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Original Article

Influence of skin-to-muscle and muscle-to-bone thickness on depth of needle penetration in adults at the deltoid intramuscular injection site

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ARTICLE INFO

Article history:

Received 24 April 2014

Accepted 5 August 2014

Available online 16 October 2014

Keywords:

Deltoid muscle

Injections

Intramuscular

Needles

Subcutaneous fat

ABSTRACT

Background: The objectives of the study were to estimate the following in adults of Indian origin: a) Gender and side differences in the skin-to-muscle (SM) and muscle-to-bone thickness (MB) at the deltoid intramuscular injection site; b) Correlation of SM thickness with the BMI, age and gender; c) The prevalence of under and over-penetration assuming a standard needle length of 25 mm and following prescribed guidelines for IM injection.

Methods: The SM, MB and skin-to-bone (SB) thicknesses were bilaterally estimated in two hundred adult Indian subjects (100 male and 100 female) using an ultrasound probe at a pre-determined point on the upper arms of the subjects. The BMI of each subject was calculated. The unpaired sample 't' test and paired 't' test were used to analyse differences between groups. Pearson's correlation coefficient was used in correlation analysis and suitable linear regression equations were generated.

Results: Females had a significantly higher SM thickness and lower MB thickness. The SM thickness was significantly greater on the left side, while the SB and MB thickness were significantly greater on the right. Multiple linear regression equations for both the dominant and non-dominant arms had good model fit properties. Under-penetration would have occurred in 2 (1%) subjects while over-penetration would have occurred in 50% of the subjects.

Conclusion: Over-penetration of deltoid IM injections is likely to be more prevalent as compared to under-penetration. Therefore, the technique of IM injection needs to be modified based on the body type of the individual patient.

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<http://dx.doi.org/10.1016/j.mjafi.2014.08.005>

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Introduction

Intramuscular (IM) injections are commonly used to deliver vaccines and drugs in all age groups. The common sites of IM injections are the deltoid, vastus lateralis, ventro-gluteal and dorso-gluteal muscles. Most vaccines should be given via the IM route into the deltoid or vastus lateralis as this optimizes the immunogenicity of the vaccine and minimizes adverse reactions at the injection site.¹

Adequate penetration of the muscle for IM injections is defined as penetration of 5 mm or more into the muscle.² 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.¹ Local reactions and complications such as irritation, inflammation, granuloma formation and necrosis are also more common with subcutaneous than IM injections.^{1–4} However, patients who are emaciated require shorter needles for IM injection. Potential risk of over-penetration include pain and damage to the bone or periosteum and detachment of the needle from the syringe.^{5,6}

A study conducted in the USA used ultrasound to determine the deltoid fat pad thickness in adult males and females.² It was found that women had a significantly thicker deltoid fat pad than men. A standard 16 mm needle would not have reached 5 mm into the muscle in 17% of the men and 48.4% of the women.² Similar studies have shown that problems with under-penetration are even more pronounced at the gluteal IM injection sites.^{7,8} In a study done in South Korea it was found that boys over 14 years of age had statistically significantly thinner subcutaneous tissue at all injection sites than that of age matched girls. It was also found that body mass index (BMI) was statistically significantly correlated with subcutaneous tissue thickness at all sites.⁹ An ultrasound study in elderly patients in Australia showed that BMI was strongly correlated with deltoid subcutaneous layer thickness in males ($r = 0.69$ dominant arm, 0.71 non-dominant arm) and females ($r = 0.79$ both arms). Females with the same BMI as males had significantly thicker subcutaneous layers ($p = 0.0001$) and thinner muscle layers ($p = 0.0003$).¹⁰

It thus follows that a standard size of needle will not guarantee successful IM injections in all people. When IM injections are to be administered, a selection of non-fixed needles should be available to allow healthcare professionals to select a length and gauge of needle appropriate to each patient.¹ Studies on the deltoid fat pad thickness have been conducted in Caucasian and South-East Asian populations. As there are likely to be significant racial differences, it was felt that it would be worthy of study in Indian populations as well.

The objectives of the study were to estimate the following in adults of Indian origin: a) Skin-to-muscle (SM) and underlying muscle-to-bone thickness (MB) at the deltoid intramuscular injection site; b) Differences of the above measurements between the right and left upper limbs; c) Gender differences in the above measurements; d) Correlation of the SM thickness and the BMI, age and gender; e) The prevalence of under-penetration and over-penetration assuming a standard needle

length of 25 mm and according to prescribed guidelines for IM injections.

Material and methods

Ethical clearance for the study was obtained from the Institutional Ethical Review Board. Written informed consent from all subjects participating in the study was taken. The study was a cross sectional, analytical study conducted at a tertiary medical college hospital in Bangalore. The data was collected between June and November, 2011. The subjects for the study were attendants of patients who came to the radiology department for investigation and who were over the age of 18 years. Those subjects who had any scarring of the upper arm region due to previous injuries or surgeries, pregnant women and subjects suffering from any chronic illnesses such as tuberculosis, chronic renal failure, chronic liver disease, and malignancies were excluded from the study. The subjects were selected at the convenience of the investigators usually between 12:30 pm and 1:30 pm or between 4:30 pm and 5:30 pm.

The sampling was purposeful to try and include subjects of varying BMIs and age groups. The dependent variable that was considered was the SM thickness, while the independent variables were the gender, BMI, arm dominance and age of the subject. The other variable that was considered was the MB thickness to assess the probability of over-penetration. The sample size was calculated for hypothesis testing to estimate the difference in means between two groups for a quantitative parameter using a sample size calculator called nMaster. A sample size of 200 for each side (right and left) was required to ensure a power of 80% and an alpha error of 5% assuming a standard deviation (SD) of 2.5 millimeters (mm) for both groups and a difference in means of 0.7 mm in the SM thickness. Therefore a total of 200 individuals, which included 100 males and 100 females were included in the study.

The dominant arm and gender of the subject were noted. The weight of the subject was recorded in kilograms in the radiology department using a single standard digital weighing machine. The height was recorded in centimeters using a wall mounted stadiometer, after which the BMI was calculated. The site for the deltoid IM injection was marked bilaterally with a skin marking pen using the method mentioned below. The tip of the acromion and lateral epicondyle of the humerus were palpated and marked with a skin marking pen. The mid-point between the above mentioned bony landmarks was marked and a vertical line was drawn between this point and the tip of the acromion. The junction of the upper one third and lower two third of this line was taken as the site for deltoid intramuscular injection (Fig. 1a).

Ultrasound measurements using a GE LOGIQ P6, 10 MHz linear probe were then made by a single co-investigator and interpreted by the same person. The arm of the subject was held in a relaxed position against the lateral thoracic wall. The ultrasound probe was held at 90° angle to the plane of the injection site, avoiding compression by the ultrasound probe (Fig. 1b). The ultrasound images were taken in the transverse plane. The SM thickness (yielding deltoid fat pad thickness) and MB thickness (yielding muscle thickness) measurements

Fig. 1 – a – Method of determining the site of deltoid IM injection; b – Ultrasound probe placed perpendicular to the skin surface at the site of deltoid IM injection; c – Screen shot of the ultrasound image. A – Tip of acromion; B – Lateral epicondyle; C – Mid-point between A and B; D – Junction of upper one third and lower two thirds between A and C; SMT – skin-to-muscle thickness; MT – muscle thickness.

were obtained in millimeters (Fig. 1c). The same process was repeated for the other arm.

The mean and standard deviation of the SM thickness and underlying MB thickness at the deltoid IM injection site were estimated. The unpaired sample 't' test and paired 't' test were used to calculate the gender and side differences respectively. Pearson's correlation coefficient was used to correlate the SM thickness with BMI, gender and age in years, following which linear regression equations were generated. Percentiles were estimated for the SM and MB thicknesses to assess the proportion of subjects in whom under or over-penetration would have occurred using a standard needle length of 25 mm. The statistical analysis was performed using SPSS version 16.

Results

A total of 10 subjects, nine females and one male were excluded from the study. Among the female subjects, one had post-burns contractures over the deltoid area, and the remaining were in various stages of pregnancy. The male subject who was excluded was diagnosed with tuberculosis. After excluding the above subjects, data was collected from

200 subjects (100 female and 100 male). All subjects stated that the right arm was their dominant one.

There were no significant differences in the baseline characteristics of males and females with respect to age and BMI (Table 1). The mean skin-to-bone (SB) thickness was nearly identical in males and females. However, the mean SM thickness was significantly greater in females, while the mean MB thickness was significantly greater in males. Similar results were noted between males and females when the SB, SM and MB thickness were estimated separately for the right and left sides. A significantly greater proportion of the SB thickness was contributed to by the SM thickness as compared to MB thickness in females (Table 1).

Across gender, the differences between the right and the left arm with respect to SB thickness, SM thickness and MB thickness were found to be statistically significant (Table 2). On the right, both the mean SB and mean MB thickness were greater, while on the left the mean SM thickness was greater (Table 2). The left side had a significantly greater proportion of the SB thickness contributed to by the SM thickness as compared to the right side (Table 2).

When side and gender differences were considered together, the side differences in the SB thickness were greater in males as compared to females (Fig. 2). The mean values are

Table 1 – Gender differences between the different variables.

Variable	Male and female (n = 200) Mean ± SD (95% CI)	Male (n = 100) Mean ± SD (95% CI)	Female (n = 100) Mean ± SD (95% CI)	p value***
Age in years	33.9 ± 12.9 (32.06–35.65)	34.8 ± 12.9 (32.27–37.39)	32.9 ± 12.8 (30.34–35.42)	0.285
BMI	24.2 ± 4.9 (23.48–24.84)	23.7 ± 4 (22.86–24.47)	24.7 ± 5.6 (23.55–25.75)	0.153 ^b
SM thickness in cm ^a	0.68 ± 0.3 (0.65–0.71)	0.54 ± 0.17 (0.52–0.56)	0.83 ± 0.34 (0.78–0.86)	<0.001 ^b
MB thickness in cm ^a	1.59 ± 0.48 (1.54–1.63)	1.69 ± 0.4 (1.63–1.75)	1.48 ± 0.52 (1.41–1.56)	<0.001 ^b
SB thickness in cm ^a	2.23 ± 0.52 (2.18–2.28)	2.23 ± 0.42 (2.18–2.29)	2.23 ± 0.61 (2.14–2.31)	0.930 ^b
Ratio of SM and MB thickness ^a	0.46 ± 0.23 (0.44–0.48)	0.34 ± 0.14 (0.32–0.35)	0.58 ± 0.24 (0.55–0.61)	<0.001 ^b

***p values are for differences between males and females; BMI – body mass index; CI – confidence interval; SM – skin-to-muscle; MB – muscle-to-bone; SB – skin-to-bone; SD – standard deviation.

^a For 400 arms of 200 subjects.

^b Unequal variances.

Table 2 – Side differences between the variables.

Variable	Right and left (n = 400) Mean $\pm$ SD (95% CI)	Right (n = 200) Mean $\pm$ SD (95% CI)	Left (n = 200) Mean $\pm$ SD (95% CI)	p value**
SM thickness in cm ^a	0.68 $\pm$ 0.3 (0.65–0.71)	0.67 $\pm$ 0.28 (0.63–0.71)	0.7 $\pm$ 0.32 (0.65–0.74)	0.012
MB thickness in cm ^a	1.59 $\pm$ 0.48 (1.54–1.63)	1.63 $\pm$ 0.47 (1.56–1.70)	1.54 $\pm$ 0.48 (1.48–1.61)	0.018
SB thickness in cm ^a	2.23 $\pm$ 0.52 (2.18–2.28)	2.26 $\pm$ 0.51 (2.19–2.33)	2.21 $\pm$ 0.53 (2.13–2.28)	<0.001
Ratio of SM and MB thickness ^a	0.46 $\pm$ 0.23 (0.44–0.48)	0.43 $\pm$ 0.2 (0.41–0.46)	0.48 $\pm$ 0.6 (0.45–0.52)	<0.001

**p values are for differences between the right and left arms; CI – confidence interval; SM – skin-to-muscle; MB – muscle-to-bone; SB – skin-to-bone; SD – standard deviation.
^a For 400 arms of 200 subjects.

shown in Fig. 2. Significant side differences were noted in males ($p = 0.01$) but not in females ($p = 0.293$). It was observed that the mean MB thickness was greater in males as compared to females (Fig. 3). Significant side differences were noted both in males ($p = 0.001$) and in females ($p = 0.014$). There were greater side differences in the SM thickness among females ($p = 0.024$) as compared to males ($p = 0.380$) (Fig. 4).

There was a positive correlation between the deltoid fat pad thickness and BMI in both right and left arms, with a correlation coefficient of 0.679 ($p < 0.001$) and 0.620 ($p < 0.001$) respectively. The following regression equations were constructed for the right and left arm: SM thickness = $0.039 \times \text{BMI} - 0.274$ and SM thickness = $0.041 \times \text{BMI} - 0.301$ respectively. For the dominant arm, the following multiple linear regression equation was generated using the SM thickness as the dependent variable and the age in years, BMI and gender (0 for male and 1 for female) as the independent variables: SM thickness = $(-0.004) \times \text{age in years} + (0.224) \times \text{gender} + (0.041) \times \text{BMI} - 0.308$. All the constants in the equation had a p value of less than 0.001. This model had an R value of 0.814 and R^2 value of 0.663. The standardized beta coefficients for the BMI, gender and age were 0.719, 0.400 and -0.181 respectively. A similar equation for the non-dominant arm was SM thickness = $(-0.005) \times \text{age in years} + (0.248) \times \text{gender} + (0.045) \times \text{BMI} - 0.334$. All the constants in the equation had a p value of less than 0.001. The R value and R^2 values of the model were 0.765

and 0.586 respectively. The standardized beta coefficients for the BMI, gender and age were 0.676, 0.384 and -0.211 respectively.

The standard needle length from the hub to the tip for a 23 gauge needle used with a 2 ml syringe is 25 mm. For an ideal IM injection into the deltoid, 3 mm of the needle closest to the hub should remain outside, with a minimum of 5 mm penetration into the deltoid muscle. It has been suggested that the needle should be oriented perpendicular to the skin surface at the site of the injection.² Using these guidelines, it was found that in 2 subjects (1%) under-penetration would have occurred. Both these subjects were females and in one of them this would have occurred bilaterally, whereas in the other this would have occurred on the left side only. Over-penetration, such that the needle tip would reach the bone, would have occurred in as many as 50% of both males and females if the aforementioned guidelines for IM injections were followed.

Discussion

In the present study, real time linear array high frequency ultrasound was used to measure SM and MB thickness at the deltoid IM injection site. Other studies have also employed ultrasound to estimate body composition and fat distribution patterns by measurement of the subcutaneous layer.² A study

Fig. 2 – Differences in the mean SB thickness when both side and gender were considered.

Fig. 3 – Differences in the mean MB thickness when both side and gender were considered.

Fig. 4 – Differences in the mean SM thickness when both side and gender were considered.

conducted at Mayo Medical Centre, Rochester, found that women had more subcutaneous fat in the upper arm compared to men. It was found that the mean subcutaneous fat thickness at the deltoid region was 11.7 mm in women and 8.3 mm in men.² In the present study, the mean values were much lower. However women were found to have greater mean SM thickness as compared to men, which was consistent with the previous study. In the present study, it was found that nearly 70% of the SB thickness was contributed by muscle and the rest mainly by subcutaneous fat.

On comparing the right and left arm, it was found that the SB and the MB thickness were greater in the right arm whereas the SM thickness was greater in the left arm. The greater SB thickness in the right arm was due to the greater muscle mass on that side. Females were found to have greater SM thickness and males, greater MB thickness, but the SB thickness was similar among both genders. An ultrasound study in elderly patients in Australia showed that females with the same BMI as males had significantly thicker subcutaneous layers and thinner muscle layers.¹⁰ Studies suggest that as body fat increases, more fat is deposited in the upper arm in women than in men and this fat is deposited preferentially over deltoid muscle.^{11,12}

Another study found that there was a strong correlation between deltoid fat pad thickness and BMI. In that study the correlation coefficients between BMI and deltoid fat pad thickness were found to be 0.69 and 0.71 for the dominant arm and non-dominant arm respectively.¹⁰ Similarly, in the present study it was found that there was a strong correlation between SM thickness and BMI with correlation coefficients of 0.68 and 0.62 for the right and left arm respectively. More accurate linear regression equations with better model fit properties were constructed using additional parameters like gender and age. The SM thickness was negatively correlated with age. The standardized beta coefficients show that variances in the SM thickness are associated maximally with the BMI, followed by gender and age in that order.

Under-penetration of intramuscular injections would lead to vaccine injection in the fat layer, where poor vascularity may result in slow mobilisation and processing of the antigen. This has been suspected to be a cause for vaccine failure.^{13–16} Another implication of the present study concerns vaccine reactogenicity. Serious complications of intramuscular deltoid injections are rare, whereas abscesses and granulomas are more common with subcutaneous injections.^{3,4} In studies comparing adverse effects of the Diphtheria, Pertussis, and Tetanus (DPT) vaccine associated with different needle lengths, use of longer needles was associated with less pain following immunisation of infants in the thigh.^{17,18} The use of shorter needles resulted in deposition of vaccine into the subcutaneous tissue, which is well innervated with pain fibres compared to muscle tissue.¹⁹

More recently an entity termed upper arm injury related to vaccine administration (UAIRVA) has been recognized. Injuries to the anterior branch of the axillary nerve, radial nerve and sub-acromial bursa have been shown to contribute to UAIRVA.²⁰ These injuries are due to inappropriately placed intramuscular injections and could also result from over-penetration. Other potential risks associated with over-penetration includes pain and/or damage to the bone or periosteum and detachment of the needle from the syringe.^{5,6}

Upper arm intramuscular injections require penetration of the needle into the deltoid muscle layer by 5 mm or more to ensure that the injection is deposited into the muscle mass.² Accepted guidelines suggest that the needle should be inserted at 90° to the arm leaving 2–3 mm of needle exposed between the skin and the needle hub to avoid losing the needle within the arm in case the needle breaks at the hub.² To fulfil the above conditions, it was suggested that a 25 mm needle had to be used for men weighing more than 60 kg and women in the weight range of 60–90 kg. Women weighing over 90 kg would require a needle length of 38 mm, whereas a 16 mm needle could be used for men and women weighing less than 60 kg.²

In the present study, using the aforementioned guidelines, under-penetration would have occurred in 1% of the subjects, in this case both females. Over-penetration, such that the needle tip would reach the bone would have occurred in as many as 50% of both males and females. As needle lengths for two ml syringes are usually 25 mm, it would be impractical to suggest changes in the needle length for different patients in the Indian scenario. It is also not feasible to estimate the weight or BMI of every individual who is to be given a deltoid intramuscular injection. Therefore from the present study it can be suggested that for poorly built and nourished individuals an adequate IM injection can be given if approximately half the needle remains outside. For moderately built individuals and obese males standard guidelines can be followed. Only for obese females is a longer needle required to ensure adequate penetration.

One of the limitations of the present study was that the age and weight distributions may have been more limited than the general population. Stratified random sampling would theoretically have been a better method to ensure the representativeness of the sample that was studied. Inferential statistics for the generalization of summary measures are ideally carried out on random samples. Therefore the results of the present study need to be substantiated by future studies where this limitation is overcome. The interobserver variability of the

ultrasound technique that was used was not estimated, and warrants further study.

In conclusion, the SM thickness was found to be significantly greater on the left side and in females. The BMI showed a high correlation with the SM thickness. More accurate multiple linear regression equations to estimate the SM thickness could be constructed if gender and age are also taken along with BMI as predictor variables. Using current techniques of IM injections, over-penetration seems much more likely than under-penetration. Thus, the build of the individual patient needs to be taken into account to ensure optimum delivery of IM injections.

Conflicts of interest

All authors have none to declare.

Acknowledgements

The authors would like to thank all the subjects who consented to participate in this study.

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