Has the quality of health-related quality of life reporting in cancer clinical trials improved over time? Towards bridging the gap with clinical decision making

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Background: Previous work highlighted a number of methodological constraints when reporting health-related quality of life (HRQOL) outcomes from randomized controlled trials (RCTs). Given this, the objective of this study was to investigate whether the quality of such HRQOL reports has improved over time.

Materials and methods: On the basis of a predefined set of criteria, 159 RCTs with a HRQOL end point, published between 1990 and 2004 were identified and analyzed. Each study was evaluated by a number of issues (e.g. sample size and industry sponsorship) and by the ‘minimum standard checklist for evaluating HRQOL outcomes in cancer clinical trials’.

Results: The quality of HRQOL reports, as measured by the overall checklist score, was independently related to more recently published studies ($P < 0.0001$). This relationship was independent of industry funded, HRQOL end point (primary versus secondary), cancer disease site, size of the study and HRQOL difference between treatment arms. While only 39.3% of studies published between 1990 and 2000 (89/159 RCTs) were identified as being probably robust, thus likely to support clinical decision making, this percentage was 64.3% for studies published after 2000 (70/159 RCTs).

Conclusion: Since we found a significant learning curve in HRQOL trial reporting since 1990, it can be expected that HRQOL data will increasingly impact on clinical decision making and treatment policies in the near future.

Key words: Cancer, clinical decision-making, clinical trial, quality of life

introduction

The need to evaluate the impact of disease and treatment on health-related quality of life (HRQOL) is increasingly acknowledged as crucial for evaluating the overall treatment effectiveness in cancer clinical trials. Information about side-effects, symptoms and treatment options are important to cancer patients as they enable them to make informed treatment decisions. Cancer patients require information not only related to survival estimates, but also regarding HRQOL issues [1]. Providing patients with such information, from a methodologically sound research basis, is therefore of paramount importance. Including HRQOL as an end point in a clinical trial setting could provide invaluable information related to functional ability as well as treatment side-effects from the patients’ perspective. Assessing HRQOL, however, requires making a number of challenging decisions with regard, for example, to data collection, appropriate timing of assessment, adequate statistical analysis as well as outcome interpretation [2]. In addition, specific information regarding the psychometric robustness of the tool has to be taken into account when selecting a questionnaire for a specific trial population.

Previous work has highlighted a number of drawbacks when reporting HRQOL results of cancer clinical trials in various cancer disease sites [3–6]. It is, however, possible that such criticism regarding the adequacy of HRQOL reporting may be premature due to the fact that these evaluations were on the basis of older studies [7]. Methodological limitations have also been shown to be the major barrier for the Food and Drug Administration oncology drug applications on the basis of HRQOL end points [8]. Moreover, inadequate or poorly designed and reported HRQOL investigations in the context of randomized controlled trials (RCTs) can mislead clinical decision making, as it will hamper a clear appraisal of the validity of the outcomes. While several guidelines have recently been published to help investigators addressing a number of issues when measuring HRQOL in clinical trials [2], no data exist regarding the quality of such assessment over time in cancer research. As it is of paramount importance that the accuracy of the reporting of key HRQOL methodological factors

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increases, in order to allow health care providers to make informed decisions about the value of HRQOL outcomes, the main objective of this study was to investigate whether there has been a learning curve in terms of the quality of HRQOL assessment in RCT reports.

**materials and methods**

**systematic literature search**

A literature search for studies meeting the criteria reported below was undertaken on several databases including Medline, Cancerlit and the Cochrane Controlled Trials Register. A hand search of the references section of electronically identified articles was also carried out. Given the lack of necessary information in conference abstracts, they were excluded. The majority of the studies analyzed in this research were previously identified in a series of systematic reviews dealing with HRQOL methodological issues in RCTs of breast, colorectal, non-small-cell lung cancer (NSCLC) and prostate cancer. Details on searching strategy have been previously reported [3–6].

**criteria for considering studies**

**types of participants.** Adult patients diagnosed with breast, colorectal, NSCLC and prostate cancer. In North America as well as in Northern and Western Europe these represent the top four major cancer disease sites in terms of incidence [9]. No restriction was applied in terms of disease stage.

**types of intervention.** Interventions included any RCTs comparing medical treatment regardless of the intervention type—radiotherapy, chemotherapy and surgical procedures. Studies dealing with psychological intervention, complementary and alternative medicine approaches or any kind of interventions other than conventional medical treatments were excluded.

**types of outcome measures examined.** Any study including HRQOL as an end point was considered. Studies exclusively using proxy-based questionnaires (i.e. completed by clinicians or significant others) were excluded. Only HRQOL self-reported patient measures were taken into account. HRQOL was defined as a multidimensional construct [10]. However, studies covering at least two HRQOL domains (e.g. physical, social, psychological) and/or those only evaluating global HRQOL were also eligible.

**types of studies.** All RCTs comparing different medical treatment modalities published between 1990 and 2004 and enrolling overall at least 100 patients were analyzed. The search was restricted to RCTs as they represent the gold standard by which health care professionals make decisions about treatment effectiveness [11].

**methods of evaluation of HRQOL reports and data collection**

Two reviewers (AB and FE) independently analyzed all identified RCTs meeting the criteria. The evaluation was on the basis of a predefined data extraction form including information regarding the design of the trial and the HRQOL assessment methodology used. When disagreement about the analysis of a study occurred, the reviewers revisited the paper to reconcile any differences until consensus was achieved. The studies were then stored on an electronic database at the Quality of Life Unit at the European Organisation for Research and Treatment of Cancer (EORTC) Data Center in Brussels. An electronic database was specifically developed for the purpose of this research to store data collected from literature reviews. A full list of articles included in the database is available from the authors.

As the aim of this research was to investigate the level of HRQOL reporting, each RCT was evaluated according the ‘minimum standard checklist for evaluating HRQOL outcomes in cancer clinical trials’ [12]. This checklist was specifically intended for reviewing and facilitating a critical appraisal and interpretation of HRQOL outcome reports and also for guiding investigators when writing the HRQOL report from a clinical trial. It consists of 11 basic items that can be scored as ‘yes’ (giving a score of one) or ‘no’ (giving a score of zero), the higher the score the higher the robustness of the outcomes. Two items, namely, ‘a priori hypothesis stated’ and ‘cultural validity verified’ can also be evaluated as not/applicable. Each report could then receive a score ranging from zero to a maximum of 11. The checklist was developed on the basis of good practice in conducting a HRQOL evaluation. The items were originally selected from the literature by consensus of HRQOL researchers with international expertise in oncology and further ranked, to determine the relative importance by an additional independent panel of 30 experts in the field of HRQOL in oncology (including clinicians, psychologists and statisticians). The items are grouped into four key categories related to the HRQOL assessment: conceptual, measurement, methodology and interpretation. Although the items are self-explanatory, the specific criteria for assessing each item and additional details on the development process have been previously reported [12].

**data analysis**

As previously indicated [12], studies scoring at least eight on this checklist including three mandatory items (i.e. baseline compliance, missing data and psychometric properties reported) could be considered as ‘probably robust’, thus being likely to possibly have an impact on clinical decision making. Hence, all studies were classified into ‘probably robust’ (as defined above), ‘limited’ (scoring higher than four but either lower than eight or not including all three mandatory items), and ‘very limited’ (all other studies, i.e. scoring four or lower on the checklist score). The frequency distribution for this checklist score categorization as well as for the arbitrary classification for date of publication (chosen a priori as before and after 2000) is presented for descriptive purposes only. In univariate analysis, a linear regression model with adjusted checklist score (i.e. raw score divided by the number of applicable questions) as dependent variable and with time as continuous independent covariate was fitted. A general multivariate linear regression model was also used to examine the effect of time on the adjusted checklist score while controlling for possible confounding factors. Factors included: industry funded (yes versus no), HRQOL end point (primary versus secondary), year of publication (continuous), disease site (prostate versus breast; prostate versus colorectal; prostate versus NSCLC), number of patients enrolled into the trial (continuous) and HRQOL difference between treatment arms (yes versus no). The latter was defined as any statistical difference between treatment arms at any given time point assessment during the trial (even if this only occurred in one HRQOL domain). Statistically significant variables were identified at the 1% level via Wald-type Chi-square tests for linear regression. All statistical analyses were two-sided and were carried out using SAS version 9.1 for Windows (SAS Institute Inc., Cary, NC).

**results**

One hundred and fifty-nine RCTs enrolling 58 635 patients were identified from 1990 to 2004 and were available for analysis (Table 1).
Prostate cancer 32 11 106
NSCLC 48 16 063
Colorectal cancer 29 10 727
Breast cancer 50 20 739

variability, however, was also evident even within the same year

P < 0.0001). The scatter plot is reported in Figure 2. A wide

trend for the adjusted checklist score over time (P = 0.025; $P < 0.0001$).

information.

there were, however, 15.7% of studies that gave ‘very limited’

‘limited’ with none being ‘very limited’. From 1990 to 2000

the studies done from 2001 to 2004 were evaluated as being

39.3% for those published earlier (Figure 1). The remainder of

for those published between 2001 and 2004 while it was only

31% and 30% of studies published before 2001 failed to provide

any detail on missing data and baseline compliance, respectively.

For both these two key aspects, however, these percentages

dropped to only 17% for the reports published after 2000.

measurement issues. Nearly all of the RCTs have used a validated

questionnaire (94.3%) covering at least the main domains

relevant to a generic cancer population (96.9%). The most

frequently used HRQOL measures were the EORTC

questionnaires being used in 76 studies (48%). Other

questionnaires frequently used were the Rotterdam Symptom

Checklist and the Functional Assessment of Cancer Therapy

(FACT) being used in 17 studies (11%) and 15 studies (9%),

respectively. For the remaining items an improvement was also

noted for the reports published after 2000. In all of the above,

reporting was higher in the years 2001–2004 than in the earlier

period.

methodological issues. While only 24.7% of the reports published

between 1990 and 2000 specified who and/or in which clinical

setting the HRQOL instrument was administered, >38% of the

reports published after 2000 reported this issue. Nearly all of

the studies documented the HRQOL timing of assessment. Some

31% and 30% of studies published before 2001 failed to provide

any detail on missing data and baseline compliance, respectively.

For both these two key aspects, however, these percentages

dropped to only 17% for the reports published after 2000.

interpretation issues. The major drawback was related to the

limited progress in addressing the clinical significance of the

HRQOL outcomes, as only 24.5% of all the studies provided

information related to clinical significance. This percentage was,

however, 34.3% for the reports published after 2000 as

compared with 16.9% for those published earlier. Nearly all of

the studies (93.1%) discussed the HRQOL findings regardless of

the results in at least one sentence.

overall checklist score over time

The percentage of studies judged as ‘probably robust’ was 64.3% for

those published between 2001 and 2004 while it was only

39.3% for those published earlier (Figure 1). The remainder of

the studies done from 2001 to 2004 were evaluated as being

‘limited’ with none being ‘very limited’. From 1990 to 2000

there were, however, 15.7% of studies that gave ‘very limited’

information.

A linear regression analysis showed a statistically significant

trend for the adjusted checklist score over time ($\beta = 0.025$; $P < 0.0001$).

The scatter plot is reported in Figure 2. A wide

variability, however, was also evident even within the same year

of publication. This relationship remained significant independent of other possible confounding factors ($P < 0.0001$).

A multivariate regression analysis was run, using the adjusted

checklist score as the dependent variable, and the following

additional covariates: industry funded, HRQOL end point, disease site, number of patients enrolled into the trial and

HRQOL difference between treatment arms. Of these, only

disease site was significant together with year of publication at

the 1% level. Details are reported in Table 3. Since the studies

conducted in various disease sites seemed to vary in terms of

quality of HRQOL reports, we further investigated this issue and

noted that the ones conducted in NSCLC had higher checklist

scores (Table 4).

discussion

The main finding of this research is that a significant

improvement has occurred since 1990 in terms of the quality of

HRQOL reporting. This trend was independent of the sample

size of the study, the industry sponsorship, the use of HRQOL as a

primary or secondary end point in the trial, the specific disease

site investigated and the evidence of a HRQOL difference

between treatment arms. This evidence has been shown in 159

RCTs conducted in the top four major cancer disease sites, in

terms of incidence, in North America as well as in Northern and

Western Europe [9]. The percentage of the studies evaluated as

being probably robust, thus likely to be reliable and possibly

better informing clinical decision making, was 64.3% for those

published after 2000, in contrast to only 39.3% for those

published earlier (Figure 1). Overall, this result confirms the

remarkable progress that has been made in a relatively short

period of time in this field [13]. This evaluation was on the basis

of a previously developed checklist specifically devised for

reviewing and facilitating a critical appraisal and interpretation of

HRQOL outcome reports from clinical trials. The strength of

this pragmatic tool is that it is on the basis of the cancer

literature and only focuses on issues related to HRQOL

reporting [12].

While investigating the reasons underlying the quality

improvement over time lies beyond the scope of this paper, and

a number of reasons could account for this evidence, it is

possible to provide some tentative explanations. Although some

major guidelines on how to conduct and incorporate HRQOL

as an end point into clinical trial protocols were published in the

early 1990s [14, 15], the majority of these were published in

or after 1997 [16–19]. It is also worthy of note that some

frequently used HRQOL psychometric robust questionnaires

devised for a generic cancer population, such as the EORTC

QLQ-C30 or the FACT-G were only published in 1993 [20, 21].

In addition, several other commonly used cancer site-specific

measures, such as the EORTC QLQ-BR23 and the FACT-B were

published later in 1996 and 1997, respectively [22, 23]. Thus, it

might be possible that the relatively poor level of HRQOL

reporting of previously published manuscripts could stem from

the general unfamiliarity of clinical researchers in oncology

with HRQOL issues as well as the lack of methodologically

sound HRQOL cancer questionnaires.

Since a difference was noted in the accuracy of HRQOL

reports conducted among the cancer disease sites investigated, it

Table 1. Number of studies analyzed

<table>
<thead>
<tr>
<th>Disease site</th>
<th>No. of RCTs (Total 159)</th>
<th>No. of patientsa (Total 58 635)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer</td>
<td>50</td>
<td>20 739</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>29</td>
<td>10 727</td>
</tr>
<tr>
<td>NSCLC</td>
<td>48</td>
<td>16 063</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>32</td>
<td>11 106</td>
</tr>
</tbody>
</table>

*Overall number of patients enrolled in the original trial.

RCT, randomized controlled trial; NSCLC, non-small-cell lung cancer.
Table 2. Level of reporting according to the minimum standard checklist for evaluating HRQOL outcomes in cancer clinical trials by year of publication

<table>
<thead>
<tr>
<th>Items</th>
<th>Publication year</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1990–2000 (N = 89)</td>
<td>2001–2004 (N = 70)</td>
</tr>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Conceptual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A priori hypothesis stated: assessed whether authors had a pre-defined HRQOL end point and/or stated expected changes due to the specific treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>21 (23.6)</td>
<td>25 (35.7)</td>
</tr>
<tr>
<td>No</td>
<td>67 (75.3)</td>
<td>41 (58.6)</td>
</tr>
<tr>
<td>N/A(^a)</td>
<td>1 (1.1)</td>
<td>4 (5.7)</td>
</tr>
<tr>
<td>Rationale for instrument reported: assessed whether authors gave a rationale for using a specific HRQOL measure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>30 (33.7)</td>
<td>46 (65.7)</td>
</tr>
<tr>
<td>No</td>
<td>59 (66.3)</td>
<td>24 (34.3)</td>
</tr>
<tr>
<td>Measurement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychometric properties reported: assessed whether a previously validated measure was used or psychometric properties were reported or referenced in the article</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>80 (89.9)</td>
<td>70 (100)</td>
</tr>
<tr>
<td>No</td>
<td>9 (10.1)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Cultural validity verified: assessed whether the measure was validated for the specific study population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>55 (61.8)</td>
<td>58 (82.9)</td>
</tr>
<tr>
<td>No</td>
<td>4 (4.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>N/A(^b)</td>
<td>30 (33.7)</td>
<td>12 (17.1)</td>
</tr>
<tr>
<td>Adequacy of domains covered: assessed whether the measure covered, at least, the main HRQOL dimensions relevant for a generic cancer population and/or according to the specific research question</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>84 (94.4)</td>
<td>70 (100)</td>
</tr>
<tr>
<td>No</td>
<td>5 (5.6)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Methodology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instrument administration reported: assessed whether authors specified who and/or in which clinical setting the HRQOL instrument was administered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>22 (24.7)</td>
<td>27 (38.6)</td>
</tr>
<tr>
<td>No</td>
<td>67 (75.3)</td>
<td>43 (61.4)</td>
</tr>
<tr>
<td>Baseline compliance reported: assessed whether authors reported the number of patients providing an HRQOL assessment before the start of treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>62 (69.7)</td>
<td>58 (82.9)</td>
</tr>
<tr>
<td>No</td>
<td>27 (30.3)</td>
<td>12 (17.1)</td>
</tr>
<tr>
<td>Timing of assessments documented: assessed whether authors specified the HRQOL timing of assessment during the trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>88 (98.9)</td>
<td>70 (100)</td>
</tr>
<tr>
<td>No</td>
<td>1 (1.1)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Missing data documented: assessed whether authors gave some details on HRQOL missing data during the trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>61 (68.5)</td>
<td>58 (82.9)</td>
</tr>
<tr>
<td>No</td>
<td>28 (31.5)</td>
<td>12 (17.1)</td>
</tr>
<tr>
<td>Interpretation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical significance addressed: this refers to the discussion of HRQOL data being clinically significant from a patient’s perspective and not simply statistically significant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15 (16.9)</td>
<td>24 (34.3)</td>
</tr>
<tr>
<td>No</td>
<td>74 (83.1)</td>
<td>46 (65.7)</td>
</tr>
<tr>
<td>Presentation of results in general: assessed whether authors discussed the HRQOL outcomes, giving any comments regardless of the results (either expected or not)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>79 (88.8)</td>
<td>69 (98.6)</td>
</tr>
<tr>
<td>No</td>
<td>10 (11.2)</td>
<td>1 (1.4)</td>
</tr>
</tbody>
</table>

\(^a\)If a study explicitly states an exploratory HRQOL evaluation.

\(^b\)If the HRQOL measure is validated in the same population as one of the trial.

HRQOL, health-related quality of life.
is possible that the learning curve identified mainly reflects the improvement of studies conducted within a specific cancer disease site (Tables 3 and 4). However, because of the small number of studies in each category and possible lack of power in the additional analysis, we did not further investigate this issue. Rather, the aim of this paper was to provide an overall picture of the quality of HRQOL research in oncology.

Measuring HRQOL in a clinical trial setting requires making a number of important decisions, including the selection of the most appropriate questionnaire, the methods of administration and data collection [2]. The statistical analysis and interpretation of HRQOL results are also crucial aspects of this process [24]. As an example, the Clinical Trials Group of the National Cancer Institute of Canada has recently proposed a simple and practical guide that may aid in the analysis and interpretation of HRQOL data [7].

On one hand, our findings show an overall improvement in the level of reporting of all the checklist items over time, while on the other they also highlight some areas that deserve further attention. For example, the current findings identify the lack of an a priori hypothesis as a major limitation (overall only 29% of the studies reported this aspect). Our findings also indicate the lack of documentation of missing data as a further possible limitation as, overall, 25% of the studies conducted failed to provide any details on the proportion of patients who dropped out during the course of the trial. Recent studies have addressed handling missing data in a comprehensive way and are likely to assist investigators when exploring this issue [25–27]. There is room for improvement in addressing the clinical significance of HRQOL outcomes since, overall, only 24% the RCTs addressed this issue. Recent work, which has investigated this aspect in a comprehensive way, is likely to help researchers when addressing the interpretability of the results [18, 28–32]. As has been noted for all the items of the checklist, however, the number of studies addressing these issues was higher for those published after 2000 as compared with previous years.

A recent editorial published in the *Journal of Clinical Oncology* [33] pointed out that it is ‘disappointing’ that despite the fact that thousands of patients have been enrolled in cancer clinical trials with a HRQOL component, ‘there are relatively few examples of formal quality-of-life measurement that have influenced individual patient decision making or treatment policies’ (p.2215). The issue raised in this editorial represents a challenging topic for all investigators involved in HRQOL cancer research. While a number of reasons could account for the arguments brought up in the editorial, the present findings indicate that the reason could merely stem from the generally poor level of methodological rigor in the HRQOL assessment of many previously conducted RCTs.

Our study has some limitations. We did not take into account unpublished reports. There is evidence that some HRQOL analyses were not reported because of a very low compliance rate [34]. It is, however, not possible to find out exactly how many studies were not submitted for publication or were rejected because of administrative and methodological problems. Since
Disease site:

HRQOL difference: no versus Yes

Number of patients: continuous <0.001 <

End point: second categories

Checklist score

Independent variables

<table>
<thead>
<tr>
<th>Disease site</th>
<th>( \beta )</th>
<th>95% Confidence interval</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year of publication: continuous</td>
<td>0.022</td>
<td>0.014, 0.030</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Industry funded: yes versus no</td>
<td>0.041</td>
<td>-0.007, 0.090</td>
<td>0.1002</td>
</tr>
<tr>
<td>End point: second versus primary</td>
<td>0.077</td>
<td>0.141, 0.013</td>
<td>0.0185</td>
</tr>
<tr>
<td>Number of patients: continuous</td>
<td>&lt;0.001</td>
<td>&lt;-0.001, &lt;0.001</td>
<td>0.1264</td>
</tr>
<tr>
<td>HRQOL difference: no versus yes</td>
<td>0.053</td>
<td>0.004, 0.103</td>
<td>0.0328</td>
</tr>
</tbody>
</table>

Disease site:

- Prostate versus breast: 0.062 -0.005, 0.131 0.0001
- Prostate versus colorectal: -0.027 -0.105, 0.049
- Prostate versus NSCLC: 0.125 0.055, 0.194

A negative sign means the disease site has a lower checklist score than that of studies of prostate cancer. A positive sign means the disease site has a higher checklist score than that of studies of prostate cancer.

Table 4. Checklist score categorization by disease site

<table>
<thead>
<tr>
<th>Checklist score categories</th>
<th>Disease site</th>
<th>Breast (N = 50)</th>
<th>Colorectal (N = 29)</th>
<th>NSCLC (N = 48)</th>
<th>Prostate (N = 32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–4 (very limited)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>3 (6.0)</td>
<td>2 (6.9)</td>
<td>2 (4.2)</td>
<td>7 (21.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5–7 (limited)</td>
<td>20 (40.0)</td>
<td>23 (79.3)</td>
<td>9 (18.8)</td>
<td>13 (40.6)</td>
<td></td>
</tr>
<tr>
<td>8–11 (probably robust)</td>
<td>27 (54.0)</td>
<td>4 (13.8)</td>
<td>37 (77.1)</td>
<td>12 (37.5)</td>
<td></td>
</tr>
</tbody>
</table>

Including three mandatory items: baseline compliance reported, missing data and psychometric properties documented.

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