Outcome Measures for Research of Lower Urinary Tract Dysfunction in Frail Older People

D. Fonda,* N.M. Resnick, J. Colling, K. Burgio, J.G. Ouslander, C. Norton, P. Ekelund, E. Versi, and A. Mattiasson

INTRODUCTION

The aim of this paper is primarily to provide a framework for investigators conducting research on incontinence in frail older people. Since it is difficult to precisely define "frailty," the definition used in this paper is "any person over age 65 years with incontinence of urine who does not leave their place of residence without assistance of others, or a person with dementia, or a person who has been admitted to a long-term care facility." These people usually suffer from multiple medical conditions and disabilities (comorbidity), which results in them becoming homebound or institutionalized. Because they require the assistance of others to perform some or all of the most basic activities of daily living (ADLs), including bathing, dressing, toileting, and ambulating, results from younger populations or from older people without disabilities cannot necessarily be extrapolated to this population. For this population there is little validated research showing long-term efficacy of treatment for urinary incontinence.

If incontinence develops in healthy older people, its management is generally similar to the approach taken in younger individuals, except that greater caution should be taken when pharmacological intervention is being considered because of the susceptibility of older people to adverse drug reactions. This paper therefore does not focus on the fit older person, and in the absence of data to the contrary, the same outcome measures should be used as for adults of the same sex [Mattiasson et al., 1998]. This paper deals with lower urinary tract dysfunction with a major emphasis on incontinence. Nocturia is a significant problem for older people, and the principles alluded to in this paper cover this area.

Because of the frailty of this population, all patients being considered for entry into a research protocol should be assessed for coexisting reversible or modifiable

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^{*}Correspondence to: D. Fonda, Head of Aged Care Services, Caulfield General Medical Centre, 260 Kooyong Road, Caulfield 3162, Australia.

(comorbid) factors such as fecal impaction, confusional states, functional disabilities, or use of medication which may be contributing to incontinence or might affect the outcome of the study. No patient should receive another intervention until such transient causes have been addressed. The extent of invasive testing should balance study requirements with the benefits, risks, and inconvenience to the patient.

Research in this population is difficult because of:

The heterogeneity of this population, resulting in difficulty in designing studies that account for comorbidity, drug use, intercurrent illness, and shorter life expectancy

Lack of standardized terminology to define and measure cure and improvement

Lack of validated research tools to measure baseline and outcome variables in the frail elderly

Lack of long-term follow-up to gauge impact, durability, and applicability of the intervention

Lack of information of the natural history of incontinence in this group.

CONSIDERATIONS IN STUDY DESIGN

General principles in designing a study on lower urinary tract dysfunction have been published elsewhere and apply equally in this group [Mattiasson et al., 1998]. Below are listed some additional considerations for research in incontinence involving the frail elderly.

Baseline Clinical Data

The following baseline clinical data should be considered when designing a study in the frail older population. Relevant information should be included in the final report of the study's findings.

Descriptive data

Type of setting of the study, e.g., home, nursing home
Patient-staff ratio (where staff are involved in the management protocol)
Usual continence care
Direct and indirect costs of current care
Patient, family, and/or staff expectations
Age and gender
Description of care givers (e.g., training, qualifications)
System incentives or disincentives that may influence management options (e.g., government funding).
Symptoms and investigations
Type of symptoms
Duration of symptoms
Response to prior treatment (e.g., pharmacological, surgical, behavioral)
Midstream urine for culture and sensitivities
Postvoid residual urine estimation.

Associated factors

- Environmental factors that might contribute to incontinence (e.g., distance to toilet, use of continence aids or appliances)
- Associated comorbid conditions that might be contributing to incontinence or the effectiveness of intervention

Bowel status (e.g., constipation, incontinence)

- Functional level of the patients (by use of a standardized scale such as Barthel or Katz ADL scales [Katz et al., 1963, Mahoney et al., 1965])
- Cognitive state/function of the patients (by use of a standardized scale such as the Mini-mental Scale Examination [Folstein et al., 1979])
- Concurrent medications that could contribute to incontinence or affect outcome of treatment (e.g., sedatives, diuretics, alcohol)

Fluid intake.

Description of Study Design

Details of study design should be provided, including methodology, recruitment, inclusion and exclusion criteria, interventions, outcome measures to be used, and statistical methods. Further information has been provided on guidelines for study design by the ICS [Mattiasson et al., 1998].

Outcome Data

To determine the effect of an intervention, accurate, valid, and meaningful outcome variables are needed. It is most important to define the major endpoints prior to commencing studies. Baseline diagnostic data should be gathered in order to characterize the patient's condition and to document the severity of incontinence (see Outcome Measurements, below). The selection of an outcome variable depends on the nature of the intervention being studied, e.g., pharmacological, surgical, or behavioral. Successful short-term interventions should, wherever possible, have long-term follow-up provided (at least 12 months) in order to gauge more accurately their impact, durability, and relevance in this frail population.

There are age-specific influences on lower urinary tract function, and normative data are generally lacking in this frail population. In addition, test-retest reliability and sensitivity to change of the more invasive measures of lower urinary tract function are poorly documented in the frail elderly. It is, therefore, the belief of the committee that it is not appropriate to repeat invasive measures at follow-up in this frail population unless these measures are fundamental in understanding components of the intervention being studied.

The following information, which could impact on outcome, should wherever possible be addressed and reported at time of follow-up:

Number and reason for dropouts and deaths (i.e., were they trial-related?)

Compliance issues (by patients, staff, or caregivers), such as compliance to exercise programs, toileting protocols, or drug use

Type of bladder training or toileting programs (if any)

Other intercurrent treatment not directly related to bladder function that might impact on outcome Medication which might impact on incontinence/continence Socioeconomic data, including impact of the intervention on the patient Changes in caregiver or staff status or numbers Cost of treatment Cost-benefit data Patient and/or caregiver satisfaction with the intervention Risk-benefit data

Recommendations/Comments

Because comorbidity and drug use contribute to the presence and severity of continence in this population, they should be addressed and/or stabilized before patients are enrolled. In any research project, it is essential to clearly determine endpoints at the outset.

OUTCOME MEASUREMENTS

In this section, the key outcome areas are identified and recommendations are made which may be of use to researchers. In keeping with the format of the ICS Outcomes Standards Reports, outcome measurements for frail elderly people are covered under the following five headings: patient observations and symptoms; documentation of the symptoms; anatomical and functional measures; quality-of-life measures; and socioeconomic measures.

Measurement of Patient Observations and Symptoms

History alone is insufficient in diagnosing the etiology of bladder dysfunction. In the frail older person this is compounded by the age-associated decline in cognitive function and increase in depression. Caregivers may be able to provide important supplementary or supportive information. One study has recently validated a nonurodynamic-based diagnostic algorithm [Resnick et al., 1996].

Recommendations/Comments

Research in this group should not be based solely on patients' subjective reporting of symptoms. Patient-derived symptoms response as an outcome measure should be supplemented where necessary by data derived from caregivers.

Documentation of Urine Loss

Bladder diaries. Bladder diaries are simple and noninvasive and have the potential to be reliable and sensitive to therapeutic intervention, especially when completed by competent staff. However, accuracy of self-report data is always a matter of concern, and interpretation of what constitutes clinical vs. statistical significance is difficult. Bladder diaries have not been validated when completed by the frail housebound or institutionalized elderly, although they may prove accurate for the cognitively intact and motivated frail older person. Bladder diaries completed by

others such as caregivers or staff (wet checks), or pad weighing, are alternatives (see below).

Recommendations/Comments

Bladder diaries should be a useful outcome measure for hospitalized or institutionalized older people. The usefulness of bladder diaries as an outcome measure when completed by the frail elderly or their "untrained" carers has not yet been validated.

Pad-weighing tests. Difficulties with determining wetness can be overcome by weighing pads before and after specified time intervals. To standardize the pad tests, the ICS introduced the 1-hr pad-weighing test, which measures urine loss as weight gain of perineal pads under standardized conditions [Abrams et al., 1988]. Only one relevant study of the 1-hr pad-weighing test in frail elderly could be identified. The 24-hr inpatient measurement of urine leakage of frail elderly patients by staff was more feasible and sensitive than the 1-hr pad test; reducibility was not directly assessed [Griffiths et al., 1991]. The 48-hr home pad test with patients weighing their own pads has been shown to be reliable for quantifying urine loss in cognitively intact and reasonably independent (but not "frail") elderly incontinent women; reproducibility was not assessed [Ekelund et al., 1988].

The principal advantages in performing pad tests at home are simplicity, costeffectiveness (as hospital personnel are not required), and the relaxed environment, which reproduces more accurately the conditions leading to incontinence when compared with the relatively unfamiliar hospital or clinic setting. It is important to provide the patient with careful written and oral instructions before attempting the test. Certain forms of handicap, such as dementia, reduced mobility, physical handicap, fecal incontinence, or defective vision, pose problems which could in some cases be compensated for by involving a caregiver in the test procedure. It should be noted that some pads leak, further reducing reliability and accuracy of this test.

Recommendations/Comments

Pad-weighing offers the potential for quantifying the degree of incontinence in older patients and can be useful in the hospital setting. Further data are still required to establish its usefulness in the frail elderly, especially in those confined to home.

Wet checks. Wet checks consist of examining the patient at regular intervals for leakage. Such checks are a commonly used measure of incontinence in nursing home residents. At least 10 clinical studies of frail incontinent elderly have been published using wet checks as an outcome measure. The exact method of determining wet or dry status is not well-described in any of the studies, while the frequency of checks varied from 1–4 hourly. Nonetheless, despite these limitations, wet checks appear to be a reliable means of documenting incontinence [Hu et al., 1989; Colling et al., 1992, 1995]. However, it should be noted that in one study, when an electronic monitor was used to document incontinence, there was considerable disagreement noted with caregivers underreporting wet episodes [Colling et al., 1995]. The Incontinence Monitoring Record (which is a record of whether the patient is wet on regular checking), particularly the colored form, has been shown in one study to be a reliable documentation tool when completed by nurses' aides [Ouslander et al., 1986].

Although these instruments are practical, understandable, and commonly used outcome measures, the following should be considered:

- It is difficult to get ward staff to reliably check and record wetness. Hence for research purposes, dedicated research staff may be needed to record these data.
- It is sometimes difficult to correctly identify wet absorbent products now, because many of them have materials which "wick" away the moisture, making it impossible to see and even difficult to feel moisture.
- Many institutes now require the use of universal precautions in handling of body fluids, which would include performing wet checks. If litmus paper is used to identify moisture, a false negative can result unless it is placed where it is likely to pick up the urine. Conversely, a false positive can occur when moisture from the skin shows up on litmus paper.
- Wet checks are intrusive and invasive to patients, and in some cases may actually stimulate patients to void.
- Absolute pad counts are not a reliable outcome measure, as it is most difficult to impose consistent criteria for changing of pads.
- While the electronic monitor shows promise of increasing the accuracy of identifying wet episodes, its use has not yet been well-studied in the frail elderly and it is not yet available commercially.

Recommendations/Comments

The wet-check method of assessing incontinence appears to be both a practical and reliable tool to assess outcome in dependent older patients, provided attention is given to the above considerations. Compliance of staff necessitates education and close supervision. The more frequent the "checking," e.g., hourly, the more likely the data will be reliable for the actual number of wet episodes.

Anatomical and Functional Measurements

"Simple" cystometry. Simple cystometry is a relatively inexpensive form of single-channel water cystometry, which can be performed without specialized equipment in an outpatient clinic, acute hospital, nursing home, or home setting. It is not so feasible and accurate in the severely cognitively impaired. The procedure is generally well-tolerated and adds little time to that needed for a postvoid residual determination by catheterization. While studies have shown comparability of results from simple and multichannel cystometry in an outpatient setting, this has not been demonstrated in institutional settings [Ouslander et al., 1988; Fonda et al., 1993]. The major disadvantage is the lack of an abdominal pressure measurement. Adequate data on the test-retest reliability of simple cystometry as an outcome measurement, nor in predicting responsiveness to various interventions or in elucidating the mechanism of action of interventions for geriatric incontinence.

Recommendations/Comments

Simple cystometry has not been validated as an outcome measure for research in frail patients.

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Multichannel urodynamics. The few available studies indicate that, when carefully performed, multichannel urodynamic testing of the frail elderly is feasible and safe, and reproducibly yields the same diagnosis. Fluoroscopic monitoring appears to increase its accuracy by facilitating detection of the low-pressure involuntary contractions that are more common in the frail elderly. However, compared with urodynamic evaluation of more robust individuals, testing in this population is technically more difficult to conduct, is less available, requires additional personnel, and is probably more susceptible to artifact. Furthermore, normative data are lacking for this population.

Few investigators have employed multichannel urodynamics as an outcome measure in the frail elderly. Cystometric capacity and reduced bladder sensation (both measured after therapy) have been shown to correlate with response to oxybutynin treatment [Griffiths et al., 1996]. In a small study, response to prostatectomy correlated with the severity of obstruction on initial pressure/flow testing, despite persistence of unstable contractions in all patients but one [Gormley et al., 1993].

Recommendations/Comments

Complex urodynamic testing has not been evaluated sufficiently to determine its utility as an outcome measure in the frail elderly.

Pelvic muscle strength. Pelvic muscle exercises may be of value in management of incontinence, either by increasing pelvic muscle strength or as a form of biofeedback. The force of voluntary pelvic muscle contraction can be determined directly (digitally or by air pressure) or indirectly (surface electromyography). For the frail elderly there are no validated data on the measurement of pelvic muscle strength as an outcome measure following teaching of pelvic floor exercises.

Recommendations/Comments

At present, measurement of pelvic muscle strength before and after treatment has not been validated as a useful outcome measure for frail older patients.

Ultrasound. Estimation of residual urine is an important adjunct to investigation of older patients, especially before addition of drugs that may impair bladder emptying. Estimation of postvoid residual by a portable ultrasound device has been shown to correlate well with that measured by catheterization [Griffiths et al., 1992]. Sensitivity may not be so good when volumes are greater than 200 ml as measured by catheter, in which case repeated measurements may be necessary to exclude a very high postvoid residual [Ouslander et al., 1994]. Improvement in the equipment's design since this study may have improved its accuracy.

Recommendations/Comments

Use of ultrasound for residual urine estimation offers much potential as a convenient noninvasive research tool for frail older people, especially for drug or surgical interventions that may affect bladder emptying. Further studies are required to validate the newer portable models.

Quality-of-Life Measurements

Health-related quality of life (HRQL) is a multidimensional concept that refers to an individual's evaluation and satisfaction with his/her physical, social, and psy-

chological health, as well as total well-being. This can be measured by a generic or condition-specific instrument. HRQL is important to measure, because a patient's life quality may improve even without change in degree of incontinence; conversely, improved continence status may not result in improved life quality. Unfortunately, few HRQL instruments have been tested for reliability, validity, and responsiveness in incontinent populations, let alone in a frail elderly population.

Recommendations/Comments

There is a need to develop tools to measure HRQL for frail elderly incontinent people.

Socioeconomic Measurements

Economic impact of continence interventions can be measured by cost, costbenefit, and cost-effectiveness. To be of real value, all costs related to actual health expenditure should be estimated before and after the intervention. This includes those related to treatment (e.g., drugs, surgery, nursing time on bladder training) and those related to managing any incontinence (e.g., pads, skin care products, laundry, caregiver time).

Cost-benefit is even more difficult to assess, as it is unclear how to define "benefit" in this population. For example, Schnelle et al. [1995] showed modest improvement in the degree of incontinence, but at increased cost compared to usual care. Is it better to be "socially continent" (dry with the assistance of pads or aids) and only occasionally disturbed by staff to change pads, or to be toileted frequently and be less wet at a greater staff cost but with a need to still wear pads?

Costs also include more nebulous areas which are borne by society as a whole rather than the health care system, such as work days lost for caregivers, impact of incontinence on the caregivers, or need for institutional care. While it is often stated that incontinence is a major factor in referral for institutional care, there are few convincing data to support this assertion.

Recommendations/Comments

There is a need to develop tools to help evaluate cost, cost-benefit, and cost-effectiveness for this population.

CONCLUSIONS

Research methodology for studying incontinence in the frail and housebound elderly is fraught with pitfalls. This has compromised the usefulness of past research. There is a great need for basic research to validate practical and useful outcome measures that will allow meaningful results to be obtained. In addition, an understanding is required of the importance of defining clinical rather than statistical significance.

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