The Bath Indices

Outcome Measures for use with Ankylosing Spondylitis Patients

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<u>The Bath Indices.</u> Outcome Measures for use with Ankylosing Spondylitis Patients

A synopsis of the creation of the Bath Indices and the research investigating the effectiveness of them.

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INTRODUCTION

This booklet provides a synopsis of the Bath AS Metrology Index (BASMI), the Bath AS Functional Index (BASFI), the Bath AS Disease Activity Index (BASDAI) and the Bath AS Patient Global Score (BAS-G). The creation of the Bath indices stem from the work of a research team consisting of rheumatologists, physiotherapists, and research associates with a specialist interest in AS. With respect to the functional and disease activity indices, the team obtained input from patients with AS. It was felt that such input heightens the clinical relevance of such measures. All indices produce a score out of 10, giving a clear numerical outcome each time the indices are used, therefore providing an easy comparable to refer to.

All four indices have been studied for reliability, speed, variability, reproducibility, and sensitivity to change. The studies involved a good sample size of between 163 and 392 subjects, some of which were in patients undergoing an intensive course of physiotherapy for 2 to 3 weeks. Comparables were made with the original metrology assessment of 20 measurements, the Dougados functional index, the previous Bath disease activity index and the Newcastle Enthesis Index. The results of this research are summarised in this booklet. For more detail, the reader is encouraged to refer to the original articles that are referenced at the back of this booklet.

With the recent licensing of anti-TNF medication for use in AS patients, the Bath Indices (in particular the BASDAI) are being proposed to form part of the screening process for anti-TNF allocation and to monitor the outcomes of the medication. Therefore, it is important that individuals standardise methods used for calculating these Bath Indices' scores. To aid this, a guide in calculating each score is provided within this booklet.

THE BATH AS METROLOGY INDEX (BASMI)

(Jenkinson et al, 1994)

In considering metrology, the aim of the research team was

"to determine the minimum number of clinically appropriate measurements that assess accurately axial status and from these derive a metrology index (BASMI) to define clinically significant changes in spinal movement."

(Jenkinson et al, 1994, p1694).

Axial status was regarded as cervical, dorsal and lumbar spine, hips and pelvic soft tissue.

Following a literature review, 5 simple clinical measurements were included in the index:

- 1) cervical rotation
- 2) tragus to wall distance
- 3) lumbar side flexion
- 4) modified Schober's
- 5) intermalleolar distance

For cervical rotation, lumbar side flexion and tragus to wall, a mean of the left and right measurements are taken. A guide in how to obtain these measurements is given in table one on page 8. There are two tables available for calculating BASMI scores from these measurements; these are explained on pages 9 & 10 of this booklet. The higher the BASMI score the more severe the patient's limitation of movement due to their AS.

By applying a similar scoring system to the original 20-measurement metrology index, the research team was able to compare the two indices. A statistically significant correlation (p<0.001) between the BASMI and the 20-measurement index was shown on 2 occasions (Jenkinson et al, 1994). At the same level of significance (p<0.001), the BASMI also proved to be accurate and reproducible for both inter- and intra- observer variability (Jenkinson et al, 1994).

With a sample of 56 patients undergoing 3 weeks inpatient treatment, the sensitivity of the index to change was found to be significant (p<0.01) regardless of the disease severity (Jenkinson et al, 1994). The mean improvement in measurements was 30% in 71% of the patients. Unfortunately this was not compared with the original 20-measurement index.

These results show that the BASMI is comparable with the original 20 measurements, it is accurate and reproducible, and it is sensitive to change. The BASMI is also quick and easy to apply – taking only 7 minutes.

THE BATH AS FUNCTIONAL INDEX (BASFI)

(Calin et al, 1994)

The BASFI is a set of 10 questions designed to determine the degree of functional limitation in those with AS. The research team recognised that although treatment is focused on pain control and the improvement of function, the available methods of assessing function were not specific to AS and were inadequately validated. The team also state that:

"after pain and stiffness, one of the most important complaints of patients with AS is disability."

(Calin et al, 1994, p2281).

The ten questions were chosen with a major input from patients with AS. The first 8 questions consider activities related to functional anatomy. The final 2 questions assess the patients' ability to cope with everyday life.

A 10cm visual analog scale is used to answer the questions (refer to page 11). The authors believe that this improves both the sensitivity of the index to change and its capacity to elicit a range of responses across the entire scale (Calin et al, 1994). The mean of the ten scales gives the BASFI score – a value between 0 and 10.

Using a sample of 47 inpatients and 116 outpatients, the authors compared the BASFI with the Dougados functional index. Results showed:

- 1) BASFI and Dougados took an equivalent amount of time to complete (100 secs max.).
- 2) Subjects expressed no preference for either instrument.
- 3) The BASFI scores illustrated a better distribution 0 to 9.5 compared with 0 to 6.5 for Dougados.
- 4) The reproducibility of both scores was statistically significant (p<0.001).
- 5) Inter-observer reliability was statistically significant (p<0.001) for both scores.
- 6) Over a 3 week treatment period:
 - the BASFI scores demonstrated a significant (p=0.004) 19.6% improvement
 - however the 5.9% improvement in the Dougados scores was insignificant.

(Calin et al, 1994).

Results 3 and 6 demonstrate the benefits of the BASFI over the Dougados index. "The BASFI scores produced a normal distribution which covered 95% of the total scale whereas the Dougados functional index used only 65% of the total range" (Calin et al, 1994, 2285). Perhaps this can be explained through the use of the visual analog scale. The Dougados index only gives patients three choices of answer to the question "can you?" of the 20 activities listed. The choices being:

- "Yes, with no difficulty"
- "Yes, but with difficulty"
- "No"

The middle option (yes, but with difficulty) is very vague and does not distinguish between minor and major degrees of difficulty. A visual analog scale accommodates a broader range of possible answers with greater ease, and therefore gives a better representation of the assessed population. The use of the visual analog scale can also explain the greater degree of sensitivity to change shown by the BASFI. A scale allows for smaller changes to be identified than the 3 choice answer system.

Ruof et al (1999) have compared the responsiveness of BASFI, the Dougados Functional Index and the AS specific version of the Health Assessment Questionnaire. They conducted a double-blind, placebo-controlled study. 174 patients were included and received either a placebo, vitamin E or diclofenac. The authors found BASFI to be more responsive than either of the other two indices for both improvements and deterioration. The authors suggested that this is because the BASFI demonstrates a better baseline distribution pattern and the visual analog scale allows for greater sensitivity. This supports the findings of Calin et al (1994).

To conclude, the BASFI is quick, easy, reliable and sensitive to change across the whole disease spectrum (Calin et al, 1994).

THE BATH AS DISEASE ACTIVITY INDEX (BASDAI)

(Garrett et al, 1994)

The research team identified that no gold standard was available for measuring disease activity in AS. The authors acknowledged research, from the Royal National Hospital for the Rheumatic diseases, that identified fatigue as a major component of AS. It was therefore suggested that this should be incorporated into measures of disease activity. The BASDAI was subsequently developed. As with the functional index, the research team included major input from patients with AS, to enhance clinical relevance and disease specifity.

Like the BASFI, the BASDAI consists of 10cm visual analog scales used to answer 6 questions pertaining to the 5 major symptoms of AS:

- Fatigue
- Spinal pain
- Joint pain / swelling
- Areas of localized tenderness
- Morning stiffness.

To give each symptom equal weighting, the mean of the two scores relating to morning stiffness is taken. The resulting 0 to 50 score is divided by 5 to give a final 0 - 10 BASDAI score (refer to page 12).

When clinically tested, results showed:

- 1) BASDAI to be a quick and simple index (taking between 30 secs and 2 mins to complete)
- 2) BASDAI demonstrated statistically significant (p<0.001) reliability.
- 3) The individual symptoms and the index as a whole demonstrated good score distribution, using 95% of the scale.
- Following a 3 week physiotherapy course, the BASDAI showed a significant (p=0.009) 16.4% score improvement, therefore demonstrating a sensitivity to change.

(Garrett et al, 1994).

By comparison, a previous disease activity index did demonstrate greater sensitivity to change (22.8% improvement being shown) (Garrett et al, 1994). However, the authors recognised that the previous index had a bias towards pain and included a scale measuring patient's sense of well being. It is felt that the BASDAI is superior in terms of symptoms considered and their weighting. This may be due to the input from patients with AS when the index was developed. The BASDAI was also found to be superior in all aspects to the Newcastle Enthesis index (Garrett et al, 1994).

Calin et al (1999) have further assessed the validity of the BASDAI. With a sample size of 473, a double-blind, placebo-controlled study of 6 weeks duration was conducted. Subjects were divided into two groups. One group received a placebo. The other group received an active NSAID. Disease activity was assessed with the BASDAI and by analysing a wide range of individual symptom components. The authors concluded that BASDAI has excellent content validity.

The BASFI and BASDAI have also been translated into Swedish for use in Sweden. Cronstedt et al (1999) and Waldner et al (1999) have assessed the Swedish version of these two indices. In agreement with the studies at Bath, the Swedish versions of the BASFI and BASDAI proved to be reliable, valid, and sensitive to change following a course of inpatient therapy.

To conclude, the BASDAI is user friendly, highly reliable, reflects the entire spectrum of the disease, and is sensitive to clinical changes (Garrett et al, 1994).

THE BATH AS PATIENT GLOBAL SCORE (BAS-G)

(Jones et al, 1996)

The BAS-G is essentially an objective way of asking the question:

"How have you been over the last x months?"

Jones et al (1996) argue that the BAS-G reflects the effect of AS on the patients well being.

The BAS-G consists of two questions which ask patients' to indicate, on a 10cm visual analog scale, the effect the disease has had on their well being over the

- last week
- last six months.

The mean of the two scores gives a BAS-G score of 0 - 10 (refer to page 13). The higher the score, the greater the perceived effect of the disease on the patient's well being.

With a sample of 177 inpatients and 215 patients reached by a postal survey, the authors found that:

- 1) BAS-G scores covered the whole 0 10 scale for both time frames (1 week & 6 months).
- BAS-G correlated well with both BASDAI and BASFI. This suggests that disease activity and functional ability play a major role in patients' well being – more than metrology.
- 3) Of the 5 BASDAI items, spinal pain followed by fatigue correlated best with BAS-G. This highlights the importance of pain and fatigue to the patient.
- 4) BAS-G demonstrated statistically significant (p<0.001) sensitivity to change.

(Jones et al, 1996).

The authors acknowledged that BAS-G cannot stand alone, and should be one element of a complete assessment. However, an index of this type provides a numerical value to the patient's sense of well being. This allows for comparison between consultations, especially when patients may not necessarily be seen by the same clinician on each occasion.

The authors conclude that they have formalized and validated a simple question frequently asked (Jones et al, 1996).

Table One: A Guide to Obtaining the BASMI Measurements

(Adapted by AStretch members from Jenkinson et al, 1994)

The following table is a guide for clinicians in how to obtain the five BASMI measurements in a standardised fashion. It is recognised that this represents an 'ideal' scenario that may need adapting depending on the patient's individual posture / circumstances. However, it is recommended that any changes be carefully documented to enable measurements to be reproducible. With all measurements, the patient should be comfortable and suitably undressed.

Measure	Starting Position	Method	Notes
Lumber Side Flexion	Standing bare feet; back to wall; knees straight; scapulae, buttocks, heels against wall; shoulders level; outer edges of feet 30cm apart & feet parallel.	Before any movement occurs, keeping arms, wrist & fingers straight, measure from tip of middle finger to floor. With palms placed on lateral aspect of thighs, patient reaches towards floor by side flexing. Re-measure from tip of middle finger to floor. Difference between 2 measurements represents amount side flexion. Repeat on other side.	Ensure patient keeps arms, fingers & knees straight and heels on floor. Ensure any forward flexion, extension or rotation of the trunk is avoided. Best to use a wall without a skirting board. May need to accommodate a leg length discrepancy with block under foot.
Tragus to Wall	Maintain same starting position as above. Ensure head in as neutral position (anatomical alignment) as possible.	Patient draws chin in as far as possible (retraction). With both eyes open and side of face against wall, examiner measures the distance between the tragus of the ear & the wall, using a rigid ruler.	Ensure no cervical extension, rotation, flexion or side flexion occurs. Best to use a wall without a skirting board. Ensure retraction is maintained whilst both sides are measured.
Lumbar Flexion (modified Schober's)	Standing with outer edges of bare feet 30cm apart and feet in line. Examiner marks a point midway along a line level with the iliac crests (at the L4/5 junction). A second point is marked 10cm above this & a third 5cm below the first to give a 15cm line.	Patient flexes forward from the waist with knees fully extended. The distance between the upper and lower 2 marks is measured. Any increase beyond 15cm represents the amount of movement achieved.	At the end of the movement, you may choose to allow slight knee flexion to decrease influence of hamstrings. This should be documented.
Intermalleolar Distance	Patient lies supine on the floor or a wide plinth. Knees in extension.	Keeping knees straight & legs in contact with the resting surface, patient is asked to take legs as far apart as possible. Distance between the medial malleoli is measured.	Measure quickly as movement can be painful. Be ready to measure before asking patient to achieve movement.
Cervical Rotation	Patient supine on plinth. Forehead horizontal & head in neutral position. May need to use pillow, books or foam block to achieve this. Carefully document to ensure same set up on future re-assessments.	Use goniometer / inclinometer as per manufacturers instructions. Patient rotates his/her head as far as possible, keeping shoulders still. Measure both sides.	Ensure no neck flexion / side flexion occurs. If good ROM may need to lie near edge of bed to allow movement to occur.

Tables two and three: Calculating the scores for each of the BASMI measurements

As previously mentioned, there are two tables available for calculating the BASMI scores from the measurements obtained. The first table shown below (table two) is that used in the original documentation for the BASMI (Jenkinson et al, 1994). The second (table three) has since been developed at Bath and is an expansion on the first. For both tables the measurement obtained is found along the appropriate row and the column in which it falls provides the score. For example, a mean cervical rotation measurement of 30 degrees would give a score of 1 in table two and a score of 7 in table three. Clinicians must be consistent in which table they choose to use – this should be documented.

Table Two

	Mild	Moderate	Severe	
	0	1	2	
Cervical rotation (Mean of L & R)	> 70 degrees	20 –70 degrees	< 20 degrees	
Tragus to wall (Mean of L & R)	< 15cm	15 – 30 cm	> 30 cm	
Lumbar side flexion (Mean of L & R)	> 10cm	5 – 10 cm	< 5 cm	
Lumbar flexion (modified schobers)	> 4 cm	2 – 4 cm	< 2 cm	
Intermalleolar distance	> 100cm	70 – 100 cm	< 70 cm	

Add the 0, 1, 2 scores for each of the five measurements using the table above (the mean for cervical spine rotation counting as one score and similarly for tragus to wall & lumbar spine side flexion). This will provide you with a figure out of 10. This is the BASMI score. The higher the BASMI score the more severe the patient's limitation of movement due to their AS.

Table Three

	0	1	2	3	4	5	6	7	8	9	10
Tragus to	≤	10–	13–	16-	19–	22-	25-	28-	31-	34-	≥
wall (cm)	10	12.9	15.9	18,9	21.9	24.9	27.9	30.9	33.9	36.9	37
Lumbar Flexion (cm)	≥ 7.0	6.4- 7.0	5.7- 6.3	5.0- 5.6	4.3- 4.9	3.6- 4.2	2.9- 3.5	2.2- 2.8	1.5- 2.1	0.8- 1.4	≤ 0.7
Intermalleolar	≥	110-	100-	90-	80-	70-	60-	50-	40-	30-	≤
distance (cm)	120	119.9	109.9	99.9	89.9	79.9	69.9	59.9	49.9	39.9	30
Cervical Rotation (degrees)	≥ 85	76,6- 85	68,1- 76.5	59,6- 68	51.1- 59.5	42.6- 51	34.1- 42.5	25.6- 34	17.1- 25.5	8.6- 17	≤ 8.5
Lumbar Side	≥	18-	15.9-	13.8-	11.7-	9.6-	7.5-	5.4-	3.3-	1.2-	≤
Flexion (cm)	20	20	17.9	15.8	13.7	11.6	9.5	7.4	5.3	3.2	1.2

For cervical spine rotation, tragus to wall and lumbar spine flexion, take the mean of the left and right measurements. Add together the scores for each measurement. This will provide you with a figure out of 50. Divide this by 5 to give you the BASMI score. The higher the BASMI score the more severe the patient's limitation of movement due to their AS.

The Bath Ankylosing Spondylitis Functional Index (BASFI)

Please draw a mark on each line below to indicate your level of ability with each of the following activities during the *past month*

HOW	DO YOU FIND:	score out of 10
1	Putting on your socks or tights without help or aids (eg sock aid)?	
	EASY	IMPOSSIBLE
2	Bending forward from the waist to pick up a pen from the floor witho	ut an aid?
	EASY	IMPOSSIBLE
3	Reaching up to a high shelf without help or aids (eg Helping Hand)?	
	EASY	IMPOSSIBLE
4	Getting out of an arm-less dining chair without using your hands or a	ny help?
	EASY	IMPOSSIBLE
5	Getting up off the floor - without help - from lying on your back?	
	EASY	IMPOSSIBLE
6	Standing unsupported for ten minutes without discomfort?	
	EASY	IMPOSSIBLE
7	Climbing 12-15 steps without using a handrail or walking aid (one for	ot on each step)?
	EASY	IMPOSSIBLE
8	Looking over your shoulder without turning your body?	
	EASY	IMPOSSIBLE
9	Doing physically demanding activities (eg physio exercises, gardening	s, sport)?
	EASY	IMPOSSIBLE
10	Doing a full day's activities at home or at work?	
	EASY	IMPOSSIBLE
	ΤΟ	TAL OUT OF 100
	TOTAL / 10	D (BASFI SCORE)

The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

a If you are currently taking medication for your AS, please give the name and dose that is on the bottle/packet.

b Please mark on the line below to indicate the effectiveness of the medication in relieving your symptoms.

NO EFFECT VERY EFFECTIVE

Please draw a mark on each line below to indicate your level of ability with each of the following activities during the <u>past week</u>

SCORE/10

1	How would you describe the overall level of fatigue/tiredness you have experienced?							
	NONE					- VERY SEVERE		
2	How would you describe the overall level of AS neck, back or hip pain you have had?							
	NONE					- VERY SEVERE		
3	How would you describe the overall level of pain/swelling in joints other than neck, back or hips you have had?							
	NONE					- VERY SEVERE		
4	How would you describe the overall level of discomfort you have had from any areas tender to touch or pressure?							
	NONE					- VERY SEVERE		
5	How would you describe the overall level of discomfort you have had from the time you wake up?							
	NONE					- VERY SEVERE		
6	How long does your morning stiffness last from the time you wake up?							
	(0	1/2	1	11⁄2	2 or more hours		
						MEAN OF 5 & 6		
	TOTAL OF 1 TO 4 ADDED TO MEAN OF 5 & 6 (TOTAL OUT OF 50)							
					TOTAL	. / 5 (BASDAI SCORE)		

The Bath Ankylosing Spondylitis Global Score (BAS-G)

How have you been over the last week?	VERY BAD	
How have you been over the last six months?	12.00 20.5	
VERY GOOD	VERY BAD	
	TOTAL OUT OF 20	
	TOTAL / 2 (BAS-G SCORE)	

BASFI Score Calculation

Score from all questions are calculated using a ruler and added. This figure is divided by 10 to obtain an average. This is the BASFI score. The higher the BASFI score, the more severe the patient's limitation of function due to their AS.

BASDAI Score Calculation

Score from all questions are calculated using a ruler. The mean measurement (score) of questions 5 and 6 is added to the scores from questions 1 to 4. This total is then divided by 5 to give the average. This is the BASDAI score. The higher the BASDAI score, the more severe the patients disability due to their AS.

BAS-G Score

Scores from the 2 questions are calculated using a ruler and added. This figure is divided by 2 to obtain an average, this is the BAS-G score. The higher the BAS-G score, the more severe the effect of AS on the patient's life.

Please Note:

When using visual analog scales of a set length (10cm in the case of the Bath Indices), great care must be taken in reproducing assessment paperwork as repeated photocopying, for example, may distort the length of the lines and therefore will affect the accuracy of the scoring.

TOTAL / 10

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