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PREDICTORS OF URINARY AND FECAL CONTINENCE STATUS AFTER STROKE

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Tomas Lindor Griebling

Submitted to the graduate degree program in Preventive Medicine and Public Health
and the Graduate Faculty of the University of Kansas
in partial fulfillment of the requirements for the degree of
Master of Public Health.

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April 17, 2006

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AFTER STROKE

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This work is dedicated to the memory of my parents

Wilma Arlene and James W. Griebling

for their constant love and support

Abstract

Background: Urinary incontinence (UI) and fecal incontinence (FI) commonly occur after stroke and can have significant negative effects on recovery including increased care needs and diminished health-related quality of life. The causes of post-stroke UI and FI are multifactorial, and function may be influenced by a variety of factors. This study sought to examine the value of clinical characteristics assessed in the immediate post-stroke period to predict continence status at 6 months.

Materials and Methods: A secondary analysis was performed using the Kansas City Stroke Study, a prospective cohort of 459 subjects examined using a battery of validated functional assessment tools administered within two weeks after stroke (baseline) and at 1, 3, and 6 month intervals. Continence status was determined using the Barthel Index items for bladder and bowel function. Inclusion criteria for this secondary analysis required subjects to have been continent and fully independent of both bladder and bowel prior to stroke, and to have completed the 6 month follow-up examination. Predictor variables measured at baseline were compared to continence outcomes at 6 months using bivariate analyses adjusted for stroke severity and multiple logistic regression models.

Results: A total of 321 subjects met inclusion criteria. At 6 months, 64 had UI and 48 had FI, including 28 who had dual incontinence. Using multiple logistic regression models, independent predictors of UI at 6 months included age and the presence of UI at baseline enrollment. For FI, independent predictors included age, stroke severity, visual impairment, and lack of independence for dressing at baseline enrollment.

Conclusions: Urinary and fecal incontinence are common after stroke. Several clinical variables which can be measured in the immediate post-stroke period can be used to help predict subsequent bladder and bowel continence status within 6 months after stroke.

Introduction

Urinary and fecal incontinence represent major causes of morbidity and disability among acute stroke survivors. The associated physical, psychosocial, and economic impacts for patients and their caregivers can be significant. Urinary and fecal incontinence are among the leading diagnoses ultimately leading to nursing home placement in the United States. Efforts to prevent or reduce the incidence of both urinary and fecal incontinence in the general population and also in specific clinical conditions have recently gained increased research attention.[1] The purpose of this study was to examine if clinical characteristics which can be measured in the immediate post-stroke period can be used to predict bladder and bowel continence status at 6 months after stroke. It is possible that these clinical factors could be potential targets for therapeutic intervention which might have significant impacts on rehabilitation efforts. Improvement in urinary and fecal continence status after stroke could lead to decreases in overall caregiver burden, enhancements in functional status and better quality of life for post-stroke survivors. In addition, enhanced continence status could lead to lower rates of healthcare resource utilization, including decreased need for nursing home admission. This could have a significant cost impact for society and our healthcare delivery system.

Background and Clinical Significance

Urinary Incontinence

Urinary incontinence has been defined by the International Continence Society as the 'complaint of any involuntary leakage of urine.'[2, 3] Urinary incontinence may be either chronic or transient. Transient urinary incontinence is often caused by extrinsic factors which influence bladder function such as urinary tract infection, delirium, diuretic use, or fecal impaction. Correction of the underlying etiology often leads to complete resolution of the incontinence symptoms. Chronic incontinence tends to be more problematic, and may be more difficult to treat. Medical, surgical, and biobehavioral therapies are all used in the management of chronic urinary incontinence.

Various forms of urinary incontinence are defined by the International Continence Society.[2, 3] Stress incontinence is an 'involuntary leakage on effort or exertion, or on sneezing or coughing.' It is caused by an increase in intra-abdominal pressure which exceeds the resistance at the bladder outlet. Anatomic defects including intrinsic urethral sphincter deficiency in men or women, or urethral hypermobility in women predispose to stress urinary incontinence symptoms. Urge urinary incontinence is defined as 'involuntary leakage accompanied by or immediately preceded by urgency.' The most common cause is involuntary contraction of the detrusor muscles with bladder filling. Detrusor instability or hyperreflexia with associated urinary urge incontinence is a common urodynamic finding in subjects with post-stroke urinary incontinence. Many patients experience mixed urinary incontinence with both stress and urge symptoms. 'Overflow incontinence' refers to involuntary leakage which occurs when the bladder is full and is usually associated with poor bladder emptying during the voiding effort. This is most typically caused by detrusor hypocontractility. Obstruction of the urethral outlet, including benign prostatic hyperplasia, bladder neck contracture, or urethral stricture disease, may also cause incomplete emptying and overflow urinary incontinence. Many patients with overflow incontinence experience some change in bladder sensation. The term 'functional incontinence' refers to urinary incontinence associated with factors extrinsic to the bladder which cause problems with chronic urinary leakage. Impairments of mobility and cognition are the two major causes of functional incontinence. 'Nocturnal enuresis' refers to the involuntary leakage of urine during sleep.

The overall prevalence of urinary incontinence among community dwelling adults has been reported to range from 9% to 69% of all women, and 17% to 58% of women over the age of sixty.[4] The prevalence in males is lower, with reported ranges from 1% to 28% of community-dwelling men experiencing chronic urinary incontinence. A recent health care utilization analysis revealed that approximately 17% of men over sixty years of age experience chronic urinary incontinence.[5, 6] Although the overall prevalence of urinary incontinence increases with age, most experts agree that age itself is not the primary cause of the problem. Rather, it is the increased comorbidity in older adults that may predispose them to problems with urinary incontinence.

The prevalence of urinary incontinence in nursing home residents is significantly higher compared to older adults living in the community. Urinary incontinence is often cited as one of the primary etiologic factors necessitating nursing home admission in the United States. In one study of 430 new patients admitted to nursing homes, 39% of both men and women were found to be incontinent of urine.[7] The prevalence of urinary incontinence has been reported to be has high as 43.8% at one year after admission to nursing homes.[8] A recent health care utilization analysis examined rates of urinary incontinence using data from the National Nursing Home Survey. In this study, more than 50% of female nursing home residents were reported to have difficulty controlling urine, and a similar number needed assistance to use the toilet.[9]

The economic impact of urinary incontinence is staggering. It is estimated that the overall cost of urinary incontinence care in the United States is approximately $19.5 billion (year 2000 dollars).[10] Of this, approximately $14.2 billion was spent on community-dwelling subjects, and $5.3 billion on institutional residents. Expenditures for urinary incontinence care have increased sharply over the past decade.[11] Among female Medicare beneficiaries over 65 years of age, the annual expenditure for urinary incontinence care rose from $128.1 million in 1992 to $234.4 million in 1998. This was due primarily to the rise in outpatient medical costs, and accounted for 27.3% of total health care expenditures in women over 65 years of age in 2000.

Urinary incontinence can also have significant negative impacts on health-related quality of life and psychosocial health. Urinary incontinence may be associated with decreased social engagement and participation in activities which in turn can lead to decreased self-esteem and increased rates of depression.[12] Even in cases where urinary incontinence does not impact social interaction or activities, incontinent individuals often report higher rates of loneliness and depression.[13] In addition, urinary incontinence adds a significant burden to the caregiving process by increasing the amount of time and costs associated with clinical care.[14] This may also have strong negative effects for those who provide clinical assistance for an incontinent person.[15]

Although urinary incontinence has been identified as a marker of frailty among community-dwelling elders, its relationship to mortality is more controversial. Some studies have found worsening urinary incontinence to be a significant risk factor for death[16], but other research studies have not supported this relationship.[17, 18]

Fecal Incontinence

Definitions of fecal incontinence have yet to be standardized in the research literature. Recent consensus conferences on incontinence organized by the World Health Organization (WHO) included committees to examine the problem of anal incontinence. They proposed that anal incontinence be defined as, ‘the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem.’ [19, 20] Most research studies on fecal incontinence exclude those with loss of flatus alone, and include only subjects who experience involuntary loss of liquid or solid stool. Depending on the specific research design and the study population analyzed, estimates of the prevalence of fecal incontinence in the general community-dwelling adult population vary widely, with reported ranges between 2% and 26%. [21-23]

Much like urinary incontinence, fecal incontinence is associated with significant negative impacts on health-related quality of life and social engagement. The condition is often associated with feelings of panic and a reluctance to go out in public.[24] Older adults with fecal incontinence also experience high levels of anxiety and depression compared to subjects without this problem.[25] There is evidence to suggest this may be linked to the associated degree of fecal soiling in stroke survivors.[26]

It is estimated that approximately 50% of nursing home residents suffer from some degree of fecal incontinence.[27, 28] There is a strong overlap with urinary incontinence. In fact, most nursing home residents with fecal incontinence also experience urinary incontinence.[29] Fecal incontinence can significantly increase the risk of developing perineal skin breakdown and wound complications. There is evidence to suggest that fecal incontinence may be associated with an increased risk of mortality.[16]

Research on fecal incontinence has been more limited compared to work on urinary incontinence. Additional studies are needed to better understand both the etiologic mechanisms and potential therapeutic interventions for this condition.[30]

Stroke

Stroke is caused by an acute disruption of the blood supply to the brain. This may be due to either ischemic or hemorrhagic factors. When symptoms are caused by an ischemic event and last for less than twenty-four hours, the diagnosis is a 'transient ischemic attack' (TIA). The World Health Organization (WHO) defines stroke as a condition of 'rapid onset and of vascular origin reflecting a focal disturbance of cerebral function, excluding isolated impairments of higher function and persisting longer than 24 hours.'[31] Stroke can lead to significant physical impairments including problems with urinary and fecal incontinence, difficulty walking, cognitive changes, and disorders of speech and language.

The overall prevalence of stroke in the United States population is estimated at 5.5 million adults. The incidence of stroke in the United States is approximately 700,000 per year, with 500,000 of these being first attacks.[32] Stroke is the third leading cause of mortality in this country, accounting for approximately 1 in 15 deaths. It is estimated that 8% to 12% of those suffering an ischemic stroke and 37% to 38% of those who experience a hemorrhagic stroke will die within thirty days of the stroke event.[33] Stoke severity is closely linked to associated mortality.

In recent years, there have been numerous efforts to enhance public awareness of the risk factors for and clinical signs and symptoms of stroke. This has led to earlier intervention and development of related therapies such as statin medications for stroke prevention[34] and tissue plasminogen activator and similar thrombolytic agents for use in ischemic stroke.[35, 36]

However, these improvements in stroke survival have been accompanied by increased rates of morbidity and disability.[37] In fact, stroke is one of the leading causes of serious chronic disability in the United States. In 1999, it was estimated that approximately 1.1 million adults experienced some type of functional limitation or impairment of activities of daily living (ADLs) due to stroke.[38] The psychological and socioeconomic impacts of stroke can be significant. Stroke has been linked to depression, although the direction of causality is incompletely understood.[39] Even though up to 65% of stroke survivors are functionally independent at one year, the overall socioeconomic burden is significant.[40, 41] The estimated costs, including both direct and indirect costs, of caring for stroke survivors in the United States in 2006 was $57.9 billion.[32] The estimated mean lifetime cost of an ischemic stroke has been estimated at approximately $140,000 (in 1999 dollars).[42] It is predicted that these figures will continue to rise as the absolute incidence of stroke increases.[40]

Post-Stroke Incontinence

Urinary incontinence can negatively influence overall quality of life after stroke.[43] In a study of 361 community-dwelling stroke survivors, 16% were found to experience urinary incontinence based on assessment using the Functional Independence Measure™ (FIM).[44] Subjects who reported experiencing at least one episode of urinary leakage each month were found to have significantly diminished health-related quality of life and decreased levels of participation in social activities compared to those who did not leak urine. These findings were independent of stroke severity. Post-stroke fecal incontinence is also associated with significant impairments in health-related quality of life.[26]

Conceptual Framework

Development of this research project was based on a conceptual framework to describe the complex interactions between various aspects of an individual's health. Baseline functional status for any individual varies in terms of overall physical, cognitive, and emotional status. Most of these factors are measurable, and some may change over time and in response to various stressors. After an acute stroke, there are alterations in many of these factors which can lead to a change in overall post-stroke functional status. In turn, this can significantly influence the need for post-stroke rehabilitation and other clinical care. This concept is summarized in Figure 1:

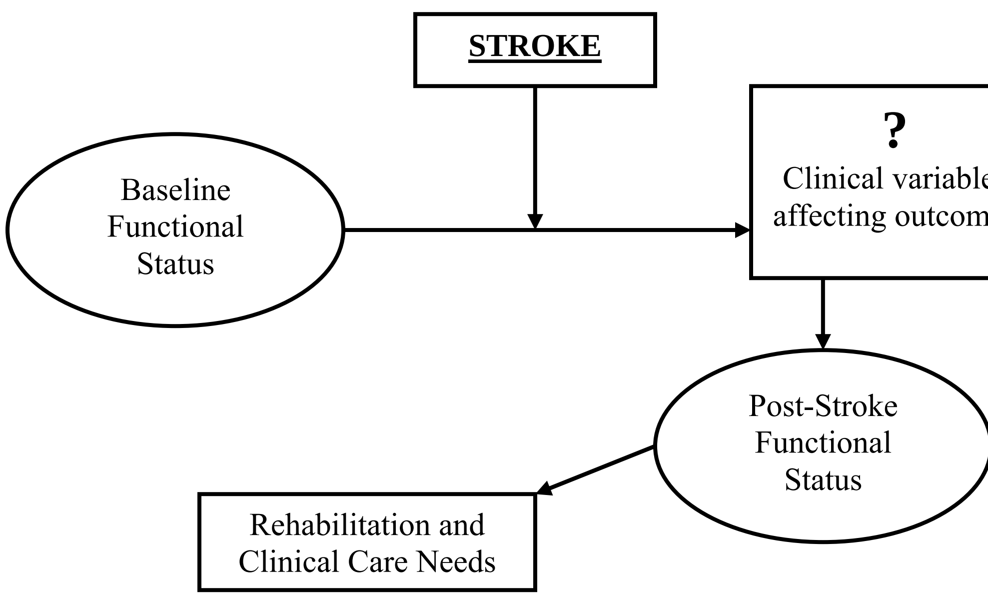

Figure 1 – Conceptual Model of the Progression of Functional Status After Stroke

The interactions between the many variables which could influence outcome after an acute stroke are complex and multidirectional. Some variables such as age, sex, and race/ethnicity are fixed and do not change for a given individual. Other variables are more fluid, and will vary in relation to improvement or deterioration in other areas such as physical mobility, cognitive status, and emotional state. Indeed, multiple contributing factors are involved in each of these broad clinical domains. A generalized concept of how these types of variables interact and how they could potentially influence urinary and/or fecal continence status is presented in Figure 2:

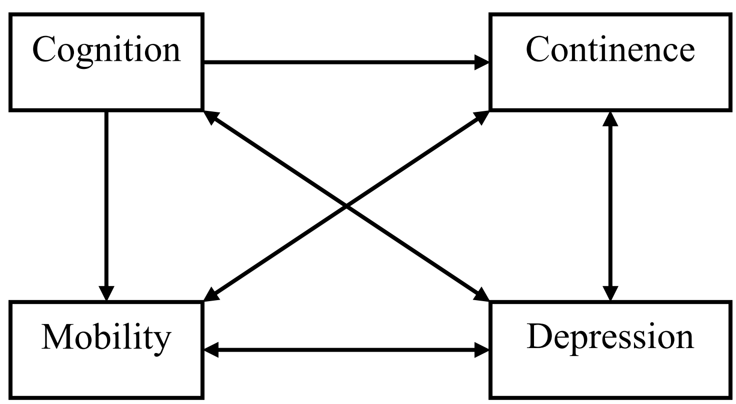

Figure 2 – Conceptual Model of the Potential Interactions Between Various Clinical Domains and Urinary and/or Fecal Continence Status

Specific Aims

Based on the previously described conceptual framework, and the hypothesis that urinary and fecal continence status after stroke are influenced by multiple factors, this study was designed to address three specific aims:

Specific Aim #1: To identify clinical characteristics which can be assessed in the immediate post-stroke period that may be predictive of urinary (bladder) continence status at six months after stroke.

Specific Aim #2: To identify clinical characteristics which can be assessed in the immediate post-stroke period that may be predictive of fecal (bowel) continence status at six months after stroke.

Specific Aim # 3: To identify if urinary and/or fecal incontinence at 6 months after stroke are associated with worse cognitive impairment, physical impairment, or depression at that time.

Materials and Methods

Original Clinical Dataset

The Kansas City Stroke Study (KCSS) served as the clinical population for this analysis. The current research project involved a secondary examination of this dataset. Details regarding the KCSS have been previously published.[45] Briefly, the KCSS was a prospective, longitudinal cohort study of 459 subjects who suffered an acute stroke, and were recruited to participate. Case enrollment was initiated in October 1995, and concluded in March 1998. Subjects were recruited from one of twelve participating health care facilities in the Kansas City metropolitan area. These facilities included one tertiary academic medical center, two Veterans Affairs hospitals, two inpatient rehabilitation hospitals, and nine regional primary or secondary medical centers. Potential subjects were identified by a review of daily facility admission records, referrals from physicians, therapists, or clinical nurse specialists on the medical, neurological, and rehabilitation units, and review of hospital discharge codes.

To be eligible for KCSS study participation, subjects had to have a confirmed stroke as defined by the World Health Organization (WHO) criteria.[31] This required an event with 'rapid onset and of vascular origin reflecting a focal disturbance of cerebral function, excluding isolated impairments of higher function and persisting longer than 24 hours.' Stroke was confirmed by clinical evaluation and/or brain imaging with either computed tomography (CT) or magnetic resonance imaging

(MRI). Prior to obtaining consent for enrollment in the study, the physical therapist or clinical nurse specialist from the study team reviewed the pertinent medical records and conducted interviews of both patients and their physicians.

Predefined exclusion criteria included: 1) subjects less than eighteen years of age at the time of stroke; 2) stroke onset more than fourteen days prior to study screening; 3) stroke caused by subarachnoid hemorrhage; 4) history of hepatic failure; 5) history of renal failure or subjects currently undergoing dialysis; 6) history of heart failure categorized as New York Heart Association functional grade III or grade IV (inability or marked limitations to perform physical activity without discomfort due to cardiac etiology); 7) those not expected to survive for more than six months; 8) those who lived in a nursing home prior to their stroke; 9) those unable to take care of their own affairs prior to their stroke; 10) subjects who were lethargic, obtunded, or comatose; 11) and subjects who lived more than seventy miles from the participating health care facility.

Eligible subjects who agreed to participate were enrolled in the study. All subjects and/or their designated proxies signed informed consent to participate. Standardized assessments were completed at baseline enrollment (within 14 days of stroke), and at intervals of one, three, and six months. All assessments were completed by trained nurses or physical therapists who were members of the study staff. Each study nurse or physical therapist completed at least two weeks of training in the administration of the assessment tools. In addition, each nurse or physical therapist was certified in the administration of the U.S. National Institutes of Health

Stroke Scale (NIHSS)[46] and the Functional Independence Measure™ (FIM).[47] Detailed information regarding the timing and methods of data collection for the Kansas City Stroke Study population have previously been reported.[45, 48]

Current Secondary Analysis

Data for this specific study were extracted from the full KCSS database. The dataset was stripped of any information which could be used to personally identify specific individuals, and each subject was then assigned a unique identifier to permit data tracking through the course of the study. Variables of interest were selected *a priori* based on a review of the prior published literature on post-stroke incontinence and the conceptual framework illustrated in Figure 2.

Additional Inclusion and Exclusion Criteria

To be included in the current secondary analysis, subjects had to be completely independent of both urinary and fecal function prior to their stroke. This was determined using the reported pre-stroke Barthel Index subscores for bladder and bowel function. Subjects also had to have successfully completed the final 6 month follow-up visit, with Barthel Index subscore data available for both bladder and bowel status at that time point.

Dependent Variables

The subscores for bladder and bowel function from the Barthel Index (full instrument described in the next section) were utilized as the dependent variables for this study. Data for each of these variables were dichotomized into categories of incontinent (wet) and continent (dry). A weighted subscore of 10 points meant that subjects were able to control their bladder or bowel during both the day and night, were able to independently use an ostomy device or other continence appliance if necessary, and stayed dry both day and night. These subjects were considered continent (dry) of bladder or bowel. A weighted subscore of 5 points meant that subjects experienced occasional accidents, could not wait for help or get to the toilet in time, or needed help with ostomy or other continence devices. A weighted subscore of 0 meant that subjects could not meet the measurement criteria or were incontinent of urine or feces. For purposes of this analysis, subjects who had weighted subscores of either 0 or 5 points were considered incontinent (wet) of bladder or bowel. The associations between the independent predictor variables, and the bladder and bowel continence status at 6 months post-stroke were analyzed separately. An additional analysis of the associations between bladder and bowel outcomes was also performed.

Independent Variables

Variables examined included sex, age at the time of stroke, race/ethnicity, education, and living situation. Race/ethnicity was determined based on selfdescribed categories including white/Caucasian, black/African American, Hispanic, Asian, Native American, or other. Due to the small numbers of subjects in some groups, the race/ethnicity variable was collapsed into three categories including white/Caucasian, black/African American, and other. Educational status was coded based on the self-reported highest level of education completed. For purposes of this analysis, educational status variables were collapsed into three categories including elementary school (grades 1-11), high school (completed grade 12 or a general education development (GED) test), and college or post-graduate training. Living situation was categorized into three groups including subjects living alone, subjects living with a spouse, relative, or friend, and subjects with other living arrangements.

Clinical variables examined included stroke characteristics, measures of depression, cognition, and functional status, and presence of comorbid disease. These variables were assessed at the initial baseline enrollment for KCSS. This examination was performed within 14 days of the acute stroke. Stroke type was determined based on the vascular etiology of the event (ischemic or hemorrhagic). Stroke location was categorized as right cerebral hemisphere, left cerebral hemisphere, brain stem, or cerebellum. Subjects could have experienced stroke in one or more locations, and all involved brain areas were coded for each subject. Anatomic location was confirmed with brain imaging using either computed tomography (CT) or magnetic resonance imaging (MRI).

Stroke severity was measured using two different assessment tools. The Orpington Prognostic Scale (OPS) is a multidimensional stroke severity scale which examines several functional domains including motor deficits in the arm, proprioception, balance, and cognition.[49, 50] Weighted points are assigned for each domain based on the level of deficit, and the domain scores are added to a base of 1.6 points. Total scores range from 1.6 to 6.8 points with higher scores representing more severe stroke. Prior studies have validated the categorization of stroke severity based on these scores and these have shown utility in clinical analysis.[45] Based on these criteria, stroke severity was categorized as a minor stroke (Orpington score < 3.2), moderate stroke (Orpington score 3.2 – 5.2), or severe stroke (Orpington score > 5.2). The National Institutes of Health (NIH) Stroke Scale was also assessed at baseline.[46] This instrument classifies stroke severity based on 11 domains including level of consciousness, gaze, vision, facial palsy, motor function, sensory function, limb ataxia, language and dysarthria, and extinction or inattention. Points are assigned based on degree of deficit, with total scores ranging from 0 to 42 points. Higher scores represent more severe stroke. This measurement was analyzed as a continuous variable.

To assess the impact of visual changes on clinical outcomes, the visual component subscore of the NIH Stroke Scale was coded for each subject at the time of baseline evaluation. The technique categorizes visual status as normal, partial hemianopia, complete hemianopia, or bilateral hemianopia (blind). To determine the influence of extinction or inattention (formerly called 'neglect'), the extinction/inattention component subscore of the NIH Stroke Scale was identified at baseline for each subject. This was categorized as normal, mild extinction/inattention, or profound extinction/inattention. Data for the visual and extinction/inattention component subscores was treated as missing if the data were known to be missing for a given subject, or if their status was unknown. In cases where the test was originally described as 'contraindicated', data were recoded to the worst level of function for that variable.

The presence and severity of other coexistent health conditions for each subject at the time of stroke were assessed using the Charlson Comorbidity Index.[51] This is a standardized, validated instrument designed to measure the degree of disease burden and comorbidity for individual patients. The tool was originally designed to help predict mortality risk. Weighted points are assigned for each condition based on the severity of the disorder and the potential for impact on mortality. Each comorbid condition is assigned 1, 2, 3, or 6 points, and the points are summed to determine a total comorbidity score. Higher scores represent more numerous or more severe coexistent illnesses. This parameter was considered as a continuous variable in this analysis.

Depression at both baseline and 6 month follow-up was assessed using the Geriatric Depression Scale (GDS).[52, 53] This is a 15-item, validated instrument which uses yes/no questions to help screen for possible depression. Scaled scoring is utilized to prevent directional response bias in the answers to the questions. A total score is calculated by summation of the scored and reverse-scored items. The range of possible scores is 0 – 15 points. Scores of 0 – 5 points are considered non-depressed, while scores > 5 points indicate possible depression.

Cognitive status was measured using the Folstein Mini Mental State Examination (MMSE).[54] This is a standardized, validated assessment instrument which is widely used in clinical practice, particularly in geriatrics and neurology. The instrument contains 13 questions which are broken into several domains of cognition. Items are scored individually and added together to determine a total MMSE score. Scores range from 0 – 30 points, with higher scores representing better overall cognitive function. Total scores of 24 – 30 are considered normal, and scores < 24 indicate cognitive impairment. For purposes of this analysis, the Folstein MMSE was considered as a continuous variable.

Physical functional status was determined using the Barthel Index.[55] This is a validated, multidimensional assessment instrument which measures levels of physical disability using a 10 item survey of activities of daily living and mobility. Specific items about activities of daily living include feeding, bathing, grooming, dressing, and toilet use. Mobility is measured by questions about transfers from a bed to a chair and back to bed, the ability to use stairs, and mobility on level surfaces. Two questions address continence status of bladder and bowels. Weighted points are assigned for each question based on the level of independence a person has for each specific activity being assessed. The total Barthel Index score ranges from 0 to 100, with higher scores representing better levels of independence and physical function. The Barthel Index has been widely used as an assessment tool in clinical rehabilitation, and for research related to stroke outcomes.

In order to assess the effects of overall physical function on urinary and fecal incontinence, these continence components needed to be removed from the measure for this independent variable. In order to correct for this confounding, a partial Barthel Index score, excluding urinary and fecal continence status, was created by taking the total Barthel Index score and subtracting the points assigned for these two components. The range for this calculated score is 0 to 80, with higher scores representing a greater degree of physical function and independence. This calculated score was examined in the outcomes analysis as a continuous variable.

Institutional Review

The original Kansas City Stroke Study was approved by the institutional review boards of the sponsoring institution and each of the other eleven participating health care facilities. The secondary data analysis presented in this study was reviewed and approved by the University of Kansas human subjects committee. The study was granted exempt status for informed consent because it was an analysis of de-identified, coded data.

Statistical Methods

Simple descriptive statistics were used to characterize the study population as well as the groups of subjects excluded from the outcomes investigation. Analysis of the retained study population was performed by comparing groups who were continent versus incontinent at 6 months after stroke. Separate analyses were performed using either urinary continence status or fecal continence status as the outcome variable. Comparisons between groups were performed using *t* tests for continuous variables and chi-square or Fisher's exact test as indicated for categorical variables. Non-parametric tests were used when sample normality was not observed. Based on the conceptual framework illustrated in Figure 2, bivariate analyses were performed to examine if clinical factors measured at the time of enrollment (within 14 days after stroke) were associated with either urinary or fecal continence status at the 6 month follow-up. Because stroke severity is known to exert such a strong influence on subsequent clinical outcomes, data were reanalyzed controlling for this factor. The categorical grade of stroke (minor, moderate, or severe) based on the Orpington Prognostic Scale was utilized for this purpose. Adjusted odds-ratios were calculated for each appropriate variable. Tests for homogeneity across strata were also performed (data not shown). Significance levels of the stratified analyses were determined using the Cochran-Mantel-Haenszel statistic.[56, 57] Factors found to be significant at the $p \leq 0.1$ level were entered into multiple logistic regression models to identify independent predictors of either urinary or fecal continence status. Separate models were created for each of these two outcome variables.

Because information on depression at the baseline examination was missing for 40 subjects (12.5%), two sets of analyses were performed for each outcome variable during multiple logistic regression modeling. In the first set of models, all subjects with missing data were categorized as non-depressed. A second set of models was created with these subjects re-categorized as depressed. Using these best case and worst case scenarios, results were compared between models. Exploratory full models were created initially. Based on the conceptual framework illustrated in Figure 2, models were developed using main effects analyses. Tests for 2-way interactions for all of the variables included in the model were also performed (data not shown). Subsequent multiple logistic regression analyses were performed using a backward, stepwise elimination technique. The analyses were created to model for predictors of either urinary or fecal incontinence (wet) status at 6 month follow-up. Variables were retained in the model at a $p \leq 0.05$ level.

Statistical analyses were performed using SAS version 9.1 (SAS Institute, Cary, North Carolina).

Results

The full Kansas City Stroke Study dataset included 459 subjects who met inclusion criteria and completed the baseline enrollment evaluation. Using the pre-defined inclusion and exclusion criteria for the current secondary analysis, a total of 138 subjects were excluded from this study. Subject flow is summarized in Figure 3 (page 69). Of the 459 total subjects, 73 were excluded because they were either incontinent or not completely independent of bladder and/or bowel function prior to their stroke (46 incontinent of urine only, 15 incontinent of stool only, and 12 incontinent of both urine and stool). Fifty-five of these subjects did complete the 6 month follow-up examination. Of the other 18 subjects excluded for a history of pre-stroke incontinence, 9 died prior to completion of the study, 4 refused continued participation, and 5 moved. Of the 386 remaining subjects, an additional 64 were excluded from the current analysis because they did not complete the entire 6 month study (23 died, 33 refused, 7 moved, 1 unknown). One additional subject who did complete the final 6 month follow-up was excluded because data on urinary and fecal continence status were missing for that visit. The remaining 321 subjects form the basis for this research study.

Selected demographic and clinical characteristics of the retained and excluded cohorts are summarized in Table 1. Of note, the excluded subjects were significantly older, and were more likely to have suffered a severe stroke or a brainstem stroke compared to the retained cohort.

Demographic and Clinical Characteristics of the Retained Cohort

The 321 subjects in the current secondary study included 157 men and 164 women. The mean age at the time of stroke was 68.4 ± 11.1 years, with a range from 42 to 92 years. The majority of subjects were white/Caucasian (80.4%) or black/African American (16.5%). Only 3.1% of subjects represented other racial/ethnic groups (6 Hispanic, 2 Asian, 2 'other'). Subjects were relatively well-educated with 53.2% having completed high school or a GED, and 24.6% having additional college or post-graduate education. The majority of subjects lived with a spouse, other relative or friend (72.6%). Eighty-four subjects (26.2%) lived alone at the time of enrollment.

The majority of subjects experienced an ischemic stroke (93.8%). In most cases, the stroke was isolated to only one anatomic location within the brain (156 left cerebral hemisphere, 136 right cerebral hemisphere, 18 brainstem, 7 cerebellum). However, 4 subjects experienced ischemic strokes involving two different anatomic locations (2 right cerebral hemisphere and cerebellum, 1 left cerebral hemisphere and cerebellum, and 1 both right and left cerebral hemispheres). The mean NIH Stroke Scale score for stroke severity was 6.4 ± 4.9 (range 0 – 31). The mean Orpington Prognostic Scale score was 3.5 ± 1.2 (range 1.6 to 6.8). Based on the OPS categorical scores, 43.9% of subjects experienced a minor stroke, 47.4% experienced a moderate stroke, and 8.7% experienced a severe stroke. The statistical correlation between these two assessment tools was strong ($r = 0.83$; $p < 0.0001$). For purposes of analysis, the categorical classification (mild, moderate, severe) based on the OPS was used to control for stroke severity.

Altered visual function was identified in 29.6% of subjects at the time of enrollment. Of those with visual impairment, 63.2% experienced partial hemianopia, 22.1% had complete hemianopia, and 14.7% had bilateral hemianopia or complete blindness. Extinction or inattention was present in 19.0% of subjects at the time of enrollment. Of these subjects, 73.8% demonstrated mild symptoms, and 26.2% had profound extinction or inattention.

Approximately half of subjects (52.7%) had minor degrees of comorbid disease based on the Charlson Comorbidity Index. All subjects scored at least one point based on their history of stroke. For 85 subjects (26.5%), the stroke was the only recorded disorder on this instrument. More severe levels of comorbidity were observed in 47.4% of subjects, with 70.4% of them (107/152) scoring 3 or 4 points, 24.3% (37/152) scoring 5 or 6 points, and 5.3% (8/152) scoring 7 or 8 points.

At the time of study enrollment, 82 subjects (25.5%) were categorized as depressed based on a Geriatric Depression Scale score of more than 5 points. However, data for this variable were not available for 40 subjects (12.5%) at the initial evaluation. At the baseline enrollment assessment, the mean Folstein MMSE score was 22.6 ± 7.7 points, with 34.6% of subjects categorized as cognitively impaired (score < 24 points).

Urinary Continence and Bladder Function

All 321 subjects were continent of urine (dry) and independent of bladder function prior to their stroke based on the pre-stroke Barthel Index score. At the time of enrollment, 99 subjects (30.9%) were rated as incontinent (wet) of urine. At the 6 month follow-up, 64 subjects (19.9%) were incontinent of urine. This included 44 subjects who were incontinent at enrollment and remained incontinent at the final examination, and 20 subjects who had been dry at the baseline evaluation but developed urinary incontinence over the 6 months of the study. A total of 201 subjects were dry at both the baseline and 6 month time points. An improvement in bladder function was noted in 55 subjects who were incontinent at the enrollment examination but regained independent continence status at the 6 month evaluation.

Bivariate analyses stratified by urinary bladder continence status at 6 months follow-up are summarized in Tables 2A and 2B. The urinary incontinent group was significantly older (72.5 ± 10.5 years) than the dry group (67.4 ± 11.1 years) ($p = 0.001$). Higher prevalence of urinary incontinence was also associated with more severe stroke as measured by the Orpington Prognostic Scale ($p < 0.001$). Based on categorical analysis, subjects who experienced a moderate stroke were 3.2 times more likely to have urinary incontinence at 6 months compared to those who experienced a minor stroke (95% CI = 1.68 – 6.27). The effect was even more pronounced when comparing those who experienced a severe stroke to those with a minor stroke (OR = 5.0, 95% CI = 1.95 – 13.03). After adjusting for stroke severity, there was a 1.48 fold increase in urinary incontinence for each decade of increased age.

Urinary incontinence was also associated with more pronounced levels of cognitive and functional impairment based on the mean Folstein MMSE scores and partial Barthel Index scores (both, $p < 0.001$). After adjusting for stroke severity, no significant differences were observed between the continent and incontinent groups based on sex, race/ethnicity, stroke type, or stroke location. Higher educational status (college or post-graduate school) was associated with better continence status (OR = 0.41, 95% CI = 0.18 – 0.94).

When adjusted for stroke severity, bladder incontinence at the baseline evaluation was strongly associated with bladder incontinence at 6 months (OR = 6.41, 95% CI = 3.29 – 12.49). Bowel incontinence at baseline was also significantly associated with urinary incontinence at 6 months (OR = 2.27, 95% = CI 1.19 – 4.32). The other physical function domains examined in this study, including the ability to independently perform toilet transfers, walking, and dressing, were not significantly associated with urinary continence status at 6 months.

Visual impairment was also associated with urinary incontinence (OR = 1.94, 95% CI = 1.04 – 3.60). However, in this cohort, extinction and inattention were not associated with urinary incontinence after adjusting for stroke severity (OR = 1.32, 95% CI = 0.63 – 2.76).

Based on multiple logistic regression modeling, age and urinary continence status in the first two weeks after stroke were independent predictors of urinary incontinence at 6 months (Table 3). Analysis revealed statistically significant main effects only. No interaction terms were found to be significant predictors for subsequent urinary incontinence. Other variables included in the model which did not emerge as independent predictors of urinary incontinence included sex, stroke severity, stroke type, comorbidity status, visual impairment, inattention/extinction or depression. In addition, baseline fecal continence status, ability to perform toilet transfers, mobility, and independence for dressing were not independent predictors of urinary incontinence at 6 months after stroke.

Fecal Continence and Bowel Function

All 321 subjects in this study were continent (dry) of stool and independent of bowel function based on their pre-stroke Barthel Index analysis. At the initial enrollment examination, 83 subjects (25.9%) were incontinent (wet) of stool. At the time of the final 6 month evaluation, 48 subjects had fecal incontinence, including 24 who were also incontinent of stool at the enrollment examination, and 24 who had previously been dry but had deterioration of bowel function over the course of the study. In contrast, 59 subjects who were incontinent at the enrollment examination had improvement in their fecal function and were continent of stool at the 6 month time point.

Bivariate analyses stratified by bowel continence status at 6 months follow-up are summarized in Tables 4A and 4B. Subjects with fecal incontinence were significantly older (mean 73.9 ± 9.4 years) compared to those without bowel problems (67.5 ± 11.2 years) ($p = 0.0002$). Increased stroke severity was also significantly associated with fecal incontinence at 6 months ($p < 0.0001$). Based on the categorical analysis, subjects who experienced a moderate stroke were 2.75 times more likely to have fecal incontinence compared to those who suffered a minor stroke (95% CI = 1.23 – 6.14). The association was even stronger between severe stroke and subsequent fecal incontinence (OR = 16.92, 95% CI 6.20 – 46.18). After adjusting for stroke severity, there was a 1.68 fold increase in fecal incontinence for each decade of increased age.

Increased comorbidity, worse cognitive function, and worse overall functional status were each associated with higher rates of fecal incontinence (all, $p < 0.001$). After adjusting for stroke severity, no significant associations were identified between fecal incontinence at 6 months and sex, race, stroke type, or stroke location. Increased educational status was associated with a lower rate of fecal incontinence compared to those with a high school education (OR = 0.30, 95% CI = 0.10 – 0.87).

Visual impairment was associated with a higher rate of fecal incontinence compared to those with normal vision (OR = 2.82, 95% CI = 1.41 – 5.65). After adjusting for stroke severity, extinction and/or inattention was not associated fecal incontinence (OR = 1.19, 95% CI = 0.52 – 2.71).

There did not appear to be an association between depression identified at baseline examination and fecal incontinence at 6 months (OR = 1.81, 95% CI = 0.84 – 3.94). In unadjusted bivariate analyses, all of the physical function parameters examined in this study were associated with higher rates of fecal incontinence. However, after adjusting for stroke severity, only bladder function measured at baseline enrollment (OR = 2.44, 95% CI = 1.16 – 5.14) and loss of independent function for dressing (OR = 4.15, 95% CI = 1.13 – 15.24) were statistically associated with fecal incontinence. Bowel function measured at baseline (adjusted OR = 1.95, 95% CI = 0.93 – 4.09) and toilet transfer independence (adjusted OR = 3.29, 95% CI = 0.97 – 11.15) were both close to reaching statistical significance.

Subjects who demonstrated less overall improvement in physical function were more likely to have persistent fecal incontinence at 6 months compared to those who had greater physical recovery. The mean partial Barthel Index scores, excluding the continence variables, only increased from 24 ± 23.7 to 38 ± 28.3 ($p = 0.0092$) in those who did not regain independent control of bowel function. In contrast, subjects who were continent of stool at 6 months had more substantial improvement in overall function with an increase in mean scores from 42 ± 24.4 to 72 ± 13.9 ($p < 0.0001$).

Multiple logistic regression modeling revealed age, stroke severity, visual impairment, and loss of independence of dressing ability at baseline to be independent predictors of fecal incontinence at 6 months (Table 5). Only main effects were found to be statistically significant. No interaction terms were significant predictors for subsequent fecal incontinence. Other variables included in the models which did not emerge as independent predictors of fecal incontinence included sex, stroke type, comorbidity status, inattention/extinction, and depression.

In addition, baseline urinary and fecal continence status, ability to perform toilet transfers, and mobility were not independent predictors of urinary incontinence at 6 months after stroke.

Relationship of Bladder and Bowel Function at 6 Months

Analysis of the relationship between bladder and bowel function at the final timepoint did reveal a statistically significant association between these conditions. Of the 321 subjects in the study, 237 (73.8%) were continent and independent of both bladder and bowel function at 6 months. Thirty-six subjects (11.2%) had urinary incontinence only, 20 (6.2%) had fecal incontinence only, and 28 (8.7%) had dual urinary and fecal incontinence. Based on unadjusted analysis, this relationship was quite strong (OR = 9.2, 95% CI = 4.7 – 18.1). This association was maintained when adjusted for stroke severity (OR = 8.6, 95% CI = 4.0 – 18.3).

Subjects with dual incontinence were older (mean age 74.8 ± 8.5 years) than those with a single type of incontinence (71.4 ± 11.3) or those who were continent and independent of both bladder and bowel (70.0 ± 11.0). These subjects with dual incontinence also tended to have suffered more severe strokes, and had worse levels of depression, cognitive impairment, and physical disability at both baseline enrollment and at 6 month follow-up. These data are summarized in Table 6.

At the 6 month follow-up, 85 subjects (26.5%) were classified as depressed, including 46 who were depressed at the time of enrollment, 26 who were previously not depressed, and 13 for whom enrollment information on depression was missing.

At the baseline enrollment assessment, the mean Folstein MMSE score was 23 ± 7.7 points, with 34.6% of subjects categorized as cognitively impaired (score < 24 points). During the course of the study, there was a general trend toward improvement in cognitive status. At the 6 month follow-up, the mean Folstein MMSE score had increased to 25 ± 6.7 points, and only 18.7% of subjects were considered cognitively impaired. Of the 111 subjects categorized as cognitively impaired at the time of enrollment, 61 (55.0%) were classified as non-impaired at the 6 month follow-up examination. Only 7 of the 197 subjects categorized as non-impaired at the time of enrollment were found to be cognitively impaired at the 6 month follow-up.

Overall physical function also tended to improve substantially with time. The mean total Barthel Index score at the time of enrollment was 55 ± 29.0 points, and the mean partial Barthel Index score (excluding the continence variables) was 38 ± 25.1 points. By the 6 month follow-up, the mean total and partial Barthel Index scores had improved to 85 ± 24.2 and 67 ± 20.7 respectively (both, $p < 0.0001$).

Examination of the partial Barthel Index scores revealed a significant improvement in both groups of subjects over the 6 months of follow-up. For those who were continent of urine at 6 months, the mean partial Barthel Index score improved from 42 ± 24.6 to 73 ± 13.7 ($p < 0.0001$). In those who remained wet at 6 months, these scores only improved from 28 ± 23.8 to 46 ± 28.6 ($p = 0.0002$). This reflects a higher overall level of physical function in those subjects who are dry and independent of bladder function at 6 months.

Discussion

Urinary and fecal incontinence occur in many stroke survivors. The development of incident incontinence can be associated with other substantial morbidity and disability which can have significant negative impacts. Identification of modifiable risk factors which influence continence outcomes could have important implications for post-stroke recovery. In this cohort of otherwise relatively healthy community-dwelling subjects who suffered stroke, several interesting primary findings emerged.

The observed rates of urinary and fecal incontinence both at baseline and at 6 months in this cohort of subjects were lower than in other studies reported in the literature. This finding may be a reflection of the overall health of the study subjects. Rates of comorbidity were lower than in other studies which could have influenced these outcomes. Subjects also tended to do well with rehabilitation, and the most dramatic improvements were seen in the first 1 to 3 months of recovery (data not shown). Most of the subjects in this study experienced mild or moderate stroke which is also generally associated with better clinical outcomes compared to more severe strokes.

Second, in terms of urinary continence status, the development of incident urinary incontinence within the first 2 weeks after stroke was an independent predictor of persistent incontinence at 6 months. This is an important finding because therapies targeted in an attempt to improve urinary continence status may be helpful for these subjects. Treatments to enhance urinary control could be actively pursued in subjects found to have new-onset incontinence in the immediate post-stroke period. The potential effects of targeted intervention are unclear, and additional research will be needed to examine this issue.

In this study, increased age was also found to be an independent predictor of both urinary and fecal incontinence at 6 months. Several factors could account for this finding. Physiologic changes in the urinary bladder and bowel associated with aging may occur which were not captured by any of the variables analyzed in this study. The multiple logistic regression analyses were developed using main effects modeling. Although interactions were tested, it is possible that variables which might influence the relationship between age and continence outcomes were not examined in this analysis.

Worse visual impairment after stroke appeared to be an independent predictor of bowel incontinence at 6 months follow-up. This was most pronounced for subjects with bilateral hemianopia or blindness compared to those with normal vision or less profound visual loss. The reason for this association is unclear. Visual impairment may be a marker of other underlying disabilities not directly measured in this study which could influence fecal continence. Again, future research on this association will be helpful to better understand these relationships.

The ability to dress and undress independently appeared to be predictive of bowel continence status at 6 months. Intuitively, it is logical that loss of the independent ability to adjust one’s clothing could influence continence status. This activity is essential for toileting, even in subjects who might use aides or devices such as a bedpan or bedside commode.

Based on the logistic regression analysis, depression was not found to be an independent predictor of either urinary or fecal incontinence at 6 months after stroke. As previously described, forty subjects did not have depression data recorded at the time of baseline enrollment. Separate models were created by assigning all of these subjects to either a depressed or non-depressed category. However, this did not affect the observed outcomes. Other researchers have identified associations between depression and continence even in subjects who have not experienced stroke.[58, 59] This may be due to biochemical factors which can influence both mood and bladder or bowel function. These differences in findings may be influenced by how depression is diagnosed and categorized.

In this cohort, the presence of symptoms of extinction or inattention was not found to be an independent predictor of urinary or fecal incontinence at 6 months. However recent data published by a Norwegian research group suggests that extinction and inattention may be important factors associated with some forms of post-stroke urinary incontinence.[60, 61] These authors concluded that this condition may cause a form of urinary incontinence associated with a diminished sense of awareness of the need to void. Potential treatment techniques could include prompted voiding or toileting of subjects with this problem in an attempt to improve continence outcomes. Additional prospective clinical trials will be necessary to help better understand this specific condition.

Several other findings from this study deserve additional consideration. In general populations of older adults, urinary incontinence tends to be more prevalent in women than men. The role of gender differences in stroke outcomes has not been completely elucidated, but there appears to be little difference in most general outcomes. This study enrolled a sizeable proportion of men in comparison to the population demographics for older adults. This may be a reflection of the fact that younger subjects were included in this study. It may also be due to the fact that two of the twelve healthcare facilities in this study were Veterans Affairs hospitals, which tend to have larger numbers of male patients.

Persistent urinary incontinence which develops after acute stroke has been identified as a potential marker for post-stroke mortality. However, the design of this study precluded modeling of a survival analysis. Overall, only 32 subjects of the original 459 were known to have died after their stroke. An additional 37 refused to continue participation at some point prior to the final 6 month follow-up visit, 12 had moved, and 1 subject was lost to follow-up. Mortality has also been closely linked to stroke severity in most studies. This study had a smaller proportion of subjects who suffered a severe stroke, and this may account for the low overall mortality observed in this cohort.

A ceiling effect was observed in this study with regard to the association between independent predictor variables and continence outcomes. Most subjects suffered either a minor or moderate stroke, and tended to have substantial overall functional recovery with time. This was particularly noticeable at the 1 month and 3 month timepoints (data not shown). Therefore, the observed rates of urinary and fecal incontinence at the 6 month timepoint were relatively low for the total study population. This suggests that successful overall post-stroke rehabilitation may be associated with improvements in urinary and fecal continence status. In contrast, those subjects with the most profound impairments in physical and cognitive function were more likely to suffer from dual urinary and fecal incontinence at the 6 month evaluation.

This study has several unique strengths. The inclusion and exclusion criteria for the secondary analysis were designed to limit the investigation to incident urinary and fecal incontinence which developed due to the acute stroke. This was possible only because questions had been asked about pre-stroke continence status using the Barthel Index. A total of 73 subjects were excluded because they had either isolated urinary or fecal incontinence or dual incontinence prior to their stroke. This is rare in the stroke outcomes literature because most studies do not attempt to separate subjects with a history of incontinence prior to stroke. It can be quite difficult to interpret the differences between incident incontinence and progression of prior disease. However, this could also be considered a potential limitation of the current study because these individuals were excluded from the overall analysis.

Another strength of this study was the use of strict definitions of continence for both bladder and bowel function. Subjects had to be dry and fully independent of function in order to be classified as continent. Although this will lead to a rather conservative assessment of continence status, it may be associated with a greater tendency toward a ceiling effect for this variable in the outcomes analysis.

This study examined a prospective cohort of community dwelling adults who were relatively healthy prior to their stroke. Most subjects lived within the Kansas City metropolitan area. Therefore, there was relatively small subject loss to follow-up, and there was limited missing data for most of the variables examined in this analysis. Multiple measures were performed at each evaluation timepoint using standardized, validated assessment instruments. This helped in the development of relevant questions and interpretation of findings.

This study also has several important limitations. The strict inclusion and exclusion criteria led to elimination of 138 subjects from the analysis. Seventy-three of these subjects had urinary and/or fecal incontinence prior to their stroke. Once these subjects had been eliminated, only 30.9% of subjects had urinary incontinence at the time of baseline enrollment examination, and 25.9% had fecal incontinence. These numbers are substantially lower than most data reported in the literature, which suggest that up to 50 – 70% of acute stroke survivors may develop urinary incontinence.[62-64] The observed rate of fecal incontinence was similar to that previously reported in the stroke outcomes literature. However, even considering the total population of subjects enrolled in the Kansas City Stroke Study, the overall observed rate of urinary incontinence (34.2%) was relatively low.

The bladder and bowel function questions from the Barthel Index were used as the dependent outcome variables in this study. In addition, the independent variables for physical function were measured using this instrument. However, the Barthel Index may not be the most sensitive tool to use for this purpose, particularly when looking for changes over a relatively short time.

There are a variety of comorbid conditions which can influence urinary and/or fecal continence status in both men and women. Examples include prostate disease or prior prostate surgery in men, increased parity or pelvic organ prolapse in women, or a history of pelvic radiation in both sexes.[5, 6, 65] Recent studies have also shown associations between obstructive sleep apnea and both nocturia and nocturnal incontinence.[66-68] In addition, some classes of medication such as diuretics, narcotics, alpha-adrenergic antagonists, or angiotensin converting enzyme (ACE) inhibitors can predispose subjects to urinary incontinence.[69-71] Unfortunately, individual data for these conditions and medications were not available in this analysis. It is possible that the urinary and fecal incontinence observed in some individuals may have been caused by one of these underlying factors rather than the direct effects of the stroke.

Stroke progression in the immediate post-event interval occurs in approximately 3 – 8 % of patients[72], and recurrent stroke occurs in 9 – 16% of subjects.[73] This phenomenon was not examined in the current study. It is possible that stroke progression or recurrence may affect clinical outcomes with regard to continence status. It would be particularly interesting to determine if stroke progression or recurrent stroke occurred in those subjects who demonstrated a deterioration of either continence outcomes or other functional abilities during the course of this study.

Living status at the 6 month follow-up was not assessed in this secondary data analysis. Urinary and fecal incontinence are generally associated with higher rates of nursing home and other institutional care. If available, it would be intriguing to add this data to the analysis to determine if continence status in this cohort was associated with subsequent place of residence. Successful efforts to improve continence could lead to changes in healthcare utilization rates and the costs of post-stroke care.

Because no specific data were available, it was not possible to determine a physiologic cause or subtype of incontinence experienced by a given individual. The most common form of urinary incontinence after stroke is urge incontinence secondary to an overactive detrusor. However, some patients experience urinary retention with overflow incontinence after stroke. The instruments used to measure incontinence in this study did not permit distinction between these various forms of incontinence. Additionally, no urodynamic data or information on post-void residual volumes were available in this cohort. Inclusion of these measures in future studies would permit this type of analysis which could have important implications.

In addition, there were no data available to know whether individual subjects had undergone any type of therapy targeted at improving either urinary or fecal incontinence. The importance of post-stroke rehabilitation has been examined in a variety of prior studies of overall function.[74-77] It would be helpful in future research to know if subjects had received any type of medical, surgical, or biobehavioral therapy targeted at improving their urinary and/or fecal continence status.

Future Directions

This study used fixed timepoints for the assessment of the independent predictor variables and the dependent outcome variables. Measurements were obtained at the time of study enrollment (within 14 days after the stroke). The dependent variables of urinary and fecal continence status were measured at the 6 month assessment for this analysis. However, data are also available for the 1 month and 3 month timepoints. It would be interesting to analyze the fluidity of those variables which can change with time, particularly in the early recovery phase. As was noted in this study, many subjects experience dramatic improvement in function for some clinical parameters, and this was most pronounced in the first months after stroke.

Other outcomes measures may provide a method to obtain a finer level of detail regarding urinary and fecal continence status as well as other levels of functional ability. The Functional Independence Measure™ (FIM) is an 18 item instrument which measures physical function using a seven level ordinal rating scale. This tool includes questions on bladder and bowel management. In addition, it has items that examine toileting and toilet transfers, bathing, tub and shower transfers, mobility, and dressing either the upper or lower half of the body. Subjects are graded on the level of independence for each item from 1 point if they require total assistance to perform the activity to 7 points if they are completely independent. Intermediate scores indicate the need for various levels of assistance, supervision, or modifications to perform the task. The FIM was administered at the baseline enrollment examination, and at the 1, 3, and 6 month follow-up examinations in the Kansas City Stroke Study cohort. Pre-stroke abilities were not assessed using this instrument. However the FIM may be more sensitive to change over time with regard to these clinical parameters.

Several of the independent variables were measured using multiple questions or assessment items. For example, the Geriatric Depression Scale uses yes/no questions to test for signs of depression, and the Folstein MMSE uses multiple questions to assess cognitive status across several domains. An examination using the component subscores for these types of instruments might prove useful in better understanding the complex relationships between these clinical conditions and continence outcomes.

It would also be interesting to repeat this type of analysis with a different cohort of subjects. This would help to verify the findings from this study, and may lead to additional information depending on the specific measurement instruments included in the dataset. Additional follow-up beyond the 6 month timepoint would also be useful. As observed in this analysis, there is often a dramatic improvement in overall function which occurs in the first several months following an acute stroke. However, 6 months is probably not adequate to fully assess the impact of urinary or fecal incontinence on other clinical outcomes. Continued improvement, or perhaps deterioration of function, might be observed with additional time.

Conclusions

Urinary and fecal incontinence are common symptomatic sequelae after acute stroke. Many stroke survivors demonstrate significant improvement in functional status, including both bladder and bowel function, in the first 6 months after stroke. Increased age and bladder function immediately following stroke is predictive of urinary incontinence at 6 months. Increased age, worse stroke severity, visual impairment, and loss of independent ability to dress and undress are predictive of fecal incontinence at 6 months. Additional research will help to identify how these predictive clinical variables may be used to direct care decisions and rehabilitation for stroke survivors.

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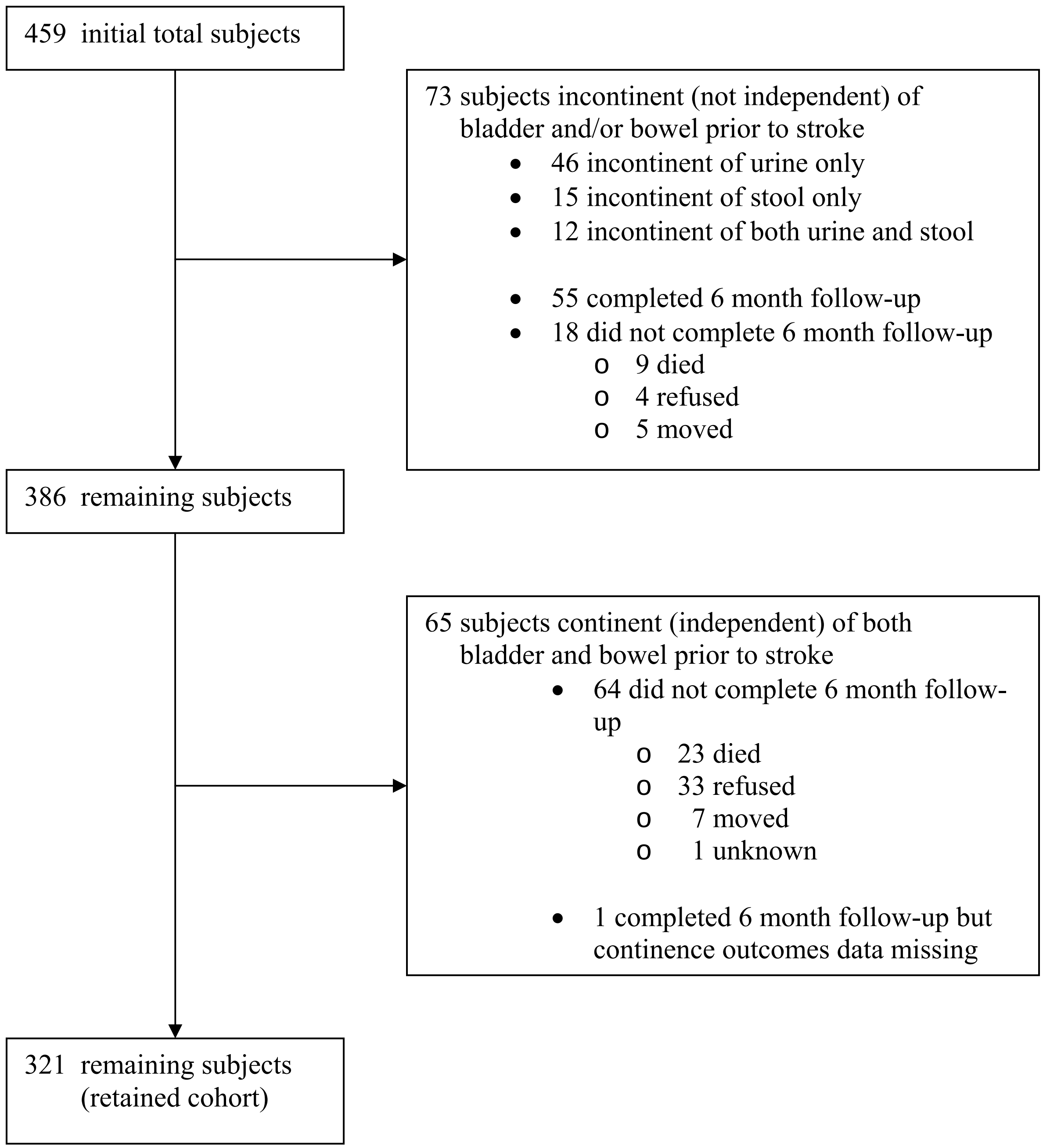

Figure 3 – Flowchart of Patient Inclusion / Exclusion for Current Study

Table 1 - Demographic and Clinical Characteristics

Characteristic	Retained Cohort (N = 321)	Eliminated Cohort (N = 138)	p-value
Sex			n.s.
Male	157 (48.9%)	57 (41.3%)	
Female	164 (51.1%)	81 (58.7%)	
Age			
Mean ± SD	68.4 ± 11.1	73.5 ± 11.2	p < 0.0001
Age Categories (%)			
≤ 64	107 (33.3%)	29 (21.0%)	
65 - 74	119 (37.1%)	36 (26.1%)	
75 - 84	71 (22.1%)	48 (34.8%)	
≥ 85	24 (7.5%)	25 (18.1%)	
Race / Ethnicity			n.s.
White / Caucasian	258 (80.4%)	108 (78.3%)	
Black / African American	53 (16.5%)	25 (18.1%)	
Other	10 (3.1%)	5 (3.6%)	
Education			n.s.
Elementary School (grades 1-11)	68 (21.2%)	27 (19.7%)	
High School / GED	171 (53.2%)	74 (54.0%)	
College or Post-Graduate	79 (24.6%)	36 (26.1%)	
Unknown	3 (0.9%)	1 (0.7%)	

Characteristic	Retained Cohort (N = 321)	Eliminated Cohort (N = 138)	p-value
Living Situation			n.s.
Alone	84 (26.2%)	43 (31.2%)	
With spouse / other relative / friend	233 (72.6%)	92 (66.7%)	
Other	4 (1.3%)	3 (2.2%)	
Stroke Type (ischemic vs. hemorrhagic)			n.s.
Ischemic	301 (93.8%)	129 (93.5%)	
Hemorrhagic	20 (6.2%)	9 (6.5%)	
Stroke Location(s)			n.s.
Right Hemisphere	139 (43.3%)	66 (47.8%)	
Left Hemisphere	158 (49.2%)	60 (43.5%)	
Brain Stem	18 (5.6%)	15 (10.9%)	
Cerebellum	10 (3.1%)	4 (2.9%)	
Stroke Severity (Orpington Prognostic Scale)			
Category			
Minor Stroke (Orpington score < 3.2)	141 (43.9%)	23 (16.7%)	Reference
Moderate Stroke (Orpington score 3.2 - 5.2)	152 (47.4%)	38 (27.5%)	n.s.
Severe Stroke (Orpington score > 5.2)	28 (8.7%)	77 (55.8%)	$p < 0.0001$
NIH Stroke Scale Visual Component Score			$p = 0.0085$
Normal (score 0)	226 (70.4%)	79 (57.3%)	
Impaired (score 1-3)	95 (29.6%)	59 (42.7%)	
NIH Stroke Scale Extinction / Inattention Component Score			n.s.
Normal (score 0)	258 (80.9%)	102 (73.9%)	
Impaired (score 1-2)	61 (19.1%)	36 (26.1%)	

Characteristic	Retained Cohort (N = 321)	Eliminated Cohort (N = 138)	p-value
Charlson Comorbidity Index			
Mean ± SD	2.7 ± 1.6	3.0 ± 1.5	p = 0.0439
Category			
Minor (0 - 2 points)	169 (52.7%)	55 (39.9%)	
Severe (≥ 3 points)	152 (47.4%)	83 (60.1%)	
Geriatric Depression Scale (baseline)			
Total score (range = 0 - 15); Mean ± SD	4 ± 3.0	5 ± 3.1	p = 0.0119
Category			
Depressed (score > 5)	82 (25.5%)	47 (34.0%)	
Non-depressed (score 0 - 5)	199 (62.0%)	68 (49.3%)	
Unknown	40 (12.5%)	20 (16.7%)	
Folstein MMSE (baseline)			
Total score (range = 0 - 30); Mean ± SD	23 ± 7.7	21 ± 8.6	p = 0.0476
Category			
Normal (score 24 - 30)	197 (61.4%)	69 (50.0%)	
Impaired (score < 24)	111 (34.6%)	59 (42.8%)	
Unknown	13 (4.0%)	10 (7.2%)	
Barthel Index (baseline)			
Total score (range = 0 - 100); Mean ± SD	55 ± 29.0	41 ± 29.7	p < 0.0001
Partial score (excluding continence variables; range = 0-80)	39 ± 25.1	30 ± 24.4	p = 0.0001
Barthel Index Subscores (# and % independent subjects)			
Toileting	131 (40.8%)	32 (23.2%)	
Bowel function	238 (74.1%)	69 (50.0%)	
Bladder function	221 (69.1%)	42 (30.4%)	
Walking	63 (19.6%)	10 (7.3%)	
Dressing	105 (32.8%)	31 (22.5%)	

Table 2A - Bivariate Analysis Stratified by Bladder (Urinary) Continence Status at 6 Months

Characteristic (measured at enrollment baseline)

Continuous Variables (Mean ± SD)	Continent (Bladder Dry) (N = 257)	Incontinent (Bladder Wet) (N = 64)	Adjusted Odds Ratio* (95% CI)	p-value
Age	67.4 ± 11.1	72.5 ± 10.5	1.0 (1.01 - 1.07)	p = 0.0046
Orpington Prognostic Scale	3.4 ± 1.2	4.1 ± 1.3		
Charlson Comorbidity Index	2.6 ± 1.6	3.0 ± 1.6	1.0 (0.86 - 1.24)	p = 0.6911
Folstein MMSE	23 ± 7.2	20 ± 9.1	0.97 (0.93 - 1.01)	p = 0.0779
Barthel Index Partial Score (excluding continence variables)	42 ± 24.6	39 ± 28.8	0.99 (0.97 - 1.00)	p = 0.1135

* Adjusted for stroke severity using Orpington Prognostic Scale categories

Table 2B - Bivariate Analysis Stratified by Bladder (Urinary) Continence Status at 6 Months

Categorical Variables	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)	p-value†
Sex			
Male	Reference	Reference	
Female	1.52 (0.87 - 2.65)	1.42 (0.80 - 2.50)	p = 0.2337
Race / Ethnicity			
White / Caucasian	Reference	Reference	
Black / African American	1.04 (0.50 - 2.15)	1.06 (0.51 – 2.20)	
Other	0.44 (0.05 - 3.55)	0.48 (0.05 – 4.53)	p = 0.7957
Education			
Elementary School (grades 1-11)	1.13 (0.59 - 2.17)	0.85 (0.37 – 1.67)	
High School / GED	Reference	Reference	
College or Post-Graduate	0.38 (0.17 - 0.86)	0.41 (0.18 – 0.94)	p = 0.1044
Stroke Type (ischemic vs. hemorrhagic)			
Ischemic	Reference	Reference	
Hemorrhagic	1.00 (0.32 - 3.11)	0.77 (0.23 - 2.55)	p = 0.6726
Stroke Location(s)			
Right Hemisphere	Reference		
Left Hemisphere	0.49 (0.28 - 0.88)	0.68 (0.37 – 1.26)	n.s.
Brain Stem	**	**	
Cerebellum	**	**	

	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)	p-value†
Stroke Severity (Orpington Prognostic Scale)			
Category			
Minor Stroke (Orpington score < 3.2)	Reference		
Moderate Stroke (Orpington score 3.2 - 5.2)	3.24 (1.68 - 6.27)		
Severe Stroke (Orpington score > 5.2)	5.04 (1.95 - 13.03)		
NIH Stroke Scale Visual Component (baseline)			
Normal (score 0)	Reference	Reference	
Impaired (score 1-3)	2.40 (1.36 - 4.22)	1.94 (1.04 - 3.60)	p = 0.0410
NIH Stroke Scale Extinction / Inattention Component (baseline)			
Normal (score 0)	Reference	Reference	
Impaired (score 1-2)	2.14 (1.14 - 4.02)	1.32 (0.63 - 2.76)	p = 0.4721
Geriatric Depression Scale (baseline)			
Non-depressed (score 0 - 5)	Reference		
Depressed (score > 5)	1.57 (0.83 - 2.98)	1.24 (0.63 - 2.42)	p = 0.5368
Barthel Index Subscores (baseline)			
Bladder Function			
Continent (dry)	Reference		
Incontinent (wet)	8.04 (4.38 - 14.75)	6.41 (3.29 - 12.49)	p < 0.0001
Bowel Function			
Continent (dry)	Reference		
Incontinent (wet)	2.86 (1.60 - 5.09)	2.27 (1.19 - 4.32)	p = 0.0137

	Unadjusted Odds Ratio (95% CI)	**Adjusted Odds Ratio* (95% CI)**	**p-value†**
Toileting			
Independent	Reference		
Non-independent	2.43 (1.31 - 4.50)	1.16 (0.49 - 2.77)	$p = 0.7531$
Walking			
Independent	Reference		
Non-independent	3.44 (1.32 - 8.97)	1.75 (0.60 - 5.07)	$p = 0.3007$
Dressing			
Independent	Reference		
Non-independent	1.97 (1.03 - 3.76)	0.80 (0.34 - 1.91)	$p = 0.6362$

* Adjusted for stroke severity using Orpington Prognostic Scale categories
** Statistic not calculated due to insufficient sample numbers
† Denotes use of Cochran-Mantel-Haenszel statistics
n.s. Not significant

<u>Table 3 - Logistic Regression Model for Bladder (Urinary) Function at 6 months</u>

Characteristic (at baseline enrollment)	Odds Ratio (95% CI)	p-value*
Age	1.0 (1.01 - 1.07)	$p = 0.0113$
Bladder Function (Barthel)	6.6 (3.40 - 13.21)	$p < 0.0001$
Stroke Severity (Moderate)	1.7 (0.92 - 3.62)	$p = 0.1581$
Stroke Severity (Severe)	1.4 (0.46 - 4.33)	$p = 0.5265$

* Considered significant at $p < 0.05$

Table 4A - Bivariate Analysis Stratified by Bowel (Fecal) Continence Status at 6 Months

Characteristic (measured at enrollment baseline)

Continuous Variables (Mean ± SD)	**Continent (Bowel Dry) (N = 273)**	**Incontinent (Bowel Wet) (N = 48)**	**Adjusted Odds Ratio* (95% CI)**	**p-value**
Age	67.5 ± 11.2	73.9 ± 9.4	1.1 (1.02 - 1.09)	p = 0.0020
Orpington Prognostic Scale	3.3 ± 1.1	4.5 ± 1.5		
Charlson Comorbidity Index	2.6 ± 1.5	3.5 ± 1.8	1.2 (1.00 - 1.50)	p = 0.0541
Folstein MMSE	24 ± 7.0	17 ± 9.6	1.0 (0.92 - 1.00)	p = 0.0311
Barthel Index Partial Score (excluding continence variables)	42 ± 24.4	24 ± 23.7	1.0 (0.97 - 1.01)	p = 0.3435

* Adjusted for stroke severity using Orpington Prognostic Scale categories

Table 4B - Bivariate Analysis Stratified by Bowel (Fecal) Continence Status at 6 Months

Categorical Variables	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)	p-value†
Sex			
Male	Reference	Reference	
Female	0.86 (0.7 - 1.59)	0.74 (0.38 - 1.42)	p = 0.3608
Race / Ethnicity			
White / Caucasian	Reference	Reference	
Black / African American	0.29 (0.09 - 0.98)	0.35 (0.10 – 1.19)	
Other	0.54 (0.07 - 4.38)	0.57 (0.05 – 6.87)	p = 0.1640
Education			
Elementary School (grades 1-11)	1.22 (0.60 - 2.47)	1.28 (0.58 – 2.81)	
High School / GED	Reference	Reference	
College or Post-Graduate	0.25 (0.09 - 0.74)	0.30 (0.10 – 0.87)	p = 0.0444
Stroke Type (ischemic vs. hemorrhagic)			
Ischemic	Reference	Reference	
Hemorrhagic	1.00 (0.28 - 3.57)	0.50 (0.12 - 2.13)	p = 0.3521
Stroke Location(s)			
Right Hemisphere	Reference	Reference	
Left Hemisphere	0.95 (0.51 - 1.76)	1.00 (0.52 – 1.94)	n.s.
Brain Stem	**	**	
Cerebellum	**	**	

	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)	p-value†
Stroke Severity (Orpington Prognostic Scale)			
Category			
Minor Stroke (Orpington score < 3.2)	Reference		
Moderate Stroke (Orpington score 3.2 - 5.2)	2.75 (1.23 - 6.14)		
Severe Stroke (Orpington score > 5.2)	16.92 (6.20 - 46.18)		
NIH Stroke Scale Visual Component (baseline)			
Normal (score 0)	Reference	Reference	
Impaired (score 1-3)	4.30 (2.28 - 8.14)	2.82 (1.41 - 5.65)	p = 0.0033
NIH Stroke Scale Extinction / Inattention Component (baseline)			
Normal (score 0)	Reference	Reference	
Impaired (score 1-2)	3.18 (1.63 - 6.21)	1.19 (0.52 - 2.71)	p = 0.6751
Geriatric Depression Scale (baseline)			
Non-depressed (score 0 - 5)	Reference	Reference	
Depressed (score > 5)	2.25 (1.07 - 4.72)	1.81 (0.84 - 3.94)	p = 0.1354
Barthel Index Subscores (baseline)			
Bladder Function			
Continent (dry)	Reference		
Incontinent (wet)	4.40 (2.32 - 8.35)	2.44 (1.16 - 5.14)	p = 0.0187
Bowel Function			
Continent (dry)	Reference		
Incontinent (wet)	3.63 (1.92 - 6.84)	1.95 (0.93 - 4.09)	p = 0.081

	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)	p-value†
Toileting			
Independent	Reference		
Non-independent	4.87 (2.11 - 11.25)	3.29 (0.97 - 11.15)	p = 0.0829
Walking			
Independent	Reference		
Non-independent	3.03 (1.05 - 8.78)	1.22 (0.34 - 4.35)	p = 0.7649
Dressing			
Independent	Reference		
Non-independent	6.31 (2.20 - 18.10)	4.15 (1.13 - 15.24)	p = 0.0341

* Adjusted for stroke severity using Orpington Prognostic Scale categories
** Statistic not calculated due to insufficient sample numbers
† Denotes use of Cochran-Mantel-Haenszel statistics
n.s. Not significant

Table 5 - Logistic Regression Model for Bowel (Fecal) Function at 6 months

Characteristic (at baseline enrollment)	Odds Ratio (95% CI)	p-value*
Age	1.0 (1.02 - 1.09)	p = 0.0052
NIH Visual Component Score	2.5 (1.23 - 5.24)	p = 0.0115
Dressing (Barthel)	3.7 (1.17 - 14.33)	p = 0.0364
Stroke Severity (Moderate)	1.3 (0.51 - 3.42)	p = 0.6203
Stroke Severity (Severe)	5.2 (1.55 - 18.54)	p = 0.0087

* Considered significant at $p < 0.05$

Table 6 - Comparison of Subjects Stratified By Continence Status at 6 Months

Characteristic Continuous Variables (Mean ± SD)	Continent both Bladder and Bowel (N = 237)	Single Incontinence Bladder or bowel (N = 56)	Dual Incontinence (Bladder and bowel wet) (N = 28)
Age	70.0 ± 11.0	71.4 ± 11.3	74.8 ± 8.5
Orpington Prognostic Scale	3.3 ± 1.1	3.9 ± 1.3	4.7 ± 1.4
NIH Stroke Scale	5.4 ± 3.9	7.9 ± 5.3	11.6 ± 6.9
Charlson Comorbidity Index	2.5 ± 1.4	3.1 ± 1.9	3.3 ± 1.4
Folsetin MMSE			
Baseline	24 ± 6.8	21 ± 8.6	16.4 ± 9.5
6 months	27 ± 4.8	24 ± 6.5	15.1 ± 11.0
Geriatric Depression Scale			
Baseline	4 ± 2.8	5 ± 3.5	6.1 ± 3.0
6 months	3 ± 3.0	6 ± 3.8	7.8 ± 3.9
Barthel Index Partial Score			
Baseline	43 ± 24.3	34 ± 24.8	18.8 ± 20.3
6 months	74 ± 11.5	60 ± 22.7	25.4 ± 23.3