Reproducibility of ultrasonographic measurements of the ulnar nerve at the cubital tunnel

Master thesis

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“ONDERGETEKENDE

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bevestigt hierbij dat de onderhavige verhandeling mag worden geraadpleegd en vrij mag worden gefotokopieerd. Bij het citeren moet steeds de titel en de auteur van de verhandeling worden vermeld.”

English summary:

Objectives

Ulnar nerve entrapment at the cubital tunnel is the second most common entrapment of the peripheral nerves of the upper extremities. Ultrasonography (US) is frequently used to ascertain the diagnosis and to evaluate tissue changes during and after treatment. However, reproducibility of US measurements of the ulnar nerve is incomplete. Therefore, the purpose of the current study was to determine the inter- and intra-rater reliability and the intra-rater agreement of US measurements of the cross-sectional area (CSA) of the ulnar nerve at the cubital tunnel in healthy adult subjects.

Methods

Throughout this test-retest study, two trained physical therapists, with three and seven years of US experience, determined the CSA of the ulnar nerve at the cubital tunnel. The CSA was obtained through a standardized protocol of the dominant arm of healthy participants. Two measurement sessions were performed per participant. Each session consisted of two measurements of the ulnar nerve per sonographer. The interval between the sessions was 15 minutes. Sonographers were blinded for their own as well as for each other's outcomes. For statistical analysis the intraclass correlation coefficient (ICC) and the smallest detectable change were calculated.

Results

From March to April 2013, 69 participants (28 men and 41 women) with a mean ± SD age of 36 ± 15 years were included. Inter-rater reliability turned out to be fair to good with an ICC value of 0.63. The intra-rater reliability was excellent for both sonographers with an ICC of 0.85 for sonographer 1 and 0.88 for sonographer 2. The smallest detectable change of sonographer 1 and 2 were 2.47 mm^2 (25% of the mean CSA) and 2.63 mm^2 (26% of the mean CSA), respectively.

Conclusion

Owing to the fair to good inter-rater reliability, the excellent intra-rater reliability for both raters and the clinical applicable intra-rater agreement, US seems to be a valuable tool to assess the CSA of the ulnar nerve at the cubital tunnel for diagnostic and evaluative purposes in the physical therapy practice.

Dutch summary:

Doelstelling

Echografie wordt tijdens het onderzoek en de behandeling van de compressie van de nervus ulnaris in de cubitale tunnel in de fysiotherapie praktijk frequent ingezet. Ondanks de talrijke inzet is de reproduceerbaarheid van echografie van de nervus ulnaris niet volledig bekend. De doelstelling van de huidige studie is het bepalen van de inter- en intra- beoordelaarsbetrouwbaarheid en de intra-beoordelaarsovereenstemming van echografie-metingen van de cross-sectionele area (CSA) van de nervus ulnaris in de cubitale tunnel bij gezonde volwassenen.

Methode

Tijdens deze test-hertest studie meten twee ervaren, getrainde en geblindeerde echografisten middels een gestandaardiseerd echografie-protocol per deelnemer twee keer de CSA van de nervus ulnaris in de cubitale tunnel. Met een interval van 15 minuten werd deze procedure herhaald. De inter- en intra-beoordelaarsbetrouwbaarheid werd berekend middels de intraclass correlation coëfficiënt (ICC) en de intra-beoordelaarsovereenstemming middels de minimaal detecteerbare verandering.

Resultaten

Zesennegentig participanten (41 vrouwen) met een gemiddelde ± SD van 36 ± 15 jaren namen aan het onderzoek deel. De inter-beoordelaarsbetrouwbaarheid is redelijk tot goed (ICC van 0.63). De intra-beoordelaarsbetrouwbaarheid is uitstekend (ICC van 0.85 voor echografist 1 en 0.88 voor echografist 2). De minimaal detecteerbare verandering is voor echografist 1 en 2 2.47 mm^2 en 2.63 mm^2 (25 en 26% van de gemiddelde CSA), respectievelijk.

Conclusie

Het lijkt, dat echografie van de nervus ulnaris in de cubitale tunnel voor diagnostische en evaluatieve doeleinden in de fysiotherapie praktijk een geschikt instrument is. Dit door de redelijke tot goede inter-, de uitstekende intra-beoordelaarsbetrouwbaarheid voor beide meters en de klinisch bruikbare intra-beoordelaarsovereenstemming.

Key words: Ultrasound, peripheral nerve, reliability, agreement, elbow

Introduction

Ulnar nerve entrapment (UNE) usually occurs at the cubital tunnel underneath the Osborne's ligament, manifesting itself in a neuropathy due to dynamic nerve compression (1,2). Pressure on, or stress of the ulnar nerve can result in pain, numbness and later on in paresthesia in the palmar part of the fourth and fifth digit (1-4). Further symptoms of UNE are muscle weakness or atrophy of the muscles innervated by the ulnar nerve (1-4). UNE has an incidence of 24.7 per 100.000 persons in the Western society in 2005 (4).

UNE is generally diagnosed through medical history, provocative clinical tests and electromyography (EMG) (5-7). However, the clinical tests and EMG have low validity (5-7) and EMG is unable to determine the exact location of the entrapment (6,7). US seems a complementary tool to clinical and EMG examination (5,8,9), and it is valuable to ascertain histopathologic tissue changes (5,9). Entrapments at the cubital tunnel can be detected using US based on increased cross-sectional areas (CSA) or thickness of the ulnar nerve (10). Therefore, US is frequently employed by physical therapists and radiologists since approximately 1995 (10,11). Compared to EMG, there are many advantages of US. US is a quickly available, pain-free, non-invasive and low-costs imaging device (10,11). Additional sensitivity and specificity of the diagnosis UNE increase using the combination of US and EMG (9,10). Despite the frequent use of US in daily practice, reproducibility is incomplete and only a few studies have been performed on the measurement properties of US measurements of the ulnar nerve. Beekman *et al.* (5) stated that US is a valid device for diagnosing UNE. However, in general US has been described as a highly sonographer-dependent diagnostic tool (12). Adequate reliability is essential for the ability to distinguish patients from each other (13-15). Satisfactory agreement is crucial for detection of a real change besides the measurement error during evaluation of the treatment (13-15). Knowledge about the reproducibility of US is essential for physical therapists for diagnostic, prognostic and evaluative purposes.

Although considerable research about US of peripheral nerves of the upper extremities (16-18) has been performed, showing fair to excellent inter-rater reliability, no attention has been paid to intra-rater agreement parameters by means of the smallest detectable change (SDC). Previous studies have calculated intra-rater reliability outcomes based on a small sample of four persons (17). Inter- and intra-rater reliability were determined for all upper extremity nerves together (18). Furthermore, different statistical analyses were performed. Given these facts, additional research is needed to determine inter- and intra-rater reliability of the ulnar nerve at the cubital tunnel separately, computing the intraclass correlation coefficient (ICC). Therefore, the research question of the current study is: what is the inter- and intra-rater reliability and intra-rater agreement of high resolution ultrasonographic measurements of the cross-sectional area in squared millimeter of the ulnar nerve at the cubital tunnel in healthy adult subjects?

Participants & Methods

Design & participants

The approval for the test-retest study was obtained by the Research Ethics Committee of the University Medical Center Utrecht. Additional, all participants gave written informed consent prior to the measurements. A convenience sample at Fontys University of Applied Sciences in Eindhoven, the Netherlands was recruited from February 2013 up to April 2013. Participants had to be 18 years or older in order to be included. Exclusion criteria were 1) complaints of one or more parts of the dominant arm; 2) physical therapy or surgery due to complaints of the dominant arm within the last three months and 3) subluxation of ulnar nerve in test position, tested during the US measurement. Conferring to Walter *et al*. (19) a minimal sample size was determined at n = 39.

Demography and anthropometry

Prior to the US measurement, characteristics of demography including age (years) and gender, anthropometry such as height (cm) and weight (kg) as well as the dominant arm of each participant were collected. Additionally, the body mass index (BMI) (kg/m^2) was calculated.

Raters & US-protocol

Two physical therapists with three (M.T.) and seven years (M.S.) of experience in clinical US, carried out the US measurements. Measurements were performed with two Mylab One (Esaote Benelux BV, Maastricht, the Netherlands) scanners with a 13 MHz linear array probe using the elbow pre-set for superficial tissue.

In order to make the US measurements reproducible the position of the participant is specified. Imaging was performed with the participant sitting parallel to the examination table. The flattened hand was placed on the table in maximal internal rotation of the upper arm and pronation of the forearm. A position of 70° - 80° of elbow flexion was chosen in this protocol due to possible physiological changes of the ulnar nerve above 90° of elbow flexion. The olecranon had to be facin g the sonographer during the measurement. To get familiar with the measurement protocol, the sonographers practiced the technique for about one hours on four participants and discussed possible difficulties.

As published in previous articles, the medial epicondyle and the olecranon were defined as bony landmarks to determine the exact position of the probe at the cubital tunnel (18,20-24). Similar to real time measurements in daily practice, the sonographers used the circumferential tracing technique on the fixed picture to measure the CSA mm^2 of the ulnar nerve at the cubital tunnel. Measurements were performed on the hyperechoic rim of the nerve. Care was taken to the transducer being perpendicular to the nerve. Data were registered by research assistants to ensure blinding of the sonographers to each other's as well as to their own previous measurements and all images were saved on digitally.

The test procedure covered approximately 30 minutes for each participant. Both sonographers started simultaneously with measuring a participant, and switched of participants after two consecutive measurements. The averages of these consecutive measurements were used for statistical analysis. With an interval of 15 minutes this process was repeated. An interval of 15 minutes was performed to diminish the recall bias. In this interval participants were expected to remain stable (5). The procedure is presented in Figure 1.

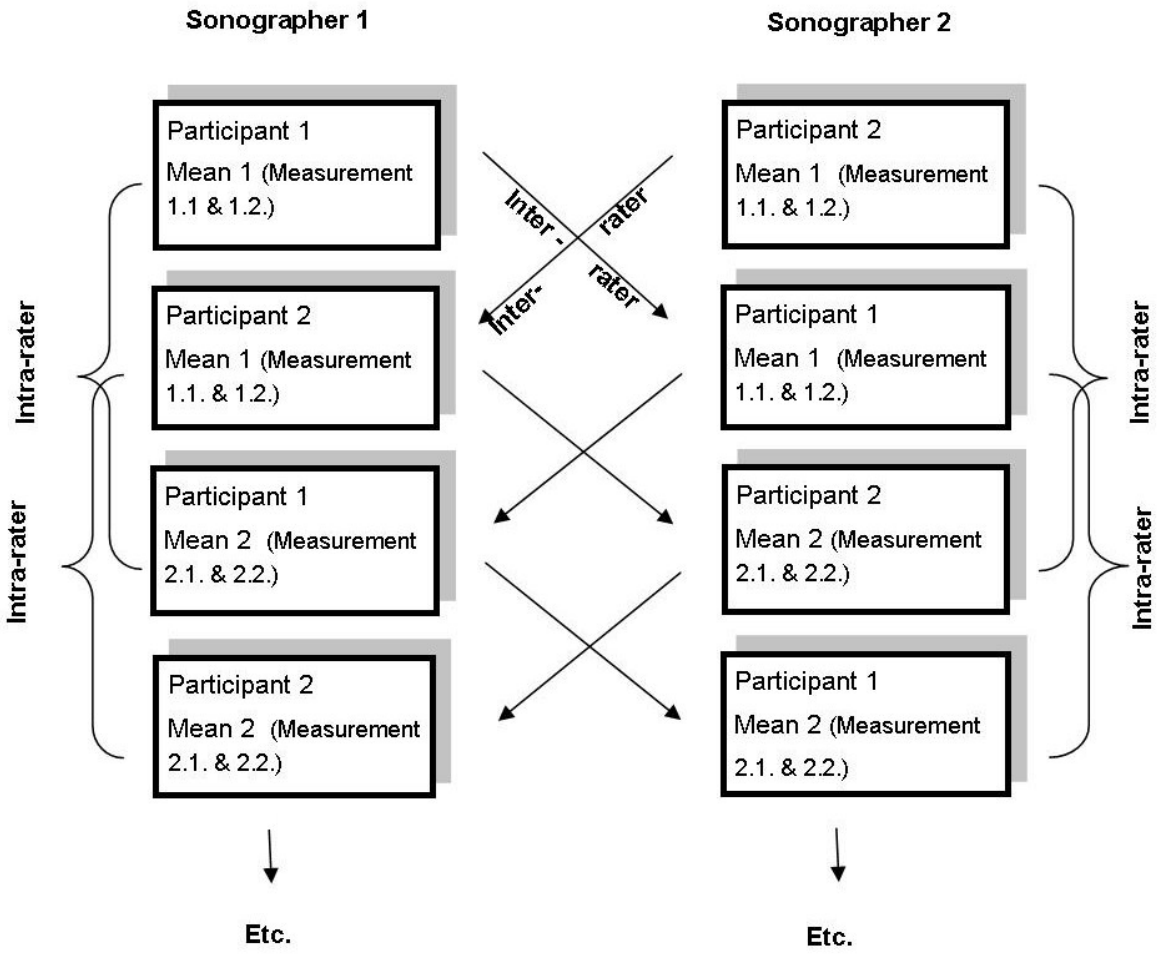

Figure 1: Study procedure.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (version 19.0, SPSS Corp., Chicago, Ill, USA).

At first, data were graphically checked for normal distribution using quantile - quantile plots. Descriptive statistics were presented as mean ± standard deviation (SD) and range for continuous data or amount (n) and percentages (%).The threshold of statistical significance was established for all measurements at alpha $p<0.05$.

Inter- and intra-rater reliability

For the inter-rater reliability, the first average of each sonographer was used.

For both inter- and intra-rater reliability of US measurements of the CSA of the ulnar nerve at the cubital tunnel the $ICC_{agreement}$ formula (model 2.2.) was utilized (13,25). The ICC of the intra-rater reliability was calculated using the $ICC_{agreement}$ for both sonographers separately (13,25). The ICC values were evaluated consistently with the rating criteria developed by Shrout *et al*. (25): excellent >0.75, fair to good 0.40–0.74 and poor <0.40.

Intra-rater agreement

The intra-rater agreement of the US measurements of the CSA of the ulnar nerve at the cubital tunnel was described by determining the smallest detectable change (SDC) with the formula $1.96 \times \sqrt{2} \times SEM_{agreement}$ (13). Therefore, the $SEM_{agreement}$ was calculated $\sqrt{(\sigma^2_{measurement} + \sigma^2_{residual})}$ with a 95% confidence interval (CI) (13).

Results

In total, 73 subjects were recruited. Four subjects were excluded due to subluxation of the ulnar nerve. This resulted in the inclusion of 69 subjects (28 men and 41 women) with a mean (± SD) age of 36 (± 15) years. No missing values were registered and data were normally distributed. Further demographic and anthropometric data are presented in Table 1. Mean values ± SD and 95% CI of the CSA of the ulnar nerve of both measurements are reported in Table 2. No adverse events were stated. Inter-rater

reliability was fair to good with an ICC value of 0.63. The intra-rater reliability was excellent with an ICC of 0.85 for sonographer 1 and 0.88 for sonographer 2. Regarding the intra-rater agreement, the SDC of sonographer 1 and 2 were 2.47 mm^2 (25% of the mean CSA) and 2.63 mm^2 (26% of the mean CSA), respectively. All reproducibility outcomes are shown in Table 3.

Table 1: Demographic and anthropometric characteristics of participants.

	N	Mean ± SD
Age (years)	69	36 ± 15
Gender (men/women)	69	28/41
Height (m)	69	1.74 ± 0.10
Weight (kg)	69	72.1 ± 13.8
BMI (kg/m^2)	69	23.82 ± 3.65
Dominant arm (right/left)	69	60/9

BMI-body mass index; SD-standard deviation.

Table 2: Mean, SD and 95% CI of the CSA of the ulnar nerve of both measurements.

	Mean ± SD	95% CI
Measurement 1 (mm^2)	9.83 ± 2.54	4.85-14.80
Measurement 2 (mm^2)	10.08 ± 2.46	4.90-14.90

SD: standard deviation;
CI: confidence interval

Table 3: Inter- and intra-rater reliability and intra-rater agreement of the CSA of the ulnar nerve at the cubital tunnel.

	ICC (95% CI)	SDC mm^2 (percentage % of the mean CSA)
Inter-rater reliability	0.63* (0.46-0.76)	-
Intra-rater reliability		
Sonographer 1	0.85* (0.76-0.90)	2.47 (25%)
Sonographer 2	0.88* (0.80-0.92)	2.63 (26%)

ICC: intraclass correlation coefficient; CI: confidence interval;
SDC: smallest detectable change; *P-values<0.001.

Discussion

The purpose of the current study was to determine the inter- and intra-rater reliability as well as the intra-rater agreement of US measurements of the CSA of the ulnar nerve at the cubital tunnel. Excellent intra-rater reliability outcomes are obtained by both raters in this study. ICC values of both raters are quite similar, suggesting that the different levels of experience between the raters seem to have little influence on the intra-rater reliability in the current study. Furthermore, fair to good ICC values are presented for inter-rater reliability. The results of the current study show that a real change of the CSA can be measured above 2.47 - 2.63 mm^2, covering 25-26% of the mean CSA.

To our knowledge, this is the first study determining all reproducibility outcomes by computing the ICC and the SDC. The reliability results of the current study confirm the results of previous research (16-18). Thoirs *et al.* (16,17) demonstrated excellent intra-rater reliability (ICC of 0.88) (17), and fair to good inter-rater reliability (Pearson's correlation coefficient of 0.81) (16) for US measurements of the ulnar nerve in healthy individuals. Tagliafico *et al*. (18) also found fair to excellent intra-rater (ICC of 0.63-0.96) and inter-rater reliability (ICC of 0.59-0.93) for US measurements of the ulnar nerve in healthy subjects. Caution has to be taken into account by the comparison with the presented results of Tagliafico *et al*. (18). The ICCs represent overall ICCs of

measurements of all peripheral nerves of the upper extremity together instead of for the ulnar nerve measurements separately, as investigated in the current study. Furthermore the results of this study confirm the outcome of previous research (5) US being sonographer-dependent. Nevertheless, the difference of the ICC values of both sonographers was small (0.03) in the current study. A possible explanation of the small difference might be the well-defined and detailed measurement protocol.

This is the first study establishing the SDC of US measurements of the ulnar nerve. A change of 25-26% of the mean CSA is needed, before a real change besides the measurement error can be detected. The SDC has to be interpreted with reference to changes of the CSA outcomes of the ulnar nerve of individuals diagnosed with UNE compared to healthy individuals. Previous studies determined CSA values of healthy individuals and individuals diagnosed with UNE (21,26,27). Statistical significant differences of the outcomes of the CSA of the ulnar nerve in both groups were found in all the three studies (21,26,27). In these studies the CSA of the ulnar nerve increases with 56% (26), 75% (27) and 192% (21), in individuals diagnosed with UNE compared to healthy individuals. Considering these detected increases of the CSA, it can be presumed that an entrapped nerve will transcend the SDC found in the current study. Based on this, it seems that the SDC of 25-26% found in this study will be clinical applicable to detect changes besides the measurement error. Care has to be taken when relating the SDC of this study to the statistical significant changes of the three previous studies, because measurement protocols differed. For example the elbow flexion ranged from 15° (21,26) to 70-80° in the cu rrent study and 90° (27). Further research is needed to determine whether different test positions influence the SDC.

Standardization of the measurement protocol was employed to increase the reproducibility. The elbow flexion was chosen to be 70-80°. This position is based on physiological changes of the ulnar nerve from approximately 90° to full elbow flexion (28). From 90° of elbow flexion, the tension of Osb orne's ligament, the boundary of the cubital tunnel, increases, the area beneath the ligament decreases and the nerve itself gets taut. This may result in varying representations of the ulnar nerve and a higher

chance of subluxation of the ulnar nerve (28). In previous studies the measurements were performed in 90° up to full flexion (16-18,22, 27,29). Consequently varying means of the CSA were stated from 4 mm^2 (27) to 7.9 mm^2 (29). The mean CSA values of the ulnar nerve in the current study are higher. An explanation for this could be that the measurements in the current study were performed on the hyperechoic rim, instead of inside the rim. Many protocols chose to exclude the rim for practical reasons and comparability to outcomes to other studies. The rim was included in this study, because excluding the rim means excluding a part of the nerve, the epineurium. Even the epineurium can change pathological during entrapment (16,21). Therefore changes of the epineurium might signify differences in the mean CSA (16). Further research is needed to determine the influence of the pathological change of the hyperechoic rim on the increase of the CSA and on reproducibility, in individuals with UNE. This, to decide whether the rim should consequently be in- or excluded during the measurements. Furthermore, future research should focus on the influence of the test positions on the mean CSA outcomes and on reproducibility of the US measurements.

A limitation of the current study might be the interval of 15 minutes between the measurements. This short interval could have caused that the sonographers remembered the outcomes of previous measurements. The interval was chosen out of organizational considerations as well as based on the expectation that the participants would remain stable between measurements. In the current study, the outcomes were not expected to be influenced by recollection because the sonographers were blinded for their outcomes. Another limitation might be generalization of the outcomes. In the current study, a convenience sample of healthy adults was measured prior to individuals with clinical appearances of UNE. Future research needs to determine and compare reliability and agreement values of US measurements of the ulnar nerve at the cubital tunnel in both groups.

Based on the inter- and intra-rater reliability outcomes, the current study shows that US is an usable device for physical therapists and radiologists. In daily practice comparison of measurements mostly takes place within one sonographer. Based on the excellent

intra-rater reliability of both the less and the more experienced sonographers, it seems that US can contribute to the quality of the diagnostic process and to evaluation of treatment effects over time. Furthermore, physical therapists with different levels of experience seem to be able to obtain highly reproducible US measurements of the ulnar nerve, with little training of the measurement protocol. According to the outcome of the SDC compared to changes of the CSA in individuals with UNE, it seems that tissue changes can be detect after treatment.

Conclusion

Based on the fair to good inter-rater reliability and excellent intra-rater reliability for both raters, US seems to be a valuable tool to determine CSA outcomes of the ulnar nerve at the cubital tunnel for diagnostic purposes and repetitive measurements in the physical therapy practice. Due to the clinical applicable intra-rater agreement values, US seems to be useful to state treatment effects like tissue changes over time.

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