The Locomonitor Study

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In order to extend the healthy life expectancy and shorten the years lived in poor health in Japan, the early treatment and prevention of motor organ disorders are urgently required. A concept named ‘locomotive syndrome’ is defined as being restricted in one’s ability to walk or lead a normal life owing to a dysfunction in one or more of the parts of the motor organ (locomotive) system. We developed the Locomonitor app using Apple’s ResearchKit and conducted the first cross-sectional nationwide observational study to evaluate the epidemiology of locomotive syndrome. The locomotive function was evaluated using the locomotive syndrome risk tests implemented in the app. The potential benefits of the smartphone–based Locomonitor study are 1) attracting participants from a wide area and different generations within a short period, 2) helping disseminate knowledge of locomotive syndrome, 3) enabling locomotive syndrome risk tests without a measurer, 4) gathering objective and continuous activity data without any burden on the participants, and 5) providing highly personalized feedback to participants. However, uncertainty with regard to accuracy and some possible selection bias are potential limitations. We predict that smartphone–based medical studies will be conducted with increasing frequency in the future.

Key words: locomotive syndrome, Locomonitor, ResearchKit, mobile health, healthy life expectancy

Locomotive syndrome

In Japan, the life expectancy at birth (LE) is 80.79 years for men and 87.05 for women, while the healthy life expectancy at birth (HLE) is 71.19 years for men and 74.21 for women. The gap between the LE and HLE (9.60 years for men and 12.84 for women) indicates that people need some support or care to live out the final few years of their life. Unfortunately, as increase of LE is longer than that of HLE, the number of years lived in poor health has also slightly increased.

The principal reason why Japanese people require support or care is motor organ disorders, such as osteoporotic fragility fractures by falling, joint disorders, or spinal cord injuries. Therefore, the prevention and early treatment of the locomotive organ disorders are required to extend the
HLE and shorten the years lived in poor health, which may also help to improve the quality of life and establish sustainable healthcare systems.

To facilitate a comprehensive understanding of motor organ disorders, the Japanese Orthopaedic Association (JOA) established the term “locomotive syndrome” in 2007. Locomotive syndrome is defined as being restricted in one’s ability to walk or lead a normal life owing to a dysfunction in one or more of the parts of the locomotive system: muscles, bones, joints, cartilage, or the intervertebral discs. Locomotive syndrome integrates individual concepts of several diseases, osteoporosis (OP), osteoarthritis (OA), spinal stenosis, sarcopenia, and neurological disorders; it is essential that these disorders not only damage one’s mobility independently but also have relationships with each other and impair the mobility in combination.

The risk of locomotive syndrome is evaluated by the locomotive syndrome risk test, which consists of a questionnaire and two different types of physical tests: the Locomo 25, which is subjective assessment of mobility, the Stand-up Test, which is an objective estimate of the quadriceps power, and the Two-step Test, which is an objective estimate of the stride length, which correlates to walking speed. The scores of each test are classified into three stages, and it has been confirmed that the worst score indicates the risk of locomotive syndrome.

The staging criteria are as follows:

**Stage 2: Progressing mobility decline**
- If a patient’s scores meet any of the following conditions, they are classified into Stage 2.
  - Locomo 25 score ≥ 16
  - Difficulty standing up from a 20-cm-high seat using both legs in the stand-up test
  - Two-step test score < 1.1

**Stage 1: Starting mobility decline**
- If a patient’s scores meet any of the following conditions, they are classified into Stage 1.
  - Locomo 25 score ≥ 7
  - Difficulty one-leg standing from a 40-cm-high seat in the stand-up test (either leg)
  - Two-step test score < 1.3

**Healthy: no mobility decline**
- If a patient’s scores do not place them in Stage 1 or 2, their mobility is interpreted as healthy.

“Health Japan 21 (second term),” which targets achieving an extension of healthy life expectancy, aims to increase the awareness of locomotive syndrome to at least 80% among the population above 20 years of age by 2022. Disseminating knowledge of the concept of locomotive syndrome is therefore a national concern. However, the awareness was only 46.8% in 2017, and while awareness was relatively high in older generations (68.0% among people ≥ 70 years old), it was 33.1% in people in their 20s.

**Previous studies on the epidemiology of locomotive syndrome**

1. Research on Osteoarthritis/osteoporosis Against Disability (ROAD) Study

The ROAD study conducted by the University of Tokyo is a multi-center prospective observational study that unveiled the epidemiology of OP, knee OA, and lumbar spondylosis. The participants were recruited from three areas in Japan: an urban region in Itabashi, Tokyo; a mountainous region in Hidakagawa, Wakayama; and a coastal region in Taiji, Wakayama. The age of the participants recruited from the urban region was ≥ 60 years old, while that of the participants from the other two regions was ≥ 40 years old.

In the mountainous and coastal regions, the bone mineral density of the lumbar spine and proximal femur was measured using dual energy X-ray absorptiometry. In the participants from these regions, the prevalence of lumbar spine OP was 3.4% in men and 19.2% in women, and that of femoral neck OP was 12.4% and 26.5%, respectively. Therefore, the number of Japanese people ≥ 40 years of age with lumbar spine OP was estimated to be about 6.4 million people (0.8 million men and 5.6 million women), that with femoral neck OP was estimated to be about 10.7 million people (2.6 million men and 8.1 million women), and the total number of Japanese people ≥ 40 years of age with OP (either of both lumbar spine OP or femoral neck OP) was estimated to be about 12.8 million people (3.0 million men and 9.8 million women).

In the mountainous and coastal regions, the knee joints and intervertebral joints of the lumbar spine...
were radiographically examined, and the participants graded with Kellgren–Lawrence grading 2 or higher were diagnosed with radiographic knee OA or lumbar spondylosis. In the participants from these regions ≥40 years of age, the prevalence of knee OA was 42.6% in men and 62.4% in women, while that of lumbar spondylosis was 81.5% in men and 65.5% in women. Therefore, the number of Japanese people ≥40 years of age with radiographically diagnosed knee OA and lumbar spondylosis was estimated to be about 25.3 million people (8.6 million men and 16.7 million women) and about 37.9 million people (18.9 million men and 19.0 million women), respectively.

The number of people ≥40 years of age with at least 1 of these 3 motor organ disorders was thus estimated to be approximately 47.0 million, 21.0 million, and 26.0 million people in total, men, and women, respectively, in Japan.

2. Wakayama Spine Study

The Wakayama Spine Study was performed as part of the ROAD study. The participants were recruited from the mountainous and coastal regions of Wakayama. Recruited participants were ≥21 years of age.

In the mountainous and coastal regions, lumbar spine stenosis was examined by total spinal magnetic resonance imaging (MRI). Among participants from these regions ≥21 years of age, the prevalence of symptomatic lumbar spine stenosis was 9.3%, 10.1%, and 8.9% in total, men, and women, respectively.

The number of people ≥21 years of age with lumbar spine stenosis was therefore estimated to be approximately 6.0 million, 3.0 million, and 2.8 million people in total, men, and women, respectively.

Locomonitor study

1. ResearchKit and Locomonitor app

In 2015, Apple (Cupertino, CA, USA) released ResearchKit, an opensource iOS application (app) framework that enabled researchers and developers to create apps for medical research. As ResearchKit works seamlessly with HealthKit (Apple), researchers can access even more relevant data for their studies.

We thus conceived of the idea of developing “Locomonitor”, an iOS app using ResearchKit, to carry out a nationwide epidemiological study of locomotive syndrome. Locomonitor, which was the first Japanese app using ResearchKit and coded by one of the authors (YY), was released in February 2016 and downloaded by more than 4,000 people in the first week of its release.

2. Contents of the Locomonitor app

All processes of the clinical research for locomotive syndrome, such as the gathering of informed consent, participant enrollment, establishment of study tasks, and receipt of personal feedback, can be completed using Locomonitor app (Figure-1). In addition, the app reads the activity data gathered by HealthKit built into iOS devices.

a) Informed consent

The prospective participants read the interactive informed consent document with intuitive animation explanations when they first launched the app. The consent process comprises education about locomotive syndrome, the purpose of the Locomonitor study, details on data gathering, the privacy policy, the data use policy, and the withdrawal policy. The data gathering section included a request for permission to collect activity data. After completing this process, the participants were asked whether or not they agreed to participate in our study.

b) Participants enrollment

The first step of the study was participant enrollment, which included the distribution of the basic information survey. The survey inquired about the height, body weight, foot size, sex, age (generation), place of residence, and ID code (optional). Regarding the ID code, participants could join the study anonymously, but if a researcher issued a personal ID and a participant shared the number in the ID code form, then the data obtained from the participant is considered to be binding data.

c) Study tasks

Study tasks were divided into necessary tasks and optional tasks.

The necessary tasks were three locomotive
Figure 1
syndrome risk tests, and participants are required to provide personalized feedback. The optional tasks consisted of the Japanese Knee Osteoarthritis Measure, a locomotion check, an exercise habit survey (with data obtained from Questionnaire on specific health factor), and the locomotive syndrome check for the young (developed by Shohiro Hayashi). These results were utilized for research purposes only and were not reflected in the feedback.

d) Feedback
We developed an algorithm for evaluating the locomotive syndrome risk in the Locomonitor app. The algorithm automatically provides both a tailor-made exercising program and daily advice to each participant.

e) Activity data
The Locomonitor app was connected to HealthKit and accessed the following health data: Active Calories; Flights Climbed; Heart Rate; Resting Energy; Stand Hours; Steps; Walking + Running Distance. These data were measured by the coreMotion sensor of the iPhone or Apple Watch.

3. Potential benefits of smartphone-based Locomonitor study
A smartphone app is suitable for an epidemiological study of locomotive syndrome for a number of reasons.

First, a smartphone app attracts a lot of participants from all generations and all over the nation in a short period. In order to draw up strategies for the prevention and early treatment of locomotive syndrome, nationwide and all-generation epidemiology data on locomotive syndrome are indispensable. While the participants in previous epidemiological studies of locomotive syndrome were largely from older generations and from limited regions due to difficulties with recruiting, the Locomonitor study was able to overcome this limitation by being smartphone-based.

Second, a smartphone app attracts a younger generation, helping disseminate knowledge about locomotive syndrome. Given that the average age of iPhone users is about 41 years old, many young people can locate the Locomonitor app on the App Store, and some will download and use it. Modifying the behavior of younger generations is expected to help increase awareness of locomotive syndrome among these populations.

Third, the Locomonitor app will help facilitate larger numbers of people perform the locomotive syndrome risk test. As the locomotive syndrome risk test typically requires a measurer, such as a physiotherapist, previous studies have had to be conducted in limited locations, and the participants in these studies were mainly from older generations. However, using a smartphone app, participants can evaluate their mobility and their risk of locomotive syndrome anytime and anywhere.

Fourth, while researchers in previous studies largely relied on one-time subjective inquiries to obtain participants’ daily activities, the app enables researchers to automatically gather continuous and objective health data, such as daily step counts, calorie use, and heart rate, using the sensors of smartphones. Participants do not have to travel to hospitals to report their activities to researchers and physicians, simply needing to place their smartphones in their pocket. This also helps both participants and researchers save time.

Finally, an app can provide personalized feedback to participants, containing advice on how to improve their exercise and diet habits, as well as educational materials about how locomotive syndrome develops and what diseases are related to locomotive syndrome.

4. Potential limitations associated with the smartphone-based Locomonitor study
In the Locomonitor study, participants had to carry out the locomotive syndrome risk tests by themselves and fill in the results form on the app. As such, the scores evaluated by nonprofessional participants may not accurately reflect their mobility compared to those evaluated by the professional measurers in previous face-to-face studies. However, the Locomonitor app is expected to be effective as a simple screening tool and have the potential to stimulate interest in locomotive syndrome for not only older but also younger generations. In fact, some of the participants in the Locomonitor study have used the app repeatedly and monitored the chronological changes in their mobility. The risk of selection bias should also be noted. The participants in the Locomonitor project downloaded the app from App Store and completed...
quite complicated examinations; they are therefore likely to be health-conscious people, although conventional epidemiological studies have also similar selection biases.

**Spread of smartphone-based studies**

Following the release of the Locomonitor app with the above-mentioned benefits associated with a smartphone-based epidemiological study, Juntendo University has launched six more projects using ResearchKit targeting Parkinson disease, asthma, dry eye, influenza, pollinosis, and chronic pain (as of July 31, 2018). A total of 25 ResearchKit apps have been developed worldwide, and Juntendo University is currently the largest developer in this field.

**Conclusion**

We developed the Locomonitor app and launched an epidemiological research project on locomotive syndrome. This new study methodology represents a breakthrough in the field of epidemiological research, albeit not without some potential limitations. It is important to understand both the strong and weak points of conventional registration-based epidemiological studies as well as smartphone-based studies. With an appropriate understanding of these points, smartphone-based studies are expected to become more common and contribute to the development of this field in the future.

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