Application of an Effective Methodology for Analysis of Fragility and Its Components in the Elderly

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Abstract

Fragility is a syndrome characterized by reduced physical and cognitive reserves making the elderly more vulnerable to adverse events, hospitalizations, falls, loss of independence, and death. Inertia sensors have been applied to quantify motion assessment in Timed Up and Go (TUG) test, accelerometers are used during balance assessment, and algorithms differentiate fragile, pre-fragile, and robust elderly people.

Objective: Developing a multifunctional sensor to evaluate fragility, based on marker phenotype and deficit accumulation index.

Methods: Primary, exploratory, interventional, analytical, and transversal study with a technological approach. The study will be developed, in partnership with researchers from the Federal University of Itajubá-MG using high-tech, multifunctional, and cost-effective sensor equipment in combination with a 3-axis gyroscope, a 3-axis accelerometer, electromyography and frequency meter, analysis of movement quality, energy expenditure, gait velocity, change in balance, heart rate variability during movement, and quality of quadriceps muscle contraction.

The data will be analyzed by software developed after the prototyping of the equipment. The fragility analysis procedure will not cause any damage or impairment to the health of the elderly participants, since the items used during the procedure will be the sensor, the measurement of the instruments, the Barthel Index, the Mental State Examination, and the Self-rated fragility assessment.

The validation of the sensor will not cause damage or impairment to the health of the participants.

Locations: Samuel Libânio Clinical Hospital, in the clinics of Health Clinic, Dementia, and Assistance Nucleus Nursing Education, and in the Basic Health Units of the municipality of Pouso Alegre-MG.

Casuistry: Convenience sample.

Eligibility criteria: 300 elderly people, 60 years of age or older, both sexes, signing the Free and Informed Consent Form (TCLE), and approval by the Research Ethics Committee of University of Vale do Sapucaí (UNIVÁS).

Criteria for non-inclusion: Elderly people with immobility or severe cognitive impairment that impedes understanding of the orientation towards the TUG.

Exclusion criteria: The waiving of continuing the study after the signing of the TCLE.

Keywords

Healthcare information technology · Frail elderly · Medical device · Wearable · Accelerometry

95.1 Introduction

Fragility is a syndrome characterized by reduced physical and cognitive reserves and makes the elderly more vulnerable to adverse events, such as hospitalizations, falls, loss of independence, and death [1, 2].

Although there is no consensus in the literature on the criteria for identifying fragility, the model created by Fried et al., is among the most widely used today. For the author, the presence of three or more criteria classifies the elderly as fragile and the presence of one or two classifies them as pre-fragile, understood here as those that present a high risk to develop the fragility syndrome [3].

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S. Latifi (ed.), *Information Technology – New Generations*, Advances in Intelligent Systems and Computing 738,
https://doi.org/10.1007/978-3-319-77028-4_95

The criteria established by Fried (2001) are:

1. Unintentional weight loss of 4.5 kg or 5% of body weight in the last year.
2. Self-rated fatigue, assessed through questions and the depression scale of the Center for Epidemiological Studies.
3. Reduction of palmar grip strength, measured by manual dynamometer, in the dominant upper limb.
4. Reduced level of physical activity measured by the weekly energy expenditure in kcal and decrease in walking speed.

The Fried (2001) model is based on sarcopenia and immunological and neuroendocrine changes and focuses on the physical dimension of fragility.

Good correlation between the Fried's fragility score and gait speed was evidenced, which makes this functional test adequate to monitor and assist in the diagnosis of fragility syndrome in the elderly [2].

The prompt and accurate identification of a person's state of fragility may allow effective multifactorial interventions that have been shown to improve health outcomes [4].

The TUG test [5, 6] is a standard evaluation of mobility since the time to do it has been a strong predictor of fragility [7] and is commonly used to assess the risk of falls in the elderly [8].

Recent research has investigated the use of inertial sensors to quantify motion assessment in the TUG test and the use of accelerometers during assessment of balance in tasks to examine the utility of derived parameters using an algorithm to discriminate between fragile, non-fragile, and robust. In addition, the accelerometer is a low cost instrument and the test is not restricted to the laboratory environment [8]; "The accelerometry patterns are used to identify normal and pathological gait, with acceleration peaks"; is considered a method of kinematic analysis of human movement [9].

A study published in 2014 investigated the use of inertial sensors in the automatic and quantitative assessment of the fragility state suggested that a protocol using the TUG and said devices can be a fast and effective means for the automatic and non-specialized evaluation of fragility [8].

At present, advances in sensor technology have provided a new method for measuring physical function [10–12] and physical activity in populations. These devices have the benefits of objectivity, portability, and low cost [11], thus making them useful for assessing fragility at home and in the community [13].

95.2 Objective

To develop a multifunctional sensor to evaluate the fragility, based on phenotypic marker and deficit accumulation index, and to validate the use of this sensor in the elderly population to identify it fragile, non-fragile and robust.

95.3 Methodology

95.3.1 Kind of Study

It is a primary, exploratory, interventional, analytical and transversal study with a technological approach.

95.3.2 Casuistry

The sample will be for convenience. Older people aged 60 or older from the community, living in the municipality of Pouso Alegre-MG, those assisted in the outpatient clinics of Clinical Medicine, Dementia, Nursing Assistance and Teaching Nucleus (NAEENF), Basic Health Units (UBS) and Long-term Institutions for elderly within a period of six months, that meet the eligibility criteria.

95.3.2.1 Eligibility Criteria

1. Participants will be patients from the community and attended at HCSL outpatient clinics. The age of the participants will be 60 years and older, both sexes, agreed to participate in the study, and have signed the Free and Informed Consent Form (TCLE).
2. An average of 300 participants.
3. The study is approved by the Research Ethics Committee of UNIVÁS.

95.3.2.2 Criteria for Non-Inclusion

People who have any of the following:

1. Immobility syndrome.
2. Severe cognitive impairment that impedes understanding of the orientation towards the TUG.

95.3.3 Exclusion Criteria

Refusal to continue the study after signing the TCLE.

95.3.4 Development of Multifunctional Analysis Sensor

The Nucleus of Technological Innovation (NIT) of UNIVÁS has as some of its main purposes:

1. To create, manage, and ensure the maintenance of the policy to encourage technological innovation.
2. To enable strategies and actions related to intellectual property rights in both the internal and external environment of the University.

A cost-effective, high-tech, multifunctional, sensor type device was created, in partnership with the Federal University of Itajubá-UNIFEI, can be used in conjunction with a 3-axis gyroscope, a 3-axis accelerometer, electromyography, thermo sensor and frequency meter, analysis of the quality of movement, energy expenditure, gait speed, change in balance, heart rate variability during movement, and quality of quadriceps muscle contraction (Fig. 95.1). The data will be analyzed by specific software which is to be developed after the creation of the equipment prototype.

Accelerometers are sophisticated electronic devices that measure the acceleration produced by body movement [14]. Acceleration is defined as the change in velocity over time, being directly proportional to the external force network involved.

Basically, accelerometers use one or multiple motion sensors to detect accelerations in different body segments [15]. The sensor used by many instruments consists of a piezoelectric element and a seismic mass inside a case. The triaxial accelerometers, in turn, are able to measure the acceleration in each of the three orthogonal planes, providing information for each plane separately as well as in a combined way from all planes [16].

Figure 95.1 show the circuit diagram of the multifunctional analysis sensor that is composed of:

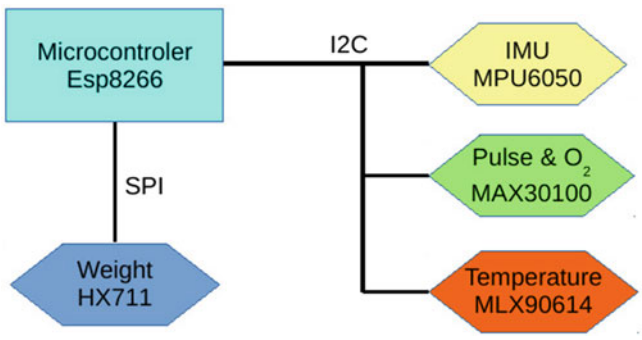

Fig. 95.1 Diagram of the electronic circuit

1. An ESP8266, a firmware and open source development kit that assists in the development of equipment that requires Wi-Fi communication and a micro-controller.
2. An MPU6050 sensor, the IMU Inertial Measurement Unit, features a 3-axis accelerometer and a 3-axis gyroscope that can measure movement.
3. An MAX30100 is an integrated pulse oximetry and heart rate monitor sensor solution for measuring pulse and O_2. It combines two LEDs, an optimized optical photodetector, and low-noise analog signal processing to detect pulse oximetry and heart rate signals;
4. An MLX90614 is an infrared sensor capable of measuring the temperature from −70 ° C to 382.2 ° C, with resolution of 17 bits, i.e., it is able to measure the temperature variation without coming into contact with the object with a resolution of 0.0034 ° C;
5. An HX711, a 24-bit converter and amplifier module, used to amplify the signal of devices as load cells, making the interconnection between these cells and the microcontroller.
6. The I2C communication protocol, a protocol used between devices that "talk" I2C (Inter-Integrated Circuit). So far we have seen some communication protocols that Arduino supports, such as SPI, One-Wire, and even the serial interface is a well-defined communication protocol.
7. The SPI (Serial Peripheral Interface), a synchronous serial communication interface specification used for serial data communication performed with peripheral devices for quick real time communication.

95.3.4.1 Timed Up and Go (TUG) Test

The TUG test's objective is to evaluate mobility and functional balance. The test quantifies in seconds the functional mobility by analyzing the time that the individual performs the task of getting up from a chair (support of approximately 46 cm in height and arms of 65 cm in height), walking 3 m, turning around, returning to the chair, and sitting again [5, 6].

In the TUG, the initial position of the elderly person is sitting in the chair with the back resting on the chair. The timing is measured after the starting and ending only when the elderly person has returned to the initial position, sitting with his back on the seat.

Bischoff et al. [17] consider that performing the test within 10 s as the time considered normal for healthy, independent adults with no risk of falls; values between 11 and 20 s is expected for the elderly with deficiency or fragility, partial independence, and with low risk of falls; over 20 s implies the test subject has a significant deficit of physical mobility and risk of falls. The same authors determine a performance of up to 12 s as the normal time for the test for community-dwelling elders [17].

The test participants in this study will be divided into three groups, according to the TUG score

1. Up to 10 s
2. Between 11 and 20 s
3. Over 20 s.

95.3.5 Ethical Considerations

The study was approved by the Research Ethics Committee of UNIVÁS (MG), protocol 2.016.179.

As the test is the application of questionnaires and the multi-functional sensor, there are no risks to the physical or psychological integrity of the subjects involved, as no invasive procedures will be performed or that explicitly expose the participants. Thus, there is minimal research risk, which can occur due to constraint arising from some question or sensor placement, which occurs during the test. Whenever the evaluator feels uncomfortable, for whatever reason, he may interrupt the interview at any time he deems appropriate.

95.3.6 Location of the Study

The study will be carried out at the Samuel Libânio Clinic Hospital (HCSL); at the clinics of Health Clinic, Dementia and Nursing Education and Assistance Center (NAEENF); in the city's Basic Health Units; and through calls on weekends for the "Fragility Day", to be held at the Fátima Campus of the UNIVÁS, where several professionals will be involved with evaluation of the elderly, coordinator of the project, graduate student and undergraduate students of the health area.

95.3.7 Instruments

Demographic questionnaire, the Barthel Index [18], the Mental State Examination [19], and the Self-rated fragility assessment [20].

95.3.8 Data Collection Procedures

95.3.8.1 Casuistry Selection

Once the terms of TCLE are signed by the patient and/or responsible party, the instruments will be applied according to protocol to be established after the prototype of the sensor is completed. The application of the instruments will be carried out by the researcher in conjunction with other health professionals and undergraduate students of the health area of UNIVAS.

95.3.8.2 Evaluation of the Elderly with the Application of the Instruments

To fulfill the purposes of the research, the following procedures will be performed:

1. Signing the TCLE by the patient or caregiver.
2. Application of the sociodemographic questionnaire to all test subjects able to communicate verbal or written, as well as their caregivers or legal guardians.
3. Application of the "self-rated assessment of fragility in the elderly", to be answered by the test subjects and possibly confirmed by the responsible caregivers.
4. Application of the MMSE: the test subjects will be classified as having/not having cognitive deficit. For purposes of classification, the cuts of 18 points for illiterates and those with only low schooling and 26 points for eight years or more of schooling will be used.
5. Application of the Barthel Index, for evaluation of mobility and personal care. The elderly will be classified into dependents, partially dependent or independent, according to the score obtained.
6. The calf circumference will be obtained in the sitting or standing positions, with the feet resting on a flat surface, to ensure that the weight is evenly distributed between both sides [21].
7. The parameters of gait velocity, energy expenditure, balance change, heart rate variability, and quality of quadriceps muscle contraction will be obtained by means of a multifunctional sensor coupled to the digital femoral quadriceps, with the patient in motion, running the Timed up and Go (TUG) test in a hallway extensive enough to conduct the measurement. The test subjects will be instructed to walk as fast as possible without running.

In order to avoid the effects of acceleration and deceleration, one meter will be added before and after the three meters of the test.

All test subjects will perform the test three times, being considered for recording the attempt with less time spent for the course. The use of walking sticks, walkers, crutches or even handrail support will be allowed for test subjects unable to walk without them [5, 6].

95.4 Conclusions

The present project is feasible, since the elderly will be recruited from the community at different levels of attention, provided they do not have immobility. Since the test is the application of questionnaires and a multi-functional sensor, there are no risks to the physical or psychological integrity of the subjects involved, as no invasive procedures will be performed or that explicitly expose the participants. Thus, the

minimum research risk is considered, which can occur due to constraint arising from some question or sensor placement. However, whenever the evaluator feels uncomfortable, for whatever reason, he may interrupt the interview at any time he deems appropriate.

The results of the study have been analyzed through the use of descriptive and inferential statistics (hypothesis tests). Frequency tables and measures such as mean, median, standard deviation, minimum value and maximum value will be used. The choice of non-parametric or parametric tests will occur according to the type of study variables. The level of significance used as acceptance or rejection criterion in the statistical tests will be 5% ($p < 0.05$). The analysis will be performed in the SPSS program, version 18.0.

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