Technical feasibility and efficacy of a standard needle magnetization system for ultrasound needle guidance in thyroid nodule-targeting punctures: a phantom study

Haein Lee*, Yoon Joo Cho*, Eun Ju Ha, Jayoung Moon, You Na Kim, Minji Kim, Kyung-Min Lee, Sung Hyun An

Department of Radiology, Ajou University School of Medicine, Suwon, Korea

Purpose: The aim of this study was to assess the feasibility and efficacy of an ultrasound needle guidance system (NGS) based on standard needle magnetization in a phantom study of thyroid nodule (TN)-targeting punctures.

Methods: Six trainees and a staff radiologist performed TN-targeting punctures with or without the NGS in phantom models (group 1, experience <50 cases; group 2, experience ≥50 cases and <100 cases; group 3, experience ≥100 cases of TN-targeting punctures). The feasibility, technical success rate, number of punctures, and procedure time were recorded.

Results: The feasibility of NGS was 98.6% (138/140). In group 1, the technical success rate increased from $60.0\%\pm8.2\%$ to $80.0\%\pm8.2\%$ when the NGS was used (P=0.046), with a reduction in the number of punctures from 2.2 to 1.2 (P=0.005). In group 2, the rate changed from $95.0\%\pm5.8\%$ to $100.0\%\pm0.0\%$ with the NGS (P=0.157), with a minimal decrease in the number of punctures from 1.1 to 1.0 (P=0.157). The procedure time significantly decreased in both groups (P=0.041 and P=0.010, respectively) when the NGS was used. In group 3, there were no significant differences in the technical success rate and the number of punctures according to whether the NGS was used (P=0.317 and P=0.317, respectively).

Conclusion: NGS using standard needle magnetization is technically feasible and has potential to improve the efficacy of TN-targeting punctures for less-experienced operators, especially beginners, according to the findings of this phantom study.

Keywords: Fine-needle aspiration; Needle guidance; Thyroid nodule; Ultrasound

Key points: The feasibility of electromagnetic needle guidance system (NGS) was 98.6% (138/140). NGS using the standard needle magnetization system could improve the technical success rate in thyroid nodule (TN)-targeting punctures in less-experienced operators. NGS using the standard needle magnetization system could decrease the number of punctures in TN-targeting punctures in less-experienced operators.

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Correspondence to:

Eun Ju Ha, MD, Department of Radiology, Ajou University School of Medicine, 206 World cup-ro, Yeongtong-gu, Suwon 16499, Korea

Tel. +82-31-219-4057 Fax. +82-31-219-5852 E-mail: radhej@naver.com

*These authors contributed equally to this work.

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Introduction

Thyroid nodules (TNs) are a common clinical finding, with a detection rate of 17%-67% on ultrasonography (US) [1,2]. In patients with TNs, US-guided fine-needle aspiration (FNA) is the initial diagnostic tool, and the rate of malignancy ranges from 8% to 12% of nonpalpable nodules evaluated by FNA [1–3]. However, although US-guided FNA is a safe and accurate procedure for the diagnosis of TNs, there is a learning curve before the procedure can be performed optimally, particularly if the target structure is small or has a deep location [4–6]. Therefore, procedures performed by less-experienced operators could generate a high rate of non-diagnostic results and increase patients' pain, discomfort, and procedure-related complications [4–6].

To address this issue, US-guided needle-tracking and guidance systems have been developed to assist operators through continuous monitoring of the needle alignment and tip position during the procedure [7–16]. Conventional in-plane techniques allow operators to trace the entire length of the needle and the needle tip after insertion. However, these techniques have limitations for use if the insertion angle of the needle is misplaced and must be reinserted to target TNs [8]. Out-of-plane techniques allow the needle tip to be visualized when it crosses the US beam plane. However, these techniques generally require a higher level of experience, and the correct insertion angle also must be previously predicted [8]. Recently, a portable US device with an implemented needle guidance system (NGS) (SC1, FCU Co. Ltd., Daejeon, Korea) based on the standard needle magnetization system became commercially

available. This system may have advantages for US-guided FNA of TNs because it can properly guide the direction and angle of the needle to the target nodules even before its insertion into the skin. Both in-plane and out-of-plane techniques can be performed safely with NGS assistance, if the system can easily magnetize a commercially available needle and accurately guide the exact insertion angle of the needle before performing skin punctures.

The present study assessed the technical feasibility and efficacy of US NGS using standard needle magnetization in a phantom study among residents being trained in TN-targeting punctures compared to the conventional in-plane technique.

Materials and Methods

All punctures were performed by six radiology residents and a staff radiologist (group 1, H.L. and J.M. with <50 cases of experience with thyroid FNA; group 2, Y.N.K. and M.K. with ≥50 cases and <100 cases of experience with thyroid FNA; and group 3, K.M.L., S.H.A., and E.J.H. with ≥100 cases of experience with thyroid FNA) using phantom models. All operators were right-handed. Before the procedure, all metallic items that would potentially interfere with electromagnetic fields, such as watches, glasses, belts, cell phones, jewelry, detachable dental implants, and brassieres, were removed. Phantom models containing two targets with maximum diameters of 7 mm or 4 mm were used to mimic TN-targeting punctures (Fig. 1).

In the conventional technique without NGS, operators performed TN-targeting punctures with free hands in the phantom models. US examinations and US-guided TN-targeting punctures were



Fig. 1. Phantom model for needle puncture.

Schematic illustration (A), ultrasonography (B), and photograph (C) of the phantom show two targets (7 mm and 4 mm) mimicking thyroid nodules.

performed using a 3-12 MHz linear probe and a real-time US system (RS85A, Samsung Medison Co. Ltd., Seoul, Korea). The TN-targeting punctures were performed using 23-gauge 25-mm needles attached to a 10-mL syringe (Kovax-Needle, Korea Vaccine Co., Ltd., Seoul, Korea). In the NGS technique, a portable US device containing a 4-14 MHz linear transducer with NGS (SC 1, FCU Co., Ltd.) was used (Fig. 2). The transducer was calibrated to the background magnetic field of the intervention room according to the instructions of the implemented calibration application. Next, the same commercially available 23-gauge 25-mm needles attached to a 10-mL syringe were magnetized with a portable device. The technical feasibility assessment was focused on gaining an understanding of the standard needle magnetization system for ultrasound needle guidance and its applicability during the TN-targeting puncture. Therefore, the functionality of the standard needle magnetization system for ultrasound needle guidance was first assessed after a short (1-2 seconds) insertion of the needle into the magnetizer. Next, the quality of visualization and correlation of the needle tip and NGS on US during the procedure were assessed. After a short test of functionality, TNtargeting punctures were performed (Fig. 3).

Six radiology residents and a staff radiologist were asked to puncture each of the target nodules using a 23-gauge needle. A staff radiologist (E.J.H.) and a radiology assistant (Y.J.C.) judged whether the puncture procedure was successful and touched the center of the target nodule, and a research nurse (Y.J.K.) observed movement of the 23-gauge needle hub outside of the phantom and recorded the procedure time. Puncture success was achieved when the 23-gauge puncture needle touched the target nodule (Fig. 3). Puncture success for the target nodule on the first attempt was recorded as technical success. If the first attempt failed, it was repeated until successful and the total number of punctures was counted. Technical success rates of right-handed needling versus left-handed needling and 7-mm versus 4-mm target attempts were also recorded. The same process was repeated five times, and the entire process was also performed with the in-plane technique using a 5–12 MHz linear transducer and conventional US machine (RS85, Samsung Medison Co. Ltd.).



Fig. 3. Ultrasonography-guided procedure with a needle guidance system. The electromagnetic needle guidance system shows spatial information of the needle (dashed lines), as well as a target box superimposed on the currently acquired ultrasonographic images.



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Fig. 2. Preparation of the needle guidance system.

A. A portable ultrasonographic apparatus with a standard needle magnetization system and a needle are used. B. After a brief insertion of the needle into the magnetizer (1-2 seconds), the performance indicator in the bottom left corner of the display shows full green bars, indicating good functionality of the system.

Statistical analyses were conducted using SPSS version 25.0 (IBM Corp., Armonk, NY, USA) with the Wilcoxon signed-rank test to compare success rates between the conventional in-plane technique and the NGS-assisted technique using standard needle magnetization, left-handed needling and right-handed needling, and 7-mm and 4-mm target attempts. In all analyses, a P-value <0.05 was interpreted as indicating statistical significance.

Results

Technical Feasibility of a Standard Needle Magnetization System for Ultrasound Needle Guidance

The performance indicator showed good functionality after a short (1–2 seconds) insertion of the needle into the magnetizer in all cases (140/140). When the needle came close to the US transducer before its insertion into the skin, the NGS recognized the spatial orientation of the needle in relation to the US transducer in real time in all cases. During the targeting puncture, the technical feasibility of NGS using standard needle magnetization was 98.6% (138/140). Among the 140 attempts, the needle tip and NGS were well visualized and correlated during the procedure except for two attempts in which the direction of the needle and NGS did not fit well during the procedure, thus requiring an additional puncture for

success.

Efficacy of Ultrasound NGS in Targeting Punctures

Table 1 compares the technical success rates between the conventional in-plane technique and the NGS-assisted technique using standard needle magnetization. In group 1, the technical success rate significantly increased from 60.0%±8.2% to 80.0%±8.2% when the NGS-assisted technique was used (P=0.046), with a decrease in the mean number of punctures from 2.2 to 1.2 (P=0.005). The rate was not significantly different for the NGS technique between left- and right-handed needling (P=0.480) or between 7-mm and 4-mm target attempts (P>0.99). In group 2, the rate slightly increased from $95.0\% \pm 5.8\%$ to $100.0\% \pm 0.0\%$ with use of the NGS-assisted technique (P=0.157), with a minimal decrease in the mean number of punctures from 1.1 to 1.0 (P=0.157), although the differences were not statistically significant. Group 3 consistently showed excellent outcomes, without significant differences in the technical success rate and the number of punctures according to whether the NGS was used (P=0.317 and P=0.317, respectively). There were no differences between left- and right-handed needling or between 7-mm and 4-mm target attempts (all P>0.05).

Table 2 compares the procedure times between the techniques. In

Table 1. Comparison of the technical success rate and t	the number of	f punctures l	between th	e conventional	in-plane tecl	hnique and
the technique assisted by the needle guidance system	l					

	Group 1				Group 2			Group 3		
	Conventional	With NGS	P-value	Conventional	With NGS	P-value	Conventional	With NGS	P-value	
Technical success rate (%)	60.0 (24/40)	80.0 (32/40)	0.046	95.0 (38/40)	100 (40/40)	0.157	100 (60/60)	98.3 (59/60)	0.317	
Right-handed needling	60.0 (12/20)	85.0 (17/20)	0.059	90.0 (18/20)	100 (20/20)	0.157	100 (30/30)	100 (30/30)	>0.99	
7 mm	50.0 (5/10)	80.0 (8/10)	0.180	90.0 (9/10)	100 (10/10)	0.317	100 (15/15)	100 (15/15)	>0.99	
4 mm	70.0 (7/10)	90.0 (9/10)	0.157	90.0 (9/10)	100 (10/10)	0.317	100 (15/15)	100 (15/15)	>0.99	
Left-handed needling	60.0 (12/20)	75.0 (15/20)	0.317	100 (20/20)	100 (20/20)	>0.99	100 (30/30)	96.7 (29/30)	0.317	
7 mm	60.0 (6/10)	80.0 (8/10)	0.157	100 (10/10)	100 (10/10)	>0.99	100 (15/15)	93.3 (14/15)	0.317	
4 mm	60.0 (6/10)	70.0 (7/10)	0.705	100 (10/10)	100 (10/10)	>0.99	100 (15/15)	100 (15/15)	>0.99	
No. of punctures ^{a)}	2.2 (87/40)	1.2 (48/40)	0.005	1.1 (42/40)	1.0 (40/40)	0.157	1.0 (60/60)	1.0 (61/60)	0.317	
Right-handed needling	2.0 (40/20)	1.15 (23/20)	0.018	1.1 (22/20)	1.0 (20/20)	0.157	1.0 (30/30)	1.0 (30/30)	>0.99	
7 mm	2.2 (22/10)	1.2 (12/10)	0.068	1.1 (11/10)	1.0 (10/10)	0.317	1.0 (15/15)	1.0 (15/15)	>0.99	
4 mm	1.8 (18/10)	1.1 (11/10)	0.102	1.1 (11/10)	1.0 (10/10)	0.317	1.0 (15/15)	1.0 (15/15)	>0.99	
Left-handed needling	2.4 (47/20)	1.3 (25/20)	0.103	1.0 (20/20)	1.0 (20/20)	>0.99	1.0 (30/30)	1.0 (31/30)	0.317	
7 mm	2.5 (25/10)	1.2 (12/10)	0.180	1.0 (10/10)	1.0 (10/10)	>0.99	1.0 (15/15)	1.1 (16/15)	0.317	
4 mm	2.2 (22/10)	1.3 (13/10)	0.380	1.0 (10/10)	1.0 (10/10)	>0.99	1.0 (15/15)	1.0 (15/15)	>0.99	

Group 1 indicates radiology residents with <50 cases of experience with thyroid fine-needle aspiration, while group 2 indicates radiology residents with ≥ 50 cases and <100 cases of experience with thyroid fine-needle aspiration. Group 3 indicates experienced radiology residents and a staff radiologist with ≥ 100 cases of experience with thyroid fine-needle aspiration.

NGS, needle guidance system.

^{a)}Numbers are mean values.

	Group 1			Group 2			Group 3		
	Conventional	With NGS	P-value	Conventional	With NGS	P-value	Conventional	With NGS	P-value
Procedure time (s)	46.3±59.2	24.4±23.1	0.041	27.9±21.3	17.6±7.9	0.010	6.3±2.4	9.0±3.6	< 0.001
Right-handed needling	53.4±59.7	34.7±31.0	0.027	25.6±19.9	18.7±9.0	0.109	5.6±2.0	8.7±3.9	0.001
7 mm	56.6±48.1	31.1±38.3	0.126	29.0±23.3	20.0±7.0	0.373	4.4±0.5	6.0±1.7	0.038
4 mm	50.1±72.0	22.2±19.1	0.123	22.1±16.3	17.3±10.8	0.138	6.8±2.3	11.4±3.6	0.005
Left-handed needling	39.2±59.3	22.2±14.2	0.641	30.3±22.9	16.5±6.8	0.070	7.0±2.6	9.2±3.4	0.018
7 mm	45.0±67.5	19.9±14.9	0.359	34.8±21.5	17.3±6.5	0.074	6.6±1.8	9.4±3.4	0.131
4 mm	33.4±52.8	24.5±13.8	0.799	25.7±24.4	15.6±7.3	0.677	7.4±3.4	9.0±3.7	0.078

Table 2. Comparison of the total procedure time between the conventional in-plane technique and the technique using the needle guidance system

Values are presented as mean \pm standard deviation. Group 1 indicates radiology residents with <50 cases of experience with thyroid fine-needle aspiration, while group 2 indicates radiology residents with \geq 50 cases of experience with thyroid fine-needle aspiration. Group 3 indicates experienced radiology residents and a staff radiologist with \geq 100 cases of experience with thyroid fine-needle aspiration.

NGS, needle guidance system.

groups 1 and 2, the time significantly decreased with the technique assisted by NGS (P=0.002). It decreased from 46.3 ± 59.2 seconds to 24.4 ± 23.1 seconds in group 1 (P=0.041) and from 27.9 ± 21.3 seconds to 17.6 ± 7.9 seconds in group 2 (P=0.010) with the NGS-assisted technique. However, in group 3, the time slightly increased from 6.3 ± 2.4 seconds to 9.0 ± 3.6 seconds when the NGS-assisted technique was used (P<0.001).

Discussion

NGS using the standard needle magnetization system showed technical feasibility and efficacy for performing TN-targeting punctures in terms of improving the technical success rate while decreasing the number of punctures and procedure time for less-experienced operators. These observations indicate that the electromagnetic NGS can be useful for practical training in TN-targeting punctures, particularly for beginners.

The use of high-resolution US, combined with increased medical surveillance and access to health care services, has markedly increased the detection of TNs and number of FNAs [1,2,17]. Although FNA is an accurate and safe procedure for the diagnosis of TNs, sampling errors and procedure-associated complications have been reported [6]. Thyroid FNA is commonly performed at primary care centers by experienced radiologists, as well as many other clinicians, including endocrinologists, surgeons, family practice physicians, and other non-imaging specialists. Therefore, it is necessary to properly guide beginners and less-experienced operators in the performance of thyroid FNA in practice. Although it is necessary to track the needle from its insertion into the skin, its advancement through the soft tissues, and its entry into the target nodule in a long-axis approach, or at least the tip of the needle in

a short-axis approach, accurate and consistent visualization of the needle alignment and tip is often difficult to achieve. In addition, insertion of the needle with an appropriate angle and direction into the skin is important to reduce targeting errors and minimize pain in the patient. Therefore, the conventional technique has a learning curve for operators. Electromagnetic needle tracking is a method that permits real-time needle spatial acquisition [8]. When the needle is located within a controlled magnetic field, voltage is induced in the sensor and used to calculate the position and orientation of the needle. In this study, we used a commercially available electromagnetic NGS in a portable US system for TNtargeting punctures to overcome the difficulty of determining the insertion angle of the needle and tracking the needle tip for targeting TNs. The system was easy to operate after magnetic polarization of the needle, and in almost all cases, it recognized the spatial orientation of the needle in relation to the US transducers in real time and guided the TN-targeting punctures before needle insertion.

The technical success rate significantly increased with the technique assisted by NGS, particularly in the beginners' group (experience <50 cases of TN-targeting punctures). This ultimately resulted in reductions in both the number of punctures and procedure-related time, thus indicating the potential of this system as an effective method to improve the puncture accuracy and to decrease procedure-related pain and complications in thyroid FNA. Although there were no significant differences in the experienced group (\geq 100 cases of TN-targeting punctures), both hands can be easily used to handle the transducer and hold the needle, regardless of the target size and depth. Freesmeyer et al. similarly reported the technical effectiveness and safety of NGS based on the standard needle magnetization system in performing thyroid FNA [8]. They

suggested that the appearance of the needle tip out-of-plane in combination with a color change in the NGS target box allows the operator to confirm the correct intranodular placement with confidence. As it is common for less-experienced operators to miss the anatomical targets, resulting in injuries to the vessels, trachea, and esophagus, we consider that this system would be effective for guiding less-experienced operators in performing thyroid FNA in the early learning period.

Several studies have reported the potential of electromagnetic NGS in many US-guided procedures, including biopsy, nerve block, spinal anesthesia, and central venous cannulation [7,9-16,18]. Kim et al. [11] reported that electromagnetic guidance significantly reduced the time required for needle placement during nerve block. In a randomized crossover study, Auyong et al. [10] demonstrated that real-time needle guidance technology significantly improved needle accuracy and performance time during cannulation of a simulated internal jugular vein in a phantom. In the present study, we developed a phantom for mimicking TN-targeting punctures. Studies were conducted by creating a situation similar to the actual depth and size of the nodules in the neck, and the results demonstrated its effectiveness. However, as performance in thyroid FNA can be affected by various factors, such as respiratory movements of the patient, swallowing, pulsating vessels, and neck muscles, as well as nodule-related factors, including location, size, and components, further studies using the NGS method in human subjects are required.

This study had several limitations. First, although the potential utility of NGS for less-experienced operators was demonstrated in this phantom study, it is uncertain whether NGS could improve the efficacy of FNA for less-experienced operators in real practice and would be helpful for training beginners in the free-hand FNA technique. However, this phantom study may suggest the potential utility of the NGS for beginners in accurate targeting and reducing the procedure time for FNA, which might shorten the learning curve and reduce the potential complication rate at an early stage of experience. Second, this study was conducted using one type of a commercially available 23-gauge 25-mm needle that we have used in practice for needle magnetization. Further studies are necessary to address these issues.

In conclusion, NGS using standard needle magnetization is technically feasible and has the potential to improve the efficacy of TN-targeting punctures for less-experienced operators, especially beginners, based on the findings of this phantom study. orcid.org/0000-0003-2771-2182; Minji Kim: https://orcid.org/0000-0002-8391-7476; Kyung-Min Lee: https://orcid.org/0000-0002-0361-0942; Sung Hyun An: https://orcid.org/0000-0003-2533-7227

Author Contributions

Conceptualization: Ha EJ. Data acquisition: Lee H, Cho YJ, Ha EJ, Moon J, Kim YN, Kim M, Kim KM, An SH. Data analysis or interpretation: Lee H, Cho YJ, Ha EJ. Drafting of the manuscript: Lee H, Cho YJ, Ha EJ, Moon J, Kim YN, Kim M. Critical revision of the manuscript: Ha EJ. Approval of the final version of the manuscript: all authors.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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ORCID: Haein Lee: https://orcid.org/0000-0002-2020-6888; Yoon Joo Cho: https:// orcid.org/0000-0002-1608-8938; Eun Ju Ha: https://orcid.org/0000-0002-1234-2919; Jayoung Moon: https://orcid.org/0000-0003-4722-3423; You Na Kim: https://

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