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Hospital-associated complications of older people: a proposed multi-component outcome for acute care

Running title: Hospital-associated complications of older people

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Abstract

Objective: Improving hospital care for older people requires meaningful, valid measures of potentially preventable hospital-associated harm. The aim of this study was to propose a new multi-component measure of hospital-associated complications of older people (HAC-OP) and evaluate its validity in a large hospital sample.

Design: Observational study using baseline (pre-intervention) data from the CHERISH cluster randomized controlled trial.

Participants: Four hundred and thirty four patients aged 65 years or older (mean age 76 years, 48% female) with length of stay 72 hours or more on acute medical and surgical wards in four hospitals in Queensland, Australia.

Measurement: We developed a multi-component measure including five well-recognized hospital-associated complications of older people: hospital-associated delirium, functional decline, incontinence, falls and pressure injuries. To evaluate construct validity, we examined associations with common risk factors (age over 75 years, functional impairment, cognitive impairment and history of falls). To evaluate predictive validity, we examined the association of length of stay, facility discharge and 6 month mortality with any HAC-OP, and with the total number of HAC-OP.

Results: Overall, 192/434 (44%) of participants had one or more HAC-OP during their admission. Any HAC-OP was strongly associated with the proposed shared risk factors, and there was a strong and graded association between HAC-OP and length of stay (9.1 days [SD 7.4] for any HAC-OP vs 6.8 days [SD 4.1] with none, $p < 0.001$), facility discharge (59/192

[31%] vs 27/242 [11%], $p<0.001$) and 6 month mortality (26/192 [14%] vs 17/242 [7%], $p=0.02$).

Conclusion: This study provides evidence for construct and predictive validity of the proposed measure of HAC-OP as a potential outcome measure for research investigating and improving hospital care for older people.

Key words 3-5: hospitalization; geriatric syndrome; delirium; functional decline; incontinence

INTRODUCTION

Older people admitted to hospital face the combined stress of the precipitating illness or injury, and a challenging hospital environment. Hospitalization may lead to complications which are not specific to the presenting illness, often called geriatric syndromes. Geriatric syndromes are conditions with increased prevalence in older people, multifactorial etiology, shared risk factors, and negative impact on patient outcomes¹⁻³. Many studies reporting geriatric syndromes in hospitalized older people refer to pre-existing issues such as mobility impairment, falls history, and cognitive impairment. These have prognostic implications for older inpatients⁴⁻⁸ and are commonly included in comprehensive geriatric assessment. In contrast, other literature refers to new issues developing during hospitalization, such as delirium and new functional impairments. These are often iatrogenic and related to processes of care, and are therefore potential quality and safety indicators for acute care of older people, consistent with other hospital-acquired complications⁹.

We propose the term ‘hospital-associated complications of older people’ (HAC-OP) to distinguish new geriatric syndromes related to hospitalization. Based on literature review and clinical experience, we focused on five syndromes (delirium, functional decline, hospital-acquired incontinence, falls, and pressure injuries) which are associated with poorer outcomes (e.g., long hospital stays, more post-acute facility discharge, poorer function and higher mortality)^{2, 10, 11} and are more common in older inpatients¹¹⁻¹³. These complications have shared risk factors and are likely to be interdependent^{2, 14, 15}. For instance, cognitive impairment is a risk factor for delirium, falls, functional decline and hospital-acquired

incontinence^{11,15-21}. Mobility impairment, falls and gait disturbance are risk factors for delirium, falls, functional decline, pressure injuries and incontinence^{13,15-19}, while functional impairment is associated with delirium, functional decline, incontinence and pressure injuries^{11,13,15,19-21}. Delirium prevention programs also reduce in-hospital falls²².

Trials aiming to improve hospital care of older people generally focus on a single HAC-OP as an outcome. However, in complex multi-faceted interventions, shared risk factors and interdependency may make it difficult to predict the most important outcome. Designating co-primary outcomes conventionally requires adjusted statistical significance levels, requiring increased sample size and costs. A multi-component outcome measure might help researchers and decision makers identify and maximize the potential benefits of complex interventions addressing multiple risk factors.

The aim of this paper was to evaluate the validity of a multi-component measure of HAC-OP. Using observational data from the pre-intervention phase of a multi-site intervention study in hospitalized older patients (24), we aimed to demonstrate that a multi-component measure is associated with shared risk factors for geriatric syndromes (construct validity), and has a graded exposure-response relationship with adverse outcomes (predictive validity).

METHODS

Setting, participants and assessments

We used data from the pre-intervention cohort of the CHERISH trial, a multi-site cluster randomized controlled trial of the *Eat Walk Engage* intervention, designed to reduce hospital-associated complications in older inpatients. The trial's methods have been published²³. In brief, during this observational phase, we enrolled consecutive consenting inpatients aged 65 years and older with length of stay 3 days or more, on eight medical or surgical wards in four hospitals October 2015 -April 2016. Patients were excluded if they were unable to be reviewed within 72 hours, discharged within 72 hours, or terminally ill. The study was approved by the Royal Brisbane and Women's Hospital Human Research Ethics Committee and written informed consent provided by all participants or their statutory health authority.

Outcomes and measures.

Standardized comprehensive assessments were undertaken by four trained research assistants at admission, day 5, and discharge from the study ward. Self-report measures included functional status (activities of daily living [ADL]) and continence two weeks prior to admission and at each assessment; cognitive status (Short Portable Mental Status Questionnaire [SPMSQ]²⁴ and the 3 minute diagnostic interview for Confusion Assessment Method-defined delirium [3D-CAM]²⁵) at each assessment; falls in 6 months prior to hospitalization and during hospitalization; and presence of pressure injuries at each assessment. Clinical records were reviewed using a structured abstraction tool, including demographic and disease variables; documentation of delirium²⁶, pressure injuries or falls; length of stay under the treating team; and discharge destination, defined as usual living situation (including return to home or usual nursing home) or new facility discharge

(continuing acute care, convalescent or rehabilitation care or new nursing home discharge).

Death within 6 months of admission was obtained from the Queensland Health Statistics Branch.

Each HAC-OP was defined to capture complications developing during hospitalization with recognized significance for patients^{10,27,28}. Hospital-associated functional decline was an increase in self-reported requirement for human assistance in any ADL (bathing, dressing, toileting, transfers, mobility or feeding) at hospital discharge compared to baseline function two weeks prior to admission. Hospital-associated incontinence was any self-reported urinary and/or fecal incontinence at discharge that was not present two weeks prior to admission. Hospital-associated delirium was identified either by direct assessment²⁵ or documented in the clinical record²⁶, excluding delirium identified within 24 hours of admission. Hospital-associated falls and pressure injuries were identified by patient report or documentation in the record, excluding pressure injuries present on admission.

The multi-component outcome 'any HAC-OP' was defined as presence of one or more of these five syndromes. 'Count of HAC-OP' (ranging from 0 to maximum of 5) was constructed to explore exposure-response effect for outcomes.

Statistical Analyses

To evaluate construct validity, we measured the association of each individual HAC-OP and any HAC-OP with four shared risk factors identified in previous studies¹¹⁻²¹: older age (75

years or older), functional impairment (any ADL impairment at admission), cognitive impairment (admission SPMSQ under 8) and falls in the previous 6 months. Two-by-two tables were used and the odds of developing each syndrome in the presence of the risk factor calculated, using MedCalc software (https://www.medcalc.org/calc/odds_ratio.php).

To clarify overlap between the different HAC-OP, a correlation matrix was constructed to measure within-patient associations between the complications, using Pearson's coefficient, which indicates the direction and relative strength of correlation for binary data. Because we anticipated the complications to represent related but distinct clinical outcomes, we hypothesized a low level of correlation.

To evaluate predictive validity of the multicomponent measure, we investigated the association between HAC-OP and facility discharge and 6 month mortality using a chi-square test, and length of stay using one-way analysis of variance with log-transformation of length of stay. We examined whether there was a graded exposure-response relationship between count of HAC-OP and hospital outcomes. Analyses were made in SPSS version 22 with $p < 0.05$ to indicate statistical significance.

RESULTS

We screened 2,042 older inpatients in 8 wards (general medicine, general surgery, orthopedics and respiratory medicine) between October 2015 and April 2016, of whom 862 (42%) were eligible (838 discharged within 72 hours, 183 admitted to different team/ward, 115 not screened within 72 hours, 36 terminally ill) and 474 (55%) participated (258 declined/withdrew, 112 unable to obtain consent). Discharge assessments were missing on 40 cases (8%; 9 critically ill or died, 9 declined, 22 transferred/discharged), so HAC-OP measures were calculated for 434 participants with complete data. Mean age was 76 years (SD 7), 206 (48%) were female, 18 (4%) were from nursing home, 115 (27%) had SPMSQ score less than 8, 106 (24%) were dependent in one or more ADL, and 153 (35%) reported falls in the previous 6 months. Proxy respondents were required for 31 (7%) participants.

Hospital-associated functional decline occurred in 114/434 (26%), delirium in 66 (15%), incontinence in 54 (12%), falls in 30 (7%) and pressure injuries in 18 (4%). Overall, 192/434 (44%) of participants had 'any HAC-OP', with 115 (26%) having one, 64 (15%) having two, and 13 (3%) having 3 or more.

Table 1 examines the association between shared risk factors and each individual HAC-OP as well as any HAC-OP. Age over 75 years increased the odds of delirium, functional decline and incontinence. Functional impairment increased odds for all syndromes. Cognitive impairment and a history of falls increased the odds of delirium, functional decline,

incontinence and falls. All risk factors were significantly associated with the multi-component outcome 'any HAC-OP'.

Table 2 shows the correlation between the five complications. There were weak although statistically significant associations between several complications: delirium was significantly associated with functional decline and falls; and functional decline was significantly associated with delirium, incontinence and pressure injuries. This pattern supports shared risk factors and/or interdependence as hypothesized, but the weak associations (correlation coefficients under 0.20) shows that these HAC-OP represent distinct domains. This means that combining them into a multi-component outcome should not exaggerate the contribution of any particular component.

Supplementary Appendix S1 shows the association between HAC-OP and adverse outcomes. Participants with any HAC-OP had a significantly longer length of stay [mean 9.1 days (SD 7.4) vs 6.8 days (SD 4.1), $p<0.001$], were more likely to be discharged to a facility [59/192 (31%) vs 27/242 (11%), $p<0.001$], and were more likely to die within 6 months [26/192 (14%) vs 17/242 (7%), $p=0.02$]. There was a graded and highly significant association between increasing count of HAC-OP and length of stay ($p<0.001$), facility discharge ($p<0.001$ for linear trend) and 6 month mortality ($p=0.007$ for linear trend) (figure 1).

DISCUSSION

Using data from older inpatients admitted to eight wards, we identified several distinct hospital-associated complications prevalent in hospitalized older adults and associated with important shared risk factors. Combining these five HAC-OP provided a multi-component end-point strongly associated with the shared risk factors, and with poor outcomes.

Importantly, there was a significant exposure-response effect whereby patients experiencing higher number of HAC-OP had substantially poorer outcomes in a graded fashion. Our analyses demonstrate construct and predictive validity of this proposed outcome of ‘any HAC-OP’ for use in clinical trials of complex interventions targeting shared risk factors. Advantages of this measure include higher prevalence than individual syndromes, which may make adequately powered trials more feasible, and potential to compare outcomes across different interventions.

Composite outcomes usually combine relatively uncommon events (e.g., death, myocardial infarction or revascularization) to optimize power. Identified problems include differential effects on different outcomes, competing risks, and assumptions about patient preferences for the composite outcomes²⁹. Our proposal differs in some important respects. Firstly, the components are not rare events; however, collecting them is labor-intensive as routine screening and measurement of geriatric syndromes in clinical practice remains under-developed. Secondly, shared risk factors and interdependence make it more plausible that they will be affected to a similar extent and direction by a multicomponent intervention. Thirdly, they are outcomes recognized as important to patients as well as to the health service

³⁰; serious new functional, cognitive and continence impairments have similar disutility for seriously ill hospitalized patients ²⁸. Like other composite outcomes, we recommend reporting the individual HAC-OP and their measurement methods.

We recognize some limitations. The observed association between greater number of HAC-OP and length of stay may reflect reverse causality, i.e. those with longer stays accrued more complications. Careful time-sensitive methods would be required to explore this in more detail. The multi-component measure did not weight different components. Discharge data were missing for 40 patients (8%) who were excluded from the analysis, and consent requirements excluded some high-risk patients (e.g. those with severe illness or cognitive impairment), which may reduce generalizability of the findings. Relatively small numbers of falls and pressure injuries compared to the other HAC-OP reduce reliability of estimates for these outcomes. Misclassification of delirium as prevalent rather than incident may have underestimated the delirium outcome. The 3D-CAM was administered at admission, day 5 and discharge, and although this was supplemented with detailed chart review to improve sensitivity, some cases may have been missed. However the incidence rate is similar to rates reported in other general medical samples (11-14%)¹¹. Prevalent delirium (with reduced SPMSQ score) might confound the associations of HAC-OP with cognitive impairment; however sensitivity analysis removing prevalent cases (n=87) did not significantly impact the strength of these associations. Strengths of our study include multiple sites, and carefully defined clinically meaningful measures including both patient reporting and record review to

maximize sensitivity. This may have led to relatively high rates of complications reported, along with only sampling older patients in hospital for 3 days or more.

In summary, the concept of HAC-OP could promote greater clarity and consistency for researchers and clinicians working to understand and improve care of hospitalized older patients. Testing this outcome in trials of complex interventions targeting multiple risk factors in a variety of acute settings will inform its usefulness for researchers, clinicians, patients and families and policy-makers.

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Conflict of interest: The authors have no conflicts of interest to declare

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Supplementary Appendix S1. Clinical outcomes (length of stay, facility discharge, and 30 day mortality) associated with each HAC-OP and the composite measure of any HAC-OP

Legend

Figure 1. Clinical outcomes according to number of hospital-associated complications of older people (HAC-OP). A. Mean length of stay in days (error bars show 95% confidence intervals). B. Percentage of participants discharged to facility (continuing, rehabilitation, post-acute or new nursing home care). C. Percentage of participants who died within 6 months of admission

Table 1. Association between each hospital-associated complication and shared risk factors, reported as odds ratios (95% confidence intervals).

	Age 75+	Dependent ≥ 1 ADL at admission	SPMSQ < 8	Falls in previous 6 months
Functional decline (n=114)	3.0 (1.9-4.8) p<0.0001	3.5 (2.2-5.6) p<0.0001	2.0 (1.3-3.2) p=0.004	2.1 (1.4-3.3) p=0.0008
Delirium (n=66)	2.6 (1.5-4.4) p=0.0008	1.6 (1.0-2.7) p=0.06	2.9 (1.7-4.8) p<0.0001	1.8 (1.1-2.9) p=0.03
New incontinence (n=54)	1.7 (0.9-3.0) p=0.09	1.7 (0.9-3.0) p=0.08	2.1 (1.2-3.8) p=0.01	2.0 (1.1-3.6) p=0.02
Fall (n=30)	0.8 (0.4-1.7) p=0.62	1.4 (0.7-2.9) p=0.36	2.1 (1.0-4.4) p=0.04	2.2 (1.1-4.6) p=0.03
Pressure injury (n=18)	1.2 (0.5-2.7) p=0.68	1.9 (0.8-4.6) p=0.13	0.9 (0.4-2.4) p=0.85	1.1 (0.5-2.6) p=0.79
Any HAC-OP (n=192)	2.4 (1.6-3.5) p<0.0001	2.2 (1.5-3.3) p<0.0001	2.8 (1.8-4.3) p<0.0001	2.1 (1.4-3.2) p=0.0002

ADL activities of daily living; SPMSQ Short Portable Mental Status Questionnaire; HAC-OP hospital associated complications of older people

Table 2: Within-patient correlations between hospital-associated complications of older people. Cells report the Pearson correlation co-efficient (and associated p value) between each pair of complications.

	Delirium	Functional decline	New incontinence	Pressure injury	Fall
Delirium	1	0.17 (p<0.001)	0.07 (p=0.13)	0.01 (p=0.86)	0.12 (p=0.01)
Functional decline	0.17 (p<0.001)	1	0.17 (p <0.001)	0.14 (p=0.004)	0.02 (p=0.63)
New incontinence	0.07 (p=0.13)	0.17 (p<0.001)	1	0.08 (p=0.10)	0.02 (p=0.68)
Pressure injury	0.01 (p=0.86)	0.14 (p=0.004)	0.08 (p=0.10)	1	0.02 (p=0.75)
Fall	0.12 (p=0.01)	0.02 (p=0.63)	0.02 (p=0.68)	0.02 (p=0.75)	1

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