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# QOL IN PATIENTS WITH NOCTURIA: DOES THE STUDY DESIGN IMPACT THE OUTCOME?

Hypothesis / aims of study

There has been a longstanding discussion within the field of lower urinary tract symptoms (LUTS) concerning when nocturia becomes bothersome and the degree of bother.(1)(2)The aim of this analysis was to explore the nocturia specific quality of life (QoL) in nocturia as assessed by number of night time voids per night across two different study designs.

Study design, materials and methods

Data were drawn from two different types of study: the LUTS Disease Specific Programme (DSP), a multinational, cross-sectional, observational study of clinical practice, conducted by Adelphi Real World, and randomized clinical trials (RCT), conducted by Ferring Pharmaceuticals.

For the DSP, primary care physicians and urology specialists in France, Germany, Spain, UK and the USA, actively managing urology patients, were asked to complete patient record forms prospectively for the next 14 OAB/BPH/nocturia patients who consulted their clinic. The same patients were asked to fill in a self-completion form with the mean number of night time voids over the previous 7 days. Nocturia related QoL data was assessed with the NI-Diary (3)

The second design was a randomised, double-blind, placebo-controlled, multicentre study (study NCT01223937 and NCT01262456) investigating the efficacy and safety of desmopressin orally disintegrating tablet in adults with ≥2 voids per night. Nocturia related QoL data was assessed with the N-QoL questionnaire.

For this study the NI Diary overall score was used for the DSP and the N-QoL total score (item 1-12) for the RCT. This choice was considered acceptable as the NI Diary is a revalidated version of the N-QoL updated to the newest PRO guidelines.

Further information about the different studies is provided in Table 1.

Table 1. Variation among study designs

| **Study** | **DSP** | **RCT** |
|---|---|---|
| Method | Cross-sectional | Multicentre, randomised, double-blind, placebo-controlled |
| Observational | Yes | No |
| Experimental | No | Yes |
| Blinding | No | Yes |
| Randomisation | No | Yes |
| Recruitment criteria | Physician diagnosis of LUTS | Yes |
| Physician contact | Yes (less than RCT) | Yes |
| Age | 18 Years and older | 18 Years and older |
| Gender | Both | Both |
| Countries | France, Spain, Germany, UK, USA | USA, Canada |
| Study completion | 2013 | 2013 |

Results

Overall, 4592 patients completed the NI Diary and voiding diary in the DSP. In the RCTs, 711 patients completed the N-QoL questionnaire and voiding diary at baseline. The QoL results of the two study designs were compared and summarised by the number of voids the patient experienced (Table 2).

Table 2. Summary of nocturia related QoL measured by two different study designs

| **DSP DATA** | | **RCT DATA** | |
|---|---|---|---|
| | NI Diary | | N-QoL |
| Number of voids | Total score (n=4592†) | Number of voids | Total score (n=711†) |
| 0-1 | 83.4 ‡ | | |

| | | | |
|---|---|---|---|
| 2 | 74.6 ‡ | 2 | 57.98 ‡ |
| 3 | 65.4 ‡ | 3 | 51.28 ‡ |
| 4 | 59.1 ‡ | 4 | 44.48 ‡ |
| 5 or more | 56.0 ‡ | 5 or more | 41.23 ‡ |
| † number who completed questions<br>‡ 0= highest bother and 100= lowest bother | | | |

Interpretation of results

Both study designs support that nocturia has a strong negative impact on QoL (Table 2) and that increasing number of voids per night increases the level of bother. The RCT design shows the highest bother compared to the DSP design in all voiding categories which may reflect that patients in real life settings underestimate the bother of nocturia as a trivial, non-important symptom, whereas patients taking part in RCT trials with a specific focus on nocturia may be more likely to express the real bother of nocturia.

The comparison has some limitations when considering that the bother of nocturia was measured by different questionnaires and within different age groups, gender and comorbid conditions. The strength of this analysis is consistent level of bother across a high number of patients.

Concluding message

This study documents that patients are bothered by nocturia and that the bother increases with symptom severity no matter the study design. Furthermore, it reveals that larger bother is demonstrated in RCTs compared to everyday practice.

References


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Disclosures


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