ORIGINAL ARTICLE

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Reductions in overactive bladder-related incontinence from pooled analysis of phase III trials evaluating treatment with solifenacin

Abstract The embarrassment and social stigma associated with urinary incontinence (UI) in overactive bladder syndrome (OAB) sufferers is a major reason for individuals to seek help for their condition. An analysis of 1,873 subjects with OAB with UI was conducted to assess the efficacy of solifenacin in reducing incontinence in a pooled population from four phase III clinical trials, stratified by severity of incontinence, urgency, and other key factors at baseline. Subjects were randomized to either 5 or 10 mg of solifenacin once daily or placebo for 12 weeks. More than 50% of the total population became continent at study end, with either dose of solifenacin ($P<0.01$ vs placebo). Significant reductions in incontinence episodes and higher rates of attainment of continence vs placebo were observed irrespective of age or severity of incontinence or urgency at baseline with solifenacin treatment. Treatment was well tolerated, with the majority of adverse events being mild in nature. Solifenacin is an effective antimuscarinic agent for the treatment of incontinence associated with OAB.

Keywords Overactive bladder · Urinary incontinence · Muscarinic receptor antagonist · Urge incontinence

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Introduction

The International Continence Society has defined overactive bladder syndrome (OAB) as urgency, with or without urge incontinence, usually accompanied by frequency and nocturia [1]. Overactive bladder is recognized as a prevalent and costly condition that significantly affects individuals' quality of life (QoL) [2]. Urinary incontinence (UI) is the complaint of any involuntary leakage of urine and should be further described by specifying relevant factors such as type, frequency, severity, precipitating factors, social impact, effect on hygiene, and QoL [1]. The embarrassment and social stigma associated with incontinence episodes is a major reason for men and women to seek help from their primary care practitioners (PCPs) [2]. Thus, the goal of treatment should be to bring them to complete continence, if possible. Urge urinary incontinence (UUI) is defined as the complaint of involuntary leakage accompanied by, or immediately preceded by, urgency (the complaint of a sudden compelling desire to pass urine that is difficult to defer) [1]. Other types of incontinence include stress urinary incontinence (SUI), which is involuntary leakage upon effort, exertion, sneezing, or coughing, and mixed urinary incontinence (MUI), which is a combination of involuntary leakage associated with symptoms of both urge and stress incontinence [1].

UUI is usually associated with OAB and has been reported by 36% of OAB sufferers [2]. The prevalence of UUI increases with age for both men and women [3]. According to a European population-based prevalence study, approximately 65% of OAB sufferers reported that their symptoms of incontinence, frequency, and urgency significantly adversely affected their daily QoL [3]. The prevalence of OAB, as well as cost of treating OAB sufferers, places a significant burden on healthcare provision in many countries. In the USA, the costs of UI and OAB were estimated to be $19.5 billion and $12.6 billion, respectively, in 2000 [4].

Antimuscarinic/anticholinergic agents are the pharmacotherapy of choice for OAB. These agents have previously been shown to achieve continence rates of 17–23% [5].

However, anticholinergic adverse events such as dry mouth, constipation, and blurred vision result in poor patient compliance and acceptance of pharmacological treatment.

Solifenacin

Solifenacin succinate is a once-daily oral antimuscarinic agent evaluated for the treatment of OAB at 5-mg (recommended starting dose) and 10-mg doses. In individual trials, solifenacin therapy has demonstrated statistically significant reductions in all symptoms of OAB, including incontinence, urgency, and frequency [6–9], as well as significantly increasing the volume voided per micturition. Rates of dry mouth with the 5-mg dose were among the lowest published for oral antimuscarinic treatment.

In this report, data on changes in episodes of incontinence were pooled from four pivotal 12-week phase III studies designed to evaluate the efficacy, safety, and acceptability of solifenacin in subjects with OAB. Subset analyses were performed to assess incontinence outcomes as a function of patient age, severity of incontinence at baseline, severity of urgency at baseline, presence of MUI or UUI at baseline, and previous response to OAB medication. We present the first analysis of incontinence in a pooled population stratified by severity of incontinence and severity of urgency at baseline.

Materials and methods

Data from 2,030 subjects experiencing episodes of incontinence at baseline were available for efficacy analysis from a total of 3,298 subjects randomized to treatment in four phase III studies evaluating the short-term efficacy, safety, and acceptability of solifenacin. This cohort represents approximately 62% of the entire study population. The four studies were conducted globally in 16 countries and involved over 200 study centers. Maintaining consistency across the studies was a key consideration during the development of the protocols, with case report forms (CRFs), diary cards, and statistical analysis plans being similar for each trial. Additionally, the combined analysis of the four studies was justified on the basis of having similar population groups and results that were reasonably balanced when reported individually for each trial [6–9]. All OAB symptoms data including incontinence data were collected from micturition diaries completed by the subjects during the 3 days prior to baseline and each subsequent scheduled study visit.

These studies were performed in accordance with the International Conference on Harmonisation-Good Clinical Practice guidelines and the principles of the Declaration of Helsinki. The study protocol was approved by the responsible ethical committee at each study site. All subjects were informed of the nature and purpose of the study, and written informed consent was obtained prior to screening.

Study design

Outpatient men and women at least 18 years of age were included. Study subjects were required to have a mean of at least eight micturitions per 24 h in addition to a mean of at least one incontinence episode per 24 h or a mean of at least one urgency episode per 24 h during the baseline 3-day micturition diary period to be eligible for study participation.

After completing a 2-week placebo run-in or washout period, all subjects underwent a baseline physical examination and started their treatment regimen on the first day of the study. In two of the studies, subjects were randomized to 12 weeks of once-daily treatment with solifenacin 10 mg or placebo. In the other two studies, subjects were randomized to solifenacin 5 mg once daily, solifenacin 10 mg once daily, placebo once daily, or tolterodine 2 mg twice daily (one study only as an active treatment arm) for 12 weeks. The cohort of subjects treated with tolterodine in the single study was not powered for comparisons and was, therefore, not included in the pooled analysis of incontinence.

Study subjects completed the 3-day micturition diary prior to each scheduled visit at weeks 4, 8, and 12. For each episode of urinary symptoms, the patient recorded the date and time of each episode, whether or not they voided, the presence of urgency and/or of incontinence, the volume voided (for 2 of the 3 days), and whether or not the episode disturbed their sleep. In addition, the patient's time of rising from, and retiring to, bed was recorded.

Statistical methods

The baseline to endpoint changes in number of incontinence episodes per 24 h were analyzed for those subjects in the pooled study population who reported incontinence at baseline. Those without a baseline assessment or at least one on-treatment efficacy assessment were excluded from the analysis.

Treatment group comparisons of mean change from baseline were based on analysis of covariance (ANCOVA), with the baseline mean number of incontinence episodes per 24 h as a covariate and terms for treatment group and pooled center as fixed effects. P values comparing the percent change from baseline were calculated using the nonparametric van Elteren's test stratified by pooled center. Subgroup analyses were performed for patient age, presence of MUI or UUI, severity of OAB at baseline, and previous OAB medication.

Results

A total of 3,298 subjects were randomized to treatment in the four studies, of whom approximately 62% recorded experiencing episodes of incontinence during their baseline diary and were included in the pooled analysis for

Table 1 Baseline characteristics for pooled study population

Characteristic	Placebo	Solifenacin 5 mg od	Solifenacin 10 mg od
Number of patients reporting incontinence at baseline	781	314	778
Number of incontinence episodes per 24 h			
Mean	2.9	2.6	2.9
Median	2.0	2.0	2.0

od Once daily

incontinence outcomes (Table 1). A relatively small cohort of subjects ($n=157$) were treated with tolterodine as part of an active treatment arm (in one of the four studies), which was not powered for comparison with solifenacin. This cohort was not included within the analysis.

More than half of the solifenacin-treated subjects reported complete restoration of continence at endpoint (51 and 52% in the 5- and 10-mg groups, respectively) compared with 34% of subjects in the placebo group (Table 2). For both solifenacin groups, this was statistically significant vs placebo ($P<0.001$). Additionally, 71 and 79% of subjects treated with solifenacin 5 and 10 mg once daily, respectively, reported that they experienced a reduction in incontinence episodes of more than or equal to half, from baseline to endpoint, compared with only 58% of subjects administered with placebo ($P<0.001$ for both the solifen-

acin 5- and 10-mg dosage groups). The reduction in mean number of incontinence episodes per 24 h from baseline to endpoint was −1.5 (−60%) for subjects treated with solifenacin 5 mg once daily and −1.8 (−60%) for subjects treated with solifenacin 10 mg once daily compared with −1.1 (−32%) for the placebo group (Table 2).

Subgroup analyses

Adjusted mean differences from placebo are shown in Fig. 1 and illustrate the effectiveness of solifenacin in comparison to placebo. Statistical significance was achieved in all patient subgroups with both doses of solifenacin, except in subjects who had failed prior OAB medication, where only the higher 10-mg solifenacin dose resulted in a statistically significant difference ($P<0.001$).

Incontinence episodes in younger (less than 65 years) and older (at least 65 years) subjects

Similar to the full pooled population, around 50% of subjects in both the younger and older cohorts were restored to complete continence at the 12-week study endpoint with both doses of solifenacin (Table 2). This was statistically significant vs placebo for both doses and in both subgroups. In addition, reductions in incontinence episodes for both younger (less than 65) and older (at least 65) subjects were statistically significant with solifenacin treatment (Table 3).

Table 2 Number and percent of patients achieving complete continence at endpoint of study for subgroups analyzed

	Percent of patients achieving continence at study endpoint[a]		
	Placebo	Solifenacin	
		5 mg	10 mg
Total population ($n=1,873$)	34%	51%*	52%*
Incontinence severity at baseline			
<3 episodes per 24 h at baseline ($n=1,203$)	44%	64%*	63%*
≥3 episodes per 24 h at baseline ($n=670$)	16%	27%***	31%*
Urgency severity at baseline			
<6 episodes per 24 h at baseline ($n=1,203$)	39%	57%*	55%*
≥6 episodes per 24 h at baseline ($n=670$)	29%	42%**	48%*
Patient age			
<65 ($n=1,184$)	37%	51%*	55%*
≥65 ($n=689$)	29%	49%*	47%*
Incontinence type at baseline			
Urge incontinence only ($n=1,011$)	35%	55%*	54%*
Mixed urinary incontinence ($n=851$)	33%	43%	49%*
OAB medication history			
Previous responders ($n=422$)	32%	50%***	44%***
Previous nonresponders ($n=332$)	23%	36%	42%**
Treatment naïve patients ($n=1,119$)	38%	56%*	58%*

*$P\leq0.001$; **$P<0.01$; ***$P<0.05$
[a] P values are based on Fisher's exact test

Adjusted mean differences (95% CI)	
Solifenacin	
5 mg	10 mg
−0.73*** (−1.01, −0.45)	−0.72*** (−0.91, −0.52)
−0.74*** (−1.11, −0.37)	−0.60*** (−0.86, −0.34)
−0.63* (−1.12, −0.13)	−0.86*** (−1.19, −0.54)
−0.88*** (−1.24, −0.53)	−0.91*** (−1.17, −0.64)
−0.55* (−1.08, −0.03)	−0.53*** (−0.84, −0.22)
−0.38*** (−0.61, −0.15)	−0.31*** (−0.47, −0.16)
−1.22*** (−1.95, −0.49)	−1.30*** (−1.80, −0.81)
−0.48*** (−0.76, −0.20)	−0.31** (−0.51, −0.10)
−0.94*** (−1.51, −0.37)	−1.14*** (−1.49, −0.78)
−0.76* (−1.44, −0.09)	−0.86*** (−1.29, −0.43)
−0.78 (−1.72, 0.16)	−1.24*** (−1.32, 0.56)
−0.56*** (−1.01, −0.32)	−0.55*** (−0.79, −0.31)
Mean (95% CI)	
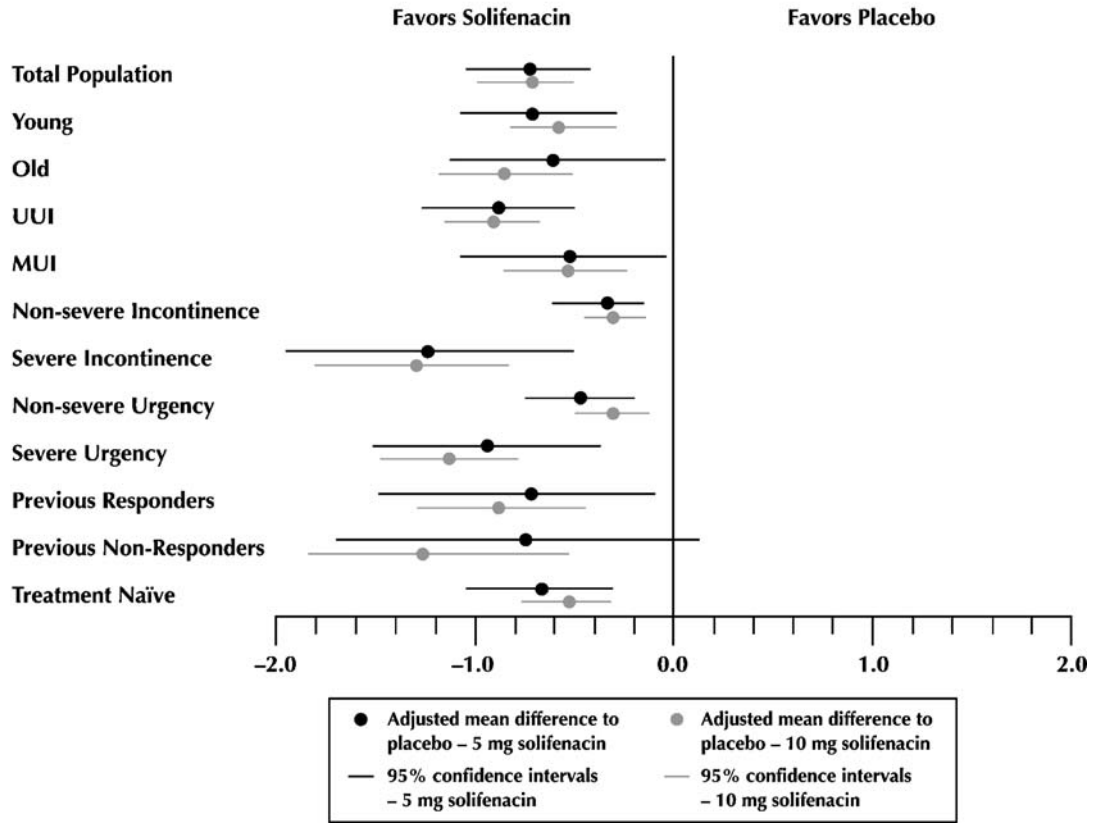
Fig. 1 Treatment effect (baseline to endpoint changes in number of incontinence episodes) of solifenacin 5 or 10 mg once daily vs placebo in total population who were incontinent at baseline and specific patient subgroups. *UUI* Urge urinary incontinence, *MUI* mixed urinary incontinence, *OAB* overactive bladder, *Young* patients less than 65 years, *Old* patients at least 65 years. Nonsevere incontinence and severe incontinence are defined as less than three incontinence episodes or at least three incontinence episodes per 24 h, respectively, measured at baseline using a 3-day patient diary. Nonsevere urgency and severe urgency are defined as less than six urgency episodes or at least six urgency episodes per 24 h, respectively, measured at baseline using a 3-day patient diary. Previous responders and previous nonresponders define effectiveness of previous OAB medication prior to the patient's inclusion in the clinical trial. Treatment naïve are patients who have previously never received OAB medication. *P* values for the mean differences from placebo are based on an analysis of covariance (ANCOVA) model with treatment and center as terms and baseline as a covariate. ***$P \leq 0.001$, **$P < 0.01$, *$P < 0.05$

Incontinence episodes in subjects reporting UUI only or MUI

Over half of the subjects with UUI at baseline were fully restored to continence in both the 5- and 10-mg solifenacin groups compared with 35% of subjects on placebo (Table 2; $P < 0.001$ vs placebo for both groups). In addition, reductions in incontinence episodes were also statistically significant for solifenacin subjects with UUI at baseline (Table 3). When subjects who reported MUI at baseline screening were evaluated, 43 and 49% became continent with 5 and 10 mg solifenacin, respectively, compared with 33% of subjects receiving placebo. Statistically significant reductions in incontinence episodes were achieved with both doses of solifenacin (Table 3).

Incontinence episodes for subjects by severity of incontinence at baseline

Reductions in incontinence episodes were evaluated for subjects reporting nonsevere (less than three) or severe (at least three) incontinence episodes per 24 h at baseline (Table 2). Subjects in both baseline incontinence severity groups showed rates of restoration of continence at endpoint that were statistically significant vs placebo, although the continence rates were higher in the less severe vs more severe cohort (Table 2). Reductions for subjects in the less than three subgroup reached statistical significance for incontinence episodes with the 5- and 10-mg doses of solifenacin. Study subjects who reported more severe incontinence (at least three episodes per day at baseline) also attained statistically significant reductions in incontinence episodes with both solifenacin doses (Table 3).

Table 3 Mean and median changes in incontinence episodes for total population and subgroups analyzed

	Actual mean change in incontinence episodes per 24 h from baseline to endpoint[a]			Mean percent change in incontinence episodes per 24 h from baseline to endpoint			Median percent change in incontinence episodes per 24 h from baseline to endpoint[b]		
	Placebo	Solifenacin		Placebo	Solifenacin		Placebo	Solifenacin	
		5 mg	10 mg		5 mg	10 mg		5 mg	10 mg
Population reporting incontinence at baseline (n=1,873)	−1.1	−1.5*	−1.8*	−32%	−60%	−60%	−64%	−100%*	−100%*
Age									
<65 (n=1,184)	−1.2	−1.6*	−1.7*	−38%	−59%	−64%	−67%	−100%*	−100%*
≥65 (n=689)	−1.0	−1.5***	−1.9*	−21%	−62%	−53%	−50%	−92%	−92%*
Incontinence type									
Urge incontinence only (n=1,011)	−0.9	−1.5*	−1.7*	−30%	−69%	−57%	−64%	−100%***	−100%*
Mixed stress/urge incontinence (n=851)	−1.3	−1.6***	−1.9*	−34%	−46%	−59%	−64%	−82%***	−94%[*]
Incontinence severity									
<3 episodes at baseline (n=1,203)	−0.5	−0.8*	−0.8*	−27%	−61%	−56%	−75%	−100%***	−100%*
≥3 episodes at baseline (n=670)	−2.2	−2.9*	−3.7*	−40%	−59%	−66%	−46%	−68%***	−81%*
Urgency severity									
<6 episodes at baseline (n=1,000)	−0.9	−1.1*	−1.2**	−32%	−58%	−55%	−67%	−100%	−100%*
≥6 episodes at baseline (n=873)	−1.4	−2.1*	−2.5*	−31%	−63%	−66%	−55%	−85%***	−94%*
Previous OAB therapy									
Previous responders (n=422)	−1.2	−1.7***	−2.4*	−33%	−61%	−58%	−62%	−97%	−89%**
Previous nonresponders (n=332)	−0.7	−1.4	−1.7*	−1%	−48%	−50%	−40%	−60%	−82%*
No previous OAB therapy (n=1,119)	−1.2	−1.5*	−1.6*	−40%	−64%	−64%	−68%	−100%**	−100%*

OAB Overactive bladder

*$P \leq 0.001$; **$P < 0.01$; ***$P < 0.05$

[a]P values comparing the actual mean change from baseline are based on an ANOVA model with treatment and center as terms and baseline as a covariate

[b]P values comparing the median percent change from baseline are based on van Elteren's test, stratified by pooled center

Table 4 TEAEs split by severity for patients who were incontinent at baseline

	Placebo, n (%) (n=823)			Solifenacin 5 mg od, n (%) (n=327)			Solifenacin 10 mg od, n (%) (n=820)		
	Mild	Moderate	Severe	Mild	Moderate	Severe	Mild	Moderate	Severe
Dry mouth	25 (3.0)	11 (1.3)	1 (0.1)	29 (8.9)	7 (2.1)	0 (0)	154 (18.8)	69 (8.4)	16 (2.0)
Constipation	19 (2.3)	11 (1.3)	0 (0)	15 (4.6)	5 (1.5)	1 (0.3)	51 (6.2)	53 (6.5)	11 (1.3)
Blurred vision	13 (1.6)	2 (0.2)	0 (0)	10 (3.1)	2 (0.6)	1 (0.3)	26 (3.2)	8 (1.0)	4 (0.5)

TEAEs Treatment emergent adverse events

Incontinence episodes in subjects by severity of urgency at baseline

Study subjects reporting less than six or at least six symptomatic urgency episodes per day at baseline were evaluated for reductions in incontinence episodes. In both groups, continence was achieved in statistically significantly more subjects on solifenacin compared with those on placebo. In the less than six urgency severity group, 57 and 55% of subjects on 5 and 10 mg solifenacin, respectively, achieved complete resolution of incontinence compared with 39% of subjects on placebo (P<0.001 for both groups; Table 2). Also, subjects in the less than six urgency episodes subgroup achieved statistical significance for reductions in incontinence episodes with both doses of solifenacin (Table 3). Study subjects who reported severe urgency (at least six episodes per day) also attained statistically significant restoration of continence on 5 mg (42% of subjects, P<0.01) and 10 mg solifenacin (48% of subjects, P<0.001) compared with subjects receiving placebo (29% of subjects; Table 2), as well as significant reductions in incontinence episodes (Table 3).

Episodes of incontinence in subjects by previous overactive bladder medication history

Reductions in incontinence episodes were analyzed for subjects who reported previous OAB therapy, and subjects were further stratified into subgroups based on their report of efficacy with previous therapy (Table 3). Subjects who reported responding to previous therapy (based on patient response to a Yes/No query at baseline assessment) were evaluated for reductions in incontinence episodes and restoration of continence. In subjects who reported response to previous OAB therapy, solifenacin treatment was associated with statistically significant restoration of continence (Table 2) and reductions in incontinence episodes at both doses (Table 3).

In the previous nonresponder cohort, solifenacin treatment was associated with a statistically significant number of subjects achieving continence (Table 2; P<0.01) and reductions in incontinence episodes (Table 3; P<0.001) at the 10-mg dose. In addition, the 10-mg dose had a mean treatment effect significantly different from placebo in this cohort (Fig. 1; mean treatment effect −1.24, P<0.001). Although the 5-mg dose achieved a similar treatment effect in the nonresponder group as in the previous responders, this difference did not reach statistical significance, possibly due

to the lower number of subjects who had no previous response to treatment (Table 2). When continence rates were calculated for subjects who reported no previous OAB medication, 56% of subjects on 5 mg solifenacin and 58% of subjects on 10 mg became continent (P<0.001 for both groups) compared with 38% of subjects on placebo. Solifenacin treatment was also associated with statistically significant reductions in incontinence episodes at both doses (Table 3).

Safety and acceptability by incontinent subjects

Solifenacin was well tolerated by the cohort of subjects included in this pooled analysis who were incontinent at baseline, with the majority of treatment emergent adverse events (TEAEs) being mild in nature (Table 4). Dry mouth was reported by 11% of subjects taking solifenacin 5 mg and 29% of subjects taking solifenacin 10 mg as compared with 5% of placebo-treated subjects. Constipation was reported by 6% of subjects taking solifenacin 5 mg, 14% of subjects receiving solifenacin 10 mg, and 4% of subjects receiving placebo. Four percent of subjects taking solifenacin 5 mg and 5% of subjects taking solifenacin 10 mg reported blurred vision (compared with 2% of subjects receiving placebo). These levels of TEAEs were comparable to those of the full/complete safety population, which also included OAB subjects who were not

Table 5 TEAE events for full/complete safety population and the incontinent subject subgroup

	Placebo (%)	Solifenacin	
		5 mg od (%)	10 mg od (%)
Subjects incontinent at baseline			
Number of patients (n)	823	327	820
Dry mouth	4.5	11.0	29.1
Constipation	3.6	6.4	14.0
Blurred vision	1.8	4.0	4.6
Patients discontinuing trial due to TEAEs	5.1	4.3	6.5
Full/complete safety population			
Number of patients (n)	1,216	578	1,233
Dry mouth	4.2	10.9	27.6
Constipation	2.9	5.4	13.4
Blurred vision	1.8	3.8	4.8
Patients discontinuing trial due to TEAEs	4.4	2.8	6.8

experiencing incontinence at baseline (Table 5), and is consistent with the label for solifenacin.

Discontinuations due to TEAEs were comparable for subjects treated with solifenacin and those treated with placebo. In the incontinent subject group, 5% of placebo-treated subjects withdrew from the studies due to adverse effects (as the primary reason for discontinuation) compared with 4% of subjects receiving solifenacin 5 mg and 7% of subjects receiving solifenacin 10 mg. These rates were comparable to the withdrawal rates due to adverse events for the full/complete safety population (Table 5).

Discussion

UI is the most embarrassing aspect of OAB, severely impacting on patients' QoL. The ultimate goal of treatment of this condition is to make patients fully continent. In the present analysis of the pooled 12-week studies, more than 50% of the total population who had incontinence at baseline achieved continence at the endpoint of the 12-week study with both doses of solifenacin. This result was the same irrespective of the age of the patients. Although the patient group with less severe incontinence at baseline showed a greater continence rate at endpoint compared with the more severe group, nevertheless, even in the more severely incontinent patients, the continence rate was statistically significantly greater than placebo.

As might be anticipated, reductions in episodes of incontinence were numerically greater in subjects reporting severe (at least three per day) incontinence at baseline. This subgroup reported baseline values for incontinence of between five and six episodes per day, and reductions in incontinence episodes exceeded three per day with solifenacin treatment.

Individuals aged 65 years and older constitute the most rapidly growing segment of the US population. In this older age group, approximately one in three women and one in five men aged more than 60 years suffer from UI [10]. In addition, the prevalence of OAB with urge incontinence continues to increase with advancing age [11], and the development of UI can precipitate institutionalization of an elderly family member [12]. Solifenacin treatment was associated with statistically significant reductions in the number of incontinence episodes and a greater proportion of subjects achieving continence, in both younger and elderly subjects. Solifenacin treatment was also demonstrated to be effective in subjects with MUI, especially at the 10-mg dose.

Urgency symptoms of OAB reduce QoL and may be associated with greater deterioration in QoL as compared with other symptoms of OAB [13, 14]. Subjects reporting less than six urgency episodes at baseline experienced an approximately 50% mean reduction in incontinence episodes relative to baseline from around two to one per 24 h. Interestingly, subjects reporting at least six urgency

episodes at baseline also had higher baseline incontinence values (slightly less than four per day) and experienced reductions in incontinence of more than two episodes per day. These findings offer support to the possibility that urgency symptoms may parallel the severity of incontinence in patients with OAB.

For OAB treatment naïve individuals, subjects receiving 5 and 10 mg solifenacin experienced mean percent reductions in incontinence episodes of 64%, compared with a 40% reduction in episodes for the patient group receiving placebo, from a baseline of two to three episodes per 24 h. In comparison, subjects who received previous OAB medication had higher baseline incontinence values (three to four episodes per day), suggesting that subjects who sought previous treatment may have experienced greater symptoms. Solifenacin treatment was significantly effective compared with placebo in subjects who had previously responded to OAB medication (mean percent reduction of approximately 60% for both solifenacin treatment groups).

Interestingly, those subjects who reported no response to previous OAB therapy demonstrated minimal placebo effect in comparison to other patient groups. This may suggest that they could be considered a more difficult to treat population. Notably, subjects receiving 10 mg solifenacin achieved statistical significance with respect to reductions in incontinence episodes in this patient population. In addition, the adverse event rate in the incontinent population was comparable to that seen in the total pooled population, and discontinuation rates in the solifenacin groups were similar to those observed in the placebo group. These findings suggest that, after establishing treatment with 5 mg solifenacin once daily, dosing flexibility will allow physicians and patients to select the right dose for each patient based on their individual requirements.

Conclusions

Solifenacin is an effective antimuscarinic agent for the treatment of incontinence associated with OAB. More than 50% of subjects reporting incontinence at baseline achieved complete continence after receiving solifenacin for up to 12 weeks of double blind study. The subgroup analyses presented here help to further define specific patient populations who may benefit from solifenacin therapy.

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