た心理的要因について傾聴する．そして解離を呈さざるを得なかった患者の歴史を共有する．

B 併用薬物療法

解離（転換）症状そのものに対し有効性が実証された薬物療法はなく，併存する精神症状に対して対症的に使用する．患者の被暗示性は高いため，薬剤効果は慎重に判定する．抑うつに対する抗うつ薬〔選択的セロトニン再取込み阻害薬（SSRI），セロトニン・ノルアドレナリン再取込み阻害薬（SNRI）〕の使用は，副作用の（特に青年期患者の）焦燥感のために，不安に対するマイナートランキライザーの使用は，副作用の向精神薬依存や脱抑制のために使用する場合は，リスクとベネフィットを慎重に検討する．強い焦燥感や興奮に対しては，少量の非定型抗精神病薬が適切である．

1. 強い焦燥感や興奮に対して

R 処方例

リスパダール内用液　1日 0.5－2.0 mg　頓用（イライラするとき）（保外）　D

身体化障害，疼痛性障害，心気症

somatization disorder, pain disorder and hypochondriasis

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病態と診断

A 病態

これらの障害は患者の自覚する身体症状が，身体疾患によって「完全に」説明されないことが基本となる．操作的診断基準では，複数の身体症状が30歳以前に始まり数年にわたって持続するものを身体化障害，痛みが臨床像の中心になるものを疼痛性障害，適切な医学的保証があるにもかかわらず重篤な病気にかかっているという恐怖が持続するものを心気症と分類している．いずれにしても執拗な症状の訴えが治療者を悩ませることが多く，患者に対する陰性感情を引き起こしやすい．しかも，このことがドクターショッピングを招き，怒りの感情になり，さらに症状を悪化させることになる．

病態としては，ストレスが身体症状として表現されるという心理的な面が強調されやすいが，身体感覚の異常，認知の障害もその基本になっていると考えられる．特に疼痛性障害では，痛覚刺激に対する脳内情報処理が障害されているとの報告も多い．

B 診断

診断で重要なことは，症状そのものよりも除外診断である．実際，多彩な患者の訴えによって身体疾患が見逃されることもあり，また身体症状の訴えが目立つ患者であっても精神疾患として気分障害，不安障害，発達障害，認知症などが背景にあることは決して少なくない．これは治療の成否に大きく影響するために，まずしっかりとした除外診断を行う必要がある．同時に，検査をしても異常を見いだすことのできない身体症状も多く存在すること，これを十分に認識する度量が医療者に求められる．

治療方針

A 基本方針，精神療法

まず，詳細な病歴の聴取，特に受診経路の理解が重要である．症状に対する忍耐強い傾聴が基本であり，患者の苦しさを理解しようという姿勢が治療同盟を形成するためのポイントとなる．また症状を生み出す病態について説明しながら，病名告知も行う．緊密な連携をとることができるような集学的治療を行うことが可能であれば望ましいが，そうでない場合には，治療にかかわる医療者の数をなるべく減らす工夫も必要となる．長期的な方針としては，患者が症状の軽減に意識を集中しすぎないよう，日常生活の改善を目指していく．

B 薬物療法

薬物療法のみでは著効しないことが多いものの，疼痛性障害では抗うつ薬の効果が得られる場合もある．また，抗てんかん薬の一部やリリカなども有用である．しかし，常用量依存の危険性のあるベンゾジアゼピン系抗不安薬の使用はなるべく控えるべきであり，頓用または長時間作用型の少量使用に抑える必要がある．また，不安に対しては柴胡加竜骨牡蛎湯などの漢方薬を用いることも可能である．

1. 疼痛を伴う場合

R 処方例

サインバルタカプセル（20 mg）　1－2 カプセル　分1　朝食後（保外）

トリプタノール錠（10 mg）（保険適用外）も効果があるが，めまい，ふらつきや抗コリン系副作用などが出やすいので，低用量から開始する．

2. 抑うつや不安または睡眠障害が強い場合

R 処方例　下記を併用する．

レメロン錠（15 mg）　1－3 錠　分1　就寝前 D
ワイパックス錠（0.5 mg）　1 錠　不安時に頓用，またはメイラックス錠（1 mg）D　1－2 錠　分2

患者説明のポイント

・まず長期間，症状でつらい思いをしてきたことを認め，病気についての説明に時間をかける．
・特に心理的な問題から入ると患者は否定的になりやすいため，まず身体症状は最終的に「脳」で感

じるという生物学的な側面を強調する．それから症状とストレスとの相互作用についてゆっくりと理解を深めてもらうよう試みる．
・薬はあくまでも補助的な役割であり，必要最低限にするように指導する．

心身症
psychosomatic disorder

吉内一浩　東京大学大学院准教授・心療内科

病態と診断

Ⓐ 病態

心身症とは，「身体疾患の中で，その発症や経過に心理社会的因子が密接に関与し，器質的ないし機能的障害が認められる病態をいう．ただし神経症やうつ病など，他の精神障害に伴う身体症状は除外する」と定義される病態である（日本心身医学会教育研修委員会編：心身医学の新しい診療指針．心身医学 31：537，1991）．つまり，心身症とは，「身体疾患」であることが必要条件で，その発症や経過に「心理社会的因子の密接な関与」が認められる「病態」である．ある疾患のなかで，この定義にあてはまる症例のみが心身症であるという意味で，「病態」という表現が用いられている．

心身症が含まれる代表的なものとしては，過敏性腸症候群，緊張型頭痛や片頭痛などの一次性頭痛，気管支喘息，消化性潰瘍，本態性高血圧，アトピー性皮膚炎などが挙げられる．保険病名は，「身体疾患名（心身症）」〔例：気管支喘息（心身症）〕のように記載する．

Ⓑ 診断

心身症の診断は，病歴，現症，検査所見に基づく身体面からの情報と，面接による生活史の聴取や心理テストなどの心理社会的側面からの情報を統合して多面的に行う．身体面のみに焦点を当てるのではなく，患者をとりまく環境をも含めて全人的に診療していく姿勢が重要である．

診断の手順としては，まず身体面の評価を行い，身体疾患の診断を行ったのち，面接により，ライフイベントや日常生活におけるストレスなどの心理社会的因子の関与の評価を行う．その際，ソーシャルサポートやストレスコーピングなども確認することが重要である．心理テストによってパーソナリティや心理状態を把握することも有用だが，その役割は補助的である．面接は，受容的態度による傾聴を基本とする．

治療方針

心身症の治療の基本は，身体面のみの治療にとどまらず，心理社会的側面からのアプローチを含めた全人的に治療することである．治療の基本的には，心身両面からの病態把握のあと，治療目標および治療方針を決定する．その際，十分に説明をおこない，患者との共同作業で決定していくプロセスを重視することが重要である．

治療方法は，薬物療法と非薬物療法に大別される．薬物療法としては，身体疾患の治療のための薬物に加え，適宜，向精神薬が併用される．非薬物療法としては，支持的精神療法が基本であるが，臨床心理家による心理療法なども行われる．専門的な心理療法としては，精神分析的精神療法，認知行動療法，自律訓練法などのリラクセーション法，家族療法などが行われる．これら専門的治療法の適応基準は，現在のところ存在しないが，認知行動療法およびリラクセーション法のエビデンスが蓄積されつつある．

Ⓐ 薬物療法

不安・緊張，抑うつ，不眠などの精神症状に対して，抗不安薬，抗うつ薬，睡眠薬が適宜用いられる．低用量から開始し，高齢者・小児や併用薬に対する用量・用法の注意・禁忌などについて，添付文書を確認する．

1. 不安に対して

℞ 処方例　下記のいずれかを用いる．
1）セディール錠（10 mg）　3–6錠　分3
2）ソラナックス錠（0.4 mg）　3錠　分3
3）メイラックス錠（1 mg）　1錠　分1　夕食後あるいは就寝前 9

●治療の終了の指標

ベンゾジアゼピン系の薬剤に関しては，長期服用で依存を生じることが問題となるので，1か月以内に投与しないよう減量・中止を計画する．

2. うつ状態に対して

℞ 処方例　下記のいずれかを用いる．
1）リフレックス錠（15 mg）　1–2錠　分1　夕食後寝前 11
2）ジェイゾロフト錠（25 mg）　1–3錠　分1　夕食後 11
3）レクサプロ錠（10 mg）　1錠　分1　夕食後
4）サインバルタカプセル（20 mg）　1–2カプセル　分1　朝食後

3. 不眠に対して

℞ 処方例　下記のいずれかを用いる．
1）マイスリー錠（10 mg）　1錠　分1　就寝前 7
2）ロヒプノール錠（1 mg），またはサイレース

Spine

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CLINICAL CASE SERIES

Gender Difference in Association Between Low Back Pain and Metabolic Syndrome

Locomotive Syndrome and Health Outcome in Aizu Cohort Study (LOHAS)

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Study Design. Cross-sectional survey.

Objective. To investigate the relationship between low back pain (LBP) and metabolic syndrome (Mets) in community-based Japanese subjects.

Summary of Background Data. Relatively few reports have demonstrated a relationship between general pain and Mets, and none have addressed the relationship between LBP and Mets.

Methods. This study enrolled 2650 people from among residents aged 40 to 74 years in Tadami and Minamiaizu, Fukushima, Japan, who participated in health checkups conducted in 2008. LBP was defined as lower back pain continuing for more than 24 hours and severe enough to merit treatment, or it was based on clinical prediction rules from the clinical diagnosis support tool to identify patients with lumbar spinal stenosis. Mets was defined according to the Japanese criteria recommended by the Japanese Society of Internal Medicine. Prevalence of Mets was recorded for subjects with and without LBP. The relationship between LBP and Mets was investigated, using a generalized linear model. With LBP as the main explanatory variable and Mets as the outcome variable, risk ratios of Mets were calculated for men and women.

Results. In this study, we analyzed a total of 1395 subjects. In men, the prevalence of Mets was 21.2% in those without LBP and 24.7% in those with LBP. In women, the prevalence of Mets was 12.4% in those without LBP and 23.7% in those with LBP. After adjusting for factors such as age, body mass index, occupational status, SF-36 mental health, and physical activity level, no relationship was noted between LBP and Mets in men. However, in women, the risk ratio for Mets in subjects with LBP compared with those without LBP was 1.5 (95% confidence interval, 1.0–2.1).

Conclusion. We observed a tendency toward higher prevalence of Mets among those with LBP than among those without it in women, but not in men.

Key words: low back pain, metabolic syndrome, community-based subject, prevalence. **Spine 2012;37:1130–1137**

Global frequency of metabolic syndrome (Mets) has been increasing in recent years,[1] with a high prevalence of 10% to 30% in the general population, which increases in frequency with age and in men.[2–7] Low back pain (LBP) is an important cause of restricted activity (disability),[8] and its prevalence within the preceding month among queried subjects has been calculated to be 15% to 40%, increasing with age.[9–13]

Markedly few reports have examined the relationship between pain and Mets. Mäntyselkä *et al*[14] surveyed 899 people and found that Mets was related to neck pain in both men and women and that men with Mets more frequently reported neck pain than did women with Mets. Loevinger *et al*[15] compared pain in women with fibromyalgia (n = 109) with healthy women (n = 46) and reported that women with chronic pain from fibromyalgia are at an increased risk of developing Mets.

Depressive symptoms and physical inactivity are thought to be intermediaries in the relationship between pain and Mets. Both depressive symptoms and low levels of physical activity are associated with Mets and LBP.[16–19] Several studies have further indicated an association between obesity and LBP,[20] and given that central obesity is one of the main features of Mets, LBP might also be related to Mets.

Mets has been cited as a major risk factor for coronary heart disease (CHD) and type 2 diabetes,[21–23] and LBP has also been reported to be a risk factor for future development of CHD.[24] Zhu *et al*[24] conducted a prospective study of the association between back pain, mortality, and coronary heart events in 1484 community-dwelling women aged

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70 to 85 years and found that daily back pain was associated with overall mortality, CHD mortality, and new CHD diagnosis.

Common features underlying increased risk of CHD and Mets included central obesity, hypertension, and dyslipidemia, strongly suggesting that CHD and Mets may be related to physical pain. Given that the relationship between Mets and pain was affected by sex[14] and that LBP has been found to predict CHD mortality and new CHD diagnosis,[24] we hypothesized that Mets would be more prevalent among subjects with LBP than among those without and that prevalence of Mets among subjects with LBP differed from sex. Here, we investigated the relationship between LBP and Mets by examining the prevalence of Mets in subjects with and without LBP by sex.

MATERIALS AND METHODS

Study Population

In this study, we aimed to epidemiologically analyze health problems related to motor system disease. The locomotive syndrome and health outcome in Aizu cohort study (LOHAS) is a cohort study whose subjects were residents of the towns of Tadami and Minamiaizu in Fukushima, Japan. Locomotive syndrome is a condition characterized by a set of associated symptoms due to problems of the locomotive organs.[25] Both towns involved in the study are located in valleys surrounded by mountains, and the main industry in the region is agriculture. In 2005, the population of Tadami was 5284, of which 40% were aged 65 years or older (elderly population). The population of Minamiaizu was 19,870, with 33% aged 65 years or older.[26] The source population of LOHAS was the general population of residents of Tadami and Minamiaizu aged 40 to 80 years in April 2008.

The study protocol was approved by the Research Ethics Committee of Fukushima Medical University School of Medicine, and written informed consent was obtained from all subjects.

Data Collection

The LOHAS baseline survey was conducted between April and July 2008, which had 3426 participants. Regular health checkups, special health checkups, and health checkups concerning musculoskeletal disease and motor dysfunction were conducted in the baseline survey. This study enrolled subjects from the LOHAS baseline survey who received special health checkups intended for people aged 40 to 74 years. Special health checkups were introduced by the Japanese government in 2008 and are conducted annually on residents by local governments. A primary purpose of these checkups is screening for Mets.

Special Health Checkups

Subjects were measured for height, weight, waist circumference, systolic blood pressure (SBP), diastolic blood pressure, serum levels of high-density lipoprotein cholesterol and triglycerides, and fasting plasma glucose level. In addition, subjects were questioned regarding their personal medical, smoking, and alcohol history.

Self-completed Questionnaire Survey

Questionnaire forms to be completed by subjects were distributed before the special health checkup and collected on the day of the checkup. The questionnaire items included the sex and the age of subjects, general health-related quality of life (HRQOL), HRQOL items related specifically to motor system disease, sociodemographic situation, dietary habits, and amount of physical activity undertaken. In this study, items related to the LOHAS motor system examination were not used.

Definition of LBP

LBP was defined as fulfilling either of the following criteria: (1) A "yes" response to the question "Do you currently have LBP severe enough to merit treatment, which has continued for more than 24 hours?" or (2) either total scores of 4 or more (questions 1–4) or total scores of 1 or more (questions 1–4) and 2 or more (questions 5–10) as evaluated, using the clinical diagnosis support tool to identify patients with lumbar spinal stenosis.[27]

Definition of Mets

Mets was defined according to the Japanese criteria recommended by the Japanese Society of Internal Medicine.[28] Briefly, to have Mets, a male must have at least an 85-cm circumference waist and a female must have at least a 90-cm circumference waist. In addition, the subject must satisfy at least 2 of the following 3 criteria: triglyceride level of 1.69 mmol/L or more (150 mg/dL), high-density lipoprotein cholesterol level of 1.03 mmol/L or less (40 mg/dL), or be receiving lipid-lowering therapy; has an SBP of 130 mm Hg or more, diastolic blood pressure of 85 mm Hg or more, or be receiving antihypertensive therapy; and fasting plasma glucose level of 6.11 mmol/L or more (110 mg/dL) or be receiving antihyperglycemic treatment.

Measurement of Other Variables

Body mass index (BMI) was calculated from the height and the weight measured during the special health checkup and categorized as less than 18.5, 18.5 to less than 23, 23 to less than 25, 25 to less than 30, and 30 kg/m^2 or more. Other variables recorded were age (40 to <50 yr, 50 to <60 yr, 60 to <70 yr, and 70 to <75 yr), sex (male/female), smoking status (current, or never or former), and alcohol consumption (every day/sometimes/rarely/never) from the questionnaire; mental health domain score on the SF-36 Health Survey (SF-36-MH) (<60, ≥60) and level of physical activity measured with the Japanese version of the International Physical Activity Questionnaire (IPAQ) were also evaluated. Using a scoring method of 0 to 100 points on the SF-36-MH, moderate or severe depressive symptoms were distinguished, with a sensitivity of 74.7% and specificity of 80% when the score was less than 60.[29] The IPAQ is one of the most widely used physical activity evaluation tools in the world,[30] and responses to the questionnaire were classified as indicating low, moderate, or high activity, according to the scoring program.[31]

TABLE 1. Baseline Characteristics of the Analysis Population*

Variables		All subjects (n = 2650)	Excluded Subjects (n = 1255)	Analyzed Subjects (n = 1395)	*P*
Age, yr	40 to <50	177 (7.2)	76 (6.1)	101 (7.2)	<0.01
	50 to <60	278 (19.9)	208 (16.6)	278 (19.9)	
	60 to <70	658 (47.2)	515 (41.0)	658 (47.2)	
	70 to <75	358 (25.7)	456 (36.3)	358 (25.7)	
Sex	Male	1063 (40.1)	461 (43.4)	602 (56.6)	<0.01
	Female	1587 (59.9)	794 (50.0)	793 (50.0)	
BMI, kg/m^2	<18.5	71 (2.9)	34 (3.2)	37 (2.7)	0.16
	18.5 to <23	861 (35.3)	364 (34.9)	497 (35.6)	
	23 to <25	686 (28.1)	291 (27.9)	395 (28.3)	
	25 to <30	735 (30.2)	307 (29.4)	428 (30.7)	
	≥30	85 (3.5)	47 (4.5)	38 (2.7)	
Smoking status	Never or former	2220 (85.8)	1046 (87.6)	1174 (84.2)	0.01
	Current	369 (14.3)	148 (12.4)	221 (15.8)	
Alcohol consumption	Every day	696 (27.2)	297 (25.4)	399 (28.6)	<0.01
	Sometimes	474 (18.5)	208 (18.8)	266 (19.1)	
	Rarely	597 (23.3)	257 (22.0)	340 (24.4)	
	Never	797 (31.1)	407 (34.8)	390 (28.0)	
Occupational status	Employed	971 (36.6)	427 (34.0)	544 (39.0)	<0.01
	Unemployed	1679 (63.4)	828 (66.0)	851 (61.0)	
SF-36-MH score	<60	476 (18.3)	216 (17.9)	260 (18.6)	0.6
	≥60	2129 (81.7)	994 (82.2)	1135 (81.4)	
IPAQ category	Low	685 (25.9)	346 (27.6)	339 (24.3)	0.11
	Moderate	555 (20.9)	265 (21.1)	290 (20.8)	
	High	1410 (53.2)	644 (51.3)	766 (54.9)	

P values were derived using the χ^2 test.

**Values represent number (percentage).*

BMI indicates body mass index; SF-36-MH, mental health domain of the SF-36 Health Survey; IPAQ, International Physical Activity Questionnaire.

Statistical Analysis

Subjects were limited to LOHAS 2008 baseline study subjects who were diagnosed with both LBP and Mets.

Background factors were recorded for all subjects, regardless of inclusion in or exclusion from analysis (Table 1). Main survey items and presence or absence of Mets were recorded for those with and without LBP, and each factor constituting Mets was recorded for men and women (Table 2). The relationship between Mets and LBP was then examined using a generalized Poisson regression model.

In the present analysis, LBP was taken as the main explanatory variable, whereas Mets was the outcome variable. Risk ratios and 95% confidence intervals (CI) were calculated for men and women who had Mets. Mental health, physical inactivity,[16–19] and variables associated with presence of LBP, with $P \leq 0.10$ in crude analysis by sex (Table 2), were considered as potential confounders and thus included as covariates in the adjusted analysis.

The level of statistical significance was set as $P < 0.05$, and all analyses were performed, using STATA version 11.2 (Stata Corporation LP, College Station, TX).

RESULTS

Subject Attributes

Of the 2650 people aged 40 to 74 years in the LOHAS baseline survey, 1255 were excluded for various reasons, leaving 1395 ultimately enrolled as subjects in the present analysis

TABLE 2. Clinicodemographic Variables According to Presence of Low Back Pain in Men and Women*

Variables		Men (n = 602)			Women (n = 793)		
		No LBP (n = 505)	LBP (n = 97)	*P*	No LBP (n = 679)	LBP (n = 114)	*P*
Age, yr†	<60	165 (90.2)	18 (9.8)	0.03	180 (91.8)	16 (8.2)	<0.01
	60 to <70	202 (80.8)	48 (19.2)		350 (85.8)	58 (14.2)	
	70 to <75	138 (81.7)	31 (18.3)		149 (78.8)	40 (21.2)	
BMI, kg/m2†	<23	200 (85.8)	33 (14.2)	0.29	269 (89.4)	32 (10.6)	0.04
	23 to <25	151 (83.4)	30 (16.6)		179 (83.6)	35 (16.4)	
	25 to <30	141 (81.5)	32 (18.5)		210 (82.4)	45 (17.5)	
	≥30	13 (86.7)	2 (13.3)		21 (91.3)	2 (8.7)	
Smoking status	Never or former	350 (83.3)	70 (16.7)	0.58	645 (85.5)	109 (14.5)	0.78
	Current	155 (85.2)	27 (14.8)		34 (87.2)	5 (12.8)	
Alcohol consumption†	Every day	282 (84.2)	53 (15.8)	0.87	61 (95.3)	3 (4.7)	0.46
	Sometimes	87 (82.9)	18 (17.1)		129 (80.1)	32 (19.9)	
	Rarely	65 (84.4)	12 (15.6)		233 (88.6)	30 (11.4)	
	Never	71 (83.5)	16 (16.5)		256 (83.9)	49 (16.1)	
Occupational status	Employed	257 (86.0)	42 (14.0)	0.17	221 (90.2)	24 (9.8)	0.01
	Unemployed	248 (81.9)	55 (18.1)		458 (83.6)	90 (16.4)	
SF-36-MH score	<60	79 (77.5)	23 (22.5)	0.05	120 (80.0)	38 (24.0)	<0.01
	≥60	426 (85.2)	74 (14.8)		559 (88.0)	76 (12.0)	
IPAQ category†	Low	116 (83.5)	23 (16.5)	0.89	172 (86.0)	28 (14.0)	0.89
	Moderate	105 (84.0)	20 (16.0)		141 (85.5)	24 (14.5)	
	High	284 (84.0)	54 (16.0)		366 (85.5)	62 (14.5)	
Mets	No	398 (84.5)	73 (15.5)	0.44	595 (87.2)	87 (12.8)	<0.01
	Yes	107 (81.7)	24 (18.3)		84 (75.7)	27 (24.3)	
Waist circumference, cm, mean (SD)		85 (7.4)	86 (7.5)	0.18	86 (8.4)	88 (9.2)	0.05
Serum triglycerides level, mg/dL, mean (SD)		111 (80.4)	140 (206.6)	0.02	96 (63.7)	92 (43.4)	0.61
Serum HDL cholesterol level, mg/dL, mean (SD)		59.5 (14.5)	59.1 (15.8)	0.84	64 (13.5)	64 (14.2)	0.84
Lipid-lowering therapy	No	458 (85.0)	81 (15.0)	0.03	556 (86.7)	85 (13.3)	0.07
	Yes	47 (74.6)	16 (25.4)		123 (80.9)	29 (19.1)	
Systolic blood pressure, mm Hg, mean (SD)		134 (15.0)	134 (16.0)	0.93	132 (15.8)	136 (17.3)	0.02
Diastolic blood pressure, mm Hg, mean (SD)		81 (9.8)	80 (9.1)	0.91	78 (9.4)	79 (9.6)	0.49
Antihypertensive therapy	No	338 (86.0)	55 (14.0)	0.05	468 (88.6)	60 (11.4)	<0.01
	Yes	167 (79.9)	42 (20.1)		211 (79.6)	54 (20.4)	

(Continued)

TABLE 2. (Continued)

Variables		Men (n = 602)			Women (n = 793)		
		No LBP (n = 505)	LBP (n = 97)	*P*	No LBP (n = 679)	LBP (n = 114)	*P*
Fasting plasma glucose, mg/dL, mean (SD)		102 (19.4)	101 (21.0)	0.77	96 (13.6)	99 (27.5)	0.14
Antihyperglycemic treatment	No	470 (83.9)	90 (16.1)	0.92	663 (86.2)	106 (13.8)	<0.01
	Yes	35 (83.3)	7 (16.7)		16 (66.7)	8 (33.3)	

Given the small number of people in the age group of 40 to <50 years, this group was combined with the age group of 50 to <60 years. For similar reasons, BMI group of <18.5 was combined with the 18.5 to <23 group.

**Values represent number (percentage).*

†Trend test.

LBP indicates low back pain; BMI, body mass index; SF-36-MH, mental health domain of the SF-36 Health Survey; IPAQ, International Physical Activity Questionnaire; Mets, metabolic syndrome; HDL, high-density lipoprotein; SD, standard deviation.

(Figure 1). Characteristics of the study population are described in Table 1. We examined 602 men and 793 women with a mean age ± SD of 62.9 ± 8.5 and 63.7 ± 7.4 years, respectively ($P = 0.047$). Mean BMI was 23.7 ± 2.8 for men and 23.9 ± 3.1 for women ($P = 0.40$). The subjects included in the analyses were more likely to be younger, male, smokers, and frequent drinkers.

Frequency of Clinicodemographic Factors by Sex for Subjects With and Without LBP

Frequency of clinicodemographic factors for men and women with and without LBP is described in Table 2. A total of 211 (15.1%) analysis subjects had LBP, including 97 men (16.1%) and 114 women (14.4%). Categories for age, BMI, and blood parameters in which the number of subjects or the number of people with Mets was small were combined for investigation. In men and women aged 40 to 49 years, 11 of 56 men and 0 of 45 women were identified as having Mets, and so this age group was combined with the age group of 50 to 59 years' category for analysis. Among men and women with BMI of less than 18.5, none were identified as having Mets, and so this group was combined with the 18.5 to less than 23 BMI category for analysis. Among men, age, triglyceride level, presence of lipid-lowering or antihypertensive therapy, and SF-36-MH score were related to LBP, whereas among women, age, BMI, SF-36-MH score, waist circumference, SBP, and presence of antihypertensive or antihyperglycemic therapy were related to LBP.

Overall, Mets was identified in 131 (21.8%) men and 111 (14.0%) women ($P < 0.01$). In men, the prevalence of Mets was 21.2% (95% CI, 17.6%–24.8%) in those without LBP, and 24.7% (95% CI, 16.0%–33.5%) in those with LBP ($P = 0.44$) (Figure 2). In women, the prevalence of Mets was 12.4% (95% CI, 10.0%–14.9%) in those without LBP, and 23.7% (95% CI, 15.8%–31.6%) in those with LBP ($P < 0.01$) (Figure 2).

Relationship Between LBP and Mets

Results of unadjusted and adjusted analyses are shown in Table 3. In unadjusted analyses, the risk ratio for Mets in men with LBP compared with those without LBP was 1.2 (95% CI, 0.8–1.7). In women, the risk ratio for Mets for those with LBP compared with those without LBP was 1.9 (95% CI, 1.3–2.8). However, although no relationship between LBP and Mets was seen in men in adjusted analyses, the risk ratio for Mets in women with LBP compared with those without LBP was 1.5 (95% CI, 1.0–2.1). In these analyses, the confounders in men were age, SF-36-MH, and IPAQ, and those in women were age, BMI, occupational status, SF-36-MH, and IPAQ.

With regard to other Mets criteria established by the International Diabetes Federation; American Heart Association; National Heart, Lung, and Blood Institute; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity,[5] the prevalence of Mets was 32.5% in men and 26.5% in women. In an investigation of the relationship between LBP and Mets based on the criteria of the above-described groups,[5] the relationship was strong in women but not in men.

DISCUSSION

We investigated the relationship between LBP and Mets by examining the prevalence of Mets in subjects with and without LBP by sex. In the target area for this study, the point prevalence of LBP was 16.1% in men and 14.1% in women. In women, we observed higher Mets prevalence in those with LBP than in those without it. Furthermore, this relationship remained even after adjusting for confounding factors, and the prevalence of Mets was 1.5 times higher in women with LBP than in those without it. In contrast, no such relationship was observed in men after adjustment.

In this study, we identified a number of sex-based differences in the relationship between LBP and Mets. Considering the factors that contribute to LBP and Mets, women with LBP tended to have higher BMI, a larger waist circumference, and higher SBP, and tended to be more likely to be receiving antihypertensive or antihyperglycemic therapy than those without LBP (Table 2). In men, age, triglyceride levels,

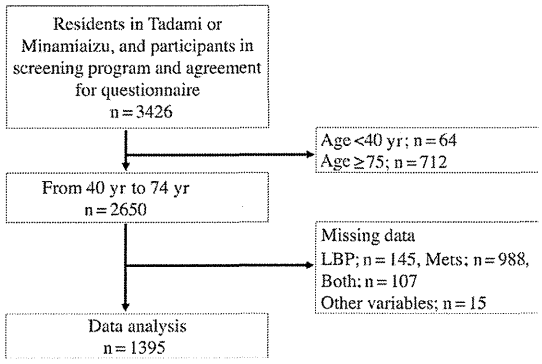

Figure 1. Flow chart. LBP indicates low back pain; Mets, metabolic syndrome.

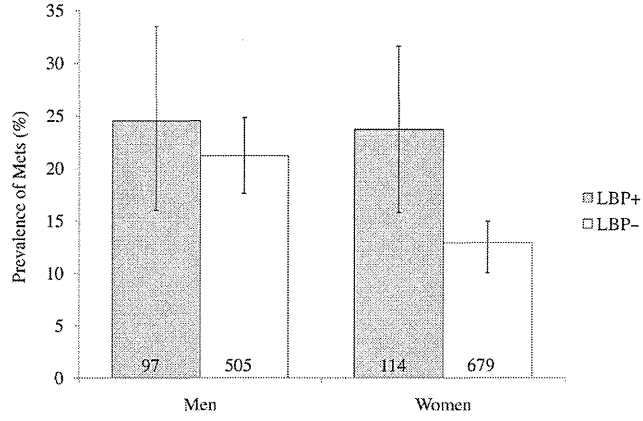

Figure 2. Prevalence of Mets in men and women with and without low back pain. Criterion (1) below must be met and 2 of the 3 criteria (2), (3), and (4) are also met. (1) Waist circumference of at least 85 cm for men and 90 cm for women. (2) Triglycerides more than 1.69 mmol/L (150 mg/dL), high-density lipoprotein cholesterol less than 1.03 mmol/L (40 mg/dL), or presence of lipid-lowering therapy. (3) Systolic blood pressure 130 mm Hg or more, diastolic blood pressure 85 mm Hg or more, or presence of antihypertensive therapy. (4) Fasting plasma glucose 6.11 mmol/L (110 mg/dL) or more, or presence of antihyperglycemic treatment. Vertical lines indicate the 95% confidence interval. LBP indicates low back pain; Mets, metabolic syndrome.

SF-36-MH score, and lipid-lowering and antihypertensive therapy status were associated with LBP, whereas alternative indicators of obesity, such as BMI and waist circumference, were not found to be associated with LBP.

The difference between men and women in the relationship between LBP and Mets (including obesity) may be affected by female-specific hormones. Elevation in blood pressure levels in postmenopausal women is known to depend on age at menopause and postmenopausal period, and reduced estrogen levels have been suggested to be related to the prevalence of hypertension after menopause.[32,33] The findings in this study show that many women with high SBP and those receiving antihypertensive therapy who reported LBP may support the earlier supposition. Second, the decreased bone mineral content resulting from decreased estrogen levels may lead to osteoporosis,[34] in turn leading to LBP.[35] In other words, the relationship detected between LBP and Mets may have been due to the occurrence of hypertension, which is one feature of Mets, resulting from decreased estrogen levels, as well as due to the relationship between LBP and osteoporosis, which is caused by this reduction in circulating estrogen levels.

Several limitations to interpreting the results of this study warrant mention. First, of our target sample, only about half of the patients were included as analysis subjects, and these subjects tended to be relatively young, male, smokers, and frequent drinkers (Table 1). Caution should therefore be practiced when extrapolating the present results to the general population. However, we think that, despite this trend, our study retained adequate internal validity given the 1395 subjects ultimately enrolled.

Second, the definition of Mets in this study used the criteria established by the Japanese Society of Internal Medicine. These criteria differ from those recommended by the International Diabetes Federation and related agencies, in which waist circumference is not an essential measurement parameter and the cutoff for fasting plasma glucose is 100 mg/dL.[5] On applying these criteria to our population, the prevalence of Mets increased by about 10% compared with

TABLE 3. The Relationship Between Low Back Pain and Metabolic Syndrome in Men and Women

Main Explanatory Variable			Unadjusted		Adjusted	
			Risk Ratio for Mets	(95% CI)	Risk Ratio for Mets	(95% CI)
Men	LBP	–	Reference		Reference	
		+	1.2	(0.8–1.7)	1.1*	(0.7–1.6)
Women	LBP	–	Reference		Reference	
		+	1.9	(1.3–2.8)	1.5†	(1.0–2.1)

CI indicates confidence interval; LBP, low back pain; Mets, metabolic syndrome.

**Men's model was adjusted for age, score of mental health domain of the SF-36 Health Survey, and category of the International Physical Activity Questionnaire.*

†Women's model was adjusted for age, body mass index, occupational status, score of mental health domain of the SF-36 Health Survey, and category of the International Physical Activity Questionnaire.

values obtained when using the criteria of the Japanese Society of Internal Medicine. Consequently, the definition of Mets used in this study is thought to be strict (to have a high threshold).

Third, given that this was a cross-sectional study, causal associations cannot be inferred. Whether or not LBP is a factor that leads to the occurrence of Mets therefore remains unconfirmed. Conversely, we cannot rule out the possibility that Mets may be a factor in the occurrence of LBP, nor that the relationship detected between LBP and Mets may have been a result of some unmeasured confounding or mediating factor. With respect to considerable confounders, such as BMI, occupational status, smoking status, and alcohol consumption,[36–38] we had similar results regardless of inclusion or exclusion of these confounding factors, suggesting a higher prevalence of Mets in women with LBP than in those without it—a pattern not observed in men, regardless of adjustment for those variables (data not shown). Although these results suggest that our model has robustness to some extent, a prospective study will be needed to support causal inferences about LBP and Mets.

In conclusion, prevalence of Mets in women tended to be higher among those with LBP than those without it, even after adjustment for confounding factors—a pattern not observed in men. Despite the limitations described above, these results provide a starting point in demonstrating an association between LBP and Mets. At the very least, from the viewpoint of maintaining health in an aging population, our observations here suggest that women with musculoskeletal disease be considered for treatment of metabolism-related diseases as well.

➢ Key Points

- ❑ Ours is the first study to investigate the relationship between LBP and Mets by examining the prevalence of Mets in community-based subjects with and without LBP.
- ❑ In men, the prevalence of Mets was 21.2% in those without LBP and 24.7% in those with LBP.
- ❑ In women, the prevalence of Mets was 12.4% in those without LBP and 23.7% in those with LBP.
- ❑ After adjusting for related factors, no relationship between LBP and Mets was noted in men. However, in women, the risk ratio for Mets was 1.5 (95% CI, 1.0–2.1) when those with LBP were compared with those without LBP.

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Lumbar spinal stenosis associated with peripheral arterial disease: a prospective multicenter observational study

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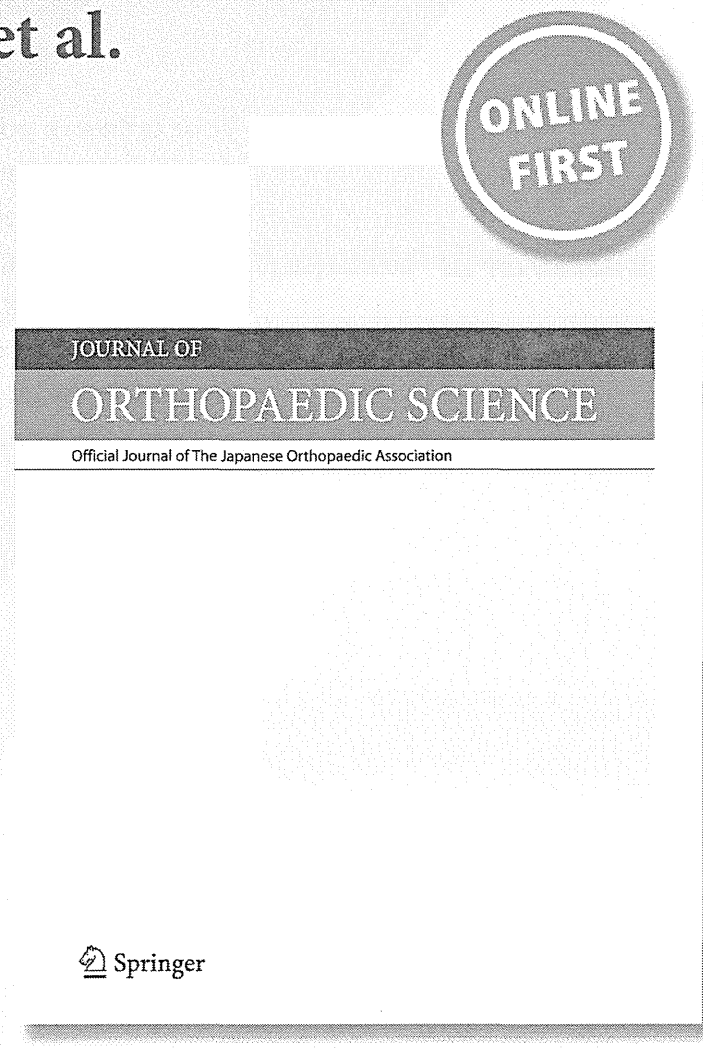

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ORIGINAL ARTICLE

Lumbar spinal stenosis associated with peripheral arterial disease: a prospective multicenter observational study

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Abstract
Background Intermittent claudication is a common symptom of both lumbar spinal stenosis (LSS) and peripheral arterial disease (PAD) in middle-aged and elderly people. However, the prevalence and clinical characteristics of LSS with PAD (LSSPAD) have not been investigated in a multicenter study. The aim of this study was to investigate the prevalence and clinical characteristics of LSS associated with PAD.
Methods 570 patients diagnosed with LSS using a clinical diagnostic support tool and MRI at 64 facilities were enrolled. We evaluated each patient's medical history, physical findings, ankle brachial index, Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ) score, and the Short Form 36 (SF-36) score. Statistical analyses were performed to compare LSSPAD patients and LSS patients without PAD using the t test, Mann–Whitney's U test, and multivariate recurrence analysis. p values of <0.05 were considered statistically significant.
Results The LSSPAD group comprised 38 patients (6.7 %); 20 (3.5 %) had pre-diagnosised PAD while 18 (3.2 %) had undetected PAD. The clinical characteristics of these patients were advanced age, diabetes, and a history of ischemic heart disease and cerebrovascular disorder. 570 patients enrolled, and 448 (78.6 %) of those patients were followed up at three - months after enrollment. Pain in buttocks and legs improved less in the LSSPAD group than in the LSS group ($p < 0.05$). Improvements in the "general health" score in SF-36 were lower in the LSSPAD group than in the LSS group ($p < 0.05$).

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Conclusions Advanced age, diabetes, and a history of cerebrovascular disorder and ischemic heart disease were associated with LSSPAD. Because LSSPAD patients show less improvement in QOL than patients with LSS but without PAD do, clinicians should consider the coexistence of PAD in LSS patients.

Introduction

Lumbar spinal stenosis (LSS) presents with lower extremity symptoms [1, 2], including neurogenic intermittent claudication as a typical symptom [3]. On the other hand, vascular intermittent claudication is also a typical symptom of peripheral arterial disease (PAD) [4, 5]. Since there is overlap in the ages at which patients develop LSS and PAD, it is important to differentiate the claudication caused by these two different pathologies.

PAD refers to a circulatory disorder caused by stenosis or occlusion of the artery by arteriosclerosis or vasculitis. It encompasses conditions such as arteriosclerosis obliterans (ASO), Buerger's disease, and acute arterial obstruction. Progression of PAD increases the risk of severe vascular events and even death [6–8]. Early diagnosis and treatment of PAD can improve the hemodynamics of the lower extremities and reduce the risk of fatal or nonfatal cardiovascular events [4, 5]. LSS patients with PAD have been reported [9]; so, when diagnosing LSS, it is important to bear in mind that concurrent PAD is possible. The prevalence of LSS associated with PAD remains unclear because there have been no large-scale epidemiological studies on this issue. One likely reason for this is that there are no established diagnostic criteria for LSS, based on an international consensus. The Japanese Society for Spine Surgery and Related Research, therefore, developed a diagnosis support tool for LSS (sensitivity of 92.8 %, specificity of 72.0 % [10]). Large-scale epidemiological studies of LSS can be executed using this tool.

The measurement of the ankle brachial index (ABI) is recommended for the diagnosis of PAD [5]. The ABI is the ratio of the arm systolic blood pressure (at the brachial artery) to the ankle systolic blood pressure (at the posterior tibial artery or dorsalis pedis artery) [11]. Highly sensitive and specific diagnosis of PAD is possible using the ABI, comparable to that obtained using angiography or Doppler examination [4, 5, 7, 8, 11–14]. Patients with a resting ABI of below 0.9 may have arterial stenosis that affects hemodynamics [4]. In recent years, instruments that automatically measure the ABI have been developed. Using such automatic ABI devices, reliable data can be easily and quickly obtained [6, 16, 17].

As society ages, it is thought that the number of patients with both PAD and LSS will increase. However, the prevalence of PAD in cases of LSS, and the clinical characteristics of such patients, remain unclear. Thus, the aims of the present study were to determine the prevalence of PAD in LSS patients, to clarify the clinical characteristics of patients with concurrent LSS and PAD, and to clarify the treatment course for these patients.

Methods

Ethics

This study was approved by the ethics committees of the participating research institutions. Written informed consent was obtained from all patients.

Study design

This study was a prospective multicenter observational study, conducted under the guidance of the Japanese Society for Spine Surgery and Related Research. The research team consisted of LSSPAD project members. The survey was conducted in 64 hospitals nationwide, all of which had attending spinal surgeons. The recruitment period was one year from October 1, 2008 to September 30, 2009.

Population

The survey subjects were LSS patients who visited and were examined at the participating hospitals during the survey period. The clinical diagnosis support tool [10] for LSS was used to identify patients with LSS (Table 1). Patients were

Table 1 Scoring scheme used for the diagnostic support tool for LSS

Item	Score
Age	
<60	0
60–70	1
>70	2
Absence of diabetes mellitus	1
Symptoms	
Intermittent claudication (+)	3
Worse when standing for a while	2
Symptoms improve on bending forward	3
Physical examination	
Symptoms induced by having patients bend forward	−1
Symptoms induced by having patients bend backward	1
Ankle brachial index (ABI) ≥0.9	3
Absence or low response of achilles tendon reflex	1
Straight leg raising test positive	−2

Patients with a total score of ≥7 were considered to have LSS

diagnosed with LSS by a spine specialist if (a) they achieved a total score of ≥7 with the LSS diagnosis support tool, and (b) their neurological findings were consistent with spinal canal stenosis found via MRI at that particular lumbar spinal level. Patients with impaired consciousness, serious complications (heart failure, kidney failure, liver failure, respiratory failure), or psychiatric diseases or symptoms were excluded. Those who were pregnant, were breastfeeding, had myelopathy, had a history of lumbar spine surgery, or were attending for a second opinion were also excluded. To avoid bias among the hospitals, the number of patients enrolled at each hospital was limited to 10.

Investigations at baseline

At the time of enrollment, the patients were interviewed individually to obtain their medical histories. They were asked about symptoms including the presence of intermittent claudication, exacerbation of symptoms when standing up, and improvement of symptoms when bending forward (lumbar flexion). The severity of symptoms was evaluated using a visual analog scale (VAS: 0–100 mm) for lower back pain, buttock or lower extremity pain, and buttock or lower extremity numbness. In physical examinations, we recorded whether symptoms appeared on lumbar forward or backward flexion, whether the Achilles tendon reflex was diminished, and whether the patient had a positive straight leg raising test. Patients were also asked if they had any comorbidities such as hypertension, diabetes mellitus, dyslipidemia, hyperuricemia and cerebrovascular disorders (stroke, cerebral hemorrhage, or transient cerebral ischemic attack), ischemic heart disease (myocardial infarction, angina pectoris, or coronary revascularization), arrhythmia, and carotid artery disease. Lifestyle questions included history of alcohol intake and smoking. Patients who drank routinely were considered to have a history of alcohol consumption. Patients who were current or past smokers were considered to have a history of smoking. Patients underwent hematological tests.

Quality of life (QOL) was evaluated using the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ) [18] and Short Form 36 (SF-36) [19]. The JOABPEQ consists of five subscales and the SF-36 consists of eight subscales. With both tests, a higher score means better maintenance of QOL.

A follow-up survey was conducted three months after enrollment. This survey included symptoms, physical findings, the type of treatment for LSS (conservative or surgical therapies), and QOL (JOABPEQ and SF-36).

Definition of PAD

PAD was diagnosed by ankle brachial pressure index (ABI). Systolic blood pressure was measured with the patient in a supine position using either BP203RPE III (OMRON Co. Ltd., Tokyo, Japan) or VaSera^{TM} VS-1500E (Fukuda Denshi, Tokyo, Japan). ABI was calculated by dividing the systolic blood pressure of the ankle arteries by the systolic blood pressure of the brachial artery. At the time of enrollment, patients who had already been diagnosed with PAD or patients with ABI ≤0.9 in either leg were diagnosed with PAD [4, 5].

Statistical analysis

Patients with coexisting PAD and LSS were designated the "LSSPAD group," and those with LSS but no PAD were denoted the "LSS group." Using the LSS group as controls, an analysis was conducted to identify the characteristics of the LSSPAD group.

To evaluate the clinical characteristics at the time of enrollment, we analysed and compared (using the t test, χ^2

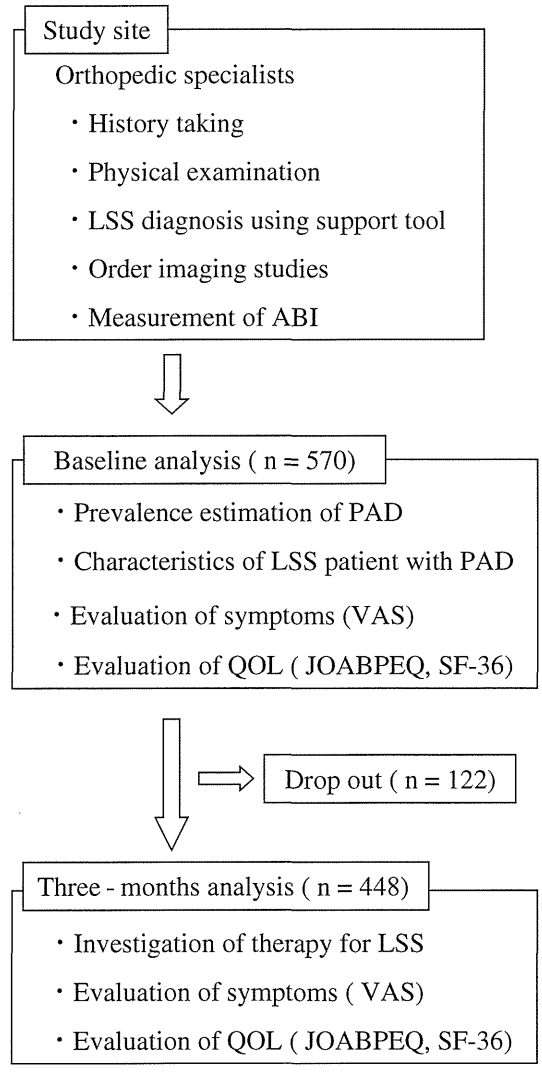

Fig. 1 Registration protocol

test, Mann–Whitney U test, and multivariate logistic regression analysis) the two groups. p values of less than 0.05 were considered significant.

In the survey performed three months after enrollment, the χ^2 test or Fisher's exact test were used to investigate differences in symptoms, physical examination findings, and types of treatment for LSS (conservative or surgical therapies). A multiple regression analysis adjusted for age, sex, comorbidities, medical history, and the type of treatment for LSS was performed to evaluate the improvement in the symptoms, JOABPEQ, and SF-36. SPSS for Windows (version 16.0; SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Data are presented as proportions and means (±SD).

Results

Description of the sample

A total of 570 LSS patients were enrolled (Fig. 1): 303 men and 267 women, with a mean age of 71 ± 8.0 years. Among the 570 LSS patients, 38 (6.7 %) had PAD (LSSPAD group). Of the 38 patients in the LSSPAD group, 20 (3.5 %) had already been diagnosed with PAD prior to enrollment in this study. The remaining 18 patients (3.2 %) had an ABI ≤0.9 and were diagnosed with PAD after enrollment in this study.

Characteristics of the LSS and LSSPAD patients at baseline and in the survey at three months

The LSSPAD group was significantly older than the LSS group: 75 ± 6.3 years versus 71 ± 8.0 years ($p < 0.01$) (Table 2). Men constituted 71.1 % of the LSSPAD group, a significantly higher percentage than in the LSS group (51.9 %) ($p < 0.01$). VAS scores for numbness in the buttocks or lower extremities were significantly smaller in the LSSPAD group than in the LSS group ($p < 0.01$).

Of the 570 registered patients, 448 completed the follow-up survey at three months—a follow-up rate of 78.6 %. Of these 448 patients, 30 (6.7 %) belonged to the LSSPAD group. The mean age was 75 ± 6.6 years in the LSSPAD group and 70 ± 8.3 years in the LSS group; the mean age was significantly higher in the LSSPAD group ($p < 0.01$) (Table 2). No significant difference in the clinical or physical findings for the LSSPAD and LSS groups was observed.

Table 2 Characteristics of the LSS and LSSPAD patients at baseline and in the survey at three months

	Mean (SD) or N (%)[†]					
	Baseline			Outcome at three months		
	LSSPAD ($n = 38$)	LSS ($n = 532$)	p	LSSPAD ($n = 30$)	LSS ($n = 418$)	p
Age (%)	75 (6.3)	71 (8.0)	<0.01	75 (6.6)	70 (8.3)	<0.01
Males (%)	27 (71.1)	276 (51.9)	0.02	22 (73.3)	212 (50.7)	0.02
Support tool	11.5 (2.1)	13.2 (2.1)	<0.01	8.5 (4.0)	9.0 (3.8)	0.76
ABI ≤ 0.9	35 (92.1)	–		–	–	
Symptoms						
Presence of Intermittent claudication (%)	36 (100)	483 (92.9)	0.16	16 (57.1)	163 (40.3)	0.08
Worse when standing for a while (%)	35 (94.6)	469 (90.2)	0.56	13 (44.8)	159 (39.4)	0.56
Symptoms improve on bending forward (%)	31 (83.8)	401 (77.1)	0.35	11 (37.9)	141 (34.9)	0.74
Lower back pain (VAS)	47.9 (29.9)	49.3 (28.6)	0.77	39.0 (31.2)	32.4 (27.2)	0.22
Buttock or lower extremity pain (VAS)	53.6 (27.0)	60.1 (28.4)	0.18	42.4 (28.4)	33.9 (31.3)	0.16
Buttock or lower extremity numbness (VAS)	42.3 (32.1)	56.4 (29.9)	<0.01	38.5 (31.1)	36.3 (30.8)	0.71
Physical examination (%)						
Symptoms induced by having patients bend forward	1 (2.7)	20 (3.8)	1.00	1 (3.4)	16 (4.0)	1.00
Symptoms induced by having patients bend backward	20 (54.1)	278 (53.5)	0.94	8 (27.6)	104 (25.9)	0.84
Absence or low response of Achilles tendon reflex	30 (81.1)	349 (67.1)	0.08	19 (65.5)	256 (63.4)	0.82
Straight leg raising test positive	0 (0)	28 (5.4)	0.25	1 (3.6)	5 (1.2)	0.31

VAS visual analog scale (scale 0–100 mm)

[†] The total numbers for some items do not add up to the total number in the top row because of missing information

Background of patients at baseline

With respect to comorbidities, there was a significantly higher prevalence of diabetes mellitus in the LSSPAD group than in the LSS group ($p < 0.01$) (Table 3). No significant differences were seen between the LSSPAD group and the LSS group in the prevalence of hypertension, dyslipidemia, or hyperuricemia. Regarding the medical history, the LSSPAD group had significantly higher rates of cerebrovascular disorder, ischemic heart disease, and arrhythmia when compared with the LSS group. No significant differences were seen between the LSSPAD group and LSS group in terms of history of alcohol intake or smoking. The LSSPAD group had significantly elevated levels of creatinine compared with the LSS group ($p < 0.05$) (Table 3). No significant difference was seen between the two groups in any other items in the hematological tests.

Table 3 Background of patients in baseline

	Mean (SD) or *N* (%)[†]		
	LSSPAD ($n = 38$)	LSS ($n = 532$)	*p*
Comorbidities			
Hypertension (%)	22 (59.5)	240 (45.1)	0.09
Diabetes mellitus (%)	15 (40.5)	103 (19.4)	<0.01
Dyslipidemia (%)	7 (18.9)	81 (15.2)	0.49
Hyperuricemia (%)	3 (8.1)	17 (3.2)	0.13
Past history			
Cerebrovascular disease (%)	8 (21.1)	38 (7.1)	<0.01
Ischemic heart disease (%)	15 (39.5)	32 (6.0)	<0.01
Arhythma (%)	5 (13.2)	19 (3.6)	0.02
Life history			
Drinking history (%)	10 (26.3)	207 (39.6)	0.11
Smoking history (%)	13 (34.2)	161 (30.3)	0.61
Hematological test			
WBC (/mm^3)	6299 (1508)	6130 (1932)	0.60
Hemoglobin (g/dl)	13.4 (1.7)	13.5 (1.5)	0.73
AST (IU/L)	24.9 (13.9)	24.8 (10.4)	0.95
ALT (IU/L)	21.2 (17.6)	22.4 (14.6)	0.62
BUN (mg/dl)	18.6 (6.8)	16.9 (7.9)	0.18
Creatinine (mg/dl)	0.95 (0.32)	0.78 (0.35)	<0.01
HbA1c (%)	5.9 (1.1)	5.9 (3.9)	0.97
Total cholesterol (mg/dl)	194.7 (32.3)	200.7 (37.9)	0.35
Triglyceride (mg/dl)	137.7 (72.0)	137.5 (75.0)	0.98
LDL-C (mg/dl)	112.3 (28.5)	116.4 (30.9)	0.44
HDL-C (mg/dl)	55.6 (15.3)	58.3 (18.6)	0.40

[†] Total numbers for some items do not add up to the total number in the top row because of missing information

Multivariate logistic analysis

From the above results, diabetes mellitus, history of cerebrovascular disorder, ischemic heart disease, arrhythmia, high serum creatinine level, and mild numbness in the buttocks or lower extremities were extracted as characteristics of LSS patients with PAD. These extracted factors were then adjusted individually by age and sex (model 1). After this adjustment, factors characteristic to the LSSPAD group ($p < 0.05$) were diabetes mellitus, history of cerebrovascular disorder, ischemic heart disease, and mild numbness in the buttocks or lower extremities. A multivariate logistic regression analysis with a forced entry method was conducted for these factors, including age and sex (model 2).

As a result of multivariate analysis, no sex differences were seen between two groups. The LSSPAD group had a significantly higher proportion of older people, a higher prevalence of diabetes mellitus, and a more frequent history of cerebrovascular disorder or ischemic heart disease than the LSS group ($p < 0.05$) (Table 4). In addition, the average VAS of numbness in the buttocks or lower extremities was significantly smaller in the LSSPAD group than in the LSS group ($p < 0.05$).

Evaluation of QOL

No significant difference was observed between the LSSPAD group and the LSS group in the JOABPEQ and SF-36 scores at baseline (Table 5).

In the JOABPEQ and SF-36 scores at three months after enrollment, the scores for walking ability, social function, role physical, and general health (GH) were significantly lower in the LSSPAD group than in the LSS group ($p < 0.05$).

Follow-up survey of LSS patients at three months

No significant difference was seen in the types of treatment implemented for LSS between the LSSPAD group (conservative 53.3 %, surgical 46.7 %) and the LSS group (conservative 48.1 %, surgical 51.9 %).

At three months after enrollment, all scores for symptoms, JOABPEQ, and SF-36 showed lower levels of improvement in the LSSPAD group than in the LSS group (Table 6). Based on the results of the multivariate logistic analysis, a multiple regression analysis was conducted, adjusting for age, sex, association of diabetes mellitus, history of cerebrovascular disorder, history of ischemic heart disease, and the types of treatment for LSS. The improvement in the VAS for buttock or lower extremity pain was significantly lower in the LSSPAD group than in the LSS group ($p < 0.05$) (Table 6). No significant difference in the improvement in the JOABPEQ subscales

Table 4 Factors related to LSSPAD in multivariate logistic regression analysis

	Model 1			Model 2		
	Odds ratio	95 % CI	*p*	Odds ratio	95 % CI	*p*
Age	–	–	–	1.06	1.00–1.12	0.04
Sex	–	–	–	1.90	0.85–4.22	0.12
Diabetes mellitus	2.97	1.46–6.04	<0.01	2.63	1.23–5.62	0.01
Cerebrovascular disease	2.67	1.11–6.43	0.03	2.80	1.04–7.55	0.04
Ischemic heart disease	8.00	3.71–17.26	<0.01	7.36	3.30–16.45	<0.01
Arrhythmia	2.66	0.88–8.02	0.08	–	–	–
Creatinine	1.38	0.75–2.52	0.30	–	–	–
Buttock or lower extremity numbness	0.99	0.98–1.00	0.02	0.99	0.97–1.00	0.02

Model 1: a multivariate logistic regression analysis adjusted for age and sex, *model 2*: a multivariate logistic regression analysis with a forced entry method (adjusted for age, sex, diabetes mellitus, cerebrovascular disease, ischemic heart disease, and numbness)

Table 5 JOABPEQ and SF-36 scores at baseline and in the survey performed at three months

	Mean (SD)[†]					
	Baseline			Outcome at three months		
	LSSPAD ($n = 38$)	LSS ($n = 532$)	*p*	LSSPAD ($n = 30$)	LSS ($n = 418$)	*p*
JOABPEQ						
Lower back pain	42.1 (30.8)	47.7 (33.6)	0.32	60.0 (33.5)	67.1 (32.0)	0.26
Lumbar function	64.5 (27.1)	61.6 (29.5)	0.57	63.3 (33.5)	67.5 (28.8)	0.53
Walking ability	27.6 (24.8)	35.4 (27.7)	0.09	41.7 (27.4)	57.5 (31.1)	<0.01
Social life function	34.7 (22.3)	41.8 (22.2)	0.06	42.8 (15.5)	55.3 (24.9)	<0.01
Mental health	43.2 (17.8)	45.8 (18.3)	0.38	52.0 (18.4)	53.7 (19.0)	0.15
SF-36						
Physical functioning	42.4 (23.7)	49.0 (23.3)	0.09	53.6 (21.2)	61.6 (24.5)	0.09
Role physical	45.9 (31.7)	47.9 (28.0)	0.68	42.0 (20.4)	57.3 (28.1)	<0.01
Bodily pain	39.5 (27.1)	34.8 (20.5)	0.19	49.9 (20.5)	51.6 (22.6)	0.69
General health	47.3 (15.1)	47.3 (17.9)	1.00	44.9 (16.8)	52.2 (18.3)	0.04
Vitality	46.2 (22.2)	47.5 (22.2)	0.72	55.2 (20.1)	55.9 (21.6)	0.86
Social functioning	54.9 (28.1)	61.4 (28.7)	0.18	65.9 (22.4)	67.4 (26.7)	0.78
Role emotional	53.8 (33.2)	55.8 (31.2)	0.71	57.5 (26.7)	62.2 (30.4)	0.41
Mental health	54.7 (24.8)	56.8 (22.5)	0.59	64.8 (19.0)	65.9 (21.0)	0.78

[†] Numbers for some items do not add up to the total number in the top row because of some missing information

JOABPEQ consists of 5 subscales. Higher score indicates better QOL

SF-36 consists of 8 subscales. Higher score indicates better QOL

between the LSSPAD group and the LSS group was observed. The SF-36 score showed a significantly lower level of improvement in GH in the LSSPAD group than in the LSS group ($p < 0.05$). No significant difference was seen in the other SF-36 subscales between the LSSPAD group and the LSS group.

Discussion

This is the first nationwide multicenter survey on the prevalence of PAD in patients with LSS in Japan. We found that 6.7 % of the LSS patients had PAD. In other countries, the prevalence of PAD in the general adult population is reported to be 3–19 % [4, 5, 14, 20, 21]. It is also reported that the risk of PAD is significantly higher in older people and in men [12, 14, 22, 23]. In LSS patients, similar to the general population, the risk of concurrent PAD increases significantly with age. However, no sex differences were recognized. Factors other than older age and male sex that are reported to be related to PAD are smoking, hypertension, diabetes mellitus, dyslipidemia, coronary artery disease, and cerebral artery disease [24–27]. We have shown that comorbidity of diabetes mellitus,

Table 6 Degrees of improvement and multiple regression analysis of results obtained in the survey performed at three months

	Mean (SD)[†]					
	Total ($n = 448$)	LSSPAD ($n = 30$)	LSS ($n = 418$)	R^2	β	p
Symptoms (VAS)						
Lower back pain	−17.0 (33.8)	−9.1 (40.4)	−17.6 (33.3)	0.16	−0.05	0.30
Buttock or lower extremity pain	−25.8 (38.2)	−9.0 (39.7)	−27.0 (37.9)	0.17	−0.12	0.01
Buttock or lower extremity numbness	−19.9 (36.2)	−4.0 (34.2)	−21.0 (36.1)	0.19	−0.09	0.06
JOABPEQ						
Lower back pain	19.6 (37.5)	15.8 (42.1)	20.0 (37.2)	0.08	0.01	0.92
Lumbar function	5.5 (31.4)	−1.5 (31.2)	6.2 (31.2)	0.02	0.07	0.17
Walking ability	22.0 (33.6)	11.8 (32.7)	22.9 (33.5)	0.21	0.07	0.12
Social life function	13.2 (26.4)	5.1 (24.4)	13.9 (26.3)	0.10	0.09	0.08
Mental health	8.1 (19.6)	6.9 (21.2)	8.3 (19.4)	0.11	0.01	0.83
SF-36						
Physical functioning	12.7 (24.6)	11.0 (28.2)	13.0 (24.0)	0.17	−0.02	0.68
Role physical	6.8 (29.9)	−3.0 (32.5)	7.7 (29.6)	0.04	0.10	0.05
Bodily pain	15.9 (26.7)	8.3 (27.4)	16.7 (26.7)	0.11	0.07	0.16
General health	5.0 (17.0)	−1.7 (19.1)	5.8 (17.0)	0.08	0.11	0.04
Vitality	7.9 (22.4)	6.3 (22.7)	8.4 (22.7)	0.10	0.02	0.74
Social functioning	5.6 (29.9)	5.6 (29.2)	5.8 (30.0)	0.02	−0.01	0.82
Role emotional	5.2 (33.7)	3.2 (33.8)	5.6 (33.7)	0.03	0.04	0.49
Mental health	8.3 (23.1)	6.9 (23.8)	8.9 (23.6)	0.07	0.02	0.74

A lower score indicates better condition

JOABPEQ consists of 5 subscales. A higher score indicates better QOL

SF-36 consists of 8 subscales. A higher score indicates better QOL

VAS visual analog scale (scale 0–100 mm)

[†] The numbers for some items do not add up to the total number in the top row due to missing data

history of cerebrovascular disorder, and history of ischemic heart disease are characteristic of LSS patients with PAD. Thus, older age, association of diabetes mellitus, history of cerebrovascular disorder, and history of ischemic heart disease may be useful for predicting PAD in LSS patients.

In the clinical setting, the pulse of the dorsalis pedis artery and posterior tibial artery is palpated to examine the peripheral circulation. Patients with diminished femoral artery or posterior tibial artery pulse are at high risk for PAD [28]. Although congenital defects in ankle arteries are rare (dorsalis pedis artery: 1.8 %, posterior tibial artery: 0.18 %) [28], it has been reported that the dorsalis pedis artery cannot be felt in 8.1 % and the posterior tibial artery cannot be felt in 2.9 % of all healthy people [11]. Consequently, the sensitivity of palpation of arterial pulses in the diagnosis of PAD is low [29, 30]. Thus, the absence of arterial pulses in the foot could lead to the overdiagnosis of PAD. The diagnosis of PAD by ABI is noninvasive and simple. Moreover, by setting the ABI cutoff to 0.9, it is possible to screen PAD with high sensitivity and specificity, comparable to that of angiography [15]. In the Trans-Atlantic Inter-Society Consensus (TASC) II treatment guidelines for PAD, screening for PAD with the use of ABI is recommended for all patients with lower extremity symptoms on exertion, patients aged 50–69 with cardiovascular risk factors, and all patients aged ≥70, regardless of risk factors [5]. Many LSS patients with lower extremity symptoms, including intermittent claudication [2, 10, 26], are elderly and at risk for PAD. Therefore, when examining LSS patients, it is important to conduct screening by ABI to avoid overlooking coexisting PAD.

In this study, patients in the LSSPAD group had significantly milder buttock or lower extremity numbness than those without PAD. However, VAS is a subjective evaluation, and it is difficult to use to predict PAD.

No significant differences were seen in the JOABPEQ or SF-36 scores between the two groups at the time of enrollment. Thus, it is difficult to gauge the presence of complicating PAD based on patient QOL or subjective evaluations. In the follow-up survey performed 3 months after enrollment, following adjustment for age, sex, comorbidities, medical history, and whether the patient had undergone surgery, the level of improvement in buttock or lower extremity pain and the GH subscale in SF-36 was

significantly lower in the LSSPAD group. The patient's subjective evaluation of their state of health is reflected in the GH score. If a patient has the impression that their state of health is gradually deteriorating, the score for GH declines [19]. In the LSSPAD group, buttock or lower extremity pain was resistant to treatment, so it is thought that patients' subjective evaluation of the treatment effect may be lower.

In this study, only about half of the LSS patients with PAD had already been diagnosed with PAD. This means that a large number of LSS patients with PAD had not undergone testing or treatment for PAD. Diagnosing coexisting PAD from claudication or patients' subjective evaluations is a difficult task, making ABI screening essential in the diagnosis of PAD.

The investigation of the comorbidities and medical histories of LSS patients with PAD in this study was cross-sectional. Therefore, one of this study's limitations is that the causal relationships between comorbidities, medical history, and coexisting PAD could not be elucidated. Another limitation was that the type of treatment for PAD was not investigated.

In the future, a longitudinal study with detailed classification of each patient's background will be needed.

Conclusion

Factors strongly associated with PAD in LSS patients are advanced age, association of diabetes mellitus, history of cerebrovascular disorder, and history of ischemic heart disease. In LSS patients with PAD, buttock or lower extremity pain is intractable, and improvement in QOL is difficult to achieve. When examining patients with LSS, it is necessary to keep PAD in mind.

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Conflict of interest The authors declare that they have no conflict of interest.

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