〔Original〕

A combination of oral care and 23-valent-pneumococcal vaccination is able to reduce pneumonia incidence in nursing homes

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Abstract

Longevity places Japan among the leading nations in the world, and worldwide the number of the elderly is expected to increase both in developed and developing countries ; with an aging population comes increases in the incidence of diseases associated with old age, and here pneumonia is one of the most common causes of death in the elderly. In an effort to reduce the incidence of pneumonia, we conducted an interventional study with elderly residents of a nursing home in Yubari and compared the incidence of pneumonia with a similar nursing home in a neighboring town between 2009 and 2010. We provided a combination of oral care and pneumococcal plus influenza vaccinations in the intervention group. The incidence of pneumonia was 2.0% in the intervention group while it was 22.3% in the non-intervention group. The death rate from pneumonia was 1.0% in the intervention group and 8.5% in the non-intervention group. The incidence of pneumonia and the death rate due to pneumonia were all significantly lower in the intervention group (p<0.05). It is concluded that appropriate oral care combined with pneumococcal and influenza vaccination can be expected to result in a significant reduction in pneumonia in nursing homes.

Introduction

According to the World Health Organization (WHO), Japan was leading the world in longevity in 2015. The average global life span is 68 years for males and 73 years for females, while in Japan the average life span is 80 years for males and 87 years for females (http : //www.who.int/gho/ publications/world_health_statistics/2015/en/, Nov. 2015). The percentage of Japanese citizens over 65 years of age was estimated as 26.0% in 2014, the highest in the world. In the future, the percentage of the elderly is likely to increase both in developed and developing countries.

Many previous reports have shown that administration of pneumococcal vaccine (against *Streptococcus pneumoniae*) is effective as a prophylaxis for pneumococcal pneumonia. Pneumococcal vaccination has been associated with a 44.8 % reduction in the incidence of pneumonia in a nursing home (Maruyama et al., 2010) and has also reduced the incidence of pneumonia by 70% in high-risk patients (Shapiro & Clemens, 1984 ; Cornu et al., 2001). Pneumococcal vaccination in the time of year with high risks of influenza has been associated with a 27% reduction in the incidence of hospitalizations for pneumonia and a 34% reduction in the rate of death (Nichol, 1999). Further, combined pneumococcal and influenza vaccinations have been reported to result in a 50-60% reduction in the incidence of hospitalizations for pneumonia and a 81% reduction in the rate of death (Nichol, 1999 ; Chiba et al., 2004 ; Christenson et al., 2001 ; Christenson et al., 2004).

Oral bacteria may be aspirated into the respiratory tract, facilitating initiation and progression of systemic infectious diseases, such as pneumonia (Scannapieco, 1999 ; Scan-

napieco et al., 2001), and adequate oral hygiene has been reported to be associated with a reduction in the incidence of respiratory infections in the elderly (Yoneyama et al., 1996). Yoneyama et al. also reported that oral care was associated with a decrease in the incidence of pneumonia in the elderly (Yoneyama et al., 1999). These studies suggest that oral hygiene may be expected to play an important role in the care of the elderly in hospitals and nursing homes.

Yubari is a small city in Northern Japan with a population of 9900. It has the highest proportion of persons over 65 years of age in Japan, estimated as 46.5% in 2013. To evaluate the effects of combined oral care and pneumococcal plus influenza vaccinations, the present study was conducted as a prospective and interventional study, non−randomized and non−blinded, comparing elderly residents in a nursing home in Yubari with residents of a similar nursing home in the neighboring similar−sized town, Hobetsu, using the rate of incidence and survival rate from pneumonia to compare the two groups (residents of homes for elderly persons).

Materials and Methods

Study design

During a 1−year period from November 1, 2009, we conducted a prospective and interventional study comparing elderly residents of a nursing home residing here for the whole year, in Yubari (105 residents) and in a similar nursing home (98 residents) in a neighboring town 30 km away.

The entry criteria were obtained with the consent of the residents or a legal representative in each nursing home. Exclusion criteria were when vaccination of a resident was not advisable, like with suspicion of allergy to components of the vaccine.

Intervention

The intervention group in Yubari was provided with oral care and was inoculated with both pneumococcal vaccine 0.5ml (MSD) and influenza vaccine 0.5ml (Mitsubishi Tanabe Pharm). The non−intervention group was given only the influenza vaccine 0.5ml (Mitsubishi Tanabe Pharm).

In the intervention group, one dentist and two dental hygienists visited the nursing home once a week. After the residents agreed to be subjected to oral care, the dentist or dental hygienist spent 15 minutes brushing the teeth of the resident, performed scaling, oral wiping, and assisted with gargling and cleaning of removable prosthesis. The aim of the intervention was to reduce dental plaque (mainly biofilms of oral bacteria) mechanically by cleaning utensils, including toothbrushes, interdental brushes, dental scalers, tongue, and sponge brushes. This took place at the washstand in the private room occupied by the resident. Residents and nursing care workers were also shown methods of administering responsible oral care and how to dye to identify dental plaque by using plaque disclosing compounds. Longer time was spent on the oral care of un−communicative residents. To improve daily oral care skills, a lecture on oral care for nursing care workers was given at the start of the study and at 6 months after the start of the trial. In the weekly visits during the six months, the nursing care workers and residents were instructed in the basics of daily mouth care and the importance of routine performance of such care. The nursing care workers cleaned the mouths of the residents using cleaning utensils after each meal every day. We evaluated the oral care with evaluation indices commonly used by dentists – the Oral Hygiene Index (OHI–S) (Greene & Vermillion, 1964), and the Community Periodontal Index of Treatment needs (CPITN) (Ainamo et al., 1982). In the non−intervention group, the nursing care workers cleaned the mouths of the residents using cleaning utensils after each meal, every day. In this group the residents did not receive oral care by the dentists and dental hygienists. Here the study was conducted in secret, to ensure that care staff did not change procedures or awareness of the value of oral care. Primary care physicians visited both facilities to determine the clinical state of the residents once a week.

Outcome measure

The primary endpoint was pneumonia diagnosis. The secondary endpoint was death from pneumonia. We diagnosed pneumonia on the basis of the Japanese Respiratory Society guidelines by the primary care physicians at both facilities.

Ethics

The study was approved by the Japan Medical Association Centre for Clinical Trials (ref. no. JMA−IIA00066) and the Clinical Trial gov. (ref. no. NCT01403805). The study was also declared ethically justified and approved by the Yubari Kibounomori, Yubari Medical Centre Review Board. All participating residents fulfilled the criteria of safety required for the vaccination.

Statistical analysis

The mean ± standard deviation (SD) and numbers (frequencies) are reported as the relevant measures throughout the manuscript. Differences between the two nursing homes were compared using Fisher's exact test or the chi−square test for categorical variables and unpaired t test or Mann−Whitney test, as appropriate, for continuous variables according to the data distributions. Differences between the two subject groups with and without pneumonia were also compared. Survival plots were constructed using the Kaplan −Meier method with comparisons between plots based on the log−rank test. Univariate and multivariate regression analyses using the Cox proportional hazards model for primary pneumonia occurrence were also performed. Variables adjusted for in the multivariate analysis were vaccine inoculation, age, gender, care level, smoking, and presence of diabetes, congestive heart failure, cerebrovascular disease, and history of pneumonia. Age, a continuous variable, was divided into two categories in the univariate analysis (≥ 90 years old or others), and was categorized for every 10 years of age in the multivariate analysis. Relative risk ratios (RR) and the 95% confidential intervals (95% CI) before and after adjustment with variables were computed to measure the strength of the association. Log (events) − log (time) graphics on significant variables in the Cox proportional regression model were used to confirm the proportional hazard model. A p value of <0.05 was considered statistically sig-

nificant. The IBM SPSS Statistics ver. 19 software was used for all computations.

Results

Residents

Seven (6.6%) of the 105 eligible participants in the intervention group were excluded : 2 residents left the nursing home during the period of the study, 3 could not be vaccinated, 1 rejected oral care, and 1 died before the start of the oral care intervention, and so 98 residents comprised the intervention group (Fig. 1). In the non−intervention group, no one was excluded out of the 94 participants. None of the participants showed notable side effects after the vaccination. Table 1 shows the baseline characteristics of the residents of the 2 nursing homes (the participants of the two groups). There were no statistically significant differences in gender, age, Japanese care score, or incidence of diabetes mellitus. In the intervention group, the rate of heart failure, cerebrovascular disease, history of pneumonia, dentulous, and removable prosthesis use, are significantly higher than those of the non−intervention group.

Comparison of the incidence of pneumonia

The incidence of pneumonia in the intervention group was 2% (2 participants) and in the non−intervention group 22.3% (34 participants) (Table 2). The death rate from pneumonia was 1.0% in the intervention group and 8.5% in the non−intervention group. The death rate from all causes, in-
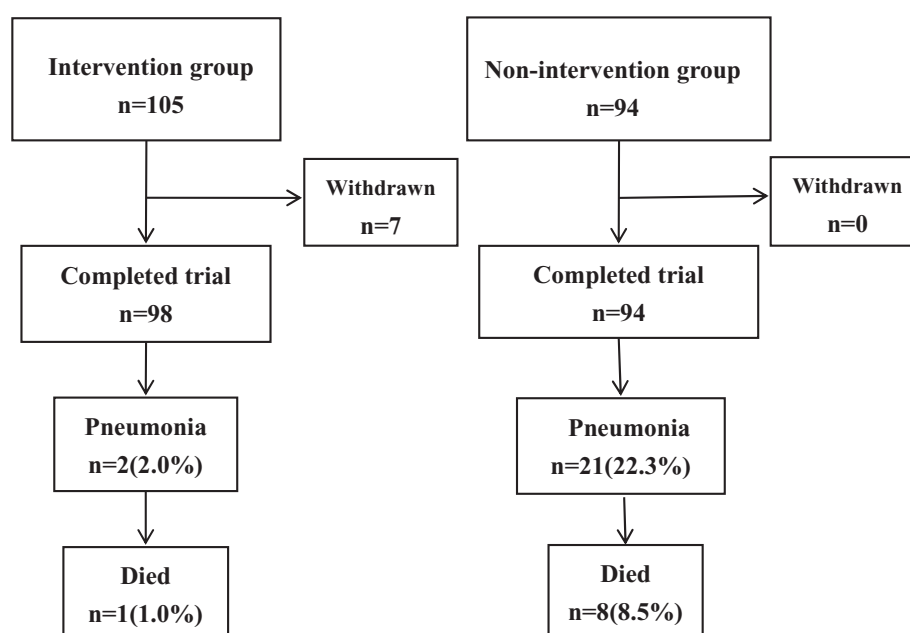

Figure 1　Flow diagram of enrolment and outcomes.

Table 1 Baseline Characteristics of Nursing Home Residents

	Intervention group (n=98)	Non-intervention group (n=94)	P values
Age, years old	86.4 ± 7.5	85.0 ± 7.5	0.202 [1]
Gender male / female, number (%)	24 / 74 (24.5/75.5)	28 / 66 (29.8/70.2)	0.422 [2]
Care level 1 / 2 / 3 / 4 / 5, number (%) *(Japanese care score : level 1-5)	2/11/32/33/20 (2/11/33/34/20)	5/6/26/32/25 (5/6/28/34/27)	0.342 [3]
Smoker, number (%)	0 (0.0)	6 (6.3)	0.013 [2]
Diabetes Mellitus, number (%)	14 (14.3)	19 (20.2)	0.340 [2]
Congestive Heart Failure, number (%)	21 (21.4)	5 (5.3)	0.001 [2]
Cerebrovascular Disease, number (%)	61 (62.2)	23 (24.5)	<0.001 [2]
History of pneumonia, number (%)	15 (15.3)	5 (5.4)	0.032 [2]
Dentulous, number (%)	46 (46.9)	28 (29.8)	0.018 [2]
Removable Prosthesis use, number (%)	57 (58.1)	40 (42.6)	0.043 [2]

Continuous variables are expressed as means ± standard deviation. [1] Unpaired t test, [2] Fisher's exact test, [3] Mann−Whitney test

*Japanese care score (level 1 − 5 : level 5 is very serious) is assessed by the level of ADL, dementia, swallowing disorders, malnutrition, physical impairment.

Table 2 Clinical Outcomes One Year after the Start of the Study in the Two Groups

	Intervention group (n=98)	Non-intervention group (n=94)	P values of between differences
Primary Pneumonia (No. %)	2 (2.0)	21 (22.3)	<0.001 [1]
Deaths caused by Pneumonia (No. %)	1 (1.0)	8 (8.5)	0.017 [1]
All deaths (No. %)	10 (10.2)	19 (20.2)	0.053 [2]
Total No. of Pneumonia (No. residents)	2 (2)	34 (21)	<0.001 [3]

[1] Fisher's exact test, [2] Chi−square test, [3] Mann−Whitney test

cluding pneumonia, was 10.2% in the intervention group and 20.2% in the non−intervention group. The incidence of pneumonia, death rate from pneumonia, and the number of pneumonia recurrences in the intervention group were statistically significantly lower than those in the non−intervention group (p<0.05). The risk ratios for pneumonia before and after the adjustments with variables as determined using a Cox proportional hazards model are shown in Tables 3 and 4. Additionally, the Log (event) – log (time) graphics for two variables, both vaccine inoculations and care score ≧ level 4 (Japanese standard), show approximately parallel survival curves, confirming the adequacy of the study based on the proportional hazard model (Table 4).

The Kaplan−Meier method was used to calculate the survival plots. There was a significant difference in the Kaplan−Meier survival plots for primary pneumonia occurrence between the 2 groups (2 residents in the intervention group vs. 21 residents in the non−intervention group) (Fig. 2−A). The mean follow−up periods in the intervention group and the non−intervention group were 11.4 ± 1.9 and 10.2 ± 3.5 months, respectively. There were no significant differences in the Kaplan−Meier survival plots for all−causes of death between the 2 groups (10 residents in the intervention group vs. 19 residents in the non−intervention group) (Fig. 2−B). The mean follow−up periods in the intervention and non−intervention groups were 11.4 ± 1.9 and 10.8 ± 3.1 months,

Table 3 Details of Baseline Characteristics of the Two Groups with and without Pneumonia vaccination

	Pneumonia (+) (n=23)	Pneumonia (−) (n=169)	P values
Two vaccines and oral care, number (%)	2 (8.7)	96 (56.8)	<0.001 [1]
Age, years old	86.2 ± 6.0	85.6 ± 7.7	0.737 [2]
Male gender, number (%)	8 (34.8)	44 (26.0)	0.453 [1]
Care level 1 / 2 / 3 / 4 / 5, number (%) *(Japanese care score : level 1-5)	0/1/6/6/10 (0/4/26/26/44)	7/16/52/59/35 (4/9/31/35/21)	0.034 [3]
Smoker, number (%)	1 (4.3)	5 (3.0)	0.540 [1]
Diabetes mellitus, number (%)	6 (26.1)	27 (16.0)	0.242 [1]
Congestive heart failure, number (%)	1 (4.3)	25 (14.8)	0.325 [1]
Cerebrovascular disease, number (%)	6 (26.1)	78 (46.2)	0.077 [1]
History of pneumonia, number (%)	3 (13.0)	17 (10.1)	0.714 [1]
Dentulous, number (%)	4 (17.4)	70 (41.4)	0.038 [1]
Removable Prosthesis use, number (%)	11 (47.8)	86 (50.9)	0.827 [1]

Continuous variables are expressed as means ± standard deviation. [1] Fisher's exact test, [2] Unpaired t test, [3] Mann−Whitney test
*Japanese care score (level 1 − 5 : level 5 is very serious) is assessed by the level of ADL, dementia, swallowing disorders, malnutrition, physical impairment.

Table 4 Relative Risk Ratios for Pneumonia before and after Adjustment with Variables

Variables	Univariate analysis		Multivariate Analysis	
	RR (95%CI)	P values	RR (95%CI)	P values
Two vaccines and oral care	0.07 (0.02 - 0.32)	0.001	0.08 (0.01 - 0.41)	0.003
Age ≥90 years old [1] Categorized by every 10 years [2]	1.06 (0.62 - 1.81)	0.844	1.20 (0.62 - 2.32)	0.586
Male gender	1.52 (0.60 - 3.82)	0.378	2.45 (0.72 - 8.33)	0.153
Care level ≥ level 4 *(Japanese care score : level 1-5)	1.69 (1.04 - 2.74)	0.034	1.90 (1.02 - 3.54)	0.045
Smoker	1.49 (0.17 - 13.36)	0.721	1.24 (0.10 - 15.37)	0.865
Diabetes mellitus	1.86 (0.67 - 5.14)	0.234	1.96 (0.59 - 6.49)	0.271
Congestive heart failure	0.26 (0.03 - 2.03)	0.200	0.25 (0.02 - 2.92)	0.274
Cerebrovascular disease	0.41 (0.16 - 1.10)	0.076	0.88 (0.27 - 2.90)	0.837
History of pneumonia	1.34 (0.36 - 4.99)	0.661	3.01 (0.59 - 15.34)	0.185
Dentulous	0.30 (0.10 - 0.91)	0.034	0.47 (0.12 - 1.80)	0.269
Removable Prosthesis use	0.89 (0.37 - 2.12)	0.783	1.31 (0.41 - 4.20)	0.651

[1] used in univariate analysis, [2] used in multivariate analysis RR indicates relative risk ratios ; CI, confidential interval.
*Japanese care score (level 1 − 5 : level 5 is very serious) is assessed by the level of ADL, dementia, swallowing disorders, malnutrition, physical impairment.
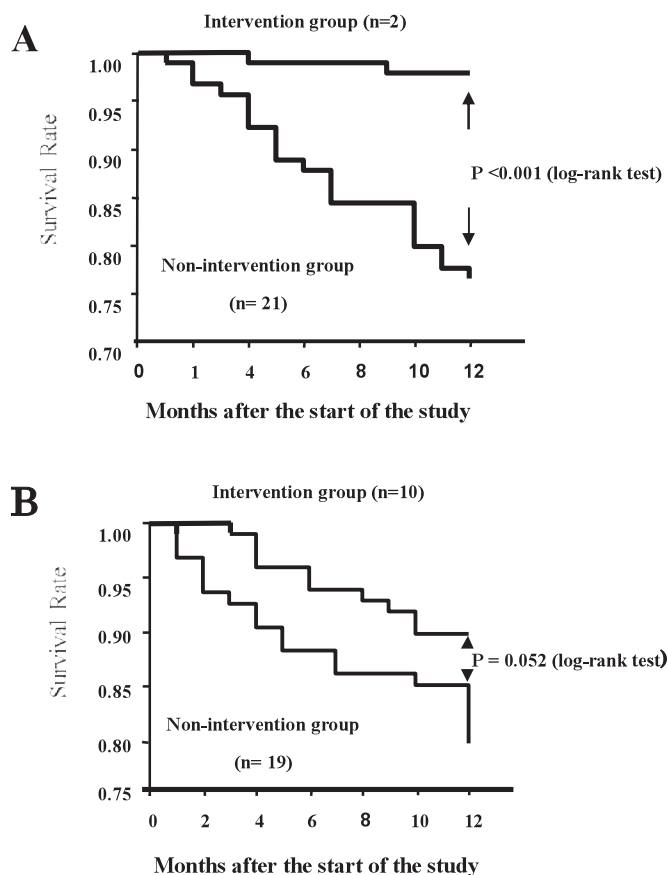
Figure 2 Kaplan−Meier survival plots of primary pneumonia occurrence (A) and all deaths (B)

    Kaplan−Meier survival plots of primary pneumonia occurrence (A) and all deaths (B). There was a significant difference in the Kaplan− Meier survival rates for primary pneumonia occurrence in the intervention group and in the non−intervention group (A). There was no significant difference in the Kaplan−Meier survival rates for all− causes of death of the intervention group and the non−intervention group (B).

Table 5 Change of the OHI−S Mean Score and CPITN Mean Score of Every 6 Month after the Start of the Study in the Intervention Group

	0 Mouth (n=51)	6 Mouths (n=45)	1 year (n=38)
OHI-S Score, mean(SD)	2.45 (1.14)	2.02 (1.42)	1.26 (1.13)
CPITN Score, mean(SD)	2.16 (1.37)	2.2 (1.39)	1.5 (1.33)

Lower numbers indicate better conditions

respectively.

Evaluation of oral care

    In the intervention group, the Hygiene Index (OHI−S) score results at the start of the study was 2.45 ± 1.14, after 6 months 2.02 ± 1.42, and after 1 year it was 1.26 ± 1.13. The Community Periodontal Index of Treatment needs (CPITN) score results at the start of the study was 2.16 ± 1.37, after 6 months 2.2 ± 1.39, and after 1 year it was 1.5 ± 1.33 (Table 5). In both these measures lower numbers show "better" states.

Discussion

    We examined the effects of a combination of oral care and pneumococcal plus influenza vaccinations on the pneumonia occurrence of elderly nursing home residents at a

small area in Japan. The results of the study showed that the combination of oral care and these vaccinations statistically significantly reduced the rate of pneumonia and reduced the death rate from pneumonia in these nursing home residents.

To the best of our knowledge, this study is the first trial showing the benefits of combined oral care and pneumococcal plus influenza vaccinations. In previous studies, either of the vaccination or oral care has been shown to prevent pneumonia in the elderly (Maruyama et al., 2010 ; Shapiro and Clemens, 1984 ; Cornu et al., 2001 ; Nichol, 1999 ; Chiba et al., 2004 ; Christenson et al., 2001 ; Christenson et al., 2004 ; Scannapieco, 1999 ; Scannapieco et al., 2001 ; Yoneyama et al., 1996 ; Yoneyama et al., 1999). Pneumococcal vaccination and influenza vaccination decrease the rate of pneumonia in the elderly by 50−60% (Nichol, 1999 ; Chiba et al., 2004 ; Christenson et al., 2001 ; Christenson et al., 2004). Oral care alone is reported to have decreased pneumonia incidence in nursing homes by about 40% (2009 Ministry of Health). We originally hypothesized that both oral care and vaccinations would reduce pneumonia and death from pneumonia more effectively than oral care or vaccination alone. The results of the study here show that with both oral care and vaccinations the incidence of pneumonia and the death rate from pneumonia reduced significantly. This would allow the conclusion that the combination of oral care with both vaccinations is a highly effective method for the prevention of pneumonia in the elderly. This points to the benefits of cooperation between physicians, dentists, para−medical staff, and the residents themselves as necessary for an optimal health care provision. The important factor in this study (the "Yubari Study") was the cooperation of all staff involved in the caring for the elderly, including physicians, dentists, nurses, care staff, and family. In many instances it may be very difficult for the elderly to access dental services and receive oral care in other countries including Denmark, Germany, Norway, Sweden, United Kingdom, and the United States, because dental health services are not fully covered by national insurance and as the costs are very high (Holm−Pedersen et al., 2005). The Yubari Study here suggests a solution to this without substantially increasing costs. The procedure in the study here is that a dentist gives a lecture on oral care to the care staff, the care stuff performs the daily oral care of the elderly and a dentist or dental hygienist periodically checks the quality of the oral care. As a result, the score on the Hygiene Index

(OHI−S) and Community Periodontal Index of Treatment needs (CPITN) improved. The only costs incurred would be the limited expense for regular dentist and dental hygienist visits. In this way, it would become possible to decrease the incidence of pneumonia as well as the cost of oral care without having to introduce significantly changes the present health care arrangements.

Among the elderly in Japan, the rate of pneumonia is 20% and death from pneumonia is 10% (Ministry of Health, 2014, http : //www.mhlw.go.jp/toukei/saikin/hw/jinkou/suii04 /, Nov. 2015 ; Morimoto K et al., 2015), and treatment of pneumonia costs $4,200 per patient ($ 4,200 at Nov. 2015 exchange rates) in Japan (All Japan Hospital Association, http : //www.ajha.or.jp/guide/1.html#p8, Nov. 2015). In the intervention group, there were only 2 pneumonia cases compared with the 34 in the non−intervention group. Therefore, in just this modestly−sized study, we succeeded in reducing medical costs by about $135,000 ($135,000 at Nov. 2015 exchange rates). Then, as the number of the elderly in nursing homes in Japan is 840,000 (Ministry of Health, 2015), such treatment may be able to prevent pneumonia in about 270,000 residents. Using these numbers, it seems possible that with administration of oral care and vaccinations to all elderly Japanese in nursing homes, medical costs could be reduced by a total of $1.1 billion($1.1 billion at Nov. 2015 exchange rates). In summary, we suggest that the combination of oral care and vaccinations for pneumonia prevention will have a positive impact on morbidity, mortality, and the costs associated with health care in the elderly.

The study here suffers from a number of limitations. First, our results were obtained with a very small number of patients in only two Japanese nursing homes. It is not certain that it is possible to generalize the results to other settings. To follow up on the results here it will be necessary to collect more data to establish more details of the effects of the combination of oral care and vaccinations. Second, the long−term benefits of the intervention are unknown as the follow−up period was for only one year. We next plan to examine the longer−term (>1 year) effects of oral care and vaccines in other nursing homes in other parts of Japan. Third, our study did not involve true randomization and a next project including randomization in the study is necessary. Fourth, in present study, we cannot determine if the effects are due to oral care vs. pneumococcal vaccination. Finally, it is unclear whether differences in the skills of the staff of the two nurs-

ing homes are relevant. There is currently no accepted method to assess individual staff objectively in Japan, however, generally similar－sized nursing homes in Japan have a similar number of staff, including nurses, certified care workers and certified helpers. Further, the intervention at the nursing home was discontinued after one year and after the discontinuation of the intervention the number of pneumonia cases in that nursing home increased about six times in the intervention period (data not shown). This result suggests that the quality of the care is similar in the two nursing homes.

Yubari City was declared bankrupt in 2007, and much of the publicly employed workforce was laid off. Medical care was scaled down from providing a large general hospital with 171 beds, to clinics with 19 beds, and residents had to be treated with fewer medical resources. As a result, the arrangements for providing support to the residents changed, now involving a smaller team of physicians, dentists, nurses, and medical stuff. This team has focused on preventing diseases, especially chronic diseases. The combination of vaccinations and oral care is one of the primary care arrangements for the prevention of diseases. Recently, Landers has suggested that the health care would be going to home owing to the rapidly rising medical expenses for the increasing incidence of chronic diseases, advances in technology, and healthcare consumerism (Landers, 2010). By 2025, the population of the world will exceed 8 billion, and we need to take measures to deal with the aging society worldwide. The Yubari Study may aid in resolving some problems in the aging of society.

In Yubari 46.5% of the population are over 65 years of age. Yubari area is one of the areas with the highest fraction of elderly population in the world, and in some respects may represent a future state of the world, especially in developed countries. It is very important to consider the problem of aging. In an aging society, the prevalence of chronic diseases and disability is higher. Therefore, to maintain the Activities of Daily Livings and Quality Of Life, it will be necessary to change medical treatment strategies from speciality－based, to arrangements involving cooperation among physicians, dentists, nurses, and para－medical staff, who engage in medicine and care. We suggest that the Yubari Study could be a model case to support the health in the elderly and believe that the study can be a guide for considering the global problems of the aging population.

Conclusions

This study shows that a combination of oral care and vaccinations dramatically reduced the incidence of pneumonia in the elderly participants here. Our results, the Yubari Study, suggest that the creation of a comprehensive community health care system would be beneficial to improve the Activities of Daily Livings and Quality Of Life of the elderly as well as it would reduce medical expenses. In the present day aging society, the elderly should be cared for with an integrated, cooperative system involving all levels of community health resources.

Acknowledgements

Conflict of Interest Statement

The authors of this manuscript have no conflicts of interest to declare.

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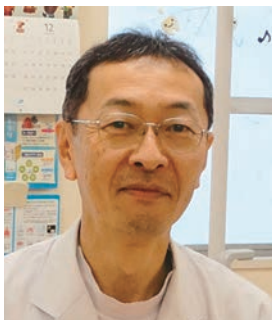
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