

The use of interactive voice response (IVR) to collect daily patient diary data in a clinical trial of seasonal rhinitis

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Electronic Patient Diaries

Electronic methods for collecting diary data directly from patients have been in use for over a decade, and the advantages are becoming increasingly accepted:

- Out of range and ambiguous data can be eliminated
- Entries are time-stamped ensuring that compliance is documented
- Data are rapidly available, and can be used to monitor compliance and assist patients.
- Minimises or eliminates missing data
- Automated item-branching
- Reduced data management workload

Two main electronic diary methods are available :
Handheld Devices, generally palm-sized with touch screens, which the user carries around. The diary application is on the device, and questions are presented on the screen.
Telephone Systems, based on a normal telephone, where the user calls a central number and enters data via the phone keypad in response to an automated spoken script.

Quality of Electronic Assessments

Quality has many aspects which should be documented, including:

- Ease of use and acceptability to patients
- Compliance with protocol, in particular documentation that entries were made at or close to scheduled times
- Ability to detect effects of active treatments

Where there is already a validated paper version of an instrument, it is also important to show

- Equivalence between electronic and paper versions of the instrument



“BLOCKED NOSE: If you have not had blocked nose at all, tap nought; If blocked nose was mild, that is present but not troublesome, tap one; If blocked nose was moderate...”

Aims of study

To evaluate the use of a telephone interactive voice response (IVR) system to collect symptoms of seasonal rhinitis in a controlled study

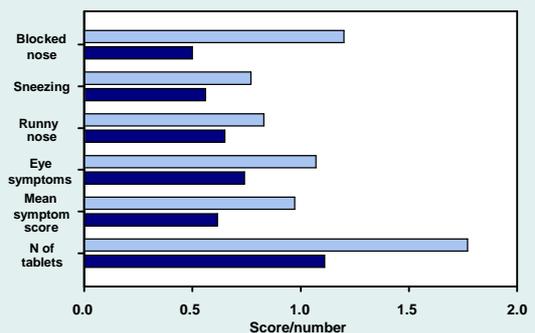
Methodology

Thirty-five patients (15 males, 17 females, aged 19-65 years) took part. They were randomised to receive either 200 µg budesonide (Rhinocort aqua) each morning or no budesonide (control). Both treatment groups also took terfenadine 60 mg as required to control acute symptoms.

Patients dialled into the IVR system each evening to record blocked nose, runny nose, sneezing and eye symptoms. Each item was scored on a four-point scale: 0 – absent; 1 – mild; 2- moderate; 3- severe. The number of terfenadine tablets taken during the day was entered.

The mean score for each item was taken over the three week study period, and compared between groups using the Wilcoxon sum of ranks test.

Results



Patient compliance was 87%, and feedback from patients was positive. The budesonide treatment group (dark bars) showed lower scores than the control group, and this was statistically significant for blocked nose ($p < 0.01$); eye symptoms ($p < 0.05$) and overall symptoms ($p < 0.05$). The number of terfenadine tablets taken in the budesonide group was also significantly lower ($p < 0.05$).

Discussion and Conclusion

IVR is widely used, but there is comparatively little published evidence supporting its use in the context of patient reported outcomes (PRO). We have shown that IVR is effective in demonstrating the efficacy of an established drug in a condition where symptom reports are generally the primary outcome measure. The small size of the sample gives an indication of the sensitivity that can be obtained with the method

The system used here was a simple one. In particular the response options to all symptom questions were the same. Many widely-used PRO instruments are more complex, and research into the use of such scales with IVR data collection is warranted.

References.

- Agel, J., Rockwood, T., Mundt, J. C., Greist, J. H., & Swiontkowski, M. (2001) Comparison of interactive voice response and written self-administered patient surveys for clinical research, *Orthopedics*, 24: 1155-1157.
- Gwaltney, C. J., Shields, A. L., & Shiffman, S. (2008) Equivalence of Electronic and Paper-and-Pencil Administration of Patient-Reported Outcome Measures: A Meta-Analytic Review, *Value in Health*, Accepted for publication.
- Tiplady, B. & Wenzel, K. (2008) Getting an accurate response: E-diaries or IVR systems?, *Good Clinical Practice Journal*, January 2008: 16-18

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