Pain induced by Non-sedated Botulinum toxin injection.

What do our patients tell us about their pain perception and what can be offered to reduce their pain experience

Breakfast seminar Sep 13th, 2014
AACPD 2014
San Diego

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McMaster University and McMaster Children’s Hospital
Disclosure Information
AACPD 68th Annual Meeting September 10-13, 2014

Speaker Name: Dr. Mesterman Ronit and Nancy Goldie

Disclosure of Relevant Financial Relationships
The Bead Strong program is sponsored by Allergan.

Disclosure of Off-Label and/or investigative uses:
I will not discuss off label use and/or investigational use in my presentation
Objectives and course outline

- Review physiology of pain perception
- Share patient data on pain perception of non-sedated Botulinum Toxin injections
- Discuss options on how to prepare children for non sedated injections
- Review different relaxation and distraction techniques
- Review possible local interventions to reduce pain
- Discussion and questions
Definition of pain

- Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” by the international association for the study of Pain (IASP)*
- Pain is much more than a simple, straightforward, sensory experience. Pain results from the interaction of multiple factors, physical, as well as emotional, cognitive, behavioural and contextual.

Sensory pathways

- Pain pathway:
  - Ascending input
  - Descending modulation
- Dorsal horn
- Spinothalamic tract
- Lateral system: nSTT
- Medial system: pSTT, SMT, SRT
- Trauma
- Peripheral nociceptors
- A-δ fibers
- C fibers

Synapse: release of neurotransmitters:
- Glutamate-aspartate, SP, FRAP, VIP, CCK
- GRP, ENK, DYN = depolarization

Release of neurotransmitters
How to measure pain

- Physiological measures
- Self reports
- Observational tools (biobehavioural):
  - Bayer et Spagrud 2007; Systematic review of observational (behavioral) measures of pain for children and adolescents aged 3 to 18 years; *Pain* 127:140–150
What do our patients tell us about their pain perception during non-sedated Botulinum toxin injections?
Prospective study on pain experience in children receiving non-sedated botulinum Toxin A injections

At McMaster Children’s Hospital we are currently performing in about 85% the injections non sedated.

The rest of our clients receive the injections under sedation.
Objectives of the study

• To assess the pain experience of our patients during the non sedated injections.
• To correlate the pain experience with age, cognitive status the number of injections, and anticipation time.
McMaster Spasticity clinic

Clinic:

- Tertiary referral center providing assessments and treatments to patients
- Multidisciplinary clinic (2 physicians, 1 nurse, 2 PTs, 1 OT, 1 child life specialist)
Process of non-sedated BoNT-A injections

The family is asked to comfort the child, while the nurse provides distraction/relaxation techniques.

Allied health worker typically positions the injected limbs.
Methods

- Patients receiving non sedated BoNT-A treatment for hypertonia at McMaster Spasticity clinic were invited to participate.

- Study enrolment: January – July 2011.

- Data was collected by two research assistants attending all the clinic appointments.

- Statistical analysis: Observational data description and multi regression analysis.
Methods: Pain measures

FACES pain scale revised (FPS-r)

**FLACC SCALE**
(FACE, LEGS, ACTIVITY, CRY, CONSOIALIZABILITY)

<table>
<thead>
<tr>
<th>FACE</th>
<th>0</th>
<th>1</th>
<th>2</th>
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<tbody>
<tr>
<td>No particular expression or smile</td>
<td>Occasional grimace or frown, withdrawn, disinterested</td>
<td>Frequent to constant frown, clenched jaw, quivering chin</td>
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<tr>
<th>LEGS</th>
<th>0</th>
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<tbody>
<tr>
<td>Normal position or relaxed</td>
<td>Uneasy, Restless, Tense</td>
<td>Kicking, Or Legs drawn up</td>
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<thead>
<tr>
<th>ACTIVITY</th>
<th>0</th>
<th>1</th>
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<tbody>
<tr>
<td>Lying quietly or Normal position or Moves easily</td>
<td>Squirming back-forth Tense</td>
<td>Arched, Rigid, Or Jerking</td>
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<tr>
<th>CRY</th>
<th>0</th>
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<tbody>
<tr>
<td>No Cry (Awake or Asleep)</td>
<td>Moans or Whimpers Occasional Complaint</td>
<td>Crying Steadily Screams or Sobs Frequent Complaints</td>
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<tr>
<th>CONSOIALIZABILITY</th>
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<tr>
<td>Content Relaxed</td>
<td>Reassured by occasional hugging, or &quot;talking to.&quot;</td>
<td>Distractable</td>
<td>Difficult to console or comfort.</td>
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The FLACC is a behavior pain assessment scale for use in non-verbal patients unable to provide reports of pain.

**Instructions:**
1. Rate patient in each of the five measurement categories
2. Add Together
3. Document total pain score
Patient Characteristics

• 58 consecutive patients were evaluated for pain response.
  – Age 2 to 18 years; and median age of 9.8 years.
  – 31 males (53%).

• 37 participants were able to report their pain using the FPS-r.

• All 58 participants were rated on the FLACC scale.
Patient Characteristics

90% had Cerebral Palsy
10 % ABI and genetic syndromes causing hypertonia
50 % had IQ above 70

GMFCS distribution

<table>
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<tr>
<th>GMFCS level</th>
<th>Series1</th>
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<tbody>
<tr>
<td>1</td>
<td>9</td>
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<tr>
<td>2</td>
<td>11</td>
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<tr>
<td>3</td>
<td>7</td>
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<tr>
<td>4</td>
<td>14</td>
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<tr>
<td>5</td>
<td>11</td>
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Patient Characteristics

Number of injected muscles: 1-11; median 4

Number of “pokes” per treatment session 1-16; median 6

Number of prior injections:
- No previous injection: 4%
- 1 previous injection: 14%
- 2-3 previous injections: 19%
- 4 previous injections: 9%
- More than 5 previous injections: 54%
FACES Pain Scale – revised
Distribution in study population (n=37)
FLACC scale
Distribution in study population (n=58)

FLACC 0: 4
FLACC 1: 5
FLACC 2: 5
FLACC 3: 5
FLACC 4: 4
FLACC 5: 5
FLACC 6: 2
FLACC 7: 6
FLACC 8: 4
FLACC 9: 16
FLACC 10: 0
FLACC 11: 0
FLACC 12: 0
FLACC 13: 0
FLACC 14: 0
FLACC 15: 0
FLACC 16: 0
FLACC 17: 0
FLACC 18: 0
FLACC 19: 0
FLACC 20: 0
Pain measure in correlation to age, number of injections, wait time and cognitive level

• Only age was slightly inversely related to pain response
• Number of injections, waiting time and cognitive did not show significant relationship
Evidence for psychological interventions for needle-related procedural pain

A Systematic Review of Randomized Controlled Trials Examining Psychological Interventions for Needle-related Procedural Pain and Distress in Children and Adolescents: An Abbreviated Cochrane Review*

Lindsay S. Uman,¹,² Christine T. Chambers¹,²,³ Patrick J. McGrath,¹,²,³,⁴ and Stephen Kisely⁴,⁵,⁶

¹ Department of Psychology, Dalhousie University, ² IWK Health Centre, ³ Department of Pediatrics, ⁴ Department of Psychiatry, ⁵ Department of Community Health & Epidemiology, Dalhousie University, and ⁶ School of Medicine, Griffith University, Australia

<table>
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<tr>
<th>Cognitive Interventions</th>
<th>Definitions</th>
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<tr>
<td>Cognitive distraction</td>
<td>Cognitive techniques to shift attention away from procedure (e.g., counting, nonprocedural talk).</td>
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<tr>
<td>Imagery</td>
<td>Techniques to encourage child to cope with the pain/distress of the procedure by having them imagine a pleasant object or experience (e.g., enchanted forest).</td>
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<tr>
<td>Hypnosis</td>
<td>Dissociation from painful experience and distress via hypnotic induction, suggestions, and imagined fantasy; similar to but more involved than imagery.</td>
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<tr>
<td>Preparation/information</td>
<td>Explaining the steps of the procedures and/or providing sensory information associated with the procedure (e.g., providing instructions about what the procedure will involve).</td>
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<tr>
<td>Thought-stopping</td>
<td>Child repeats “stop” or a similar statement during times of distress/pain, to block out negative thoughts.</td>
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<td>Coping self-statements</td>
<td>Child repeats a set of positive thoughts (e.g., “I can do this”; “This will be over soon”).</td>
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<tr>
<td>Suggestion</td>
<td>Providing verbal or nonverbal cues to the child suggesting that the administered intervention will or can reduce pain and/or distress.</td>
</tr>
<tr>
<td>Memory change</td>
<td>Helping child to reframe negative memories of the procedure into positive ones.</td>
</tr>
<tr>
<td>Parent training</td>
<td>Training the parent (not the child) to engage in one of the above cognitive strategies. The goal is to decrease the parent’s distress that in turn may decrease the child’s distress or pain, or both.</td>
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<tr>
<th>Behavioral Interventions</th>
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<tr>
<td>Behavioral distraction</td>
<td>Behavioral techniques to shift attention away from procedure (e.g., videotapes, games).</td>
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<tr>
<td>Muscle relaxation</td>
<td>Tensing and relaxing various muscle groups of the body.</td>
</tr>
<tr>
<td>Breathing exercises</td>
<td>Deep breathing or breathing from the diaphragm rather than the chest (e.g., using party blowers, blowing bubbles, pretending to inflate or deflate a tire through inhaling/exhaling).</td>
</tr>
<tr>
<td>Modeling</td>
<td>Demonstration of positive coping behaviors during a mock procedure by another child or adult.</td>
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<tr>
<td>Rehearsal</td>
<td>Practice using positive coping behaviors demonstrated during modeling.</td>
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<tr>
<td>Desensitization</td>
<td>Gradual systematic exposure to the feared stimuli, generally involving a hierarchy of feared stimuli.</td>
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<tr>
<td>Positive reinforcement</td>
<td>Providing positive statements and/or tangible rewards (e.g., toys) to the child following the procedure.</td>
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<tr>
<td>Parent training</td>
<td>Training the parent (not the child) to engage in one of the above behavioral strategies.</td>
</tr>
<tr>
<td>Parent/staff coaching</td>
<td>Training the parent or medical staff to actively coach the child to use one of the above strategies.</td>
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<tr>
<td>Virtual reality</td>
<td>Using technology and equipment (e.g., goggles, headphones) to absorb the child’s attention; more involved than distraction.</td>
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<tr>
<th>Combined Cognitive-Behavioral Therapy (CBT)</th>
<th>Definition</th>
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<tr>
<td>Combined CBT</td>
<td>Any intervention using at least one of the above cognitive interventions in combination with at least one of the above behavioral interventions.</td>
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Now let’s become more practical

• Family centred approach to decision making sedated versus non-sedated
• Prepping the child
• Principles of autonomy and control
• Review options strategies to optimize the pain experience in non-sedated injections
Decision making about sedated versus non-sedated

• No existing tool to assess and give directions which way to go.
• Getting to know the family and past experiences.
• Observations of patient and families dynamics that during exam that might guide us
• Child life involvement
• Finally: shared decision model - choices
Education by child life specialist
Setting the patient up for success by offering choices to child and family in…

• Positioning
• Speed of injections
• Where to start injections: upper versus lower limbs or specific muscles
• Having parents close by
• Give warning 1-2-3
• Breaks in the procedure
• Parental involvement/ parent training
What might work for you

Video showing counselling of our child life specialist
Different positions to accommodate the wishes of the child
More positions to choose from
Relaxation and breathing techniques

Breathing with toys

Windmill

Bubble blowing
Relaxation and breathing techniques cont’

Breathing imagery

• Breath to move the clouds, helicopter
• Feel how your chest is going up and down
• Blow the tree over
• Blow on my finger
Relaxation/breathing cont’

• Give age appropriate advises that are meaningful for developmental state rather than saying relax your muscle. i.e let you muscles go like a noodle.

• Be playful.

• Counting
• ABCs
• Shared breathing (yoga breath)
• Singing
Distractions

- Videos
- i-Pad playing
- Windmill blowing
- Blow into their face
- Therapeutic clown

Specific local interventions to reduce pain

• Local sedation (Ametop®, Emla®)
• Icing
• Buzzy
Local anesthetics (Emla®, Ametop®)

Pros
• Does numb the surface reducing the decreased pain of skin puncture
• Psychological effect of having a numbing cream

Cons
• Doesn’t take away the anxiety
• Prolongs the wait time which can increase stress
• Pulling off the tegaderm can be painful by itself in hairy children
• Doesn’t numb the deeper muscle
Local icing to reduce pain with botulinum Toxin

ORIGINAL ARTICLE

Effect of Topical Anesthetics on Needle Insertion Pain During Botulinum Toxin Type A Injections for Limb Spasticity

Sharon Fung, MD, Chetan P. Phadke, PhD, Alice Kam, MD, Farooq Ismail, MD, Chris Boulias, MD, PhD
Buzzy

- Vibration device applied for local painful interventions such as i.v.
- gate control theory of pain
What else can we offer?
Positive reinforcements
Tangible rewards

• High fives
• BEad Strong Program
• Toy box
BEad Strong program
Our yellow bus

There is nothing wrong with a reward system
Take home message

- Pain perceptions are very variable in the individual experiencing non-sedated Botulinum toxin injections.
- Work together with the patient and their family to decide on a joint plan.
- Include distraction and relaxation techniques.
- Consider using additional specific local interventions to alleviate pain.
- Continue to re-evaluate and work with the child and family of what is working or not.
Thank you’s to…

• Our patients and families for participating in the videos and pictures
• Danute from our Audiovisual department
Please share with us any additional ideas