Vanderbilt University Department of Anesthesiology
Center for Evidence-Based Anesthesia
Evidence-Based Guidance and Practice Protocol

Pediatric PeRioperative Interdisciplinary Surgical hoMe (PRISM)

Post-Dural Puncture Headache Protocol

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Individuals Involved:	Pediatric Pain Service, Pediatric Emergency Medicine, Pediatric Hospitalist Service
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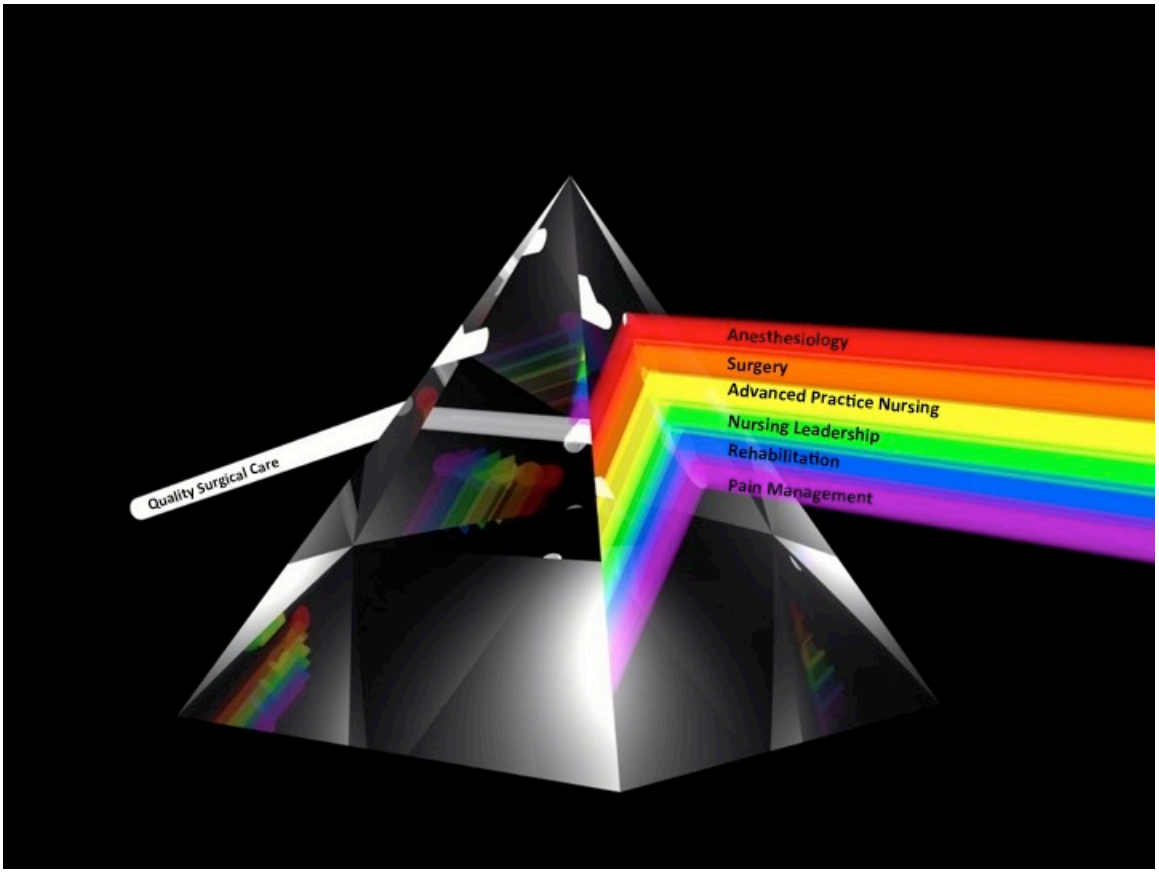
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TABLE OF CONTENTS

Post-Dural Puncture Headache Management

Emergency Dept

Meets diagnostic criteria for PDPH*:

- A. Headache that worsens within 15 minutes after sitting or standing & improves within 15 minutes after lying, with at least one of the following (as well as criteria B & C):
  - Neck stiffness
  - Tinnitus
  - Hypacusia
  - Photophobia
  - Nausea
- B. Dural puncture has been performed
- C. Headache develops within 5 days after dural puncture

Administer IV crystalloid fluid bolus 20ml/kg

Begin caffeine therapy

Start Analgesic Regimen
- Acetaminophen
- Ketorolac
- Gabapentin

Adjuncts for nausea/vomiting
- Ondansetron
- Diphenhydramine

Additional therapy at discretion of ED physician

* Diagnostic criteria for PDPH based on the International Headache Society criteria

Inpatient Admission

Admit to appropriate inpatient service

Consult Pediatric Pain Service (835-5759)

Continue maintenance IVF at 1.5 x normal maintenance fluid rate

Continue Caffeine PO BID

Continue Analgesic Regimen
- Acetaminophen
- Ketorolac
- Gabapentin

Continue adjuncts for nausea/vomiting
- Ondansetron
- Diphenhydramine

Assess potential need for sedation if EBP required
- If sedation required → Pediatric Pain Service will enter appropriate NPO orders
- Encourage continued PO hydration with clear liquids up until 2 hours prior to expected procedure time

Re-evaluation of headache after 24 hours of conservative therapy
- Headache improved/ resolved → discharge
- No improvement → proceed with epidural blood patch if no contraindication

Epidural Blood Patch

Epidural blood patch performed by Pediatric Pain Service if indicated

Patient to remain supine post-procedure x 1 hour

Re-evaluation of headache post-procedure
- Headache resolved → Discharge
- Headache not improved → re-consider other potential etiologies

Discharge

Conservative treatment:
- Acetaminophen x 3 days then prn
- Ibuprofen x 3 days then prn
- Gabapentin x 3 days
- Continue PO hydration

Epidural blood patch:
- Acetaminophen prn
- Ibuprofen prn
- Continue PO hydration
- Follow up phone call post-discharge day 1 by Pediaitric Pain Service

Follow up with PCP as needed

Recommended Dosing Guidelines:

- Caffeine
  - If ≥ 40 kg: 200mg PO BID
  - If < 40 kg and ≥ 20 kg: 100mg PO BID
  - If unable to take PO: one time dose of IV caffeine sodium benzoate 10mg/kg
    - Max dose 500mg
- Acetaminophen
  - If > 65 kg: 1000 mg PO Q6h X 24h; then 1000 mg Q8h
  - If > 50 kg but ≤ 65 kg: 650 mg PO Q6h
  - If > 35 kg but ≤ 50 kg: 500 mg PO Q6h
  - If ≤ 35 kg: 15 mg/kg liquid PO Q6h
    - Not to exceed 500 mg
- Ketorolac x 24 hours
  - If ≥ 60 kg: 30mg IV Q6h
  - If < 60 kg: 0.5 mg/kg IV Q6h
- Ibuprofen (after first 24 hours)
  - 10mg/kg PO q6h
  - Max dose 400mg
- Gabapentin
  - If ≥ 50 kg: 300 mg capsule PO Q8h
  - If > 40 kg but < 50 kg: 200 mg capsule PO Q8h
  - If ≤ 40 kg: 5 mg/kg solution PO Q8h
    - Gabapentin solution is 50 mg/ml
- Ondansetron
  - 0.1mg/kg IV q6hr prn nausea
  - Max dose 4mg
- Diphenhydramine
  - 1.25 mg/kg IV q6hr prn nausea
  - Max dose 25mg

MONROE CARELL JR. Children's Hospital at Vanderbilt

Please contact the Pediatric Pain Service for questions: 835-5759

Executive Summary

This evidence based practice protocol applies to all patients presenting with symptoms suggestive of a post-dural puncture headache (PDPH) at Monroe Carell Jr. Children's Hospital at Vanderbilt (MCJCHV). This protocol is included within the Pediatric peRioperative Interdisciplinary Surgical hoMe (PRISM), a dynamic collection of protocols built on best available evidence and updated annually. The primary aim of this protocol is to formalize interdisciplinary collaboration to enhance the overall clinical care experience of patients presenting with post-dural puncture headaches at MCJCHV. Secondary aims that support the primary aim include reduction of delays in initiation of conservative therapy, reduction of readmissions, timely consultation of the Pediatric Pain Service for performance of epidural blood patch, reduction of pain scores, and reduction in hospital length of stay. The protocol outlines a clinical continuum of care that begins upon identification of a patient with a post-dural puncture headache. The potential exists that adherence to the protocol may reduce total hospital stay, initiate prompt treatment of post-dural puncture headaches, and restore function to children suffering with this condition.

I. Literature Search Strategy

PubMed databases were queried for publications from 2010 to 2016 using the following keywords: post-dural puncture headache. Then using the binary operator AND, the search result was combined with the results for keyword terms analgesia, treatment, epidural blood patch, pediatric, etc. Searches were limited to human studies and English language studies. No meeting abstracts or unpublished references were included. Searches were hand sorted to yield those studies looking at pediatric patients in particular as well as controlled trials in adults. Key articles on the subject matter dating prior to 2010 were also included given the limited number of more recent publications.

II. Evidence Summary

Medical and surgical home models like PRISM share the following five characteristics:

1. Patient centered focus
2. Multi-specialty care teams
3. Shared decision making
4. Cost-efficient use of resources
5. Continuity of care delivery models

A medical home is a novel healthcare philosophy that focuses less on quantity of care but instead on quality of care, with emphasis given to integrating healthcare teams to reduce costs and improve outcomes.

The medical evidence supporting perioperative medical/surgical home models in the care of adult patients is robust [1], while outcome data are limited for pediatric patients [2]. It may be assumed that similar gains will be seen by reducing variability and error in the delivery of care to children with the implementation of perioperative medical/surgical home models.

As stated above, specific evidence based recommendations in the pediatric population are lacking and this protocol seeks to extrapolate and appropriately apply data from the adult patient population to the care of younger patients.

The medical evidence behind specific medications and techniques will be discussed below:

<u>Post-dural Puncture Headache (PDPH)</u>

PDPHs are low-pressure headaches attributed to the loss of cerebrospinal fluid (CSF) after a dural puncture. The loss of the CSF cushion around the brain leads to traction on pain sensitive intracranial structures leading to pain felt in the distribution of the trigeminal nerve (frontal region) as well as the distribution of the vagus and upper cervical nerves (occipital and neck region) [3,4]. The International Headache Society classifies PDPH as a headache that worsens within 15 minutes after sitting or standing; and improves within 15 minutes after lying, with at least one of the following associated

symptoms: neck stiffness, tinnitus, hypacusia, photophobia, or nausea. The quality of the headache may be burning, dull and/or throbbing and the intensity is usually severe [5].

Conservative Therapy

The majority of PDPH resolve within a week with conservative management (rest, hydration, symptomatic treatment) [6,7]. Symptomatic treatment with analgesics (acetaminophen and NSAIDs) and anti-emetics may control the symptoms and reduce the need for aggressive forms of therapy [5]. However, randomized trials for symptomatic treatments are lacking in children.

Intravenous Fluids

There is no evidence to support the efficacy of this intervention though intravenous hydration is commonly included as part of conservative medical management. Rehydration and prevention of dehydration is important in the management of PDPHs, as these headaches are recognized as low-pressure headaches. Hydration may increase the rate of CSF production and reduce the CSF hypotension that leads to the low-pressure headache [8,9].

Acetaminophen

Though the exact analgesic mechanism of acetaminophen remains elusive, analgesia is likely conferred due to weak inhibition of centrally mediated prostaglandin synthesis as well as peripheral pain amplification.

NSAIDs

Non-steroidal anti-inflammatory drugs (NSAIDs) produce their analgesic effect through a combination of peripheral and central mechanisms. NSAIDs are most classically known for their ability to inhibit cyclooxygenases leading to a decrease in prostaglandin production. This leads to a reduction in pain as well as inflammation.

Caffeine & Methylxanthines

Methylxanthine derivatives such as caffeine or aminophylline are often used in the treatment of PDPH, although their efficacy is not consistently proven. Review of RCTs by the Cochrane Review in 2015 "Drug therapy for treating post-dural puncture headache" found that caffeine did show a significant decrease in patients with persistent PDPH and reduction in the number needing supplemental interventions[10]. Both oral caffeine and IV caffeine sodium benzoate formulations have shown a transient reduction in pain scores [4,11,12]. Oral caffeine is well absorbed and offers the advantage of being more convenient and less expensive[9]. These medicines are thought to negate the compensatory cerebral vasodilation that occurs in response to loss of CSF volume [7]. This vasodilation is considered to be one potential cause of pain associated with PDPH. Methylxanthines are thought to lead to vasoconstriction by blocking adenosine receptors and are thought to stimulate sodium-potassium pumps to increase CSF production [13,14].

Theophylline use has also been described and is associated with a decrease in pain severity score, however the side effect profile remains a significant concern. Side effects of methylxanthine use include GI irritation, cardiac dysrhythmia, CNS stimulation (including restlessness, nervousness, palpitations), and seizures. Given the increased side effect profile of Theophylline, this medication was not selected as a first line treatment for patient's presenting with PDPH.

Gabapentin

Gabapentin has shown a reduction in pain severity scores when compared with placebo or with ergotamine in the treatment of PDPH as well as a reduction in nausea/vomiting [15,16]. The exact mechanism of gabapentin in the treatment of PDPH is unknown. Possible hypothesis suggests its efficacy may be through its GABAergic actions, combined with other mechanisms such as calcium channel blockade [15].

Hydrocortisone

Compared to the placebo or conventional treatment, hydrocortisone has shown a reduction in pain severity scores [17,18]. Alam et al [17] showed a reduction in headache intensity with 48-hour administration of hydrocortisone 100mg IV q8h compared to placebo. However, given the concern that a proportion of patients presenting with PDPHs have undergone a lumbar puncture due to infectious concerns this medication was not included as first line treatment in this protocol.

Epidural Blood Patch

Epidural blood patch (EBP) has a high success rate in the treatment of post-dural puncture headache in pediatric patients [19] and low incidence of complications.

Mechanism of action of EBP is thought to be twofold:

1. The blood placed into the epidural space is thought to act as a mass lesion compressing the dural sac and raising intracranial pressure [20].
2. The dural sac is compressed and the blood seals off the dural hole so the CSF leak stops leading to increased intracranial pressure [21,22].

Studies of epidural injection of saline have failed to relieve PDPH because the fluid does not seal off the dural hole and a persistent leak continues [23]. Epidural blood patch is most effective when it is done more than 24 hours after the dural puncture [24]. Cochrane review supports the efficacy of EBP as the standard of treatment for PDPH [25,26]. Review of controlled trials of EBP for treatment of PDPH identifies a success rate of ranging from 77-96 %. Although treatment of PDPH with placement of an epidural blood patch is supported by evidence, according to the Cochrane Review in [25,26], clear conclusions cannot be drawn about the potential utility of preventative epidural blood patch placement. Risks of epidural blood patching include

backache, lower limb parasthesia, elevated intracranial pressure, bradycardia, epidural infection, and radicular pain from nerve root compression. [5,27-29]. The suggested volume of autologous blood for an epidural blood patch in children sedated for the procedure is 0.2-0.3ml/kg [30-32].

Other Interventions Without Significant Benefit
Evaluation performed by the Cochrane Review did not show a consistent benefit with any of the following medications in the treatment of PDPH: sumatriptan, adrenocorticotropic hormone (ACTH), pregabalin, and cosyntropin[10].

III. Outcome, Purpose, Goals

The purpose of this clinical care pathway is to develop evidence-based strategies to improve the clinical care of patients with post-dural puncture headaches at MCJHV. It is anticipated that systematic use of this guideline will lead to improved overall patient care, reduced length of stay, and decrease readmissions and/or repeat emergency room visits related to post-dural puncture headaches.

IV. Protocol Application and Inclusion Criteria

These standards apply to all patients at MCJCHV who present with a clinical presentation consistent with a post-dural puncture headache.

V. Consent

a. Patient and/or parental verbal consent and/or verbal assent will be obtained for the screening process. If a patient refuses to have the criteria applied, then the involved personnel should document such refusal in the chart.

b. Exclusion by Physician
Emergency Medicine, Hospitalist, or Anesthesiology attending physicians may override this process if the clinical picture changes and is no longer consistent with post-dural puncture headache. Such exclusion should be documented in the medical record.

VI. Timing

These guidelines should be initiated once any patient in the MCJCHV emergency department is identified as having a post-dural puncture headache.

VII. Guidelines for Management of Post-Dural Puncture Headaches

Phase 1: Emergency Department

- Meets diagnostic criteria for post-dural puncture headache according to The International Classification of Headache Disorders Diagnostic Criteria for Post-dural Puncture Headache (International Headache Society):

    A. Headache that worsens within 15 minutes after sitting or standing & improves

within 15 minutes after lying, with at least one of the following and fulfilling criteria C and D:

1. Neck stiffness
2. Tinnitus
3. Hypacusia
4. Photophobia
5. Nausea

B. Dural puncture has been performed

C. Headache develops within 5 days of dural puncture

D. Headache resolves either*:

1. Spontaneously within 1 week
2. Within 48 hours after effective treatment of the spinal fluid leak (usually by epidural blood patch)

* Note: In 95% of cases this is so. When headache persists, causation is in doubt.

- Administer intravenous crystalloid fluid bolus: 20 ml/kg, maximum volume 2L

- Begin caffeine therapy
  - If ≥40kg: 200mg PO BID
  - If <40kg and ≥20kg: 100mg PO BID
  - If unable to take PO: one time dose of IV caffeine sodium benzoate 10mg/kg
    - Max dose 500mg

- Start Analgesic Regimen:

  - Acetaminophen:
    - If > 65 kg: 1000 mg tablet PO
    - If > 50 kg but ≤ 65 kg: 650 mg tablet
    - If > 35 kg but ≤ 50 kg: 500 mg tablet
    - If ≤ 35 kg: 15 mg/kg liquid
      - Not to exceed 500 mg

  - NSAID: Ketorolac (*caution with elevated creatinine or coagulopathy*)
    - If ≥ 60 kg: 30mg IV
    - If < 60 kg: 0.5 mg/kg IV

  - Gabapentin:
    - If ≥ 50 kg: 300 mg capsule PO
    - If > 40 kg but < 50 kg: 200 mg capsule PO
    - If ≤ 40 kg: 5 mg/kg solution PO
      - Gabapentin solution is 50 mg/ml

- Adjuncts as needed for nausea/vomiting:
  - Ondansetron 0.1 mg/kg IV
    - Max dosage 4 mg
  - Diphenhydramine 1.25 mg/kg IV
    - Max dosage 25 mg
- Additional therapy at discretion of ED physician

Phase 2: Inpatient Admission & Pediatric Pain Service Consult

- Admission to the Pediatric Hospitalist Service unless another primary service is deemed more appropriate for the patient
- Consult Pediatric Pain Service (835-5759)
  - Assure PDPH protocol is implemented and questions/concerns are addressed
  - Evaluate patient's candidacy for epidural blood patch
  - Order PTT/INR/Platelet count if needed based on patient's history and physical exam
  - Assess potential need for sedation should epidural blood patch be indicated
  - Formulate tentative plan of when and where procedure is to be performed should EBP be indicated
  - Place appropriate NPO orders in WIZ
    - Encourage continued PO hydration with clear liquids up until 2 hours prior to expected procedure time
- Continue hydration with maintenance intravenous fluids at 1.5 x normal MIVF rate
- Continue regular diet and encourage oral hydration
  - If sedation thought to be required for epidural blood patch → Pediatric Pain Service will enter appropriate NPO orders
- Continue Caffeine
  - If ≥40kg: 200mg PO BID
  - If <40kg and ≥20kg: 100mg PO BID
  - If unable to take PO: one time dose of IV caffeine sodium benzoate 10mg/kg may be administered (do not administer if already given in ED)
    - Max dose 500mg
  - IV caffeine citrate should NOT be used as a substitute- the dosing conversion is not 1:1 and there is no evidence to support its use in the management of PDPH
- Continue analgesic regimen
  - Acetaminophen:
    - If > 65 kg: 1000 mg tablet PO Q6h X 24 H; then to 1000 mg Q8H

        - If > 50 kg but ≤ 65 kg: 650 mg tablet PO Q6h
        - If > 35 kg but ≤ 50 kg: 500 mg tablet PO Q6h
        - If ≤ 35 kg: 15 mg/kg liquid PO Q6h
            - Not to exceed 500 mg

    - Ketorolac 0.5mg/kg IV q6h x 24 hours
        - If ≥ 60 kg: 30mg IV Q6h
        - If < 60 kg: 0.5 mg/kg IV Q6h

    - Ibuprofen (after 24 hours of Ketorolac)
        - 10mg/kg PO q6h
        - Max dose 400mg

    - Gabapentin
        - If ≥ 50 kg: 300 mg capsule PO Q8h
        - If > 40 kg but < 50 kg: 200 mg capsule PO Q8h
        - If ≤ 40 kg: 5 mg/kg solution PO Q8h
            - Gabapentin solution is 50 mg/ml

- Continue adjuncts as needed for nausea/vomiting

    - Ondansetron 0.1 mg/kg IV q6hr prn nausea
        - Max dosage 4 mg

    - Diphenhydramine 1.25 mg/kg IV q6hr prn nausea
        - Max dosage 25 mg

- Re-evaluation of headache after 24 hours of conservative therapy
    - Headache improved/resolved → discharge
    - No improvement → proceed with epidural blood patch if no contraindication

<u>Phase 3: Epidural Blood Patch</u>

- Epidural blood patch to be performed by the Pediatric Pain Service if indicated

- Contraindications for epidural blood patch:
    - Fever
    - Bacteremia
    - Coagulopathy
    - CNS infection
    - Intra-cranial pathology
    - Circulating blasts [9]

- Epidural blood patch:
    - 0.2-0.3 ml/kg recommended volume for injection if sedated

- 10-30 mL if not sedated as assessed by verbal feedback of backpressure

- Procedure location
  - Sedation NOT required: procedure may be performed in patient's room
  - Sedation required:
    - Option 1- Sedation Service: Coordinate time with Sedation Service. Contact the SIC (sedation in charge) at pager 835-9999 to provide patient information. Provide the CPT code for an EBP (62273). Provide anticipated length of procedure (30 minutes) as well as any special requests (positioning, sedation specifics).
    - Option 2- OR: if Sedation Service unavailable or patient does not meet criteria for Sedation Service contact OR board to arrange OR time. To board a case, call the OR board at 936-0027. Provide the MR (day) or the OR charge nurse (night) specific information about the case including patient name, MRN, NPO status, length of procedure, allergies, contact precautions, and the CPT for EBP (62273). You will also need to include specific requests including positioning, fluoroscopy, Sonosite, etc. The CPT for EBP includes fluoroscopy. However, if ultrasound is also needed you will also provide the CPT for ultrasound 76942.

- Supplies: All procedural supplies needed for an epidural blood patch are located in pain service cart and epidural bucket. Consider potential need for the Sonosite for venous/arterial access and have the ultrasound available if indicated.

- Patient to remain supine for 1 hour post-procedure

- Re-evaluation of headache post-procedure
  - Headache resolved → discharge
  - Headache not improved → re-consider other potential etiologies

Phase 4: Discharge

- Conservative treatment
  - Acetaminophen scheduled x 3 days then prn
  - Ibuprofen scheduled x 3 days then prn
  - Gabapentin scheduled x 3 days then discontinue
  - Continue PO hydration

- Epidural blood patch
  - Acetaminophen prn
  - Ibuprofen prn
  - Continue PO hydration
  - Follow up phone call post-discharge day 1 by Pediatric Pain Service

- Follow up with PCP as needed

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