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ScienceDirect
Applied Nursing Research 23 (2010) 101 – 105
Applied Nursing Research
www.elsevier.com/locate/apnr

The pain response of infants in Turkey to vaccination in different injection sites

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Received 27 March 2007; revised 18 January 2008; accepted 22 March 2008

Abstract This study was carried out with the aim of comparing pain responses of children who receive intramuscular (IM) vaccination in deltoid muscle versus the pain responses of those who receive IM vaccination in the vastus lateralis. A total of 185 infants were randomly assigned to one of the two study groups. The deltoid group and the vastus lateralis group were vaccinated respectively in the deltoid muscle and the vastus lateralis. Our results indicated that pain response of infants was similar in each group. However, crying duration of the children who received the vastus lateralis vaccination was shorter than that of the deltoid group after the procedure.

1. Introduction

When routine procedures such as intramuscular (IM) injections and vaccinations are performed on infants, it is assumed that such procedures cause a certain degree of pain (Gallo, 2003). Unlike the widely held belief of the past years, today, it is accepted that small children and even newborns are able to feel pain and respond to painful stimuli. Thus, it is crucial to find methods to reduce pain when vaccinating small children (Anand & Carr, 1989; Johnston, Stevens, Yang, & Horton, 1995; Shah, Taddio, Bennet, & Speidel, 1997; Stevens & Johnston, 1994). Generally, there are no methods for pain reduction during vaccination of children in Turkey. It is thought that choosing a suitable injection site and muscle may be effective in reducing pain during childhood immunization procedures (Diggle, 2006). The pain associated with immunization is a source of anxiety and distress for children. At the same time, painful experiences in the early childhood period have the potential to affect long-term outcomes. The infant undoubtedly has the neuronal apparatus to detect a painful stimulus and perhaps remember it (Stevens & Franck, 1995).

Evaluation of pain and subsequent nursing care plans to reduce pain are necessary steps for reduction of pain in young patients. Although the most reliable way to evaluate the level of pain is to make use of verbal responses to questions about perceived pain, this is not a viable choice in young children. Alternative methods for pain assessment in small children are usually classified in two groups (Byers & Thornley, 2004; Celebioglu & Polat, 2004; Harrison, Evans, Johnston, & Loughnan, 2002; Kocaman, 1994; Stevens & Franck, 1995; Stevens, Johnston, & Grunau, 1995; Stevens, Johnston, & Horton, 1993). Behavioral indicators of pain include evaluation of facial expressions, crying, and body movements. Physiologic or autonomic indicators consist of the following measurements: heart rate, respiratory rate, vagal tone, blood pressure, palmar sweating, transcutaneous oxygen saturation, pO_2 level, and intracranial pressure and cortisol levels (Byers & Thornley, 2004; Fuller, 1991; Johnston & Strada, 1986; Stevens et al., 1995; Lindh, Winklund, & Hakansson, 2000).

Because verbal feedback is not available from infants and young children, it is necessary to consider physiological and behavioral responses to evaluate pain and then to design interventions to decrease pain levels (Savaşer, 2001). To measure and assess physiologic and behavioral responses to pain, various scales have been developed (Grunau & Craig, 1987; Lawrence et al., 1993; Taddio, Nulman, Koren,

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doi:10.1016/j.apnr.2008.03.003

Stevens, & Koren, 1995), and the use of these scales improves nurses' efficiency and facilitates improved nursing care (Stevens et al., 1995).

Although the infliction of pain during vaccination cannot be eliminated, nurses must seek ways to provide optimal comfort and security for patients during such procedures (Gallo, 2003) and should use methods that inflict the least amount of pain possible. Among possible methods, the choice of injection site suitable for the age of the patient is one of the most important considerations. The size of the muscle and nerve density at the injection site are important factors when evaluating the potential for pain at specific injection sites (Balcı Akpınar & Çelebioğlu, 2005; Elkin, Perry, & Potter, 2004; Kuğuoğlu & Kürtüncü, 2005; Green Book, 2006).

Drehobl (1980) has reported that in infants under 6 months old, the gluteus maximus and deltoid are not developed enough to be used for IM injection and that these areas should be avoided to prevent nerve damage. Elkin et al. (2004) conclude that due to the small area of the deltoid site, the number and volume of injections that can be given into this area are limited. Therefore, only injections that are small in volume (0.5–1 ml) tend to be administered into the deltoid site (Elkin el al., 2004).

In a study by Rodger and King (2000) which investigated this issue, it has been reported that pain after injection is one of the most frequently reported complications associated with the use of the deltoid injection site. In contrast, Ipp et al. (1989) reported that children receiving vaccine in the thigh had more severe pain than those injected in the arm.

The vastus lateralis is a recommended injection site for IM injections in infants. There is, in fact, no viable alternative to this site in infants because the deltoid has insufficient muscle mass to be a safe site, whereas the vastus lateralis is well developed. For babies receiving their recommended immunizations, current literature supports the administration of IM vaccines in the anterolateral aspect of the vastus lateralis (Chiodini, 2000; Chiodini, 2001; Daly, Johnston, & Chung, 1992; Diggle, 2006; Drehobl, 1980; Elkin et al., 2004; Green Book, 2006).

The guide provided by The Ministry of Health of Turkey (2006), entitled Expanded Program of Immunization, suggests that either the vastus lateralis or deltoid muscle may be selected for vaccination. In the city where this study was conducted, the deltoid muscle was selected as the vaccination site in some health care centers, whereas the vastus lateralis was the choice in others.

This study aimed to compare pain responses of children who received IM vaccination in the deltoid muscle versus the pain responses of those who received IM vaccination in the vastus lateralis. The research questions for this study were the following:

Is there a difference in the results of the Neonatal Infant Pain Scale (NIPS) scores of the infants who were vaccinated in the deltoid muscle (deltoid group) and those who were vaccinated in the vastus lateralis (vastus lateralis group)?

Similarly, is there a difference between the deltoid group and vastus lateralis group of infants in terms of their heart and respiratory rates and duration of crying in response to the vaccination?

2. Methods

2.1. Study design and sampling method

The study was descriptive and conducted between March 1, 2004, and June 30, 2004. The study sample consisted of 185 healthy infants (all were approximately 4 months old) who were presented to the local primary care clinics for the third dose of the diphtheria, tetanus, and pertussis (DTP) vaccination series. The infants were randomly divided into two study groups for their vaccination sites. The deltoid group contained 90 children, all of whom were vaccinated in the deltoid muscle, and the vastus lateralis group consisted of 95 children, whose injection site was the vastus lateralis.

2.2. Study setting

Primary health care clinics are typically the initial point of contact in the Turkish health care system. They provide free public services to children, such as vaccination, growth monitoring, and primary health care, and are mainly staffed by physicians, nurses, and midwives. These clinics are financially supported by The Ministry of Health of Turkey. This study was carried out at two such clinics in Erzurum, a city in Turkey with a population of 400,000.

2.3. Instruments

2.3.1. Questionnaire form

Data on demographic characteristics were collected using a questionnaire to determine the gender, weight, and age of the infants.

2.3.2. Neonatal Infant Pain Scale

Neonatal Infant Pain Scale was developed for newborn infants who were 0–6 weeks old (Lawrence et al., 1993). However, some references show that NIPS can be used in infants up to 1 year old (NIPS, 2007; Pain Assessment Tools Neonatal/Infant Pain Scale [NIPS], 2007; Walker & Arnold, 2004). The NIPS scores observe infant pain on a scale of 0 to 7 (Lawrence et al., 1993). Items on the NIPS assess six behavioral responses to pain (breathing patterns, facial expression, arms, legs, cry, and state of arousal). Internal consistency ranges from .87 to .95, as reported by Lawrence et al. (1993). Language and comprehensive validity studies of the scale for use in Turkey were previously reported by Akdovan (1999). Internal consistency in the study of Akdovan (1999) was .83. In this study, the alpha coefficient was .71.

A chronometer was used to measure crying duration, and heart rate was measured with a stethoscope. Current weights of the infants were measured with a digital weighing machine.

Table 1
Demographic characteristics

Characteristics	*n*	%
Gender		
Female	88	47.6
Male	97	52.4
Mean age (in weeks)	15.9 ± 3.9	
Mean weight (in grams)	7,390.78 ± 2,321.67	

2.4. Ethics considerations

The aim of the research and the study methods were explained to the parents of the study participants, and verbal informed consent was obtained before vaccination, observations, and measurements. In addition, the study was approved by the local health administration organization.

2.5. Procedures

All the participants received DTP vaccination for 4-month-old infants. For each group, the injections were administered with the participant in supine position on the examination table by the same staff nurse from the primary health care clinics. All the infants were awake at the time of the injection, and their parents were in the procedure room. The preparation and actual procedure were consistent for all the infants. The injection site was cleaned with alcohol and allowed to air dry before the needle was inserted. The vaccination was administered when infants were in the quiet alert state. A dose of 0.5-ml DTP was given with a 24- to 25-mm-gauge needle and a 2-ml syringe into either the deltoid or vastus lateralis muscle at a 90° angle. The duration of injection was approximately 10 seconds. Light pressure was applied to the site after injection. The infants were presented back to parental holding after the injections.

On the basis of the NIPS and measurement of heart and respiration rates of the infants, an evaluation was performed for 60 seconds before and after the procedure. The nurses who administered the vaccination observed the NIPS scores. After vaccination, the heart rate was counted by the first research nurse, and the respiratory rate was counted by the second research nurse. The respiration rate was determined through observation of chest movement. The third research nurse observed and recorded crying duration in seconds. Crying was recorded as the duration from the onset of crying until the infant was completely silent.

2.6. Data analysis

Descriptive statistics were used to evaluate the demographic characteristics. Independent-samples *t* test was used to compare the results of the deltoid group with the results of the vastus lateralis group. The significance level was set at .05. Power analysis was based on a two-sided alpha of .05, with a power of .90 when calculated at the end of the study.

3. Results

The study sample was composed of 90 infants in the deltoid group and 95 infants in the vastus lateralis group. The infants participating in the current study ranged in age from 14 to 19 weeks (M = 15.9 weeks, SD = 3.9 weeks). There were 88 female infants (47.6%) and 97 male infants (52.4%; Table 1). No significant differences were detected between the groups for the demographic characteristics and the NIPS score, heart rate, and respiratory rate before the procedure.

An independent-samples *t* test was used to determine differences between the NIPS scores of the infants who were vaccinated in the deltoid muscle and the NIPS scores of those who received their vaccinations in the vastus lateralis muscle. The results indicated no significant differences between the NIPS scores of the groups ($t = -0.769$, $p > .05$; Table 2). Independent-samples *t* tests were used to determine differences in the heart rate, respiratory rate, and crying duration of the groups. The results indicated no significant differences between the groups for heart rate ($t = 1.352$, $p > .05$; Table 2) or respiratory rate ($t = 0.241$, $p > .05$; Table 2). However, there was a significant difference for crying duration between the groups ($t = 4.805$, $p < .05$; Table 2). The crying duration of the children who received their vaccination in the vastus lateralis muscle was shorter (M = 34.22, SD = 24.11) than the crying duration of those who received their vaccination in the deltoid muscle (M = 62.08, SD = 50.81).

4. Discussion

The study is limited by its small sample size and the fact that it was carried out in an outpatient health care setting. In addition, this study included only infants who were brought to two specific primary health care clinics. Therefore, the findings may not be generalized. Nonetheless, given the lack of research in this area, the study offers a useful preliminary exploration of the pain response of infants to vaccination in different IM injection sites. According to published literature, there have been no similar studies conducted in Turkey and elsewhere to date. In this study, we observed behavioral and physiologic responses to pain

Table 2
Mean NIPS score, heart and respiration rates, and crying duration after the procedure

Variables	Deltoid group (n = 90), $M \pm SD$	Vastus lateralis group (n = 95), $M \pm SD$	t	p
NIPS score	5.71 ± 1.43	5.85 ± 1.04	−0.769	.443
Mean heart rate	143.22 ± 18.41	139.07 ± 23.15	1.352	.178
Mean respiration rate	42.29 ± 10.19	42.67 ± 11.38	0.241	.810
Mean crying duration	62.08 ± 50.81	34.22 ± 24.11	4.805	.000

to compare the two groups who were vaccinated at different IM injection sites.

Although IM injection is considered a basic nursing skill, it must be undertaken with due diligence. The choice of site must be based on sound clinical judgment using the best evidence available and on individualized client assessment. To avoid postinjection complications, nurses must be knowledgeable about the anatomy and advantages and disadvantages of specific injection sites.

In this study, the NIPS scores, heart rate, and respiratory rate were similar in each group. It is well known that invasive procedures such as vaccination are stressful and painful in children. For instance, Akdovan (1999) reported increased pain in infants, whereas in another study, healthy full-term infants displayed rigorous gross movement and withdrawal from painful stimuli (Stevens et al., 1995). This same study also reported that physiological and behavioral responses were noted in the neonate in response to noxious stimuli. According to Fuller (1998, 1999), the nurse must determine whether the infant is in distress and then act accordingly.

Comparisons of the durations of crying in the two groups showed that crying duration was shorter in the infants of the vastus lateralis group. The difference between the groups for crying duration was statistically significant ($p < .05$; Table 2). An infant's crying duration can provide important information about procedural pain. Findings in the literature related to crying after painful procedures note the changes in crying characteristics after such interventions (Harrison et al., 2002; Stevens et al., 1993, 1995). The cry in response to procedural pain has been characterized as intense, high energy (more energy in the higher frequencies of the sound spectrum), and often high pitched with a sense of urgency. Such crying occurs immediately after the administration of the painful stimuli (Fuller, 1991). Pain at the injection site is commonly reported after IM vaccination (Elkin et al., 2004), and therefore, our observations are not unexpected. It is important to remember, however, that the vastus lateralis muscle is free of major blood vessels and nerves; thus, there is less potential for damage at this site (Balcı Akpınar & Çelebioğlu, 2005; Chiodini, 2000; Kuğuoğlu & Kürtüncü, 2005). Nevertheless, deltoid injection site lies close to the peripheral nerves and the deep brachial artery, which may be injured if the injection is mistakenly applied to the posterior lateral aspect of the middle upper arm (Losek & Gyuro, 1992). Rodger and King (2000) reported that pain after injection is one of the most frequently reported complications associated with the use of the deltoid injection site. In contrast, Ipp et al. (1989) reported that children receiving vaccine in the thigh had more severe pain than those injected in the arm. Considering the importance of crying duration as an indicator of pain, the findings of this study are in conformity with the findings presented in earlier literature supporting that the vastus lateralis muscle is the correct site of IM injection for vaccination of the infants.

5. Conclusion

Consequently, the selection of the injection site must be based on considerations for whether the injection site is suitable for vaccination to reduce pain in infants. Because infants cannot respond verbally to pain, their behavioral and physiological responses assume greater importance. Nurses working with infants must actively assess and prevent pain as much as possible in infants. Nursing care of infants should include up-to-date knowledge of infant anatomy and physiology, infant physiological and behavioral pain responses, and appropriate care of the infant during painful procedures. Careful assessment of injection site in vaccination can result in decreased pain for such procedures and more comfort and more safety for infants.

In conclusion, although no differences in the NIPS scores of the infants in the two groups were detected, on the basis of the comparisons of the crying durations of the infants, the vastus lateralis muscle has been determined to be the best site of injection for procedures involving IM injections in infants under 1 year old.

Acknowledgments

This research was presented at the fourth National Congress of Pediatric Nursing, September 21–24, 2004, Samsun, Turkey. We are grateful to all the parents and infants who participated in this study and to the nurses who assisted in the conduct of this study.

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