

Optimal needle insertion length for intramuscular injection of risperidone long-acting injectable (RLAI)*

Tetsuya Tanioka^{1#}, Sakiko Sakamaki², Yuko Yasuhara¹, Masahito Tomotake¹,
Kensaku Takase³, Chie Watari⁴, Kouichi Makiguchi⁴, Rozzano Locsin⁵,
Kazushi Motoki³, Tatsuya Inui⁶

¹Department of Nursing Management, Institute of Health Biosciences, The University of Tokushima Graduate School, Tokushima, Japan; [#]Corresponding Author: tanioka@medsci.tokushima-u.ac.jp

²Graduate School of Health Biosciences, The University of Tokushima, Tokushima, Japan

³Tokushima Prefectural Central Hospital, Tokushima, Japan

⁴Fujishiro Kensei Hospital, Hirosaki, Japan

⁵Department of Nursing, Christine E. Lynn College of Nursing, Florida Atlantic University, Boca Raton, USA

⁶Fujii Hospital, Tokushima, Japan

Received 6 October 2013; revised 16 November 2013; accepted 28 November 2013

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ABSTRACT

Risperidone long-acting injectable (RLAI) is approved for the treatment of schizophrenia in many countries. The suggested site is the gluteal muscle with a needle length of two inches (50 mm) in Japan, which is longer than the ordinarily used needle for intramuscular injections. The aim of this study was to determine the optimal needle insertion length for accurate delivery of RLAI procedure among subjects who have normal body mass index (BMI: 18 to 25) and high BMI (>25). Thirty-seven patients with schizophrenia were administered RLAI intramuscularly into the dorsogluteal muscle. The standard procedure required inserting 80% of the two inch needle. By using data collected by ultrasonography, the findings confirmed that the median needle insertion lengths for subjects with normal and high BMI were 39.0 and 45.5 mm, respectively. To deliver RLAI effectively and safely, the authors strongly recommend that a specialized needle be used that is “marked” at the 40 mm point from the tip of the needle to the base. In this way regardless of subcutaneous fat content, the RLAI can be safely delivered into the muscle without causing untoward or side effects.

Keywords: Risperidone Long-Acting Injectable; Gluteal Muscle; Intramuscular Injection; Optimal

*Disclosure of interest: The authors report no conflicts of interest.

Needle Insertion Length; Body Mass Index; Ultrasonography

1. INTRODUCTION

Patients with schizophrenia are almost always treated with antipsychotic medications. However, many patients cannot tolerate taking the regular oral medication, and adhere to the treatment regimen such as in situations when they experience side effects, lack of social support and insight into the disease pathology, and poor adherence to medication protocol, resulting in symptom recurrence [1-3]. Therefore, long-acting injectable antipsychotics are often used in the treatment of these patients. The first atypical antipsychotic long acting injectable medication was the Risperidone long acting injection (RLAI) launched in Japan and used to treat not only non-adherent patients but also those who are able to partially adhere to the protocol. RLAI is a water-based suspension, whereas other antipsychotic medications are oil-based solutions [4-6].

Intramuscular (IM) injection of medications is usually administered into the deltoid muscle and/or the gluteal muscles [7-9]. The most common reasons for preferring the deltoid muscle for IM injections include ease of access allowing for increased patient privacy and less embarrassment to the patient, and faster delivery of medication with lesser observed untoward or side effects such as painful reactions. IM injection in the gluteal muscle is less painful than injection into the deltoid muscle [10].

Because the gluteal muscles are dense enough to permit the injection of larger volumes of fluid, these were

found to be the best areas for IM injections of high-volume medications [11]. Larger volumes of fluid may induce more pain and the volume limit for IM injection into the deltoid muscles is approximated to be only 1 mL [12,13].

Most muscles are adjacent to nerves, blood vessels and other important anatomical structures. The gluteus minimus muscle and the nearby sciatic nerve are less likely to be injured by injection of medication into the gluteus medius muscle. This can be located externally in the upper outer quadrant of the buttocks [14,15].

In a study by Chan *et al.* [16] fifty Irish patients who were to undergo Computerized Tomography (CT) procedure were injected with 1 mL of air into the upper outer quadrant of the buttocks. CT images were subsequently analyzed to determine the position of the injected air bubble and to assess whether it was within the muscle or not. Results showed that only 32% ($n = 16/50$) of the air bubble were in the intramuscular area, while majority (68%, $n = 34/50$) showed that the air bubbles were at the subcutaneous area. This indicated that widely held assumption of intramuscular injections are actually subcutaneous injections.

Problems can arise if drugs designed to be absorbed from the muscle are only delivered into the subcutaneous tissue. With increasing obesity in all developed and many developing countries, this may pose as an increasing concern. A study [17] of 119 healthy adults with a body mass index (BMI) of more than 24.9 kg/m^2 considered to be overweight, obese, or extremely obese was conducted to determine the optimal needle length insertion at the dorsogluteal and ventrogluteal IM injection sites. Using ultrasonography, the findings revealed that the standard 1.5 inch (38 mm) needle is not long enough to deliver medications to the dorsogluteal and ventrogluteal muscles of healthy adults with a BMI of more than 24.9 kg/m^2 . Furthermore, the results also revealed that neither site should be used in women whose BMI is more than 24.9 kg/m^2 , although the dorsogluteal site may be used for overweight and obese men, and the ventrogluteal site only for overweight men. Zaybak *et al.* [17] concluded that if alternative routes are not possible, longer *specialized* needles should be produced by manufacturers and recommended for use among obese individuals.

Based on this recommendation, a study of four subjects with schizophrenia who received the RLAI medication was conducted. Using a *specialized* (2-inch) needle designed for RLAI medication, ultrasonography data revealed that the location (gluteus medius or maximus) and diffusion of the RLAI medications administered intramuscularly can be visualized, illustrating depth of needle injection, location of needle, and diffusion of medication [18]. Moreover, through ultrasonography,

this study revealed that in some cases, the drug was shown to be injected into the gluteus maximus instead of the gluteus medius, affirming that IM injection to the accurate muscle is critical to ensuring the desired effects of medications.

Visualizing through ultrasonography is possible since the microspheres of RLAI have characteristics like a contrast medium, thereby allowing a picture to be ultrasonically and simultaneously seen when medications are injected into the muscles. Ultrasonography data also revealed that injection sites hardened when typical antipsychotics are injected into areas other than the desired muscle for example into the subcutaneous layer. This was visible through ultrasonography at 16 days post injection.

These results confirmed that the gluteus muscle was the ideal muscle for IM injection as evidenced by the dispersion/absorption of the medication solution. With the use of ultrasonography, injection sites and drug dispersions can be evaluated under a direct visual guidance, affirming that ultrasonography is a useful method for establishing evidence for determining correct insertion of IM injection, diffusion of medications, and the effective administration of IM injections.

In Japan, with the RLAI, (as it cannot be administered in the deltoid muscle Ministry of Health, Labour and Welfare of Japan [19]) being recognized as a medication that can only be administered intramuscularly and in the gluteal region, a new standardized protocol for its administration was sought. The major consideration is safety because the RLAI is an approved medication for treatment of schizophrenia given as a biweekly injection and only in the gluteal muscle.

It is critical therefore that, avoiding injection into the subcutaneous fatty tissue [20] is assured. RLAI was approved to be administered to patients in the gluteal muscle using a 2-inch needle length. In addition, considering the volume of the RLAI (in Japan, it is distributed as 25 mg, 37.5 mg, or 50 mg risperidone/2 mL IM Syringe) and its properties such as absorption and its safety (such as possible damage to tissues including subcutaneous, blood vessels, or nerve-endings), the appropriate protocol for the administration of the RLAI is to use the gluteal muscles as the primary injection site.

Subcutaneous fat tissue and muscular thickness are critical determinants to establishing the adequate length of needle to use and the accurate angle of injection into muscle areas. Currently, about 50% of clinical nurses do not assess subcutaneous fat level when they administer an IM injection [21]. Furthermore, it was pointed out that standardized needles commonly used for IM injections are the 20 - 23 gauge needles (1 to 1 1/2 inches: 25 - 38 mm) that do not always reach their intended target—the gluteal muscles in a considerable number of patients [16,

17,22-24].

Cocoman and Murray [25] strongly advised that to adequately, accurately, and safely administer IM injections, the upper outer quadrant region should be the site of choice. To be effective, an imaginary division of the area into quadrants is suggested. Injection, therefore, is given in the upper outer quadrant of the upper outer quadrant (land marking is done by making a double cross. (See **Figure 1(a)**).

However, like the recommendation by Cocoman and Murray [25], in Japan, it is the “four- and three-way split” method that is most commonly used for IM injection [26]. When the nurses perform IM injection, competent assessment of the hypodermic site area is critical especially because most nurses tend to hesitate to insert the needle deep enough for patients who have less subcutaneous fat at the injection site areas, such as of patients who are thin.

Based on the findings described in the aforementioned

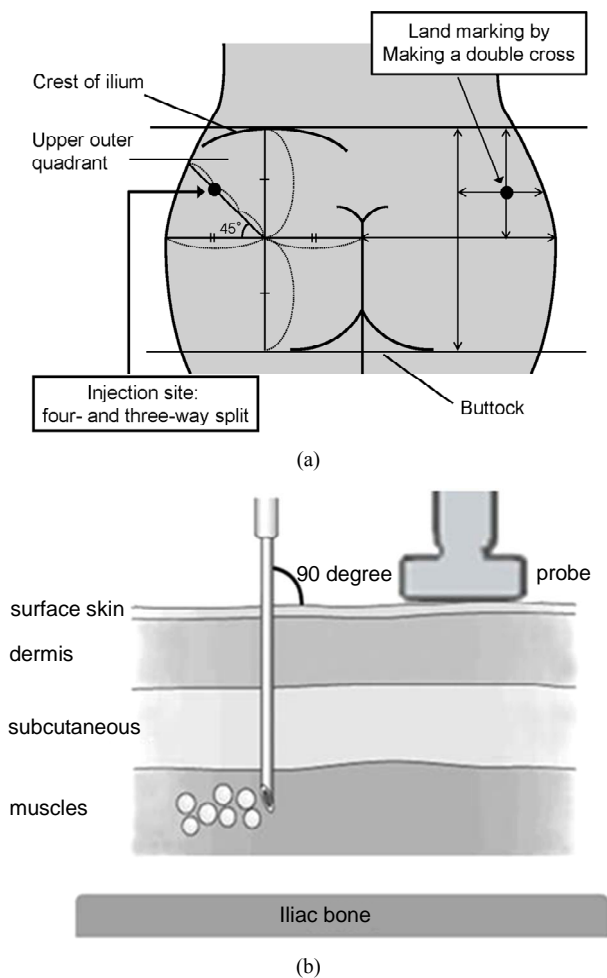


Figure 1. Intramuscular Injection Part and Ultrasonographic Images. (a) Intramuscular site in the buttocks by “four- and three-way split” method; (b) An illustration of sagittal section with IM injection site and ultrasonograph probe.

research studies and the standards of IM injections established in Japan for administering the RLAI, it is critical that the size and length of needle and the identification of respective areas of choice for particular injection sites be determined using empirical data. Other than the study by Chan *et al.* [16], no other research studies have been reported that answered the question whether or not medications administered through IM injections are actually administered to the gluteus medius or to the subcutaneous layer. Furthermore, the avoidable consequences of using inaccurate needle size and length must be assured so that if the needle length is too short to reach the intended muscle, then the drug will be injected into the subcutaneous tissue, decreasing absorption rate and decreasing efficacy of the drug and thereby providing inadequate effect. Important as well is the possible pain, abscess or granuloma formation at the injection site [17].

2. AIM

The aim of this study is to determine the optimal insertion length of the specialized (2-inch) needle indicated for administering the RLAI among Japanese subjects with normal BMI (between 18 and 25) and those with high BMI (>25).

3. METHODS

3.1. Subjects

There were thirty seven adult subjects diagnosed with schizophrenia of whom twenty-two were men and fifteen were women. They were all prescribed to receive RLAI. These subjects were recruited from two hospitals within the Tokushima and Aomori prefectures in Japan.

3.2. Data Collection

The study was conducted from June 2010 to January 2011. Body weight and height were measured, and BMI was calculated in all patients. Just before RLAI injection, the distance from the epidermis to the under-fascia (DEUF), and distance from the epidermis to the iliac bone (DEI) at bilateral gluteal sites were assessed using a standardized ultrasonography. Similarly, needle-length insertion (INL) was also identified guided by the mark up on the needle using a felt-tip pen before withdrawal of the needle.

To identify the injection site by the “four- and three-way split”, the buttocks area was imaginarily divided into four quadrants. The proper injection site was located at the upper outer quadrant, and at one third the distance from the iliac crest on the imaginary 45 degree line (See **Figure 1(a)**).

All ultrasonographic measurements were performed by an experienced Sonographer using a 7.5 MHz linear

and convex array transducer and real-time-B-mode ultrasonograph diagnostic system (Hitachi Medical Corporation, Japan). Ultrasonograph images were made at the dorsogluteal injection site. Gluteus maximus, medius and minimus muscles are commonly used as regions for IM injection. DEUF and DEI measurements were made above and outside a line drawn from the posterior superior iliac spine to the greater trochanter of the femur. Ultrasonograph probe was held at right angle to the skin at the gluteal region (See **Figure 1(b)**).

Two measurements were made: the internally inserted length of the two-inch needle from the epidermis to the muscle, and the remaining (exposed) needle length external to the injection site. Thereafter, ultrasonography was used to determine whether the length of the internally inserted needle was adequately inserted into the gluteus muscle.

Nurse investigators who have used the “four- and three-way split” method to determine the gluteal muscle injection site, performed the procedure to ensure consistency in the insertion method. Results of ultrasonographic measurements were done based on the recorded ultrasonographic images.

3.3. Ethical Considerations

This study was conducted after approval was received from Tokushima University Hospital’s Ethics Committee. Both verbal and written consents were obtained from the prospective subjects of the study. Patient consent for ultrasonography images was also obtained. The consent also included a statement of understanding that images may be used for educational purposes, lectures, and publications.

3.4. Data Analysis

Statistical analysis of data was performed using PASW Statistics (Ver. 18.0J). All collected data were stratified by normal BMI (between 18 and 25) and high BMI (>25), and the median, lower and upper quartile, and range were calculated. The Mann-Whitney U test was used to test for differences between stratified groups with normal and high BMI.

4. RESULTS

Table 1 provides description of the subjects’ BMI distribution. In the group with normal BMI, there were 5 men and 5 women. In the group with high BMI there were 17 men and 10 women. Both left gluteus ($p < 0.001$) and right gluteus ($p < 0.01$) DEIs were significantly different between the groups with high and normal BMIs. No significant differences were observed in the left and right DEUF.

Table 1. Distribution of BMI.

Sample (n)	Median	Lower quartile	Upper quartile	Range
Overall (37)	26.8	24.7	31.2	19.1 - 35.7
Normal BMI (10)	21.2	19.6	23.6	19.1 - 24.8
High BMI (27)	27.3	26.2	31.7	25.0 - 35.7

BMI: body mass index (kg/m^2), Normal BMI: 18 - 25, High BMI: >25.

In the group with normal BMI, median distance from the epidermis to the under-fascia (DEUF) was 16.0 mm (left), 15.7 mm (right). Distance from the epidermis to the iliac bone (DEI) was 54.7 mm (left), 55.9 mm (right). Median of needle-length insertion (INL) was 39.0 mm and range was 27.0 - 47.0 mm. On the other hand in a high BMI group, median DEUF was 20.2 mm (left), 16.5 mm (right). DEI was 71.9 mm (left) 75.9 mm (right). INL was 45.5 mm and range was 30.0 - 50.0 mm (**Table 2**). It was confirmed ultrasonographically that RLAI had been injected under the fascias and into the gluteus muscle, in all cases.

Figure 2(a) shows the typical example of a man patient with a high BMI, diagnosis of schizophrenia and age of 50 years. Height: 158 cm. Weight: 79 kg. BMI: 31.6 Kg/m^2 . The injection site was on the left side, and the INL was 42.0 mm. Also, the DEUF was 16.9 mm, and the distance from epidermis to the ilium was 84.8 mm.

Figure 2(b) shows the typical example of a woman patient with a normal BMI schizophrenia, aged 52. Height: 165.5 cm. Weight: 53 kg. BMI: 19.4 Kg/m^2 . The injection site in this situation was on the left side, and the INL was 30.0 mm. Also, the distance from the epidermis to subcutaneous area was 13.4 mm, and the distance from epidermis to the ilium was 55.9 mm.

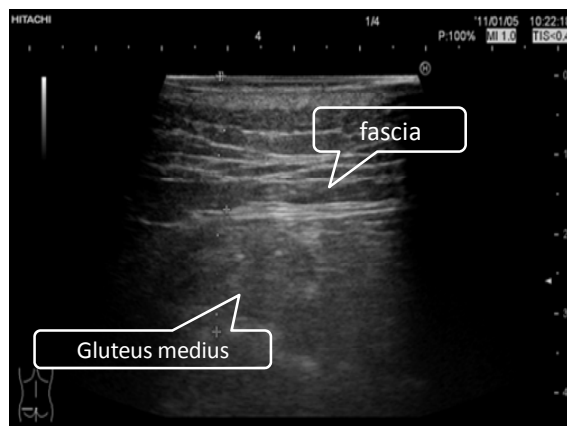
5. DISCUSSION

Cocoman and Murray [25] recommended that to provide appropriate estimate of correct muscle location, the buttocks be viewed divided into four equal areas and the IM injection selected as the top outside quarter (See **Figure 1(a)**). The upper outer quadrant must be used to avoid any damage to the sciatic nerve. The gluteus medius is distributed directly under the epidermis, the subcutaneous fat tissue and the gluteus maximus [27]. The “four- and three-way split” method procedure ensures the estimation of the correct location for the insertion of the injection needle to a depth that extends through the thickness of the subcutaneous tissue and into the gluteus maximus. It is important to inject to the level of the gluteus medius during IM injection because it is thick enough to hold the volume of the medication and prevent damage to the nerves or prevent insertion of the needle to

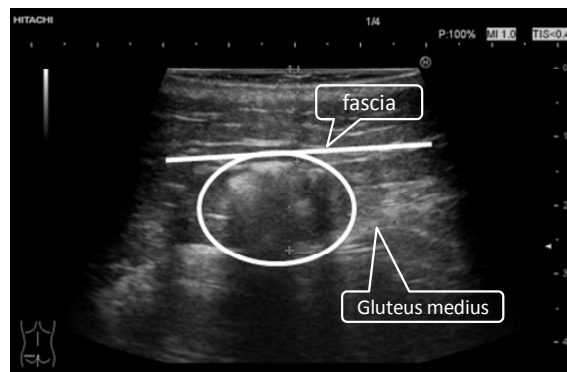
Table 2. Body mass index-based differences in patients with schizophrenia.

Variable	Normal BMI (kg/m ²), n = 10				High BMI (kg/m ²), n = 27				z	p
	Median	Lower quartile	Upper quartile	Range	Median	Lower quartile	Upper quartile	Range		
INL (mm)	39.0	34.8	40.8	27.0 - 47.0	45.5	37.5	46.0	30.0 - 50.0	-1.34	n.s.
DEUF/left (mm)	16.0	13.6	20.0	10.5 - 19.0	20.2	12.6	21.3	10.3 - 27.1	-0.48	n.s.
DEUF/right (mm)	15.7	12.5	15.9	10.3 - 19.7	16.5	13.1	19.5	11.1 - 25.0	-0.27	n.s.
DEI/left (mm)†	54.7	51.3	61.1	42.7 - 64.2	71.9	68.8	74.6	62.1 - 87.3	-3.06	***
DEI/right (mm)†	55.9	51.6	67.3	42.7 - 71.9	75.9	68.8	78.0	60.5 - 94.1	-2.63	**

BMI: body mass index (kg/m²), Normal BMI: 18 - 25, High BMI: >25, INL: Inserted needle length; DEUF: distance from the epidermis to the under-fascia; DEI: distance from the epidermis to the iliac bone; †: number of subjects (normal BMI: n = 5, high BMI: n = 17) that was able to be measured in DEI; Mann-Whitney U test, ***p < 0.001, **p < 0.01, n.s.: not significant.



(a)



(b)

Figure 2. Intramuscular injection part and ultrasonographic images. (a) Representative ultrasonographic images of patients with schizophrenia after RLAI injection; a man patient with a high body mass index (BMI) and (b) A woman patient with a normal BMI. Circle is the area which the dedicated needle of RLAI reached in the gluteus medius.

a blood vessel [28].

The range and average of the hypodermic thickness was reflected well when using the “four- and three-way split” procedure. Kikuchi *et al.* [29] examined the thick-

ness of the hypodermis by the ultrasonography. The thickness of the subcutaneous tissue was found to vary from a mean score of 1.03, range 0.32 to 3.08 cm in adult Japanese men, and a mean of 1.42, range 0.86 to 3.66 cm in adult Japanese women. Thus, if the needle length was too short, the injected solution may not reach the gluteus muscle.

In the current study, a case of one male subject indicated that the insertion needle length was 32.0 mm and the DEUF was 20.0 mm. Nonetheless, the ultrasonographic data indicated that the RLAI was administered in the gluteus maximus muscle. Given this data, it seems that the needle must have been inserted obliquely against the skin surface.

One of the significant findings of this study was determining the appropriate length of needle using ultrasonography data. Patients with high BMI (31.6 Kg/m²), showed DEUF of 16.9 mm, DEI 84.8 mm, and INL 42.0 mm. In contrast, patients with normal BMI (19.7 Kg/m²), showed DEUF 13.4 mm, DEI 55.9 mm, and INL 30.0 mm. These findings show that in both high and normal BMI groups, the inserted needle did not reach the iliac bone. This indicated that the RLAI was and can be administered appropriately into the muscle even in patients with normal or very high BMI when using a specialized RLAI needle. This is because as illustrated using the ultrasonographic data, the RLAI needle was inserted at the injection site into the intended gluteal muscle after using the “four- and three-way split” method to find the correct gluteal muscle injection site.

The ideal is to inject the RLAI into the gluteus medius muscle. Nevertheless, even with the “four- and three-way split” method, there is a possibility that the medication may be administered into the gluteus maximus muscle when the needle is inserted obliquely. There is also the possibility that significant differences may be found when patients have varying BMI and/or when needles other than the specialized needles for RLAI are used.

Generally, in Japan, a 23-gauge (1.25 inch) needle is

used for IM injection [26]. Also, the recommendation is to leave about 1/2 or 1/3 of the injection needle from the skin surface. For RLAI, however, the result indicates that it was necessary to insert 80% of the IM needle, leaving only 20% exposed at the skin level. It was found that the RLAI can be safely delivered into the muscle without untoward or side effects such as reaching the iliac bone.

To ensure that the intended effect of using RLAI for patients with schizophrenia is achieved the study indicated that a specialized needle be manufactured that is marked at the 40 mm level to indicate the insertion limits. These marked needles should guide the nurse when administering RLAI to patients with either high or low BMI. While these specialized needles may be marked to ensure depth of insertion considering BMI, an important consideration is the correct estimation of the location of the gluteus muscle using the “four- and three-way split” method to determine the insertion site as the method of choice to find the ideal gluteus muscle.

6. CONCLUSIONS

This is the first study which is based on the sonographic diagnosis that is carried out to confirm by ultrasonography data the use of a marked needle specially for administering RLAI, assuring that indeed it is injected into the ideal muscle. However, even with this study, there remains a possibility that injection site untoward reactions and side effects can occur as a result of RLAI being injected into the subcutaneous tissue instead of the gluteal muscles. Therefore, it is critical to assure injection of the RLAI into the gluteus muscle by using the four- and three-way split method technique to find the site, and to use the specialized and marked two-inch RLAI needle.

With 37 subjects, it was confirmed by ultrasonographic images that using a two-inch RLAI needle could ensure IM administration at the injection site when using the “four- and three-way split” method and the specialized needle marked at 40 mm level. With the “four- and three-way split” method, the RLAI was administered into the gluteus maximus muscle even when the injection needle was not inserted at a vertical angle. It is recommended that RLAI can be safely delivered into the muscle, if the two-inch specialized needle is marked at the 40 mm point indicating that the needle must only be inserted up to this level. As shown by ultrasonographic data, insertion up to this level assures insertion of the needle past the subcutaneous level and into the gluteus muscle regardless of the patients' BMI.

7. LIMITATIONS

The study has several limitations. One of these is the small sample size which may limit the generalization de-

rived from the findings. Likewise, the researchers failed to equalize the numbers of people in the gender groups. Oftentimes, men and women have significantly different BMIs which may influence their dermal (skin) thickness, thereby significantly affecting the difference between the thickness of subcutaneous fat and the subsequent muscle. These differences may have influence on the outcomes of the study.

Because of the limited number of subjects, the researchers suggest that studies using larger samples may be needed to re-affirm the results and recommendations of the study. Finally, this study was conducted to confirm the use of specialized 2-inch needles in RLAI by providing evidence using ultrasonography data.

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