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Comparison of Two Selective Muscarinic Receptor Antagonists (Solifenacin and Darifenacin) in Women with Overactive Bladder – the SOLIDAR Study

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A B S T R A C T

Overactive bladder (OAB) is a common, often debilitating, condition defined as urgency and urge incontinence, usually with frequency and nocturia. The use of muscarinic receptor antagonists are the mainstay of treatment, but their non-selectivity can result in unacceptable adverse effects that limit their usefulness. The purpose of this study was to evaluate 2 of the newer antimuscarinic agents, solifenacin and darifenacin, which demonstrate greater selectivity, in order to compare their tolerance and effectiveness. This was a multicentre, prospective, randomised, comparative (1:1) open-label study conducted in 4 centres comprising Slovenian gynaecologists and urologists. A total of 77 female patients with OAB were enrolled who received either solifenacin 5 mg or darifenacin 7.5 mg once daily. Study measurements consisted of changes in OAB symptoms and quality of life (QOL) evaluations after 1 and 3 months of treatment. Both treatment groups showing a reduction in all OAB symptoms but with no notable difference being seen between the 2 groups. Solifenacin though showed statistically greater improvements in QOL, better overall treatment satisfaction, and a decreased incidence of dry mouth after 3 months of treatment compared to the darifenacin group. This study demonstrates interesting initial results and indicates that these 2 drugs have a different profile that may confer an advantage to patients, but further methodologically rigorous studies comparing the use of solifenacin and darifenacin in OAB are required to establish the differences between these drugs over longer periods of treatment.

***Key words**: anticholinergic, muscarinic receptors, overactive bladder, quality of life*

Introduction

Overactive bladder syndrome (OAB) comprises a set of symptoms, among which the most significant are urgency (a sudden, compelling desire to pass urine which is difficult to defer), increased daytime frequency (frequent voiding by day), urge incontinence (involuntary leakage accompanied by, or immediately preceded by, urgency), and nocturia (a need to wake once or more at night in order to void)[1].

OAB is a common, serious and often debilitating condition, and is associated with high economic and social costs[2]. Epidemiological surveys estimate that the condition affects approximately 50 million adults in Europe and the USA, with prevalence increasing with age[3–5]. The prevalence of OAB is approximately 16% in men and women aged ≥40 years, and it is associated with a significant impairment in quality of life (QOL)[3,4,6–8]. Approximately one third of OAB sufferers (32%) are depressed, and approximately one quarter (28%) feels extremely stressed because of this condition. Urge urinary incontinence is especially troublesome since it causes the affected person great concern and embarrassment, consequently limiting their everyday activities, both at home and at work[8].

OAB is a chronic condition requiring long-term, continuous treatment, usually comprising of an integrated approach involving behavioural therapy (scheduled voiding), physical therapies (pelvic floor muscle training, nonimplantable electrical stimulation) and pharmacolog-

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ical therapy. Anticholinergic drugs, commonly tolterodine and oxybutynin, represent the 'gold standard' of pharmacological treatment. These drugs competitively inhibit postsynaptic muscarinic receptors, thereby preventing detrusor muscle contraction. However, the use of these antimuscarinic agents has been limited by sub-optimal efficacy or adverse events (AEs) due to generalised muscarinic receptor blockade[9].

Anticholinergic agents exert their effect non-selectively on the 5 sub-types of muscarinic (M) receptors and hinder their activity, thereby giving rise to a range of AEs. M3 receptors are found in the salivary glands, soft muscles of the intestine and in the ciliary apparatus of the eye, therefore blockade of these receptors results in dry mouth, the most frequent and generally most problematic AE which often leads to treatment discontinuation[10–12]. In addition, constipation and blurred vision are frequently reported. Other AEs occur less frequently, however, blockade of M1 receptors in the central nervous system (CNS) can result in serious cognitive disturbances, such as impaired concentration and memory loss.

In recent years, 2 new drugs have become available for the treatment of OAB: solifenacin and darifenacin. Solifenacin was launched throughout most of Europe in 2004 and is available in both 5mg and 10mg formulations, offering flexible once-daily dosing for alleviating symptoms of OAB, specifically urge incontinence and increased urinary frequency through its action on muscarinic receptors. Darifenacin 7.5mg and 15mg was also granted Marketing Authorisation by the European Commission for the treatment of OAB in 2004. Initial studies have shown that the greater selectivity of these drugs results in a smaller incidence of AEs and improved clinical efficacy[13–16]. However, head-to-head studies comparing solifenacin and darifenacin are lacking and, therefore, this study aimed to compare the efficacy and tolerability of these 2 antimuscarinic agents.

The objective of this patient-oriented study was to assess the clinical efficacy of solifenacin and darifenacin (SOLIDAR Study: SOLIfenacin DARifenacin) in women with OAB after 1 and 3 months of treatment. The primary endpoint of this study was urgency, specifically the frequency and intensity of urge episodes.

Materials and Methods

This study comprised a multicentre, prospective, randomised, comparative (head-to-head) open-label study, in which 100 female patients with OAB were planned to be enrolled by 8 Slovenian gynaecologists and urologists in 5 centres. Patients were enrolled between October 2007 and October 2008 on a consecutive basis, with 100 patients randomised on a 1:1 basis to one of 2 drugs, solifenacin 5 mg or darifenacin 7.5 mg from a computer generated randomisation list. The study was approved by the Ethics Committee at the Ministry of Health, Republic of Slovenia and IRB University Medical Center, Maribor. All patients provided written informed consent prior to participation in any study-specific procedures.

Patient inclusion criteria comprised females with idiopatic OAB, defined as urgency intensity and urgency urinary incontinence (UUI) of ≥3 on the Urgency Perception Scale (UPS) and frequency of ≥1 urgency episodes (UE) per day. Patients were required not to have received any anticholinergic drugs for at least 6 months prior to study inclusion. Patients were excluded from participation if they were pregnant, suffered from angular glaucoma, urinary infection, urinary tract stones, bladder disease (i.e. stones or tumours), or if they were incapable of actively participating in the study (e.g. dementia). Patients with neurogenic OAB and those with severe orthopaedic difficulties (e.g. need for crutches or wheelchair etc.) were also excluded from the study.

Treatment was evaluated at baseline, and at 1and 3 months post-treatment in order to assess subjective improvement. Patients were issued with 2 questionnaires: the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ), these being patient--reported outcomes instruments used to determine the effect of treatment from the patient's perspective. Patients were also issues with a Visual Analogue Scale (VAS) and Urgency Perception Scale (UPS). Secondary endpoints comprised the occurrence of a pre-defined list of AEs and treatment success.

The study schedule consisted of 4 clinic visits. At the first visit (baseline) patient history was taken (including date of birth, body weight, height, body mass index (BMI), gynaecological history, duration of OAB symptoms, duration of urinary incontinence, previous treatment of incontinence, and concomitant diseases and therapies). A clinical examination was also performed and a urine sample was taken for analysis. At the end of the first visit, patients were issued with 2 questionnaires: the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ). The UDI questionnaire is used for screening for stress, irritative and obstructive symptoms while the IIQ questionnaire asks how these symptoms affect the quality of life (QoL) of affected women in terms of physical activity (PA), travel (T), social relations (SR), and emotional health (EH)[17].

Visit 2 was performed 7 days following the baseline visit. Information about voiding and the UDI and IIQ questionnaire data were checked for accuracy and urinalysis results were checked for normality. Patients were then administered their first dose of study medication comprising either solifenacin 5 mg or darifenacin 7.5 mg, with both drugs taken at a dose of one tablet during the evening. The physician requested that the patient did not change their habits during the course of the study, for example by performing bladder training or pelvic floor muscle training, and patients were asked to drink the same quantity of liquid during the study as prior to study participation. Patients then received 2 forms for completion 3 days before the next clinic visit; one to record details of any AEs and the other a voiding diary to be used over a 3-day period.

Visit 3 was performed 1 month after commencing treatment. During the visit, voiding diaries were checked

for completion, AEs assessed, and an assessment made of the intensity of OAB symptoms and treatment efficacy from the patient's perspective. Patients then received a new voiding diary for completion, together with UDI and IIQ questionnaires.

The final visit, Visit 4, was scheduled 3 months after starting the treatment. Voiding diaries and UDI and IIQ questionnaires were checked for completion, and any AEs that had emerged since the previous follow-up visit were noted. OAB symptoms and treatment efficacy were assessed, and each patient was asked to provide an estimate of treatment success using a Visual Analogue Scale (VAS). Results of a second urinalysis were assessed. Finally, a decision was taken as to whether the patient would continue with treatment at the same or at a higher dose.

Statistical Analysis

Scores were calculated for the following study endpoints: urgency (how strong), urgency (how often), urgency (how bothersome), frequency, nocturia, number of pads used, IIQ total score, UDI total score, and subjective success. All scores were recorded on a scale of 0 to 10, with the exception of urgency (how bothersome) that was recorded on a scale of 0–100.

Although there were departures from the normal distribution, median and mean scores, lower/upper quartiles, and standard deviations were used as a consistent and convenient method to summaries the results. Data were summarized by treatment, and changes from baseline to 1 and 3 months presented. Due to non-normal distributions, treatment differences were tested using the Wilcoxon Rank Sum Test. Treatment differences in the numbers continuing at the same dose were tested using Fisher's Exact Test. Spearman correlation coefficients (with 95% confidence intervals) were calculated for improvement scores versus improvement in symptoms. Following good statistical practice no significance testing of baseline data were performed.

As this was regarded as an exploratory study, no formal adjustments for multiple significance testing were performed. Statistical analysis was performed using SAS statistical software (SAS Institute Inc., Cary, NC, USA).

Results

Four centres participated in this study, recruiting a total of 77 patients (40 solifenacin, 37 darifenacin). Sixteen patients withdrew prematurely from the study (8 solifenacin, 8 darifenacin) and 61 patients completed the study (solifenacin 32 (80%), 29 darifenacin (78.4%)). The reasons for withdrawal were adverse events in (8 patients), lack of efficacy (4 patients), withdrawal of consent (3 patients), and one patient was advised to stop taking study medication on psychiatric advice (Figure 1).

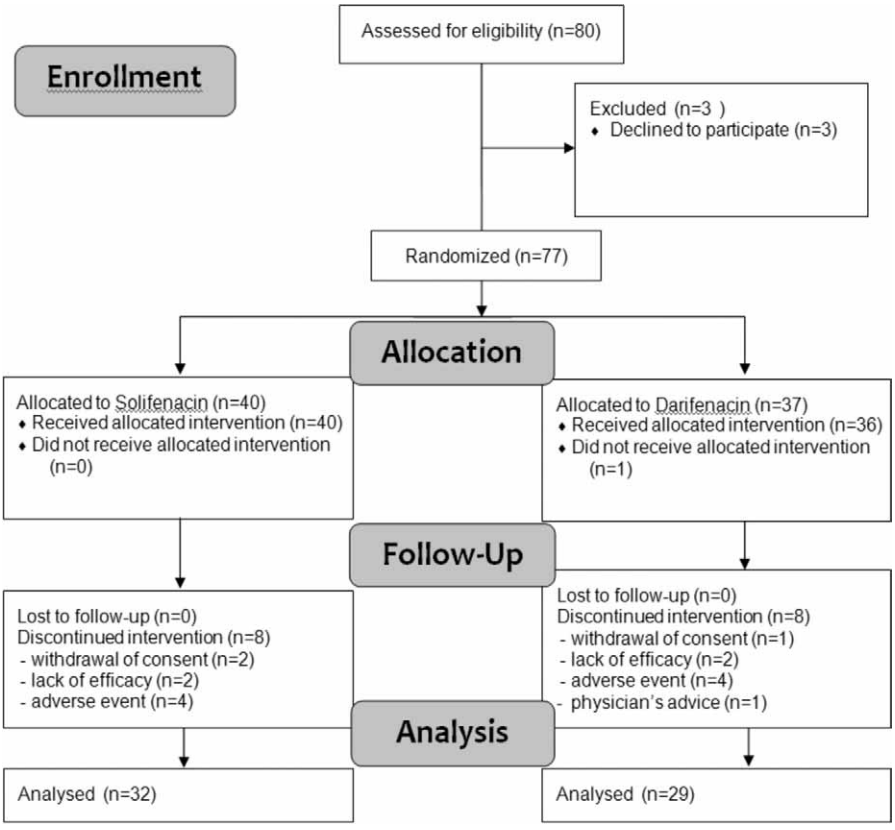

Fig. 1. Patient Flow Chart.

One darifenacin patient was withdrawn before receiving any treatment so was not included in any of the analyses.

The median age of patients enrolled into the study was 54 years (X: 54.8 years (SD: 11.5)) (median 52 years in the solifenacin group and 56 years in the darifenacin group), and the median BMI was 26.9 kg/m^2 (X: 27.6 kg/m^2 (SD: 5.0) (median 26.4 kg/m^2 in the solifenacin group and 28.4 kg/m^2 in the darifenacin group). The median duration of prior urgency incontinence was 60 months (X: 86.0 months (SD: 82.6)) (54 months in the solifenacin group and 72 months in the darifenacin group) and the median duration of urge urinary incontinence was 36 months (X: 46.5 months (SD: 55.7)) (27 months in the solifenacin group and 36 months in the darifenacin group).

Analysis of OAB symptoms at baseline were generally similar between the 2 treatment groups, although urgency (bothersome) scores were higher in the darifenacin group, and frequency scores were higher in the solifenacin group (Table 1). Following 1 month and 3 months of treatment, all measured OAB symptoms decreased, with no statistically significant treatment differences being seen between the groups (Table 1). However, it is of note that nocturia decreased to a greater extent in the solifenacin group at 1 month and this group also used less incontinence pads than those in the darifenacin group at 3 months (Table 1).

The majority of patients in the solifenacin group who completed the study maintained the same dose post--study (21 patients, 66%), with only 4 patients (13%) considered to need an increase in dose to maintain efficacy. However, in the darifenacin group only 11 patients (38%) who completed then maintained the same dose, with 13 patients (45%) considered to need an increase in dose to maintain efficacy (treatment difference: p= 0.041).

Evaluation of the effects on QOL were assessed using the IIQ and UDI questionnaires (Table 2). In both the UDI and IIQ questionnaires, patients treated with solifenacin indicated a greater improvement in QOL compared to patients treated with darifenacin, and for the IIQ total score the difference between the 2 groups reached statistical significance (p=0.018). The social relationship component of the IIQ also showed a significant difference between the groups in favour of solifenacin (p=0.02), with the emotional health and transport components also bordering on statistical significance (p= 0.06 and p=0.05, respectively).

Overall patient subjective and objective assessment of treatment improvement was higher for solifenacin compared to darifenacin, with the difference again being statistically significant in favour of solifenacin (p=0.01 for subjective improvement) (Table 3).

AEs of dry mouth, constipation, blurred vision, headache, dizziness, concentration problems, memory prob-

TABLE 1
TREATMENT DIFFERENCE IN OAB SYMPTOMS OVER 1 AND 3 MONTHS OF TREATMENT

	Baseline		Change from Baseline					
	Solifenacin Median X (SD) N=40	Darifenacin Median X (SD) N=36	Solifenacin Median X (SD) N=40		Darifenacin Median X (SD) N=36		Treatment difference: Median X (SD)	
			1 month N=39	3 months N=32	1 month N=33	3 months N=29	1 month N=33	3 months N=29
Urgency (how strong)	3.0 3.2 (0.6)	3.0 3.1 (0.5)	–1.0 –0.8 (0.7)	–1.0 –1.1 (0.8)	–1.0 –0.6 (0.7)	–1.0 –0.8 (0.8)	0.0 –0.1 (0.7) (p=0.55)	0.0 –0.3 (0.8) (p=0.23)
Urgency (how often)	6.0 5.7 (0.99)	7.0 5.9 (1.5)	–1.0 –1.0 (1.1)	–1.0 –1.0 (1.95)	–1.0 –1.0 (1.2)	–2.0 –1.6 (1.8)	0.0 0.03 (1.2) (p=0.90)	0.0 –0.4 (1.9) (p=0.66)
Urgency (how bothersome)	70.5 72.8 (17.3)	75.5 73.2 (20.2)	–20.0 –20.1 (19.95)	–28.5 –30.8 (27.7)	–10.0 –14.2 (22.8)	–26.0 –24.6 (24.6)	–8.0 –5.9 (21.3) (p=0.19)	–9.0 –6.2 (26.3) (p=0.34)
Frequency	9.3 9.3 (3.2)	7.9 8.9 (4.1)	–1.4 –1.78 (2.0)	–1.7 –2.17 (2.5)	–1.4 –2.0 (2.7)	–1.4 –2.1 (3.4)	0.0 0.3 (2.4) (p=0.82)	–0.3 –0.1 (2.99) (p=0.70)
Nocturia	2.5 2.5 (1.6)	2.3 2.6 (1.3)	–1.0 –1.1 (1.1)	–1.0 –1.2 (1.1)	–0.4 –0.5 (1.1)	–1.0 –0.8 (1.3)	–0.6 –0.5 (1.1) (p=0.051)	–0.3 –0.3 (1.2) (p=0.43)
Number of pads	2.9 2.8 (2.4)	2.4 2.9 (2.9)	–0.3 –0.6 (1.8)	–0.7 –1.1 (1.5)	–0.3 –0.4 (2.6)	–0.3 –0.4 (2.3)	0.0 –0.3 (2.2) (p=0.76)	–0.6 –0.7 (1.9) (p=0.19)

X = Mean; SD = standard deviation; p-values calculated using Wilcoxon Rank Sum Test

TABLE 2
INCONTINENCE IMPACT QUESTIONNAIRE (IIQ) AND UROGENITAL DISTRESS INVENTORY (UDI) RESULTS

	Median baseline value (lower – upper quartile) Mean baseline value (SD)		Treatment difference from baseline to 3 months Median X (SD) N=29
	Solifenacin N=40	Darifenacin N=36	
IIQ Score			
Total score	232.9 (100.9–302.7) 211.8 (113.5)	256.7 (161.0–309.8) 231.6 (109.7)	–34.9 –35.9 (79.1) (p=0.018)
Emotional health	39.6 (10.8–74.9) 43.9 (33.7)	50.0 (22.2–77.7) 49.3 (31.5)	–8.3 –11.0 (21.6) (p=0.057)
Physical activity	63.9 (41.7–83.3) 60.0 (27.3)	72.2 (44.4–88.8) 64.1 (28.6)	–5.6 –6.9 (19.7) (p=0.14)
Social relationship	37.8 (23.3–70.0) 44.9 (30.7)	60.0 (26.6–76.6) 52.1 (31.3)	–10.0 –8.7 (18.0) (p=0.020)
Transport	70.0 (30.6–94.4) 63.0 (32.2)	72.2 (44.4–91.6) 67.6 (29.0)	–5.7 –9.31 (21.3) (p=0.051)
UDI Score			
Irritative symptoms	50.0 (36.1–72.2) 54.0 (24.5)	66.7 (50.0–83.3) 66.5 (20.5)	–5.6 –5.7 (25.4) (p=0.34)
Stress symptoms	50.0 (33.3–66.7) 49.6 (32.6)	58.4 (33.3–100.0) 59.3 (36.0)	0.0 –7.5 (30.9) (p=0.46)
Obstructive symptoms	15.1 (7.6–27.2) 20.4 (18.6)	27.2 (12.1–42.4) 26.4 (17.8)	–1.4 –1.1 (14.7) (p=0.58)

p-values calculated using Wilcoxon Rank Sum Test

TABLE 3
SUBJECTIVE SUCCESS (VAS SCORE)

	3 months		
	N	Median	(25–75 perc.)
Solifenacin	32	84	55.0–92.5
Darifenacin	29	55	33.0–88.0
Treatment difference in change from baseline	Median 22.5, p=0.010		

lems, and insomnia were solicited at the 1 month and 3 month assessments, as well as at baseline. Symptoms of dry mouth and constipation increased during the first month of treatment in both groups, but by 3 months of treatment had decreased again to baseline levels, with the exception of dry mouth in the darifenacin group, where 62% of patients still reported symptoms after 3 months of treatment (compared to only 41% in the solifenacin group) (Table 4).

Discussion

OAB is a common, often debilitating, condition defined by the International Continence Society as urgency, with or without urge incontinence, usually with frequency and nocturia[18], and is associated with high economic and social costs[2]. Patients commonly state that the symptoms of urinary urgency has a significant effect on their QOL[19]. The use of muscarinic receptor antagonists are the mainstay of treatment, but their non-selectivity can result in unacceptable AEs that limit their usefulness. Two newer antimuscarinic agents, solifenacin and darifenacin, which demonstrate greater selectivity, were evaluated in this small, prospective study in order to compare their effectiveness.

Solifenacin and darifenacin have been shown by previous research to exhibit lower AEs rates but with similar efficacy rates to established drugs in this field such as tolterodine and oxybutinin[15]. Our hypothesis for the design of this study was that selective inhibition of M3 receptors by both drugs would effectively improve OAB

TABLE 4
SOLICITED ADVERSE EVENTS

Solicited Adverse events	Solifenacin N=40 N (%)			Darifenacin N=36 N (%)		
	Baseline N=40	1 month N=39	3 months N=32	Baseline N=36	1 month N=35	3 months N=29
Dry mouth	15 (38%)	24 (62%)	13 (41%)	17 (47%)	27 (77%)	18 (62%)
Constipation	16 (40%)	17 (45%)	8 (25%)	10 (28%)	15 (44%)	8 (28%)
Blurred vision	16 (40%)	13 (33%)	10 (31%)	16 (44%)	11 (33%)	9 (31%)
Headache	12 (30%)	11 (28%)	5 (16%)	16 (44%)	13 (38%)	3 (21%)
Dizziness	12 (30%)	10 (26%)	7 (22%)	15 (42%)	8 (24%)	4 (14%)
Lack of concentration	15 (38%)	9 (23%)	8 (25%)	14 (39%)	11 (33%)	8 (28%)
Memory problems	19 (48%)	11 (28%)	10 (31%)	20 (56%)	11 (33%)	9 (31%)
Insomnia	17 (43%)	8 (21%)	9 (28%)	18 (50%)	12 (36%)	7 (24%)

symptoms, as evidenced by decreased incontinence pad use and improved QOL. This assumption was met, with both treatment groups showing a reduction in all OAB symptoms. However, solifenacin showed statistically greater improvements in quality of life (IIQ score), better overall treatment satisfaction, and a decreased incidence of dry mouth after 3 months of treatment compared to patients treated with darifenacin.

These results concur with the findings of Kobayashi et al who found that solifenacin provided a promising therapeutic advantage for reducing AEs such as dry mouth, due to its greater selectivity for bladder smooth muscle cells over salivary gland cells[20]. This seems to correlate with the results of our study, where increased patient satisfaction was seen with solifenacin treatment, with this translating into an improvement in QoL In the long term it can be hypothesised that these advantages may increase patient compliance and thus maintain the effects of treatment over a longer period of time.

It is important to note that this was the first head-to--head study comparing these antimuscarinic drugs. However, it was only a small study so a calculation to establish sample size and power was not performed and subsequently the study could have been underpowered. Also the full number of intended patients were not enrolled due to difficulties enrolling patients and the fact that very few centres deal with treatment of this condition in Slovenia. Finally, neither physicians nor patients were blinded to the treatments administered which could have introduced significant bias. Despite these limitations, this study provides an interesting indicator that these 2 drugs have a different profile that may confer an advantage to patients with this distressing condition, but a further large-scale, long-term study would be needed to confirm our findings.

In conclusion, solifenacin and darifenacin are both effective and well-tolerated drugs for the treatment of OAB. The results of this study indicate that these 2 drugs have a different profile that may confer an advantage to patients with OAB. Whilst this study demonstrates interesting initial results, further methodologically rigorous studies comprising large, long-term, prospective, randomised clinical trials comparing the use of solifenacin and darifenacin in OAB are required to establish the effectiveness of these drugs over longer periods of treatment.

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USPOREDBA DVA SELEKTIVNA ANTIMUSKARINSKA LIJEKA (SOLIFENACIN I DARIFENACIN) U ŽENA S PREKOMJERNO AKTIVNIM MOKRAĆNIM MJEHUROM

S A Ž E T A K

Prekomjerno aktivan mokraćni mjehur (OAB) je često stanje definirano urgencijom i urgentnom inkontinencijom, te učestalim dnevnim i noćnim mokrenjem. Terapija izbora danas je primjena antimuskarinskih lijekova. Medjutim, ograničavajući čimbenik primjene navedenih lijekova je njihova neselektivnost što može rezultirati neželjenim učincima i nuspojavama. Cilj ove studije je usporediti učinkovitost i podnošljivost solifenacina i darifenacina, dva novija visokoselektivna antimuskarinska lijeka. U multicentričnu, prospektivnu, randomiziranu »open-label« studiju uključeno je 77 pacijentica s OAB-om koje su uzimale 5 mg solifenacina ili 7.5 mg darifenacina u jednokratnoj dnevnoj dozi. Procjena učinkovitosti oba lijeka temeljila se na subjektivnoj i objektivnoj procjeni smanjenja OAB simptoma i kvalitete života nakon mjesec i tri mjeseca liječenja. U obje ispitivane skupine dokazana je podjednaka učinkovitost u smanjenju svih simptoma OAB-a. U skupini pacijentica koje su koristile solifenacin dokazano je statistički značajno poboljšanje kvalitete života, bolje ukupno zadovoljstvo i smanjena učestalost suhoće ustiju nakon tri mjeseca liječenja u usporedbi sa skupinom pacijentica koje su koristile darifenacin. Ova studija je dokazala da solifenacin i darifenacin predstavljaju učinkovite i dobro podnošljive lijekove u liječenju OAB-a. Rezultati ove studije da primjena oba lijeka s različitim profilom glede potencijalnih nuspojava može značajno poboljšati učinkovitost i sigurnost liječenja u pacijentica s OAB. Za nadati se da će buduće veće, prospektivne i randomizirane kliničke studije jasnije pozicionirati učinkovitost i podnošljivost solifenacina i darifenacina u žena s prekomjerno aktivnim mokraćnim mjehurom.