Development and longitudinal validation of the overall benefit of analgesic score: a simple multi-dimensional quality assessment instrument

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Key points
- Standard pain intensity scores are limited as they do not assess usage or adverse effects of analgesic drugs in practice.
- The overall benefit of analgesic score (OBAS) comprises simple seven questions to assess pain intensity, adverse effects, and patients’ satisfaction with analgesia.
- In retrospective and prospective studies, the OBAS performed well in comparison with simple pain ratings and other scores.

Background. The goal of this study was to develop and validate the overall benefit of analgesic score (OBAS), which assesses pain intensity and the opioid-related adverse effects.

Methods. The score was developed and validated in four trials (n=1470 patients). Data from randomized trial I were used to develop the OBAS (factor analysis). Data from randomized trial II were used to compare the resolution of rofecoxib’s analgesic effects between OBAS and pain scores. Randomized trial III (spine surgery) was conducted to evaluate prospectively the reliability of the OBAS and to compare its resolution of analgesic treatment with the opioid-related symptom distress scale (OR-SDS) and the modified brief pain inventory short form (m-BPI-sf). Trial IV was conducted to evaluate in patients with a moderate-to-high level of postoperative pain (after major abdominal surgery) the relation of OBAS and pain scores for patients’ satisfaction with analgesic therapy.

Results. The seven-item OBAS yielded a higher resolution of analgesic treatment effects than pain scores, the OR-SDS and m-BPI-sf. The OBAS has a fair inter-rater reliability (concordance correlation of 0.71 c) and is more sensitive (P=0.03) in indicating the delivery of opioid boluses than the dedicated OR-SDS. The OBAS, but not pain scores at rest or pain scores during movement, explained significant variance in patients’ satisfaction with postoperative pain therapy.

Conclusions. The OBAS is a simple, multi-dimensional quality assessment instrument to measure patients’ benefit from postoperative pain therapy. Opioid symptom distress, pain relief, and patients’ satisfaction are combined in a reliable and valid tool.

Keywords: adverse effects; analgesics, opioids; clinical trials; pain measurement; pain, postoperative; patient satisfaction

Accepted for publication: 1 June 2010

Despite increased emphasis on adequate postoperative pain management, pain continues to be under-treated.¹ It is well recognized that inadequate pain assessment contributes to inadequate pain therapy. Beginning in 2000, the Joint Commission [previously known as Joint Commission for Accreditation of Healthcare Organizations (JCAHO)] has made pain assessment and management a priority in its national standards and accreditation process. An important part of the current recommendations is regular assessment of pain intensity.² However, it does not take into account the potential adverse effects of the analgesic therapy, which continues to be heavily dependent on the use of opioids. Patients usually trade off pain relief for avoiding adverse effects of a pain treatment regimen (e.g. opioid-related side-effects).³ Not surprisingly, both pain intensity and opioid-related symptoms are important predictors of patient satisfaction.⁴ Therefore, in addition to regular pain intensity assessments, it is necessary to evaluate the adverse effects of an analgesic regimen.

Recently, clinically meaningful opioid-related adverse events assessed daily using the opioid-related symptom distress scale (OR-SDS),⁵ the modified brief pain inventory exploratory (m-BPI-e), and the pain intensity score of the modified brief pain inventory short form (m-BPI-sf) have been validated for use in the postoperative period.⁶-⁷
However, the pain intensity score of the m-BPI-sf and OR-SDS provides only one dimension of pain assessment (i.e. pain intensity and the opioid-related side-effects, respectively). In addition, these tools are extensive and their implementation in daily practice may not be practical. A tool that is easy to implement and provides a broader perspective on the effectiveness of postoperative pain treatment might be helpful to the clinician as to balance patients’ needs and time constraints.

We developed and validated a simple, multi-dimensional tool that assesses pain intensity and opioid-related adverse effects and also patient satisfaction, the overall benefit of analgesic score (OBAS), designed to guide postoperative pain therapy in daily clinical practice. Here, we present a retrospective analysis from two studies, which were conducted to develop the score by factor analysis (trial I) and to test the hypothesis that OBAS better detects than pain scores rofecoxib’s analgesic effects (trial II). We then conducted two prospective trials to validate the OBAS. Firstly, we measured inter-rater reliability and compared the resolution for analgesic effects with the OR-SDS and the m-BPI-sf (trial III). Finally, we prospectively evaluated in patients with a moderate-to-high level of postoperative pain (after major abdominal surgery) the predictive values of OBAS and pain scores for patients’ satisfaction with analgesic therapy.

Methods

The OBAS was longitudinally developed and validated in four trials, which are summarized in Table 1. Some data from trials I–III that are not presented here have been published previously.

Data from trial I were used to develop the OBAS (retrospective design and factor analysis). Five hundred patients after abdominal, orthopaedic, gynaecological, and obstetric surgery received morphine (n=250) or piritramide (n=250) for pain treatment.

Data from trial II were used to test the hypothesis that OBAS better detects than pain scores rofecoxib’s analgesic effects. Five hundred and forty patients treated with morphine and rofecoxib (or placebo) after breast, orthopaedic, and spine surgery were included.

Subsequently, in a prospective study, in trial III, we evaluated the reliability of the OBAS and compared its validity with the OR-SDS and the m-BPI-sf. Three hundred and twenty patients treated with morphine and parecoxib (or placebo) after lumbar discectomy were included.

Finally, in trial IV, a prospective study in 100 patients after major abdominal surgery treated with morphine, we evaluated the relation of OBAS and pain scores to patients’ satisfaction with postoperative analgesia.

Patients

After approval of the institutional ethics committee (University of Duisburg-Essen, Medical Faculty) and obtaining informed consent, 1470 patients were included in the four studies. Excluded from participation for any of the following reasons: mental or physical inability to handle a patient-controlled analgesia (PCA) device or to answer pain questionnaires, ASA risk classification >III, preoperative opioid therapy >1 week, administration of steroids or non-steroidal anti-inflammatory drugs (NSAIDs) within 24 h before skin incision, renal insufficiency (serum creatinine concentration >130 μmol litre⁻¹), severe liver dysfunction, congestive heart failure, history of myocardial infarction, stroke, pulmonary embolism, or gastrointestinal bleeding, patients’ refusal of study participation, or pregnancy/lactation period.

All patients received an i.v. PCA system (IV-PCA, Multifuse, B. Braun, Melsungen, Germany) containing morphine.

Table 1 Description of four trials included in this study. m-BPI-sf, modified brief pain inventory short form; NSAID, non-steroidal anti-inflammatory drugs; NRS, numerical rating scale; OBAS, overall benefit of analgesic score; OR-SDS, opioid-related symptom distress scale; PCA, patient-controlled analgesia

<table>
<thead>
<tr>
<th></th>
<th>Trial I</th>
<th>Trial II</th>
<th>Trial III</th>
<th>Trial IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients/</td>
<td>n=500, prospective</td>
<td>n=540, prospective</td>
<td>n=320, prospective</td>
<td>n=100, prospective</td>
</tr>
<tr>
<td>design with respect to OBAS development</td>
<td>analysis of data on file</td>
<td>analysis of data on file</td>
<td>study</td>
<td>study</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>48 (18–87)</td>
<td>48.5 (16–94)</td>
<td>42 (18–82)</td>
<td>47 (18–80)</td>
</tr>
<tr>
<td>Opioid</td>
<td>Morphine, piritramide (n=250 each) PCA</td>
<td>Morphine PCA</td>
<td>Morphine PCA</td>
<td>Morphine PCA</td>
</tr>
<tr>
<td>NSAID</td>
<td>None</td>
<td>Rofecoxib</td>
<td>Parecoxib</td>
<td>None</td>
</tr>
<tr>
<td>Surgical procedures</td>
<td>Abdominal, orthopaedic, gynaecological, and obstetric surgery</td>
<td>Breast, orthopaedic, and spine surgery</td>
<td>Lumbar discectomy</td>
<td>Major abdominal surgery</td>
</tr>
<tr>
<td>OBAS development and validation aims</td>
<td>Development of OBAS</td>
<td>Resolution of rofecoxib’s treatment effects</td>
<td>Reliability and validity of the OBAS</td>
<td>Validity in patients with moderate-to-high intensity postoperative pain</td>
</tr>
<tr>
<td>OBAS comparator</td>
<td>None</td>
<td>Pain intensity score (NRS)</td>
<td>OR-SDS and m-BPI-sf, pain intensity scale (NRS)</td>
<td>Pain intensity score (NRS)</td>
</tr>
</tbody>
</table>
also obtained.

addition, the m-BPI-sf severity and impairment scores were
difficulty with urination, nausea, and retching/vomiting. In
to concentrate, confusion, dizziness, constipation, itching,
very much). Symptoms included fatigue, drowsiness, inability
degree of bother (a little bit, somewhat, quite a bit, and
severity (slight, moderate, severe, and very severe), and
distress from opioid-related symptoms in terms of frequency
in the answers. If a patient was still not able to answer a ques-
tion, it was graded as ‘Ø’, and the patient was excluded from
the study. The order of the two OBAS exams was randomized.

In trial III, in addition to above techniques, an OR-SDS
scoring system was used in which the patients rated their
distress from opioid-related symptoms in terms of frequency
(rarely, occasionally, frequently, and almost constantly),
severity (slight, moderate, severe, and very severe), and
degree of bother (a little bit, somewhat, quite a bit, and
very much). Symptoms included fatigue, drowsiness, inability
to concentrate, confusion, dizziness, constipation, itching,
difficulty with urination, nausea, and retching/vomiting. In
addition, the m-BPI-sf severity and impairment scores were
also obtained.

**Measurements**

In all trials, at 24 h (± 1 h) after surgery, patients recorded
their average pain level during the previous 24 h in a pre-
printed diary with patients on PCA.

Using the preprinted diary, patients were also asked to fill
out the OBAS questionnaire within 30 min. In addition,
research personnel visited the patients and read to the
patients the OBAS questionnaire (Table 2) in a standardized
manner without giving any further comments and recorded
the answers. If a patient was still not able to answer a ques-
tion, it was graded as ‘Ø’, and the patient was excluded from
the study. The order of the two OBAS exams was randomized.

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very much). Symptoms included fatigue, drowsiness, inability
to concentrate, confusion, dizziness, constipation, itching,
difficulty with urination, nausea, and retching/vomiting. In
addition, the m-BPI-sf severity and impairment scores were
also obtained.

### Table 2: The OBAS
To calculate the OBAS score, compute the sum
of scores in items 1−6 and add ‘4−score in item 7’. For example, a
patient with minimal pain (NRS=0), severe vomiting (NRS=4),
and no itching, sweating, and freezing who is slightly dizzy
(NRS=1) and is not very satisfied with his postoperative pain
treatment (NRS=1) has an OBAS of 8. Note that a low score
indicates high benefit.

1. Please rate your current pain at rest on a scale between
   0= minimal pain and 4= maximum imaginable pain
2. Please grade any distress and bother from vomiting in the past
   24 h (0= not at all to 4= very much)
3. Please grade any distress and bother from itching in the past
   24 h (0= not at all to 4= very much)
4. Please grade any distress and bother from sweating in the past
   24 h (0= not at all to 4= very much)
5. Please grade any distress and bother from freezing in the past
   24 h (0= not at all to 4= very much)
6. Please grade any distress and bother from dizziness in the past
   24 h (0= not at all to 4= very much)
7. How satisfied are you with your pain treatment during the past
   24 h (0= not at all to 4= very much)

**Statistical analysis**

Data from trial I were analysed using Spearman’s corre-
lations and factor analysis. Data from trial II were analysed
using the Kruskal–Wallis test. The OBAS, OR-SDS, and
m-BPI-sf (average pain severity) scores from trial III were
compared using Spearman’s correlation coefficients. The
inter-rater reliability between the OBAS recorded by
the patient and that obtained by the research personnel
was evaluated using the concordance correlation coefficient.11
The construct validity in trial III data was assessed using
factor analysis. The trial III data (OBAS recorded by
the patient, OBAS obtained by the research personnel, OR-SDS
score, and m-BPI-sf average pain score) were analysed
using ANOVA to disclose possible differences in resolution
of treatment effects. Standardized effect sizes12 for the treat-
ment group vs the placebo group for each score as the differ-
ence between mean scores per group, divided by pooled
standard deviation and adjusted for sample size, were esti-
mated with their 95% confidence intervals (CIs). Sample
sizes for a fictitious two-armed study based on these effect
sizes (two-sided t-test, equal variances, equal group size, sig-
nificance level 5%, and power 90%) are calculated. To assess
the sensitivity and specificity of the OBAS, the OR-SDS, and
the m-BPI-sf (average pain) to opioid treatment (defined as
patients who received more than the initial opioid bolus),
receiver operator characteristics (ROC) from logistic regression
was applied. The maximal Youden index was chosen to define
the respective cut-points. Using the methods of DeLong
and colleagues,13 the difference in ROC was statistically evaluated.
To assess in patients with moderate-to-high intensity pain
the relationship between the OBAS and patients’ satisfaction
with postoperative pain therapy (trial IV), we compared
these values using Spearman’s correlation coefficient.

**Results**

**Score generation (trial I)**

The aim was to define a score that covers as many different
aspects of analgesia benefit with as few items as possible.
Therefore, the items constituting the score should be
mutually independent. Spearman’s correlation matrix
suggested that (i) pain on movement and pain at rest and
(ii) nausea and vomiting exhibited respective correlations
larger than 0.2, and thus were rated as not independent.
Factor analysis showed that the remaining seven items
relate to four components contributing between 14.0% and
24.9% to the total variance. This resulted in shortening
the OBAS scoring system to the seven items given in Table 2
(i.e. pain on movement and nausea were omitted).

**Pilot assessment of validity (trial II)**

The treatment resolution of the OBAS, pain scores at rest (an
OBAS item), and pain on movement is presented in Table 3.
Effects of treatment with rofecoxib were revealed in a more
pronounced fashion with the use of the OBAS compared
with pain intensity scores.
Concordance These values reflect moderate relations between OBAS, the OR-SDS and OBAS was 0.55 (\(P\) amounted to 0.48 (\(P\), the OR-SDS explained more variance of the OBAS than either OR-SDS and OBAS was 0.55 (\(P\), and the OR-SDS, OR-SDS explained more variance of the OBAS than either OR-SDS and OBAS was 0.55 (\(P\), but still left 56% of its variance unexplained.

Relations to validated scales, inter-rater reliability, and construct validity. Spearman’s correlations between the pain item of the OBAS and the m-BPI-sf items of the pain severity scale (minimal, average, and maximum pain) were 0.55, 0.52, and 0.43, respectively (all \(P<0.0001\)). Correlation between OBAS and m-BPI-sf average pain severity score amounted to 0.48 (\(P<0.0001\)). The correlation between OR-SDS and OBAS was 0.55 (\(P<0.0001\)). A linear model for the OBAS including both mean m-BPI-sf (average pain) and OR-SDS explained more variance of the OBAS than either score alone, but still left 56% of its variance unexplained.

These values reflect moderate relations between OBAS, the m-BPI-sf pain severity scale, and the OR-SDS. Concordance correlation between OBAS filled by a patient and OBAS recorded by a pain specialist was 0.71 (95% CI 0.65–0.76), suggesting a fair inter-rater reliability. Construct validity in trial III data, assessed by exploratory factor analysis, showed results similar to the score generation trial I with components contributing between 10.4% and 24.3% to the total variance. The seven items of the OBAS are related to four components, one with pain and satisfaction as main contributors, one with sedation, itching, and sweating, one with vomiting, and one with freezing.

Resolution of COX-2 inhibitor treatment effects. The effect size for the study drug (i.e. rofecoxib or parecoxib) vs placebo was greater when measured with the OBAS compared with the m-BPI-sf average pain severity scale and the OR-SDS, amounting to 0.8, 0.42, and 0.45, respectively, for parecoxib (Table 4). As a consequence, designing a study with OBAS instead of OR-SDS as the endpoint may considerably decrease the number of patients required. On the basis of the data provided in Table 4, a corresponding two-armed study with equal group size would at a significance level of 5% (two-sided) require 34 patients per arm using the OBAS as the endpoint, whereas using the OR-SDS would require 105 patients per arm (when calculated to achieve a power of 90%). Sample sizes were calculated for Student’s t-test assuming equal variances. Also, as the effect sizes show, the OBAS as the endpoint would yield considerable reduction in sample size compared with the m-BPI-sf average pain severity scale.

Resolution of opioid bolus application. We assessed the responsiveness of the OR-SDS and the OBAS to detect whether the patient has received at least one self-administered bolus of an opioid. Logistic regression followed by ROC analysis revealed at the optimal cut-point for the OR-SDS a sensitivity of 66% and a specificity of 71.4%. The area under the ROC curve (AUC) was 0.70 (0.59, 0.81). For the OBAS, the figures were: sensitivity 72.4%, specificity 76.2%, and AUC 0.78 (0.71, 0.86) (Fig. 1). A formal test revealed that the OBAS was more efficacious than the OR-SDS in detecting whether or not a patient had received a self-administered bolus of an opioid during the first 24 h (\(P=0.03\)). As for the m-BPI-sf average pain severity scale, its sensitivity and specificity amounted to 79.7% and 71.4%, respectively, AUC=0.81 (0.72, 0.90) (Fig. 1). Although a difference between OBAS and BPI ROC curves is not found (\(P=0.48\)), the OR-SDS also less sensitively indicates opioid application than the BPI (\(P=0.046\)). Even the distress subscore of the OBAS (five-item OBAS with pain and satisfaction items removed) performs numerically comparable with the OR-SDS.

Table 3 Trial II: resolution of rofecoxib’s analgesic effects. Comparison between OBAS and pain scores (five-point NRS taken at rest and during movement). \(P\) values from Kruskal–Wallis test; *\(P<0.001\); NS, not significant

<table>
<thead>
<tr>
<th>Score</th>
<th>Instrument used for assessment of analgesia</th>
<th>n</th>
<th>Mean (SD)</th>
<th>(\chi^2) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBAS</td>
<td>Placebo before and after operation</td>
<td>171</td>
<td>0.59 (0.40)</td>
<td>9.61*</td>
</tr>
<tr>
<td></td>
<td>Rofecoxib before and after operation</td>
<td>175</td>
<td>0.47 (0.37)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo before operation and rofecoxib after operation</td>
<td>173</td>
<td>0.57 (0.42)</td>
<td></td>
</tr>
<tr>
<td>Pain at rest</td>
<td>Placebo before and after operation</td>
<td>171</td>
<td>1.07 (0.99)</td>
<td>4.17 ((P=\text{NS}))</td>
</tr>
<tr>
<td></td>
<td>Rofecoxib before and after operation</td>
<td>175</td>
<td>0.83 (0.82)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo before operation and rofecoxib after operation</td>
<td>173</td>
<td>0.99 (1.01)</td>
<td></td>
</tr>
<tr>
<td>Pain during movement</td>
<td>Placebo before and after operation</td>
<td>171</td>
<td>2.03 (1.08)</td>
<td>1.48 ((P=\text{NS}))</td>
</tr>
<tr>
<td></td>
<td>Rofecoxib before and after operation</td>
<td>175</td>
<td>1.93 (1.16)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo before operation and rofecoxib after operation</td>
<td>173</td>
<td>2.06 (1.16)</td>
<td></td>
</tr>
</tbody>
</table>

Prospective validation

Postoperative pain after spine surgery (trial III)

Relations to validated scales, inter-rater reliability, and construct validity. Spearman’s correlations between the pain intensity pain [numerical rating scale (NRS) at rest: 4 (SD 2); NRS during movement: 7 (1.5)] the relation of the OBAS and pain scores for patient satisfaction, we calculated Spearman’s correlation coefficients. The OBAS without patient satisfaction (\(r=-0.34, P=0.001\), Fig. 2a), but not pain scores at rest (\(r=0.15, P=0.11\), Fig. 2c) and pain during movement (\(r=0.1, P=0.31\), Fig. 2a), explained significant variance of patients’ satisfaction with analgesia.

Postoperative pain after abdominal surgery (trial IV)

For the sake of calculating in patients with moderate-to-high intensity pain [numerical rating scale (NRS) at rest: 4 (SD 2); NRS during movement: 7 (1.5)] the relation of the OBAS and pain scores for patient satisfaction, we calculated Spearman’s correlation coefficients. The OBAS without patient satisfaction (\(r=-0.34, P=0.001\), Fig. 2a), but not pain scores at rest (\(r=0.15, P=0.11\), Fig. 2c) and pain during movement (\(r=0.1, P=0.31\), Fig. 2a), explained significant variance of patients’ satisfaction with analgesia.
Discussion

This study shows that the OBAS system yields a higher resolution of treatment effects than pain intensity scores, m-BPI-sf average pain severity scale, and the OR-SDS when used independently. This suggests that a combination of pain intensity and opioid symptom distress should be used to guide pain treatment. One should expect that a score designed to measure symptom distress (OR-SDS) reacts to whether an opioid bolus was applied or not. A very simple subscore of the OBAS made up of five items on five-point Likert scales, comprising the opioid distress dimension, performed as good as the much more involved OR-SDS in this respect. The full OBAS (seven items) was superior to OR-SDS in indicating whether or not a patient received opioids. As patients attempt to achieve a balance between pain intensity and opioid-related adverse events, one could speculate that the OBAS may provide more clinically meaningful information to guide treatment including but not limited to optimizing the use of adjuvants used to spare opioids.

This study corroborates previous reports suggesting that pain intensity scores alone should not be used to manage postoperative pain. The use of pain intensity scores alone, as mandated by the Joint Commission, has been reported to inadvertently increase the use of opioids and associated opioid-related side-effects. Therefore, in recent years, there is increased emphasis on the study of patient-reported outcomes that allow identifying improved pain control by reduced analgesic-related side-effects. The OBAS has the potential of helping combine the goals in postoperative pain treatment of low pain intensity and low opioid-induced side-effects. Our data from trial IV show that the OBAS but not pain scores alone relate to patients’ satisfaction with postoperative pain treatment, confirming the view that pain treatment should not be guided by looking at pain intensity alone.

The patient-reported outcome instruments that have been validated include the m-BPI-sf or m-BPI-e that evaluates pain intensity and functional impairment from pain, and the OR-SDS that evaluates opioid symptom distress caused by opioid-related adverse events. It is possible that the combination of m-BPI-sf and OR-SDS may provide the

Table 4  Prospective evaluation of parecoxib’s analgesic effects (trial III). Comparison between OBAS, operating theatre symptom distress score (OR-SDS), and modified brief inventory short form (m-BPI-sf pain scale). Mean (sd) in each treatment group in trial III, F-values from ANOVA, and standardized effect size estimates with 95% CI

<table>
<thead>
<tr>
<th>Score</th>
<th>Instrument used for assessment of assessment</th>
<th>Mean (sd)</th>
<th>F-value</th>
<th>Effect size study drug vs placebo (95% CI)</th>
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<tr>
<td>OR-SDS</td>
<td>Placebo</td>
<td>0.61 (0.50)</td>
<td>3.69</td>
<td>0.45 (0.13, 0.77)</td>
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<tr>
<td></td>
<td>Study drug</td>
<td>0.40 (0.43)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Placebo/study drug</td>
<td>0.54 (0.48)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Study drug/placebo</td>
<td>0.43 (0.41)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBAS</td>
<td>Placebo</td>
<td>0.85 (0.54)</td>
<td>10.33</td>
<td>0.80 (0.47, 1.13)</td>
</tr>
<tr>
<td></td>
<td>Study drug</td>
<td>0.4 (0.36)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Placebo/study drug</td>
<td>0.60 (0.43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Study drug/placebo</td>
<td>0.55 (0.42)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBAS (pain sp.)</td>
<td>Placebo</td>
<td>0.66 (0.46)</td>
<td>11.17</td>
<td>0.73 (0.41, 1.06)</td>
</tr>
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<td></td>
<td>Study drug</td>
<td>0.37 (0.31)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo/study drug</td>
<td>0.40 (0.30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Study drug/placebo</td>
<td>0.39 (0.32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>m-BPI-sf (average pain severity scale)</td>
<td>Placebo</td>
<td>3.29 (1.96)</td>
<td>2.78</td>
<td>0.42 (0.11, 0.74)</td>
</tr>
<tr>
<td></td>
<td>Study drug</td>
<td>2.48 (1.84)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo/study drug</td>
<td>2.99 (1.78)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Study drug/placebo</td>
<td>2.83 (1.52)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
same benefit as the OBAS. However, their combination would require the patients to respond to 44 questions (14 questions for the m-BPI-sf and 30 questions for OR-SDS), which has been used in research but is not clinically feasible for routine daily practice.

The OR-SDS can be used to evaluate patient assessments of the presence/absence of the 10-opioid-related symptoms, the frequency (rarely, occasionally, frequently, and almost constantly), severity (slight, moderate, severe, and very severe), and degree of bother (not at all, a little bit, somewhat, quite a bit, and very much) caused by the symptoms. The OR-SDS score needs to be translated to the clinically meaningful events score that is more relevant to practitioners, thus further increasing the difficulty in using this scoring system in day-to-day clinical practice.

The m-BPI-sf includes a four-item pain intensity scale (worst pain, least pain, average pain, and current pain) and pain interference scale (general activity, mood, walking ability, relations with others, sleeping, coughing, deep breathing, and concentration). The original English m-BPI-sf version has been translated and culturally adapted to more than 30 languages and the linguistic validation and cultural adaptation process followed a well-accepted practice (two forward and two backward translations and pilot testing) resulting in linguistic versions of the instrument that demonstrated similar psychometric properties as the original questionnaire.

Since the OBAS yields a higher resolution of treatment effects than pain intensity scores (either using NRS or the average pain severity from m-BPI-sf), the calculated sample size for a two-armed study may be more than two-fold smaller using OBAS compared with pain intensity scores. This observation needs further investigation as the benefits of smaller, but appropriate, sample sizes are numerous including lower research costs and possible ethical implications.

As opposed to using multiple scales to assess pain intensity and opioid-related adverse effects, a single scale might be easier to implement. This is important in current clinical settings that are already taxed with increasing documentation requirements but limited staff resources. Increasing requirements for documentation put a burden on clinical personnel, and often documentation of pain assessment, treatment, and treatment outcome data is incomplete and inconsistent.

This study has certain limitations. The OBAS initial parameters were included to address the different aspects of successful pain therapy (i.e. pain scores, opioid-related adverse

Fig 2 Relations between patients’ satisfaction with postoperative analgesia and the OBAS, the OBAS without the criterion patients’ satisfaction, and pain scores at rest and during movement. The OBAS and the modified OBAS but not pain scores correlate significantly with patients’ satisfaction with postoperative analgesia. (A and B), comparison between OBAS and patient satisfaction; (C and D), comparison between pain scores and patient satisfaction.
events, and patient satisfaction). One might argue that the OBAS does not include a complete list of opioid-related adverse events or of the influence of pain on function (e.g. general activity, mood, walking ability, relations with others, sleeping, coughing, deep breathing, and concentration). However, the OBAS was developed for daily clinical use, it included the commonly reported opioid-related adverse events, and only the least commonly reported symptoms were excluded. Similarly, patient satisfaction included in the OBAS was thought to address a patient’s mood and relations with others, whereas pain on movement would address general activity, ability to walk, coughing, and deep breathing.

Interestingly, our strategy of shortening the OBAS from the initial nine-item score including pain during movement and nausea did not abridge its treatment resolution abilities. Previous reports emphasized the evaluation of pain during movement in achieving optimal pain therapy. Wilk and colleagues found that hyperalgesia correlated with movement-evoked pain, but not pain at rest, indicating that pain during movement might involve sensitization of the nociceptive response. We speculate that the low magnitude of pain intensity in our patients (either due to inclusion of surgical procedures with low postoperative pain intensity or due to optimized pain therapy from the combined use of non-opioids and opioids) may have resulted in lower separation between pain at rest and pain during movement (on average 20% of maximum pain intensity during movement).

It is possible, therefore, that pain during movement may play a more important role in guiding postoperative pain therapy in surgical procedures with a very high postoperative pain intensity (e.g. after upper abdominal or thoracic surgery). However, in patients with moderate to severe pain after abdominal surgery (trial IV), OBAS but not pain intensity correlated with patient satisfaction. Accordingly, our data suggest that the OBAS is a viable quality assessment instrument to measure patients’ benefit from postoperative pain therapy throughout a high range of pain levels. We speculate that omitting nausea did not impair the OBAS’ properties because of its subjective nature. A patient’s recollection of nausea, particularly if it was mild-to-moderate, may be lower than their recollection of retching/vomiting.

Attempts to exclude sweating and freezing decreased the predictive value of the OBAS on whether or not a patient required opioids, suggesting that sweating and freezing independently influence variance of the OBAS. Sweating and freezing may indicate stress-induced activation of the sympathetic nerve system, which in turn can be attenuated by optimum pain management.

In addition, it is necessary to determine whether the OBAS is applicable to acute pain settings beyond that studied in this investigation. With the concept of procedure-specific pain management being increasingly accepted, and specific recommendations for the management of postoperative pain associated with individual surgical techniques developed, the applicability of OBAS in specific surgical procedures must be evaluated in further studies. Finally, since the OBAS has not formally been used to guide pain therapy, but to measure it post hoc, it will be important to assess prospectively in a randomized trial if the patients’ outcome is improved if the OBAS is being used to guide therapy.

In summary, the seven-item OBAS is a simple questionnaire with acceptable inter-rater reliability. Because of its simplicity, it can be administered frequently without too much burden on the clinical personnel. Further studies are necessary to determine whether the routine use of OBAS would improve the quality of perioperative pain therapy.

Acknowledgement

We are grateful to Gunther Riest, MD, for helping us with acquisition and analysis of trial III data.

Conflict of interest

G.P.J. has received honoraria from Pfizer Inc. New York, NY for giving advice to the company.

Funding

This work was supported financially by the Klinik für Anästhesiologie und Intensivmedizin, Universitätsklinikum Essen, Essen, Germany, and the Massachusetts General Hospital in Boston, MA, USA. The OBAS was not designed to make fortunes from inventions of measurement tools. Accordingly, we decided not to have patents or copyrights involved.

References


14 White PF, Kehlet H. Improving pain management: are we jumping from the frying pan into the fire? *Anesth Analg* 2007; **105**: 10–2

15 Frasco PE, Sprung J, Trentman TL. The impact of the joint commission for accreditation of healthcare organizations pain initiative on perioperative opiate consumption and recovery room length of stay. *Anesth Analg* 2005; **100**: 162–8

16 Smetzer JL, Cohen MR. Pain scales don’t weigh every risk. *J Pain Palliat Care Pharmacother* 2003; **17**: 67–70


20 Rakel B, Frantz R. Effectiveness of transcutaneous electrical nerve stimulation on postoperative pain with movement. *J Pain* 2003; **4**: 455–64


22 Verleye M, Gillardin JM. Effects of etifoxine on stress-induced hyperthermia, freezing behavior and colonic motor activation in rats. *Physiol Behav* 2004; **82**: 891–7

