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VALIDITY OF THE NEW BACKACHE INDEX (BAI) IN PATIENTS WITH LOW BACK PAIN

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ABSTRACT.

Background context: *The Backache-Index (BAI) is applied to patients with low back pain (LBP) in order to help the doctors/surgeons perform physical examinations easily and it is carried out within a short space of time (< 2 min.) without using inclinometric instruments.*

Purpose*: To explore the reliability, validity and responsiveness of this new Backache-Index in patients with low back pain, which can fulfil the existing need for a reliable routine examination in the clinical environment.*

Study design/setting: *Patients with LBP filled in disability questionnaires, pain rating scales and physical impairment tests were completed in function of construct validity and correlation studies. A subgroup was evaluated for inter-observer and test-retest reliability and a second group was reassessed after two active treatment sessions in order to verify the responsiveness compared with other examined variables.*

Patient sample: *In total, 75 patients with subacute LBP (3-12 weeks) participated in a randomized controlled study.*

Outcome measures: *The validity of the BAI was explored through a correlation with the standard Oswestry LBP Disability Index (ODI), the McGill LBP Questionnaire Index (MPQ), and the Visual Analogue Scale (VAS).*

Methods: *The BAI consisted of a scoring system that includes pain factors and stiffness estimation at the end of a series of five different lumbar movements of a patient standing in an erect position.*

Results: *The correlations between the separate outcomes and the BAI ranged from 0.61 to 0.76 ($P < 0.001$). The inter-observer reliability between two experienced observers for the 5 outcome scores was good (ICC > 0.86) and even perfect for the BAI (ICC = 0.96). A BAI change of one unit is able to exclude a measurement error. A significantly good correlation ($P < 0.001$) was found between the BAI at baseline, and the ODI ($R = 0.62$) and the MPQ-PRIT, as the total degree of pain rating index ($R = 0.57$), a moderate correlation with the MPQ-NWCT, as the total number of chosen adjectives from the whole list of adjectives ($R = 0.48$) and the VAS ($R = 0.47$), but a lower correlation was found with the MPQ-Quality of life index ($R = 0.43$). The effect size and discriminative ability of the measures were explored after two treatment sessions of deep transverse friction myotherapy by means of the study of the receiver operating characteristics curve (ROC) and the greatest area under the curve (AUC). The greatest level of distinction was found for the MPQ-PRI-T and the BAI (AUC > 0.93), followed by the ODI (AUC = 0.92). A lower level of distinction was found for the MPQ-NWC-T and the VAS (AUC > 0.82).*

Conclusions: *The Backache Index or BAI appears to be a reliable and valid assessment of overall restricted spinal movements in case of LBP and discriminates between successful and unsuccessful treatment outcome.*

Keywords:
Low back pain – outcome scales - reliability - validity – responsiveness- impairment – pain rating scales.

1. INTRODUCTION

In current clinical examinations of a patient with low back pain (LBP) and when the percentage of impairment in function of work-compensation procedures has to be estimated, the use of an inclinometer is recommended for measuring the amount of different lumbar movements. A review of the literature has revealed that the absolute lumbar active range of motion (AROM) scores were only of value in studying the biomechanical characteristics of the spinal column [1-8]. No evidence was found for a relationship between low back AROM and the assessed percentage of impairment.

Therefore it seemed illogical to evaluate impairment in chronic LBP patients using a spinal ROM model when aiming to measure or compensate disability [9]. In routine clinical practice a physical examination should include an assessment of ability/function. The use of a scale or index in low back pain is mainly used to categorize patients and to measure syndrome severity [10-11]. An ideal approach for the clinical evaluation of backache seems to be difficult to realize [5, 9-13], and individual pain rating during spinal movements can be accurate [14] or not depending on the patient's subjective report e.g. the visual analogue scale [4].

In order to fulfil the existing need for a reliable routine clinical examination scale in the follow-up of intradiscal electrothermal therapies and radiofrequency treatments [15], or musculoskeletal manipulations [16] and deep friction therapies [17], we have developed a new Backache Index (BAI).

The present study reports on an easy and quick to perform standardised measuring procedure of impairment in patients with back complaints without using inclinometers and which accounts for different clinical presentations. We added the factor of presence or absence of pain with respect to different lumbar movements, and this resulted in outcome scores for five impairment examinations of the trunk. The purpose of this study was to assess the reliability, the validity and the discriminative ability of the BAI as a new physical impairment "backache index".

2. METHODS

2.1 Subjects

Seventy-five patients with LBP symptoms in a pain centre (48% males) participated in this study. The following *inclusion criteria* were used for the patients with LBP: men and women between the ages of 20 and 75 years with subacute low back pain. *The exclusion criteria* were: acute ($\leq$ 3 weeks) and chronic ($\geq$ 12 weeks) low back pain and/or neuropathy (sciatica or severe root compression), use of medication, psychological treatment, pregnancy and the existence of any significant pathology (no reported abnormal spinal X-ray findings e.g. trauma, infection, inflammatory disorders). A cohort of 75 patients were consecutively assessed at baseline in order to verify the validity by means of correlation coefficients between the BAI and other baseline measures. Of this group, two separate sample subgroups were randomly formed per block of five subjects. The reliability was checked in sample one, a subgroup of 35 patients, during the first session by means of a subject retest after a few minutes of rest while sitting at ease.

The patients of the second subgroup (N=40) were reassessed at the 3rd week follow-up period. They received deep transverse friction myotherapy on both sides of the Erector spinae mass from T6 to L5 and the gluteal area for a total of 30 min. in each session. Because the purpose was not to assess treatment effectiveness, the detailed description is not relevant to this study. This group of patients was reassessed in the week after the last treatment session as a follow-up in order to verify the responsiveness through testing the discriminative ability of measures after two myotherapy sessions. Again, the same sequencing order and time schedule of both patients and observers was respected.

2.2. Measurements

All patients filled in the standard Oswestry LBP Disability Questionnaire validated Dutch version (ODQ) [18]. The Visual Analogue Scale (VAS in mm), was employed for both sample groups. The McGill Pain Questionnaire, Dutch Language Version (MPQ-DLV) [19, 20] was used with respect to the total group resulting in the calculation of the Quality of Life Index (MPQ-QLI). The total number of words chosen in the sensory, affective and evaluative subscales (MPQ-NWC-T) and the total pain-rating index (MPQ-PRI-T) were re-used only in the follow-up period (MPQ-short form).

Two manual therapists (observers A & B), with more than two years of experience in functional examinations of the trunk, took part in the study and were changed randomly in a sequential list order per five trial subjects. The observers were blinded to each other's scoring until data collection was completed. The tests consisted of 1 flexion test, both sides of lateral flexion and extension combined with both sides of lateral flexion. Each of the 5 active ROMs (guided by the observer) were actively performed by the patient, standing relaxed in an erect position. The observer made his assessment by means of a scoring system that includes pain factors obtained by asking the patient, and combined with the stiffness estimation at the end of the different lumbar motions.

In order to minimise the tension of the hamstrings, we asked the patient –if needed- to flexion the knee not more than 10°. The results were recorded on a special form on which the 4-point score per outcome was indicated. The observer noted down the scoring outcomes (points), and the sum of the 5 outcomes yields the "Backache Index" or BAI with a maximum of 15 points.

2.3 Statistic analysis

The Spearman's Test (Rho) was calculated to examine the bivariate correlation among the tests, between each test and the BAI, and the backache outcomes were calculated at baseline in function of their internal consistency. The overall correlation among the outcomes should be above 0.70 for an acceptable homogeneity but not higher than 0.90 showing a too important outcome value [21].

Sample one was studied for inter-observer reliability (absolute agreement definition) within two-way intra-class correlation coefficients (ICC) and their 95% confidence intervals (CI). In accordance with observer agreement for categorical data criteria, an ICC of $R < 0.40$ for scoring was defined as poor reliability, $0.40 \leq R \leq 0.75$ as fair to good reliability and $R > 0.75$ as excellent reliability [22-24]. The standard error of mean (SEM) and 95% CI as the minimum detectable change (MDC = 2.77 x SEM) of the backache outcomes scores at baseline were calculated as recommended by Beaton [25]. The backache score outcomes and

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Table 1
Characteristics of the total group patients with LBP (N = 75)

Measures	*Means & S.D.*
Height (cm)	171 ± 9
Weight (Kg)	74 ± 13
Age	42 ± 12
Gender (males-females (%)	48 - 52
Oswestry Disability Index	31 ± 11
Visual Analogue Scale	51 ± 24
MPQ-QLI	10.8 ± 3.3
MPQ-NWC-T	8.1 ± 2.3
MPQ-PRI-T	13.5 ± 5.1

index before and retesting after a few minutes, were compared with the 2-tailed Wilcoxon tests. The significance level has been fixed at alfa = 0.05.

The total group was studied for validity of the BAI using correlation coefficients (Spearman's rho) between the baseline BAI and other measurements e.g. ODQ sections and the ODI, the MPQ-QLI, the MPQ-PRI-T, the MPQ-NWC-T and the VAS.

Sample two was explored for the responsiveness after the retest in the 2nd week. We only used the MPQ short-form and calculated, with the aid of the MPQIN.EXE program of Van der Kloot & Vertommen [20], the MPQ-NWC-T and the MPQ-PRI-T outcomes.

The comparisons were made with the one-way ANOVA test between the measures at baseline and those in the follow-up period.

The effect sizes (general linear model: repeated measurements*)* were calculated [26] and the discriminative ability of the BAI was examined by calculating the receiver operating characteristics curve (ROC) and the greatest area under the curve (AUC) [27] for each of the five separate outcomes of lumbar impairment scoring and for the ODI, the VAS, the MPQ-PRI-T and the MPQ-NWC-T. The measurements may be viewed as diagnostic tests for discriminating between patients who improved and those who did not improve and, accordingly, can be described in terms of sensitivity and specificity in detecting improvement (yes/no) as established by another criteria of important change [27] . The true area for the null hypothesis = 0.05 and the asymptotic significance of AUC, standard error (S.E.) and the 95% confidence interval (CI) was calculated.

The statistical analyses were done using version 11.0.1 for Windows of the SPSS program (SPSS Inc. Headquarters, 233s, Wacker Drive, Chicago, Illinois 60606, USA).

3. RESULTS

Baseline outcome data in patients with LBP are expressed in Table 1. The mean BAI in patients with LBP (6.5 ± 2.8) showed a normal distribution and had a range of 1-12.

3.1 Construct validity

The bivariate correlations ranged from 0.21-0.64 among the 5 outcomes and from 0.61-0.76 between the separate outcomes and the BAI (*P < 0.001*) (Table 2).

Table 2
Correlation (Rho) between the separate backache outcomes and the BAI (Backache Index) in patients with LBP (N = 75).

Tests Outcomes	*Flexion*	*Left lateral flexion*	*Right lateral flexion*	*Extension & Left side bending*
Flexion	1.00			
Left lateral flexion	0.47**	1.00		
Right lateral flexion	0.21*	0.64**	1.00	
Extension & left side bending	0.43**	0.41**	0.23*	1.00
Extension & right side bending	0.33*	0.29*	0.40**	0.26*
BAI	0.76**	0.72**	0.62**	0.61**

The MDC (SEM x 2.77) for all 5 outcomes ranged from 0.23-0.37 and for the BAI the MDC = 0.90. These results indicate that a change in 1 point or unit on the BAI should be considered as the minimal clinically important change.

3.2 Reliability

There was no significant difference (P = 0.65) between the mean BAI of observer A (4.45 ± 2.4) and the results of retesting by observer B (4.35 ± 2.3). The *inter-observer (absolute) agreement* of all 5 outcomes between observer A and B retest (N = 20), was good and excellent for the BAI (Table 3.) with an ICC alfa = 0.955.

In order to test the interobserver reliability of the subgroup (N = 35), independently of the sequence of observers (absolute agreement), the ICC and CI of the ICC for each score and BAI were calculated.

There was no difference between the mean BAI and the retest after a few minutes (both BAI = 3.97). For all 5 outcome scores, the (absolute) agreement between the two *examinations* was perfect (ICC ≥ 0.86) and excellent for the BAI (ICC = 0.952) with an alfa-value = 0.951.

3.3 Validity

The validity of the BAI was explored by using Pearson's product correlation coefficients between the BAI and the other measures assessed at baseline e.g. pain sensitivity, pain descriptions and disability indexes (Table 4). A good and significant correlation was found between the BAI and the ODI (R = 0.62), followed by the MPQ-PRI-T (R = 0.57). The correlation between the BAI and the MPQ-NWC-T was significantly moderate (R = 0.48), less with the VAS (R = 0.46), but poor with the MPQ-QLI (R = 0.43).

3.4 Discriminative ability

The difference between the measures of LBP patients at baseline and the ones after being treated twice with myotherapy was evident: the ODI, VAS, MPQ-NWC-T and MPQ-PRI-T sections as well as the BAI decreased significantly (Wilcoxon-test, P < 0.001) in the 2nd week-retest (Table 5).

The effect sizes and the responsiveness figures of the BAI, calculated by means of the AUC, are expressed in Table 6. In this study both the MPQ-PRI-T, the ODI and the BAI had a better ability to distinguish patients who have progressed from those who remained stable than the MPQ-QLI, the MPQ-NWCT and the VAS.

Table 3
Inter-observer reliability (N = 20) ICC and 95% confidence interval (CI) of five tests and the BAI.

Baseline measurements	*ICC*	*95 % CI of ICC*
Flexion	0.94	0.84-0.97
Left lateral flexion	0.86	0.65-0.94
Right lateral flexion	1.00	-
Extension & left side bending	0.96	0.90-0.98
Extension & right side bending	0.95	0.88-0.98
BAI	0.96	0.89-0.98

Table 4
Bivariate correlations between the BAI, ODI, MPQ-indexes and the VAS at baseline in patients with LBP (N = 75)

Baseline measurements	*BAI*	*VAS*	*ODI*	*MPQ-QLI*	*MPQ-NWC-T*
Visual analogue scale	0.46*	1.00			
Oswestry Disability Index	0.62*	0.40*	1.00		
MPQ-QLI	0.43*	0.40*	0.60*	1.00	
MPQ-NWC-T	0.48*	0.41*	0.45*	0.52*	1.00
MPQ-PRI-T	0.57*	0.51*	0.57*	0.61*	0.89*

Table 5
Comparison of the measurements between baseline and a 2-week post-treatment follow-up period (N = 40).

Variables	*Baseline* *Mn & S.D.*	*p-values**	*Post treatment follow-up* *Mn & S.D.*
Flexion	1.3 ± 1.2	< 0.001	0
Left lateral flexion	0.8 ± 0.8	< 0.001	0.03 ± 0.2
Right lateral flexion	1.0 ± 0.9	< 0.001	0.1 ± 0.3
Extension & left side bending	2.1 ± 1.1	< 0.001	0.4 ± 0.7
Extension & right side bending	2.2 ± 1.2	< 0.001	0.5 ± 0.6
BAI	7.3 ± 3.0	< 0.001	2.5 ± 1.8
Oswestry Disability Index	35 ± 11	< 0.001	17 ± 7
Visual analogue scale	56 ± 23	< 0.001	29 ± 17
MPQ-QLI	10.8 ± 3.3	< 0.001	5.5 ± 2.0
MPQ-NWC-T	8.7 ± 2.6	< 0.001	5.8 ± 1.2
MPQ-PRI-T	15.4 ± 5.4	< 0.001	7.1 ± 1.9

Table 6.
Effect size (GLM, repeated measurements) and discriminative ability of measurements between baseline and a 2-week post-treatment follow-up period (N = 40): the receiver operating characteristics curve (ROC) & Area under the curve (AUC), standard error (S.E.), significance (sign.) and 95% CI (confidence interval)

Measurement	*Effect size*	*AUC*	*S.E.*	*Sign.*	*95% CI*
Oswestry Disability Index	0.86	0.92	0.03	P< 0.001	0.86 – 0.98
Visual analogue scale	0.74	0.82	0.05	P< 0.001	0.73 – 0.92
MPQ-QLI	0.74	0.87	0.04	P< 0.001	0.79 – 0.95
MPQ-NWC-T	0.64	0.83	0.05	P< 0.001	0.73 – 0.92
MPQ-PRI-T	0.76	0.93	0.03	P< 0.001	0.86 – 0.99
BAI*	0.82	0.91	0.03	P< 0.001	0.84 – 0.97
Flexion	0.62	0.81	0.05	P< 0.001	0.72 – 0.91
Left Lateral flexion	0.42	0.76	0.06	P< 0.001	0.65 – 0.87
Right Lateral flexion	0.51	0.79	0.05	P< 0.001	0.69 – 0.89
Extension & left side bending	0.63	0.77	0.05	P< 0.001	0.67 – 0.87
Extension & right side bending	0.82	0.85	0.04	P< 0.001	0.77 – 0.94

For the expression of the cut-off results for each of the scores, the sensitivity is taken to be 100 %. In our study, the cut-off point for the ODI with 7 points, and the VAS with 6.5 mm, and for the MPQ-PRI-T with 4.5 points, and for the MPQ-NWC-T with 3.5 points, gives an overall specificity equal to 98%. The cut-off point for the BAI with 1.0 point gives a specificity equal to 76%.

4. DISCUSSION

The construct validity demonstrated correlations within each of the separate outcome scores and contributed sufficiently to the total Backache Index. The overall correlation among the 5 outcomes and the BAI showed sufficient homogeneity and is acceptable as an index for clinical examinations of patients with LBP. As mentioned in the studies of Patrick [27] and Strand [28], it is indicated that sufficient items examining the same impairment concept should be included in a scale to obtain an acceptably high coefficient Alfa. In our study the good consistency of the BAI was proved and represented a sufficient index construction.

For all 5 outcome scores, the MDC did not exceed 0.90 points, which means that the precision of the scoring of the backache outcomes was less than 1 point, as required.

The inter-observer reliability with respect to the 5 backache outcome scores after a few minutes of rest between two (blinded) experienced observers showed a high reliability. In our study the inter-observer ICC of the BAI between observer A and retesting by observer B, was excellent (R = 0.96). The inter-observer test of the BAI *for the whole group* was also perfect (R = 0.95).

The validity of the BAI was explored through correlations with other measures of pain e.g. the VAS and disability indexes as a result of questionnaires e.g. standard MPQ-DLV and ODQ. Some other clinical examination procedures however have reached an acceptable level of reliability and validity such as the Physical Impairment Index (PII) as described in the study of Fritz et al. [29]. The correlation in this study was found to be good between the BAI and the MPQ-PRI-T and the ODI but relatively weak with the MPQ-QLI. The BAI in our study correlated better with the ODI in case of patients with subacute LBP (N = 75, ICC = 0.62, $P < 0.001$), than when compared with the PII [29] in case of patients with acute LBP (N = 78, ICC = 0.43, $P < 0.001$).

The ability to detect changes in pain rating, disability and assessment of lumbar impairment, between baseline variables and after 2 myotherapy sessions over 2 weeks, was detected by means of the ROC curve and calculating the AUC. In this study the responsiveness of the BAI was nearly equal to that of the MPQ-PRI-T and the ODI, but was much better than the MPQ-NWC-T and the VAS. With the exception of MPQ-NWCT, our findings do not confirm the results of earlier studies [30,31] concluding that the VAS was more responsive to clinical change than the MPQ subscales in a rehabilitation retest procedure. In our study, the BAI (AUC = 0.91) showed a nearly equal effect size and responsiveness as the ODI (AUC = 0.92). In the study of Fritz [5] the ODI (AUC = 0.96) was more responsive than the PII (AUC = 0.88).

The precision of the BAI was found in the minimal clinical change value (MDC = 0.90) and, in combination with the best cut-off values of responsiveness found in the study, it has been proposed that the *minimal clinically important difference* should be *equal or more than 1 point.*

In the serial of BPS and PII physical impairment tests, the patient with LBP has to change a lot of times of position, while in our BAI method the patient can stand easily in only one position: the erect position and the tests are not complicated for the subject to be executed. Our tests are more reliable, correlates higher with LBP-questionnaires & VAS and are much quicker to perform for the examiner & patient. In fact the BPS and PII takes each minimum 5 minutes, while our BAI method only a minimum of 1 min is normally needed. The cited BPS and PII are also examined for the relationship between the golden standard questionnaires and pain scales. When our BAI method correlates higher with those other standards and even the responsiveness is nearly equal to that of the ODQ, proves the validity of it.

Examining a patient following the BAI method is easier to perform for the patient than each time filling in questionnaire (which takes also a 5 min of time). Although not all aspects (emotional and or psycho-social pain related items) of the lower back pain are covered by the BAI, it can be used as a guideline for treatment in clinical practice.

The new index appears to be easy, quick to apply, reliable and measures the pain and mobility outcome as an assessment score of physical impairment in patients with low back pain. Although the efficiency of this new method in

routine clinical practice has turned out to be promising, further research with a greater range of subjects, observers and other pain evaluation methods should be carried out.

5. CONCLUSION

The applied original impairment examination outcomes and Backache Index (BAI) used in case of patients with low back pain was based on a set of functional examinations of the trunk in an erect position by scoring pain intensity rather than measuring the absolute range of motion.

The (blinded) inter-observer reliability after a few minutes for the BAI was sufficient.

The validity of the BAI was found to be good with the Oswestry LBP Disability Index (ODI) and moderate with the Visual Analogue Scale (VAS).

The greatest discriminative ability of the measures were found for the McGill Pain questionnaire (MPQ) pain ratings and the BAI, followed by the ODI. In this study a lower level of distinction was found for the MPQ evaluative subscales and the VAS. A Backache Index change of one unit is able to exclude a measurement error.

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