negative parent), showing attitudes such as excessive comforting or avoidance behaviours without favouring the child's distraction (Sadhasivam et al., 2010; Bulut, & Calik 2020), which was positively associated with the level of anxiety experienced by the patient. The results show this factor as the predictor variable of greater weight for the development of anxiety in the child with an increased risk of experiencing anxiety and stress during the procedure of up to 7 times higher.

The presence of the parents can play a key role and be a very successful analgesic treatment during venipuncture, since parental involvement distracts children, reduces stress and has the potential to improve the success of the procedure (Krauss et al., 2016; Harding et al., 2020). However, the results of this study suggest that parents presenting a blocking or unadaptable response to the process can sporadically generate increased anxiety for their children. This statement agrees with the results of other studies, suggesting that children may exhibit anticipatory anxiety behaviour due to their parents´ anxiety, motivated by unawareness and lack of experience or information about the procedure (Krauss et al., 2016; Schmitz et al. 2015; Svendsen et al., 2016; Vetri Buratti et al., 2015). In the absence of parents, children can show even lower levels of anxiety and pain during venipuncture (Casanovas-Marsal & García Martínez, 2017).

There are clear differences in the experience and manifestation of anxiety depending on the age. Patients aged 3 - 4 years show a lower percentage of anxiety while those children with advanced ages (>6 years) register higher rates of suffering stress during the procedure. Perhaps this is conditioned by the maturity of the older paediatric patient, being teenagers more capable of recognizing the situation as a painful process and therefore generating stress, as well as expressing more clearly their discomfort and perception of the situation (Figueroa Jaramillo, 2015). However, the categorization of the level of anxiety shows that the highest levels are reflected in the young paediatric patient, which may again be due to the variation in the child's response maturity.

Therefore, we can define age as a variable for predicting variability in the level of stress or anxiety in the infant of the study. This correlation regarding lower levels of anxiety in young patients and the increase in level of anxiety related to the age is an aspect already observed and analysed in other studies (Hedén et al., 2020) that the regressive analysis of this study has allowed identification as a finding due to chance, without statistically significant value.

In relation to this finding, we can conclude that the older the patient is, the greater ability to understand the treatment procedures and objectives. Also, they better recognize the experience of anxiety (Figueroa Jaramillo, 2015).

Female gender is a marked predictor of a higher level of anxiety, almost doubling the risk of suffering anxiety with respect to male sex, without knowing the conditioning cause. Researchers have found that estrogen in the female sex has an important effect, since it releases cytokines in response to pain, causing higher levels of pain experienced. This may be one of the conditioning factors of the variability found according to gender (Berke et al. 2016; Fillingim, 2017; Sorge & Totsch, 2017).

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Finally, there is a clear reciprocity in the level of pain and anxiety registered during the insertion of the needle. Doubts whether children's distinction between fear and pain experiences is made correctly may arise. However, previous studies suggest that children are likely to make this distinction clearly (Hedén et al., 2020).

Similar results have been found in the interpretative analysis of the level of pain experienced by paediatric patients. There is a clear correlation between lower levels of pain (mild pain, 1/10 and 2/10) with lower levels of anxiety and vice versa, showing on the Wong-Backer Scale.

Likewise, these scales detect a manifestation of higher levels of anxiety in girls, identifying sex as a conditioning factor for its increased expression or experience.

Other conditioning factors of the level of anxiety perceived by patients during the phlebotomy process were the duration of the technique and the type of technique performed. Both aspects are related since the intravenous catheter canalization presents longer time cadences, showing that longer duration of the procedure is correlated with an elevation in the levels of anxiety. Another study with similar results regarding the duration of the technique and the number of attempts (Casanovas-Marsal & García Martínez, 2017) makes us think about the need to work on distraction techniques to reduce the time of the procedure including the preparation of the patient and the realization of the procedure. Like other studies (Hedén Von Essen, & Ljungman, 2016; Hedén et al, 2020), it has been found that high levels of anxiety were conditioned by multifactorial causes such as sex and the level of pain experienced before the technique.

These findings highlight the need to implement interventions to decrease these levels of pain and anxiety caused by invasive procedures, addressing other influential factors such as the previous experiences and the response provided by parents (Aldiss et al., 2015; Gates et al., 2018).

The need to improve the structure of the studies on the paediatric patient population is appreciated, delimiting their study by age groups with more even psycho-emotional development, and allowing obtaining reliable results, suggesting, for example, the distribution of future studies on populations 2-6 years old and 7-14 years old.

It should be a priority to recognize and develop tools that work on two key points.

Preparation by means of information and empowerment of parents, allowing a proactive response to be shown during the procedure. This will allow them to respond as facilitators, encouraging the well-being and confidence perceived by the child and reducing the patient's preparation time for the technique.

Also, the creation or development of a protocol to clearly identify the steps to be followed prior to the venepuncture process, through the inclusion of distraction techniques, would improve the experience of the patient and those parents.

Study limitations

It is worth mentioning that some variability in data collection may have happened, since it was not always the same professional carrying out the technique or the registration, although the research team provided detailed information on the data collection procedure. Furthermore, the number of professionals involved (4) was limited to the maximum possible.

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CONCLUSIONS

The level of anxiety experienced by the paediatric patient undergoing venepuncture is elevated, which is a conditioning factor in the well-being of the paediatric patient.

The level of anxiety is affected and mainly conditioned by the age and three principal factors. These principal factors or predictor variables are sex (female), pain (presence and elevated levels of pain) and attitude of the accompanying family member.

These factors directly correlated with the level of anxiety and should be analysed and worked on in greater depth to detect tools aiming to reduce the anxiety levels experienced by children from invasive procedures.

Declaration of interest:
This research study has been carried out with the support of research grants provided by the Spanish Foundation for Science and Technology (FECYT) through the *Precipita* program. The sponsor has not been involved in the development of the study or in the writing of the report, they have not been involved in the publication decision.

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Table 1. Inferential analysis of the variation in the level of anxiety according to various variables analysed.

	Anxiety level				p-sig
	Mild = 0	Moderate = 1	Intense = 2	Total	
According to type of technique					
Puncture	45.7% (164)	18.7% (67)	9.2% (33)	73.5% (264)	0,000*
Canalization	11.1% (40)	8.4% (30)	7% (25)	26.5% (95)	
Total	56.8% (204)	27% (97)	16.2% (58)	100% (359)	
According to the duration of the technique					
< 1min	30.1% (108)	6.4% (23)	5.3% (19)	41.85% (150)	0.000 *
1-2min	18.9% (68)	16.4% (59)	6.1% (22)	41.5% (149)	
2-3min	9.8% (20)	1.9% (7)	3.1% (11)	10.6% (38)	
>3min	2.2% (8)	2.2% (8)	1.7% (6)	6.1% (22)	
Total	56.8% (204)	27% (97)	16.2% (58)	100% (359)	
According to pain level					
Absence of pain	7% (15)	0.5% (1)	0.5% (1)	8% (17)	0.000 *
Mild pain	31% (66)	3.3% (7)	1.4% (3)	35.7% (76)	
Moderate pain	24.9% (53)	8.9% (19)	0.9% (2)	34.7% (74)	
Intense pain	8.9% (19)	7.5% (16)	1.9% (4)	18.3% (39)	
Unbearable pain	0.9% (2)	1.4% (3)	0.9% (2)	3.3% (7)	
According to severity of the process					
Urgent (2)	4.6% (5)	5.5% (6)	5.5% (6)	15.6% (17)	0.577 *
Preferred (3)	26.6% (29)	22.0% (24)	18.3% (20)	67.0% (73)	
Not urgent (4)	7.3% (8)	4.6% (5)	5.5% (6)	17.4% (19)	
Total	38.5% (42)	32.1% (35)	29.4% (32)	100.0% (109)	

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Table 2. Perception of anxiety according to age.

			Anxiety		Total
			No	Yes	
Age (years)	2	Count	7 (20%)	28 (80%)	35 (100%)
	3	Count	13 (39.4%)	20 (60.6%)	33 (100%)
	4	Count	11 (32.4%)	23 (67.6%)	34 (100%)
	5	Count	4 (17.4%)	19 (82.6%)	23 (100%)
	6	Count	2 (8.7%)	21 (91.3%)	23 (100%)
	7	Count	3 (14.3%)	18 (85.7%)	21 (100%)
	8	Count	1 (4.2%)	23 (95.8%)	24 (100%)
	9	Count	2 (8.7%)	21 (91.3%)	23 (100%)
	10	Count	4 (12.5%)	28 (87.5%)	32 (100%)
	11	Count	3 (15.8%)	16 (84.2%)	19 (100%)
	12	Count	3 (10.7%)	25 (89.3%)	28 (100%)
	13	Count	2 (7.1%)	26 (92.9%)	28 (100%)
	14	Count	3 (11.5%)	23 (88.5%)	26 (100%)
	15	Count	0	10 (100%)	10 (100%)
Total		Count	58	301	359
		% within age	16.2%	83.8%	100.0%

Table 3. Regressive analysis on the main statistically significant variables.

Variables	**Wald**	**Sig.**	**Exp(B)**	**95% CI for Exp (B)**	
				lower	**higher**
Age	18.073	< 0,01	0.860	0.803	0.922
Girls	5.714	0,017	1.881	1.121	3.158
Pain	36.097	< 0,01	1.338	1.216	1.471
Parental lack of adaptation	14.640	< 0.01	7.084	2.599	19.312

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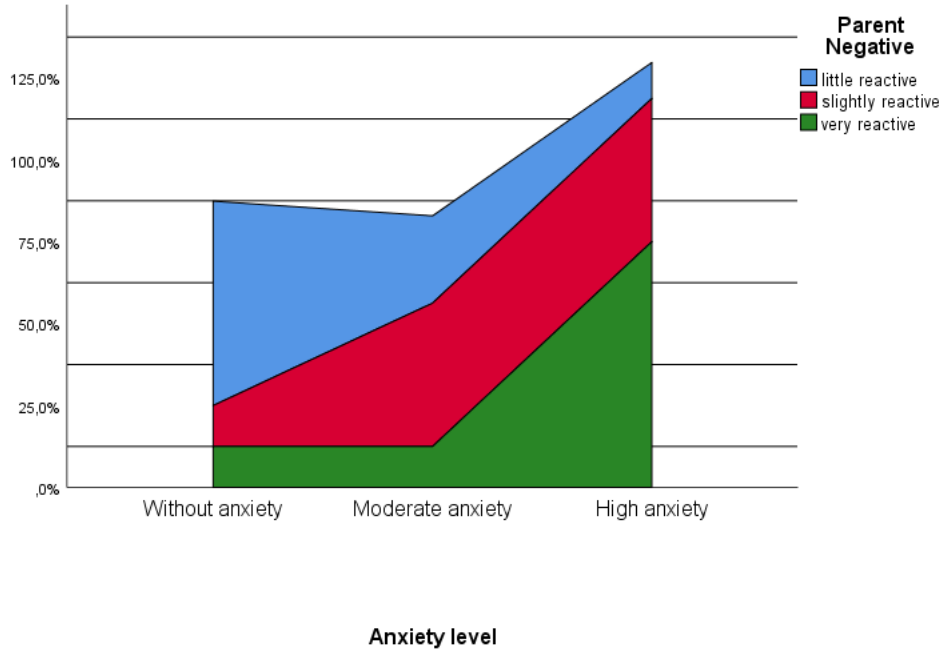
Constant	7.221	0.007	0.217		
Variable	**Punctuatión**	**g.l.**	**Sig.**		
Time	2.855	1	0.091		

Graph 1. Anxiety level rate according to the family's reactive or blocked response



Graph 2. Anxiety level rate according to pain measured by the FLACC scale

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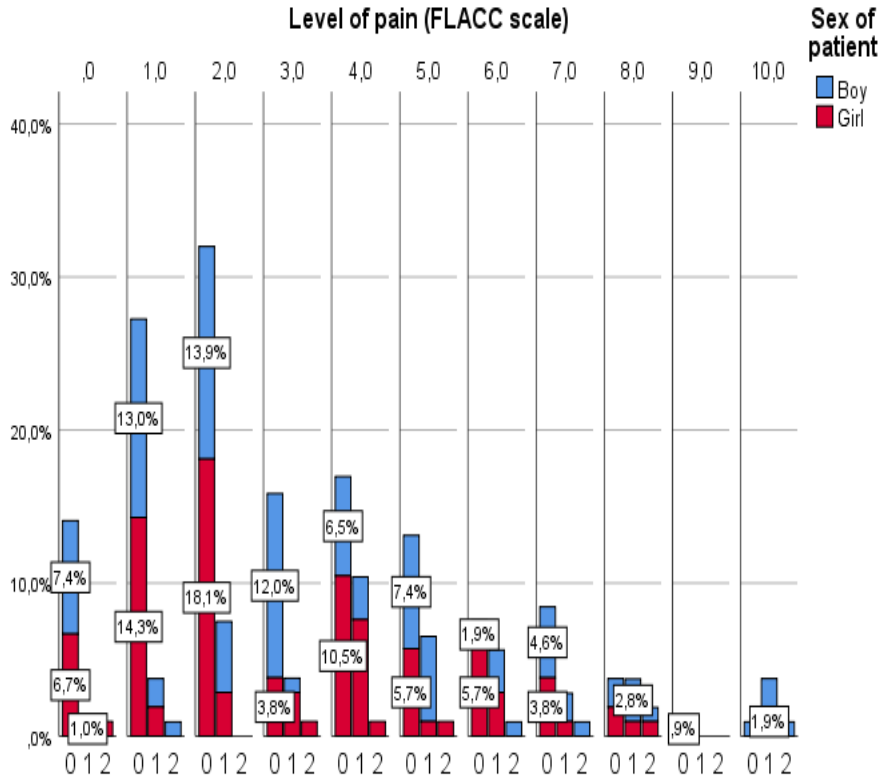

0= without anxiety; 1=moderate anxiety; 2= high anxiety

Graph 3. Pain level rate according to pain measured by the Wong-Backer scale

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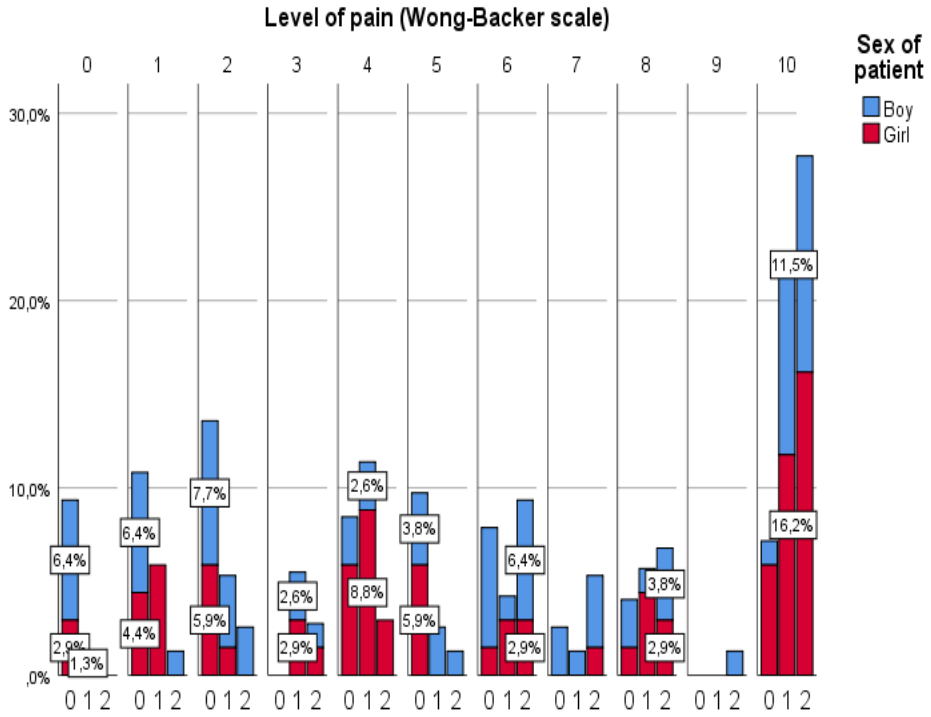

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