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RESEARCH ARTICLE

EFFECT OF TOPICAL TETRACAINE GEL %4 ON INTENSITY OF PAIN DUE TO INTRAMUSCULAR INJECTION OF DPT VACCINE FOR 18 MONTH OF AGE

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ABSTRACT

Introduction: Intramuscular injection is an invasive and painful method for medication. Previous studies have indicated that tetracaine has ability to decrease pain via decreasing transmission and perception. The effect of local tetracaine severity of pain during DPT vaccine IM injection is not known. The aim of this study was to evaluate if topical Tetracaine reduce the pain of IM DPT injection compared to placebo.

Materials and methods: In this RCT, 40 children were taken and divided into case and placebo group using a randomized Allocation sampling . In case group used from topical tetracaine gel %4, 30 second before DPT injection; in placebo group used from lubricant gel (placebo) before DPT injection. Data was collected using FLACC scale and were analyzed with wilcaxon signed rank test.

Results: Results showed that tetracaine could not significantly decreased the severity of pain due to DPT vaccine IM injection in case group as compared with placebo group ($p>0/05$).

Conclusion: Finding of this study indicated that topical tetracaine Application could not play an important role in decreasing of pain during DPT vaccine IM injection .Although it did lead to faster recovery time. However, more studies are needed to determine of effect of pain reduction strategies.

INTRODUCTION

Pain is one of the most common causes of human suffering. Pain serves as a mechanism to warn us about the potential for physical harm(Joyce, and Jane, 2009). Pain is typically undertreated (American society of pain management Nurses, 2002). New medications and the recognition of Complementary Pain management strategies have contributed to the improved ability to manage pain and to provide satisfactory Pain reduction or relief (McCaffery, 1999). Margo Mccaffery (1999) defined pain defined pain as "whatever the experiencing Person Says it is, and existing whenever the Person Says it does ".Although many of medical interventions are Painful, but intramuscular injections are one of the common causes of pain (Lander, 1992). Immunizations prevent millions of death every year by controlling and eliminating life-threatening infectious diseases (world health organization, 2009a). Because more deaths could be prevented with optimal use of vaccines, attainment of "a world in which all people at risk are protected against vaccine preventable diseases "is the current mission of the world health organization department of immunization, vaccines, and biological (2009).DPT is a mixture vaccines that administered in to immunize against diphtheria, pertussis, and tetanus infectious(world health organization , 2009b).In Iran three time DPT vaccination are performing period for 2006 month of age infants.

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However, the pain form these injections may have long-lasting effects. It is widely accepted that neonates. Infants, and children experience pain, yet the pain is not optimally managed (Anand and international evidence-based group for neonatal pain, 2001;Schechter,2008).several reactions to pain have been described in infants including increased blood. Pressure, heart rate, respiratory rate, palmar weating, changes in facial expression, crying, and increased body movements (Coleman, Solarin, and Smith,2002).repetitive pain can lead to abnormal behavioral response to pain later in childhood, and once pain has been undettreated, it becomes more difficult to treat (weisman *et al.,*1998). It id well known that fear and anxiety can enhance pain perception. Reducing or preventing procedural pain will decrease the risk of pain sensitization, phobia of needles, and avoidance of health care (murtagh,2006).

There are many options available to treat pain; however, pharmaceutical options are limited for managing pain associated with immunizations (Schechter *et al.,* 2007).sucrose is recommended for infants less than 6 months of age, and local anesthetics including eutetie mixture of lidocaine has been shown to be effective for reducing pain associated with immunizations without affecting antibody response (Smith and Houston, 2002; OBRIEN, Taddio, Lpp, Goldbach and Koren 2004). Tetracaine has some advantages over EMLA including a faster onset of action (30 vs.60 minutes),a lower risk of methemoglobinemia, greater anesthetic potency and a longer duration of action (Obrien, Taddio, Lysazakiewics and

Koren, 2005). Bioavaliability from topical application of tetracaine is low approximately 15%; therefore, systemic effects are unlikely when used on normal healthly intact skin (Obrien *et al.,* 2005). Meyerhoff, weniger and Jacobs (2001) reported that parents are willing to pay considerable amounts of money to redouce or avoid the pain and emotional distress associated with childhood immunizations. Therefore, we considered it important to determine if topical. Anesthetics clouds reduce the pain for these infants. The objective of this study was to determine if tetracaine 4% gel (ametop) reduced the pain of intramuscular dpt compared to placebo.

MATERIALS AND METHODS

This study occurred in the centers of vaccination of shirvan city. In this study 40 children 18 months of age receiving DPT. Intramuscular injections, whose parent provided written informed consent, were included. patients were excluded if they had an allergy/ sensitivity to tetracaine or estar-type anesthetics. The children were randomized to receive 3 g of either tetracaine 4% gel or placebo before administration of the next DPT injection (study injection 1) at the subsequent injection(study injection 2), the patient received either tetracaine or placebo, whichever agant they did not receive at study injection days, a clinic nurse applied tetracaine or placebo to the patients thigh, and covered it with a dressing (opsite; smith and nephew).the clinic nurse removed the dressing and study gel after 30 minutes immediately before the injection, the site was cleaned with an alcohol swab then the dose of dpt was administered using a one-half to five-eighths inch,23- to 25- guage needle all clinic nurses and the patients parents were blinded to the treatment assignment.

Study injections 1 and 2 were video recorded. A video recording continued until the child clamed down following the injection. The child cloud be held by a parent during the injection and provide whatever usual comfort measures they world normally provide once all study injections were complete, the video was reviewed and pain assessed for all injections by the same scorer using the FLACC pain scale (Merkel, Voepel-lewis, Shayevitz and Malviya, 1997). The scorer was a pediatric registered nurse nurse who was competent in completing pain analysis for children. The scorer was blinded to which dose was tetracaine and which was placebo. The videotaoe was also reviewed to determine the time required for the patient to return to their baseline following the injection. The number of participants with informed consent determined sample size. Statically analysis involved the wilcoxon signed rank test to determine if there was a difference between tetracaine and placebo with regard to pain scores and the time required for the patient to return to baseline. Statistical significance was indicated by p values less than.05.ethics approval was obtained from the north khorasan university of medical sciences research ethics board.

RESULTS

The mean FLACC scores postinjection for placebo and tetracaine were 9.2 and 8.5 respectivly (p=0.96).the mean time required for the patient to return to their baseline following the injection was 51 seconds for the tetracaine injections and 26 seconds for placebo group a wilcoxon signed rank test indicated significantly faster recovery times with tetracaine than with placebo.

Table 1. The mean FLACC scores post injection for placebo and tetracaine

Groups	Recovery time (Range)	Mean (Range) FLACC	Base LINE, Mean (Range) FLACC
Tetracaine	26(15-70)	8.5(6-10)	1.8(0-9)
Placebo	51(35-105)	9.2(8-10)	1.7(0-6)
P-VALUE	(0.04) sig	NOsig(0.96)	NOsig(1)

DISCUSSION

Finding of this study indicated that topical tetracaine gel application could not play an important role in decreasing of pain during IM injection of PDT vaccine; although it did lead to faster recovery time. Some former studies investigating that topical tetracaine gel provided effective, rapid, long lasting and safe local anesthesia, and was significantly better than EMLA cream in reducing pain during venous connotation in children (Rosiny, 1992).But the study of Brandi (2009) and study of Yiliu (2005) showed that " topical tetracaine gel was not associated with a significant reduction in pain score , although it did lead to faster recovery time". Also the study of Balantyn (2003) showed that "tetracaine gel was not effective for pain relief for PICC inserting in infant" and study of Brigitte and *et al.,* (2007) showed that " tetracaine did not significantly decrease procedural pain in infants under going venipunvture".

However infants in this study also had high postinjection pain scores using the FLACC pain scale whether they received tetracaine or placebo prior to injection.althogh the mean pain scores were slightly lower, 8.5 when tetracaine was used compared to 9.2 for placebo, they were not statistically different.the time required for the patient to return to their baseline was reduced by approximately half with the use of tetracaine compared to placebo,which may represent a small decrease in emotional distress associated with the dpt injection. Many parents defer immunizations to limit the number of injections given at one visit in an attempt to limit pain and emotional distress for their child (Meyerhoff *et al.,* 2001). Because pain experienced in the first years of life can lead to significant complications later in life.it is important to prevent or reduce pain whenever possible (Murtagh, 2006: Weisman *et al.,*1998). In this study,topical tetracaine prior to dpt reduced the time needed for the infant to return to their baseline. However, tetracaine use did not prevent pain or lead to a significant reduction in pain score. Becouse this was only a small pilot study, the results are limited and a langer study needs to be completed to determine if there is a benefit with topical tetracaine.

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