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Original Research Article

Estimation of Anterolateral Thigh Muscle Thickness by High Frequency Sonography in Newborns to Ensure Safe Intramuscular Injections

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Abstract:
Introduction: Use of same length needle for intramuscularly administered vaccines can cause under and over penetration among newborns due to varying body weights and fat/muscle thickness. The injection technique and needle size both determine how deep a substance is injected. Injection technique involves stretching the skin flat before inserting the needle or pinching a fold of skin before injection, which may necessitate the use of longer needles.
Objectives: 1. To measure the depth of subcutaneous tissue layer (STMD) and skin to bone distance (STBD) and muscle thickness (STBD-STMD) over the anterolateral thigh of newborns using high-frequency sonography and suggest appropriate needle length for safe intramuscular injections. 2. To estimate the risk of over penetration and under penetration with standard size needle being used in newborn vaccinations and intramuscular injections.
Methodology: A cross-sectional analytical study was done among 150 newborns in four different weight bands of <7 days of life using convenient sampling at a tertiary teaching institute People's College of Medical Sciences and Research Centre Bhopal Madhya Pradesh in central part of India. Those newborns who were sick and admitted to the NICU, had limb anomalies, or whose parents did not provide consent were excluded from the study.
Results: Mean STBD was 14.69 mm, mean STMD was 4.01mm, and mean muscle thickness was 10.71mm. Significant correlations found between weight, STBD, STMD, and muscle thickness. Under penetration and over-penetration risk with 16mm and 25mm needles varied by weight band. Based on needle penetration, with results showing that none of the subjects (0%) experienced under-penetration. However, a significant proportion of subjects experienced over-penetration, with 107 subjects (71.33%) experiencing over-penetration using a 16mm needle and all 150 subjects (100%) experiencing over-penetration using a 25mm needle at a 90-degree angle to the skin surface.
Conclusion: Customized needle length based on newborn weight is necessary to ensure safe intramuscular injections. This study provides estimates of thigh muscle thickness to inform appropriate needle size selection. Further large-scale studies are needed to inform future recommendations.
Keywords: Intramuscular injections, Immunizations, STMD, STBD, Muscle thickness, LMIC.

Introduction

Use of same length needle for intramuscularly administered vaccines had been reported to cause under and over penetration among newborns due to their different body weights and underlying variations in the fat and muscle thickness. [1] Data regarding thigh compartment thickness are, however, lacking among newborn particularly in low- and middle-incoming countries. In low and middle – income countries (LMIC) like India injectable vaccines are administered intramuscularly in anterolateral part of thigh. However local reaction to these vaccine are common ranging from 6 to 50%. [2,3] The recommended use of 23-gauge, 25mm long needles for anterolateral thigh intramuscular injections is based on limited studies, including one by Hick JF et al, [8] which suggested that a 16mm needle may not consistently penetrate the muscle. However, other studies and the World Health Organization support the use of 16mm needles for intramuscular injections. [9] A study by Diggle L et al found that using 25mm needles reduced local reaction rates to infant immunizations, preventing one reaction for every five infants vaccinated. [3] The choice of needle length and gauge (diameter) is crucial to ensure proper vaccine delivery, maximize immune response, and minimize harm. A higher gauge number indicates a smaller diameter, with 25G being narrower than 23G. [5] Studies regarding appropriate needle length in newborn from LMIC countries are lacking. The injection technique and needle size both determine how deep a substance is injected. Injection technique involves stretching the skin flat before inserting the needle or pinching a fold of skin before injection, which may necessitate the use of longer needles. To make sure the needle reaches the muscle and that vaccine does not seep into subcutaneous tissue the decision on the size of the needle and injection site should be made individually for each person. It should also be based on the person's age, weight, the volume of material to be administered, and the size of the muscle. [6] Adequate penetration of the muscle for IM injections is defined as penetration of 5 mm or more into the muscle. Under-penetration will lead to subcutaneous injection. Injecting a vaccine into the layer of subcutaneous fat will result in slow mobilization and processing of the antigen, causing vaccine failure due to poor vascularity. [7] From the above mentioned details and as not much studies have been conducted in past to evaluate the depth of muscle layer in anterolateral aspect of thigh, thus, due to lack of such data and there is no consensus regarding appropriate needle length for intra muscular injections in newborns, hence, this study is planned for measuring depth of the subcutaneous tissue layer and depth of the muscular layer over the anterolateral thigh of newborn using high frequency sonography for safe intramuscular injections. The estimated thigh muscle thickness can be used to suggest appropriate needle size to ensure safe intramuscular injections in newborns.

Objectives:

1. To measure the depth of subcutaneous tissue layer and skin to bone distance and muscle thickness over the anterolateral thigh of newborns using high-frequency sonography and suggest appropriate needle length for safe intramuscular injections.
2. To estimate the risk of over penetration and under penetration with standard size needle being used in newborn vaccinations and intramuscular injections.

Materials and Methods:

The present cross-sectional analytical study was conducted among 150 newborns less than 7 days old using convenient sampling at the Department of Pediatrics, People's College of Medical Sciences and Research Centre in Bhopal, India. The study collected data on newborn weight, skin-to-muscle distance, skin-to-bone distance, and muscle thickness. Newborns were included if they were less than 7 days old and admitted to the post-natal care ward, while those who were sick and admitted to the NICU, had limb anomalies, or whose parents did not provide consent were excluded. The study utilized a Voluson S-8 color Doppler ultrasound machine with a high-frequency linear probe (7.5-12 MHz) to measure the thickness of the anterolateral thigh muscle in newborns. The study was conducted in the post-natal care ward of People's College of Medical Sciences and Research Centre, Bhopal, after obtaining ethical clearance and informed consent from parents. 150 newborns, within 7 days of birth and categorized into four weight bands, were enrolled. This study included 150 newborns delivered within 7 days in 4 different weight bands (2-2.5 kg, 2.5-3kg, 3.01-3.5kg ,>3.5kg) from postnatal ward in Peoples hospital who fulfilled criteria were enrolled with parents' consent. Neonates born to normal vaginal delivery and to caesarean section are usually kept for 3-5 days in maternity ward due to maternal indication. Out of these, babies without surgical or medical indications were included in the study. Their details regarding demographic information and anthropometric measurements were recorded using preformed proforma. The newborns were taken to Radiodiagnosis department for ultrasonography of thigh. On anterolateral aspect of left thigh at the junction of upper 1/3 and lower 2/3 of thigh the transducer of high frequency ultrasound machine was applied lightly so as to ensure the tissue under the transducer are not compressed. The distance from the skin to bone and skin to starting of muscle layer was noted and the thickness of muscle layer was calculated. A modern USG machine with high frequency probe 7.5-12 MHTz was used for study. The collected data was analyzed using standard geometric formulas to estimate the appropriate needle length for intramuscular injections. The analysis aimed to determine the maximum perpendicular length of needle penetration, considering the depth of penetration equal to the needle length when injected at a 90-degree angle. The proportion of correctly placed injections in the intramuscular layer was calculated using 25mm and 16mm needle lengths. A safe needle length was defined as one that exceeds the subcutaneous layer thickness (STMD) but is less than the skin-to-bone thickness (STBD). Conversely, over-penetration occurred when the needle length equaled or exceeded STBD, and under-penetration occurred when the needle length was less than or equal to STMD. Statistical analysis was performed using IBM, SPSS Statistics version 28 (IBM Inc.). Chi-square test was applied to find statistical significance with p value less than 0.05. Independent t tests were performed to ensure group similarities at baseline. A one- way analysis of variance (ANOVA) was conducted to determine whether there were significant differences in mean test values.

Observation and Results:

Table 1 shows distribution of study subjects according to age results revealed that the study included 150 subjects distributed across different age days. The highest frequency of participants was on the 3rd day (37 subjects, 24.7%), followed by the 4th day (30 subjects, 20.0%). The least number of subjects was on the 1st day (4 subjects, 2.7%). Table 2 shows descriptive statistics of clinical parameters overall among study subjects results found that the following statistics: Skin to bone distance (STBD) ranged from 8.9 to 20.9 with a mean of 14.69 and an SD of 2.30; Skin to muscle distance (STMD) ranged from 1.8 to 6.9 with a mean of 4.01 and an SD of 1.03; the difference between STBD and STMD (muscle thickness)rangedfrom6.2to17.3with a mean of 10.71 and an SD of 1.90.Table 3A shows distribution of study subjects as per weight and STMD for under penetration results revealed that none the subject in all 4 weight bands have STMD>16 mm. Therefore none have chance of under penetration with needle 16mm/25mm.

Table 3B shows distribution of study subjects as per weight and STMD for over penetration results revealed that in weight band 2-2.5kg 39 out of 43 subjects have STBD<16mm therefore 90.7% subjects have changes of over penetration with 16mm needle at 90 degree and 43 out of 43 have STBD<25mm. Therefore 100% have chances of over penetration with 25mm at 90 degree. In weight band 2.51-3kg 55 out of 70 subjects have STBD<16mm therefore 78.6% subjects have changes of over penetration with needle 16 mm needle at 90 degree and 70 out of 70 have STBD<25mm.

Therefore 100% subjects have chances of over penetration with 25mm at 90 degree. In weight band 3.0-3.5 kg 9 out of 29 subjects have STBD<16mm therefore 31% subjects have changes of over penetration with needle 16mm needle at 90 degree and 29 out of 29 have STBD<25mm.

Therefore 100% subjects have chances of over penetration with 25mm at 90 degree. In weight band >3.5 kg none out of 8 subjects have STBD<16mm therefore 0% subjects have changes of over penetration with needle 16mm needle at 90 degree but all 8 out of 8 have STBD<25mm. Therefore 100% subjects have chances of over penetration with 25 mm at 90 degree.

Table1: Distribution of study subjects according to age

Age (days)	Frequency	Percent
1	4	2.7
2	22	14.7
3	37	24.7
4	30	20.0
5	15	10.0
6	22	14.7
7	20	13.3
Total	150	100.0

Table 2: Descriptive statistics of clinical parameters overall among study subjects

Clinical parameters	Minimum	Maximum	Mean	Std. Deviation
STBD (Skin to bone distance)	8.9	20.9	14.69	2.30
STMD (Skin to muscle distance)/(subcutaneous layer)	1.8	6.9	4.01	1.03
STBD-STMD (Muscle thickness)	6.2	17.3	10.71	1.90

Table 3A: Distribution of study subjects according to needle penetration based on STMD

Weight category (Kg)		STMD>16mm		STMD>25mm	
	Total	Frequency	Percent	Frequency	Percent
2-2.5	43	0	0	0	0
2.51-3	70	0	0	0	0
3.01-3.5	29	0	0	0	0
>3.5	8	0	0	0	0

Table 3B: Distribution of study subjects according to needle penetration based on STBD

Weight category (Kg)		STBD<16mm		STBD<25mm	
	Total	Frequency		Frequency	Percent
2-2.5	43	39	90.7	43	100.00
2.51-3	70	55	78.6	70	100.00
3.01-3.5	29	9	31.0	29	100.00
>3.5	8	0	0.0	8	100.0

Table 4: Correlation between various variables among study subjects

		Age days	Weight	Gest age	STBD	STMD	STBD-STMD
Age days	r value	1	-.070	.097	-.199*	-.010	-.236**
	p value		.391	.239	.014	.906	.004
Weight	r value	-.070	1	.204*	.606**	.566**	.410**
	p value	.391		.012	.000	.000	.000
Gest age	r value	.097	.204*	1	.204*	.200*	.161*
	p value	.239	.012		.012	.014	.048
STBD	r value	-.199*	.606**	.204*	1	.562**	.869**
	p value	.014	.000	.012		.000	.000
STMD	r value	-.010	.566**	.200*	.562**	1	.149
	p value	.906	.000	.014	.000		.069
STBD-STMD	r value	-.236**	.410**	.161*	.869**	.149	1
	p value	.004	.000	.048	.000	.069	

Table 4 shows correlation between various variables among study subjects results found that significant correlations between various clinical parameters. Age in days negatively correlated with STBD (r = -0.199, p = 0.014) and muscle thickness (r = - 0.236, p = 0.004). Weight had significant positive correlations with gestation age, STBD, STMD, and muscle thickness ($p < 0.05$).

Table 5: Distribution of study subjects according to needle penetration based on STMD and STBD

Needle penetration	Frequency	Percent
Under penetration	0	0.00
Over penetration	107	71.33

Table 5 shows distribution of study subjects according to needle penetration based on STMD and STBD results revealed that none of the subject (0%) undergone under penetration while 107 subjects (71.33%) experienced over penetration using 16mm needle and all 150 subjects experienced over penetration using 25mm needle at 90 degree to skin surface.

Discussion:

Analysis of clinical parameters overall in our 150 study subjects found that skin to bone distance (STBD) ranged from 8.9 to 20.9 with a mean of 14.69 and mean and SD of 2.30; skin to muscle distance (STMD) ranged from 1.8 to 6.9 with a mean of 4.01 and an SD of 1.03; the difference between STBD and STMD (muscle thickness) ranged from 6.2 to 17.3 with a mean of 10.71 and an SD of 1.90. Lo YS et al. conducted a comparable study to quantify muscle thickness and determine the optimal site for intramuscular vaccine injections in neonates. They utilized ultrasonography to measure the muscle and subcutaneous fat thickness of the anterolateral mid-thigh in 50 full-term infants (group 1) and thirty low birth weight infants (group 2). No substantial difference existed among male and female newborns in either of the groups. The thickness of muscle and subcutaneous fat in the thigh region was measured at 11.8 ± 1.9 mm and 3.8 ± 0.4 mm, respectively, in group 1; and 8.6 ± 1.7 mm and 2.7 ± 0.5 mm in group 2. A notable logarithmic association existed between muscle thickness and body weight in the thigh (r = 0.6, 0.8, 0.6).

The distribution of study subjects as per wt in 4 different weight bands 2-2.5 kg, 2.51- 3 kg., 3.01 - 3.5 kg, 3.5 kg > and Skin to muscle distance for under penetration results revealed that none of the subject in all 4weight bands have STMD>16 mm. Therefore, none have chance of under penetration with needle 16mm/25mm because the range of subcutaneous fat thickness in the highest quartile of study subjects was between 3.2 to 5.6. This range allows for the suggested penetration cut off of at least 5 mm into the muscle using a 16 mm needle. [28] The results of our study contradict the study exclusively use longer length needles (25 mm) in newborns based solely on their chronological age. [9] It is also important to consider their present body weight.

UK Australian guidelines clearly recommend use of 16mm length needle for premature or very small weight infants. Further, The distribution of study subjects as per wt in 4 different weight bands 2-2.5kg, 2.51-3kg., 3.01-3.5kg, 3.5kg > and Skin to bone distance (STBD) for over penetration results revealed that in weight band 2-2.5 kg 39 out of 43 subjects have STBD <16mm therefore 90.7% subjects have chances of over penetration with needle 16mm needle at 90 degree and 43 out of 43 have STBD <25mm. Therefore 100% have chances of over penetration with 25 mm at 90 degree. In weight band 2.51-3kg, 55 out of 70 subjects have STBD <16mm therefore 78.6% subjects have changes of over penetration with needle 16mm needle at 90 degree and 70 out of 70 have STBD <25mm. Therefore 100% subjects have chances of over penetration with 25mm at 90 degree. In weight band 3.0-3.5 kg 9 out of 29 subjects have STBD <16mm therefore 31% subjects have changes of over penetration with needle 16mm needle at 90 degree and 29 out of 29 have STBD <25mm. Therefore 100% subjects have chances of over penetration with 25mm at 90 degree.

In weight band >3.5 kg none out of 8 subjects have STBD <16mm therefore 0% subjects have changes of over penetration with needle16mm needle at 90 degree but all 8 out of 8 have STBD <25mm. Therefore 100% subjects have chances of over penetration with 25 mm at 90 degree. While AAP, UK, and Australian recommendations notably advocate for the use of a 16 mm needle for premature or very young newborns, when using a 16 mm needle length in low birth weight babies. Our study found probability of unsafe injection using16 mm length needle at 90 degree is 68.6%. 90% unsafe in 2-2.5 kg , 78.6% unsafe in 2.5-3 kg 21% in 3-3.5 kg babies, 100% safe for >3.5kg. Whereas 25mm needle is unsafe for all four weight bands. Our results are in concordance with another study conducted by Bhowmick R et al [1], revealed a 60.44% probability of unsafe injection with 16 mm needle among low weight Indian infants.

Even if a needle with a suggested length of 16mm is injected all the way to the hub, it may not decrease the risk of over-penetration in this specific group of people. However, vaccinators usually utilize their clinical expertise to estimate the muscle thickness by leaving a portion of the needle outside the skin, so minimizing the risk of excessive penetration. However, if the vaccine is not put into the correct location, it may decrease its ability to stimulate an immune response. Ajana F et al [9] also recommended that the optimal needle length should be adjusted based on morphological factors such as the thickness of subcutaneous tissue and muscle for the immunogenicity and safety of intramuscular immunization.

Hence, the necessity to consider customization of needle length or needle penetration depth based on body weight in low- and middle-income countries (LMICs) such as India should be given more consideration. Further there was no risk of under-penetration in our study group because the subcutaneous fat thickness ranged from1.8-6.9, with a mean of 4.01and a standard deviation of 103. The results of our investigation align with the findings of Bhowmick R et al1, who discovered a range of subcutaneous fat thickness between 6.68+/-.0.74 in <3kg This range allows for the suggested penetration depth of at least 5 mm into the muscle using a 16 mm needle. We conducted a comparative analysis of our mean muscle thickness 10.71 mm with SD1.9 and mean subcutaneous fat thickness 4.01with SD 1.03mm and mean skin to bone distance 14.69 mm with SD 2.3mmin relation to existing research. A study conducted by Kanazawa H et al [10] on healthy preterm Japanese babies found that the mean muscle thickness at delivery was 12.94 (SD2.04) mm, whereas the mean subcutaneous thickness was 4.84 (SD1.26) mm which is close to our study. Another study conducted by Heckmatt JZ et al [11] in the United Kingdom found that the average muscle thickness of the quadriceps thigh muscle in infants aged 0-1 year was 16.4 (with a standard deviation of 2.8), as measured using ultrasound imaging. The current approach of using a single strategy for intramuscular injections in infants, without considering the variations in muscle and fat thickness among babies, lacks sufficient proof. Therefore, it is crucial to study to ensure safe intramuscular injections. Assessing the correlation between various variables among study subjects, age in days negatively correlated with STBD (r = -0.199, p = 0.014) and muscle thickness (r = - 0.236, p = 0.004). Weight had significant positive correlations with gestation age, STBD, STMD, and muscle thickness ($p < 0.05$). Our findings aligns with Lo YS et al [8], which identified a strong logarithmic association between muscle thickness and body weight (r = 0.6, 0.8, 0.6) as well as muscle thickness (r = 0.4, 0.6, 0.6) in the thigh.

The distribution of our study subjects according to needle penetration based on STMD and STBD results revealed that none of the subject (0%) undergone under penetration while 103 subjects (68.6%) experienced over penetration using 16 mm length needle at 90 degree. All 150 (100%) subjects experienced over penetration with 25 mm length needle at 90 degree. Lippert WC et al [12] proposed revising the parameters for needle length in thigh in order to reduce the danger of excessive needle penetration, taking into account the observed diversity in fat thickness. The US Centers for Disease Control and Prevention provides guidelines on the appropriate needle length for intramuscular vaccines in the thigh taking into account the child's age. While there is evidence of insufficient penetration of the intramuscular layer using short needles, there is a lack of research on the potential for excessive penetration using needles that are too long. The objective of this study was to ascertain the most effective needle length for intramuscular vaccination in children of different ages and sizes in the thigh areas, utilizing measurements obtained from MRI and computed tomography scans. 250 MRI and computed CT scans of thighs were examined at a prominent children's hospital. Measurements were taken to determine the thicknesses of the subcutaneous fat tissue and muscle layers. Age and weight were used as variables to correlate with the measurements, and a regression analysis was conducted. Using the Centers for Disease Control and Prevention recommended 1- and 1 ¼-inch needles for injecting vaccines into the thigh muscles of children who are 1 year or older would lead to 11% (11 out of 100) and 39% (34 out of 88) cases of the needle going too deep, respectively. There is a very low chance of the needle not going deep enough, with only 2% (2 out of 100) cases of under penetration.

The current Centers for Disease Control and Prevention recommendations for immunization needle lengths pose a significant danger of penetrating too far into the intramuscular layer. The size of the syringe used should be determined by selecting the smallest possible to accommodate the given volume. Volumes of less than 0.5 ml should be given with low dose 1ml syringes to ensure accuracy. [13] An administration rate of no faster than 1 ml per 10 seconds to facilitate absorption and minimize pain is recommended. [14-15] To avert glass contamination Hahn (1990) [16], McConnell (1993)17, and Preston and Hegadoren (2004) [18] advocate for the utilization of a filter needle while extracting medication from a vial or ampoule to avert the injection of glass shards or rubber particles into the youngster and to mitigate potential damage. If a filter needle is unavailable, nurses are instructed to draw up the medication using a 23-gauge needle [19-20] and thereafter replace it with the proper needle for injectable administration. For all intramuscular injections, the needle must be sufficiently long to access the muscle mass and prevent drug from infiltrating subcutaneous tissue, yet not excessively lengthy to engage underlying nerves, blood vessels, or bone. [21,22]

The needle length is denoted either empirically, for instance, 25 Gauge (1 inch) 0.6 mm by 25 mm length. The RCPCH (2002) advises a minimum needle length of 16mm (5/8 inch) for all intramuscular injections, however the DH (2005) asserts that a 25mm (1 inch) needle is appropriate for all ages, except for pre-term or extremely young newborns, for whom a 16mm needle is recommended. The suitable needle length is contingent upon the child's age and body mass, as it is impractical to use the same gauge and length needle for a two-year-old toddler as one would for a ten-year-old child. Various patients require distinct needle diameters. [22] The utilization of longer needles has been correlated with less redness or swelling compared to shorter needles due to injection into deeper muscle tissue (Ipp et al, 1989). [23] This conclusion is corroborated by the research conducted by Diggle et al. (2006) [24], who administered vaccinations to 696 healthy infants with a 23 gauge, 25 mm needle; a 25 gauge, 16 mm needle; or a 25 gauge, 25 mm needle at two, three, and four months of age, targeting the vastus lateralis site in accordance with WHO intramuscular injection guidelines. The utilization of a long, wide needle elicited a comparable immune response and reduced local responses compared to a narrow, short needle during baby vaccination. [24]

Therefore, from the a fore mentioned details, there is availability of data regarding immune responses, regarding under penetration and over penetration of needle length in infants within 7 days of life. Nonetheless in our study vaccinators used their clinical judgement to assess the approximate muscle thickness by keeping some part of needle outside above the skin and hence reduces chances of over penetration. Our study stresses the necessity to consider customization of needle length or needle penetration depth based on body weight in low- and middle-income countries (LMICs) such as India.

Limitation of study:

The present study is limited by cross-sectional assessment in a single tertiary care hospital yet our study sample included different weight groups of <7 days. Further, there is a scarcity of data regarding the estimation of anterolateral thigh muscle thickness in newborn less than 7 days of life for safe intra muscular injection by use of high frequency ultrasound.

Conclusion:

In conclusion, this study successfully estimated the anterolateral thigh muscle thickness in newborns using high-frequency sonography, providing valuable insights for safe intramuscular injections. The findings indicated that muscle thickness increases with weight and gestation age. Newborns weighing less than 3.5 kg are at risk of over-penetration with standard 16 mm and 25 mm needles. None of the newborns had under-penetration risk with the studied needle lengths. Clinical parameters like STBD, skin-to-muscle distance /subcutaneous layer (ST MD), and muscle thickness vary significantly across weight categories. Age and gestation age have a significant impact on clinical parameters, with muscle thickness increasing with gestation age. No significant gender differences were found in clinical parameters. These results have important implications for healthcare professionals, highlighting the need for careful consideration of newborn weight and gestation age when administering intramuscular injections to ensure safe and effective vaccination practices.

Ethical approval: The study was approved by the institutional ethical committee.

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