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Does vitamin D stop inpatients falling? A randomised controlled trial

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Abstract

Background vitamin D deficiency is common in older people and may increase risk of falls and fracture. Hospital inpatients are at particular risk of falling. Previous studies suggest that vitamin D improves neuromuscular function and reduces falls.
Objective to determine whether routine supplementation with vitamin D plus calcium reduces numbers of fallers and falls in a cohort of hospital admissions while they are inpatients.
Design randomised, double-blind, controlled study.
Participants two hundred and five acute admissions >65 years to a geriatric medical unit.
Methods patients were randomised to intervention of daily vitamin D 800 iu plus calcium 1,200 mg or control group of daily calcium 1,200 mg, until discharge or death.
Results baseline characteristics were similar in both groups with a median age 84 years and a median length of stay = 30 days (IQR 14.75–71.00). In a pre-selected sub-group (54/205 participants), median admission vitamin D level = 22.00 nmol/l (IQR 15.00–30.50). This did not significantly increase in the treatment versus control group. Median study drug adherence = 88%, with no significant difference between study groups (Mann–Whitney: $P = 0.711$). Although there were fewer fallers in the vitamin D cohort, this did not reach statistical significance (vitamin D: calcium = 36:45 fallers; RR 0.82 (CI 0.59–1.16). Neither the mean number of falls (vitamin D: calcium = 1.040:1.155; Mann–Whitney $P = 0.435$) or time to first fall (Log-rank test $P = 0.377$) differed between groups.
Conclusions in a population of geriatric hospital inpatients, vitamin D did not reduce the number of fallers. Routine supplementation cannot be recommended to reduce falls in this group.

Keywords: *vitamin D, accidental falls, elderly, hospitalisation, randomised controlled trial*

Introduction

Falls are common and can cause considerable distress, minor injuries and fractures as a result [**1**]. Inpatients are at particular risk with the incidence of falls in hospital and nursing homes being almost triple that for community-dwelling older people [**1**]. Despite this, the evidence for effective falls prevention in hospitals, and indeed care homes, is limited [**2–4**].

Vitamin D and calcium supplementation may reduce the incidence of non-vertebral fractures, albeit in selected patient groups [**5, 6**]. In addition, vitamin D is involved in muscle metabolism with receptors identified in muscle tissue amongst others [7]. Deficiency in vitamin D is common in older adults [**8**]. High levels of vitamin D insufficiency have been demonstrated in community [**9**], falls clinic [**10**], general outpatient [**11**], and medical inpatient [**12**] populations. Low vitamin D levels have been significantly correlated with reduced muscle strength [**13**, 14], impaired neuromuscular coordination [**15**], increased falls risk [**16**], and increased body sway [**17**]. Recently published randomised controlled trials have suggested that regular supplementation with vitamin D plus/minus calcium reduces falls perhaps through its influence on neuro-muscular functioning [**15, 17, 18**, 19, **20, 21, 22**]. Other trials have been less positive showing no reduction in falls or fallers with regular vitamin D [**23–25**] although falls reduction was a secondary outcome.

Older geriatric inpatients are likely to be vitamin D deficient and are known to be at significant risk of falling. They have potentially much to gain if vitamin D does indeed reduce the risk of falling. For these reasons, this trial was designed to determine whether vitamin D supplementation has an effective role in falls prevention in older hospital inpatients.

Methods

Design

Prospective, randomised, double-blind, controlled study.

Intervention

Patients meeting trial inclusion criteria, who consented to study participation (in cases of incapacity, the next-of-kin consented in keeping with the Adults with Incapacity Scotland 2000 Act [26]), were randomised using a random numbers table to treatment or control groups. Randomisation was known only to the statistician and pharmacist who subsequently issued an appropriate uniquely numbered drug blister pack to each patient's ward. Thereafter, trained staff nurses administered study drugs as part of routine drug rounds. The researchers, therapists, and patients remained blinded to study drug allocation. Treatment group received a total of 800 iu cholecalciferol plus 1,200 mg calcium carbonate once daily, and the control group received 1,200 mg calcium carbonate only once daily. The intervention was continued until time of patient discharge or death. There were no other differences to patients' usual care throughout their inpatient stay.

Participants

Patients newly transferred or admitted into the general assessment and rehabilitation wards in an acute geriatric unit were screened for eligibility for trial entry. All patients were aged 65 years or over. Exclusion criteria included known hypercalcaemia, urolithiasis or, renal dialysis therapy. Patients who were terminal or bed-bound with a reduced Glasgow Coma Scale (GCS), those already prescribed calcium and vitamin D supplements, and those who were deemed 'nil by mouth' at time of admission were also excluded. Patient progress throughout the trial is shown in Figure 1.

Reduction in number of fallers was used for calculating the required sample size.

From previous unit data it was known that 41% admissions were fallers during their inpatient stay. In order to demonstrate, with 80% power, a 50% relative reduction in the number of fallers, we required a total of 166 patients when the null hypothesis was rejected at *P*-values of 0.05 and below. Given the frail nature of the study population, we planned to recruit at least 216 inpatients to allow for an anticipated 30% 'drop-out' rate during the study period.

Assessments

Details concerning patient demographics, medical, drug and social history were recorded. In addition, the Mini Mental State Examination (MMSE) and nutritional status (underweight/adequate weight/overweight—as judged by the principal investigator) was noted. Adherence to intervention was recorded as a percentage (total study drug taken/total study drug prescribed, as recorded in drug prescription charts). Reasons for non-adherence were ascertained from nursing and medical case notes, and discussions with nursing staff. Barthel scores, Elderly Mobility Scores (EMS) and falls risk assessment scores (Cannard) was also noted. This falls risk assessment tool is employed citywide as part of health board policy.

Falls and fractures

A fall was defined as the patient unintentionally coming to rest on the ground, or other lower level, other than as a consequence of sustaining violence or an epileptic seizure [27]. All falls were documented by ward nursing staff in an official accident form as part of routine practice in this geriatric unit. This information was made available to the researcher who kept a copy of each report. Any fracture incurred during the inpatient stay was verified in medical and nursing notes.

Biochemical analyses

Urea, creatinine, adjusted calcium, phosphate, alkaline phosphatase and albumin levels were measured on admission and prior to discharge. In cases of death, results closest to time of death were used as a substitute. Serum vitamin D (25

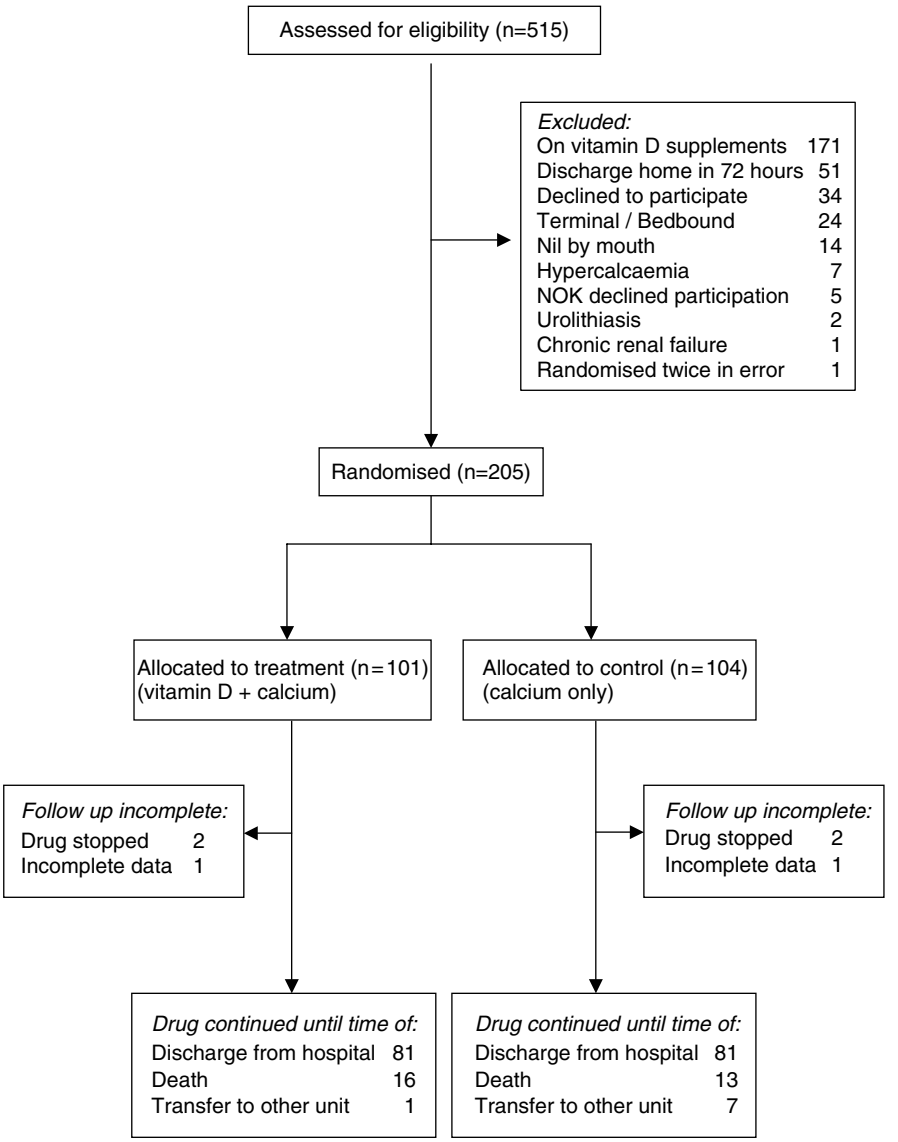

Figure 1. Participant flow through trial.

OHD) levels were measured using the Nichols Advantage Analyser (Nichols Institute Diagnostics, San Juan Capistrano, California, USA). Owing to financial constraint, this was performed in only 1 in 4 patients chosen, using a random numbers table.

Statistical analyses

The other primary outcome was number of falls. All other parameters described above were deemed secondary outcome measures. Data was analysed on an intention-to-treat basis with all statistical calculations conducted by a statistician (J McC) using SPSS version 12.0.1 for Windows. Medians and inter-quartile ranges were calculated for non-normally distributed data and Mann–Whitney U tests were used to compare groups. For categorical variables, chi-square tests were used to test for differences between the groups. Survival analyses using Kaplan Meier Survival Curves were performed to demonstrate treatment effect over time between groups.

Ethical approval

This study was approved by the Multi Centre Research Ethics Committee for Scotland.

Results

Baseline characteristics

This was a frail elderly cohort with high levels of co-morbidity, mortality and polypharmacy (Table 1). Ninety-seven per cent of participants lived at home, housebound, supported by social care packages. A previous falls history was stated in 85% of participants, with approximately half reporting at least monthly falls. Just over one-quarter also had previous fractures. Intervention and control groups were well matched at baseline for all characteristics (Table 1).

Table 1. Baseline characteristics of study cohort

	Control $n = 104$	Intervention $n = 101$
No. of females[a]	60 (57.7%)	61 (60.4%)
Age[b]	83.7 (7.6)	82.3 (7.6)
No. of co-morbid conditions[b]	4.3 (1.7)	4.2 (1.7)
No. of drugs[b]	4.6 (2.9)	4.7 (2.6)
Admission from:[a]		
RH/NH	1 (1.0%)	5 (5.0%)
Home	103 (99.0%)	96 (95.0%)
Housebound[a]	55 (52.9%)	61 (60.4%)
Falls at least monthly[a]	50 (48.1%)	53 (52.5%)
History of fractures[a]	27 (26.0%)	26 (25.7%)
Mobility on admission:[a]		
Unaided/stick	9 (8.6%)	11 (10.8)
Zimmer frame	68 (65.4%)	50 (49.5%)
Transferring only	27 (26.0%)	40 (39.6%)
Nutritional status:[a]		
Underweight	41 (39.4%)	45 (44.5%)
Normal	56 (53.8%)	43 (42.6%)
Overweight	7 (6.7%)	13 (12.9%)
MMSE ≤ 21[a]	49 (62.0%)	52 (61.2%)
Cannard <13[a] (low falls risk)	52 (55.3%)	50 (56.8%)
Barthel score[b]	8.8 (3.8)	8.5 (4.3)
Vitamin D[c]	24.7 (10.0)	21.7 (7.1)

[a] Results as count (%).
[b] Results as mean (SD).
[c] Results as mean (SD). Measured in a random subset (1 in 4) of the total study population.

Table 2. Falls and fractures

	Control $n = 103$	Intervention $n = 100$	Test result
No. of fallers:[a]			
Total group	45 (43.7)	36 (36.0)	$P = 0.263$
Mobile (stick/ZF/unaided)	33 (32)	25 (25)	$P = 0.889$
Immobile (transfer/bed)	12 (11.6)	11 (11)	$P = 0.120$
$\geq$56 days treatment	11 (10.7)	10 (10)	$P = 0.791$
No. of falls/person:[b]			
Median	0 (0–16)	0 (0–11)	$P = 0.435$
Mean	1.155	1.040	
% compliance:[b]			
All subjects	87 (0–100)	89 (0–100)	$P = 0.711$
Fallers only	79 (0–100)	82 (3–100)	$P = 0.999$
No. of fractures[a]	3 (2.9)	1 (1)	$P = 0.327$

[a] Results as count (%), chi-square test.
[b] Results as median (range), Mann–Whitney U test.

Median length of hospital inpatient stay was 30 days (IQR 14.75–71.00) for the whole cohort.

Falls and fractures

Although the number of fallers was lower in the treatment compared to the control group (36 versus 45 respectively, Chi^2 $P = 0.263$; RR 0.82, CI 0.59 to 1.16), this difference was not statistically significant. There was no difference in the number of falls in the treatment and control groups either. In patients who were mobile with a stick/zimmer frame, or unaided on admission (137/205), once again, there was no significant difference in the number of fallers between groups (25:33 in interventions : controls respectively, Chi^2 $P = 0.889$). Similar results were seen in those patients who were relatively immobile on admission (transferring with assistance or bed-bound, Table 2). Because earlier clinical trials had suggested that falls reduction with vitamin D could be demonstrated after 8 weeks of therapy [18], an analysis of those individuals who had received at least 56 days of study drug was performed. This showed no difference in the number of fallers between groups (10 fallers in interventions versus 11 fallers in controls, Chi^2 $P = 0.790$).

The Kaplan Meier Survival Curve suggested that time to the first fall was longer, in general, in the treatment group, but once again, no statistical significance was demonstrated (Appendix 1 in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/). Time to the second fall was also insignificant (Log-rank test $P = 0.751$). There were four fractures in total; three in the control group (two hip, one pubic ramus), and one in the intervention group (hip). This was non-significant. Improvements in Cannard, EMS, and Barthel scores did not vary significantly between groups at the end of treatment.

Biochemical assessments

Vitamin D levels for the total cohort were low at baseline (median 25 OHD = 22.00 nmol/l, IQR 15.00–30.50) with most people fitting the classification of vitamin D deficiency (Table 1). During their inpatient stay, there was some suggestion that vitamin D levels increased in the treatment group, but not in the control group, but this did not reach statistical significance (median change in vitamin D level in control group; 0.00, IQR −9.00 to 2.00 versus intervention group; 2.00, IQR −1.75 to 20.75, Mann–Whitney U test $P = 0.113$). There were four cases of asymptomatic hypercalcaemia (as defined by serum adjusted calcium >2.60) at time of discharge/death; 3:1 in intervention : controls respectively. In two cases, the hypercalcaemia had been present on admission but the laboratory result was delayed; neither patient received more than 4 days treatment prior to the study drug being discontinued. The remaining two individuals developed hypercalcaemia during the study and were both acutely medically unwell at time of checking biochemistry.

Adherence to therapy

Vitamin D and calcium were well tolerated in the total study cohort with a median compliance level of 88%, IQR 68.50 to 99.50. In the intervention group, four patients experienced nausea and vomiting as side effects from the study drug (drug discontinued as a result in 1 case). By comparison in the control group, one patient complained of diarrhoea, and two patients of nausea (Chi^2 $P = 0.671$). Three further patients had their study drugs discontinued at the discretion of their medical teams, principally because they were converted to

named vitamin D preparations following inpatient fractures. Number of deaths did not vary between groups (16:13 in intervention : controls respectively, Chi^2 $P = 0.492$), the majority succumbing to bronchopneumonia.

Discussion

This study has shown that short-term oral vitamin D3 800 iu plus calcium supplementation compared to calcium alone, did not reduce the number of fallers or falls in a geriatric inpatient population. Difference in time to the first fall was also insignificant between groups. Adherence to the intervention was high at 88% with few side effects experienced. However in a subset of the study population, we could not demonstrate a significant increase in serum 25 OHD levels at the end of their treatment period calling into question the true level of compliance and dose effectiveness of this vitamin D preparation.

Explanations for the null results may lie within the methodological constraints of the study. First, this population was different from others studied previously [**15–18**, 19, **20–25**, 28–30]. Our cohort was extremely frail with high levels of co-morbidity and mortality. As a consequence, it may be that any beneficial effects from vitamin D were overshadowed by the significant burden of other co-morbid diseases. Second, the duration of treatment may not have been long enough to produce a significant effect of vitamin D on the neuro-muscular system. Although *in vitro* work has shown that treatment durations of 6–12 months may be necessary to reverse the muscle changes of osteomalacia [31], clinical trials have demonstrated an effect functionally with much shorter prescribing periods of 8–12 weeks [**17, 18**]. The median length of inpatient stay was only 30 days in this cohort (less than anticipated), although the range was very wide with some individuals spending over a year in hospital. Perhaps a longer period of vitamin D supplementation would have provided a positive result, but we were not funded to continue the intervention post discharge from hospital.

Also, our estimation of treatment effect may have been too ambitious. A reduction in fallers of 50% was chosen primarily because orders of this magnitude had been established in previous studies at the time of designing this trial [**17, 18**]. Nevertheless, a subsequently published meta-analysis [**32**] has shown a more conservative corrected odds ratio for falling with vitamin D of 0.78 (95% CI 0.64–0.92). In retrospect, the trial may have been underpowered. Furthermore, some falls may have gone undetected by the researcher (because accident forms may not have been completed for every fall) thus further diluting the power of the trial to detect a benefit. This seems less likely given that the expected faller rate of 40% was achieved during the study.

So, should routine supplementation of vitamin D plus calcium be a key feature of falls prevention in older hospital inpatients? The evidence so far is extremely limited. Only one published study has been performed in a quasi-hospital setting [**18**]. In reality this was a cohort of long-stay inpatients awaiting nursing home care, and hence, not typical of acute medical admissions. Nevertheless, 12 weeks of cholecalciferol 800 iu plus calcium accounted for a 49% reduction of falls compared to calcium alone. The population studied in this study is unquestionably different both in the complexities of the medical conditions and the lengths of stay. It is this diversity in patients' characteristics that inevitably makes fall prevention complicated within the hospital setting. Equally performing high-quality research in this population is difficult also. A recent review of effective strategies to prevent inpatient hospital falls and fractures has shown that multifaceted interventions (including fall risk assessment, care planning, medication review, exercise and hip protectors amongst others) can produce a modest reduction of 18% in falls, when data is pooled from 13 heterogeneous studies [3]. This trial will add to the evidence base for hospital fall prevention, but clearly, further work is needed before routine vitamin D plus calcium can be recommended as a single intervention in this population and setting.

Other trials have focused on vitamin D with or without calcium supplementation to reduce falls in care home patients or community dwellers, and have been included subsequently in systematic reviews or meta-analyses [**3, 6, 32, 33**]. The results have been conflicting. In 2005, pooling data from five randomised controlled trials involving 1,237 participants (three studies in the community, one in residential apartments and one in long-stay inpatients) reduced the corrected odds ratio of falling by 22% [**32**]. Conversely, an earlier meta-analysis of four trials did not demonstrate falls reduction with vitamin D and its metabolites (RR 0.99; CI 0.89–1.11) [**34**]. Similarly the most recent Cochrane update in 2005 on interventions for preventing falls in elderly people concludes that 'there is currently no evidence of the effectiveness of vitamin D supplementation in reducing the number of people who fall amongst community dwelling or hospitalised older people' [**33**]. More recently, Oliver *et al.* found some evidence supporting vitamin D in care home vitamin D deficient residents from two randomised controlled trials [**3**]. Since these reviews, two further well-conducted studies have been published. One showed a significant reduction for falling (OR 0.73; CI 0.57–0.95) [**21**] whilst the other demonstrated no effect on numbers of fallers (RR 1.09; CI 0.95–1.25) [**35**]. Once again, it is difficult to advocate a blanket prescription of vitamin D to prevent falls in the care home environment. More research is welcomed.

Finally, current recommendations from expert groups who have looked at the evidence in community, hospitalised and care home populations, have stated that vitamin D and calcium supplementation should be considered for all older, frailer, housebound or institutionalised people [**5**, 36–37 **38–40**]. Based on these, many from this inpatient cohort would have been eligible for treatment in any case, and yet were never prescribed it. Many had multiple risk factors for fracture or osteoporosis and

many were sunlight deprived by virtue of their social circumstances. Unsurprisingly, given the population studied and this geographical location, the prevalence of vitamin D deficiency was also high (median 25 OHD = 22 nmol/l, IQR 15.00–30.50) again suggesting need for replacement therapy on nutritional grounds alone. We suggest that an acute hospital admission is a good time to make this part of the medication review.

In summary, this study has shown that routine prescription of vitamin D and calcium was not effective in preventing falls in an inpatient setting most likely because of an insufficient treatment period, and perhaps, participant numbers. Further work is needed to clarify if prolonged vitamin D therapy does indeed prevent falls and, also to ascertain exactly which interventions work to reduce falls in hospital populations.

Key points

- Vitamin D deficiency is common in older people and is related to an increased falls risk.
- Hospital inpatients are at particular high risk of falling.
- Previous studies have suggested that vitamin D (with or without calcium) supplementation improves neuromuscular function and, as a result, may reduce falls.
- This study shows no significant reduction in numbers of fallers or falls in hospital in the intervention group receiving vitamin D plus calcium.
- Most patients admitted were largely vitamin D deficient and many would have qualified for vitamin D and calcium prescription prior to admission.

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Supplementary data

Supplementary data for this article are available online at http://ageing.oxfordjournals.org.

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Please note: The full list of references supporting this paper is available on the journal website http://www.ageing.oxfordjournals.org/ as appendix 2. The most important have been listed below and are represented in bold throughout the text.

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