THERAPEUTICS

Antimuscarinic drugs to treat overactive bladder

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This is one of a series of occasional articles on therapeutics for common or serious conditions, covering new drugs and old drugs with important new indications or concerns. The series advisers are Robin Ferner, honorary professor of clinical pharmacology, University of Birmingham and Birmingham City Hospital, and Philip Routledge, professor of clinical pharmacology, Cardiff University. To suggest a topic for this series, please email us at practice@bmj.com

Coming next week, Clinical Review: Management of overactive bladder syndrome

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- Newer antidepressants for the treatment of depression in adults (*BMJ* 2012;344:d8300)
- Newer drugs for focal epilepsy in adults (*BMJ* 2012;344:e345)
- Hormone replacement therapy (*BMJ* 2012;344:e763)
- Protease inhibitors for treatment of genotype 1 hepatitis C virus infection (*BMJ* 2011;343:d6972)

A 45 year old woman presents to her general practitioner complaining of troublesome urinary symptoms increasingly affecting her quality of life. She is currently voiding more than 10 times a day and rising three times at night. In addition she notices a sudden urgent desire to void and on two occasions has leaked urine before reaching the toilet. She gives no history of urinary tract infection or haematuria. Her periods remain regular.

In the past she has had two vaginal deliveries, has no significant medical history, and is not taking any medication. Pelvic examination is unremarkable and urine analysis normal. Ultrasound examination shows no post-void residual urine.

Based on the history, clinical examination, and basic investigations you make a symptomatic diagnosis of overactive bladder. After discussing her bladder symptoms, you offer lifestyle advice including the moderation of fluids and reduction of caffeine intake. In addition you refer her for bladder retraining and start treatment with antimuscarinic drugs.

What is overactive bladder?

Overactive bladder is the term used to describe the symptom complex of urinary urgency, usually accompanied by frequency and nocturia, with or without urge urinary incontinence, in the absence of urinary tract infection or other obvious pathology.[1]

Epidemiological studies in North America have reported a prevalence of overactive bladder in women of 16.9%, and the prevalence increases with age—from 4.8% in women under 25 years to 30.9% in those aged over 65 years.[2] Prevalence data from Europe are similar, with frequency the most commonly reported symptom (85%), and 54% reporting urgency and 36% urge incontinence.[3]

The symptoms of overactive bladder are most likely due to involuntary contractions of the detrusor muscle during the filling phase of the micturition cycle; abnormalities in afferent sensation may also play a role. Detrusor overactivity[1] is mediated by acetylcholine induced stimulation of muscarinic receptors in the bladder, under the control of the parasympathetic nervous system. Although the cause of detrusor overactivity is unknown, there is evidence to support both neurogenic and myogenic causes.[4 5] Antimuscarinic drugs used to treat overactive bladder (see box 1) act by blocking muscarinic receptors at the neuromuscular junction and thus prevent acetylcholine mediated bladder contraction.

Consequently, overactive bladder is a symptom based diagnosis, and detrusor overactivity can be diagnosed only after urodynamic investigation. The two terms are not synonymous: 64% of women with overactive bladder have urodynamically proved detrusor overactivity, while 83% of women with detrusor overactivity have symptoms suggestive of overactive bladder.[6]

Box 1 | Antimuscarinic drugs used to treat overactive bladder

Darifenacin
Fesoterodine
Oxybutynin
Propiverine
Solifenacin
Tolterodine
Trospium

Based on level I evidence for all these drugs, the International Consultation on Incontinence has made grade A recommendations for their use in overactive bladder syndrome.[7] (See box 2 for definitions of levels of evidence and recommendations)

Box 2 | Categories of clinical evidence and recommendations[8 9]

Levels of evidence

I—Systematic review of all relevant randomised controlled trials
IIA—One randomised controlled trial, with low probability of bias and high probability of causal relationship
IIB—One randomised controlled trial
IIIA—Well designed controlled trials (no randomisation)
IIIB—Cohort or case-control studies
IIIC—Multiple time series or dramatic results in uncontrolled experiments
IV—Expert opinion (traditional use)

Grades of recommendations

A—A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as level I directly applicable to the target population and showing overall consistency of results
B—A body of evidence including studies rated as level IIA directly applicable to the target population and showing overall consistency of results, or extrapolated evidence from studies rated as level I
C—A body of evidence including studies rated as IIB directly applicable to the target population and showing overall consistency of results, or extrapolated evidence from studies rated as level II
D—Evidence level III or IV, or extrapolated evidence from studies rated as II

How well do antimuscarinic drugs work?

Several antimuscarinic drugs are licensed and available in the UK. These have all been recently recommended by the International Consultation on Incontinence[7] to treat overactive bladder syndrome (box 1) and all have level I evidence[8] and a grade A recommendation (see box 2 for definitions).[9]

The clinical effectiveness of antimuscarinic agents was first questioned in a systematic review of 32 randomised controlled trials including 6800 participants.[10] Cure or improvement after treatment were all significantly in favour of antimuscarinic drugs (relative risk 1.41 (95% confidence interval 1.29 to 1.54), P<0.0001), although the differences from placebo were small and

Box 3 | Antimuscarinic drug interactions

Antiarrhythmics—Darifenacin and tolterodine may increase risk of arrhythmias when given with antiarrhythmics

Antifungals—Solifenacin and fesoterodine levels increased by itraconazole and ketoconazole. Avoid use of darifenacin and tolterodine with itraconazole and ketoconazole

Antipsychotics—Reduce the effect of haloperidol and phenothiazines

Antiretrovirals—Fesoterodine and solifenacin levels increased with antiretrovirals. Avoid darifenacin with antiretroviral agents

Domperidone—Antimuscarinics may antagonise the effects on gastric motility

Levodopa—Antimuscarinics may reduce absorption

Metoclopramide—Antimuscarinics may antagonise the effects on gastric motility

Phenothiazines—Antimuscarinics may increase risk of antimuscarinic side effects

Tricyclic antidepressants—May increase risk of antimuscarinic effects

From *British National Formulary* 2011;61

of questionable clinical significance. A subsequent Cochrane review of 61 randomised controlled trials including 11 956 patients was supportive of these findings, with a significantly greater cure or improvement rate in the antimuscarinic group compared with placebo (relative risk 1.39 (1.28 to 1.51)). Importantly, there was also a significant improvement in quality of life, implying clinical as well as statistical significance.[11] The overall number needed to treat (NNT) was seven.

The most recent meta-analysis of 83 randomised controlled trials, including 30 699 patients and six different drugs (fesoterodine, oxybutynin, propiverine, solifenacin, tolterodine, and trospium), also supports the efficacy of antimuscarinic drugs in the treatment of overactive bladder. Overall there was a significantly higher return to continence with active treatment compared with placebo—the pooled relative risk across different studies and different drugs was 1.3–3.5 (P<0.01). Antimuscarinic therapy was also shown to be significantly more effective in reducing the daily number of incontinence episodes (pooled differences in mean change 0.4–1.1), micturitions (0.5–1.3), and urgency episodes (0.64–1.56).[12]

While these data confirm the efficacy of antimuscarinic drugs, the evidence for comparing different drugs is less robust. Some randomised controlled data suggest that extended release oxybutynin[13] and tolterodine[14] may have superior efficacy to the immediate release preparations[15] In addition, solifenacin is as effective as extended release tolterodine,[16] and fesoterodine is superior to it.[17] However, the incidence of adverse effects increases with increasing dose.

How safe are antimuscarinic drugs?

Antimuscarinic drugs are associated with the common anticholinergic adverse effects of dry mouth, constipation, blurred vision, and somnolence. Although these are not life threatening, they may be associated with poor compliance or persistence with treatment. A recent systematic review of 149 papers found discontinuation rates of 43–83% in the first 30 days of treatment, and more than half of patients never refill the initial prescription.[18] More serious adverse effects include cognitive and cardiac effects, specifically prolongation of the QT interval,[19] though all the safety data suggest that routine electrocardiography is not required. A recent meta-analysis of prospective randomised trials investigating the effect of antimuscarinic drugs on the central nervous system found the incidence of adverse effects was poorly reported overall, and 77% of studies neither measured nor reported central nervous system outcomes.[20] In those that did, dizziness was the most common adverse effect (oxybutynin 3%, propiverine 3.2%, tolterodine 1.8%, and placebo 1.6%), and confusion was found in <1% of cases. Small randomised studies have also shown no effect on cognition in elderly patients with solifenacin,[21] darifenacin,[22] and trospium chloride.[23]

What are the precautions?

- Hepatic or renal impairment—As antimuscarinic drugs undergo both hepatic metabolism and renal excretion, the dose may need to be decreased in such patients
- Elderly patients—A lower dose should be considered because of the risk of postural hypotension and cognitive impairment
- Voiding dysfunction—In men there may be some concerns regarding the exacerbation of voiding difficulties, but this is only rarely reported in women, so post-void residual urine volumes need not be monitored routinely
- Contraindications—Do not prescribe these drugs in patients with angle closure glaucoma, myasthenia gravis, severe ulcerative colitis, toxic megacolon, or intestinal obstruction because of their anticholinergic effects
- Pregnancy—There is limited evidence for all antimuscarinic agents. Oxybutynin is generally felt to be safe if essential, but avoid darifenacin, fesoterodine, propiverine, tolterodine, solifenacin, and trospium
- Drug interactions—Box 3 summarises possible interactions
  - Antimuscarinics may interact with drugs that compete for hepatic metabolism via cytochrome P450 and renal excretion,[16] especially in patients with mild hepatic and renal impairment and in elderly patients, who may be receiving polypharmacy
  - Concomitant use of other drugs that have antimuscarinic effects may increase the risk of adverse effects.

How cost effective are antimuscarinic drugs?

In a recent assessment of cost effectiveness of all antimuscarinic therapies within the UK National Health Service, solifenacin was associated with the highest quality adjusted life year (QALY) gain in terms of urinary urgency, frequency, and incontinence. Solifenacin was found to be more cost effective than fesoterodine, tolterodine, and propiverine, though not oxybutynin.[24] A cost utility analysis comparing solifenacin and tolterodine found that solifenacin was less expensive and more effective than tolterodine: solifenacin was found to have an incremental cost of £8087 per QALY, and the one year costs were £509 with solifenacin compared with £526 for tolterodine.[25]

How are antimuscarinic drugs taken and monitored

All antimuscarinic drugs can be taken orally, and oxybutynin is also available as a transdermal preparation

Alternatives to antimuscarinic drugs for treating overactive bladder and the strength of clinical evidence for their use[7]

Drug	Level of evidence	Grade of recommendation
Drugs acting on membrane channels		
Calcium channel antagonists	II	D
Potassium channel openers	II	D
Drugs with mixed actions		
Flavoxate	II	D
α antagonists		
Alfuzosin	III	C
Doxazosin	III	C
Prazosin	III	C
Terazosin	III	C
Tamsulosin	III	C
β agonists		
Terbutaline	III	C
Salbutamol	III	C
Antidepressants		
Imipramine	III	C
Duloxetine	II	C
Prostaglandin synthesis inhibitors		
Indometacin	II	C
Flurbiprofen	II	C
Vasopressin analogues		
Desmopressin	I	A

See box 2 for explanation of levels of evidence and grades of recommendations

(gel and patch). Counsel patients on the adverse effects associated with antimuscarinic treatment (see box of tips for patients) and always review concomitant medication before starting treatment. Some patients may have sufficient improvement in their symptoms with conservative measures and be reluctant to take drugs. In general start at a low dose and titrate against efficacy and adverse effects. It is not necessary to monitor liver and renal function in patients with hepatic and renal impairment.

How do antimuscarinic drugs compare with conservative therapy and other drugs?

Antimuscarinic drugs may be a useful addition to non-drug therapy in the management of overactive bladder. In a Cochrane review of 13 trials including 1770 patients, symptomatic improvement was more common among those taking antimuscarinic drugs compared with bladder retraining (relative risk 0.73 (0.59 to 0.90)), and combination treatment was also associated with more improvement than bladder training alone (0.55 (0.32 to 0.93)). Similarly there was a trend towards greater improvement with a combination of antimuscarinic drugs with bladder retraining compared with antimuscarinics alone (relative risk 0.81 (0.61 to 1.06)), although this was not significant.[26]

Many other drugs are used to treat overactive bladder, but evidence for their effectiveness is variable (see table).[5] Of these, only desmopressin, a synthetic vasopressin analogue used primarily to treat nocturia and nocturnal enuresis, has level I evidence to support its use, although there are no comparative studies with antimuscarinic drugs.

Although the use of calcium blocking agents and potassium channel opening drugs showed initial promise, neither have proved to be useful in the clinical setting.[27 28] The search for novel agents to treat overactive bladder continues and has recently focused on the use of neurokinin antagonists,[29] vitamin D analogues,[30] and β adrenoceptor agonists.[31]

TIPS FOR PATIENTS

Overactive bladder is a common and distressing condition

Bladder retraining, lifestyle advice, and pelvic floor exercises should help to improve the symptoms of overactive bladder

Think about fluid intake and try to avoid caffeinated drinks, artificially sweetened carbonated drinks, and alcohol. Try not to drink too much (generally no more than 1.5 litres a day), and limit your fluid intake before bed

Your local continence advisory service will be able to provide you with tips for coping strategies and advice about containment products such as continence pads

Antimuscarinic drugs may be useful in addition to conservative measures when trying to control your bladder symptoms; these may be required long term as overactive bladder is a chronic condition

Antimuscarinic drugs may be associated with a dry mouth. Try sucking a sweet or chewing gum to increase salivation

Constipation may also be associated with taking antimuscarinic drugs: it may be necessary to alter your diet or consider laxatives

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10-MINUTE CONSULTATION

A scaly rash on the hands

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- Epistaxis (*BMJ* 2012;344:e1097)
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- Reviewing a patient with coeliac disease (*BMJ* 2012;344:d8152)
- Dyspepsia (*BMJ* 2011;343:d6234)

A 30 year old mechanic attends with a scaly rash on both his palms. He describes cuts on his skin which are painful and affect his grip strength. This has caused him to have time off work.

What issues you should cover

Common causes of diffuse scaly rashes on the hands are eczema (atopic, irritant or allergic contact dermatitis, and pompholyx), psoriasis, scabies, and tinea. A patient can have more than one diagnosis (such as atopic eczema plus an occupational allergic contact dermatitis).

To help identify the cause(s) and effects of the rash, inquire about

- Duration and evolution of disease
- Presence of itch or rash elsewhere
- Personal or family history of atopy (eczema, asthma, or hay fever) or psoriasis
- Occupation and hobbies, and the impact of the rash on these
- Suspected triggers and a review of work practices—particularly relevant for allergic and irritant contact dermatitis. Ascertain
  - What does the patient come into contact with at work?
  - What is the duration from exposure to a suspected trigger to the rash flaring?
  - Does the rash improve if the suspected trigger is removed or when the patient is off work?
  - What is the frequency of hand washing?
- Contacts with symptoms—relevant for scabies, although asymptomatic contacts do not exclude scabies in the index patient.

Pointers to diagnosis

Eczema is associated with itch, symmetrical erythema (redness), vesicles (small fluid filled lesions), scaling, papules (small spots), and lichenification (that is, accentuation of skin creases). Fissuring can occur and be tender. Fingernails might exhibit small depressions on the nail surface ("pitting"). Patients with atopic eczema might have signs in other flexural sites (such as forearms, backs of knees, eyelids, behind ears).

Irritant contact dermatitis presents with signs of eczema on the sides of digits and dorsal hands, particularly within finger web spaces. High risk employment (with exposure to solvents, detergents, etc) and frequent hand washing with soap and water are often implicated.

Allergic contact dermatitis presents with signs of eczema, but a clue to the diagnosis may come from the history. High risk workers include cleaners and healthcare professionals (use of rubber gloves), construction workers (cement use), and mechanics (contact with nickel, cobalt, and use of cutting oils). A geometric distribution matching the area of contact with the allergen is suggestive of the diagnosis (for example, a rash with cut-off at both wrists might suggest an allergy to rubber gloves).

USEFUL READING

Primary Care Dermatology Society website. www.pcds.org.uk/clinical-guidance-and-guidelines/a-z-of-diagnosis. Contains information on hand dermatitis, pictorial examples, and patient information leaflets

NHS Clinical Knowledge Summaries. Clinical topics: skin and nail. www.cks.nhs.uk/clinical_topics/by_clinical_specialty/skin_and_nail. Evidence based information and practical, work based scenarios discussing the management of eczema, psoriasis, and scabies in primary care

Perry AD, Trafeli JP. Hand dermatitis: review of etiology, diagnosis, and treatment. *J Am Board Fam Med* 2009;22:325-30. doi:10.3122/jabfm.2009.03.080118

REASONS FOR REFERRAL TO SPECIALISTS

Suspected allergic contact dermatitis, for patch testing

Cases of eczema or psoriasis that fail to improve with seemingly appropriate topical treatment; these might require phototherapy or oral therapies

When the diagnosis remains unclear

Pompholyx eczema is an endogenous form of eczema (not caused by an exogenous allergen or irritant) on the palms or soles and presents with itch, vesicles, and scale.

Psoriasis is not usually itchy, generally symmetrical, and—in addition to erythema, scaling, and well defined plaques on the palms—can present with small, white, fluid-filled lesions (pustules) that become brown in later stages. Psoriasis should be looked for elsewhere (such as the elbows, knees, ears, scalp, umbilicus, soles of feet). Nail pitting can be accompanied by subungual hyperkeratosis (scale beneath the distal nail plate) and onycholysis (lifting of the distal nail plate).

Tinea of the palms can be itchy (but not always), be asymmetrical, have slow progression, and present with fine powdery scale of the palmar creases. Nail changes (such as onycholysis) or tinea elsewhere (such as the toenails, finger web spaces) can coexist.

Scabies should be considered in the presence of itch and burrows (wavy lines) on the palms, finger web spaces, or volar wrists with black or brown dots at the ends (representing mites). Examine other body parts (feet, genitalia, buttocks) to look for corroborating evidence.

What you should do

Empathy, reassurance, and patient information leaflets on hand care can help (available from Primary Care Dermatology Society website www.pcds.org.uk). If confident with the diagnosis, treat accordingly:

Eczema and psoriasis—Liberal use of greasy emollients as soap substitutes is important. Patients may require emollient pots (500 g) for home and workplace. Suspected allergens or irritants should be avoided if possible. Potent topical corticosteroids may be required for palmar involvement. Patients may fear the risks of topical steroids (such as skin thinning), so explain their potential benefit (a chance of rapid response and long term control) and effective use (how much to use, how to wean off slowly when the condition improves, and how to resume if the condition returns). Topical steroids can be applied under cotton gloves at night to improve penetration and disease control. One fingertip unit is the amount recommended to treat an area twice the size of an adult's palm,[1] and a 30 g tube applied to both palms daily may last an adult for two months, but quantities should be guided by disease severity.

Tinea—Take skin scrapings to confirm the diagnosis. Abstain from using topical corticosteroids and treat with an antifungal preparation. Often topical therapies are not sufficient and oral antifungal drugs might be needed.

Scabies—Appropriate anti-scabetic measures are needed for the patient and close contacts.

Follow-up

A patient with significant signs or disability should be reviewed within two to four weeks. If the condition shows no sign of improvement, consider whether the patient is compliant with treatment or if the diagnosis is correct.

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1 Patient.co.uk. Fingertip units for topical steroids. www.patient.co.uk/health/Fingertip-Units-for-Topical-Steroids.htm.

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On nakedness at work

It's a dangerous feeling, being at work with no clothes on. Work and nakedness don't obviously pair up. Clothes rank and protect. We may even think our clothes look smart.

Yet, standing here in the middle of my place of work with nothing on whatsoever, I feel liberated and alive. I'm in the shower, having cycled from home. It's the start of the day. Here I am, in my tired old body, standing naked where no one can see me. I feel fantastic.

The uphill work weaving through traffic, that murderous young mother blindly cutting through the cycle lane . . . all forgotten. I'm standing here as God made me, old but fit, tired but pleased. My cold bits are warm, my sweaty bits washed. I'm feeling blissfully alive. And, I'm at work. Everybody else, upstairs and downstairs, they've all got their clothes on. They were protected in their cars and are now protected in their clothes. They gently pretend and tell only half their truth. But me . . . I'm wet and warm with my bald head and naked as a babe.

And there's a serious side. Cycling is exactly as rewarding as it's hard. Let's not dwell on the immorality of our increasing carbon emissions, but instead I'll shout out that my toil climbing Sheffield's hills delivers me precisely the reward it should. I'm paid with delight at being alive and being at one with the world. And the icing on this delicious cake is the shower. And the icing on the icing, is knowing that, just for a moment, I can actually be as I am, naked, even at work.

So I'm grinning. I'm flying above my comfortable, isolated, car driving workmates. They're all around, clothed in subtle pretence and protected from what others might think. I'm no nudist, and I know I'm naked at work only for a moment . . . but it is a lovely moment. I feel like Thoreau, wanting to "live deliberately, fronting only the essential facts of life . . . and not, when I came to die discover that I had not lived" (Henry David Thoreau, *Walden*, 1894).

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