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Clinical Practice Guideline: Needle-Related or Minor Procedural Pain in Pediatric Patients

Clinical Question

Is there evidence of pain and distress reduction in pediatric patients who receive analgesic or anxiolytic interventions during needle-related or minor invasive procedures in the emergency department?

Background and Significance

Approximately 17% of children in the United States visited the emergency department (ED) in 2016 (National Center for Health Statistics, 2017). During these ED visits, pediatric patients frequently experience invasive procedures including intravenous (IV) catheterization, bladder catheterization, venipuncture, immunization administration, and nasogastric tube placement. These procedures contribute to the stress and anxiety of treatment in the ED for pediatric patients (Ali, McGrath, & Drendel, 2016; Babl et al., 2009; Farion, Splinter, Newhook, Gaboury, & Splinter, 2008). Because procedural pain is commonly associated with ED visits, safe and effective interventions addressing pain in the pediatric population are essential. Researchers have revealed deficiencies in ED pain assessment and management, particularly with children (Ali et al., 2016).

Common causes of fear and anxiety in children presenting to the ED include the use of needles and a child's perceived lack of control, which may lead to a long-term adverse impact on their psychological well-being (Ali et al., 2016; Miller et al., 2016). Current management of pediatric pain is often inadequate, and the presence of moderate pain likely plays a significant role in negatively shaping the pain response to future events (Ali et al., 2016; Trottier, Ali, May, & Gravel, 2015). Barriers to adequate pain management for invasive procedures include the misperception that managing procedural pain is overly time-consuming and results in treatment delay, the misrepresentation of pain as anxiety, a lack of pain assessment, inadequate knowledge of pharmacological and non-pharmacological pain management strategies, and fear of adverse reactions to medications (Spanos et al., 2008). There is a relationship between pain and anxiety (Chieng, Chan, Klainin-Yobas, & He, 2014). The reduction of anxiety may therefore influence the child's perception of pain during and after painful procedures (Chieng et al., 2014). Evidence exists regarding effective pain management, yet use of this evidence in clinical practice may be less than optimal (Twycross, Forgeron, & Williams, 2015). With the knowledge that there is a relationship between pain and anxiety, pain management should focus not only on preventing pain, but also on preventing anxiety and providing adequate pain and anxiety management during painful procedures (Merritt, 2014).

This Clinical Practice Guideline (CPG) focuses on needle-related procedures. The lack of published data on the treatment of procedural pain associated with urinary bladder catheterization and nasogastric tube placement in pediatric ED patients precludes recommendations for these practices.

Methods

This CPG was created based on a thorough review and critical analysis of the literature following the ENA Clinical Practice Guidelines Development Manual (ENA, 2018). All articles relevant to the topic were identified in a comprehensive literature search. Searches were performed using: PubMed, CINAHL, The Cochrane Library, British Medical Journal, Agency for Healthcare Research and Quality, and the National Guideline Clearinghouse. Searches were conducted with the search terms "pediatrics", "procedural pain", "minor procedures", "emergency department", "intravenous cannulation", "anxiety", and "pain", using a variety of search combinations. Searches were limited to English language articles on human subjects. The

original search included January 2005–October 2014. A new search was conducted, following the guidelines used for the initial search, that included October 2014 to February 2018. In addition, the reference lists in the selected articles were scanned for pertinent research findings. Meta-analyses, systematic reviews, and research articles from ED settings, non-ED settings, position statements, and guidelines from other sources were reviewed. Clinical findings and levels of recommendation regarding patient management were made by the CPG Committee according to ENA's classification of levels of recommendation for practice (Table 1). The articles reviewed to formulate the recommendations in this CPG are described in Appendix 1.

Table 1. Levels of Recommendation for Practice

Level A Recommendations: High
• Reflects a high degree of clinical certainty • Based on availability of high quality level I, II, and/or III evidence rated using the Melnyk and Fineout-Overholt grading system (Melnyk & Fineout-Overholt, 2015) • Based on consistent and good quality evidence; has relevance and applicability to emergency nursing practice • Is beneficial
Level B Recommendations: Moderate
• Reflects moderate clinical certainty • Based on availability of Level III and/or Level IV and V evidence rated using the Melnyk and Fineout-Overholt grading system (Melnyk & Fineout-Overholt, 2015) • There are some minor inconsistencies in quality evidence; has relevance and applicability to emergency nursing practice • Is likely to be beneficial
Level C Recommendations: Weak
• Has limited or unknown effectiveness • Level V, VI, and/or VII evidence rated using the Melnyk and Fineout-Overholt grading system (Melnyk & Fineout-Overholt, 2015) - Based on consensus, usual practice, evidence, case series for studies of treatment or screening, anecdotal evidence, and/or opinion
Not Recommended for Practice
• No objective evidence or only anecdotal evidence available, or the supportive evidence is from poorly controlled or uncontrolled studies • Other indications for not recommending evidence for practice may include: ◦ Conflicting evidence ◦ Harmfulness has been demonstrated ◦ Cost or burden necessary for intervention exceeds anticipated benefit ◦ Does not have relevance or applicability to emergency nursing practice • There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. For example: ◦ Heterogeneity of results ◦ Uncertainty about effect magnitude and consequences ◦ Strength of prior beliefs ◦ Publication bias

Summary of Literature Review

This summary of the literature is organized with a review of pain scales that can be used to evaluate pain in the pediatric population followed by the relationship of anxiety to pain response along with supporting research. There are a variety of measures used to reduce pain and anxiety in the pediatric patient, and the review of the literature includes the following measures: psychological and behavioral interventions (hypnosis, distraction, virtual reality, music, clown therapy, animal therapy, coaching, parent information and preparation, breastfeeding and skin-to-skin contact, and holding), and topical pharmacological interventions (vapocoolant sprays and local application of ice and vibration), use of sucrose, and local anesthetic preparations (subdermal local anesthetic with needlefree delivery).

PAIN SCALES

Pain management in the pediatric population presents challenges for emergency nurses. A thorough initial pain assessment along with ongoing assessment is vital for successful pain management (Tanabe, Holleran, & Reddin, 2009). In the pediatric population, the use of developmentally appropriate pain assessment scales is essential (Pasek, Wright, & Campese, 2003). As with adults, self report remains the clinical standard when assessing a child's pain (Tanabe et al., 2009). Because the pain experience is subjective, the emergency nurse incorporates the child's caregiver's report while also taking into consideration the child's age, gender, race, culture, cognition, emotions, and previous experiences (Tanabe et al., 2009). Children as young as three years of age may be able to quantify pain intensity levels with the use of simple pain scales (Pasek et al., 2003).

Standardized pediatric pain scales include the N-PASS (Neonatal Pain, Agitation, and Sedation Scale) (Hummel, Puchalski, Creech, & Weiss, 2008), r-FLACC (facial expression, leg movement, activity, cry, and consolability) (Malviya, Voepel-Lewis, Burke, Merkel, & Tait, 2006), Wong-Baker FACES (Wong & Baker, 1988), and the visual analog scale. The N-PASS is a validated scale for pre-term and term infants used to assess those less than three months old (Pasek et al., 2003). The r-FLACC may be used for children from three months to three years of age along with cognitively impaired children and those unable to use a subjective scale. The Wong– Baker FACES scale is used for children three years of age and older. Children eight years of age and older are also able to use a visual analogue scale (Stapleton, 2018).

ANXIETY

Anxiety increases a person's awareness of pain owing to increased sympathetic responses to pain stimuli. Pain thresholds are reduced by the increased awareness and can result in increased pain for a particular procedure (Chieng et al., 2014). Chieng et al. (2014), in a systematic review of 10 studies, evaluated the relationship between pre-operative anxiety and postoperative pain in children and adolescents undergoing elective surgical procedures. Eight of the 10 studies evaluated the relationship between pain and anxiety. Pre-operative anxiety in children and adolescents was correlated with higher postoperative pain. Four of the studies reviewed reported statistically significant correlations between pre-operative anxiety and pain (2 studies $p < 0.001$; 2 studies $p < 0.05$). Three of the studies reviewed evaluated postoperative anxiety and pain, and found correlations that were significant at $p < 0.01$ (2 studies) or 0.05 (1 study). The authors suggested that the evaluation of pain should include management of the patient's anxiety owing to the effect that anxiety has on pain perception and subsequent pain. Several studies indicated that the use of distraction in addition to analgesia reduces children's anxiety during painful procedures (Chieng et al., 2014; Felluga, et al., 2016; Goettems, Zborowski, Costa, Costa, & Torriani, 2017; Hyland, D'Cruz, Harvery, Moir, Parkinson, & Holland, 2015; Matziou, Chrysostomo, Vlahioti, & Perdikaris, 2013; Meiri, Ankri, Hamad-Saied, Konopnicki, & Pillar, 2016).

PSYCHOLOGICAL/BEHAVIORAL INTERVENTIONS

Pain management interventions include a variety of distraction techniques. These may be described as cognitive, behavioral, or cognitive–behavioral measures, and include other interventions such as hypnosis or teaching coping skills. These can be used to decrease pain or distress in children or adolescents during procedures that involve needles (Uman et al., 2013). Multiple studies address the effects of cognitive–behavioral interventions for needle-related procedures in children and adolescents. Techniques aimed at modifying emotions and behaviors can be a combination of cognitive behavioral interventions (Chambers, et al., 2009; Uman et al., 2013). Distraction techniques include listening to music, watching videos, interactions with clowns and animals, storytelling, or talking about another topic to decrease the anxiety, distress, and pain experienced by children and adolescents during painful procedures (Felluga et al., 2016; Uman et al., 2013; Vagnoli et al., 2015; Wolyniez et al., 2013). Chambers et al. (2009) define distraction in terms of child-directed distraction, such as video, music, or story playing; parent-led distraction, where parents are instructed on how to distract the child; or nurse-led distraction, where nurses are instructed on how to distract the child. Parent coaching is an intervention where parents are instructed to provide assistance to the child using techniques such as humor, nonprocedural talk, toys, pacifier, or rocking (Chambers, et al., 2009). Uman et al. (2013) describe cognitive interventions as those that provide positive statements and thoughts to replace negative beliefs and attitudes, and behavioral interventions as those that use movies, for example, to replace negative behavior. Cognitive interventions studied include various distraction methods, preparation and education, and suggestion (positive verbal comments to the child by the nurse). Behavioral interventions include behavioral distraction through virtual reality, audiovisuals, games, muscle relaxation, and breathing exercises.

Hypnosis

Hypnosis has been used for over 250 years in various fields of medicine and has been used at times by emergency clinicians (Iserson, 2014). Hypnosis is beneficial because it can reduce individuals' subjective and objective perception and an individual's emotional response to pain (Iserson, 2014). In the emergency setting, hypnosis has been used for pediatric patients undergoing incision and drainage, foreign-body removal, suturing, and reduction of fractures and dislocations (Iserson, 2014). Hypnosis has been found to be effective in reducing needle-related procedural pain and distress in a variety of settings (Birnie et al., 2014; Curtis, Wingert, & Ali, 2012; Uman et al., 2013). Birnie et al. (2014), in a systematic review and meta-analysis of 7 hypnosis trials including 222 children ages 3–16 years, found hypnosis significantly reduced children's self-reported pain and distress during needle related procedures (SMD $= -1.32$, 95% CI $[-1.88, -0.75]$, $Z = 4.55$, $p < 0.01$, $I2 = 0\%$). There was also a reduction in behavioral measures of distress when hypnosis was used. Curtis et al. (2012), in a review of hypnosis interventions, found that hypnosis reduced self-reported pain (SMD $= -1.69$, 95% CI $[-2.76, -0.62]$), self-reported distress (SMD $= -.260$, 95% CI $[-4.06, -1.15]$) and behavioral measures of distress (SMD $= -1.36$, 95% CI $[-2.16, -0.56]$) in children undergoing bone marrow procedures, lumbar puncture (LP), or venipuncture related to cancer treatment or cancer monitoring procedures. Uman et al. (2013), in a systematic review of five randomized control trials (RCTs), found a significant effect ($Z = 2.97$, $p = 0.003$) on the reduction of self-reported pain with the use of hypnosis (SMD $= -1.40$, 95% CI $[-2.32, -0.48]$) and I2 of 85%) to reduce procedural pain and distress. In a variety of clinical areas with trained individuals to provide hypnosis, hypnosis has been found to be effective in reducing procedural pain and distress. However, not all individuals are receptive to the practice of hypnosis (Uman et al., 2013).

Distraction

Distraction techniques that have been evaluated to reduce procedural pain and distress in children and adolescents include a variety of psychological interventions such as breathing exercises or the use of toys with breathing, videos, distraction cards, kaleidoscopes, balloons, play dough, bubble making, music, and clowns. Rezai, Goudarzian, Jafari-Koulaee, & Bagheri-Nesami (2016) performed a systematic review of 31 RCTs and 2 review articles and reported that distraction techniques

(music, animation, audio-visual such as cartoons, video games, virtual reality, squeezing rubber balls, distraction cards, ice massage, bubble making, kaleidoscope, breathing exercise, and touching the palm of the hand) can reduce pain for children during venipuncture. In a meta-analysis of 26 RCTs that evaluated the effects of distraction in 2,548 children between the ages of 2 and 19 years, Birnie et al. (2014) found significant reductions in self-reported pain and distress, and in behavioral measures of distress in middle childhood (6 to 11 years of age) (SMD = −0.57, 95% CI [−0.88, −0.27], Z = 3.64, $p < 0.01$, I2 = 89%). Uman et al. (2013) completed a systematic review and found support for distraction for reduction of self-reported pain, but no clear evidence to support a specific type of distraction. Chambers et al. (2009) conducted a meta-analysis of RCTs and quasi-experimental studies to examine the efficacy of different psychological interventions during immunizations in children 0 through 18 years of age. They concluded that breathing exercises are an effective intervention for reducing self-reported pain, observer-rated distress, and nurse-reported distress. Distraction can either be directed by the child (e.g., watching a video or listening to music with headphones), parent (i.e., parents educated on how to provide age-appropriate distraction), or nurse (i.e., a nurse educated on how to provide age-appropriate distraction). Chambers et al. (2009) found sufficient evidence to support child-directed distraction as a method to reduce self-reported pain during immunizations. Both parent- and nurse-initiated distraction had an effect on reducing observer-rated pain, but the results were not statistically significant (Chambers et al., 2009). In six trials including 368 children (3–9 years old), breathing techniques in which children are directed to blow on a toy (pinwheel or blowing bubbles) showed a benefit for pain reduction (SMD = −0.49, 95% CI [−0.85, −0.13]) (Birnie et al., 2015).

Distraction cards (visual cards with pictures or shapes) have been compared with other techniques such as the use of a kaleidoscope or music and balloon inflation. Canbulat, Inal, and Sonmezer (2014) conducted a study of 188 children (mean age 8.8 ± 1.5 years) and compared distraction cards, use of a kaleidoscope, and a control group, and found that self-reported pain levels and procedural anxiety were significantly lower with the use of distraction cards ($p = 0.001$) and the kaleidoscope ($p < 0.001$) when compared with the control group. The distraction card group was significantly lower for both self-reported pain and anxiety than the kaleidoscope and control groups. Şahiner and Bal (2016) compared the use of distraction cards, listening to cartoon music, and balloon inflation with a control group. The study included 120 children (mean age 9.1 ± 1.6 years) and found a significant difference in self-reported pain among study groups ($p = 0.04$). Although not significant, lower pain levels ($p = 0.057$) were found in the distraction card group (2.33 ± 3.24) when compared with the control group (4.53 ± 3.23). They found no significant differences between parent and nurse–observer evaluations of procedural pain. Matziou et al. (2013), in an RCT, evaluated the effect of parents being close to a child during painful procedures. The study compared a parental presence group, a toy (kaleidoscope) group, and a control group for reduction of pain and anxiety in children during a painful procedure. Children who had a parent close to them during the procedure had a slower respiratory rate ($p < 0.001$), decreased pulse rate ($p < 0.01$), decreased stress ($p < 0.001$), and a decreased pain score ($p < 0.001$) when compared with the toy and control groups. The toy group also demonstrated a reduced intensity of pain and stress when compared with the control group ($p < 0.001$). They concluded that a toy, such as a kaleidoscope, is useful in reducing pain and stress in the pediatric patient, but not as effective as having a parent close during painful procedures. In an RCT, Mutlu and Balci (2015) compared balloon inflation to the use of a cough trick to evaluate reduction of pain during venipuncture in 9-to-12-year-olds. Children in the cough trick group were told to take a deep breath and then cough during the venipuncture procedure, and children in the balloon inflation group blew up a balloon during the venipuncture. The pain experience was lower in both groups when compared with the control group ($p < 0.001$). No significant difference in the mean scores for pain experienced were found between the cough trick and balloon inflation groups, suggesting that both interventions are equally effective.

Maghsoudi, Sajjadi, Vashani, Nekah, and Manzari (2015), in an RCT, compared the effect of play dough and bubble making on pain during venipuncture in children with a control group with no distraction (mean ages: play dough 4.5 ±1.1, bubble making 4.2 ± 1.1, control 4.3 ± 0.9 years). Both interventions were started five minutes before the procedure. The mean pain intensity reduction was significant between all three groups ($p < 0.001$). Play dough was found to be significantly more

effective than bubble making for reducing pain ($p < 0.009$) and was considered more effective than the use of bubbles or no distraction (play dough: 5.1 ± 1.8, bubble making: 6.2 ± 1.4, and control group: 8.2 ± 1.5).

Handheld electronic devices are another means for providing distraction for children during painful procedures. In an RCT, Burns-Nader, Joe, and Pinion (2017) ($N = 30$, aged 4 to 12 years) evaluated the use of a computer tablet with interactive games during hydrotherapy for burn treatment. The decrease in self-reported pain was not significant, but observed pain was significantly less for the tablet group (mean difference = 12.47) than the control group (mean difference = 18.53, $U = 67.00$, $p = 0.48$). The tablet group was found to have a moderate positive correlation between self-reported pain and observed pain ($rs(18) = 36$, $p = 0.052$). The tablet group had significantly less anxiety than the control group ($p = 0.001$) and returned to baseline more quickly after the procedure ($p < 0.005$). Miller et al. (2016), in an RCT ($N = 98$), evaluated Ditto™ (Diversionary Therapy Technologies, Brisbane, Australia), a handheld electronic device that provides preparation and distraction to reduce pain and distress during the insertion of an IV in the ED. Pain levels and distress were reduced in children using the Ditto™ device during both the preparation and the procedure when compared with the standard distraction (use of toys, nursing and caregiver interaction) ($p \leq 0.01$). The combined use of the Ditto™ before and during the procedure was found to have the greatest reduction (73%) in child reported distress. In another RCT, Stinley, Norris, and Hinds (2015) evaluated the effect of using a mandala intervention to reduce pain and anxiety in children ($N = 40$, ages 7 to 18) during needle sticks. The mandala intervention involved circle drawing as an outline and the patients using the circle as the focus to draw and color in and around. The group using the mandala had less stress ($p = 0.03$) and decreased anxiety ($p = 0.04$, SD = 1.66, Cohen's $d = 0.08$). The mandala group had a significant reduction in anxiety post-procedure when compared with pre-procedure anxiety ($p = 0.02$, SD = 1.57, Cohen's $d = 1$). Pre- and post-procedure anxiety did not change in the control group. In summary, various distraction methods have been shown to reduce procedural pain and anxiety.

Virtual Reality

Virtual reality has been used in various settings to decrease pain and anxiety. Goettems et al. (2017), in a systematic review, reported one study evaluating two treatment sessions using virtual reality eyeglasses at one visit and no device the next visit. Between the two treatment sessions, virtual reality eyeglasses were found to significantly decrease both anxiety and pain ($p < 0.001$). In an RCT of adolescents ($N = 28$) receiving burn care, Jeffs et al. (2014) compared the effects of virtual reality to passive distraction and standard care. Adolescents in the virtual reality group reported significantly less pain during the procedure than the passive distraction group (difference = 23.7 mm, 95% CI [2.4, 45.0], $p = 0.029$) and the standard care group (difference = 9.7 mm, 95% CI [−9.5, 28.9], $p = 0.32$). Of the three groups, the virtual reality group reported decreased pain perception after the procedure compared with pre-procedural pain. Patients who received opiate analgesics reported more pain during the procedure (95% CI [7.0, 37.1], $p = 0.004$).

Music

Listening to music has also been studied for reduction of procedural pain and anxiety in children. Yinger and Gooding (2015) evaluated music interventions for pain and/or anxiety during medical procedures in a systematic review of 50 RCTs. They found that 48% of the studies demonstrated a decrease in anxiety and 38% showed a decrease in reported pain with the use of the musical intervention during medical procedures. Eight of the 50 studies reviewed included pediatric populations. Yinger and Gooding (2015) concluded that the findings supported the use of musical interventions to reduce pain and anxiety during painful procedures in the pediatric population. Birnie et al. (2015) conducted a systematic review of RCTs and quasi-experimental studies, and reviewed 3 pooled trials on music as a distraction, finding reduced pain with children ($n = 417$)

(SMD = −0.45, 95% CI [−0.71, −0.81]) but no reduction of pain in adolescents (n = 118) (SMD = −0.04, 95% CI [−0.42, 0.34]). They concluded that musical distractions were beneficial for children but may not be for adolescents. In a systematic review of music therapy for painful medical procedures, Uman et al. (2013) found that passive music therapy (listening) was as effective as active (playing instrument or singing) music therapy for the reduction of pain. Hartling et al. (2013) conducted an RCT to evaluate the emerging use of technology in providing distraction and evaluated the use of music as a distraction technique with 3- to 11-year-old participants undergoing IV placement. The children were randomly assigned to either the music or non-music group during the process of IV placement. Although the sample size was small (N = 42), the children who had musical distraction had significantly less pain during IV placement as compared with the standard care group (p = 0.04).

Clown Therapy

The use of clowns as an intervention to reduce pain levels and anxiety in children during painful procedures has been investigated. Meiri et al. (2016), in an RCT of 100 patients (2 to 10 years of age), evaluated the use of a medical clown and EMLA (local anesthetic cream) to decrease pain, stress, and anxiety for children who had venous blood drawn or IV cannulation performed. The length of crying was measured before, during, and after the procedure. The evaluation of the child's pain and anxiety was measured by parents using the visual analog scale (VAS). The duration of crying was significantly lower in the medical clown group when compared with the control group (1.3 ± 2.0 vs. 3.8 ± 5.4 min, p = 0.01). The degree of pain was significantly lower in the EMLA group when compared with the control, but there was no significant difference between the EMLA group and the clown group. The parents' assessment of the child's anxiety for future venipunctures was significantly lower in the clown group than in the control or EMLA groups (2.6 ± 1.2 vs. 3.7 ± 1.3 or 3.8 ± 1.6, p < 0.01 for both).

The use of medical clowns for the reduction of pain and anxiety was evaluated in an RCT using clowns during painful procedures in patients presenting to a pediatric ED (Felluga et al., 2016). The Wong–Baker Scale was used for children 8 years of age or under and the Numerical Rating Scale for children over 8 years of age, along with anxiety scales. Forty patients were randomized into two equal groups (entertained by clown compared with entertained by parents or ED nurses). The pain levels were not affected by the use of a clown, but there was a significant decrease in the anxiety scores (p = 0.013) in the clown group.

Wolyniez et al. (2013) sought to determine the effect of the presence of a medical clown during IV insertions in an RCT (N = 47 patients, n = 26 for clown intervention) utilizing a modified block randomization technique to assure equal distribution of subjects. The Faces Pain Scale (children aged 3 to 7 years) and a 100 mm VAS (children older than 7 years) were used to assess pain. The State Trait Anxiety Inventory was used to measure anxiety. They found a tendency for the pain scores to be lower when the clown was present with younger children while they were unchanged with older children. There was a decrease in average pain score in the younger group, with the average score of 3.3 in the control group and 1.6 in the intervention group (p = 0.18), but this result was not statistically significant.

Ben-Pazi et al. (2017), in a quasi-experimental controlled trial, evaluated the use of a medical clown during the injection of botulinum toxin (BTX) in children with cerebral palsy (CP). The children with clown-care during the procedure had lower pain scores after the procedure (VAS after, 2.89 ± 1.36) when compared to children without clown-care (VAS after, 3.85 ± 1.39; p = 0.036). The effect of clown care on the children was moderate (Cohen's d = 0.71). The children with clown-care reported less pain than expected (VAS before–VAS after: mean −0.34 ± 1.58, n = 19) and the standard care children reported greater pain after the procedure (mean +0.74 ± 1.78, n = 19). With the second injection, the children in the standard care group received clown-care and the clown-care group in the first injection received standard care. When children received the second injection, children who had clowncare with the first injection reported less pain (VAS after 2.84 ± 1.38) when compared with children who had standard care with the first injection (4.11 ± 0.93; 2-tailed t-test, p = 0.032). The influence of

clown-care during the first injection was evaluated beyond the crossover trial and the effect of medical clowning on reported pain was influential in up to four recurrent injections ($p = 0.0139$).

The influence of medical clowning on the reduction of pain and anxiety among Bedouin ($n = 50$) and Jewish ($n = 19$) children (7.5 to 12 years) was evaluated by Gilboa-Negari, Abu-Kaf, Huss, Hain, and Moser (2017) in a mixed-method study design. The use of a medical clown was found to reduce pain ($p < 0.001$) and anxiety ($p < 0.01$) in both groups. Anxiety was reduced more in the Bedouin children than the Jewish children ($p < 0.01$). The variation in the reduction of anxiety between the two groups was evaluated using a regression model. Three variables that accounted for 73% of the variance were: pre-intervention anxiety, level of enjoyment of the clowning intervention, and the interaction of the verbal components of the intervention. The child's enjoyment of verbal humor was found to predict the level of anxiety after the clown intervention and was significantly higher among Bedouin children (34%) when compared with Jewish children (8%). This suggests that the effectiveness of interventions to decrease pain and anxiety may be influenced by cultural factors.

Animal Therapy

Animals have been used to assist children undergoing various medical interventions. Vagnoli et al. (2015) investigated the beneficial effects of animal-assisted interventions in children ($N = 50$) undergoing blood tests in a hospital in Florence, Italy. Children comfortable with the presence of a dog were invited to participate in the study. The children were told they were in a study about pain and behaviors. The intervention group was told a dog would be in the room while their blood was being drawn and the control group did not have a dog in the room. The Observation Scale of Behavioral Distress (OSBD-A), Wong–Baker Faces Scale, VAS, and State Trait Anxiety Inventory (STAI) were used along with serum cortisol plasma levels to determine if the presence of a dog during blood draw decreased anxiety, pain, and cortisol levels. The distress levels (as measured using the OSBD-A) of the intervention and control groups were compared before, during, and after the procedure and were significantly higher in the control group before procedure ($p = 0.18$) and during the procedure ($p = 0.46$), yet no significant difference in distress was found after the procedure between the two groups ($p = 0.244$). There were no significant differences in pain scores, yet cortisol levels were higher in the control group ($p = 0.34$). These results indicate that, for children who were comfortable being around dogs, the presence of a dog reduces distress.

Coaching

Coaching is another cognitive–behavioral intervention studied by numerous researchers. Riddell et al. (2015) conducted a systematic review and found parental involvement did not differ from non-parental distraction for the reduction of pain. Uman et al. (2013) updated their previous systematic review from 2006 and found only one study on parent coaching for self-reported distress. Uman et al. (2013) determined a recommendation could not be made for the reduction of distress using coaching during needlerelated procedural pain based on one study. Parent coaching effectively reduced the distress when rated by the observer, but was not effective on other pain-related variables during immunization (Chambers et al., 2009). McCarthy et al. (2014) evaluated three levels of predicted risk for procedural-related distress (mild, medium, or high) with three levels of distraction (parents with basic information, parents with enhanced instructions, and professionals). No significant differences were found for self-reported pain between the three groups for predicted level of distress and the three levels of intervention. When the professional was providing the intervention, however, there was less behavioral distress reported ($p = 0.07$).

Parent information/Preparation

Educating parents and providing information to prepare patients for procedures has been evaluated for effectiveness in decreasing pain and distress in children during procedures, with conflicting results. For example, in a systematic review that evaluated two studies ($N = 154$), Uman et al. (2013) found parent preparation and information did not have a significant effect on self-reported pain in children (SMD $= -0.22$, 95% CI [−1.20, 0.76]). Conversely, Taddio et al. (2015) reported that

education of parents (of infants to age 17 years) and individuals undergoing vaccination (3 years and older) before receiving the injection increased the use of pain interventions during the procedures (RR = 2.08, 95% CI [1.51, 2.86], n = 300). Education was also found to decrease fear in children before the procedure (SMD = 0.67, 95% CI [−1.28, −0.07], n = 51). Hyland et al. (2015) evaluated the use of Child Life Therapy (CLT) for the first dressing change of children less than 16 years of age (median age CLT group, 2.3 years; standard care group, 2.2 years). Before the procedure, the CLT group received preparation based on the age of the patient, education was provided to parents, and distraction techniques determined by the age of the child were provided by the therapist. The children in the CLT group had lower combined and scaled pain and anxiety scores (p = 0.02) during the treatment. Based on the more recent studies, parent education before pediatric procedures may be beneficial.

Breastfeeding/Skin-to-Skin Contact/Holding

Breastfeeding has long been known to provide multiple health benefits including physical comfort, nutrition, and relief of distress in infants up to two years of age (Taddio et al., 2015). Numerous behavioral strategies for infants include direct or indirect skin-to-skin contact with the infant's caregiver (Curtis et al., 2012). Taddio et al. (2015) recommended breastfeeding, skin-to-skin contact, and parental holding while infants receive vaccinations. Taddio et al. (2015), in a meta-analysis (N = 792 infants), identified breastfeeding as beneficial during vaccination (SMD = −1.78, 95% CI [−2.35, −1.22]). Lee, Yamada, Kyololo, Shorkey, and Stevens (2014), in a summary of pediatric clinical practice guidelines, recommended breastfeeding of infants during procedures whenever possible.

TOPICAL PHARMACOLOGICAL INTERVENTIONS

Vapocoolant Sprays

The use of ethyl vinyl chloride (mild topical anesthetic) in the ED has decreased over the past decade because of handling and storage requirements (The Joint Commission, 2013). Research on the use of ethyl vinyl chloride to reduce pain associated with pediatric needle-related procedures is limited, and its effectiveness appears to be related to patient age. Waterhouse, Liu, and Wang (2013) compared the effectiveness in reducing pain during IV insertion of vapocoolant spray (Pain Ease®) vs. a topical icepack. The patients (N = 95, aged 9 to 18 years) were randomly enrolled in either the Pain Ease® group or the topical ice group; the VAS was used to measure pain. The treatment was reported as more effective by the Pain Ease® group (76%) when compared with the topical ice group (49%). Changes from the baseline VAS were greater in the Pain Ease® group. Costello, Ramundo, Christopher, and Powell (2006) found that ethyl vinyl chloride vapocoolant spray failed to measurably reduce pain associated with IV cannulation in children aged 9–18 years. Farion et al. (2008) researched the effects of the Pain Ease® (pentafluoropropane and tetrafluoroethane) vapocoolant spray with children aged 6–12 years who required urgent intravenous catheterization. The achieved 15 mm pain reduction on the visual analogue scale was significant (mean difference = 19 mm, 95% CI [6, 32], p < 0.01).

Local Application of Ice and Vibration

Local application of ice has been used for treatment of pain in many areas of healthcare. A novel application of a device that combines local ice application with vibration was examined by Baxter, Cohen, McElvery, Lawson, and von Baeyer (2011). The Buzzy® (MMJ Labs, Atlanta, GA) was applied proximal to the planned location of the IV insertion and remained in vibration mode during the catheterization procedure. Researchers compared the Buzzy® to vapocoolants or distractions in an RCT with children aged 4 to18 years. Success rates with the Buzzy® were three times higher for first-attempt cannulations (odds ratio = 3.05, 95% CI [1.03, 9.02]), with significantly lower pain scores reported by parents (−2, 95% CI [−4, −2]). Canbulat et al. (2015) reported similar findings with Buzzy® as well as a significant (p <0.001) decrease in patient pain and anxiety. Another important benefit of the device was decreased time to intervention. The use of topical anesthetics such as

creams requires 30–60 minutes for absorption, while the Buzzy® can be used after as little as 3 minutes of training time for the patient (Canbulat et al., 2015). Faroukh, Pouraboli, Rostami, Jahani, and Mohsentavanaei (2016), Redfern, Chen, and Sibrel (2018), Şahiner, Inal, and Akbay (2015), and Schreiber et al. (2016) all reported improvements in needle-related pain with application of ice and vibration in the pediatric population. Redfern et al. (2018), in an RCT of 50 children aged 2 to 18 years, evaluated the use of cold and vibration (Buzzy®) in children receiving vaccinations. The Buzzy® group had significantly lower pain scores when compared with the control group (mean difference = −2.39, 95% CI [−0.48, −4.24], t = −2.53, p = 0.015). The use of Buzzy® reduced pain but did not have an effect on pre-procedural anxiety. Şahiner et al. (2015), in an RCT of 104 children, evaluated pain reduction during immunizations with the use of Buzzy® and reported significantly lower pain levels in the Buzzy® group (p = 0.001). Schreiber et al. (2016), in an RCT of 70 children (average age 9 years), found 91.4% of children in the Buzzy® group reported no or mild pain as compared to 61.1% in the no-intervention group (p = 0.003).

Sucrose

Sucrose solutions are often used as comfort measures in children. Harrison et al. (2015) updated the original 2011 Cochrane Review of studies addressing the pain-reducing effects of sweet solutions for painful needle-related procedures in children one to 16 years of age. Conflicting results were found for young children aged one to four years. Two studies demonstrated decreased crying time and pain score compared with a control group. However, when the data were pooled, there was no significant effect of sweet-tasting substances on crying time. In older children (7 to 12 years), sweet-tasting substances showed no effect on self-reported pain or unpleasantness during IM injection or venipuncture when compared with a control group. Harrison et al. (2017) in a cumulative meta-analyses on behavioral pain outcomes in neonates found sufficient evidence demonstrating that sweet solutions reduced crying time and pain intensity composite scores when compared with a placebo or no treatment (mean difference = −0.90, 95%, CI [−1.09, −0.70]). Desjardins et al. (2016) conducted an RCT to determine if the administration of sucrose decreased pain during needle placement in children 28 days to 3 months of age. Pain scores using the FLACC did not differ between groups, yet there was a significant difference in crying times. Wente (2013) conducted a systematic review to investigate the non-pharmacologic methods of pain management in pediatric ED patients (0 to 18 years of age) and found sucrose solutions decreased pain scores for children. In a systematic review, Hatfield, Chang, Bittle, Deluca, and Polomano (2011) sought to evaluate the efficacy and safety of oral sucrose as a procedural intervention for mild to moderate procedural pain in infants. A total of 46 RCTs were evaluated, and the investigators concluded that sucrose is an effective, convenient, safe, and immediate-acting analgesic for reducing crying time and significantly decreasing the bio-behavioral pain response following painful procedures in infants. Sethi and Nayak (2015) evaluated the use of a 24% sucrose solution used 2 minutes before venipuncture in 30 neonates (28–34 weeks and 35–40 weeks). The neonates first venipuncture was conducted using standard care and served as the control group. The same infants served also as the experimental group and received the 24% sucrose solution before the second venipuncture. The control group was observed to have greater pain (22 or 73.4%) compared with the sucrose group (2 or 6.7%). A significant reduction in pain was found in the sucrose group (p < 0.0001).

LOCAL ANESTHETIC PREPARATIONS

Multiple studies have addressed the use of various lidocaine preparations for needle-related procedures in different pediatric age groups. Lee et al. (2014) evaluated guidelines to assist the practitioner in pain management during IV cannulation in the pediatric population. The researchers strongly recommended topical medications for needle-related pain management in children of all ages. In a systematic review, Curtis, Wingert, and Ali (2012) reported that amethocaine is superior to EMLA

cream for pain reduction with intravenous cannulation in pediatric patients. According to Schmitz, Zempsky, and Meyer (2015), the use of a lidocaine powder preparation administered by needle-free jet injection was found to be effective in treating needle-related pain in the pediatric population ($p = 0.0022$). Taddio et al. (2015) strongly recommended that topical medications such as creams, gels, or patches be used, because they significantly reduced pain with vaccination in children twelve years and under. Sethna et al. (2005) compared a topical lidocaine patch (S-Caine Patch™) to a placebo in children aged 3–17 years. The researchers found that 59% of those in the intervention group reported no pain compared with 20% in the placebo group. In a similar study, Singer, Taira, Chisena, Gupta, and Chipley (2008) found a modest reduction in pain during IV cannulation with the application of a topical lidocaine/tetracaine patch in children aged 3–17 years ($p = 0.04$). Taddio, Soin, Schuh, Koren, & Scolnik (2005) evaluated the cannulation success rate using topical lidocaine vs. a placebo. The results showed a significant difference (74% vs. 55%) in cannulation at the first attempt for those in the intervention group. The results suggest that topical lidocaine preparations are capable not only of decreasing pain, but also of increasing the cannulation success rate.

SUBDERMAL LOCAL ANESTHETIC WITH NEEDLE-FREE DELIVERY

The use of needle-free systems that deliver local anesthetic into the dermal layers with a carbon dioxide injector (e.g. J-Tip®) have been investigated. The needle-free systems did not affect the success rate of IV cannulation on the first attempt. Spillman (2012) conducted a systematic review of four studies concerning needle-related pain in pediatric patients. The results indicated a reduction in pain between 25 and 47% with the use of needle-free lidocaine compared with control groups. Spanos et al. (2008) studied the J-Tip® application of 1% buffered lidocaine prior to peripheral intravenous (PIV) insertion and compared its effect with that of ELA Max (since renamed LMX4; Ferndale Laboratories Inc., Ferndale, MI) in a pediatric ED. Patient reports of pain were statistically significantly lower in the J-Tip® group. Blinded observers also identified clinically significant decreases in pain defined as a difference on the visual analogue scale of 10 mm following J-Tip® jet injection, although the findings were not statistically significant. Jimenez, Bradford, Seidel, Sousa, and Lynn (2006) compared 1% buffered lidocaine with EMLA when applied via J-Tip® prior to peripheral IV cannulation. There was a significant difference between the groups, with 84% of patients reporting no pain at the time of IV insertion with J-Tip® lidocaine application vs. 61% in the EMLA group ($p = 0.004$). It is noted, however, that 40% of the patients had EMLA applied for less than the recommended 60 minutes. However, when a subset of the original EMLA group was reviewed, all of which had application times equal to or greater than the recommended 60 minutes, the difference remained significant. Ferayorni, Yniguez, Bryson, and Bulloch (2012) investigated the use of a needle-free injection of lidocaine or saline into the subcutaneous tissue prior to lumbar puncture in an RCT of infants younger than three months. The lidocaine group was noted to have a significantly shorter duration of crying ($p = 0.04$) and lower pain scores ($p = 0.01$).

Description of Decision Options/Interventions and the Level of Recommendation

Description of Decision Options/Interventions and the Levels of Recommendation		
Behavioral Interventions	Breastfeeding, skin-to-skin contact, and parental holding are beneficial behavioral interventions to reduce procedural pain in infants (Curtis et al, 2012; Lee et al., 2014; Taddio et al., 2015).	A
	There is sufficient evidence to support the use of hypnosis for reducing procedural pain and distress in areas with appropriately trained personnel (Birnie et al., 2014; Curtis et al, 2012; Uman et al., 2013).	A
	There is sufficient evidence to support the efficacy of developmentally appropriate use of distraction cards, kaleidoscope, balloon inflation, play dough, and the cough trick in reducing pain and distress (Canbulat et al., 2014; Maghsoudi et al., 2015; Mutlu & Balci, 2015; Şahiner & Bal, 2016).	A
	There is evidence that verbal coaching, breathing exercises alone or with toys, and handheld electronic devices decrease procedural pain and distress (Birnie et al., 2015; Birnie et al., 2014; Chambers et al., 2009; Curtis et al., 2012; McCarthy et al., 2014; Miller et al., 2016; Rezai et al., 2016; Riddel et al., 2015; Stinley et al., 2015; Uman et al., 2013).	A
	The presence of clowns may reduce procedural pain and anxiety in some children (Ben-Pazi et al., 2017; Felluga et al., 2016; Gilboa-Negari et al., 2017; Meiri et al., 2016; Wolyniez et al., 2013).	A
	Evidence supports the effectiveness of patient information/preparation in combination with distraction to decrease pain and distress (Taddio et al., 2015; Uman et al., 2013).	A
	Listening to music is an effective distraction technique in reducing pain and distress (Birnie et al., 2015; Burns-Nader et al., 2017; Hartling et al,, 2013; Rezai et al., 2016; Uman et al., 2013; Yinger & Gooding, 2015).	A
	There is evidence that reduction of anxiety may decrease procedural pain (Chieng et al., 2014; Goettems et al., 2017; Hyland et al., 2015; Matziou et al., 2013; Meiri, et al., 2016).	A
	There is insufficient evidence to make a recommendation for a dog being present during a procedure to decrease distress levels in children accustomed to being around dogs (Vagnoli et al., 2015).	I/E
Dermal Anesthetic Preparations	All transdermal forms of lidocaine/tetracaine (amethocaine) are effective in reducing pain associated with IV cannulation, venipuncture, and immunization. Preparations in the form of cream or patches take longer to exert an effect (60 minutes or more), which makes them less feasible for use in the ED environment. (Curtis et al., 2012; Lee et al., 2014; Schmitz et al., 2015; Sethna et al., 2005; Singer et al., 2008; Taddio et al., 2015).	A
	Pentafluoropropane and tetrafluoroethane (Pain Ease®) results in a moderate reduction in pain in patients 6–12 years of age undergoing IV cannulation (Farion et al., 2008; Waterhouse et al., 2013).	B
	Ethyl vinyl chloride may be effective in relieving pain associated with venipuncture (Costello et al., 2006; Taddio et al., 2015).	B
Sucrose	Evidence suggests that sucrose is beneficial as a form of analgesia in children from zero to three months of age; no benefit has been demonstrated for children older than three months. (Desjardins et al., 2016; Ferayorni et al., 2012; Harrison et al., 2017; Harrison et al., 2015; Hatfield et al., 2011; Lee et al., 2014; Sethi & Nayak, 2015; Taddio et al., 2015).	A
Local Application of Ice and Vibration	Local application of ice along with vibration decreases the pain and distress associated with venipuncture. (Baxter & Cohen, 2011; Canbulat et al., 2015; Faroukh et al., 2016; Şahiner et al., 2015; Schreiber et al., 2016).	B
Subdermal Local Anesthetic with Needle-Free Delivery	The use of a needleless injection device (e.g., J-Tip®) as a delivery method for lidocaine is superior to other forms of preparation when rapid local anesthesia is required. (Ferayorni et al., 2012; Jimenez et al., 2006; Spanos et al., 2008; Spillman, 2012).	A

Level A (High)	Based on consistent and good quality of evidence; has relevance and applicability to emergency nursing practice.
Level B (Moderate)	There are some minor inconsistencies in quality evidence; has relevance and applicability to emergency nursing practice.
Level C (Weak)	There is limited or low-quality patient-oriented evidence; has relevance and applicability to emergency nursing practice.
N/R	Not recommended based upon current evidence.
I/E	Insufficient evidence upon which to make a recommendation.
N/E	No evidence upon which to make a recommendation.

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Wolyniez, I., Rimon, A., Scolnik, D., Gruber, A., Tavor, O., Havir, E., & Glatstein, M. (2013). The effect of a medical clown on pain during intravenous access in the pediatric emergency department: A randomized prospective pilot study. *Clinical Pediatrics, 52*(12), 1168–1172. https://doi.org/10.1177/0009922813502257.

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Appendix 1. Evidence Table

Reference	Research Purpose Questions/Hypothesis	Design Sample/Setting	Variables/Measures Analysis	Findings/Implications	Quality of Evidence	Level of Evidence
Baxter, A. L., Cohen, L. L., McElvery, H. L., Lawson, M. L., & von Baeyer, C. L. (2011). An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department. *Pediatric Emergency Care, 27*(12), 1151–1156. doi:10.1097/PEC.0b013e318237ace4	To compare a reusable device combining cold and vibration to standard care (vapocoolant or distraction) for pediatric venous access pain relief using a prototype of a novel battery-powered device, Buzzy®, that combines cold with vibration, along with distraction	Design: Prospective randomized controlled trial at single center IRB approved $N = 81$ Sample: Convenience sample 4–18 yr. Randomized to vibration device or standard care Setting: Freestanding urban/suburban ED	Categorical values are presented as the % of frequency with χ^2 comparisons or Fisher exact test when appropriate.	Compared with standard care, the combination of cold and vibration significantly reduced venipuncture pain without compromising procedural success.	2	II
Ben-Pazi H., Cohen A., Kroyzer N., Lotem-Ophir R., Shvili Y., Winter G., . . . Pollak, Y. (2017) Clown-care reduces pain in children with cerebral palsy undergoing recurrent botulinum toxin injections – A quasi-randomized controlled crossover study. *PLoS ONE 12*(4), e0175028. doi.org/10.1371/journal.pone.0175028	Hypothesis: "Clown-care would have an impact on pain experience during recurrent BTX injections in children with CP" (p. 2)	Design: First part: quasi-randomized controlled trial; Second part: cross-over trial. Sample: $N = 45$ (1.5 to 18 years. Setting: Shaare Zedek Medical Center	Measures: Visual Analog Scale	Findings: Pain after the procedure was lower with clown care. With medical clown (VAS after, 2.89 ± 1.36) compared with standard care (VAS after, 3.85 ± 1.39; 2-tailed t-test, $p = 0.036$). Children with clown care reported less pain than without clown. Children with clown care during their first experience for injections reported lower pain levels with subsequent injections. Clown care before the procedure is not effective, but needs to be conducted during the needle-related procedure.	1	II
Birnie, K. A., Chambers, C. T., Taddio, A., McMurtry, C. M., Noel, M., Riddell, R., Shah, V., . . . HELPinKins&Adults Team. (2015). Psychological interventions for vaccine Injections in children and adolescents: Systematic review of randomized and quasi-randomized controlled trials. *The Clinical Journal of Pain, 31*(10 Suppl.), S72–S89. doi:10.1097/AJP.0000000000000265	To evaluate the effectiveness of psychological interventions for reducing pain during vaccinations in children and adolescents.	Design: Systematic review of randomized and quasi-randomized controlled trials. Sample: 22 studies evaluated	GRADE (Grading of recommendations assessment development and evaluation) and the Cochrane Collaboration. Statistical analysis: Effects reported as standardized mean difference *(SMD)* with 95% CI or relative risk and CI.	Findings: Some benefit for the following: Verbal distraction ($n = 46$) reduced distress (*SMD* −1.22 [−1.87, −0.58]) but not pain; video distraction ($n = 328$) reduced distress (*SMD* −0.58 [−0.82, −0.34] but not pain; music distraction (from 3 pooled trials) reduced pain with children ($n = 417$) (S*SMD* −0.45 [−0.71, −0.81]) but not with adolescents ($n = 118$); breathing with a toy ($n = 368$) showed a benefit for pain (*SMD* −0.49 [−0.85, −0.13]) but not fear Conclusion: Music distraction more consistent with being beneficial for children	I	I
Birnie, K. A., Noel, M., Parker, J. A., Chambers, C. T., Uman, L. S., Kisely, S., & McGrath, P. J. (2014). Systematic review and meta-analysis of distraction and hypnosis for needle-related pain and distress in children and adolescents. *Journal of Pediatric Psychology, 39*(8), 783–808. doi:10.1093/jpepsy/jsu029	To provide an in-depth review of the evidence for distraction and hypnosis when used as a psychological intervention to distract children and adolescents who experience procedural pain. The characteristics of distraction interventions, child age, and risk of bias in the study design were reviewed.	Systematic review	GRADE (Grading of recommendations assessment, development, and evaluation) Needle procedures included venipuncture, Immunizations, IV insertion(s), allergy testing, bone marrow aspiration, lumbar puncture, sutures, and dental anesthetic.	GRADE summary for distraction was very low (self-reported pain, self-reported distress, observer-reported pain, observer-reported distress, behavioral measures – pain, behavioral measures – distress). GRADE summary for hypnosis was very low (outcomes were self-reported pain, self-reported distress, and behavioral measures – distress). Distraction significantly reduced children's self-reported pain and distress, and behavioral measures of distress. There was no evidence to support the efficacy of distraction for behavioral measures of pain.	I	I
Burns-Nader, S., Joe, L., & Pinion, K. (2017). Computer tablet distraction reduces pain and anxiety in pediatric burn patients undergoing hydrotherapy: *A randomized trial. Burns, 43*(6), 1203–1211. doi:10.1016/j.burns.2017.02.015	To evaluate the use of a tablet as distraction during burn hydrotherapy to decrease pain and anxiety.	Design: RCT Sample: 30 (ages 4–12 years), randomized Setting: Children's of Alabama Burn Center, Birmingham, AL	Measures/Instruments: Computer tablet (iPad by Apple Inc.), FACES pain scale, Children's Emotional Manifestation Scale (CEMS) Statistical analysis: Independent samples t-test, χ^2, Mann–Whitney U, Spearman's rank-order correlation	Findings: No statistical difference in child self-reported pain between tablet group and control group ($p = 0.24$). Observed pain was significantly lower in tablet group (Mdn = 12.47) than control (Mdn = 18.53, $U = 67.00$, $p = 0.48$). Emotions in tablet group were lower and returned to baseline normal after procedure while the control group displayed higher anxiety ($p < 0.001$).	I	II
Canbulat, N., Ayhan, F., & Inal, S. (2015). Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients. *Pain Management Nursing, 16*(1), 33–39. doi:10.1016/j.pmn.2014.03.003	Does the Buzzy® (device used to administer pain and vibration) reduce procedural pain or anxiety during IV cannulation and peripheral IV sticks in pediatric patients?	Randomized clinical trial Pediatric patients either had IV started without the use of the cold/vibration device (control group) or with the use of the cold/vibration device (experimental group) IRB approval obtained Setting: Pediatric surgical unit in Turkey $N = 220$ divided into randomized groups Sample ages 7–12 years undergoing surgical procedures	Children's Fear Scale, Wong–Baker Faces Scale, and Visual Analog Scale continuous data measured with Student's t-test and categorical data were compared using frequency and χ^2 analysis – both appropriate for sample size and type of data	Children in experimental group had significantly less perceived pain and anxiety than control group.	I	II

Canbulat, N, Inal, S., & Sonmezer, H. (2014). Efficacy of distraction methods on procedural pain and anxiety by applying distraction cards and kaleidoscope in children. *Asian Nursing Research 8*(1), 23–28. doi:10.1016/j.anr.2013.12.001	To compare the reduction in pediatric pain with distraction cards or kaleidoscope with a control group for phlebotomy draw	Design: Prospective randomized control trial Sample: $N = 188$, 7–11 years Setting: Phlebotomy station, Turkey Maternity and Children's Hospital	Tools: Wong–Baker Faces and Children Fear Scale Statistical Analysis: SPSS V 21; parametric data analyzed with χ^2 test, Student's t-test. Statistical significance set at $p < 0.05$ Nonparametric one-way analysis of variance, Kruskal–Wallis and Mann–Whitney U test ($p < 0.05$)	Self-reported pain levels: distraction card group "significantly lower than control group ($p = 0.001$), kaleidoscope ($p = < 0.001$)" Decrease in procedural anxiety "distraction card group ($p = 0.004$) lower than kaleidoscope group ($p = < 0.001$), control group ($p = 0.001$)" (p. 26) 1) Distraction cards most effective 2) Kaleidoscope alternative 3) Nurses to be aware of the need to decrease pain and anxiety during painful procedures (p. 27)	I	II
Chambers, C. T., Taddio, A., Uman, L. S., McMurtry, C. M., & HELPinKIDS Team. (2009). Psychological interventions for reducing pain and distress during routine childhood immunizations: A systematic review. *Clinical Therapeutics, 31*(Suppl. 2), S77–S103. doi:10.1016/j.clinthera.2009.07.023	To identify and synthesize randomized controlled trials and quasi-RCTs that examine the efficacy of different psychological interventions for reducing injection pain and distress in children 0 to 18 years of age during routine childhood immunizations.	RCT and quasi-RCT Children 0 to 18 years undergoing immunization in any setting were reviewed. $N = 1380$ infants and children Age range 1 month to 11 years	1) Breathing exercises (blowing the hurt away) 2) Suggestion (telling the child something that would make them believe that the procedure would hurt less) 3) Child-directed distraction (directed at the child, such as video, music or story played via headphones) 4) Parent-led distraction (parents instructed on how to distract the child) 5) Nurse-led distraction (nurses instructed on how to distract the child using age-appropriate toys) 6) Parent coaching (parents instructed to provide assistance to the child using different techniques, not limited to distraction). 7) Combined cognitive–behavioral interventions (techniques aimed at modifying emotions, behaviors, and cognitions)	Breathing exercises: Evidence suggested breathing exercises were effective in reducing children's self-reported pain, observer-rated distress, and nurse-reported distress. Breathing exercises were effective in reducing children's self-reported distress in 1 of 2 studies. Suggestion: No evidence that suggestion was effective in reducing pain from immunization. Child-directed distraction: Effective in reducing self-reported pain. Observer-rated pain appeared to be lower with this intervention, but the difference was not statistically significant. Parent-led distraction: Effective in reducing observer-rated distress, but not other measures of pain or distress during immunization. Nurse-led distraction: effective in reducing observer-rated distress and parent and nurse ratings of distress.	I	I
Chieng, Y. J., Chan, W. C., Klainin-Yobas, P., & He, H. G. (2014). Perioperative anxiety and postoperative pain in children and adolescents undergoing elective surgical procedures: A quantitative systemic review. *Journal of Advanced Nursing, 70*(2), 243–255. doi.10.1111/jan.12205	To examine the relationship between anxiety before and pain after surgical procedures.	Design: Systematic review Reviewed 10 studies: 2 RCTs, 2 cohort studies, 6 descriptive studies	Instruments: Anxiety measures in studies using instruments reported as valid and reliable; pain intensity measured by NRS-pain, VAS-pain, Bieri Faces Pain Scale, salivary cortisol. Radioimmunoassay used to evaluate pain intensity.	Findings: 8 of 10 reviewed looked at relationship between anxiety and pain. Perioperative anxiety was highly correlated with post-operative pain in 5 studies reviewed. Three studies evaluated postoperative anxiety and pain and found a positive correlation. Higher postoperative anxiety was found to have a moderate correlation with postoperative pain. Differences in anxiety and pain among subgroups (age, gender, age and surgical experience) were inconclusive.	I	I
Costello, M., Ramundo, M., Christopher, N. C., & Powell, K. R. (2006). Ethyl vinyl chloride vapocoolant spray fails to decrease pain associated with intravenous cannulation in children. *Clinical Pediatrics, 45*(7), 628–632. doi:10.1177/0009922806291013	1. To determine the effect of ethyl vinyl chloride vapocoolant spray on pain reported by children undergoing IV cannulation. 2. To determine whether there is an effect on cannulation success rates when compared with those receiving isopropyl alcohol spray or no pretreatment.	Randomized, double-blinded, placebo-controlled trial Children 9 to 18 years seen in a pediatric ED requiring IV cannulation	Enrolled subjects had distraction techniques and preprocedural educational interventions regardless of the group they were assigned. Spray applied for 5 seconds or until skin blanched 22G 1-inch IV catheter Rate pain based on 100 cm VAS Failed starts recorded pain only after first attempt. Recorded patient demographics, indications for IV cannulation, time from IV insertion to VAS score, cannulation site, success or failure of first attempt, history of prior IV cannulation or blood draws, memory of prior cannulation attempts.	Effect of ethyl vinyl chloride vapocoolant spray on pain: Ethyl vinyl chloride vapocoolant spray failed to measurably reduce pain associated with IV cannulation when compared with those pretreated with isopropyl alcohol spray or receiving no intervention. Effect on cannulation success rates: There was no difference in the proportion of subjects in whom successful cannulation occurred on the first attempt.	II	II
Curtis, S., Wingert, A., & Ali, S. (2012). *The Cochrane Library* and procedural pain in children: An overview of reviews. *Evidence-Based Child Health; A Cochrane Review Journal, 7*(5), 1363–1399. doi:10.1002/ebch.1864	To provide a summary of the Cochrane reviews that assess the efficacy of various interventions used to reduce pain in children undergoing painful procedures.	Sample: $N =$ Four systematic reviews that included a total of 46 previously reported and 13 new trails	Risk ratios and confidence intervals appropriate for review	Sweet tasting substances: No evidence to support effectiveness in older infants and children No statistically significant effects between rocking or holding in children aged 0–48 months Non-nutritive sucking shown to be effective (*SMD* −0.89, 95% CI −1.53 to −0.25) Distraction/coaching /hypnosis/ combined cognitive, behavioral, and video distraction require further research Amethocaine provides greater relief than EMLA for intravenous cannulation	I	I

Desjardins, M. P., Gaucher, N., Curtis, S., LeMay, S., Lebel, D. & Gouin, S. (2016). A randomized controlled trial evaluating the efficacy of oral sucrose in infants 1 to 3 months old needing intravenous cannulation. *Academic Emergency Medicine, 23*(9), 1048–1053. doi:10.1111/acem.12991	To compare the use of sucrose versus control in infants 1–3 months of age on pain reduction during IV cannulation	Randomized double-blinded placebo-controlled CT $N = 87$ IRB approval Settings: Pediatric ED, university-affiliated hospitals in Montreal, Quebec, Edmonton, and Alberta, Canada.	FLACC pain score used Inclusion criteria had to be met with age of 28 days to 3 months. NIPS was also used (neonatal infant pain score).	$N = 87$ [$n = 45$ (sucrose) and 42 (placebo)] PA = 90% No difference in pain scores between the two studied groups: $p = 0.36$ (NIPS) and $p = 0.49$ (FLACC) with the Mann–Whitney U test. Pain scores were evaluated at 1 min and 3 min post-procedure, with no difference. However, the big difference occurred with post-crying times. The sucrose group had babies crying for 17 seconds, while the control group had 41 seconds of crying ($p = 0.04$).	I	II
Farion, K. J., Splinter, K. L., Newhook, K., Gaboury, I., & Splinter, W. M. (2008). The effect of vapocoolant spray on pain due to intravenous cannulation in children: A randomized controlled trial. *Canadian Medical Association Journal, 179*(1), 31–36. doi:10.1503/cmaj.070874	Primary outcome measure was the children's self-reported pain during intravenous cannulation. Secondary outcome measures included the success rate on first attempt, and assessments from the children's parents, nurses and child life specialist (CLS).	Double blind randomized controlled trial Children age 6–12 years who required urgent (within 30–45 minutes) IV cannulation.	Recorded baseline demographic data, patient self-report of anxiety on a 100 mm color visual analogue scale from "not scared" to "extremely scared". Recorded presence of CLS, nurse experience, distraction activity. All participants received standard preparation and distraction. Only the data of the first attempt was measured. Vapocoolant sprayed for 4–10 seconds until the skin blanched. Child rated pain immediately following IV cannulation.	Effect of vapocoolant spray to placebo on pain due to IV cannulation: Results indicated a modest but significant reduction in pain.	I	II
Faroukh, A., Pouraboli, B., Rostami, M., Jahani, Y., & Mohsentavanaei. (2016). The effect of hoku point massage with ice on venipuncture pain in children with thalassemia. *i-manager's Journal on Nursing, 5*(4), 13–19. doi:10.26634/jnur.5.4.4812	To determine the effectiveness of ice massage of Hoku point to decrease pain during venipuncture.	Design: Double blind RCT Sample: $N = 86$ school-age children with thalassemia Setting: Clinic, Iran	Tools: Wong–Baker Faces and FLACC Measurements before and during venipuncture Statistical analysis: Kappa descriptive analytic; SPSS V22; Shapiro–Wilke test; Variables: Mann–Whitney *U*	"Mann–Whitney test showed a significant difference between both groups in terms of pain; … mean pain score on the ice massage of hoku point group (0.65) ice touch on fake point (2.56)" (p. 15) ($p = 0.0001$)	II	II
Felluga, M., Rabach, I., Minute, M., Montico, M., Giorgi, R., Lonciari, I., . . . Barbi, E. (2016). A quasi randomized-controlled trial to evaluate the effectiveness of clowntherapy on children's anxiety and pain levels in emergency department. *European Journal of Pediatrics, 175*(5), 645–650. doi:10.1007/s00431-015-2688-0	To determine if the use of clowns would reduce pain and anxiety during painful procedures.	Design: Randomized controlled trial Sample: 40, randomized 20 per group Setting: Community teaching level 1 pediatric and adult ED	Measures: Numerical Rating Scale (children older than 8); Wong–Baker Scale (younger than 8); Children Anxiety and Pain Scales. Statistical Analysis: Mann–Whitney test; Fisher's exact test.	Findings: Pain levels were not changed by use of clown. Anxiety levels did change in the clown group ($p = 0.013$).	II	II
Ferayorni, A., Yniguez, R., Bryson, M., & Bulloch, B. (2012). Needle-free jet injection of lidocaine for local anesthesia during lumbar puncture: A randomized controlled trial. *Pediatric Emergency Care, 28*(7), 687–690. doi:10.1097/PEC.0b013e31825d210b	To compare needle-free jet injection of lidocaine to saline in reducing pain before LP in infants.	Prospective randomized controlled trial – single center IRB approved $N = 55$ infants less than 3 months of age, weight greater than 4 kg, and meeting clinical criteria for lumbar puncture	Categorical values are presented as the % of frequency with χ^2 comparisons; Fisher's exact test when appropriate	Infants in the lidocaine group demonstrated significantly shorter cry duration (38.5 versus 48.8 seconds ($p = 0.04$) and lower pain scores: 4.1 (1.3) for the lidocaine group and 4.8 (0.5) for the saline group ($p = 0.01$)).	II	II
Gilboa-Negari, Z., Abu-Kaf, S., Huss, E., Hain, G., & Moser, A. (2017). A cross-cultural perspective of medical clowning: Comparison of its effectiveness in reducing pain and anxiety among hospitalized Bedouin and Jewish Israeli children. *Journal of Pain Research,* 10, 1545–1552. doi:10.2147/JPR.S135678	"To assess the effectiveness of medical clowning in reducing levels of pain and anxiety among Bedouin and Jewish–Israeli children, and the influence of culture on that effectiveness." p. 1546	Design: Mixed-method Sample: $N = 89$ children (7.5 to 12 years) and 69 parents (19 Jewish, 50 Bedouin) Setting: Four pediatric wards, oncology ward, orthopedics ward, and oncology outpatient clinic, Soroka University Medical Center in Beer-Sheva.	Measures: Faces pain scale revised (FPS-R); subjective units of distress (SUDS) for anxiety level; 8-question questionnaire to evaluate clowning intervention; qualitative - semi-structured interviews with children and parents	Findings: Significant reduction in pain in medical clown group ($p < 0.01$) and reduced anxiety ($p < 0.001$). Anxiety levels higher in Bedouin group than Jewish group ($p < 0.01$). Variables significant in predicting children's anxiety level post-intervention: 1) level before; 2) level of enjoyment of nonverbal components of clowning intervention; 3) two-way interaction of cultural group and enjoyment of verbal component. Qualitative component: Three main themes: verbal humor, nonverbal humor, less-enjoyable components of clowning intervention. Children and parents felt clowning helped with reduction of pain, anxiety and stress.	1	IV

Goettems, M., Zborowski, E. J., Costa, F. D., Costa, V. P., & Torriani, D. D. (2017). Nonpharmacologic intervention on the prevention of pain and anxiety during pediatric dental care: A systematic review. *Academic Pediatrics, 17*(2), 110–119. doi:10.1016/j.acap.2016.08.012	To systematically review the literature on RCTs that evaluated the effects of nonpharmacologic interventions related to behavior, anxiety, and pain perception in children undergoing a dental procedure compared with inactive or active controls.	Design: Systematic review	PRISMA guidelines followed.	Findings: Videos - Two studies, no statistically significant difference in anxiety with video distraction. One study demonstrated reduction in FACES pain scale and anxiety with virtual reality. No significant differences in behavior, pain perception, or anxiety with upbeat music. Nursery rhyme music produced some anxiety reduction. Magic tricks showed more cooperation. Live modeling showed decreased heart rate with mother compared with father, Positive Images showed decreased anxiety.	I	I
Harrison, D., Larocque, C., Bueno, M., Stokes, Y., Turner, L., Hutton, B., & Stevens, B. (2017). Sweet solutions to reduce procedural pain in neonates: A meta-analysis. *Pediatrics, 139*(1), e20160955. doi:10.1542/peds.2016-0955	To review all trials evaluating sweet solutions used for analgesia in neonates in conducting a cumulative meta-analysis focused on behavioral pain outcomes.	Cumulative meta-analysis (CMA)	Cry duration, composite pain intensity scores	There was sufficient evidence demonstrating that sweet solutions reduced crying time and pain intensity composite scores compared with a placebo or no treatment.	I	I
Harrison, D., Yamanda, J., Adams-Webber, T., Ohlsson, A., Beyene, J., & Stevens, B. (2015). Sweet tasting solutions for reduction of needle-related procedural pain in children one to 16 years. *Cochrane Database of Systematic Reviews, (5)*:CD008408. doi:10.1002/14651858.CD008408.pub3	To systematically review studies that addressed pain-reducing effects of sweet solutions (sucrose or glucose) for painful needle procedures in children 1–16 years of age.	Cochrane Review	Seven published and one unpublished study. The efficacy of sweet tasting substances was assessed in children from 12 months to 16 years old while undergoing IM or SQ injections, venipuncture, or a finger lance.	Conflicting results were found for young children aged one to four years: two studies demonstrated decreased crying time and pain score compared with control group. When pooled, however, there was no significant effect of sweet tasting substances on crying time. In older children, sweet tasting substances showed no effect on self-reported pain or unpleasantness during IM injections and blood collection.	I	I
Hartling, L., Newton, A. S., Liang, Y., Jou, H., Hewson, K., Klassen, T. P., & Curtis, S. (2013). Music to reduce pain and distress in the pediatric emergency department: A randomized clinical trial. *JAMA Pediatrics,* 167(9), 826–835. doi:10.1001/jamapediatrics.2013.200	To compare music with standard care in managing pain and distress.	Design: Two-arm parallel randomized clinical trial Sample: $N = 42$ aged 3–11 years undergoing IV placement IRB approval	Mann–Whitney U test, additional model-based analyses (multiple linear regression). Additional analyses were performed for a subgroup with nonzero OSBD-R scores - all statistical tests were performed at a significance level of 0.05 (2-sided).	Results indicated that music may have a positive impact on pain and distress in children during IV placements.	III	IV
Hatfield, L. A., Chang, K., Bittle, M., Deluca, J., & Polomano, R. C. (2011). The analgesic properties of intraoral sucrose: An integrative review. *Advances in Neonatal Care, 11*(2), 83–92. doi:10.1097/ANC.0b013e318210d043	To evaluate the efficacy and safety of oral sucrose as a pre-procedural intervention for mild to moderate procedural pain in infants.	Systematic review of 46 randomized clinical trials identified from Medline and CINAHL databases that examined the utilization of oral sucrose as a pre-procedural intervention for mild to moderate procedural pain in infants.	N/A	Overall, studies indicated that oral sucrose is an effective, safe, convenient, and immediate-acting analgesic for reducing crying time and significantly decreasing biobehavioral pain response following painful procedures with infants.	II	I
Hyland, E. J., D'Cruz, R., Harvey, J. G., Moir, J., Parkinson, C., & Holland, A. J. A. (2015). An assessment of early child life therapy pain and anxiety management: A prospective randomized controlled trial. *Burns, 41*(8), 1642–1652. doi:10.1016/j.burns.2015.05.017	To compare the use of Child Life Therapy (CLT) to standard care for the reduction of pain and anxiety in children undergoing burn therapy.	Design: RCT Sample: $N = 100$ Stratified randomization (age: 0–3 years, > 3 years; < 1% BSA, > 1% BSA) (computer generated) Setting: Burn unit, children's hospital, Westmead, Sydney, Australia	Measures/Instruments: Children's Hospital of Eastern Ontario Pain Scale (CHEOPS), Children's Fear Scale, Wong–Baker Faces Scale, VAS. Statistical Analysis: Wilcoxon rank-sum test, χ^2 tests	No statistical differences between groups, Combined and scaled pain and anxiety scores were statistically better in the CLT group (1.7 vs. 2.9; $p = 0.03$). CHEOPS was significantly less ($p = 0.02$ in the CLT group; no significant differences in fear scores ($p = 0.3$).	I	II
Jeffs, D., Dorman, D., Brown, S., Files, A., Graves, T., Kirk, E., . . . Swearingen, C. J. (2014). Effect of virtual reality on adolescent pain during burn wound care. *Journal of Burn Care and Research, 35*(5), 395–408. doi:10.1097/BCR.0000000000000019	To compare the effects of virtual reality, passive distraction, and standard care during burn care.	Design: RCT Sample: $N = 28$, randomized Setting: Outpatient burn clinic in large academic children's hospital, mid-south US	Measures/Instruments: Adolescent Pediatric Pain Tool, Spielberger State-Trait Anxiety Inventory for Children, pre-procedure questionnaire, post-procedure questionnaire. SnowWorld virtual environment via Kaiser Optics SR80a VR helmet mounted on articulated-arm tripod	Findings: Adolescents using the virtual reality (VR) group reported significantly less pain than the passive distraction group (difference −23.7mm, 95% CI 2.4–45.0; $p = 0.029$). VR group had less procedural pain than the standard care (SC) group, but difference was not significant (9.7mm, 95% CI −9.5 to 28.9; $p = 0.32$). Effect size: VR to SC groups = 0.535, VR to PD = 1.25. VR group had decreased pain perception reported from pre-procedural to procedural pain. No correlation between desire for distraction and belief in distractions effect with state anxiety, trait anxiety, or procedural pain. Reported that as trait anxiety increased, distraction engagement decreased.	I	II

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. *Anesthesia and Analgesia, 102*(2), 411–414. doi:10.1213/01.ane.0000194293.10549.62	To compare the effectiveness of J-Tip® versus EMLA to facilitate IV cannulation and provide adequate analgesia before IV placement in children.	Design: RCT Sample: 116 Children 7–19 years old who required IV placement before elective surgery. EMLA group, $n = 59$; J-Tip® group, $n = 57$ Setting: Children's Regional Medical Center, Seattle, WA.	Two possible sites for venipuncture were covered by a thick layer of cream and an occlusive dressing. Mean time from application to IV cannulation: EMLA group - 69 minutes; J-Tip® group - 1.8 minutes.	Pain rating during IV cannulation: Significant difference ($p = 0.0001$) between the EMLA group (median, 3) and the J-Tip® group (median, 0) Studies primarily a preteen and adolescent group. Study stopped early because of identification of significant findings.	I	I
Lee, G. Y., Yamada, J., Kyololo, O'B. M., Shorkey, A., & Stevens, B. J. (2014). Pediatric clinical practice guidelines for acute procedural pain: A systematic review. *Pediatrics, 133*(3), 500–515. doi:10.1542/peds.2013-2744	To review quality of CPGs for acute procedural pain in children.	Systematic review of clinical practice guidelines from 2000 to July 2013	18 guidelines were reviewed using the Appraisal of Guidelines for Research and Evaluation (AGREE) II.	Scope and purpose: Mean domain score = 80.9 +/- 19.2%. 9 of the guidelines scored > 85%. Clarity: Mean domain = 85.7 +/- 15.4%, with 12 CPGs > 85%. Applicability: Average domain = 25.5 +/- 33.7%. 14/18 CPGs scored less than 50% with no indication of how to implement. Stakeholder involvement: 22.2–100%. 17/18 had domain ratings < 85%. The CPG development group had not been described here. Editorial independence: Describes bias with funding; average = 28.7 +/- 33.8%. 8/18 provided no source of funding. Rigor of development: Average = 47.3 +/- 28.2%. "7/18 provided a systematic method to evaluate the risk of bias." Overall, 5/18 scored as excellent resources for clinicians with the AGREE II criteria. Four guidelines provided tools to assist the practitioner in pain management interventions during painful procedures with pediatric patients, including distraction, sucrose, breast feeding, topical anesthesia, swaddling, psychological methods, and positioning.	I	I
Maghsoudi, S., Sajjadi, Z., Vashani, H. B., Nekah, S. M. A., & Manzari, Z. S. (2015). Comparison of the effects of play dough and bubble making distraction techniques on venepuncture pain intensity in children. *Evidence Based Care Journal, 5*(4), 25–32.	To compare the use of play-dough and/or bubble-making on the severity of venipuncture pain in children.	RCCT with post-intervention design $N = 90$ Setting: Pediatric EDs in Iran IRB approval	$N = 90$ with 30 in each group: play dough, bubbles, and control. Strict inclusion criteria removed those with previous history of needle stick. Intervention was begun approximately 5 minutes before the needle stick.	PA = 80%; CI = 95%. Mean pain intensity measured as 5.1 +/- 1.8 for play-dough; 6.2 +/- 1.4 for bubble-making; 8.2 +/- 1.5 for control. "Significant difference between play dough and control groups ($p < 0.001$); bubble-making and control ($p < 0.001$), and bubble-making and play dough ($p = 0.009$)" (p. 25). Conclusion: The use of play dough in distraction techniques was more effective than bubbles and the control (no distraction).	I	II
Matziou, V., Chrysostomo, A., Vlahioti, E., & Perdikaris, P. (2013) Parental presence and distraction during painful childhood procedures. *British Journal of Nursing, 22*(8), 470–475. doi:10.12968/bjon.2013.22.8.470	"To investigate the effect of parental presence and the distraction of the attention by a toy in children undergoing a painful procedure." (p. 470)	Design: RCT Sample: $N = 130$ (aged 7–10 years) randomized to 3 groups: 2 experimental, 1 control	Measures/Instrument: State–Trait Anxiety Inventory for children, pain rating scale, vital signs (respiratory and heart rates, blood pressure), kaleidoscope. Statistical analysis: Kolmogorov–Smirnov test, Spearman's correlation, χ^2 tests, Man–Whitney U, Kruskal–Wallis test, multiple linear regression	Findings: Parental presence reduced pain score (parental presence group = 2.00; kaleidoscope group = 3.09; control group = 5.53, $p < 0.001$). Parental presence group (19.7) less breaths per minute than kaleidoscope (21.1) or control groups (23.2) ($p < 0.01$). Systolic and diastolic blood pressure was significantly lower in the parental presence group ($p < 0.05$). Stress was lower in parental presence group compared with the kaleidoscope group (B = −8.48, 5.50, respectively). Conclusions: Parents' presence reduced pain and anxiety during procedures. Use of a kaleidoscope was effective, but parents being present was more effective.	I	II
McCarthy, A. M., Kleiber, C., Hanrahan, K., Zimmerman, M. B., Ersig, A., Westhus, N., & Allen, S. (2014). Matching doses of distraction with child risk for distress during a medical procedure: A randomized clinical trial. *Nursing Research, 63*(6), 397–407. doi:10.1097/NNR.0000000000000056	To investigate the effects of three distraction doses on children who identified as being at medium or high risk for distress from a procedure (IV insertion)	RCT	The Children, Parents and Distraction (CPaD); Distraction Coaching Index; Observation Scale of Behavioral Distress Revised (OBSD-R); salivary cortisol levels; Oucher Scale; parent report of child distress (PRCD).	CPaD validation for identification of parent-child dyads at low, medium, and high risk for distress during a medical procedure. In high-risk distress, no significant difference in Oucher ($p = 0.48$), PRCD ($p = 0.11$), and total OSBD-R ($p = 0.24$). Cortisol levels compared with clinic increased by 85% in the enhanced group and by 37% in the professional group, but no significant differences between the groups. No significant differences between the Oucher and PRCD for the 3 interventions. OSBD-R scores were significantly lower for the professional group ($p = 0.005$) compared with the enhanced or basic interventions.	I	II
Meiri, N., Ankri, A., Hamad-Saied, M., Konopnicki, M., & Pillar, G. (2016). The effect of medical clowning on reducing pain, crying, and anxiety in children aged 2–10 years old undergoing venous blood drawing – A randomized controlled study. *European Journal of Pediatrics, 175*(3), 373–379. doi:10.1007/s00431-015-2652-z	To evaluate the use of a medical clown to decrease pain, crying time, anxiety in children undergoing a venous blood drawing procedure. Hypothesis: "That a medical clown will reduce pain, crying, and anxiety in children undergoing the procedure" (p. 373).	Design: RCT Sample: $N = 100$ (age range 2–10 years), randomized	Measures/Instrument: Visual analogue scale (VAS), assessment of crying time Statistical analysis: ANPVA, unpaired two-tailed t-test	Findings: No child had coulrophobia (fear of clowns); crying duration significantly lower in clown group than control (1.3 ± 2.0 vs. 3.8 ± 5.4 min, $p = 0.01$). EMLA group not statistically different to clown or control group. Parents' assessment of child anxiety during physical exam significantly lower in clown group than EMLA group (2.98 ± 3.21 vs. 5.60 ± 3.43, $p = 0.05$). Conclusions: Medical clowns are effective to reduce pain and anxiety during blood drawing.	I	II

Miller, K., Tan, X., Hobson, A. D., Khan, A., Zivani, J., O'Brien, . . . Kimble, R.M. (2016). A prospective randomized controlled trial of nonpharmacological pain management during intravenous cannulation in a pediatric emergency department. *Pediatric Emergency Care, 32*(7), 444–451. doi:10.1097/PEC.0000000000000778	Does the Ditto electronic device used during IV cannulation in pediatric patients distract the patient and decrease pain?	Design: RCT Sample: $N = 98$ aged 3–12 years Setting: Australian pediatric ED, Brisbane Ethical approval from equivalent IRB/Ethics board	Wong–Baker, Visual Analog scale, FLACC scale 5 intervention groups: #1 = standard distraction; #2 = play station distraction; #3 = Ditto; #4 = Ditto procedural preparation; #5 = Ditto preparation and distraction. Three evaluation points were addressed: before intravenous cannulation, during IV cannulation, and after IV cannulation.	$N = 98$ aged 3–12 years. Self-reported pain with the Ditto-C ($p = 0.006$), PSP ($p = 0.41$), Ditto-D ($p = 0.49$), or Ditto-PP ($p = 0.88$). These scores did not differ significantly from standard distraction. Ditto-C provided the greatest pain reduction during and after procedure (73% improvement), while the other methods provided pain reduction at lower levels (37–65%). The Ditto tool was found to work well and have promise for future use.	II	II
Mutlu, B., & Balci, S. (2015). Effects of balloon inflation and cough trick methods on easing pain in children during the drawing of venous blood samples: A randomized controlled trail. *Journal for Specialists in Pediatric Nursing, 20*(3), 178–186. doi:10.1111/jspn.12112	"To determine the effects of balloon inflation and cough trick methods in easing pain of children during the drawing of venous blood samples" (p. 178)	Children who presented to blood draw room between April and July 2011 in Turkey. 202 children assessed for eligibility, 52 excluded, 150 put into randomized groups. Exclusion criteria were children who had: taken analgesics within 24 hours before blood draw; fever, medical, or neurological disorders; a history of fainting; and chronic diseases requiring multiple venipunctures. 15 children were unable to complete the process, and were not included in final evaluation. Groups were randomized into 44 (control group), 44 (balloon inflation) and 44 (cough trick) groups.	Facial Pain Score Revised (FPS-r) and demographic questionnaire. Demographic questionnaire was completed by parents. Data obtained were expressed descriptive data (mean, standard deviation, frequencies). Statistical tests: one-way analysis of variance, *t*-test, and χ^2 appropriate for type of data obtained.	Measurement of perceived expected pain of children in control, balloon, and cough trick groups pre- procedure showed no significant differences between groups. Post-procedure children in balloon and cough trick groups reported significantly lower perceived pain than the control group, but no significant differences between the balloon and cough trick group ($p = 0.604$).	I	II
Redfern, R. E., Chen, J. T., & Sibrel, S. (2018) Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients: A randomized controlled trial. *Journal of Pediatric Nursing,* 38, 1–7. doi:10.1016/j.pedn.2017.09.009	To evaluate the use of cold and vibration on pain reduction as reflected in pain scores.	Design: RCT Sample: $N = 50$ (aged 2–18 years) Setting: Primary care office, urban community care center, ProMedica Toledo Children's Hospital and ProMedica Toledo Hospital	Measures/Instruments: Buzzy® device, Wong–Baker Faces scale Statistical analysis: χ^2 test, Student's *t*-test, Pearson correlation	Findings: No difference in anxiety. Pain after procedure significantly lower in Buzzy® group compared with control (mean difference −2.39 (95% CI −0.48 to −4.24, $t = -2.53$, $p = 0.015$). Ratings of satisfaction by parents strongly correlated to child's pain rating ($R = 0.58$, $p < 0.001$). Conclusion: Use of Buzzy® effective in reducing pain during vaccination but did not affect pre-procedural anxiety.	I	II
Rezai, M. S., Goudarzian, A. H., Jafari-Koulaee, A., & Bagheri-Nesami, M. (2016). The effect of distraction techniques on the pain of venipuncture in children: A systematic review. *Journal of Pediatric Review, 5*(1), 1–11. doi:10.17795/jpr-9459	To evaluate the effect of distraction techniques on the pain of children receiving venipuncture.	Sample: 31 RCTs, 2 review articles	PRISMA checklist	Findings: Distraction techniques used during venipuncture do reduce pain in children. Types of distraction techniques reviewed: music, audio-visual, virtual reality (cartoons, animations, video games), distraction cards, squeezing rubber balls, ice massage, bubble making, breathing exercise, kaleidoscope, and touching palm of hand.	1	I
Riddell, P., Racine, N. M., Gennis, H. G., Turcotte, K., Uman, L. S., Horton, R. E., . . . Lisi, D. M. (2015). Non-pharmacological management of infant and young child procedural pain (review). *The Cochrane Database of Systematic reviews,* (12), CD006275. doi:10.1002/14651858.CD006275.pub3	Update of 2011 review asking the question: How effective are non-pharmacological interventions in reducing the pain response and pain regulation in infants and young children up to age three (excluding music and kangaroo care).	63 studies totaling 4,905 participants. Studies related to heel sticks for blood sampling and venipuncture were excluded.	Standard mean difference, quality of evidence	There was evidence that non-nutritive sucking, swaddling, massage, tucking, environmental modification, rocking, video distraction, and non-parental distraction might be effective; however, there were no two high-quality studies from at least two independent sites, so strong recommendations for any single method could not be made.	I	I

Şahiner, N. C., & Bal, M. D. (2016). The effects of three different distraction methods on pain and anxiety in children. *Journal of Child Health Care, 20*(3), 277–285. doi:10.1177/1367493515587062	Three different distraction techniques were utilized with children during phlebotomy to evaluate which one alleviated pain the best.	Prospective RCT approved by the ethics committee. *N* = 120 Phlebotomy unit in Turkey Two nurses volunteered to collect the data and were trained by the researcher.	*N* =120, mean age 9.1 +/- 1.6 years. Four groups of children: one control group, one with distraction card, one with balloon inflation, and a music distraction group. Each group comprised of 30 children. Procedural pain was self-reported. Wong–Baker face scale utilized.	Compared use of distraction cards, listening to cartoon music, and balloon inflation. Power analysis = 0.08. *N* = 120 children, age range 6–12 years. Self-reported pain levels were significant ($p = 0.040$) among the study groups. Control group self-reported pain = 4.53 +/- 3.23. Distraction card group = 2.33 +/- 3.24 with a decreased pain level reported ($p = 0.057$). All distraction groups were lower than the control group. No significant differences between the parent and nurse-observer on procedural pain reporting. Anxiety levels were lower with all distraction techniques, but much lower than control group with the balloon-inflation method.	I	II
Şahiner, N. C., Inal, S., & Akbay, A. S. (2015). The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. *Journal of PeriAnesthesia Nursing, 30*(3), 228–235. doi:10.1016/j.jopan.2014.05.011	To evaluate the combined effects of cold and vibrations on pain and anxiety during immunizations in children.	Prospective RCT *N* = 104 Setting: Pediatric units, EDs, and surgical wards in Trieste, Italy (children's hospital) Approval from bioethics committee Power analysis determined appropriate sample size.	Wong–Baker Faces and Children's Fear Scale Ages of children = 7 yrs Immunization with DPT	Pain and anxiety evaluation before and during immunization with DPT. Pre-procedural anxiety in experimental group (1.23 +/- 1.66) and control (0.83 +/- 1.16). Pain in the experimental group during procedure (1.38 +/- 1.92) vs. 3.42 +/- 3.10 in control group. *p*-values less than 0.05 considered significant. Pre-procedural anxiety *p*-values (0.53 and 0.55). Pain *p*-values during procedure ($p = 0.001$).	I	II
Schmitz, M. L., Zempsky, W. T., & Meyer, J.M. (2015). Safety and efficacy of a needle-free powder lidocaine delivery system in pediatric patients undergoing venipuncture or peripheral venous cannulation: Randomized double-blind COMFORT-004 trial. *Clinical Therapeutics, 37*(8), 1761–1772. doi:10.1016/j.clinthera.2015.05.515	To determine if lidocaine hydrochloride monohydrate powder intradermal system (active system) compared with a sham placebo system provided an efficacious, safe, and tolerable analgesia for pediatric patients.	Design: Randomized, double-blind, placebo-controlled study Sample: 535, 269 intervention group, 266 sham placebo; 3 to 18 years of age Setting: 9 hospitals in US	Measures/Instruments: Wong–Baker FACES pain scale, visual analog scale (VAS). Active system: needle-free powder lidocaine delivery system - contained 0.5 mg lidocaine hydrochloride monohydrate powder and medical grade helium at a pressure of 21 +/- 1 bar. Sham placebo contained no lidocaine but otherwise identical. Statistical analysis: ANOVA, Cochran–Mantel–Haenszel test	Findings: Group with lidocaine powder had significantly ($p = 0.0022$) less pain than sham placebo in all age groups by modified Wong–Baker FACES scale. Secondary effect: Less pain on VAS for ages 8–18 ($p = 0.1856$), responder analysis ($p = 0.054$), parents VAS ($p = 0.002$). More minor erythema and hemorrhage/petechiae. Nausea and vomiting reported with the active system and sham placebo.	I	II
Schreiber, S., Cozzi, G., Rutigliano, R., Assandro, P., Tubaro, M., Wiel, L. C., … Barbi, E. (2016). Analgesia by cooling vibration during venipuncture in children with cognitive impairment. *Acta Paediatrica, 105*(1), e12-e16. doi:10.1111/apa.13224	To determine if cold therapy with vibration would decrease pain during venipuncture in cognitively impaired children.	Design: Prospective RCT Ethics board approval Power analysis determined sample size *N* = 70 children with 35 for each group for an alpha of 0.05 Setting: Tertiary level children's hospital ED in Italy	Median age = 9 years Parents were instructed in the use of the non-communicating children's pain checklist scale (post-operative version).	34 children in Buzzy® group, 36 in control group. Experimental group reported no pain or mild procedural pain in 32 cases (91.4%); in the control group, 22 (61.1%) children reported no pain ($p = 0.003$). Cognitively impaired children can benefit with the use of cold and vibration during IV cannulation.	I	II
Sethi, R. & Nayak, G. (2015). Effect of 24% oral sucrose in pain reduction during venipuncture in neonates. *Asian Journal of Nursing Education and Research, 5*(4), 457–460. doi:10.5958/2349-2996.2015.00093.2	To investigate the effectiveness of 24% oral sucrose in reducing pain during venipuncture among neonates admitted in NICU. Their primary aim was to determine an association between pre-intervention pain score with selected socio-demographic variables.	Design: Quasi-experimental (infants served as their own control), venipuncture with routine care was the control, second venipuncture was with sucrose. Sample: Convenience Setting: Infants admitted to NICU	Neonatal Infant Pain Scale (NIPS)	There was a significant reduction in mean pain scores during venipuncture after 24% oral sucrose solution was given ($p < 0.0001$). There was no association observed between pre-intervention pain scores for age, gender, weight, day of life, and method of delivery.	1	II
Sethna, N. F., Verghese, S. T., Hannallah, R. S., Solodiuk, J. C., Zurakowski, D., & Berde, C. B. (2005). A randomized controlled trial to evaluate S-CaineTM patch for reducing pain associated with vascular access in children. *Anesthesiology, 102*(2), 403–408.	Purpose of study: Prospectively investigated the efficacy and tolerability of a novel delivery device.	Design: RCT *N* = 64 patients with a 2 :1 randomization Population: 3–17 years old IRB approval: Yes Setting: Study Center – healthy subjects, not patients	Applied patch for 20 minutes and then removed. Oucher pain scale – has been tested for validity and reliability in children S-Caine™ patch or placebo placed for 20 minutes All participants (investigators, child, parents) blinded to treatment. Evaluated erythema and edema, skin blanching, patient's skin type and behavior before the vascular access.	This study demonstrated that the S-Caine™ patch significantly reduced pain in children compared with the placebo within a 20-min application time. 59% reported a painless procedure in the S-Caine™ group compared with 20% in the placebo group. Severe pain was reported by 5% of patients in the S-Caine™ group vs. 20% in the placebo group. A higher incidence of erythema and edema occurred with the patients receiving S-Caine™ treatment compared with placebo, but this was not statistically significant. 100% success rate for initial PIV placement and cannulation was reported. This was attributed to the vasodilation associated with the heating element contained in both control and study patches. Transient skin irritation occurred in both groups.	I	II

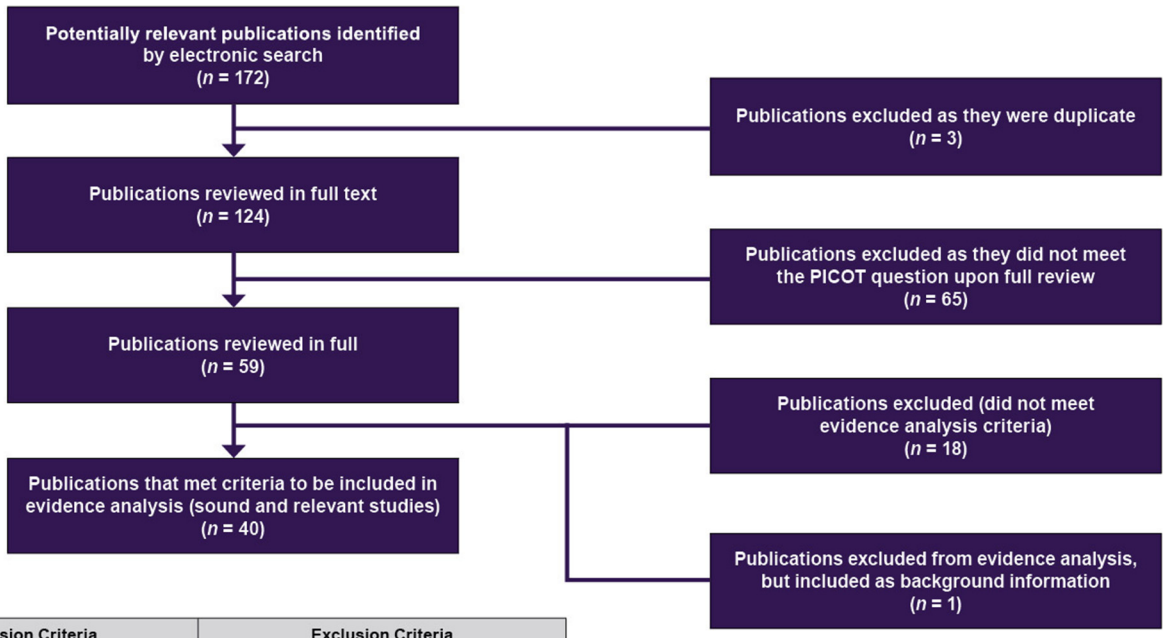
Singer, A. J., Taira, B. R., Chisena, E. N., Gupta, N., & Chipley, J. (2008). Warm lidocaine/tetracaine patch versus placebo before pediatric intravenous cannulation: A randomized controlled trial. *Annals of Emergency Medicine, 52*(1), 41–47. doi:10.1016/j.annemergmed.2008.01.336	Will the use of a topical lidocaine decrease the pain associated with PIV insertion in the pediatric patient by at least 15 mm as rated with the VAS?	Design: Randomized double-blind placebo-controlled prospective study *N* = 40 with 80% power to detect a 13% difference in pain scores; 20 in treatment group, 20 in placebo group Population: 3 to 17 yrs IRB Approval: Yes Academic suburban ED	Lido patch and placebo were identical in appearance and both contained a small warming element. Both nurses and patients were blinded. 23 G angiocatheter was used for all PIV attempts. 100 mm VAS used (or the Wong–Baker Faces scale if unable to use the VAS; both scales are validated). Pain assessed immediately after the first cannulation attempt.	A modest reduction in the pain of IV cannulation in pediatric ED patients was found and did not alter the rate of successful cannulation. Pain was significantly less in the study group (18 mm) compared with 35 mm in the control group. There was no difference in initial successful IV cannulations in both groups. Parents believed adequate pain relief was obtained in the lidocaine/tetracaine group and said they would probably ask for a lidocaine patch placement for future IVs. Nurse satisfaction was higher with the subjects in the lidocaine/tetracaine group relative to less pain. There was no statistical difference in the ease of use or adverse events with either patch.	I	II
Spanos, S., Booth, R., Koenig, H., Sikes, K., Gracely, E., & Kim, I. K. (2008). Jet injection of 1% buffered lidocaine versus topical ELA-Max for anesthesia before peripheral intravenous catheterization in children: A randomized controlled trial. *Pediatric Emergency Care, 24*(8), 511–515. doi:10.1097/PEC.0b013e31816a8d5b	To evaluate the use and anesthetic effectiveness in the PED of J-Tip® needle-free jet injection of 1% buffered lidocaine versus topical ELA-Max before pediatric PIV catheter insertion.	Design: Prospective block-randomized controlled clinical trial Sample: *N* = 77 (2 not analyzed) = 75 Convenience sample Population: 8–15 yrs old requiring PIV IRB approved Setting: Tertiary care children's hospital A VAS score reported with a difference of 10 mm showed clinical and statistical relevance. Power of 80% required 31 subjects in each group.	Use of music and television were excluded to prevent distraction from aiding in pain reduction. All included subjects used the VAS to determine their anxiety and pain levels before and after PIV insertion. Subjects in the J-Tip® group rated their pain immediately prior to and after the jet injection of 1% buffered lidocaine. Five minutes post-injection, the subjects rated their pain. After PIV insertion, pain rating was again reported by the patient. All subjects were video-taped during the study for pain assessment review by a blinded observer.	The nurse inserting the PIV rated the insertion difficulty and general satisfaction via a questionnaire using a Likert scale. Both control and study groups experienced no differences in pain during enrollment and prior to PIV insertion. Both groups reported similar scores for anxiety, but different pain scores. Patient-reported pain score differences were statistically significant. After PIV catheter insertion, patients reported much less pain in the J-Tip® jet-injection group compared with the ELA-Max group. The scores of the blinded observer for pain post-PIV insertion were not statistically significant. The reported scores of the nurses inserting the PIVs reflected positively on ease of insertion and nurse satisfaction. Route of lidocaine administration did not affect success with the first attempt at PIV insertion.	I	II
Spillman, N. (2012). A synthetical view of pediatrics, lidocaine, and procedural pain relief. *Plastic Surgical Nursing, 32*(2), 54–58. doi:10.1097/PSN.0b013e31825859d8	Focus of all studies looked at the use of needle-free lidocaine with IV insertion and venipuncture in children aged 3–18 years.	Design: Systematic review Study 1: An experimentally designed trial Study 2: A randomized placebo-controlled study Study 3: Randomized placebo-controlled experimental study Study 4: Randomized controlled study	Wong–Baker and VAS scales	All 4 studies reviewed showed the use of needle-free lidocaine made a significant reduction in the needle-related pain of PICU patients. Study 1 showed a mean pain score reduction of 42–43% in all ages between 3–18 years; Study 2 showed a pain reduction of 25%; Study 3 demonstrated a 47% decrease in mean VAS scores; Study 4 addressed the use of needle-free lidocaine compared with 4% topical ELA-Max. The mean pain score for needle-free lidocaine was reported as 17.3 compared with 44.6 in the ELA-Max group.	I	I
Stinley, N. E., Norris, D. O., & Hinds, P. S. (2015). Creating mandalas for the management of acute pain symptoms in pediatric patients. *Art Therapy, 32*(2), 46–53. doi:10.1080/07421656.2015.1028871	To assess the feasibility and outcomes of the mandala-making pain management intervention to determine if this intervention reduces pain during a needle stick procedures in a pediatric population.	Design: RCT Sample: *N* = 40 (7 to 18 years old); M = 12.3 (*SD* = 2.9); 20 male, 20 female Setting: Laboratory medicine clinic	Measures: Masimo Radical-7® Pulse CO-Oximeter machine (records heart rate and oxygen saturation), Hospital Fears Rating Scale (visual analogue scale), Wong–Baker visual analogue scale for pain	The treatment group had fewer stress behaviors during the needle stick procedure ($p = 0.03$). More control group cried during the procedure ($p = 0.05$) and there was a significant decrease in anxiety in the treatment group over time ($p = 0.04$, $DS = 1.66$, Cohen's $d = 0.8$). Change in heart rate was not significantly different at 1 and 7 minutes. Results indicate the mandala intervention is clinically feasible for pain management.	1	II
Taddio, A., McMurtry, C. M., Shah, V., Riddell, R. P., Chambers, C. T., Noel, M., . . . HELPinKids&Adults. (2015). Reducing pain during vaccine injections: Clinical practice guideline. *Canadian Medical Association Journal, 187*(13), 975–982. doi:10.1503/cmaj.150391 Full guideline: http://www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.150391/-/DC1	Clinical practice guideline on the reduction of pain during vaccine injections	Methodology: AGREE II tool Framework: GRADE and Cochrane methods.	n/a	Strong recommendations: Procedural: No aspiration (*SMD* −0.82, 95% CI −1.18 to −0.46), most painful last (*SMD* −0.69, 95% CI −0.98 to −0.40) Physical interventions: Breastfeeding < or = 2 yrs during injection (*SMD* −1.78, 95% CI −2.35 to −1.22), skin-to-skin contact during injection (*SMD* −0.65, 95% CI −1.05 to −0.25), holding during (*SMD* −1.25, 95% CI −2.05 to 0.46; *n* = 107), sitting upright (allows child feeling of control) decreases fear (*SMD* −0.39, 95% CI −0.77 to −0.01; *n* = 107) and observed distress (*SMD* −10.3, 95% CI −20.18 to −0.42; *n* = 107) Pharmacologic: Topical anesthetics (*SMD* −0.91, 95% CI −1.36 to −0.47, *n* = 1424), sweet-tasting solutions before vaccine (*SMD* −0.76, 95% CI −1.19 to −0.34, *n* = 2017) Process interventions: Education of clinicians, parents present, education of parents and individuals undergoing vaccine (3 years and older)	I	I

Taddio, A., Soin, H. K., Schuh, S., Koren, G., & Scolnik, D. (2005). Liposomal lidocaine to improve procedural success rates and reduce procedural pain among children: A randomized controlled trial. *Canadian Medical Association Journal, 172*(13), 1691–1695. doi:10.1503/cmaj.045316	To investigate the use of liposomal lidocaine for improvement of cannulation success rates and to determine whether it reduced pain and procedure duration.	Design: Double-blind randomized controlled trial Setting: Pediatric ED in Toronto, Canada Sample: Children 1 month to 17 years who required peripheral IV cannulation Liposomal lidocaine, n = 69; placebo, n = 73 5% liposomal lidocaine or placebo (base without active ingredient) in a 5-g tube 1 g of active drug or placebo applied to two potential sites for 30 minutes under an occlusive dressing Cream removed after 30 minutes.	Baseline pain assessment after 25 minutes by parents or by children who were 5 years of age or older using the Faces Pain Scale-Revised (FPS-R). Nurse rated difficulty expected for cannulation. Pain was rated by a research assistant for children less than 5 years and self-assessed by children 5 years and older. Pain was rated by the parents on all children.	Cannulation success rate: 74% with liposomal lidocaine compared with 55% for placebo. Total procedure time: Successful cannulation took less time with the use of liposomal lidocaine (6.7 min vs. 8.5 min). Skin reactions: Same in both groups. In the subset of children who were able to rate their own pain (age > 5 years, n = 67), those who received liposomal lidocaine reported less pain than those who received placebo.	II	II
Uman, L. S, Birnie, K. A., Noel, M., Parker, J. A., Chambers, C. T, McGrath, P. J., & Kisely, S. R. (2013). Psychological interventions for needle-related procedural pain and distress in children and adolescents *Cochrane Database of Systematic Reviews,* (10), CD005179. doi:10.1002/14651858.CD005179.pub3	Update of 2006 review to assess effects of psychological interventions for needle-related procedural pain/distress in children and adolescents.	Systematic review with meta-analysis of RCT that had a control group with only a psychological intervention. Review included 39 studies (21 from original review and 18 new studies).	n/a	Evidence supported distraction for reducing pain and hypnosis for reduction of pain and distress. No clear evidence for specific type of distraction. 19 studies on the effects of distraction on self-reported pain: *SMD* = −0.61 (95% CI −0.91 to −0.32) and I^2 of 88%, effect significant (A = 4.08, $p < 0.0001$). Five studies analyzed effects of distraction of observer-reported pain, *SMD* = −0.87 (95% CI −1.75 to 0.02) and I^2 of 94%, effect marginally significant, ($Z = 1.92$, $p = 0.05$). Five studies on effects of hypnosis on self-reported pain: *SMD* = −1.40 (95% CI −2.32 to −0.48) and I2 of 85%. Effect significant ($Z = 2.97$, $p = 0.003$). Five studies on the effects of hypnosis on self-reported distress: *SMD* = −2.53 (95% CI −3.93 to −1.12) and I^2 of 91%, effect size significant ($Z = 3.53$, $p = 0.0004$). Six studies on the effects of hypnosis on behavioral measures of distress, *SMD* = 1.15 (95% CI −1.76 to −0.53) and I^2 of 71%, significant ($Z = 3.66$, $p = 0.0003$).	I	I
Vagnoli, L., Caprilli, S., Vernucci, C., Zagni, S., Mugnai, F., & Messeri, A. (2015). Can presence of a dog reduce pain and distress in children during venipuncture? *Pain Management Nursing, 16*(2), 89–95. doi:10.1016/j.pmn.2014.04.004	To investigate the beneficial effects of animal-assisted intervention (AAI) in children undergoing blood testing in the hospital setting.	RCT	Observation Scale of Behavioral Distress (OSBD-A), Wong–Baker Faces Scale, VAS, State Trait Anxiety Inventory (STAI), serum cortisol plasma levels.	Total, before, and during distress levels were significantly higher in the control group, yet no significant difference in distress after the procedure. No significant differences in pain. Cortisol levels were higher in the control group.	II	II
Waterhouse, M. R., Liu, D. R., & Wang, V. J. (2013). Cryotherapeutic topical analgesics for pediatric intravenous catheter placement: Ice versus vapocoolant spray. *Pediatric Emergency Care, 29*(1), 8–12. doi:10.1097/PEC.0b013e31827b214b	Purpose: Comparison of vapocoolant vs. ice in reducing pain in pediatric patients undergoing IV insertion in the ED	Design: RCT Sample: N = 95, aged 9–18 yrs Setting: ED	Visual Analog Scale (VAS) to measure pain	More subjects in the Pain Ease® group (76%) felt their treatment was effective compared with the ice group (49%). IV placement was effective (83%). Visual analogue scale changes from baseline were more pronounced in the vapocoolant group. Median VAS scores were similar in both groups.	II	III
Wente, S. J. (2013). Nonpharmacologic pediatric pain management in Emergency Departments: A systematic review of the literature. *Journal of Emergency Nursing, 39*(2), 140–150. doi:10.1016/j.jen.2012.09.011	To review the non-pharmacologic methods of pain management in pediatric ED patients. 14 articles were reviewed after meeting inclusion criteria: Ten addressed distraction, two addressed the use of sucrose, one addressed cold application, and one examined parental holding.	Systematic review		Distraction: Decreased pain significantly, with the use of multiple methods. Pain improvement was noted in infants 0–6 months with the use of a pacifier. Sucrose: Reduced pain for children 0–30 days only. Cold therapy: Significantly reduced pain. Holding: Decreased distress for children, made no difference for parents; improved nurse satisfaction with better positioning.	I	I
Wolyniez, I., Rimon, A., Scolnik, D., Gruber, A., Tavor, O., Havir, E., Glatstein, M. (2013). The effect of a medical clown on pain during intravenous access in the pediatric emergency department: A randomized prospective pilot study. *Clinical Pediatrics, 52*(12), 1168–1172. doi:10.1177/0009922813502257	To determine the effect of the presence of a medical clown during an IV insertion.	Pilot study, prospective, randomized, modified block randomization to assure equal gender distribution.	Primary outcome was pain intensity. Children 3–7 used the Faces Pain Scale-Revised, 7 and older children the 100 mm VAS. State Trait Anxiety Inventory.	Tendency with younger children for the pain score to be lower when the clown was present but unchanged with older children. Decrease in average pain score from 3.3 in the control group to 1.6 in the intervention group ($p = 0.187$). Most differences did not reach statistical significance.	II	II
Yinger, O. S., & Gooding, L. F. (2015). A systematic review of music-based interventions for procedural support. *Journal of Music Therapy, 52*(1), 1–77. doi:10.1093/jmt/thv004	To determine how anxiety and pain levels respond to music during medical procedures.	Systematic review	50 studies met inclusion criteria; 84% had an increase in risk of bias. This review could not be completed as a meta-analysis because of multiple variables in the interventions and procedures.	48% of the studies demonstrated a decrease in anxiety during medical procedures with musical intervention; 38% showed a decrease in pain during the medical procedure with musical intervention. Even though only 8 studies included pediatric populations, this systematic review addressed the effect of musical intervention related to pain and anxiety relief during painful procedures.	I	I

Appendix 2. Other Resources Table

Reference	Description	Conclusions
Ali, S, McGrath, T., & Drendel, A. L. (2016). An evidence-based approach to minimizing acute procedural pain in the emergency department and beyond. *Pediatric Emergency Care, 32*(1), 36–42. doi:10.1097/PEC.0000000000000669	Review article and provided a summary of strategies used for procedural pain.	Summary of studies on procedural pain covering use of sucrose/sweet-tasting solutions, topical anesthetics, and nonpharmacological strategies including contextual, cognitive (psychological), and behavioral strategies, and other strategies including breastfeeding/breast milk, tissue adhesives, venipuncture vs. heel lance and pH adjustment of lidocaine.
Bahorski, J. S., Hauber, R. P., Hanks, C., Johnson, M., Mundy, K., Ranner, D., . . . Gordon, G. (2015). Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study. *International Journal of Nursing Studies, 52*(10), 1553–1564. doi:10.1016/j.ijnurstu.2015.05.014	To determine if the type of preparation before venipuncture were associated with the perceived pain and if age, sex, or ethnic group were associated with the effectiveness of the intervention.	Findings: No statistical difference among treatment groups based on observation measures (CHEOPS) ($F = 1.830$, $p = 0.164$) or self-report of pain (WBFPRS) ($F = 1.467$, $p = 0.235$). There was a statistically significant interaction between ethnic group and treatment group ($p = 0.006$) based on observation, and also between ethnic group and treatment group based on self-report ($p = 0.04$).
Bice, A. A., & Wyatt, T. H. (2016). Holistic comfort interventions for pediatric nursing procedures: A systematic review. *Journal of Holistic Nursing, 35*(3), 280-295. doi:10.1177/0898010116660397	To compare the efficacy of IV ketamine with pethidine in reducing pain and anxiety in children who had been diagnosed with cancer and were undergoing bone marrow aspiration or biopsy.	Hemodynamic stability and reported pain were significantly reduced using IV ketamine. The ketamine had an increased but not significant incidence of nausea and vomiting. Ketamine and midazolam provided better analgesia and less hemodynamic instability than pethidine and midazolam.
Cummings, J. A. F. (2015). Pediatric procedural pain: How far have we come? An ethnographic account. *Pain Management Nursing, 16*(3), 233–241. doi:10.1016/j.pmn.2014.06.006	Ethnography used to evaluate pediatric pain management practices in a non-pediatric ED.	Two main themes were identified: 1) treatment of pain and 2) procedural pain. No standardized assessment or measurement tools were used for the assessment of procedural pain. There was no measurement of pain related to treatment or procedures, and restraints were often used.
Harrison, D., Bueno, M., & Reszel, J. (2015). Prevention and management of pain and stress in the neonate. *Research and Reports in Neonatology, 5*, 9–16. doi:10.2147/RRN.S52378	Review of methods to assess neonatal pain and a review of evidence supporting measures to reduce pain and barriers to use of the measures in the practice setting.	Pain indicators of neonatal pain were reviewed along with the pain-mitigating strategies of breastfeeding, skin-to-skin contact, and sweet solutions, and facilitators and barriers to implementation of each discussed.
Krauss, B. S., Calligaris, L., Green, S. M., & Barbi, E. (2016). Current concepts in management of pain in children in the emergency department. *Lancet, 387*(10013), 83–92. doi:10.1016/S0140-6736(14)61686-X	Review of the state of ED pain management in children, specifically addressing pain recognition, assessment, and pharmacological and non-pharmacological interventions.	Current pain management of children was discussed including the recognition and assessment of pain, children with special needs, non-pharmacological approaches for acute pain and anxiety, the role of parents, and the pharmacological treatment of acute pain for mild, moderate, and severe pain.
Olmstead, D. L., Scott, S. D., Mayan, M., Koop, P. M., & Reid, K. (2014). Influences shaping nurses' use of distraction for children's procedural pain. *Journal for Specialists in Pediatric Nursing, 19*(2), 162–171. doi:10.1111/jspn.12067	To evaluate the pediatric nurse's choices of distraction methods for use during painful procedures.	Factors that contributed to nurses' perceptions of efficacy of distraction as an intervention included nurse experience/knowledge, age appropriateness of distraction method, parental support, time window, and child's autonomy.
Wong, D. L., & Baker, C. M. (1988). Pain in children. Comparison of assessment scales. *Pediatric Nursing, 14*(1), 9–17.	This study is an attempt to provide the basis for selecting suitable research scales for pain assessment. Second objective is the identification of painful events as perceived by hospitalized children. Hypothesis/theoretical framework: No difference between the first test and the retest for preference, validity, and reliability of the six scales.	Preference: Statistically significant. Most-preferred for all age groups was the FACES scale. Validity and Reliability: Not statistically significant. No significant differences exist among the scales for any age group. Colors chosen for pain ratings were analyzed using a frequency table. No one color scale predominated. Colors often differed in the test and retest. Orange was most often associated with least pain and black with most. χ^2 was significant for least and most pain colors for the overall age group.

Appendix 3. Study Selection Flow Chart and Inclusion/Exclusion Criteria



Inclusion Criteria	Exclusion Criteria
Studies published in English	Studies not published in English
Studies involving human subjects	Non-human studies
January 1990 - February 2016	Studies not in the timeframe listed
Studies addressing the PICOT question	Studies not addressing the PICOT questions

Searches were performed using: PubMed, CINAHL, The Cochrane Library, British Medical Journal, Agency for Healthcare Research and Quality, and the National Guideline Clearinghouse.

Search terms included: pediatrics, procedural pain, minor procedures, emergency department, intravenous cannulation, anxiety, and pain using a variety of search combinations.

Synopsis

CLINICAL QUESTION

Is there evidence of pain and distress reduction in pediatric patients who receive analgesic or anxiolytic interventions during needle-related or minor invasive procedures in the emergency department?

PROBLEM

Approximately 17% of children in the United States visited the emergency department (ED) in 2015 (National Center for Health Statistics, 2017). During these emergency department visits, pediatric patients frequently experience invasive procedures including intravenous (IV) catheterization, bladder catheterization, venipuncture, immunization administration, and nasogastric tube placement. These procedures contribute to the stress and anxiety of treatment in the ED for pediatric patients (Ali, McGrath, & Drendel, 2016; Babl et al., 2009; Farion, Splinter, Newhook, Gaboury, & Splinter, 2008). Because procedural pain is commonly associated with ED visits, safe and effective interventions addressing pain in the pediatric population are essential. Researchers have revealed deficiencies in ED pain assessment and management, particularly with children (Ali et al., 2016). Multiple techniques to reduce pain and distress for needle-related procedural pain or minor invasive procedures are presented in the CPG. This CPG includes behavioral interventions, dermal anesthetic preparations, subdermal local anesthetic with needle-free delivery, application of ice and vibration, the use of sucrose, or a combination of therapies.

Description of Decision Options/Interventions and the Level of Recommendation

Description of Decision Options/Interventions and the Levels of Recommendation		
Behavioral Interventions	Breastfeeding, skin-to-skin contact, and parental holding are beneficial behavioral interventions to reduce procedural pain in infants (Curtis et al, 2012; Lee et al., 2014; Taddio et al., 2015).	A
	There is sufficient evidence to support the use of hypnosis for reducing procedural pain and distress in areas with appropriately trained personnel (Birnie et al., 2014; Curtis et al, 2012; Uman et al., 2013).	A
	There is sufficient evidence to support the efficacy of developmentally appropriate use of distraction cards, kaleidoscope, balloon inflation, play dough, and the cough trick in reducing pain and distress (Canbulat et al., 2014; Maghsoudi et al., 2015; Mutlu & Balci, 2015; Şahiner & Bal, 2016).	A
	There is evidence that verbal coaching, breathing exercises alone or with toys, and handheld electronic devices decrease procedural pain and distress (Birnie et al., 2015; Birnie et al., 2014; Chambers et al., 2009; Curtis et al., 2012; McCarthy et al., 2014; Miller et al., 2016; Rezai et al., 2016; Riddel et al., 2015; Stinley et al., 2015; Uman et al., 2013).	A
	The presence of clowns may reduce procedural pain and anxiety in some children (Ben-Pazi et al., 2017; Felluga et al., 2016; Gilboa-Negari et al., 2017; Meiri et al., 2016; Wolyniez et al., 2013).	A
	Evidence supports the effectiveness of patient information/preparation in combination with distraction to decrease pain and distress (Taddio et al., 2015; Uman et al., 2013).	A
	Listening to music is an effective distraction technique in reducing pain and distress (Birnie et al., 2015; Burns-Nader et al., 2017; Hartling et al,, 2013; Rezai et al., 2016; Uman et al., 2013; Yinger & Gooding, 2015).	A
	There is evidence that reduction of anxiety may decrease procedural pain (Chieng et al., 2014; Goettems et al., 2017; Hyland et al., 2015; Matziou et al., 2013; Meiri, et al., 2016).	A
	There is insufficient evidence to make a recommendation for a dog being present during a procedure to decrease distress levels in children accustomed to being around dogs (Vagnoli et al., 2015).	I/E
Dermal Anesthetic Preparations	All transdermal forms of lidocaine/tetracaine (amethocaine) are effective in reducing pain associated with IV cannulation, venipuncture, and immunization. Preparations in the form of cream or patches take longer to exert an effect (60 minutes or more), which makes them less feasible for use in the ED environment. (Curtis et al., 2012; Lee et al., 2014; Schmitz et al., 2015; Sethna et al., 2005; Singer et al., 2008; Taddio et al., 2015).	A
	Pentafluoropropane and tetrafluoroethane (Pain Ease®) results in a moderate reduction in pain in patients 6–12 years of age undergoing IV cannulation (Farion et al., 2008; Waterhouse et al., 2013).	B
	Ethyl vinyl chloride may be effective in relieving pain associated with venipuncture (Costello et al., 2006; Taddio et al., 2015).	B
Sucrose	Evidence suggests that sucrose is beneficial as a form of analgesia in children from zero to three months of age; no benefit has been demonstrated for children older than three months. (Desjardins et al., 2016; Ferayorni et al., 2012; Harrison et al., 2017; Harrison et al., 2015; Hatfield et al., 2011; Lee et al., 2014; Sethi & Nayak, 2015; Taddio et al., 2015).	A
Local Application of Ice and Vibration	Local application of ice along with vibration decreases the pain and distress associated with venipuncture. (Baxter & Cohen, 2011; Canbulat et al., 2015; Faroukh et al., 2016; Şahiner et al., 2015; Schreiber et al., 2016).	B
Subdermal Local Anesthetic with Needle-Free Delivery	The use of a needleless injection device (e.g., J-Tip®) as a delivery method for lidocaine is superior to other forms of preparation when rapid local anesthesia is required. (Ferayorni et al., 2012; Jimenez et al., 2006; Spanos et al., 2008; Spillman, 2012).	A

Level A (High)	Based on consistent and good quality of evidence; has relevance and applicability to emergency nursing practice.
Level B (Moderate)	There are some minor inconsistencies in quality evidence; has relevance and applicability to emergency nursing practice.
Level C (Weak)	There is limited or low-quality patient-oriented evidence; has relevance and applicability to emergency nursing practice.
N/R	Not recommended based upon current evidence.
I/E	Insufficient evidence upon which to make a recommendation.
N/E	No evidence upon which to make a recommendation.

Clinical Practice Guideline: Needle-Related or Minor Procedural Pain in Pediatric Patients

ENA Clinical Practice Guidelines (CPGs) are evidence-based documents that facilitate the application of current evidence into everyday emergency nursing practice. CPGs contain recommendations based on a systematic review and critical analysis of the literature about a clinical question. CPGs are created following the rigorous process described in ENA's Requirements for the Development of Clinical Practice Guidelines. The purpose of CPGs is to positively impact patient care in emergency nursing by bridging the gap between practice and currently available evidence.

Access the full CPG at: www.jenonline.org

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