SUPPLEMENT

What contributes to patient and parent satisfaction with medication in the treatment of children with ADHD? A report on the development of a new rating scale

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Abstract Satisfaction with medication is important in the evaluation of overall treatment outcome. There is a lack of consistent and validated rating scales for satisfaction with medication in ADHD, therefore comparison across studies is difficult. Here, we analyse the psychometric properties of the satisfaction with medication scale (SAMS), a new item-based questionnaire that assesses satisfaction with ADHD medication. Furthermore, we evaluate the predictive effect of ADHD symptoms and quality of life (QoL) on satisfaction. Data on satisfaction with Equasym XL® (methylphenidate) were collected in the OBSEER study using the parent (SAMS-P, $n = 589$) and patient (SAMS-S, $n = 552$) versions of the SAMS questionnaire. Internal consistency, item-total and cross-informant correlations, and the stability of satisfaction ratings over time were assessed. Satisfaction with medication scores were then correlated with ratings of ADHD symptoms and QoL. Rates of overall satisfaction with Equasym XL® among parents and children were high (>70%), as was internal consistency for both SAMS-P and SAMS-S (Cronbach's alpha > 0.9). Similarly, item-total correlations were high ($r = 0.71$–0.90) for SAMS-P and medium–high ($r = 0.57$–0.77) for SAMS-S. Cross-informant correlations and the stability of satisfaction ratings were moderate ($r = 0.54$–0.59 and 0.48–0.60, respectively). ADHD symptom and QoL ratings were significantly negative and positive predictors of satisfaction, explaining 36–52% of satisfaction variance at the final visit. The results show that parent and patient satisfaction was high and could be assessed reliably with the new SAMS questionnaire. Parent and patient ratings were moderately correlated, and symptom severity, functional impairment and QoL were the most significant predictors of satisfaction.

Keywords ADHD · Medication satisfaction · Rating scale · Treatment

Introduction

Attention deficit hyperactivity disorder (ADHD) is the most common mental health condition among children and adolescents, with a worldwide prevalence of over 5% [22]. Pharmacological therapies such as stimulant medications have proven to be effective in helping control both ADHD core symptoms (inattention, hyperactivity and impulsivity) and the behavioural problems associated with the disease (e.g. aggressive behaviour, depressive mood, anxiety, tics, impaired social functioning and academic productivity) in affected children [2]. Over the past few years, several new medications for ADHD have become available, many of which are modified, long-acting formulations of stimulants (i.e. methylphenidate [MPH] and amphetamine) developed to eliminate the need for multiple doses during the day, thus reducing the adherence issues that multiple dosing can cause [15]. Equasym XL®[1] (Shire Pharmaceuticals Ireland Limited)

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[1] Equasym XL is the UK trade name, and is registered and marketed by Shire in the following countries under the following trademarks: Denmark, Equasym Depot; Finland, Equasym Retard; France, Quasym LP; Germany, Equasym Retard; Ireland, Equasym XL; Netherlands, Equasym XL; Norway, Equasym Depot; Sweden, Equasym Depot; South Korea, Metadate CD; Mexico, Metadate CD. Information correct at August 2011.

is a long-acting MPH formulation that combines 30% immediate-release (IR) and 70% modified-release (MR) MPH and has been shown to be as effective as twice-daily MPH-IR [13].

Patient satisfaction with medication is an important factor in the evaluation of overall treatment outcome. Although improvement of symptoms is the main aim, treatments cannot be considered effective in real life if they are not accepted and patients are not willing to use them [5]. Satisfaction with medication is considered to be predictive of better adherence and compliance to treatment, and to prevent premature treatment termination [20]. It is influenced by several determinants, including treatment effectiveness, consumer expectations, demographic characteristics, social validity or acceptability of the treatment and provider factors, such as patient–physician bonding and the physician's knowledge, competence and ability to communicate with patients and their families. The cultural setting can also deeply affect satisfaction and the perception of treatment, as it shapes patients' beliefs and their reactions to symptoms [5].

Measuring the satisfaction with medication of children or adolescents with ADHD, their parents and teachers can help identify expectations and define therapies that are most appropriate; this is of particular interest in the case of ADHD given the diversity of effective treatment options offered [18]. Unfortunately, data in the literature are limited, and satisfaction measures are rarely included in study protocols. Despite the effectiveness of ADHD medications, parents and teachers generally consider non-pharmacological or combination (pharmacological and non-pharmacological) therapies more acceptable [17, 19, 23], which can clearly have an influence on the way children perceive medication [28]. However, satisfaction with stimulant medication alone is relatively high, with 63–87% of patients, parents and teachers making positive assessments [7, 10, 11, 28, 29]. Results from a recent qualitative UK study commissioned by the National Institute for Health and Clinical Excellence (NICE) ADHD guideline group in 16 young (9- to 14-year-old) people with ADHD treated with stimulants also indicate that stimulant medication is generally perceived as beneficial by patients, particularly for social relationships, and that those who are already taking stimulants are more positive about medication than other types of intervention [26].

The available evidence from the trials of ADHD medications does not demonstrate higher satisfaction with a particular drug class [5], although there are indications of a preference for long-acting formulations. In a double-blind comparison of a long-acting MPH formulation (osmotic release oral system [OROS] MPH [Concerta, Janssen-Cilag Ltd]) given once-daily versus three-times-daily MPH-IR, 47% of parents preferred the long-acting formulation, 31%

the IR formulation, and 15% their previous MPH treatment [21]. Similarly, in an 8-week open-label study of the same long-acting formulation, 50% of parents were 'completely satisfied' with it, compared with 21% with MPH-IR given two or three times daily [27]. Another 1-year open-label study of OROS MPH reported that 50% of parents/caregivers and 75% of investigators evaluated the treatment positively, which may reflect the longer duration of symptom control [14]. Finally, in a post-marketing study of the 30:70 combination of IR and MR MPH of which Equasym XL® consists, 84.6% of patients previously treated with MPH-IR and 59.4% of those previously treated with a different long-acting formulation rated the study medication better or much better than their prior treatment [7].

Although several measures of satisfaction with medication have been used for ADHD, for example the medication satisfaction questionnaire (MSS) [6] or the parent consumer satisfaction questionnaire (PCSQ) [16], clinical trials do not generally apply the same methodological rigour to satisfaction measures as they do to other outcomes. The assessment of satisfaction is often reduced to asking children, parents or teachers how satisfied they are with a specific medication, usually at a low level of detail. One of the main limitations when considering satisfaction with medication in ADHD is the lack of consistent, uniform and validated rating scales for satisfaction that enable comparison across studies [5].

In this paper, we analyse the psychometric properties (validity and reliability) of the satisfaction with medication scale (SAMS), a new rating scale designed to assess the satisfaction with ADHD medication of parents and children on a per item basis. We report data on satisfaction with Equasym XL® collected using this scale in the OB-SEER (OBservation of Safety and Effectiveness of Equasym XL® in Routine care) study [8]. We correlate these data with ratings of ADHD symptoms by physicians, teachers and parents [8], and with ratings of quality of life (QoL) by patients and parents [25] collected during and at the end of the OBSEER study, evaluating the predictive effect of such ratings on patient and parent satisfaction with medication.

Methods

Participants and study design

OBSEER was a post-marketing observational study of Equasym XL®, primarily designed to assess the effectiveness and safety in clinical practice, conducted in 169 centres in Germany in accordance with local regulations and under the therapeutic responsibility of the attending

physicians; ethics or institutional review board approval was not required for this study. The study included children aged 6–17 years with a confirmed diagnosis of ADHD according to the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM-IV-TR) [1] or hyperkinetic disorder (HKD) according to the International Classification of Diseases (ICD-10) [30], for whom therapy with Equasym XL® was already planned by the treating physician. Details regarding study design, participants, effectiveness of Equasym XL® and safety profile are described elsewhere in this supplement [8].

Outcome measures

Satisfaction with medication

In the OBSEER study, satisfaction with medication was assessed using the SAMS tool at baseline (Visit 1), in a follow-up visit 1–3 weeks after the first use of Equasym XL® (Visit 2) and at a final visit 6–12 weeks after the first use of Equasym XL® (Visit 3). This paper analyses the satisfaction with medication as measured at Visit 3.

SAMS is a newly designed questionnaire for the assessment of satisfaction with medication and consists of 12 items, which are scored on a six-point scale with values from 1 to 6. High values indicate positive attitudes to drug therapy, and low values indicate negative attitudes (1 = strongly disagree; 2 = disagree; 3 = slightly disagree; 4 = slightly agree; 5 = agree; 6 = strongly agree); a score of 5 or 6 was classified as high satisfaction.

The first 11 items evaluate satisfaction with the effects of the medication on the following aspects: (1) behaviour of the child, (2) ability to pay attention, (3) reduction of hyperactivity, (4) ability to sustain attention and stick to tasks, (5) ability to cope better with homework assignments and other tasks, (6) ability to get along with other children, (7) ability to get along with family, (8) ability to get along at school, (9) onset of medication effect in the morning, (10) duration of medication effect and (11) general well-being. Item 12 assesses the overall satisfaction with the medication. Two versions of the SAMS questionnaire have been developed: the parent report form (SAMS-P), which assesses parent satisfaction with their child's medication, and the self-report form (SAMS-S), which assesses patient satisfaction. Both forms include the same items, but questions are phrased differently and adapted for parents and children (see Tables 1 and 2 for the exact wording). The total score of each rating scale is the sum of the scores of the different items divided by the number of items and also ranges from 1 to 6.

Other measures

Satisfaction with medication measures were correlated with measures of ADHD symptoms and QoL from the OBSEER study, which were obtained using the following tools.

1. German ADHD symptom checklist (Fremdbeurtei-lungsbogen für Aufmerksamkeitsdefizit-Hyperakti-vitätsstörung, FBB-ADHD) [4, 9, 12]: FBB-ADHD is part of the German diagnostic system for mental

Table 1 Item statistics for parent satisfaction (SAMS-P, $n = 589$)

Item	Mean	SD	Parents expressing high satisfaction (%)	Item-total correlation
1 I am satisfied with how my child behaves while taking this medication	4.80	1.18	71.30	0.85
2 I am satisfied with how this medication helps my child to pay attention	4.88	1.14	75.60	0.89
3 I am satisfied with how this medication helps my child getting less hyperactive	4.73	1.22	70.80	0.80
4 I am satisfied with how this medication helps my child sustain attention and stick to tasks	4.84	1.13	72.20	0.87
5 I am satisfied with how this medication helps my child cope better with homework assignments and other tasks	4.66	1.20	64.30	0.84
6 I am satisfied with how this medication helps my child get along with other kids	4.61	1.24	64.30	0.68
7 I am satisfied with how this medication helps my child get along with my family	4.57	1.23	63.00	0.77
8 I am satisfied with how this medication helps my child to get along at school	4.83	1.14	73.00	0.82
9 I am satisfied with the onset of the medication's effect in the morning	4.80	1.15	73.00	0.71
10 I am satisfied with the duration of the medication's effect	4.42	1.32	57.60	0.79
11 I am satisfied with how this medication helps my child feel good	4.42	1.32	57.60	0.79
12 Overall, I am satisfied with the medication	4.70	1.24	70.50	0.90
Total score (sum of item scores/12)	4.69	1.02	–	–

SAMS Satisfaction with medication scale, *SD* Standard deviation

Table 2 Item statistics for patient satisfaction (SAMS-S, $n = 552$)

Item	Mean	SD	Patients expressing high satisfaction (%)	Item-total correlation
1 My medicine helps me reduce the trouble I have	4.87	1.10	74.10	0.73
2 My medicine helps me pay attention	5.07	0.95	80.40	0.71
3 My medicine helps me stay in my seat when I am supposed to	4.85	1.29	71.60	0.57
4 My medicine helps me sustain attention and stick to tasks	5.04	1.01	78.30	0.70
5 My medicine helps me cope better with homework assignments and other tasks	4.85	1.14	72.10	0.66
6 My medicine helps me get along with other kids	4.69	1.37	65.20	0.57
7 My medicine helps me get along with my family	4.63	1.36	63.60	0.57
8 My medicine helps me get along at school	5.03	1.02	78.10	0.77
9 The effects of my medicine start in good time in the morning	4.98	1.15	75.50	0.62
10 My medicine is effective long enough during the day	4.73	1.33	66.10	0.71
11 My medicine makes me feel good	4.73	1.33	66.10	0.71
12 Overall, I am quite happy with my medicine	5.01	1.20	79.00	0.77
Total score (sum of item scores/12)	4.87	0.87	–	–

SAMS Satisfaction with medication, *SD* Standard deviation

disorders in children and adolescents (DISYPS-II) [9] and assesses 20 symptom items, which are rated by teachers and parents on a scale ranging from 0 = not at all to 3 = very much, with higher scores indicating more severe symptoms. Nine symptom items are combined into a subscale assessing inattention and 11 items are combined to assess hyperactivity and impulsivity; the total symptom score covers all 20 symptom items. In addition, four items evaluate functional impairment with respect to school performance, relationship towards adults and children and the subjective level of suffering (functional impairment subscale), and six items assess competences regarding attentive, reflexive and enduring behaviour (attention–reflexivity subscale).

2. ADHD-Clinical Global Impression-Severity (ADHD-CGI-S) and ADHD-Clinical Global Impression-Improvement (ADHD-CGI-I) scales, assessing ADHD core symptoms (inattention, hyperactivity and impulsivity) and disease-associated problems (aggressive behaviour, depressive mood, anxiety, tics and learning difficulties).

3. Day profile of ADHD symptoms (DAYAS) [3]: DAYAS assesses the daily profile of ADHD and other externalising symptoms from early morning until bedtime. A teacher version of the questionnaire (DAYAS-T) considers the first and second part of the morning at school. This complements the parent version (DAYAS-P), which covers the remaining four daily periods: early morning (before school), early afternoon until 4.00 pm, late afternoon until 7.00 pm and evening. The rating scale evaluates six items: (1) hyperactivity, (2) inattention, (3) impulsivity, (4) oppositional behaviour, (5) aggressive

behaviour and temper tantrums and (6) a global rating of problem behaviour. A subscale, 'ADHD symptoms', comprises items 1–3, and items 4 and 5 are combined into a second subscale, 'oppositional defiant disorder (ODD) symptoms'. For each period, parents and teachers rate each item on a four-point scale using the following values: 0 = not at all; 1 = just a little; 2 = pretty much; 3 = very much.

4. Kinder Lebensqualitätsfragebogen (KINDL) questionnaire for the assessment of health-related QoL [24]: This is a short, validated tool comprising 24 items, with six subscores (physical well-being, emotional well-being, self-esteem, family, friends and school). Three different versions were used according to age group: KID-KINDL (children aged 6–11 years old), the self-reported KIDDO-KINDL (adolescents aged 12–17 years old) and KINDL for parents of patients aged 6–17 years old.

Details about these instruments, as well as their use and results in the OBSEER study, are described elsewhere in this supplement [3, 8, 25].

Statistical analysis

In a post hoc analysis, internal consistency was assessed by calculating Cronbach's alpha. Additionally, part-whole-corrected correlations were calculated to assess the correlation between item scores and scale scores. Exploratory principal component analyses with varimax rotation were conducted to explore the factor structure of the scales. The stability of ratings was assessed by correlating ratings at

Visit 2 with the corresponding ratings at Visit 3. Pearson's correlations were computed to assess the relationships between parent and patient satisfaction and ADHD symptoms and QoL at Visit 3 or symptom changes from Visit 1 to Visit 3. Stepwise regression analyses were conducted to identify predictors for satisfaction with medication.

Results

Parent and patient satisfaction and internal consistency of the satisfaction scales

The SAMS-P questionnaire was completed by parents for 589 patients (all receiving Equasym XL®) at Visit 3. Table 1 shows the statistics for each item of the questionnaire. Means and standard deviations are reported, as well as the percentage of parents who agreed or strongly agreed with each statement (i.e. high satisfaction, item score $\geq$ 5). The item-total correlation (r) is the part-whole-corrected correlation of one item with the total scale score (sum of all 12 items). Over 70% of parents expressed a high overall satisfaction with the medication (item 12), and 63.0–75.6% agreed or strongly agreed with the first eight items of the questionnaire, which indicates high satisfaction with the effects of the medication on the attention and behaviour of their children, not only in academic situations, but also in their social interactions with other children and within the family. A high rate of satisfaction could also be found with respect to the onset of the effect of the medication in the morning (73.0%), while a somewhat lower rate was observed with the duration of the medication effect (57.6%). Finally, 57.6% of parents also reported high satisfaction with how the medication helped their child feel good. The item-total correlations were in the high range, from $r = 0.71$ to $r = 0.90$, indicating close correlations between the single item scores and the total scale score. The internal consistency was also high (Cronbach's alpha = 0.96), indicating a good reliability of the scale.

The SAMS-S questionnaire was completed by 552 patients at Visit 3, and the item statistics for patient satisfaction are shown in Table 2. Overall satisfaction with the medication (item 12) was high for 79.0% of patients—slightly more than for parents—and 63.6–80.4% agreed or strongly agreed with the first eight items of the questionnaire. A high rate of satisfaction could also be found with the onset of the medication effect in the morning (75.5%), while a somewhat lower rate was observed with the duration of the medication (66.1%); 66.1% of children also reported high satisfaction with how the medication helped them feel good. The item-total correlations were in a medium-to-high range from $r = 0.57$ to $r = 0.77$, indicating good correlations between the single items and the

total scale score. As observed for SAMS-P, the internal consistency was again high (Cronbach's alpha = 0.92), indicating a good reliability of the scale.

Exploratory principal component analyses with varimax rotation of SAMS-P results revealed only one factor with an eigenvalue above 1, which explained 71.3% of variance, indicating that the one-factor solution is the most suitable for this scale. Conversely, exploratory principal component analyses of SAMS-S results revealed two factors with eigenvalues above 1, which explained 66.9% of variance, while the one-factor solution only explained 54.5% of variance.

In the two-factor solution, the first factor had highest loadings with items describing effects on attention, cognitive demands and onset and duration of effects (items 2, 4, 5 and 9–12). The second factor comprised satisfaction regarding hyperactive behaviour and getting along with others (items 1, 3 and 6–8).

The analysis of rating stability (correlation between ratings at different time points) from Visit 2 to Visit 3 (the two visits being 3–10 weeks apart from one another) gave a correlation of $r = 0.54$ ($n = 569$) for SAMS-P and $r = 0.59$ ($n = 535$) for SAMS-S. Satisfaction with medication showed a slight, but statistically significant ($P < 0.001$) increase from Visit 2 to Visit 3 for both SAMS-P and SAMS-S (Table 3a).

Cross-informant correlations between SAMS-P and SAMS-S were $r = 0.48$ at Visit 1 ($n = 504$), $r = 0.50$ at Visit 2 ($n = 701$) and $r = 0.60$ at Visit 3 ($n = 692$), indicating stable correlations in the medium range across the three visits. At all three visits, patients reported slightly higher satisfaction than parents, which was statistically significant ($P < 0.001$, Table 3b).

Prediction of parent and patient satisfaction

Correlation between satisfaction with medication, ADHD symptoms and QoL at Visit 3

No substantial correlations were found between parent and patient satisfaction, and patient age or gender or Equasym XL® dosage at Visit 3.

We calculated the correlations between SAMS-P and SAMS-S total scale scores and ratings of ADHD symptoms at Visit 3 from the OBSEER study, which were obtained using different ADHD rating scales [8].

Table 4 shows the Pearson's correlations between satisfaction with medication, and parent and teacher ratings of ADHD symptoms, of ADHD-related functional impairment and of attentive–reflexive and enduring behaviour on the FBB-ADHD scale [4, 12], physician ratings of ADHD core symptoms on the CGI-S scale, and parent and teacher

Table 3 Analysis of (a) rating stability from Visit 2 to Visit 3 and (b) cross-informant correlations between SAMS-P and SAMS-S at each study visit

SAMS Satisfaction with medication, *SD* Standard deviation, * *P* values refer to the difference between Visit 2 and Visit 3; ** *P* values refer to the difference between SAMS-P and SAMS-S

	Visit 2, mean (SD)	Visit 3, mean (SD)	*r* (*n*)	*t* (*t* test)	*P* value*
(a) Rating stability					
SAMS-P	4.46 (1.03)	4.69 (1.02)	0.54 (569)	−5.61	<0.001
SAMS-S	4.75 (0.86)	4.87 (0.87)	0.59 (535)	−3.52	<0.001
	SAMS-P, mean (SD)	SAMS-S, mean (SD)	*r* (*n*)	*t* (*t* test)	*P* value**
(b) Cross-informant correlations					
Visit 1	4.11 (1.08)	4.38 (0.96)	0.48 (504)	−5.84	<0.001
Visit 2	4.39 (1.08)	4.67 (0.92)	0.50 (701)	−7.36	<0.001
Visit 3	4.61 (1.07)	4.78 (0.93)	0.60 (692)	−4.98	<0.001

Table 4 Pearson's correlations between parent and patient satisfaction with medication (SAMS-P and SAMS-S) and ratings of ADHD symptoms at Visit 3

Variable	SAMS-P *r* (*n*)	SAMS-S *r* (*n*)
Parent ratings of ADHD symptoms (FBB-ADHD-total)	−0.60 (716)	−0.38 (693)
Parent ratings of impairment due to ADHD symptoms (FBB-ADHD-impairment)	−0.62 (719)	−0.40 (696)
Parent ratings of attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity)	0.42 (718)	0.29 (695)
Teacher ratings of ADHD symptoms (FBB-ADHD-total)	−0.34 (545)	−0.30 (536)
Teacher ratings of impairment due to ADHD symptoms (FBB-ADHD-impairment)	−0.33 (545)	−0.29 (536)
Teacher ratings of attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity)	0.21 (542)	0.19 (533)
Clinical Global Impression (CGI)	−0.31 (691)	−0.25 (683)
Parent ratings of ADHD symptoms in the morning (DAYAS-P-ADHD-morning)	−0.22 (718)	−0.19 (718)
Parent ratings of ADHD symptoms in the afternoon (DAYAS-P-ADHD-afternoon)	−0.54 (712)	−0.31 (697)
Parent ratings of ADHD symptoms in the late afternoon (DAYAS-P-ADHD-late afternoon)	−0.44 (719)	−0.26 (703)
Parent ratings of ADHD symptoms in the evening (DAYAS-P-ADHD-evening)	−0.34 (718)	−0.22 (702)
Teacher ratings of ADHD symptoms in the first half of school morning (DAYAS-T-ADHD-first half)	−0.29 (574)	−0.27 (567)
Teacher ratings of ADHD symptoms in the second half of school morning (DAYAS-T-ADHD-second half)	−0.28 (573)	−0.23 (566)

All correlations are statistically significant at $P \leq 0.001$

CGI Clinical global impression, *DAYAS* Day profile of ADHD symptoms, *FBB-ADHD* Fremdbeurteilungsbogen für Aufmerksamkeitsdefizit-Hyperaktivitätsstörung

ratings of ADHD symptoms at different times of the day on the DAYAS scale (ADHD symptoms subscale) [3].

The highest correlations were found between parent ratings of satisfaction and parent ratings of total ADHD symptoms on the FBB-ADHD scale ($r = -0.60$), parent ratings of impairment due to ADHD symptoms on the same scale ($r = -0.62$) and parent ratings of ADHD symptoms in the afternoon on the DAYAS scale ($r = -0.54$). As expected, the correlations between parental satisfaction and teacher (FBB-ADHD and DAYAS) or physician (CGI-S) ratings of symptoms were weaker, but still substantial. In general, the correlation between symptom ratings and patient satisfaction (SAMS-S) was also weaker than the correlation between the same ratings and parent satisfaction (Table 4). All of the correlations in Table 4, except for the rating of attentive–reflexive and enduring behaviour, were negative, indicating lower satisfaction with medication in children with higher ratings of ADHD symptoms.

The correlation between satisfaction with medication and QoL data from the OBSEER study [25] was also evaluated. Table 5 shows the correlations between satisfaction (SAMS-P and SAMS-S) and patient QoL (total QoL and subscales) at Visit 3, as assessed using the KINDL questionnaire by parents (KINDL), children (KID-KINDL) or adolescents (KIDDO-KINDL). Parent total ratings of QoL correlated in the medium range with parental satisfaction with medication ($r = 0.53$), indicating higher parental satisfaction with medication for children with higher QoL. The correlations between parental satisfaction and patient (child or adolescent) ratings of QoL were somewhat lower, but still in the medium range. Conversely, patient satisfaction with medication showed highest correlation with child ratings of total QoL ($r = 0.53$), while the correlation with parent ratings of QoL was somewhat lower. Adolescent ratings of QoL correlated to a similar degree with both parent and patient satisfaction. All subscales of QoL showed substantial

Table 5 Pearson's correlations between parent and patient satisfaction with medication (SAMS-P and SAMS-S) and ratings of QoL at Visit 3

Variable	SAMS-P r (n)	SAMS-S r (n)
QoL total		
Parent rating	0.53 (627)	0.38 (608)
Child rating	0.45 (448)	0.53 (446)
Adolescent rating	0.37 (167)	0.39 (171)
QoL physical well-being		
Parent rating	0.29 (638)	0.22 (619)
Child rating	0.37 (454)	0.35 (452)
Adolescent rating	0.23 (170)	0.26 (174)
QoL emotional well-being		
Parent rating	0.37 (637)	0.27 (618)
Child rating	0.25 (454)	0.31 (452)
Adolescent rating	0.22 (170)	0.23 (174)
QoL self		
Parent rating	0.47 (634)	0.35 (615)
Child rating	0.37 (454)	0.42 (452)
Adolescent rating	0.24 (170)	0.35 (174)
QoL family		
Parent rating	0.47 (637)	0.30 (615)
Child rating	0.31 (454)	0.37 (452)
Adolescent rating	0.34 (170)	0.26 (174)
QoL friends		
Parent rating	0.32 (633)	0.23 (614)
Child rating	0.27 (451)	0.33 (449)
Adolescent rating	0.17 (168)	0.28 (172)
QoL school		
Parent rating	0.40 (629)	0.27 (610)
Child rating	0.29 (449)	0.43 (447)
Adolescent rating	0.35 (167)	0.29 (171)

All correlations are statistically significant at $P \leq 0.05$

Parent ratings used the Kinder Lebensqualitätsfragebogen (KINDL) scale, child ratings the KID-KINDL scale and adolescent ratings the KIDDO-KINDL scale

QoL Quality of life, *SAMS* Satisfaction with medication

positive correlations with parent and patient satisfaction, indicating that QoL in all domains contributes significantly to satisfaction with medication.

Subsequently, we conducted stepwise regression analyses with teacher and parent ratings of ADHD symptoms (FBB-ADHD total), ADHD-related functional impairment and attentive–reflexive and enduring behaviour on the FBB-ADHD scale, parental ratings of ADHD symptoms (items 1–3) and ODD symptoms (items 4–5) in the afternoon on the DAYAS scale, and parent (KINDL total score) and patient (KID-KINDL total score) ratings of QoL as predictors.

Criteria were parent and patient satisfaction with medication. In the stepwise regression analyses for parental

satisfaction with medication, in a sample of 327 patients with all data present, four variables entered the final equation: (1) parent rating of impairment due to ADHD symptoms (FBB-ADHD-impairment), (2) parent rating of attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity), (3) parent rating of ADHD symptoms in the afternoon on the DAYAS and (4) parent rating of QoL (KINDL total score). The multiple correlation of these four predictors with parent satisfaction was $R = 0.72$, which explained 52.3% of the variance (corrected R^2) of parent satisfaction. All other potential predictors did not increase the variance in a statistically significant manner. In the stepwise regression analyses for patient satisfaction with medication, in a sample of 321 patients with all data present, four variables entered the final equation: (1) patient rating of QoL (KID-KINDL total score), (2) parent rating of ODD symptoms in the afternoon on the DAYAS, (3) parent rating of attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity) and (4) teacher rating of ADHD symptoms (FBB-ADHD-total). The multiple correlation of these four predictors with patient satisfaction was $R = 0.61$, which explained 36.4% of the variance (corrected R^2) of patient satisfaction. All other potential predictors did not increase the variance in a statistically significant manner.

Correlation between satisfaction with medication at Visit 3, and changes in ADHD symptoms and QoL from Visit 1 to Visit 3

Satisfaction with medication was also evaluated in relation to changes over time in ADHD symptoms and QoL, as assessed in the OBSEER study [8, 25]. Table 6 shows the correlations between satisfaction with medication and the reductions from Visit 1 to Visit 3 in parent and teacher ratings of ADHD symptoms (FBB-ADHD-total), attention-reflexivity and functional impairment on the FBB-ADHD scale [4, 12], physician ratings of ADHD core symptoms on the CGI-S scale and parent and teacher ratings of ADHD symptoms at different times of the day on the DAYAS scale (ADHD symptoms subscale) [3].

The highest correlations were found between parental satisfaction and the reductions in parent-rated ADHD symptoms on the FBB-ADHD scale ($r = 0.43$), in parent-rated functional impairment on the same rating scale ($r = 0.44$) and in parent-rated ADHD symptoms in the afternoon on the DAYAS ($r = 0.40$). This indicates higher parent satisfaction for children showing a greater reduction in ADHD symptoms. As expected, the correlation between parent satisfaction and changes in teacher ratings of symptoms and in physician ratings of change on the CGI-I scale was lower, although still substantial. In general, the correlation of a given measure with patient satisfaction

Table 6 Pearson's correlations between parent and patient satisfaction with medication (SAMS-P and SAMS-S) and reduction in ADHD symptoms from Visit 1 to Visit 3

Variable	SAMS-P r (n)	SAMS-S r (n)
Reduction of parent-rated ADHD symptoms (FBB-ADHD-total)	0.43 (691)	0.28 (670)
Reduction of parent-rated impairment due to ADHD symptoms (FBB-ADHD-impairment)	0.44 (690)	0.31 (670)
Increase in parent-rated attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity)	0.35 (691)	0.27 (670)
Reduction of teacher-rated ADHD symptoms (FBB-ADHD-total)	0.27 (499)	0.25 (495)
Reduction of teacher-rated impairment due to ADHD symptoms (FBB-ADHD-impairment)	0.28 (499)	0.27 (495)
Increase in teacher-rated attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity)	0.25 (491)	0.25 (487)
Improvement in Clinical Global Impression (CGI)	0.25 (629)	0.22 (626)
Reduction in parent-rated ADHD symptoms in the morning (DAYAS-P-ADHD-morning)	0.24 (680)	0.16 (667)
Reduction in parent-rated ADHD symptoms in the afternoon (DAYAS-P-ADHD-afternoon)	0.40 (669)	0.23 (659)
Reduction in parent-rated ADHD symptoms in the late afternoon (DAYAS-P-ADHD-late afternoon)	0.34 (680)	0.17 (668)
Reduction in parent-rated ADHD symptoms in the evening (DAYAS-P-ADHD-evening)	0.24 (678)	0.12 (666)
Reduction in teacher-rated ADHD symptoms in the first half of school morning (DAYAS-T-ADHD-first half)	0.23 (530)	0.25 (528)
Reduction in teacher-rated ADHD symptoms in the second half of school morning (DAYAS-T-ADHD-second half)	0.23 (509)	0.25 (506)

All correlations are statistically significant at $P \leq 0.001$

DAYAS Day profile of ADHD symptoms, *FBB-ADHD* Fremdbeurteilungsbogen für Aufmerksamkeitsdefizit-Hyperaktivitätsstörung

(SAMS-S) was also lower than the correlation between the same measure and parent satisfaction (SAMS-P, Table 6).

Table 7 shows the correlations between satisfaction with medication and improvements in patient QoL from Visit 1 to Visit 3, as rated by parents (KINDL), children (KID-KINDL) and adolescents (KIDDO-KINDL). The improvement in parent ratings of total patient QoL correlated with parent satisfaction with medication (SAMS-P) in the low to medium range ($r = 0.39$), indicating that parental satisfaction is higher for children with greater improvements in QoL. The correlations between improvements in child or adolescent ratings of QoL and parent satisfaction were in the same range. Patient satisfaction with medication (SAMS-S) showed the highest correlation with improvements in patient ratings of QoL (KID-KINDL and KIDDO-KINDL), while the correlation with improvements in parent rating was somewhat lower. Table 7 also shows that all subscales of QoL correlated with parent and patient satisfaction with medication, indicating that improvements in all QoL domains contribute to satisfaction with medication; however, not all these correlations were statistically significant.

We then conducted stepwise regression analyses with changes between Visit 1 and Visit 3 in teacher and parent ratings of ADHD symptoms (FBB-ADHD-total), functional impairment (FBB-ADHD-impairment) and attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity) on the FBB-ADHD scale, changes in parental ratings of ADHD and ODD symptoms in the afternoon on the DAYAS and changes in parent and patient ratings of QoL (KINDL-total and KID-KINDL-total) as predictors.

Criteria were parent and patient satisfaction with medication. In the stepwise regression analysis for parental satisfaction with medication, in a sample of 255 patients with all data present, three variables entered the final equation: improvement in (1) parent ratings of functional impairment (FBB-ADHD-impairment), (2) parent ratings of attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity) and (3) parent rating of QoL (KINDL-total). The multiple correlation of these three predictors with parent satisfaction was $R = 0.58$, which explained 33.0% of the variance (corrected R^2) of parent satisfaction. All other potential predictors did not increase the variance in a statistically significant manner. Similarly, in the stepwise regression analysis for patient satisfaction with medication, in a sample of 253 patients with all data present, three variables entered the final equation: improvement in (1) patient ratings of QoL (KID-KINDL-total), (2) parent ratings of attentive–reflexive and enduring behaviour (FBB-ADHD-attention-reflexivity) and (3) functional impairment (FBB-ADHD-impairment). The multiple correlation of these three predictors with patient satisfaction was $R = 0.44$, which explained 17.9% of the variance (corrected R^2) of patient satisfaction. All other potential predictors did not increase the variance in a statistically significant manner.

Discussion

Satisfaction with medication is an important factor in the evaluation of treatment outcome and is predictive of better

Table 7 Pearson's correlations between parent and patient satisfaction with medication (SAMS-P and SAMS-S) and improvement in QoL from Visit 1 to Visit 3

Visit 1 to Visit 3 improvement	SAMS-P r (n)	SAMS-S r (n)
QoL total		
Parent rating	0.39 (593)	0.22 (577)
Child rating	0.38 (430)	0.31 (428)
Adolescent rating	0.33 (148)	0.30 (151)
QoL physical well-being		
Parent rating	0.16 (612)	0.12 (596)
Child rating	0.26 (443)	0.19 (441)
Adolescent rating	0.12 (154)[ns]	0.14 (157)[ns]
QoL emotional well-being		
Parent rating	0.27 (611)	0.13 (595)
Child rating	0.20 (443)	0.19 (441)
Adolescent rating	0.24 (154)	0.12 (157)[ns]
QoL self		
Parent rating	0.34 (607)	0.20 (591)
Child rating	0.27 (442)	0.23 (440)
Adolescent rating	0.21 (154)	0.30 (157)
QoL family		
Parent rating	0.31 (607)	0.17 (591)
Child rating	0.25 (440)	0.22 (438)
Adolescent rating	0.21 (153)	0.12 (156)[ns]
QoL friends		
Parent rating	0.23 (606)	0.15 (590)
Child rating	0.26 (438)	0.23 (436)
Adolescent rating	0.34 (151)	0.36 (154)
QoL school		
Parent rating	0.28 (596)	0.15 (580)
Child rating	0.26 (434)	0.20 (432)
Adolescent rating	0.19 (149)	0.14 (152)[ns]

All correlations are statistically significant at $P \leq 0.05$, except those marked [ns]

Parent ratings used the Kinder Lebensqualitätsfragebogen (KINDL) scale, child ratings the KID-KINDL scale and adolescent ratings the KIDDO-KINDL scale

QoL Quality of life, *SAMS* Satisfaction with medication

adherence and compliance [20]. In this analysis of satisfaction data collected using the SAMS questionnaire, we show that satisfaction with Equasym XL® among parents and children enrolled in the OBSEER trial was high, with rates of overall satisfaction reaching 70.5 and 79.0%, respectively. This is in agreement with the results of previous studies with stimulant medications [7, 10, 11, 28, 29]. Approximately 30% of parents were dissatisfied with the medication. While efficacy was highly rated, approximately half of parents and patients were recorded as not satisfied with the duration of action of Equasym XL® (item 10 of the SAMS questionnaire). This result highlights the importance of treatment individualisation and the need for multiple treatment options to give parents and patients more choice.

With respect to the psychometric properties of the SAMS tool, the item-total correlation was high for all items in the parent version (SAMS-P) of the questionnaire ($r = 0.71$–0.90) and medium–high for the patient version (SAMS-S, $r = 0.57$–0.77). Internal consistency was also high for both SAMS-P and SAMS-S, with Cronbach's alpha values > 0.9. Principal component analyses showed that the one-factor solution best fit the SAMS data, explaining a high percentage ($>71\%$) of variance; together with the high internal consistency of the scale, this further emphasises the adequacy of the SAMS total score for describing satisfaction with medication. The analysis of the stability of ratings (correlation between the same rating at different time points) revealed correlations in the medium range between Visit 2 and Visit 3, indicating a moderate stability of satisfaction with medication for both parents and patients ($r = 0.54$ and 0.59, respectively). Cross-informant rating correlations at each visit were also moderate ($r = 0.48$–0.60), underlining the importance of assessing the perspectives of both patients and parents.

In the analysis of predictors of satisfaction at the end of the study (Visit 3), the highest correlations ($r = -0.62$ to -0.54) were found between parent satisfaction and parent rating of ADHD symptoms and impairment (FBB-ADHD scale) and of ADHD symptoms in the afternoon (DAYAS scale) at Visit 3; as expected, correlations between satisfaction and ADHD symptoms were negative, indicating lower satisfaction with medication in children with higher ratings of symptoms. Regarding QoL at Visit 3, the highest correlations ($r = 0.53$) were observed between parent satisfaction and parent overall ratings of QoL and between patient satisfaction and patient overall ratings of QoL; correlations in the case of QoL were positive, indicating higher satisfaction with medication in patients with better QoL. Stepwise regression analyses for parental satisfaction with medication at Visit 3 showed that parental satisfaction could be explained to a high degree ($>52\%$ of variance) by four variables, which mainly reflected ADHD impairment and ADHD symptoms (three variables), but also QoL (one variable). The explained variance in the regression analysis for patient satisfaction was somewhat lower (36% of variance explained), but still substantial. As in the case of parents, four variables contributed significantly to the prediction of patient satisfaction and included patient ratings related to QoL (one variable) along with parent ratings of ODD symptoms and attentive–reflexive and enduring behaviour as well as teacher ratings of ADHD symptoms.

When satisfaction with medication was evaluated in relation to changes in ADHD symptoms during the study from baseline (Visit 1) to the end of the study (Visit 3), the highest correlations were found between parent satisfaction

and the same ratings that showed highest correlation at the end of the study ($r = 0.40$–0.44). Regarding QoL, the highest correlations were observed between parent satisfaction and parent ratings of QoL ($r = 0.39$); correlations between parent satisfaction and patient ratings and between patient satisfaction and patient ratings were in the same range ($r = 0.30$–0.38). Stepwise regression analyses showed that changes in symptom ratings from Visit 1 to Visit 3 could explain satisfaction with medication, but to a lesser degree compared with symptom ratings at Visit 3 (33% of variance for parents and 17% for patients). Taken together, these analyses show that symptom severity and/or functional impairment at the end of the study, as well as QoL, are the most significant predictors for parent and patient satisfaction, underscoring the importance of functional impairment and QoL, besides ADHD symptoms, as outcome parameters in the treatment of children with ADHD.

One of the recognised limitations of observational studies is that inclusion and exclusion criteria are not as rigorous as in clinical trials, and treatment conditions (e.g. dosing) are less controlled and standardised. However, these features of observational trials can at the same time represent an advantage, as they reflect routine care conditions in the real population. In particular, for satisfaction with medication, ratings from clinical trials are less informative as they are influenced by the fact that the sample is likely to be biased, given that those who agree to participate in the studies tend to do so because they are not satisfied with their previous medication [5].

In conclusion, these results show that parent and patient satisfaction can be assessed reliably with the new SAMS-P and SAMS-S questionnaires. It is important to assess the perspectives of parents and patients separately, with rating scales asking comparable questions, as their perceptions of medication are correlated, but only to a medium degree. Both symptom severity at the end of the study and symptom reduction during treatment have a strong influence on parent and patient satisfaction; however, functional impairment and QoL at the end of the study as well as their improvement during treatment are also important factors and should be taken into consideration.

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