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URODYNAMIC OBSERVATIONS CORRELATE WITH PATIENT BLADDER DIARY MEASURES OF 24-HOUR FREQUENCY AND URGE URINARY INCONTINENCE

Aims of Study

Although most urologists believe that there is an association between urodynamic observations and symptoms of overactive bladder [increased 24-hour frequency and urge urinary incontinence (UUI)], few clinical studies have offered evidence of this association. During the clinical development of trospium, a 358-patient European randomized (Trospium or Oxybutynin), double-blind, active-controlled trial of patients with increased 24-hour frequency and UUI was conducted that collected data from both conventional urodynamic studies and patient bladder diaries at pre-treatment and during treatment over a 52-week study period. This study offers an opportunity to evaluate the association of the urodynamic observations, maximum cystometric capacity (CC_{max}), volume at the first involuntary detrusor contraction (Vol_{ic}) and volume at first desire to void (Vol_{fd}), to clinical symptoms of overactive bladder (OAB), increased frequency and UUI.

Method

Analyses were performed to determine the association of each of these urodynamic observations (CC_{max}, $Vol_{fd,}$ and Vol_{ic}) with 24-hour frequency and frequency of UUI. Treatment groups were pooled since the purpose of this analysis was not to assess by-treatment groups but rather whether these associations exist at all.

Analyses were performed to assess the association of the parameters using the observed values at baseline and Weeks 26 and 52, and using the change from baseline values at Weeks 26 and 52. In order to allow for greater sensitivity to detect potential associations the assumption was made that within-patient observations over time were independent. Correlations then assessed the values utilizing data from baseline and Weeks 26 and 52. For the calculation of the mean change values, changes from baseline were first calculated within patient, at both weeks. These changes were then averaged across the weeks, within patient, to obtain a mean change from baseline value for each patient. If data from both Week 26 and 52 was not available for a patient, data from the Week where data did exist was used as the mean value. The 24-hour frequency and urge urinary incontinence episodes (and change from baseline) were not normally distributed thus nonparametric statistical methods were used. When correlations to assess the linear association of variables were performed, the ranked values were utilized, and the non-parametric Spearman Rank correlation coefficient was presented. P-values presented test the null hypothesis that the correlation coefficient for the association is equal to zero. Univariate logistic regression models were utilized to assess how the odds of being incontinent were impacted by urodynamic observations. Patients were categorized as either being incontinent at either week or not. Logistic regression models then used this dichotomized UUI variable to determine the odds of being incontinent as $CC_{max,}$ Vol_{fd} or Vol_{ic} changed.

Results

There was a statistically significant negative correlation of both CC_{max} and Vol_{fd} and with 24-hour frequency. The correlation of Vol_{ic} showed marginal significance (p=0.070) to 24-hour frequency.

Table 1: Correlations with 24-Hour Frequency

Urodynamic observations	n	Correlation Coefficient	p-value
CC_{max}	853	-0.337	<0.001
Vol_{fd}	848	-0.320	<0.001
Vol_{ic}	449	-0.086	0.070

There was a statistically significant ($p<0.006$) negative correlation (-0.163) of the change in CC_{max} and the change in 24-hour frequency from baseline. Neither the change in Vol_{uc} nor the change in Vol_{fd} demonstrated a significant correlation to the change in frequency from baseline.

There was a statistically significant negative correlation of both CC_{max} and Vol_{fd} with the number of UUI episodes/day. No correlation was found between Vol_{ic} and the number of UUI episodes/day.

Table 2: Correlations with Number of UUI Episodes

Urodynamic Observations	n	Correlation Coefficient	p-value
CC_{max}	464	-0.437	<0.001
Vol_{fd}	461	-0.404	<0.001
Vol_{ic}	248	-0.029	0.647

Using logistic regression analysis the odds of being incontinent exhibited a statistically significant ($p<0.001$) decrease as CC_{max} and Vol_{fd} increased. For each 50 ml increase in CC_{max} or Vol_{fd}, the odds of being incontinent were decreased by approximately 35% or 38%, respectively. No statistically significant findings were noted for Vol_{ic}.

Conclusions

Reductions in 24-hour frequency and UUI episodes measured by patient bladder diaries correlates with an increase in the CC_{max} and Vol_{fd} during conventional urodynamic studies. These results suggest that CC_{max} and Vol_{fd} are indicators of whether a patient is likely to have more or less voids or UUI episodes per day. In addition, a qualitative change in CC_{max} and Vol_{fd} can predict the likelihood of being incontinent. Vol_{ic} offers little or no indication of the status of the symptoms of OAB.