

Określenie minimalnej wykrywalnej różnicy oraz rzetelności test- retest dla testów Wstań i Idź, Pięciokrotnego Wstania z Krzesła, Chodu 10-metrowego oraz Maksymalnego Świadomego Skurczu Izometrycznego prostowników i zginaczy kolana wśród pacjentów z chorobą zwyrodnieniową kolan leczonych zachowawczo

STRESZCZENIE

Wstęp. Testy Wstań i Idź (ang. TUG), Pięciokrotnego Wstania z Krzesła (ang. STS) oraz Chodu 10-metrowego (ang. 10WT) są często używane w badaniach klinicznych.

Cel. Celem badania jest określenie rzetelności test- retest dla TUG, STS, 10WT oraz Maksymalnego Świadomego Skurczu Izometrycznego (ang. MVIC) prostowników i zginaczy kolana, a także obliczenie Minimalnej Wykrywalnej Różnicy (ang. MDC) dla ww. testów wśród pacjentów z chorobą zwyrodnieniową (ChZ) kolan leczonych zachowawczo.


Materiał i Metody. 61 pacjentów z objawową ChZ kolan zostało włączonych do badania. Protokół badawczy obejmował TUG, STS, 10WT oraz MVIC prostowników i zginaczy kolana. Każdy uczestnik badany był dwukrotnie.

Wyniki. Testy funkcjonalne: TUG, STS, 10WT oraz MVIC i MVIC_{standaryzowane} prostowników i zginaczy kolana wykazały doskonałą zgodność test- retest. Standardowy Błąd Pomiarowy oraz MDC dla ww. testów wyniosły odpowiednio: TUG- 0.37s oraz 1.01s; STS- 0.69s oraz 1.91s; 10WT- 0.23s oraz 0.65s; MVIC prostowników- 19.66N oraz 54.5N; MVIC zginaczy- 9.73N oraz 26.96N; MVIC_{standaryzowane} prostowników- 0.22 oraz 0.62; MVIC_{standaryzowane} zginaczy- 0.11 oraz 0.31.

Wnioski. TUG, STS, 10WT oraz pomiary MVIC wykazały doskonałą zgodność test- retest wśród pacjentów z łagodnym lub umiarkowanym stadium ChZ kolan. Zmiany większe niż 1.01s w TUG, 1.91s w STS, 0.65s w 10WT, 0.62 w MVIC_{standaryzowane} prostowników oraz 0.31 w MVIC_{standaryzowane} zginaczy mogą być uważane za istotne klinicznie.

Słowa kluczowe: testy funkcjonalne; minimalna wykrywalna różnica; test- retest; choroba zwyrodnieniowa kolan; ból kolan

Determining Minimal Detectable Change And Test- Retest Reliability Of Timed Up And Go Test, 5 Times Sit To Stand Test, 10 Meters Walk Test And Maximal Voluntary Isometric Contraction Of Knee Extensors And Flexors In Patients With Knee Osteoarthritis Treated Conservatively

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SUMMARY

Introduction. Timed Up and Go test (TUG), 5 Times Sit to Stand test (STS) and 10 meters Walk test (WT) are often used in clinical trials.

Aim. The purpose of this study is to determine test- retest reliability of TUG, STS, 10WT and Maximal Voluntary Isometric Contraction (MVIC) of knee extensors and flexors and to determine Minimal Detectable Change (MDC) for those tests in a population of patients with knee osteoarthritis (OA) who will undergo a conservative treatment. **Material and Methods.** 61 patients with symptomatic knee OA were included in this study. Testing protocol consisted of TUG, STS, 10WT and Maximal Voluntary Isometric Contraction (MVIC) of knee extensors and flexors. Participants were tested twice.

Results. TUG, STS, 10WT and MVIC and MVICstandardised of knee extensors and flexors showed an excellent test-retest reliability. Standard Error of Measurement and MDC95 for TUG was 0.37s and 1.01s, respectively; for STS was 0.69s and 1.91s, respectively; for 10WT was 0.23s and 0.65s, respectively; for MVIC of extensors was 19.66N and 54.5N, respectively; for MVIC of flexors was 9.73N and 26.96N, respectively; for MVICstandardised of extensors was 0.22 and 0.62, respectively; for MVICstandardised of flexors was 0.11 and 0.31, respectively.

Conclusions. TUG, STS, 10WT and MVIC measurements have an excellent test- retest reliability in patients with mild to moderate knee OA. Changes greater than 1.01s for TUG, 1.91s for STS, 0.65s for 10WT, 0.62 for MVICstandardised of knee extensors and 0.31 for MVICstandardised of knee flexors may be used as clinically significant.

Keywords: functional test, minimal detectable change, test-retest, knee arthritis, knee pain

Date received: 4th August 2021

Date accepted: 24th September 2021

Authors reported no source of funding.

Authors declared no conflict of interest.

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Introduction

Pain, joint swelling and restricted range of motion are characteristic for knee osteoarthritis (OA) (Bąkowski et al., 2020; Kaszyński et al., 2020). Those symptoms are induced by degeneration of joint structures especially cartilage and chronic inflammation process (Chahla and Mandelbaum, 2018; Hermann et al., 2018). Walking and getting up from the chair are the most basic activities of daily living (ADL) which performance is often impeded by the affected joints' condition. Those activities are crucial in the matter of independent existence (Unver et al., 2005). That is why it is extremely important to assess them in patients struggling with knee OA.

Functional tests, or rather performance-based tests, comprise a necessary tool in a general assessment of a patient with knee problems, especially OA (Yeung et al., 2008; Gkrilias et al., 2018). They objectively show what patients are or are not able to do, rather than what they think that they can do from their own perspective. Therefore, the

functional tests are the perfect complement to the patient-reported outcome measures (PROMs) (Dobson et al., 2013). Performance-based tests are not specific to any joint or their function. They are specific to ADLs, such as walking, standing up from a chair or climbing the stairs. In general, it is a tool which reliably quantifies changes over time in the whole body function in patients with a variety of orthopedic or neurologic conditions and elderly people (Podsiadlo and Richardson, 1991; Steffen et al., 2002; Kennedy et al., 2005; van Hedel et al., 2005; Ries et al., 2009; Hiengkaew et al., 2012; Fearon et al., 2017).

Timed Up and Go test (TUG), 5 Times Sit to Stand test (STS) and 10 meters Walk test (WT) are often used in clinical trials (van Hedel et al., 2005; Yeung et al., 2008; Goldberg et al., 2012; Fearon et al., 2017;). Those valid performance-based tests are simple, not time-consuming and not requiring any specialized equipment but a stopwatch. Our functional examination protocol is completed with Maximal Voluntary Isometric Contraction (MVIC) of knee extensors and flexors measurement. It is a safe and relatively easy way to assess strength of key muscle groups around the knee joint (Zabik and Dawson, 1996; de Ruiter et al., 2003; Salomoni et al., 2016).

It is important to investigate the reliability of a chosen battery of tests in a targeted group of patients. Reliability must be specific for the studied group (Haley and Fragala-Pinkham, 2006). So far, our set of tests has not been investigated in patients with knee OA treated conservatively.

Clinicians need an objective, precise and reliable tool for assessing the effectiveness of the applied treatment. In statistics, reliability is determined by the standard error of measurement (SEM), which evaluates the variability of a measure. Minimal detectable change (MDC) is associated with SEM. Moreover, MDC gives researchers a possibility to determine whether the observed change is clinically relevant. That is why the MDC of functional tests should be determined for a specific population (Haley and Fragala-Pinkham, 2006).

Aim

The purpose of this study is (1) to determine test- retest reliability of data for TUG, STS, 10WT and MVIC of knee extensors and flexors and (2) to determine MDC for those tests in a population of patients with knee OA who will undergo a conservative treatment.

Material and Methods

Sixty-one patients with symptomatic knee OA were included in this study. Each participant was examined just before the desired method of conservative treatment. It was exactly the same group of patients as in our current study comparing the effectiveness of knee OA treatment with autologous adipose tissue (AAT) and platelet rich plasma (PRP) (Bąkowski et al., 2020). Inclusion criteria consisted of: symptomatic knee OA with Kellgren- Lawrence grade I- III, age 45-60 y.o., pain level in Visual Analog Scale (VAS) minimum 4 in one knee and <2 in the contralateral knee, no or minimal positive effect of previous conservative treatment (physiotherapy, steroid injections, hyaluronic acid). Exclusion criteria were explained in details in the study protocol (Bąkowski et al., 2020).

Testing protocol consisted of Timed Up and Go test (TUG), 5 Times Sit to Stand test (STS), 10 meters Walk test (10WT) and Maximal Voluntary Isometric Contraction (MVIC) of knee extensors and MVIC of knee flexors. Participants were tested twice with this protocol by the same examiner (JK). Subjects were allowed to rest up to 2 minutes

between each test. After completion of the first trial, the patient rested in a comfortable position for about 30 minutes and then proceeded with a second trial.

TUG (Figure 1) is a first test in our protocol. The participant is asked to stand up from a chair (45 cm height) and walk forward at a comfortable pace, turn around beyond the line placed on the floor 3m from the chair and go sit back down in the chair. The patient is allowed to use hand support while standing up and sitting down or use crutches if needed. The results of TUG is time measured with a stopwatch (Bąkowski et al., 2020).



Figure 1. Timed Up and Go test.

STS (Figure 2) is performed on a standard chair (45 cm height). The patient sits with arms crossed on the chest without back support. Then, the participant is asked to stand up and completely extend knees and hips and sit down 5 times. The trial starts on the examiner's command and the examiner counts repetitions. Using hand support, bouncing up from the chair and lifting feet is forbidden (Bąkowski et al., 2020). The result of STS is time measured with a stopwatch.



Figure 2. 5 Times Sit to Stand test.

To perform 10WT, the patient stands in an upright position and on rater's command starts to walk straight on as fast as possible to the finish line, which is marked on the floor 10 meters from the starting line. The participant is allowed to use crutches. Running is forbidden (Bąkowski et al., 2020). The results of 10WT is time measured with a stopwatch.

MVIC (Figure 3) is performed with a dynamometer Forcemeter FB 500 (AXIS, Gdansk, Poland). The participant sits on a bench with legs placed freely beyond the table, hands laid on thighs. A non-elastic belt is put around the waist to stabilize the patient on the table. The measuring belt (160cm for knee extensors, 60 cm for knee flexors) is anchored just above the ankle joint with knee flexed to 90 degrees. The belt must be placed parallel to the floor, so the height of the bench should be adjusted firstly. The measurement starts with a belt pretension and then the subject is asked to straighten/bend the knee maximally and hold it for 6s. The result is presented in Newtons [N] (MVIC) and for further statistical analysis it will be divided by the patient's weight (MVIC_{standardised}) (Bąkowski et al., 2020).

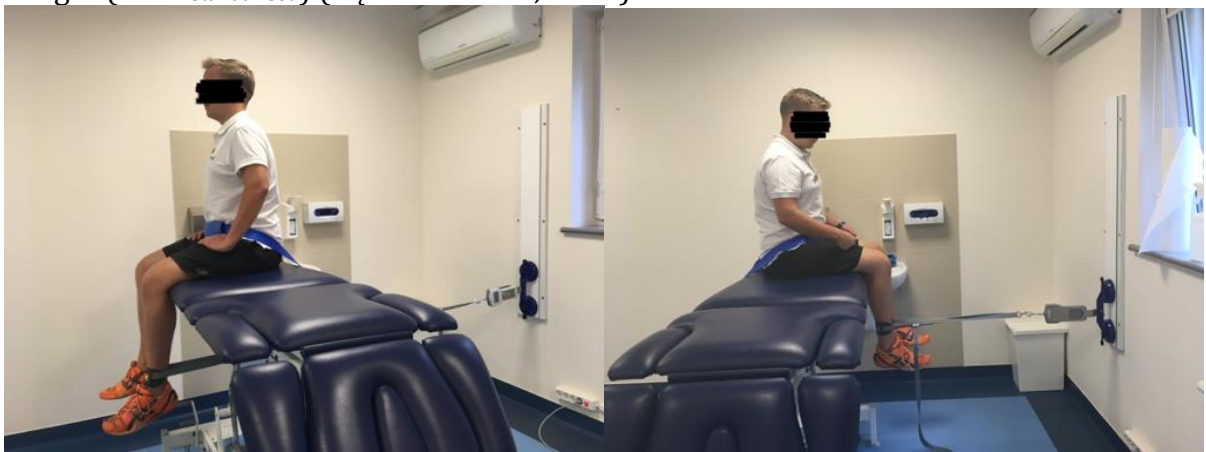


Figure 3. Maximal Voluntary Isometric Contraction of knee extensors (left picture) and flexors (right picture).

Statistical analysis was conducted in Statistica 12.0. The Shapiro-Wilk test was used for determination of the data distribution. T- test or Willcoxon test was used for comparing the difference between the two trials of each test. The intra-class correlation coefficient (ICC (2.1)) was used for calculation of test- retest reliability for the TUG, STS, 10WT, MVIC extensors and MVIC flexors. SEM was calculated to assess the accuracy of measurement methods. MDCs were calculated at the 95% confidence level (MDC₉₅) with

the following formula: $MDC_{95} = SEM \times 1.95 \times \sqrt{2}$ (Koo and Li, 2016; Luque-Siles et al., 2016; Yuksel et al., 2017).

Results

The characteristics of the tested group is presented in Table 1. 1 patient did not perform STS because of the pain and discomfort during the first attempt. There were no other adverse events reported.

Table 1. Characteristics of the patients.

Variables	Mean± Standard Deviation or Frequency (%), n= 61
Age (years)	56.3 ± 8.2
Sex:	
female n (%)	38 (62%)
male n (%)	23 (38%)
Height (cm)	1.70 ± 0.10
Weight (kg)	79.93 ± 17.71
Body mass index (kg/m ²)	27.22 ± 4.38
Knee OA stage (Kellgren- Lawrence) n	
	I 0
	II 34
	III 18
	IV 9

Test- retest reliability results including SEM and MDC_{95} are presented in Table 2. There was no significant difference between the first and the second trial in STS and 10WT ($p > 0.05$). However, a significant difference was observed between the first and the second trial in TUG and each MVIC test ($p < 0.001$). Functional tests: TUG, STS and 10WT showed an excellent test-retest reliability. ICC (2.1) were 0.951, 0.955 and 0.974, respectively. MVIC and MVIC_{standardised} of knee extensors and flexors showed an excellent test- retest reliability. ICC (2.1) were 0.968 and 0.969 for MVIC of extensors and flexors,

respectively. For MVIC_{standardised} of extensors and flexors ICC (2.1) were 0.968 and 0.969, respectively.

SEM and MDC₉₅ for TUG was 0.37s and 1.01s, respectively; for STS was 0.69s and 1.91s, respectively; for 10WT was 0.23s and 0.65s, respectively; for MVIC of extensors was 19.66N and 54.5N, respectively; for MVIC of flexors was 9.73N and 26.96N, respectively; for MVIC_{standardised} of extensors was 0.22 and 0.62, respectively; for MVIC_{standardised} of flexors was 0.11 and 0.31, respectively.

Table 2. Minimal detectable changes and reliability of the performance-based tests and MVIC of knee extensors and flexors in patients with knee OA.

	First trial (Mean ±SD)	Second trial (Mean ±SD)	ICC(2.1) (95% CI)	SEM (%)	MDC ₉₅ (%)
TUG	6.54 ± 1.69	6.31 ± 1.64 ^{*b}	0.951 (0.911 – 0.971)	0.37 (5.7%)	1.01 (15.8%)
STS	10.45 ± 3.26	10.26 ± 3.29	0.955 (0.932 – 0.970)	0.69 (6.6%)	1.91 (18.4%)
10WT	5.79 ± 1.38	5.76 ± 1.51	0.974 (0.960 – 0.983)	0.23 (4.0%)	0.65 (11.2%)
MVIC extensors	300.80 ± 111.01	284.07 ± 109.79 ^{*a}	0.968 (0.905 – 0.985)	19.66 (6.7%)	54.5 (18.6%)
MVIC _{standardised} extensors	3.43 ± 1.27	3.24 ± 1.25 ^{*a}	0.968 (0.906 – 0.985)	0.22 (6.7%)	0.62 (18.6%)
MVIC flexors	145.34 ± 56.95	139.28 ± 54.90 ^{*b}	0.969 (0.943 – 0.982)	9.73 (6.8%)	26.96 (18.9%)
MVIC _{standardised} flexors	1.66 ± 0.65	1.59 ± 0.63 ^{*b}	0.969 (0.943 – 0.982)	0.11 (6.9%)	0.31 (19.0%)

*- $p < 0.001$; a- T test; b- Willcoxon test

MVIC- maximal voluntary isometric contraction; TUG- timed Up and Go test; STS- Five times sit to stand test; 10WT- 10 meters Walk Test; ICC- intraclass correlation coefficient; CI- confidence interval; SEM- standard error of measurement; MDC₉₅- minimal detectable change at the 95% confidence level; SD- standard deviation.

Discussion

Assessing the reliability of an outcome measure and determining the minimal detectable change is prerequisite to creating a meaningful database. An outcome measure must be responsive and must give a clear information about changes of a given patient's condition. Moreover, it is crucial that the measurement tools must be population-specific. This study shows an excellent test- retest reliability of TUG, STS, 10WT and MVIC as well as MDC₉₅ not greater than 20% in each tool in patients with mild to moderate knee OA.

TUG is a very simple test which does not require any additional equipment or special facilities but a standard chair and a 3 meter distance. It consists of getting up from the chair, walking, turning around and sitting down (Yuksel et al., 2017). Those basic functional abilities as well as the balance are crucial for a patient's independence in the performance of daily living activities. With this test one can assess the participant's functional strength, ability to maintain balance and gait speed as well (Schilke et al.,

1996; Mizner et al., 2011). In the literature there are many studies which reported validity and reliability of TUG (Podsiadlo and Richardson, 1991; Siggeirsdóttir et al., 2002; Kennedy et al., 2005; Haley and Fragala-Pinkham, 2006; Yeung et al., 2008). Kennedy et al. found an excellent test- retest reliability (ICC of 0.75) in patients with knee or hip OA, who were scheduled for a primary total knee or hip arthroplasty (Kennedy et al., 2005). Furthermore, an excellent test- retest reliability was observed in elderly people (Podsiadlo and Richardson, 1991). In the present study TUG showed an excellent test- retest reliability as well, with ICC 0.951 and MDC₉₅ of 1.01s.

From our observations, in the proposed battery of tests, STS was undoubtedly the most difficult one for all participants. The results support this observation, because STS was the only test a patient refused to attempt because of pain inside the knee. It was proven that a subject needs an average of 97% of lower extremities muscle strength to stand up from a chair (Schilke et al., 1996). STS eliminates hand support and this limitation makes it so difficult to perform for patients with quadriceps femoris strength deficits (Lord et al., 2002). In our opinion, a very important aspect of this test is that the examiner should be very precise while explaining this test to avoid compensations. The patient's feet should not lose contact with the ground and he/she should not make a swing with the trunk. Sit to stand tests can be both repetition-based (5 Times Sit to Stand Test) and time-based (30s chair stand test) (Dobson et al., 2013). Both forms are valid and reliable. Osteoarthritis Research Society International (OARSI) emphasizes that the chair used for the test should not have armrests and should be approximately 43 cm high (Dobson et al., 2013). The height of an individual participant may have an influence on the results and possible difficulties while performing this test, so OARSI recommends that the chair height must be consistent across time and may slightly vary from standard height of 43 cm (Dobson et al., 2013). STS is a valid and a reliable tool in assessing elderly people as well as in assessing elderly females separately with ICC 0.89 and 0.95, respectively (Lord et al., 2002; Goldberg et al., 2012). This study showed an excellent test- retest reliability with ICC 0.955 and MDC₉₅ 1.91s.

It is necessary to assess walking ability in patients with knee OA. Furthermore, clinical walk tests provide very important information about this basic activity, which is the key for an independent and active lifestyle (Steffen et al., 2002). Walk tests can be both distance-based (10WT, 20-m shuttle test, 1-mile walk test) or time-based (12-minute walk test (12MWT), 6-minute walk test (6MWT), 2-minute walk test (2MWT)) (Pin, 2014; Chan and Pin, 2019). The 6MWT is the most common walk test in the literature (Bartels et al., 2013). However, it is very demanding for the participant. For patients with muscle weakness and poor endurance it may be a very challenging test (Brooks et al., 2007; Pin, 2014). Moreover, it requires at least 15 or, according to American Thoracic Society, even 30m of distance to perform (ATS Statement, 2002; Bartels et al., 2013). 10WT is not very time consuming and does not require specific facilities. It is not a demanding test for the patients struggling with knee OA as well. There was no incident of stopping this test reported or refusing to attempt this test because of pain or other symptoms in the affected joint. 10WT is a valid and reliable tool for walking assessment in older adults with dementia and in subjects with spinal cord injury (van Hedel et al., 2005; Chan and Pin, 2019). To our knowledge, this study is the first one that investigated reliability and determined MDC₉₅ on the 10WT in patients with knee OA. We have observed that 10WT showed an excellent test-retest reliability with ICC 0.974 and MDC₉₅ 0.65s.

Quadriceps muscle weakness is commonly associated with knee OA. Moreover, it is hypothesized that this clinical impairment, also known as arthrogenic muscle inhibition,

occurs due to the altered afferent signals coming from the affected joint (Deandrade et al., 1965; Hopkins et al., 2001; Palmieri et al., 2005; Héroux and Tremblay, 2006; Pietrosimone et al., 2011). This mechanism contributes to the modulation of the motor neurons within healthy, uninjured muscles of the lower limb (Pietrosimone et al., 2011). It could be measured as a percentage of voluntary activation (Kean et al., 2010). Pietrosimone et al. reported that percentage of quadriceps voluntary activation in involved limb was 82.2% (CI95% 81.4-83.3), while in control uninvolved limb - 90% (CI95% 88.9-91.7) (Pietrosimone et al., 2011). An impairment of the volitional quadriceps muscle activation affects the peak torque value, gait, as well as performance of activities of daily living (Torry et al., 2000; Fitzgerald et al., 2004). To the authors knowledge, there are two studies determining MDC for MVIC of knee extensors in population of patients suffering from knee OA (Madsen and Brot, 1996; Kean et al., 2010). Madsen and Brott reported that the change beyond 46.9% can be considered as clinically significant (Madsen and Brot, 1996). On the other hand, Kean et al. determined MDC as approximately 15% in absolute value and approximately 18% when normalized to the body mass (Kean et al., 2010). In the present study, MDC₉₅ for MVIC of knee extensors was 18.6% for both, absolute and normalized to body mass values, and for knee flexors 18.9% and 19% for absolute value and normalized to body mass value, respectively.

MDC₉₅, also called the smallest real change, is a statistical estimation of a value which can be detected by a measure which correlates with noticeable change in the performance. MDC₉₅ shows which changes fall outside the SEM of a given test (Beckerman et al., 2001). Changes in measurement which exceed MDC₉₅ are clinically relevant (de Vet et al., 2006). In practice, no improvement beyond MDC₉₅ in TUG after applied therapy suggests the clinician to plan an alternative strategy of treatment in order to improve the results. Estimation of MDC₉₅ gives the researchers confidence that the detected change reflects a real functional change in a rehabilitation process. Therefore, it is of crucial importance to determine MDC₉₅ in a specific population. Previous studies in reported MDC₉₅ in TUG values between 2.27s in patients after total knee arthroplasty and 11s in patients with Parkinson's disease (Steffen and Seney, 2008; Yuksel et al., 2017). In this study, we have observed that MDC₉₅ value for TUG was 1.01s. In STS MDC₉₅ was determined by Goldberg et al. as 2.5s in population of older females (Goldberg et al., 2012), while in our study MDC₉₅ value was 1.91s. Up to date, there was no study determining MDC₉₅ for 10WT and MVIC of knee extensors and flexors. SEM values in each test did not exceed 6.9% and MDC₉₅ values did not exceed 19% which proves great consistency of the results. Large SEM and MDC₉₅ values can occur due to learning or change in physical condition of the participants (Yeung et al., 2008). In this study, none of them were present.

Conclusions

TUG, STS, 10WT and MVIC measurement of knee extensors and flexors have an excellent test- retest reliability in patients with mild to moderate knee OA. Each test from this battery is simple, not time-consuming and sensitive for monitoring patients and quantifying changes over time in performance of activities of daily living. Changes greater than 1.01s for TUG, 1.91s for STS, 0.65 for 10WT, 0.62 for MVIC_{standardised} of knee extensors and 0.31 for MVIC_{standardised} of knee flexors may be used as a clinically significant.

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