

Incontinence in the Frail Elderly: Report From the 4th International Consultation on Incontinence

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Aims: To summarize current knowledge on the etiology, assessment, and management of urinary incontinence (UI) in frail older persons. “Frail” here indicates a person with a clinical phenotype combining impaired physical activity, mobility, muscle strength, cognition, nutrition, and endurance, associated with being homebound or in care institutions and a high risk of intercurrent disease, disability, and death. **Methods:** Revision of 3rd ICI report using systematic review covering years 2004–2008. **Results:** We focus on the etiologic, management, and treatment implications of the key concept that UI in frail persons constitutes a syndromic model with multiple interacting risk factors, including age-related physiologic changes, comorbidity, and the common pathways between them. We present new findings with evidence summaries based on all previous data, and an evidence-based algorithm for evaluation and management of UI in frail elderly. We also present new evidence and summarize the data on etiology and management of nocturia and urinary retention in frail elderly. **Conclusions:** Despite the overwhelming burden of UI among this population, there remains a continuing paucity of new clinical trials in frail elderly, limiting evidence for the effectiveness of the full range of UI therapy. Future research is needed on current UI treatments (especially models of care delivery, and pharmacologic and surgical therapies), novel management approaches, and the etiologic mechanisms and pathways of the syndromic model. *NeuroUrol. Urodynam.* 29:165–178, 2010. © 2009 Wiley-Liss, Inc.

Key words: frail elderly; incontinence; nocturia; urinary retention

INTRODUCTION

Older persons have the highest known prevalence of urinary incontinence (UI) of any age group. With global population aging, the absolute numbers of older persons with UI are increasing exponentially. Despite this epidemiological imperative, there is a continuing paucity of new clinical trials in frail elderly, leaving little evidence for the effectiveness of the full range of UI therapy. In this summary of our full report, we focus only on the frail elderly, not healthy older persons. The text includes only new data since the 3rd ICI, but evidence summaries are based on all previous data.

MATERIALS AND METHODS

In our search strategy, we used multiple PubMed, Ovid, and Ovid Expert Search Filter searches using the MESH terms and phrases: 2004–08, AGED, AGED OVER 80, ACTIVITIES OF DAILY LIVING, DEPRESSION, elderly, FALLS, frail, FRAIL ELDERLY, FRAILTY, function, geriatrics, LONG TERM CARE, MEDICATIONS, NURSING HOME, older, QUALITY OF LIFE, RANDOMIZED CONTROLLED TRIAL; and BLADDER, GYNAECOLOGICAL SURGICAL PROCEDURES, PELVIC FLOOR, PROSTATE, STRESS INCONTINENCE, SURGERY, URETHRA, URINARY INCONTINENCE, URINATION DISORDERS, UROGYNECOLOGY, UROLOGY, VAGINA, VOIDING DYSFUNCTION. We included non-English

language articles if there was a sufficient abstract in English. References in retrieved articles were reviewed for additional relevant articles. We searched the Cochrane Database and National Guideline Clearinghouse for relevant systematic reviews, meta-analyses, and evidence-based recommendations.

FRAILTY AND INCONTINENCE

We use the *evidence-based* definition of “*frail older persons*”: a clinical phenotype combining impaired physical

Christopher Chapple led the review process.

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activity, mobility, balance, muscle strength, motor processing, cognition, nutrition, and endurance; associated high medication use and being homebound or in care institutions; and a high risk of intercurrent disease, increased disability, hospitalization, and death.¹ Frailty overlaps with but is not identical to disability and comorbidity.¹ UI is related to the severity of comorbidity and functional impairment and may be an early marker of frailty.² Internationally, UI is a risk factor for nursing home (NH) placement⁴, likely due to caregiver stress. UI is not associated with increased mortality, except among stroke patients.⁵ Its management must be multi-component and incorporate the severity of comorbidity, shared underlying impairments with other geriatric syndromes, altered pharmacology, polypharmacy, susceptibility to adverse effects (ADEs), and available models of care and management.

ETIOLOGY

UI as a Geriatric Syndrome

In frail elderly, UI constitutes a *syndromic model* with multiple interacting risk factors (age-related physiologic changes, comorbidity, and common pathways between them), in which the accumulated effects of multiple impairments increase vulnerability to situational challenges.⁶ This broader conception of “disease” includes patient-level factors and a perspective that extends beyond the lower urinary tract (LUT) and its neurological control.^{6,7} This multifactorial complexity has complicated the development of a pathophysiological framework for UI in the frail.⁶ Impaired activation of the right insula and anterior cingulate gyrus,⁸ together with evidence of white matter disease involving these areas in incontinent elderly,⁹ suggest a potential role for these regions in geriatric UI and urgency.¹⁰

Ageing-Related Changes in the Lower Urinary Tract (Table 1)

Detrusor contraction strength declines with age in women as well as men, and there is no detrusor overactivity (DO)-associated increase in contractility.¹¹ Lack of estrogen contributes to, and estrogen replacement reverses, ultrastructural changes of impaired contractility (caveolar depletion and detrusor fibrosis), while low estrogen also may contribute to bladder muscle cell differentiation.¹²

In the urethra, closure pressure decreases by an estimated 15 cmH₂O per decade,¹³ possibly related to mucosal changes

extending to the bladder trigone, irritating sensory afferent nerves and triggering DO,¹⁴ and decreased urethral vascular density and blood flow (note: these studies did not control for vascular risk factors).^{15,16} Circular smooth muscle mass and fiber counts decrease, with striated muscle loss in the anterior urethra.¹⁷ Little remains known about urethral changes in older men other than prostatic obstruction. Despite evidence for levator denervation and decreased muscle fiber number, type, and diameter, *pelvic floor* dysfunction—whether defined as stress UI (SUI), resting and volitional vaginal closure force, or pelvic organ prolapse—is not associated with age after controlling for obesity, parity, menopause, and hormone use.¹⁸ The *vagina* shortens by a clinically insignificant 0.08 cm per 10 years.¹⁹ Post-menopausal atrophy may cause loss of lactobacillus and colonization with pathogenic organisms (*E. coli*, enterococci), leading to higher rates of bacteriuria and symptomatic urinary tract infections (UTIs).²⁰ However, current consensus criteria for UTI are poorly sensitive and only fairly specific for UTI in frail elderly.²⁰

Age-related *prostate* epithelial hyperplasia is mediated by numerous stromal factors.²¹ It remains unclear whether prostatic inflammation (acute or chronic) contributes to urinary retention and LUT symptoms (LUTS) in frail older men.²²

Factors Outside the Lower Urinary Tract Causing or Contributing to UI

There is new confirmatory evidence that *comorbid medical illness and impairments* (e.g., dementia, falls, dizziness, decreased vision and hearing) are independently associated with UI, especially if multiple conditions exist (Table II).^{23,24} Comorbidity may affect continence through multiple mechanisms: for example, in diabetes mellitus, detrusor dysfunction (DO, cystopathy), hyperglycemia (causing osmotic diuresis and polyuria), medications, constipation, and impairment (amputation, vascular dementia).

Neurological and psychiatric disorders are highly prevalent and increase the risk of UI.²⁴ Dementia, however, is not a strong risk factor,²⁵ and other etiologies (especially impaired mobility) should be considered first. We found no new studies on UI with *normal pressure hydrocephalus*. In *Parkinson's disease*, LUTS, UI, and DO may be related more to age and comorbidity than Parkinson's-specific CNS pathophysiology.²⁶ UI increases the risk of falling in Parkinson's patients by sixfold.²⁷ *Stroke* patients with UI are less likely to regain and more likely to decline in physical function.⁵ Confirmatory studies of the association between UI and *depression* include a large US population-based cross-sectional study²⁸ and a smaller Japanese study.²⁹ Negative findings in a Korean study may reflect the definition of depression and patient selection.³⁰ A recent study³¹ contradicts earlier demonstration of no association between UI and self-reported sadness. The direction of the association between UI and depression in frail persons is unclear, as nearly all studies have been cross-sectional.

Medications with LUT effects (Table III) increase the risk of UI.³² *Functional impairment* is a common pathway by which medical and neuropsychiatric disorders can cause or contribute to UI in frail elderly. Cross-sectional²³ as well as longitudinal studies^{25,33} show that *ADL and physical performance impairment* increase UI risk. Recent international studies confirm a bi-directional association between UI and *falls*.^{34,35} We located no new studies on the known association between *environmental factors* and UI.

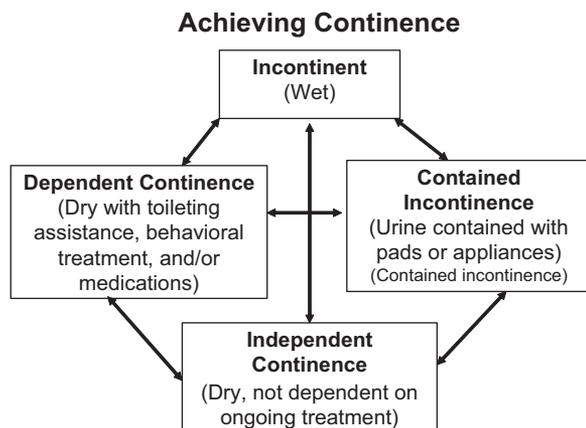


Fig. 1. A paradigm for continence (see text for explanation).

TABLE I. Age-Related Changes That Can Contribute to UI in Frail Elderly Persons

Age-related change	Potential effects on continence
Bladder ultrastructure on electron microscopy Dysjunction pattern Muscle and axon degeneration	Bladder overactivity and urgency UI Impaired bladder contractility, increased residual urine, and decreased functional bladder capacity
Bladder function Decreased capacity Increased detrusor overactivity Decreased detrusor contractility Increased residual urine	Increased likelihood of urinary symptoms and UI
Urethra Decreased closure pressure in women	Increased likelihood of stress and urgency UI
Prostate Increased incidence of benign prostatic obstruction Increased incidence of prostate cancer	Increased likelihood of urinary symptoms and UI
Decreased estrogen (women)	Increased incidence of atrophic vaginitis and related symptoms Increased incidence of recurrent urinary tract infections
Increased night-time urine production Altered central and peripheral neurotransmitter concentrations and actions Altered immune function	Increased likelihood of nocturia and night-time UI Increased likelihood of lower urinary tract dysfunction Increased likelihood of recurrent urinary tract infections

ASSESSMENT OF THE FRAIL ELDERLY WITH UI (SEE ALGORITHM)

We located *no evidence-based guidelines* for the assessment of UI in frail elderly. The United Kingdom NICE guidelines for UI in women do not address the assessment of frailer elderly women.³⁶ Basic fundamental principles of UI and the US federal quality standards for UI assessment and management in long-term care are insufficiently understood by long-term staff and NH regulators.³⁷ The US Assessing Care of Vulnerable Elders project and the UK Clinical Effectiveness and Evaluation Unit developed quality performance measures for UI care in frailer older persons, using structured literature and expert panel review.^{38,39} These measures are not guidelines per se, and in some instances lack sufficient detail. Studies using these measures demonstrate the poor quality of UI assessment and care by community practitioners in the US and UK. There remains an urgent need to re-establish the fundamentals of UI assessment and management for all personnel who care for frail older persons with UI.

Healthcare providers can *screen older patients with UI for frailty* using the Vulnerable Elders Survey, which can be administered in person or by phone (Table IV);⁴⁰ a score ≥ 3 is associated with a fourfold increased risk of death and functional decline. A systematic review based on five eligible studies found insufficient evidence of efficacy for *office-based history and physical* in women in differentiating the type of UI,⁴¹ except for one study using history and exam to diagnose SUI. We identified no new studies regarding *cough stress test*, *post-void residual volume (PVR)*, or *urodynamic testing*.

Evidence Summary

- (1) Active case finding and screening for UI should be done in all frail older persons (Level 1).
- (2) Screening for frailty is possible with short screening instruments (Level 1).
- (3) Current quality of primary care assessment of UI in frail elders is poor (Level 2).
- (4) Cough stress test has moderate accuracy in frail institutionalized women (Level 2).
- (5) There are insufficient data to determine the utility of PVR testing (Level 4).

- (6) Urodynamic testing is feasible (Level 1), but unlikely to change management or outcomes except in frail patients considering surgical treatment (Level 3).

FACTORS IN MANAGEMENT

This section, introduced in the 3rd ICI, highlights issues that distinguish UI management in this population and provides a framework for UI management in frail persons, *regardless* of the specific treatment (Fig 1).

Comorbidity is an important factor in UI management decisions, yet we found no new studies. *Remaining life expectancy* (RLE) is a key yet often misunderstood factor in treatment decisions for frail older persons. Again, we found no studies on RLE in urological or gynecological surgery, except for cancer treatment. RLE is not uniformly limited in this population; moreover, there is a demographic trend of increasing RLE, with a smaller proportion of persons spending their remaining years living with disability.⁴² RLE can be estimated using a simple graphical tool (Fig. 2). *Preferences for UI care* are important, can be elicited even from frail elderly, and differ among geriatric hospital patients, their families, and hospital staff.⁴³ Most patients preferred diapers (79%), medications (78%), and scheduled toileting (79%) over urinary catheters. Patients with greater functional dependence were more likely to prefer catheters, and those who used diapers previously were more likely to prefer medications and toileting. Patient preferences agreed with those of their spouses but not other family members.

Outcomes assessment of UI treatment in frail elderly is fundamentally different because of the heterogeneity in comorbidity, RLE, patient perceptions, and personal values, and the involvement of caretakers and proxy decision makers. The ability to define the benefit of UI treatment in frail older people is highly dependent on the individual, their caregivers, and the healthcare system. Even in cognitively impaired persons, one can elicit treatment preferences,⁴³ evaluate domains of quality of life (e.g., social interaction),⁴⁴ and assess treatment satisfaction directly or behaviorally.

In the 3rd ICI, we introduced an UI outcome paradigm for frail elderly (Fig. 1), which was subsequently generalized for all persons with UI.⁴⁵ However, there is still a critical need

TABLE II. Comorbid Conditions That Can Cause or Contribute to UI in Frail Elderly Persons

Conditions	Comments	Implications for management
Comorbid medical illnesses		
Diabetes mellitus	Poor control can cause polyuria and precipitate or exacerbate incontinence; also associated with diabetic neuropathic bladder	Better control of diabetes can reduce osmotic diuresis and associated polyuria, and improve incontinence
Degenerative joint disease	Can impair mobility and precipitate urgency UI	Optimal pharmacologic and non-pharmacologic pain management can improve mobility and toileting ability
Chronic pulmonary disease	Associated cough can worsen stress UI	Cough suppression can reduce stress incontinence and cough-induced urgency UI
Congestive heart failure	Increased night-time urine production at night	Optimizing pharmacologic management of congestive heart failure, sodium restriction, support stockings, leg elevation, and a late afternoon dose of a rapid acting diuretic may reduce nocturnal polyuria and associated nocturia and night-time UI
Lower extremity venous insufficiency	can contribute to nocturia and UI	
Sleep apnea	May increase night-time urine production by increasing production of atrial natriuretic peptide	Diagnosis and treatment of sleep apnea, usually with continuous positive airway pressure devices may improve the condition and reduce nocturnal polyuria and associated nocturia and UI
Severe constipation and fecal impaction	Associated with “double” incontinence (urine and fecal)	Appropriate use of stool softeners Adequate fluid intake and exercise Disimpaction if necessary
Neurological and psychiatric conditions		
Stroke	Can precipitate urgency UI and less often urinary retention; also impairs mobility	UI after an acute stroke often resolves with rehabilitation; persistent UI should be further evaluated Regular toileting assistance essential for those with persistent mobility impairment
Parkinson’s disease	Associated with urgency UI; also causes impaired mobility and cognition in late stages	Optimizing management may improve mobility and improve UI Regular toileting assistance essential for those with mobility and cognitive impairment in late stages
Normal pressure hydrocephalus	Presents with UI, along with gait and cognitive impairments	Patients presenting with all three symptoms should be considered for brain imaging to rule out this condition, as it may improve a ventricular-peritoneal shunt
Dementia (Alzheimer’s, multiinfarct, others)	Associated with urgency UI; impaired cognition and apraxia interferes with toileting and hygiene	Regular toileting assistance essential for those with mobility and cognitive impairment in late stages
Depression	May impair motivation to be continent; may also be a consequence of incontinence	Optimizing pharmacologic and non-pharmacologic management of depression may improve UI
Medications	See Table III	Discontinuation or modification of drug regimen
Functional impairments		
Impaired mobility	Impaired cognition and/or mobility due to a variety of conditions listed above and others can interfere with the ability to toilet independently and precipitate UI	Regular toileting assistance essential for those with severe mobility and/or cognitive impairment
Impaired cognition		
Environmental factors		
Inaccessible toilets	Frail, functionally impaired persons require accessible, safe toilet facilities, and in many cases human assistance in order to be continent	Environmental alterations may be helpful; supportive measures such as pads may be necessary if caregiver assistance is not regularly available
Unsafe toilet facilities		
Unavailable caregivers for toileting assistance		

UI, urinary incontinence.

for novel and specific outcomes for use in treatment trials and clinical care. Unfortunately, intervention studies in frail elderly continue to focus on UI frequency, and the International Continence Society standardization report on outcomes in older patients is over 10 years old. There remains only one UI-related QoL measure based on qualitative data from older persons, and all were healthy. An alternative QoL domain for frail elderly is social interaction; in NH residents prevalent and especially incident UI were associated with fewer social interactions, particularly among those with moderate ADL impairment.⁴⁴ We found no data on the value or utilities frail elderly persons or their caregivers assign to varying degrees of UI severity, with or without treatment.

UI-related costs for older persons have increased with societal aging,⁴⁶ are expected to rise exponentially,⁴⁷ and are especially high for persons with comorbidity.⁴⁸ Extrapolated

costs from NH admissions due to UI are high,⁴⁹ as are costs for NH UI care^{3,50} (estimated at \$6 billion US 2000⁵¹), largely due to high labor costs. In the community, UI costs include caregivers’ lost wages, decreased productivity (both within and outside of the home), and additional caretaking hours.⁵² There remain limited data on costs of UI treatment in other residential (e.g., assisted living and rest homes) and acute care settings.

Age- and comorbidity-related *changes in pharmacokinetics and pharmacodynamics* affect many drugs, but there remain little data concerning their impact on antimuscarinic treatment. *Polypharmacy* is the norm among frail elderly, increasing the risk of *adverse drug reactions (ADEs)* and *drug interactions*.⁵³ Cholinesterase inhibitors (CEIs) used for dementia may cause or worsen UI,^{54,55} and when combined with antimuscarinics may impair ADLs.⁵⁶

TABLE III. Medications That Can Cause or Contribute to UI in Frail Elderly Persons

Medications	Effects on continence
Alpha adrenergic agonists	Increase smooth muscle tone in urethra and prostatic capsule and may precipitate obstruction, urinary retention, and related symptoms
Alpha adrenergic antagonists	Decrease smooth muscle tone in the urethra and may precipitate stress urinary incontinence in women
Angiotensin converting enzyme inhibitors	Cause cough that can exacerbate UI
Anticholinergics	May cause impaired emptying, urinary retention, and constipation that can contribute to UI. May cause cognitive impairment and reduce effective toileting ability
Calcium channel blockers	May cause impaired emptying, urinary retention, and constipation that can contribute to UI May cause dependent edema which can contribute to nocturnal polyuria
Cholinesterase inhibitors	Increase bladder contractility and may precipitate urgency UI
Diuretics	Cause diuresis and precipitate UI
Lithium	Polyuria due to diabetes insipidus
Opioid analgesics	May cause urinary retention, constipation, confusion, and immobility, all of which can contribute to UI
Psychotropic drugs	
Sedatives	May cause confusion and impaired mobility and precipitate UI
Hypnotics	
Antipsychotics	Anticholinergic effects
Histamine ₁ receptor antagonists	Confusion
Selective serotonin re-uptake inhibitors	Increase cholinergic transmission and may lead to urinary UI
Others	
Gabapentin	Can cause edema, which can lead to nocturnal polyuria and cause nocturia and night-time UI
Glitazones	
Non-steroidal anti-inflammatory agents	

UI, urinary incontinence.

Evidence Summary

- (1) Patients and caregivers have clear preferences regarding UI management, which may be discordant (Level 2).
- (2) Age-related changes in pharmacokinetics affect antimuscarinic UI drugs and should be considered in treatment planning (Levels 1 and 2).
- (3) Drugs may be effective at lower doses in frail older persons (Level 3).
- (4) Polypharmacy increases the risk of ADEs (Level 1).
- (5) ADEs are more common in the frail elderly (Level 2).
- (6) Drug–drug and drug–disease interactions are common in frail elderly (Levels 1–3).
- (7) There are insufficient data to determine the economic burden of UI, including cost–benefit, cost–effectiveness, and cost–utility of treatment in frail elderly (Level 4).

- (2) Functional Incidental Training decreases wet checks and improves endurance in NH residents, including those with psychiatric disease (Level 1).
- (3) Efficacy of behavioral interventions decreases when implemented by indigenous NH staff (Level 1), and the associated labor costs may be difficult to offset (Level 2).
- (4) There are insufficient data to determine whether habit training or timed voiding improves UI (Level 4).

TREATMENT

Lifestyle Interventions

There continues to be no studies in frail elderly.

Behavioral Interventions

Behavioral therapies are the mainstay of UI treatment in frail elderly because of their efficacy in persons with cognitive and physical impairments.⁵⁷ However, we found no new studies on *prompted voiding, timed voiding, habit training, or operant behavioral strategies*. There is further evidence that *Functional Incidental Training*, combining prompted voiding and exercise, improves physical endurance and UI.⁵⁸

Evidence summary

- (1) Prompted voiding is effective in the short-term treatment of daytime UI in targeted NH residents and home-care clients who can state their name; transfer with the assistance of no more than one person; and have compliant

Interventions With Long-Term Care Staff and Caregivers

Nurses in acute and long-term care continue to provide urine containment rather than specific UI treatment.⁵⁹ Quality assurance and improvement programs for NH staff have been proposed,⁶⁰ but their long-term effectiveness and generalizability are unknown.

Evidence summary

- (1) Long-term care staff believe prompted voiding is helpful but fail to implement it (Level 2).
- (2) Quality assurance and improvement programs for NH staff may improve continence care (Level 2) but effectiveness beyond research trials and durability are unknown (Level 4).
- (3) Family caregivers providing behavioral therapy experience fatigue and social isolation (Level 2).
- (4) Computerized programmes to improve quality of UI management demonstrate efficacy only during research trials (Level 2).
- (5) Use of mechanical lifts during toileting may reduce staff injury and decrease NH resident agitation (Level 2).

TABLE IV. Vulnerable Elders Survey (VES-13)⁴⁰ (See Text for Scoring)

1. Age _____ (1 point for age 75-84, 3 points for age 85 or greater)
2. In general, compared to other persons your age, would you say that your health is:
 - A. Poor (1 Point)
 - B. Fair (1 Point)
 - C. Good
 - D. Very Good, or
 - E. Excellent
3. How much difficulty, on average, do you have with the following physical activities: (SCORE 1 POINT FOR EACH BOLD RESPONSE, MAXIMUM OF 2 POINTS)

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do
Stooping, crouching or kneeling					
Lifting, or carrying objects as heavy as 10 pounds					
Reaching or extending arms above shoulder level					
Writing, or handling and grasping small objects					
Walking a quarter of a mile					
Heavy housework such as scrubbing floors or washing windows					

4. Because of your health or a physical condition, do you have any difficulty: (SCORE 4 POINTS FOR ONE OR MORE YES RESPONSES IN THIS SECTION)
 - A. Shopping for personal items (like toilet items or medicine)?
 - YES>> Do you get help with shopping? YES NO
 - NO
 - DON'T DO: Is that because of your health? YES NO
 - B. Managing money (like keeping track of expenses or paying bills)?
 - YES>> Do you get help with managing money? YES NO
 - NO
 - DON'T DO: Is it because of your health? YES NO
 - C. Walking across the room? (USE OF CANE OR WALKER ALLOWED)
 - YES>> Do you get help with walking? YES NO
 - NO
 - DON'T DO: Is that because of your health? YES NO
 - D. Doing light housework (like washing dishes, straightening up, or light cleaning)?
 - YES>> Do you get help with light housework? YES NO
 - NO
 - DON'T DO>> Is that because of your health? YES NO
 - E. Bathing or showering?
 - YES>> Do you get help with bathing or showering? YES NO
 - NO
 - DON'T DO>> Is that because of your health? YES NO

(6) There are insufficient data to determine whether UI quality improvement programs in long-term care decrease costs (Level 4).

Pharmacological Treatment

Antimuscarinics are currently used in only a small proportion of frail elderly, especially in NHs.⁶¹ We summarize recent studies below.

In RCTs, *oxybutynin extended release (ER)* decreased UI in healthier older women,⁶² and a 5 mg dose did not increase delirium in NH residents.⁶³ Although published trials of

transdermal oxybutynin included very old and some frailer persons, outcomes analysis was not stratified by age or comorbidity.⁶⁴

There were no new studies of *tolterodine*, other than a case report of a cognitive ADE. There are no published data on *fesoterodine* in the frail elderly; healthy persons aged ≥65 comprise ~33% of trial subjects, but no published results stratify by age.⁶⁵ *Solifenacin* has a longer t_{max} and a higher maximum plasma concentration in healthy older subjects, but differences from younger persons were small.⁶⁶ Pooled RCT data from healthier patients aged ≥65 demonstrate efficacy, but there were no direct comparisons with

TABLE V. Pharmacokinetic Changes in Older Persons

Parameter	Age-associated changes	UI drugs potentially affected
Absorption	Minimal quantitative change despite ↓ gastric motility, yet little is known regarding effect on slow-release agents ↓ Skin thickness	Extended release preparations Transdermal preparations
Distribution	Decrease in lean body mass leads to ↓V _d /↓T _{1/2} for hydrophilic drugs and ↑V _d /↑T _{1/2} for lipophilic agents Decreased protein binding in frail patients with low albumin, leading to higher concentration of free drug	Lipophilic agents, tricyclic antidepressants Tolterodine
Hepatic metabolism	↓ Phase I reactions (oxidation/reduction) No change in Phase II reactions (glycosylation) ↓ Hepatic blood flow and ↓ hepatic mass, leading to reduced clearance for agents with first-pass metabolism Stereoselective selectivity in metabolism (hypothetical) Cytochrome P450	Tricyclic antidepressants Oxybutynin Tolterodine Solifenacin Darifenacin Enantiomers Oxybutynin Tolterodine Solifenacin Darifenacin Tolterodine
Clearance	Decrease in renal clearance	Darifenacin Tolterodine

V_d, volume of distribution; T_{1/2}, half-life.

younger persons in the same trials.⁶⁷ Treatment-emergent ADEs are higher in persons aged >80 years.⁶⁸

A RCT of *darifenacin* in persons aged ≥65 found no significant benefit for the primary end point of UI episodes, but urinary frequency and QoL significantly improved.⁶⁹ No cognitive ADEs in older persons were found in either a three-

period crossover RCT⁷⁰ or a 3-week RCT comparing titrated *darifenacin* with titrated *oxybutynin-ER* and placebo.⁷¹ However, results in the crossover trial were aggregated (patients did not serve as their own controls); in the RCT, *oxybutynin-ER* was titrated 1 week earlier than *darifenacin* and to a very high final dose (20 mg), and there were no differences between *solifenacin*, *oxybutynin*, and placebo in several cognitive domains.

Despite promotion for its safety in older persons, we found no studies of *trospium* in frail elderly, and studies in healthy older persons do not stratify results by age.⁷² RCTs of *duloxetine* have included older healthy women, but outcomes were not stratified by age. We found no new comparison trials or data for *propiverine*, *estrogen* (oral or topical), or *bethanechol chloride*.

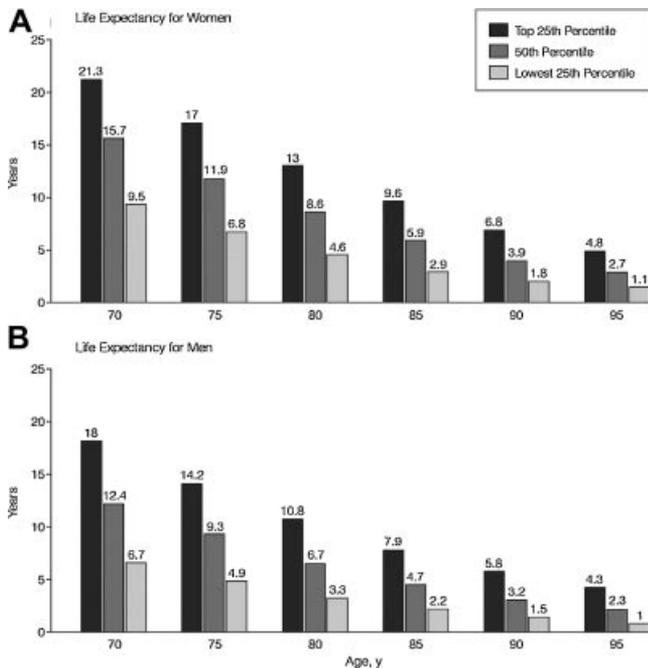


Fig. 2. Estimating remaining life expectancy (reproduced with permission from Ref. 115). The graphs represent the quartiles of remaining life expectancy by age for women (A) and men (B). The lower quintile (25%) can be thought to represent persons with extensive comorbidity and dependence, the middle two quintiles (50%) represent persons with moderate comorbidity, and the top quintile (75%) represents the healthiest group. Reproduced with permission from Walter LC, Covinsky KE. Cancer screening in elderly patients: A framework for individualized decision making. JAMA 2001; 285:2750-2756.

Evidence summary

- (1) Short-term treatment with *oxybutynin-immediate release (IR)* has small-to-moderate efficacy in reducing frequency and urgency UI when added to behavioral therapy in NH residents (Level 2).
- (2) *Oxybutynin-ER* 5 mg daily does not cause delirium in cognitively impaired NH residents (Level 1).
- (3) *Oxybutynin-IR* has been associated with cognitive adverse effects in persons with dementia and/or Parkinson’s disease (Level 3), although the incidence, prevalence, and absolute risk are unknown (Level 4).
- (4) *Oxybutynin* has been associated with tachycardia (Level 3) but neither QTc prolongation (Level 3) nor ventricular arrhythmia (Level 2).
- (5) *Oxybutynin-IR* is less effective in persons with impaired orientation, cerebral cortical under-perfusion, and reduced bladder sensation (Level 2).
- (6) There are insufficient data to determine the efficacy, tolerability, and safety of intravesical *oxybutynin*, *trospium*, *tolterodine*, *fesoterodine*, *darifenacin*, *solifenacin*, *duloxetine*, and oral and topical *estrogen* (all Level 4).
- (7) *Emepronium bromide* (Levels 2 and 3), *propantheline* (Level 2), *imipramine* (Level 2), and *flavoxate* (Level 3) are not efficacious.

Surgical Treatment

Very little remains known about surgical treatment of UI in the frail elderly, likely reflecting a bias toward conservative therapy for patients with comorbidity and functional impairments. Although the number of ambulatory UI and prolapse surgeries in women increased in the US, the proportion in women aged ≥ 80 remained the same.^{77,78} The American Geriatric Society's *New Frontiers in Geriatrics Research: An Agenda for Surgical and Related Medical Specialties*⁷³ reviews surgical UI, treatment⁷⁴ gynecological surgery,⁷⁵ and general care of the older surgical patient.⁷⁶ Their conclusions include:

- Morbidity and mortality of UI surgery are similar to major non-cardiac surgical procedures.⁷⁴
- Mortality is associated with cardiac and cancer comorbidity, but inconsistently with age, possibly because many studies do not control for comorbidity.^{74,75}
- Pre-operative estrogen does not improve wound healing.⁷⁶
- Patient-controlled analgesia provides adequate pain control and sedation and increased patient satisfaction compared with standard fixed-dose and time-administered medications, and specific anesthetics agent may affect post-operative cognition and urinary retention.⁷⁶
- Bulking agents in women are effective, with age unrelated to outcomes.⁷⁴

In a single-center case series in older, non-frail, tension-free vaginal tape (TVT) improved QoL, patient satisfaction, and urinary problems at 6 months versus a wait-list control; complications included bladder perforation requiring catheterization (22.6%), retention (12.9%), but rare UTI and de novo urgency (<5%).⁷⁹ In a similar study of the suprapubic arch procedure, at a mean of 36 months, 91% had urodynamic and 95% subjective cure, with no reported severe intra- or post-operative complications or de novo urgency.⁸⁰

We found no new data on UI surgery in frail older men. Methylnaltrexone is emerging as a possible treatment for opioid-related post-operative urinary retention.⁸¹

Evidence summary

- (1) There are insufficient data regarding efficacy of gynecological surgery in institutionalized elderly women (Level 4).
- (2) Exogenous administration of estrogen is ineffective in promoting wound healing after gynecological surgery in older women (Level 3).
- (3) Injection of bulking agents is effective in older women, and age does not correlate with outcomes (Level 3).
- (4) There are insufficient data regarding functional and QoL outcomes after UI surgery (Level 4).
- (5) Morbidity and mortality risks of UI surgeries are similar to that of other major non-cardiac procedures (Level 2).
- (6) There are inconsistent data whether operative mortality increases with age (Levels 2 and 3).
- (7) Patient-controlled analgesia provides adequate pain control and sedation and increased patient satisfaction compared with standard fixed-dose and time-administered medications in cognitively intact patients (Level 2).
- (8) Choice of agent for patient-controlled analgesia may affect post-operative cognition (Level 3).
- (9) Minimally invasive surgical approaches may be effective (Level 3), yet there are insufficient data regarding the generalizability of these results and appropriateness of surgery versus other management (Level 4).

URINARY RETENTION IN THE FRAIL ELDERLY

Retention, either acute (AUR) or chronic (UR), is a potential problem in frail elderly due to detrusor underactivity, outlet obstruction, comorbidity, and medications.¹² However, there remains no consensus on the definition of UR or "elevated PVR." Median and mean PVR in healthy older women are <35 ml.^{11,82,83} Risk factors include hospitalization, male gender, poor mobility, neurologic disease, dementia, UI, prostate disease, LUTS, recent UTI, and medications.^{12,84,85} AUR risk increases among men from age 75 to 100⁸⁶ and is associated with persistent UI⁸⁴ and 1-year mortality⁸⁷ although inconsistently with UTI.^{84,88} In randomized trials, short-term indwelling and intermittent catheterization effectively restore normal voiding.^{12,89}

Evidence Summary

- (1) There is no consensus for a standardized definition of UR in frail older persons (Level 4).
- (2) UR is common in hospitalized frail elders and long-term care residents (Level 2), but not in healthy, asymptomatic older persons (Level 2).
- (3) Risk factors for UR in frail elders include male sex, impaired mobility, cognitive impairment, neurologic disorders, prior UI and LUTS, history of prostate disease, prior UR or AUR, fecal impaction, anticholinergic medications, and hip fracture and orthopedic surgery (Level 2).
- (4) UR is associated with increased morbidity (including delirium) and mortality (Level 2).
- (5) There are insufficient data on the risk of UTI with UR (Level 4).
- (6) UR can be effectively treated with either indwelling or intermittent catheterization (Level 2).

NOCTURIA

Nocturia is defined as waking at night from sleep one or more times to void, with each void being preceded and followed by sleep.⁹⁰ Patients are more likely to consult a provider if they have three or more episodes.⁹¹ Because data on assessment and treatment in frail elderly are limited, recommendations reflect expert opinion.⁹²

Prevalence and Impact

Approximately half of men aged 70–79 report nocturia of ≥ 2 episodes.⁹³ Nocturia makes patients "feel old" and worry about falling at night.⁹⁴

Pathophysiology

The association with hypertension, diabetes, and depression is variable.^{95,96} New studies show an association with nocturnal polyuria (night-time output of at least 50% of 24 hr total urine volume)⁹⁷ and sleep disordered breathing and obstructive sleep apnea (OSA).^{98,99} Whether nocturia from OSA is due to increased atrial natriuretic peptide,⁹⁸ mechanical forces on the bladder generated during apnea events,⁹⁹ or other mechanism(s) is unknown.

Assessment

The approach is similar to that for UI, plus: in all patients, bladder diary (frequency–volume chart); questioning patient and bed partner about OSA symptoms (poor sleep quality,

daytime sleepiness, snoring, nocturnal leg movements); and evaluation for volume overload (e.g., lower extremity venous insufficiency, heart failure).

Treatment

Management should depend on the likely underlying cause(s), using patient-based outcomes (satisfaction, bother, and quality of life (e.g., ICIQ-NQOL¹⁰⁰)). An uncontrolled clinical trial demonstrated that *OSA treatment* with continuous positive airway pressure decreases nocturia,¹⁰¹ but there are no data in frail elderly. Uncontrolled data support *combination therapy* with behavioral strategies, treatment of medical and sleep disorders, and medications.¹⁰² *Antimuscarinics* (oxybutynin-IR,¹⁰³ solifenacin,⁶⁷ tolterodine¹⁰⁴) decrease nocturia related to overactive bladder (OAB) or urgency UI, yet net benefit over placebo is small (0–0.3 episodes), and a secondary analysis of a RCT found *behavioral therapy* decreased nocturia more than antimuscarinic or placebo in women with urgency-predominant UI.¹⁰³ *5-Alpha reductase inhibitors* and *melatonin* had no clinically significant effects on nocturia episodes,^{105,106} yet melatonin reduced nocturia-related bother.¹⁰⁶ Although low, individually titrated doses of *desmopressin (DDAVP)* (0.1–0.2 mg) reduce nocturia in older persons,¹⁰⁷ DDAVP has a prolonged half-life in older persons¹⁰⁸ and can cause significant hyponatremia,^{109,110} especially in the frail.¹⁰⁷ There are no new studies on *alpha-adrenergic blockers* or *estrogen*.

Evidence Summary

- (1) Late afternoon administration of a loop diuretic may reduce nocturia in persons with lower extremity venous insufficiency or congestive heart failure unresponsive to other interventions (Level 2).
- (2) If OAB or urgency UI is the likely major cause, antimuscarinic agents should be considered (Level 3).
- (3) If nocturia is due to insomnia alone, then a very-short acting sedative hypnotic may be considered (Level 3).
- (4) DDAVP should not be used in frail elderly because of the risk of hyponatremia (Level 1).
- (5) Behavioral therapy may be effective (Level 2).
- (6) 5-Alpha reductase inhibitors provide minimal to no reduction in nocturia (Level 1).
- (7) Melatonin does not decrease nocturia episodes in men (Level 1).

MODELS OF UI CARE FOR FRAIL ELDERLY

We located no new data on *home care, interventions with caregivers, continence nurse advisors, advance practice nurse–physician collaborative practice, assisted living programmes, or academic nurse specialty practice* models of continence care for frail elderly. The US revised its *federal guidance for UI and catheter care in long term care* in 2005,¹¹¹ shifting emphasis from care plan documentation to assessment, but neither state NH regulators nor NH staff understand this shift in emphasis, and discordance in their knowledge of UI management and the guidance revision³⁷ mitigates against improving care quality.¹¹² *NH quality assurance programmes* have been proposed.

RECOMMENDATIONS FOR MANAGEMENT

- (1) Basic Assessment (See Algorithm)
 - (a) Screening for frailty is possible (Grade A) and encouraged (Grade C).

- (b) The basic assessment of UI should focus on potentially treatable conditions and factors that may cause or worsen UI, contribute to its burden, and impact management decisions (Grades A–C).
- (2) Management principles.
 - (a) Individualized management plans (Grade B).
 - (b) Inclusion of the following:
 - (i) Most likely type of UI (Grade C).
 - (ii) Patient and caregiver preferences for care (Grade B).
 - (iii) Patient-centered care goals of care (Grade C).
 - (iv) The likelihood that the treatment will achieve the patient's/carer's goals within the patient's expected RLE.
 - (v) Understanding the potential direct and indirect costs and benefits of treatment for the individual, their caregiver(s), and health systems (Grade C).
 - (vi) Gender differences.
 - (a) Less comorbidity and functional impairment in men (Grade C).
 - (b) Men more likely to have living spouses (caregivers) (Grade C).
 - (c) Stronger relationship between UI and cognition in women (Grade C).
 - (d) Possibility of benign and/or malignant prostate disease in men (Grade C).
 - (c) Inclusion of the following in planning and choosing drug therapy:
 - (i) Age-related changes in pharmacology (Grade B).
 - (ii) Pre-existent polypharmacy (Grade B).
 - (iii) Drug–drug interactions (Grade A).
 - (iv) Drug–disease interactions (Grade B).
 - (d) No recommendation is possible regarding gender differences in the risk of urinary retention with antimuscarinics, or the cost–benefit, cost–effectiveness, or cost–utility of specific interventions for retention (Grade D).
- (3) Lifestyle interventions
 - (a) Fluid restriction should be avoided in long-term care residents and other frail elders (e.g., persons with dementia) who may not have ready access to fluids or accurately sense thirst (Grade C).
 - (b) No recommendation is possible regarding other lifestyle interventions (Grade D).
- (4) Behavioral therapy
 - (a) Prompted voiding should be offered to NH residents and homebound frail elders who have <4 daytime UI episodes, are able to state their name or point to one of two named objects, and transfer with the assist of at most one person (Grade A).
 - (b) Prompted voiding should be continued after a 3-day trial only if the patient demonstrates at least 20% reduction in UI (wet-checks) or toilets appropriately at least two-thirds of the time (Grade A).
 - (c) Caregivers require support to maximize and maintain compliance with prompted voiding (Grade B).
 - (d) Combined toileting and exercise programs should be considered for inactive frail elderly if there are resources to conduct and continue the intervention (Grade A).
 - (e) No recommendation is possible regarding behavioral treatment for nocturnal UI (Grade D), habit training (Grade D), and timed voiding (Grade D).
- (5) Pharmacological therapy
 - (a) Antimuscarinics should be considered for frail persons who have OAB symptoms, urgency UI, or mixed UI, and

TABLE VI. Challenges of and Recommendations for Research Studies on UI in Frail Older Persons

Challenges	Recommendations
Incomplete standard criteria of “frailty” for research	Provide specific definition of frailty Explicitly define variables in the domains of mobility, cognition, and nutrition
Incomplete understanding of natural history of UI	Include control/placebo arms that consider time effects and measurement of primary and secondary outcomes of interest
Multifactorial nature of incontinence	Collect and describe measures to assess and address relevant comorbidity, e.g. Medication changes Interval illnesses Interval bacteriuria Care setting Interventions affecting domains of continence (e.g., exercise programs)
Complexity and expense of enrolment	Multistage selection process Exclude robust/healthy Identify the frail Identify subset according to specific domain of frailty (e.g., need for toileting assistance) Prepare to contact family members or other proxy decision makers for consent ^{11,3}
High trial attrition rates	Plan for intention-to-treat analysis with explicit plans for dealing with drop-outs/deaths in the analysis Improve intervention adherence by Designing interventions feasible by most, and incorporating caregivers/care setting in that consideration Allowing flexible time frame for follow-up assessments Prioritizing safety Providing transportation Preplanning alternatives to clinic-based follow-up (e.g., home visit, telephone) Establishing good relationship and incentives to participate for family, caregivers, and/or care setting Understanding priority rank and definition of important potential outcomes to patients, caregivers, and care settings Anticipated attrition rates should not preclude attempts at long-term follow-up
Exclusions that decrease generalizability	Principle exclusion should be factors that prevent participation Avoid exclusions for comorbidity Exclude only those persons whose cognition is not compatible with the <i>specific</i> intervention Use explicit procedures for consenting participants; involve a surrogate/proxy when needed. Include discussion of ethical concerns and how they were addressed in report
Problems using self-report to assess outcomes	Supplement <i>self-report</i> to primary outcomes with “hard” measures, e.g., assist with toileting Collect “ <i>objective</i> ” measures of function and proxy information in parallel, e.g., percent of wet checks, hours of caregiver time Set outcomes to be less sensitive to random fluctuations (e.g., end point of “50% decrease in UI”) Use outcome measures specific to the target population: e.g., for quality of life, use established measures of social interaction ¹⁴ rather than existing UI-specific scales; re-validate existing UI-specific scales; for community-dwelling persons, transfer to setting with higher level of care (e.g., from home to residential/institutional care) Include measures related to caregiver time commitment, burden, costs, morbidity, quality of life, and satisfaction with intervention (regarding the patient and themselves) Assess possible caregiver(s) preference(s) for care
Mechanism by which intervention changes continence status is unclear	Use as secondary outcomes or covariates any physiological, functional, and care measures that are in the theoretical pathway between the interventions target and need for continence care: e.g., improvement in mobility; changes in functional MRI or SPECT; change in nursing home staffing Evaluate multicomponent interventions
Improvements in continence status may not translate into well-being or better quality of life	Develop and use standardized measures of adverse effects particular to/of special importance for frail persons: e.g., assessment of cognitive and behavioral effects of drug therapy in persons with cognitive impairment (ranging from mild to end-stage dementia); visual changes; bowel frequency; falls Use secondary outcome measures that assess perceived well-being and factors (such as somatic symptoms, social interaction, activities of daily living) that are important for frail older persons and their caretakers Include assessment not just of intervention effectiveness but also its efficacy, durability, and applicability Emphasize patient- and caregiver-centered outcome measures; minimize use of/dependence on provider/researcher-based outcomes assessment
Translating research into clinical practice	Consider development of clinical global impression scales (i.e., as used in dementia and depression studies) Imbed qualitative research into quantitative trials in order to determine potential barriers to implementation Conduct feasibility studies of evidence-based interventions within non-research settings, preferably using pre-existing services (e.g., care home staff, primary care providers) rather than research staff

who have been assessed for contributing comorbid factors, *and* who are appropriate for and have had a trial of behavioral treatment (Grade C).

- (b) Antimuscarinic selection should be based on
- (i) Age-related changes in pharmacokinetics that could affect metabolism and clearance (Grade C).
 - (ii) Likelihood of worsening ADEs the patient already experiences (e.g., such as pre-existing constipation) (Grade C).

- (iii) Drug–drug and drug–disease interactions (Grade C).
- (c) Start drugs at the lowest possible dosage (Grade C).
- (d) Proactively monitor and re-evaluate explicit efficacy goals, ADEs, and appropriateness of continued therapy (Grade C).
- (e) Oxybutynin-IR may be effective for OAB, urgency UI, and mixed UI in frail elders in whom behavioral therapy is feasible, but monitoring for ADEs is needed (Grade C).

- (f) Topical estrogens (cream, tablet, ring) may be considered for adjunctive treatment of symptomatic urogenital atrophy (Grade B).
 - (g) No specific recommendation is possible regarding: oral or topical estrogen, tolterodine, topical or ER oxybutynin, darifenacin, solifenacin, trospium, fesoterodine, bethanechol, duloxetine, propiverine, and flurbiprofen (all Grade D).
 - (h) The following agents should not be used: emepromium bromide (Grade B), propantheline (Grade B), imipramine (Grade B), flavoxate (Grade B), procaine hematorporphyrin (Grade C).
 - (i) Combinations of bladder antimuscarinics should not be used (Grade C).
- (6) Surgical therapy
- (a) Age alone is not a contraindication to surgical treatment (Grade C).
 - (b) Urodynamic evaluation should be done before considering anti-UI surgery (Grade B).
 - (c) Pre-operative risk should be stratified using established indexes (Grade A).
 - (d) Insure adequate post-operative nutrition especially in patients who cannot take oral feeding or who become delirious (Grade C).
 - (e) Employ evidence-based programs to prevent post-operative delirium (Grade A) and proactively use established delirium diagnosis tools (Grade A).
 - (f) For cognitively impaired persons, assess pain using measures designed specifically for frail elders, not general pain scoring tools (Grade B).
 - (g) Use proactive preventative approaches to hospitalization-related functional impairment (Grade A).
 - (h) Specialized hospital care units may improve selective outcomes for frail older patients (Grade A).
 - (i) Begin discharge planning before surgery (Grade C).
 - (j) Patient controlled analgesia may be used in cognitively intact frail older persons (Grade B).
 - (k) Avoid analgesic agents associated with delirium (e.g., meperidine) (Grade B).
- (7) Nocturia
- (a) Diagnostic assessment should focus on identifying potential underlying cause(s), including nocturnal polyuria, primary sleep disorder, OAB/urgency UI, or combinations (Grade C).
 - (b) Focus treatment on likely underlying cause(s):
 - (i) For OAB/urgency UI, antimuscarinics and/or behavioral therapy emphasizing pelvic floor muscle exercises and urge suppression strategies (both Grade C).
 - (ii) For comorbidity, targeted treatment for peripheral edema (and its potential medical and drug etiologies), congestive heart failure, and/or type and timing of fluids (Grade C).
 - (iii) For nocturnal polyuria unresponsive to treatment of contributing factors or of uncertain cause, afternoon dose of rapidly acting diuretic, with careful monitoring of efficacy, volume status, electrolytes, and renal function (Grade C).
 - (iv) For primary sleep disorders, appropriate targeted treatment (e.g., positive airway pressure for apnea [Grade B]), with assessment of the impact on nocturia (Grade C).
 - (v) For patients without cognitive impairment and nocturia inadequately responsive to the above approaches who remain most bothered by inability

to achieve sleep after an episode of nocturia, low dose of short-acting hypnotic (Grade C).

- (c) DDAVP should not be used because of the risk of hyponatremia (Grade A).
- (8) Interventions with long-term care staff
- (a) Implement long-term care staff development programs to increase knowledge and skills about continence care and the efficacy of behavioral methods (Grade C).
 - (b) Consider computerized databases may help caregivers determine the effectiveness of UI programs (Grade C).
 - (c) Monitor and provide resources to counteract fatigue, social isolation, and other burdens related to continence care among family caregivers (Grade C).
 - (d) Consider mechanical lifts to reduce staff injury and increase adherence to toileting programs (Grade C).

RECOMMENDATIONS FOR RESEARCH

- (1) Etiology
 - (a) Racial and ethnic differences in LUT- and comorbidity-related causes of UI.
 - (b) Etiological models and translational research in the causes of UI in frailer older persons, incorporating principles of concentric, interacting, multiple risk factors models of geriatric syndromes.
 - (c) Relationship of models of frailty and vulnerability with UI.
 - (d) Relative roles of LUT disorders, comorbidity, hormonal factors, sleep disorders, and other conditions in the pathophysiology of nocturia in frail older persons.
 - (e) Longitudinal studies incorporating basic science and clinical measures.
- (2) Evaluation
 - (a) Efficacy and effectiveness of current evaluation guidelines and recommendations across settings (home, clinic, assisted living, long-term care).
 - (b) Development and validation of consensus standards for the definition of elevated PVR and UR in men and women, in both clinical and research settings.
 - (c) Development and validation of consensus standards for evaluation of nocturia in frail older persons.
- (3) Treatment
 - (a) Proactive incorporation of frailer, older-old persons in all UI intervention trials.
 - (b) New outcome measures relevant to geriatric care, including quality of life, socialization, institutionalization, comorbidity, caregiver burden, and alternatives to wet-checks for long-term care residents.
 - (c) Outcome measures sensitive to differences across cultures and healthcare systems, for example, reimbursement for continence services and supplies.
 - (d) Association between expectations, preferences, and outcomes.
 - (e) New approaches and tools to assess UI-specific QoL in cognitively impaired elderly.
 - (f) Evaluation of the interaction between functional impairment and UI impact.
 - (g) Determination of the utilities frail elderly and caregivers assign to varying degrees of UI (with or without treatment) versus “dryness”.
 - (h) Evaluation of multicomponent interventions.
 - (i) Development and validation of predictive models for guiding treatment decisions.
 - (j) Caregiver characteristics associated with, and optimum interventions to improve, effective behavioral treatment in the home.

- (k) Racial-ethnic differences in UI treatment efficacy, tolerability, and safety across care settings (home, assisted living, long-term care, hospital).
- (l) Racial-ethnic disparities in UI treatment across care settings.
- (m) Efficacy and effectiveness of policy and regulatory approaches to improve the quality of UI management in long-term care.
- (n) Efficacy and tolerability of antimuscarinics in older-old and frail persons across care settings:
 - (i) Include adequate numbers of patients (including persons with cognitive and/or functional impairment, and common comorbid conditions); use outcome measures specific for frail elderly, including caregivers impact; stratify outcomes by age, comorbidity, function, and frailty; specify diagnostic methods; and use clinically relevant durations of treatment.
 - (ii) Determine the characteristics of frail older persons responsive to drug therapy.
 - (iii) Incidence, prevalence, and risk factors for adverse cognitive and functional effects, and optimum research and clinical measures to detect them.
 - (iv) Cost-benefit, cost-effectiveness, and cost-utility studies of UI treatments, using models incorporating patient and caregiver preferences, variable definitions of benefit for this population, and a comprehensive approach to costs across a range of care settings.
- (o) Inclusion of older-old and frailer patients in surgical studies, with stratification of outcomes by age, comorbidity, estrogen status (women), and urodynamic findings.
- (p) Prospective evaluation of the magnitude and severity of common geriatric complications following anti-UI surgery.
- (q) Develop and validate guidelines for identifying frail elders who could benefit from anti-UI surgery.
- (r) Efficacy and effectiveness of specific devices and procedures to prevent complications from long-term indwelling catheters.
- (4) Efficacy and effectiveness of multicomponent treatment for nocturia, including interventions targeted at comorbidity and drug therapy.
- (5) Comparative efficacy of specific models of UI care for frail elderly around the world, including healthcare system-level correlates of efficacy.

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