Assessment of Patient Functional Status after Surgery

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BACKGROUND: Improvement in day-to-day functioning is a valued outcome of surgical intervention. A new functional status assessment instrument, the Activities Assessment Scale (AAS), was designed for a randomized clinical trial evaluating laparoscopic versus open hernia repair procedures.

STUDY DESIGN: The study data set included 2,164 patients at baseline and 1,562 patients at 3-month followup. Only male patients were enrolled in the trial. The psychometric characteristics of the AAS were examined in statistical analyses of cross-sectional and longitudinal data from the trial. Correlational analyses, factor analyses, and t-tests were used to evaluate scale performance.

RESULTS: We found that the AAS was a reliable measure (Cronbach’s Coefficient Alpha = 0.85) in the patient population studied. Factor analyses identified three subscales (sedentary activities; ambulatory activities; work and exercise activities). Construct validity was demonstrated by a correlation of 0.65 between the AAS and the physical functioning (PF) dimension of the SF-36 (p < 0.001); comparisons between clinical subgroups further confirmed its validity (p < 0.001). Patients reporting improvement on the physical functioning dimension after surgery showed an effect size of 1.20 for preoperative-postoperative change in their AAS scores.

CONCLUSIONS: The AAS has been demonstrated to be a reliable, valid, and clinically responsive instrument that can be used to evaluate patient functioning after hernia surgery. It is easy to administer and requires less than 5 minutes of patient time to complete. This measurement system may prove useful in assessing surgical outcomes in both research and office practice settings. (J Am Coll Surg 2005;201:171–178. © 2005 by the American College of Surgeons)

The effects of treatment procedures on day-to-day functioning and quality of life have been studied by medical and surgical investigators during the past 2 decades, and Ellwood’s vision of a “technology of patient experience” is being realized in many specialty areas. These patient-reported outcomes measures complement and extend traditional indicators such as perioperative morbidity and mortality. Rather than simply reporting the presence or absence of a symptom or describing treatment effects in qualitative terms, it is now possible to quantify and track objective measures, such as complication rates, and subjective phenomena, such as perceived levels of pain, between and within patients over time. Both generic and disease-specific self-report measures are increasingly used in tandem to assess the full range of outcomes in clinical research studies. Patient-reported data have been collected in trials of general surgical procedures, and a number of instruments have been created or adapted for assessment of orthopaedic surgical interventions.

We describe the conceptual and methodologic foundations for the Activity Assessment Scale (AAS), a new measure of functional status, and report the results of reliability, validity, and clinical responsiveness analyses for the scale in this article. In a related article, we de-
scribed development of a set of visual analog pain measures, the Surgical Pain Scales (SPS). These instruments were constructed to assess patient-level outcomes in a multicenter randomized clinical trial of open versus laparoscopic inguinal herniorrhaphy procedures and in a second trial comparing watchful waiting versus open hernia repair. The psychometric analyses presented here are derived from the first clinical trial.15

**METHODS**

**Conceptual foundation of the Activity Assessment Scale items**

We conducted a semistructured focus group session with six general surgeons attending a Chicago Surgical Society meeting in 1995. The discussion identified relevant aspects of open and laparoscopic hernia repair procedures for inclusion in a measurement scale. In-depth personal interviews were conducted with six hernia patients who had undergone either open or laparoscopic repair or had experienced the two procedures at different times. Surgeons and patients were both concerned about functional status before and after operation, with the extent of improvement resulting from treatment, and with the time frame required for recovery. Information from these sources was used to develop a pool of condition-specific and procedure-specific items; prototype scales were then constructed that focused on activities that were meaningful to patients and would be useful to surgeons in assessing treatment outcomes after the two types of operations.

**Pilot study**

Surgical practices in seven cities across the United States were identified and the draft Activities Assessment Scale (AAS) was pilot-tested with a sample of 96 hernia patients from these settings. A preliminary assessment of the psychometric characteristics of the scales was then conducted and the best-performing items were selected for inclusion in the research protocol.

**Sample for current study**

The AAS was incorporated into a multicenter Cooperative Studies Program project conducted within the Department of Veterans Affairs.15 This randomized clinical trial compared open and laparoscopic hernia repair procedures. Recruitment of patients began in January 1999 and the analyses we present were based on data available as of June 2002. That data set included 2,164 patient records at baseline and 1,562 patients at 3-month follow-up. All study participants were men, and the mean age was 58.6 years (median 58 years; range 19 to 90 years). Caucasians made up 75% of the sample, 22% were African American, 3% were Asian or other; 5% of the sample identified themselves as Hispanic. Approximately equal numbers of patients were randomized to the open or the laparoscopic procedure. Major findings of this study are reported separately.16

**Study variables**

Demographic information, operative data, health status assessments, and clinical measures were collected at baseline and over the course of the study. In addition to undergoing physical examinations, all patients provided detailed information about their functional status and health-related quality of life at 3 months, 6 months, 1 year, and 2 years after operation. The SF-36 was included as the generic health status measure because of its wide scope and its previous use in other health service research studies on hernia repair.17,18 All data were collected onsite at Veterans Affairs facilities in the immediate preoperative and postoperative period; later followup information was provided by patients in telephone interviews conducted by a research nurse.

The AAS includes 11 items covering a broad sample of sedentary (eg, lying in bed), movement-related (eg, walking outdoors), and graded-intensity physical activities (extending from housekeeping to various forms of exercise to construction work). The preoperative scale references the impact of the hernia itself, and the postoperative version assesses the effects of the hernia repair on functioning. The time frame for all questions is the previous 24 hours. Five categories ranging from “no difficulty” to “not able to perform” were used for responses; a “did not perform for other reasons” category was included but was not scored. The scale requires from 3 to 5 minutes of patient time to complete. The AAS scores are then numerically transformed to produce a range extending from 0 to 100, with higher values indicating
better functional ability. The final version of the Activities Assessment Scale with both preoperative and postoperative instructions is shown in the Appendix.

Data analyses
Reliability assesses the extent to which measurements from a test or a scale or subscale are reproducible. Cronbach’s alpha evaluates the degree to which the individual items or questions covary when measured at a single point in time. These coefficients can range between 0 and 1, and they were used to assess the internal consistency of the new scale.19

Validity indicates whether a scale measures what it is intended to measure; three aspects of validity were examined in assessing the performance of the AAS. One important consideration was the underlying structure of the relationship among the scale items in the period after operation. So the relationships between the 11 items were investigated at 3 months postoperatively to establish factorial validity.

Construct validity considers the extent to which a scale or subscale produces scores consistent with those from another instrument with known characteristics. A series of correlational analyses examined the relationships between the AAS and the eight individual subdimensions of the SF-36. Patterns of convergence were assessed to establish the ability of the new scale to produce similar results when compared with the previously validated SF-36; the divergences were evaluated to determine if the AAS was able to discriminate between other aspects of health status.20

Known group comparisons were used to assess another aspect of validity. Groups of patients who would be expected to have higher or lower functional status relative to other subgroups with known clinical characteristics were compared by analyses of variance. For example, levels on the AAS were compared using t-tests for independent groups for patients with and without limitations in activities of daily living (ADL), and for those with and without serious comorbidities. These analyses were conducted to further confirm the validity of the new measure.

Health status and quality-of-life instruments must also be able to detect and quantify change after an intervention or over time.21 We used methods described by Peterman and colleagues22 and patient data from the baseline and 3-month followup assessments to evaluate clinical responsiveness. Scores on the SF-36 physical functioning scale, a measure with demonstrated sensitivity to change, were used to classify patients into three groups—those exhibiting improvement, no change, or worsening—within this time interval. A one-half standard deviation interval was used to define the minimal clinically significant amount of change.23 These categorizations were then used in assessing the direction and the amount of change on the AAS measures between the preoperative and postoperative periods. Analyses of variance were then conducted to compare the AAS change scores for the three SF-36 defined groups.

All analyses of the psychometric characteristics of the new scales were conducted using Version 8 the SAS/STAT system.24

RESULTS
Reliability
Cronbach’s alpha for the 11-item AAS was 0.85 at both baseline and 3-month followup. Three subscales were identified in later analyses of factorial validity (see following paragraph) and the alphas for these subscales were all 0.86 at each of the two time points. These coefficients substantially exceed the lower bound for internal consistency of 0.70 recommended by Nunnally and Bernstein.25 The preoperative and the postoperative versions of the AAS have demonstrated excellent reliability in this research study.

Factorial validity
A statistical procedure called common factor analysis was used to examine the correlations among the 11 items in the scale and to explain the patterns of relationship in terms of a smaller number of underlying variables called factors.26 These analyses were done to establish whether the AAS was a coherent measure of surgical outcomes. The number of factors, the adequacy of the factor structure, the fit of individual items, and evidence about factor correlations were evaluated according to standard criteria.27,28 Two-, three-, and four-factor solutions were considered, and the three-factor solution was judged to be optimal. As Table 1 shows, this solution also produced the “simplest” factor structure, with only the light physical activities item loading on more than one of the three dimensions.29 Additional information about the technical issues involved in factor analysis is available to readers on the www.statsoft.com Web site and in the text by Pett and associates.27

The first factor contained four items assessing a pa-
tient’s ability to perform a variety of tasks ordered along an intensity continuum. The gradient extended from lower-effort tasks such as cooking and dusting; through middle-range activities such as sweeping and playing golf; to high-exertion activities such as shoveling, weight lifting, and engaging in sexual intercourse. This was described as the “work and exercise” subscale. The second factor included four activities requiring minimal effort such as lying in bed, sitting in a chair, getting in or out of a bed or chair, and reaching or stretching. This was labeled the “sedentary activities” subscale. The third factor consisted of three items assessing “ambulatory activities” such as walking inside a house or apartment, climbing stairs, and walking around outdoors.

As Table 2 indicates, the sedentary, ambulatory, and work and exercise subscales were correlated with each other. The three factors measure related aspects of functional status, and because they exhibited strong levels of correlation, we used the total score across all AAS items in the analyses reported here.

**Convergent and divergent validity**

We hypothesized that the summed Activities Assessment Scale score would show the largest correlation with the SF-36 physical functioning (PF) subscale, and would demonstrate smaller correlations with other dimensions of the SF-36. As Table 3 shows, this was the case at both baseline and 3-month followup. The correlations with the PF and the PF role performance dimensions were high, and the correlations with other subscales such as the mental health dimension were lower. The bodily pain dimension also showed a substantial correlation with the total AAS score in this population at both time points.

Similar patterns of relationship were seen for the three AAS subscales at baseline and 3-month followup. Correlations between the sedentary, ambulatory, and work and exercise subscales and the SF-36 PF dimension were 0.51, 0.60, and 0.60 at the preoperative assessment and 0.39, 0.45, and 0.52, respectively, at the 3-month postoperative time point. The AAS subscales also demonstrated correlations with bodily pain in the 0.56 and 0.43 range at these two points in time, with smaller correlations found for the other SF-36 dimensions (subscale data not shown). All correlations reported were statistically significant (p ≤ 0.0001).

**Known group comparisons**

Additional evidence of the discriminative properties of the AAS was generated using clinically defined subgroups of patients. The mean AAS score at baseline was expected to be higher for patients reporting themselves to be independent versus partially or completely dependent with regard to activities of daily living. Similarly, patients reporting comorbidities such as chronic

<table>
<thead>
<tr>
<th>Table 1. Rotated Factor Pattern Matrix*</th>
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<tbody>
<tr>
<td>Item from scale</td>
</tr>
<tr>
<td>Lying in bed</td>
</tr>
<tr>
<td>Sitting</td>
</tr>
<tr>
<td>Getting in or out of bed or chair</td>
</tr>
<tr>
<td>Reaching or stretching</td>
</tr>
<tr>
<td>Walking around inside</td>
</tr>
<tr>
<td>Climbing stairs</td>
</tr>
<tr>
<td>Walking outside or at work</td>
</tr>
<tr>
<td>Cooking, dusting, clerical work...</td>
</tr>
<tr>
<td>Engaging in sexual intercourse</td>
</tr>
<tr>
<td>Sweeping, dancing, hiking...</td>
</tr>
<tr>
<td>Construction work, playing tennis...</td>
</tr>
</tbody>
</table>

*Indicates the factor loadings that define the subscales.

<table>
<thead>
<tr>
<th>Table 2. Correlations Between Activities Assessment Scale Factors</th>
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<tbody>
<tr>
<td>Work/exercise factor 1</td>
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<tr>
<td>Work/exercise</td>
</tr>
<tr>
<td>Sedentary</td>
</tr>
<tr>
<td>Ambulatory</td>
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</tbody>
</table>

All correlations are significant at p < 0.0001.

<table>
<thead>
<tr>
<th>Table 3. Correlations Between SF-36 Subscales and Total AAS Score</th>
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<tbody>
<tr>
<td>Subscale</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Physical functioning</td>
</tr>
<tr>
<td>Physical role performance</td>
</tr>
<tr>
<td>Bodily pain</td>
</tr>
<tr>
<td>General health perceptions</td>
</tr>
<tr>
<td>Vitality</td>
</tr>
<tr>
<td>Social functioning</td>
</tr>
<tr>
<td>Emotional role performance</td>
</tr>
<tr>
<td>Mental health</td>
</tr>
</tbody>
</table>

All correlations are significant at p ≤ 0.0001. Numbers in parentheses are 95% confidence intervals.
obstructive pulmonary disease, a recent myocardial infarction, cerebral vascular accident with residual neurologic deficit, and similar significant health problems were anticipated to have lower total AAS scores relative to patients with no comorbidities.

The results of the t-tests for independent groups are shown in Table 4. The activities of daily living independent patients had a 12.4-point higher total AAS score than the dependent patients (p < 0.0002), and the patients with no comorbidities had a 6.6-point higher score than those with comorbidities (p < 0.0001). The three subscales of the AAS also demonstrated notable differences between the subgroups of patients. For the activities of daily living comparisons, the magnitude extended from a low of 4.0 points on the sedentary subscale to an intermediate value of 10.2 for the ambulatory subscale to a high of 19.3 points on the work and exercise subscale. The differences between the two comorbidity-defined groups were smaller and ranged from 5.1 points for sedentary pursuits to 5.8 points for the ambulatory activities to 8.9 points for the higher-effort work and exercise-related activities. All differences reported were significant at p < 0.002.

### Clinical responsiveness

Change scores for the overall AAS and its subscales were calculated between baseline and 3-month followup to assess the responsiveness of the new measure. Anchor points on the PF dimension of the SF-36 were established using the one-half standard deviation interval discussed in the article by Norman and colleagues. Patients with PF change scores of +7 points or greater were classified as improved, and those with PF change scores of −7 points or less were categorized as worse; patients whose PF scores stayed the same or were within the ±7 point interval around their baseline score were classified as no change. The amount of change in the AAS scores was then compared for these three subgroups.

Figure 1 summarizes the results for the analysis of variance for the total AAS scores. The differences in the mean change scores between the three groups were significant (p < 0.0001). The largest change in total AAS score was for the patients in the PF-improved group, with a mean increase of 24.0 points, followed by a 7.6-point increase for those in the PF–no change group, and a −1.3-point change for the PF–worse group. Similar patterns of change in functioning between baseline and 3-month followup were also found for the subscales. For the patients showing improved functioning on the PF, there was an increment of 17.1 points on the sedentary subscale of the AAS, an increase of 24.4 points on the ambulatory subscale, and a 29.5-point positive change on the work and exercise subscale. Patients with no change on the PF dimension had change scores of 5.9, 7.4, and 10.5; patients reporting worsening had scores extending from 0.3, to 0.5, to −3.5 points, respectively, on the sedentary, ambulatory, and work and exercise subscales. These differences were all significant with p values < 0.0001.

Effect size (ES) indicates the strength of a treatment intervention. These statistics are computed as ratios representing the amount of change in the mean values between the two time points divided by the standard deviations for the change score. Cohen classified effect sizes of 0.8 and above as large, in the 0.5 range as medium, and 0.2 and less as small. The ES for the total AAS score for patients reporting improved physical functioning was quite large, at 1.20. Patients who reported no change had a moderate ES of 0.53, and those who worsened showed a smaller ES of 0.06. This patterns of larger ESs...
for patients who improved and smaller ESs for patients whose functioning did not change or worsened were found for the AAS subscales as well. For example, the range extended from 0.01 for the patients who worsened on the sedentary activities subscale to an intermediate value of 0.42 for those with no change on the ambulatory activities subscale to a large ES of 1.13 for those who improved on the work and exercise dimension.

**DISCUSSION**

The findings reported here demonstrate that the AAS and its constituent sedentary, ambulatory, and work and exercise subscales are reliable measures. The internal consistency statistics from both baseline and 3-month followup indicate that the overall scale and its subscales can be used to compare different groups of hernia patients at the same time point or the same group of patients at multiple time points. Our analyses have also established the validity of the AAS in this patient population. This is a coherent scale that can discriminate between different measurement constructs and can distinguish between groups of patients with and without other health problems. The AAS has been shown to be clinically responsive and to mirror changes on other scales with established characteristics among the patients who provided followup data. The overall AAS score was more sensitive to change than the PF subscale of the SF-36 for hernia patients reporting improvement and no change in these analyses. The lack of a notable effect size for the small number of patients reporting worse postoperative functioning is an artifact. Given that all study participants underwent surgical repair of their hernias, the range of low scores on these functional status measures was considerably restricted.

The three subscales for the AAS were substantially correlated and either the total score or the subscale values can be used in patient assessment. The ability to distinguish between problems centered on sedentary and ambulatory activities may prove to be useful early in the recovery period; the work and exercise subscale may be more sensitive to changes later in the postoperative period. This subscale information could help to identify problems associated with a particular type of intervention or with specific complications resulting from an operation. The earlier patient interviews and the substantial correlations between the AAS subscales and the bodily pain dimension of the SF-36 both suggest that pain was a significant limiting factor in the functioning of hernia patients.¹⁴

Functional status is clearly an important aspect of the day-to-day experience of patients before and after operations. The AAS measures a full spectrum of low-intensity to high-intensity activities, it references a more immediate time interval than the baseline and followup versions of the SF-36, and the new instrument requires considerably less time to complete than most generic health status assessment scales. We hope that it will prove useful to surgeons assessing patient outcomes after hernia repair.

For example, the AAS and its subscales can be used to track the trajectory of recovery from laparoscopic and open hernia repair in both research and clinical practice venues. Additional condition-specific and procedure-specific modules will be developed to extend the scope of the measurement system and enable assessment of the impact of other surgical interventions on patient-reported functioning. Our longer-term goal is to develop a modular surgical outcomes assessment system organized around a common core of items augmented with tailored questions from an item bank.³¹ Online data capture and graphical display of patient health status data will allow surgeons to quickly and easily monitor change over time and subsequent to a procedure.³² Instruments such as these can provide a shared framework within which patients and providers can visualize and review the effects of treatment interventions. Availability of such a measurement system can be expected to lead to greater patient understanding and increased satisfaction with the outcomes of their surgical care.³³

**Appendix**

**Activities Assessment Scale**

We want to know how much your hernia or hernia operation has interfered with your ability to perform various activities. Please read the examples in the following table and then circle the number that corresponds to how difficult it was for you to engage in that activity within the last 24 hours. Please circle 8 if you were able to perform that activity but did not in fact do so, or if you do not ordinarily engage in that activity.
How much difficulty did you have performing the following activities in the last 24 hours as a result of your hernia? [Preoperative Instruction]

How much difficulty did you have performing the following activities in the last 24 hours as a result of your hernia operation? [Postoperative Instruction]

<table>
<thead>
<tr>
<th>Activity</th>
<th>No difficulty</th>
<th>A little difficulty</th>
<th>Some difficulty</th>
<th>A lot of difficulty</th>
<th>Not able to do it</th>
<th>Did not do it for other reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lying in bed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Sitting</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Getting in or out of bed or chair</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Reaching or stretching</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Lifting 3 to 5 pounds</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Walking around inside</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Climbing up or down stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Walking outside or at work</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Engaging in sedentary activities, such as typing, talking on the phone, playing cards, watching TV</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Engaging in light physical activities, cooking, dusting, clerical work, visiting friends</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Engaging in moderate physical activities such as sweeping, washing the car, dancing, playing golf, hiking</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Engaging in vigorous physical activities such as construction work, shoveling, playing tennis or basketball, weight lifting</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Engaging in sexual intercourse</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
</tbody>
</table>

**Author Contributions**

Study conception and design: McCarthy, Edelman

Acquisition of data: Jonasson, Neumayer

Drafting of manuscript: McCarthy

Critical revision: McCarthy, Jonasson, Chang, Pickard, Gibbs, Fitzgibbons, Neumayer

Statistical expertise: Chang, Pickard, Giobbie-Hurder

Obtaining funding: Jonasson, Gibbs, Fitzgibbons, Neumayer

Supervision: Jonasson, Gibbs, Neumayer

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