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# PRELIMINARY RESEARCH ARTICLES

# Do Children Undergoing Cancer Procedures under Pharmacological Sedation Still Report Pain and Anxiety? A Preliminary Study

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#### Abstract

Objectives. We aimed to quantify children's levels of pain and fear during needle puncture procedures in a context where intravenous sedation-analgesia seems to be effective for pain and anxiety relief. The relevance of a nonpharmacological intervention in the pharmacological regimen was evaluated.

Design. Fear and pain were assessed by children, parents and physicians, on a visual analog scale (VAS, 0–10 cm), before and during puncture procedures. Higher scores represented more intense pain/fear.

Results. During 4 consecutive months, 18 children were recruited, but four were excluded from analyses because they did not receive the full sedation regimen (midazolam/ketamine) (N = 14, mean age  $\pm$  SD: 9.9  $\pm$  3.4 years). Parents self-reported their own anxiety before the procedure (4.69  $\pm$  3.17),

but no correlation was found with their children's self-reported fear. Before procedures, the children's fear was self-reported on a VAS by children (2.93  $\pm$  2.93), parents (4.45  $\pm$  2.87), and physicians (3.67  $\pm$  2.48). During procedures under sedation, the children's pain (1.71  $\pm$  2.74) did not correlate with the parents' (4.01  $\pm$  3.23) and physicians' (1.83  $\pm$  2.32) ratings. Children anticipating high levels of pain and fear on the VAS experienced higher levels of pain (r= 0.65, P < 0.05) and fear (r= 0.59, P < 0.05) during the procedures. Sixteen parents (16/18) agreed to participate with their children if a study evaluating hypnosis for pain and anxiety was conducted.

Conclusions. Sedation is effective in lowering levels of fear and pain in children during procedures, but they still anticipate fear before the procedures. Parents are anxious for their children. Future hypnotic intervention could be helpful for children as well as parents to cope with anxiety during procedures.

Key Words. Pain; Anxiety; Children; Cancer; Needle Procedures

#### Introduction

Cancer therapies produce distressing situations and discomfort for children and their parents. Pharmacological approaches to pain management during cancer procedures have thus been investigated to develop wellestablished guidelines [1,2]. Still, nonpharmacological interventions, such as acupuncture, distraction, and mind-body therapies (self-hypnosis, guided imagery) have been proposed as a complementary way of relieving both pain and anxiety/distress in children undergoing medical procedures related to cancer [3-5]. Among mind-body therapies, hypnosis has been shown to somehow reduce pain, anxiety, anticipation, vomiting, and nausea in children and adults [6-11]. A Cochrane systematic review [12] suggests that hypnotic intervention can help children by diminishing pain and distress related to needle procedures. Indeed, based on physiological data [13], hypnosis has been demonstrated to be effective in children in decreasing pain and anxiety

during medical procedures [14], and is, therefore, proposed as a useful tool easily mastered by children [15].

A Canadian study revealed that children experience pain during hospitalization [16]. Children with cancer never get used to the symptoms, which could influence the entire treatment effect [17–19]. Therefore, assessments of children's pain, fear, and medication efficacy are needed from different perspectives and with different scales [20–22]. As parents' expectations of their children's pain and distress could mediate the relationship between pediatric-anticipated and reported procedurerelated pain [23], parental perspectives should be investigated too. Physicians as well are potentially key agents in pain relief among children undergoing invasive procedures, and their empathy and role during procedures should be examined in further research [24].

In our center, cancer needle procedures, such as lumbar puncture (LP) or bone marrow aspiration (BMA), are performed under a protocol for light to moderate intravenous sedation in addition to local analgesia. In a 4-month observational study, we assessed the levels of fear and pain experienced by pediatric cancer patients undergoing these painful procedures under such sedation. This investigation aimed to quantify their experience in a context where pharmacological management is used to relieve pain and anxiety at procedure time. We attempted to identify potential targets (such as anticipatory anxiety, parents' expectations, physicians' evaluation) for further intervention. The results will serve to determine if and how a nonpharmacological intervention might be implemented.

## Methods

## Patients

The study subjects were recruited in the Department of Pediatrics at Centre Mère-Enfant, Centre hospitalier universitaire de Québec (CHUQ), Quebec, Canada. For a 4-month consecutive period (December 2006-April 2007), children aged 6-17 attending the pediatric oncoloav unit for a scheduled needle procedure under light to moderate sedation (LP, BMA and/or biopsv), for diagnostic or therapeutic purposes, were invited with their parents to participate in this study. The exclusion criteria were: 1) a neurological condition making the child unable to understand pain scales, and 2) non-French-speaking subjects. The protocol and questionnaires received approval of the Institutional Ethics Board of the CHUQ. On the day of the scheduled procedure, the eligible children and their relative(s) were met at the oncology unit by a research assistant. The study was presented as an assessment of the children's anxiety and pain during cancer-related procedures. If they accepted to participate, the children and their relatives who planned to attend the medical procedures in the procedure room were asked to fill out a consent form. Any child coming back for a second scheduled procedure before the end of the study was invited to participate again. During the procedure, each child was accompanied by a relative. A physician (different from the oncologist) was in charge of administering sedation before needle puncture.

## Scale Assessment

We assessed the children's and relatives' self-reported measurements and behavioral observations at different time points, from the period prior to the medical procedure (Time 1, T1) through several minutes after its completion (Time 4, T4) (Figure 1).

## Self-reported Measures

The Faces Pain Scale Revised (FPS-R) [25] assigns scores from 0 (none) to 5 (very). Appearing to be the most psychometrically-sound measure of self-reported pain intensity in 4- to 12-year-old children, it has been validated for acute pain assessment. Stinson's systematic review reported evidence of test-retest reliability of the FPS-R [22]. It also possesses good correlations with the visual analog scale (VAS) in children aged 5-12 years [25], but is easier to use by children aged 4-8 years [26]. The VAS [22] is a horizontal scale of 10 cm on which endpoints represent intensity extremes, from 0 (not hurt) to 10 (very seriously hurt) [27]. A recent review demonstrated good validity of the VAS in children aged 8 or more years [22]. In children younger than 8 years old, preliminary assessments of magnitude changes were conducted by the research assistant to familiarize them with the VAS. Measurements other than pain (anxiety, fear, anticipated pain, and fear) were also assessed on both the VAS and FPS-R. Furthermore, in children aged 10 or more years (except for one child aged 9 years and 8 months), the State Trait Anxiety Inventory for Children (STAI) was administered to assess state and trait anxiety on two different 3-point Likert scales (scores ranged from 20 to 60). The STAI has been previously translated and validated in French [28]. State anxiety is described as current feelings of tension, anxiety, nervousness, and worry, while trait anxiety is defined as the individual's tendency to generally perceive a stressful situation as dangerous.

## Behavioral Observations

The Procedure Behavior Checklist (PBCL) [29] gathers ratings of distress: muscle tension, screaming, crying, forced restraint, pain verbalization, anxiety verbalization, verbal stalling, and physical resistance. The intensity of each component is evaluated on a numerical scale from 0 (none) to 5 (extremely intense), and the overall value at each measurement time is determined by the addition of scores for eight behaviors. The nurses and physicians were trained to use the PBCL before the procedure.

## Measurements (Figure 1)

Assessment times are reported in Figure 1. At every measurement time, the children's pain and fear were simultaneously self-reported by them on the VAS and FPS-R, and rated by their relatives and the oncology nurses (or physi-

### Cancer Procedure-related Pain/Anxiety in Children

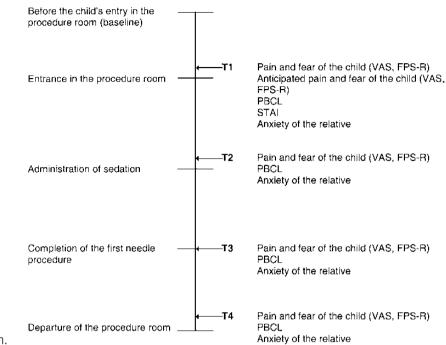


Figure 1 Procedure algorithm.

cians) on the VAS. Relatives also self-reported their own anxiety on the VAS. The oncology nurses (T1) and physicians (T2, T3, and T4) always assessed behavioral observations of the children 1 minute prior to the next time measurement. Additional assessments were made according to the time of the procedure.

### Needle Procedures

# T1: Baseline Assessments before the Children's Entry into the Procedure Room

If over 10 years old, the children also self-reported their state and trait anxiety on the STAI. Their anticipated fear and pain during needle insertion were assessed by relatives on the VAS, and by the children on the VAS and the FPS-R.

# T2: From Entry into the Procedure Room to the Administration of Sedation

After the completion of pre-procedure questionnaires, the children were taken into the procedure room. After the medical monitoring devices were set up, they were placed on the procedure table and maintained on the side facing their relatives, ready for the assessments. The children's pharmacological management of pain and anxiety was evaluated independently of this study by the physicians according to a protocol. All children received a eutectic mixture of local anaesthetics cream (EMLA cream) (APP Pharmaceuticals, Schaumburg, IL) about 60 minutes prior to the procedure, and a buffered lidocaine injection at the puncture site. Light to moderate sedation was administered by the physicians through a central venous catheter.

Midazolam (0.05–0.1 mg/kg/dose) and ketamine (0.5– 1 mg/kg/dose) were the usual sedation regimen at the time of the study in our unit.

# T3: From Sedation Administration to Completion of the First Needle Procedure

The oncologist then proceeded with the needle procedure. If the children underwent more than one procedure, only the first one was assessed right after termination, considering that it was done at removal of the first puncture needle. To avoid disturbing the children and because of the sedation influence, we delayed T3 measures to T4.

# T4: From the Children's Recovery to Departure from the Procedure Room

Right before their departure, measurements were taken and the children were asked to self-assess the pain they remembered having felt during puncture.

## Statistical Analysis

As pharmacological regimen was a confounding factor, only children who received both midazolam and ketamine were considered for analysis. Conclusion remains the same following analyses with and without their inclusion. Pearson's test was used to assess the strength of correlations between scales (VAS, FPS-R, PBCL, STAI), between self-reported measures of the children (fear, pain, anticipated fear, anticipated pain), and between measures reported by the children, physicians, and relatives. All frequencies, means, standard deviations, confidence intervals, repeated-measures ANOVA and Pearson's coef-

ficients were calculated by SAS 9.1 (SAS Institute Inc., Cary, NC). Paired *t* tests served to compare measures between the children and relatives or physicians. The results were considered significant with an alpha of 0.05, 2-sided. Age and the number of previous procedures were considered as continuous variables.

### Results

### Patient Characteristics

Eighteen patients were recruited during the study period, but four were excluded from the analyses because they did not receive the full sedation regimen (ketamine and midazolam). The reasons for not having received the usual sedation were mostly medical (i.e., physician's choice). Fourteen patients were analyzed (six females and eight males, mean age  $\pm$  SD: 9.9  $\pm$  3.4 years, body mass index  $\pm$  SD: 18.8  $\pm$  5.5) (Table 1). Six children were the oldest in their family (43%) and three did not have any siblings (21%). Nine children (64%) were diag-

**Table 1**Patients characteristics (N = 14)

Characteristics	Frequency (%)
Age	
≤7	5 (36)
8–9	1 (7)
≥10	8 (57)
Sex	. ,
Female	6 (43)
Male	8 (57)
Number of siblings	( )
0	3 (21)
1	6 (43)
≥2	5 (36)
Pathology	( )
Leukemia	9 (64)
Tumour	1 (7)
Other*	2 (14)
Undetermined	2 (14)
Type of procedure	
Lumbar puncture (LP) <sup>†</sup>	9 (64)
Bone marrow aspiration (BMA)	5 (36)
Number of previous procedures	
0	3 (21)
1	1 (7)
2–3	7 (50)
$\geq 4$	3 (21)
Attendance in the procedure room	
Both parents	3 (21)
Mother	8 (57)
Father	2 (14)
Other <sup>‡</sup>	1 (7)

\* Thrombopenia (1) or pancytopenia (1).

<sup>†</sup> Four LP were followed by a BMA.

<sup>‡</sup> Mother with grandfather.

nosed to have leukemia (acute lymphoblastic leukemia, nonlymphoblastic leukemia, acute myeloid leukemia, and Burkitt leukemia). Nine children underwent LP (64%), of which four had subsequent BMA. Three children underwent such a procedure for the first time (21%) (mean number of previous procedures by child  $\pm$  SD: 2.4  $\pm$  1.5). The children's mothers attended the procedure 11 times out of 14 (79%).

### Descriptive Statistics

Table 2 summarizes the mean values  $(\pm SD)$  of pain and fear assessment at every measurement time, as described in Methods (i.e., T1, T2, T3, and T4). All the children's relatives (n = 14) and physicians (n = 4) completed the scales. A few data were missing because one child refused to complete all the scales, and another was crying at T2 and was still under the influence of sedation at T4.

# Measurement of Children's Fear (T2) and Pain (T3) during Procedures

We focused our analysis on anxiety before the procedure at T2, and pain during the procedure at T3 (Table 2). As expected, the children reported their highest levels of fear at T2 in the procedure room just before sedation (VAS:  $2.93 \pm 2.93$ ; FPS-R:  $1.33 \pm 1.23$ ). They self reported the level of pain at T3 as being the highest (VAS:  $1.71 \pm 2.74$ ; FPS-R:  $1.17 \pm 1.03$ ). However, repeated-measures ANOVA failed to demonstrate significant changes in fear and pain over time (i.e., T1 to T4), no matter which scale the child used.

Table 3 reports high correlations between the two scales (VAS and FPS-R) used by the children for the assessment of their pain and anxiety. Relatives seemed to well assess the children's fear at T2, but correlations between relatives' ratings of the children's pain at T3 and the children's self-reported pain at T3 were not significant. Physician ratings of the children's fear and pain generally failed to correlate with the children's self-reported measures of fear at T2 and pain at T3. Among the nine children who completed the STAI, the trait anxiety score evaluated at T1 was correlated with their self-reported fear at T2 on the VAS (r = 0.94, P = 0.0002) and on the FPS-R (r = 0.92, P = 0.0004).

Seven children returned for a second visit after the end of the study and were tested all the same. Those who perceived more fear at the first visit continued to perceive high levels of fear at the second visit (data not presented). In our population, about one-quarter of the 14 children (21%) had more than three previous procedures (Table 1), but neither age nor the number of previous procedures was correlated with the children's self-reported measures of fear at T2 or pain at T3 (data not shown).

#### Relatives' Anxiety

Interestingly, relatives experienced high anxiety levels during the procedure at T2 (4.69  $\pm$  3.17) and T3

ted by the child, the relative and the physician and the levels of anxiety of the relative rated	
Table 2 Child's levels of pain, anxiety and distress rated by the ch	by the relative and the physician (Means $\pm$ SD) (N = 14)

$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$							
	Outcomes	Assessor	Scale	Time 1	Time 2	Time 3	Time 4
Child   STAI*   33.56 ± 7.38 (N = 9) <th< td=""><td>Trait anxiety</td><td>Child</td><td>STAI‡</td><td>± 6.15 (N</td><td>Ι</td><td>Ι</td><td>I</td></th<>	Trait anxiety	Child	STAI‡	± 6.15 (N	Ι	Ι	I
Child   VAS <sup>5</sup> 2.86 ± 2.63 (N = 13)	State anxiety	Child	STAI <sup>♯</sup>	± 7.38 (N			
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	Anticipatory pain	Child	VAS <sup>§</sup>	± 2.63 (N =			
Relative   VAS   3.97 ± 2.76 (N = 18)         FPS-R   1.36 ± 1.15 (N = 18)           FPS-R   1.36 ± 1.15 (N = 18)            FPS-R   1.36 ± 1.15 (N = 18) <t< td=""><td>of the child*</td><td></td><td>FPS-R<sup>¶</sup></td><td>+ 1.50</td><td> </td><td> </td><td> </td></t<>	of the child*		FPS-R <sup>¶</sup>	+ 1.50			
Child   VAS   2.73 ± 2.42 (N = 13)		Relative	VAS	± 2.76			
FPS-R1.36 $\pm$ 1.15 (N = 18)RelativeVAS4.64 $\pm$ 2.82 (N = 18)RelativeVAS0.24 $\pm$ 0.46 (N = 13)1.35 $\pm$ 2.18 (N = 12)1.71 $\pm$ 2.74# (N = 12)1.13 $\pm$ 1.22 (NRelativeVAS0.24 $\pm$ 0.46 (N = 13)1.35 $\pm$ 2.18 (N = 12)1.71 $\pm$ 2.74# (N = 12)1.13 $\pm$ 1.19 (NRelativeVAS0.29 $\pm$ 0.83 (N = 14)0.75 $\pm$ 1.06 (N = 12)1.17 $\pm$ 1.03# (N = 12)1.13 $\pm$ 1.19 (NRelativeVAS1.89 $\pm$ 3.38 (N = 14)1.11 $\pm$ 1.04 (N = 14)4.01 $\pm$ 3.23 (N = 14)1.13 $\pm$ 1.19 (NRhysiciantVAS0.29 $\pm$ 0.80 (N = 14)0.31 $\pm$ 0.48 (N = 14)1.83 $\pm$ 2.32 (N = 14)1.13 $\pm$ 1.19 (NRhysiciantVAS0.21 $\pm$ 0.71 $\pm$ 0.73 (N = 14)1.33 $\pm$ 1.23 (N = 12)1.17 $\pm$ 1.64# (N = 12)1.66 $\pm$ 2.58 (NRelativeVAS3.29 $\pm$ 3.28 (N = 14)1.33 $\pm$ 1.23 (N = 14)1.33 $\pm$ 2.32 (N = 14)0.45 $\pm$ 1.27 (NRelativeVAS3.29 $\pm$ 3.28 (N = 14)1.33 $\pm$ 1.23 (N = 14)1.94 $\pm$ 2.43 (N = 14)0.45 $\pm$ 1.27 (NRiditionVAS1.86 $\pm$ 2.67 (N = 14)2.86 $\pm$ 4.59 (N = 14)1.94 $\pm$ 2.43 (N = 14)0.45 $\pm$ 1.27 (NRiditionVAS1.86 $\pm$ 2.68 (N = 14)2.68 $\pm$ 4.59 (N = 14)0.93 $\pm$ 2.67 (NRiditionVAS1.86 $\pm$ 2.68 (N = 14)2.69 $\pm$ 3.17 (N = 14)0.93 $\pm$ 2.67 (NRiditionVAS2.20 $\pm$ 2.98 (N = 14)2.58 $\pm$ 2.65 (N = 14)0.93 $\pm$ 2.67 (NRiditionVAS4.74 $\pm$ 3.18 (	Anticipatory fear	Child	VAS	+ 2.42			
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Child     VAS     0.24 ± 0.46 (N = 13)     1.35 ± 2.18 (N = 12)     1.71 ± 2.74 <sup>#</sup> (N = 12)     1.13 ± 1.22 (N = 1.2)       FPS-R     0.71 ± 0.83 (N = 14)     0.75 ± 1.06 (N = 12)     1.17 ± 1.03 <sup>#</sup> (N = 12)     1.13 ± 1.19 (N = 1.2)       Physiciant     VAS     0.29 ± 0.80 (N = 14)     1.11 ± 1.04 (N = 14)     1.17 ± 1.03 <sup>#</sup> (N = 12)     1.13 ± 1.19 (N = 1.1)       Physiciant     VAS     1.89 ± 3.38 (N = 14)     1.11 ± 1.04 (N = 14)     1.83 ± 2.32 (N = 14)     1.13 ± 1.19 (N (N = 1.2))       Physiciant     VAS     0.29 ± 0.80 (N = 14)     0.31 ± 0.48 (N = 14)     1.17 ± 1.64 <sup>#</sup> (N = 12)     1.16 ± 2.58 (N (N = 1.2))       Child     VAS     1.71 ± 2.27 (N = 14)     2.93 ± 2.93 (N = 12)     1.77 ± 3.05 <sup>#</sup> (N = 12)     1.66 ± 2.58 (N (N = 1.2))       Relative     VAS     3.29 ± 3.28 (N = 14)     1.33 ± 1.23 (N = 14)     1.54 ± 1.94 (N (N = 1.2))       Physician     VAS     1.86 ± 2.67 (N = 14)     1.36 ± 2.58 (N = 1.2)     0.65 ± 0.60 (N (N = 2.2))       Physician     VAS     1.86 ± 2.67 (N = 14)     1.36 ± 2.58 (N = 1.2)     0.65 ± 0.60 (N (N = 2.2))       Physician     VAS     1.86 ± 2.67 (N = 14)     1.367 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14) </td <td></td> <td>Relative</td> <td>VAS</td> <td>+ 2.82</td> <td> </td> <td> </td> <td> </td>		Relative	VAS	+ 2.82			
FPS-R $0.71 \pm 0.83$ $(N = 14)$ $0.75 \pm 1.06$ $(N = 12)$ $1.17 \pm 1.03^{\#}$ $(N = 12)$ $1.00 \pm 0.95$ $(N$ RelativeVAS $1.89 \pm 3.38$ $(N = 14)$ $1.11 \pm 1.04$ $(N = 14)$ $1.13 \pm 1.19$ $(N$ PhysiciantVAS $0.29 \pm 0.80$ $(N = 14)$ $0.31 \pm 0.48$ $(N = 14)$ $1.13 \pm 1.19$ $(N = 12)$ ChildVAS $0.29 \pm 0.80$ $(N = 14)$ $0.31 \pm 0.48$ $(N = 14)$ $1.77 \pm 3.23$ $(N = 12)$ $1.13 \pm 1.19$ ChildVAS $0.71 \pm 2.27$ $(N = 14)$ $2.93 \pm 2.93$ $(N = 12)$ $1.77 \pm 3.05^{\#}$ $(N = 12)$ $1.66 \pm 2.58$ RelativeVAS $3.29 \pm 3.28$ $(N = 14)$ $1.33 \pm 1.23$ $(N = 14)$ $1.77 \pm 3.05^{\#}$ $(N = 12)$ $0.67 \pm 0.98$ RelativeVAS $3.29 \pm 3.28$ $(N = 14)$ $1.33 \pm 1.23$ $(N = 14)$ $1.77 \pm 3.05^{\#}$ $(N = 12)$ $0.67 \pm 0.98$ PhysicianVAS $1.86 \pm 2.67$ $(N = 14)$ $1.33 \pm 1.23$ $(N = 14)$ $1.94 \pm 2.43$ $(N = 14)$ $1.54 \pm 1.94$ PhysicianVAS $1.86 \pm 2.67$ $(N = 14)$ $3.67 \pm 2.48$ $(N = 14)$ $1.94 \pm 2.43$ $(N = 14)$ $0.45 \pm 1.27$ NildPhysicianVAS $1.86 \pm 2.67$ $(N = 14)$ $2.86 \pm 4.59$ $(N = 14)$ $2.94 \pm 2.43$ $(N = 14)$ $0.45 \pm 1.27$ NildPhysicianVAS $1.36 \pm 2.67$ $(N = 14)$ $2.64 \pm 3.26$ $(N = 14)$ $2.14 \pm 2.69$ $(N$ PhysicianVAS $2.74 \pm 3.18$ $($	Pain of the child	Child	VAS	+ 0.46	± 2.18 (N = <sup>-</sup>	± 2.74 <sup>#‡</sup> (N =	± 1.22 (N
Relative     VAS     1.89 ± 3.38 (N = 14)     1.11 ± 1.04 (N = 14)     4.01 ± 3.23 (N = 14)     1.13 ± 1.19 (N       Physician <sup>†</sup> VAS     0.29 ± 0.80 (N = 14)     0.31 ± 0.48 (N = 14)     1.83 ± 2.32 (N = 14)     1.13 ± 1.19 (N       Child     VAS     0.29 ± 0.80 (N = 14)     0.31 ± 0.48 (N = 12)     1.77 ± 3.05# (N = 12)     1.66 ± 2.58 (N       Relative     VAS     0.71 ± 0.73 (N = 14)     1.33 ± 1.23 (N = 12)     1.17 ± 1.64# (N = 12)     0.67 ± 0.98 (N       Relative     VAS     3.29 ± 3.28 (N = 14)     1.33 ± 1.23 (N = 14)     1.54 ± 1.94 (N     N       Physician     VAS     1.86 ± 2.67 (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       Physician     VAS     1.86 ± 2.67 (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       Nild     Physician     VAS     1.86 ± 2.06 th (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       Nild     Physician     VAS     1.86 ± 2.06 th (N = 14)     2.66 ± 4.59 (N = 14)     0.45 ± 1.27 (N       Physician     VAS     4.74 ± 3.18 (N = 14)     2.64 ± 2.3 (N = 14)			FPS-R	+ 0.83	± 1.06 (N = .	+1	± 0.95 (N
Physiciant     VAS     0.29 ± 0.80 (N = 14)     0.31 ± 0.48 (N = 14)     1.83 ± 2.32 (N = 14)     0.25 ± 0.60 (N       Child     VAS     1.71 ± 2.27 (N = 14)     0.31 ± 0.48 (N = 12)     1.77 ± 3.05# (N = 12)     1.66 ± 2.58 (N       Relative     VAS     1.71 ± 0.73 (N = 14)     1.33 ± 1.23 (N = 12)     1.17 ± 1.64# (N = 12)     1.66 ± 2.58 (N       Relative     VAS     3.29 ± 3.28 (N = 14)     1.33 ± 1.23 (N = 12)     1.17 ± 1.64# (N = 12)     0.67 ± 0.98 (N       Relative     VAS     3.29 ± 3.28 (N = 14)     1.33 ± 1.23 (N = 14)     4.47 ± 3.74 (N = 14)     1.54 ± 1.94 (N       Physician     VAS     1.86 ± 2.67 (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       nild     Physician     VAS     1.86 ± 2.06 <sup>T</sup> (N = 14)     2.86 ± 4.59 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       stitve     Relative     VAS     4.74 ± 3.18 (N = 14)     2.64 ± 3.17 (N = 14)     0.33 ± 2.67 (N       Physician     VAS     4.74 ± 3.18 (N = 14)     2.64 ± 0.56 (N = 14)     0.33 ± 2.67 (N       Physician     VAS     2.20 ± 2.98 (N = 14)     2.65 (N = 14)     0.93 ± 2.67 (N		Relative	VAS	+ 3.38	± 1.04 (N = .	+1	± 1.19 (N
Child     VAS     1.71 ± 2.27 (N = 14)     2.93 ± 2.93 (N = 12)     1.77 ± 3.05 <sup>#</sup> (N = 12)     1.66 ± 2.58 (N       FPS-R     0.71 ± 0.73 (N = 14)     1.33 ± 1.23 (N = 12)     1.17 ± 1.64 <sup>#</sup> (N = 12)     0.67 ± 0.98 (N       Relative     VAS     3.29 ± 3.28 (N = 14)     1.33 ± 1.23 (N = 12)     1.17 ± 1.64 <sup>#</sup> (N = 12)     0.67 ± 0.98 (N       Relative     VAS     3.29 ± 3.28 (N = 14)     1.33 ± 1.23 (N = 14)     4.47 ± 3.74 (N = 14)     1.54 ± 1.94 (N       Physician     VAS     1.86 ± 2.67 (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       nild     Physician     VAS     1.86 ± 2.06 <sup>#</sup> (N = 14)     2.86 ± 4.59 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       ative     Relative     VAS     4.74 ± 3.18 (N = 14)     2.86 ± 4.59 (N = 14)     0.93 ± 2.67 (N       Physician     VAS     4.74 ± 3.18 (N = 14)     2.54 ± 2.65 (N = 14)     0.92 ± 2.69 (N       Physician     VAS     2.20 ± 2.98 (N = 14)     2.58 ± 2.65 (N = 14)     1.99 ± 2.52 (N = 14)     0.82 ± 1.41 (N		Physician <sup>†</sup>	VAS	+ 0.80	± 0.48 (N =	+1	± 0.60 (N
FPS-R   0.71 ± 0.73 (N = 14)   1.33 ± 1.23 (N = 12)   1.17 ± 1.64 <sup>#</sup> (N = 12)   0.67 ± 0.98 (N     Relative   VAS   3.29 ± 3.28 (N = 14)   4.45 ± 2.87 (N = 14)   4.45 ± 3.74 (N = 14)   1.54 ± 1.94 (N     Physician   VAS   1.86 ± 2.67 (N = 14)   3.67 ± 2.48 (N = 14)   1.94 ± 2.43 (N = 14)   0.45 ± 1.27 (N     Physician   VAS   1.86 ± 2.67 (N = 14)   3.67 ± 2.48 (N = 14)   1.94 ± 2.43 (N = 14)   0.45 ± 1.27 (N     Physician   VAS   1.07 ± 2.06 <sup>th</sup> (N = 14)   2.86 ± 4.59 (N = 14)   4.57 ± 3.78 (N = 14)   0.93 ± 2.67 (N     Relative   VAS   4.74 ± 3.18 (N = 14)   2.86 ± 4.59 (N = 14)   5.43 ± 3.22 (N = 14)   0.93 ± 2.67 (N     Physician   VAS   2.20 ± 2.98 (N = 14)   2.58 ± 2.65 (N = 14)   1.99 ± 2.52 (N = 14)   0.82 ± 1.41 (N	Fear of the child	Child	VAS	± 2.27	± 2.93 (N = .	+1	± 2.58 (N
Relative     VAS     3.29 ± 3.28 (N = 14)     4.45 ± 2.87 (N = 14)     4.45 ± 2.87 (N = 14)     1.54 ± 1.94 (N       Physician     VAS     1.86 ± 2.67 (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       Physician     VAS     1.86 ± 2.67 (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       Physician     VAS     1.07 ± 2.06 <sup>th</sup> (N = 14)     2.86 ± 4.59 (N = 14)     4.57 ± 3.78 (N = 14)     0.93 ± 2.67 (N       Relative     VAS     4.74 ± 3.18 (N = 14)     2.86 ± 3.17 (N = 14)     5.43 ± 3.22 (N = 14)     0.93 ± 2.67 (N       Physician     VAS     2.20 ± 2.98 (N = 14)     2.58 ± 2.65 (N = 14)     1.99 ± 2.52 (N = 14)     0.82 ± 1.41 (N			FPS-R	± 0.73	± 1.23 (N =	+1	± 0.98 (N
Physician     VAS     1.86 ± 2.67 (N = 14)     3.67 ± 2.48 (N = 14)     1.94 ± 2.43 (N = 14)     0.45 ± 1.27 (N       Physician     PBCL**     1.07 ± 2.06 <sup>th</sup> (N = 14)     2.86 ± 4.59 (N = 14)     4.57 ± 3.78 (N = 14)     0.93 ± 2.67 (N       Relative     VAS     4.74 ± 3.18 (N = 14)     2.86 ± 4.59 (N = 14)     4.57 ± 3.78 (N = 14)     0.93 ± 2.67 (N       Relative     VAS     4.74 ± 3.18 (N = 14)     2.86 ± 3.17 (N = 14)     5.43 ± 3.22 (N = 14)     2.14 ± 2.69 (N       Physician     VAS     2.20 ± 2.98 (N = 14)     2.58 ± 2.65 (N = 14)     1.99 ± 2.52 (N = 14)     0.82 ± 1.41 (N		Relative	VAS	+ 3.28	± 2.87 (N =	+1	± 1.94 (N
Physician     PBCL**     1.07 ± 2.06 <sup>+1</sup> (N = 14)     2.86 ± 4.59 (N = 14)     4.57 ± 3.78 (N = 14)     0.93 ± 2.67 (N       Relative     VAS     4.74 ± 3.18 (N = 14)     4.69 ± 3.17 (N = 14)     5.43 ± 3.22 (N = 14)     2.14 ± 2.69 (N       Physician     VAS     2.20 ± 2.98 (N = 14)     2.58 ± 2.65 (N = 14)     1.99 ± 2.52 (N = 14)     0.82 ± 1.41 (N		Physician	VAS	± 2.67	± 2.48 (N =	+1	± 1.27 (N
Relative     VAS     4.74 ± 3.18 (N = 14)     4.69 ± 3.17 (N = 14)     5.43 ± 3.22 (N = 14)     2.14 ± 2.69 (N       Physician     VAS     2.20 ± 2.98 (N = 14)     2.58 ± 2.65 (N = 14)     1.99 ± 2.52 (N = 14)     0.82 ± 1.41 (N	Distress of the child	Physician	PBCL**	+ 2.06	± 4.59 (N = 1	± 3.78 (N = 1	± 2.67 (N
VAS 2.20 $\pm$ 2.98 (N = 14) 2.58 $\pm$ 2.65 (N = 14) 1.99 $\pm$ 2.52 (N = 14) 0.82 $\pm$ 1.41 (N	Anxiety of the relative	Relative	VAS	+ 3.18	± 3.17 (N = 1	± 3.22 (N = .	± 2.69 (N
	1	Physician	VAS	+ 2.98	± 2.65 (N = 1	± 2.52 (N = 1	± 1.41 (N

<sup>&</sup>lt;sup>+</sup> In charge of the sedation administration.

State Trait anxiety Inventory (STAI), child aged  $\ge 10$  (N = 9), scales from 20 to 60. ++

 <sup>&</sup>lt;sup>§</sup> Visual analog scale (VAS), scale from 0 to 10.
<sup>¶</sup> Faces Pain Scale Revised (FPS-R), scale from 0 to 5.
\*\* Procedure Behavior Checklist (PBCL), scale from 0 to 40.
<sup>††</sup> Replaced by the nurse.
<sup>‡‡</sup> Retrospectively evaluated at Time 4.

**Table 3** Correlations between fear and pain levels at T2 and at T3 as reported by the child, the relative and the physician (N = 14)

		Child's Self-re	ported Assessmen	ts	
		Fear at T2		Pain at T3	
		VAS	FPS-R	VAS	FPS-R
Anxiety of the pare	nt rated by				
Parent		<i>r</i> = 0.40	<i>r</i> = 0.46	r = 0.53	<i>r</i> = 0.41
Fear of the child at	T2 rated by				
Child	VAS	NR	r = 0.86**	NR	NR
	FPS-R	r = 0.86**	NR	NR	NR
Parent		r = 0.65*	r = 0.61*	NR	NR
Physician	VAS	<i>r</i> = 0.47	r = 0.44	NR	NR
-	PBCL	r = 0.09	<i>r</i> = 0.08	NR	NR
Pain of the child at	T3 rated by				
Child	VAS	NR	NR	<i>r</i> = 1.00	r = 0.88**
	FPS-R	NR	NR	r = 0.88**	<i>r</i> = 1.00
Parent		NR	NR	r = 0.42	r = 0.36
Physician	VAS	NR	NR	r = 0.38	r = 0.47
-	PBCL	NR	NR	<i>r</i> = 0.15	<i>r</i> = 0.27

\* *P* < 0.05; \*\* *P* < 0.01.

NR = not reported.

(5.43  $\pm$  3.22). A strong correlation existed between the level of anxiety self-reported by relatives and the level of fear they rated their children at T2 (r = 0.83, P = 0.0002), and between the children's self-reported level of anxiety at T3 and what level of pain they rated their children at T3 (r = 0.74, P = 0.0022). However, the relatives' own anxiety at T2 was not correlated with the children's self-reported pain at T3 (Table 3).

## Expectation of Fear and Pain from the Needle Procedure

The children's own expectancy of pain was not significantly higher than their self-reported measure of pain at T3 on the VAS (P = 0.0533) and the FPS-R (P = 0.0874), and no significant difference was found between the children's expectancy of fear and their self-reported measure of fear at T3 on the VAS (P = 0.1321) or the FPS-R (P = 0.4627). Nevertheless, good correlations between anticipated and self-reported measures of pain as well as fear at T3 were observed (Table 4). In our study, neither age nor the number of previous procedures was correlated with the children's anticipated fear and pain.

Furthermore, relatives expected high levels of pain  $(3.97 \pm 2.76)$  and fear  $(4.64 \pm 2.82)$  for the children during the needle procedure (T3) (Table 2). However, there was no correlation between the relatives' expectations of their children's pain at T3 and the children's self-reported pain at T3 either on the FPS-R or the VAS (Table 4). Finally,

relatives' expectations of their children's fear and pain failed to correlate with, respectively, the children's own expectations of fear (VAS: r = 0.27, P = 0.3702; FPS-R: r = 0.17, P = 0.5664) and pain (VAS: r = 0.18, P = 0.5615; FPS-R: r = 0.21, P = 0.4682).

#### Discussion

Our data suggest that light to moderate sedationanalgesia usually leads to low levels of pain and fear during procedures, as self-reported by children. Our study made reliable assessments of children's pain and fear through procedure times, using both the VAS and facial scale as recommended in Richardson's review [21]. As expected, the children assessed, in a satisfactory manner, their own fear and pain on both scales [22,25]. In our investigation, parents seemed to better assess the fear of their children than their pain. Physician estimations of the children's levels of fear and pain were less accurate and not significantly associated with the children's selfreported measures.

In our study, preparation for needle procedures seemed distressful for children, independently of the number of previous procedures. Moreover, children who were generally anxious in life, according to the STAI, reported higher levels of distress, underlining that patient with cancer never get used to painful procedures [17–19]. Moreover, those who anticipated pain and fear during needle insertion tended to experience more pain and fear during the procedure [30]. These results support the

		Child's Self-r	reported Assessr	nents	
		Fear at T3		Pain at T3	
		VAS	FPS-R	VAS	FPS-R
Anticipated child's pa	ain at puncture rated by				
Child	VAS FPS-R	$r = 0.62^*$ $r = 0.60^*$	$r = 0.63^*$ $r = 0.58^*$	$r = 0.65^*$ $r = 0.64^*$	$r = 0.63^*$ r = 0.56
Parent		$NR^{\dagger}$	NR	r = 0.49	<i>r</i> = 0.40
Anticipated child's fe	ar at puncture rated by				
Child	VAS FPS-R	$r = 0.59^*$ $r = 0.75^{**}$	$r = 0.75^{**}$ $r = 0.72^{**}$	$r = 0.58^*$ $r = 0.73^{**}$	$r = 0.69^*$ $r = 0.62^*$
Parent		<i>r</i> = 0.31	<i>r</i> = 0.57	NR	NR

Table 4 Correlations between anticipated fear and pain and self-reported fear and pain at T3 (N = 14)

\* *P* < 0.05; \*\* *P* < 0.01.

NR = not reported.

n = not reported.

fact that the children's pain and fear perception may be largely influenced by anticipation, often seen as a trigger to pain in an anxiety-pain spiral way [31]. Guidelines thus recommend managing it as well as pain [1,2]. Offering a hypnotic intervention could target the release of children's distress, fear, pain, and their anticipated fear and pain [6,7,10,31,32]. Such hypnotic interventions are relevant in addition to medication because hypnosis can be easily mastered and self-reused to help children facing subsequent procedures and other stressful cancerrelated events [10].

Relatives worried about their children's distress, but this did not seem to influence the current emotional state of the children. Some suggest that, when high levels of fear and pain for the children are reported by relatives, these levels correlate with their own parental anxiety and with the children's self-reported levels [33], but in our study, no correlations were found between self-reported anxiety by the relatives and self-reported fear and pain by the children. Neither the current state of the relatives nor their expectations for pain and anxiety correlated with the children's fear or pain. As others have reported a mediator role of parental expectations [23], we wonder, to what extent in our results, small sample size, and the use of sedation-analgesia scramble the relationship between parental and children's expectations and their selfreported measures of pain. In addition, we did not measure how confident the parents were toward the relief of pain and distress by medication in our study. Furthermore, in our study population, most of the children underwent previous procedures, and their parents could have learned to cope with their anxiety, avoiding negative attitudes. Consequently, assessment of parental behavior is needed and still recommended [34], considering that parental attitudes (i.e., reassuring, empathizing) could have a negative effect on the children's distress [35].

There were limitations in this preliminary study. Even if the procedures were well standardized, the limited sample

size may have tempered the results. Indeed, lack of power may sometimes reject the alternative hypothesis (i.e., significant relationship between variables). Small sample size also prevented us from controlling for age and the number of previous procedures. Still, sedation was effective in reducing the children's pain and fear, but possibly interfered with the children's recall of pain during the procedure at T3 [36].

In conclusion, even if sedation achieves the relief of pain and distress during cancer procedures, this pilot study underlines the need for a nonpharmacological intervention to ease anxiety before they are undertaken. As negative experience can amplify both pain and anxiety, this intervention should be started early in disease management. Anxious patients will probably benefit more from such interventions [37]. Furthermore, parents and physicians could be key agents in the relief of pain in children undergoing invasive, painful procedures, and their involvement in any further intervention is essential [24]. How parents or relatives evaluate, and finally, sympathize with children's emotions and pain are also important, seeing that language may greatly impact the pain experience [38]. As hypnosis could be induced conventionally and also conversationally, it could provide helpful coping strategies for children as well as good and positive communication skills for both parents and physicians [15,38]. Overall, a larger study is needed [12] to confirm the role and interactions between children, relatives, and medical staff, and to evaluate the benefits of a suitable complementary intervention as an adjunct to sedation-analgesia in the management of pain and anxiety, the need for medication, staff empathy, and patient satisfaction.

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