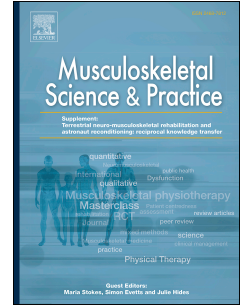


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The Liverpool Elbow Score, patient-answered section: Cultural adaptation, validity and reliability of Turkish version

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Informed consent

Written informed consent was obtained from all subjects before the study.

Ethical approval

Ethical approval for this study was obtained from Pamukkale University Non-invasive Clinical Researches Ethics Committee, Denizli, Turkey (20.02.2018/04).

Contributorship

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Nihal Büker, Raziye Şavkın and Şule Şimşek. The first draft of the manuscript was written by Nihal Büker, Raziye Şavkın and Şule Şimşek and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Abstract

Background: The use of self-assessment questionnaires in addition to clinical evaluations is gradually increasing. Liverpool Elbow Scale (LES) is an elbow-specific outcome score that provides a comprehensive assessment of by both the clinicians and patients. However, it has not been adapted and validated to Turkish language.

Objective: To conduct the translation, cross-cultural adaptation and validation of Liverpool Elbow Score-patient answered outcome (LES-PAQ) into Turkish for patients with elbow fracture.

Design: Study of diagnostic accuracy/assessment scale.

Methods: This study was carried out in three consecutive phases: translation, cross-cultural adaptation and validation. In the third phase, we used the Quick Disabilities of the Arm, Shoulder and Hand (Quick-DASH), Mayo Elbow Performance Score (MEPS) and 12-Item Short Form Survey (SF-12) physical health score.

Results: Sixty-one patients were included for the analysis. Neither a ceiling nor a floor effect was observed. Cronbach's α coefficient was 0.89. Intraclass correlation coefficient was 0.94 (95% CI 0.89 to 0.96; $p < 0.001$). SEM was 0.28 and MDC_{95} was 0.79. The LES-PAQ showed a high negative correlation with the Quick-DASH ($r = -0.72$, $p < 0.001$) and high positive correlation with MEPS ($r = 0.77$, $p < 0.001$), and with SF-12 physical health subscale ($r = 0.73$, $p < 0.001$).

Conclusions: The Turkish version of the LES-PAQ is a reliable and valid tool for the assessment of the patients with elbow fracture.

Keywords Elbow fracture; Liverpool elbow score; Outcome measures; Validation studies

1 **1. Introduction**

2 Elbow fractures constitute 5% of all fractures in adults (Pollock et al., 2019). Distal humerus
3 fractures account for 30% of elbow fractures. One third of the elbow fractures is radial head
4 (Kaas et al., 2010) and %10 olecranon fractures (Gradl G, 2012). Treatment options are
5 conservative or surgical treatment. Surgical treatment options include open reduction-internal
6 fixation (ORIF), resection arthroplasty and radial head arthroplasty (Ellenbogengelenk et al.,
7 2018). The elbow tends to stiffness after injury and fractures, it can often lead to significant
8 functional impairment. Treatment procedures purpose to reduce functional impairments.
9 Patients with limited elbow motion often complain difficulties in work, leisure activities, and
10 even daily living activities. Functional and clinical tests or questionnaires have become
11 increasingly used to detect severity of dysfunction, evaluate treatment effectiveness, and
12 compare different treatment methods (The et al., 2013).

13 Clinician-reported outcome and patient-reported outcome are most commonly used clinical
14 outcome assessment tools. Clinician-reported outcomes reflect the evaluation of patient's
15 clinical and functional condition by a healthcare professional while patient-reported outcome
16 reflects patients' self-views of their health status (Powers et al., 2017). However, the
17 questionnaire completed by the clinician may not associated with patient satisfaction
18 (Capuano 2011). Therefore, the use of self-assessment questionnaires in addition to clinical
19 evaluations is gradually increasing (Longo et al., 2008).

20 The Disability of Arm, Shoulder and Hand (DASH) questionnaire mainly consists of a 30-
21 items which evaluates impairments and activity limitations (Gummeson et al., 2003). Quick
22 DASH has been developed to provide faster measurement, less responder burden, and
23 decreases in nonresponse items (eg, sexual activities), making survey more accessible and
24 efficient. It consists of 11 items to measure physical function and symptoms in people with

25 musculoskeletal disorders of the upper limb. The final score ranges between 0 (no disability)
26 and 100 (most severe disability) (Gummesson et al., 2006).

27 Mayo Elbow Performance Score (MEPS) can be used to determine the limitations caused by
28 elbow pathology. It consists four subscales: pain, range of motion, stability, and patient rating
29 of daily function. The scale ranges from 0 to 100, with a higher score indicating a better
30 outcome (Cusick et al., 2019).

31 Short Form-12 (SF-12) developed from the 36-item Short-Form (SF-36) Health Survey
32 covers the same eight health domains as the SF-36. It is a 12 item survey composed of
33 physical and mental components. Each component has their own score. Total score ranges
34 from 0 to 100. Higher score indicates high quality of life (Jakobsson et al., 2012).

35 Liverpool Elbow Scale (LES) is an elbow-specific outcome score that provides a
36 comprehensive assessment of by both the clinicians and patients. The questionnaire consists
37 of two section: 6-item clinical assessment section (CAS, C1-6) and 9-item patient-answered
38 section (PAQ, P1-9). The CAS comprises items that evaluate range of motion (C1-C4),
39 muscle strength (C5), and ulnar nerve function (C6), whereas the PAQ assesses function and
40 the ability to perform activities of daily living (P1-P7), levels of pain (P8), and participation in
41 sports and leisure activities (P9). The patient answered items are graded using a five-point
42 Likert scale, from 0 (worst/ least function) to 4 (best/most function). All responses are
43 transformed to a scale of 0–10 for calculation of the total score. Therefore, the final score
44 ranked from 0 (worst) to 10 (best) (14). The original report of LES noted that, of the two main
45 components, the PAQ had better internal consistency (Sathyamoorthy et al., 2004).

46 The purpose of this study was to translate and culturally adapt The Liverpool Elbow Score,
47 patient-answered section (LES-PAQ) into Turkish and to investigate the reliability and
48 validity of the translated version in patients with elbow fracture.

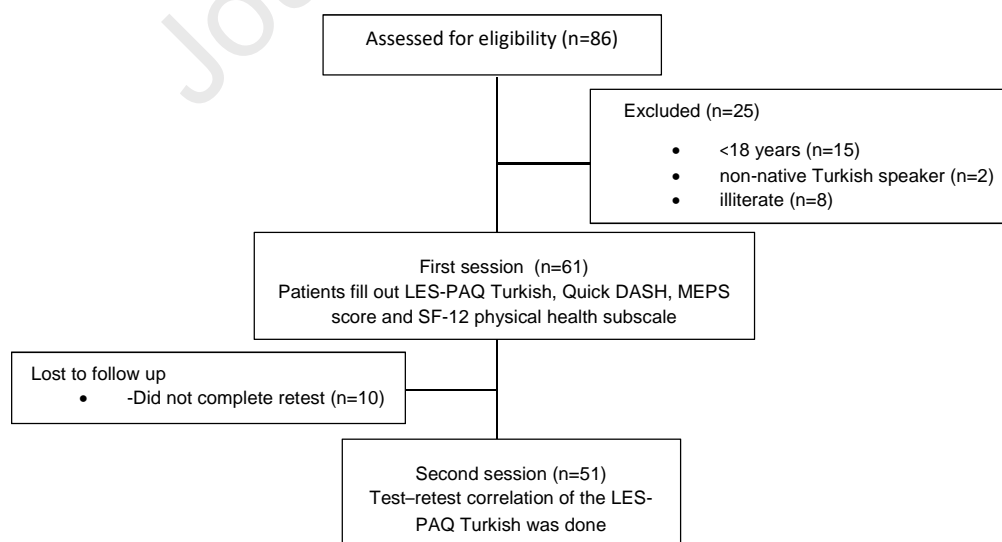
49 **2. Material and methods**

50 *2.1. Study design and patients*

51 The study was approved by the Non-invasive Clinical Researches Ethics Committee and an
52 informed consent form was signed by all patients.

53 Sixty-one patients with elbow fracture who were referred to the university hospital were
54 included in this study. Patients who aged between 18 and 80 years, had unilateral elbow
55 fracture treated conservatively or surgically, ability to understand and read Turkish and who
56 had given pre-informed consent were included. Patients who non-native Turkish speakers, are
57 illiterate, had serious visual defect, severe hear loss and cognitive dysfunction were excluded.

58 Patients with elbow fracture completed The LES-PAQ Turkish version twice, with at an
59 interval of 7 days. For minimize short-term clinical change, no treatment was given in this
60 process. In the first session, 61 patients fill out LES-PAQ Turkish, Quick DASH, MEPS score
61 and SF-12 physical health subscale validated Turkish versions. In the second session, 51
62 patients were asked to fill out LES-PAQ Turkish version questionnaire again. The flow chart
63 of the validation process is shown in Fig. 1.



74 **Fig. 1.** Flow chart.

75 2.2. Method of translation and cross-cultural adaptation

76 The LES was developed by Sathyamoorthy et al. and published in 2004. We took permission
77 from the author for this scoring scale's Turkish version. The guideline suggested by Beaton
78 was followed for the translation and cross-cultural adaptation (Beaton et al., 2000).

79 Scale was translated into Turkish by two independent, native, Turkish-speaking translators.
80 Consensus was reached after comparing translations and inconsistencies. After agreeing on a
81 Turkish version, it was translated back into English by two independent translators who are
82 native speakers of English and second language was Turkish. The translators were not access
83 to the original version of the scale and were unaware of the purpose of the study. Finally, an
84 expert committee (article authors, forward and backward translators) reached a consensus in
85 the pre-final version of the Turkish LES-PAQ. The pre-final version was performed to
86 patients with elbow fracture (n=10) for cultural adaptation. A research assistant received
87 general comments from the patient about the comprehensibility of the Turkish version of
88 LES-PAQ and asked patients to make suggestions for questions that led to comprehension
89 problems. The LES-PAQ Turkish version is given in the Appendix A.

90 2.3. Sample size

91 In the patient-reported outcome validation study, the number of respondents could be five
92 times the number of items in the analysis (Anthoine et al., 2014). LES-PAQ has 9 items, and
93 at least 45 patients should have recruited for analysis. We collected data from 61 patients.

94 2.4. Statistical analysis

95 Continuous variables were given as mean and standard deviation (SD), median (minimum and
96 maximum) and categorical variable values are presented as absolute numbers and
97 percentages. The Kolmogorov-Smirnov test was used to determine the distribution of the

98 sample. A p value ≤ 0.05 was considered statistically significant. Obtained data were analyzed
99 by using the Statistical Package for Social Scientist (version 21; SPSS Inc., Chicago, IL).

100 2.5. Factor analysis

101 Indicating suitability of the data for factor analysis was assessed by Bartlett's test and "Kaiser
102 Meyer Olkin" tests (Cerny and Kaiser, 2010). The test developed by Barlett is a test of
103 sphericity. This test assesses whether there is a relationship between the variables in the main
104 mass. Small values (less than 0.05) of the significance level indicate that a factor analysis may
105 be useful with your data. The "Kaiser Meyer Olkin" test, which is another test showing the
106 validity of factor analysis, deals with the sample size. The test value should be above 60%.
107 After determining the suitability of our data for factor analysis; the factor structure was
108 evaluated using principle components analysis with Varimax rotation.

109 2.6. Floor and ceiling effect

110 In orthopaedic studies a ceiling or floor effect is usually defined as 15% (or more) of the
111 patients achieve the highest or lowest possible score (Lim et al., 2005). Similarly, we defined
112 the presence of floor or ceiling effects, if more than 15% of our patient collective would
113 achieve the highest (100 points) or lowest (0 point) possible score of the LES-PAQ.

114 2.7. Test-retest reliability and internal consistency

115 Intra-class correlation coefficient (ICC) analysis and Cronbach's α was performed to
116 determine test-retest reliability and internal consistency between the LES-PAQ Turkish
117 version. ICC estimates and their 95% confident intervals were calculated based on absolute-
118 agreement, 2-way mixed-effects model. Values between 0.75 and 0.9 indicate good reliability,
119 values greater than 0.90 indicate excellent reliability (Koo and Li, 2016); satisfactory internal

120 consistency indicates values of 0.70 or greater (Terwee et al., 2007). Also, the Pearson
 121 correlation analysis was applied for the test–retest reliability.

122 2.8. Construct validity

123 The construct validity correlations between LES-PAQ and Quick-DASH, MEPS and SF 12
 124 physical health scores was tested by Pearson correlation analysis. The correlation strength
 125 categories are accepted as follows: < 0.5 = “low”, 0.5–0.69 = “moderate”, 0.7–0.89 = “high”
 126 and 0.9–1.0 = “very high” (Büker et al., 2017). A P-value of <0.05 was considered to be
 127 statistically significant.

128 3. Results

129 3.1. Patient Characteristics

130 A total of 61 patients (24 males and 37 females; mean age, 41.54±13.28 years) with elbow
 131 fracture participated in this study. The elbow fracture was on the dominant side in 40 patients
 132 (36 right-handed and 4 left-handed). Demographic characteristics of the patients was provided
 133 in Table 1. LES-PAQ, Quick-DASH, MEPS and SF-12 physical health scores of the patients
 134 were shown in Table 2. According to skewness and kurtosis coefficient; all outcome measures
 135 match normal distribution (Table 2).

136 **Table 1** Demographic characteristics of the study population (n=61).

	Min-Max	Mean (SD)
Age (years)	23-71	48.07 (12.36)
Body mass index (kg/m ²)	17.91-37.20	27.60 (3.19)
	n	%
Sex		
Male	24	39.3
Female	37	60.7
Educational level		
Primary education	27	44.3
Basic education	6	9.7
High school	18	29.6
University	8	13.1

Non-education	2	3.3
Dominant Extremity		
Right	57	93.4
Left	4	6.6
Injured Extremity		
Dominant	40	65.6
Nondominant	21	34.4
Type		
Radial head arthroplasty	10	16.4
ORIF	11	18.0
Resection arthroplasty	8	13.1
Conservative	32	52.5

137

138

139 **Table 2**

140 Descriptive statistics (n=61).

	Min-Max	Mean (SD)	Skewness		Kurtosis	
			Statistic	Std. Error	Statistic	Std. Error
LES-PAQ	1.50-6.00	4.54 (1.13)	-0.466	0.306	-0.582	0.604
Quick-DASH	0.00-72.75	29.84 (18.56)	0.101	0.306	-0.662	0.604
MEPS	30-100	75.98 (17.58)	-0.576	0.306	0.021	0.604
SF-12/Physical Health	14.00-100.00	67.18 (21.37)	-0.011	0.306	-0.691	0.604

141 LES-PAQ, The Liverpool Elbow Score, patient-answered section; Quick DASH, The Disability of Arm,
 142 Shoulder and Hand; MEPS, Mayo Elbow Performance Score; SF-12, Short Form-12; SD, Standard deviation.

143

144 *3.2. Factor Structure*

145 The KMO and Barlet tests scores are 0.856 and 0.000 respectively. These values indicated
 146 that this scale was suitable for factor analysis and sample size was perfect. Components
 147 analysis with Varimax rotation was performed to assess the internal structure of the cultural
 148 adapted questionnaire. It was observed that LES-PAQ had have no sub-dimension with a
 149 variance ratio of 57.8% (Table 3).

150

151

152

153

154

155 **Table 3**

	156	157	158
	Component		
	1		
Washing himself (question 3)	0.838		
Dressing (question 5)	0.835	159	
Combing hair (question 2)	0.822		
Lifting (question 7)	0.821	160	
Household activities (question 6)	0.809	161	
Sport and leisure activities (question 9)	0.772		
Feeding (question 4)	0.711	162	
Pain (question 8)	0.700		
Other arm use (question 1)	0.454	163	

Factor analyses of the LES-PAQ Turkish.

164

165 LES-PAQ, The Liverpool Elbow Score, patient-answered section.

166

167 *3.3. Floor and ceiling effects.*

168 No floor or ceiling effects were observed. None of the patients achieved the minimum score
 169 of 0 and in the first session 9.8% of the patients, in the second session 13.7% of the patients
 170 reached the maximum score of 6.

171 *3.4. Reliability*

172 Test-retest reliability and internal consistency of the LES-PAQ Turkish determined from the
 173 data provided from 61 patients. ICC was found 0.858 (95% CI 0.784 to 0.910; p=0.000).
 174 Cronbach's α values of the LES-PAQ Turkish was found 0.894. Item-total correlations were
 175 between 0.403 and 0.770 (Table 4). Test-retest correlation of the LES-PAQ Turkish
 176 determined from the data provided from 51 patients. A high positive correlation was found
 177 between a 7 days' interval ($r=0.880$, $p=0.000$) (Table 5).

178

179

180 **Table 4**

181 Internal consistency and test–retest reliability of the LES-PAQ Turkish (n=61).

	Mean (SD)	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
PAQ			
Other arm use (question 1)	2.48 (1.25)	0.403	0.907
Combing hair (question 2)	3.43 (0.96)	0.701	0.879
Washing himself (question 3)	3.36 (0.93)	0.729	0.877
Feeding (question 4)	3.67 (0.60)	0.593	0.890
Dressing (question 5)	3.51 (0.77)	0.726	0.880
Household activities (question 6)	2.75 (1.14)	0.767	0.873
Lifting (question 7)	2.67 (1.22)	0.770	0.872
Pain (question 8)	2.43 (1.16)	0.654	0.883
Sport and leisure activities (question 9)	2.93 (1.00)	0.726	0.877

182 LES-PAQ, The Liverpool Elbow Score, patient-answered section; PAQ, patient-answered section; SD, Standard
183 deviation.

184

185

186

187 **Table 5**

188 Values of LES-PAQ Turkish on a 7-day time interval and correlation between the two
189 sessions (n=51).

Liverpool Elbow Score	Test	Re-test	r (p value) ^a
	Mean (SD)	Mean (SD)	
PAQ score	4.41 (1.13)	4.36 (1.18)	0.880 (0.000)
Other arm use (question 1)	2.45 (1.24)	2.61 (1.15)	0.829 (0.000)
Combing hair (question 2)	3.37 (1.00)	3.33 (0.97)	0.795 (0.000)
Washing himself (question 3)	3.33 (0.95)	3.29 (0.94)	0.734 (0.000)
Feeding (question 4)	3.69 (0.55)	3.57 (0.57)	0.706 (0.000)
Dressing (question 5)	3.47 (0.78)	3.31 (0.84)	0.808 (0.000)
Household activities (question 6)	2.63 (1.15)	2.67 (1.18)	0.912 (0.000)
Lifting (question 7)	2.49 (1.22)	2.63 (1.15)	0.774 (0.000)
Pain (question 8)	2.24 (1.12)	2.24 (1.11)	0.775 (0.000)
Sport and leisure activities (question 9)	2.80 (1.00)	2.75 (1.11)	0.818 (0.000)

190 LES-PAQ, The Liverpool Elbow Score, patient-answered section; PAQ, patient-answered section; SD, Standard
191 deviation.

192 ^aPearson's correlation coefficient

193

194 3.5. *Validity*

195 61 patient participated the validation analysis of LES-PAQ. The LES-PAQ showed a high
196 negative correlation with the Quick-DASH ($r=-0.716$, $p=0.000$) and high positive correlation
197 with MEPS ($r=0.769$, $p=0.000$), and with SF-12 physical health subscale ($r=0.734$, $p=0.000$).

198 **4. Discussion**

199 The most important finding of this study, The LES-PAQ Turkish demonstrated good
200 reliability, satisfactory internal consistency, and validity to assess function in Turkish
201 speaking patients with elbow fracture.

202 Surveys and rating systems are widely used as a helpful tool to determine clinical and
203 functional outcome of the elbow fracture treatment. In addition to clinical evaluation, it is also
204 very useful for objectively communicating the patient's subjective feelings to the doctor. The
205 LES consists of both clinician and patient-answered questions. In this study, the patient-
206 answered section of the questionnaire was used for translation, cultural adaptation, validity
207 and reliability. In translation and cross-cultural adaptation stage, we did some minor changes
208 pre-final version. For example, explanatory examples were added to the “household
209 activities” item because “household” was not clearly understood by the Turk patients.
210 Household activities examples added to the question: cleaning, cooking, shopping, bill
211 payment, gardening, repairs etc. Minor changes were made in the explanations of the scoring
212 scale explanations (none, little, moderate, severe, unable to do) in accordance with the
213 questions asked.

214 LES-PAQ Turkish can be routinely used clinically by surgeons, physiotherapists and other
215 health professionals. Because it is easy to use, short, understandable and can be completed in
216 a short time, it also provides evaluating patient by telephone or mail practically. LES was

217 validated in patients with elbow stiffness (Sun and Fan, 2018) and the minimum clinically
218 important difference of the scale in elbow arthroplasty was examined examined
219 (Vishwanathan et al., 2017). However due to the retrospective nature of Sun and Fan study,
220 they did not measured reliability. Vishwanathan et al. found that the internal consistency of
221 LES was estimated at 0.87. Development and validation study of the LES, researchers were
222 found good internal consistency (Cronbach's $\alpha=0.997$) (Sathyamoorthy et al., 2004). In our
223 study test-retest reliability of LES-PAQ Turkish was good (ICC=0.858), and internal
224 consistency of the scale was high (Cronbach's α of 0.894). No floor or ceiling effects were
225 observed in our study. Test-retest reliability and internal consistency results showed that LES-
226 PAQ Turkish version is a reliable scale.

227 We used an upper extremity-specific score and health related quality of life questionnaire
228 similar to the previous studies. The validation process of the LES-PAQ Turkish has shown
229 that it has a high correlation with Quick-DASH ($r=-0.716$, $p=0.000$), MEPS ($r=0.769$,
230 $p=0.000$), and SF-12 physical health subscale ($r=0.734$, $p=0.000$). Sathyamoorthy et al. used
231 DASH and SF-12 scoring for measuring validity. They found a high correlation with DASH
232 ($r=-0.76$, $p=0.000$) and a low correlation with SF-12 physical health ($r=-0.39$, $p=0.000$). Sun
233 and Fan was found high correlations with DASH ($r=0.88$ preoperatively and 0.87
234 postoperatively, $p<0.001$), moderate correlations with MEPS ($r=0.65$ preoperatively and 0.53
235 postoperatively, $p<0.001$), and SF-36 physical health subscale ($r=0.63$ preoperatively and
236 0.50 postoperatively, $p<0.001$).

237 In recent years, the use of patient self-reported questionnaires has become quite popular.
238 Although these questionnaires are easy to use, failure to evaluate objective parameters in
239 elbow problems (such as muscle strength, instability, nerve dysfunction) may overlook
240 important aspects of the pathology. Therefore, joint symptoms and functions cannot be
241 evaluated accurately only with patient self-reported or subjective questionnaires. However, it

242 is known that evaluating objective parameters alone is not related to patient satisfaction,
243 quality of life, because expectations and satisfaction differ between individuals. The use of
244 LES in the evaluation of elbow joint functions may be preferred because it includes both
245 clinician and patient-answered sections. Health and disability should be assessed in three
246 areas with International Functioning, Disability and Health Classification (ICF) guidance:
247 clinician-assessed body structures and functions, patient self-reported activity, participation
248 and quality of life. However, LES did not contain substances that provided information about
249 the patient's quality of life (Vishwanathan et al., 2017). Researchers may use a different
250 questionnaire to assess the quality of life.

251 The data obtained from this study confirms that the Turkish version of LES-PAQ is a reliable
252 and valid tool. LES-PAQ can be used to evaluate joint function in patients with elbow
253 fractures.

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255 **Appendix A.** Supplementary data

256

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The Turkish version and validation of the LES-PAQ was conducted.

The Turkish version of the LES-PAQ is a feasible tool for clinical practice.

LES-PAQ is a reliable and valid tool and can be used for elbow fracture.

The correlation between the LES-PAQ and the Quick-DASH and MEPS were high.

Journal Pre-proof