Clinical Documentation for QbTest and QbCheck

1. Background

QbTest and QbCheck are objective tests that can be used in the assessment of ADHD and for the evaluation of different treatments in patients with ADHD. Both tests involve motion tracking systems and computerized tasks that requires continuous attention and impulse control. As a result, the tests provide data on all core signs of ADHD, that is, hyperactivity, impulsivity and inattention. The tests can be used in children (6-12 years) and in adolescents/adults (12-60 years). The computerized tasks differ in cognitive demand between the child version (go-no go paradigm) and the adolescent/adult version (unconditional identical pair paradigm). This document describes the principal clinical studies supporting the use of QbTest/QbCheck in the assessment of ADHD and for treatment follow-up in patients with ADHD. In total, the clinical documentation consists of around 30 independent publications. Documentation referred to as Data on file can be delivered at request. The documentation is based on studies with QbTest but since QbCheck is substantially equivalent to QbTest with the main difference that QbCheck can be performed online using a web-camera, the below documentation can also be considered valid for QbCheck.

2. Normative Data

To evaluate a given test person's QbTest performance, a representative control group is needed as comparison. Therefore, normative tests have been gathered from several different cohorts resulting in a normative database of 1307 individuals between 6 and 60 years with an even age and gender distribution. The characteristics of this normative group and the methods to generate age and gender specific comparisons are described in study 1 and the age dependent development of QbTest performance in children is described in study 2.

3. Validity Studies

The test is not designed to be a stand-alone tool for the diagnosis of ADHD. Rather it should be seen as a key component in the assessment together with other clinical data such a structured clinical interview and subjective information from validated rating scales. It is, however, important that QbTest can differentiate patients with ADHD from normative individuals. To evaluate this capability, two discriminant validity studies (3,4) were performed, one in children with ADHD (N = 86) and one in adolescents/adults with ADHD (N = 135). In both studies, age matched normative individuals were used as control groups. Both test versions showed sensitivity (correct classification of individuals with ADHD) and specificity (correct classification of non-clinical individuals) of around 90%, supporting that the test can be a valuable tool in the assessment of ADHD. Another study (5) in 266 individuals (148 males), with a mean age of 22 years old (13-53 years), was performed to evaluate if computer experience was associated with QbTest performance for the adolescent/adult version of the test. Pearson correlations were conducted examining relations between weekly time spent with computers and/or video-console games and QbTest performance. No correlations were observed, indicating that computer experience is unlikely to be a confounder for the adolescent/adult version of QbTest and does not seem to increase the risk of false negative results.

In addition, 11 published studies (6-16) have evaluated the clinical validity of QbTest. In study 6, 50 clinical cases (5-15 years) subjected to assessment for ADHD were used to evaluate the ability of QbTest to identify ADHD in a clinical population. The study showed a 96% sensitivity and an 81% specificity of the test to differentiate individuals with ADHD from individuals with disconfirmed ADHD. Study 7 examined the discriminant validity of the test in a sample of 55 adult patients with ADHD (mean age 33 years) and 202 normative participants (mean age 31 years). A composite measure of ADHD based on three cardinal symptom variables from the test representing hyperactivity, inattention, and impulsivity yielded 86% sensitivity and 83% specificity.

In study 8, with the primary objective to evaluate if hyperactivity measured during the test, not only is present in children but also in adults with ADHD, 20 adult patients diagnosed with ADHD (mean age 37.3 years) and 20 matched healthy controls (mean age 37.5 years) were included and QbTest results were compared. The study showed that not only inattention but also hyperactivity, measured by QbTest, was statistically significantly more prominent in ADHD than in controls, increased with test duration, and only covaried with cognitive performance in the subjects with ADHD. Interestingly, there was a correlation between self-rated hyperactivity (ASRS) and objectively measured hyperactivity in the normal control group ($r = .56$), but not in the ADHD group ($r = .07$), indicating that the group with ADHD had difficulties to assess their symptoms.

In study 9, with the primary objective to correlate biochemical brain markers with objective measurements for ADHD, 21 children with ADHD (mean age 8.9 years) and 21 normative children (mean age 11.0 years) were included. Group comparisons on QbTest performance revealed statistically significant differences between the ADHD and normative group. In addition, several QbTest variables were associated with different biochemical brain markers in the ADHD group.

In study 10, an exploratory factor analysis was performed in 828 children, resulting in a three-factor model representing Hyperactivity, Inattention, and Impulsivity respectively. Hyperactivity explained the largest amount of variance and the two other factors, Inattention and Impulsivity, each explained additional unique parts of variance. Convergent validity with the Conner's teacher rating scales was found for the Hyperactivity factor but not for the Inattention and Impulsivity factors. It was hypothesized that teachers are better able to detect externalizing behavior (i.e., hyperactivity) that is highly visible in classroom situations than internalizing behavior (i.e., inattention), that normally does not disturb classroom proceedings. Also, the relatively low correlations between the subjective and objective methods was explained by the fact that these two methods measure different aspects of behavior.

In study 11, the three factors above (Hyperactivity, Inattention, and Impulsivity) were evaluated in 45 ADHD children (mean age 9.2 years), 22 non-affected siblings (mean age 11.2 years), and 45 unrelated controls (mean age 8.9 years) with no family history of ADHD. The ADHD children showed the greatest impairments on all three QbTest factors, followed by their non-affected siblings, with control children showing the lowest scores. Group differences between the non-affected siblings and controls were only statistically significant for the motion tracking-based Hyperactivity factor, indicating that Hyperactivity assessed by QbTest may be a useful intermediate phenotype in ADHD. The authors concluded that since the QbTest factors are based on the neuropsychological level of the disorder they may represent a marker for ADHD that could ultimately help to improve phenotype definition.

Study 12 and 13 evaluated the discriminant validity for the adult version of the test in different psychiatric populations. In one of the studies (12), a naturalistic sample of 61 clinic-referred patients with suspected ADHD, of which 41 patients met the criteria for ADHD and only 20 did not, were used to evaluate the discriminant validity of the three QbTest factors (Hyperactivity, Impulsivity, and Inattention). The Impulsivity and Inattention factors showed high stand-alone specificity (80 and 100% respectively) but low stand-alone sensitivity (59 and 36% respectively), whilst the Hyperactivity factor showed moderate stand-alone sensitivity and specificity (68 and 65% respectively). Interestingly, the self-rating scales (ASRS and CSS) showed the inversed results, with high sensitivity (90 and 85% respectively) and low specificity (35 and 40% respectively). A stepwise discriminant function analysis showed that a combination of the Hyperactivity and Inattention factors yielded 72.1% correct classification of the individuals with a sensitivity of 87.8% and a specificity of 40.0%. The low specificity could be explained by the fact that the patients were referred by psychiatric clinics to a specialized ADHD clinic due to suspected ADHD and therefore several of the patients who did not meet the diagnostic criteria (control group) had ADHD-like symptoms. In a somewhat larger study (13), a weighted symptom score was developed by operationalizing the three cardinal symptom variables from QbTest representing Hyperactivity, Inattention, and Impulsivity to yield a summary score between 0 and 100, with low scores indicating higher likelihood of ADHD. The respective scores for normative individuals (n = 179), patient with disconfirmed ADHD diagnosis (n = 29), patients with Bipolar II/Borderline Personality disorder (n = 45) and patients with ADHD (n = 53) were 71, 40, 46, and 18. The ADHD group scored statistically significantly lower than all other groups and the normative group scored statistically significantly higher than all other groups, indicating that a summary score from the test in an adult population not only can differentiate ADHD from norm but also from other clinical groups.

Another study (14) in an adult clinical population under assessment for ADHD (N = 108) evaluated which variables commonly used in different objective tests during assessment best predicted final clinical diagnosis. The study showed that the variables with best validity were the cardinal variables for hyperactivity (QbActivity) and inattention (QbInattention) from QbTest, and the variable Commission Errors used in Conner's CPT II. When these variables were used in combination with DIVA (Diagnostic Interview for ADHD in adults), the specificity of the diagnosis was increased by 10%.

Two studies (15-16) have evaluated the ability for QbTest to differentiate ADHD from ASD (Autism Spectrum Disorder). One of the studies (15) included 182 children who had been referred to a specialist clinic for the assessment of ADHD/ASD. Of these children, 124 received a clinical diagnosis of ADHD and 58 received other clinical diagnoses (82% ASD). In this study, the Hyperactivity and Inattention cardinal variables (QbActivity and QbInattention) could differentiate these clinical groups with a statistical significance of $p < .01$. These cardinal variables were more effective in predicting ADHD (PPV .76 – .86) than in ruling out ADHD in children who predominantly had ASD (NPV .37 – .50). The authors concluded that the test variables showed high validity in differentiating ADHD from normatives and moderate validity in differentiating other clinical groups. Study 16 examined QbTest's ability to differentiate ADHD from ASD in an adult population. In similarity with the study performed in children, QbActivity ($p < .001$) and QbInattention ($p < .001$) were the most effective variables in differentiating ADHD from ASD, but also the cardinal variable for impulsivity (QbImpulsivity) showed a statistically significant effect in this respect ($p < .01$).

By adding the information from QbTest to the results from the subjective rating scales, correct classification could be increased from 84% to 94% (ADHD) and from 76% to 84% (ASD).

4. Reliability Studies

To evaluate the reliability of QbTest, two test-retest studies (17, 18) using similar methodology, were performed in children and adolescents/adults. The study in children included 24 individuals (mean age 11 years) and the study in adolescents/adults included 37 individuals (mean age 25 years). Paired sample correlations for the two test occasions revealed adequate to high retest correlations for the majority of the standard QbTest variables. In addition, a placebo-controlled study in 128 children evaluating atomoxetine treatment (19), where the children performed the test 3 times a day at 5 different occasions over 8 weeks, showed that the QbTest variables only changed marginally in the placebo group during the study period, highlighting the high reliability of the test.

5. Treatment Response

Several studies (19-30) in children, adolescents, and adults have been performed in which QbTest was used to evaluate treatment response: In study 19 with the objective to evaluate the effect of atomoxetine by means of QbTest and clinical rating scales, 128 children with ADHD, aged 6-12 years, were randomized to treatment with atomoxetine or placebo and followed for 8 weeks. A QbTest was performed three times per day at baseline and after 1, 2, 4, 6, and 8 weeks of treatment. The study showed statistically significant effects after 8 weeks of treatment for all QbTest variables. In addition, the observed effects were corroborated by the validated clinical rating scales used in the study. The highest correlations for treatment effects between the clinical rating scales and QbTest results were around .60. Another study (20) in the same child cohort showed that by using QbTest, not only treatment effect over time, but also circadian pattern of treatment response across the day could be measured.

In a group of 36 children with ADHD aged 8-12 years, the effect of immediate-release and long-acting methylphenidate formulations was studied (21). All included children performed a QbTest four times during the same day within 8 hours. Also in this study, circadian fluctuations of treatment response could be detected by using QbTest. In study 22, with the objective to identify responders to methylphenidate, 44 children and adolescents aged 7-18 years with confirmed hyperkinetic disorders performed a QbTest before and after a test dose of methylphenidate. A robust treatment response was confirmed in 84% of the patients. 7% demonstrated a partial response and 9% were determined as non-responders due to deteriorating activity measures together with no improvement in attention and impulse control measures. The authors concluded that objective measures are effective in the early identification of treatment response to stimulant medication. In another study (23) with the objective to investigate clinical gains from including both dextroamphetamine and methylphenidate in stimulant trials, QbTest was performed in 36 medication-naïve children aged 9-14 years diagnosed with ADHD in a cross-over design. High effect sizes, meassured by a composite QbTest variable, were shown for both methylphenidate and dextroamphetamine. Also, in this study, the observed treatment effects using QbTest were corroborated by clinical rating scales.

Study 24 evaluated the effect of methylphenidate in 23 adult prisoners (mean age 34.4 years) with ADHD and other coexisting disorders, QbTest was performed after 16 and 52 weeks. The study showed statistically significant effects after 16 weeks of treatment for all QbTest variables. Additional improvements were observed in some QbTest variables after 52 weeks of treatment. In accordance with the findings in studies in children, the observed effects using QbTest were corroborated by clinical rating scales.

Another study (25) in 63 adult patients with ADHD (mean age 35.2 years) showed that a single dose of methylphenidate (mean dose 13.7 mg) yielded statistically significant ($p<0.001$) decreased symptom levels measured by QbTest for all cardinal symptoms and a weighted symptom score. In a second part of the above study, 10 patients were subjected to methylphenidate dose titration up to 72 mg. The weighted symptom score derived from QbTest, but not the different rating scales used in the study, was able to identify symptom level reduction between baseline and all investigated dose levels.

Study 26 compared response to stimulant treatment in patients with ADHD measured by objective QbTest or a subjective ADHD rating scale (ADHD-RS). The study showed statistically significant ($p < .01$) but low (.33) correlations in Total score changes for the two methods. The QbTest Total score was calculated as the mean value of the three cardinal parameters; QbActivity, QbImpulsivity, and QbInattention. The authors suggested that subjectively and objectively measured symptoms may be different ADHD-related constructs.

QbTest was more sensitive to medication effects and could objectify an improvement in 54% of patients who did not subjectively report an improvement. In contrast, 36% of patients not showing objective improvement on the QbTest did subjectively report an improvement.

In about 50% of the cases, the subjective and objective measures agreed in the classification of the treatment effects. High baseline QbTest scores predicted large treatment effects measured both with objective (QbTest) and subjective (ADHD-RS) methods. In contrast, high ADHD-RS scores at base-line were not able to predict treatment effects. In addition to the studies above on stimulant medication and atomoxetine, QbTest has also been utilized to evaluate the effect of other type of treatments such as essential fatty acid supplementation (27), cognitive behavior therapy (28), transcranial direct current stimulation (29), and cannabinoids (30).

6. Clinical Utility

In a series of studies, the clinical utility of QbTest has been evaluated. The first two studies (31 and 32) had a pre- vs. post-test audit design. In study 31, with the objective to evaluate if adding QbTest could impact clinical accuracy, 46 children (mean age 9 years) were diagnosed without using QbTest and 62 children (mean age 10.5 years) were diagnosed with QbTest as part of the diagnostic procedure. The study showed that QbTest significantly increased the diagnostic accuracy (p= .0035) measured by subsequent rates of revised diagnosis over a 12-month period. In study 32, with the objective to evaluate if adding QbTest could impact the efficiency of the diagnostic procedure, 40 children (mean age 8.1 years) were diagnosed without using QbTest and 40 children (mean age 9.2 years) were diagnosed with QbTest as part of the diagnostic procedure. The study showed that the children in the QbTest group needed significantly fewer consultations to reach diagnosis (mean 2.18 vs. 3.05 visits; p= .02). QbTest particularly added important information in cases with missing or conflicting data resulting in less prolonged assessments. These results were later confirmed by a randomized controlled study (RCT) in 250 children aged 6-17 years: the AQUA-trial (33). In this study, all patients performed QbTest, but patients and clinicians were randomized to either receive the QbTest results immediately or the QbTest was withheld. Clinicians with access to QbTest were 44% more likely to receive a diagnostic decision within the 6-months follow-up period (p = .029). At 6 months, 76% of the patients in the QbTest group had received a diagnosis compared to 60% in the control group (p = .003). Clinicians in the QbTest group were twice as likely to exclude a diagnose of ADHD (p = .049) and were also more confident in their diagnostic decision (p = .022). These results were achieved without compromizing the diagnostic accuracy. Semi-structured interviews and a survey assessing the experience of the QbTest were conducted in a sub-set of clinicians and families participating in the AQUA-trial. The QbTest was found to facilitate communication between clinicians, families and schools and was also found useful both among clinicians and families, reassuring the feasibility of the test (34).

Health economic data from the AQUA study showed small cost-savings for the health service and improved outcomes. However, the overall health economic impact of QbTest was considered as neutral. The health economic analyses were however compromised by the limited study period and therefore longer-term costs associated with cases still waiting for their diagnosis (24% in the QbTest group and 40% in the control group) could not be accounted for. In an audit study performed at three community pediatric mental health centers in the UK, an economic evaluation and return on investment analysis was performed (35). The audit showed that, after the implementation of QbTest, the number of days to reach a clinical decision changed from 161-453 days (approximately 5-15 months) to 15-252 days (approximately 2 weeks to 8.5 months). In addition, the average days from assessment to commencing medical treatment decreased from 42-179 days to 15-96 days. Based on above mean estimates these effects could be translated into cost reductions ranging from 9-39%.

7. Conclusions

Taken together, the enclosed documentation shows that QbTest is based on a representative control group, has high validity when used to discriminate ADHD from normative individuals, and high test-retest reliability. In addition, QbTest can add important clinical information in the process of differentiating ADHD from similar disorders, improve the diagnostic accuracy, and shorten the time to diagnosis. The effectiveness of the test during treatment follow-up has been documented in different patient populations and for different types of treatments. Several studies showed that QbTest results were in line with results from validated rating scales but also added unique information, supporting the usefulness of the test during treatment follow-up. Different clinical utility studies with QbTest showed good feasibility, improved accuracy and efficiency as well as cost-savings for the participating health services. These data suggest that QbTest and QbCheck should be key components in the clinical assessment and treatment follow up of ADHD.

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