

Parents and Procedures: A Randomized Controlled Trial

Howard Bauchner, MD*; Robert Vinci, MD†; Sharon Bak, MPH‡; Colleen Pearson*; and Michael J. Corwin, MD§

ABSTRACT. *Introduction.* Previous work has shown that parents prefer to be present when their children undergo common invasive procedures, although physicians are ambivalent about parental presence.

Purpose. To determine the effect of a parent-focused intervention on the pain and performance of the procedure, anxiety of parents and clinicians, and parental satisfaction with care.

Population. Children younger than 3 years old undergoing venipuncture, intravenous cannulation, or urethral catheterization.

Setting. Pediatric emergency department of Boston City Hospital.

Design. Randomized controlled trial with three groups; parents present and given instructions on how to help their children; parents present, but no instructions given; and parents not present.

Intervention. The parents were instructed to touch, talk to, and maintain eye contact during the procedure.

Results. A total of 431 parents was randomized to the intervention (N = 153), present (N = 147), and not present (N = 131) groups. The groups were equivalent with respect to measured sociodemographic variables and parents' previous experience in the pediatric emergency department. No differences emerged with respect to pain (3-point scale measured by parent and clinician, and analysis of cry); performance of the procedure (number of attempts, completion of procedure by first clinician, time); clinician anxiety; or parental satisfaction with care. Parents who were present were more likely to rate the pain of the children as extreme/severe (52%) in comparison to clinicians (15%, κ .07, poor agreement) and were significantly less anxious than parents who were not present.

Conclusion. Overall, the intervention was not effective in reducing the pain of routine procedures. Parental presence did not negatively affect performance of the procedure or increase clinician anxiety. Parents who were present were less anxious than those who were not present.

Clinical Implication. In general, parents have indicated that they want to be present when their children undergo procedures. The results of this study challenge the traditional belief that parental presence negatively affects our ability to successfully complete procedures. We should encourage parents who want to be present to stay during procedures. *Pediatrics* 1996;98:861-867; pain, parents, procedures, RCT.

ABBREVIATIONS. PED, pediatric emergency department; STAI, state-trait anxiety inventory.

Previously, we reported that the majority of parents prefer to be present when their children undergo common invasive medical procedures, such as venipuncture or intravenous cannulation.¹ Of 250 parents who responded to a questionnaire about their preferences, 78% indicated that they would want to be present if their child needed to have blood drawn or an IV started. Of the group who indicated a preference to be present, 80% said it would make them feel better, 91% believed the child would feel better, and 73% replied it would help the physician.¹ After this report, Merritt and others² reported the preference of physicians with respect to parental presence. We confirmed their findings that for common procedures, the majority of physicians are comfortable with parents being present.³ However, as procedures become more invasive, eg, arterial blood sampling or chest tube insertion, physicians prefer that parents not be present.^{2,3}

Despite these reports, what actually happens during encounters when children undergo procedures is unclear. In 1991, we reported the results of an observational study of 50 children undergoing venipuncture or intravenous cannulation in the pediatric

From the *Divisions of General Pediatrics, †Emergency Room Services, and §Neonatology, Boston University School of Medicine, Boston Medical Center (formerly Boston City Hospital) and ‡Department of Social and Behavioral Sciences, Boston University School of Public Health, Boston, Massachusetts.

Received for publication Nov 7, 1995; accepted Dec 28, 1995.

Reprint requests to (H.B.) Boston City Hospital, 818 Harrison Ave, Boston, MA 02118.

PEDIATRICS (ISSN 0031 4005). Copyright © 1996 by the American Academy of Pediatrics.

emergency department (PED).³ Parents remained with their children during 62% of the procedures.³ Parents were more likely to stay if the index child or his or her sibling had previously undergone a procedure. Only 43% of the parents who did stay were given that option by the physician, and of those who did not stay, 37% reported that the physician asked them to leave.³

Physician ambivalence about parental presence results from a number of factors.⁴ First, some physicians perceive that they are less proficient at procedures if parents are present. Parents make us nervous. Second, parents are anxious when their children are ill and can be difficult when procedures are performed during prolonged emergency department evaluations. Parents can communicate anxiety to their children and, on occasion, be physically intrusive. Third, having parents present can be time-consuming, because the clinician needs to explain the procedure to the parent. In a busy office or emergency room, sometimes it is just faster to get the procedure done. Fourth, some parents are uncertain how best to help their children during procedures. Although some instinctively soothe and calm their children, parental anxiety and fear may prevent others from offering optimal support for their children.

Believing that parental presence during procedures is important and that parents should be instructed on how to help their children, we designed a study in which parents were taught how to help their children during common invasive medical procedures. The intervention was kept simple, so it could be used in other settings, and focused on younger children, because they are more amenable to an intervention than older children. By the time children reach the ages of 5 through 6 years they already have well-defined coping strategies.⁵ The overall purpose of the study was to determine the effect of a parent-focused intervention on the pain and performance of the procedure, anxiety of the parents and physicians, and parental satisfaction with care. Our primary objective was to determine if the parent-focused intervention would reduce the pain of the procedure. Other questions asked included: (1) do parents perceive pain similarly to physicians? and (2) could parents be taught how to implement the intervention?

METHODS

The study was a randomized controlled trial with three groups: parent present and given instructions on how to help their child (intervention); parents present, but no instructions given (present); and parents not present (absent). Children younger than 3 years old, being seen in the PED and undergoing venipuncture, intravenous cannulation, or urethral catheterization were eligible to participate. Attending, residents, and nurses performed the procedures. Parents were excluded if children needed emergency medical attention, had previously participated in the study, or had a history of chronic disease that frequently requires invasive procedures, such as sickle cell anemia.

Consent Procedure

Randomization was performed using a technique developed by Zelen^{6,7} referred to as prerandomization. Traditionally, informed consent is obtained before randomization. With prerandomization, participants are randomized before obtaining informed con-

sent. There were two benefits to using this technique: (1) participants were less likely to withdraw because they were not specifically aware of the other groups and (2) the measure of anxiety was less influenced by parents being assigned to a group they did not want, and hence the measure of anxiety more accurately reflected anxiety related to the procedure rather than group assignment.

After a physician in the PED determined that a parent-child pair was eligible to participate, they notified the research assistant who told the parents, depending on the randomization assignment, that: (1) we like parents to be with their children when they are having blood drawn, an intravenous started, or urine obtained, we think it helps the child, we would like you to be present and we will tell you what to do to help calm your child down (intervention); (2) we like parents to be with their children when they are having blood drawn, an intravenous started, or urine obtained, could you please stay with them (present); or (3) we do not like parents to be with their children when they are having blood drawn, an intravenous started, or urine obtained, it makes the doctor nervous and is not helpful (absent). If parents wanted to be present, but were assigned to the not present group, they could opt not to enroll in the study. The study was approved by the Human Investigation Committee of the Boston City Hospital.

Parental Instructions

Parents were instructed how to calm and relax their child (Appendix). The intervention was brief and was based on clinical experience and data suggesting that children are calmer and their vital signs return to normal more quickly when two sensory modalities (touch and sound) are engaged.⁸ The parents were asked to sit at the head of the bed and talk to, touch, and maintain eye contact with their children. They were told not to help restrain their children. The research assistant recorded whether the parents were able to implement the intervention. The categories included: most successful (talked to, touched, and maintained eye contact with child); very successful (talked to and touched child); successful (maintained eye contact and talked to or touched child); somewhat successful (talked to or touched or maintained eye contact); and not successful (none of three).

Measurement of Pain

Pain was measured using analysis of cry and an observational scale completed by the physician and parent. These two measures were chosen because they reflect physiologic and behavioral measurements, and have been reported to change when infants and children undergo painful procedures.¹⁰⁻¹³

Over the last decade, computerized analysis of cry has been used in a number of investigations of infants and young children.¹² In general, computerized analysis of cry confirms the reports of parents that the cry of children in pain is higher pitched and more turbulent.¹⁴

Each procedure served as a stimulus for the cry. Each 30-second cry signal was filtered above 10 kHz and digitized at 20 kHz by the computer. For each cry utterance (defined as a cry sound lasting at least 0.5 seconds), Fourier transformation was used to compute the log magnitude spectrum for each 25-millisecond block of each cry utterance. Variables analyzed included level of energy; frequency variables (fundamental—frequency of vocal fold vibration, first formant—first resonance frequency resulting from the filtering of the sound by the vocal tract); cry modes (phonation—periodic signal with a fundamental frequency no more than 1000 Hz, hyperphonation—aperiodic signal with a fundamental frequency exceeding 1000 Hz, dysphonation—turbulent or aperiodic sound); and number of cry utterances (number of cry sounds that last at least 0.5 seconds). Frequency variables were determined for each 25-millisecond block in the phonation mode. The cry mode was determined for each 25-millisecond block. The percentage of blocks in each cry mode was determined for each utterance.

As mentioned above, some of the cry variables analyzed have been reported to changed as a consequence of pain.¹⁰⁻¹⁵ More specifically, we hypothesized that total energy reflects pain and would be reduced for children in the intervention group. Analysis was conducted controlling for age, because cry technique has generally been used for children younger than six months old.

There are a number of scales available to measure the pain of procedures, although none have been widely used in infants.^{10,15,16}

Because the study was conducted in an urban PED, there were significant time and space constraints, and hence, we chose to use a global measure of pain that could easily be completed by the parents and clinicians. Each was asked to rate the extent of pain of the procedure on a 3-point categorical scale with 1 = severe/great; 2 = moderate; and 3 = some/little.

Performance of Procedure

The performance of the procedure was measured by assessing (1) the number of needles/catheters used; (2) how often the procedure was completed by the first clinician attempting it; and (3) the amount of time from insertion of the needle to withdrawal of blood (or insertion of the catheter to withdrawal of urine).

Anxiety of Parent and Physician

The anxiety of the parents, physicians, and nurses was measured using the state-trait anxiety inventory (STAI). The STAI is a 20-item forced choice questionnaire that measures current anxiety. It has excellent reliability and validity.¹⁶ Sample questions include: I feel calm, I am tense, I feel strained, I am relaxed. It was completed by the parents and clinicians approximately 10 minutes after the procedure was completed.

Satisfaction With Care

Parents were asked, "Overall, how satisfied were you with the care your child received?" There were five possible responses ranging from extremely unsatisfied to extremely satisfied. For the first 100 enrollees, satisfaction was assessed by telephone 48 through 72 hours after discharge from the PED. However, because of difficulty contacting families, satisfaction was assessed at the end of the visit for the remainder of participants.

Sample Size Calculations

The sample size calculations were based on two of the outcome measures: pain of the procedure (main outcome variable) as analyzed by cry and performance of the procedure. Based on previous research,¹⁵ it was assumed that the fundamental frequency of the cry of children whose parents were not present would be 627 Hz (SD 150 Hz) and that of children whose parents were in the intervention group would be 575 Hz (SD 150 Hz). A difference of

50 Hz is audible to the human ear, hence the sample size calculation reflected both statistical as well as clinical significance. Assuming an α of 0.05 and a power of 0.80, the sample size estimate was 131 per group, for a final sample size estimate of 393. The sample size estimate for the performance of the procedure was smaller.

χ^2 was used to analyze categorical variables and t tests or analysis of variance for continuous variables. Kappa was used to measure agreement between parent and clinician pain ratings and multiple logistic regression was used to analyze cry, controlling for confounding variables, such as age.

RESULTS

A total of 431 of 572 (75%) eligible parents consented and participated in the study: 153 in the intervention group; 147 in the present-not taught group; and 131 in the not present group. The groups were similar with respect to parental and child sociodemographic variables, parental experience in the PED, procedure performed, and frequency of hospitalization (Tables 1 and 2). The accompanying parent was usually the mother (87%), most were between the ages of 20 and 24, described themselves as American-born blacks, single, and had completed high school (Table 1). Most of the children had previously been to a PED (69%) and the majority (82%) of parents had previously been with a sibling in a PED.

The majority of children were male (57%), younger than 1 year old age (53%), and 33% were admitted to the hospital (Table 2). The most common procedure performed was venipuncture (62%), followed by intravenous cannulation (28%) and urethral catheterization (10%, Table 2). The majority of procedures were performed by residents (Table 2).

Parents who did not consent to participate were similar to parents who did consent with respect to

TABLE 1. Demographic and Other Characteristics of Accompanying Adult

	Intervention (N = 153) (%)	Present (N = 147) (%)	Not Present (N = 131) (%)
Adult			
Mother	128 (84)	129 (88)	113 (87)
Father	16 (11)	11 (8)	12 (9)
Other	8 (5)	6 (4)	5 (4)
Age (y)			
≤19	20 (13)	31 (22)	21 (16)
20–24	50 (33)	47 (33)	37 (29)
25–29	45 (30)	33 (23)	31 (24)
≥30	36 (24)	33 (23)	40 (31)
Ethnicity			
Foreign-born black	21 (14)	19 (14)	18 (14)
American-born black	66 (45)	66 (48)	59 (45)
Hispanic	37 (25)	29 (21)	26 (20)
White	12 (8)	12 (9)	11 (9)
Other	11 (7)	12 (9)	16 (12)
Marital status			
Married	33 (22)	25 (25)	31 (24)
Single	106 (70)	90 (64)	89 (68)
Other	12 (8)	16 (11)	11 (8)
Educational status			
Less than high school	65 (43)	52 (37)	37 (28)
Completed high school	58 (38)	54 (38)	61 (47)
More than high school	28 (19)	35 (25)	33 (25)
Index child previously to PED			
Yes	104 (68)	98 (69)	94 (72)
No	47 (31)	44 (31)	36 (28)
Other children previously to PED			
Yes	82 (85)	65 (81)	57 (74)
No	15 (15)	15 (19)	20 (26)

TABLE 2. Demographic and Other Characteristics of Child

	Intervention (N = 157) (%)	Present (N = 147) (%)	Not Present (N = 131) (%)
Gender			
Male	73 (48)	59 (40)	50 (38)
Female	80 (52)	88 (60)	80 (62)
Age			
0-6 mo	37 (24)	38 (26)	43 (33)
7-12 mo	38 (25)	40 (27)	29 (22)
13-24 mo	54 (36)	47 (32)	40 (31)
>24 mo	23 (15)	22 (15)	17 (13)
Insurance			
Medicaid	76 (52)	65 (47)	69 (56)
Self-pay	33 (22)	27 (19)	20 (16)
Commercial	38 (26)	47 (34)	35 (28)
Procedure			
Intravenous cannulation	44 (29)	34 (23)	42 (32)
Venipuncture	87 (57)	101 (69)	79 (61)
Urethral catheterization	21 (14)	11 (8)	9 (7)
Individual performed procedure			
Attending, nurse, fellow	19 (13)	17 (13)	16 (13)
Resident	129 (87)	126 (88)	111 (87)
PL1	43 (33)	33 (26)	35 (32)
PL2	42 (33)	49 (39)	38 (34)
PL3	37 (29)	34 (27)	33 (30)
PL4	7 (5)	10 (13)	5 (5)
Admitted to hospital			
Yes	45 (29)	46 (31)	50 (39)
No	108 (71)	101 (69)	79 (61)

relationship to child (mother, 86%), ethnicity American-born blacks, 59%), and educational level (completed at least high school, 47%). Nonparticipants were more likely to be assigned to the not present group (65%) than participants (30%, $P < .001$).

Pain Assessment

No differences between groups emerged with respect to the following cry variables: mean level of energy, mean fundamental frequency, mean variability of the fundamental frequency, mean first formant frequency, mean variability of the first formant frequency, mean percent hyperphonation or dysphonation, and the number of cry utterances. In particular, mean fundamental frequency was 454 Hz (SD \pm 333) in the intervention group, 447 Hz (SD \pm 199) in the present group and 448 (SD \pm 276) in the not present group. Age was found to affect the following cry variables: mean level of energy, mean variability of the fundamental frequency, and first formant.

There were no differences between the groups in the pain ratings of the clinicians or parents (Table 3). In the intervention, present, and not present groups, clinicians rated the children's pain as extreme/great in 14%, 18%, and 13% of the encounters, respectively ($P = .56$). In the intervention and present groups, parents rated

their children's pain as extreme/great in 55% and 50% of the encounters, respectively ($P = .60$).

Because our previous work and clinical experience suggest that some parents are better at following instructions, reanalysis of the clinician and parent ratings was performed based on the ability of parents to successfully implement the intervention (Table 4). Clinicians rated the pain of children whose parents successfully implemented all three aspects of the intervention (spoke to, touched, and maintained eye contact with their children, $n = 106$) as significantly less (extreme/great, 10%) than parents in the intervention group who were not as successful combined with those in the present group (extreme/great, 19%, $P = .036$). Similar analysis of parent ratings was not significant (Table 4, $P = .249$). Only two parents in the present not taught group were categorized as most effective.

The comparison of physician and parent pain ratings showed poor agreement (Table 5). Parents in the intervention and present groups rated their children's pain as extreme/great for 52% of the procedures although clinicians rated 15% of same procedures as extreme/great ($\kappa = 0.07$).

TABLE 3. Pain Ratings of Clinicians and Parents

	Intervention		Present		Not Present	
	Clinicians (%)	Parents (%)	Clinicians (%)	Parents (%)	Clinicians (%)	Parents (%)
Extreme/great	21 (14)*	77 (55)†	25 (18)	68 (50)	17 (13)	N/A
Moderate	75 (49)	32 (23)	71 (50)	32 (24)	57 (45)	N/A
Some/little	56 (37)	31 (22)	47 (33)	36 (26)	53 (42)	N/A

* $P = .56$ for clinician ratings of all three groups.

† $P = .60$ for parent ratings in intervention and present groups.

TABLE 4. Pain Ratings of Clinicians and Parents by Effectiveness at Intervention

	Intervention-Effective		Intervention (Other)/Present	
	Clinicians (%)	Parents (%)	Clinicians (%)	Parents (%)
Extreme/great	11 (10)*	33 (50)†	35 (19)	112 (53)
Moderate	49 (46)	19 (29)	97 (51)	45 (21)
Some/little	46 (43)	14 (21)	57 (30)	53 (25)

* $P = .036$ for clinician ratings in both groups.

† $P = .249$ for parent ratings in both groups.

TABLE 5. Pain Ratings of Parents and Clinicians*

Parents	Clinicians		
	Extreme/Great	Moderate	Some/Little
Extreme/great	27	79	36
Moderate	7	30	26
Some/little	8	25	33

* $\kappa = .07$.

Anxiety of Parents and Physicians

Parents who were not present reported being more anxious (STAI, 45.2) than parents who were present (intervention, 40.7; present, 41.4, $P = .025$). There was no difference between groups in anxiety scores of the clinicians (intervention, 34.0; present, 33.6; not present, 32.5, $P = .430$).

Performance of Procedure

There were no differences between the three groups in the performance of the procedure (Table 6). Only one needle was used for 78% of the procedures and 90% of the procedures were completed by the first clinician attempting it. The time needed to complete the procedure was similar for the three groups.

Satisfaction With Care

Overall, 71% of parents indicated that they were very or extremely satisfied with the care that they received. Specific group responses (very or extremely satisfied) were: intervention, 94%; present, 86%; and not present, 85% ($P = .135$).

DISCUSSION

We were not able to demonstrate a reduction in pain in the intervention group. However, parental presence did not negatively affect performance of the procedure nor increase clinician anxiety. Parents who were present were less anxious than those who

were absent. Overall, satisfaction with care was high, and there was a trend suggesting that parents who were in the intervention group were more satisfied than parents in the other two groups.

The majority of major pediatric and emergency medicine textbooks contain little information about parental presence during procedures.¹⁷⁻²² In contrast, general information about parental presence during procedures, anxiety of children and parents, types of coping mechanisms, and techniques to reduce pain appear in the pediatric psychology and dental literature.²³⁻³¹ Unfortunately, few controlled trials have demonstrated that parental presence is effective in reducing children's pain in any setting.^{23,25,26} Because of the complexity of measuring pain, the episodic nature of medical encounters during which procedures are performed, and practical restrictions on how much can be done to teach parents how to help their children in the acute care setting, it may be difficult to demonstrate that parental presence reduces the pain of procedures. The difference in pain ratings of parents and clinicians is disturbing. Parents were more than three times as likely to report that their children were in severe/extreme pain in comparison to clinicians. Because assessment of pain is quite subjective, it is difficult to know how to interpret this difference. Regardless, reconciling the difference between parent and clinician ratings of pain is important. If parents are asked to assist us in assessing children's pain, and they consistently report that their children are in more pain than we believe, it is unclear who is correct. Because pain reduction is a basic tenet of medicine, the difference in pain assessment creates a complicated dilemma. The use of physiologic measures may be critical in order to assess the effectiveness of pain reduction interventions.

Parents who were present reported that they were equally as satisfied with care as parents who were not present. The lack of difference between groups may have occurred for a number of reasons. First, overall satisfaction was quite high. Parents in the not present group indicated that they were very or extremely satisfied after 85% of the encounters. It is difficult to improve on such high levels of satisfaction, although there was a trend suggesting that parents in the intervention group may have been more satisfied (94%). Second, the question reflected all aspects of care in the PED, and not just their presence or absence during procedures. In response to additional questions about satisfaction, 94% of parents in the two present groups indicated that they thought their presence helped the child, 87% indicated it helped them to be present, and 93% said they would

TABLE 6. Performance of the Procedure

	Intervention (%)	Present (%)	Not Present (%)
No. of needles used*			
1	121 (79)	108 (75)	103 (80)
2 or more	32 (21)	36 (25)	26 (20)
Completed by first clinician†			
Yes	135 (88)	129 (88)	119 (92)
No	18 (12)	17 (12)	10 (8)
Mean time in sec‡	241 (SD611)	190 (SD265)	167 (SD274)

* $P = .573$.

† $P = .473$.

‡ $P = .330$.

want to be present in the future. Third, because of the inability to contact parents 2 to 3 days after the encounter in the pediatric emergency department, the assessment of satisfaction changed after the first 100 enrollees. However, there was no difference in satisfaction ratings between the two time periods.

Many physicians report that they are not as proficient at procedures when parents are present.⁴ We used three different measures of proficiency and could find no difference between the groups. It is possible that the residents, nurses, and attending staff in the PED at Boston City Hospital are comfortable with parental presence and hence it does not effect their performance. The similarity in anxiety rating scores of the physicians and nurses among the three groups support this position. With respect to the time of the procedure, although there was no statistical difference between groups, the procedure did take longer in the intervention group. In addition, we did not count the amount of time it took the research assistant to explain the intervention to the parents (approximately 10 minutes).

This study has a number of limitations. First, the type of randomization used, prerandomization, is unusual, and may have created bias. Although the families who refused to participate were similar to those who consented, more of the refusers were assigned to the not present group. This finding reinforces our previous report indicating that parents want to be present during procedures.¹ It is possible that the group of parents who refused to participate would have been more effective at implementing the intervention. Second, the measurements of pain, a global rating score, and cry analysis, are limited. However, we tried to address all of the issues that impact on parental presence, including anxiety and performance, rather than measuring one outcome in great detail. Because this study was conducted in a busy urban PED it would not have been possible to add any additional or more elaborate measures of pain. In addition, it is unclear if detailed observation scales are more valid measures of pain.^{15,16} Our goal was to ensure that this study reflected the issues that impact on parental presence and that the results be generalizable. Third, the age range of the children was quite wide. In general, cry analysis has been used with only young infants. We did control for age in the analysis of cry. Fourth, the difference in clinician pain ratings seen when the intervention group was recategorized (Table 4) may be subject to bias. Clinicians may have rated the pain of children whose parents were effective as less because the parent performed the intervention well, rather than because the child exhibited fewer signs of pain. Regardless, it was encouraging that this difference emerged. Finally, no interobserver reliability was assessed during the study. This was not possible with the clinicians, because so many were involved. In part, the global measurement of pain was used to simplify how clinicians would interpret the scale. With respect to measurement of parent effectiveness, only one research assistant enrolled patients during the entire study, and precise definitions were used. The pain assessment was performed by the clinicians and

parents, both of whom were unaware of the research assistant's ratings of parent effectiveness.

It is possible that if the intervention was more intensive we would have found greater differences among the groups. However, our goal was to use an intervention that was simple, based on our clinical experience and the research literature, and reproducible. Emergency rooms, inpatient units, and physician offices are busy places. Few providers have sufficient time to teach parents elaborate techniques to help their children. Asking parents to sit at the head of the bed, and talk to, touch, and maintain eye contact with their children takes only a few minutes.

Clinical Implications

Previously we have shown that the majority of parents want to be present when their children undergo common invasive procedures. Traditionally, many of us have objected because of concerns about our technical proficiency and anxiety level. The results of this study challenge these beliefs—parental presence did not negatively effect performance, and clinicians were not more anxious when parents were present. Furthermore, parents who were present were less anxious than those who were absent. Therefore, despite the fact that we were not able to demonstrate a reduction in pain measures, we believe parents who wish to be with their children should be encouraged to be present when their children undergo common invasive procedures. It also seems reasonable to provide instruction to parents regarding strategies they may use to help their children, although the efficacy of specific strategies remain to be defined.

APPENDIX

I am going to read you some instructions to help your child relax when he/she has blood drawn, an IV started, or urine obtained. If you do not understand them, just stop me and I will explain them again.

I know you are going to be with (child's name) when he/she has blood drawn (or IV started or urine obtained). We know that you can help (child's name) during this procedure and help (him or her) and the doctor.

We want you to go to the head of the bed, sit down, and just talk to (child's name). If there is anything you usually say to (child's name) to comfort (him or her) you should do that after you sit down. If not, it is important for you just to talk to (him or her). Perhaps you can sing to (him or her), or count with (him or her) from 1 to 10. It is also helpful if you can touch his face while your talking to (him or her) and hold (his or her) hand if possible. (Child's name) will want to hear your voice, see you, and feel that you are with (him or her).

Your child may cry, but that is okay. Sometimes children cry to release some of their tension. It is not your fault if your child cries and you should keep talking and touching (him or her).

It is important not to tell your child that this will not hurt—it may hurt and its always important to be honest with children.

ACKNOWLEDGMENTS

The study was supported by grants from the Maternal and Child Health Bureau, MCJ25062, entitled "Parent Focused Intervention To Reduce Pain" and an Institutional Grant for Excellence in Pain Research from Bristol-Myers Squibb.

This study was conducted in a busy pediatric emergency room. It would not have been possible without the remarkable patience and contribution of the nurses, physicians, and families; we thank them. H.B. particularly thanks Barry Zuckerman and Chris McElroy. They both said this was an important area of research and offered the intellectual and emotional support to accomplish the project.

REFERENCES

- Bauchner H, Vinci R, Waring C. Pediatric procedures: do parents want to watch? *Pediatrics*. 1989;84:907-909
- Merritt K, Sargent J, Osborn L. Parental presence during medical procedures. *Am J Dis Child*. 1989;144:270-271
- Bauchner H, Waring C, Vinci R. Parental presence during procedures in an emergency room: results from 50 observations. *Pediatrics*. 1991;87:544-548
- Bauchner H. Commentary: procedures, pain and parents. *Pediatrics*. 1991;8:563-565
- McGrath PA. *Pain in Children—Nature, Assessment, Treatment*. New York: Guildford Press; 1990
- Zelen M. Statistical options in clinical trials. *Semin Oncol*. 1977;4:441-448
- Zelen M. Strategy and alternate randomized designs in cancer clinical trials. *Cancer Treat Rev*. 1982;66:1095-1099
- Brackbill Y. Cumulative effects of continuous stimulation on arousal levels in infants. *Child Dev*. 1971;42:17-26
- Erickson CJ. Pain measurement in children: problems and directions. *Dev Behav Pediat*. 1990;11:135-138
- Johnson CC. Pain assessment and management in infants. *Pediatrician*. 1989;16:16-23
- Bauchner H, Corwin MJ, Sznajderman SD, Baldwin SE, Golub H, McCarthy PL. Computerized cry analysis: differences between the cries of seriously ill infants and well or mildly ill infants. *Am J Dis Child*. 1987;141:371
- Lester BM, Boukydis CFZ. *Infant Crying—Theoretical and Research Perspectives*. New York: Plenum Press; 1985
- Grunau RV, Craig KD. Pain expression in neonates: facial action and cry. *Pain*. 1987;28:395-410
- McGrath PA, Hillier LM. The enigma of pain in children. *Pediatrician*. 1989;16:6-15
- Owens ME. Pain in infancy: conceptual and methodologic issues. *Pain*. 1984;20:213-30
- Spielberger CD. *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologists Press, Inc.; 1983
- Oski F, Deangelis C, Feigin R, et al. *Principles and Practice of Pediatrics*, 2nd ed. Philadelphia: J. B. Lippincott Company; 1994
- Fleisher G, Ludwig S. *Textbook of Pediatric Emergency Medicine*. 2nd ed. Baltimore: Williams & Wilkins; 1988
- Reece RM. *Manual of Emergency Pediatrics*. 4th ed. Philadelphia: WB Saunders; 1992
- Behrman RE, Vaughan VC. *Nelson Textbook of Pediatrics*. 13th ed. Philadelphia: WB Saunders; 1987
- Rudolph AM. *Pediatrics*. 18th ed. Norwalk, CT: Appleton and Lance; 1987
- Hoekelman RA, Blatman S, Friedman SB, et al. *Primary Pediatric Care*. St. Louis, MO: CV Mosby Company; 1987
- Winer GA. A review and analysis of children's fearful behavior in dental settings. *Child Dev*. 1982;53:1111-1133
- Jacobsen PB, Manne SL, Gorfinkle K, et al. Analysis of child and parent behavior during painful medical procedures. *Health Psychol*. 1990;9:559-576
- Shaw EG, Routh DK. Effect of mother presence on children's reaction to aversive procedures. *J Pediatr Psychol*. 1982;7:33-42
- Gonzalez JC, Routh DK, Saab PG, et al. Effects of parent presence on children's reaction to injections: behavioral, physiological, and subjective aspects. *J Pediatr Psychol*. 1989;14:449-462
- Broome ME, Endsley R. Parent and child behavior during immunization. *Pain*. 1989;37:85-92
- Johnson R, Baldwin DC. Relationship of maternal anxiety to the behavior of young children undergoing dental extraction. *J Dental Res*. 1968;5:801-805
- Rayman MS. Parent observation. *California Dent Assoc*. 1987;20-24
- Wright GZ, Alpern GD, Leake JL. The modifiability of maternal anxiety as it relates to children's cooperative dental behavior. *J Dentist Child*. 1973;265-271
- Gonzalez JC, Routh DL. Effects of maternal distraction versus reassurance on children's reactions to injections. *J Pediatr Psychol*. 1993;18:593-604

Parents and Procedures: A Randomized Controlled Trial

Howard Bauchner, Robert Vinci, Sharon Bak, Colleen Pearson and Michael J. Corwin
Pediatrics 1996;98;861

Updated Information & Services

including high resolution figures, can be found at:
<http://pediatrics.aappublications.org/content/98/5/861>

Permissions & Licensing

Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
<http://www.aappublications.org/site/misc/Permissions.xhtml>

Reprints

Information about ordering reprints can be found online:
<http://www.aappublications.org/site/misc/reprints.xhtml>

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Parents and Procedures: A Randomized Controlled Trial

Howard Bauchner, Robert Vinci, Sharon Bak, Colleen Pearson and Michael J. Corwin

Pediatrics 1996;98;861

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://pediatrics.aappublications.org/content/98/5/861>

Pediatrics is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. Pediatrics is owned, published, and trademarked by the American Academy of Pediatrics, 345 Park Avenue, Itasca, Illinois, 60143. Copyright © 1996 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 1073-0397.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

