BACKGROUND

Given Japan’s rapidly aging population, it is estimated that 290,000 people will require home health care by the year 2025. Due to its role in caring for postacute and chronic patients and in end-of-life care, the need for home health care is increasing.

Patients receiving home health care are thought to be a population with a low level of activities of daily living (ADL); for such patients, visiting the hospital is difficult and the risk of falls is higher than the general population. A variety of risk factors related to falls and other injuries in residents of elderly care facilities has been reported. In a cross-sectional study, Kuzuya et al reported that caregiver burden was associated with falls in frail elderly community residents, but the causal relationship was not clear. We conjectured that a stronger sense of burden in caregivers may cause more patient falls. If a causal relationship between the caregiver’s sense of burden and patient falls can be identified, interventions to reduce this sense of burden may be used as a means to prevent falls.

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Abstract

Aim: To investigate the relationship between caregiver burden and patient falls, and the incidence of falls in patients receiving home health care.

Methods: A prospective cohort study was conducted on patients receiving home health care provided by 3 home-care support clinics and their primary caregivers from November 2015 to February 2016. Cox proportional hazards analysis was performed on the Burden Index of Caregivers (BIC) and the presence of falls.

Results: Of the eligible 114 subjects, 47 were included in the final analysis. Nineteen subjects (40.4%) reported falls in the 3-month observation period. The incidence of falls was 1120 per 1000 person-years. The unadjusted hazard ratios for BIC score, patient gender (female), fall assessment score, and lack of physical barriers within the home were 1.46, 1.39, 0.52, and 0.52, respectively, and differences were not statistically significant. Adjusted hazard ratios were 1.56, 1.44, 0.65, and 0.62, respectively, and were also not statistically significant.

Conclusion: The incidence of falls was found to be roughly 5 times more than that in the general community elderly population. No causal relationship was found between caregiver burden and patient falls.

KEYWORDS
Burden Index of Caregivers, caregiver burden, falls, home health care, incidence of falls
The purpose of this study was to investigate whether the likelihood of falls can be predicted by the degree of the caregiver’s sense of burden, and to investigate the nature of falls in patients receiving home health care in Japan, as there have been very few such reports to date.

2 | METHODS

2.1 | Study design

A prospective cohort study was conducted using a questionnaire to assess the primary caregiver’s sense of burden at the initiation of and during the study period and its relationship to the incidence of falls during this period.

2.2 | Study population

Individuals who were receiving home health care from Motowanishi Family Clinic, Sakaemachi Family Clinic, or Hokusei Family Clinic as of October 1, 2015, and their primary caregivers were included. These clinics were in Muroran, Sapporo, and Asahikawa respectively. All of them were in Hokkaido, Japan. Subjects whose primary caregivers were unable to complete the questionnaires due to dementia, schizophrenia, or other psychiatric diseases, those who were receiving monetary compensation for providing care, patients who were unable to turnover and completely bedridden, or who were residents of assisted-care living facilities were excluded, resulting in 114 study subjects.

2.3 | Data collection

The observational period was roughly 3 months, from November 2015 to February 2016.

Questionnaires were distributed to subjects and their primary care physicians at the beginning of the study to collect information on age and gender of the subject and caregiver, the subjects’ fall assessment scores, physical barrier, and the primary caregivers’ sense of burden. The fall assessment score assesses fall risk based on 19 items in 7 categories including age, prior history of falls, range of activity, cognition, continence, medication use, and environment. Existing risk factors for falls are reported to be decreased muscle strength, loss of balance, gait disorders, vision impairments, movement disorders, cognitive dysfunction, ADL disorders, orthostatic hypotension, aging, history of falls, presence/absence of chronic disease, drugs, and the presence of steps in the residence. However, Kuzuya et al. reported from an investigation of falls in elderly persons in the community and caregivers’ sense of burden that no significant difference was seen between the fall and no-fall groups in the Charlson comorbidity index, which is scored according to the type of chronic disease. From these existing findings, we took the fall assessment score to be an indicator that encapsulates the factors strongly related to falls.

Burden Index of Caregivers (BIC) was used to assess the caregiver’s sense of burden. BIC consists of a total of 11 items that contain 2 in each of the following 5 categories, in addition to a total care burden: time-dependent burden, emotional burden, existential burden, physical burden, and service-related burden.

To ensure accurate assessment and documentation of falls by the primary caregiver, explanations were provided by the primary care physician in accordance with a manual. The primary caregiver documented the number of falls on the questionnaire, which was collected by the primary care physician during bimonthly visits. In this study, as defined by Gibson, a fall was classified as follows: “unintentionally coming to the ground or some lower level other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure”.

2.4 | Statistical analyses

The subjects were divided into 2 groups at the end of the study period based on the occurrence of falls. The chi-squared test was performed between the 2 groups for patient gender, caregiver gender, and the presence or absence of physical barriers or assistive devices (eg, steps, hand rails). Differences in patient age, caregiver age, fall assessment scores, and average BIC between the 2 groups were assessed using an independent t test. The incidence of falls was also calculated.

2.5 | Analysis of factors related to falls

To investigate the factors related to falls, a Cox proportional hazards analysis was performed using the duration until the occurrence of a fall as the dependent variable. The duration until the occurrence of a fall was measured based on the reports every 14 days by the caregiver. In cases when the caregiver did not report a fall, the period without a fall was taken to be 14 days. In cases when the caregiver reported a fall during those 14 days, the period without a fall was taken to be 13 days and the analysis was performed with the 14th day as the day of the fall. The following potential confounding factors were initially considered: patient factors (gender, cognitive function, prior history of falls, fall assessment score), primary caregiver factors (caregiving period, time providing care in the home, physical capabilities, and presence of depression or anxiety disorders), and social services factors (physical barriers, home rehabilitation services, use of home nursing care, and presence of additional caregivers). In selecting the independent variables, the fall assessment score, which contains multiple confounding and effect modification factors, was chosen, and patient gender, a known confounding factor not included in the fall assessment score, was added. In addition, we identified the presence of physical barriers to be significantly associated with BIC and falls through univariate analysis; this variable was also used as an independent variable in the Cox proportional hazards analysis. The independent variables that were ultimately included in the Cox proportional hazards analysis were BIC score, patient gender, fall assessment score, and the presence of physical barriers. P-value of <.05 was considered statistically significant. JMP software (JMP, version 13.1.0; SAS Institute Inc., Cary, NC, USA) was used for statistical analyses.
2.6 | Ethical considerations

The research protocol for this clinical study was approved by The Japan Primary Care Association's Ethics Committee (H27-No.2).

3 | RESULTS

3.1 | Patient demographics

There were a total of 192 home patients. Of the 114 eligible participants, 12 declined consent and 2 were hospitalized prior to start of the study, resulting in 100 participants. Following the initiation of the study, 5 subjects withdrew consent, 11 were hospitalized, 2 were placed in long-term care facilities, 7 died, and 2 became permanently bedridden. There were no instances of falls in these 27 patients, resulting in 73 subjects who were able to complete the study. Of these, 26 were found to have an incomplete collection of questionnaires, leaving 47 subjects to be included in the final analysis (Figure 1).

Nineteen subjects (40.4%) reported falls during the 3-month study period. The incidence of falls was 1120 per 1000 person-years.

Table 1 shows the distribution of age, gender, confounding factors, and BIC between the subjects with and without falls. The subjects with falls included more women, were older, and lived in environments free of physical barriers. Also, although not statistically significant, those with falls had lower average BIC compared with those without falls.

3.2 | Association between falls and BIC

Table 2 shows the results of the Cox proportional hazards analysis with falls as the dependent variable. The unadjusted hazard ratio for BIC score, patient gender (female), fall assessment score, and lack of physical barriers within the home were 1.46 (95% CI: 0.40-5.14), 1.39 (95% CI: 0.76-2.50), 0.52 (95% CI: 0.11-2.02), and 0.52 (95% CI: 0.25-1.15), respectively, and differences were not statistically significant. Adjusted hazard ratios were 1.56 (95% CI: 0.38-6.28), 1.44 (95% CI: 0.74-2.82), 0.65 (95% CI: 0.12-2.91), and 0.62 (95% CI: 0.28-1.48), respectively, and were also not statistically significant.

| All home patients | n = 192 |
|-------------------|---------|
| Eligible          | n = 114 |
| Declined          | n = 12  |
| Hospitalized      | n = 2   |
| Total recruited   | n = 100 |
| Incomplete data   | n = 28  |
| Hospitalized      | n = 11  |
| Died              | n = 7   |
| Withdrew          | n = 5   |
| Admitted to a facility | n = 2 |
| Became bedridden  | n = 2   |
| Finally analyzed  | n = 47  |

FIGURE 1  Flow of subjects analyzed

4 | DISCUSSION

We performed a prospective study investigating the relationship between patient falls and the caregiver’s sense of burden. In addition, we provided the first report regarding the incidence of falls in patients receiving home health care in Japan. The study focused on the caregiver’s sense of burden and investigated the relationship to patient falls, but no clear association was found.

The incidence of falls in this study was 1120 per 1000 person-years, indicating that a patient will fall at least once during a 1-year period. There are few similar studies on the incidence of falls, but in 1 analogous study, Xu et al found that the incidence of falls in a group of elderly Chinese veterans was 249 per 1000 person-years. In contrast, our study subjects suffered falls at a rate 5 times higher. The reason for this difference is thought to be that our study consisted of patients who were receiving home health care as they were unable to go to medical facilities for care and were likely to have reduced muscle strength and difficulty with ambulation in comparison with the previous studies.

Also, our study included a higher proportion of females (previous studies 0%, our study 53.1%) and the average age was high. Those are possible reasons for the higher incidence of falls, as female gender and advanced age are known risks.

The inability to find a statistically significant relationship between falls and BIC score may be due to an inadequate sample size. Of the initial 114 subjects to be enrolled, the final analysis included only 47 subjects. Withdrawal of consent and the incomplete collection of questionnaires in 31 subjects was 1 factor that led to a lower number of subjects than predicted. The average BIC score in the 47 subjects that completed the study vs the 31 that were excluded was 15.2 and 17.1, respectively, and thus higher in the excluded subjects. Requests for the reports regarding falls from the patients may have placed an additional burden on them, leading to withdrawal from the study.

Our study has social and policy implications. Aiba has reported on the incidence of severe injuries related to falls in patients certified to receive nursing care. Prevention of falls is important, as even in the absence of serious injuries, falls may reduce patient confidence and lead to a postfall syndrome with reduced ADL. Our study reported on the incidence of falls, including those that did not lead to serious injury, and found an incidence 5 times higher than that in the community-dwelling elderly population, which further emphasizes the need for fall prevention in the home health care setting.

Based on this study, areas requiring further study were noted. Hitomi has reported that the use of nursing care services eases family caregivers’ sense of burden when caring for elderly family members with dementia. The role of the family physician is not only to care for the patient but also to consider the patient’s environment in planning care. By providing opinions on how to coordinate services and attending to the needs of the caregivers, the family physician may be able to reduce the caregiver’s sense of burden. Due to the relatively small sample size, this study was not able to show a causal relationship between the caregiver’s sense of burden and patient falls, but should subsequent studies show such a relationship,
the family physician’s role in reducing falls in patients receiving home health care will become more evident.\textsuperscript{18}

In this study, we provide the first report regarding the incidence of falls in patients receiving home health care in Japan. We were not able to show a causal relationship between the caregiver’s sense of burden and the incidence of patient falls. Further studies involving a larger sample, however, may elucidate such a relationship.

**TABLE 1** Characteristics of the subjects and caregivers

| Characteristic                                           | Falls (n = 19) | Nonfalls (n = 28) | Total (n = 47) | P value |
|---------------------------------------------------------|---------------|------------------|---------------|---------|
| No. of female patients (%)                              | 13 (68)       | 12 (43)          | 25 (53)       | .019    |
| Mean age of patients [SD]                               | 89.1 [8.04]   | 82.4 [12.9]      | 85.1 [11.6]   | .039    |
| No. of long-term care level ≥3 (%)                      | 8 (42)        | 10 (36)          | 18 (38)       | .66     |
| No. of past history of fall (%)                         | 14 (88)       | 10 (42)          | 24 (60)       | .0024   |
| No. of using home nursing service (%)                   | 14 (74)       | 21 (75)          | 35 (74)       | .92     |
| No. of using home rehabilitation (%)                    | 2 (11)        | 9 (32)           | 11 (23)       | .074    |
| Mean hours of using adult day care per month [SD]       | 16.8 [29]     | 29.7 [41.7]      | 24.5 [37.3]   | .25     |
| Mean days of using short-term admission per month [SD]  | 0 [0]         | 24 [54.7]        | 14.3 [43.5]   | .063    |
| Mean fall assessment score of patients [SD]             | 10.9 [4.53]   | 10.1 [3.75]      | 10.4 [4.03]   | .55     |
| No. of female caregivers (%)                            | 15 (79)       | 24 (86)          | 39 (83)       | .88     |
| Mean age of caregivers [SD]                             | 69.5 [11.1]   | 66.9 [9.35]      | 67.9 [10.0]   | .39     |
| No. of caregivers patient’s own child (%)               | 7 (41)        | 10 (42)          | 17 (41)       | .98     |
| No. of secondary caregivers (%)                         | 5 (31.3)      | 7 (29)           | 12 (30)       | .88     |
| No. of caregivers have past history of mental illness (%)| 1 (6.3)       | 5 (22)           | 6 (15)        | .19     |
| Mean years of giving care [SD]                          | 5.24 [4.4]    | 6.43 [6.18]      | 5.95 [5.5]    | .51     |
| Average BIC of caregivers [SD]                          | 14.7 [7.92]   | 15.4 [7.09]      | 15.2 [7.37]   | .72     |
| No. of patients with no physical barrier within the home (%)| 18 (95)       | 19 (68)          | 37 (79)       | .027    |

| Quantile                                               | Falls (n = 19) | Nonfalls (n = 28) | Total (n = 47) |
|---------------------------------------------------------|---------------|------------------|---------------|
| BIC 1st quantile(0-<10)                                 | 5             | 6                | .8633         |
| BIC 2nd quantile(10-<15)                                | 5             | 6                |
| BIC 3rd quantile(15-<21)                                | 5             | 7                |
| BIC 4th quantile(21-<33)                                | 4             | 9                |

BIC, Burden Index of Caregivers.
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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTION

Study concept and design: TC, TN, YU, and KS. Acquisition of participants and data: TC, TN, YU, and KS. Analysis and interpretation of data: TC, TN, YU, KK, and KS. Preparation of manuscript: TC, TN, YU, and KK.

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TABLE 2 Results of Cox proportional hazards analysis of falls

| Variables                | Crude Hazard ratio (95% CI) | P-value | Adjusted Hazard ratio (95% CI) | P-value |
|--------------------------|-----------------------------|---------|-------------------------------|---------|
| BIC                      | 1.46 (0.40-5.14)            | .559    | 1.56 (0.38-6.28)              | .534    |
| Patient gender (female)  | 1.39 (0.76-2.50)            | .274    | 1.44 (0.74-2.82)              | .28     |
| Fall assessment scores   | 0.52 (0.11-2.02)            | .363    | 0.65 (0.12-2.91)              | .602    |
| Lack of physical barriers| 0.52 (0.25-1.15)            | .102    | 0.62 (0.28-1.48)              | .268    |

BIC, Burden Index of Caregivers.

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