ISSLS PRIZE IN CLINICAL SCIENCE 2019: clinical importance of trunk muscle mass for low back pain, spinal balance, and quality of life—a multicenter cross-sectional study

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Citation	European Spine Journal, 28(5); 914-921
Issue Date	2019-05-01
Type	Journal Article
Textversion	Author
Description	研究グループは、大規模なデータを用いて世界で初めて体幹筋量の臨床的意義を明らかにし、体幹筋量が腰痛に関連することを示しました。本研究成果は、国際腰椎学会「The International Society for the Study of the Lumbar Spine（ISSLS）」の優秀論文賞（ISSLS PRIZE IN CLINICAL SCIENCE 2019）を受賞し、2019 年 2 月 6 日に国際学術誌『European Spine Journal』のオンライン版に掲載されました。 '体幹筋量と腰痛が関連することを世界で初めて明らかに　国際腰椎学会（ISSLS)の優秀論文賞を受賞'. 大阪市立大学. https://www.osaka-cu.ac.jp/ja/news/2018/190219-2 （参照 2019-02-19）
Rights	This is a post-peer-review, pre-copyedit version of an article published in European Spine Journal. The final authenticated version is available online at: https://doi.org/10.1007/s00586-019-05904-7 See Springer Nature terms of use. https://www.springer.com/gp/open-access/publication-policies/aam-terms-of-use.
DOI	10.1007/s00586-019-05904-7

Introduction

Japan is one of the fastest ageing countries in the world with a population that has started to shrink since 2008[1]. In this super-aged society, one of the medical problems that Japan has is the elongation of a healthy life expectancy, which represents an important factor of the problem to overcome in the future.

Low back pain is one of the critical factors that jeopardizes healthy life expectancy. In 2015, low back pain and neck pain were ranked the fourth leading causes of disability-adjusted life years globally just after ischemic heart disease, cerebrovascular disease, and lower respiratory infection[2]. Moreover, low back pain and neck pain are the leading causes of years lived with disability in most countries and age groups[2, 3]. Spinal sagittal imbalance is one of the common causes of back pain in the elderly population[4]. Corrective surgery has been actively performed for back pain in patients with spinal imbalance, with remarkable evolution of spinal instrumentation and technique in recent years[5]. However, these surgeries are highly invasive, and high complication rates have been reported[6, 7]; thus, they are not the fundamental solution to spinal sagittal imbalance. Elucidating the mechanism of low back pain and spinal sagittal imbalance and taking preventive measures are considered as important solutions to the elongation of a healthy life expectancy in the elderly population.

Trunk muscles, including the iliopsoas and paravertebral muscles, play a very important role in supporting the spinal column, and it is expected that decreasing trunk muscle mass affects low back pain and spinal sagittal imbalance. Many studies investigated the relationship of the cross-sectional area and fat infiltration of trunk muscles, especially the paravertebral muscle, with low back pain and spinal alignment[8–15]. However, most of these studies were based on magnetic

resonance imaging (MRI) or computed tomography (CT), and it is difficult to conduct large-scale research studies because of radiation exposure, the time required for the examination, facilities, and costs. Bioelectrical impedance analysis (BIA), which is a noninvasive, easily applicable, inexpensive, and practical method[16], can be used in a large population-based study. Several studies have developed BIA equations for estimating whole-body skeletal muscle or fat free mass, not only in Western populations but also in Japanese populations[17–19]. The appendicular skeletal muscle mass (ASM) is used as a diagnostic criterion for sarcopenia[20, 21], and attention to ASM has been increasing in recent years. Nevertheless, few studies have investigated the relationship between trunk muscle mass and low back pain and spinal balance, and the clinical significance of trunk muscle mass has not been clarified.

Therefore, we planned a large-scale multicenter study to clarify the significance of trunk muscle mass. If the trunk muscle mass can be used as a reliable index related with low back pain and spinal sagittal imbalance, it can serve as a useful indicator in clinical practice. The purposes of this study were to clarify the relationship between trunk muscle mass and low back pain, spinal sagittal balance, and quality of life (QOL), and to elucidate the significance of trunk muscle mass in patients with spinal diseases.

Materials and Methods

This study was approved by the local ethics committee of the Faculty of Medicine, Osaka City University (number 3806).

Subjects

In this multicenter cross-sectional study, Osaka City University, Chiba University, and Kitasato University collaborated to investigate 10 facilities including relevant hospitals in each

area. Patients who visited the spinal outpatient clinic at one of the facilities from June 2017 to March 2018 were enrolled in this study. BIA data of patients who agreed to undergo the measurement of muscle mass were collected, except for those who in whom muscle mass could not be measured because of an indwelling pacemaker or incapability to maintain standing position. Among them, data on patients with metals in the body, such as spinal implants, artificial joints, or implants for fracture surgeries, were excluded because the reliability of the BIA method was unknown. Additionally, patients younger than 30 years were excluded, as they did not fit the purpose of this study.

Measurement of muscle mass

Muscle mass was measured by BIA with a MC-780A or MC-980A Body Composition Analyzer (Tanita Co., Tokyo, Japan). BIA is a method of measuring the electric resistance (bioimpedance) of living tissue and determining the body composition. The amount of fat and other parameters are mainly calculated based on the measurement value of dual energy x-ray absorptiometry (DXA). Muscle mass is a value obtained by subtracting fat mass and bone mass from body weight, and muscle mass obtained by the BIA method shows a high correlation with muscle mass obtained by the DXA method[17–19]. Trunk muscle mass was calculated by subtracting the ASM from the muscle mass of the whole body. Body mass index (BMI) was calculated by dividing the body weight by the square of the height at the time of the measurement.

Questionnaires

The Oswestry Disability Index (ODI) was used to evaluate daily living problems due to low back pain. The degree of low back pain in the last week was evaluated by the visual analog scale (VAS). The 5-level classification system of the EQ-5D (EQ5D) was used to evaluate QOL. We

investigated comorbidities, such as hypertension, diabetes mellitus, myocardial infarction, rheumatoid arthritis, Parkinson disease, and malignant tumor, and we calculated the Charlson Comorbidity Index (CCI). The type of spinal disease and history of spinal surgery were collected from medical records and outpatient physicians.

Radiographic assessment

The sagittal vertical axis (SVA) was measured in participants with whole-spine radiographs in the lateral view.

Statistical analysis

We investigated whether trunk muscle mass was related to the ODI as a primary outcome. We also investigated the relationship between trunk muscle mass and the VAS score, SVA, and EQ5D score as a secondary outcome. Statistical analysis was carried out using multiple nonlinear regression analysis to elucidate these relationships. The objective variables were ODI, the VAS score, SVA, and EQ5D score, and their association with trunk muscle mass was analyzed after the data were adjusted for age, sex, BMI, ASM, CCI, and history of lumbar surgery. ODI and Vas score were transformed to natural logarithm. Sex and history of lumbar surgery were categorical variables, and all other variables were continuous variables. The relationship between age, trunk muscle mass, and ASM was also analyzed using nonlinear regression analysis after adjusted for sex and BMI. Nonlinearity of the associations between the objective variable and trunk muscle mass, was assessed by including restricted cubic splines in the regression models. Statistical tests were considered significant at $p < 0.05$, and all p values were two-sided. We used R (version 3.5.1, patched, http://www.r-project.org; The R Foundation, Vienna, Austria) for all statistical analyses.

Results

Among 2551 patients in whom the measurement of muscle mass was obtained, 1738 patients (mean age 70.2 ± 11.0 years; men 781, women 957), excluding those with metals in their body and those younger than 30 years, were analyzed (Table 1). The average trunk muscle mass was 22.2 ± 4.4 kg, which had a significant negative correlation with age when adjusted by sex and BMI ($p < 0.0001$), and the decrease accelerated at approximately 70 years of age (Figure 1A). Moreover, the mean ASM was 18.0 ± 5.1 kg, which negatively correlated with age when adjusted by sex and BMI ($p < 0.0001$) and decreased continuously (Figure 1B).

Trunk muscle mass was negatively correlated with the ODI ($p < 0.0001$) when adjusted by age, sex, BMI, CCI, ASM, and history of lumbar surgery. The ODI increased with a decrease in trunk muscle mass, and the increase accelerated from approximately 23 kg (Figure 2). Trunk muscle mass was also negatively correlated with the VAS score ($p = 0.0032$) when adjusted by age, sex, BMI, CCI, ASM, and history of lumbar surgery. The VAS score increased slightly with a decrease in trunk muscle mass until approximately 23 kg, and it increased rapidly from about 23 kg (Figure 3).

In 1546 patients who had whole-spine radiographs, the relationship between trunk muscle mass and SVA was investigated. Trunk muscle mass was negatively correlated with SVA ($p < 0.0001$) when adjusted by age, sex, BMI, CCI, ASM, and history of lumbar surgery. SVA almost plateaued with trunk muscle mass over approximately 23 kg, and it started to increase with a decrease in trunk muscle mass from approximately 23 kg (Figure 4). Trunk muscle mass was positively correlated with the EQ5D score when adjusted by age, sex, BMI, CCI, ASM, and history of lumbar surgery ($p < 0.0001$). The EQ5D score decreased with a decrease in trunk muscle mass, and the decrease accelerated below approximately 23 kg (Figure 5). However, ASM

was not related to the ODI, VAS score, SVA, and EQ5D score when adjusted by age, sex, BMI, CCI, trunk muscle mass, and history of lumbar surgery (p = 0.9327; 0.3786; 0.4141; 0.1254, respectively).

Discussion

To our knowledge, this is the first large-scale study to investigate trunk muscle mass measured by the BIA method. Most studies that investigated the relationship of trunk muscle mass with low back pain and spinal sagittal imbalance were based on MRI or CT, so the number of subjects was limited. We measured muscle mass by BIA, a simple and noninvasive method, so we were able to recruit a large number of subjects, and we believe that we were able to improve the reliability of the results. Moreover, this study was able to evaluate the relationship of trunk muscle mass with not only the extent of back pain but also daily living disorder due to low back pain, spinal balance, and QOL. In most studies, only the relationship between the trunk muscle mass and a single element could be evaluated. In the current study, trunk muscle mass was significantly associated with ODI, the VAS score for low back pain, SVA, and EQ5D even after adjusted for age, sex, BMI, CCI, ASM, and history of lumbar surgery. We believed that we demonstrated the clinical importance of trunk muscle mass in this study.

Several studies have elucidated that ASM decreases with age[22]. Regarding the trunk muscles, changes in the cross-sectional area and fat degeneration of paraspinal muscles due to aging have been reported[10]. In this study, as expected from those research results, it was proven that trunk muscle mass decreases with age. Furthermore, a decrease of trunk muscle mass with age was not constant but accelerated from the 70s. Moreover, ASM decreased constantly with age. There may be a difference in the decrease with age between trunk muscle mass and ASM.

The loss of skeletal muscle mass and strength with biological and pathological aging is now commonly described as sarcopenia[23], and attention has focused on the effect of sarcopenia on various diseases in recent years. The relationship between sarcopenia and lumbar spinal disorder has been studied. Park et al. reported that the prevalence of sarcopenia was higher in people with lumbar spinal stenosis than in normal people[24]. Tashima et al. reported that ODI values were significantly higher in the sarcopenia group than in the other groups[25]. However, the diagnostic criteria of sarcopenia include ASM, not trunk muscle mass, so a diagnosis of sarcopenia cannot reflect a decrease of trunk muscle mass, which is thought to be more important for the lumbar spine. The importance of trunk muscle mass for lumbar function has been proven[26]. The volume of trunk muscles has been mainly assessed with the cross-sectional area and fatty infiltration of trunk muscles, such as the multifidus, erector spinae, and psoas. Many studies have reported a positive correlation of trunk muscle mass or fat infiltration with low back pain[14, 15, 27], whereas other studies have reported a negative correlation[9]. CT or MRI is necessary to evaluate the muscle cross-sectional area and fat degeneration, but from the viewpoint of invasiveness, the time, cost, and facilities required for the examination, these methods are not suitable for large-scale research studies or screening. Under these circumstances, we measured trunk muscle mass by BIA, which is a simple and noninvasive method. As a result of this study, it was proven that a decrease in trunk muscle mass is related to the ODI and VAS score for low back pain. ASM was not clearly related to ODI and VAS. This result is reasonable considering the importance of trunk muscles for lumbar function.

Trunk muscles are also an important factor for maintaining posture, including spinal alignment and balance. Various reports had proven that the cross-sectional area and fat infiltration

of paravertebral muscles at the lumbar spine were related to spinopelvic alignment and sagittal balance[12, 13]. While the development of kyphosis is often attributed to osteoporosis and vertebral fractures, almost two-thirds of cases of severe kyphosis occur independently of these risk factors[28]. A decrease in trunk muscle mass may be part of the occurrence of kyphosis; Yamamoto et al. reported that lower trunk muscle mass measured by DXA is associated with hyperkyphosis in older persons[29]. Interestingly, they reported that ASM did not display a significant association with hyperkyphosis in most measurements. These results were consistent with those of the current study. Herein, the trunk muscle mass was significantly related to SVA, and it was shown that the decrease in trunk muscle mass and spinal sagittal imbalance might be related in light of previous reports.

In the present study, trunk muscle mass and the EQ5D score were significantly related, and the decrease in trunk muscle mass could lead to a decrease in the QOL of spinal outpatients. In this study, most of the population had spinal disorders, especially lumbar spine disease, so low back pain and dysfunction of the lumbar spine are expected to have a large impact on QOL. Therefore, it is unknown whether the decrease in trunk muscle mass is related to QOL of the general population, especially in those without spinal disease. However, for patients with spinal disorders, this study showed that maintaining trunk muscle mass may prevent the occurrence of low back pain and spinal sagittal imbalance, and consequently, prevent the deterioration of QOL.

This study has several limitations. Firstly, this research was a cross-sectional study, so the causal relationship could not be proven. Currently, it is unknown whether low back pain and spinal sagittal imbalance occur because of a decrease of the trunk muscle mass or whether trunk muscle mass decreases as a result of low back pain or spinal sagittal imbalance. It is a future task to

conduct a longitudinal study and prove the causal relationship. Secondly, subjects were spinal outpatients, and about one-third had a history of lumbar surgery; thus, they did not represent the general population. However, general residents without spinal disorders usually had low prevalence of lumbar spinal dysfunction or spinal imbalance, which might not be fully evaluated. In the current study, since patients who presented sever low back pain or kyphosis were included, association between trunk muscle mass and lumbar dysfunction and spinal imbalance was elucidated. History of lumbar surgery was included in the analysis as an adjustment factor; hence, its effect was supposed to be reduced. Therefore, our subjects might be reasonable to clarify the importance of trunk muscle mass for lumbar spinal dysfunction and spinal imbalance.

Conclusions

Trunk muscle mass was significantly associated with ODI, the VAS score for low back pain, and SVA, and it was found that trunk muscle mass was a more important factor than ASM in spinal pathology. In addition, since trunk muscle mass was an independent related factor to the EQ5D score, it seems necessary to establish an effective intervention method to maintain trunk muscles, which contributes to extending healthy life span. Trunk muscle mass may assume an important role to elucidate and treat lumbar spinal dysfunction and spinal imbalance that may deteriorate with trunk muscle mass below approximately 23kg.

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Table 1. Baseline characteristics of patients

Characteristic	n (%) or mean (SD)
Age, y	70.2 (11.0)
Sex (male)	781 (44.9)
BMI, kg/m^2	23.3 (3.9)
Appendicular skeletal muscle mass, kg	18.0 (5.1)
Trunk muscle mass, kg	22.2 (4.4)
ODI	22.5 (17.5)
VAS scale of low back pain, mm	32.5 (28.2)
SVA, mm	38.9 (44.7)
EQ5D	0.77 (0.19)
History of surgery	
Cervical surgery	142 (8.2)
Thoracic surgery	28 (1.6)
Lumbar surgery	531 (30.5)
Charlson Comorbidity Index	1.1 (2.8)

BMI: body mass index; ODI: Oswestry Disability Index; VAS: visual analog scale; SVA: sagittal vertical axis; EQ5D: EuroQol 5 Dimension

Figure 1. A, Association between age and trunk muscle mass. Trunk muscle mass declined with age when adjusted for sex and body mass index (BMI) ($p < 0.0001$, p for nonlinear < 0.0001), and the decline was accelerated approximately 70's. Grey zone indicates 95% CIs. **B,** Association between age and appendicular skeletal muscle mass (ASM). ASM declined with age when adjusted for sex and BMI ($p < 0.0001$, p for nonlinear $= 0.4154$), and the decline was consistent. Grey zone indicates 95% CIs.

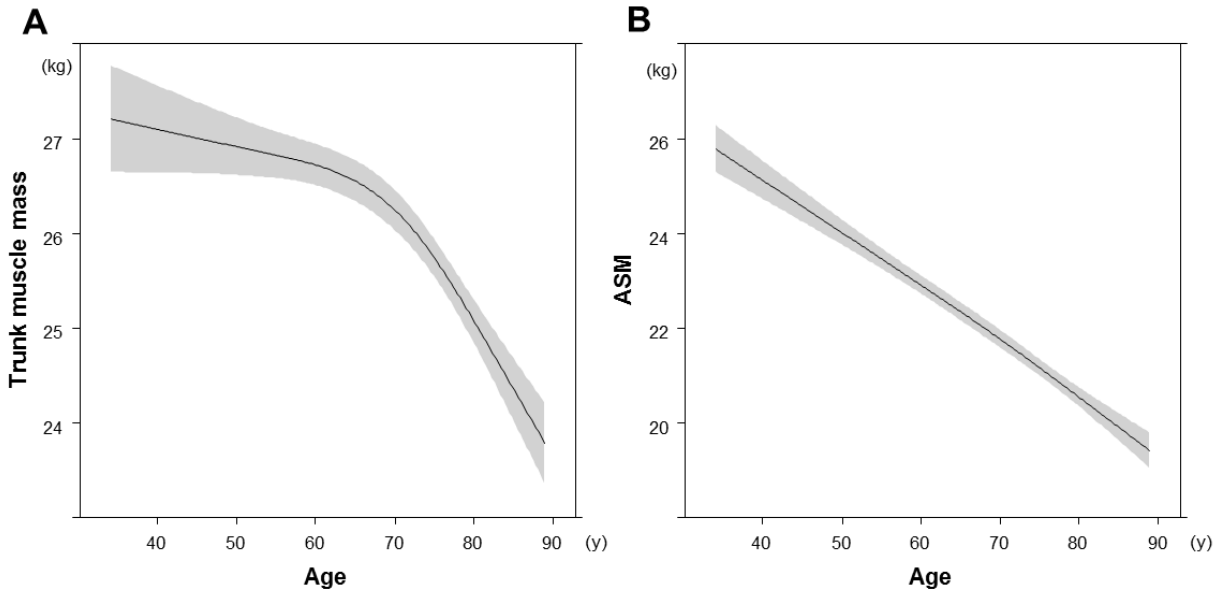

Figure 2. Association between trunk muscle mass and log for the Oswestry Disability Index (ODI) when adjusted for age, sex, body mass index, Charlson Comorbidity Index, appendicular skeletal muscle mass, and history of lumbar surgery. As trunk muscle mass decreased, log ODI increased ($p < 0.0001$, p for nonlinear = 0.0176), and the increase accelerated from approximately 23 kg. Grey zone indicates 95% CIs.

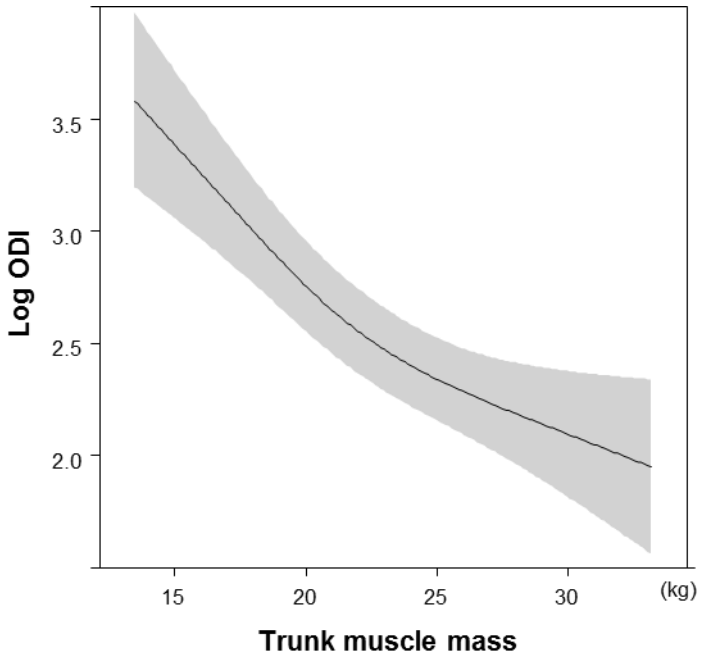

Figure 3. Association between trunk muscle mass and log for visual analog scale (VAS) score for low back pain when adjusted for age, sex, body mass index, Charlson Comorbidity Index, appendicular skeletal muscle mass, and history of lumbar surgery. As trunk muscle mass decreased, log VAS increased (p = 0.0032, p for nonlinear = 0.0376), and it started to increase rapidly from approximately 23 kg. Grey zone indicates 95% CIs.

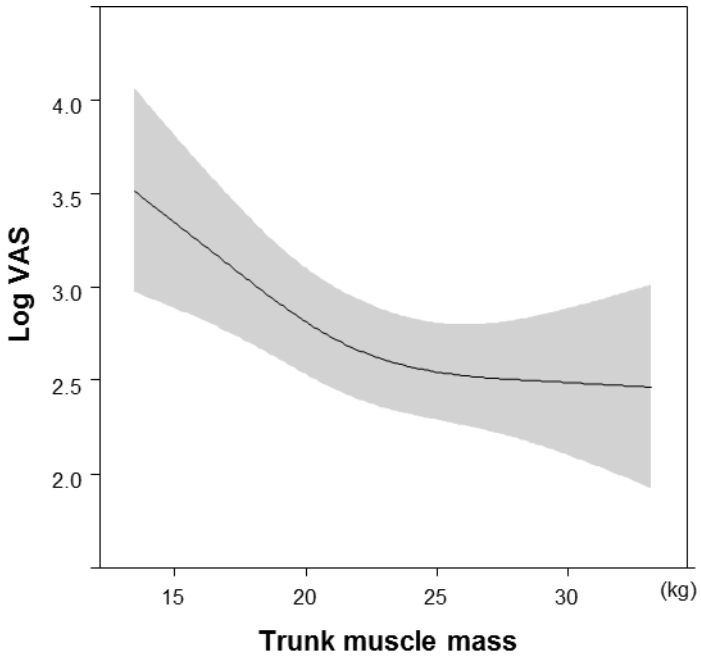

Figure 4. Association between trunk muscle mass and sagittal vertical axis (SVA) when adjusted for age, sex, body mass index, Charlson Comorbidity Index, appendicular skeletal muscle mass, and history of lumbar surgery. Trunk muscle mass was negatively correlated with SVA ($p < 0.0001$, p for nonlinear = 0.0001). SVA almost plateaued with trunk muscle mass over approximately 23 kg and started to increase with a decrease in trunk muscle mass from approximately 23 kg. Grey zone indicates 95% CIs.

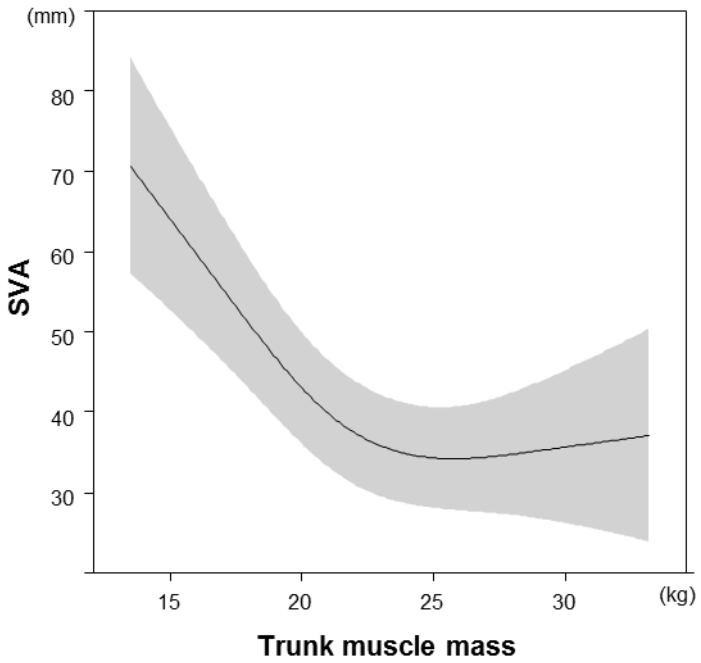

Figure 5. Association between trunk muscle mass and EuroQol 5 Dimension (EQ5D) when adjusted for age, sex, body mass index, Charlson Comorbidity Index, appendicular skeletal muscle mass, and history of lumbar surgery. Trunk muscle mass positively related to EQ5D ($p < 0.0001$, p for nonlinear = 0.0006). Decrease of EQ5D accelerated from below approximately 23 kg. Grey zone indicates 95% CIs.