The impact of frailty on the utilisation of antithrombotic therapy in older patients with atrial fibrillation

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Abstract

Objective: to investigate the impact of frailty on the utilisation of antithrombotics and on clinical outcomes in older people with atrial fibrillation (AF).

Design: prospective study of a cohort of 220 acute inpatients aged ≥70 years with AF, admitted to a teaching hospital in Sydney, Australia (April–July 2007), with 207 followed up over 6 months.

Results: a total of 140 patients (64%) were identified as frail using a validated tool. Frail patients were less likely to receive warfarin than non-frail on hospital admission (P = 0.002) and discharge (P < 0.001). During hospitalisation, the proportion of frail participants prescribed warfarin decreased by 10.7% and that of non-frail increased by 6.3%. Over the 6-month follow-up, 43 major or severe haemorrhages (20.8%), 20 cardioembolic strokes (9.7%) and 40 deaths (19.2%) were reported. Compared to non-frail, frail participants were significantly more likely to experience embolic stroke (RR 3.5, 95% CI 1.0–12.0, P < 0.05), had a small non-significant increase in risk of major haemorrhage (RR 1.5, 95% CI = 0.7–3.0, P = 0.29) and had greater mortality (RR 2.8, 95% CI 1.2–6.5, P = 0.01).

Conclusion: frail older inpatients with AF are significantly less likely to receive warfarin than non-frail and appear more vulnerable to adverse clinical outcomes, with and without antithrombotic therapy.

Keywords: atrial fibrillation, antithrombotic, aged, haemorrhage, stroke, death, frailty, elderly

Background

Atrial fibrillation (AF), the commonest arrhythmia in clinical practice, is most prevalent in those aged over 70 years and predisposes individuals to cardioembolic stroke [1]. Warfarin therapy significantly reduces the risk of cardioembolic stroke in patients with AF of all ages [2]. A major adverse effect of warfarin is haemorrhage, with the risk heightened in older adults [3]. Consequently, clinicians may be reluctant to prescribe warfarin to older patients [4]. While older adults with AF are at the highest risk of stroke, studies consistently report the underuse of oral anticoagulants in older patients with AF [4]. Clinician surveys have cited a high risk of falls, cognitive impairment and poor patient adherence among the many factors contributing to warfarin non-prescription [5]. Current risk schemes have limited ability to predict thromboembolism in persons with AF [6]. Identification of the patients who are most vulnerable to haemorrhage and/or cardioembolic stroke may assist clinicians in the decision to prescribe warfarin.

There is a disparity between the rates of haemorrhage reported in clinical trials and clinical practice. Pooled results from primary and secondary stroke prevention trials suggest that the annual rates of major haemorrhage secondary to warfarin or aspirin are 1.8% and 1.4% respectively [2]. A recent randomised clinical trial in older patients with AF reported that the annual rates of major haemorrhage were 1.9% with warfarin and 2.2% with aspirin [7]. However, observational studies of warfarin in older patients with AF record annual major haemorrhage rates of 8–13% [3, 8]. This disparity suggests that a particular sub-population of older patients may be more susceptible to major haemorrhage with warfarin therapy. We hypothesise that this population may be ‘frail’ older adults.

As the population ages, the prevalence and clinical importance of frailty are increasing. Frailty is a state of vulnerability that carries an increased risk of poor outcomes in older adults [9]. Recently, several objective tools have been developed to define frailty [9–11], facilitating studies of the physiologic
changes and clinical outcomes associated with frailty [12, 13]. In older patients with AF, frailty assessment may guide prescribing of antithrombotics and may help clinicians identify patients who are at increased risk of adverse outcomes from AF and/or antithrombotic therapy.

This study aims to investigate the relationship between frailty and antithrombotic utilisation among older patients with AF in an acute-care clinical setting. A secondary aim is to assess the association of frailty with clinical outcomes associated with AF and its treatment (cardioembolic stroke, haemorrhage and death) over 6 months.

Methods

A prospective observational study was performed on a cohort of patients aged ≥70 years with AF admitted to Royal North Shore Hospital, a teaching hospital in Sydney, Australia, between April 2007 and July 2007 (11 weeks). The study was approved by the institutional human research ethics committee.

Patients were eligible to participate if they were aged ≥70 years and diagnosed with AF (paroxysmal or persistent). Exclusion criteria were inability to communicate in English, severe illness, severe cognitive impairment and severe hearing or visual impairment. Eligible patients were identified daily from the study wards (aged care, cardiology and general medicine) and invited to participate. Prior to enrolment, patients (or their caregivers) were asked to sign two consent forms: one for the initial interview and medical records review; the other to receive follow-up telephone calls 3 and 6 months after recruitment.

Baseline data collected from inpatient/caregiver interviews and medical records included sociodemographics, clinical characteristics (haemorrhage and stroke risk factors, current medication and medical history), antithrombotic therapy prescribed on admission and discharge and clinical outcomes. The reported version of the Edmonton Frail Scale (adapted from [11]), Mini-Mental State Examination (MMSE) [14], Charlson Comorbidity Index (CCMD) [15] and Katz Daily Activity Living Scale [16] were performed to assess frailty, cognition, co-morbidities and disability respectively. The Edmonton Frail Scale [11] has been validated for assessment of frailty by non-medically trained researchers. To avoid confounding by the effects of acute illness, the reported Edmonton Frail Scale substitutes the observed ‘get up and go’ with a self-report of function 2 weeks prior to admission. Reports of function were taken from three Rosow–Breslau items [17]: walking up- and downstairs, walking half a mile and doing heavy housework, which correlate well with observed function [18].

Three and six months after enrolment, participants or their caregivers were contacted by telephone and asked to report haemorrhages, strokes or death. When participants or caregivers could not be contacted attempts were made to contact general practitioners and hospital medical records were assessed for outcomes during subsequent hospital admissions. Loss to follow-up was recorded for participants/caregivers who were uncontactable and had no medical records beyond recruitment. Stroke was classified as cardioembolic or other. Episodes of haemorrhage were classified as minor (self-inflicted cuts or other bleeding/bruising that did not require hospitalisation), major (internal bleeding, excluding intracerebral bleeds or bleeding/bruising requiring hospitalisation) or severe (intracranial or fatal haemorrhage) based on definitions from studies of antithrombotics in similar cohorts [8].

Data analysis

Based on previous studies, detection of a significant difference between frail and non-frail participants at a power of 80% and $\alpha = 0.05$ required 65 participants in each arm to detect a difference in warfarin prescription [5] and 140 in each arm to detect a difference in haemorrhage and stroke rates [2, 3, 7].

Data were analysed using SPSS version 15.0.1 (SPSS Inc., Chicago, IL, USA). All significance tests were two sided, and a $P$-value of <0.05 was considered statistically significant. Categorical data were analysed using chi-square tests and binary logistic regression. To maximise the power, the frailty scale was collapsed into two groups, frail and non-frail [19]. Relative risk (RR) and 95% confidence intervals (CI) were calculated to determine whether frailty was significantly associated with haemorrhage, stroke or death. To compare the time to event rate (major/severe haemorrhage, stroke or death) in frail and non-frail participants, the Kaplan–Meier estimator was employed to compute survival curves over the 6 month follow-up period (at two weekly intervals), and differences between frail and non-frail groups assessed using log rank tests. Follow-up rates are reported over 6 months. Logistic regression analysis to identify predictors of warfarin prescription (on admission and discharge) considered warfarin, another antithrombotic or no antithrombotic therapy as outcome variables. Logistic regression analysis to identify predictors of clinical outcomes considered the presence or absence of incident major/severe haemorrhage, stroke or death over 6 months as outcome variables. All logistic regression models incorporated the same variables (Appendix 1, available on Age and Ageing online). Haemorrhage and stroke risk factors were based on variables from haemorrhage (HEMORR2HAGES) and cardioembolic stroke risk (CHADS2) stratification schemes, which synthesise the evidence available from randomised controlled trials [20, 21]. Falls risk was determined using the Ontario Stratify risk assessment tool [22]. Patients lost to follow-up were included in the analyses of prescription patterns and excluded from 6-month outcome analyses.

Results

Of the 236 patients screened, 220 were enrolled and 13 were lost over the 6-month follow-up (Figure 1A). The mean age of the study population was 82.7 ± 6.3 years. Compared to
non-frail participants, frail participants were older, were prescribed more medications, used less complementary medicines, had a lower level of education, were less well nourished and were more likely to use dentures and to reside in residential aged care (Appendix 2, available on Age and Ageing online).

Frail patients were significantly less likely to utilise warfarin (compared with other antithrombotics or no antithrombotic therapy) than non-frail patients on admission (P = 0.002) and discharge (P < 0.001). These findings were consistent amongst patients admitted to the geriatric medicine, general medicine and cardiology services. During hospitalisation, the proportion of frail patients prescribed warfarin decreased by 10.7% and the proportion of non-frail patients prescribed warfarin increased by 6.3% (Figure 2A). The likelihood of being admitted to and discharged from hospital on warfarin decreased by 2.9 times (95% CI 1.5–6.0) and 8.6 times (95% CI 4.3–17.5) respectively if the patient was frail (Table 1).

Thirteen participants were lost to follow-up (three were discharged on warfarin, nine on other antithrombotic therapy and one on no antithrombotic therapy) and were excluded from the analyses of outcomes. The majority of haemorrhages (major or severe) occurred in patients utilising warfarin, while the majority of strokes occurred in patients who were not prescribed antithrombotic therapy (Figure 1B). Figure 2B shows the incidence of haemorrhage, stroke and death stratified by frailty over 6 months.

Forty-three major or severe haemorrhages were recorded. The incidence of major or severe haemorrhage over 6 months was 20.8%: 23.0% in the frail group and 16.9% in the non-frail (Figure 2B, RR = 1.5, 95% CI 0.7–3.0, P = 0.29). Subgroup analysis by antithrombotic utilisation (Figure 1B) found that the incidence of major/severe haemorrhage over 6 months was 30.0% in the frail and 18.9% in the non-frail participants prescribed warfarin: 25.0% for frail and 13.6% for non-frail participants receiving aspirin/other antithrombotic therapy, and 8.3% for frail and 0% for non-frail participants receiving no antithrombotic therapy. The Kaplan–Meier survival function indicates that over 6 months, frail participants seemed to have an elevated risk of suffering a major/severe haemorrhage, compared to non-frail, but the difference was not statistically significant [hazard ratio (HR) = 1.35, P = 0.34] (Appendix 3a, available on Age and Ageing online). Frailty was not a significant independent predictor of major/severe haemorrhage incidents on follow-up using forward stepwise logistic regression (Table 1).

Cardio-embolic strokes occurred in 9.7% of participants overall: 12.3% of the frail group and 3.9% of the non-frail (Figure 2B, RR = 3.5, 95% CI 1.0–12.0, P < 0.05). The small number of strokes (n = 20) did not allow a comparison by antithrombotic medication utilisation. The Kaplan–Meier survival function indicates that over 6 months, frail participants had a higher probability of suffering a cardioembolic stroke than non-frail (HR = 3.37, P = 0.04) (Appendix 3b, available on Age and Ageing online). On forward stepwise
logistic regression, frailty was the variable most strongly associated with cardioembolic stroke ($P = 0.06$, Table 1).

Forty (19.2%) participants died over the 6-month follow-up: 24.6% in the frail cohort and 10.4% in the non-frail (Figure 2B, RR = 2.8, 95% CI 1.2–6.5, $P = 0.01$). The Kaplan–Meier survival function indicates that over 6 months, frail participants had a higher probability of death than non-frail (HR = 2.62, $P = 0.009$, Appendix 3c, available on Age and ageing online). Forward stepwise logistic regression demonstrated that frailty did not predict death, but that disability did ($P = 0.03$, Table 1).

**Discussion**

Frailty was the strongest predictor of the type of antithrombotic medication prescribed to older patients with AF on discharge from a tertiary referral hospital. Frail participants were significantly less likely to receive warfarin than non-frail on admission and discharge. After 6 months, frail participants were significantly more likely to die or to have an embolic stroke and appeared to have higher rates (not statistically significant) of major/severe haemorrhage.

During hospitalisation, warfarin utilisation decreased by 10.7% in frail participants and increased by 6.3% in non-frail participants. The prevalence of warfarin utilisation in discharge in this cohort was 39%, which is consistent with warfarin utilisation rates reported previously [5, 23]. The Edmonton Frail Scale adapted for use in our study correlates moderately well with the Clinicians Global Impression of Frailty [11]. This suggests that a physician’s judgement of frailty may deter prescription of warfarin. Previous studies investigating the barriers to warfarin prescription have found that high risk of falls, history of bleeding, impaired cognitive status, increasing co-morbidities and decreased patient adherence are negatively correlated with warfarin prescription [5]. Interestingly, there is very little evidence that some of these factors, including predisposition to falls and recently resolved peptic ulcer bleeding (with Helicobacter pylori testing and treatment), increase the chance of anti-coagulant-related major bleeding [24]. While the previously reported barriers to prescribing warfarin were significantly associated with frailty, in our study, frailty itself was more strongly associated with prescription of warfarin on discharge (Figure 2A and Table 1). Definitions of frailty include age, nutritional deficits [25], decreased mobility [10, 18], disease [9, 12, 26], social withdrawal [26], poor income [11], number of hospitalisations [11, 26] and cognitive impairment [9, 11]. Frailty is more strongly associated with a reduced capacity to withstand environmental stresses and an increased risk of adverse events than any single condition [26, 27].

The 6-month incidences of major/severe haemorrhage, stroke and death were high in our cohort, with the frail group experiencing a small non-significant increase in the risk of haemorrhage and a significantly increased risk of stroke and death, compared to the non-frail (Figure 2B). The 6-month major/severe haemorrhage rate of 21% is, to our knowledge, the highest reported for a study of older people with AF. The overall 6-month stroke rate was 9.7%: 3.3% in participants prescribed warfarin, 8.1% in participants on other antithrombotic therapy and 30.8% in those on no antithrombotic therapy. A meta-analysis of primary stroke prevention trials in patients with AF found annual stroke rates of 3.4% and 6.5% for patients prescribed warfarin and aspirin respectively [2]. In this observational study, participants had more advanced age, frailty and co-morbidities and probably poorer adherence and monitoring than participants in randomised clinical trials [28]. The high rates of haemorrhage, stroke and death observed in this cohort may also be due to their post-acute hospitalisation status and to seasonal bias, with recruitment over autumn and winter [27]. Furthermore, the definition of major haemorrhage used in our study may be broader than definitions used in studies of comparable populations [3, 8].
The association of frailty with disability, which was strongly correlated with death (Table 1), is consistent with previous studies [26].

Our study has several important strengths. The participants in this study are highly representative of an older inpatient cohort with AF in clinical practice, due to the broad inclusion criteria, 93% recruitment rate and 94% follow-up rate. Validated scales were used to measure frailty, cognition, disability and co-morbidities. Our study also has several limitations. Generalisability may be limited by the recruitment of all patients from one tertiary referral hospital. However, the association between frailty and prescription of warfarin was consistent across three distinct clinical services; geriatric medicine, general medicine and cardiology. The reliability and validity of the outcome data may be compromised by interview, memory and phone call biases. The study was powered to detect significant differences in the prescription of antithrombotic medications with frailty, but not to detect differences in outcomes between frail and non-frail groups, or between participants receiving different therapies. The vast difference in the utilisation of antithrombotic medications among the frail and non-frail populations limits the accuracy of conclusions about the impact of frailty on outcomes. The models for utilisation of warfarin and for clinical outcomes predicted less than one-third of the variability in these events, which confirms that there are many other poorly described factors that explain inter-individual variability in old age [29].

**Conclusion**

Frailty was highly negatively correlated with warfarin prescription in this cohort of older inpatients with AF. After 6 months, frail participants were significantly more likely to have an embolic stroke and to die than non-frail participants, and it appeared that frail participants had a higher probability of experiencing a major or severe haemorrhage, which was not statistically significant.

A large prospective cohort study enrolling equivalent numbers of frail and non-frail older patients with AF, with similar numbers utilising warfarin, other antithrombotics and no antithrombotic therapy, would provide further information on the role of frailty in response to therapy and clinical outcomes. This is important, given the ongoing uncertainties in clinical practice regarding the appropriateness of antithrombotic medication in older patients with AF.

**Key points**

- In older adults, frailty, a multidimensional state of increased vulnerability, may be associated with prescribing of antithrombotics and clinical outcomes.
- In a cohort of acute hospital inpatients aged ≥70 years with AF, frailty was strongly negatively associated with prescription of warfarin.
- Over 6 months of follow-up, this cohort reported a rate of major or severe haemorrhage of 21%, thrombo-embolic stroke of 10% and death of 19%.
- Compared to the non-frail participants, the frail participants had a small non-significant increase in the rate of major or severe haemorrhage, and significantly higher rates of stroke and death.

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**Table 1. Logistic regression analyses illustrating the combinations of factors that may predict the utilisation of warfarin on admission to and discharge from hospital, and those that predict a major/severe haemorrhage, cardioembolic stroke and death**

<table>
<thead>
<tr>
<th>Variables in model</th>
<th>Exp(B)</th>
<th>95% CI for Exp(B)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Utilisation of warfarin</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Admission ($R^2 = 0.31$)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Frailty (yes)</td>
<td>0.34 (0.17 − 0.68)</td>
<td>0.002</td>
<td></td>
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<tr>
<td>Increasing number of medications</td>
<td>1.18 (1.06 − 1.31)</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>Previous bleed with aspirin (yes)</td>
<td>2.85 (1.46 − 5.59)</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>Previous bleed with warfarin (yes)</td>
<td>0.28 (0.12 − 0.66)</td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td>Congestive heart failure (yes)</td>
<td>2.09 (1.05 − 4.16)</td>
<td>0.04</td>
<td></td>
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<tr>
<td>Increasing albumin concentration</td>
<td>1.07 (1.00 − 1.15)</td>
<td>0.04</td>
<td></td>
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<tr>
<td>Discharge ($R^2 = 0.30$)</td>
<td></td>
<td></td>
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<tr>
<td>Frailty (yes)</td>
<td>0.12 (0.06 − 0.23)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Increasing number of medications</td>
<td>1.14 (1.03 − 1.27)</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Herbal medication use (yes)</td>
<td>2.23 (1.08 − 4.62)</td>
<td>0.03</td>
<td></td>
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<tr>
<td><strong>Outcome at 6 months</strong></td>
<td></td>
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<tr>
<td>Haemorrhage ($R^2 = 0.32$)</td>
<td></td>
<td></td>
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<tr>
<td>Reduced platelet count (yes)</td>
<td>11.13 (1.78 − 69.67)</td>
<td>0.01</td>
<td></td>
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<tr>
<td>History of alcohol abuse (yes)</td>
<td>6.83 (1.14 − 40.82)</td>
<td>0.04</td>
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<tr>
<td>Previous bleed with warfarin (yes)</td>
<td>4.96 (1.02 − 5.12)</td>
<td>&lt; 0.01</td>
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<tr>
<td>Warfarin utilisation on admission (yes)</td>
<td>2.70 (1.71 − 6.22)</td>
<td>0.02</td>
<td></td>
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<tr>
<td>Stroke ($R^2 = 0.05$)</td>
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<td></td>
<td></td>
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<tr>
<td>Frailty (yes)</td>
<td>3.39 (0.95 − 12.02)</td>
<td>0.06</td>
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<tr>
<td>Death ($R^2 = 0.18$)</td>
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<td></td>
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<tr>
<td>Sex (male)</td>
<td>3.15 (1.44 − 6.86)</td>
<td>0.004</td>
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<tr>
<td>Anaemia (yes)</td>
<td>3.10 (1.33 − 7.24)</td>
<td>0.009</td>
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<tr>
<td>Katz disability score &gt;5</td>
<td>1.86 (1.08 − 3.22)</td>
<td>0.03</td>
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<tr>
<td>Nationality (Caucasian)</td>
<td>0.69 (0.48 − 0.98)</td>
<td>0.04</td>
<td></td>
</tr>
</tbody>
</table>

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a Binary logistic regression (forward stepwise) was conducted using warfarin or other (including other antithrombotic therapy or no antithrombotic therapy) as the two outcomes.

b Binary logistic regression (forward stepwise) was conducted using major or severe haemorrhage/no haemorrhage, cardioembolic stroke/no stroke and death/no death as the two outcomes in the respective analysis.

Nagelkerke $R^2$ is reported for each analysis. Variables from Appendix 1 (available on *Age and Ageing* online) were included in analysis. Reference categories for variables indicated in parentheses.

Exp(B), exponential beta.
Frail older patients with AF appear to be more vulnerable to adverse clinical outcomes with and without antithrombotic therapy.

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Conflicts of interest

None declared.

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Supplementary data

Supplementary data are available online at http://www.ageing.oxfordjournals.org/.

References

Poor vision accompanied with other sensory impairments as a predictor of falls in older women

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Abstract

Objectives: we studied visual acuity (VA) and co-existing hearing impairment and poor standing balance as predictors of falls.

Design: prospective study with 1-year follow-up.

Setting: research laboratory and residential environment.

Participants: 428 women aged 63–76 years from the Finnish Twin Study on Aging.

Measurements: participants were followed up for incidence of falls over 1 year. VA, hearing ability and standing balance were assessed at the baseline. The incidence rate ratios (IRR) for falls were computed using the negative binomial regression model.

Results: during the follow-up, 47% of participants experienced a fall. After adjusting for age and interdependence of twin sisters, participants with vision impairment (VA of < 1.0) but no other sensory impairments had a higher, but non-significant, risk for falls compared to persons with normal vision (IRR 1.5, 95% CI 0.6–4.2). Co-existing vision impairment and impaired balance increased the risk (IRR 2.7, 95% CI 0.9–8.0), as also did co-existing vision and hearing impairment (IRR 4.2, 95% CI 1.5–11.3), compared to those with normal vision. Among persons with all three impairments, the IRR for falls increased to 29.4 (95% CI 5.8–148.3) compared to participants with good vision.

Conclusion: the impact of vision impairment on fall risk was higher when accompanied with other sensory and balance impairments, probably because the presence of other impairments prevented the reception of compensatory information about body posture and environment being received from other sensory sources. When aiming to prevent falls and their consequences in older people, it is important to check whether poor vision is accompanied with other impairments.

Keywords: falls, vision, co-impairment, older adults, ageing, elderly