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KEY WORDS
cross-cultural comparison, distraction, immunization, injection, pain management

ABBREVIATION
VAS—visual analog scale

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WHAT'S KNOWN ON THIS SUBJECT: Pediatric immunizations are the most common painful procedures occurring in pediatric medical settings. Although a number of strategies are available to help reduce immunization pain, they often are not used because of time, effort, or cost associated with use.

WHAT THIS STUDY ADDS: The cough trick is easily taught and requires no additional cost, equipment, or staff time. These results suggest that the cough trick may be effective for some children. Observed differences according to the race/ethnicity of participants are discussed.

abstract

OBJECTIVE: The goal was to investigate the effect of a "cough trick" technique on self-reported pain of children receiving routine immunizations. The strategy requires minimal equipment, time, or training for parents, children, and nursing staff members.

METHODS: A randomized, controlled, unblinded, within-subject study of 68 children receiving prekindergarten (ages 4–5) or pre–junior high school (ages 11–13) immunizations was performed. Participants were recruited from an outpatient pediatric clinic at a large public hospital in the Midwest. The strategy required a single "warm-up" cough of moderate force, followed by a second cough that coincided with needle puncture. The principle outcome was self-reported pain, although parent and nurse report of pain was used to support the accuracy of self-report. Older participants and all nurses completed a measure of their satisfaction with the procedure.

RESULTS: In the initial analysis, the procedure was found not to be effective. However, post hoc tests revealed that the procedure was effective at a statistically and clinically significant level for participants identified as Hispanic white or non-Hispanic white but not for those identified as non-Hispanic black. Participants and clinic nurses found the procedure acceptable and effective.

CONCLUSIONS: The results of this study suggest that the cough trick can be an effective strategy for the reduction of pain for some children undergoing routine immunizations. However, additional research is needed to clarify the observed moderation by self-identified race. *Pediatrics* 2010;125:e367–e373

Pediatric immunizations are the most-common painful procedures occurring in pediatric medical settings.[1] Although some children seem to cope well with immunization pain, almost all children benefit from strategies to control the pain and anxiety associated with immunizations. A number of strategies have been used to ameliorate immunization pain in school-aged children,[1,2] but no technique has been found to work for all children, and children are likely to benefit from having a range of techniques from which to choose.

Many strategies to address immunization pain function by anesthetizing the skin with products such as eutectic mixture of lidocaine and prilocaine (EMLA), amethocaine, or vapocoolant sprays.[3–6] Other strategies stimulate nerves in the skin near the injection site with a device or through pinching, rubbing, or stroking.[7,8] Another important group of strategies function, at least in part, by distracting the patient before and during painful procedures such as immunization.[1,8–10] Still other strategies involve training parents[11,12] or nurses[13,14] to provide distraction for children. Although they are effective,[1,15] nearly all of the existing strategies require increased time, cost, and/or effort on the part of clinic staff members or patients, which increasingly are being recognized as barriers to implementation of evidence-based practices in pediatrics and primary care.[16,17]

One novel alternative has the potential to reduce significantly the time, effort, and cost associated with addressing pediatric immunization pain. This strategy, referred to as the "cough trick," requires that the patient be prompted to give a single "warm-up" cough of moderate force, followed by a second cough that coincides with needle puncture. The cough trick was evaluated recently with adult volunteers and resulted in clinically and statistically significant decreases in reported pain.[18] The effectiveness of the procedure may result from distraction (concentrating on coughing on cue), competing sensory stimuli (noise and feeling of the cough), competing physiologic stimuli (eg, increased pressure in the subarachnoid space or increased blood pressure), or some combination of these factors. The strategy can be taught easily and requires no additional cost, equipment, or staff time. Therefore, it may prove to be a practical strategy even in busy pediatric clinics.

The purpose of this investigation was to evaluate the efficacy of the cough trick in reducing perceived pain in children undergoing routine immunization injections in a primary care clinic. We hypothesized that use of the cough trick at the moment of injection would result in reduction in perceived pain, compared with injections received without use of the cough trick. In addition, we hypothesized that the strategy would be rated as acceptable and effective by participants and participating nurses. Finally, although we did not have a specific directional hypothesis, we planned to conduct post hoc comparisons to assess the impact of the order of injections and whether demographic factors such as age,[19] gender,[19] and ethnicity or race[20,21] would alter the effectiveness of the procedure.

METHODS

Ethics Approval

All procedures were reviewed and approved by the institutional review board at the University of Nebraska Medical Center.

Participants

Children and their families were recruited from an outpatient pediatric clinic in a large public hospital in the Midwest. Participants were required to be 4 to 5 years or 11 to 13 years of age and scheduled to receive 2 of the targeted injections [diphtheria-tetanus-acellular pertussis (DTaP) and inactivated poliovirus (IPV) vaccines or tetanus toxoid-reduced diphtheria toxoid-acellular pertussis (Tdap) and meningococcal conjugate vaccines]. These ages and immunizations were chosen because they represent health care maintenance visits in which children typically receive multiple injections. Potential participants were excluded if they could not speak English, could not learn how to use the primary self-report pain measure, or refused to cough or if the research assistant was unavailable during their visit. Results of a power analysis suggested that a total sample of 51 would be necessary to find a moderate-sized effect while maintaining adequate power (0.8) and α level ($<.01$) with a paired t test.

One hundred fifteen patients were identified as meeting the inclusion criteria. Forty-seven participants or their families declined to participate, typically indicating concern about the additional amount of time required for participation (eg, completing consent forms). Therefore, 68 children who were scheduled to receive preschool immunizations completed the study. Twenty-two participants were in the younger age group, and 46 were in the older age group. Table 1 provides additional demographic information related to gender, ethnicity, and race. Although demographic information is not available for families who declined to participate, demographic features of the sample are similar to those of the clinic population from which the sample was drawn.

The 13 clinic nurses scheduled to deliver immunizations during the study period were invited, and all elected

TABLE 1 Demographic Characteristics of the Sample

	n (%)		
	Younger	Older	Total
Gender			
Female	11 (50)	28 (61)	39 (57)
Male	11 (50)	18 (39)	29 (43)
Total	22	46	68
Ethnicity/race[a]			
Non-Hispanic black	9 (47)	22 (48)	31 (48)
Non-Hispanic white	8 (42)	14 (30)	22 (34)
Hispanic white	2 (11)	10 (22)	12 (18)
Total	19	46	65

Younger participants were 4 to 5 years of age; older participants were 11 to 13 years of age. Proportions represent gender or ethnicity/race within age groups.
[a] Ethnicity/race totals are smaller because 3 participants did not fit into the included groupings.

to participate in the study. Although demographic information on nurses was not collected formally, all participating nurses were female, differing in age and experience. One nurse was non-Hispanic black, and the others were non-Hispanic white or Hispanic white.

Measures

Self-Report of Pain

Participants reported their pain on a 100-mm visual analog scale (VAS). There is a large body of research supporting the reliability and validity of the VAS for children as young as 5 years of age,[22–25] and differences of ≥10 mm are generally accepted as clinically significant.[22,26] For older children, anchors were listed as "no pain at all" and "the worst imaginable pain"; for younger children, anchors were listed as "no hurt at all" and "really bad hurt." All participants were trained to use the VAS. For younger participants, the research assistant first modeled how to use the scale. Next, both older and younger participants were asked to think of a recent pain or hurt and to practice marking the scale accordingly.

Observer Report of Child Pain

On a separate VAS, parents and nurses of participating children were asked to indicate their perception of the child's pain after each injection.

Child Satisfaction

The older children completed a brief treatment satisfaction questionnaire that was adapted for this study from the Abbreviated Acceptability Rating Profile,[27] which was originally designed to measure acceptability to parents of treatments for child behavior problems. The original measure had a strong single factor, high reliability, internal consistency (Cronbach's $\alpha = .97$), and evidence of content and discriminant validity.[27]

For the current study, the measure was adapted by changing item wording from third person to first person and from conditional tense to past tense and by replacing "behavior" with "pain." Therefore, the satisfaction questionnaire prompted children to rate their agreement from 1 (strongly disagree) to 6 (strongly agree) on 8 items and included statements such as "the treatment was a good way to handle my pain" and "I am willing to continue to use this treatment." Internal consistency in the current sample was high (Cronbach's $\alpha = .93$). Younger children did not complete the satisfaction form because they often were more distressed after their injections; asking them to answer 8 additional questions might have been unpleasant for them and their families.

Nurse Satisfaction

At the conclusion of the study, each participating nurse completed a treatment satisfaction questionnaire, which was adapted from the child questionnaire. Questions were worded to assess nurse satisfaction with the cough trick and perceived benefit to the patient.

Procedure

Patients who met inclusion criteria were invited to participate in the study and were told, "This research is trying to see if kids feel shots differently when they use a technique called the 'cough trick,' as compared with when they do not use the technique." Although this was not a single- or double-blinded design, the research assistant did not indicate to participants or parents that this strategy might be expected to reduce pain. A within-subject design was used for this study. After counterbalancing for age, gender, and type of immunization, participants were assigned randomly to use the cough trick for either their first or second immunization.

During immunizations, the nurse performed "treatment as usual" for the control condition. Nurses were not instructed regarding what strategies to use for this condition, and the procedures varied to some extent. Nurses were observed to hold the child, to ask parents to hold the child, to prompt the child to take a deep breath, or simply to instruct the child to look away. In the experimental condition, the nurses gave the following instruction to participants, "OK, now we are going to try the cough trick. Let's try a practice cough now. Please give me one good cough. Great! Now give me one more good cough, just like the first one." The immunization was delivered with the second cough.

Immediately after each injection, the child, parent, and nurse each rated the child's pain independently, on separate VAS scales. After the second injection was completed and all pain ratings were recorded, the older children completed the treatment satisfaction questionnaire. At the conclusion of the study, all participating nurses completed the nurse satisfaction questionnaire. Data were analyzed with the JMP program designed for SAS (SAS Institute, Cary, NC).

RESULTS

Correlation of Self-Report and Observer Report of Pain on the VAS

Self-report of pain was correlated with observer report for all participants. Self-report by younger participants was correlated significantly with parent ratings ($r = 0.71$; $P < .001$) and with nurse ratings ($r = 0.41$; $P = .05$). Self-report by older participants was correlated significantly with parent ratings ($r = 0.47$; $P = .001$) and with nurse ratings ($r = 0.72$; $P < .001$). A perfect correlation would not be expected, because pain is a subjective state that cannot be judged completely by an external observer. These results support the validity of participant self-report of pain; therefore, self-report was used as the primary dependent variable for all further analyses.

Overall Treatment Effect

The average self-reported pain intensity was 42.6 mm (SD: 33.1 mm; median: 46.0 mm) on the VAS for injections given in the control condition and 37.1 mm (SD: 32.3 mm; median: 27.5 mm) for injections given with the cough trick. Overall treatment effects were tested by using within-subject *t* test statistics. This allowed each subject to serve as his or her own control and greatly reduced the amount of variability introduced because of the subjective nature of pain ratings. Because this method of analysis was used, means and SEs refer to the difference in pain between the control and experimental conditions across subjects. Calculation of these difference values was performed by subtracting the ratings made in the control condition from the ratings made in the experimental condition; therefore, negative values represent differences in the hypothesized direction. Overall, the cough trick did not reduce significantly the intensity of pain reported by participants (mean: −5.43 mm; SE: 4.82 mm; $t_{67} = -1.13$; $P > .25$). Figure 1 provides an illustration of these results.

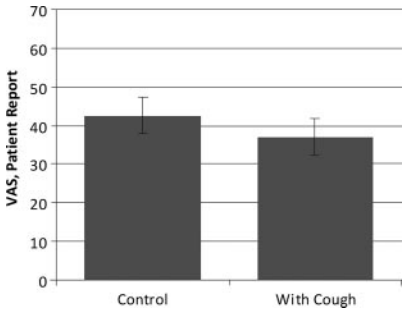

FIGURE 1
Overall treatment effect. The overall treatment effect was not statistically or clinically significant (within-subject analysis); error bars represent SEs.

Order Effect

The presence of an order effect was evaluated by using within-subject *t* test statistics. This analysis was performed by subtracting the pain ratings for the second injection from the ratings for the first injection; therefore, negative values indicate more pain during the second injection. These results indicated no significant order effect for the overall group (mean: −0.69 mm; SE: 4.86 mm; $t_{67} = -0.14$; $P > .50$), for the younger children (mean: −3.32 mm; SE: 9.63 mm; sign test with $N = 22$, $P > .50$), or for the older children (mean: 0.57 mm; SE: 5.59 mm; $t_{45} = 0.10$; $P > .50$).

Interaction of Treatment Effect With Age and Gender

Age and gender have been found to be important variables associated with pain tolerance, although gender differences in pain responses are less reliable.[19] To test for potential moderation according to gender, 1-way, repeated-measures analysis of variance was performed to evaluate the interaction between gender and treatment group with respect to self-reported pain. This interaction was not significant ($F_1 = 0.90$; $P > .25$). To test for potential moderation according to age group, a second analysis of variance was performed, to evaluate the interaction between age group and treatment group with respect to self-reported pain. This interaction was not significant ($F_1 = 0.39$; $P > .25$).

Interaction of Treatment Effect With Ethnicity/Race

Analyses also were conducted to evaluate the presence of an interaction between treatment effectiveness and self-reported ethnicity/race. All except 3 of the participants in the study self-identified membership in 1 of 3 broad ethnic/racial groups, that is, non-Hispanic black, Hispanic white, or non-Hispanic white. Two of the other participants were identified as being of unknown ethnicity/race, and 1 was identified as being of other ethnicity/race; those 3 participants were not included in these analyses.

Results of a 3-group, 1-way, repeated-measures analysis of variance indicated a significant interaction between ethnicity/race and treatment effectiveness ($F_2 = 4.91$; $P = .01$). Follow-up *t* tests revealed significant differences between participants identified as black and those identified as non-Hispanic white ($t_{62} = 2.80$; $P < .01$) and between participants identified as black and those identified as Hispanic white ($t_{62} = 2.27$; $P < .05$), whereas no significant difference was found between those identified as non-Hispanic white and those identified as Hispanic white ($t_{62} = 0.03$; $P > .50$).

Mean differences in pain between control and experimental conditions were similar for Hispanic white and non-Hispanic white participants (mean differences of 19.3 mm and 19.7 mm, respectively), and the results seemed to be related to race rather than ethnicity. Therefore, participants in the Hispanic white and non-Hispanic white groups were combined. The mean pain

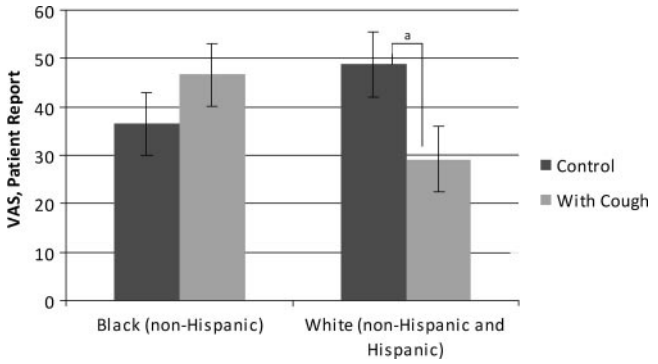

FIGURE 2

Average pain report and treatment effect by race. The cough trick was more effective for participants identified as non-Hispanic or Hispanic white, compared with those identified as non-Hispanic black. [a] Indicates a statistically significant difference ($P < .01$). Error bars represent SEs.

rating in the control condition was 48.8 mm, compared with 29.2 mm in the experimental condition, which indicated that the cough trick was associated with a 40% reduction in pain, which is both statistically (mean: −19.56 mm; SE = 6.8 mm; $t_{33} = -2.86$; $P < .01$) and clinically[22,26] significant. Participants identified as non-Hispanic black were then evaluated with a separate, within-subject *t* test (mean: 10.3 mm; SE: 6.4 mm; $t_{30} = 1.59$; $P > .10$), which revealed a nonsignificant increase in pain associated with the cough trick. Figure 2 illustrates the average pain reported in control and experimental conditions according to race.

Participant and Nurse Preferences

The overall treatment acceptability ratings indicated that most participants (32 of 42 participants) thought that the strategy helped with their injection pain. However, differences were observed when these responses were separated according to self-identified race, because 8 of the 10 participants who did not find the strategy valuable were identified as black (χ^2 (1) = 5.52; $P < .05$). Differences also were observed for the total score of the satisfaction measure. More specifically, participants who were identified as Hispanic or non-Hispanic white (mean score: 39.5; SD: 7.2) were more likely than black participants (mean score: 30.6; SD: 9.2) to agree that the strategy was acceptable, effective, and worth doing ($t_{40} = 3.5$; $P < .001$). Finally, of the 11 nurses who rated their satisfaction with the cough trick, 10 thought that the strategy was both acceptable and effective.

DISCUSSION

Overall Findings

These results suggest that the cough trick can be an effective strategy for the reduction of pain for some children undergoing routine immunizations. The finding that the strategy was not universally effective is not surprising. Children have varying degrees of distress, different histories of pain, and different experiences of effective coping with pain. Indeed, the results of a qualitative study of children's preferences for pain coping strategies demonstrated that individual differences affect the strategies children choose to cope with pain.[28] Nevertheless, the cough trick emerged as a helpful strategy for many children who participated in this study and its effectiveness was not moderated by gender or age group, which supports the potential utility of this strategy in a busy pediatric clinic setting.

Ethnic background (defined as Hispanic or non-Hispanic) and race (defined as Asian, black, American Indian or Alaskan Native, Pacific Islander, white, or other) have been associated with differences in pain perception, reports of pain, and coping.[20,21] The effectiveness of the cough trick was significantly influenced by self-reported race in this sample. Although participants identified as black did not experience a statistically significant change in pain when using the cough trick, participants in the non-Hispanic and Hispanic white groups experienced a mean decrease in pain of 40% (~20 mm) when using the cough trick. This result is both statistically and clinically[22,26] significant.

Although broad ethnic/racial categories are biologically imprecise, on the basis of comparisons of genetic heritage and self-reported group membership,[29] ethnic/racial identification has been associated with differences in how individuals respond to and cope with pain.[20,21,30] Some ethnic/racial differences may be attributable to social or cultural factors. For example, whether and how individuals communicate their pain to health care professionals are influenced by social and cultural factors.[31] Pain assessment can be confounded when nurses have different cultural backgrounds than their patients, which results in a discrepancy between the expression of pain by patients and the interpretation of pain by nurses.[32] This might be of particular importance in the present study, because participating nurses and the research assistant were primarily non-Hispanic or Hispanic white but almost one half of the participants were black. These differences might have played a role in some participants' willingness to disclose pain or in their belief that this procedure could be of benefit. Racial differences might have other determinants beside culture, however, and future research is needed to investigate the reliability and causes of the racial differences

observed in this study. Readers are directed to a recent review specifically discussing cultural factors influencing how children report and express pain[33] and a book chapter that provides a broad overview of private, public, and societal factors that affect the interpretation and reporting of pain.[34]

Limitations

Although the cough trick proved beneficial for some children, the cough trick itself was not without limitations. Some children, after learning that the injection would not occur until they coughed, delayed their cough or refused to comply, apparently to avoid the injection. However, this would not necessarily be a significant drawback to offering the cough trick strategy, because in practice nurses could simply provide the cough trick as one option, allowing the child to choose an alternative strategy if desired.

In addition to children who refused to cough, ~40% of invited parents refused their child's participation in the study. Families who refused typically indicated that they were concerned about the time it would take to be in the study. Notably, before they were even approached about the research, most families had already spent considerable time in the waiting room and then in the examination room, seeing nurses, residents, and pediatricians. Other families were not invited to participate because the research assistant was not in the clinic during their appointments. Therefore, we were unable to collect data for a fairly large sample of patients, and we could not determine whether the remaining participants reflected a sampling bias. However, the demographic information on the participants in this study was representative of that for the clinic from which the participants were drawn, which indicates that, in general, participants did not reflect a sampling bias.

The use of the VAS for pain self-reporting is a potential source of concern, because it has not been validated for use with children <5 years of age and some children in this study were 4 years of age. However, specific steps were taken to train participants in the valid use of the VAS, and the observations of the research assistant, as well as the comparisons with parent and nurse ratings of pain, support its validity. Finally, the study itself included a relatively small number of participants. Although the prospective power analysis indicated that this would be an adequate sample from a statistical standpoint, the small number of participants somewhat limits the external validity of these findings.

Conversely, the study is strengthened by the use of a within-subject design that, statistically, allows for greater power and more confidence in observed results. This design is of particular utility in the present study, because it controls for the inherently subjective nature of pain ratings. Because each participant served as his or her own control, the results provide a clearer picture of the actual effect of the procedure on individually perceived pain.

Future Directions

Overall, these results extend the literature by introducing a brief, simple technique for reducing the pain associated with immunization injections. The results also extend the literature by highlighting the potential influence of race in the perception of pain and the effectiveness of at least one specific pain management procedure. Of course, this invites speculation about the role of race/ethnicity in the effectiveness of pain management procedures for children. Future research might evaluate the interactions of the race/ethnicity of clinic staff members and that of patients or might target culturally mediated factors such as willingness to disclose pain, trust in the medical system, and belief in pain management strategies.

A belief in the value of pain management is relevant not only for patients but also for staff members. A significant barrier to the clinical implementation of any pain management strategy may be the perception of some that the pain associated with pediatric immunizations is not worth treating.[30] In this study, however, nurses were observed to use a variety of strategies in the control condition to help children manage the pain, which suggests that the nurses were interested in helping to reduce immunization pain. None of the strategies that the nurses were observed to use was an empirically supported treatment for immunization pain, and all of the observed strategies were fast and required no separate materials. Future research should continue the quest for techniques that are effective and require little time, expense, or effort.

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