Feasibility of an Electronic (eCOA) Prompted Yale Global Tic Severity Scale (YGTSS) with Blinded Internal Scoring

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ABSTRACT

The Methodological Question Being Addressed: Can an electronic (eCOA) prompted Yale Global Tic Severity Scale (YGTSS) be developed with rater-blinded, algorithm-driven internal scoring quality checks?

Introduction (Aims): The YGTSS is a gold-standard tic severity assessment in Tourette Syndrome (TS) studies. Inconsistency in administration and scoring may compromise signal detection. To improve ratings quality, we developed an eCOA prompted YGTSS that provided rating guidance, captured rater scores, and generated rater-blinded algorithm-derived scores as quality checks.

Methods: An eCOA prompted YGTSS was developed on a validated platform using feedback and guidance from TS experts. The eCOA YGTSS ensured correct navigation through the scale and displayed lists of endorsed tics to assist the rater in making severity ratings. Scoring algorithms were developed for an experimental second set of rater-blinded "tandem" scores. The algorithms were based on responses the rater had entered (e.g., presence of orchestrated sequence of tics), which were then applied to the scale anchors. The scale is being piloted in two ongoing, placebo-controlled multisite TS trials, one pediatric and one adult, with rater scores serving as efficacy data. Raters first received YGTSS scoring and administration training, and were required to demonstrate both scoring and administration competency prior to study start. We present the comparison of rater vs computer algorithm-derived scores using Pearson correlations and t-tests.

Results: 37 subjects (12 pediatric, 25 adult) completed 99 visits by 20 raters at the time of the analysis. Correlations between rater and computer scores were high for each of the 10 YGTSS severity scores (range: .74 - .91, all p's < .0001); for the Total Tic Score (TTS) (primary efficacy measure) the correlation was .95 (p < .0001). The mean rater vs computer TTS scores were almost identical (28.8 and 28.5, respectively, NS). The findings did not differ by patient population (pediatric vs adult).

Conclusions: Our internal scoring algorithms correlated significantly with all rater-selected motor, phonic, and TTS scores, with the latter nearly identical. The work provides preliminary validation of our algorithms and supports the feasibility of the approach. In a risk-based monitoring model, less trained raters whose scores deviate significantly from those of the internal algorithm might be selected for additional scrutiny and intervention. Our results support the utility of a computer-prompted YGTSS with internal tandem scoring for multisite TS trials.

Disclosure: One or more authors report potential conflicts which are described in the program.

THE METHODOLOGIC QUESTION BEING ADDRESSED

- Can an electronic (eCOA) prompted Yale Global Tic Severity Scale (YGTSS) be developed with rater-blinded, algorithm-driven internal scoring quality checks?

INTRODUCTION (AIMS)

- The YGTSS is a gold-standard tic severity assessment in Tourette Syndrome (TS) studies
- Inconsistency in administration and scoring may compromise signal detection
- To improve ratings quality, we developed an eCOA prompted YGTSS that provided rating guidance, captured rater scores, and generated rater-blinded algorithm-derived scores as quality checks

METHODS

- An eCOA prompted YGTSS was developed on a validated platform using feedback and guidance from TS experts
- The eCOA YGTSS followed the format of the YGTSS: motor and tic checklist followed by 5 severity domains for motor tics and 5 severity domains for phonic tics
- The eCOA YGTSS helped ensure correct navigation through the scale and assisted the rater by redisplaying the tics endorsed on the respective checklist at the time the motor and phonic severity ratings were required
- Scoring algorithms were developed for an experimental set of second ("tandem") scores that were blinded to raters
- The algorithms were based on responses the rater had entered (e.g., presence of orchestrated sequence of tics), which were then applied to the scale anchors
- The scale is being piloted in two ongoing, placebo-controlled multisite TS trials, one pediatric and one adult, with rater scores serving as efficacy data
- Raters first received YGTSS scoring and administration training, and were required to demonstrate both scoring and administration competency prior to study start
- We present the comparison of rater vs. computer algorithm-derived scores using Pearson correlations and t-tests

RESULTS

- 37 subjects (12 pediatric, 25 adult) completed 99 visits by 20 raters at the time of the analysis
- The mean rater vs. computer Total Tic Scores (TTS) (primary efficacy measure) were almost identical (28.8 and 28.5, respectively, NS) (see Figure 1 for individual severity domains)
- Correlations between rater and computer scores were high for each of the 10 YGTSS severity scores (range: .74 - .91, all p's < .0001)
- Correlations between rater and computer scores for the Total Tic Score (TTS) (primary efficacy measure) was .95 (p < .0001) (see Figure 2 for all correlations)
- The findings did not differ by patient population (pediatric vs. adult)

Figure 1: Mean Rater and Computer YGTSS Scores by Domain

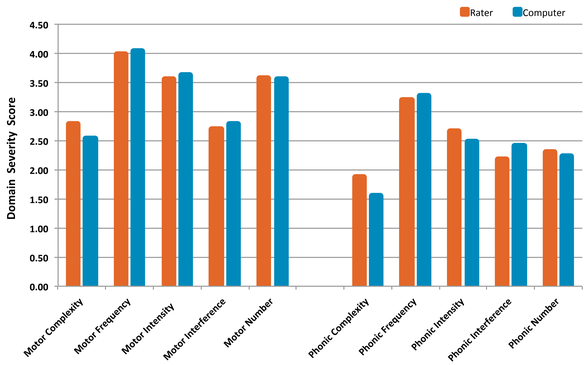
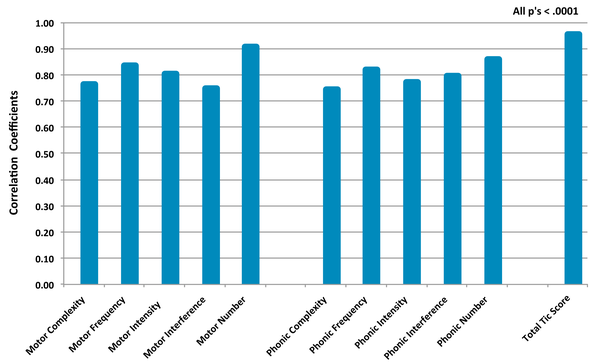


Figure 2: Correlation of Rater and Computer YGTSS Domain and Total Scores



CONCLUSIONS

- Our internal scoring algorithms correlated significantly with all rater-selected motor, phonic, and TTS scores, with the latter nearly identical
- The work provides preliminary validation of our algorithms and supports the feasibility of the approach
- In a risk-based monitoring model, less trained raters whose scores deviate significantly from those of the internal algorithm might be selected for additional scrutiny and intervention
- Our results support the utility of a computer-prompted YGTSS with internal tandem scoring for multisite TS trials

DISCLOSURE

- One or more authors report potential conflicts, which are described in the program

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