ISSN 2188-1375

# リンパ浮腫管理の研究と実践

LYMPHOEDEMA RESEARCH AND PRACTICE



国際リンパ浮腫フレームワーク・ジャパン 研究協議会

International Lymphoedema Framework Japan

# 目 次

# [Research]

### Research

Development of a health service evaluation dataset for lymphedema patients and assessment of its content-related validity and operability

Terumi Iuchi<sup>1)</sup>, Misako Dai<sup>2)</sup>, Yukie Sakai<sup>1)</sup>, Gojiro Nakagami<sup>3)</sup>, Hiromi Sanada<sup>3)</sup>, Mayumi Okuwa<sup>2)</sup>, Toshio Nakatani<sup>2)</sup>, Christine J. Moffatt<sup>4)</sup> and Junko Sugama<sup>2)5)</sup>

Graduate School of Medical Sciences, Division of Health Sciences, Graduate Course of Nursing Science, Kanazawa University, Kanazawa, Japan.<sup>1)</sup>

Department of Clinical Nursing, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, Kanazawa, Japan.<sup>2)</sup>

Department of Gerontological Nursing/Wound Care Management, Division of Health Science and Nursing, Graduate School of Medicine, University of Tokyo, Japan.<sup>3)</sup>

Department of Clinical Nursing Research, Faculty of Medicine & Health Sciences, The University of Nottingham, Nottingham, United Kingdom. 40

Wellness Promotion Science Center, College of Medical, Pharmaceutical and Health Sciences, Kanazawa University, Ishikawa, Japan.<sup>5)</sup>

#### **ABSTRACT**

The aim of the present study was to develop a health service evaluation dataset for lymphedema patients and assess its content validity and operability. We established a working group to produce English and Japanese versions of the Health Service Evaluation Dataset (HSED), which consisted of input interface the following domains: a characteristic domain, combined health service/objective domain, and subjective domain. Data were collected from six lymphedema experts from Japan, four from the United Kingdom, and one each from Canada and Denmark. The experts were asked to enter data of five patients into either the Japanese or English version of HSED. Following the collection and analysis of responses, we evaluated the content validity using the content validity index and assessed operability using two factors. When >50% of the participants responded that HSED was "easy" to use and when input times were less than the standard value, we considered that the input screen was easy to operate.

In both the English and Japanese versions, content validity indices were ≥0.8 for all the domains, suggesting that HSED had a high validity. In terms of operability, 60.0-100.0% of the participants found it easy to input data into all domains. Input times were less in the Japanese version than the standard value, except for the health service/objective domain. Two participants did not know how to edit or delete the data, which could be corrected by providing an operational guide in the future.

KEY WORDS: lymphedema, dataset, content validity, operability

Correspondence author: Junko Sugama

Manuscript received: 13 August 2013

Department of Clinical Nursing, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, Kanazawa, Japan.

University, Kanazawa, Japan.

5-11-80 Kodatsuno, Kanazawa, Japan, 920-0942

#### Introduction

Lymphedema is a chronic condition characterized by edema, usually involving one or more limbs and, in some cases, the trunk, head, and/or genital region<sup>1)</sup>. Primary lymphedema is caused by congenital or acquired abnormalities or diseases originating in the lymphatic system, whereas secondary lymphedema results from surgery, trauma, or disease not originating in the lymphatic system. Causes of secondary lymphedema include filariasis, neoplasms, radiation injury, and surgical excision of lymph nodes<sup>2)</sup>.

Although primary and secondary lymphedema can significantly impair the quality of life (QOL), evidencebased treatments are few and little is known regarding issues within various healthcare services. According to a study conducted by the South West London Community Trust, only 64% of 823 patients with lymphedema were receiving treatment<sup>1)</sup>. However little is known about the scale of this problem; therefore, it is difficult to suggest meaningful recommendations with regard to healthcare service delivery. Problems within individual healthcare services also remain poorly understood. Therefore, these issues should be clarified through international, institutional, and individual comparisons to avoid unnecessary patient suffering because of deficits in both healthcare delivery and reimbursement. A potential solution is the development of a web-based dataset to collect data regarding lymphedema treatment and

For other diseases, web-based datasets have been successfully employed for epidemiological clarification. For example, clinical data on auto-inflammatory diseases was collected using a registry that allows users to analyze clinical presentation, disease course, and treatment response<sup>3)</sup>. In Japan, datasets have been employed to collect data in the fields of oncology and cardiovascular surgery and have been shown to be useful for research in disease prevalence and treatment effects.

However, there is no international web-based lymphedema dataset. On the basis of success in other areas, we propose that the development of a web-based lymphedema dataset would be useful to assess healthcare services.

Here, we present an international web-based lym-

phedema dataset for collecting medical data of patients with lymphedema and assess its content validity and system operability.

#### Methods

#### 1. Dataset Development

The dataset was developed according the flowchart detailed in Fig. 1. The International Lymphoedema Framework (ILF) and ILF Japan (ILFJ) collaborated to develop the dataset and formed a working group of lymphedema specialists comprising therapists, nurses, and university professors. In total, the working group included three ILF members and nine ILFJ members. A draft of the proposed data collection form was produced according to the Donabedian model of structure, process, and outcome4 to assess the quality of healthcare services. In addition, similar datasets from other fields for reference (e.g., oncology and cardiovascular surgery) were used. We finally produced a conceptual model of the structure, process, outcome, influencing factors, and diagnosis. Items suitable for inclusion in the dataset were selected from pre-existing guidelines<sup>5)</sup> and determined on the basis of a consensus. To discuss the design of the dataset, contents, and operational method, consensus meetings were held between June and October 2011, with a final meeting in June 2012, to discuss the operational methods for the first edition of the dataset. It was decided that the dataset would be named the Health Service Evaluation Dataset (HSED). First, we developed the English version, and the Japanese version was translated from the English one.

HSED consisted of four main domains: characteristic, health service, objective, and subjective (Fig. 2). The website used three input interfaces to collect data regarding the four domains. The structure of the conceptual model along with the influencing factors and diagnosis were included in the characteristic domain, the process was included in the health service domain, and the outcome was included in the objective and subjective domains. The contents of the items in each domain are shown in Table 1. Briefly, the characteristic domain included demographic data and lymphedema characteristics consisting of nine items and 11 questions. The health service and objective domains were grouped and then divided into cancer and lymphedema treat-

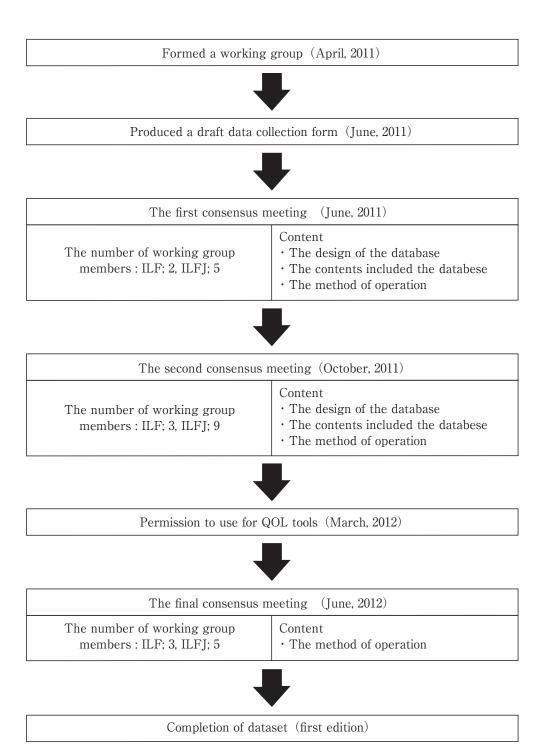


Fig. 1 Flow chart of the consensus process.

ment received by healthcare professionals, self-care, and physical examination/cellulitis/wound management, which consisted of 20 items with 47 questions. The subjective domain included symptoms, health-related QOL (HR-QOL), and social support influencing HR-QOL, which consisted of seven items and 55 questions. The HR-QOL tool employed the EuroQol 5 dimension<sup>6</sup> standardized instrument for the measurement of health

outcome, the World Health Organization Disability Assessment Schedule  $\mathrm{II}^{7)}$ , and Quality of life measure for limb lymphedema<sup>8)</sup>.

HSED users were healthcare providers who had first applied to the HSED manager for entry to the dataset. After application for entry, the HSED managers registered the users and issued user names and passwords. A separate information technology firm

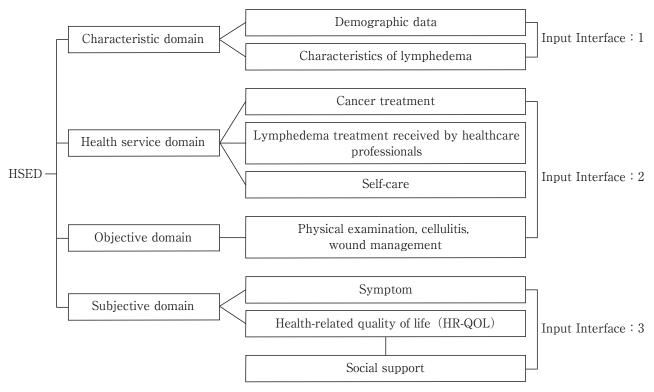


Fig. 2 Design of Health Service Evaluation Dataset (HSED).

Table 1 Contents of item in each category

Domain	Item	Number of questions	
Demographic data	data <sup>a</sup> , visit <sup>a</sup> , gender <sup>b</sup> , age <sup>a</sup> , nationality <sup>c</sup> , ethnic background	11	
Characteristics of lymphedema	time of onset of edema $^{a}$ , lymphedema classification $^{bc}$ , diagnosis $^{abc}$	11	
Cancer treatment	medical treatments (cancer treatment) in the past 6 months <sup>a,b</sup> , current medical treatments (cancer treatment) <sup>a,b</sup>		
Lymphedema treatment received by healthcare professionals	examinations (lymphedema) in the past 6 months <sup>a,b,c</sup> , status of examination <sup>a,b,c</sup> , sleeve & hosiery <sup>a</sup> , bandage <sup>a</sup>		
Self-care	selfcare in the past 6 months <sup>a</sup>	47	
Physical examination, cellulitis, wound management	swelling site <sup>b</sup> , skin stiffness <sup>b</sup> , wound <sup>b</sup> , lymphorrhoea <sup>b</sup> , cellntis <sup>b</sup> , number of infection and hospitalization <sup>a</sup> , circumference <sup>a</sup> , height/weight/body mass index <sup>a</sup> , impression <sup>b</sup> , ankle-brachial pressure index/toe brachial index <sup>a</sup> , severity <sup>b</sup> , stemmer sign <sup>b</sup>		
Symptom	status of lymphedema <sup>b</sup> , satisfaction of care <sup>b</sup>		
HR-QOL	Euroqol 5 dimension <sup>b</sup> , The World Health Organization Disability Assessment Schedule II <sup>b</sup> , Quality of life measure for limb lymphedema <sup>b</sup>	55	
Social Support	marital status <sup>b</sup> , living arrangements <sup>b</sup>		

Note

<sup>&</sup>lt;sup>a</sup> self-administering method <sup>b</sup> check method <sup>c</sup> item selective system

managed system maintenance and security, including the installation of a firewall and a secure sockets layer.

# Evaluation of Content-related Validity and Operability of HSED

#### 1) Participants

Six Japanese lymphedema experts, who were introduced to the members of the dataset working group, evaluated the Japanese version. For the English version, six lymphedema experts with good English language skills were introduced to the members of the dataset working group, of whom four were from the United Kingdom, one from Canada and one from Denmark.

#### 2) Methods

Participants were asked to enter information for either five patients or dummy patients into either the Japanese or English versions of HSED. Selection of the patients or dummy patients was dependent on each participant. After data entry, the researchers were asked to complete a questionnaire regarding HSED.

#### 3) Data Collection

All HSED domains were evaluated. The health service and objective domains were treated as a single domain for the purpose of evaluation because they were displayed on the same input screen. Participants were questioned about content validity and operability after inputting data on five patients. The question used for content validity was "Do you think that this domain is valid to cover the actual conditions of lymphedema patients?" The responses were based on a scale ranging from 1 (strongly disagree) to 5 (strongly agree). The following question was used to determine operability: "Is it easy to operate the screen and answer the question?" The responses were based on a scale ranging from 1 (very difficult) to 5 (very easy). In addition, we inquired about the time taken to input the data for one patient as well as the error content when inputting data and aspects that were unclear.

#### 4) Data analyses

The content validity index was calculated as follows: 1 (strongly disagree), 2 (disagree), and 3 (undecided) were categorized as "disagree," whereas 4 (agree) or 5 (strongly agree) were categorized as "agree." The content validity index was calculated by dividing the number of affirmative responses (agree) with the domain into all participants and an index of  $\geq 0.8$  was

considered to be highly valid<sup>9)</sup>. To assess operability, 1 (very difficult), 2 (difficult), and 3 (undecided) were categorized as "difficult," whereas 4 (easy) and 5 (very easy) were categorized as "easy." When >50% of the participants answered that operability was easy, this input screen was considered easy to operate. Input time was calculated by estimating the standard input time of one question at approximately 10s. To be considered as easy to operate, the median completion time criteria were as follows: within 4 min for the characteristic domain, within 7 min for the combined health service/objective domain, and within 9 min for the subjective domain.

The study protocol was approved by the Ethics Committee of Kanazawa University (permit no. 331). Written informed consent was obtained from all participants. Patient-data inputted by the participants was not used in this analysis, and all data were erased without confirmation of the contents after the questionnaires were returned.

#### Results

Demographic data of the participants is presented in **Table 2**. Five (83.3%) participants were female and four (66.7%) were nurses in both groups to assess the English and Japanese HSED versions. In the Japanese version, five (83.3%) participants had 6-10 years of experience in lymphedema treatment. In the English version, two (33.3%) participants had 0-5 years of experience in lymphedema treatment and two (33.3%) had >16 years.

#### 1. Content validity

In two domains, (the characteristic and combined health service/objective), six (100%) and five (83.3%) specialists were "agree." For each domain, the content validity index was 1.0 for the Japanese version and 0.8 for the English version. In the subjective domain, five (83.3%) specialists were "agree" for both versions. The content validity index was 0.8. The data are summarized in **Table 3**.

#### 2. Operability

For the characteristic domain, four (66.7%) and six (100%) specialists rated the Japanese and English HSED versions as easy to use, respectively. The median input time was 3.0 min (range, 1-5 min) for the

Table 2 Demographic data of participants

Contents	Japanese ver. (%)	English ver.
Gender		
Female	5 (83.3)	5 (83.3)
Male	1 (16.7)	1 (16.7)
Professionals		
Nurse	4 (66.7)	4 (66.7)
Doctor	1 (16.7)	1 (16.7)
Physiotherapist	1 (16.7)	0 (0.0)
Researcher	0 (0.0)	1 (16.7)
Years of clinical experience (year)		
0 to 5	1 (16.7)	1 (16.7)
6 to 18	3 (50.0)	2 (33.3)
>18	2 (33.3)	3 (50.0)
Years of experience in lymphedema (year)		
0 to 5	1 (16.7)	2 (33.3)
6 to 10	5 (83.3)	1 (16.7)
11 to 15	0 (0.0)	1 (16.7)
>16	0 (0.0)	2 (33.3)

Table 3 Content validity index

Donata	Ag	gree	Disagree			- CM
Domain	5	4	3	2	1	- CVI
Characteristic domain						
Japanese Ver. n (%)	1 (16.7)	5 (83.3)	0 (0.0)	0 (0.0)	0 (0.0)	1.0
English Ver. n (%)	0 (0.0)	5 (83.3)	0 (0.0)	1 (16.7)	0 (0.0)	0.8
Combined health service/ objective domain						
Japanese Ver. n (%)	1 (16.7)	5 (83.3)	0 (0.0)	0 (0.0)	0 (0.0)	1.0
English Ver. n (%)	0 (0.00)	5 (83.3)	0 (0.0)	1 (16.7)	0 (0.0)	0.8
Subjective domain						
Japanese Ver. n (%)	5 (83.3)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0.8
English Ver. n (%)	1 (16.7)	4 (66.6)	0 (0.0)	1 (16.7)	0 (0.0)	0.8

Note.

 $<sup>\</sup>mathbf{5}$  ; strongly agree.  $\mathbf{4}$  ; agree.  $\mathbf{3}$  ; undecided.  $\mathbf{2}$  ; disagree.  $\mathbf{1}$  ; strongly disagree.

CVI; content validity index. Content validity index=number of agree/number of all participant.

 $<sup>1 \ (</sup>strongly \ disagree), 2 \ (disagree), 3 \ (undecided) \ were \ categorized as \ disagree, and 4 \ (agree) \ or 5 \ (strongly \ agree) \ were \ categorized as \ agree.$ 

Table 4 Operability

D	Easy		Difficult			Input median time
Domain	5	4	3	2	1	(min) (Range)
Characteristic domain						
Japanese Ver. n (%)	1 (16.7)	3 (50.0)	2 (33.3)	0 (0.0)	0 (0.0)	3.0 (1-5)
English Ver. n (%)	1 (16.7)	5 (83.3)	0 (0.0)	0 (0.0)	0 (0.0)	3.8 (1-5)
Combined health service/objective domain						
Japanese Ver.ª n (%)	0 (0.0)	3 (60.0)	1 (20.0)	1 (20.0)	0 (0.0)	7.5 (3-22)
English Ver. n (%)	1 (16.7)	3 (50.0)	1 (16.7)	1 (16.7)	0 (0.0)	5.0 (2-10)
Subjective domain						
Japanese Ver. n (%)	0 (0.0)	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	6.0 (4-10)
English Ver.ª n (%)	0 (0.0)	3 (60.0)	1 (20.0)	1 (20.0)	0 (0.0)	6.0  (5-15)

Note.

Japanese version and 3.8 min (range, 1–5 min) for the English version.

For the combined health service/objective domain, three (60.0%) and four (66.7%) specialists rated the Japanese and English HSED versions as easy to use, respectively. The median input time was 7.5 min (range, 3-22 min) for the Japanese version and 5.0 min (range, 2-10 min) for the English version.

For the subjective domain, four (66.7%) and three (60.0%) specialists rated the Japanese and English HSED versions as easy to use, respectively. The median input time was 6.0 min (range, 4-10 min) for the Japanese version and 6.0 min (range, 5-15 min) for the English version (**Table 4**). Comments were provided in the Japanese version regarding errors and unclear aspects by two Japanese participants who indicated that they did not know how to edit or delete data in the combined health service/objective domain.

# Discussion

With regard to care of patients with lymphedema, little is known about the magnitude of the problems associated with healthcare deficits. Therefore, problems within international, institutional, and individual healthcare services must be clarified, which indicates a need for a web-based dataset that is capable of collecting

international data on healthcare received by patients with lymphedema. Here, we developed a lymphedema dataset to assess clinical settings of healthcare services worldwide.

In both of the Japanese and English versions, content-related indices were ≥0.8 for all domains. Because previous studies have shown this index to be highly valid<sup>9)</sup>, we concluded that HSED was highly valid. Although one participant responded that the content validity was consistently disagreeing with the English version because HSED has many items, all items were considered pertinent to identify factors influencing lymphedema treatment. Therefore, content-related validity indices were high in all domains. It is necessary to clarify the goal of the dataset to all users. In future, it will be necessary to collect patient data to further elucidate the actual condition of patients with lymphedema. With regard to operability, 60.0-100.0% of the participants found it easy to input data to all domains. Input times were less than expected, with the exception of the combined health service and objective domain in the Japanese version; therefore, HSED deemed as easy to use. Here, two participants required ≥20 min to input data because they did not know how to edit or delete data, thereby resulting in variable input times. This problem could be solved by providing

<sup>5;</sup> very easy. 4; easy. 3; undecided. 2; difficult. 1; very difficult.

<sup>1 (</sup>very difficult), 2 (difficult), 3 (undecided) were categorized as difficult, and 4 (easy) or 5 (very easy) were categorized as easy.

<sup>&</sup>lt;sup>a</sup> There was a deficit value (n=5).

operational guidelines and an example of data input in the future.

HSED may help to clarify problems associated with healthcare services for treating patients with lymphedema and can improve evidence-based healthcare practices worldwide, if it is used accurately. To assess the quality of healthcare services, it is useful to collect data on the combined health service/objective domain because it includes content regarding healthcare services and outcomes. Furthermore, it will be useful to include nationality in the characteristic domain to compare international healthcare services.

In conclusion, it remains unclear if all types of lymphedema were assessed in this study because we did not have access to patient data. Users also need to search the inputted data for revisions and additions. We plan to assess the ease of searching the dataset in future studies. In addition, we produced only English and Japanese versions of the dataset. For HSED to be globally applicable, translation into other major languages will be necessary.

#### Conclusions

We developed a lymphedema HSED with characteristic, health service, objective, and subjective domains and found that it had high content validity and was easy to use.

#### Conflicts of interest

The authors declare no financial and/or personal conflicts of interest with any individuals or organizations that inappropriately influenced this work.

#### References

- 1) Moffatt CJ, Franks PJ, Doherty DC, et al.: Lymphoedema: an underestimated health problem, QJM, 96 (10), 731–738, 2003.
- 2) Sitzia J, Stanton AW, Badger C: A review of outcome indicators in the treatment of chronic limb oedema, Clin Rehabil, 11 (3), 181–191, 1997.
- Toplak N, Frenkel J, Lachmann HJ, et al.: An international registry on autoinflammatory diseases: the Eurofever experience, Ann Rheum Dis, 71 (7), 1177-1182, 2012.
- 4) Donabedian A: Evaluating the quality of medical care. 1966, Milbank Q, 83 (4), 691–729, 2005.
- Lymphoedema Framework: Best practice for the management of lymphoedema. International consensus, MEP Ltd, London, 2006.
- 6) Franks PJ, Moffatt CJ, Doherty DC, et al.: Assessment of health-related quality of life in patients with lymphedema of the lower limb, Wound Repair Regen, 14 (2), 110-118, 2003.
- Ustün TB, Chatterji S, Kostanjsek N, et al.: Developing the World Health Organization Disability Assessment Schedule 2.0, Bull World Health Organ, 88 (11), 815–823, 2010.
- Keeley V, Crooks S, Locke J, et al.: A quality of life measure for limb lymphoedema (LYMQOL), J Lymphoedema, 5 (1), 26–37, 2010.
- Gephart SM, Effken JA, McGrath JM, et al.: Expert consensus building using e-Delphi for necrotizing enterocolitis risk assessment, J Obstet Gynecol Neonatal Nurs, 42 (3), 332-347, 2013.

# リンパ浮腫 Health Service Evaluation Dataset の構築と内容妥当性 および操作性の評価

井内 映美 $^{1)}$  臺 美佐子 $^{2)}$  酒井 透江 $^{1)}$  仲上豪二朗 $^{3)}$  真田 弘美 $^{3)}$  大桑麻由美 $^{2)}$  中谷 壽男 $^{2)}$  Christine J. Moffatt $^{4)}$  須釜 淳子 $^{2)5)}$ 

金沢大学大学院医薬保健学総合研究科保健学専攻看護科学領域<sup>1)</sup> 金沢大学医薬保健研究域保健学系看護科学領域<sup>2)</sup> 東京大学大学院医学系研究科健康科学・看護学専攻<sup>3)</sup>

Department of Clinical Nursing Research, Faculty of Medicine & Health Sciences, The University of Nottingham, Nottingham, United Kingdom.<sup>4)</sup>

金沢大学医薬保健研究域附属健康増進科学センター50

# 要旨

研究目的はリンパ浮腫におけるデータセットを構築し、内容妥当性および操作性を評価することである。

リンパ浮腫に精通した研究者でワーキンググループを構成し、リンパ浮腫ケアの評価を行う Health Service Evaluation Dataset (HSED) を構築した。HSED は、基本属性、ヘルスサービス/客観的評価、主観的評価の3画面で構成し、英語版と日本語版を作成し、評価を行った。対象者は、リンパ浮腫の専門家(日本語版6名、英語版6名)とし、患者5名のデータ入力と、調査票の記載を依頼した。調査票は、内容妥当性を問う質問、操作性を問う質問とした。内容妥当性は内容妥当性指数を算出した。操作性は、対象者の50%以上が容易であると回答し、さらに患者1名あたりの入力時間の中央値が基本属性4分、ヘルスサービス/客観的評価7分、主観的評価9分の基準内を容易とした。

内容妥当性指数は、全画面で 0.8 以上であった。操作性は、容易 60.0-100.0%であった。入力時間の中央値は日本語版のヘルスサービス/客観的評価で日本語版 7.5 分であったが、それ以外は基準内であった。

内容妥当性は全画面で高かった。入力の操作容易性は、全画面で基準をクリアした。しかし入力時間は1画面で基準を超えた。入力に時間のかかった対象者は、データの編集や削除の方法が不明であったとしており、オペレーションガイドの追加が必要である。

**キーワード**:リンパ浮腫、データセット、内容妥当性、操作性

# Research

# Qualitative research for risk factors of lymphoedema among nine breast cancer survivors

Emiko Kimura 1)

Aomori University of Health and Welware 10

#### **ABSTRACT**

BACKGROUND: The aims of this study were to examine risk factors (RFs) to breast cancer survivors.

**METHOD**: This qualitative and descriptive study involved nine women who had undergone breast cancer surgery and had developed lymphoedema (LE). All patients participated in a semi-structured interview to elicit specific characteristics. The interviews were transcribed. Meaningful excerpts about RFs of LE were extracted from the interview transcripts, coded, examined for similarities, and sorted into categories.

**RESULTS**: Patients were 58.6±11.0 years old at the interview. Mean body mass index (BMI) was 23.4±2.5 kg/m² at the interview. Mean LE onset was 36.9±32.2 months after surgery. ISL classification were that IIa was 7 and IIb was 2. We got 17 categories about RFs of LE. They were "using hands", "using arm", "women's role", "help for events", "working hours", "interval before returning to work", "ineffective use of sleeves", "infection", "side effects of medication", "lack of exercise", "gaining weight after surgery", "financial circumstances", "onsen", type A behavior pattern", "inability to remain still", "feeling that they would not get LE" and "no considering the affected arm".

**CONCLUSION**: This suggests that physically burdensome of life style and psychological and personality traits such as type A behavior pattern are major risk factor for patients whose right arm was affected.

KEY WORDS: lymphoedema, risk factor, breast cancer

#### Introduction

In Japan, one report claims that about 120,000 people suffer from LE<sup>1)</sup>, but this number is not based on a nationwide epidemiological study. The incidence rate of LE in women following breast cancer surgery is about 10%, and it is estimated to be about 25% following uterine cancer in Japan<sup>2)</sup>. LE is a chronic condition that has physical and psychological consequences. It can

lower quality of life, impair mobility, alter body image, lead to pain and other dysfunctions.

To assess the risk factors (RFs), information is needed on not only treatment details but also social factors and the presence of two or more other diseases<sup>3)</sup>, since LE is reported to arise from multiple factors<sup>4)</sup>. It is that the primary RFs are not just surgery and cancer treatment, but a combination of many factors, such as personal characteristics, characteristics of daily living

Correspondence author: Emiko Kimura

Aomori University of Health and Welware 58–1 Mase, Hamadate, Aomori city, Aomori pref.

Manuscript received: 27 February 2014

activities, and self-care for prevention of LE.

A review of the literature concerning the RFs reveals that no studies have been done in Japan on the RFs of post-breast cancer LE. A study that extracted the RFs from the literature of other countries presented an RF map<sup>5)</sup> with: 'individual characteristics' that include BMI, age, marital status, insurance plan, income, flying, resident area and hand dominance; 'treatment details' that include years of follow-up, medical history, lymph node metastasis, lymph node dissection, number of lymph nodes dissected, type of surgery, radiation therapy, chemotherapy, anti-hormone therapy, infection, pain, and limitation in range of motion; and other factors such as 'preventive actions', 'instruction for LE', 'activity level'. However, these RFs are from literature originating from countries outside of Japan. Therefore, we conducted a research as pilot study about RFs of LE.

The study objectives were to explore RFs of LE to breast cancer survivors.

The significance of the study is that it will sensitize health care providers to perceived causes of or identification of conditions related to the onset or exacerbation of LE, and may help to improve the quality of life of breast cancer survivors. Specifically it will assist in clarifying the RFs of LE for breast cancer survivors, including regional characteristics and characteristics of daily living activities and will enable nurses to provide evidence–based instruction to patients leaving the hospital on how to prevent LE or to reduce exacerbations of LE.

#### Method

#### 1. Design

The investigation was a qualitative and descriptive study using a convenience sample of participants meeting the inclusion criteria.

#### 1) Subjects and setting

An outpatient hospital, situated in Aomori prefecture, agreed to participate in the study. The hospital had a large population of cancer survivors. The only nine women who had undergone surgery for breast cancer in the past were consented to participate, currently suffered from LE (irrespective of whether unilateral or bilateral or of duration of LE), met the below conditions,

and provided consent to participate in the study. Conditions for participation were being 20 years old or older, able to communicate, able to understand the purpose and meaning of the study, and able to join or withdraw from the study on their own will.

#### 2) Data Collection

Data were obtained through a face sheet and semistructured interviews. The author was the researcher and collected all the data. Contents of a face sheet and semi-structured interviews were referenced RF map.

Participants were given a face sheet (age, height, weight, marital status, annual income, type of insurer, resident area, travel time to hospital, and presence or absence of other illnesses not caused by LE for which they are receiving treatment, so on ) prior to the interview and requested to complete it on their own to the best of their ability.

Semi-structured interviews consisted of focused questions about: a) living situation at the time of onset, b) seasonal work and activities, c) treatment details, d) type of instruction received regarding LE and from whom, e) types of preventive behaviours undertaken, f) activity level at that time LE developed, g) whether they travelled by plane after surgery and h) perceived cause of LE.

3) Definition of term the occurrence of lymphoedema It used Stage I that represents an early accumulation of fluid relatively high in protein content which subsides with limb elevation, and pitting may occur  $^{6}$ .

#### 2. Recruitment method

Nurses in charge of LE outpatients explained to patients the procedure for selection of participants and study details. Those who agreed to participate were requested to adjust their schedule so that they could be interviewed on the same day as their next outpatient visit. Interviews were conducted from September through December 2012.

#### 3. Ethical considerations

St. Luke's College of Nursing ethics committee approved the study (approval no. 12–015). The participating hospitals ethics committee also approved the study. Researcher told participants about permission to IC recorder, confidentiality, anonymity, withdraw from study at any time without penalty, and care would not be affected. Researcher got signature of all participants.

#### 4. Analysis

To maintain anonymity and managing tracking data, participants were assigned ID numbers. Recorded interviews were transcribed and summarized as follows: (1) Face sheet responses were summarized and tabulated; (2) Meaningful excerpts about RFs of LE were extracted from the interview transcripts and coded. They were then examined for similarities and sorted into categories. Codes are shown in quotations. All analysis process made by the primary author.

To establish the credibility and validity of analyzed interview transcripts the emergent codes and categories were supervised by four experts: professor of fundamental nursing, qualitative nurse researcher, and two nurse LE care therapists providing LE care at the hospitals.

They were asked to read the interview transcripts, and to check adequateness about the emergent codes and categories. We discussed some disagreement of them to consensus on the matter.

#### Results

#### 1. Demografic data

Nine women were interviewed, and each interview took 40-60 minutes. No participants complained of feeling ill during the interview.

Individual characteristics. Age at the time of surgery the mean age was  $51.4\pm9.1$  years (Mean  $\pm$  SD), According to the International Society of Lymphoedema (ISL) staging classification, LE symptoms at the time of participation in this study were stage IIa in seven participants and stage IIb in two participants, BMI at surgery was  $22.9\pm2.1$  kg/m²,. At the time of LE onset, five participants were under treatment for other illnesses. All nine participants were right-handed. (Table 1 Individual characteristics and treatment details)

Duration of sleep was from 4.5 hours to a maximum of 9 hours. All participants prepared breakfast after awakening. Regardless of whether they worked during the day, they all did chores such as preparing dinner, grocery shopping, laundry, and house cleaning, and 3 participants cleared snow. Four participants did not work outside of the home, but they continued activities such as housework, caring for grandchildren, and

clearing snow as they did prior to surgery.

#### 2. Instruction (explanation) regarding LE.

Instruction on how to prevent LE was not covered by insurance until April 2008, with six participants undergoing surgery prior to that date. Of the six, three of were instructed regarding LE and three participants were not. Prior to April 2008, participants reported receiving instructions such as: "LE may occur," "wear long sleeves", "avoid insect bites", and "Indian massage may help". When ask where they received this advice responses were: "acquaintance", "someone from a patient support group", "supporter referrer" and "nurse". Participants had other sources also such as: "information from media" and/or "TV".

For the three participants that underwent surgery after April 2008, instruction such as "swelling may occur due to the removal of lymph nodes", try to avoid using the affected arm", "Do not lift heavy objects" and "Exercise often" were received from a "nurse" by "video and pamphlet" and/or "verbally."

#### 3. RFs of LE

A total of 54 codes were extracted from the interview transcripts and sorted into 17 categories. ( Table 2 RFs of LE)

Categories were 17 as "using hands", "using arm", "women's role", "help for events", "working hours", "interval before returning to work", "ineffective use of sleeves", "infection", "side effects of medication", "lack of exercise", "gaining weight after surgery", "financail circumstances", "onsen", type A behavior pattern", "inability to remain still", "feeling that they would not get LE" and "no considering the affected arm".

#### Discussion

#### Instruction (explanation) regarding LE

There were various types of instructions that were given by a variety of sources. Providing lymphoedema information has an effect on symptom reduction and more risk-reduction behaviors being practiced among breast cancer survivors<sup>7)</sup>, and Park reported that patients should be advised of the risk of lymphoedema and educated to detect its symptom<sup>8)</sup>.

In April 2008, a revision (Notification from the Head of the Medical Economics Division, Health Insurance Bureau, Health Ministry: Hoihatsu no. 0305001) was

Table 1 Individual characteristics and treatment details (n=9)

			n or mean $(\pm SD)$	Range
A	ge (years)	Age at surgery	51.4 (±9.1)	40-68
		Age at the interview	$58.6 \ (\pm 11.0)$	44-82
Н	leight (cm)		$156.6 \ (\pm 5.5)$	147-165
	Veight (kg)	Weight at surgery	$56.9 \ (\pm 6.4)$	49-65
-   ''	reight (hg)	Weight at LE occurrence	$58.9 (\pm 8.1)$	50-67
D	$MI (kg/m^2)$		$22.9 (\pm 2.1)$	20-26
B	WII (kg/m)	BMI at surgery		
		BMI at the interview	$23.4 (\pm 2.5)$	21-28
lr	nsurance	National health insurance	1	
		Social insurance	8	
		Other	0	
M	Iarital status	Married	8	
		Single (or divorced)	1	
		In a relationship	0	
Ir	Income (/10000 yen):	1; less than 150	2	
		2;150-200	1	
Talactorisms T		3; 201-300	1	
3		4; 301-400	0	
3			*	
3		5; more than 400	1	
		No response	4	
)  F	lying after surgery	Yes	1	
		No	8	
Т	ravel time to hospital (min)		$61.7 (\pm 47.3)$	25-180
Т	ravel means to hospital	Own vehicle	6	
		Bus	0	
		Other person's vehicle	3	
		On foot	0	
		Other	0	
	reatment for other illness at LE	Yes	5	Type of illness:
		res	3	Hypertension
00	ccurrence			
				Diabetes
				Hyperlipidemia
				Ulcerative colitis
				Angina
				Meniere's disease
		No	4	
Т	ime of LE onset after surgery (months)		36.9 (±32.2)	7-108
	ocation of breast cancer (of LE*)	Left (left)	3 (3)	
	ocation of steam cancer (of BB)	Right (right)	6 (6)	
т	ype of surgery	Mastectomy + LND <sup>§</sup>	7	
1	ype of surgery		1	
		Mastectomy + LND +		
		pectoral muscle	2	
		preservation		
A	Adjuvant therapy	With chemotherapy	6	
		Without chemotherapy	3	
1		With radiation therapy	5	
3		Without radiation therapy	4	
$ \mathbf{H} $	formone treatment	Yes	8	
A H	official treatment	No	1	
	to me of garage		1	
S	tage of cancer	I	1	
		I	1	
		Unknown	7	
P	ostoperative infection	Yes	1	1 year after surge
		No	8	
	ymphoedema: ISL <sup>†</sup> class	Stage IIa	7	
L	ymphoedema, ist. class	otage na		

Note.\*=Lymphoedema, §-Lymph node dissection, †=International Society of Lymphoedema

Table 2 RFs of LE

Tabl	e 2 RFs of L	E
	Category	Code
1	using hands	
		Massaging shoulders
		Putting hair in curlers Using scissors (cutting hair)
		Adding book supplements (book store)
		make bread or pizza
		knit: 1 hour or longer
		turn the pages of magazines
		use a computer cook fish every day
2	using arm	COOK IISH EVELY day
_	doing drin	Pouring hot water on self
		Carrying grandchild
		Carrying grandchild on back
		Ironing Cleaning with a wet cloth (hall, floor, window sills, etc.)
		Dressing someone in a kimono
		Yard maintenance (including weeding)
		Clearing snow (depending on the snowfall)
		Moving objects back and forth from the floor to shelves
3	women's role	Carrying packages (heavier than 5 kg)
J	., 51116113 1016	preparing food for Bon festival and New Year's holiday
		major house cleaning
4	1. 1. C	setting up guest futon mattresses
4	help for even	preparing food for a kindergarten or event
		tidying and preparing food of a send-off party for a baseball team
5	working hour	rs
		11 hours or more
6	interval before	7 hours re returning to work
U	interval belor	Returned to work 1 month after surgery
		Began working 3-4 hours (a day) one and a half years after surgery
7	ineffective us	
		Removing sleeves to cook Wearing ill-fitting sleeves
8	infection	wearing in-nitting sieeves
		Insect bite
0	. 1	Cutting finger with knife
9	side effects o	f medication  Hormone treatment
		Side effect of Meniere's disease medicine (Merislon)
10	lack of exerci	ise
		not getting exercise.
11		Lift arm 3-4 times a day if inclined
11	gaining wei	ght after surgery BMI of 40 kg/m² after surgery
12	financial circu	
		I have to work to pay for childcare costs and medical bills.
13	onsen	C. 1''. (b (b )
14	type A behav	Soaking in the onsen (hot spring)
11	type 11 bena	I try hard for the sake of my job
		I work hard
		my job is time-based, so I work quickly
		I don't feel busy because I do it myself I hate working slowly
		I'm not satisfied unless I do everything myself
		I do everything myself without noticing
15	inability to re	
16	feeling that t	Even when at home, I am always doing something hey would not get LE
10	recuild man r	I did not receive adjuvant therapy, so I would not get LE
		I went for routine check-ups, so I would be fine
		I did not get LE for one year, so I would not get it in the future
177		I only worked for 3-4 hours at a time, so I would be fine
17	no considerin	g the affected arm I was too busy to consider the affected arm
		I did my work without considering which arm I was using
		I prioritized work over swelling

made to the medical fee remuneration as 'Instruction for LE Management Fee' to allow 100 points (1 point is 10 yen. So, this instruction become revenue of a hospital.) of remuneration for one instance of instruction during a hospital stay for individuals who had already received such instruction before or after surgery for specified types of cancer (breast, ovarian, uterine, or prostate). It has passed 5 years. So, we need to research for the actual circumstances and an effect of instruction for prevent of LE in Japan.

#### 2. RFs of LE

#### 1) Using hands and arm

RF map <sup>9</sup> shows lack of movement to be a risk factor, for example, with the activity level being sedentary, insufficient, or moving around occasionally. However, we get very specific behaviour that were using hands and using arm, for example to "make pizza or bread" or "knit: 1 hour or longer" "cook fish every day" "carrying grandchild on back" "cleaning with a wet cloth (hall, floor, window sills, etc.)", so on.

A study that quantitatively classified level of hand use into low, medium, and high levels revealed that the combination of medium to high level of hand use, BMI>  $25 \text{ kg/m}^2$ , and an infection was related to LE incidence <sup>10)</sup>. For upper limb, level of arm and hands use may be an important risk factor.

The codes of "putting hair in curlers" and "using scissors" were unique activities of the participant's occupation (hairdresser). While occupation was not given as a factor in previous studies, it may be useful to add this as a factor if it involves use of the hands.

#### 2) Life style

Other categories were characteristic activities that are often seen in life styles such as onsen, "women's role" and help for events. "soaking in the onsen (hot spring)" is personal hobby or cleanly custom for us. "women's role" involved For the Bon Festival and New Year's holiday such as meal preparation and, setting up guest futon mattresses, and major house cleaning come about every half year. They are very burdensome for women. "clearing snow" was related to the seasons in the residential area. The fact that participants felt these were the causes of their LE indicates that those activities were physically burdensome to a certain degree. This suggests that physically burdensome is a

major risk factor for patients whose right arm was affected.

#### 3. Psychological and personality traits as RFs

Psychological and personality aspects were not mentioned in the literature review <sup>11)</sup>. Categories of Psychological and personality aspects were "no considering the affected arm", "feeling that they would not get LE" and "inability to remain still". This suggests that they experienced feelings of denial and not wanting to acknowledge the breast cancer, and that they wanted to believe that they would not get LE because they did not get it until that point.

Furthermore, There is "type A behaviour pattern" <sup>12)</sup>. A desire to do everything quickly and perfectly may be the cause of continuing to work hard or do tasks such as weeding despite a cramp in the arm.

To the best of our knowledge, no studies can be found on the relationship between patients with LE and type A behaviour pattern in Japan or any other countries. If the type A behaviour pattern is characteristic of patient with LE, preventive methods to lower the risk may be very useful.

### Study limitations

The results only examined the characteristics of LE patients living in the north of Japan, and their activities were closely linked to their lifestyle. Sample size was small. Next step would be make a questionnaire of RFs for LE based on this interviews.

## Conclusions

Semi-structured interviews were administered to nine patients with LE regarding the risk factors for LE.

We got 17 categories about RFs of LE. They were "using hands", "using arm", "women's role", "help for events", "working hours", "interval before returning to work", "ineffective use of sleeves", "infection", "side effects of medication", "lack of exercise", "gaining weight after surgery", "financial circumstances", "onsen", type A behavior pattern", "inability to remain still", "feeling that they would not get LE" and "no considering the affected arm". And there were various types of instructions of LE that were given by a variety of sources.

#### References

- Arai T: Foeldi shiki iryoutoshu lymphdrainage (rinpafushu hozon ryouhou), Rinshoukango, 31 (3), 310, 2005. (in Japanese).
- 2) Kato I, Matsuo H: Rinpafushu shinryou no jissai genjou to tenbou, Bunkoudou, 31, 2003. (in Japanese).
- 3) Norman SA, Localio AR, Kallan MJ, et al.: Risk factors for lymphedema after breast cancer treatment, Cancer Epidemiol Biomarkers Prev, 19 (11), 2734–2746, 2010.
- 4) Pain SJ, Purushotham AD: Lymphoedema following surgery for breast cancer, Br J Surg, 87 (9), 1128–1141, 2000.
- 5) Kimura E: A Systematic Review about Risk factor of lymphoedema, International Lymphoedema Framework of Japan, 1 (1), 5–24, 2013. (in Japanese).
- 6) International Society of Lymhology: The Diagnosis

- and Treatment of Peripheral Lymphoedema, Lymphology, 42, 51–60, 2009.
- 7) Fu MR, Axelrod D, Haber J: Breast-cancer-related lymphedema. information, symptoms, and risk-reduction behaviors, Journal of Nursing Scholarship, 40 (4), 341–348, 2008.
- 8) Park JH, Lee WH, Chung HS: Incidence and risk factors of breast cancer lymphoedema, Journal of Clinical Nursing, 17 (11), 1450–1459, 2007.
- 9) above 5)
- 10) Soran A, Wu WC, Dirican A, et al.: Estimating the Probability of Lymphedema After Breast Cancer Surgery, Am J Clin Oncol, Nov 30. DOI. 10.1097/ COC.0b013e3181f47955
- 11) above 5)
- 12) Momoo H, Hayano J, Hosaka T: Type A kodou pattern, 3, Tokyo to, Seiwa shoten, 1993. (in Japanese)

# 9人の乳がん術後患者のリンパ浮腫のリスクファクターに関する質的研究

木村恵美子1)

青森県立保健大学看護学科10

#### 要旨

【はじめに】本研究の目的は、術後乳がん患者のリンパ浮腫に関するリスクファクター (RFs) を明らかにすることである。

【方法】乳がん術後でリンパ浮腫がある9人を対象とし、半構成的インタビュー調査を行った。インタビュー内容は 逐語録を作成し、リンパ浮腫のリスクファクターに関する語句を意味の通じる範囲で抽出しコード化し、それらの 類似性を検討しカテゴリー化した。

【結果】インタビュー時平均年齢  $58.6\pm11.0$  歳で,平均 BMI は  $23.4\pm2.5$  kg/m²,術後平均発症期間は  $36.9\pm32.2$  月だった。リンパ浮腫のレベルは IIa が 7 人 IIb が 2 人だった。RFs については 17 のカテゴリーが得られ,それらは手を使う,腕を使う,女性の役割,行事の手伝い,経済的事情,タイプ A 的行動パターン,じっとしていられない性格,リンパ浮腫にならないという気持ち,患肢を気にしないなどがあった。

【結論】リンパ浮腫のある9人の術後患者のリスクファクターは、女性が担う家事や生活スタイルが多く関与しており、行動に結びつくタイプA行動パターンなど心理面もあった。

**キーワード**:リンパ浮腫,リスクファクター,乳がん

# ケースレポート

# 微小変化型ネフローゼ症候群患者に対する複合的理学療法の効果

永井 美沙10 小林 範子20 若林佐緒理10 茂庭 仁人30 滝沢 英毅30 藤野 敬史40

手稲渓仁会病院看護部<sup>1</sup> 北海道大学病院婦人科<sup>2)</sup> 手稲渓仁会病院腎臓内科<sup>3)</sup> 手稲渓仁会病院産婦人科<sup>4)</sup>

# Effect of complex physical therapy on minimal change nephrotic syndrome patient

Misa Nagai<sup>1)</sup>, Noriko Kobayashi<sup>2)</sup>, Saori Wakabayashi<sup>1)</sup>, Izumi Tanaka<sup>1)</sup>, Norihito Moniwa<sup>3)</sup>, Hideki Takizawa<sup>3)</sup> and Takafumi Fujino<sup>4)</sup>

Department of Nursing, Teine Keijinkai Hospital<sup>1)</sup>
Department of Gynecology, Hokkaido University Hospital<sup>2)</sup>
Department of Nephrology, Teine Keijinkai Hospital<sup>3)</sup>
Department of Obstetrics and Gynecology, Teine Keijinkai Hospital<sup>4)</sup>

Key words: minimal change nephrotic syndrome, complex physical therapy, systemic edema, ADL, QOL

キーワード: 微小変化型ネフローゼ症候群、全身性浮腫、複合的理学療法、ADL、QOL

#### はじめに

浮腫は皮下組織に間質液が過剰に貯留した状態で、全身性浮腫と局所性浮腫に大別される。全身性浮腫を生じる病態では、心、腎、肝疾患が約半分を占め、3大原因はうっ血性心不全、肝硬変、ネフローゼ症候群である<sup>1)</sup>。ネフローゼ症候群では腎臓から血漿アルブミンの

著明な喪失のため低タンパク血症をきたし、血漿膠質浸透圧低下によりタンパクが漏出し末梢組織などに水分が 貯留する。尿量減少に伴い体重は増加し、進行例では全 身性浮腫となる。同じタンパク尿を認める病態であって も、糸球体腎炎、血管炎などは局所の血管透過性亢進が 浮腫形成の重要な因子とも言われており、ネフローゼ症 候群の病態とは異なっている。

連絡先(Corresponding author):永井 美沙

手稲渓仁会病院看護部

〒006-8555 札幌市手稲区前田1条12丁目1-40

受理日:2014年8月22日

#### CPT 開始前



写真 1 CPT 前後における下肢浮腫状態



CPT 開始後

リンパ浮腫の治療法は、国際リンパ学会により複合的 理学療法 (CPT: Complex Physical Therapy) が標準 治療として認められている<sup>2)</sup>。CPT は基本的に用手的リ ンパドレナージ、圧迫療法、圧迫下の運動療法、スキン ケアの4要素により構成されている。CPTの主な適応 は局所性浮腫であり、通常、全身性浮腫においては浮腫 の原疾患の治療が最優先と考えられてきた<sup>3)</sup>。ネフロー ゼ症候群における高度な浮腫は、患者の ADL (Activities of Daily living, 日常生活動作)を制限し、QOL (Quality of Life, 生活の質)を著しく低下させること、 胸水・腹水が大量に貯留することで呼吸が障害されるこ と、さらに高度な浮腫は皮膚の組織障害や蜂窩織炎の原 因になることなどから、ネフローゼ症候群治療において 浮腫のコントロールは重要な位置を占めている40。しか し、現在までネフローゼ症候群をはじめ、全身性浮腫に 伴う高度な下肢浮腫に対して CPT を実践した報告は認 められていない。

本研究では、高齢の難治性微小変化型ネフローゼ症候群により著明な下肢浮腫を認めた1症例に対してCPTを試みたので、考察を交えて報告する。

#### 症 例

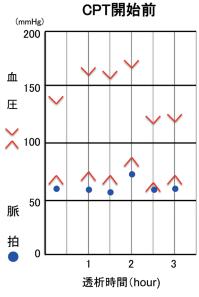
82 歳、男性。身長 166 cm、体重 60 kg。特記すべき 合併症はない。妻と 2 人暮らしであり、入院前の ADL は自立していた。

2013 年 11 月、両下肢浮腫に引き続き陰嚢の浮腫、食 欲低下、倦怠感を自覚し、体重が 1 週間で  $8 \, \mathrm{kg}$  増加  $(60 \, \mathrm{kg} \rightarrow 68 \, \mathrm{kg})$  した。2013 年 12 月、下肢・陰嚢浮

腫、全身倦怠感、体重増加を主訴に腎臓内科を受診し、即入院となった。入院時データでは、一日尿タンパク量12.5g、BUN 81.9 mg/dl、s-Cr 2.97 mg/dl、TP 4.3g/dl、Alb 2.0 g/d と高齢急性発症の急性腎障害を認めた。入院後に腎生検を行い、『微小変化型ネフローゼ症候群』の診断となった。

入院後7日(治療開始0日目)より経口プレドニゾロン(プレドニン®)40 mg/day と血液透析(以下、透析)が開始された。ステロイド治療に抵抗性であることから、入院後37日(治療開始30日目)よりシクロスポリン(ネオーラル®)の併用療法を開始した。ステロイドの減量(1/11:30 mg/day、1/25:25 mg/day)と並行して、シクロスポリン(ネオーラル®)は50 mg/day → 100 mg/day へ徐々に増量された。当時、患者の腹部、殿部、陰嚢、両下肢には緊満の強い浮腫が見られ、浮腫部位の皮膚は乾燥して赤みを帯び、右下腿部後面にはリンパ漏が見られた(写真1)。患者からは、足が重くて動けない、太い足をどうにかしてほしいとの訴えがあった。両下肢浮腫により歩行も困難となり、移動は全て車椅子介助を行っていた。

全身性浮腫が背景であるものの、薬物治療が難渋し著明な下肢浮腫のために ADL が低下している患者に対し、病棟スタッフは浮腫軽減のため薬物療法以外に何か介入できることはないものかと思案していた。腎臓内科病棟勤務の看護師の中に、医療リンパドレナージセラピストの資格を持ち、当院「リンパ浮腫外来」で専門治療に携わっている者がいたこともあり、患者の浮腫に対するケアについて検討することになった。そこで、前例の





CPT施行中

(mmHg)
200

血 150
圧
100

脈 50
拍 0 1 2 3
透析時間(hour)

ない初めての試みであったが、リンパ浮腫治療で行っている CPT の導入を試みることになった。主治医の指示のもと CPT の開始前には超音波診断装置にて深部静脈血栓がないことが確認され、圧迫療法の許可を得た。深部静脈血栓症発症予防として、入院後へパリンナトリウム(ヘパリン®)点滴投与に引き続き、ワーファリンカリウム(ワーファリン®)投与が行われていた。

患者に CPT の目的、内容を説明し、聴取した個人情報は全て保護され、個人を特定できないよう匿名化したデータを公表すること、得られた結果は本研究以外で使用されないことを説明し同意を得た上で、入院後 57 日より CPT を開始した。

介入時の CPT の内容を以下に記載する。

- 1) 用手的リンパドレナージ: 病棟スタッフがほぼ毎日、肩回し、腹式呼吸を含めた前処置(排液ルート作成)を約10分間実施し、医療リンパドレナージセラピストが患肢のマッサージを週2回20~30分間実施した。
- 2) 圧迫療法:筒状包帯(素材:コットン85%、天然ゴム10%、ポリアミド5%)で皮膚を保護し、その上からショートストレッチ弾性包帯を使用した。患者の体調に合わせて巻く範囲や使用本数を調節した。なお、透析施行中は透析時間内(約3時間)にCPTを行った。CPT開始前には、透析中は血圧が不安定になり一時的に低下することもみられたが、CPT開始後は安定した血圧を保ったまま終了することができた(図1)。
- 3) 圧迫下の運動療法:患者は治療開始時には両下肢に弾性包帯を使用したため、弾性包帯の重みにより歩行が思うようにいかず、移動は車椅子を使用した。患者

は、トイレや足浴以外は多くの時間をベッド上で過ごされていた。

4) スキンケア: リンパ漏は悪化すると潰瘍を形成し 難治性になることもあり、蜂窩織炎の原因ともなりうる。 スキンケアの際には、リンパ漏がみられた部位に皮膚の 損傷予防と保護目的に保護剤を貼付し治療を行った。

下肢周径計測点は足関節部、下腿部(膝窩より 12 cm 下部)、大腿部(膝窩より 20 cm 上部)の 3 ヶ所で行った。計測及び CPT は 1 名の医療リンパドレナージセラピストが継続して担当した。体重測定は起床後に、下肢周径計測は透析開始前(午前中)、透析治療終了後(午後)に実施した。

原疾患に対する治療については、経口プレドニゾロン (プレドニン®) とシクロスポリン (ネオーラル®) 併用 治療においても奏功せず、入院後64日(治療開始57日 目/CPT 開始後7日目) に LDL (low density lipoprotein)アフェレーシスを開始した。入院後67日(治療 開始 60 日目/CPT 開始後 10 日目) に一時的に導入して いた透析を終了したが、透析は Hemodialysis (HD)、 Extracorporeal Ultrafiltration Method (ECUM) を含 め、計31回行われた。この頃には両下肢ともに全体的 に周径が減少し、右下腿部のリンパ漏が消失した。患者 からは足が楽になった、軽くなって動きやすくなったと 喜びの声が聞かれた。弾性包帯による終日の圧迫も快適 と実感されており、夜間も良眠されていた。病棟スタッ フの協力により、日中は毎日足浴を実施し、足浴後に両 下肢に保湿クリームを塗布した。下肢の清潔保持、感染 予防に努め、皮膚状態は改善した。

#### 弾性ストッキング







写真 2 圧迫療法

入院後 69 日 (治療開始 62 日目/CPT 開始後 12 日目) には用手的リンパドレナージを継続しながら、圧迫を弾性包帯から弾性ストッキングへ変更した (圧迫圧 20~30 mmHg、パンティストッキングタイプ、写真 2)。日中の弾性ストッキング着用により患者は行動拡大しやすくなり、病棟内の移動手段も車椅子から歩行器となり、トイレまでの歩行も行えるようになった。ベッドサイドでは、椅子に座って過ごす時間も長くなった。

しかし弾性ストッキングへの圧迫変更後、浮腫は数日 後には再び増悪し、1度消失したリンパ漏が再発した。 治療目標を歩行器での ADL 維持として、圧迫方法を入 院後82日(治療開始75日目/CPT開始後25日目)に 日中は弾性包帯、夜間は筒状包帯の併用(写真2)へ変 更し、用手的リンパドレナージを引き続き行った。同日 から利尿剤フロセミド(ラシックス®) 40 mg/day の投 与も開始され、経口プレドニゾロン (プレドニン®) 15 mg/day とシクロスポリン (ネオーラル®) 125 mg/day が継続された。2日後にはリンパ漏は消失し、硬く張っ ていた皮膚も徐々に柔軟になった。原疾患の治療効果も 見られ、尿中一日タンパク量と体重が減少した。入院後 82 日に LDL アフェレーシスを終了 (計9回) し、入院 後83日には(治療開始76日目/CPT開始後26日目) 一日尿中タンパク量 0.24 (g/日) (0.3 g/日未満) とな り、完全寛解に至った(図2)。下肢周径の減少ととも に (図3、写真1) 筒状包帯の圧迫下で病棟内を杖歩行 することも可能となった。リハビリ室で行う理学療法士 が介入した定期的なリハビリテーションに加えて、入院 病棟でも積極的に離床を促し、圧迫下で歩行訓練を行っ た。歩行訓練は午前・午後にわけて病棟内を各3~5周 するもので、患者の体調に合わせて休息も入れながら実 施した。患者は次第に介助にてシャワー浴も行えるよう になり、引き続き皮膚の清潔保持に努めた。

寛解後、リハビリテーション施設転院まで少し時間を要したが、入院後95日(CPT開始後38日目)には下肢に圧痕がみられる弱い浮腫が残存したのみで、腹部、臀部、陰嚢の浮腫および両下肢の発赤はほぼ消退した。用手的リンパドレナージとスキンケアを継続し、終日筒状包帯を用いた圧迫療法を行った。その際、下肢に対して筒状包帯を大腿部と下腿部~足部までの2部位に分けてサイズや長さを調節した。

入院後 111 日(CPT 開始後 53 日目)には、大腿部の浮腫は改善し下腿部~足部までの浮腫のみが残存した。転院まで、スキンケアおよび筒状包帯で作成したソックス(写真 3)を用いた終日の圧迫を継続した。転院時の内服薬は経口プレドニゾロン(プレドニン®)10 mg/dayとシクロスポリン(ネオーラル®)100 mg/day であった。「長い入院にはなったけど、丸太のような足がもとに戻って嬉しい。」転院前に患者が笑顔で話された言葉である。

#### 考 察

微小変化型ネフローゼ症候群は若年発症が多く、ステ

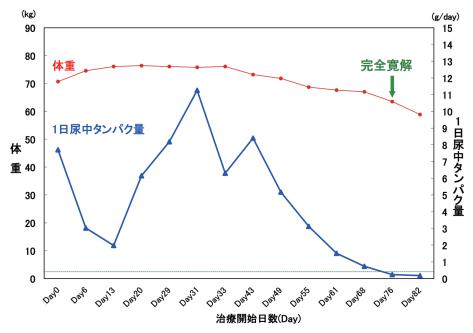


図2 体重と1日尿中タンパク量の推移

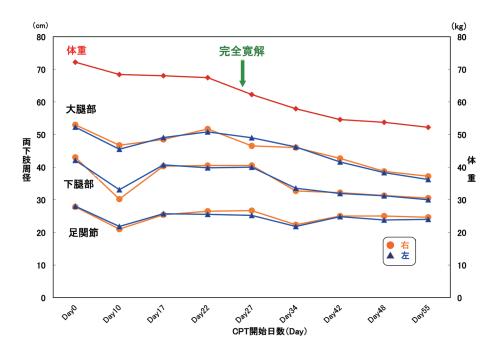


図3 両下肢周径と体重の推移

ロイドが奏功するケースが多いと言われているのに対し、本症例は高齢発症でステロイド抵抗性であった。高齢者ではステロイド高用量を長期間使用しにくく、免疫抑制剤などを含め治療薬剤の副作用を最小限にする注意が必要である。本症例で用いたステロイド治療薬はミネラルコルチコイド作用を持っており、Na 貯留を生じて一時的に浮腫を増悪させる可能性もある他、高用量のステロイド治療は感染を助長するリスクもある。浮腫を起こしている患肢は、通常でも感染に対する防御能が局所

的に低下しており、感染を発症後も増悪しやすい状態と考えられている<sup>5)</sup>。低タンパク血症を伴う場合は創傷遅延が危惧されることから、リンパ漏消退の遅延やリンパ漏部位からの感染に対してさらなる注意を要する。そこで CPT の際には、炎症や新たな皮膚トラブルの出現なく治療をすすめるため、リンパ漏部位や日々の浮腫・皮膚状態の把握に細心の注意を払った。

原疾患に対して各種治療でコントロールが困難な難治性の浮腫に対しては、ECUMによる除水が有効である





写真3 筒状包帯で作成したストッキング

と言われている<sup>4)</sup>が、透析中の留意点として血圧低下や心不全により患者の QOL が低下することが懸念されている<sup>6,7)</sup>。浮腫が強い状態すなわち患者の血管内の水分が間質に移動して血管内の循環血液量が減少している状態で除水を行うと、過剰な除水となり透析時に血圧が低下することがある。高齢者では自律神経や血管神経、心臓の機能低下からも低血圧を起こしやすいとも言われている。そのため、透析中に血圧が低下せず予定通りの除水を行えることは、原疾患の治療上きわめて重要と思われる。透析中に血圧低下が起こると、透析の中断あるいは透析条件の緩和が必要になり、体位の変更や補液、昇圧剤の投与が必要になる場合もある。順当に透析を行うことで全体の治療をすすめていくことができたという点で、透析中の CPT 介入は試みる意義がある可能性が示唆されたが、今後の検討が必要である。

また本症例では、下肢の圧迫療法の際、循環血液量の増加により心不全を起こさないよう、浮腫状態や胸水・腹水といった体液貯留がないことを確認した。圧迫が過負荷とならないよう、弾性包帯の使用本数を標準治療より少なくし、日々の状態により巻く範囲を柔軟に変更しながら包帯療法を行った。本症例のような高齢者では、加齢により皮膚の弾性力が弱く組織圧が低下しているため、皮下組織に過剰な間質液が貯留しやすい状態である。さらに、高齢者では加齢による臓器の機能低下や心臓への還流を促す筋肉運動量の低下も、浮腫を助長する要因となる。そのため浮腫量に対する圧迫力の調整は、全身状態を把握した上で十分な配慮のもと施行されるのが望ましいと思われる。

本症例では患者の ADL 拡大のため、CPT 施行中に 一時的に弾性包帯から弾性ストッキングへ変更したが、 結果的に浮腫とリンパ漏の増悪がみられた。原疾患の治 療と並行して浮腫への保存的治療を行う際には、日々の 浮腫状態の変動をデータのみから予測することは必ずし も容易なことではなく、本症例でも圧迫内容の変更によ り浮腫増悪・リンパ漏の再発が早々に起こるとは予想で きなかった。弾性ストッキングから再度包帯療法へ変更 したところ浮腫は軽減した。包帯療法は多層式であり、 弾性ストッキングに比べると組織圧を高める力が強く、 間質への漏出液の減少とともに間質液が血管内へ移行し 取り込まれたことが、リンパ漏の改善に寄与したと推測 される。また、包帯療法再開のタイミングで利尿剤の投 与を開始したことが、本症例で大きな相乗効果を生んだ 原因と思われる。利尿亢進がみられ、経過中にはなかな か減らなかった体重が減少するとともに浮腫が改善する 契機になったと思われる。

本症例では患者の全身状態を考慮し、浮腫の評価法として、1下肢3点の簡便な周径計測を行った。下肢周径は体重の変化による影響を受けるため、体重減少により下肢周径値が減少したのか、あるいは浮腫改善に伴う下肢周径値減少に伴って体重減少が生じたのかを判断することは難しいと思われる。しかし、治療経過の中で同一測定法を継続して行い、治療効果を経時的に評価するという意味で、周径と体重計測は患者への浸襲が少ない方法であったと思われる。両下肢浮腫の際に浮腫評価法をどうするべきかは、引き続き今後の課題である。

近年、透析患者に対する運動療法の意義と「腎臓リハ

ビリテーション (以下腎臓リハビリ)」について提唱さ れるようになってきた6。「腎臓リハビリ」とは腎臓障 害者に対して行う新たな内部障害リハビリであり、運動 療法、薬物療法、栄養療法、教育、精神的ケアなどを要 素とする包括的リハビリの一つであるが、その中心的役 割は運動療法である。高齢者は加齢に伴う心肺機能の低 下や筋力低下・予備力の低下などから、疾患によって入 院し治療を受ける中で活動耐性が低下し、寝たきりやそ れに近い状態(廃用症候群)に陥り、移動困難になるこ とがあることが知られている<sup>8)</sup>。本症例においても長期 間の入院治療により体力や筋力の低下がみられ、難治性 の浮腫のため活動の制限を生じていた。本症例では、リ ハビリ室でのリハビリテーションと病棟内での圧迫下の 運動療法を並行して行い、介助で車椅子に移乗していた 状態から、付き添いで病棟内を杖歩行できる状態まで回 復した。圧迫下の運動療法は、関節の屈伸運動により筋 ポンプ作用を向上し排液を促す効果があるだけではな く、廃用症候群の防止・改善や ADL・QOL を向上させ る効果も兼ね備えているものと思われた。

本症例の新たな試みを通して、全身性浮腫においても 浮腫により ADL・QOL の低下を伴う場合は、原疾患の 治療とともに、対症療法とはいえ安全性を確認しながら CPT を補助的に実施することが可能であることが示唆 された。緩和的 CPT<sup>®</sup>は、緩和ケア患者に対して行わ れる CPT で、患者のニーズに合うように標準的 CPT に治療内容の構成、あるいは実施の過程で柔軟な修正変 更を加えたものである。本症例では、全身状態を考慮 し、緩和的 CPT<sup>®</sup>を慎重に行っていくことが重要であ ると思われた。また本症例では、入院病棟、透析室、リ ハビリテーション部、リンパ浮腫専門外来といった病院 内の多職種間で、患者の情報を積極的に共有し、連携を 行うことができた。本症例のような新たな試みに対し、 病院内で広く理解や協力を得られるバックアップ体制に 恵まれていたことは、今後も当院でリンパ浮腫治療を 行っていくメリットとして活かしていきたいと思う。今 後、全身性浮腫症例であっても CPT の介入の可能性に ついてプロスペクティブに検討し、患者の ADL・QOL 向上のため症例を集積して検討を重ねていきたいと考え ている。

## 文 献

1) 小林範子, 藤野敬史, 櫻木範明: リンパシステムの 病態生理 - 特性とその理解 - , ターミナルケア, 14 (2), 94-98, 2004.

- Consensus document of the International Society of Lymphology Executive Committee: The diagnosis and treatment of peripheral lymphedema. Lymphology, 28, 113–117, 1995.
- 小川佳宏, 佐藤佳代子: 浮腫疾患に対する圧迫療法, 文光堂, 65, 東京, 2009.
- 4) 厚生労働省難治性疾患克服研究事業進行性腎障害に 関する調査研究班, 難治性ネフローゼ症候群分科会 編:ネフローゼ症候群診療指針 [完全版]. 東京医 学社, pp13-16, 2012.
- 5) 小林範子, 藤野敬史, 櫻木範明: リンパ浮腫に合併 する蜂窩織炎の予防と管理, 臨牀看護, 30 (9), 1343-1347, 2004.
- 6) 上月正博:透析患者における運動療法の必要性. 臨 株透析, 20 (10), 1291-1298, 2011.
- 7) 社団法人日本透析医学会編:血液透析患者における 心血管合併症の評価と治療に関するガイドライン, 透析会誌,44 (5),363-368,2011.
- 8) 堀内ふき, 大渕律子, 諏訪さゆり編: ナーシング・ グラフィカ 高齢者の健康と障害, MC メディカ出版, 4, 191, 2013.
- 9) International lymphoedema framework and Canadian lymphedema framework: The management of lymphoedema in advanced cancer and oedema at the end of life (Position Document), 15, 2010.