Utilizing the Airlock technique for intramuscular injection- associated pain in newborn babies

استخدام تقنية قفل الهواء في علاج آلام الحقنة العضلية عند حديثي الولادة

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المستخلص

يجب أن يتلقى الأطفال في أول ست سنوات من العمر ٣٠ لقاحًا أو أكثر، يتم إعطاء غالبيتها في غضون الأشهر الستة الأولى. للحقن العضلي تطبيقات عديدة ويتم استخدامها بشكل متكرر، مع تقدير عدد الحقن العضلي التي يتم إجراؤها على مستوى العالم بنحو ١٦ مليون حقنة كل عام. أجريت التجربة العشوائية المُحكمة في مستشفى تعليم النساء والأطفال في محافظة المثنى. شملت الدراسة حديثي الولادة الذين خضعوا للحقن العضلي بفيتامين ك من الفترة ٢٥ نوفمبر ٢٠٢٤ إلى ٢٤ يناير ٢٠٢٥. تم تضمين ما مجموعه ٨٠ رضيعًا في التحقيق. تم جمع البيانات من كل مريض من خلال استخدام استبيان اجتماعي ديموغرافي ومقياس الألم عند حديثي الولادة / الرضع (*NIPS*) لتقييم مستوى الألم. وجدت الدراسة أن استخدام تقنية *Airlock* أثناء الحقن العضلي كان مفيدًا كاستراتيجية لتقليل الألم عند مقارنته بالتقنية القياسية (*Z = − 4.34*؛ *P <0.001*). التأكيد على أهمية استخدام التقنية غير الدوائية أثناء الإجراءات الجراحية والإجراءات المرتبطة بالإبر.

الكلمات المفتاحية: إدارة الألم غير الدوائية، الحقن العضلي، الاطفال حديثي الولادة، تقنية قفل الهواء

ABSTRACT:

Children within the first six years of life should receive 30 or more vaccinations, the majority of which are administered within the first six months. IM injections have numerous applications and are frequently utilized, with an estimated 16 millions IM injections administered globally every year. The randomized controlled trial was conducted at the Feminine and children teaching hospital in the Al-Muthanna Government. The study included neonates who

underwent intramuscular injection of vitamin K from the period November 25th 2024 to January 24th 2025. A total of 80 term infants were included in the investigation. Data was gathered from each patient through the use of a sociodemographic questionnaire and the neonatal/ infant pain scale (NIPS) to evaluate pain level. The study found that using the Airlock technique during intramuscular injection was beneficial as a pain reduction strategy when compared to the standard technique (Z= - 4.34; P <0.001). emphasizing on the importance of using non-pharmacological technique during invasive procedures and needle related procedures.

KEYWORDS: non- pharmacological pain management, intramuscular injection, neonate, Airlock technique

Introduction

Pain is often called the 'Fifth vital sign', Pain is an unpleasant sensation and emotional response caused by real or potential tissue injury.(Obeidat & Shuriquie, 2015) Pain is considered a significant problem for children of all ages in all health care settings. Needle procedures are one of the most painful and fear-inducing procedures for children. (McMurtry et al., 2015)

Most Newborn infants undergo painful procedures required for routine care during the first few days of their life, these include routine intramuscular administration of vitamin K to prevent hemorrhage, blood collection from the heel, artery, or vein, and intravenous or injections through the muscle.(Mohamed et al., 2019) Additionally, many newborns will have an intramuscular injection of the hepatitis B vaccine as a prophylactic measure shortly following birth.(Campbell-Yeo et al., 2022)

The International Association for the study of pain (2017) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage". One of the local side effects of IM injections is intense pain has been shown to be distressing for hospitalized neonates.(Canbulat et al., 2015; Inangil & Inangil, 2020) hence, applying the best strategy for pain management is the major duty of nurses. ("Efficacy of Helfer Skin Tapping Technique on Pain

Intensity as Perceived by the Patients Receiving Intramuscular Injection," 2016)

The phenomenon of pain experienced by neonates as a result of medical procedures has garnered significant concern over the past two decades. On average, a neonate undergoes approximately 7 to 17 medical interventions daily during the initial 14 days postnatally. Within the context of neonatal care, these individuals encounter various painful experiences, including intramuscular administration of Vitamin K, vaccinations such as Hepatitis B and BCG, as well as blood sampling and venipuncture procedures.(Bhattacharya & Batra, 2020)

There are three leading societies in the fields of pediatrics and neonatology: the Canadian Pediatric Society (CPS), the American Academy of Pediatrics (AAP), and the Polish Neonatal Society (PTN) that believe the preparation of plans regarding pain prevention and medical procedures on the basis of the most recent scientific research to bring about positive effects in relation to the monitoring process , treatment regiment , and pain prevention plan in neonatal intensive care units.(COMMITTEE , 2016) these associations concur that it is essential to establish standardized protocols for neonatal care and therapy, as well as to employ recognized and conventional pain management techniques.(Witt et al., 2016a)

In recent years, the importance of non-pharmacological approaches has increased due to the potential side effects of pharmacological methods, such as respiratory depression, apnea, and bradycardia. As a result, nursing research has concentrated on these methods. While pain experienced by newborns after normal vaccination is not considered a symptom of disease, it has been suggested that non-pharmacological pain relief techniques are preferable. Non-pharmacological treatment options include things like using balloons to distract from pain, listening to music, massages, and therapeutic applications of heat and cold. (Öztürk Şahin, 2020)

A precise assessment is essential for pain management.(Witt et al., 2016b) Developed by Lawrence et al., Neonatal Infant Pain Scale (NIPS), is one of Various scales that was developed to describe pain severity.(Kanbur et al., 2021; Lawrence et al., 1993) NIPS is appropriate for assessing interventional pain in extubated term and preterm neonates and is frequently utilized.(Aslan & Nart, 2023)

Najafidolatabad et al. (Najafidolatabad et al., 2010) studying the airlock and z-track techniques effect on intramuscular injection pain, drug leakage, also ecchymosis among adult female patients. Another study by *Yilmaz D. et al* (Yilmaz et al., 2016) conducted to examine the impact of Z-track approach on pain and drug leak after diclofenac sodium intramuscular administration in adult patients. However, no comparative studies were found in the literature as to which one of the two techniques is more effective or the combined application of these two techniques on pain and drug leakage among neonates undergoing their first intramuscular injection.

Materials and Methods

Study design and setting

This study was a prospective randomized controlled clinical trial with a parallel group design was carried out between November 25th 2024 to January 24th 2025 at a Feminine and Children Educational Hospital in Al-Muthanna Governorate. The study encompassed health neonates undergoing intramuscular injection between November 2024 and January 2025.

Sample selection

The current study comprised a sample of neonates who were chosen using a simple random sampling technique. The research involved a total of 80 term infants. participants who met the inclusion criteria were aged 1 hour or older and had received an Intramuscular injection. The study excluded preterm neonates and those with low Apgar score or suffering from illness or disease, and whose caregivers declined to participate in the current research.

Ethical Considerations

The Baghdad University Nursing College Local Research Ethics Committee approved the study protocol and granted ethical clearance with the number (Approval number: 2024/37) in 2024-11-6. The study also received the endorsement of the Al-Muthanna Health Directorate. All study participants primary sibling or caregivers have provided informed consent, indicating their agreement to participate, and ensuring the protection of their human rights.

Data collection tool and technique

1. Sociodemographic characteristics:

The provided data was collected from each patient by a questionnaire, including details such as age, gender, gestational age and birth weight.

2. Neonatal/infant pain scale (NIPS)

A scale developed specifically for newborn infants. Consists of 6 criteria (Face Expression, cry, Patterns of Breathing, leg and arm movements, Arousal status) Recommended for children less than 1 year old. Only (crying) has 3 scorings (0-1- 2) and all the other categories have 2 scorings (0-1) . A score of zero represents no pain, (1-2) is considered mild pain, (3-4) is moderate pain, and (5-7) is severe pain. Lawrence et al. (Lawrence et al., 1993) developed NIPS and the validity and reliability test were conducted by Akdovan and Yıldırım(Kanbur et al., 2021) in their Turkish study. The values of Cronbach test in the original study ranged from 0.87 to 0.95(Lawrence et al., 1993), it was reported that in the Turkish study to obtain the validity and reliability for the NIPS scale resulted as ranging from 0.83 to 0.86 using the Cronbach Alpha coefficient test.

Procedures

In the postnatal ward where the study was conducted, routine care (cleaning, drying, navel care) is carried out under a radiant heater. Vitamin K is administered during the first few hours of life when the child is feeding or before feeding. The newborn stays in the postnatal ward until they are delivered to their mother / primary caregiver (father, grandfather). In this study, the newborn pain was

evaluated by NIPS and Pain was evaluated at one timepoint during the injection procedure. In the study, neonates who received ALT during the IM injection were included in the experimental group while those who received IM injection with the routine method were included in the control group. All interventions to the newborns in the control group were performed under a radiant heater. All newborns should receive vitamin K prophylaxis, as it has been proven that oral and intramuscular prophylactic vitamin K given after birth are effective for preventing classical the hemorrhagic disease of the newborn (HDN) ((Jullien et al., 2021)). Vitamin K deficiency in an infant can cause bleeding known as HDN or vitamin K deficiency bleeding (VKDB) (Clarke et al., 2015)). When the IM route is chosen with standard precautions in the anterolateral thigh, the risk of local hematoma, infection, and neuromuscular damage at the injection site is very low (Jullien et al., 2021).

The intervention group: During the administration of the injection, the neonate in supine position, the position of his/her legs was normally flexed, and the Airlock technique was adopted when administer the injection. During injection, the skin was pulled laterally, and, thereby, the cutaneous and subcutaneous tissues were moved by approximately 1 to 2 cm. The researcher who injected the drug used the nondominant hand to displace the cutaneous and subcutaneous tissues. A co-observer recorded the pain score after withdrawal of the needle on the neonatal clinical data form.

The control group: During the administration of the injection, the neonate in supine position, the position of his/her legs was normally flexed and the injection was administered using the
routine method. During the routine injection technique practice, the skin was not pulled laterally. A co- observer (nurse) recorded the pain score on the neonatal clinical data form.

Statistical analysis

The data was analyzed using IBM SPSS for Windows, Version 27.0. Categorical data presentation entailed the use of numbers and frequencies. We represented continuous parameters using the mean and standard deviation. A chi-squared test was used to find out the association between sociodemographic characteristics

and pain level. A statistical significance was accepted as significant when the *P*-value was less than 0.05.

Results

Table 1 shows that more than half (55.5%) of neonates in the study group, and half (50%) in control group had 38 weeks of gestational age. It was also found that more than half (60%) of the study group were males and slightly more than half (52.5%) of control group were females. The table shows that the mean birth weight in the study group was (2947.5 ± 288.7) and in the control group was (2875.7 ± 255.7). however, there was no statistically significant differences between the study and control groups regarding gestational age, sex, and birth weight indicating similarity between groups .

Table 2 There were 11 neonates (27.5%) had no pain in experimental group. Twenty-one neonates (52.5%) who had moderate pain when Z- track technique was applied, and the remaining eight (20%) suffered severe pain. Contrary to the findings in the experimental group, 23 (57.5%) had severe pain in the control group, and the result was statistically significant. This clarifies that neonates who underwent ZTT during their IM injection suffered less pain than those with the routine technique.

Table 4 reveals the correlation between mean pain score and demographic variables. There was no significant association between pain score and demographic variables in the experimental group. However, a significant but weak and negative correlation was noted between pain scores and the gestational age of the newborns (r = -0.365, p value= 0.021). Although there was no statistically significant correlation observed between birth weight within both the experimental group and the control group and their mean scores on the Neonatal Infant Pain Scale (NIPS).

Table 5 Illustrates that mean Pain scores were higher among female neonates when compared to male in the study and control group however this difference was not of statistical significance.

Discussion

Pain management is a primary responsibility of nurses working in neonatal wards. Various non-pharmacological interventions have demonstrated efficacy in preventing and relieving pain in infants undergoing painful procedures. It is important that these methods are effective, low-risk and cost-effective. pain response in infants is affected by factors such as gestational week, sex, weight ((Pekyiğit & Açıkgöz, 2023)). In this study no statistically significant difference was found between the study groups in term of those factors and hence the groups were similar ($p>0.05$). From the researcher perspective, factors such as gestational age, sex, weight affect infants' response to pain so that; the researchers focused on the homogenous distribution of these characteristics which thought to affect IM pain levels and thus contributing to eliminating these confusions. this finding is in line with the study conducted by Elshahat M. and colleagues(Mohamed Elshahat et al., 2023) (2023) who conducted a study the effect of cold and heat on pain of pentavalent vaccination and reported that no statistically significant difference is noted between the study and control groups with regards to the sex, birth weight, nutrition status and gestational age.

In the current study the level of pain in the experimental group was significantly lower than the control group, this finding is similar to a study conducted by Subedi R. and colleagues(Subedi et al., 2024) (2024) on the effect of facilitating tucking on reducing pain and using the same outcome measurement as our research and the study found that neonates in the experimental group had lower Neonatal Infant Pain Scale scores than the ones in the control group. Another study conducted by Saji J. et al. (2024) on adult patients provided evidence on the difference between the pain levels of using ZTT and the standard method which clarified that majority of study group had moderate levels of pain in experimental group while the control group sample had moderate to severe pain levels.

Regarding the mean score of pain, applying the airlock technique during IM injection resulted in significantly lower mean pain score than neonates who had vitamin K injection using the

routine method. This goes with a study by (Elsaid R, & Abdelkhalek W. 2019)(Elsaid & Abdelkhalek, 2019) It revealed that the pain score was lower when IM injections were administered using Z-track technique rather than standard method. A study by (Kara D, 2014)(Kara & Yapucu Güneş, 2016) agreed with our results which found that less pain is noted with the Z- track technique use during IM injection. Moreover, another study conducted in Turkey by (Yilmaz DK, 2016)(Yilmaz et al., 2016) stated that intensity of pain was reduced when IM sodium diclofenac injected using Z-track technique. Our results are supported by (Tambunan EH, 2015)(Tambunan & Wulandari, 2015) who illustrated that both Z-track and air lock method resulted in less pain compared to standard method.

Table 4 illustrates the association between demographic variables and mean pain score. The table shows no statistical correlation between the gestational age of neonates and their pain score in the experimental group, however, this correlation is a negative and significant in the control group indicating that pain increase in neonates born early or before term. From the researcher's point of view, this can be as result of preterm infant are more sensitive to stimuli when compared to term or near term infants.

There was no statistically significant correlation observed between birth weight with the experimental and the control groups and their mean scores on the Neonatal Infant Pain Scale (NIPS). In accordance (**Das et al., 2020)**(Das et al., 2020) reported that there was no statistically significant association between birth weight and pain score. In contrast with our results (**Gol & Ozsoy, 2017)**(Göl & Altuğ Özsoy, 2017) illustrated that pain score of neonates decreased as their weight increased and concluded that birth weight affected pain score.

Regarding sex of the neonates in study and control groups, the study reveals that mean score of female neonates in both experimental and control groups were higher than males, however this difference is not of a statistical significance. From the

researcher perspective, these findings can result from recent studies that show females demonstrated great sensitivity to pain when compared to males' neonates. Our results are in line with those finding by (**Sapçi et al., 2021)**(Sapçi et al., 2021) that underwent a study regarding the effects of applying external cold and vibration to children on pain and concluded that no statistically significant difference was noted between the sex and the mean pain score of infants in both study and control group.

Conclusion

The study has concluded that using the Airlock technique as a non-pharmacological pain reduction strategy during IM injection for neonates helps alleviate pain level and hence providing optimum care during the first few hours of life

Recommendations

The study has recommended that greater emphasis be placed on discovering alternate non pharmacological methods to improve pain levels when the conventional method is used. Future research should conduct large-scale studies involving both preterm and term infants to distinguish the impact of Airlock technique between the two populations. These studies should utilize longitudinal or experimental research methods to allow for the analysis of causal factors.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Table 1: Distribution of Sample According to Sociodemographic Characteristics

Demographic Variables	**Categories**	**Airlock technique (n=40)**	**Control group (n=40)**	**Statistical test**	
		n (%)	n (%)	Test	P value
Gestational week	37 weeks	1(2.5%)	7(17.5%)	X^2= 5.7	.124

	38 weeks	22(55.0%)	20(50.0%)		
	39 weeks	14(35.0%)	12(30.0%)		
	40 weeks	3(7.5%)	1(2.5%)		
Sex	Male	24(60.0%)	19(47.5%)	X^2= 1.257	.185
	Female	16(40.0%)	21(52.5%)		
Weight	Mean (SD)	2947.5 (288.7)	2875.7 (255.7)	T= 1.176	.243

n: Frequency, %= Percentage, x^2: chi-square

Table 2: Association of injection technique with the pain level of the neonates

Pain level	ALT (experimental group) (n=40)	Control group (n=40)	Total (n=80)
	N (%)	**N (%)**	**N (%)**
No pain (NIPS score 0–2)	11(27.5)	2(5.0)	13(16.3)
Moderate pain (NIPS score 3–4)	21(52.5)	15(37.5)	36(45.0)
Severe pain (NIPS score > 4)	8(20.0)	23(57.5)	31(38.8)

N: Frequency, %: Percentage, M.S: Mean of total scores, SD: Standard Deviation for total score.

Table 4: Correlation between the demographics variables of the newborns based on neonatal / infant pain scale mean score

Demographics variables		NIPS score	
		Airlock group	Control group
Gestational age (weeks)	Pearson correlation	-.037	**-.365**
	P value	.822	.021*
	N	40	40
Weight in grams	Pearson correlation	-.308	.133
	P value	.054	.412
	N	40	40

Table 5: Effect of sex on mean NIPS score among newborns

Groups	Sex	N	Mean	SD	MW	P value
Airlock group	Male	24	2.96	1.083	125.500	.059
	Female	16	3.75	1.390		
Control group	Male	19	4.32	1.003	143.000	.105
	Female	21	4.71	1.146		

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