[Original Research]

Changes in Quality of Life of Cancer Outpatients at Community Pharmacies

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Abstract: Improvement of quality of life (QOL) is one of the important goals in cancer therapy. However, there were no reports of community pharmacists' involvement in QOL for cancer outpatients. To explore the relationship between community pharmacists' intervention and the QOL of cancer outpatients, we investigated QOL changes in cancer outpatients after pharmaceutical interventions that were instructed by the Board Certified Pharmacist in Palliative Pharmacy. The QOL of cancer outpatients was assessed initially and after 3 months using the Medical Outcomes Study 8 Form Health Survey (SF-8) at 14 community pharmacies. Changes in each of the SF-8 scores between the initial survey and the survey 3 months later were analyzed. Each score was compared in the intervention group in which the community pharmacist intervened and the non-intervention group. Of the 126 patients who completed the first questionnaire, 70 responses to second survey were obtained. Only the body pain score significantly decreased 3 months after the first survey. In the non-intervention group, neither score showed a significant change. The only domain that showed improvement was the Role Emotional of the intervention group. In addition, it was suggested that community pharmacists' intervention may have supported the patients' psychological well-being. Therefore, it is possible that community pharmacists can contribute to improving cancer outpatients' QOL by regularly assessing their QOL and performing interventions that meet their needs.

Key words: cancer outpatient; community pharmacy; SF-8; quality of life

INTRODUCTION

Palliative care refers to improving the quality of life (QOL) of patients who are facing life-threatening diseases and their families¹⁾. In cancer treatment, improvement of QOL becomes one of the important goals. Many cancer outpatients reportedly indicated that they suffer from multiple physical and psychological burdens²⁾. According to the previous literature, the World Health Organization recognizes that community pharmacists are the most accessible medical professionals³⁾. In addition, it is also reported that the role of community pharmacists in cancer treatment now involves advocating, promoting, supporting, and providing cancer-related health promotion. However, in our previous report, community pharmacies were not perceived by patients as providing palliative care⁴⁾. Recently, cancer treatment has shifted from inpatient to outpatient settings⁵⁾, and the number of cancer patients has increased as the population ages⁶. Moreover, in recent years, the development and use of anticancer drugs has significantly increased⁷). Therefore, community pharmacists are increasingly expected to contribute to

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improving cancer outpatients' QOL by interdisciplinary approach based on community medicine.

In Japan, it is a requirement to conduct screening for cancer pain and other types of total pain at designated cancer hospitals, and the symptoms and QOL assessment for cancer patients are addressed as a routine practice^{8,9)}. Morita et al. reported that the combined intervention of introducing specialized palliative service using screening tools and providing on-demand specialized palliative care might be useful in identifying patients with underrecognized palliative care needs and referring them to specialized palliative care service at the appropriate time⁵⁾.

Many studies have reported the QOL of cancer outpatients, including each cancer type¹⁰⁻¹², those with advanced cancer¹³, with metastatic or recurrent cancer², or receiving cancer chemotherapy¹⁴. However, there were no reports on the influence of community pharmacists' involvement in the improvement of QOL for cancer outpatients. Therefore, to explore the relationship between community pharmacist intervention and QOL of cancer outpatients, we investigated the QOL change of cancer outpatients after pharmaceutical interventions, providing the information of relevant medical providers and/or facilities, and others by community pharmacists.

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METHODS

1. Patients

This survey was carried out between January 2016 and February 2018 at 14 community pharmacies located in Aichi and Mie prefectures, Japan. The subjects were cancer outpatients who visited community pharmacies to receive their oral agents for cancer treatment, supportive treatment, or cancer pain. Exclusion criteria included an inability to complete the questionnaire, poor physical condition causing an inability to complete the questionnaire, or being under 20 years old. In general, the answer from the patients who have difficulty responding due to physical and mental characteristics were excluded.

2. Procedure

The participating pharmacists were instructed on how to utilize the QOL scale used in this study by the Board Certified Pharmacist in Palliative Pharmacy. In this survey, no standardized intervention protocol was provided for participating pharmacists. However, at this brief introduction, the criteria for intervention were indicated as follows: 1) pharmaceutical interventions (dosage adjustment, pain and adverse events management, proposal for supportive care, patient information feedback to doctor), 2) providing information on related occupations and/or facilities (home medical care, the Cancer Consultation Support Center, related administrative organizations, etc.), and 3) others, and pharmacists' understanding was unified. Patients who received only routine medication counseling by the pharmacist who did not intervene were set to be included as a non-intervention group. We also introduced the Cancer Consultation Support Center and cancer support booklets issued by each prefecture as information sources of other occupations.

The purpose of this survey was explained to cancer outpatients by community pharmacists who attended a lecture on this research. Written informed consent was obtained from the all participants who agreed to be included in this survey. They were asked to answer a self-completed questionnaire initially and in a second survey (3 months after the initial survey). Patients' age, gender, and address were also obtained from the questionnaires. The initial survey was conducted at the community pharmacy. The pharmacist assessed each patient's QOL from the answer sheet. In addition to routine medication instruction, if the community pharmacist performed an intervention, its content was reported by selecting the most appropriate type as mentioned above. The case where the pharmacist intervened was designated as the intervention group, while the other cases were assigned to the non-intervention group. According to the previous QOL survey¹⁴, respondents were also assigned to the older group for those 60 years or older and to the younger group for those under 60 years old. Three months after the initial survey, the same questionnaires were mailed to the respondents' homes. The respondents answered within 2 weeks and returned the answer sheets by mail.

For the participating pharmacists, information was collected by questionnaire regarding the age, number of years of the pharmacist's experience, and professional pharmacists such as Board Certified Pharmacist in Palliative Pharmacy and others.

3. QOL assessment and measures

General health-related QOL was measured using the Medical Outcomes Study 8 Form Health Survey Japanese version (SF-8)¹⁵⁾. The SF-8 comprises eight subscales, each of which evaluates a different dimension of health: General Health (GH); Physical Functioning (PF); Role Physical (RP); Body Pain (BP); Vitality (VT); Social Functioning (SF); Mental Health (MH); Role Emotional (RE). The scale is summarized by the physical comprehensive score (PCS) and mental comprehensive score (MCS) based on the eight subscale scores. Higher scores on each subscale or summary measurements indicate better health. The Japanese population-based standard scores are set at SF-8, and based on that scores, the health of the object group can be considered. Before using SF-8, registration was applied in advance.

4. Analysis

Group comparisons about the respondents' characteristics between the intervention and non-intervention group were made using the Fisher's exact test. QOL scores were shown as means with standard deviation. Each QOL score was compared between the initial survey and the second survey using the paired *t*-test or the Wilcoxon signed rank test. The comparison of the scores at the first survey between the unpaired groups were performed by Mann-Whitney *U* test. Statistical evaluation was conducted using EZR software¹⁶. The difference was significant if the *p*-value was less than 0.05. The study had the approval of the Ethics Committee of Nagoya City University Graduate School of Medical Sciences and Nagoya City University Hospital Institutional Review Board (#60160041).

RESULTS

1. Respondent characteristics

In total, 129 cancer outpatients who visited a community pharmacy to fill a prescription participated in this survey. Three respondents did not complete the questionnaire. Thus, we sent a second questionnaire to 126 respondents. Of these, 73 respondents responded. Excluding 3 inadequate answers, we analyzed 70 respondents (56%). Table 1 summarizes the respondents' backgrounds. There were 42 (60%) and 28 (40%) respondents in the intervention group and the non-intervention group, respectively. There was no difference in the backgrounds of the two groups.

2. Pharmacists characteristics

Fourteen pharmacists whose average age was 38 (29-49) participated, and the average pharmacist's experience was 12.1 (3-26) years. Only one participating pharmacist was a Board Certified Pharmacist in Palliative Pharmacy.

3. QOL comparison between the initial survey and after 3 months

Table 2 shows each SF-8 score comparison between the initial survey and 3 months after the initial survey. Only the BP score showed a significant decrease 3 months after the first survey. There was no significant difference in other scores after 3 months.

4. QOL of BP comparison in the initial survey

In the initial survey, the BP score in the group aged under 60 years (51.2 \pm 7.8) did not show significant difference from the group aged 60 years or older (53.2 \pm 7.8). There was no significant difference between the intervention (50.8 \pm 7.7) and non-intervention group (54.4 \pm 7.6) in the BP score.

5. QOL comparison between the initial survey and after 3 months by age

Table 3 shows each SF-8 score comparison between the initial survey and 3 months later by age. There was no significant difference in the score in those under 60 years old. At 60 years or older, the BP score significantly decreased after 3 months.

6. QOL comparison between the initial survey and 3 months later in the intervention/nonintervention groups

Table 4 indicates changes in the SF-8 scores by the intervention group and non-intervention group. In the intervention group, the BP score significantly decreased, while the RE score significantly increased. The score in the non-intervened group did not show significant changes in all subscales after 3 months.

7. Intervention contents by community pharmacists

The contents of the pharmacists' intervention for cancer outpatients were as follows: pharmaceutical interventions, such as dosage adjustment, pain and adverse events management, proposal for supportive care, patient information feedback to doctor (n = 25, 59.5%), providing relevant occupations or facilities' information (n = 6, 14.3%), and others, such as dietary counseling, exercise therapy, listening to patient's feelings of anxiety, and others (n = 11, 26.2%).

Table 1 Respondents characteristics									
	All cases $n = 70$		Interv n =	Intervention ^a n = 42		Non- intervention ^a n = 28			
_	n	%	n	%	n	%			
Gender									
Male	24	34.2	15	35.7	9	32.1	<i>n.s.</i>		
Female	46	65.7	27	64.3	19	67.9			
Age									
< 60	33	47.1	23	54.8	14	50.0	<i>n.s.</i>		
≥ 60	37	52.9	19	45.2	14	50.0			

Values are presented as number or %. ^a Statistical analyses was performed using Fisher's exact test. p < 0.05 is considered statistically significant. *n.s.* no significant.

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QOL	Init	ial	After 3		
(SF-8)	mean	SD	mean	SD	<i>p</i> -value
\mathbf{PF}	45.8	8.3	45.0	7.6	<i>n.s.</i>
RP	46.1	9.2	45.7	7.7	<i>n.s.</i>
BP	52.2	7.8	48.8	8.9	< 0.01
GH	47.6	6.5	47.6	6.6	<i>n.s.</i>
VT	49.2	6.4	49.4	6.7	<i>n.s.</i>
SF	46.7	9.3	44.8	9.9	<i>n.s.</i>
RE	45.1	9.6	46.4	8.4	<i>n.s.</i>
MH	48.3	7.3	47.3	6.8	<i>n.s.</i>
PCS	46.9	8.1	45.6	7.1	<i>n.s.</i>
MCS	46.4	8.6	46.6	8.0	<i>n.s.</i>

Table 2QOL comparison between the initial survey and after 3 months(n = 70)

Values are presented as score. SD indicate standard deviation. Statistical analyses was performed using paired *t*-test. p < 0.05 is considered statistically significant. *n.s.* no significant, PF physical functioning, RP role physical, BP body pain, GH general health, VT vitality, SF social function, RE role emotional, MH mental health, PCS physical comprehensive score, MCS mental comprehensive score.

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QOL - (SF-8) -	< 60 (<i>n</i> = 33)					$\geq 60 \ (n = 37)$				
	Initial		After 3 months			Initial		After 3 months		1
	mean	SD	mean	SD	- p-value -	mean	SD	mean	SD	- <i>p</i> -value
PF	46.9	7.1	46.6	6.2	<i>n.s.</i>	44.7	9.3	43.5	8.4	<i>n.s.</i>
RP	46.1	9.8	47.2	6.5	<i>n.s.</i>	46.0	8.8	44.4	8.5	<i>n.s.</i>
BP	51.2	7.8	49.0	6.4	<i>n.s.</i>	53.2	7.8	48.7	10.7	< 0.05
GH	47.9	6.8	48.4	6.7	<i>n.s.</i>	47.3	6.4	47.0	6.5	<i>n.s.</i>
VT	49.5	5.3	50.4	6.4	<i>n.s.</i>	49.0	7.4	48.4	6.9	<i>n.s.</i>
SF	48.0	8.1	45.6	10.3	<i>n.s.</i>	45.5	10.3	44.1	9.7	<i>n.s.</i>
RE	44.9	9.5	46.8	9.4	<i>n.s.</i>	45.2	9.8	46.1	7.6	<i>n.s.</i>
MH	48.1	7.9	46.8	7.6	<i>n.s.</i>	48.4	6.8	47.7	6.0	<i>n.s.</i>
PCS	47.4	8.4	47.2	6.2	<i>n.s.</i>	46.5	7.9	44.1	7.7	<i>n.s.</i>
MCS	46.5	9.4	46.3	9.7	<i>n.s.</i>	46.3	8.0	47.0	6.2	<i>n.s.</i>

Table 3 QOL comparison between the initial survey and after 3 months by age

Values are presented as score. SD indicate standard deviation. Statistical analyses was performed using Wilcoxon signed rank test. p < 0.05 is considered statistically significant. n.s. no significant. PF physical functioning, RP role physical, BP body pain, GH general health, VT vitality, SF social function, RE role emotional, MH mental health, PCS physical comprehensive score, MCS mental comprehensive score.

 Table 4
 QOL comparison between the initial survey and 3 months later in the intervention/non-intervention groups

QOL - (SF-8) -	Intervention $(n = 42)$					Non- intervention $(n = 28)$				
	Initial		Three months later		1	Initial		Three months later		1
	mean	SD	mean	SD	<i>p</i> -value	mean	SD	mean	SD	<i>p</i> -value
PF	45.1	8.8	43.9	8.6	<i>n.s.</i>	46.8	7.6	46.5	5.5	<i>n.s.</i>
RP	45.6	9.3	44.6	8.6	<i>n.s.</i>	46.8	9.2	47.4	6.0	<i>n.s.</i>
BP	50.8	7.7	47.3	8.7	< 0.05	54.4	7.6	51.1	8.7	<i>n.s.</i>
GH	46.3	6.3	47.1	6.1	<i>n.s.</i>	49.4	6.5	48.5	7.3	<i>n.s.</i>
VT	47.8	6.5	49.4	6.7	<i>n.s.</i>	51.5	5.9	49.3	6.9	<i>n.s.</i>
SF	46.0	10.2	43.7	10.1	<i>n.s.</i>	47.7	7.9	46.5	9.6	<i>n.s.</i>
RE	42.7	10.2	45.7	9.0	< 0.05	48.7	7.5	47.5	7.5	<i>n.s.</i>
MH	47.5	8.0	47.0	6.8	<i>n.s.</i>	49.4	5.9	47.7	6.8	<i>n.s.</i>
PCS	46.1	8.4	44.3	7.7	<i>n.s.</i>	48.1	7.5	47.5	5.8	<i>n.s.</i>
MCS	45.0	9.8	46.5	8.5	<i>n.s.</i>	48.5	6.1	46.8	7.2	<i>n.s.</i>

Values are presented as score. SD indicate standard deviation. Statistical analyses was performed using Wilcoxon signed rank test. p < 0.05 is considered statistically significant. *n.s.* no significant. PF physical functioning, RP role physical, BP body pain, GH general health, VT vitality, SF social function, RE role emotional, MH mental health, PCS physical comprehensive score, MCS mental comprehensive score.

DISCUSSION

Outpatient chemotherapy has been reported to reduce the overall QOL for patients owing to multiple adverse events¹⁰. Thus, cancer outpatients may have to balance their usual activities at work and/or at home with their treatment, thereby decreasing their QOL. Moreover, one report highlighting the importance of pharmacist interventions showed that pain and adverse events' management can be appropriately achieved by pharmacist interventions through continuous interviews and assessments of cancer patients before consultations with physicians in hospitals¹⁷). In addition, there was also a report concerning the successful use of community pharmacist-led telephone follow-ups for the management of adverse events associated with oral anticancer agents¹⁸⁾. In this survey, only the QOL in the BP domain worsened 3 months after the initial survey. Moreover, no significant change was observed in the BP score (51.2 to 49.0) in the younger group, but a significant decrease (53.2 to 48.7) was observed in the older group. It was reported that the

elderly have difficulty expressing their pain properly and tend to endure pain¹⁹⁾. Therefore, the QOL of BP in the older group might further worsen due to the insufficient pain assessment by community pharmacists. Furthermore, physiological systemic changes associated with aging could affect the pain assessment. Based on these previous reports and the results of this survey, community pharmacists need to conduct periodic physical QOL assessment of cancer outpatients continuously, even for patients who controlled pain well, especially in the elderly BP domain.

In this study, we compared the QOL changes in the intervention group with the sequential change in the non-intervention group as a control. The QOL of the BP domain tended to get worse not only in the nonintervention group but also in the intervention group. No significant difference in BP score change in the nonintervention group may be due to the small sample size. In addition, pain medications such as NSAIDs and opioids, cancer treatments, and the stage of cancer might affect assessment of their QOL of the BP domain. Since community pharmacies do not have access to hospital medical records, accurate information of the stage of cancer is very difficult to obtain. In addition, no information was collected on pain treatment in this survey. In the future, it is necessary to investigate the effects of pharmacists' intervention on patient's satisfaction with the pain management and cancer patients' QOL.

The QOL of physical domains (PF, RP, SF, PCS) tended to worsen in the intervention group. It is possible that the evaluation of physical symptoms of their patients varied at each community pharmacist. It is important to investigate the impact of assessing and managing pain and physical symptoms of cancer outpatients based on certain protocols by community pharmacists on the QOL of cancer outpatients.

Cancer patients not only have physical but also psychological and social anxiety2). However, in a nationwide survey in Japan, many community pharmacists reported that they perceived extreme difficulties in communicating with terminally ill cancer patients and the psychological support of cancer patients²⁰⁾. In our survey, the QOL of the RE domain significantly improved only in the intervention group. The community pharmacists assessed the patients' QOL, then paid attention to their suffering, and responded in some way. The pharmacists not only instructed on medication, but also introduced other related occupations that can respond to their problems, doing dietary counseling, exercise therapy, and listening to their feelings of anxiety. Several studies have reported the importance of hospital pharmacists' intervention with cancer patients²¹⁻²⁴⁾. Tanaka et al. reported that on anxiety/depression dimensions, the health status of the pharmacist intervention group was better at the second and third counseling sessions by the hospital pharmacist than at the initial counseling session, and counseling by pharmacists influenced patient QOL improvement²¹⁾. In randomized control trials in Malaysia, it was reported that repetitive counseling by pharmacists was shown to be effective in improving QOL and in decreasing anxiety and depression among cancer patients²⁴⁾. Furthermore, it was reported that pharmaceutical interventions have obtained obvious efficacy in cancer patients by improving positive emotions²²⁾. These studies indicated that pharmacists' interventions to cancer patients can improve patients' QOL. Although these reports showed the impact of interventions by hospital pharmacists, they strongly support the present finding that the community pharmacists' interventions may improve patients' anxiety and depression, and supported the patients' psychological well-being. These results showed that even a typical pharmacist intervention can improve the QOL of cancer patients. This might also implicate that the explanation regarding the interventions for cancer patients from a Board Certified Pharmacist in Palliative Pharmacy had a positive influence on the interventions of the participating pharmacists.

This study had several limitations. Our study involved only 14 pharmacies in a geographically limited area of Japan. In addition, the follow-up time was only 3 months. Another limitation is that the results may differ depending on the pharmacist's expertise or whether the community pharmacy is close to a designated cancer hospital. In addition, there are limitations in the background of participating patients. In this survey, participating patients were divided into sex and age, without considering their treatment contents, type, and stage of cancer. The difference between patients who required intervention and patients who showed stable condition without pharmacists' intervention is not clear. This survey did not evaluate several factors affecting the QOL, such as medication and treatment. Based on this survey, it will be necessary to conduct a study of a larger number of participating patients, evaluating the several factors affecting the QOL, such as pain medication and cancer treatment, and to conduct longer-term surveys in a wider area of Japan in the future.

CONCLUSIONS

This survey suggested that community pharmacists' interventions may decrease patients' anxiety and depression. Therefore, it is possible that community pharmacists can contribute to improving cancer outpatients' QOL by periodic assessments of it and performing interventions that meet patients' needs. Further investigation of the impact of periodic QOL assessments and interventions by community pharmacists is needed to improve cancer outpatients' QOL.

Conflict of Interest: The authors declare no conflict of interest.

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