VALIDATION OF THE GENITAL HERPES TREATMENT SATISFACTION QUESTIONNAIRE (GHerpTSQ) IN STATUS AND CHANGE VERSIONS

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Purpose

- To validate a new measure of treatment satisfaction for patients with recurrent genital herpes simplex virus (GH).

Background

- The clinical symptoms of GH outbreaks are frequently associated with profound psychosocial morbidity[1].
- Two antiviral therapeutic strategies are widely used for the management of GH:
  - episodic treatment, where individual herpes outbreaks are treated as they arise;
  - suppressive therapy, where treatment is taken daily to prevent GH outbreaks.
- Valacyclovir may be prescribed as episodic therapy, with a dosage regimen of 500mg twice daily, usually taken for 5 days. When administered as suppressive therapy, valacyclovir is effective for the prevention for GH outbreaks when taken once daily[2].
- Suppressive therapy has been shown to be preferred by patients with GH over episodic therapy[2]. Patient satisfaction in genital herpes is important since suppressive therapy involves taking medication in the absence of clinical symptoms.

Methods

- A 12-item questionnaire was designed using a modified form of the widely used Diabetes Treatment Satisfaction Questionnaire (DTSQ)[3]. Figure 1 shows the Status version of the questionnaire. The Change version used the same questions with different text for the introduction.
- The GHerpTSQ was evaluated within a sample of 202 Canadians (120 English, 82 French) with a history of GH (herpes simplex virus type 1, or type 2) participating in a 48 week randomised crossover trial.
- Participants were randomised to receive valacyclovir either once daily as suppressive therapy or as episodic treatment for 24 weeks before crossover to the other regimen. A status version of the GHerpTSQ was completed every 12 weeks and a change version at weeks 36, 48.
- The primary study endpoint, subject treatment preference, was measured at the end of study (week 48), or at early termination once both treatments had been taken.
- The question was: "Overall, which treatment did you prefer while you were in this study?
  - Treatment A suppressive therapy (one pill per day plus treatment of outbreaks)
  - OR
  - Treatment B episodic therapy (treatment of outbreaks only)"

Figure 1

Statistical Analyses

- Exploratory factor analyses were use to explore the psychometric properties of the GHerpTSQ. The analyses were performed on the responses to the GHerpTSQ to determine the number of constructs measured by the GHerpTSQ and the nature of those constructs. Both the English and French versions of the questionnaire were evaluated separately.
- To eliminate the possibility of the existence of artificial correlations within subgroups (language and type of therapeutic strategy) a regression analysis was performed. Two sets of factor loadings on a forced one factor solution, obtained from the raw scores and scores following standardisation within subgroup (English/episodic, French/ episodic, English/suppressive, French/suppressive), were compared using regression analysis.
- Scale reliability was assessed by computing Chronbach's alpha[3].
- The mean scores at weeks 12, 24, 36, 48 were compared using a t-test. The reported P-values were not adjusted for multiple comparisons.
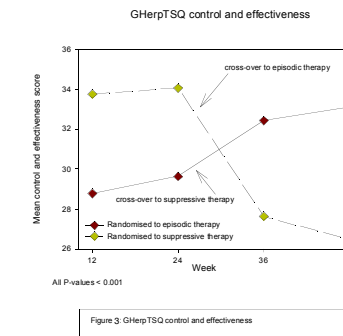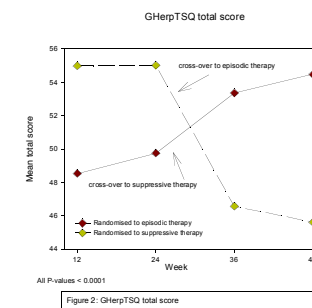
Results

- There was no evidence for the existence of artificial correlations created by subgroup differences.
- A preliminary unforced factor analysis on English 12-week status data suggested:
  - the 12 items could be divided into two subscales plus a single item for separate analysis;
  - the item relating to the subjects satisfaction with their, "... understanding of genital herpes" was dropped due to a very low factor loading.
  - the single item for separate analysis is related to the extent by which a subject has been, "... bothered by any side effects of ... treatment".
- Valacyclovir may be prescribed as episodic therapy, with a dosage regimen of 500mg twice daily, usually taken for 5 days. When administered as suppressive therapy, valacyclovir is effective for the prevention for GH outbreaks when taken once daily[2].
- Suppressive therapy has been shown to be preferred by patients with GH over episodic therapy[2]. Patient satisfaction in genital herpes is important since suppressive therapy involves taking medication in the absence of clinical symptoms.
- In the combined sample:
  - The first subscale related to control and effectiveness
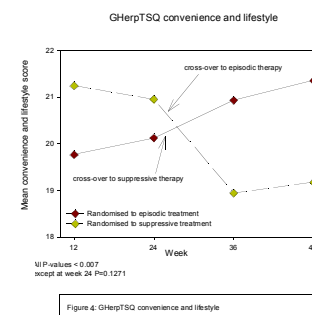 - The second subscale related to convenience and impact on lifestyle (table 1)

Control and Effectiveness α=0.9			Convenience and Impact on Lifestyle α=0.8		
Item	Factor Loading	Question	Item	Factor Loading	Question
1	0.8	... satisfied	1	0.8	... convenience
2	0.8	... control	2	0.7	... flexibility
3	0.9	... recommend	3	0.8	... demanding
4	0.9	... continue.	4	0.8	... lifestyle.
5	0.9	... effectiveness	-	-	-
6	0.9	... QOL impact	-	-	-

Table 1: factor loadings on each of 2 factors and alpha coefficients for items retained in subscales.

- The subscales were verified using the French 12-week status and 36-week English/French change data.
- The control and effectiveness scale has a range from 0 (very dissatisfied) to 36 (very satisfied); the convenience and impact on lifestyle scale has a range from 0 (very dissatisfied) to 24 (very satisfied); the total score has a range of 0 (very dissatisfied) to 60 (very satisfied).
- The 10 items from the two subscales may be used as a total score (factor loadings > 0.56; α=0.92).
- Subjects who were randomised to suppressive therapy had significantly higher satisfaction with treatment overall (P<0.001) and in the control of GH outbreaks (P<0.001); after cross-over to episodic therapy this cohort of subjects experienced a significant drop in overall satisfaction and with GH control (P<0.001). (figures 2-3)

Figure 2: GHerpTSQ total score

Figure 3: GHerpTSQ control and effectiveness

- Subjects who were randomised to suppressive therapy found their treatment significantly (P<0.007) more convenient at weeks 12, 36, 48, with a trend at week 24 (P=0.13); after cross-over to episodic therapy this cohort of subjects experienced a significant drop in satisfaction (P<0.007) with the convenience of their GH treatment (figure 4).

Figure 4: GHerpTSQ convenience and lifestyle

Conclusions

- The GHerpTSQ status/change can be analysed as either: two separate subscales (convenience/lifestyle and control/effectiveness) plus a single item related to side-effects; or by combining the two subscales into a 10-item total score (overall treatment satisfaction).
- The GHerpTSQ status/change measures have good reliability, clear structure and evidence of validity.
- The GHerpTSQ status/change measures have good reliability, clear structure and evidence of validity.
- The GHerpTSQ indicates that overall subjects had a significantly higher rate of satisfaction with suppressive therapy compared to episodic therapy. This result is in concordance with the main result of the clinical trial: 72% of subjects preferred suppressive therapy[2].
- The GHerpTSQ has the potential to be a useful instrument in evaluating new treatment regimens.
- The strategy of modifying the DTSQ, used successfully for other conditions[5,6], provides a useful measure of satisfaction with treatment for GH.

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