3-4-2008

Hypnosis for Relief of Pain and Anxiety in Children Receiving Intravenous Lines in the Pediatric Emergency Department

Maya Maxym

Hypnosis for Relief of Pain and Anxiety in Children Receiving Intravenous Lines in the Pediatric Emergency Department

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degree of Doctor of Medicine

by

Maya Maxym

2007

HYPNOSIS FOR RELIEF OF PAIN AND ANXIETY IN CHILDREN RECEIVING INTRAVENOUS LINES IN THE PEDIATRIC EMERGENCY DEPARTMENT.

Maya Maxym and Linda Arnold, Section of Pediatric Emergency Medicine, Department of Pediatrics, Yale University School of Medicine, New Haven, CT

Intravenous line placement is one of the most common procedures performed on children presenting to the Emergency Department. Anxiety about needles is widespread, and many children experience high levels of fear and/or pain with their IV line placements. Hypnosis is a behavioral intervention that shows significant promise for alleviating procedure-related pain and anxiety in children. Twenty-five developmentally normal, English-speaking children between the ages of five and fifteen who required IV line placement in the Pediatric Emergency Department at Yale-New Haven Children's Hospital were randomized to receive either the standard of care or standard of care plus a brief hypnotic intervention. The groups were similar with regard to baseline demographic and socioeconomic status, previous experience with medical care, and presence or absence of chronic medical conditions. Children's pre-procedural anxiety ratings on a 10cm visual analog scale (VAS) and expected procedural pain ratings by 10-point oucher and 10cm VAS were not significantly different between the groups. Children randomized to the hypnosis group reported less anxiety during the procedure (mean 5.0 vs 3.1, median 7.2 vs 2.2, $p = 0.28$) than children randomized to the standard of care group. Cases also had a decrease in anxiety from expected to actual of 1.6 on a 10cm scale, while those randomized to the control group had an increase from expected to actual anxiety of 1.1 ($p=0.01$). A smaller trend towards decreased pain in the hypnosis group was also present. As measured by VAS, cases had lower mean pain scores (3.4 vs 4.3) than controls. In a comparison of anticipated and actual pain scores between groups, the hypnosis group had a mean decrease of 0.8 on a 10cm VAS , while the control group had a mean increase of 0.5 ($p=0.14$). Recruitment of subjects is ongoing, but preliminary results suggest that hypnosis is effective for alleviating needle-related anxiety in children undergoing IV line placement and may be helpful for alleviating the pain of IV line placement as well.

Acknowledgments

I would like to thank my thesis advisor, Dr. Linda Arnold, for all her help and support throughout this project. I am so very grateful for the time she carved out of her busy schedule to help me with every aspect of this research, for her careful guidance, and for her attentive teaching about research design and methods, scientific writing, and data analysis. I would also like to thank Dr. Haleh Saadat for her assistance with research design and for the invaluable training she provided in techniques for hypnosis with children. Jim Dziura and Dr. Zeev Kain generously contributed their time to help with statistical analysis, and I thank them for that. Above all, I would like to thank the patients who participated in this study and the many PED physicians and nurses who lent their support to the project.

Table of Contents

Introduction

Pain in children is a long-neglected but fundamental part of pediatric medical care. Through the 1960s, and to some extent even more recently (1), it was widely believed by health care professionals that children did not perceive pain as fully as adults, had a higher relative tolerance for pain, and/or would not remember the pain they did experience (2, 3). Numerous studies conducted well into the 1980s showed that misunderstandings about children's experience of pain, coupled with fears about possible side effects of pain medications and anxiolytics, resulted in consistent patterns of fewer pain-relieving interventions being undertaken for children than for adults with comparable medical conditions (2, 4). Although recent advances in the understanding of the neurophysiology of pain, as well as the relation between pain and the healing process, have increased awareness and brought many significant advances in the understanding and treatment of pain in children, there remains much to be done.

Among the problems faced by children receiving medical care is the problem of the pain and anxiety associated with minor procedures such as intravenous cannulation, which is the focus of the research presented in this thesis. Although, as discussed in detail below, there are numerous local anesthetics available to decrease the pain of IV line placement, there are currently few proven options for decreasing the associated anxiety. One promising intervention is hypnosis, in which a clinician guides a child to focus attention on an imaginary experience as a way of dissociating from the experience of the moment and thus decreasing pain and anxiety. In the study presented here, we

examine preliminary data on whether hypnosis significantly decreases pain and anxiety associated with IV placement in children treated in the Pediatric Emergency Department.

Work with pediatric patients has identified five major stressors that children associate with hospitalization. These are: fear of separation from parents; fear of physical pain, mutilation and death; fear of the strange environment and procedures; fear of loss of control, autonomy and competence; and fear due to uncertainty about expected acceptable behavior (5). Fear of needles, specifically, is one of the most commonly expressed fears among children in the PED (6). Likewise, in a separate survey of over one hundred hospitalized children, 55% stated that "a shot or a needle was the most painful experience during their stay" (7).

The Emergency Department is a very stressful place for ill children, and the prospect of having to undergo any procedure involving a needle is a major source of fear and anxiety for many ED patients. Although intravenous cannulation may appear insignificant to medical providers, it fits into two of the five major categories of children's fear listed above: fear of physical pain and fear of procedures. Moreover, when children are told they have no choice about having an IV, they may rightfully fear and/or resent the loss of control and autonomy that this represents. As a recent survey demonstrated, parents of children presenting to the ED are also concerned about the pain of IV placement. Of 108 parents surveyed, 89% stated they would choose a painless IV placement if possible for their child. Sixty-five percent of these parents expressed a willingness to stay an extra hour, and 77% a willingness to pay at least $15, in order to achieve this goal (8).

In recognition of the problem of pain associated with minor procedures, numerous studies have been published over the last ten to twenty years evaluating various anesthetic agents and delivery systems for reducing or eliminating the pain of intravenous cannulation. In general, research initially focused on whether there was a significant benefit to children of using local anesthetic in general and subsequently on the question of the ideal method for delivering local anesthetic. Numerous transdermal delivery systems have been developed and compared with one another; virtually all are at least somewhat effective in relieving pain associated with intravenous cannulation, although none reduce pain to zero in all children tested.

In one study from the University of Washington (9), patients were randomized to receive either intradermal buffered lidocaine, delivered by a 27 gauge needle, or no intervention prior to intravenous cannulation. The children were instructed to rate the pain of the initial IV placement attempt on a ten point scale, including the subcutaneous lidocaine injection if it was used. The median pain score of 2.3 for the intervention group was significantly lower than the median score of 4.4 in the control group. Transdermal delivery of local anesthetic has the added benefit of eliminating the second needle stick.

The first transdermal anesthetic to be widely used was EMLA cream, which is a eutectic mixture of lidocaine and prilocaine. However, the use of EMLA is hampered by the long application period: although the manufacturer recommends one hour, one randomized controlled trial (10) found that EMLA requires 90-120 minutes for best effect. Additionally, this same trial showed that EMLA was effective at eliminating the pain associated with IV insertion only about half of the time**.** Subsequently, Jimenez *et. al.* studied the J-tip transdermal lidocaine delivery system and found it to be significantly

more (84% vs 61%) effective than EMLA cream in completely eliminating pain associated with intravenous cannulation in children aged 7-17 (11). Another transdermal delivery system, the S-Caine Patch, was shown to be effective in eliminating the pain of IV placement in 59% of children in a randomized, placebo-controlled trial (12). In a separate study comparing fast-acting ELA-Max with the slower-acting EMLA cream, participants aged 7-13 volunteered to have an IV line placed in each hand after a 30-minute application of ELA-max on one hand and a 60-minute application of EMLA on the other. The study authors found that the two types of local anesthetic provided equally (mean of 20.5 for EMLA vs mean of 24 for ELA-Max on a 100mm VAS) effective anesthesia (13).

The literature strongly supports the use of some form of local anesthetic prior to IV placement in children, but it is clear that local anesthetics are not universally effective (9, 10, 11, 12). Most studies evaluating local anesthetics have not addressed anxiety or its relation to the children's pain. Notably, one study that compared EMLA to placebo cream in children ages 5 to 18 found a significant correlation between higher situational anxiety and higher pain scores (10). Several other studies and observational reports support a similar association between anxiety and pain (12, 14, 15 pp. 53-54, 16, 17)

A small number of studies have looked at behavioral or psychological interventions aimed at reducing needle-associated pain and/or anxiety in children. For example, a recent study by Sinha *et. al.* (14) evaluated a variety of distraction techniques for the alleviation of pain and anxiety in children aged 6-18 undergoing laceration repair in the emergency department. Most children chose music or videogames as their distractor, and imaginative techniques were not used. In this study, the authors found that

distraction reduced self-reported situational anxiety but not pain in children 10-18 years old, while it reduced distress among younger children as estimated by the parents. Another recently completed study evaluated virtual reality as a method of alleviating pain and anxiety associated with IV placement in children requiring conscious sedation prior to a procedure. Although numbers were small (two groups of ten patients each), the authors report that children in the virtual reality group had lower pain scores and greater satisfaction with the procedure than children in the control group (17).

A recent Cochrane Review evaluated evidence for psychological interventions for the treatment of needle-associated pain in children (18). The studies included evaluated a variety of interventions ranging from hypnosis and guided imagery to cognitive behavioral therapy (CBT), distraction by parents, behavior modeling by videotape, and many others. The "needle-related interventions" included in the review were also numerous, including routine immunizations, intravenous cannulation, lumbar puncture, among others. Although the review included relatively few studies specifically evaluating nonpharmacologic methods for alleviating pain and/or anxiety during IV placement, the authors of the review found hypnosis to be the psychological/behavioral technique with the strongest evidence supporting its use in a wide range of clinical settings. They do suggest that the results of the studies reviewed be interpreted with caution, as no objective measures of pain were recorded and significant heterogeneity existed between studies, but they strongly recommend further and larger-scale research into hypnosis for needle-related pain in children.

As the conclusions of the Cochrane review suggest, hypnosis has several potential advantages as a method for alleviating pain and anxiety associated with intravenous

cannulation in the emergency setting. As a behavioral intervention, it addresses both pain and anxiety rather than simply assuming that decreasing pain will necessarily also decrease anxiety. It is quick and easily implemented, with a maximum lead time of five minutes, it requires no additional equipment, it can be used with or without topical analgesia, as dictated by the clinical situation, and it has no significant side effects.

In studies with adult patients, hypnosis has been shown to be effective in a wide range of medical conditions and clinical contexts. Research using hypnosis either alone or as a supplemental therapy has shown promise or definite benefit in areas as wide-ranging as pre-operative anxiety (19), fibromyalgia (20), irritable bowel syndrome (21), migraine (22), asthma (23), and many other chronic, painful medical conditions (24).

Until recently, research investigating hypnosis for relief of procedural pain and anxiety in children focused almost exclusively on oncology patients undergoing Bone Marrow Aspirations (BMA) and Lumbar Puncture (LP). Early articles demonstrated decreases in pain and anxiety with hypnosis during both of these procedures (25, 26). For instance, Kuttner *et. al.*, (25) studied 48 children with pediatric cancers and found that hypnosis significantly reduced both pain and anxiety, particularly in younger children (ages 3-7). Older children were helped equally by distraction and hypnosis, although the reduction in anxiety (vs pain) was still greater in the hypnosis group, particularly during the first-time intervention. This study, like many other early studies of hypnosis, only evaluated small numbers of patients, which resulted in some data showing only a trend rather than statistical significance. Notably, over the course of the study, the authors also observed improvements in the control group's pain and distress scores, which they attributed to the fact that, part way through the study, medical staff

began using techniques they had seen to be effective in the two treatment groups with the children in the control group.

A separate study performed by Zeltzer and LeBaron (26) showed similar results: although both supportive and distraction techniques reduced the pain of BMA, the difference seen was much greater with hypnosis. In addition, hypnosis significantly reduced pain associated with LP, while distraction produced a smaller, nonsignificant reduction in pain score. Finally, hypnosis significantly reduced the anxiety felt by the study participants during both procedures, while distraction reduced anxiety during LP only moderately and non-significantly during BMAs.

The majority of research studies of hypnosis suffer from methodological flaws such as small sample size, lack of randomization, confounding variables, lack of standardized and well-defined interventions or a manual, and lack of valid outcome measurement tools (27, 28). Nonetheless, these studies have consistently supported the effectiveness of hypnosis as a clinical tool, and there is a general consensus that further, large-scale trials examining the utility and efficacy of hypnosis in pediatric patients are warranted.

Research in hypnoanalgesia is beginning to be conducted outside of pediatric oncology, and larger and more methodologically sound trials are beginning to emerge. For instance, hypnosis was shown to be effective in reducing the pain and anxiety associated with VCUG in children (29). In a randomized trial comparing hypnosis to the standard of care, in which a child-life intervention "includes demonstration of the procedure with dolls, relaxation and breath work training, and assistance during the procedure," the authors evaluated pain, anxiety, and distress, as well as the objective

outcome of procedure length, for children undergoing follow-up VCUGs for urinary tract abnormalities. They showed that hypnosis was effective for reducing children's distress, as rated by their parents and by a trained observer, as well as for making the procedure easier and shorter for the medical staff to complete. Perhaps due to the small numbers in the study (44 subjects total), there was a trend seen towards reports of lower fear and pain scores among the children in the hypnosis group, but no statistical significance was achieved.

A recent publication by Liossi *et. al.* (30) showed that, among 45 children who required serial LPs as part of their treatment for cancer, children who received EMLA cream plus hypnosis (and, later, training in self-hypnosis) had lower pain, anxiety, and distress than children receiving either the standard of care (EMLA alone) or EMLA plus attention. The trial was ingeniously blinded, in that a nonverbal cue (cheek-stroking) was used by the therapist to trigger hypnosis in the hypnosis group. In addition, after an initial post-intervention LP, the children received several more LPs in the absence of the therapist, during which time their training in self-hypnosis proved to be adequate to provide them with lower pain, anxiety, and distress scores than were reported by the subjects in either of the two comparison groups.

Despite growing interest in the potential applications of hypnosis for procedural pain beyond the field of pediatric oncology, there is limited literature on the use of hypnosis with pediatric patients in the emergency setting. One case series, published in 1999, describes the use of hypnosis during closed reduction of forearm fractures among four children in a Mexican hospital where neither sedation nor anesthesia were available (31). In this article, the author describes giving suggestions for relaxation, analgesia, and

amnesia to four children, aged 3-12, who required closed fracture reduction. Although he acknowledges that the four children cried and showed other evidence of pain during the procedure, he points out that the suggestion for amnesia was quite successful, in that none of the four children remembered the pain of the reduction or could explain how they had gotten the cast on their arm when they were questioned about it a few hours later. An earlier case series from 1989 reports the successful use of clinical hypnosis in five ED patients, three of whom were children (32). In all three cases, the hypnosis was used to produce analgesia, and the analgesia was sufficient to allow a necessary procedure (wound debridement, suturing, or injection of medication).

As the limited literature on hypnosis suggests, hypnosis is seldom used in the ED setting. The feasibility and effectiveness of a hypnotherapeutic intervention for a brief, painful procedure such as IV line placement in an emergency setting have not, to our knowledge, been investigated. The relative simplicity and frequency of intravenous cannulation means that it is often performed with minimal lead-time, analgesia, or anxiolysis. In our Emergency Department, topical anesthetic agents are available, but their use varies greatly among nurses. Informal discussions with staff suggest several possible reasons for this. Ethyl chloride spray works on contact, but many doubt its effectiveness or feel that the vasoconstriction it causes results in a more difficult IV placement and the potential for longer manipulation and/or additional sticks. EMLA cream is available, but needs to be in place for a minimum of one hour prior to the procedure. It is thus not typically used for IV line placement, as it is perceived as both delaying the care of the individual patient and interfering with the overall flow of patients through the ED. The presence of these barriers to the use of anesthetic agents make a

quickly implemented and widely effective behavioral intervention that reduces both pain and anxiety associated with intravenous cannulation highly desirable.

The aim of the present randomized controlled study is to evaluate the efficacy of hypnosis, when compared to the standard of care, on subjective ratings of pain and anxiety for children having peripheral IV lines placed in the PED. Our hypothesis is that children randomized to the hypnosis group will report equal expected pain and pre-procedural anxiety to the children in the control group, but that their actual experienced pain and anxiety during the procedure of IV cannulation will be significantly lower than that of the control group.

A brief introduction to clinical hypnosis

Behavioral interventions for pain relief trace their roots back hundreds and most likely even thousands of years (33, 34). For instance, as discussed by Patricia McGrath in the introduction to her book *Pain in Children*, the Tenth Century Persian physician Avicenna (Ibn Sina) listed "drugs [and] herbal preparations," but also "therapeutic physical treatments and mental relaxation techniques [such as] walking about gently for a considerable time to relax the tissues, agreeable music, and being occupied with something very engrossing" as remedies for pain (15). As McGrath points out, "[m]any of these therapeutic remedies are similar to those prescribed for pain relief today" (p. 2).

Hypnosis as a technique within Western medicine traces its roots back to the innovations of Franz Anton Mesmer, whose theory of animal magnetism held that imbalances in the body's magnetic fluid caused illness, and that a re-balancing of the body's magnetic forces by means of certain techniques could restore health. Throughout the Eighteenth and Nineteenth Centuries, examples of patients cured by what was by then called "mesmerism," as well as of minor and major surgeries performed with anesthesia produced by mesmeric techniques, abounded. During this time, debate raged about the validity of "animal magnetism" and whether perhaps its effects were more clearly attributable to the power of the imagination than to any magnetic force (33, 34).

The term "hypnosis," which has persisted until our time, was coined in the mid-nineteenth century by the British physician James Braid. Interest in hypnosis as a modality of treatment within medicine was limited throughout much of the Twentieth Century, although the AMA formally endorsed hypnosis in 1958 (35) and the British

Medical Association even earlier, in 1955. By 1961 the APA issued a position statement endorsing the use of hypnosis, stating that it "has definite applications in the various fields of medicine" (24).

Hypnosis has been defined in numerous ways, but certain features are common to almost all commonly accepted definitions. First, hypnosis is not a state of sleep; rather, it is a an altered state of awareness characterized by narrowly focused attention and heightened susceptibility to suggestion. There are important distinctions between stage, or popular, hypnosis and clinical hypnosis as practiced in a medical or psychotherapeutic context. Most importantly, clinicians using hypnosis operate under the basic tenet that "all hypnosis is self hypnosis" and that no patient can be hypnotized against his/her will (33). Hypnosis, as defined by the American Psychological Association, is "a procedure wherein changes in subjective experience, alterations in perception, sensation, emotion, thought, or behavior are suggested" (36). Leora Kuttner, one of the leading researchers in the field of pediatric pain management by means of hypnosis, describes hypnosis in the following way:

> Hypnosis is an altered state of consciousness utilizing intensified attention within a relaxed physical state to achieve a trance state that is different from both the normal waking state and any of the stages of sleep. It resembles, but is not identical to, various meditative states with its narrowly focused attention, primary process thinking, and ego receptivity. In a trance, attention is narrowed, focused, and absorbed, allowing perceptions and sensations to be enhanced, modified, or changed" (37).

Most scholars agree that the hypnotic state, or trance, is a focused state of awareness that permits the patient to accept suggestions, including suggestions for analgesia and relaxation, without censoring them (24, 29).

Hypnosis with children resembles hypnosis with adults in many ways: a trained clinician guides a child (or teaches him/her to guide him/herself) to focus attention away from the aspects of a procedure that cause fear, pain, or anxiety, and instead turn attention to an imaginary experience that feels comforting, safe, enjoyable, or interesting (38). The redirection of attention may decrease distress, reframe painful experiences, and thus help children to dissociate from their physical pain. Hypnosis with children differs from hypnosis with adults in several ways, including fluid and sometimes frequent transitions in and out of trance, more physical activity and verbal interaction with the clinician during trance, and, frequently, unwillingness to close the eyes (34, 39).

The process of hypnosis typically involves several stages: 1) preparation, in which the child is asked about specific activities s/he enjoys doing and perhaps specific things s/he would rather avoid during the hypnotic trance; 2) induction (assisting child in dissociating from the environment and achieving a focused state of attention); 3) deepening the dissociation; 4) giving suggestions that result in increased feelings of comfort and decreased pain, distress, and fear; and 5) realerting the child to the environment and receiving confirmation of that realerting. Examples of common hypnotic suggestions include the "magic glove," which is used to produce hypnotic anesthesia, and "distancing" techniques, such as imagining going to a favorite place or a place of safety (34). As Zeltzer and LeBaron emphasize (26), "[i]ntense imaginative involvement is the distinguishing feature between the hypnotic and nonhypnotic situations in children." Olness and Kohen add that the "goal of hypnotherapy is always to teach the patient an attitude of hope in the context of mastery" and to "focus on creating a solution rather than on enduring a problem" (34, p. 89).

Although hypnosis is not a technique currently used by large numbers of mainstream medical professionals, most textbooks on pain now routinely include a chapter on behavioral interventions for pain, including hypnoanalgesia. For example, the comprehensive *Pain in Infants, Children, and Adolescents* devotes several chapters to nonpharmacological methods of pain control, including an entire chapter devoted solely to hypnosis (4). Similarly, Wall & Melzack's *Handbook of Pain Management* devotes a whole chapter to the techniques, applicability, possible mechanisms, and existing research into hypnosis (40).

Although hypnosis may on occasions be a substitute for other clinical interventions, it is often used along with them. Although our study investigates the usefulness of hypnosis for analgesia and anxiety reduction during IV line placement in children, the use of hypnosis does not preclude the use of any of the topical anesthetic agents discussed above.

Materials and Methods

Key Study Personnel

All aspects of the clinical study evaluating hypnosis for relief of pain and anxiety in children undergoing IV line placement in the PED were primarily designed by Maya Maxym (MM) and Linda Arnold (LA). Haleh Saadat (HS) advised us on some aspects of study design and provided invaluable training in hypnosis with pediatric patients. A volunteer research assistant, Cristina Novoa (CN), recruited one patient and guided the hypnosis intervention in two patients. Of the twenty-five patients enrolled in the study at the time of writing, twenty-three were recruited by MM, one by LA, and one by CN. All interventions were conducted by the individual initially recruiting the patient into the study, with the exception of one subject, who was recruited by MM but for whom the clinical hypnosis was guided by CN. Linda Arnold, Zeev Kain (ZK), and Maya Maxym participated in the statistical analysis of the data and the interpretation of the results. The study was approved by the Yale University Human Investigations Committee.

Subject Selection

Research study participants were recruited from a convenience sample of patients presenting to the Yale-New Haven Children's Hospital Emergency Department at times when the student researcher (MM), faculty investigator (LA), or research assistant (CN) was available, and child life therapists were not present in the ED. Children between the ages of five and fifteen who spoke fluent English, were developmentally normal, and required an IV line as part of their ED care were eligible to participate in the study.

Potential study participants were identified by the researcher and/or the PED staff and then approached by the researcher and evaluated for willingness to participate in the study. Subjects were excluded from participation if they did not meet criteria, were unable to understand the questions or provide consent or assent for participation, or if IV placement was required emergently for stabilization or analgesia. In all cases, children and their parents or guardians were aware that an IV line was required as part of the medical treatment prior to the consent procedure being initiated. The researcher explained the study procedure, emphasizing particularly the non-threatening nature of the hypnotic intervention and the differences between stage hypnosis and clinical hypnosis, but also ensuring that the patient and family understood the concept of randomization and the fact that their decision whether to participate in the research study would have no effect, positive or negative, on any other aspect of the patient's medical care. In addition, the child and family were assured that they would be able to withdraw at any point during the study, including after giving informed consent in writing. If the patient and family were willing to participate, the parents were asked to read and then sign a parental permission form, giving consent for their child's participation; all children over the age of seven signed age-appropriate assent forms in accordance with guidelines issued by the human investigations committee (HIC) of Yale University.

Randomization

Subjects enrolled in the study were randomized to either case (standard of care plus hypnosis intervention) or control (standard of care, no hypnosis) using a random numbers table. The group assignment was concealed in a closed envelope inside the

numbered folder containing the study documentation. Researchers, patients, and the medical team were blinded to the child's group assignment until after the decision to participate in the study had been made by the child and family.

Data Collection

Before the child's group assignment was revealed, the child was asked how much s/he expected the IV placement to hurt using both an oucher facial pain scale (FPS) and a 10cm visual analog scale (VAS). The child was also asked to rate, on a second 10cm VAS, his/her level of anxiety prior to the IV line placement (younger children and those not familiar with the word "anxiety" were asked "how worried are you about having the IV put in?"). The child's parent was asked to fill out a form with basic demographic information and questions about the child's previous experiences with medical care and presence or absence of recent life stressors. The parents were also asked to fill out the EASI scale of child temperament, which consists of twenty questions that evaluate the child's temperament at baseline. These forms were filled out either before, during, or after the procedure to allow the parent maximum ability to attend to the child's immediate needs and to avoid delaying the placement of the IV line. Finally, the nurse placing the IV was asked to observe the child's behavior prior to the procedure and use the mYPAS (modified Yale Preoperative Anxiety Scale, a scale that has been validated for use in assessing preoperative anxiety in children) to assess the child's pre-procedural anxiety-related behaviors.

Standard practices for IV placement vary in our hospital, according to the preferences and experiences of the nurses caring for the patient, individual patient and

family requests or characteristics and, even, patient volume and staffing patterns in the PED. For instance, some nurses use more distraction than others when placing IVs; some nurses routinely use a fast-acting local anesthetic spray (ethyl chloride), while others do so only if asked or if the child seems particularly anxious. There is also great variability in the amount of time a child may be required to wait between finding out s/he will have to have an IV and the time when it is actually placed. Nurses caring for children enrolled in the study were instructed to interact with the child just as they normally would, regardless of group assignment, and to place the IV exactly as they would if the child was not in the study. For example, regardless of the child's group assignment, nurses were able to explain the procedure beforehand, interact with the child throughout the procedure and use topical anesthetic agents, in accordance with their standard practice.

The nurses, family members, and any other members of the medical team who were in the room were free to engage in any conversation designed to distract or comfort the child. In other words, no limits were placed on interactions with the child or attempts to comfort in any way (e.g. distraction by a parent, hand-holding, instructions to breathe). For children randomized to the control group, the researcher remained in the room and interacted with the child in a warm, friendly way (chatting about school, family, hobbies, etc.), but did not engage in any hypnotic or focused imaginative interactions with the child.

For subjects randomized to the hypnosis group, each induction was individualized to the particular child. The researcher typically asked the child a few basic questions about his/her favorite place or activity (examples varied from Disneyworld to the Tower of London to dancing to rap music with friends). If the child did not volunteer

an answer the researcher would suggest an age-appropriate activity to daydream about, such as making a snowman for a six year-old or skiing for an adolescent, and then suggest a hypnotic "daydream" about that place or activity. Most inductions for older children (ages approximately 9-15) included a few slow, deep breaths and/or some progressive relaxation, such as muscle relaxation or the suggestion of a "warm, comfortable feeling" flowing up the body from the feet to the head. Younger children, unless they expressed an interest in deep breathing or relaxation, were typically asked simply to imagine themselves arriving at their favorite place and/or beginning their favorite activity. After a light to moderate state of trance was achieved, usually within two to four minutes, the researcher gave a signal to the nurse to begin placing the IV. Usually the researcher would refer to what was happening in the room as a parenthesis to the imaginary events of the trance, e.g. "and there might be a part of your mind that knows that that arm in the hospital is getting its IV now, but you don't need to worry about it, because you're skiing down the mountain and enjoying the speed, feeling the wind in your hair and the cold air on your skin…"

The process of re-alerting was typically begun as the last pieces of tape were being secured. On some occasions, children spontaneously re-alerted during or after the IV placement. Depending on the individual situation, the child's apparent level of anxiety, the researcher's estimate of the effectiveness of the trance, and how near the procedure was to completion, the researcher either guided the child back into trance until the procedure was done or gently asked him/her to confirm that s/he felt "completely back in the room, and not in [that special place] any more."

Once the IV was securely taped and, if applicable, the child was calm enough to answer questions, s/he was asked to rate the actual pain experienced when the IV was placed using the same Oucher FPS and the VAS scale as before the procedure. The child was also asked to rate the anxiety s/he had felt at the moment the IV was going in, using a VAS scale as above. Any additional comments by the child or family, as well as the induction and techniques used (if the child was in the intervention group), were recorded by the researcher.

The nurse who had placed the IV was asked to record the duration of the procedure from the moment the tourniquet was placed until the moment the IV was completely taped up. The number of "sticks" was recorded, as was the number of nurses who attempted IV placement, whether any local anesthetic agent was used, and whether any distraction other than hypnosis (e.g. TV, parent talking to the child) was used with the child during the procedure.

Parents were contacted by telephone by the researcher 1-2 weeks after the study with a short questionnaire about their satisfaction with the clinical encounter in general and the process of IV placement in particular, the child's experience in the study, any behavior changes they might have noted in the child after the ED experience, and any other general comments.

Physiologic indicators of pain (e.g. tachycardia) were not recorded. The reason for this was that they were not deemed relevant to the goals of the study, as the goal of the intervention is to reduce the patient's subjective pain and anxiety rather than effecting and recording changes in objective measurements that may not correspond to the patient's lived experience. Parent were not asked to rate their children's pain and anxiety

at the time of the intervention, but they were asked to compare actual with expected pain and anxiety in the post-intervention telephone questionnaire.

Statistical Methods

Power calculation

Previous studies utilizing VAS scales to rate pain in children have reported standard deviations on the order of 1.5 on a ten point scale. Assuming a standard deviation of 1.5, power calculations suggest that 45 subjects in each of two groups (total n = 90) will provide sufficient power to detect a moderate treatment effect of 1.0 between groups with 90% certainty. A total of 100 subjects will be recruited (50 per group) to allow for withdrawals.

Data analysis

Statistical analysis of the collected data was processed using SPSS version 14.0 (2006). Descriptive analyses on participant baseline characteristics were performed using Pearson chi-square for categorical variables and independent samples t-tests for continuous variables. Groups were compared for similarity of demographic information and socioeconomic status, presence or absence of chronic illness, history of recent life stressors, and usual ability to cope with medical encounters. In addition, the groups were compared for similarity of personality traits as measured by the EASI scale of child temperament, which is composed of a score for each of four personality traits: emotionality, activity, sociability, and impulsivity. Pre- and post-procedural pain and anxiety scores, and differences between anticipated and experienced pain and anxiety were compared between groups using the Mann-Whitney U test for non-normally

distributed continuous data. Parental satisfaction with the procedure as expressed during the follow-up telephone interview, and parental perceptions of whether their child had experienced more, less, or equal pain and anxiety to the amount they had anticipated were also compared between groups.

The extent of the analysis to date is limited by the small number of patients enrolled thus far. Once subject enrollment is complete, logistic regression will be used to identify covariates for significant interactions.

Results

The results presented here represent preliminary findings of a clinical study that is ongoing in the YNHCH PED. Ultimately, we will recruit one hundred subjects. To date, out of forty-five patients approached for inclusion in the study, twenty-nine patients initially consented to participate. Four patients who initially consented were disqualified or withdrew before or during the IV placement: one patient was disqualified after giving verbal consent but before her group assignment was revealed when it became clear that she was too emotionally distraught to provide informed consent. A second subject was too anxious about the upcoming IV placement to answer the pre-procedural questions. A third patient was assigned to the hypnosis group, but withdrew prior to hypnotic induction, initially by screaming, "I can't, I can't" and then stating that she wanted to "just get it over with." A fourth patient completed study participation but was disqualified when it became clear that, despite multiple explanations, she could not understand the instruments being used to evaluate pre- and post-procedural pain and anxiety. As a result, twenty-five patients participated in the trial. Of those twenty-five, twenty families were successfully contacted for follow-up data.

There was no significant difference between groups with respect to gender, age, racial/ethnic background, or socioeconomic status. The mean age of cases was 9.92 ± 3.12 years, while the mean age of controls was 9.79 ± 3.46 years ($p=0.921$). Six of the 13 cases (46.1%) were male, compared to 4 of 12 (33.3%) controls ($p=0.513$). Seven of 13 (53.8%) cases identified themselves as White or Caucasian, compared to 9 of 12 (75.0%) controls. One case (7.7%) was African American or Black, as was one control (8.3%).

The remainder identified their race/ethnicity as Hispanic, Asian, other or multiple (see Table 1).

TABLE 1. Demographic Characteristics of Study Participants

	Cases	Controls	p value
Mean Age in years (n=25)	9.92 (±3.12)	9.79 (±3.46)	0.921
Gender (n=25)			0.513
Male	6/13 (46.1%)	4/12 (33.3%)	
Female	7/13 (53.9%)	8/12 (66.7%)	
Race (n=25)			0.758
White	7/13 (53.8%)	9/12 (75%)	
Black	1/13 (7.7%)	1/12 (8.3%)	
Hispanic	2/13 (15.4%)	1/12 (8.3%)	
Asian	1/13 (7.7%)	0/12 (0%)	
Other or Multiple	2/13 (15.4%)	1/12 (8.3%)	
Family Income (n=24)			0.865
<10,000	1/12 (8.3%)	0/12 (0%)	
11 - 20,000	1/12 (8.3%)	0/12 (0%)	
21 - 30,000	1/12 (8.3%)	2/12 (16.7%)	
31 - 50,000	1/12 (8.3%)	1/12 (8.3%)	
51 - 80,000	3/12 (25%)	3/12 (25%)	
81 - 100,000	3/12 (25%)	3/12 (25%)	
> 100,000	2/12 (16.7%)	3/12 (25%)	
Parental education (n=23)			0.257
Middle School	4/12 (33.3%)	0/11 (0%)	
High School	0/12 (0%)	1/11 (9.1%)	
Some college	3/12 (25%)	3/11 (27.3%)	
Bachelor's Degree	3/12 (25%)	4/11 (36.4%)	
Advanced Degree	2/12 (16.7%)	3/11 (27.3%)	

The groups were also similar with respect to history of chronic illness, prior ED visits, parental assessment of the child's ability to cope with medical interventions, or recent life stressors or changes. Among cases, 9 of 13 (69%) had been to the ED before, compared to 8 of 12 (67%) controls (p=0.891). Five of 13 (38.5%) cases and 4 of 12 (33.3%) controls had a history of chronic illness (p=0.790), while 6 of 13 (46.2%) cases and 3 of 12 (25%) controls had been previously hospitalized (p=0.27). The mean VAS

score (on a scale of 0 to 10) for subjects' ability to cope with medical interventions, as rated by the parents, was 8.03 (±2.48) for the cases and 8.31 (±2.29) for the controls (p=0.39). Four of 13 (30.1%) cases and 3 of 12 (25%) controls reported a recent major life change or stressor in the child's life (p=0.75). The EASI Child Temperament scores for emotionality, activity, sociability, and impulsivity were also similar between groups (see Table 2).

TABLE 2. Pre-procedural Experiences and Temperament

	Case	Control	p value
History of Chronic Illness	5/13 (38.5%)	4/12 (33.3%)	0.790
At least one prior ED visit	9/13 (69.2%)	8/12 (75%)	0.891
Previous hospitalizations	6/13 (46.2%)	3/12 (25%)	0.271
Recent life stressors	4/13 (30.8%)	3/12 (25%)	0.748
Ability to cope with medical interventions (0-10)	8.03 ± 2.48	8.31 ± 2.29	0.389
EASI temperament survey subgroup means			
Excitability	11.2 ± 4.9	12.8 ± 6.1	0.503
Activity	15.3 ± 3.3	12.8 ± 2.8	0.206
Sociability	19.6 ± 2.8	18.8 ± 2.8	0.470
Impulsivity	11.5 ± 4.1	12.5 ± 4.3	0.406

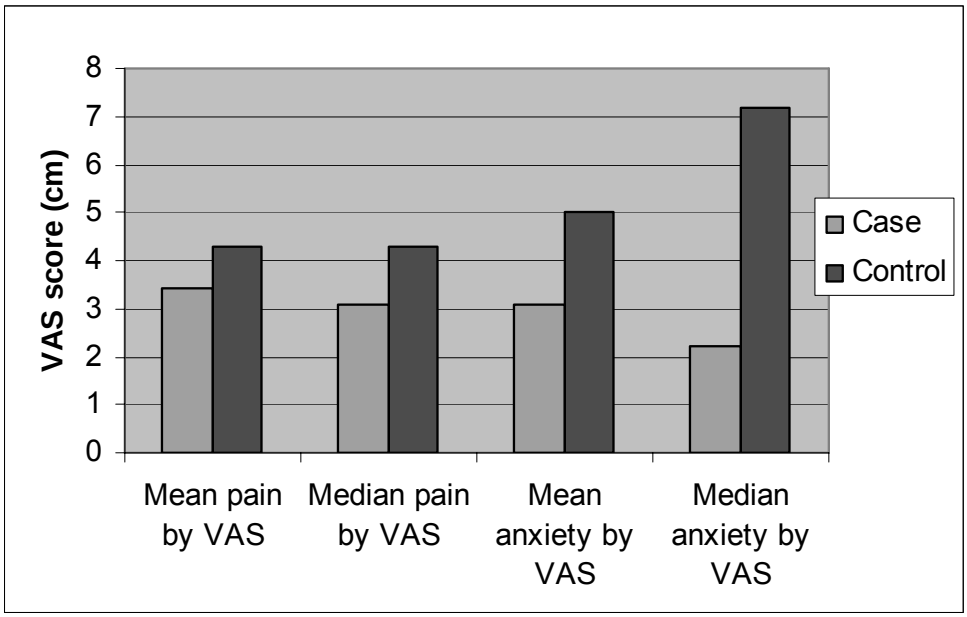
Mean anticipated pain as measured by the Oucher FPS was 4.6 ± 2.6 among cases and 3.7 ± 3.1 among controls (p=0.43). When children used the 10cm VAS, the mean anticipated pain among cases was 4.2 ± 2.1, compared to 3.9 ± 3.3 among children in the control group (p=0.65). Mean scores for actual pain experienced during the IV line placement, as rated by Oucher FPS, were 3.7 ± 3.1 for cases and 3.6 ± 3.5 for the control group (p=0.83). Actual mean pain, as assessed by VAS, was 3.4 ± 2.5 among cases and 4.3 ± 3.6 among controls (p=0.62). Mean anxiety actually experienced during the

procedure, as measured by VAS, was 3.1 ± 2.9 among cases and 5.0 ± 4.0 among controls; medians for the two groups were 2.2 and 7.2 respectively (p=0.28). See Table 3, Figure 1.

TABLE 3. Anticipated vs. Experienced Pain and Anxiety Associated with Intravenous Line Placement

	Cases	Controls	p value
Anticipated pain			
Oucher (0-10)	4.6 ± 2.6	3.7 ±3.1	0.43
VAS (0-10)	4.2 ± 2.1	3.8 ± 2.7	0.65
Pre-procedural anxiety (0-10)	4.7 ± 2.6	3.9 ± 3.3	0.52
Post-procedural pain			
Mean Oucher score (0-10)	3.7 ± 3.1	3.6 ± 3.5	0.83
Mean VAS score (0-10)	3.4 ±2.5	4.3 ± 3.6	0.62
Post-procedural VAS anxiety score (0-10)	3.1 ± 2.9	5.0 ± 4.0	0.28
Expected vs. observed			
Mean pain by Oucher (0-10)	-0.9	-0.1	0.30
Mean pain by VAS (0-10)	-0.8	0.5	0.14
Mean anxiety by VAS (0-10)	-1.6	1.1	0.01

Figure 1. Comparison of mean and median pain and anxiety scores between groups randomized to standard of care or standard of care + hypnosis for IV line placement.



Some trends between groups were observed with respect to differences between the pre-procedural expected pain to that actually experienced, and differences in pre-procedural versus actual procedure-related anxiety. Mean anticipated versus experienced pain for the hypnosis group decreased 0.9 by FPS and 0.8 by VAS. Conversely, for the control group, there was an increase in mean pain of 0.5, as measured by VAS (p=0.14). Changes in pre-procedural versus procedural anxiety were significantly different between groups. The subjects in the hypnosis group reported a mean decrease in anxiety of 1.6 on the VAS, whereas the subjects in the control group reported a mean increase in 1.1 (p=.01).

There were no differences between groups in terms of parental satisfaction with the ED visit, the interactions with the health care team, or the process of IV placement (see Table 4).

TABLE 4. Follow up questionnaire rating parental satisfaction

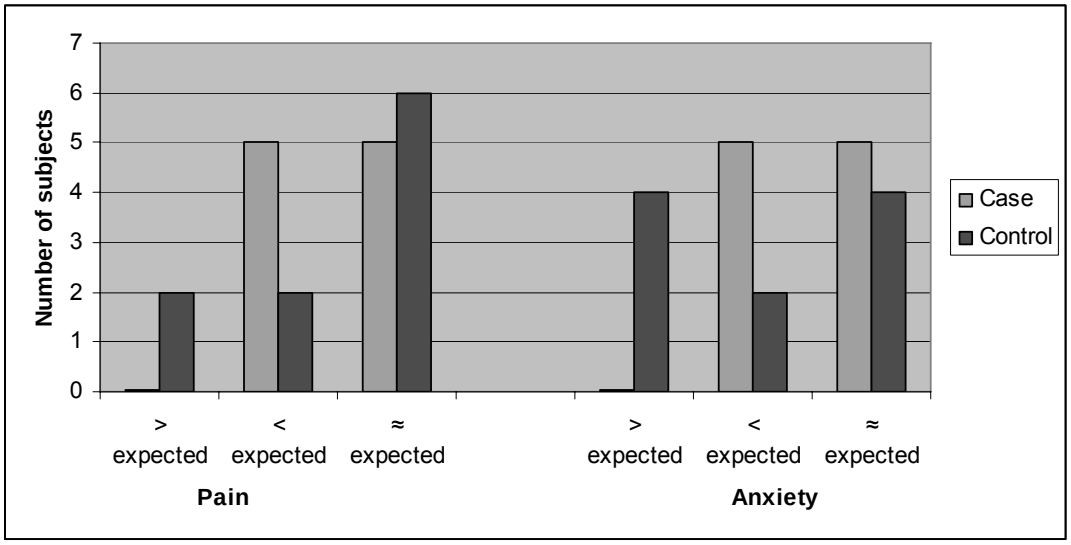
	Case	Control	p value
Overall Satisfaction with ED visit	4.7 ± 0.7	4.5 ± 0.8	0.568
Satisfaction with health care team	4.7 ± 0.7	4.6 ± 0.5	0.714
Satisfaction with IV line placement	4.6 ± 0.7	4.5 ± 0.7	0.754

There were, however, some trends suggesting differences between groups in parental reports of pain and anxiety, as expressed during the follow-up telephone interview. When parents were asked if their children experienced more, less or the same amount of pain and anxiety as they had anticipated, approximately half in each group stated that their child experienced "about the same" pain and anxiety as expected. However, for the remaining study subjects, the parents of more children in the hypnosis group reported decreases in pain and/or anxiety, whereas parents of children in the control group reported more increases in pain and/or anxiety. (see Table 5, Fig. 2).

TABLE 5. Parental Reports of Expected vs. Actual Pain and Anxiety for Children during IV Line Placement.

	Case	Control	p value
Pain			0.185
Pain > expected	0	2	
Pain < expected	5	2	
Pain ≈ expected	5	6	
Anxiety			0.067
Anxiety > expected	0	4	
Anxiety < expected	5	2	
Anxiety ≈ expected	5	4	

Fig. 2. Parental report of their children's expected vs. experienced pain and anxiety with standard of care vs standard of care + hypnosis for IV line placement.



Discussion

The preliminary results presented here lend support to our hypothesis that a decrease in procedure-related anxiety may be achieved using hypnosis in the emergency setting. In addition, there was a trend towards decreased pain scores among the children randomized to the hypnosis intervention when pain was measured using the visual analog scale, although, interestingly, this trend was not present in the pain scores collected using the Oucher facial pain scale. Additionally, compared with parents of children randomized to the control group, parents of children randomized to the hypnosis group more commonly reported that their children had experienced less pain and anxiety than they expected. These trends toward decreased pain and anxiety with the use of hypnosis are consistent with previously published reports that hypnosis is effective in reducing procedural pain and anxiety in a wide variety of clinical contexts.

Observations of individual children randomized to the hypnosis group showed some dramatic responses to the hypnotic intervention. Spontaneously offered comments from study subjects who underwent hypnosis ranged from “That was so relaxing!” to “Wow! I didn’t feel anything at all when he put the IV in!” During follow-up phone calls with parents of children who participated in the study, some parents reported that their children “absolutely loved” the hypnosis, that they “would recommend it to all their friends,” and that “it really helped a lot!” In contrast, positive comments from parents of children randomized to the control group generally referred to the technical skill of the PED nurses or the concept of the hypnosis study rather than to specific anxiety-reducing interventions by staff.

There are several important limitations to our study. The patients enrolled in this study represent a convenience sample of children seeking care in the PED when the researcher was available. Subjects were recruited mostly during morning and early afternoon hours. A minority of patients were recruited in the evenings and on weekends, which are typically busier times. Although we did not specifically investigate this, it is plausible that children coming to the PED during busier times or during nighttime hours may have higher levels of baseline stress due to interrupted sleep, higher levels of ambient noise and activity, or greater parental anxiety. Additionally, children being seen at the busiest times typically have had longer waits prior to being seen by a health care provider and/or prior to IV placement than children coming in during less busy times.

The possibility of selection bias in determining study participants cannot be excluded. Although the researchers made every effort to invite all eligible patients to participate in the study, differences among the PED's many care providers (e.g. number of patients being cared for at a particular time, remembering that the study was taking place, inadvertent assumptions about whether a particular child might be "good for the study") could have contributed to the selection of children who were more or less likely to benefit from hypnosis.

Although the majority of previous studies evaluating hypnosis procedural pain in children have small numbers, similar to those reported here, we plan to recruit one hundred patients in total. The limitation of our small sample size to date is primarily that the full extent of any effect may not be able to be determined. Conversely, although our groups are equivalent in terms of baseline measures, it is possible that individual differences among the children recruited into the study play a meaningful role in the

differences observed between the case and control groups. Finally, the small number of subjects enrolled to date precludes analysis of potential covariates.

One surprise in our data thus far was the discrepancy between the pain scores using two validated and frequently used pain scales, the 10cm VAS and the Oucher. One possible explanation for this discrepancy may have to do with the fact that the Oucher allows only whole numbers and displays only six faces, which means that children are pushed towards "rounding" their pain up or down according to those six faces. In addition, children may remember the face or number they chose and consciously or unconsciously relate their post-procedural anxiety and pain ratings to the numbers they reported prior to the IV line placement. Another explanation may have to do with the ages of children in our sample. We did note that younger children occasionally had difficulty understanding the concept of the VAS, while they had less difficulty using the Oucher. Conversely, older children sometimes added in decimal points, suggesting that they were seeking greater freedom in defining their pain than afforded by the Oucher.

It is important to note that we did not design our study to compare hypnosis to the distraction and other interventions provided by child life specialists who are available at certain times in our PED. The main reason for excluding a child life arm in our study was an ethical one: when child life is available (approximately 40-60 hours per week), the standard of care includes child life interventions for any child who has difficulty with or anxiety about any procedure. The benefits of the distraction techniques such as those used by our child life specialists have been previously demonstrated (14). Thus, including a child life arm in the trial would have necessitated asking patients to consent to being randomized to something less than the standard of care, i.e. the control group. In

addition, child life interventions are not standardized, which would have made comparisons difficult.

Importantly, in terms of the generalizability of our findings, child life specialists are not universally available. Even in the Pediatric Emergency Department of a dedicated children's hospital such as the one in which this study is being conducted, child life is only available for 25-40% of the time. Most community hospitals and many smaller children's hospitals have limited or no child life availability and, thus, could benefit greatly from our findings. We hope that hypnosis will prove to be a viable alternative, to be administered by nurses, physicians, or other members of the health care team, in the many clinical settings where child life specialists are not available to alleviate pain and anxiety for children who require IV line placement.

We did not measure hypnotizability. Although there exist validated scales of hypnotizability in children (34, Ch. 3), their use was impractical in the context of our study. More importantly, their use would be impractical in any emergency setting: administering a time-consuming standardized instrument to determine whether the pain and anxiety of a minor procedure might be reduced would be extremely cumbersome. As with many medical treatments, there will be differences among children in terms of how well they respond. However, requiring a measure of hypnotizability prior to an evidence-based intervention would simply decrease the likelihood that caregivers would make use of the intervention at all.

The nature of hypnosis in an emergency setting precludes any possibility of blinding the study participants, the parents, the researchers, or the nurses to the intervention. Although methods of blinding observers and parents to group assignment

have been developed for longer-term interventions (30), blinding was impossible in this context. It is thus possible that, despite all efforts to interact neutrally with the children and parents when collecting data, the very fact of the study's existence may have given the suggestion that the hypnosis group would experience less pain and anxiety than the control group. For instance, there were isolated instances when the child reported understanding the process of randomization completely, but then stated, "I don't think it's going to hurt that much after what you said." In cases such as this, the researcher explained that the child needed to disregard any expectations about what group s/he would be in when rating expected pain and preprocedural anxiety; however, this may have been difficult for the child to implement. However, since group assignment was not revealed until after these ratings were completed, any effect should be equal between the two groups.

In many of the cases where patients were randomized to the hypnosis group, family members and caregivers tended to interact less with children than did caregivers of children in the control group. Parents and nurses typically did not interrupt the hypnotherapeutic interaction unless the child initiated the interruption. An exception was that most nurses usually gave the child a verbal warning when they placed the tourniquet and when they initially pierced the skin with the needle. However, the absence of spontaneously offered comforting behaviors by parents or nurses would seem to suggest that they felt the hypnosis was helping the child. Additionally, if we assume that such behaviors would soothe the child, their absence would decrease rather than increase any observed effect size.

Our inclusion criteria were broad and did not require that patients express anxiety about the procedure in order to be included. There was thus a subset of children who had minimal or no anxiety about the IV placement at baseline. For these subjects, pain and anxiety scores were typically low both before and after the procedure regardless of group assignment. While it might have helpful to limit the study to children who expressed anxiety about the IV placement, it seemed reasonable that there might be certain children who would express little anxiety and/or expect little pain when asked prior to the procedure but still benefit from the relaxation afforded by hypnosis when their anxiety might otherwise have peaked during the procedure. Indeed, this did occur in one or two cases, although we recognize that in a clinical, non-experimental situation, it might make the most sense to offer hypnosis to children who express fear or anxiety about their procedure.

Another subset of children for whom it was impossible to evaluate the effectiveness of hypnosis consisted of the handful of children who were so anxious at baseline that they were unable to attend to the questions being asked by the researcher and/or give informed consent to the study. Although hypnosis might have been helpful for these children, and although specific techniques have been developed for inducing trance in highly anxious or screaming children, the investigational circumstances precluded the use of hypnosis with children who were unable to give informed consent and/or unable to attend to the researcher secondary to anxiety. Thus, it is not possible to draw any conclusions about whether our results are generalizable to patients with the highest level of anxiety.

We encountered a few obstacles in the course of recruiting patients into this study. Some parents approached for consent expressed skepticism or distrust in response to the suggestion that hypnosis might be clinically useful for their children. Other common reasons given for not participating in the trial were religious and/or cultural beliefs, concern that it would take up too much time, and other or not given. Although the researcher made every effort to define clinical hypnosis early in the conversation and dispel any concerns the family or patient might have had, and although the families were assured that participation in the study would in no way affect the amount of time they spent in the Emergency Department, misunderstandings about hypnosis and unwillingness to participate in research did limit somewhat the number of patients recruited into our study.

An additional problem with the study involves the possible presence of confounders. Subjects were asked to rate pre- and post-procedural pain and anxiety by the same person who obtained consent and administered the hypnosis (if the child was in the hypnosis group). Although the researcher remained in the room and interacted with the child in a friendly and warm manner during all control procedures, it is possible that children felt a stronger connection to the researcher when they were randomized to the hypnosis group than when they were randomized to the control group, and that this impacted on their pain and anxiety ratings. In addition, any questions answered by the patients or parents after group assignment was revealed could have been affected by knowledge of the group assignment or expectations about hypnosis.

Although limited by small sample size and concomitant lack of statistical power at this time, our data suggest that hypnosis may decrease anxiety associated with IV line

placement in school-age and adolescent children in the Pediatric Emergency Department. If data from the remaining study subjects supports our hypothesis, it will make an important contribution to the literature, which focuses on alleviating the pain of IV placement but does not adequately address the issue of anxiety. Our preliminary data are inconclusive with respect to alleviation of pain, but observations made during the course of the study suggest that pain scores may differ between groups once enrollment is complete.

Once enrollment in this study is complete, we will rerun the analyses detailed above to determine the effect of hypnosis on children's ratings of pain and anxiety associated with their IV line placement. In addition, we will analyze for covariates and investigate whether baseline EASI scores, preprocedural anxiety and expected pain ratings, and children's medical history play any role in influencing the response to hypnosis.

Thus far, one researcher (MM) has guided the hypnotic intervention in all but two cases. As enrollment continues, we will also be looking for an effect of formal training in hypnosis on the effectiveness of the intervention. Maya Maxym has participated in a twenty-hour basic hypnosis training workshop administered by ASCH (The American Society for Clinical Hypnosis), but has limited experience as a pediatric clinician. In contrast, Linda Arnold comes to the project, as a Pediatric ED attending, with many years of experience interacting with children; however, her hypnosis training consisted only of introductory readings and a one-hour training session with an ASCH-trained pediatric anesthesiologist, Haleh Saadat. We hypothesize that the presence or absence of formal hypnotic training will not significantly affect outcomes of children randomized to the

hypnosis group; however, at this time we have no data to support or refute this hypothesis. If this hypothesis is supported by our data, it will have important implications for the generalizability of the intervention, as clinicians will be able to learn to use hypnosis without having to devote several days to learning hypnotic techniques.

If our final results support the conclusions drawn from this preliminary data, future studies would be indicated to look at whether the benefits are generalizable to other minor procedures (e.g. venipuncture, LP, suture laceration, NG tube placement) in the emergency setting, and/or to similar procedures on inpatient floors. Ultimately, it would be fruitful to compare child life interventions with hypnosis, with the thought that if hypnosis is helpful to any significant subset of children for whom distraction techniques do not work, or if hypnosis shows greater clinical benefit than distraction, it could be taught both to members of the medical team and the child life team.

Appendix: Two Sample Hypnotic Intervention Scripts

I.

Why don't you start by allowing yourself to become completely comfortable on the bed. Wiggle your fingers and toes, do any fidgeting that you need to do, and then start to notice how completely the bed supports your weight. Allow your feet to flop however they want to, and allow your arms to rest comfortably by your side. [Pause]. Good. Now why don't you start by taking a few really nice, deep, relaxing breaths while we get ready for our daydream. [following pt's breathing pattern] In… and out… and in… and out. Good. That's right. Notice how with each breath you start to feel just a little more calm, a little more relaxed, a little more comfortable. Just notice and enjoy that feeling.

And now why don't you imagine that you're just arriving at your favorite sledding spot. Wherever it is, just imagine it. Look around, and notice how the sun is sparkling on the fresh, white snow. Feel how cold the air is on your face, but how comfortable and warm you feel all layered up in your snow pants and coat and hat and gloves. Notice who's with you. You don't have to tell me, but just notice. Perhaps you are with your brother or sister, or a cousin you really love, or a friend from school. Whoever it is, just notice that they're there, say hello to them in your imagination, and let them say hello back.

Now why don't you grab your sled and start walking up the hill so that you can sled down it. Notice how the snow feels under your boots. Is it crunchy, with just a little ice crust on the top, or is it fluffy so that you sink in with every step? Make the snow just

the way you like it, your very favorite snow, because you're in charge here. Good. Feel yourself pulling your sled up the hill. Notice what color your sled is, what it's made of, how it feels to pull it up the hill. And now why don't you get yourself to the top of the hill so that you can sled all the way down, all the way. Are you at the top now? [pt nods or answers "yes"]. Good. Take just a minute to look around before you go down the hill. Pay attention to what you can see. Are there trees nearby covered in snow? Can you see some cars on the road, or some rocks, or other people going up or down the hill? I don't know what you see, but you do… just notice it. Take a deep breath, and feel the cold air in your nose. Sit down on your sled, aim it in just the right direction, dig your heels into the ground, and push yourself so that now you're flying down the hill. Allow that hill to be as long as you want it to be. You can go as fast as you like for as long as you like. You can go around curves or just go straight, whatever you want. If you start to go too fast, that's fine, just slow yourself down; if you want to go faster, go faster. Can you feel the snow slippy-sliding under your sled? Can you feel yourself going down… and down… and down that hill, and with each part of your trip down you feel yourself going deeper and deeper into this pleasant trance. Deeper, and deeper. Can you feel the wind in your hair? Can you feel yourself going down that hill, just the way you like it? Good.

Now imagine that your right glove has fallen off, and so has the right sleeve of your coat. Just imagine that you can unzip it right at the shoulder. As you keep sledding down the hill, reach out and touch the snow with your right hand and arm. Take some of that snow in your other hand, and just rub it all the way up your arm to your elbow. Good. Notice how that one arm is starting to feel cold, so cold, so very, very cold. Feel how the wind is blowing on your cold, cold arm and making it even colder, so that you

start to get a pleasant tingly feeling all up and down your arm, and, by now, you're surprised and glad to notice that you almost can't feel your arm at all. Pack the snow onto your arm, thick and cold and sparkly, and at the same time, keep flying down the hill on your sled. Feel the wind in your hair, on your face, in your coat, and above all on your arm, skimming little tiny puffs of snow off the packed snow on your arm, with each puff making your arm colder and colder, more and more numb.

And there's a little part of you that knows that a different arm in a hospital room is getting a poke [sign to nurse to start IV line placement], but you don't have to worry about that at all, because you're out in the snow, having a great time, sledding down the longest, slipperiest hill you've ever sledded down in your life, and your arm is so cold that you just might not be able to feel it at all. Hold on tight, because you might find yourself going a little faster and a little faster right now. Feel the wind cooling your arm even more, hear the wind rushing by your ears, feel the slippery hill under your sled as you keep going down… and down… and down… and down. [IV now done] And now you might get ready to notice that your IV is all done and that it's time to come back to the hospital room. You can stay on that hill for a couple more minutes, enjoying that feeling of sledding on a perfect winter day, but why don't you slowly start wiggling a couple fingers and toes, getting ready to open your eyes [if they are closed], and letting us know that you're completely back here. [voice tone changes to a much more professional tone] That's right, you did really well with that, great job! Are you feeling like you're all back now? Good.

II.

Are you ready to take that trip to Disneyworld that we talked about? You are? Good. So why don't you start by getting all comfy on your bed, letting your feet flop out to the side, holding that teddy of yours nice and tight, and letting yourself get on the fastest pretend plane ever to Disneyworld. Forget about your suitcase, forget about the boring airport, just fly on down to Florida, right now, and walk in the gate of Disneyworld, right now, because this is your imagination and you're in charge of it. Look at the gate, notice its shape, how tall it is, where you walk through, how excited you feel as you walk into this incredibly special place. Are you there yet? [Patient nods]. Good. Now why don't you look around you, and start to notice what you can see. Maybe you see the sun shining on the pavement, the roller coaster over there, people waiting in line for a ride, someone selling all different colors of cotton candy… Take a look around and notice who's with you. Is it your mom, or your dad, or your friend from school, or is it just you? Make it be just the way *you* want. If anyone's with you, why don't you give them a smile and say hello, in your imagination. Good.

Now take a deep breath, and notice what you can smell. Are there smells of food, or people's sunscreen, or flowers? Just notice. And listen: what can you hear? Are people shouting on the roller coaster, or is there music playing? Now why don't you start walking over to your favorite ride, to the teacup ride that you told me about. With each step along the path to the teacup ride, allow yourself to get more comfortable, allow yourself to go deeper and deeper into this comfortable state of relaxation, just keep walking, step by step, and allow yourself to go deeper and deeper, so that by the time you get to the teacup ride, you will be very deeply in trance.

As you walk, keep noticing what's around you. Keep taking those breaths to see what you can smell, feel the warm pavement under your feet, touch something as you walk by it, let your ears hear any music or any happy sounds that are there in Disneyworld. Are you ready to get on the teacup ride yet?

Good. Why don't you get into your favorite teacup. I don't know which one is your favorite, but that doesn't matter, because what matters is that you choose your favorite one. Is it blue, or pink, or yellow, or is it lots of different colors? Notice the colors as you climb in and get ready for the ride to start. Feel the plastic seat underneath you and against your back, and lean back comfortably against it if you'd like to. Now hear the music starting, and feel your teacup starting to turn, slowly at first, and then a little faster. Feel yourself keep turning and turning, turning and turning, until the only thing you can feel is that pleasant feeling of turning, round and round, round and round. Look at whoever's with you in the teacup, and let yourself feel glad to be here, now, with that special person. Feel the warm sunshine on the skin of your arms and on your face. Feel yourself turning and turning, as the music keeps playing. Turning… and turning. Just turning and turning.

And there's a part of you that knows that that arm in the hospital will be getting its IV around now, but you, you don't need to worry about it at all, because you're turning and turning, round and round, in your favorite teacup. And if anything starts to bother you at all, just let yourself turn and turn, and let the music get louder and louder, until it completely drowns out anything else. That's right. [signal to nurse to begin procedure] Just keep turning and turning, turning and turning, feeling your body there, in the teacup, feeling the seat against your back, the warm sun on your hair, hearing the

music, and feeling the comfortable, fun turning feeling of the teacup ride. Listen to the music, see if you can feel the beat of the music in rhythm with your turning and turning, turning and turning. Just keep going round and round in your favorite teacup. Look at whoever's with you and notice how they're enjoying this ride too. Look around, and see other kids enjoying it. Feel the sunshine, and smell the delicious smells of all the Disneyworld treats wafting your way as you keep turning and turning, turning and turning, in your special, wonderful teacup.

And now, slowly, notice that the teacup is slowing down and the ride is almost over. Let yourself enjoy it for just a moment more, but start getting ready to come back to this room… Your IV is all done now, and it's time for you to come back to your room in the Emergency Department. Ok, open your eyes, look around, and let me know when you feel like you're all back here and not at Disneyworld any more. Great.

References

1. Maurice S.C., O'Donnell J.J., Beattie T.F. 2002 Emergency analgesia in the paediatric population. Part 1: current practice and perspectives. *Emerg Med J*. 19: 4-7.
2. Schechter, N.L. 1989. The undertreatment of pain in children: an overview. *Pediatr Clin North Am*. 36(4): 781-794.
3. Gerik S.M. 2005. Pain management in children: developmental considerations and mind-body therapies. *South Med J*. 98(3): 295-302.
4. Schechter N.L., Berde C.B., Yaster, M. 1993. Pain in infants, children, and adolescents: an overview. In *Pain in Infants, Children, and Adolescents*. Schechter N.S., Berde C.B., Yaster, M., editors. Baltimore: Williams & Wilkins. 3-9.
5. O'Donnell J.J., Maurice S.C., Beattie T.F. 2002. Emergency analgesia in the paediatric population. Part III: nonpharmacological measures of pain relief and anxiolysis. 19: 195-197.
6. Brent A.S. 2000. The management of pain in the emergency department. *Pediatr Clin North Am*. 47(3): 651-679.
7. Eland J.M., Anderson J.E. 1977. The experience of pain in children. In *Pain: A Source Book for Nurses and Other Professionals*. Jacox AK, editor. Boston: Little, Brown. 453-473.
8. Walsh B.M., Bartfield J.M. 2006. Survey of parental willingness to pay and willingness to stay for "painless" intravenous catheter placement. *Pediatr Emerg Care*. 22(11):699-703.
9. Klein E.J., Shugerman R.P., Leigh-Taylor K., Schneider C., Portscheller D., *et. al.* 1995. Buffered lidocaine: analgesia for intravenous line placement in children. *Pediatrics*. 95(5):709-12.
10. Lander J., Hodgins M., Nazarali S., McTavish J., Ouellette J., *et. al.* 1996. Determinants of success and failure of EMLA. *Pain*. 64(1):89-97.
11. Jimenez N., Bradford H., Seidel K.D., Sousa M., Lynn A.M. 2006. A comparison of a needle-free injection system for local anesthesia versus EMLA for intravenous catheter insertion in the pediatric patient. *Anesth Analg*. 102(2): 411-414.
12. Sethna N.F., Verghese S.T., Hannallah R.S., Solodiuk J.C., Zurakowski D., *et. al.* 2005. A randomized controlled trial to evaluate S-Caine patch for reducing pain associated with vascular access in children. *Anesthesiology*. 102 (2): 403-408.
13. Kleiber C., Sorenson M ., Whiteside K., Gronstal B.A., Tannous R. 2002. Topical Anesthetics for intravenous insertion in children: a randomized equivalency study. *Pediatrics*. 110(4): 758-761.
14. Sinha M., Christopher N.C., Fenn R., Reeves L.R. 2006. Evaluation of nonpharmacologic methods of pain and anxiety management for laceration repair in the Pediatric Emergency Department. *Pediatrics*. 17(4): 1162-1168.
15. McGrath P.A. 1990. *Pain in children: nature, assessment, and treatment*. New York: The Guilford Press. 466pp.
16. Liebelt, E.L. 1996. Reducing Pain during Procedures. *Curr Opin Pediatr*. 8(5):436-441.
17. Gold J.I. 2006. Effectiveness of Virtual Reality for Pediatric Pain Distraction during IV Placement. *Cyberpsychol Behav*. 9 (2): 207-212.

18. Uman L.S., Chambers C.T., McGrath P.J., Kisely S. 2007. Psychological Interventions for Needle-Related Procedural Pain and Distress in Children and Adolescents. *Cochrane Database Syst Rev*. 1.
19. Saadat H., Drummond-Lewis J., Maranets I., Kaplan D., Saadat A., *et. al*. 2006. Hypnosis reduces preoperative anxiety in adult patients. *Anesth Analg*. 102(5):1394-6.
20. Haanen H.C., Hoenderdos H.T., van Romunde L.K., Hop W.C., Mallee C., *et. al*. Controlled trial of hypnotherapy in the treatment of refractory fibromyalgia. 1991. *J Rheumatol*. 18(1):72-5.
21. Gonsalkorale W.M., Whorwell P.J. 2005. Hypnotherapy in the treatment of irritable bowel syndrome. *Eur J Gastroenterol Hepatol*. 17(1):15-20.
22. Olness K., MacDonald, J.T., Uden D.L. 1987. Comparison of self-hypnosis and propranolol in the treatment of juvenile classic migraine. *Pediatrics*. 79(4):593-597.
23. Hackman, R M. Stern, J S. Gershwin, M E. 2000. Hypnosis and asthma: a critical review. *J Asthma*. 37(1):1-15.
24. Stewart, J.H. 2005. Hypnosis in Contemporary Medicine. *Mayo Clin Proc*. 80(4): 511-524.
25. Kuttner L., Bowman M., Teasdale M. 1988. Psychological treatment of distress, pain, and anxiety for young children with cancer. *J Dev Behav Pediatr*. 9(6): 374-381.
26. Zeltzer L and LeBaron S. 1982. Hypnosis and nonhypnotic techniques for reduction of pain and anxiety during painful procedures in children and adolescents with cancer. *J Pediatr*. 101(6):1032-5
27. Wild M.R., Espie C.A. 2004. The efficacy of hypnosis in the reduction of procedural pain and distress in pediatric oncology: a systematic review. *J Dev Behav Pediatr*. 25(3): 207-213.
28. Milling L.S., Costantino C.A. 2000. Clinical Hypnosis with children: first steps toward empirical support. *Int J Clin Exp Hypn*. 48: 113-137.
29. Butler L.D., Symons B.K., Henderson S.L., Shortliffe L.D., Spiegel, D. 2005. Hypnosis reduces distress and duration of an invasive procedure for children. *Pediatrics*. 115: 77-85.
30. Liossi, C., White P., Hatira P. 2006. Randomized clinical trial of local anesthetic versus a combination of local anesthetic with self-hypnosis in the management of pediatric procedure-related pain. *Health Psychol*. 25(3): 307-315.
31. Iserson, K.V. 1999. Hypnosis for Pediatric Fracture Reduction. *J Emerg Med*. 17 (1): 53-56.
32. Bierman S.F. 1989. Hypnosis in the Emergency Department. *Am J Emerg Med*. 7(2): 238-242.
33. Hammond D.C. 1998. *Hypnotic Induction and Suggestion*. Chicago: ASCH. 175 pp.
34. Olness K., Kohen D. 1996. *Hypnosis and Hypnotherapy with Children*. 3rd ed. New York: Guilford Press. 457pp.
35. Anon. 1958. Medical Use of Hypnosis. *JAMA*. 168(2):186-189.
36. www.apa.org/divisions/div30, accessed 3/20/07
37. Kuttner L., Solomon R. 2003. What is Hypnosis? In *Pain in Infants, Children, and Adolescents*. Schechter N.S., Berde C.B., Yaster, M., editors. 2nd ed. Baltimore: Williams & Wilkins. 317-327.

38. Chen E., Joseph M.H., Zeltzer L.K. 2000. Behavioral and cognitive interventions in the treatment of pain in children. *Ped Clin N Am.* 47: 513-25.
39. Kuttner L. 1988. Favorite stories: a hypnotic pain-reduction technique for children in acute pain. Am J Clin Hypnosis. 30(4): 289-295.
40. Melzack R., Wall P.D., editors. 2003. *Handbook of pain management : a clinical companion to Wall and Melzack's Textbook of pain* / edited by. Edinburgh : Churchill Livingstone. 753pp.