

Hypnosis Reduces Distress and Duration of an Invasive Medical Procedure for Children

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ABSTRACT. *Objective.* Voiding cystourethrography (VCUG) is a commonly performed radiologic procedure in children that can be both painful and frightening. Given the distress that some children experience during the VCUG and the need for children to be alert and cooperative during the procedure, finding a psychological intervention that helps children to manage anxiety, distress, and pain is clearly desirable. This study was designed to examine whether relaxation and analgesia facilitated with hypnosis could reduce distress and procedure time for children who undergo this procedure.

Methods. Forty-four children who were scheduled for an upcoming VCUG were randomized to receive hypnosis ($n = 21$) or routine care ($n = 23$) while undergoing the procedure. The sample consisted of 29 (66%) girls and 15 (34%) boys with a mean age of 7.6 years (SD: 2.5; range: 4–15 years). Ethnic/racial backgrounds were 72.7% white, 18.2% Asian, 4.5% Latino, 2.3% black, and 2.3% Filipino. The mean number of previous VCUGs was 2.95 (SD: 2.51; mode: 2; range: 1–15). Potential participants were identified through computerized hospital records of upcoming VCUGs. Parents were contacted by telephone and invited to participate if their child was eligible. To be eligible for the study, the child must have undergone at least 1 previous VCUG, been at least 4 years of age at that time, and experienced distress during that procedure, and both the child and the participating parent had to be English speaking. Each eligible child and parent met with the research assistant (RA) before the day of the scheduled procedure for an initial assessment. Children were queried regarding the degree of crying, fear, and pain that they had experienced during their most recent VCUG. Parents completed a series of parallel questions. Immediately after this assessment, those who were randomized to the hypnosis condition were given a 1-hour training session in self-hypnotic visual imagery by a trained therapist. Parents and children were instructed to practice using the imaginative self-hypnosis procedure several times a day in preparation for the upcoming procedure. The therapist was also present during the procedure to conduct similar exercises with the child. The majority (83%) of those who were randomized to the routine care control group chose to participate in a hospital-provided recreation therapy program (offered as

part of routine care). The program includes demonstration of the procedure with dolls, relaxation and breath work training, and assistance during the procedure. On the day of the VCUG, the RA met the family at the clinic before the procedure, and both the child and the parent rated the child's present level of fearfulness. During the procedure, the RA recorded observational ratings of the child's emotional tone and behavior and timed the overall procedure and its phases. Immediately after the VCUG, the child was asked how much crying, fear, and pain he or she had experienced during the procedure; the parent rated the child's experience on the same dimensions and also how traumatic the procedure had been (both generally and compared with their previous one), and the medical staff rated the degree of procedural difficulty. Outcomes included child reports of distress during the procedure, parent reports of how traumatic the present VCUG was compared with the previous one, observer ratings of distress during the procedure, medical staff reports of the difficulty of the procedure overall, and total procedural time.

Results. Results indicate significant benefits for the hypnosis group compared with the routine care group in the following 4 areas: (1) parents of children in the hypnosis group compared with those in the routine care group reported that the procedure was significantly less traumatic for their children compared with their previous VCUG procedure; (2) observational ratings of typical distress levels during the procedure were significantly lower for children in the hypnosis condition compared with those in the routine care condition; (3) medical staff reported a significant difference between groups in the overall difficulty of conducting the procedure, with less difficulty reported for the hypnosis group; and (4) total procedural time was significantly shorter—by almost 14 minutes—for the hypnosis group compared with the routine care group. Moderate to large effect sizes were obtained on each of these 4 outcomes.

Conclusions. Hypnotic relaxation may provide a systematic method for improving the overall medical care of children with urinary tract abnormalities and may be beneficial for children who undergo other invasive medical procedures. Because the VCUG is an essential part of the evaluation of urinary tract infections and vesicoureteral reflux in children, lower distress during the procedure may improve patient and family compliance with initial as well as follow-up evaluations. These findings augment the accumulating literature demonstrating the benefits of using hypnosis to reduce distress in the pediatric setting. The present findings are noteworthy in that this study was a controlled, randomized trial conducted in a naturalistic medical setting. In this context, we achieved a convergence of subjective and objective outcomes with moderate to large effect sizes, including those that may have an impact on patient care and pro-

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cedure cost, that were consistently supportive of the beneficial effects of hypnosis—a noninvasive intervention with minimal risk. The findings, therefore, have immediate implications for pediatric care. Limitations of this study include the lack of participant and staff blindness to the child’s condition assignment, which could have introduced bias into reports. However, the objective procedural time differences between groups were consistent with the other, more subjective outcome findings. The sample was also small and primarily white in ethnic/racial makeup, which may have restricted our ability to detect some differences and may limit the generalizability of findings to more representative samples. In addition, the sample comprised children who had already undergone at least 1 VCUG during which they had had difficulty. Consequently, additional research is needed to determine whether hypnosis would be helpful to those who are undergoing their first VCUG. Additional limitations, clinical observations, and directions for future research are also discussed. *Pediatrics* 2005; 115:e77–e85. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2004-0818; VCUG, pediatric, distress, pain, trauma, medical procedure, hypnosis, voiding cystourethrogram.

ABBREVIATIONS. VCUG, voiding cystourethrogram; RA, research assistant.

Some medical procedures are painful and frightening, particularly so for children. Children are less likely than adults to understand the rationale for a given procedure, how long it may take, or how much discomfort may be involved. Research indicates that children remember their experiences of medical procedures quite accurately.^{1–3} However, distress at the time of the procedure can exaggerate negative memories of the procedure, which in turn can increase distress at subsequent procedures.¹ Our goal in this randomized trial was to evaluate whether hypnotic relaxation, when compared with routine care, could decrease children’s distress and the effects of distress on the ease and duration of performing an invasive medical procedure, a voiding cystourethrogram (VCUG). (Technically, the term “voiding cystourethrogram” refers only to the x-rays taken during the procedure, whereas “voiding cystourethrography” describes the whole procedure; however, “voiding cystourethrogram” is the term most commonly found in the literature, so we continue with this latter usage.)

The VCUG is the most important radiologic examination in assessing vesicoureteral reflux in children and bladder anatomy. Ordinarily, urine flows from the kidney to the bladder and does not flow retrograde because contraction of the bladder compresses the ureterovesical junction, blocking reflux of urine during voiding. In the common congenital and developmental problem of vesicoureteral reflux that affects 1% to 2% of all children and 21% to 57% of children who get urinary tract infections,⁴ urine flows retrograde from the bladder to the kidney as a result of anatomic differences that make the virtual “valve” incompetent. If children with vesicoureteral reflux get a urinary tract infection, then they have a high likelihood of its spreading to the kidney, causing pyelonephritis (urinary infection involving the

kidney), and, depending on the severity of the reflux and infection, an average of 25% may develop kidney scarring or damage.⁴

When reflux is discovered, the common follow-up evaluation consists of repeating the VCUG at periodic intervals (usually annually) until either the reflux resolves spontaneously with the child’s growth or surgical correction is required. When spontaneous resolution of reflux occurs, the average time required is ~3 years. This means that most children who have vesicoureteral reflux have an average of 4 VCUGs from the time of diagnosis to resolution.⁴

The VCUG consists of urethral catheterization and instillation of radiologic contrast material (or nuclear agent) into the bladder under fluoroscopic or nuclear imaging until the bladder is filled. The child then urinates as fluoroscopic imaging continues, to determine whether there is reflux of urine from the bladder to the kidney. For optimal evaluation, the child must be awake and cooperative, as vesicoureteral reflux may occur only during active voiding or be exacerbated by it. The entire experience and the urethral catheterization in particular can be painful, frightening, embarrassing, and even traumatic.^{5,6} In addition, because of the proximity of the urethra to other genital structures and perhaps because of concerns of future sexuality-associated memory, parents find this procedure particularly anxiety provoking. As a result, the procedure is often a difficult and stressful experience for parents and medical personnel as well. Furthermore, children can be sensitized by their previous experiences and, as they get older, become more combative and able physically to resist catheterization.

Stachinko and Goldberger⁶ observed that the VCUG examination is done primarily on an outpatient basis with little or no preparation of the child or the parent, even though memories of procedure successes or failures in mastering this experience will contribute to the child’s evolving self-concept and will be carried into future situations, including future procedures. As a result of the apprehension, distress, and pain associated with the VCUG procedure, children can form negative associations with the physicians, hospital, and medical visits and experience escalating difficulty in undergoing the procedure. In addition, some parents may avoid scheduling or may cancel initial or follow-up VCUGs because of stories that they hear from other parents or because of their concerns about further traumatizing their children (as several parents have reported to us). Difficult VCUG examinations, therefore, can lead to poor patient and parent compliance with evaluation and follow-up of urinary tract infections. In addition, negative responses to the experience can increase the time required to explain to parents the need for the procedure and the time spent performing the procedure, both because the child is uncooperative and because the catheterization may require locating additional personnel to physically restrain the child during the procedure. Given the distress that some children experience during the VCUG and the need for children to be alert and cooperative during the procedure, finding a psychological inter-

vention that helps children to manage anxiety, distress, and pain is clearly desirable.

There is a growing body of evidence indicating that hypnosis can be a useful adjunct to medical procedures (eg, ⁷⁻¹²). Hypnosis is a state of highly focused attention, with a reduction in peripheral awareness and a heightened responsiveness to social cues.¹³ It is not in itself a treatment but rather facilitates a primary treatment strategy, such as relaxation or analgesia.¹⁴ The techniques most often used involve instructions that connote physical relaxation, such as imagined floating, coupled with imagery that provides a substitute focus of attention for the painful sensation. Hypnosis can be induced in a matter of seconds, and patients can be taught self-hypnosis to provide ongoing analgesia and to maintain physical relaxation even in the face of emotional distress.¹³ Lang et al^{10,11} reported that adults who underwent invasive radiologic procedures and were randomized to learn hypnosis used less medication, reported less pain and anxiety, experienced fewer procedural complications, and were able to complete their procedures in an average of 17 minutes less time. The implementation of these procedures also saved money, an average of \$338 per procedure, despite the addition of a professional conducting the hypnosis, as a result of reduced medication use, fewer complications, and shorter procedure time.¹⁵

Hypnotic techniques are likely to be even more effective among children who undergo painful procedures, because children are more hypnotizable than adults and thus are easily absorbed in images.^{16,17} In using hypnosis with children, some find it helpful to play in an imaginary baseball game or to picture themselves going to another room in the house or watching a favorite TV show. This enables children to restructure their experience of what is occurring and dissociate themselves psychologically from pain and fear of the procedure. This approach uses the intense focus in hypnosis to help children to dissociate their attention and imagination from their immediate physical surroundings and experiences. It is also helpful to have parents assist and rehearse the procedure so that the children do not encounter anything unfamiliar (eg, ^{18,19}).

There is considerable evidence that hypnosis can provide anxiety and pain relief to children with medical conditions,¹⁸⁻²¹ including cancer,²²⁻²⁵ cystic fibrosis,²⁶ pain problems,^{27,28} pulmonary symptoms,²⁹ and postoperative course.³⁰ In addition, hypnosis is a noninvasive intervention with minimal risk, which returns control of the experience to the child.³¹

Thus, training in hypnotic analgesia and anxiety control would seem to provide a fertile opportunity for improving the experience of children who undergo a VCUG examination. Indeed, our preliminary experience with several cases indicated that children who were previously terrified by the procedure and who, in one case, spent 30 minutes on the floor of the procedure room refusing treatment, were able to undergo the VCUG with the help of hypnosis and showed markedly reduced observable levels of distress.

Our goal in this randomized trial was to evaluate

whether hypnotic relaxation, when compared with routine care, could decrease children's distress during a VCUG and the subsequent effects of distress on the difficulty and duration of conducting the procedure. Consequently, we hypothesized that, compared with children who receive routine care, (1) children who use hypnosis would report less distress during the procedure, (2) their parents would report that the procedure was less traumatic for their child than their previous VCUG experience, (3) observational ratings of distress during the procedure would be lower overall, (4) medical staff would rate the procedure as less difficult to conduct, and (5) the procedure would take less time.

METHODS

Participants

Forty-six children and their parents were recruited for this study. Two participant VCUG appointments were canceled after randomization; consequently, their assessments were not conducted. The sample size of 46 was chosen after balancing the need for adequate statistical power for testing our hypotheses with limiting study cost. The final sample consisted of 29 (66%) girls and 15 (34%) boys with a mean age of 7.6 years (SD: 2.5; range: 4-15 years). Ethnic/racial backgrounds were 72.7% ($n = 32$) white, 18.2% ($n = 8$) Asian, 4.5% ($n = 2$) Latino, 2.3% ($n = 1$) black, and 2.3% ($n = 1$) Filipino. Participants were randomized into 2 study conditions, with 47.7% ($n = 21$) assigned to the hypnosis group and 52.3% ($n = 23$) assigned to the routine care group. Nineteen (83%) of those in the routine care group chose to participate in the hospital-provided recreation therapy program, which is a service offered as part of routine care. The mean age of the children at the time of their last VCUG was 6.54 years (SD: 2.27; range: 4-14). The mean number of previous VCUGs was 2.95 (SD: 2.51; mode: 2; range: 1-15).

Procedure

Recruitment

Potential child participants were identified through computerized hospital records of scheduled upcoming VCUG procedures at Lucile Packard Children's Hospital and the Nuclear Medicine Clinic at Stanford Hospital. When potential participants were identified, their parents were telephoned and invited to participate in the study when they qualified. Parents were asked a series of screening questions to determine the child's study eligibility. To be included in the study, the child and participating parent had to be English speaking, the child had to have undergone at least 1 previous VCUG, the child had to have been at least 4 years of age at the time of the most recent VCUG, and the parent had to report that the child had experienced some difficulty (eg, at least some crying, pain, or fear) during that procedure. Reasons for participation refusal were not recorded over the entire study; however, analysis of refusal data over the first 6 months of recruitment indicated that of those who met the inclusion criteria, ~46% chose to participate. Among the reasons for nonparticipation, parents indicated that they did not want any intervention (25%), more people in the procedure room (12.5%), to take the child out of school for the initial assessment/training (8%), or to tell the child about the procedure ahead of time (8%). Study recruitment was conducted from January 1999 to August 2002.

Once a child was deemed eligible for the study and his or her parent agreed to participate, the child was randomized by the research assistant (RA) to the hypnosis treatment or routine care control condition by consulting a printout of a computer-generated randomization sequence (using SAS for Windows, version 8.2; SAS Institute, Inc, Cary, NC). The randomization order was not concealed from the RA. When the child was randomized to the hypnosis condition, a 2-hour appointment was scheduled within 1 week of the procedure so that the initial assessment and hypnosis training could be conducted. When the child was randomized to the routine care control condition, the parent and child were scheduled for a 1-hour initial assessment and informed of the availability of Lucile Packard Children's Hospital's Recreation

Therapy Program. Parents made their own contact with and arrangements for this program, as is the case in routine care.

Initial Assessment

On arrival for the initial assessment, the parent was given a consent form to read and sign, and the child was read an equivalent age-appropriate consent form by the RA, in the presence of the parent, and asked to sign it. All procedures and materials in this study were approved by Stanford's Institutional Review Board's Panel on Human Subjects.

After completion of the informed consent, the child was asked a short series of open-ended and specific questions regarding elements of their previous VCUG experience. Past research has demonstrated that both question types are necessary because children usually provide more information in response to specific questions but tend to be more accurate in response to open-ended questions (results of these responses will be reported elsewhere; see also ^{3,32,33}). In addition, each child was asked to indicate how much he or she cried, how fearful he or she was, and how much pain he or she experienced during the previous procedure. To answer these questions, the child was trained with a series of practice questions (materials are described in the following) to be able to provide the distress reports. Their answers to these and other questions provided practice in using these assessments.

The parent also completed a series of parallel questions. When both parents came to the assessment, the parent who was to attend the procedure was designated to complete the assessment, or if both parents planned to be at the VCUG (or they did not know who would be there), they both completed the assessment and the one used for analysis was determined by who was present at the procedure or by coin toss.

Hypnosis Training

After the initial assessment, children in the hypnosis condition were given a 1-hour assessment and hypnotic training session at the Department of Psychiatry at Stanford University School of Medicine. The training session involved measurement of the child's level of hypnotizability with the Hypnotic Induction Profile,¹³ which provides a nonthreatening means of introducing hypnosis through the standard structured experience of developing lightness in 1 arm in a manner that allows for reliable evaluation of the degree of responsiveness. This was followed by training and practice in self-hypnosis as the parent watched. The child was taught to count to 3: "On 1, look up; on 2, close your eyes and take a deep breath; on 3, let the breath out, let your eyes relax but keep them closed, and let your body float." A comfortable physical sense of floating was reinforced by having the child imagine being in a bath, a lake, or a hot tub. The child then was instructed to become absorbed in a competing imaginary experience by visualizing visiting a favorite amusement park, a friend's house, or a playground. A list of the child's favorite places and activities was developed for use during the VCUG procedure. Thus, the suggested intervention was individualized on the basis of the child's preferences. All hypnotic treatment was administered or supervised by D.S. Parents and children were instructed to practice using the imaginative self-hypnosis procedure several times a day—every day, if possible—in preparation for the upcoming procedure. Assistance from the parent during both practice and the procedure was especially important with younger children. The therapist was also present at the VCUG and conducted similar hypnotic exercises with the child during the procedure. This approach is brief and relatively time-efficient.

Routine Care With Recreational Therapy

Children who were randomized to receive routine care and who chose to participate in recreation therapy arranged an appointment to meet with a recreation therapist at Lucile Packard Children's Hospital. Recreation therapy in this context involves familiarizing the child with the VCUG procedure by describing it; using an anatomic doll to demonstrate the catheterization procedure; answering questions; and practicing relaxation and breath work using a pinwheel, feather, or bubble-blowing apparatus that the child could also use during the procedure. The recreation therapist was also present during the VCUG to assist the child. Although most children are highly hypnotizable,^{16,19,22} meaning that some might spontaneously enter hypnotic-like states during

such instructions, the recreation therapy program was less intensive and focused on understanding and familiarity with the VCUG procedure itself rather than an imagined focus away from it. However, to the extent that hypnotic-like responses occurred, this would reduce the likelihood of observing a difference between the 2 conditions.

VCUG Assessments

On the day of the procedure, the RA met with the family, typically in the clinic waiting room or the waiting room outside the changing area, 10 to 15 minutes before the appointment and assessed the child's present level of fearfulness. Immediately after the procedure, the child reported how scared/afraid he or she was during the procedure, how much he or she cried, and how much it had hurt. The children were also asked what had frightened them the most, what made them cry the most, and what hurt them the most. The parent also rated his or her child's fearfulness before the procedure and, immediately after the procedure, rated the child's fearfulness, amount of crying, and level of pain during the procedure and how traumatic the procedure was generally and compared with the previous experience. In addition, the RA made observational ratings of the child's emotional tone and behavior during the procedure, timed the overall procedure and its phases, and distributed and collected the rating forms from the radiology technician and radiologist. Because it was necessary that the RA be present for the procedure, she was not blind to the child's randomization status; neither was the child, the parent, or the medical staff.

Measures

Demographic and Medical Variables

During the initial assessment, parents of participants provided information about the child's age and gender and described the nature and number of and reactions to previous VCUG examinations. The child's ethnicity was determined from hospital records.

Distress: Child Self-Report

The fear, pain, and crying assessments were conducted using materials adapted from the "How Much Did It Hurt" and the "How Much Did You Cry" scales developed by Bruck et al³⁴ that use poker chips and visual analogs (pictures of faces) to quantify the children's responses. For the fear and pain assessments, children indicated with the number and color of poker chips to report their distress levels on 5-point scales ranging from "no fear (pain) at all" to "the most fear (pain) you can have." Crying was assessed by having the child point to a picture on a continuous visual analog scale of 6 different faces representing increasing levels of distress, ranging from a smiling face to a face crying intensely. Several child assessments were not completed because some children started the procedure early or late (and therefore were not available for the initial assessment) or reported, "I don't know," or, "I don't want to answer," when queried on the distress measures.

Distress: Parent Report

The parent assessments of child distress (fear, pain, and crying) and overall trauma were completed on 5-point scales, ranging from "not at all" to "extremely"; the parent rating of how traumatic the present VCUG procedure was compared with the previous one was completed on a 6-point scale ranging from "much less traumatic" to "much more traumatic."

Distress: Observational Ratings

The RA rated the child's distress from the time he or she entered the procedure room until the procedure was completed (or abandoned). The rating procedure was developed in piloting the study and used a modified 8-point version of the Torrance Global Mood Scale; the 7-point version of this scale has been used in a previous study of children's memories of painful inoculations (eg, ³⁴). Ratings are made on the basis of facial features, verbalizations, degree of crying, and whether physical restraint is required. For example, a score of 1 indicates the child is happy, attentive, or smiling; a score of 4 is coded when the child is unhappy, worried, or anxious; a score of 5 is coded when there is marked unhappiness, whimpering, or soft crying; and a score of 7

is coded when there is intense crying (or screaming). In the present study, when the child needed restraint, a score of 8 was coded.

Observational ratings were conducted with respect to 6 phases of the procedure: (1) getting to the table: the period from when the child entered the room until he or she was on the examination table; (2) initial radiograph: the period from when the child got on the examination table until the initial radiographs were completed; (3) catheterization preparation: the period from when the radiologist entered the room until the genital cleaning began (when the swab was dipped in the cleanser); (4) catheterization: the period from the start of genital cleaning until the catheter was inserted successfully; (5) bladder fill and radiograph: the period from catheterization insertion, through the filling of the bladder, to completion of the second set of radiographs; and (6) voiding and catheter removal: the period from when the child was instructed to void until the catheter was removed. During each procedure phase, 3 aspects of distress were rated by the RA: the highest or peak level of distress reached, the most prevalent or typical level of distress, and the lowest level of distress. For the present analyses, ratings across phases were averaged to create summary scores for the peak, the typical, and the lowest levels of distress during the procedure.

Difficulty of Procedure: Medical Staff Ratings

Immediately after the procedure, the attending radiologist and the technician each were asked to rate the degree of difficulty of conducting the procedure generally. In a subset of cases ($n = 24$), the difficulty of conducting the catheterization specifically was also rated. Medical staff were asked to make the ratings with respect to children of similar ages on a 7-point scale ranging from "far easier" to "far more difficult." Radiologist and technician ratings were averaged to create 2 medical staff ratings: overall procedure and catheterization.

Duration of Procedure

The time required to complete each phase of the procedure, along with the total time in the procedure room, were recorded by the RA.

Data Analyses

Statistical analyses were conducted with SPSS for Windows, version 11.5.0 (SPSS, Inc, Chicago, IL). Before analyses, the zero-order correlations (available from the first author) among the various summary distress, difficulty of procedure, and time outcomes were examined. To avoid multiplication of tests of similar constructs (ie, the various distress measures) and to address the questions of greatest interest, we chose 5 outcomes to examine for treatment effects with between-groups (hypnosis vs routine care) t tests. Both the medical staff ratings of procedural difficulty and total procedure time were chosen for testing because they were

objective assessments with important medical procedure relevance. Among the distress measures, the child and the parent reports of child distress were strongly and significantly correlated (0.54), as were parent reports of child distress with trauma overall (0.83) and relative trauma (0.59), and parent reports of child distress and trauma overall with the observational ratings of typical (0.62 and 0.53, respectively) and peak (0.80 and 0.70, respectively) distress. Consequently, we chose to limit tests of distress outcomes to the child's subjective reports of distress, the parents' assessment of how traumatic the procedure was compared with the previous one, and observational ratings of distress. With respect to the observational ratings, both the typical level and the peak level were of most interest; however, they were very highly correlated (0.92). Because typical-level ratings had the fewest missing data, we chose to test this variable. In sum, tests were conducted on child reports of distress during the procedure, parent reports of how traumatic the present VCUG was compared with the previous one, observer ratings of the typical level of distress during the procedure, medical staff reports of the difficulty of the procedure overall, and total procedural time.

RESULTS

Descriptive statistics for raw distress and procedure difficulty variables are provided in Table 1. Descriptive statistics for test variables are provided in Table 2.

Parent and Child Reports of Distress

Parents of children in the hypnosis group, compared with those in the routine care group, reported that the procedure was significantly less traumatic for their children compared with their previous VCUG procedure (see Table 2 for test results). In 39 (89%) of 44 cases, the mother was the parent who completed the distress assessments, in 4 (9%) cases, the father did the assessments, and in 1 (2%) case, both parents conferred to complete the assessments. Child reports of overall distress during the procedure did not differ significantly between the groups.

Observational Ratings of Distress

Observational ratings of typical distress level during the procedure were significantly lower for children in the hypnosis condition compared with those in the routine care condition (see Table 2 for test results; see Fig 1 for a depiction of typical and peak

TABLE 1. Number, Means, and SDs by Study Condition of Additional Variables Assessed or Used to Create Summary Scores

	<i>n</i>	Hypnosis	<i>n</i>	Routine Care
Child report				
Fear before procedure	21	1.81 (1.40)	19	2.42 (1.50)
Fear during the procedure	21	2.48 (1.21)	21	2.95 (1.12)
Pain during the procedure	21	2.71 (0.96)	21	2.90 (0.94)
Crying during the procedure	21	4.24 (1.30)	22	4.68 (1.09)
Parent report				
Fear before procedure	21	3.43 (0.93)	23	3.52 (1.08)
Fear during the procedure	21	3.67 (1.11)	23	3.96 (0.82)
Pain during the procedure	21	3.05 (0.92)	23	3.13 (0.81)
Crying during the procedure	21	2.62 (1.28)	23	3.26 (1.25)
How traumatic was VCUG overall?	21	3.10 (1.09)	23	3.39 (0.94)
Observational rating				
Lowest distress level	15	1.83 (0.64)	22	2.39 (0.75)
Highest distress level	13	3.68 (1.30)	17	4.53 (1.07)
Medical staff rating				
Difficulty of overall procedure: radiologist	19	3.00 (1.92)	23	4.04 (1.60)
Difficulty of overall procedure: technician	19	2.58 (1.78)	23	3.43 (1.62)
Difficulty of catheterization: radiologist	12	2.83 (1.64)	14	4.36 (1.98)
Difficulty of catheterization: technician	12	2.08 (0.79)	14	3.86 (1.70)

TABLE 2. Group Means (SDs), *t* Test Results, *P* Values, Effect Sizes, and 95% Confidence Intervals

	Hypnosis	Routine Care	Test Result	<i>P</i> Value	Effect Size*	Mean Difference ± 95% CI
Child report						
Distress during the procedure (<i>df</i> = 40)	2.91 (0.91)	3.24 (0.86)	-1.25	.11	0.38	-0.34 ± 0.53
Parent report						
Trauma compared with last VCUG (<i>df</i> = 42)	2.14 (1.28)	2.91 (1.38)	-1.92	.03	0.56	-0.77 ± 0.78
Observational rating						
Typical distress level (<i>df</i> = 35)	2.52 (0.90)	3.19 (0.78)	-2.40	.01	0.86	-0.67 ± 0.55
Medical staff rating						
Overall difficulty of procedure (<i>df</i> = 40)	2.79 (1.82)	3.74 (1.46)	-1.88	.03	0.65	-0.95 ± 0.99
Total procedure time; min (<i>df</i> = 41)	35.30 (12.79)	49.22 (16.75)	-3.02	.002	0.83	-13.92 ± 9.02

CI indicates confidence interval. All tests were hypothesized and directional; therefore, *P* values are 1-tailed.

*Cohen's *d* = difference in group means/SD of the control group.

distress levels by condition, rated over the 6 procedure phases). Visual examination of Fig 1 indicates that children in both groups found the catheterization to be the most distressing aspect of the procedure on average and that it was during the period leading up to the cleaning and catheter insertion when the initial radiograph was taken and the children were asked to lie still (and, for girls, spread their legs) for the cleaning and catheter insertion that the 2 groups' distress levels diverged most markedly.

Of note, physical restraint was necessary in 5% (1 case in 21) of VCUGs conducted with hypnosis, whereas it was necessary in 22% (5 cases in 23) of routine care VCUGs. There were also 2 uncompleted procedures, both in the hypnosis condition and involving the same therapist. In one case, after repeated attempts to conduct the catheterization, a nurse who was present persuaded the parents to abandon the procedure so that force would not have to be used. In the other case, the hypnosis seemed ineffectual and the therapist repeatedly reminded the child and her parent that the procedure could be ended. On hearing this, the child began to insist that the procedure end, and the mother ultimately complied with this request. Although overall hypnotizability was not significantly correlated with child

distress in the hypnosis group ($r = .22$), in both noncompletion cases, the child's Hypnotic Induction Profile score (2.5 and 4.5) was below the group mean (5.33; SD: 2.5; range: 0.5–9.0).

Ease of Conducting the Procedure

The medical staff reported a significant difference between groups in the overall difficulty of conducting the procedure (see Table 2 for test results), with less difficulty reported for the hypnosis group.

Total Time of Procedure

The total procedural time was significantly shorter—by almost 14 minutes—for the hypnosis group compared with the routine care group (see Table 2 for test results; see Fig 2 for illustration of the mean times for the 6 phases of the procedure). Visual examination of Fig 2 indicates that between-group times diverged during the period leading up to catheterization and continued to spread during the catheter insertion itself, paralleling the observed distress during those periods.

Effects sizes and 95% confidence intervals for the mean differences between groups are presented in Table 2. In 4 of 5 outcomes, effects sizes were moderate to large.³⁵

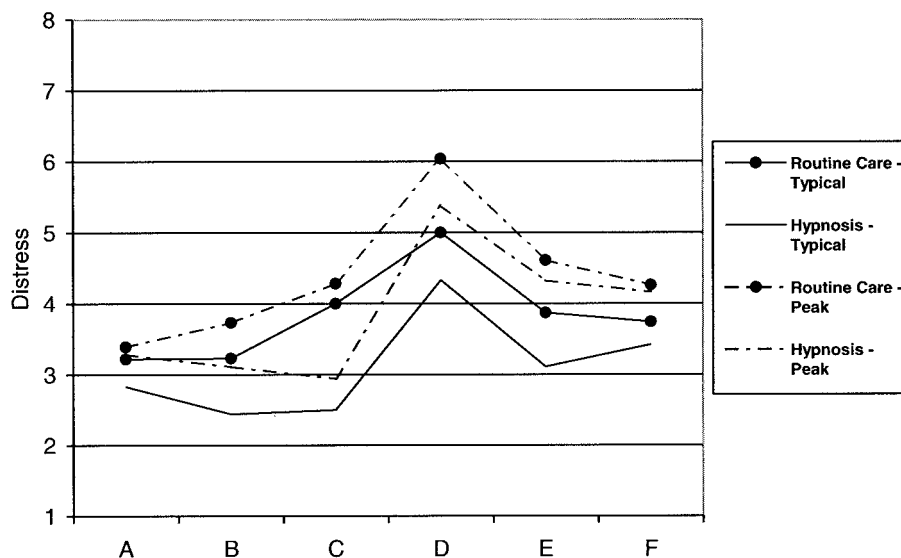
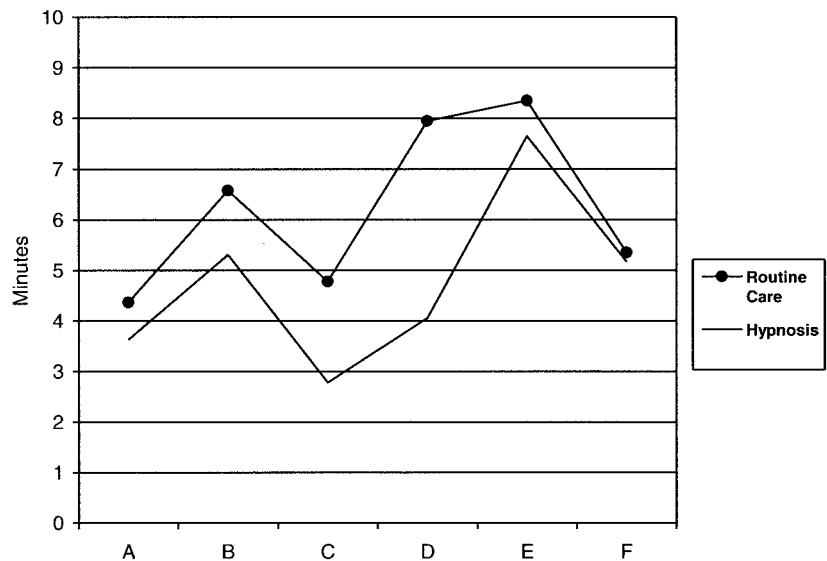


Fig 1. Observer ratings of typical and peak distress levels over phases of the procedure by condition. A, getting to the table; B, initial x-ray; C, catheterization preparation; D, cleaning and catheterization; E, bladder infusion and x-rays; F, voiding and catheter removal.

Fig 2. Times (in minutes) by condition over phases of the procedure. A, getting to the table; B, initial x-ray; C, catheterization preparation; D, cleaning and catheterization; E, bladder infusion and x-rays; F, voiding and catheter removal.



DISCUSSION

This preliminary examination of the use of hypnosis (compared with routine care) to help children get through an invasive medical procedure found that observational ratings of distress, parental assessments of relative trauma, medical personnel ratings of procedural difficulty, and the time required to conduct the procedure all showed significant advantages for children in the hypnosis condition. These findings augment the accumulating literature demonstrating the benefits of using hypnosis to reduce distress in the pediatric setting (for a review, see ³⁶). Moreover, hypnosis in this case helped children who had had difficulty with the procedure in the past and were, in many cases, dreading the next procedure—a particularly challenging sample. Children with previous VCUG experiences may be more fearful and less cooperative than children who are undergoing the procedure for the first time,³⁷ and procedure-related distress may spawn negative memories of the experience, which result in higher distress at subsequent procedures.¹

The findings are noteworthy in several additional respects. This study was a controlled, randomized trial conducted in a naturalistic medical setting. In this context, we achieved a convergence of subjective and objective outcomes with moderate to large effect sizes, including those that may have an impact on patient care and procedure cost, that were consistently supportive of the beneficial effects of hypnosis—a noninvasive intervention with minimal risk. The findings, therefore, have immediate implications for pediatric care.

In addition, in the present study, the comparison sample (those who received routine care) provided a stringent test of the hypothesis. In our setting, routine care typically involves recreation therapy—an intervention itself and one that is similar in its features to others that have been found to be efficacious in their own right (eg, ³⁷). That we achieved significant results demonstrates the potency of hypnosis in the pediatric setting and suggests that hypnosis may be the intervention of choice for children who have a

history of difficulties during the VCUG examination. Although the child reports did not differ significantly between the 2 conditions, all means were in the expected direction, suggesting that a larger sample size may have yielded significant differences, as others have suggested.³⁷

Clinical Observations to Inform Research and Practice

While conducting this study, the investigators made a number of clinical observations that we believe may be useful to consider in future research and practice (see also ⁶). First, we were struck by the range of spontaneous parental behaviors before and during the procedure and their apparent impact on the child. Some parents were comforting yet firmly focused on getting the child through the procedure by supporting the therapist's efforts, which seemed to reassure the child. Other parents, in their attempts to manage their child's (and perhaps their own) distress, inadvertently denied or minimized the child's experience with statements such as, "It's not so bad," or "It doesn't really hurt," which seemed to infuriate some children into more vigorous vocalizations of their plight and exacerbate their distress overall. This observation is consistent with other studies (eg, ⁵) that have found parental reassurance and other "distress-promoting" behaviors such as criticism, empathic comments, and apology to be among the strongest predictors of child distress during the procedure.

A related observation concerns parental avoidance behaviors, which were apparently enacted as short-term attempts to limit the child's anticipatory distress and resistance but may have long-term implications for their child's treatment options and/or experience of the VCUG overall. For example, 8% of our eligible sample refused to participate in the study, despite their child's reportedly difficult VCUG history, because they did not want to have to inform the child that he or she had an upcoming procedure. Similarly, 7% of the study sample arrived for their initial assessment without informing their child of its purpose (which, perhaps predictably,

generated considerable in-office panic and distress for some children). It is not clear whether the decision to protect the child from this information for as long as possible has any long-term benefits or negative consequences for the child's experience of the VCUG. Additional elucidation of the contribution of parent personality characteristics and coping strategies to child outcomes seems warranted.

We were also surprised that children's reports of internal states (eg, fear and pain) did not strictly map onto the more objective ratings of trained observers, medical staff, or procedure time. This finding is similar to that of Zelikovsky et al,³⁷ who found that although their intervention (compared with routine care involving no intervention) did not significantly reduce child-reported fear and pain, it did result in significantly fewer distress behaviors, greater coping behaviors, and more child cooperativeness during the procedure. Such discrepancies may reflect limitations of the child assessment method (ie, it is not sensitive enough), the pervasiveness and intractability of fear and discomfort during the procedure despite reductions in other determinants of distress behaviors and the additional benefits of the intervention (cf ³⁷), or perhaps the children's motivation to assert their views on the unpleasantness and unacceptability of the experience per se, regardless of their experience in that particular case. In support of this last possibility, one investigator on the present study observed that several children, after spontaneously vocalizing sentiments equivalent to "that wasn't so bad" after the procedure, endorsed high ratings of fear and pain when they completed the assessment. This phenomenon could represent the child's determination to assert their displeasure with the procedure "on the record" regardless of condition, and/or it could be an attempt to ward off future procedures.

An additional unanticipated observation concerns the effectiveness of involving parents before and during the procedure as trainers of the child's use of self-hypnosis. As previously mentioned, parent behavior can influence children's reactions to medical procedures.^{5,38} In the present study, the requirements of the hypnosis condition gave parents a task to practice with their children in preparation for and during the procedure, and, consequently, these parents seemed to be more effective in helping their child. In addition, parental involvement in the hypnosis intervention seemed to counter the helplessness, distress, and anxiety that may come from observing one's child's discomfort and resistance to efforts of medical staff to complete the procedure. In sum, these observations have convinced us of the worthiness of further developing and empirically examining the contributions that can be made by the parents as active participants in a hypnosis intervention during a VCUG procedure.

Limitations

A number of limitations to this study should be noted. The study was conducted on a relatively small sample, thereby potentially decreasing our statistical power to identify group outcome differences. The

sample was also primarily white in ethnic/racial makeup, which may limit the generalizability of findings. Although we did not collect data on household income, it is possible that less affluent families were less likely to participate because of the time commitment that may necessitate that the parent take time off work and/or obtain child care for other children left at home. It is also possible that less educated parents may be more wary of psychological interventions such as hypnosis and consequently less inclined to participate. Future investigations should put effort into recruiting larger samples, together with families from a variety of backgrounds, including underserved groups, to systematically examine reasons for refusals and whether there are ethnic/racial differences in treatment outcomes with hypnosis. In addition, our sample comprised children who had already undergone ≥ 1 previous VCUG during which they had had difficulty. Consequently, research is needed to determine whether hypnosis would help children during their first VCUG experience and reduce anticipatory distress with respect to future procedures.

As mentioned previously, neither the participants (children and parents) nor the observers (RA raters and medical staff) were blind to the condition to which the child had been assigned, and all concerned knew that the purpose of the study was to examine whether hypnosis might help children get through the procedure with less distress. Consequently, biases, expectations, or hopes could have influenced the self-report and other distress and difficulty ratings. For example, anecdotal observations indicated that some parents and medical personnel were optimistic about the potential of hypnosis to help children, whereas others stated explicitly that they did not think that anything could make the procedure less difficult. It should be noted, however, that the objective procedural time rating difference between groups was consistent with other, more subjective outcome findings and corresponded directly to those periods of highest rated distress. Additional limitations include the large age range of the sample, which could have introduced variance into results, stemming from possible developmental differences in memory, reporting characteristics, child coping, and, perhaps, parent coping and rater expectations.

CONCLUSIONS

The results of this study suggest that hypnosis provides a systematic, noninvasive method for reducing distress and resistance to VCUG procedures for children and their families, as well as reducing staff time and strain in administering such procedures. Because the VCUG is an essential part of the evaluation of urinary tract infections and vesicoureteral reflux in children, improved relaxation and decreased anxiety during the procedure may improve patient and family compliance with initial as well as follow-up evaluations for this condition. Relaxation training using hypnosis, therefore, has the potential to improve the overall medical care of children who have vesicoureteral reflux and may be a more generally beneficial intervention for children

who undergo other painful or anxiety-provoking medical procedures.

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