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Research

The changes of chronic leg oedema after recumbent position at night in chair-bound elderly Japanese individuals

Sayumi Tsuchiya[1)*], Terumi Iuchi[2)*], Aya Sato[3)], Misako Dai[4)], Imran[1)], Masato Kobayashi[2)] and Junko Sugama[2,5)]

*Tsuchiya S and Iuchi T contributed equally to this article

1) Division of Health Sciences, Graduate School of Medical Sciences, Kanazawa University, Kanazawa, Japan
2) Wellness Promotion Science Center, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, Kanazawa, Japan
3) Faculty of Nursing & Social Welfare Sciences, Fukui Prefecture University, Fukui, Japan
4) Faculty of Health Sciences, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, Kanazawa, Japan
5) Institute for Frontier Science Initiative, Kanazawa University, Kanazawa, Japan

ABSTRACT

AIM: Although many chair-bound elderly individuals suffer from leg oedema, many physicians and nurses do not place much emphasis on this condition because leg oedema usually decreases after sleeping. The aims of this study were to examine whether recumbent position at night reduces leg oedema in chair-bound elderly individuals and whether the effect of recumbent position depends on different parts of the leg.

METHODS: Participants included in this longitudinal observational study were elderly individuals of a nursing home. Leg circumference measurements, pitting tests and subcutaneous echo-free space (SEFS) grades using ultrasonography were recorded in the dorsum pedis, ankle joint, distal and proximal lower limbs, and thigh (only the leg circumference measurements and pitting test) before and after recumbent position.

RESULTS: A total of 13 participants who were over 65 years old were recruited for this study. The leg circumference decreased after recumbent position. Pitting oedema and SEFS also decreased at some sites in the leg after recumbent position, but oedema remained after recumbent position, especially in the dorsum pedis and distal lower limbs.

CONCLUSION: Oedema of the leg decreased after recumbent position at night. However, the leg oedema remained in chair-bound elderly individuals without showing any improvement, even after recumbent position at night. New treatments are needed for leg oedema, particularly ones that have an effect on the distal lower limbs and dorsum pedis.

KEY WORDS: chronic oedema, lower extremity, aged

Corresponding author: Junko Sugama
Institute for Frontier Science Initiative, Kanazawa University, 5-11-80, Kodatsuno, Kanazawa, Japan
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BACKGROUND

Leg oedema is likely to occur and become chronic among the elderly due to their lower levels of physical activity and periods of prolonged sitting, along with various other environmental and physical factors of ageing, such as a decline in cardiovascular function, lower limb muscle pumping, increased skin tension and a decline in nutritional status. In Japan, the prevalence of oedema throughout the body is 66.2% for patients in long-term care facilities, with most of the oedema occurring in the legs[1], and the prevalence of leg oedema in the elderly was 75% and that of the chair-bound elderly was 92%[2]. Among the elderly, those who are chair-bound are more likely to have leg oedema.

Although numerous problems associated with chronic leg oedema have been reported in the elderly, many medical and nursing professions do not place much emphasis on this condition because leg oedema usually decreases after sleeping. Leg oedema causes lethargy and listlessness[3,4]. It not only reduces physical activity and the willingness to be active but also may increase the risk of falling due to an impaired range of movement in the ankle[5]. Numerous studies have also shown that leg oedema has a large impact on the quality of life (QOL) in the elderly as they become more susceptible to skin injuries, such as pressure ulcers[6] and skin tears[7,8], through the increasing fragility of their skin. Proper relief for chronic leg oedema is therefore important for improving the safety and comfort of elderly individuals while maintaining their QOL. However, their oedema is less likely to be under control compared to the oedema of those under 65 years old[9]. Similarly, a large number of elderly individuals have not received any specific treatment for oedema[10]. Therefore, we need to demonstrate the importance of the care for chronic leg oedema among the elderly using objective data.

Previous studies have found that the leg oedema in chair-bound elderly individuals worsened over time. Kitamura reported that the leg circumferences of chair-bound elderly individuals increased significantly over time[11,12] and that a number of subjective leg symptoms, such as the feeling of swelling, heaviness and awkwardness when moving the leg, increased significantly over time among the chair-bound elderly[12].

However, no studies have assessed whether leg oedema decreases in chair-bound elderly individuals after recumbent position at night. As oedema from sitting is strongly affected by gravity, a reduction in swelling can be expected with recumbency at night. However, the degree of reduction is not yet known. If the oedema is not sufficiently reduced when the individuals are laying down to sleep at night, the need for care is clear. The aims of this study were to examine whether recumbent position at night effectively reduces leg oedema in chair-bound elderly individuals and to examine whether the effect varies according to different parts of the leg.

METHODS

1. Study design and participants

This study had a longitudinal observational design and was conducted between March 2015 and July 2015 at a special nursing home for the elderly in Ishikawa Prefecture, Japan.

The participants in this study included elderly residents of the special nursing home for the elderly who were ≥65 years old. The inclusion criteria for this study are as follows: i) chronic leg oedema, which was defined as persistent swelling of the lower limb for more than 2 weeks and ii) sitting for a longer period than standing during the daytime. The exclusion criteria are as follows: i) a poor general condition by a nurse's judgement and ii) an inability to obtain informed consent from the individual and/or their family members.

The ethics committee of Kanazawa University approved this study (permit no. 556-1), and all of the participants or their family members gave informed written consent.

2. Methods

Leg circumference measurements, pitting tests and ultrasonography were recorded for all of the study participants before and after recumbent position. Each set of observations required approximately 50 min, and all of the measurements were taken while the participants were in a supine position.

1) Leg circumference

Measuring the leg circumference is one of the

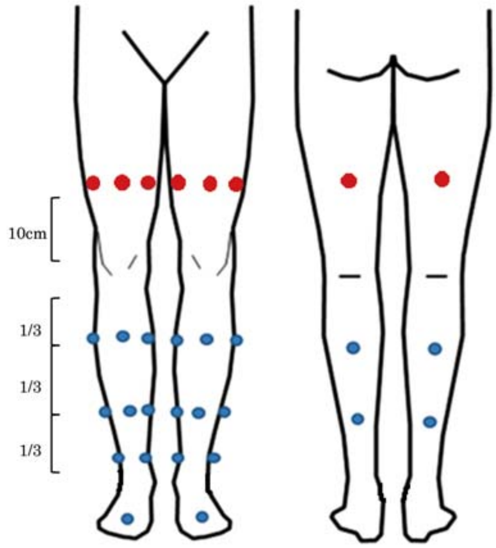

Fig. 1 Measurement sites
Blue circle indicates sites of leg circumference, pitting test and ultrasonography, and red indicates sites of leg circumference and pitting test.

methods used to determine the severity of oedema, the appropriate treatment, and the effectiveness of treatment[13]. This measurement is the most widely used method because it is easy and reliable[13]. In this study, repeated training was performed until the investigator was able to take accurate measurements (the intraclass correlation coefficient (ICC (1,1)) was 0.999), and all of the measurements were made by the same investigator. Measurements were taken for both the right and left sides at the following sites (a total of 10 sites): dorsum pedis, ankle joint, distal lower limb, proximal lower limb, and thigh (**Fig. 1**).

2) Pitting test

Pitting indicates the presence of excess interstitial fluid, and the depth of indentation reflects the severity of the oedema[13]. The pitting test was conducted as it was described in a previous study[14]. The investigator applied an even amount of pressure on the measuring site with the right thumb for 10 seconds, and the depth of pitting was then assessed. The depth of pitting was measured using the physical examination method with a 5-point grading scale: 0: 0 mm; 1+: ≤2 mm; 2+: ≤4 mm; 3+: ≤6 mm; and 4+: >6 mm[15]. Repeated training was conducted until the investigator was able to apply a consistent pressure (ICC (1,1): 0.923), and all of the measurements were made by the same investigator. Measurements were taken for both the right and left sides at the following sites (a total of 30 sites): dorsum pedis, lateral and medial ankle joints, distal lower limbs (anterior, posterior, lateral, and medial), proximal lower limbs (anterior, posterior, lateral, and medial) and thighs (anterior, posterior, lateral, and medial) (**Fig. 1**).

3) Ultrasonography

Ultrasonography is useful for assessing leg oedema because it can assess fluid accumulation[16-18], inflammation[16,17,19], and fibrosis[19]. In this study, it was used to assess fluid accumulation. Both the right and left sides of the following sites were recorded by ultrasonography (a total of 22 sites): dorsum pedis, lateral and medial ankle joints, distal lower limbs (anterior, posterior, lateral, and medial) and proximal lower limbs (anterior, posterior, lateral, and medial) (**Fig. 1**). We did not measure their thighs by ultrasonography because the images of this site did not change between before and after recumbent position. An ultrasound device (Noblus; Hitachi Medical, Tokyo, Japan) was used for the imaging. Using a 15 MHz to 18 MHz linear probe (L64), the setting was standardized as follows: gain: 15; dynamic range: 70 dB; and focus: 0.5 cm. The probe was placed in the dorsum pedis on the short-axis view, with the other sites on the long-axis views. Repeated training in ultrasound imaging techniques was performed by the investigator beforehand, and the same investigator took all of the images.

4) Participants' characteristics

The following information was collected from the medical records of the participants: age, gender, past and current medical histories, body mass index (BMI), total protein (TP), serum albumin (Alb), and status of drug intake. The following anthropometric measurements were taken: triceps skin folds (TSF), arm circumference (AC), and arm muscle circumference (AMC).

5) Exogenous variables

Daytime sitting and recumbent hours were determined through participant observation. Night-time sitting and recumbent hours were determined by interviewing the nursing staff and through information gathered by placing a sheet sensor (Nemuri Scan; Paramount Bed, Tokyo, Japan)[20] under the mattress, which recorded the time that the individual spent in bed.

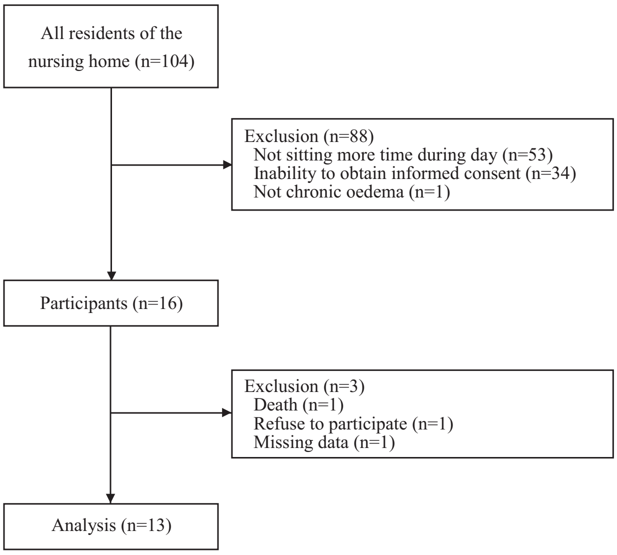

Fig. 2 Flow chart of participants

3. Analysis

1) Leg circumference

The leg circumference was determined by calculating the medians on the right and left sides of each participant. We compared the differences before and after recumbent position.

2) Degree of pitting

We defined ≥2 + as the presence of oedema and assessed the degree of oedema for each site. We compared differences before and after recumbent position.

3) Ultrasonography

The subcutaneous echo-free space (SEFS) grade was used for the assessment[17,18]. SEFS indicated the accumulation of fluid in the subcutaneous tissue and serves as a direct indicator that allows for the determination of the presence and severity of oedema. In this study, the grading range was between grade 0 and grade 2. A higher grade indicated a higher level of intercellular fluid accumulation or more severe oedema. We defined grade 1 or grade 2 as the presence of oedema and counted the degree of oedema for each site. The validity of the grading was ensured by verifying the consistency of the investigator's assessments with those of an expert in ultrasonography of the lower limb.

4. Statistical analysis

For the analysis of the leg circumference, the Wilcoxon signed-rank test with Bonferroni correction was performed to determine the extent of the difference between before and after recumbent position. SPSS version 22 software (IBM-SPSS, Inc. Chicago, IL, USA) was used for the statistical analysis, and the level of significance was set at 5%. For the degree of pitting and ultrasonography, we calculated the percentage of participants who had oedema and compared it between before and after recumbent position.

RESULTS

1. Participants' characteristics

All 104 individuals of the nursing home were assessed to determine whether they were eligible to participate in the study. A total of 16 participants were recruited after excluding those who did not meet all of the inclusion criteria or who met any of the exclusion criteria. An additional 3 participants were subsequently excluded due to the following reasons : death (n=1), refusal to participate (n=1), and missing data (n=1). Therefore, a total of 13 participants were included in the analysis (**Fig. 2**). The demographic data of the participants are shown in **Table 1**. The median age and median BMI were 85 years (interquartile range (IQR) : 82-92 years) and 21.0 kg/m^2 (IQR : 18.8-22.5 kg/m^2), respectively. In terms of gender, 10 of the participants (76.9%) were women. According to the International Statistical Classification of Diseases and Related Health Problems Tenth Revision (ICD-10), the majority of participants (8 participants ; 61.5%) had mental and behavioural disorders. The next most common disease was disease of the circulatory system (7 participants ; 53.8%), and one of these patients suffered from heart failure. While none of the participants were taking diuretics, 7 participants (53.8%) were taking medications for which oedema was reported to be a side effect. The median daily sitting time of the participants was 9 h 45 min.

2. The change in leg circumference (Table 2)

The median leg circumference after recumbent position was decreased compared to that before recumbent position in all of the sites. In the Wilcoxon signed-rank test with Bonferroni correction, the median leg circumference after recumbent position was significantly lower than that before recumbent position in the dorsum pedis, ankle joints, distal lower limbs, and proximal lower limbs ($p<0.05$).

3. The change of pitting oedema sites ≥2 + (Table 3)

After recumbent position, the number of pitting

Table 1 The demographic data of the individuals included in the study.

	N	%	Median	IQR
Age			85	82–92
Sex				
Male	3	23.1		
Female	10	76.9		
BMI (kg/m^2)			21.0	18.8–22.5
ICD-10				
Mental and behavioural disorders	8	61.5		
Diseases of the circulatory system	7	53.8		
Endocrine, nutritional and metabolic diseases	3	23.1		
Diseases of the digestive system	1	7.7		
Diseases of the genitourinary system	1	7.7		
Medicine				
Diuretics	0	0		
Medications with oedema as a reported side effect	7	53.8		
Sitting time			9 h 45 min	8 h 50 min–11 h 45 min
Recumbent time			12 h 50 min	10 h 30 min–14 h 20 min
TSF (mm)			9.7	8.0–18.3
AMC (cm)			20.2	19.2–20.5
TP (g/dl)[a]			7.0	6.9–7.1
Alb (g/dl)[b]			3.6	3.5–3.9

N=13. [a]N=9 ; [b]N=11.
IQR : interquartile range ; ICD-10 : International Statistical Classification of Diseases and Related Health Problems, Tenth Revision ; TSF : triceps skin folds ; AMC : arm muscle circumference ; TP : total protein ; Alb : serum albumin.

Table 2 The change in the leg circumferences of the individuals from before recumbent position to after recumbent position.

	Before recumbent position Median (IQR) cm	After recumbent position Median (IQR) cm	*p*
Dorsum pedis	22.0 (21.8–22.8)	21.7 (21.4–22.0)	<0.05
Ankle joints	24.5 (24.1–25.0)	24.1 (23.6–24.3)	<0.05
Distal lower limbs	21.3 (21.2–21.9)	20.8 (20.7–21.2)	<0.05
Proximal lower limbs	28.2 (28.2–29.0)	27.2 (27.0–27.9)	<0.05
Thigh	36.1 (35.2–36.4)	35.3 (34.8–36.2)	n.p.

IQR : interquartile range.

oedema sites ≥2 + decreased in the dorsum pedis, lateral and medial ankle joints, posterior and medial distal lower limbs, lateral proximal lower limbs, and anterior and posterior thighs. However, pitting oedema sites remained after recumbent position and were observed at the dorsum pedis, lateral and medial ankle joints, anterior, posterior, lateral, and medial distal lower limbs, and posterior proximal lower limbs.

4. The change in the SEFS (Table 4)

The number of sites with SEFS decreased at night

Table 3 The change of pitting oedema sites ≥2 + of the patients from before recumbent position to after recumbent position.

	Before recumbent position Number of sites	%	After recumbent position Number of sites	%
Dorsum pedis	13	50.0	4	15.4
Lateral ankle joints	5	19.2	2	7.7
Medial ankle joints	7	26.9	4	15.4
Anterior distal lower limbs	1	3.8	1	3.8
Posterior distal lower limbs	4	15.4	5	19.2
Lateral distal lower limbs	2	7.7	2	7.7
Medial distal lower limbs	6	23.1	3	11.5
Anterior proximal lower limbs	0	0.0	0	0.0
Posterior proximal lower limbs	1	3.8	1	3.8
Lateral proximal lower limbs	1	3.8	0	0.0
Medial proximal lower limbs	0	0.0	0	0.0
Anterior thigh	1	3.8	0	0.0
Posterior thigh	1	3.8	0	0.0
Lateral thigh	0	0.0	0	0.0
Medial thigh	0	0.0	0	0.0

Table 4 The change in the SEFS of the patients from before recumbent position to after recumbent position.

	Before recumbent position Number of sites	%	After recumbent position Number of sites	%
Dorsum pedis	26	100.0	23	88.5
Lateral ankle joints	22	84.6	14	53.8
Medial ankle joints	22	84.6	19	73.1
Anterior distal lower limbs	13	50.0	8	30.8
Posterior distal lower limbs	17	65.4	15	57.7
Lateral distal lower limbs	17	65.4	3	11.5
Medial distal lower limbs	14	53.8	7	26.9
Anterior proximal lower limbs	4	15.4	2	7.7
Posterior proximal lower limbs	13	50.0	10	38.5
Lateral proximal lower limbs	9	34.6	3	11.5
Medial proximal lower limbs	5	19.2	5	19.2

while the individuals took recumbent position, except for the proximal medial lower limb. However, the SEFS remained after the individuals took laying recumbent position, and it was observed in over half of the sites in the dorsum pedis, lateral and medial ankle joints and posterior distal lower limbs after recumbent position.

DISCUSSION

Our findings indicate that recumbent position did not fully relieve oedema by itself. In this study, the leg circumference in chair-bound elderly individuals was improved with recumbency. However, pitting oedema sites ≥2 + and sites with SEFS grades 1 and 2 remained after recumbent position. Many medical and nursing professions do not place much emphasis on leg oedema because it usually decreases after sleeping, but leg oedema is present after recumbent position. Therefore, we need to identify better treatments for leg oedema in chair-bound elderly individuals.

The changes in the degree of oedema observed in this study were due to prolonged sitting. In general, heart failure is known to cause oedema[21], but only one participant in this study had been diagnosed with heart failure. Furthermore, no participants had cancer or liver or kidney disorders. In addition, the lowest Alb level of any of the individuals was 2. 8 g/dl. While some participants had Alb levels below average, the concentrations remained above 2.5 g/dl, which is the level at which oedema arises due to malnutrition. For the participants without Alb data, only 1 participant showed a below average BMI, TSF and AMC. The chronic leg oedema observed among the participants in this study was thus attributed to physical changes associated with ageing. Sodium, along with hormones, could also play a role in the oedema, but there were no data on these parameters in the participants. However, since the degree of oedema was alleviated by recumbent position at night, the oedema was considered to be very likely caused by the reduced venous and lymphatic refluxes that result from prolonged sitting.

Based on the results of this study, the leg oedema in chair-bound elderly individuals did not improve after recumbent position. In this study, the leg circumferences decreased by 0.3 cm in the dorsum pedis, decreased by 0.6 cm in the ankle joints, and decreased by 0.5-1.0 cm in the lower limbs. In a previous study, the leg circumferences of chair-bound elderly individuals increased by 0.8-0.9 cm in the dorsum pedis, increased by 0.5-0.6 cm in the ankle joints, and increased by 1.1-1.2 cm in the lower limbs[11]. Therefore, recumbent position would be effective in reducing leg oedema. However, pitting oedema and SEFS were shown in the dorsum pedis, ankle joints, and lower limbs after recumbent position. Because pitting oedema and SEFS are not normally observed in the subcutaneous tissue of the legs of healthy adults after sleeping, these findings indicate that the leg oedema in chair-bound elderly individuals is chronic and severe. Leg oedema remained in the chair-bound elderly individuals, and this condition may greatly affect the QOL of this patient population[12], as lethargy and listlessness decrease their levels of daytime activity.

The present study indicates that palliative treatment for oedema of the distal lower limbs and dorsum pedis may be necessary for chair-bound elderly individuals. After recumbent position, the study participants experienced a greater pitting oedema of 2+ or SEFS of the distal lower limbs and dorsum pedis. Leg oedema is known to impair the range of movement of the ankle[5]. An impaired range of movement of the ankle may, in turn, affect transfer motions and upright activities, possibly leading to falls during daily activities. Oedema relief in the distal lower limbs and dorsum pedis is important for chair-bound elderly individuals so that they can maintain their activities of daily living.

There are some limitations to this study. Because each participant was observed for only one day, the degree of change in the levels of oedema with continuous observation over the long-term remains unknown. Maintaining a prolonged sitting position may continuously aggravate the degree of oedema. If that is the case, the need for oedema relief care will become even more important. A long-term study is needed to clarify the need for this type of care. Additionally, the number of participants used in this study was small because the study was conducted at one facility to unify the sitting time. Furthermore, our participants were chair-bound elderly individuals, and elderly individuals who have a loss of mobility may not apply to this population.

CONCLUSION

We compared the degree of oedema and the effect that recumbent position has in chair-bound elderly individuals because many medical and nursing professions do not place much emphasis on this condition because leg oedema usually decreases after sleeping. In the results of this study, the leg oedema of these individuals decreased after recumbent position. However, leg oedema remained in the chair-bound elderly individuals even after recumbent position, and their oedema did not improve. Thus, a better treatment for leg oedema, particularly in the distal lower limbs and dorsum pedis, is required.

Acknowledgements

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座位をとる日本の高齢者における夜間臥床による慢性下腿浮腫の変化

土屋紗由美[1)]* 井内 映美[2)]* 佐藤 文[3)] 臺 美佐子[4)] Imran[1)] 小林 正和[2)] 須釜 淳子[2,5)]

1)金沢大学大学院医薬保健学総合研究科保健学専攻
2)金沢大学医薬保健研究域附属健康増進科学センター
3)福井県立大学看護福祉学部
4)金沢大学医薬保健研究域保健学系
5)金沢大学新学術創成研究機構
＊共同筆頭著者

要 旨

座位をとる高齢者の多くが下腿浮腫を有しているにも関わらず，夜間臥床により浮腫が軽減することから，浮腫ケアに重点がおかれていない現状がある。本研究の目的は，夜間臥床により下腿浮腫は軽減するのかどうかを評価すること，および下腿の部位によって夜間臥床の効果は異なるのかどうかを評価することである。

研究デザインは縦断的観察研究で，対象者は特別養護老人ホーム 1 施設に入所する高齢者 13 名とした。夜間臥床前後に，下腿の周囲径測定，圧痕検査，超音波検査を用いた皮下組織内の水分貯留状況の評価（SEFS）を行った。

周囲径測定では，夜間臥床によって周囲径の減少が認められた。圧痕検査および SEFS では，下腿の数か所で浮腫の軽減が認められたが，浮腫が完全になくなることはなく，特に足背と下腿遠位に浮腫が残る結果となった。

夜間臥床により浮腫は軽減するが，浮腫がなくなることはない。そのため，座位をとる高齢者に対する下腿浮腫，特に足背と下腿遠位の浮腫に対するケアの必要性が示された。

キーワード：慢性浮腫，下肢，高齢者

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Research

Validity of pocket ultrasound device to measure thickness of subcutaneous tissue for improving upper limb lymphoedema assessment

Misako Dai[1], Miho Shogenji[1], Kiyoko Matsui[2], Keiko Kimori[3], Aya Sato[4], Hiroko Maeba[1], Mayumi Okuwa[1], Chizuko Konya[2], Junko Sugama[5] and Hiromi Sanada[6)7]

1) Faculty of Health Sciences, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University
2) School of Nursing, Kanazawa Medical University
3) Faculty of Nursing, Ishikawa Prefectural Nursing University
4) Faculty of Nursing & Social Welfare Sciences, Fukui Prefectural University
5) Advanced Health Care Science Research Unit, Innovative Integrated Bio-Research Core, Institute for Frontier Science Initiative, Kanazawa University
6) Department of Gerontological Nursing/Wound Care Management, Division of Health and Nursing, Graduate School of Medicine, The University of Tokyo
7) Global Nursing Research Center, Graduate School of Medicine, The University of Tokyo

ABSTRACT

Ultrasonography can be used to assess the pathology of lymphoedema. The aim of the present study was to evaluate the validity of measuring the thickness of subcutaneous tissue with a Vscan portable ultrasound device with a linear-type probe compared with the gold standard Noblus ultrasound device and to clarify the ability of the Vscan to differentiate early- and late-stage lymphoedema. Ultrasound images of subcutaneous tissue in the 102 forearms of 51 healthy volunteers were assessed qualitatively and quantitatively. We identified the subcutaneous tissue, and then qualitatively classified the clarity of the results. In the quantitative analysis, we calculated the correlation, limits of agreement (LoA), and counted the number of differences within and outside the LoA to determine the cut-off point. Subcutaneous tissue could be discerned clearly in all images. Thicknesses measured using the Vscan and Noblus were highly correlated (R^2=0.86 ; $P<0.01$). A Bland-Altman plot revealed that slightly higher thicknesses were measured with the Vscan ; the difference between thickness measurements was 0.320 mm (LoA : -0.64 to 1.28). Using the cut-off point, the Vscan can be used to estimate thickness within 5.0 mm of that measured with the Noblus. The Vscan will contribute to the management of patients with early-stage lymphoedema.

KEY WORDS : lymphoedema, pocket ultrasoud device, thickness of subcutaneous tissue, validity

Corresponding author : Misako Dai
Faculty of Health Sciences, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, 5-11-80, Kodatsuno, Kanazawa, Japan
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Introduction

Ultrasonography can be used to assess the pathology of lymphoedema in real time, directly and noninvasively. Upper limb lymphoedema is chronic oedema caused by dysfunction of the lymphatic system in the upper limb following axial lymph node dissection and radiotherapy[1) for breast cancer. It results from the accumulation of protein-rich fluid in the skin and subcutaneous tissue[2) of the upper limb. In early-stage lymphoedema (stages 0, I and part of II), as classified by the International Society of Lymphology (ISL)[3), there is accumulation of fluid. Subsequently, in advanced-stage lymphoedema (ISL late stage II and stage III) the volume of fluid increases and becomes an accumulation of lipids[4). These changes in the skin and subcutaneous tissue due to upper limb lymphoedema can be visualized on ultrasound images.

Some studies have identified particular aspects of lymphoedema using ultrasonography[4-9). For example, subcutaneous tissue is thicker and has a cobblestone appearance on images acquired using 7.5- to 10-MHz probes[4-9). The skin of affected limbs exhibits increased thickness[4) and numerous low echogenicity pixels (LEP)[5, 6) on images acquired using a 20-MHz probe. These reports indicate that the accumulation of fluid and lipids[7) can be visualized on ultrasound images as increased thicknesses of the skin and subcutaneous tissue.

Although ultrasonography can be used to assess the pathology of lymphoedema, its use in clinical settings is currently limited by the lack of devices that can be easily moved to different assessment locations. Patients with lymphoedema need to be assessed in multiple environments, including outpatient clinics, rehabilitation rooms and home-care settings. This is because management of patients with lymphoedema spans all stages of the condition. We therefore focused on pocket ultrasound devices (PUD), which are approximately the same size as a smartphone. These devices can fit in a clinician's pocket, are simple to operate, and provide real-time images. Given their small size, PUD can be easily transported between assessment locations.

Previous studies have reported the use of PUD to examine cardiac patients[10, 11) and perform abdominal ultrasound[12) using a sector-type probe. However, because a sector-type probe focuses on deep areas of the body, it is not suitable for assessing subcutaneous tissue. Recently, PUD with a linear-type probe have been developed, and are expected to be used for measuring the thickness of subcutaneous tissue for assessment of upper limb lymphoedema.

Several studies have examined the results of using PUD with a linear-type probe, including bedside screening for carotid artery stenosis[13) and visual assessment at several sites where pressure ulcers frequently occur (i. e. sacrum, greater trochanter, heels)[14). However, these anatomical structures differ from the limbs of patients with lymphoedema. Furthermore, the validity of measuring the thickness of subcutaneous tissue using a PUD has not yet been confirmed.

The validity of measuring the thickness of subcutaneous tissue using a PUD with a linear-type probe needs to be assessed by comparison with traditional, high-specificity ultrasonography. Furthermore, clarification of the lymphoedema stage (early or advanced) should be possible using a PUD for application in the clinical setting.

Aim

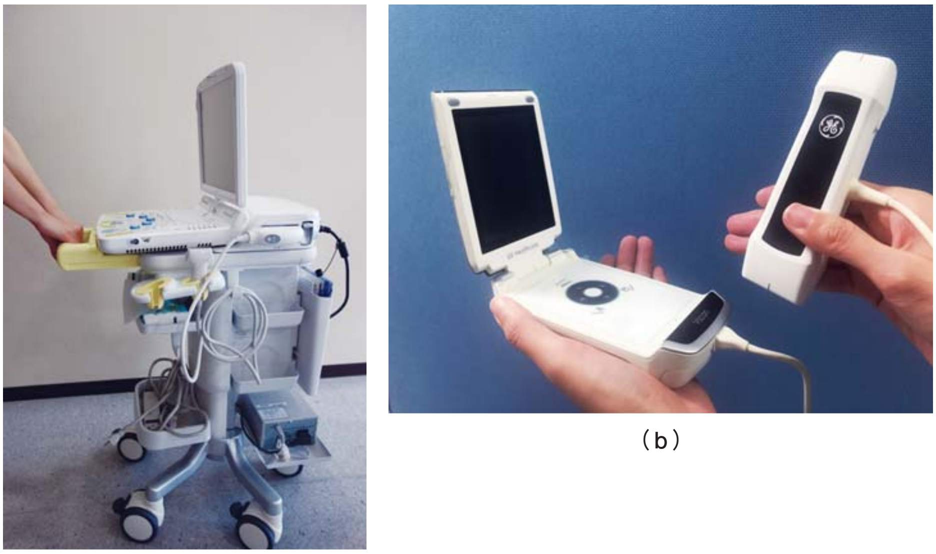
The objectives of this study were to evaluate the validity of measuring the thickness of subcutaneous tissue using a PUD compared with using a standard ultrasound device (SUD) for healthy subjects.

Materials and methods

1. Study design and participants

This observational study was performed between April and July 2015. We recruited participants from a university and the local community. At the university, we informed two teachers who understood about this study and then informed the students in their classrooms. In the local community, we informed a group of residents living in the same neighbourhood who were interested in researches.

Participants who fulfilled the following criteria were eligible for the study : more than 20 years old and no oedematous disease in the upper limbs. Participants with skin disease or evidence of skin trauma at the



(a) (b)

Fig. 1 Portable ultrasound device (Noblus) (**a**) and hand-held ultrasound device (Vscan Dual Probe) (**b**).
The Noblus is transported on a cart. The Vscan is small enough to fit in a clinician's pocket.

measurement site on the forearm were excluded.

All protocols were approved by the ethics committee at Kanazawa University (No. 587-1), and all participants signed an informed consent form prior to participation in the study.

2. Ultrasound devices

The PUD selected for the present study was the Vscan (Vscan dual probe ; General Electric Vingmed Ultrasound, Horten, Norway), which has a linear probe. The SUD was the Noblus (Hitachi Aloka Medical, Tokyo, Japan), the gold standard for ultrasonography in both research and clinical settings. According to the efficiency of the Vscan, we focused on measuring the thickness of subcutaneous tissue excluding the skin and assessing the internal echo.

The Noblus is 350×380×513 mm (width×height×depth), weighs 9 kg, and has a screen size of 300×350 mm. This portable ultrasound device can be transported on a cart (**Fig. 1a**). The images generated using its 10-MHz linear-type probe have a distance resolution of 0.8 mm with display resolution of 3,114×4,448 pixels. This type of ultrasound device is used most often in clinical settings and research facilities.

The Vscan is 135×73×28 mm, weighs 400 g, and has a screen size of 70×25 mm (**Fig. 1b**). This hand-held device easily fits into a clinician's pocket. The images generated using its 5.2-MHz linear-type probe have a distance resolution of 2.0 mm with display resolution of 240×320 pixels.

3. Procedures

Before the start of measurements, the investigator marked the measurement site at 10 cm proximal to the ulnar styloid process[5] on both medial forearms of participants using a dermatological pen (**Fig. 2**). The participants sat in a chair with the arm supported initially in abduction. The examiner measured the circumference of each participant's arm three times at the marked point. The thickness of the subcutaneous tissue was then measured using the Noblus and Vscan. Both ultrasound devices were operated by a researcher who was instructed on how to perform the assessment and has experience for lymphoedema assessment by ultrasonography over five years.

The examinations were initially performed using the Noblus, and then the same researcher repeated the examination using the Vscan. The examiner set the probe on the marked site longitudinally. Images were recorded in the native format for the specific device. The gain was adjusted to increase the resolution of the deeper boundaries and compensate for the natural attenuation of signals as the ultrasound waves passed through the tissue. In each image of the subcutaneous

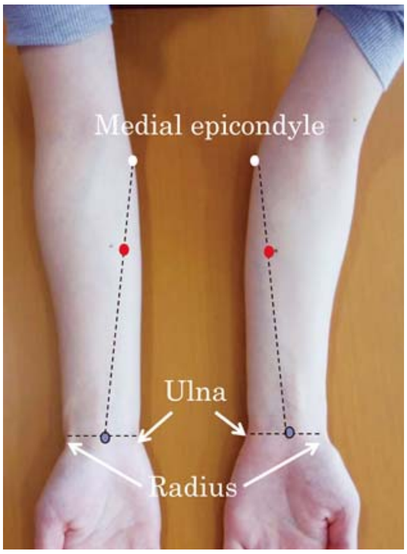


Fig. 2 Illustration of the process for determining the site on the forearm for measuring the thickness of subcutaneous tissue.

A hypothetical straight line was drawn from the midpoint (blue circle) between the ulna and radius to the medial epicondyle. The point along the line 10 cm proximal to the ulnar styloid process was marked with a dermatological pen as the measurement site (red circle).

tissue, we measured the thickness using the software provided with the respective devices. When measuring the subcutaneous tissue, we initially identified the subdermal layer and deep fascia, and then measured the centre of these images, because this point was matched with the centre of the probe (**Fig. 3**). We obtained three images and measured the thickness three times at the same point. Mean thicknesses were used for subsequent analyses. In a pilot study, a researcher calculated an intraclass correlation coefficient (ICC) of 0.96 for the Noblus and 0.98 for the Vscan.

4. Analysis

1) Qualitative analysis

Firstly, we identified the subdermal layer and deep fascia as the boundaries to define the subcutaneous tissue[4, 6, 7]. The Vscan has a lower resolution than the Noblus; therefore, we evaluated the feasibility of identifying the subcutaneous tissue even if it thickens. We compared the findings of the subdermal layer and deep fascia qualitatively between normal weight [body mass index (BMI) <25 kg/m^2] and overweight (BMI ≥25 kg/m^2) individuals[15] in consideration of clinical applications for a PUD.

These images were visually classified as *very clear*, *clear*, or *unclear*. We defined *very clear* as images with clearly observable features, *clear* as images with clearly observable features, but with some indistinct findings, and *unclear* as images without any observable features.

2) Quantitative analysis

The correlation between the thicknesses of subcutaneous tissue measured using the Vscan and Noblus was analysed using Pearson's correlation coefficient.

Subsequently, a Bland–Altman plot was generated to evaluate the level of agreement between the two methods. Bland–Altman plot analysis is a way to evaluate a bias between mean differences, and to estimate an agreement interval[16]. In the present study, the Bland–Altman plot is a scatterplot of the mean of the subcutaneous thicknesses measured using the Vscan and Noblus plotted against the differences in measurements between the two methods. This plot provides a visual representation of the level of agreement between the differences in subcutaneous thicknesses [(thickness by Noblus) − (thickness by Vscan)] determined by both methods. The average of the differences allows us to estimate whether one of the two methods underestimated or overestimated the thickness more than the other. The other two lines in the plot represent the limits of agreement (LoA). If the points on the graph are between the LoA, the two methods provide consistent results. Furthermore, to determine the cut-off point for the Vscan when measuring the thickness of subcutaneous tissue, we counted the number of differences within and outside the LoA.

Statistical analysis was conducted using JMP® statistical software (SAS Institute, Cary, NC, USA). Descriptive data were expressed as mean and standard deviation for continuous variables and were analysed statistically. P values < 0.05 indicated statistical significance.

5. Data availability

The datasets analysed during the current study are not publicly available because it is not included in contents of the ethical approval, but datasets are available from the corresponding author on reasonable request.

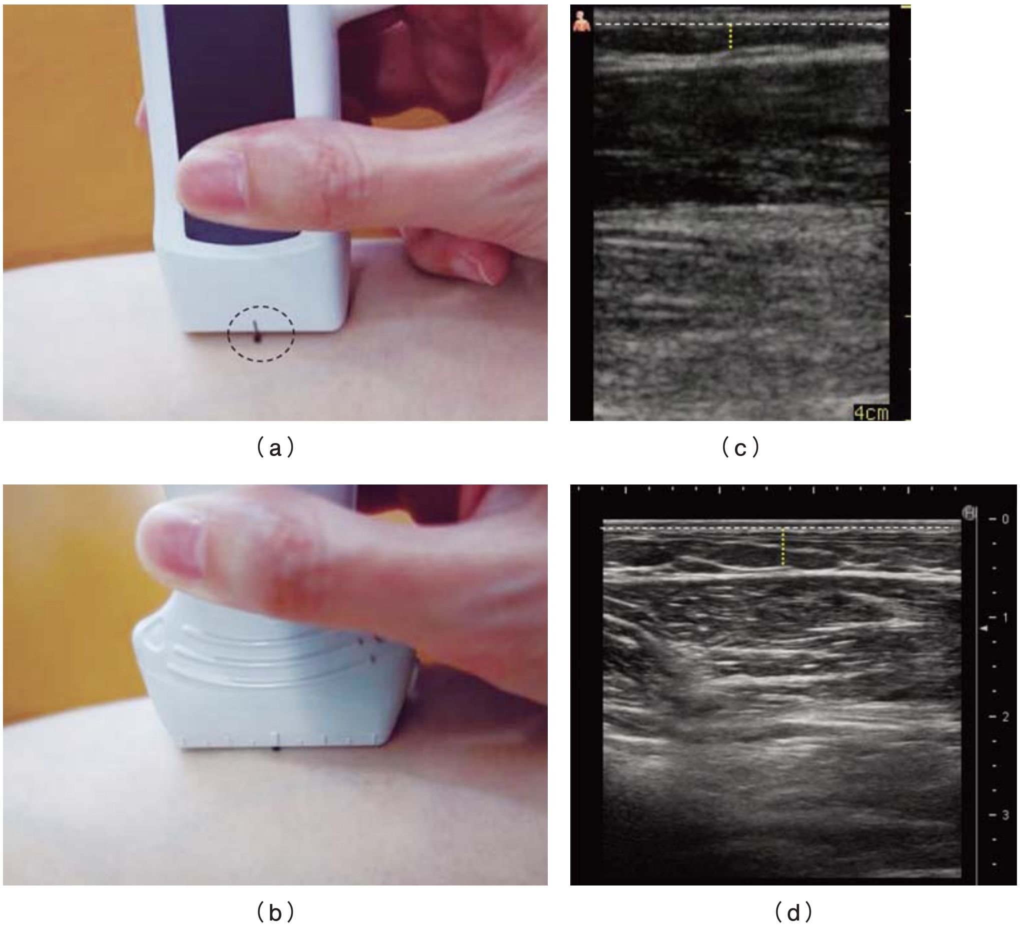


Fig. 3 Alignment of the measurement site and the center of the probe : Vscan (**a**) and Noblus (**b**). Imaging of subcutaneous tissue and selection of the measurement point (center of image) : Vscan (**c**) and Noblus (**d**).

Results

Fifty-one students and residents who agreed to participate in the study were enrolled and 70% were females. The mean age at the day of measurement was 41.5 ± 20.8 years, and the mean BMI was 23.2 ± 4.8 kg/m^2. We analysed 102 limbs from all participants both of the right and left forearms (right 22.8 ± 2.9 cm, left 22.5 ± 2.8 cm).

For the qualitative findings, subcutaneous tissue could be discerned in all images by locating the dermal layer and deep fascia in both normal weight (**Fig. 4**) and overweight cases (**Fig. 5**). Although we were able to discern the subcutaneous tissue clearly in all images, the rate of *very clear* for the Vscan was lower than that for the Noblus, especially in the overweight cases (**Table 1**).

Fig. 6 shows a plot of the subcutaneous thicknesses measured using the Noblus and Vscan. The thicknesses of subcutaneous tissue in the forearm represent the mean of three measurements (Noblus : 3.20 ± 1.74 mm, Vscan : 2.88 ± 1.54 mm, respectively) ; Pearson's correlation coefficient for the thicknesses measured by the Noblus and Vscan was high (R^2 = 0.86 ; $p<0.01$).

The Bland-Altman plot in **Fig. 7** indicates agreement between the thicknesses measured using the Noblus and Vscan. The horizontal lines represent the average of the differences, the upper and lower LoA and the mean difference of 0.32 ± 0.59 (95% confidence interval : 0.20-0.43). Slightly higher differences were obtained between the thicknesses measured using the Vscan. The 95% LoA ranged from -0.64 to 1.28.

The distribution of the differences within and outside the LoA showed a large number of differences within the LoA when the thicknesses measured using the Noblus were less than 5.0 mm (**Table 2**).

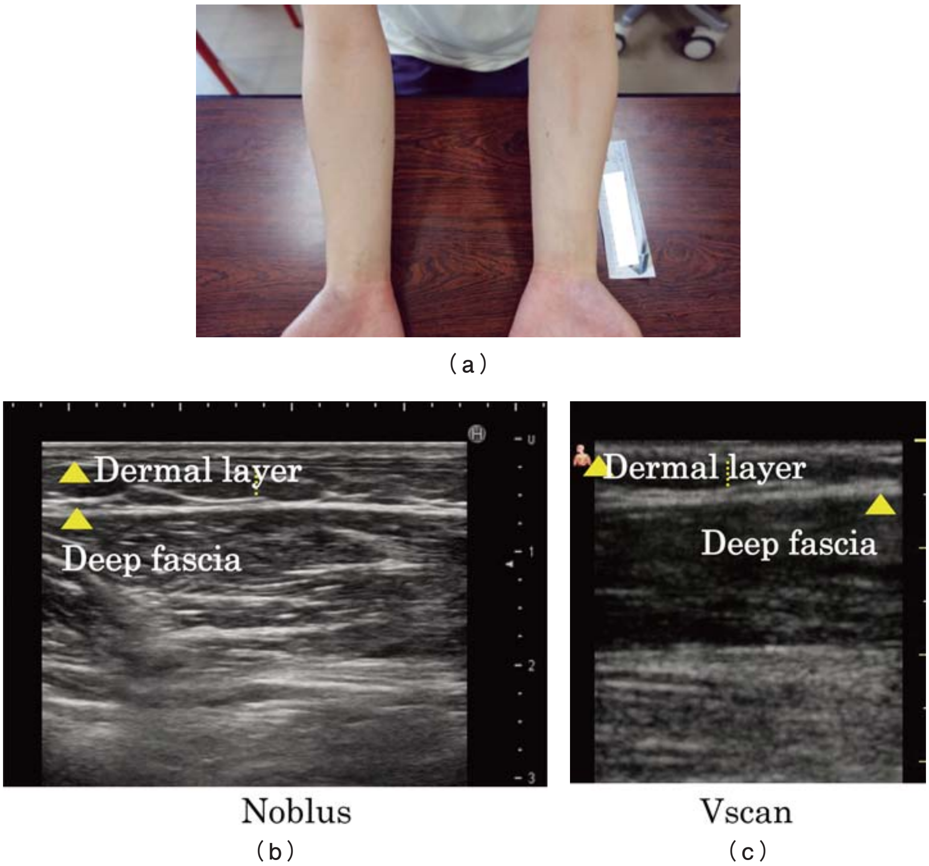


Fig. 4 Example images of subcutaneous tissue acquired using the Noblus and Vscan (normal weight case).

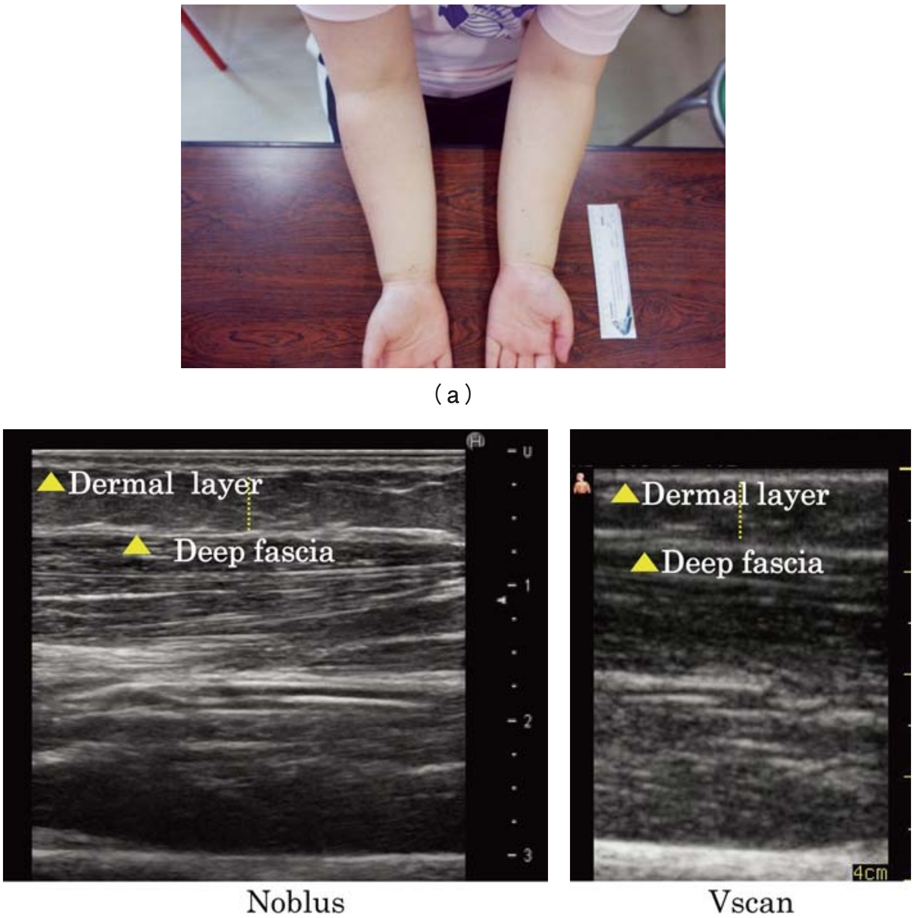
The participant (**a**) was a 20-year-old female with a BMI of 20.4 kg/m^2. The dermal layer and deep fascia are visible in both images. The thickness of the subcutaneous tissue was 3.4 mm by Noblus (**b**) and 3.7 mm by Vscan (**c**).

Discussion

We showed in this validation study that a PUD with a linear-type probe can be used to measure the thickness of subcutaneous tissue in the medial forearm. To the best of our knowledge, this is the first study to reveal the feasibility and validity of measuring the thickness of subcutaneous tissue using a hand-held ultrasound device. The subcutaneous tissue could be identified clearly in all images acquired by the Vscan, and thicknesses measured using the Vscan correlated highly with those measured using the Noblus. Furthermore, at thicknesses less than 5.0 mm, the Vscan was able to measure the thickness of subcutaneous tissue within the LoA.

The gold standard for the assessment of lymphoedema is measuring the circumference of the affected and unaffected limbs[17)]. The site recommended for measuring the arm circumference is located 10 cm distal from the elbow[18)]. This site was used in the present study. Circumference measurements are very easy, and have excellent intra-rater and inter-rater reliability[18)]. However, differences less than 0.5 cm, including error, cannot be assessed using circumference measurements. Furthermore, circumference measurements include the skin, muscle, bone, fat and fluid[19)], which makes assessment of the pathology of lymphoedema difficult.

In the qualitative assessment, the subcutaneous tissue could be identified clearly in all images acquired by the Vscan. In the quantitative analysis, the thicknesses of subcutaneous tissue measured using the Vscan were highly correlated with those measured using the Noblus ($R2=0.86$, $P \leq 0.01$). In the Bland-Altman analysis, the difference between the Noblus and Vscan was 0.320 (LoA : -0.64 to 1.28), indicating that thicknesses measured using the Vscan were thinner than those measured using the Noblus. The distribution of differ-



(b) (c)

Fig. 5 Example images of subcutaneous tissue acquired using the Noblus and Vscan (overweight case).

The participant (**a**) was a 20-year-old female with a BMI of 32.8 kg/m^2. The dermal layer and deep fascia are visible in both images. The thickness of the subcutaneous tissue in the left arm was 6.1 mm by Noblus (**b**) and 5.2 mm by Vscan (**c**).

Table 1 Qualitative assessment of detecting the dermal layer and deep fascia using the Vscan and Noblus

	BMI<25 kg/m^2 (n=72)		BMI≥25 kg/m^2 (n=30)	
	Vscan	Noblus	Vscan	Noblus
Dermal layer [a]				
Very Clear	61 (84.7)	67 (93.1)	22 (73.3)	23 (76.6)
Clear	11 (15.2)	5 (6.9)	8 (26.7)	5 (16.6)
Unclear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deep fascia [a]				
Very Clear	59 (81.9)	71 (99.7)	20 (66.7)	28 (93.4)
Clear	13 (18.1)	1 (1.3)	10 (33.3)	2 (6.6)
Unclear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Number (%)
BMI : Body mass index. a ; *Very clear* : each feature clearly visible, *Clear* : some features partly unclear, *Unclear* : no visible features

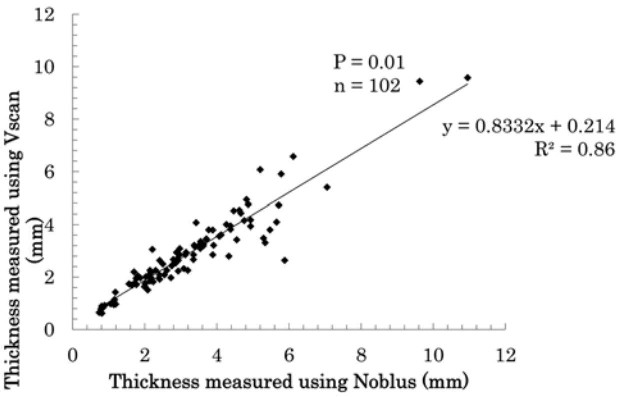


Fig. 6 Correlation of thicknesses of subcutaneous tissue measured using the Noblus and Vscan.

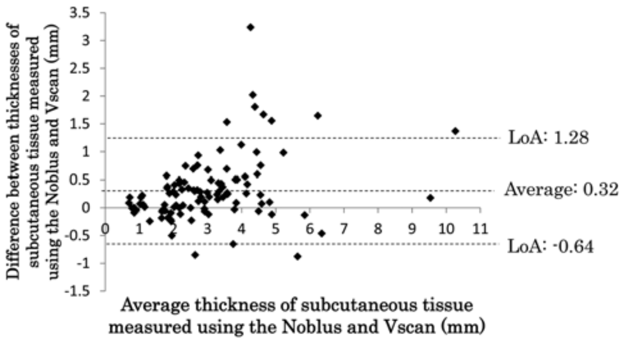


Fig. 7 Bland-Altman plot of thicknesses of subcutaneous tissue measured using the Noblus and Vscan. LoA: limit of agreement.

Table 2 Distribution of differences in subcutaneous thicknesses measured using the Noblus and Vscan within and outside the LoA

Thickness measured using Noblus (mm)	n	Difference between Noblus and Vscan (mm)	Within LoA (n)	Outside LoA (n)
t<2.0	24	-0.04 (-0.50 – 0.35)	24	0
2.0≤t<3.0	31	0.26 (-0.84 – 0.74)	30	1
3.0≤t<4.0	20	0.28 (-0.65 – 1.02)	19	1
4.0≤t<5.0	15	0.50 (-0.12 – 1.53)	14	1
5.0≤t<6.0	8	1.61 (-0.87 – 3.23)	3	5
t≥6.0	4	0.77 (-0.46 – 1.64)	2	2
Total	102		92	10

t : thickness of subcutaneous tissue measured using Noblus, n : number, LoA : limit of agreement
Differences between the Noblus and Vscan are shown as the median and range.

ences within and outside the LoA indicated that most of the differences at thicknesses over 5.0 mm were outside the LoA. In a previous study, the mean thickness of subcutaneous tissue in the medial forearm on the affected side in patients with upper limb lymphoedema was 5.5 ± 2.2 mm, while the mean thickness on the unaffected side was 3.3 ± 2.0 mm[4]. The participants in that study were likely patients with advanced lymphoedema. Our results suggest that the Vscan will be able to measure clearly the thickness of subcutaneous tissue in patients with early-stage (stage 0 or I) lymphoedema.

This study has a limitation. The Noblus and Vscan were not used in a random order. All images were first acquired using the Noblus, followed by the Vscan. This indicates that images of subcutaneous tissue can be acquired easily using the Vscan following use of the Noblus. However, the Vscan could be focused easily on subcutaneous tissue, and images could be acquired easily in all cases. Therefore, problems are not likely to be encountered when obtaining images of subcutaneous tissue using only the Vscan.

In this study, we evaluated the validity of measuring the thickness of subcutaneous tissue using a Vscan with a linear-type probe by comparison with measurements obtained using a Noblus. Clinically, measuring the thickness of subcutaneous tissue using ultrasonography systems such as the Noblus is the standard method to assess patients with lymphoedema. A hand-held device with appropriate specificity would be useful for assessment of patients with early-stage lymphoedema in clinical settings. The Vscan is compact and easy to use; therefore, it will contribute to improvement of lymphoedema assessment.

Conclusion

The Vscan can measure the thickness of subcutaneous tissue in the forearm to within 5.0 mm of thicknesses measured when using the Noblus. This device will contribute to management of patients with early-stage lymphoedema.

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Author Contributions Statement

M.D. designed the study and concepts and performed the experiments, analysis the data and drafting of the manuscript. J.S., M.O. and H.S. reviewed the research data and all manuscript text. M.S., K.M., K.K., A.S and C.K. assisted correcting the data. H. M. put the data to analysis. All the authors discussed about the results and commented on manuscript.

Additional Information

Competing financial interests：None

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上肢リンパ浮腫評価向上に向けたポケット型エコーの皮下組織厚計測の妥当性評価

臺　美佐子[1)]　正源寺美穂[1)]　松井希代子[2)]　木森　佳子[3)]　佐藤　　文[4)]　前馬　宏子[1)]　大桑麻由美[1)]
紺家千津子[2)]　須釜　淳子[5)]　真田　弘美[6)7)]

1)金沢大学医薬保健研究域保健学系
2)金沢医科大学看護学部
3)石川県立看護大学看護学部
4)福井県立大学看護福祉学部
5)金沢大学新学術創成研究機構革新的統合バイオ研究コア 先端的ヘルスケアサイエンスユニット
6)東京大学大学院医学系研究科健康科学・看護学専攻 老年看護学/創傷看護学分野
7)東京大学グローバルナーシングリサーチセンター

要　旨

【背景と目的】リンパ浮腫患者の病態評価に超音波画像診断装置（エコー）を用いた真皮・皮下組織観察は有効な方法である。本研究では，臨床や在宅への応用が期待されるポケット型エコーであるV scanを高性能エコーであるNoblusと比較して，皮下組織厚計測の妥当性を検証した。
【方法】研究デザインは横断観察研究で，対象は健康成人51名の102肢とした。前腕内側にエコーのリニア型プローブを長軸に当て皮下組織厚を計測した。VscanとNoblusで計測した皮下組織厚を比較し，誤差範囲（LoA）及びBland-Altmanプロットによる妥当性評価を行った。本研究は金沢大学医学倫理審査委員会の承認を得た。
【結果】健康成人51名の102肢に対して実施した。ポケット型エコーV scanは高性能エコーNoblusで計測した皮下組織厚と高い相関を示した（R^2＝0.86；P＜0.01）。Bland-Altman plotでは，V scanで計測した皮下組織厚の値がNoblusに比較して0.320 mm厚かった（LoA：−0.64 to 1.28）。また，5.0 mm以内の皮下組織厚の場合に高い妥当性が示された。
【結論】ポケット型エコーによる前腕内側の皮下組織厚計測に，ポケット型エコーは有用であることが示唆された。ただし，皮下組織厚5.0 mm以内の対象者への計測が望ましく，皮下組織の薄い早期リンパ浮腫患者への適用が期待される。

キーワード：リンパ浮腫，ポケットエコー，皮下組織厚，妥当性

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Travels

Lessons learnt from the 8th International Lymphoedema Framework Conference in Rotterdam, the Netherlands

Gojiro Nakagami

Department of Gerontological Nursing/Wound Care Management and Global Nursing Research Center The University of Tokyo

From September 6th to 9th, 2018 we attended the 8th International Lymphoedema Framework Conference in Rotterdam, the Netherlands, which was held on a beautiful ship, the SS Rotterdam. Originally, this ship was used to bring people from Rotterdam to New York since her maiden voyage in 1959. After completing her service as a cruise ship, she was restored and restarted as a hotel/museum in 2010. As the attendees of the conference come from across the world, this venue is best located to make people focused on discussing the challenges and future perspectives of lymphoedema management.

The events hosted by ILF attract more people each time, as the framework continues to grow internationally. This time, about 560 clinicians and researchers gathered together. In all, 85 research papers and 54 poster abstracts were presented to move lymphoedema management forward. Among them, poster prizes were awarded to two fascinating studies: one went to Jane Armer for her research entitled "A study of incidence of and risk factors for breast cancer-related lymphoedema in Ghana," and the other went to Margareta Haag for her study "Patient empowerment by increased knowledge and practice."

Members of ILF Japan had a great opportunity to introduce the advanced techniques for managing lymphoedema and chronic edema that have been developed and practiced in Japan. Our workshop, titled "Comprehensive approach for assessing chronic edema," was composed of five presentations focusing on two major health challenges in chronic edema management in Japan: dependent chronic edema in the elderly, and recurrent cellulitis in secondary lymphoedema patients. As for the introductory talk, Professor Hiromi Sanada (Director of ILF Japan, The University of Tokyo) pointed out the significance of having edema as an independent risk factor for pressure ulcer development, which was confirmed by medical big-data analysis. After that Professor Junko Sugama (Board member, Kanazawa University) reported the brief results from the LIMPRINT (Lymphoedema IMpact and PRevalence-INTernational Lympoedema Framework) study to emphasize the impact of chronic edema. She also introduced the prognosis of chronic edema in the Japanese elderly population, among which 13.3% will worsen in severity. Dr. Aya Sato (Board member, Fukui Prefectural University) presented the relationship between the severity of edema in the lower extremities and nutritional status among elderly Japanese individuals. The two presentations relating to

Corresponding author : Gojiro Nakagami
Department of Gerontological Nursing/Wound Care Management and Global Nursing Research Center, The University of Tokyo, 7-3-1 Hongo, Bunkyoku, Tokyo, Japan
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Figure 1　SS Rotterdam

Figure 2　Workshop

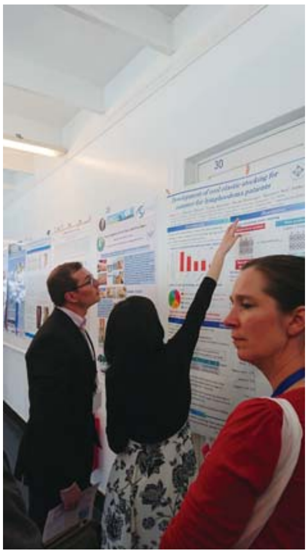

Figure 3　Poster session

Figure 4　ILF board members

chronic edema gained international attention by shedding light on this underestimated problem. Following these impressive presentations, Dr. Misako Dai (Administrator, Kanazawa University) presented an advanced approach for assessing skin structure and function with the aid of sophisticated modalities, ultrasonography and thermography, for secondary lymphoedema patients. The major issue in this population includes the recurrence of cellulitis, which has a considerable impact on lymphoedema severity and therefore patients' quality of life. Her approach enables clinicians to objectively detect the subtle structural and functional changes within the skin which might predispose cellulitis development. Combining these modalities, cellulitis will be further explored to understand the pathophysiology, and to establish an effective prevention strategy for recurrent cellulitis. Finally, I introduced a new direction in predicting secondary lymphoedema onset after cancer surgery. For assessing the potential of local skin tissue to regrow the collateral lymph vessels after lymph node dissection or sentinel lymph node biopsy followed by obstruction of lymph flow, quantifying locally secreted vascular endothelial growth factor-C (VEGF-C) would be a promising way. Skin blotting is a method that can capture and quantify the secreted protein noninvasively through the skin. Our workshop went well with great cooperation by the kindest audience. The ILF conference is always encouraging and full of the warmest atmosphere, which makes us so relieved and confident.

There have been some exciting technological advancements in lymphoedema management devices. One unique device that was recently introduced can apply negative pressure and mechanical vibration on the skin in order to accelerate lymphatic drainage (LYMPHATOUCH, LymphaTouch, Inc).

At one ceremony, Emeritus Professor Hugo Partsch was awarded for his life-time achievement for edema management. Everyone on the ship celebrated his dedication to patients with various types of edema.

Rotterdam is a beautiful city with a lot of rivers. Watertaxi is the most convenient transportation for going downtown. Every time we got on board we felt as though we were on an exciting adventure. Among all of the beautiful and modern architecture, we were able to contemplate the future of our direction in lymphoedema and chronic edema management.

The next ILF conference will be held in Chicago, USA from June 13^{th} to 15^{th} 2019. This 9^{th} conference will be co-hosted by the American Lymphedema Framework Project. We do look forward to attending the next conference with an even greater number of participants from Japan!