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Black L[1], Seifeldin R[2], Rasouliyan L [3]
1. GlaxoSmithKline, 2. Astellas, 3. Ovation

IMPACT OF SOLIFENACIN ON HEALTH UTILITY, WORK PRODUCTIVITY, AND MEDICAL CARE UTILIZATION

Hypothesis / aims of study

To assess changes in health utility scores, work productivity, and medical care following 12 weeks of solifenacin succinate (SOL) therapy compared with Pre-Washout assessments during treatment with tolterodine tartrate extended release (TOL).

Study design, materials and methods

This was a prospective, multicenter, open-label US study assessing the efficacy and safety of SOL in treating urinary urgency in patients with overactive bladder syndrome. Males and females ≥ 18 years of age who had been treated with TOL for at least 4 weeks and had switched from TOL to SOL due to lack of sufficient improvement in urgency episodes were enrolled. Subject must have had, at least 3 urgency episodes per 24 hours while receiving TOL, with or without urge incontinence, usually with frequency and nocturia.

Health utility, work productivity, and medical care resource utilization were assessed using the Health Utility Index (HUI), the Work Productivity Assessment Index (WPAI), and the Medical Care Use Index (MCUI) and were administered during Pre-Washout (Visit 2) and Post-Washout Week 12 (12 weeks of SOL therapy, Visit 7).

The Health Utilities Index Mark 2 and Mark 3 (HUI) is a 15-item health utility scale which assesses functional health status in nine areas: Vision, Hearing, Speech, Emotion, Pain, Ambulation, Dexterity, Cognition, and Self-Care.

The Work Productivity Assessment Index (WPAI) assesses the impact of a subject's bladder condition on four areas of productivity: absenteeism (time missed at work), presenteeism (impairment while at work), work productivity loss (combination of absenteeism and presenteeism), and activity impairment.

The Medical Care Use Index (MCUI) is a 10-item questionnaire capturing medical care use. Five items capture information on medical resource utilization (frequency of physician's office visits related to the bladder condition, urinary tract infections, skin rashes, and falls). The remaining 5 items capture data on the use of behavioral therapy strategies (timed voiding, fluid management, pelvic floor exercises, biofeedback, and electrical stimulation).

While the HUI and WPAI are validated instruments, the MCUI is not; questions about resource utilization are study specific questions and therefore differ among studies.

Analyses were performed on the Full Analysis Set (all subjects who received at least one dose of SOL and completed questionnaires at Visit 2 and 7). Change from Pre-Washout was calculated by subtracting the Visit 2 from Visit 7 values. A paired t-test was used to test changes from Visit 2 to 7, using two-sided tests at the α=0.05 significance level.

Results

A total of 426 subjects met analyses criteria. The mean age of subjects was 61.3 years, approximately 88% were female, and most subjects (89%) were white. For the HUI, no significant difference between Visit 2 and Visit 7 HUI scores were observed. Significant improvements were seen for all items on the WPAI at Visit 7(figure).

Regarding medical care utilization (MCUI), a significant reduction was observed in the number of physician office visits, UTIs, pads/diapers used, and days with fluid management. Reductions in the number of days subjects used timed voiding existed, but did not achieve statistical significance. There were no significant differences in the number of skin rashes, falls, or number of days with pelvic floor exercises, biofeedback, or electrical stimulation (figure).

Mean Change in Outcomes From Pre-Washout to Week 12.

Outcome	N	Pre-Washout Mean ± SE	Week 12 Mean ± SE	Change Mean ± SE	p-value*
Health Stat Utility Scale (HUI)	383	0.80 ± 0.01	0.81 ± 0.01	0.01 ± 0.01	0.2078
WPAI: % work time missed	142	2.04 ± 0.58	0.21 ± 0.10	-1.82 ± 0.59	0.0024
WPAI: % impairment while working	154	22.66 ± 1.73	11.17 ± 1.04	-11.49 ± 1.67	<0.0001
WPAI: % overall work impairment	142	23.85 ± 1.82	11.75 ± 1.09	-12.10 ± 1.81	<0.0001
WPAI: % activity impairment	393	31.48 ± 1.27	18.58 ± 1.08	-12.90 ± 1.34	<0.0001
MCUI: Number of physician office visits	374	1.23 ± 0.08	0.25 ± 0.04	-0.99 ± 0.08	<0.0001
MCUI: Number of UTIs	360	0.22 ± 0.03	0.10 ± 0.02	-0.12 ± 0.03	<0.0001
MCUI: Number of skin rashes	347	0.62 ± 0.35	0.15 ± 0.06	-0.47 ± 0.35	0.1852
MCUI: Number of falls	361	0.19 ± 0.04	0.23 ± 0.07	0.04 ± 0.08	0.5808
MCUI: Number of pads/diapers used each week	357	10.61 ± 0.89	7.65 ± 0.81	-2.96 ± 0.86	0.0006

MCUI: Number of days with timed voiding	331	10.58 ± 1.47	7.85 ± 1.23	-2.73 ± 1.55	0.0791
MCUI: Number of days with fluid management	312	17.86 ± 1.78	14.08 ± 1.66	-3.78 ± 1.85	0.0421
MCUI: Number of days with pelvic floor exercises	330	6.98 ± 1.14	6.37 ± 1.15	-0.60 ± 1.17	0.6078
MCUI: Number of days with biofeedback	333	0.50 ± 0.30	0.07 ± 0.06	-0.43 ± 0.31	0.1617
MCUI: Number of days with electrical stimulation	333	0.11 ± 0.04	0.10 ± 0.09	-0.02 ± 0.10	0.8814

Interpretation of results

Key findings from this study were:

- 51% improvement in work productivity following the use of solifenacin succinate for 12 weeks compared to Pre-Washout (tolterodine ER).
- 41% improvement in activity impairment following the use of solifenacin succinate for 12 weeks compared to Pre-Washout (tolterodine ER).

Use of solifenacin succinate resulted in improvements in medical care use over Pre-Washout (tolterodine ER) for the following endpoints:

- 80% reduction in physician office visits
- 55% reduction in UTIs
- 76% reduction in skin rashes (not significant)
- 28% reduction in the number of pads/diapers used.
- 21% reduction in the number of days with timed voiding.

Concluding message

Overall, solifenacin succinate reduced medical care use, work loss, work impairment, and improved ability to carry out normal activities in patients with overactive bladder syndrome.

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HUMAN SUBJECTS: This study was approved by the Copernicus group and followed the Declaration of Helsinki Informed consent was obtained from the patients.