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Development and evaluation of the Korean version of the Gynecologic Cancer Lymphedema Questionnaire in gynecologic cancer survivors

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HIGHLIGHTS

- The GCLQ-K was successfully developed with minimal modifications to adapt the original GCLQ to Korean culture.
- The GCLQ-K showed high internal consistency and reproducibility in gynecologic cancer survivors.
- Gynecologic cancer survivors with and without lymphedema could be satisfactorily distinguished using the GCLQ-K.

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ABSTRACT

Objective. The purpose of this study was two-fold: first, to develop a Korean version of the Gynecologic Cancer Lymphedema Questionnaire (GCLQ-K) and evaluate its reliability and reproducibility and second, to examine the diagnostic efficacy of GCLQ-K in predicting lymphedema in gynecologic cancer survivors.

Methods. We designed a case–control study, and the GCLQ-K was completed by 33 gynecologic cancer survivors with lymphedema and 34 gynecologic cancer survivors without lymphedema. A follow-up GCLQ-K was completed 3 weeks after the baseline questionnaire.

Results. The GCLQ-K showed high reliability with a Cronbach's α of 0.83 and high reproducibility with an intraclass correlation of 0.96. Of the 7 symptom clusters, 6 identified patients with lymphedema with statistical significance; identification of lymphedema using the physical functioning and infection-related symptom clusters did not reach significance. The area under the receiver operating characteristic curve (AUC) to distinguish patients with and without lymphedema was 0.868 (95% confidence interval [CI], 0.779–0.956). Following the exclusion of the physical functioning and infection-related symptom clusters, which showed poor prediction value for lymphedema, the AUC of the GCLQ-K total score further improved to 0.922 (95% CI, 0.864–0.981).

Conclusion. The GCLQ-K was successfully developed with minimal modifications to adapt the original GCLQ to the Korean culture and showed high internal consistency and reproducibility. Moreover, gynecologic cancer survivors with and without lymphedema could be satisfactorily distinguished using the GCLQ-K. Thus, GCLQ-K was proven to be a reliable tool, capable of identifying lymphedema in Korean gynecological cancer survivors.

Introduction

In 2013, an estimated 49,560 endometrial cancers and 22,240 ovarian cancers were diagnosed in the USA, ranking them the fourth and tenth most common female cancers, respectively [1]. In Korea, in 2013, the estimated incidences of cervical, ovarian, and endometrial cancers were 3240, 2199 and 2174, respectively [2]. Based on the annual percent change, the prevalence of these cancers has changed in Korea, and the incidence is now similar to that in the USA: −4.3% for cervical cancer, +6.9% for ovarian cancer, and +1.5% for endometrial cancer [3]. For most gynecologic cancer patients who are candidates for surgery, lymphadenectomy is performed for staging and therapeutic purposes. Moreover, lymphadenectomy is one of the definitive factors contributing to lymphedema: the estimated incidence of lymphedema is 1.3–38% for uterine cancer, 4.7–21.1% for ovarian cancer, 3.6–49%

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for cervical cancer, and 5.5–81.2% for vulvar cancer [4]. The reported frequencies vary according to the primary cancer site, extent of lymphadenectomy, lymphedema estimation method, and adjuvant treatment after lymphadenectomy [4]. Lymphedema limits physical function and house work in 45% and 29% and hinder social activities (27%) and to meet friends (20%) of the gynecologic cancer survivors, respectively [5]. Chronic uncontrolled lymphedema induces lymphangiogenesis and local immune suppression and may ultimately result in catastrophic angiosarcoma, also called Stewart–Treves syndrome, which has an extremely poor prognosis [6].

However, the incidence and patterns of lymphedema have not been thoroughly evaluated in gynecologic cancer prospective cohorts. Recently, the Gynecologic Oncology Group (GOG) performed prospective studies to examine the incidence of lymphedema after primary treatment of gynecologic cancers [7,8] using the Gynecologic Cancer Lymphedema Questionnaire (GCLQ), which is an effective screening questionnaire to identify women with lymphedema [9]. The Korean GOG (KGOG) considers participation in international GOG collaborative trials using GCLQ. Therefore, the development and evaluation of a Korean version of GCLQ (GCLQ-K) is required. The aim of the current study was to develop and evaluate the GCLQ-K in Korean women.

Methods

The GCLQ is a one-time self-reported patient survey that usually takes less than 10 min to complete [9]. It consists of 20 items with 7 symptom clusters: physical functioning (6 items), numbness (4 items), swelling-general (3 items), infection-related (3 items), heaviness (1 item), aching (1 item), and swelling-limb (2 items), and each item is scored as 0 (no) or 1 (yes) [9].

After obtaining the Institutional Review Board approval (NCCNCS-12-642), the GCLQ-K was developed via forward translation, backward translation, discussion, modification after the pilot test, and finalization.

Women who visited the outpatient department were enrolled according to the study criteria. The inclusion criteria were 1) age >18 years, 2) pelvic lymph node dissection after gynecologic cancer diagnosis, 3) time of surgery for gynecologic cancer to time of study enrollment >6 weeks, and 4) understanding of the study and willingness to provide written informed consent. The exclusion criteria were 1) unclear lower extremity edema, 2) severe cardiopulmonary and renal disease, 3) active thrombosis, 4) lower extremity tumors, 5) local infection in the lower extremities, 6) long-term use of systemic corticosteroids, 7) alcohol or drug abuse, 8) uncontrolled diabetes, 9) pregnancy or lactation, and 10) auto-immunological disorders or vasculitis. Patients with lymphedema were clinically diagnosed after consideration of their history, physical examination, limb volume measurement using circumference estimation or perometry, lymphoscintigraphy, soft tissue imaging by magnetic resonance imaging (MRI), or computed tomography (CT) surveillance [4,10]. All patients with one or more swollen limbs were evaluated using limb sonography and/or CT venography to exclude deep vein thrombosis.

The first GCLQ-K was completed at an outpatient clinic. Re-tests were conducted in 60 women (89.6%) by a clinical researcher by telephone, 3 weeks after the first questionnaire. The focus of the analysis was two-fold: first, to evaluate the reliability and reproducibility of the Korean-translated GCLQ version and the second is to evaluate the usefulness of GCLQ-K in identifying patients with lymphedema. The internal structural validity of the questionnaire was first assessed by item-symptom cluster correlations: item internal consistency (IIC) and item discriminant validity (IDV). IIC measures how well the item correlates with its scale (items in the same symptom cluster are measured on the same scale and are generally expected to be scored >0.4), and IDV measures the percentage increase in each item's correlation with its scale compared with items in the other symptom clusters. For each symptom cluster (with >2 items) and the total questionnaire, internal consistency reliability was assessed using Cronbach's α coefficient. Reproducibility was evaluated through test–re-test reliability based on intraclass correlation coefficients (ICC) between two assessments (based on the 60 patients who completed both questionnaires) for scales of each symptom cluster and total score. To evaluate diagnostic usefulness, the distribution differences of the item scores for each symptom cluster were tested using Fisher's exact tests to compare groups with and without lymphedema. In addition, the receiver operating characteristic (ROC) curve and area under the ROC curve (AUC) were

Table 1
Demographic and clinical characteristics of the study population.

	Lymphedema (n = 33; 49%)		No lymphedema (n = 34; 51%)		Total sample (n = 67)		p-Value
	N	%	N	%	N	%	
Age							
Mean; SD	48.7	10.7	50.8	8.1	49.8	9.5	0.370[a]
28–35 years	4	12.1%	1	2.9%	5	7.5%	0.361[b]
36–50 years	12	36.4%	15	44.1%	27	40.3%	
51–65 years	14	42.4%	17	50.0%	31	46.3%	
66–80 years	3	9.1%	1	2.9%	4	6.0%	
Type of cancer							
Endometrial cancer	8	24.2%	4	11.8%	12	17.9%	0.170[b]
Cervical cancer	16	48.5%	13	38.2%	29	43.3%	
Ovarian cancer	9	27.3%	15	44.1%	24	35.8%	
Other	0	–	2	5.9%	2	3.0%	
Stage (FIGO, 1989)							
I	13	39.4%	18	52.9%	31	46.3%	0.268[b]
II	7	21.2%	2	5.9%	9	13.4%	
III	12	36.4%	13	38.2%	25	37.3%	
IV	1	3.0%	1	2.9%	2	3.0%	
Time since cancer diagnosis							
Median; (Q1–Q3)	2	(1–5)	3	(2–6.8)	3	(1–5.5)	0.114[c]
At least 5 years ago	9	27.3%	12	35.3%	21	31.3%	0.638[b]
3–5 years ago	5	15.2%	8	23.5%	13	19.4%	
1–3 years ago	13	39.4%	10	29.4%	23	34.3%	
Less than 1 year ago	6	18.2%	4	11.8%	10	14.9%	

[a] p-Value based on two-sample *t*-test.
[b] p-Value based on Fisher's exact test.
[c] p-Value based on Wilcoxon rank sum test.