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Commentary

Clinical meaning of a decline in pain intensity in children and its implications in care and research

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The prevalence of pain in children is higher than previously thought (Finley et al., 2005). Surveys of school children show that 83% of these children experienced pain at some point in the three months prior to the survey and that up to 12% of those children use medications regularly because of pain (Jones et al., 2004; Roth-Isigkeit et al., 2005). Efforts to focus attention on pain and to improve pain relief in children throughout the world have been launched. For example, the International Association for the Study of Pain, which is the largest multidisciplinary international association in the field of pain, designated 2005-06 as the "Global Year Against Pain in Children".

To assure adequate pain relief and prevent unnecessary suffering in children, a systematic evaluation of pain and understanding of the clinical importance in declines in pain intensity are necessary. The purpose of this commentary is first to summarize the evidence about the clinical meaning of declines in pain intensity in children, which includes research to determine the minimum clinically significant difference (MCSD) in pain scores, and second to discuss its repercussions in care and research.

Pain evaluation

Pain is a subjective experience; therefore, the best method to evaluate pain is self-report. Thus, the child is the only one who can attest to the intensity of their pain. Self-report is also central in assessment of the effects of pain on daily living and the effectiveness of pain treatments. Children as young as 3 years old can report the intensity of their pain (Champion et al., 1998; Stinson et al., 2006).

Pain intensity evaluation

The intensity of the child's pain is its most commonly assessed characteristic in clinical practice and in research. However, pain affects many dimensions of life. Although we will focus on pain intensity, how pain affects quality of life – sleep patterns, ability to play and enjoy life – should be part of any evaluation of pain and its response to treatment.

Pain scales

The quantification of pain intensity in young children is challenging because it is more difficult to obtain a self-report. In infants, observations of behavior are used to indicate the presence and intensity of pain. These include vocal or verbal expressions (i.e. cry, scream), facial expression (i.e. open mouth, lips pulled back at corners), and movements (i.e. restless motor behavior, rubbing or touching painful area; Tarbell et al., 1992; von Baeyer & Spagrud, 2006). However, these behavioral signs dissipate as time passes despite the presence of pain and, therefore, observation of behavior is recommended to assess acute, but not chronic pain (von Baeyer & Spagrud, 2006).

In children 3 years of age or older the Pieces of Hurt Tool can be used to self-report pain. This tool uses four red plastic poker chips representing "a little hurt" to the "most hurt you could ever have." The child is asked to select the chip that represents his/her pain intensity and the score goes from 0 to 4. This scale has been validated in acute and cancer pain; it is reliable and responsive to changes in pain intensity (Stinson et al., 2006).

In children 4 years old or older, the Faces Pain Scale-Revised (Hicks et al., 2001), the Wong-Baker FACES Pain Rating Scale (Wong & Baker, 1988) and the Oucher (Beyer et al., 1992; Luffy & Grove, 2003) scales are available. They depict six cartoon faces or photographs of "real" children representing increased levels of pain. In each scale, the child selects the face that represents his/her pain intensity. These scales also have been subjected to extensive validation in acute and cancer pain (Stinson et al., 2006).

Numerical verbal scale and visual analog scale

Children who understand numbers (8 years or older) can use the numerical rating scale (NRS) or the visual analog scale (VAS) to rate their pain. The NRS goes from 0, representing no pain, to 10 or 100, representing the worst pain imaginable. The VAS employs a printed straight line with verbal anchors at each end – "no pain" and "pain as bad as it could be". The child should mark or point to that place on the scale that represents the intensity of their pain. The distance from the anchor that represents "no pain" to the point selected by the child is then measured in cm or mm (0 to 10 or 0 to 100, respectively).

An extension of the VAS is the Colored Analog Scale. This scale provides a vivid gradation in color and area so that children can see how different positions of the slider on the scale reflect different values of pain intensity. On its reverse side, this scale indicates the numerical value of the rating corresponding to the position at which the child has placed the slider (McGrath et al., 1996).

On these scales, children on average rate moderate pain as 6 and severe pain as 8 (on a 0 to 10 scale; McConahay et al., 2006). These valuations are similar to the values reported by adults (Cepeda et al., 2003b; Cepeda, 2005).

The attractiveness of the VAS or NRS for the clinic and in clinical research is their ease of use and application, and that summary statistics such as mean can be easily calculated. Their simplicity, however, has been overstated. First, these scales require ample explanation to assure proper use in children (Stinson et al., 2006). Second, these (and other pain intensity scales) are not necessarily true interval scales, at least as applied by children. In other words, a similar magnitude of decrease in pain might have different meaning depending on the initial level of pain. For example, a decrease in pain level from 5 to 4 does not have the same clinical importance as a decrease in pain level from 9 to 8. If pain is severe, a 1-unit decrease might pass unnoticed in children. The intensity of the baseline or starting, pretreatment pain has important implications when treating pain in children and in the design, analysis, and interpretation of the efficacy of pain treatments. These considerations will be discussed below.

Clinical meaning of a decline in pain intensity

To evaluate the clinical meaning of declines in pain intensity scores, researchers have asked children to describe the decrease in pain intensity and at the same time, to rate their pain relief using Likert scales – "a little better", "a lot better", etc. – after analgesic administration.

In children between ages of 8 to 15 years, the minimal clinically significant decrease is equivalent to 1 unit on a 0 to 10 scale (Powell et al., 2001). When pain is severe, the minimal clinically significant decline is equivalent to 2/10 (Bulloch & Tenenbein, 2002). These findings are consistent for pain of different origins in children (Dhanani et al., 2002).

How low is enough?

More important than to establish the minimal decline in pain intensity that is noticeable to children is to know how large the decline in pain intensity should be so that the children feel substantial improvement and satisfactory comfort, and aim to achieve that level.

In children, the decline in pain score should be at least 4 units (on a scale from 0 to 10) to obtain moderate relief when pain is severe (Bulloch & Tenenbein, 2002; Bernstein et al., 2006). In the case of the Faces Pain Scale, this decrease is equivalent to selecting two faces lower (i.e. in the direction of less pain; Bulloch & Tenenbein, 2002). Efforts should be made to maintain pain intensity below 4 on a scale from 0 to 10 as such scores represent mild pain in children (McConahay et al., 2006).

Degree of pain relief

In addition to asking children to estimate the decline in their pain intensity at multiple times, they should also be queried as to the degree of pain relief to assess the clinical meaning of these declines in pain intensity. A single global assessment of relief provides a measure of analgesic efficacy that is similar to hourly measures of pain intensity (Collins et al., 2001).

Information on the degree of pain relief is necessary to calculate the number needed to treat (NNT), an estimate of the effect size of the treatment that also allows comparisons of the efficacy and safety of various treatments. When making these comparisons there should be assurances that the baseline pain intensities in the studies included to estimate the NNTs are similar. If not, the comparisons could be misleading and could lead to an overestimate of the efficacy of one of the treatments (Cepeda et al., 2005; Gray et al., 2005). For instance, morphine and nonsteroidal antiinflammatory drugs (NSAIDs) have similar NNTs suggesting similar analgesic potency. But in a head-to-head comparison more subjects receiving morphine achieved at least 50% of pain relief than with ketorolac (Cepeda et al., 2005). Additionally, the efficacy of paracetamol varies with the type of surgery, being more effective in dental than in orthopedic surgery (Gray et al., 2005). Differences in baseline pain intensity, and a distinct profile of efficacy for the same agent against pain of differing mechanisms and intensities associated with different operations, could explain the above findings. To achieve the same degree of pain relief, larger decreases in pain scores are required when the initial pain is severe than when the initial pain is moderate.

In addition, the reporting of the proportion of subjects who achieved a specific degree of pain relief overcomes the shortcoming of reporting mean pain intensity. In clinical practice it is common that a few children will continue to report high levels of pain intensity despite receiving analgesics; such outlier values can distort the mean and overall estimates but these outliers have little effect on non-parametric summaries of the proportion who achieved a specified level of pain relief.

Clinicians should aim to obtain at least a 30% reduction in pain intensity when pain is moderate independent of the origin of the pain (Farrar et al., 2000; Salaffi et al., 2004); this figure represents moderate relief. A larger percent decline, around 45%, is necessary if pain is severe (Cepeda et al., 2003b; Salaffi et al., 2004). The percent reduction could be obtained mathematically from pre- and post-treatment measurements of pain intensity or directly from the patient. In adolescents and adults there is a good overall agreement between the mathematically calculated percent pain relief and the percentage of pain relief reported by the patient (Cepeda et al., 2003a). It has been recommended that trials also report the proportion of pain patients with various degrees of pain relief (i.e. 30%, 50%, and complete pain relief) as the use of various cut-offs can affect the estimates of the effect size of the treatments (Moore et al., 2005).

Children's preferences

There is poor agreement between the report of pain by parents and children. This mismatch in pain intensity reports from parents and children may be as large as 4 units on a 0 to 10 scale (Kelly et al., 2002).

This disparity between children and parents in regards to the assessment of outcomes indicates the need to develop practice guidelines that incorporate children's preferences for outcomes, although these are seldom incorporated in practice guidelines. Efforts to elicit children's preferences in the postoperative period have been initiated. A recent survey shows that children between 10 and 18 years old are willing to accept a 32% risk of vomiting in order to have complete pain relief. Gender differences in preferences also have been suggested. For example, girls are more likely than boys to accept a higher

risk of vomiting to obtain complete pain relief (Cucchiaro et al., 2006).

In summary, self-report is the best method to evaluate pain and its response to treatment. The meaning of a decrease in pain intensity depends on the initial pain intensity: larger declines are necessary to obtain the same degree of pain relief when the initial, pretreatment pain is severe.

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