SPONTANEOUS AMBULATORY ACTIVITY AS A QUANTIFIABLE OUTCOME MEASURE FOR OSTEOARTHRITIS OF THE KNEE

D. J. WALKER, P. S. HESLOP, L. J. KAY and C. CHANDLER*

Musculoskeletal Unit, Freeman Hospital, Newcastle and *University of Northumbria at Newcastle

SUMMARY

Objective. Quantifiable outcome measures for disabling diseases such as osteoarthritis (OA) of the knee are necessary if we are to compare the benefits of different interventions. This is becoming ever more important when the expenditure of financial resources has to be justified and the best way of spending money identified. Quantifying the benefit of an intervention is, therefore, important.

Current methods that are used to assess interventions vary from subjective assessments, such as patient and physician opinion, through structured questionnaires and assessments of pain, to objective tests such as X-rays, which have a subjective element in their interpretation. These methods produce results that are ordinal, but not interval. A result that is numerically twice another is not necessarily twice as bad, or good. As such, they are not ideal to quantify improvement.

Spontaneous ambulatory activity can now be measured using the Numact monitor [1]. Early studies have shown it to be applicable in arthritic patients [2] and to be sensitive to change of condition [3]. The data are objective and relevant to the patient’s normal circumstances. The data produced are interval in that 100 steps are twice as many as 50, and so quantification is possible. The relationship between ambulatory activity and disability needed to be defined.

We sought to test the validity of monitoring spontaneous ambulatory activity as an assessment of OA of the knee. We chose OA of the knee because it is an identifiable condition that can occur in isolation, affects mobility and is not complicated by the systemic effects of inflammatory arthritis.

METHODS

Two populations were used for this study. Population 1 comprised 29 patients attending hospital with OA of the knee, confirmed radiologically, and thought suitable for trial with anti-inflammatory medication. Population 2 comprised 28 patients with OA of the knee awaiting total knee replacement. For both populations, the knee under study had to be the most symptomatic joint and, therefore, the joint that most limited activity. The objective and subjective data were collected on these subjects on the same day as the 24 h activity recordings were taken.

Patient and physician opinions of condition, and X-ray grade, were collected on all patients. Analogue pain scale, night pain score and OA severity index were collected for population 1. For population 2, data were collected using the Nottingham Health Profile (NHP) [4] in place of this.

Spontaneous ambulatory activity was recorded using the Numact monitor. This logs posture (sit, stand, lie) and counts the number and vigour of steps. It logs the data in real time over 24 h periods. This is described in detail elsewhere [1]. It uses tilt switches to deduce posture and a chest-mounted accelerometer to count the number and vigour of the steps. The general layout is shown in Fig. 1. The monitor has been validated against observation [1]. The summary result used in this study was total ambulatory energy expenditure (number of steps x average amplitude of steps) over 24 h.

Submitted 11 August 1997; revised version accepted 12 May 1998.

Correspondence to: D. Walker, Department of Rheumatology, Freeman Hospital, High Heaton, Newcastle-upon-Tyne NE7 7DN.

© 1998 British Society for Rheumatology
Subjective data on the patient's condition were collected on five-point scales of patients' and physicians' opinions.

Pain was measured using a 10 cm visual analogue scale and a four-point scale for night pain.

Questionnaire data on disability were collected using the Osteoarthritis Severity Index (OSI) [5]. This is a structured questionnaire for symptoms and activities, validated in OA.

X-rays were graded by comparison with the standard films of Kellgren. This is a five-point scale [6]. In addition, joint space was measured 1 cm medial to the medial tibial spine and 1 cm lateral to the lateral tibial spine on A-P films.

Statistical analysis
Correlations were tested using Spearman rho correlations.

RESULTS

Face validity
It is logical that a disabled person will be less physically active than a non-disabled person. If the disability is caused by arthritis, then they will get worse symptoms when active compared to being at rest. They are likely, therefore, to spend more time at rest and to move more slowly.

It is equally logical that if the disability is reduced, as with effective treatment, then the person will, on average, be more active. Monitoring ambulatory activity will sample this activity and has face validity.

Construct validity
This is shown by comparison with current measures. As there is no gold standard, this comparison has to be with several currently favoured measures.

Correlation between the total energy usage and patients' opinion of their condition was \( r = 0.2 \) \( [P = \text{not significant (NS)}] \). For physicians' opinion of their condition, it was \( r = 0.4 \) \( (P < 0.005) \). Visual analogue pain scale and night pain score did not correlate with the 24 h activity \( r = 0.01 \) and neither did the OSI \( (r = -0.29) \).

Correlations between the various scales of the NHP and 24 h activity are shown in Table I. As can be seen, the best correlation was with poor sleep \( r = 0.33, \ P < 0.05 \). Surprisingly, there was no correlation with the mobility scale \( (r = -0.15) \) or with the pain scale \( (r = -0.13) \). There was no correlation with other scales.

Correlation between 24 h activity and X-ray grade is shown in Fig. 2, and was significant at \( r = -0.45 \) \( (P < 0.05) \). Correlation with medial joint space was positive and just significant \( (r = 0.3, \ P < 0.05) \), but was greater with lateral joint space \( (r = 0.5, \ P < 0.05) \).

Discriminant validity
Comparison of 24 h ambulatory activity between the OA patients recruited to anti-inflammatory studies and those who where awaiting joint replacement is shown in Fig. 3. The non-steroidal anti-inflammatory drug (NSAID) patients were significantly more active than the pre-replacement group \( (P = 0.002) \). This amounted to them being, on average, 69% more active. It is,

<table>
<thead>
<tr>
<th>TABLE I</th>
<th>Numact energy correlated with NHP (n = 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>Pain</td>
</tr>
<tr>
<td>( r )</td>
<td>0.103</td>
</tr>
<tr>
<td>( P )</td>
<td>NS</td>
</tr>
</tbody>
</table>

Fig. 2.—Correlation of X-ray grade with ambulatory energy \( (r = 0.4, \ P = <0.01) \).

Fig. 1.—The Activity Monitor as worn (Inset: The Numact monitor).
Spontaneous ambulatory activity therefore has some construct validity. It is also able to detect differences between mild and severe disease. The differences represent quantifiable changes in ambulation that are of relevance to the patient.

Spontaneous activity will be affected by many influences. People will do what they need or wish to do, provided that they are able. Despite the possible variation, validity in relation to disability has been demonstrated. This indicates that ability is a major factor determining activity in this population. In testing interventions with this machine, studies should be crossover in design. In this situation, wish and need will largely be controlled for, and it will be ability that is being tested.

The Numact monitor has the advantage over other accelerometer-based devices in that the use of position sensors allows the activity to be more clearly related to ambulation. The accelerometer is only sampled in this situation, wish and need will largely be controlled for, and it will be ability that is being tested. Therefore, possible to discriminate between these different populations on the basis of their activity.

**DISCUSSION**

We have tested the monitoring of spontaneous ambulatory activity against outcome measures currently used by researchers and the drug industry for assessing OA of the knee. There are many other possible assessments that we could have used, but we have used an example of most types. These were: subjective opinions, visual analogue scales, structured questionnaires, combinations and objective X-rays.

Correlations of ambulatory activity are higher with the more objective measures (physician > patient opinion, X-ray > questionnaire or pain). The difference between the correlations of activity with patients’ and physicians’ opinions is interesting. When asked about their condition, patients are likely to judge it in the context of how they usually are. They will have adapted to and allowed for their usual condition, and will report changes. The physician, on the other hand, will judge the patient’s condition according to their wider, if less deep, experience of patients with arthritis. It would, therefore, be expected that ambulatory activity would correlate better with the physician’s more global view. This proved to be the case.

Patients with OA of the knee are usually in little pain at rest and more pain on activity. Some correlation between measures of pain and activity would therefore be expected. It may be that pain questions relating to pain on activity would have increased the correlations. More surprising is the lack of correlation with the mobility scale of the NHP. This is in contrast to our findings in a smaller previous study including RA sufferers [7]. This may relate to the narrow range of severe disease included in this study and variation in patient expectation from their impending surgery.

The correlation with X-rays was stronger, but, as with clinical experience, leaves room for disagreement between the clinical and radiological assessments.

**REFERENCES**