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Title (type in CAPITAL LETTERS, leave one blank line before the text)

DEVELOPMENT OF AN ELECTRONIC PATIENT DIARY FOR THE COLLECTION OF URINARY SYMPTOMS ASSOCIATED WITH OVERACTIVE BLADDER.

Aims of the Study

Overactive bladder(OAB) is a distressing condition, which relies on the patient report of urinary symptoms for a diagnosis. For many years the paper frequency-volume chart has been used to collect patient urinary symptoms (1). However, there are a number of issues with the paper chart including, poor patient compliance, poor legibility of patient entries, times rounded to the nearest hour, potential for retrospective completion and an inability to collect information on the symptom of urgency. Poor quality data can delay analysis or even render the data un-interpretable. Thus, we have developed an electronic diary programme in conjunction with MiniDoc Ltd. Prior to use in a clinical trial setting the electronic diary was tested in subjects in the UK and US. The study evaluated the acceptability of the electronic diary and its effectiveness for the collection of urinary symptoms compared with a paper voiding diary.

Methods

The electronic diary is a custom built unit and is programmed with customised software. It allows the patient to record urinary symptoms (leak, micturition, urgency and volume voided). Subjects aged over 18 years, who were suffering from symptoms of OAB and who were capable of independently completing the diary were identified via hospital based incontinence clinics. Subjects were assigned to receive either a paper or electronic diary at Visit 1 and appropriate training was given. After 7 days the subject returned for visit 2 (the first diary collected and training on second diary given). After a further 7 days subjects returned for Visit 3 and collection of the second diary. Subjects were asked to give structured feedback via questionnaires at Visits 2 and 3 on the use of the diary. Patients were asked to rate the ease of use by using a rating scale (1-9) where 1 - *Not at all Easy* and 9 - *Extremely Easy*. Urinary symptom data was collected from both the paper and electronic diary for further analysis.

Results

Demography

35 subjects were recruited into this study (32 females and 3 males) with a mean age of 58 years (30-88years). 20 subjects were from 2 regions in the US and 15 from 3 cities in the UK.

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Subject Acceptability Data

Subjects generally found the electronic diary very easy to use with only 6% of subjects experiencing difficulty. The patient rating scores for ease of use of the electronic are shown in the table below and are compared to those for a paper diary.

Parameter Assessed	Electronic Diary (n=35)	Paper diary (n=35)
	Mean Rating	Mean Rating
Training	7.5	8.0
Daily Use	7.3	8.1
Log-in	7.6	N/A
On Screen Menu	8.1	N/A

N/A- Not Applicable

Data Quality

Subjects reported that they entered the majority of the events in the diary within two hours of the event but this could only be confirmed for the electronic diary (73%), as all data is time stamped for audit purposes. Over 80% of the paper diaries had errors requiring resolution such as incomplete times, incomplete events and conflicting events compared to none with the electronic diary. Data quality with the electronic diary was good but with the paper diary it was poor.

The electronic diary was an effective tool for the recording of urinary symptom data.

Conclusion

This study demonstrates an electronic diary is an acceptable method by which urinary symptoms can be collected in the clinical trial setting. In general, OAB patients irrespective of age are able to use an electronic diary with ease. The major benefit is that all data is entered in real time, there is potential for reduced data errors, reduced queries on the data and rapid transfer of the data from the diaries to the database.

References

1) Abrams, P and Levmark, B. Scand. J. Urol. & Nephrol., Vol. 30, Suppl. 179, 1996: p 47-53.

This work was carried out for Pfizer by NOP Healthcare in the UK and by J Reckner Associates in the US.