Urinary Incontinence and indwelling urinary catheters as predictors of death after new-onset stroke: a report of the South London Stroke Register.

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Running title: Catheters, incontinence and mortality after stroke

Abstract

Objective: To explore the relationship between indwelling urinary catheters, urinary incontinence and death in the post-stroke period and to determine when, after the neurologic event, urinary incontinence has the best ability to predict one-year mortality.

Methods: In a prospective observational study, 4477 patients were followed up for one year after a first-ever stroke. The impact of urinary incontinence or urinary catheters on time to death was adjusted in a Cox model for age, sex, Glasgow Coma Scale, pre- and post-stroke Barthel Index, swallow test, motor deficit, diabetes, and year of inclusion. The predictive values of urinary incontinence assessed at maximal deficit or seven days after stroke were compared using receiver-operating curves.

Results: Urinary incontinence at the maximal neurologic deficit and urinary catheters within the first week after the stroke were present in 43.9% and 31.2% patients respectively. They were both associated with one-year mortality in unadjusted and adjusted analysis (HR 1.78; 95%CI 1.46-2.19 and HR 1.84; 95%CI 1.54-2.19). Patients with urinary incontinence and urinary catheters had twice the mortality rate of incontient patients without urinary catheters (HR 10.24; 95%CI 8.72-12.03 versus HR 4.70; 95%CI 3.88-5.70, $p<0.001$). Urinary incontinence assessed after one week performed better to predict one year mortality than urinary incontinence assessed at maximal neurologic deficit.

Conclusion: Indwelling urinary catheters in the post-stroke period is associated with death, especially among incontinent patients. Urinary incontinence assessed at one week after the neurological event has the best predictive ability.

Introduction

Urinary incontinence (UI) is frequent after stroke. Functional status, haemorrhagic stroke, aphasia, motor deficit, mental impairment and post-stroke depression have all been associated with the risk of developing UI.[1,2] Its prevalence ranges between 33% and 79% in the days following acute stroke with almost half of those patients remaining incontinent one-year after stroke.[1,3] UI has been reported to be an independent predictor of institutionalization, severe disability, and death in the post-stroke period.[1,4-6]

Indwelling urinary catheters (IUC) are often used after the occurrence of an acute stroke (in almost 25% of patients), but are only seldom reported in studies.[7] IUC is responsible for most of the urinary track infections among hospitalized patients, with a risk of approximately 5% per day.[8] The acquisition of a catheter-associated urinary tract infection prolongs hospital length of stay, increases cost burden, and is associated with poorer functional outcome and mortality.[9-11]

Thus the association between UI and death after a new-onset stroke might be confounded by the inclusion of indwelling urinary catheters. We explore if UI and the IUC are independent predictors of mortality and if the insertion of an IUC among patients presenting UI after a new-onset stroke has an impact on their risk of mortality. We also determined the best time to assess UI in regard to its predictive value for one-year mortality.

Methods

For the purpose of this study we used data collected by the South London Stroke Register (SLSR). This register prospectively includes all first-ever stroke patients of all ages in an inner-city area of South London, covering the north of the boroughs of Lambeth and Southwark. In 2001, the population of the Register area was 271 817. Hospital surveillance of admissions for stroke included 5 teaching hospitals. Community surveillance of stroke included patients under the care of all general practitioners within and on the borders of the study area.[12]

Data are collected in the acute stroke phase by trained fieldworkers and follow-up is carried out using postal questionnaire or in face-to-face interviews at 3 months, 1 year and then annually thereafter.

Patients or their relatives gave written informed consent. The study was approved by the ethics committees of Guy's and St Thomas' Hospital NHS Foundation Trust, King's College Hospital Foundation, National Hospital for Neurology and Neurosurgery, Queen's Square Hospital, St George's Hospital, and Chelsea and Westminster Hospital. The detailed methods of patient notification and data collection have been previously described.[13]

Patients and measurements

We included all participants recorded in the register between 1st January 1995 and 31st December 2011. Stroke diagnosis was made according to the World Health Organization definition of stroke and was verified by a study clinician.[14] Stroke subtypes were classified using CT or MRI, or at post-mortem examination. Impairments at the time of maximal neurological deficit were initially recorded either on physical examination or from medical record notes.

Urinary incontinence and urinary catheters

Continence status was specifically assessed in the SLSR’s initial questionnaire at the time of maximum neurological impairment. UI was defined as any involuntary leakage of urine. Continence status at prior to stroke, one week, three months and one year after the neurological event was extracted from the continence items of the Barthel Index (BI).[15]

Any indwelling urinary catheter inserted during the first week following the stroke was recorded. No information on the indication to place the catheters or the duration of the catheterization was available. The information on IUC was not recorded on the data collection forms used in 1999 and 2000.

Disability and covariates

The BI was used in order to assess patient's activities of daily living before and after the stroke. Level of consciousness, was determined using the Glasgow Coma Scale (GCS) and patients who died immediately after stroke were given a GCS score of 3. Swallowing capacity was determined using a water swallowing test and patients who couldn't undergo this test were classified as having failed. Dysphasia, dysarthria, visual field deficits and limb weakness were clinically assessed. Stroke risk factors such as prior ischaemic heart disease, current tobacco use, hypertension and diabetes were also registered.

Follow-up and death assessment

All patients were followed for at least one year. Survival time was calculated as time between date of stroke onset and date of death and participants who had not died were censored at one year after stroke.

Statistical analysis

Patients were divided in four groups depending on the presence or absence of two variables: UI at the maximal neurologic deficit and IUC. The main outcome was the difference in mortality among those categories. We calculated that 4477 participants (45% with UI) followed during one year with a 12% expected rate of event in the control group (without UI or IUC), could detect a minimum hazard ratio (HR) of 1.3 with a statistical power of 90% and an α error of 5% (Freedman method).

Comparisons of characteristics between groups were performed using the chi-square test or Fisher's exact test, where appropriate, for categorical variables. The Mann Whitney test was used for continuous variables, as these were not normally distributed.

The unadjusted impact of UI and indwelling urinary catheters on time to death was analysed using Kaplan Meier survival analysis and unweighted two-sided log-rank test to compare groups. Multivariate Cox models were used to adjust for potential confounding factors. The factors of adjustment were chosen from previous publications or when they were associated with mortality in univariate analyses.[5,6] Continuous variable were introduced as categorical or dichotomous variable when not linear in the Cox model. Furthermore, the proportion of UI, the proportion of IUC, and one-year mortality decreased over the study period (**Table e-1**). Thus association between UI and death was adjusted for age (continuous), GCS<13 (binary), BI before the stroke <15 (binary), BI after the stroke <15 (binary), sex, failed swallow test, limb motor deficit (binary), diabetes, and the year of inclusion (five-year periods). The UI subscale was excluded from the BI scores used. The cutoff point for the BI was chosen accordingly to Uyttenboogaart et al.[16] This cutoff maximise sensitivity and specificity for unfavourable outcome after stroke. GCS was dichotomized according to previous work published by the SLSR.[17] No variable were colinear in the model. The proportional hazards assumption was verified by visual inspection of the log minus log plots.

Given that there was a high level of missing data of some variables included in the cox models (**Table e-2**), multiple imputation method was used in a sensitive analysis. Missing data were inspected to ensure that the missing at random assumption was reasonable. Imputation involved all baseline responders and utilised the following variables: age, sex, BIs before and after the neurological event, GCS, diabetes, failed swallow test, motor test, UI and IUC. Missing data were imputed using chained equations. The outcome was included in the imputations as log transformed survival time and an indicator for death. Twenty imputed datasets were generated and parameter estimates were combined using Rubin's rules.

In another sensitive analysis we explored whether impact of UI or IUC on one-year mortality was different between female and male, younger and older patients or depending on the year of entry in the Register (five-year periods). The subgroups differences were tested by including terms for interaction between UI or UIC and subgroup variables in the Cox models.

We compared UI assessed at maximal neurologic deficit (admission) and at seven days after stroke in patients with and without excluding pre-existing UI . Thus, four modalities of UI were possible. To compare the predictive value of the four unadjusted and adjusted models, area under the receiver operating curves were computed and compared according to the nonparametric approach proposed by Delong et al.[18] The variable of adjustment were age, GCS, BIs before and after the stroke, sex, failed swallow test, limb motor deficit, diabetes, and the year of inclusion (five-year periods). Areas under the receiver operating curves and corresponding 95% confidence intervals were also calculated using multiply imputed data. All analyses were performed using STATA statistical software, version 12.0 (StataCorp LP, College Station, TX, USA).

Results

4477 patients with first ever stroke were followed for one year and 1492 (33.3%) died. Continence status was determined for 4161 patients. Urinary incontinence was present in 1827 participants (43.9%) at maximal neurologic deficit. Information on IUC insertion was available for 3756 patients, and was present among 1171 (31.2%) patients. Most of the patients with UIC were incontinent of urine (1040 (91.1%), p<0.001). Patients with UI and patients with an IUC were older, more frequently women and had worst functional status or neurologic deficit, when compared to patients without UI or without IUC (**Table 1**).

	Urinary incontinence at maximal neurologic deficit (UI)		**Indwelling urinary catheter**	
	No (N=2334)	**Yes** (N=1827)	**No** (2585)	**Yes** (1171)
Age, y median (IQR)	69.2 (59-77.8)	76.6 (65.9-84.2)*	71.1 (60.7-79.9)	75.1 (63.3-83.2)*
Male (N)	1299 (55.7%)	794 (43.5%)*	1376 (53.2%)	517 (44.1%)*
Ischemic heart disease	310 (18.1%)	328 (21.6%)†	382 (19.4%)	224 (22.5%)
Current smoker	674 (46.9%)	454 (39.6%)*	780 (47.4%)	301 (42.0%)†
Hypertension	1467 (65.2%)	1118 (63.2%)	1682 (65.5%)	733 (63.3%)
Diabetes	442 (19.6%)	322 (18.1%)	505 (19.8%)	198 (17%)†
Ischemic stroke	1954 (83.7%)	1230 (67.3%)*	2140 (82.8%)	717 (61.2%)*
Haemorrhagic stroke	169 (7.2%)	338* (18.5%)	18 (16-18)	234* (20.0%)*
Barthel before, median (IQR)	20 (20-20)	20 (18-20)*	20 (20-20)	20 (18-20)*
Barthel after, median (IQR)	19 (13-20)	1 (0-7)*	17 (10-20)	0 (0-5)*
GCS, median (IQR)	15 (15-15)	12 (7-15)*	15 (15-15)	10 (6-14)*
Swallow deficit	270 (12.8%)	1209 (71.8%)*	500 (21.6%)	829 (78.3%)*
Dysarthria	824 (40.6%)	759 (58.0%)*	1107 (44.6%)	487 (56%)*
Dysphasia	514 (22.4%)	729 (47.3%)*	632 (25.2%)	471 (49.3%)*
Anopsia	365 (16.2%)	632 (43.0%)*	502 (20.4%)	403 (44.3%)*
Weakness of the upper limb	1477 (64.1%)	1584 (90.4%)*	1762 (69.4%)	1005 (90.0%)*
Weakness of the lower limb	1270 (55.3%)	1531 (87.6%)*	1559 (61.6%)	967 (87.0%)*
* p<0.001; †p<0.05. UI: urinary incontinence; IUC: indwelling urinary catheters, GCS: Glasgow coma scale, IQR: interquartile range 25-75%.				

Table 1: Characteristics of the participants by urinary incontinence and indwelling urinary catheters.

Association between urinary incontinence, indwelling catheter and mortality

After one year, 1063 patients with UI (56.8%) and 285 without UI (11.9%) had died (p <0.001). The respective figure for IUC was 729 deaths among patients with IUC (62.3%) compared to 470 among patients without IUC (18.2%, p <0.001). UI and IUC were both associated with death in unadjusted survival analysis: hazard ratio (HR) 6.84 (95%CI 5.98-7.83) and HR 5.30 (95%CI 4.70-5.98), respectively. The associations persisted after adjustment: adjusted HR 1.78 (95%CI 1.46-2.19) for UI and 1.84 (95%CI 1.54-2.19) for IUC. Following multiple imputation the adjusted HRs were 1.74 (95%CI: 1.47-2.06) and 1.67 (95%CI: 1.38-1.93) for UI and IUC, respectively.

Mortality in continent and incontinent patients was higher among those receiving an IUC (**Figure 1**). Compared to patients without UI or IUC, patients with IUC (HR 3.42; 95% CI 2.35-4.97), patients with UI but no IUC (HR 4.70; 95% CI 3.88-5.70), and patients with UI and IUC (HR 10.24; 95% CI 8.72-12.03) were at higher risk of death. After adjustment, the HRs were respectively 1.75 (95% CI 1.10-2.82), 1.47 (95% CI 1.14-1.89), and 2.39 (95% CI 1.88-3.04).

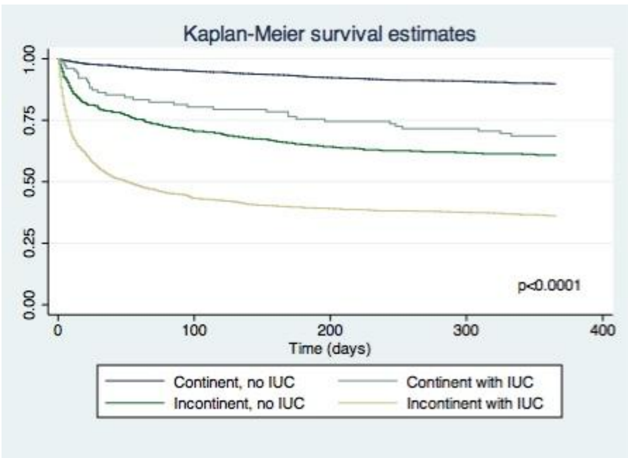

Figure 1: Mortality rate by urinary and IUC status.UI was assessed at maximal neurologic deficit. All group difference (p<0.001) except between continent patient with an IUC and UI patients without a IUC, where the difference was not statistically significant (log rank test 0.085). IUC: indwelling urinary catheter; UI: urinary incontinence.

An interaction was found for sex and age, but not for the year of inclusion (**Table 2**). The association between UI or IUC and death was stronger for younger patients and men.

	Unadjusted HR	**Adjusted HR***	**Adjusted HR, multiple imputation ***
Urinary incontinence			
Age			
<70 years	9.76 (7.45-12.80)†	2.09 (1.27-3.43)	2.08 (1.44-3.02)‡
>70 years	5.07 (4.34-5.92)	1.75 (1.40-2.18)	1.63 (1.35-1.969
Sex			
Female	5.64 (4.72-6.73)‡	1.64 (1.26-2.14)	1.55 (1.24-1.94) ‡
Male	8.17 (6.63-10.05)	1.93 (1.40-2.65)	1.97 (1.52-2.55)
Year of inclusion			
1994-1999	5.69 (4.61-7.02)	1.75 (1.29-2.39)	1.72 (1.32-2.24)
2000-2004	7.84 (6.07-10.13)	2.16 (1.47-3.19)	1.96 (1.42-2.70)
2005-2012	7.19 (5.65-9.15)	1.59 (1.09-2.30)	1.61 (1.20-2.16)
Indwelling urinary catheter			
Age			
<70 years	9.08 (6.99-11.81)†	2.08 (1.34-3.24)	2.13 (1.56-2.93)†
>70 years	4.27 (3.72-4.90)	1.78 (1.47-2.16)	1.53 (1.31-1.80)
Sex			
Female	4.70 (4.01-5.51)‡	1.78 (1.41-2.24)	1.56 (1.28-1.89)‡
Male	5.90 (4.90-7.10)	1.89 (1.43-2.48)	1.82 (1.48-2.26)
Year of inclusion			
1994-1999	5.84 (4.78-7.16)	2.21 (1.68-2.92)	2.01 (1.57-2.56)
2000-2004	4.67 (3.74-5.82)	1.42 (0.99-2.02)	1.37 (1.05-1.79)
2005-2012	5.05 (4.10-6.21)	1.80 (1.33-2.44)	1.62 (1.28-2.05)

Predictive values are given for one-year mortality. * Adjusted for age (continuous), GCS<13 (binary), BI before the stroke <15 (binary), BI after the stroke <15 (binary), sex, failed swallow test, limb motor deficit (binary), diabetes, and the year of inclusion (five-year periods).
† p<0.001 for interaction term; ‡ p<0.05 for interaction term; § p<0.05 compared to AUC of UI assessed one week after stroke excluding pre-existing UI. HR: hazard ratio; UI: urinary incontinence.

Table 2: Hazard ratios of death at 1 year among incontinent patients and patients with indwelling urinary catheters stratified by age and sex.

Best predictive period to assess UI

UI was found in 310 patients (7.3%) preceding stroke, in 1827 (43.9%) at the maximal neurologic deficit, and in 1392 (39.9%) patients at one week after stroke. UI patients that regain continence in the first week had a similar prognosis as patients without UI (HR 1.36; 95% CI 0.96-1.94; p 0.08) (**Figure e-1**).

The area under the operative curves (AUC)) for UI assessed at the maximal neurologic deficit and UI assessed one week after the stroke, with or without excluding pre-existing UI, in unadjusted and adjusted models, are shown in **Table 3**. They all showed good predictive AUC, but the UI assessed after one week performed slightly better. AUC after multiple imputations were close to the non-imputed dataset.

	Complete cases		**Multiple imputation**	
	Unadjusted	**Adjusted ***	**Unadjusted**	**Adjusted ***
UI assessed at the maximal neurologic deficit excluding pre-existing UI	0.75 (0.74-0.77)	0.84 (0.83-0.86)	0.76 (0.74-0.77)	0.83 (0.81-0.84)
UI assessed at the maximal neurologic deficit not excluding pre-existing UI	0.76 (0.74-0.77)	0.85 (0.83-0.87)	0.76 (0.75-0.77)	0.83 (0.82-0.85)
UI assessed at one week after stroke excluding pre-existing UI	0.76 (0.75-0.78)[‡]	0.85 (0.83-0.86)[† §]	0.79 (0.77-0.80)	0.84 (0.83-0.86)
UI assessed at one week after stroke not excluding pre-existing UI	0.77 (0.75-0.78)[‡]	0.85 (0.84-0.87)[†§]	0.79 (0.78-0.80)	0.85 (0.83-0.86)

Predictive values are given for one-year mortality. * Adjusted for age (continuous), GCS<13 (binary), BI before the stroke <15 (binary), BI after the stroke <15 (binary), sex, failed swallow test, limb motor deficit (binary), diabetes and the year of inclusion (five-year periods).
† p<0.05 compared to AUC of UI assessed at the maximal neurologic deficit without excluding pre-existing UI; ‡ p<0.001 compared to AUC of UI assessed at the maximal neurologic deficit, with or without excluding pre-existing UI; § p<0.05 compared to AUC of UI assessed one week after stroke excluding pre-existing UI. UI: urinary incontinence.

Table 3: Area under the operative curves for UI assessed at different moment after a new-onset stroke.

Discussion

Urinary incontinence and insertion of urinary indwelling catheters are both strong and independent predictors of death after a stroke. The results of this study also suggests that to assess UI one week after the stroke onset is better than assessing UI at the maximal neurologic deficit in order to predict one year mortality.

Our observations are consistent with a recent meta-analysis of post-stroke UI [5], and previous smaller studies that showed unfavourable outcomes for patients with IUC.[7,19] The link between UI and death is probably complex and not explained solely by indwelling catheter placement. UI increases the risk of infection [20,21], falls, fall related injuries [22], and malnutrition [23], factors which contribute to the increased mortality. Mortality among incontinent patients or patients with IUC could reflect the severity of strokes -severely impaired patients have higher risk of becoming incontinent and an IUC is often warranted in order to monitor urine output. However, in this large-scale register, the association persists after statistical adjustment for many confounders.

The indication for the catheterization is inconstantly notified in medical or nursing charts.[24] The South London Stroke Register also lacks this information. However, IUC insertion without a specific medical indication is associated with higher risk of death, institutionalization and functional decline.[8,19,25] The present study shows that insertion of an IUC among incontinent patients doubles their one-year mortality. Thus post-stroke mortality might be reduced by an appropriate utilization of IUC.

To our knowledge no previous study has described the predictive ability of UI depending on the time of assessment after stroke. Patients regaining urinary continence within the first week after stroke have the same one-year mortality risk as continent patients. This confirms the recent findings by Rotar et al. and explains why UI assessed one week after the onset of a stroke has the best ability to predict mortality.[26] The reduction of the risk of death could be explained by the fact that these patients have less severe strokes than patients with persistent UI, or that those patients are less exposed to inappropriate uses of IUC and its adverse effects. Nevertheless, determining UI at the time of maximal neurologic deficit is also of value independently of pre-existing UI, and could be more convenient for establishing a predictive model or score for mortality.

Our study has several limitations. Firstly we lack a standardized definition of UI and we used two different techniques to assess UI: clinical observation in the acute period and bladder subscore of the BI during follow-up. Secondly, an important drawback is the lack of information about the indications of IUC placement that precludes the appreciation about the appropriateness of the catheterization. Moreover patients with a urinary catheter at any time during the first week after the onset of the stroke were considered as catheterized in this study, regardless of the duration of catheterization. The prevalence of UI, death and their association after a new-onset stroke is consistent with previous reports.[4] However, the prevalence of urinary catheterization (31.2%) is slightly higher than previous reports [7], which could reveal a more liberal use of IUC. Thirdly, no validated stroke-severity score was recorded in the Register (e.g.: National Institutes of Health Stroke Scale). We tried to account for the severity of the event by adjusting for GCS, failed swallow test, motor test, and functional status (BIs after the neurological event), but this might have resulted in underadjustment. There were finally many missing data in this study, but the multiple imputations were close to the non-imputed dataset.

Conclusion

In conclusion, our study raises warning against IUC placement after a new onset stroke, especially for UI treatment and stresses the need for specific UI management after stroke. Further studies are warranted to explore the effect of UI treatment on one-year mortality or the benefice of adding UI to traditional post stroke mortality score.

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