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Impact of prenatal education on maternal utilization of analgesic interventions at future infant vaccinations: A cluster randomized trial

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ABSTRACT

Analgesic interventions are not routinely used during vaccine injections in infants. Parents report a desire to mitigate injection pain, but lack the knowledge about how to do so. The objective of this cluster-randomized trial was to evaluate the effect of a parent-directed prenatal education teaching module about vaccination pain management on analgesic utilization at future infant vaccinations. Expectant mothers enrolled in prenatal classes at Mount Sinai Hospital in Toronto were randomized to a 20-30 minute interactive presentation about vaccination pain management (experimental group) or general vaccination information (control group). Both presentations included a PowerPoint (Microsoft Corporation, Redmond, WA, USA) and video presentation, take-home pamphlet, and "Question and Answer" period. The primary outcome was self-reported utilization of breastfeeding, sugar water, or topical anaesthetics at routine 2-month infant vaccinations. Between October 2012 and July 2013, 197 expectant mothers from 28 prenatal classes participated; follow-up was obtained in 174 (88%). Maternal characteristics did not differ ($P > 0.05$) between groups. Utilization of one or more prespecified pain interventions occurred in 34% of participants in the experimental group, compared to 17% in the control group ($P = 0.01$). Inclusion of a pain management module in prenatal classes led to increased utilization of evidence-based pain management interventions by parents at the 2-month infant vaccination appointment. Educating parents offers a novel and effective way of improving the quality of pain care delivered to infants during vaccination. Additional research is needed to determine if utilization can be bolstered further using techniques such as postnatal hospital reinforcement, reminder cards, and clinician education.

1. Introduction

Vaccine injections are associated with severe distress in >90% of infants and young children [7,10]. Concern about this distress leads some clinicians and parents to avoid or delay vaccination [16]. Infants and young children can go on to develop a lifelong fear of needles due to negative experiences with vaccination, and avoid future vaccination [16,18,23]. Injection-induced pain therefore undermines immunization programs and contributes to societal outbreaks of vaccine-preventable disease.

Numerous interventions are available for reducing immunization pain in infants, including topical anaesthetics, sucrose, and breastfeeding [3,14,17]. The majority of infants, however, do not receive them [8,20,21]. Parents report a desire to mitigate pain, but lack the knowledge about how to do so [9,21]. Specifically, parents report being unaware of evidence-based methods of reducing pain. Directing education about pain management to parents is a novel approach to addressing this neglected and clinically important care gap.

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According to the Knowledge-to-Action Framework [5], successful translation of research knowledge is based on development of knowledge tools that are subsequently customized and implemented within the local context. We developed a clinical practice guideline for vaccination pain management with accompanying educational resources, including a fact sheet and video [15]. We subsequently tailored and pilot-tested these resources with new parents [22]. This cluster-randomized trial was undertaken to evaluate the impact of implementing the educational resources in prenatal classes on parental utilization of analgesic interventions at future infant vaccinations.

2. Materials and methods

We carried out a partially blinded cluster-randomized trial at a perinatal teaching hospital in Toronto (Mount Sinai Hospital [MSH]). The trial was approved by the ethics boards of MSH and the University of Toronto.

Eligible individuals included expectant mothers attending the weekend series prenatal educational program, with or without a partner, and planning to immunize their unborn. An additional inclusion criterion applied after delivery included birth of a healthy infant(s) > 35 weeks gestational age.

The entire prenatal curriculum includes 2 days of group instruction (6 hours/day; total, 12 hours). Participants consented the first day and received the allocated education over 20-30 minutes the second day. Deception was used to maintain participant blinding. Eligible individuals were told they would receive one of 2 interactive educational presentations about infant vaccination and that researchers wanted to know if the information was useful. At the end of the study, the purpose was revealed and consent reaffirmed.

The randomization sequence was generated off site by a statistician using a random numbers table. Each weekend class (cluster) was randomized in blocks of 4 to a 20-30 minute education presentation consisting of: 1) education about pain management during infant vaccination (experimental group), or 2) general education about vaccination (control group).

The randomization sequence was concealed using sequentially numbered opaque sealed envelopes. The educator opened the next envelope on the second day, prepared the relevant supplies, and delivered the allocated education. One educator delivered all presentations.

Both education presentations were similarly structured and scripted. They included: a PowerPoint (Microsoft Corporation, Redmond, WA, USA) slide presentation, take-home pamphlet [12,22], video presentation [1,11], and "Question & Answer" period. The control group presentation included general information about infant vaccination (ie, rationale for vaccination, definition of a vaccine, general vaccine safety information, and vaccination schedule for Ontario). The experimental group presentation included general information about vaccination and information about pain management (ie, importance of pain management, evidence-based pain interventions for infants), with a focus on breastfeeding, sugar water, and topical anaesthetics, and demonstrations on how to make sugar water and apply topical anaesthetics. Participants agreed to a follow-up telephone survey after their infant's 2-month routine vaccinations to report experiences with vaccination.

A researcher accessed hospital records to determine infant date of delivery and health status at birth. After eligibility was confirmed, one of 2 trained interviewers blinded to group allocation collected outcome data using a structured questionnaire [19,20]. Participants answered questions about utilization of pain interventions, attempted and unsuccessful utilization of pain interventions due to barriers imposed by health providers (ie, physicians, nurses, pharmacists), knowledge about pain interventions, satisfaction with pain management, and perceptions of infant pain during vaccination. Knowledge was assessed using a knowledge test whereby participants first answered true/false questions about whether interventions were effective, followed by level of certainty of response using a 5-point Likert scale, where 5 = very sure and 1 = very unsure [19,20,22]. They also specified timing of use (ie, before, during or after the needle puncture), followed by certainty of response. Only responses that were right and whereby mothers were sure or very sure were coded as correct. Pain interventions were coded as utilized only if administered at the optimal time (eg, breastfeeding during needle puncture). Satisfaction was assessed using a 5-point Likert scale, where 0 = very satisfied and 4 = very dissatisfied. Perception of infant pain was assessed using a 0-10 numerical rating scale, where 0 = no pain and 10 = worst possible pain.

In a random subset of participants, parents were contacted prior to infant vaccinations to obtain permission to observe vaccination appointments. A blinded observer recorded pain interventions utilized. Later, these recordings were compared with participants' self-report during follow-up interviews to provide evidence for self-reported utilization as a valid outcome. Telephone interviewers were blinded to observation data.

2.1. Sample size calculation and statistical analysis

The primary outcome was maternal-reported utilization of breastfeeding, sugar water, and topical anaesthetics during routine 2-month infant vaccination. These interventions were selected because they are the most effective based on their effect sizes [3,14,17], yet the least used [9,20,21]. Based on a control group mean number of interventions = 0.1, SD = 0.3 [20], $\Delta = 0.5$, intracluster correlation coefficient = 0.6 [2], $\alpha = 0.05$, and $\beta = 0.8$, 136 participants were required, equivalent to ~14 classes, with up to 10 participants/class. The sample size was doubled to 28 classes to account for fewer individuals/class and losses to follow-up.

Demographic characteristics were compared between groups using t test or χ^2 test. The mean number of interventions utilized was non-normally distributed, with few participants utilizing >1 intervention; hence, data were dichotomized into "0" (no interventions) or "1" ($\geqslant$1 intervention) for analysis. All dichotomous outcomes were compared using logistic regression with generalized estimating equation to account for correlation within clusters. Chance imbalance was observed in infant sex distribution; a post hoc logistic regression analysis correcting for this factor was therefore performed. Continuous outcomes were compared using linear regression with generalized estimating equation. Analyses were repeated, accounting for success carrying out intended interventions. A modified intent-to-treat analysis was used whereby all available data were included (ie, participants that were absent during the education and lost to follow-up were excluded). A P-value of 0.05 was considered significant. Analyses were performed using SPSS v.22 (IBM, Armonk, NY, USA) and SAS v.9.0 (SAS Institute Inc., Cary, NC, USA).

3. Results

The study was conducted between October 20, 2012 and July 23, 2013. Altogether, 264 women from 28 classes were approached; 197 (75%) agreed and were present on the study day: 96 women from 14 classes were allocated to the pain education group and 101 women from 14 classes were allocated to the control group. The mean age of participants did not differ from nonparticipants (33.5 years [SD = 4.2] vs 33.6 years [4.5], $P = 0.96$). Study outcomes were obtained in 174 participants (88%) (Fig. 1). Maternal characteristics did not differ between

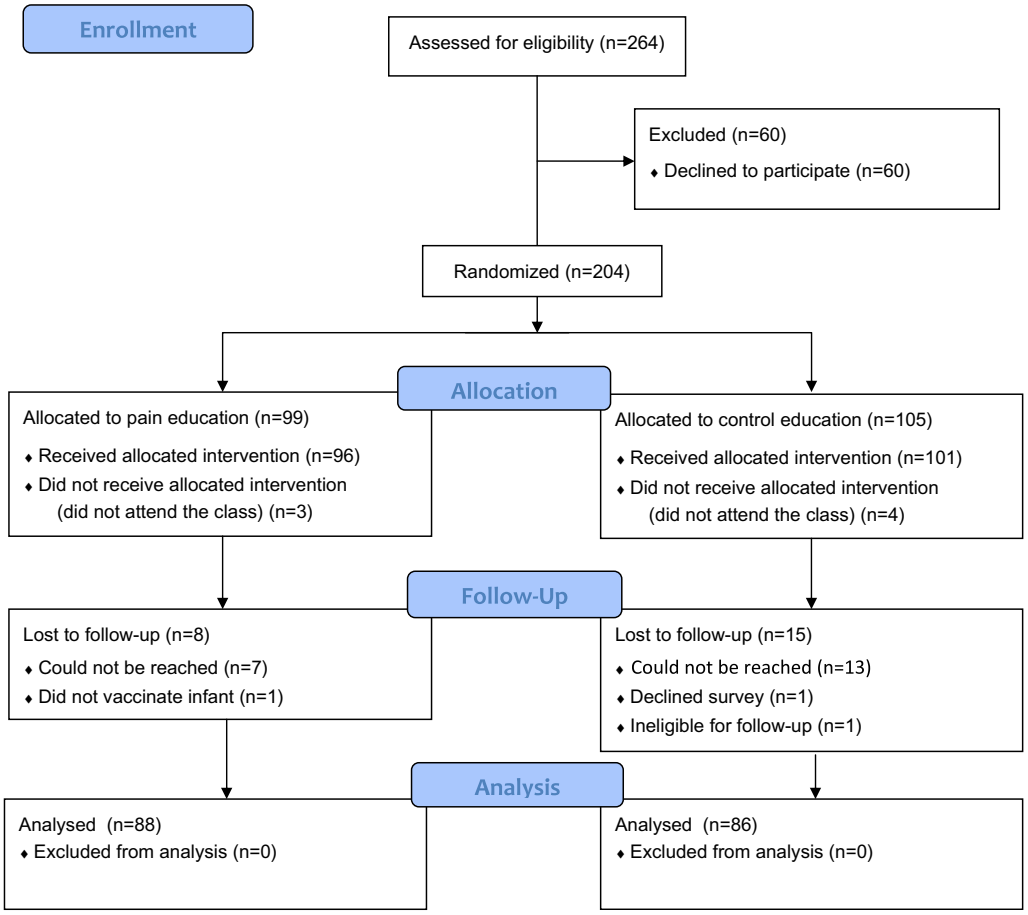

Fig. 1. CONSORT participant flow diagram.

Table 1
Characteristics of participating mothers and infants.

	Pain education	Control education	*P*-value[a]
Prenatal data	(n = 96)	(n = 101)	
Maternal age, years	33.4 ± 3.9	33.7 ± 4.4	0.62
Married or common law	95 (99)	99 (98)	0.59
University-educated	83 (86)	91 (90)	0.43
Partner present at prenatal class	95 (99)	99 (98)	0.59
Follow-up data	(n = 88)	(n = 86)	
Delivered infant at index hospital	86 (98)	82 (95)	0.39
Vaginal delivery	59 (67)	61 (71)	0.58
Infant gestational age at birth, weeks	39.7 ± 1.4	39.5 ± 1.4	0.28
Infant birth weight at birth, Kg	3.4 ± 0.5	3.4 ± 0.5	0.55
Male infant	38 (43)	53 (62)	0.02
Infant age at vaccination, days	64 ± 8	63 ± 11	0.80
Elapsed time between infant vaccination and follow-up	22 ± 18	25 ± 19	0.24

Values are frequency (%) or mean ± SD.
[a] χ^2 or *t* test.

Table 2
Pain management (PM) interventions utilized at infant 2-month vaccinations.

	Pain education (n = 88)	Control education (n = 86)	*P*-value[a]
Utilization of ⩾1 PM intervention	30 (34)[b]	15 (17)[c]	0.01
Breastfeeding	17 (19)	14 (16)	
Sugar Water	10 (11)	3 (3)	
Topical anaesthetics	10 (11)	0 (0)	
Attempted and unsuccessful utilization of ⩾1 PM intervention	17 (19)[d]	4 (5)	0.001
Breastfeeding	14 (16)	3 (3)	
Sugar water	1 (1)	0 (0)	
Topical anaesthetics	3 (3)	1 (1)	

Values are frequency (%).
[a] Logistic regression model with generalized estimating equation.
[b] n = 6 utilized ⩾2 interventions.
[c] n = 2 utilized 2 interventions.
[d] n = 1 intended to use 2 interventions.

groups (Table 1). Infant characteristics revealed a higher frequency of males in the control group.

Significantly more participants in the pain education group reported utilizing one or more pain interventions compared to the control group (34% vs 17%, respectively; $P = 0.01$) (Table 2). This difference persisted after correcting for infant sex distribution ($P = 0.03$). The percentage of participants that attempted and were unsuccessful utilizing at least one intervention was higher ($P = 0.001$) in the pain education group (Table 2).

The percentage of participants responding correctly to knowledge questions was higher in the experimental group (Table 3). There was less satisfaction ($P = 0.05$) with pain management interventions during infant vaccination in the experimental group (0.6 [0.9] vs 0.3 [0.7], respectively); this difference was not significant ($P = 0.18$) when success utilizing interventions was taken into account. Maternal-reported infant pain was lower ($P = 0.05$) for the experimental group (6.1 [2.0] vs 6.6 [2.1]) after correcting for successful utilization, but not before correction ($P = 0.11$).

Table 3
Correct responses to knowledge questions about pain management (PM) interventions.

	Pain education (n = 88)	Control education (n = 86)	*P*-value[a]
Breastfeeding	62 (70)	31 (36)	<0.001
Sugar water	45 (51)	21 (24)	<0.001
Topical anaesthetics	68 (77)	43 (50)	<0.001

Values are frequency (%).
[a] Logistic regression model with generalized estimating equation.

Fifteen vaccination appointments were observed in the pain education group and 17 in the control group. There was perfect agreement between observer-recorded utilization of pain interventions in real time and participant self-reported utilization later at telephone follow-up (breastfeeding [n = 7], sugar water [n = 1], and topical anaesthetics [n = 1]); including timing of use.

4. Discussion

This study demonstrated that implementing a fairly simple, one-time parent-directed educational intervention in prenatal classes increased maternal knowledge and utilization of evidence-based pain management interventions during routine 2-month infant vaccination. To our knowledge, this is the first study targeting expecting parents for education about infant pain management. The findings confirm the prenatal period as a suitable time for parents to learn about infant pain and that parents are interested in and capable of directing pain management during vaccination in their children.

The absolute utilization rate for one or more of the 3 targeted pain interventions (breastfeeding, sugar water, topical anaesthetics) was 17% higher for mothers educated about pain compared to those that were not educated. This is above the cutoff of 10% considered a clinically important difference for studies examining behaviour change [6] and well above reported rates of use of any of these interventions [9,20,21]. In relative terms, this represents a 100% increase in the use of these interventions. Including unsuccessful utilization yielded an absolute difference in utilization rate of 31% – almost 2-fold the observed difference or a relative difference of 140%, and represents the potential impact of the intervention.

We focused our educational intervention on parents rather than clinicians because parents are primarily responsible for all aspects of their children's care and want to reduce vaccination pain [9,21,22]. In addition, parents can transfer knowledge about pain management to any clinical setting and advocate for better practices. Furthermore, clinicians report that pain management is primarily a parental rather than clinician responsibility, and that they do not actively educate parents about mitigating vaccination pain [21]. The finding that many parents were able to carry out planned pain interventions suggests that clinicians are supportive of parental efforts to reduce pain during vaccination.

A substantial percentage of parents (12%), however, were unsuccessful implementing pain interventions, most commonly breastfeeding, due to disapproval by clinicians. Breastfeeding requires that a clinician is agreeable to administering vaccines while infants are being held (rather than positioned supine) and breastfed. Clinicians raise concerns about technical difficulties posed by this position, and infant choking, which is not supported by research evidence. Being able to carry out planned interventions was significantly related to differences between groups in maternal ratings of satisfaction with pain management utilized during infant vaccination and parent-reported infant pain. Ensuring that clinicians are aware of and supportive of parents' efforts to mitigate pain in their infants is therefore important. It has previously been demonstrated that teaching paediatricians and public health nurses leads to demonstrable increases in the utilization of interventions to reduce vaccination pain [4,13]. Based on this prior research and the current findings, we recommend additional measures to target clinicians to achieve even higher utilization rates.

Parent factors, child factors, and other contextual factors may have also influenced the use of pain interventions during infant vaccinations. Mothers in both groups employed breastfeeding more frequently than other interventions. Breastfeeding is used at MSH during newborn needle procedures, and parents in both groups may have transferred this hospital routine to their infant's vaccination appointments; hence, positively impacting the baseline utilization rates for both groups. The role of the postnatal hospital ward on further supporting and facilitating better pain management practices postdischarge was not specifically investigated. Determinants of what parents prefer to learn about, how they remember, and how they decide what they will do are recommended for future research. The specific role of fathers, either directly or indirectly through supporting the mother, also requires further study.

There are limitations that warrant discussion. Firstly, one educator in one institution delivered the education. However, both the education and script were standardized and can be transferred to different educators and settings. Secondly, prenatal classes are attended by expectant women who may be more likely to implement pain interventions due to their characteristics (eg, higher education, socioeconomic status). However, 20%-25% of expectant mothers at MSH attend prenatal classes – with > 6500 deliveries/year, this represents a significant proportion of the expectant population. Thirdly, contamination of community health care providers and participants was possible, whereby the same health care provider who provided care to participants in both the experimental and control groups became aware of pain interventions and subsequently incorporated them into their practice, or parents in the control group discovered methods to reduce pain because of being primed about this topic. It is unlikely that contamination played a major role, as 97% of participants in the control group did not administer sugar water or topical anaesthetics. General information about vaccination was chosen for the control condition because: 1) this topic was not included in detail in the curriculum and all parents might benefit, 2) it prevented bias from sensitization to the topic in one group, 3) it facilitated observation of vaccination appointments, and 4) it facilitated follow-up interviews because all parents were asked about vaccination.

Strengths of this study include: cluster design, blinding of participants and outcome assessors, high follow-up rate, and validation of primary outcome. The unit of randomization was the class rather than individual. This design was chosen to limit the potential for contamination among participants (information sharing) that may have occurred if individual participants received different interventions. Blinding of participants and outcome assessors minimized bias in study outcome assessment. A high retention rate (88%) minimized the risk of attrition bias. Finally, the primary outcome was validated in a subsample of participants by correlating observed analgesic use with recalled use.

In summary, prenatal education about infant vaccination pain management resulted in increased utilization of pain interventions by mothers at routine 2-month infant vaccination. This finding has important implications for using prenatal education programs to facilitate parental competence in promoting optimal infant health. Additional research is needed to determine if utilization can be bolstered further using techniques such as postnatal hospital reinforcement, reminder cards, and provider education.

Conflict of interest statement

A. Taddio received research funding from Pfizer and study supplies from Ferndale and Natus for a separate clinical trial related to this topic. S. Smart and C. Parikh received a Trainee Award from a Canadian Institutes of Health Research (CIHR) Pain in Child Health Training Consortium. R. Pillai Riddell is supported by a New Investigator Award from CIHR. E. Yoon is supported by the Ministry of Health and Long-Term Care. The other authors declare no conflicts of interest relevant to this article.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.pain.2014.03.024.

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