Table 1 Participants' demographic information

Variables	Total $n = 93$	Men $n = 50$	Women $n = 43$	P-value
Age (years)	75.8 (6.7)	76.0 (6.5)	75.7 (6.9)	0.84
Height (cm)	154.6 (8.4)	159.9 (5.6)	148.4 (6.7)	<0.001
Weight (kg)	55.9 (8.7)	58.6 (7.8)	52.7 (8.6)	<0.001
BMI (kg/m^2)	23.3 (2.8)	22.9 (2.6)	23.8 (3.0)	0.10
OD (log1/I)				
Forearm				
OD1	1.090 (0.118)	1.138 (0.107)	1.036 (0.104)	<0.001
OD2	1.122 (0.108)	1.163 (0.099)	1.074 (0.096)	<0.001
Thigh				
OD1	1.036 (0.099)	1.059 (0.102)	1.010 (0.087)	0.01
OD2	1.100 (0.087)	1.114 (0.091)	1.084 (0.079)	0.10
Subcutaneous thicknesses (mm)				
Forearm				
Fat	4.7 (1.7)	4.4 (1.4)	5.0 (1.9)	0.09
Muscle	30.2 (3.0)	31.6 (2.4)	28.5 (2.7)	<0.001
Thigh				
Fat	6.6 (2.7)	5.8 (1.5)	7.5 (3.3)	<0.01
Muscle	18.9 (5.1)	18.7 (4.3)	19.0 (5.9)	0.75
Grip strength (kg)	25.6 (8.1)	30.8 (5.9)	19.6 (5.9)	<0.001
Knee-extension strength (N m/kg)	1.007 (0.381)	1.145 (0.347)	0.847 (0.356)	<0.001

Values are mean (SD). BMI, body mass index; OD, optical density; OD1, optical density at 937 nm; OD2, optical density at 947 nm.

Table 2 Correlation coefficients between subcutaneous thicknesses or strengths and each optical density value

	Forearm OD1	OD2	Thigh OD1	OD2
Men ($n = 50$)				
Subcutaneous thickness				
Fat in the forearm (mm)	−0.37**	−0.30*	−0.32*	−0.28*
Muscle in the forearm (mm)	−0.02	0.03	−0.01	0.04
Fat in the thigh (mm)	−0.38**	−0.35*	−0.63***	−0.58***
Muscle in the thigh (mm)	0.00	0.07	−0.05	−0.03
Grip strength (kg)	0.24	0.23	0.13	0.14
Knee-extension strength (N m/kg)	0.33*	0.35*	0.08	0.12
Women ($n = 43$)				
Subcutaneous thickness				
Fat in the forearm (mm)	−0.50***	−0.44**	−0.48**	−0.48**
Muscle in the forearm (mm)	−0.10	−0.08	−0.12	−0.09
Fat in the thigh (mm)	−0.28	−0.26	−0.51***	−0.45**
Muscle in the thigh (mm)	−0.25	−0.23	−0.12	−0.03
Grip strength (kg)	0.09	0.09	0.10	0.14
Knee-extension strength (N m/kg)	0.13	0.15	0.01	0.01

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$. OD, optical density; OD1, optical density at 937 nm, OD2, optical density at 947 nm.

tissue at a depth of 1.0–2.5 cm from the skin surface.[30] In the participants of the present study, the mean values of subcutaneous fat thickness were 7.2 mm (forearm of men), 8.8 mm (thigh of men), 8.8 mm (forearm of women), and 16.1 mm (thigh of women); the mean values of subcutaneous muscle thickness were 31.6 mm (forearm of men), 18.7 mm (thigh of men), 28.5 mm (forearm of women) and 19.0 mm (thigh of women).

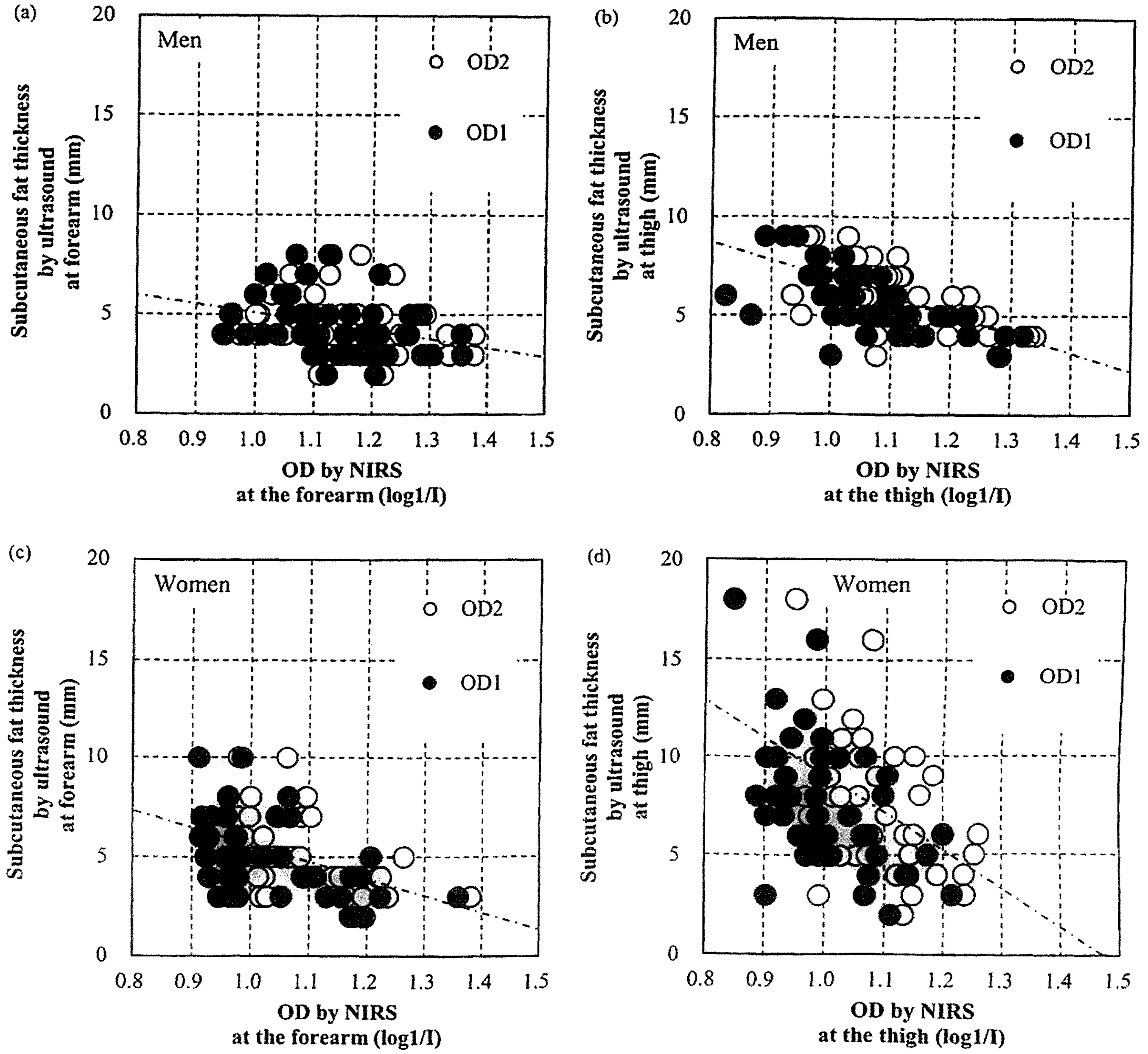

Figure 1 Scatter plot graphs showing the correlation between the subcutaneous fat thickness measured by ultrasound and the optical density (OD) from near-infrared spectroscopy (NIRS). (a,b) Data for men. (c,d) Data for women. Straight lines represent the regression line of OD at 937 nm (OD1), and broken lines represent the regression line of OD at 947 nm (OD2).

These results suggest that the near-infrared lights used in the present study did not reach the deepest point of the subcutaneous muscle layer of the participants. They also suggest that there was no significant correlation between OD and subcutaneous muscle thickness, although there were significant correlations between OD and subcutaneous fat thickness. In the stepwise multiple regression analysis, only subcutaneous fat thickness was included as a significant independent variable relevant to the OD value, and subcutaneous muscle thickness was excluded. Therefore, the estimation of muscle mass by NIRS is interpreted as lacking construct validity. However, this implies the opposite interpretation that the estimation of fat mass by NIRS has sufficient construct validity.

A two-component model dividing the human body into fat mass and fat-free mass is used when considering body composition at the molecular level.[31] This two-component model was the foundation of many methods for estimating body composition developed in the past. In this model, the construct validities for estimation of the fat mass and the fat-free mass are equally sufficient.

Table 3 Determinants of optical density at 937 nm in men and women

Independent variable	Men ($n = 50$) β	Men ($n = 50$) *P*-value	Women ($n = 43$) β	Women ($n = 43$) *P*-value
Forearm				
Entered				
Thickness of subcutaneous fat	−0.37	0.01	−0.50	<0.001
Removed				
Age	−1.33	0.19	−1.00	0.32
Thickness of subcutaneous muscle	−0.53	0.60	0.46	0.64
Grip strength	1.65	0.11	1.11	0.27
Thigh				
Entered				
Thickness of subcutaneous fat	−0.63	<0.001	−0.52	<0.001
Removed				
Age	−1.12	0.27	−0.62	0.54
Thickness of subcutaneous muscle	−0.02	0.99	−0.24	0.81
Knee-extension strength	0.79	0.43	0.33	0.74

Standardized beta values represent the correlation between optical density at 937 nm and each independent variable. OD, optical density; OD1, optical density at 937 nm.

Therefore, the results of the present study suggest that estimation of fat-free mass by using OD from NIRS has sufficient construct validity. When body composition is considered at the tissue level, the skeletal muscle is known to make up most of the fat-free mass.[31]

However, no significant correlation was found between OD and muscle strength in the present study. This suggests that the variable derived from NIRS is not the only index for estimating fat-free mass. A previous study has shown that there is a relationship between lean body mass and strength.[32] Furthermore, one report[33] suggested that the coefficient of determination became highest when the factors of maximum grip strength and physical performance were added as independent variables in the multiple linear regression model wherein lean mass was the dependent variable (adjusted for age, height, fat mass and activity) A high accuracy might be achieved if the muscle mass is determined by a multivariable estimation that includes OD plus physique indexes (such as height and fat mass), age and activity as independent variables.

To appropriately evaluate sarcopenia, it is ideal to directly measure the whole body skeletal muscle mass. However, it is very difficult to directly measure the body composition of a living human being; thus, an estimation is usually used. Because sarcopenia is related to critical risk factors, body composition needs to be estimated with high accuracy. If the body compositions of a population comprising various body forms are estimated from a single variable, great differences between the true values and the predicted values will be inevitable. Therefore, two or more variables should be used for estimation of body composition. For estimating body composition by using several variables, NIRS, which can appropriately estimate fat-free mass, might be an effective tool.

The present study was limited by all participants having a normal physique. In addition, we did not confirm the predictive validity, because the design of the present study was cross-sectional. Thus, the validity of the method should be confirmed by using longitudinally monitored populations including both thin and obese participants.

In conclusion, the OD value obtained by NIRS was strongly related to subcutaneous fat thickness. This result suggests that NIRS can appropriately estimate fat-free mass. If other variables are added to the OD as the predictive variable, skeletal muscle mass might be estimated with high accuracy in the elderly population.

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Disclosure statement

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ORIGINAL ARTICLE

Risk factors for a poor outcome following surgical treatment of cervical spondylotic amyotrophy: a multicenter study

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Abstract

Introduction Cervical spondylotic amyotrophy (CSA) is characterized by muscle atrophy in the upper extremities without gait disturbance. However, the indications and outcomes of surgical treatment for CSA have not been clarified. The purpose of this study was to determine the risk factors for a poor outcome following surgical treatment of CSA.

Materials and methods We performed a retrospective review of CSA in patients from 1991 to 2010 through a multicenter study. We collected information regarding age, type of muscle atrophy, preoperative manual muscle test (MMT), duration of symptoms, high-intensity areas on T2-weighted MR images, low-intensity areas on T1-weighted MR images, levels of spinal canal stenosis, cervical kyphosis and surgical procedures (laminoplasty, anterior cervical discectomy and fusion and posterior spinal fusion), and calculated overall risk factors related to a poor outcome following surgery. Univariate analyses and multivariate logistic regression analysis were performed to identify correlates of a poor outcome.

Results Fifty-nine patients, 95 % male (56 patients), were included in our analysis with a mean age of 59 years (range 32–78 years). Eighteen patients did not improve after surgery. Symptom duration (OR = 1.263), preoperative MMT grade (OR = 0.169) and distal type of CSA (OR = 9.223) were all associated with an increased risk of a poor surgical outcome.

Conclusion Early surgery is recommended for CSA patients in whom conservative treatment has not been successful. We also recommend surgery for patients who have severe preoperative muscle weakness or have the distal type of CSA.

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Keywords Cervical spondylotic amyotrophy · Poor outcome · Risk factor · Surgical treatment

Abbreviations

CSA	Cervical spondylotic amyotrophy
CSM	Cervical spondylotic myelopathy
ALS	Amyotrophic lateral sclerosis
MMT	Manual muscle test
HIA	High-intensity areas
LIA	Low-intensity areas
ACDF	Anterior cervical discectomy and fusion
PSF	Posterior spinal fusion
OR	Odds ratio
EMG	Electromyography

Introduction

In 1952, Brain et al. [1] first reported on a case of cervical spondylosis with muscle atrophy of the upper extremities but without sensory disturbance. Keegan [2] later reported on this case at autopsy and described this condition as dissociated motor loss in the upper extremities with cervical spondylosis. In Japan, Yanagi et al. [3] labeled this condition "Cervical Spondylotic Amyotrophy (CSA)". After analyzing the clinical features of CSA, they concluded that this condition was caused, not only by mechanical compression of the spinal cord, but also by selective damage to the anterior horn of the spinal cord secondary to circulatory disturbance. Kameyama et al. [4] reported that the pathophysiological basis for this syndrome was multisegmental damage possibly caused by circulatory insufficiency.

Cervical spondylotic amyotrophy is classified as either a proximal or distal type of muscle atrophy. The proximal type of CSA is characterized as weakness of the deltoid and biceps, such as a drop shoulder, whereas, the distal type is characterized as weakness of the hand muscles such as a drop finger. CSA patients are in their 30s–70s, but most are over 50 years old.

Usually, patients with CSA are first treated conservatively, such as with cervical traction or a neck collar. If the conservative treatment is ineffective, surgery is performed. Most cases have been successfully treated with surgery [5–7]; however, some surgeries have resulted in poor outcomes. It is in the best interest of patients and surgeons to understand potential risk factors related to a poor outcome following surgery. Several studies on CSA mentioned risk factors related to a poor outcome following surgery [6, 7], but there has not been a full multivariate analysis on this type of data. To the best of our knowledge, this is the first report incorporating a multivariate analysis on the results of surgical treatment for CSA. Our goal was to conduct a retrospective case–control study and multivariate analysis to assess the risk factors for a poor outcome after surgical treatment for CSA.

Materials and methods

All institutions that participate in the Nagoya Spine Group (NSG) obtained institutional review board approval for this study. We performed a retrospective review on both prospectively and retrospectively collected data for this study. The medical records of patients who underwent surgical treatment from January 1991 to December 2010 were reviewed to identify those who did not improve after CSA surgery. Orthopedic spine surgeons performed all the surgical procedures on 59 patients with CSA at hospitals in the NSG. Ten institutions participated in this multicenter study, and 18 surgeons performed the operations on CSA patients. We collected data on patients' ages, types of muscle atrophy, preoperative manual muscle test (MMT) results, duration of symptoms, high-intensity areas (HIA) on T2-weighted MR images (both sagittal and axial views), low-intensity areas (LIA) on T1-weighted MR images, levels of spinal canal stenosis, presence of cervical kyphosis and surgical procedures [laminoplasty, anterior cervical discectomy and fusion (ACDF) and posterior spinal fusion (PSF)]. We examined those factors related to poor outcomes following CSA surgery by applying univariate analyses and multiple logistic regression analysis of the surgical outcomes. To evaluate the effect of surgical treatment, we used MMT, and improvements in the muscle strength of the most atrophic and impaired muscles were classified into 4 grades: "excellent", full recovery or recovery to a MMT grade of 2; "good", 1 grade of recovery; "fair", no improvement; "poor", worsening effect. Taken together, we categorized two groups: a good outcome included "excellent" and "good"; a poor outcome included "fair" and "poor". We performed statistical analyses between the two groups.

To differentiate between amyotrophic lateral sclerosis (ALS) and CSA, we always examined for the presence of sensory disturbance, bulbar symptoms and diffuse muscle atrophy, and also performed electromyography (EMG) in some cases before surgery. Furthermore, a neurologist ascertained that these patients did not have motor neuron disease before surgery. Finally, there were no cases which were diagnosed as ALS or other motor neuron disease after surgery.

Data analysis

Data were analyzed using SPSS (version 18.0). Univariate analyses were performed to examine the relationship between outcome at the final follow-up and prognostic factors. We used Mann–Whitney *U* tests for non-normally distributed variables, and Chi-square tests for categorical variables. Variables were included in a logistic regression model if their univariate analysis *p* value was $\leq$0.15. The threshold for significance was a *p* value of <0.05.

Results

A total of 59 patients with CSA underwent surgical treatment. There were 56 men and 3 women, with an average age of 59.4 years (range 32–78 years). The mean follow-up period was 2.7 years (range 1–12 years and 9 months). The duration of symptoms averaged 11.4 months (range 0.8 months to 15 years). Forty-one patients had proximal-type CSA, and 18 patients had distal-type CSA. HIA on T2 MRI was confirmed in 21 of 59 patients, and LIA on T1 MRI was confirmed in five of 59 patients. Spinal canal stenoses were found at an average of 2.7 intervertebral levels (range 1–5 levels). Forty-five patients received laminoplasty with or without foraminotomy, eight patients received ACDF, and six patients received PSF with laminoplasty/laminectomy. The surgical results were excellent for 33 patients, good for 8, fair for 17, and poor for 1 (Table 1). On univariate analyses of surgical outcomes, the duration of symptoms and preoperative MMT grade were statistically associated with a poor outcome after surgery ($p < 0.05$). There was a trend for patients with the distal type of muscle atrophy to have a poorer surgical outcome compared to patients with the proximal type of muscle atrophy ($p = 0.123$). Also, there was a trend in patients who received ACDF to have a better surgical outcome compared to patients receiving other surgical procedures ($p = 0.09$) (Table 2). As described in the "Materials and methods" section, potentially significant predictors of a poor outcome were used to fit a logistic regression model. On multivariate analyses of surgical outcomes, preoperative MMT grade and distal-type CSA were significant predictors of poor surgical outcome ($p \leq 0.05$) (preoperative MMT grade: OR = 0.169, and distal type of CSA: OR = 9.223), whereas, symptom duration was a highly significant predictor (OR = 1.263, $p \leq 0.001$). However, type of surgical procedure was not significantly associated with a poor surgical outcome. The full model is presented in Table 3.

Table 1 Demographic data of CSA patients

	All patients ($n = 59$)
Mean age (years)	59.4 (32–78)
Male/female	56/3
Mean follow-up (years)	2.7
Duration of symptoms (months)	11.4
Type of muscle atrophy	
Proximal	41
Distal	18
Preoperative MMT grade	2.3
Levels of stenosis	2.7
HIA on T2 MRI	21
LIA on T1 MRI	5
Kyphosis	17
Surgical procedure	
Laminoplasty	45
ACDF	8
PSF + laminoplasty/laminectomy	6
Surgical outcome	
Excellent	33
Good	8
Fair	17
Poor	1

CSA cervical spondylotic amyotrophy, *MMT* manual muscle test, *PSF* posterior spinal fusion, *ACDF* anterior cervical discectomy and fusion, *HIA* high-intensity area, *LIA* low-intensity area

Discussion

In our study, we demonstrated clinical features of CSA and used a logistic regression model to determine the risk factors related to having a poor postoperative outcome. We demonstrated that patients with poor surgical outcomes tended to have CSA symptoms for a longer duration and to have lower preoperative MMT grades than those patients with good outcomes (OR: 1.263, $p = 0.006$; OR: 0.169, $p = 0.015$, respectively). Based on our results, we recommend surgery for CSA patients with MMT grades of 1 or 2, and if conservative treatment has not been successful for 3–6 months. Furthermore, in our study, the surgical outcome for distal-type CSA was inferior to the outcome for proximal-type CSA (OR, 9.223; $p = 0.025$). Similarly, Uchida et al. [7] reported that surgical outcome in patients with the distal type of muscle atrophy was inferior to that in patients with the proximal type. Neuroradiologically, Kaneko et al. [8] mentioned that the pathophysiology of distal-type CSA included widespread gray matter lesions with less involvement of the lateral posterior spinal column. Fujiwara et al. reported that muscle power improved in 92 % of the proximal-type cases but only

Table 2 Univariate analyses of surgical outcome in 59 patients with CSA

	Group 1 Good ($n = 41$)	Group 2 Poor ($n = 18$)	p value
Age	58.9	60.4	0.57
Duration of symptoms (months)	4.9	27.3	<0.0001
Preoperative MMT grade	2.5	1.9	0.019
Type of muscle atrophy			
Proximal	31	10	
Distal	10	8	0.123
Levels of stenosis	2.7	2.9	0.517
HIA on T2 MRI	16	5	0.406
LIA on T1 MRI	4	1	0.514
Kyphosis ≥10	7	5	0.272
Surgical procedure			0.09
Laminoplasty	30	15	
ACDF	8	0	
PSF	3	3	

Table 3 Multiple logistic regression analysis for the risk factors of poor postoperative outcome

Variable	OR	p value	95 % CI
Duration of symptoms (months)	1.263	0.006	1.070–1.492
Preoperative MMT grade	0.169	0.015	0.040–0.710
Distal-type CSA	9.223	0.025	1.329–63.979
Surgical procedure	1.431	0.970	0.084–24.376

CI confidence interval

improved in 38 % of the distal-type cases. They speculated that the distal type basically involves impingement against the anterior horn which has less ability than the ventral nerve roots to regenerate [5].

In the present study, the HIA on T2 MRI, the LIA on T1 MRI, the number of vertebral levels with cervical canal stenosis, and the presence of cervical kyphosis were not significantly associated with a poor postoperative outcome. It has been reported that edema, myelomalacia and gliosis involve high-signal intensity on spinal cord T2-weighted MR images and low-signal intensity on T1-weighted MR images, suggesting irreversible changes of the spinal cord, and this signal intensity change was significantly associated with the poor postoperative outcome of cervical spondylotic myelopathy (CSM) [9–12]. In CSM patients, the intramedullary signal intensity change is usually consistent with damage in the central portion of the spinal cord [9]. However, CSA occurs with compression and damage of the anterior horn of the spinal cord or the ventral nerve root. This may be why there is no correlation between signal intensity change on MRI and a poor surgical outcome. In fact, in our series, all cases which showed the signal intensity change demonstrated damage to the central portion of the spinal cord.

Previous reports also suggested that cervical kyphosis ≥10 was associated with a poor surgical outcome in CSM patients [13, 14]. Although our results indicated that cervical kyphosis was not associated with a poor surgical outcome, severe kyphosis may still influence outcome when laminoplasty is performed because kyphosis limits appropriate posterior shifting of the cord from the anterior compression. However, when root impingement, not compression of the anterior horn of the cord causes the muscle atrophy in CSA patients, cervical kyphosis would not be associated with surgical outcome.

On the other hand, Inui et al. [6] reported on conservative and surgical treatments for CSA patients. They mentioned that patients who fulfilled predictive factors such as age <50 years, duration of symptoms <6 months, single-level stenosis, foraminal stenosis, and a good response to traction therapy improved with conservative treatment. Although they attempted to determine the predictive factors related to surgical outcome, there was no statistical difference between the improvement group and the no improvement group.

Both ALS and CSA can have similar symptoms, and it can be difficult to distinguish the clinical manifestations of CSA during early stages of the disease [15]. Furthermore, although the clinical presentation of ALS closely resembles CSA, and both diseases preferentially affect middle-aged and elderly populations [16], it is very important to understand the differences between the diseases in order to distinguish one from the other prior to surgery. Cervical spondylosis does not cause atrophy of the tongue or fasciculations as we see with ALS. Amyotrophic lateral sclerosis patients can also have bulbar muscle involvement, articulation disorder and dysphagia. Muscle atrophy around the neck, such as the sternocleidomastoid muscle, and diffuse muscle atrophy of upper extremities are affected in ALS patients, but CSA involves only a few muscles. Apparent segmental sensory disturbance is characteristic of cervical spondylosis but not ALS, and ALS is more likely when there are widespread denervation potentials on EMG. However, if ALS cannot be definitively ruled out, surgery should not be performed, and patients should be carefully observed because ALS is always progressive.

The appropriate surgical methods for CSA are controversial. Some authors advocated that anterior decompression is reasonable for eliminating the anterior and anterolateral lesions [17–20]. The results from our series demonstrated a tendency for a better surgical outcome with ACDF than the other procedures, but it was not significant on univariate analysis ($p = 0.09$). Srinivasa et al. [19]

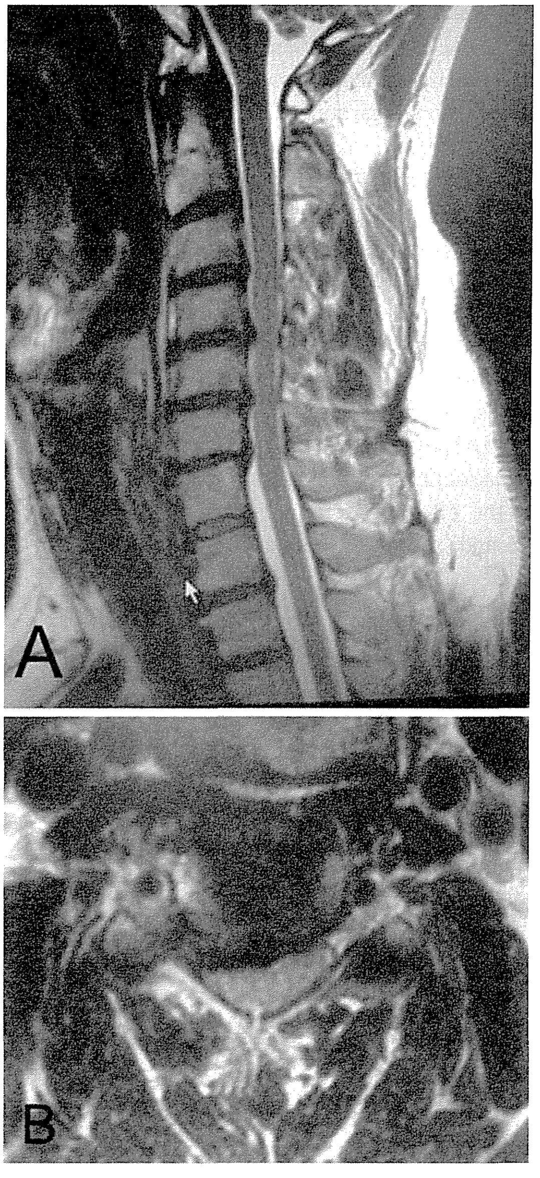

Fig. 1 a Sagittal image on T2 MRI showing multiple stenoses of the cervical spine. b Axial image on T2 MRI showing compression of the right anterior horn of the spinal cord (C4/5) and nerve root

reported that central corpectomy resulted in a good and long-lasting surgical outcome for distal-type CSA patients. However, these were elderly CSA patients with a tendency to have multiple and foraminal stenoses due to spondylosis making it difficult to correctly identify the lesion affecting the spinal cord or nerve root (Fig. 1). Thus, when patients had more than three lesions, we performed laminoplasty, whereas, with 1–2 levels of stenosis we performed ACDF. If the patients had severe kyphosis, we performed PSF with laminoplasty/laminectomy. In the present study, laminoplasty, with or without foraminotomy, was the most popular and effective operation for these patients. Our results demonstrated good outcomes for 30 of the 45 patients (67 %) treated by laminoplasty. We decided to add foraminotomy in case foraminal stenosis was causing the root impingement. Previously, some authors also reported laminoplasty and foraminotomy as effective treatments for most patients with this syndrome [5, 20].

Several limitations of our study must be acknowledged. First, this was a retrospective, observational survey, and there was no standardized treatment protocol due to the number of surgeons at different hospitals involved in the care of these patients. Second, since this was a multicenter study, different surgeons have different skill levels which might influence the surgical outcome. Third, our patient sample size is small; it was underpowered for statistically evaluating the difference in risk for a poor outcome following surgery. However, this study is the first report in which we identify the risk factors related to a poor outcome through multivariate analysis, and this series contained the largest number of surgically treated CSA patients so far reported.

In conclusion, the present study offers a foundation for a deeper understanding of the factors that influence the risks of a poor outcome following surgical treatment in CSA patients. Early surgery is recommended for CSA patients in whom conservative treatment has not been successful and the clinical status before surgery (symptom duration, preoperative MMT grade and distal type of CSA) significantly influences the surgical outcome. This information may be useful for clinicians in counseling patients and family members, and to develop more realistic treatment expectations for CSA patients.

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Conflict of interest The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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Utility of "loco-check," self-checklist for "locomotive syndrome" as a tool for estimating the physical dysfunction of elderly people*

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ABSTRACT

Aim: A new concept of locomotive syndrome has been proposed by the Japanese Orthopaedic Association. The aim of this study is to clarify the utility of its self-checklist, "loco-check," as a tool for estimating the physical dysfunction of elderly people. Methods: Subjects were 1124 community-dwelling Japanese people, 557 men and 567 women, aged 40 - 89 years. Information about the seven "loco-check" items was obtained from present inquiry sheets. Physical functions were examined by grip strength, knee extension strength, walking speed and one-leg standing time with open eyes. The averages of these test values, controlled for age and BMI, were compared between the "loco-check" (+) group and the "loco-check" (−) group. Also we examined about the trend of decline of physical function, together with SF36 physical function subscale score, as the number of the items chosen increased. Results: Adjusted average values of all four physical function examinations in the "loco-check" (+) group were significantly lower than those of the "loco-check" (−) group (all, p < 0.001). Also the adjusted average values of the majority of four tests were significantly lower in those who checked each of the "lococheck" items than those who did not, for most of the items. It was also revealed that the more items subjects checked, the lower the adjusted average values were, except for one-leg standing time. It was also the case with SF36 physical function subscale score. Conclusion: We showed the utility of "loco-check" as a simple tool not only for noticing the physical dysfunction of elderly people, but also for estimating the extent of it, except for balancing ability, particularly by counting the number of checked items.

Keywords: Locomotive Syndrome; Loco-Check; Physical Dysfunction; Estimation; Elderly People

1. INTRODUCTION

Recently, the population of elderly people has been growing larger and larger in developed countries. Among those countries, Japan has gained the top status as a super-aging society [1] and the population needing nursing care has naturally become larger. In order to cope with this situation, the Japanese Orthopaedic Association (JOA) proposed the new concept "Locomotive Syndrome" [2-4] in 2007. The JOA then used the short term "Locomo" for easy recall by Japanese people in general and to alert them about the importance of the locomotive organs in maintaining their independence all through their lives, because orthopedic problems have become one of the main reasons for the nursing care [2]. This syndrome refers to those elderly who are in need of nursing care services due to problems with their locomotive organs, or those who have risked conditions which may lead them to use such services in the future. For the greater self-awareness of the possibility of such a risk condition, the JOA prepared a self-checklist composed of seven items with which individuals can test themselves during their activities of daily living in and

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outside of the house (described in the Materials and methods section) [4]. These 7 items, called "loco-check," are very well-considered and cautiously chosen by the experts in this field, but their usefulness for estimating the physical dysfunction (particularly its extent) has not been revealed yet. Hence, the purpose of this study is to verify its usefulness in the originally targeted self-awareness of a person's physical disability, and also to investigate if it is available to surmise its extent by counting the number of checked items. We examined the relationship of the "loco-check" and the physical functional status evaluated by grip strength, leg extension strength, walking speed, one-leg standing time with eyes open, and compared with the SF36 (physical function subscale), most of which are popularly used to represent physical status. The verification of the utility of "loco-check" will help acquaint not only Japanese but people worldwide with the enlightened new notion of "Locomotive Syndrome".

2. MATERIALS AND METHODS

2.1. Subjects

The subjects were selected among people who participated in the 7th wave of the National Institute for Longevity Sciences Longitudinal Study of Aging (NILS-LSA). Details of the NILS-LSA are described elsewhere [5]. It is a biannual examination checking the physical and mental condition of ordinary Japanese people, so as to clarify the effect of aging. It is conducted by the National Center for Geriatrics and Gerontology (NCGG) in Japan. The National Institute for Longevity Sciences (NILS) is a research section of NCGG. The participants were chosen randomly from residents of Obu City and Higashiura-cho, in Aichi Prefecture, Japan. For this study, data from 1,124 persons were analyzed (61.5 ± 13.3, mean ± SD). Participants were 557 men and 567 women, whose ages ranged from 40 to 89, and the period of participation ranged from July 2010 to June 2011.

2.2. Information on Seven "Loco-Check" Items

The pre-mailed inquiry sheets completed by participants were utilized to determine whether they thought themselves to be fit in the seven "loco-check" items [4]: 1) You cannot put on a pair of socks while standing on one leg; 2) You stumble or slip in your house; 3) You need to use a handrail when going upstairs; 4) You cannot get across the road at a crossing before the traffic light changes; 5) You have difficulty walking continuously for 15 min; 6) You find it difficult to walk home carrying a shopping bag weighing about 2 kg; and 7) You find it difficult to do housework requiring physical strength. The "loco-check" (+) group was defined as those who checked at least one of the seven items, and the "loco-check" (−) group as those who checked none.

2.3. Evaluation of Physical Functions

Physical functions of participants were evaluated by the internationally commonly utilized four fundamental physical function tests; grip strength (kg), leg extension strength (kg), walking speed (m/sec), and one leg standing time with open eyes (seconds; maximum 30 seconds). Also, for comparison with the similar questionnaires about physical function, the subscale from SF36 [6,7] (SF36 PF in the following context) was used. It is composed of 10 questions and the maximum score was set as 100 points; for each item 0, 5 or 10 points were allocated; namely, very difficult—0 points, slightly difficult—5 points, and not at all difficult—10 points.

2.4. Comparison of Physical Function of Those Who Selected "Loco-Check" Items and Those Who Did Not

Average values of five tests: grip strength, leg extension strength, walking speed, and one leg standing time with open eyes, controlled for age and BMI, were compared between the "loco-check" (+) group of those who checked at least one of seven "loco-check" items, and the "loco-check" (−) group who checked none. Also, adjusted average values of five tests were compared between the group of those who checked each of the seven loco-check items, and the group of those who did not. Furthermore, the values of four tests, together with the total score of SF36 PF, were compared among groups who checked none, 1, 2, 3, 4 and 5 items and examined if there was a decreasing trend as the checked number increased. This served to find out whether the numbers of checked items have significance in judging individual levels of physical disability.

The study protocol was approved by the Committee on Ethics of Human Research of the National Institute for Longevity Sciences. Written informed consent was obtained from each subject.

Statistical analyses were conducted with a general linear model, controlled for age and BMI as mentioned above, using SAS (Ver. 9.1.3). Comparison between those who checked or did not was conducted by Student *t*-test, and investigation about the significance of the numbers checked was done by trend analysis.

3. RESULTS

Characteristics of the subjects are shown in **Table 1**. The adjusted average values of four tests (grip strength, leg extension strength, walking speed, and one leg standing time with open eyes of the "loco-check" (+) group) were significantly lower than those of the "loco-check" (−) group in all of the tests (all $p < 0.001$) as described in **Table 2**.

Also, in the comparison between the two groups (those

Table 1. Subject characteristics.

	"loco-check" (+)	"loco-check" (−) group	p
N (male/female)	310 (143/167)	814 (414/400)	0.156
Height (cm)	156.7 ± 9.5	160.6 ± 9.3	<0.0001
Weight (kg)	57.8 ± 11.6	58.1 ± 10.9	0.607
BMI	23.5 ± 3.8	22.4 ± 3.0	<0.0001

Table 2. Adjusted average values of four tests.

	"loco-check" (+) group	"loco-check" (−) group	p
Grip strength (kg)	28.8 ± 0.3	30.6 ± 0.2	<0.0001
Leg extension strength (kg)	36.6 ± 0.6	39.1 ± 0.3	0.0008
Walking speed (m/min)	77.8 ± 0.6	81.9 ± 0.4	<0.0001
One leg standing time with eyes open	50.7 ± 4.4	77.0 ± 3.6	<0.0001

who checked or did not) the adjusted average values of four examinations concerning each question on the seven items, the values of those who checked the items 1), 2), and 3) were significantly lower in all four tests (**Table 3**). Furthermore, those who checked; 4) showed lower values in the grip strength than those who did not check; those who checked; 5) showed lower values in the grip strength and walking speed than those who did not check; and those who checked; 6) and 7) showed lower values in 3 of the tests other than the one leg standing time (**Table 3**). As for the investigation of the trends in the values of the four tests, together with the SF36 PF score, with a decrease as the number of checked items increased until five, most of the tests, other than one leg standing time, showed a significant declining trend in physical function (as for the knee extension strength, p = 0.0043, and other 3 items p < 0.0001) (**Figures 1-4**).

4. DISCUSSION

The locomotive syndrome, or so-called "Locomo," is a new concept that was proposed by the Japanese Orthopaedic Association (JOA) in 2007. This concept is intended to help prevent elderly people from coming to need nursing care services due to problems with their locomotive organs. Seven items, called a "loco-check," have been prepared so that elderly people can perform a self-check of locomotive problems [4]. These items, rather than being selected after a close examination of their validity, were selected with priority for ease of communication among the general population. Thus, items that people can easily understand were selected. This study is intended to reveal the utility of the full "loco-check" list not only as a means to help people themselves become aware of their gradual decline in various motor functions but also to estimate the extent of their physical dysfunction in the general population, by comparing the "loco-check" with very popularly used indices such as grip

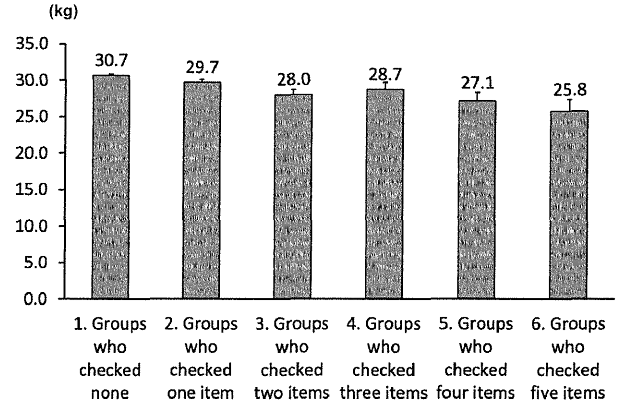

Figure 1. As the number of checked items increased, average grip strength declined significantly (p trend <0.0001).

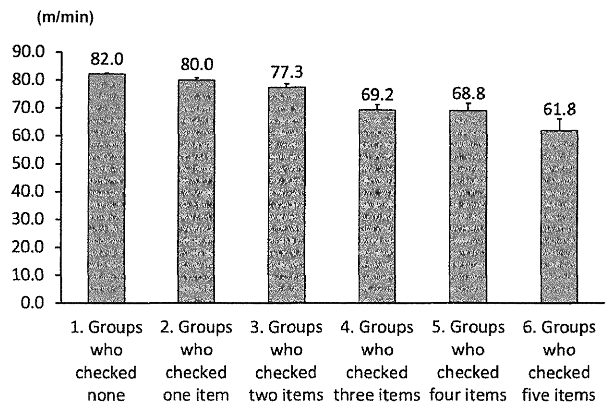

Figure 2. As the number of checked items increased, average leg extension strength declined significantly (p trend = 0.0043).

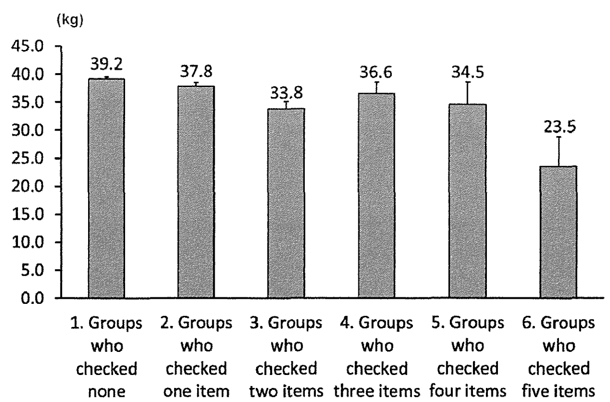

Figure 3. As the numbers of checked items increased, average walking speed declined significantly (p trend < 0.0001).

strength, knee extension strength, walking speed, one-leg standing time, and also with the internationally widely used questionnaire with the SF36 PF score as well. From this study, we have shown that the first three questions [1) You cannot put on a pair of socks while standing on one leg; 2) You stumble or slip in your house; and 3) You need to use a handrail when going upstairs] are particu-

Table 3. Comparison between two groups (those who checked or did not) and the adjusted average values from five exams concerning each question on seven items.

	Grip strength (kg)		p	Leg extension strength (kg)		p	Walking speed (m/min)		p	One leg standing time with eyes open (sec)		
"Loco-check"	(+)	(−)		(+)	(−)		(+)	(−)		(+)	(−)	
1) You cannot put on a pair of socks while standing on one leg	28.6 ± 0.4	30.5 ± 0.2	<0.0001	36.6 ± 0.8	38.9 ± 0.3	0.01	77.3 ± 0.8	81.6 ± 0.3	<0.0001	49.8 ± 5.2	72.6 ± 3.2	0.0003
2) You stumble or slip in your house	28.3 ± 0.5	30.3 ± 0.2	0.0005	36.4 ± 1.0	38.8 ± 0.3	0.031	78.5 ± 1.1	81.1 ± 0.3	0.0225	49.5 ± 8.2	68.5 ± 3.0	0.0312
3) You need to use a handrail when going upstairs	27.7 ± 0.5	30.4 ± 0.2	<0.0001	34.6 ± 1.2	38.9 ± 0.3	0.0006	71.7 ± 1.1	81.8 ± 0.3	<0.0001	50.2 ± 6.6	70.0 ± 3.1	0.0079
4) You cannot cross the road at a crossing before the traffic light changes	25.6 ± 1.7	30.2 ± 0.2	0.0063	30.4 ± 5.4	38.6 ± 0.3	n.s.	86.5 ± 7.3	80.9 ± 0.3	n.s.	68.1 ± 34.2	66.2 ± 2.8	n.s.
5) You have difficulty walking continuously for 15 min	27.4 ± 1.1	30.2 ± 0.2	0.0085	39.7 ± 3.1	38.6 ± 0.3	n.s.	69.9 ± 2.8	81.0 ± 0.3	<0.0001	43.8 ± 15.4	66.9 ± 2.8	n.s.
6) You find it difficult to walk home carrying a shopping bag weighing about 2 kg	27.0 ± 0.9	30.3 ± 0.2	0.0002	33.4 ± 2.5	38.6 ± 0.3	0.0395	72.5 ± 2.2	81.1 ± 0.3	0.0001	52.0 ± 12.8	66.9 ± 2.9	n.s.
7) You find it difficult to do housework requiring physical strength	27.1 ± 0.7	30.3 ± 0.2	<0.0001	33.5 ± 1.8	38.7 ± 0.3	0.0037	72.0 ± 1.6	81.2 ± 0.3	<0.0001	58.5 ± 10.6	66.8 ± 2.9	n.s.

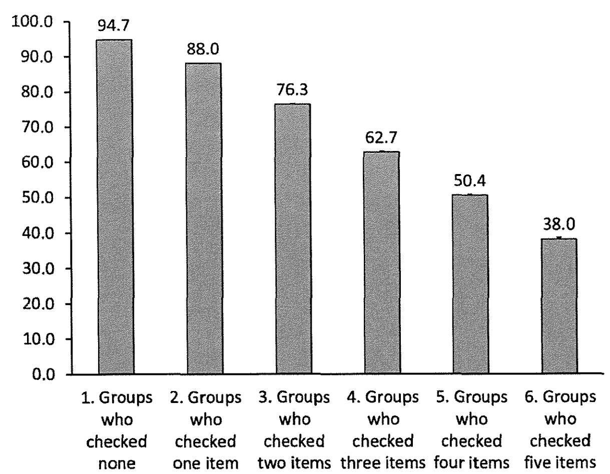

Figure 4. As the numbers of checked items increased, average SF36 PF scores declined significantly (p trend < 0.0001).

larly useful to know the decline of your physical function in strength, walking ability, as well as balancing ability. We have also shown that the number of items checked is important to understand the severity of the decline; that is, the more items are checked, the greater the physical dysfunction is, except for balancing ability.

In recent years, a new scale consisting of 25 question items, the Geriatric Locomotive Function Scale, now called "Locomo 25," was developed by Seichi *et al.* [8] as a screening tool for the risk of locomotion syndrome in elderly people. This scale has a greater number of questions and items, and also includes the level of severity of each item, so that it can express small differences in the QOL of elderly. It also shows a good correlation with the European Quality of Life Scale—5 Dimensions (EQ-5D) [9], and SF36 [10]. Therefore, this scale is considered useful in evaluating the degree of locomotive dysfunction in many situations, particularly for research purposes [11,12]. Meanwhile, our study revealed that the original loco-check and a count of the number of items checked may also be used for estimating the extent of the physical dysfunction. Thus, "loco-check" may be available particularly for people in general to know their own approximate decreased state of physical ability. The number of checked items was also recently reported to be useful for predicting the risk of requiring nursing care

[13].

The basic idea behind "Locomotive Syndrome" is to have a simple and accessible method to help people in general to become aware of their own risk of declining motor function so that they will seek help at a special orthopedic clinic at an early stage. In fact, the prevalence of orthopedic diseases has been shown to be higher than expected [14,15]. The early consultation with a specialist will lead to increased opportunities for the proper treatment at an earlier stage of disease.

The loco-check is also introduced with cartoon drawings for easier understanding by everyone [16,17]. To make this new idea of the loco-check more widely known among the general Japanese population, and even among people worldwide in the future, the greater use of these kinds of accessible question items is beneficial. The present study shows their usefulness through comparison with four fundamental physical function tests, together with the internationally-used questionnaires about physical function from SF36. In fact, some reports have shown that the loco-check (whether there are any of the applied items) is related to physical functions like muscle strength or walking speed [18,19]. Also, Sasaki *et al.* [20] recently reported that a non-loco-check group showed significantly better performances in the functional reach and reach tests than the loco-check group in males and females, as well as better grasping power and one-leg standing with the eyes open in females, by age adjusted comparison. These findings partly coincide with our own results. Increased self-awareness of a decline in physical function may also induce people to perform "loco-training" exercises [16], such as standing on one leg or half squats, which previously have been reported to be effective [18,21-23].

A limitation of our study is that the subjects accounted for only about half of all participants in the 7^{th} wave of the NILS-SA. It is possible that the results do not accurately reflect the results of all participants. However, the number of subjects should still be large enough to discuss the trends in all participants and to show the value of the loco-check.

The strength of the study is that the subject sample was selected randomly from the local community with very little bias in the process.

In summary, we investigated the relationship between the loco-check and physical function status as evaluated by grip strength, knee extension strength, walking speed, one-leg standing time and the SF36 (physical function subscale). We thereby demonstrated the utility of the loco-check not only as a means of screening to promote self-awareness of locomotive organ impairments, but also as a simple way to surmise the severity of the impairment by counting the number of items checked, excluding balancing ability.

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第2章 ヒッププロテクター

第２節　ヒッププロテクターの使用評価状況

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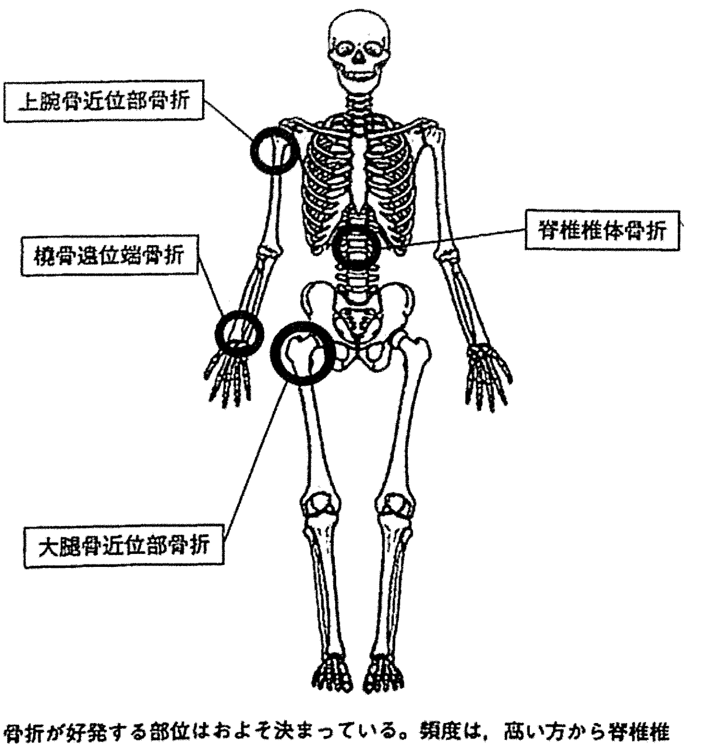
1.　はじめに

若い成人健常者はごくたまにしか転倒しないし，仮に転倒したとしても重度の外傷を被る率は低い。健常成人にとっては，転倒は文字通り軽微な外力とみなしてよい状況である。しかし，転倒頻度は小児期と高齢期では成人期より共に高く，わが国では在宅高齢者の1/5～1/4が毎年転倒し，性別，地域にかかわらず，74歳以下の前期高齢者と75歳以上の後期高齢者とを比較すると後者で有意に高く，高齢になるほど発生率は急上昇する[1]。一方で，骨強度は女性では閉経以後，男性でも高齢期以後は徐々に低下して骨粗鬆症（軽微な外力でも骨折するリスクが高まった病態）が増加するため，転倒による骨折も年齢とともに指数関数的に増加する。その典型が骨折として最も重篤な大腿骨近位部骨折（図1）で，発生の原因としては転倒が最も多く[1]，骨折後は寝たきりになるリスクが高い。わが国における大腿骨頸部/転子部骨折の年間発生数は2002年では約12万人であった。発生率は40歳から年齢とともに増加し，70歳を過ぎると急激に増加していた。高齢者での発生率は男性より女性が高かった。この年齢階級別発生率は2002年まで経年的に増加していた[2]。現在では年間15万人以上が受傷しているものと推定される。母集団となる高齢者数の増加だけでなく，図2に示したように，年齢・性別の発生頻度自体も上昇傾向にあるため，骨折数は今後も著しく増加するとされている。



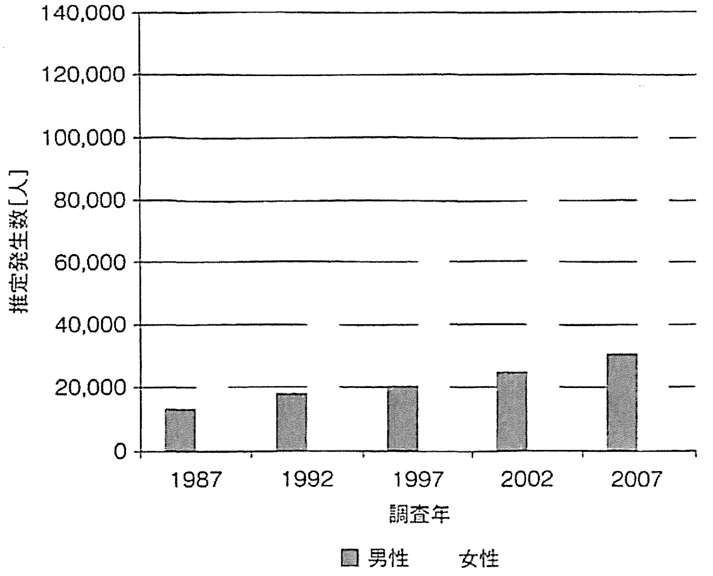
骨折が好発する部位はおよそ決まっている。頻度は，高い方から脊椎椎体骨折，大腿骨近位部骨折，橈骨遠位端骨折，上腕骨近位部骨折の順である

図１　高齢者が転倒によって骨折する部位

そのような状況に対して，転倒予防対策や骨粗鬆症薬による治療は大腿骨近位部骨折を減らすことを最大の目標として，多くの開発が実施されてきた。同様な目的で開発された転倒で大腿骨近位部骨折が起こるのを防止するための股関節保護具がヒッププロテクターである。

そもそも事故などで外力が加

わっても体を保護する装置や装具などで外力を減衰させて生じる外傷を最小限にしようとする考えは古くから定着しており，剣道やアメリカンフットボール，スノーボードなどのスポーツにおける防具や，自動車内のシートベルト・エアバッグ，危険度の高い工事現場におけるヘルメットなどは広く普及しているだけでなく，一部法的に義務化されている。これらは，それぞれが危険な外力が事故的に生じるリスクが高い場面に限定して使用されている。それでは，転倒リスクが高い高齢者にヒッププロテクターの有効性はどうであろうか。



５年ごとに調査されているが，発生頻度は最近も増加傾向にある。どの時期も女性が男性より多い

文献２）による

図２　大腿骨近位部骨折の年齢・性別の発生頻度

2. ヒッププロテクターに対する無作為比較対照試験およびそのシステマティックレビューによる臨床的有効性の評価

これから述べる臨床試験で使用されたヒッププロテクターは，開発初期の硬性品などの限られた製品によるものばかりで，現在販売していないものがほとんどである。また，その後に開発され，現時点で販売されている製品にはそのような大規模臨床試験で検証されたものはないことを明らかにしておく。臨床試験で有効性を検証するには，多額の費用と時間労力が必要であるためかもしれないが，今後にその実施が期待される。

さて，開発されたヒッププロテクターを使用して大腿骨近位部骨折を実際にどの程度予防できるのかを検討するためにデザインされた無作為比較対照試験（RCT）は，1993 年の北欧[3]に始まって，2008 年までにわが国の研究[4)5)]も含め，16 の RCT が発表されてきた。そこから２つの RCT を除き，残りの研究を一定の基準で選定し，統計学的に合成解析をしたシステマティックレビューが多数行われている（表１)。これらの研究結果を見ると，ヒッププロテクターは，特に介護施設生活者においては大腿骨近位部骨折リスクが有効に減少した試験が多く存在する。介護施設試験では，Parker らによればヒッププロテクターによって本骨折は 25 % 減少した[6)]。さらに，Sawka らによれば一層厳しい選定条件に合致する６つの RCT を解析した結果，有意性は境界領域にとどまったが，介護施設には高齢者アパートなど ADL 自立者集団も含まれていたので，ナーシングホーム試験だけに絞って大腿骨近位部骨折減少率を検討すると 50 % に相当した[7)]。さらに，筆者らはナーシングホーム試験に限定して Bayesian 解析をしたところ，大腿骨近位部骨折減少率は 60 % とさらに良好な予防効果が認められ，感度分析でも結果は安定していた[8)]（表１)。

表1　ヒッププロテクターの RCT とシステマティックレビュー（SR）

著者と発表年	n	RR	SR1）とその解析 95 %CI		SR1）とその解析 対象試験*	SR2）とその解析	SR2）とその解析 対象試験*	SR3）とその解析	SR3）とその解析 対象試験*
Birks 2003	366	3.03	0.62, 14.83	*	在宅者試験	*	在宅者試験		
Cameron 2003	600	0.94	0.53, 1.68	*	RR=1.16	*	RR=1.07		
Birks 2004	4,169	1.18	0.8, 1.75	*	95 %CI（0.85, 1.59）	*	95 %CI（0.85, 1.59）		
van Schoor 2003	561	0.93	0.5, 1.72	*		*			
Jantti# 1996	72	0.2	0.02, 1.81	*		*		*	
Chan 2000	71	0.39	0.11, 1.41	*					
Cameron 2001	174	1.17	0.44, 3.1	*	介護施設試験	*	介護施設試験		介護施設試験
Hubacher 2001	548	1.49	0.31, 7.14	*	RR=0.77		RR=0.56		OR=0.40
Lauritzen 1993	665	0.44	0.16, 1.21	*	95 %CI（0.62, 0.97）		95 %CI（0.31, 1.01）		95 %CRI（0.25, 0.61）
Ekman 1997	744	0.34	0.02, 5.19	*				*	
Kannus 2000	1801	0.34	0.16, 0.71	*					
Harada 2001	164	0.11	0.01, 1.89	*				*	
Meyer 2003	942	0.57	0.31, 1.07	*		*		*	
O'Halloran 2004	4,117	1.05	0.58, 0.97	*					
Kiel 2007	1,042	1.24	記載なし						
Koike 2008	672	0.56	0.31, 1.03						
	202	0.375	0.14, 0.98						
	206	0.37	0.14, 0.9						

RCT（無作為比較対照試験）
SR1）は文献 3），SR2）は文献 4），SR3）は文献 5）によった。それぞれの解析対象を*で示した。van Schoor 試験は在宅生活者と介護施設生活者が混在しており，SR1）では介護施設試験，SR2）では在宅者試験として扱われている。
RR（相対危険度），CI（信頼区間）　RR，95 %CI は筆者自身が計算した Kiel 以外は文献 4）によっており，ハザード比などで記載されたオリジナル文献の数値と異なっている。
Koike の成績は ハザード比で転倒歴既往者や低 BMI 者では大きな有効性が示された。
OR（オッヅ比）CRI（信頼区間）

わが国の最新の RCT は Koike らによる介護施設大規模試験で，本法によって本骨折は転倒既往者や BMI 19 以下の者など転倒・骨折リスクの一層高い対象者に限ると 63 % 減少し，Sawka のナーシングホーム解析結果に匹敵する高い有効性をもつことが示された[5]。

一方，在宅者試験で有効だったものはなく，在宅者には無効であることは一致した見解となった。これは，在宅高齢者の 1/5 ～ 1/4 が毎年転倒するとはいえ，大腿骨近位部骨折を発生する率は 1 % 程度とかなり低いため，危機感も少ないことに加えて，ヒッププロテクターを年間履き続けることを遵守できないことが要因となっているものと思われる。

3. ガイドラインにおけるヒッププロテクターの評価

わが国においては，上述したようなヒッププロテクターに関する無作為比較対照試験およびそのシステマティックレビューによる評価をもとに日本整形外科学会が大腿骨頸部/転子部骨折診療ガイドラインを作成して，2005 年に初版が出版され，その改訂 2 版が 2011 年に出ている。それによれば，大腿骨頸部/転子部骨折に対して「ヒッププロテクターは予防に有効か」という Clinical Question へ「ヒッププロテクターは介護施設高齢者の大腿骨頸部/転子部骨折予防に有効である」という Grade A の推奨が記載されている[1]。ちなみに Grade A とは，臨床的に重要なアウトカムが検討されており，かつ高いエビデンスレベルの文献があるという条件に合致するもののみが当てはまる最高レベルで，「行うよう強く推奨する」というものである。

そのサイエンティフィックステートメントには，「ヒッププロテクターは，大腿骨頸部/転子部骨折のリスクの高い介護施設高齢者の大腿骨頸部/転子部骨折を減少させるという，高いレベルのエビデンスがあるが，在宅高齢者では有効性は認められない[1]」と記載されている。

ヒッププロテクターについて記載されたもう一つのわが国のガイドラインは，日本骨粗鬆症学会・日本骨代謝学会・骨粗鬆症財団が作成した骨粗鬆症の予防と治療ガイドライン 2011 年版である。それによれば，転倒リスク評価と転倒予防の章で「ヒッププロテクターに骨折予防効果はあるか」という Clinical Question に対して，「ヒッププロテクターは施設入居高齢者に有効である」というやはり Grade A の推奨が記載されている[9]。その解説によれば「ヒッププロテクターは転倒骨折リスクの高い集団の大腿骨近位部骨折の予防に有効である」，さらに「介護施設生活者では大腿骨近位部骨折リスクが 25 % 程度低下し有効と考えられているが，在宅高齢者での有効性はコンプライアンスの低さもあり，否定的である」と記述されている[9]。

さて，このようにヒッププロテクターは予防するべき最大の標的骨折である大腿骨近位部骨折に対して，国際的に多数の高レベル臨床試験である RCT が実施され，大腿骨近位部骨折リスクを減らすという高いレベルの結果が得られている。骨粗鬆症治療薬として市場で販売されている薬剤には，大腿骨近位部骨折減少のエビデンスがないものも少なくないこと，運動訓練などによる転倒予防プログラムには，転倒そのものを減少させるエビデンスレベルは高いにもかかわらず，大腿骨近位部骨折に限らず，転倒による骨折リスクを減少させることに成功した RCT はいまだに一つもないことを考慮すれば，ヒッププロテクターの有効性に関する信頼度には大きなものがあるといえる。

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