TITLE: Pain After Tonsillectomy (PAT) Study

SPONSOR: Alberta Children's Hospital Foundation

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BACKGROUND:

Pain is a common experience in childhood. Healthy children who are compliant with medical care undergo up to 20 painful procedures by the age of 5.[1] Moreover, millions of children undergo surgery (e.g., tonsillectomies) each year, which is commonly linked to pain and distress.[2] Pain from, and fear of, medical experiences are neither short lasting or benign and can influence children long after the painful stimulus is removed.[3] Children's memories of needle-related, experimental, post-surgical, and procedural pain are a powerful predictor of future pain experiences, and are sometimes more influential to future pain than the initial experience of pain itself.[4-6] Memory is susceptible to distortion. Negative biases in pain memories (i.e., recalling higher levels of pain as compared to initial pain report) are associated with higher subsequent pain, distress, and worse medical compliance.[4,7] Empirical and theoretical work[3,8] has implicated a number of factors in the development of negatively biased pain memories in children. Child sleep and language abilities have been shown to influence memory development following stressful and painful events.[9-11] Children who are more anxious and who experience greater pain are more likely to develop negatively biased pain memories,[12] which then leads to greater fear and pain at subsequent pain experiences.[5] Parents and adolescents who think in more catastrophic ways about child pain prior to surgery tend to develop more negatively biased pain memories months later.[13] In fact, parents' catastrophic thinking about child pain was found to be the single most important predictor of children's memory biases[13] and subsequent pain trajectories.[14] It has been suggested that parental and child anxiety lead to memory biases

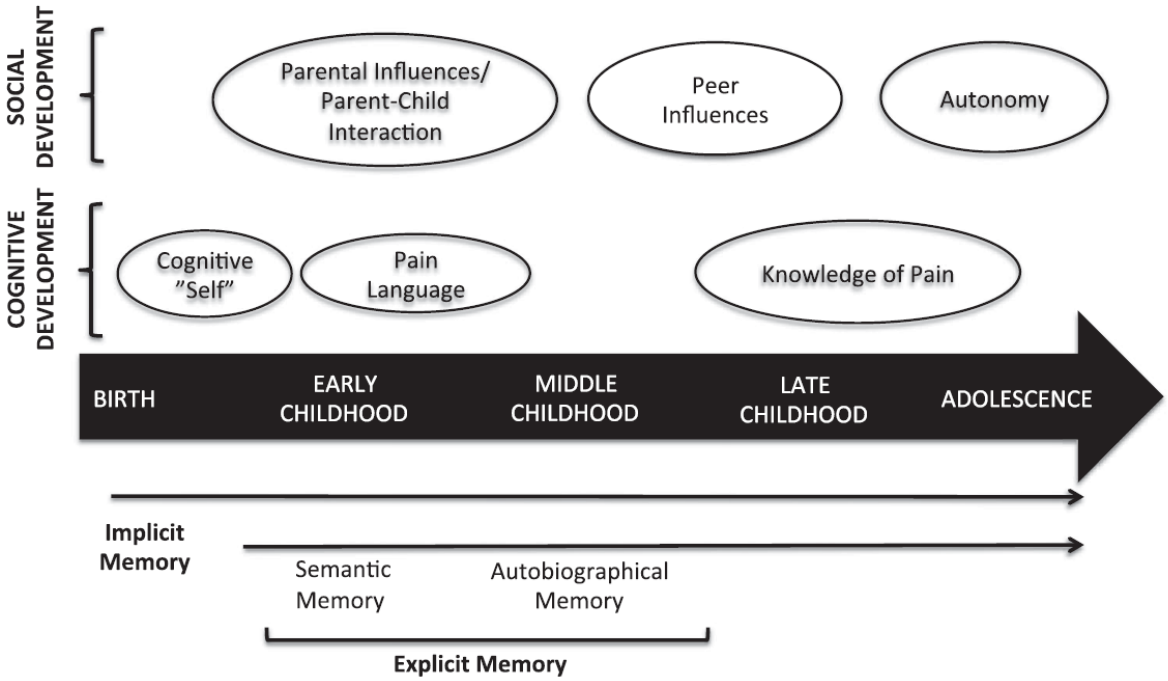

Figure 1. Cognitive and social developmental factors underlying the formation and expression of pain memories in childhood.

because of the ways in which parents and children talk about pain following painful events (e.g., by emphasizing threatening aspects of the experience).[8]

We recently published a conceptual developmental framework in the journal PAIN[8] outlining the cognitive and social factors that are thought to influence children's pain memory development (Figure 1). Of particular importance is early childhood (ages 4-7 years) when children are *most* susceptible to memory biases due to suggestibility effects. It is also during this time that parents are most influential in shaping children's cognitions, emotions, and behaviors.[8] Our model posits that the socio-linguistic context (e.g. parent-child narratives about pain) in which pain memories develop is most important in early childhood and sets the stage for future pain experiences.

There have only been a few studies examining memory reframing interventions in the context of children's recall of (needle) pain. In our recent systematic review, existing trials of memory reframing interventions were found to be efficacious in reducing negative memory biases.[15] Indeed, parent-child language-based interactions about past negative events play a powerful role in how autobiographical memories of those events are subsequently retrieved and reframed.[16] Parent-child narrative style also influences children's coping and psychological functioning.[16] Young children whose parents are topic-extending and elaborative (e.g., who ask open-ended questions to pull for richer, more detailed accounts of the past) and who use emotional language, have children who are more accurate and detailed in recalling their pasts, which is adaptive.[17]

Recent data from our lab provides compelling evidence that parents who reminisce with their children about surgery using a particular style (e.g., more elaborative, less topic-switching) and content (e.g., less content about pain, fear, medical procedures; more explanations) have children who later remember post-surgical pain in a more accurate and positively biased way. Parental reminiscing style and content have been effectively targeted in interventions to improve children's memory development. However, memories of post-surgical pain, that can be negatively biased and lead to persistent pain problems,[4] have not been targeted, despite a relative dearth of, and need for, interventions for this pediatric population.[18,19] Moreover, existing memory reframing interventions did not employ parents, who play a critical role in children's pain memory formation and are underutilized intervention agents.[16,20] Indeed, parents are potentially the most powerful and accessible agents of change, and our recent data provides strong evidence that the language parents use when reminiscing with children following tonsillectomies influences children's pain memory biases. Interventions requiring an interventionist and separate visits have limited utility in routine clinical practice. Engaging parents would greatly increase the availability of such interventions.

The objective of the proposed research study is ***to conduct a pilot study to examine the preliminary efficacy, feasibility, and acceptability of a brief parent-led memory reframing intervention following pediatric surgery to foster more adaptive (i.e., less negatively biased) pain memories***. The intervention will draw from our recent data and extant memory reframing and narrative-based intervention techniques to promote more accurate/positive pain memories by teaching parents more adaptive styles of reminiscing with their children about a past surgery. We will accomplish our aims by extending our existing program of research on post-surgical pain memory development of children (aged 4-7 years) and randomly assigning parents to receive a memory reframing intervention or attention control following surgery and subsequently assessing children's memories for pain. This study will be the first to develop and pilot test a brief, parent-led intervention aimed at changing the way children recall their pain after surgery, thereby extending memory-reframing techniques to the post-surgical pain context. Given the integral role of pain memories in shaping future pain experiences and the need for interventions in the pediatric surgery context,[18,19] this study has great potential to contribute an accessible and feasible post-surgical pediatric pain management intervention and foster more adaptive pain trajectories and medical experiences in childhood.

STUDY AIMS

Primary Aim

1) To examine the preliminary efficacy, feasibility, and acceptability of a parent-led memory reframing intervention on children's post-surgical pain memories.
   Hypothesis 1: Children in the intervention group will go on to recall post-surgical pain in a more accurate or positively biased way as compared to the control group who will remember pain in a more negatively biased way. The intervention will be judged by parents to be feasible and acceptable.

Secondary Aim

2) To examine the influence of baseline individual child and parent characteristics on children's pain memories.
   Hypothesis 2: Children who are more anxious, less self-efficacious, have worse sleep quality, and whose parents are more anxious and catastrophize more about child pain prior to surgery will subsequently remember pain in a more negatively biased way.

METHODS

Sample

One hundred children (50 intervention, 50 control) between the ages of 4-7 years and one of their parents will be recruited from the Ear Nose and Throat Clinic at Alberta Children's Hospital, where the PI's research laboratory is housed. A child will be eligible to participate in the proposed study if he/she 1.) is between 4 and 7 years old at the time of recruitment; 2.) is scheduled for an elective outpatient tonsillectomy (with or without adenoidectomy); 3.) is able to understand and speak English 4.) has at least one of his/her parents/caregivers consent to participating in the study and this caregiver is able to speak and read English.

Exclusion criteria include: 1) receiving pre-medication with anxiolytics (Midazolam; administered to < 5% of youth), as it might interfere with child's preoperative anxiety[21] and memory formation;[22] 2) serious medical co-morbidities (American Society of Anesthesiologists [ASA] ≥ III physical status) that would interfere with standardized protocols of analgesic administration and surgical technique; 3) developmental disabilities or speech/language delays, as it may make it difficult for the participants to complete all necessary study tasks (e.g., assent, narrative task, memory interview).

Procedure

Patients will be identified through surgery schedule lists. At entry into the clinic, a member of the Ear, Nose and Throat Clinic will provide potentially eligible patients with information about the study. Parents provide permission to be contacted by the research team. Several weeks before surgery, a member of the research team will conduct a recruitment phone call with all eligible patients' parents to discuss the study. Following the recruitment phone call, online consent forms will be emailed to interested participants. Parents will provide consent for the child's participation; children, who are 7 years old or over or turn 7 during the course of participation in the study, will provide assent. One week before surgery, parents will complete measures of parent catastrophizing about child pain, child language, and child sleep. For descriptive purposes, parents will report on socio-demographics (parent education, child age, household income), preparation that they/their child received about the surgery and what this entailed (e.g., coping skills, pain management), and family history of tonsillectomies and surgeries. On the day of surgery, measures of parental state anxiety will be obtained as well as children's levels of pain and pain-related fear. A trained observer will objectively assess

preoperative child anxiety at the time of anesthesia induction using a well-validated behavioral scale (described below).

As per standard clinical care (the following has been indicated by our Anesthesiologist colleague, Dr. Nivez Rasic): In Day Surgery, all patients will receive Tylenol 15 mg/kg orally pre-operatively, unless there is a specific contraindication. One parent may be present at anesthesia induction with their child. The child will receive an inhalational induction with sevoflurane, oxygen, and nitrous oxide. An intravenous will then be inserted, and the child will be maintained on either volatile anesthetic or total intravenous anesthetic (TIVA) for the procedure. The child will then be extubated deep or awake at the end of the procedure and transferred to the Post-Anesthesia Care Unit (PACU). During the procedure, all patients will receive dexamethasone 0.2 mg/kg IV, ondansetron 0.1 mg/kg IV, and morphine for analgesia. Again, as per standard clinical care: All of the ENT surgeons will use cautery to the tonsillar bed as their surgical technique for tonsillectomy with or without adenoidectomy. The patients will be recovered in the PACU. A decision of whether or not to bring a parent or caregiver into the PACU will be made at the discretion of the PACU nurse and the anesthesiologist. Information regarding the surgical technique used and analgesic and anesthetic agents administered on the day of surgery will be collected via medical chart review (using Clinibase and Sunrise Clinical Manager).

A researcher will obtain ratings of child pain intensity shortly following surgery and again prior to discharge home. Parents will be given and instructed on how to administer the pain scales so that child-reports of pain can be captured at home. These scales and instructions will also be provided to parents via emailed survey links (REDCap). Consistent with timelines used in previous studies,[23] proxy and self-reports of child average and worst pain intensity and pain-related fear will be assessed on days 1, 2, 3, 7 and 14 post-surgery. Proxy-reports of child sleep will be assessed on day 14 post-surgery. Parents will also report on the use of analgesics at home. At 2-weeks post-surgery, parents and children will come to the PI's research lab within the Vi Riddell Pain Centre at Alberta Children's Hospital during which time they will be randomized into an intervention or control group. Randomization will be conducted by an external statistician using a computer random number generator. Allocation concealment will be achieved using sequentially numbered, opaque, and sealed envelopes. Group allocation will be revealed by a researcher at the outset of the lab visit.

During the lab visit, parents in both groups will talk to a researcher for approximately 20 minutes while another researcher plays with the child (e.g., watching a video, coloring, playing toys) in a separate room.

Control Group. Similar to previous narrative and memory interventions, parents in the control group will receive instructions from a researcher on how to engage in child-directed play.[24] Importantly, they will not talk about pain or the past surgery experience. After this 20-minute period, parents in the control group will be instructed to reminisce with their children about the in-hospital and post-surgery periods *as they normally would*.

Intervention Group. Parents in the intervention group will spend the same about of time (20 minutes) with a researcher and receive instructions about adaptive ways of reminiscing about

the in-hospital and post-surgery periods. The intervention will draw from existing narrative-based interventions that have taught parents to reminisce with their children about past negative events in more elaborative and emotion-rich ways (e.g., using more open-ended questions, to follow up on children's answers by providing new details about the event, to talk more about emotions, and to praise children's answers). We will also include elements of past pain memory reframing interventions and findings from our recent data. Specifically, parents will be taught to reminisce with their children about the in-hospital and post-surgery periods by providing more explanations for events, using less utterances about pain, fear, and medical procedures, emphasizing positive aspects of the child's surgery memory (e.g., when children used coping methods such as deep breathing, when they got a treat),[25] and enhancing children's self-efficacy regarding their ability to cope with pain.[26] Similar to previous interventions, to boost mastery of the material, the researcher will use short videos of prototypical parent-child reminiscing about the in-hospital and post-surgery periods to illustrate adaptive and maladaptive reminiscing style and content. Researchers will also provide suggestions for specific questions and remarks to make while reminiscing. Parents and researchers will engage in brief role-plays to solidify the techniques, which will be followed by researcher feedback. After this training period, parents in the intervention group will be instructed to reminisce with their children about the in-hospital and post-surgery periods *using the intervention strategies*.

After parents have finished reminiscing about the in-hospital and post-surgery periods with their child, parents in both groups will be asked to complete a short questionnaire containing similar measures as completed at baseline.

Three to four weeks after surgery, children in both groups will complete a telephone pain memory interview to assess children's recall of the in-hospital and post-surgery periods.[13,27] Then, parents in the intervention group will complete a brief semi-structured telephone interview to assess feasibility and acceptability of the intervention.[19,28]

Incentives

As a token of appreciation for their commitment to the study, each family (a parent and a child) will receive $20 gift card (e.g., to Amazon.ca, ToysRUs, etc.) at the end of the lab visit and another $20 gift card after the completion of the memory interview. Given the longitudinal nature of the study, we consider this to be a modest incentive that will not coerce participants into participation. Moreover, it is consistent with honoraria provided in our previous studies of similar nature. Families will also be reimbursed for any parking costs during their lab visit.

Measures

Child state anxiety. Proxy ratings of children's state anxiety will be assessed by parents using a numeric 0-10 scale (NRS). Parents and research assistants will use the NRS to provide proxy ratings of the child's state anxiety in the preoperative holding area and operating room.[29]

Child pain-related fear. Children's pain-related fear will be assessed using the Children's Fear Scale (CFS).[30] This scale depicts five faces of varying degrees of fear from 'not at all scared' to

'most scared possible'. It shows evidence of good concurrent and discriminant validity and test-retest reliability.[30]

Child preoperative anxiety. The 27-item Modified Yale Preoperative Anxiety Scale (mYPAS)[31] will be used by two trained observers to assess preoperative anxiety. The mYPAS assesses five domains of behaviour: activity, emotional expressivity, state of arousal, vocalization, and use of parents. Higher scores indicate greater preoperative anxiety. The scale has been shown to be reliable and demonstrated high convergent validity when validated against other behavioural measures of pediatric anxiety.[32]

Child post-operative pain. Pain intensity will be assessed using a well-validated single-item faces pain scale (Faces Pain Scale-Revised; FPSR),[33] by parents (proxy reports of child pain) and children themselves. A parent-report behavioural checklist (Parent's Postoperative Pain Measure; PPPM)[34] will also be used. The FPSR is the most psychometrically sound measure of pain intensity for children in this age range.[35] The PPPM is a 15-item measure intended for use with parents of children aged 2-12 to reliably evaluate child pain after surgical procedures. It is intended for use at home and is the most validated observational measure of postoperative pain.[36]

Child self-efficacy. Parents and children will rate their pain-related self-efficacy regarding post-surgical pain. Children will use a 100-mm visual analogue scale (VAS) to assess "how well (they) think (they) will do after surgery".[26] Parents will rate their self-efficacy about their ability to control their child's post-surgical pain on a 0-10 Numerical Rating Scale.

Child sleep quality. The 26-item Sleep Disturbance Scale for Children (SDSC) will be used to assess parental reports of child sleep quality.[37] The SDSC yields six subscales: sleep initiation and maintenance, sleep-related breathing disorders (SRBD), sleep arousal, sleep-wake transition disorders, excessive daytime sleepiness, and sleep hyperhydrosis. The SDSC has been validated for use with children aged 3 to 18 years,[37,38] and shows strong evidence of reliability and validity against polysomnography.[39]

Child language and communication skills. The Children's Communications Checklist-2 (CCC-2)[40] is a psychometrically sound 70-item measure designed to assess communication skills and to identify clinically significant language and speech impairment in youth aged 4-16 years. The CCC-2 assesses articulation, phonology, language structure, and vocabulary, as well as pragmatic aspects of children's communication skills. Items assess areas of strengths and weaknesses and are rated on a 4-point Likert frequency scale.

Parent state and trait anxiety. Parents will use the 40-item State-Trait Anxiety Inventory (STAI) to assess their own state and trait anxiety.[41] Items are rated on a 4-point Likert Frequency Scale. The STAI has been used to assess parents' anxiety during children's tonsillectomies[42] and has excellent psychometric properties.[43] Parents will also use an NRS to report how anxious they feel about the child's upcoming tonsillectomy 1 week before the surgery and before anesthesia is given to their child. If anxiety ratings are 1 or greater at the first point of assessment, a follow-up question will be asked to determine the specific content of their anxiety (e.g., anesthesia, pain control, surgery, side effects, etc.).

Parent catastrophic thinking about child pain. The Pain Catastrophizing Scale-Parent Version (PCS-P) is a 13-item self-report measure that assesses catastrophic thoughts and feelings that parents may have when their child experiences pain.[44] Items on the PCS-P are rated on a 5-point Likert scale. The PCS-P is both valid and reliable among parents of youth with and without pain problems.[44]

Feasibility. Similar to previous research,[28] feasibility will be assessed using study recruitment/enrollment statistics, completion of the study elements; and researchers' and parents' ratings of parents' motivation to learn, understanding of the intervention, and parent-child and parent-researcher rapport rated on 11-point Likert scales.

Acceptability and satisfaction. Acceptability will be assessed at study completion (i.e., after memory interviews). The parent-report 9-item Treatment Evaluation Inventory-Short Form (TEI-SF) will be used to assess parental acceptability and satisfaction with the intervention; however, items will be slightly modified to pertain to the memory reframing intervention. Semi-structured telephone interviews will be conducted to assess treatment satisfaction and elicit feedback.[28]

Parent-child narratives. Narratives will be video-recorded, transcribed, broken down into utterances, and coded by two independent coders using established coding schemes derived from the child development literature on children's narratives and memories.[45] Coders have been trained and will be blinded to treatment condition. The following aspects of narratives will be coded: Reminiscing style/level of elaboration (elaboration vs. repetition) and content (e.g., references to pain, anxiety/fear, medical procedures, emotions, explanations). Proportions of narrative utterance type over the entire number of utterances used will be calculated. Based on previous research,[8,17] the primary narrative codes for the analyses will be parent reminiscing style (elaboration), and content related to pain, anxiety, medical procedures, and explanations. Inter-rater reliability will be calculated using intra-class correlation coefficients.

Memory. Three to four weeks following surgery, children will be asked to complete a pain memory interview via telephone that is based on a previously published protocol used with children aged 5-10 years following venipuncture.[27] Children will be asked to recall the in-hospital and post-surgery periods (i.e., while at home) time periods and complete the same pain intensity and pain-related fear scales based on their memories of those time periods. Biases in memory will be defined as the deviation in recalled and initial/experienced pain reports. Similar to our previous research, statistical models predicting pain memories will control for initial pain ratings that correspond to each memory question.[4,9,10] Negatively biased pain memories will be defined as children who remember more pain and fear as compared to their initial pain reports. Positively biased pain memories will be defined as recalled pain that is less than initial pain reports. Accurate memories reflect no difference between recalled and experienced levels of pain.

Medical records review. Through the medical records review, we will gather information about the surgery technique, parental presence at induction, anesthetic technique (maintenance with volatile or TIVA), intraoperative opioid administration, awake or deep extubation, duration of PACU stay, pain scores using FPSR, analgesic administration, parental presence in PACU, analgesic administration in Day Surgery (and overnight stay if that applies), etc.

Analgesic consumption after discharge. Analgesic administration (or absence thereof) will be recorded after discharge on days 1, 2, 3, 7, and 14 at home. The questions will include medicine type (including any specific remedies to reduce pain due to swallowing), dose, and number of times medicine was administered.

Socio-demographic forms. A brief socio-demographic form will be administered to account for such variables as ethnic background, level of education, household income, and family composition.
Medical history questionnaire. A brief questionnaire will be administered to assess variables such as family surgical and medical history and surgery preparation and knowledge.

Statistical Analyses

A sample size of 52 children is required to detect medium effect sizes and exceeds the published recommendations for pilot interventions.[46] We will inflate the sample size to N=100 (50 per group) to account for attrition rates.

Group differences in memory will be analyzed using analysis of covariance, while controlling for child age, sex, language ability, and initial pain ratings. Similar analyses will examine group differences in pain narratives to provide evidence of treatment fidelity. Feasibility and acceptability will be summarized using descriptive statistics. Hierarchical regression models will be used to examine the predictive value of child and parent characteristics on pain memories. Prior to consideration for inclusion in the models, variables will be subjected to multicollinearity diagnostics via assessment of variance inflation factors. Remaining candidate variables will be included in the models. Similar to previous research, semi-structured interviews will be conducted with parents to assess acceptability and satisfaction. Interviews will be analyzed using semantic thematic analysis conducted using NVivo software.[19]

TIMEFRAME

A 9-month timeframe is proposed for the completion of the present pilot study project: 7 months will be needed for continuous recruitment of participants. We aim to recruit 15 families per month. The final two months will be used to complete the last wave of memory interviews and data entry, run statistical analyses and prepare manuscripts for publication.

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