Incidence and associated risk factors for falls in older adults following elective total knee replacement surgery - a prospective cohort study

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Conflict of Interest

The authors have no conflicts to declare.
Abstract

Objective
The aim of the study was to determine the incidence and associated risk factors for falls in older adults in the 12 months after elective, primary total knee replacement (TKR) surgery.

Design
A prospective observational cohort of older adults undergoing TKR were followed. Baseline measurements included risk factors of history of falls, using a gait aid and number of medications. Falls data were recorded after discharge for 12 months alongside patient reported outcomes (Oxford knee score). Analyses used logistic and negative binomial regression modelling.

Results
There were 267 participants [mean age 70 (6.7) years] enrolled. Participants who fell [n=162 (40.6%)] reported 200 falls in the 12 months after surgery. The incidence of falls was 2.4 falls per 1000 patient days in the 12 months after surgery, with the highest incidence (2.6 falls per 1000 patient days) in month one. Risk factors for falling were a history of falls [AOR 2.41, 95% CI (1.35-4.31)] and number of central nervous system acting medications taken prior to surgery [AOR 1.66, 95% CI (1.25-2.21)]. Using a walking aid at baseline was associated with falls after discharge [AIRR 2.38, 95% CI (1.57-3.60)].
Conclusion

Older adults experience a high incidence of falls after elective TKR. Further research that investigates fall prevention after TKR is required.

*Key words:* patient discharge; accidental falls; knee arthroplasty, total; adverse effects
What is Known
Approximately 30% of older adults fall annually. Substantial growth in the number of elective total knee replacement surgery performed has been reported across countries. There is conflicting evidence about whether older adults have an increased risk of falls after a total knee replacement.

What is New
A prospective cohort study of older adults (mean age 70 years) observed for 12 months after total knee replacement surgery found that 40% of older adults fell once or more with the highest fall rate in the first month after hospital discharge.
Background

Total knee replacements (TKR) are projected to increase in the United States (US) from 1,065,000 in 2020 to 3,416,000 in 2050.\(^1\) Substantial growth in the number of TKR surgery performed has also been reported in Australia and the United Kingdom.\(^2,3\) There is evidence from randomized trials and systematic reviews that a range of rehabilitation programs facilitate patients’ recovery and return to function after undergoing TKR.\(^4-6\) However a recent Australian study that reviewed facility compared with home-based rehabilitation after TKR concluded that private health insurance is the major determinant of whether patients receive inpatient rehabilitation, rather than clinical considerations.\(^7\) Multiple studies strongly suggest it is critical to develop best practice guidelines that direct evidence based, cost effective care.\(^6,7\) Hence it is important to determine what components of care, including specific fall preventive interventions, should be consistently included in such guidelines.

There is conflicting evidence about whether older adults are at increased risk of falls after TKR surgery. A study conducted using a US national joint replacement registry reported no increased risk of falls or fractures in adults following TKR,\(^8\) and a study in China reported that falls rates were significantly reduced in the 12 months after surgery.\(^9\) However a recent systematic review focused on falls after TKR reported the prevalence of falls ranged widely from 6.2% to 42.6%, and older adults are at increased risk of falls after undergoing TKA.\(^10\) In contrast, a second systematic review that evaluated the effect of TKR on balance and incidence of falls reported that TKR significantly improves balance for up to one year after surgery and reduces the incidence of falls.\(^11\) This review concluded that due to methodological flaws of included studies,
the level of evidence was not high enough to allow the generalization of results and robust studies that investigate the effect of TKR on falls incidence are required.11 However none of the studies included in these reviews followed recommended guidelines for conducting falls research such as using a prospective design and a standard definition of a fall, collecting falls data for 12 months and reporting the incidence of falls for the observational period as well as the risk of falling.12 Therefore to address this gap a study that followed recommended guidelines for conducting falls research and only enrolled participants who underwent primary elective TKR surgery was conducted. It was hypothesized that falls rates would be highest in the first three months after surgery.

The primary aim of this study was to determine the incidence of falls in the first 12 months after hospital discharge in older adults who underwent elective primary TKR surgery. Secondary aims were to identify the incidence of injurious falls and risk factors associated with falls in this population.

Methods

Design
A prospective observational cohort study was conducted, with data collection occurring between August 2015 and February 2018. The cohort consisted of participants (n=160) who underwent elective total hip replacement (THR) and participants (n=257) who underwent elective TKR. Results from the TKR cohort are reported in this study, following findings from the THR cohort that have been reported previously.13 Participants were observed for 12 months after their
discharge from hospital. This study conforms to all STrengthening the Reporting of OBservational studies in Epidemiology guidelines and reports the required information accordingly\(^\text{14}\) (see Appendix 1 Supplementary Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/B352) and was designed using the international consensus guidelines for conducting falls related research.\(^\text{12}\) The study was prospectively registered in the Australian Clinical Trials Registry (ACTRN1261500653561) and the study protocol has been published previously.\(^\text{15}\)

Ethics approvals

All participants provided written, informed consent prior to enrolment in the study. The study received ethical approval from university and hospital ethics committees.

Setting and participants

Participants were older adults admitted to a 507-bed tertiary, private hospital in Perth, Western Australia hospital for elective, primary TKR surgery. Patients eligible for inclusion were those aged 60 years or older, who had undergone elective TKR surgery up to one week prior to recruitment, and could understand and speak English. A Short Portable Mental Status Questionnaire\(^\text{16}\) was completed at the time of enrolment and for those participants who scored less than 8/10, family consent was sought for their participation in the study. Exclusion criteria were having revision TKR surgery, residing in a nursing home prior to admission or being unable to provide written informed consent. The setting consisted of orthopaedic wards in the hospital where one of 12 orthopaedic surgeons performed participants’ TKR surgery. All wards had previously established post-surgical care and discharge pathways for TKR and participants
continued with these pathways in hospital and after discharge.

Outcomes

The primary outcome was the rate of participant falls in the 12 months following hospital discharge (number of falls / 1000 patient days). Secondary outcomes were the rate of injurious falls (number of injurious falls / 1000 patient days) and the proportion (number) of participants who experienced one or more falls. The definition of a fall was “an event which results in a person coming to rest inadvertently on the ground, floor or lower level”.17 A fall was classified as injurious if the participant reported resultant bruising, laceration, dislocation, fracture, head injury or complaints of an onset of persistent pain.18

Data Collection

The data collection procedure has been described previously in the published protocol.15 Briefly, eligible patients were approached during admission to assess their interest in participation and subsequently enrolled in the first week following their surgery, but prior to discharge from hospital. There were two research assistants (RA) who were experienced, registered nurses trained by the researchers to undertake all data collection procedures. Demographic information recorded by accessing the medical records included age, gender, date of operation, date of hospital discharge and if the patient went to a rehabilitation facility rather than home. The RA recorded number and type of medications prescribed at admission and discharge and confirmed any changes in medications at discharge when conducting the one month follow-up telephone interview. Participants were also categorized as being prescribed / not prescribed central nervous system acting (CNS) medications (anti-depressants, benzodiazepines, opioids or any
neurological medications such as carbamazepine) or pain-relieving medication [neurological acting pain medications such as pregabalin, non-steroidal anti-inflammatories, non opioids or opioids] prior to surgery or after surgery at point of hospital discharge. Medications were classified using the Australian Medicines Handbook [https://amhonline.amh.net.au]. The RA subsequently administered a series of measurement tools at the bedside. Functional independence immediately prior to hospital admission was measured using both Katz index for activities of daily living (ADL) and Lawton’s index for instrumental activities of daily living (IADL).\textsuperscript{19,20} The Oxford knee score (OKS) was used to measure participants’ perspectives about their knee function immediately prior to surgery.\textsuperscript{21} Other risk factors for falls in community older adult populations were also measured at baseline. These included history of falls in the 12 months prior to surgery, fear of falls measured using the Falls Efficacy Scale – international,\textsuperscript{22} self-reported diagnosis of depressed mood in previous 12 months and diagnosis of visual impairment (glaucoma, untreated cataracts, macular degeneration or diabetic eye disease). Participants’ use of any type of walking aids prior to admission and after their surgery (at point of discharge from hospital) were recorded. Previous studies have identified walking aid use as a risk factor for falls as it is considered a surrogate measure of unsteady gait and balance.\textsuperscript{23} Health-related quality of life (HRQOL) immediately prior to admission was also measured using the EQ-5D-5L tool, including the Visual Analogue Scale (VAS).\textsuperscript{24}

Participants were provided with a diary prior to discharge and given instructions about what constituted a fall and how to record any falls that occurred. Participants who had impaired cognition or a sensory impairment (e.g. decreased vision), were able to have their nominated next of kin or family assist them to keep their diary and respond to telephone calls. Participants
were subsequently contacted by telephone each month for 12 months, and using recommended questioning, asked if they had sustained any falls. The RA collected information during each phone call about the circumstances of any fall reported, including time of day, location, whether there were any injuries and if the participant received any medical attention following the fall. The diary and telephone call data were used as a means of cross checking falls information, with both forms of data collections contributing to the falls circumstances. For example, if the participant reported by phone a detail that was not in the diary, the RA discussed this to verify, then included it in the data set.

Statistical analysis

The incidence of falls (primary outcome) and injuries related to falls were expressed as an incidence rate of falls (number of falls per 1000 patient days) and incidence rate of injurious falls (number of injurious falls per 1000 patient days). The number of participants (proportion of participants who experienced one or more falls during the observation period) and injurious falls (a fall that resulted in one or more injuries) were also reported. Patients who fell were also characterized as single or multiple fallers. Patient baseline characteristics were summarized using descriptive statistics [frequency distributions for categorical data and means and standard deviations or medians and interquartile ranges (IQR) for continuous data]. Categorical comparisons were undertaken using Chi squared or Fisher Exact tests, as appropriate. Continuous data were compared using t tests or non-parametric Mann-Whitney U tests, depending on normality. For all models, univariately significant risk factors and other known risk factors for falls were entered into multivariable regression models. Univariable and clinical
characteristic risk factors of single and multiple falls in the 12 months after discharge. Logistic regression results were summarized using odds ratios (OR) and corresponding 95% confidence intervals (CI). Variables entered in the models were history of falls or depression in the past 12 months, using a walking aid, CNS or pain medication prescription at baseline and discharge, health related quality of life, the OKS prior to surgery and length of stay in hospital (see eTable 4 Supplementary File, Supplemental Digital Content 2, http://links.lww.com/PHM/B353). Univariable negative binomial regression models were performed to identify patient and clinical characteristic risk factors associated with fall counts. Negative binomial regression results were summarized using risk ratios (RR) and 95% CIs. Univariable Cox proportional hazard regression models were performed to identify patient and clinical characteristic risk factors of time to first fall. Cox regression results were summarized using hazard ratios (HR) and 95% CIs. Kaplan-Meier survival probabilities were used to plot time to first fall between single or multiple faller, history of falls, use of walking aids and any baseline CNS or pain medications. Results were summarized using median and 95% CIs days to first fall and compared using log rank tests. All analyses were performed using Stata 16 (Stata Statistical Software, College Station, TX: StataCorp LLC).

Sample size
The study sample size for the cohort (n=267) was powered to estimate the Poisson parameter to within 11% of its true value using a 5% significance level. This was calculated by assuming there would be approximately 328 falls (1.23 falls/person year) if the present study was consistent with a previous study that reported the falls rate of a post hospital discharge older population.18
Results

Participants’ flow through the study is presented in Supplementary eFigure 1 (Supplemental Digital Content 2, http://links.lww.com/PHM/B353). There were 267 older adults enrolled into the study, of whom 251 (94%) were included in the final analysis. There were 227 (85%) participants who provided falls data for all 12 months of the study. Of the 26 (10.35%) participants who reported post-operative complications, 16 (6.37%) participants reported an infection in the operated joint: of these eight were hospitalized for treatment and eight received antibiotics from their community doctor. Six (2.39%) other participants were hospitalized for a manipulation of the TKA under anesthesia. No deaths were reported during the observation period.

Characteristics of the cohort are presented in Supplementary eTable 1 (Supplemental Digital Content 2, http://links.lww.com/PHM/B353). Briefly, participants’ mean age was 70.1 (6.7) years. Sixty-one (24.3%) participants received assistance with IADL such as gardening or shopping. In the 12 months prior to undergoing TKR 28.3% of participants reported they experienced one or more falls. The mean (SD) baseline OKS for the cohort was 24.57 (7.26). Participants stayed a median (IQR) of 5 (4-6) days in hospital and 37 (14.7%) participants were transferred onwards to a rehabilitation facility rather than to home after discharge.

Falls and injurious falls outcomes are presented in Table 1 and the monthly rate of falls is presented in Figure 1. Falls rates were highest in the first month after discharge (2.6/1000 patient days) and the rate declined rapidly after month five to less than 0.5/1000 patient days. There
were 200 falls of which 123 (61.5%) were injurious. Six (2.3%) participants sustained a fracture [wrist (2), shaft of femur (1), finger (1), toe (1), ribs (1)]. Cumulative falls are presented in Supplementary eFigure 2 and eTable 2 (Supplemental Digital Content 2, http://links.lww.com/PHM/B353), demonstrating that 52.5% of all falls occurred by the end of month five.

Group comparisons of fallers [n=102, (40.64%)] and non-fallers [n=149, (59.36%)] are presented in eTable 3 (Supplemental Digital Content 2, http://links.lww.com/PHM/B353). A greater proportion of those who fell after surgery had a history of falls in the 12 months prior to TKR (fallers 40.2%, non-fallers 20.1%; p=0.001) and used a walking frame prior to surgery (fallers 39.2, non-fallers 21.5%; p=0.002).

Univariable logistic regression for the outcomes of the risk of falling once or more and negative binomial regression for the outcome of falls are presented in Supplementary eTable 4 and eTable5 (Supplemental Digital Content 2, http://links.lww.com/PHM/B353), respectively. Univariable analysis found that using a walking aid, history of falls, CNS medications, OKS prior to surgery, HRQOL and LOS in hospital were significantly associated with falling (see eTable 4, Supplemental Digital Content 2, http://links.lww.com/PHM/B353). However final multivariable modelling (presented in Table 2) demonstrated that risk factors for falling were a history of falls and the number of CNS acting medications prescribed prior to surgery.

Participants’ time to first fall is presented in Supplementary eFigure 3 (Supplemental Digital Content 2, http://links.lww.com/PHM/B353). Participants who had multiple falls (see Figure 2)
or a history of walking aid use or were prescribed CNS medications prior to surgery fell significantly earlier in the observation period (see eTable 6, Supplemental Digital Content 2, http://links.lww.com/PHM/B353).

Discussion

These findings from a prospective cohort study demonstrate that older adults who undergo elective primary TKR surgery experienced a high falls incidence of 2.39 per 1000 person days (0.9 per person year) in the 12 months after hospital discharge. Fall rates were highest in the first three months after discharge, in particular in the first month (2.6 per 1000 person days). There was also a high injury rate, with over 60% of falls resulting in one or more injuries. Rates dropped rapidly after month three and remained below 0.5 per 1000 person days for the last seven months of observation. These results contrast sharply with a previous study using a large national database that reported no increased risk of falls after surgery and two studies (one a systematic review) that reported a reduction in falls after TKR surgery. However falls events in those studies were not collected using prospective monthly reporting. Results contrast with recently published falls incidence data after elective THR surgery. In the THR cohort falls rates peaked at month five after surgery and continued to be elevated through to month 12, suggesting that timing of delivery of any fall preventive interventions may require different emphasis for these two populations.

The proportion of participants who fell in our cohort (40%) is at the upper end of the prevalence range reported (6.2% to 42%) in a systematic review. However these results were determined
to be low grade evidence because the five synthesized studies had methodological limitations.\textsuperscript{10} Additionally, both systematic reviews included studies that investigated unilateral, bilateral and revision TKR,\textsuperscript{10,11} making it difficult to generalise these findings to the specific population of elective primary TKR surgery. The present study is the first to the authors’ knowledge to prospectively measure and report falls prevalence in an elective primary TKR population using a recommended falls definition, monthly follow up and patient diaries to aid accurate recall.\textsuperscript{12}

Number of medications prescribed prior to surgery, OKS at baseline and LOS in hospital were significantly associated with falling once or more in univariable models. However the only fall risk factors identified in multivariable models were taking CNS acting medications, using a gait aid and a history of falls, which are all established risk factors for falling in older adult populations.\textsuperscript{23,25,26,27} A history of falls was also identified as a risk factor for falling in two other TKR studies.\textsuperscript{28,29} Taking CNS acting medications that included benzodiazepines, opioids and neurological drugs increased fall risk by over 60\%, however only baseline (pre-surgery) use of CNS active medications was independently associated with post-surgical falls, rather than post-surgical prescription of these medications. Univariable risk factors for the outcome of falls were LOS in hospital, being discharged to a rehabilitation unit after hospitalization and living alone. However the only fall risk factors identified in final adjusted modelling were taking CNS acting medications and using a gait aid. These findings suggest that conducting a fall risk assessment prior to surgery\textsuperscript{25} and providing tailored interventions is important for this population.

Overall findings suggest that participants’ fall risk increased post TKR. Impaired strength, balance and gait are significant predictors of falls and there is evidence that older adults
experience significant declines in lower limb strength and balance after TKR. Additionally, pre-operative risk factors were present in some participants. Established national guidelines recommend that all older adults over 65 years of age be screened annually by their physician for fall risk, recognising that the older adult may not initiate a discussion about falls. Further research should investigate whether prehabilitation programs should routinely include fall risk screening and management and how strength and balance training (which is known to reduce falls) should be managed during post TKR rehabilitation. Other studies also recommend that older adults’ fall risk be addressed as part of TKR rehabilitation. A recent systematic review regarding rehabilitation after TKR identified that it is important that an evidence-based clinical practice guideline for TKR rehabilitation that aligns practice with the most up-to-date evidence is developed.

There were low numbers of adverse events reported during the 12 months of observation, with approximately 6% of participants being diagnosed with a post-operative infection that required treatment, but no revisions required. Outputs from joint registries demonstrates the long term success of TKR surgery with less than a 5% risk of revision. Falls data were prospectively collected for a large patient cohort for 12 months after TKA surgery, with only 6% of participants lost to follow-up. A key strength of the study was that it was conducted following recommended procedures for falls research, including using prospective daily recording of falls events, monthly follow up, and simultaneous collecting and reporting falls data related to injuries. Findings are broadly generalizable to other populations undergoing elective, primary TKR surgery. Patients who underwent revision or partial surgery were excluded and our cohort [mean age 70 (±6.7) years] is similar to large population-based registries that report mean ages
ranging from 66 to 69.7 years.\textsuperscript{2,3} Limitations included that while measured some predictive fall risk factors at baseline were measured, participants were not recalled for face-to-face follow up after surgery. Therefore post-surgical measures of balance and strength were not completed and these outcomes have been found to decline after TKR surgery.\textsuperscript{30} These factors are known to influence postural control and falling after TKR surgery\textsuperscript{9,28} and in the general older population.\textsuperscript{25} Data on participants’ engagement in post-operative rehabilitation were not collected. Rehabilitation post TKR has been found to improve strength and balance\textsuperscript{30} and therefore may have reduced participants’ fall risk.

Conclusion

Elective primary TKR is associated with a high prevalence of falls with 40% of older adults falling once or more in the 12 months after surgery. Falls rates were highest in the first three months after surgery, compared with later in the post-operative period. Further studies are required to determine what interventions reduce falls and injury in this population and how they may be effectively included in rehabilitation pathways.
References


7. Naylor JM, Hart A, Harris IA, Lewin AM. Variation in rehabilitation setting after


**Figure Legends.**

**Figure 1.** Falls rates in 12 months after discharge

**Figure 2.** Participants’ time to first fall: single compared to multiple fallers
Figure 1. Falls rate per month post-discharge
Figure 2

Kaplan–Meier curve: time to first fall by single/multiple fallers

- Single fall
- Multiple falls
Table 1. Falls outcomes in the 12 months after surgery

<table>
<thead>
<tr>
<th>Outcomes in 12 months after surgery</th>
<th>n=251</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falls/injurious falls/fractures, n</td>
<td>200/123/6</td>
</tr>
<tr>
<td>Fallers, n [%]</td>
<td>102 [40.64]</td>
</tr>
<tr>
<td>Falls, rate per 1000 patient days&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.39</td>
</tr>
<tr>
<td>Injurious falls, rate per 1000 patient days</td>
<td>1.47</td>
</tr>
<tr>
<td>Falls per participant, n [%]</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>58 [23.11]</td>
</tr>
<tr>
<td>2</td>
<td>25 [9.96]</td>
</tr>
<tr>
<td>3</td>
<td>9 [3.59]</td>
</tr>
<tr>
<td>4</td>
<td>3 [1.20]</td>
</tr>
<tr>
<td>≥ 5</td>
<td>7 [2.78]</td>
</tr>
<tr>
<td>Injury&lt;sup&gt;b&lt;/sup&gt; severity, n [%]</td>
<td></td>
</tr>
<tr>
<td>Mild [bruise, graze, pain]</td>
<td>173 [79.73]</td>
</tr>
<tr>
<td>Moderate [laceration, head injury, dislocation]</td>
<td>38 [17.51]</td>
</tr>
<tr>
<td>Severe [fracture]</td>
<td>6 [2.76]</td>
</tr>
</tbody>
</table>

<sup>a</sup> Total days of participant observation in the 12 months after surgery = 83,551

<sup>b</sup> All injuries resulting from falls in the 12 months after surgery; some participants sustained more than one injury from a fall
Table 2. Adjusted multivariable models for falls outcomes

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>Risk of Falling</th>
<th>Falls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AOR(^a) 95%CI</td>
<td>p</td>
</tr>
<tr>
<td>History of falls in 12 months prior to surgery</td>
<td>2.41 1.35 - 4.31</td>
<td>0.003</td>
</tr>
<tr>
<td>Use of walking aid prior to surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of CNS medications prior to surgery</td>
<td>1.66 1.25 - 2.21</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prescribed CNS medications prior to surgery</td>
<td>1.99 1.33 – 3.00</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Note. AOR = adjusted odds ratio, CI = confidence interval, AIRR = adjusted incident rate ratio, CNS = central nervous system

\(^a\) univariable risk factors that were not significant in the final multivariable models are presented in supplementary file eTables 4 and 5.

\(^b\) Logistic regression

\(^c\) Negative binomial regression

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