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Incidence of venous thromboembolism in care homes:

a prospective cohort study

Abstract

Background

Care home residents have venous thromboembolism (VTE) risk profiles similar to medical inpatients; however, the epidemiology of VTE in care homes is unclear.

Aim

To determine the incidence of VTE in care homes.

Design and setting

Observational cohort study of 45 care homes in Birmingham and Oxford, UK.

Method

A consecutive sample of care home residents was enrolled and followed up for 12 months. Data were collected via case note reviews of care home and GP records; mortality information was supplemented with Health and Social Care Information Centre (now called NHS Digital) cause of death data. All potential VTE events were adjudicated by an independent committee according to three measures of diagnostic certainty: definite VTE (radiological evidence), probable VTE (high clinical indication but no radiological evidence), or possible VTE (VTE cannot be ruled out). [Study registration number: ISTCTN80889792.]

Results

There were 1011 participants enrolled, and the mean follow-up period was 312 days (standard deviation 98 days). The incidence rate was 0.71 per 100 person years of observation [95% confidence interval (CI) = 0.26 to 1.54] for definite VTE, 0.83 per 100 person years (95% CI = 0.33 to 1.70) for definite and probable VTE, and 2.48 per 100 person years (95% CI = 1.53 to 3.79) for definite, probable, and possible VTE.

Conclusion

The incidence of VTE in care homes in this study (0.71–2.48 per 100 person years) is substantial compared with that in the community (0.117 per 100 person years) and in people aged ≥ 70 years (0.44 per 100 person years). Further research regarding risk stratification and VTE prophylaxis in this population is needed.

Keywords

care home residents; deep vein thrombosis; nursing home residents; pulmonary embolism; venous thromboembolism; VTE incidence.

INTRODUCTION

Venous thromboembolism (VTE), comprising deep vein thrombosis (DVT) and pulmonary embolism (PE), is a serious global health problem associated with significant morbidity and mortality.^{1,2} VTE risk significantly increases with advancing age, and age ≥ 75 years has been established as an independent risk factor.^{3–6} Other important risk factors include immobilisation, hospitalisation, malignancy, previous VTE, and comorbidities such as heart failure, stroke, chronic obstructive pulmonary disease (COPD), and diabetes mellitus.^{7–14}

Approximately 50% of VTE is associated with hospital admission, and VTE risk assessment of hospitalised patients is strongly recommended by evidence-based guidelines.¹⁵ It could be argued that care home residents have VTE risk profiles similar to those of medical inpatients,^{16,17} although the impact of VTE risk factors in the UK care home population is unknown.¹⁶ Nursing home stay is an independent risk factor for VTE;⁸ moreover, US data suggest an eightfold risk of VTE associated with residence in a long-term care facility.¹⁸

The epidemiology of VTE in care homes remains unclear and accurate data are needed on rates of VTE in care homes. The present study is a prospective cohort observational study to determine, for the first time, the incidence of VTE in UK care homes.

METHOD

Study design

This was an observational cohort study. Study staff extracted clinical data from case notes of participants' care home and GP records over 12 months for all events of interest. Mortality data were complemented with cause of death data from the Health and Social Care Information Centre (HSCIC) (now called NHS Digital), the national provider of population data relating to health and social care. The main outcome of interest was the rate of VTE events per 100 person years (PYs).

Setting and participant selection

'Care home' as used in this study, in accordance with the UK definition,¹⁹ included care homes with nursing and care homes without nursing. A sample of care homes was recruited in Birmingham and Oxford, stratified by type, size, and ownership to increase generalisability. Care homes with fewer than 10 beds were excluded. Each resident from participating care homes was assessed for study inclusion. Inclusion criteria were care home resident and able to provide consent (either by consenting personally or via consultee declaration; that is, asking a family member to advise whether a person who lacks mental capacity would want to participate). Temporary residents and residents with a life expectancy of < 6 months were excluded. GPs were asked to provide access to participants' medical records.

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How this fits in

Residence in a nursing home is an independent risk factor for venous thromboembolism (VTE). The incidence of VTE in care home residents (with and without nursing) may be up to 21 times the community incidence and five times that of people aged ≥ 70 years. Care home residents are not risk assessed for VTE.

Data collection

Clinical researchers reviewed the care home and GP medical records for each participant at baseline and at 12 months' follow-up, or when the participants died or moved away. Baseline data comprised demographic data, medical history, comorbidities, and current medications. The Rivermead Mobility Index (RMI)²⁰ was administered by care home staff. Follow-up data comprised hospital admissions (including accident and emergency attendances), deaths, and GP consultations.

Outcomes

Endpoint definition. The study endpoint was defined as development of VTE during time in the study. VTE events were categorised into three levels of diagnostic

certainty: definite VTE (clinical evidence of VTE, including radiological or post-mortem diagnosis, evidence of treatment, PE listed as main cause of death on death certificate); probable VTE (high clinical suspicion or indication of VTE but no radiological diagnosis); and possible VTE (no clinical suspicion of VTE recorded in patient's notes, although VTE could not be ruled out, for example, due to pleuritic chest pain or haemoptysis).

Endpoint adjudication. First, two research nurses with VTE training reviewed the complete case report form for each patient and adjudicated on each death, hospital admission, and GP consultation where there was any suggestion that there were VTE symptoms. Events that were not VTE related were adjudicated as probably not VTE or definitely not VTE, and cases with insufficient information for a sensible decision were adjudicated as 'VTE unknown'. The principal investigator adjudicated where there was a difference of opinion. All events adjudicated as definite VTE, probable VTE, and possible VTE were then referred to a second stage of adjudication: an independent adjudication panel comprising two haematologists and a GP; two members assessed anonymised information to adjudicate on events and any difference of opinion was judged by the third member.

Statistical analysis

Person time at risk commenced from date of enrolment until 12 months, lost to follow-up, or death. Incidence of VTE was calculated per 100 PYs of observation with corresponding 95% confidence intervals (CIs), using the Poisson exact method. The incidence of VTE was calculated based on definite, probable, and possible VTE events. Participants' baseline VTE risk was calculated for both the Department of Health risk assessment tool²¹ and QThrombosis[®] score.²² The individual risk of VTE was assessed for selected factors using Poisson regression, reporting relative risks, associated 95% CI, and *P*-values. Statistical analysis was performed using SAS (version 9.4).

RESULTS

Sites

Forty-five care homes in Birmingham and Oxford participated. Participating care homes varied according to type, size, and ownership, and were representative of UK care homes (Table 1). Eighty-three out of 86 GPs granted access to participants' medical records.

Table 1. Characteristics of study care homes^a

Care home characteristics	All Birmingham and Oxford care homes ^b	Study care homes
Number	231	45
Type		
With nursing	119 (52)	27 (60)
Without nursing	112 (48)	18 (40)
Size, number of beds		
<30 (small)	89 (39)	15 (33)
30–49 (medium)	82 (35)	15 (33)
≥ 50 (large)	60 (26)	15 (33)
Mean number of beds (SD)	NA	43.96 (21.38)
Ownership		
Private/for profit	146 (63)	35 (78)
Not for profit	85 (37)	10 (22)
Location		
Birmingham	144 (62)	27 (60)
Oxford	87 (38)	18 (40)
Study participants per care home		
Mean (SD) participants per home	NA	22.47 (10.00)
Median number participants per home (IQR)	NA	20 (15–29)
Number of participants per home (range)	NA	6–45

^aData are n or n (%) unless otherwise specified. ^bAll care homes in Birmingham and Oxford registered on the Care Quality Commission website during the care home recruitment phase of the study in 2013. IQR = interquartile range. NA = not applicable. SD = standard deviation

Figure 1 reports the numbers of individuals at each stage of the study. All residents in participating care homes were assessed for eligibility ($n = 1876$); 95.0% (1783 out of 1876) were eligible. Reasons for exclusion were life expectancy <6 months ($n = 35$) and being temporary residents ($n = 58$). Sixty-seven patients were excluded as they lacked capacity to consent and no suitable consultee was identified. Of eligible residents, 56.7% (1011 out of 1783) invited to participate were consented and enrolled to the study between August 2013 and June 2014; 466 (46.1%) of those enrolled lacked capacity.

Baseline data were obtained for 1011 participants. Follow-up analysis consisted of 989 participants (22 patients were excluded from follow-up analysis because of restricted access to GP records). Six hundred and ninety-eight out of the 989 were followed up for 12 months, 45 moved away, and 246 died while in the study (after

less than 12 months). The total follow-up period was 847.52 PYs with median (IQR) follow-up period 365 (300–365) days.

Participants

The mean age (standard deviation [SD]) was 85.1 (8.6) years, 58.1% (587 out of 1011) were aged ≥ 85 years; mean BMI was 24.4 kg/m² (SD 6.1), with 14.1% (142 out of 1011) having BMI ≥ 30 kg/m² and 11.8% (119 out of 1011) having a BMI <18.5 kg/m² (Table 2). Most of the participants, 96.8% (979 out of 1011), were of white ethnic group and 71.4% (722 out of 1011) were female; 52.7% (530 out of 1011) had dementia. Of the participants, 22.2% (224 out of 1011) were completely bedridden (RMI score = 0) and a further 36.5% (369 out of 1011) had significantly reduced mobility (RMI score = 1–6).

The main reason for requiring care home admission was mental health conditions (41.4%, 419 out of 1011), with 89.3% (374 out of 419) of this being caused by dementia.

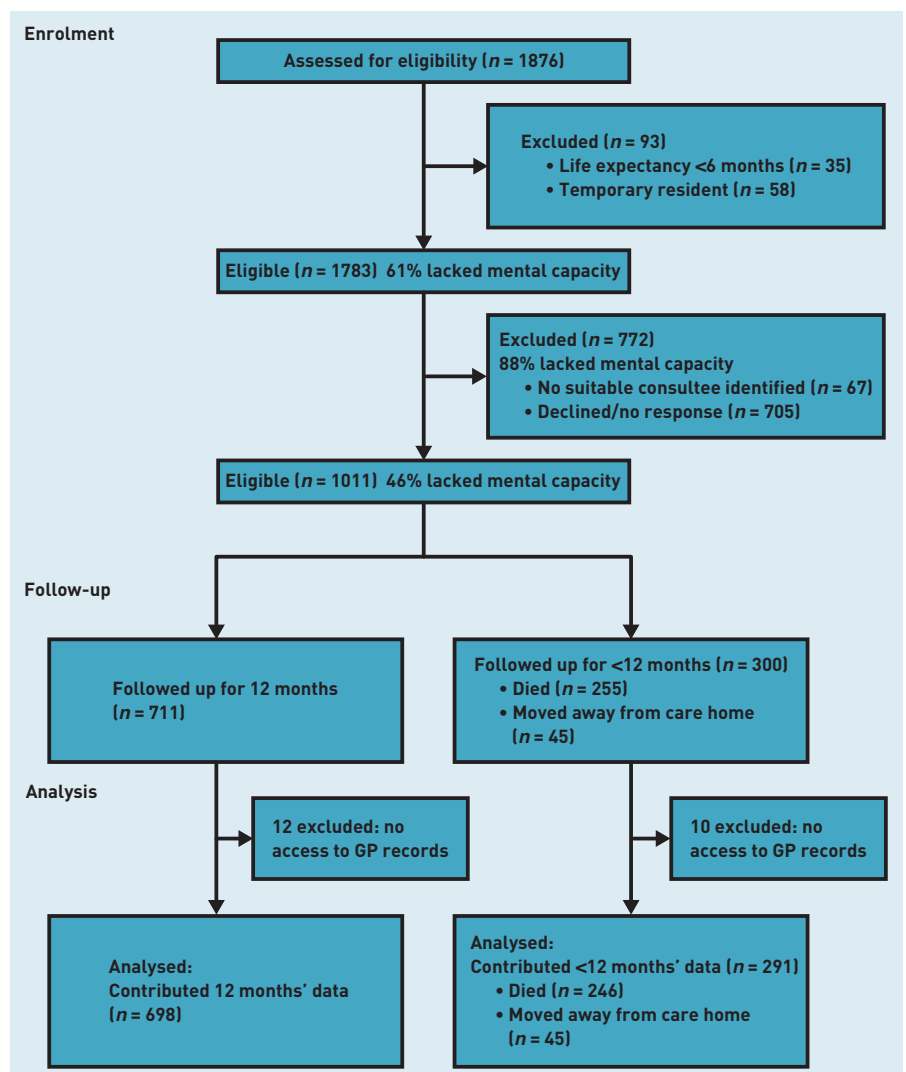


Figure 1. Study flow diagram.

Table 2. Participants' characteristics

N= 1011	n	%
Age, years		
<65	34	3.4
65–74	85	8.4
75–84	305	30.2
≥85	587	58.1
Female	722	71.4
White ethnic group	979	96.8
Dementia ^a	530	52.7
Main condition requiring care home admission		
Mental health condition	419	41.4
Social/emotional problems	187	18.5
Somatic disorders	340	33.6
Other	65	6.4
Length of stay since admission		
<1 year	378	37.4
1 year to <5 years	528	52.2
≥5 years	105	10.4
Do-not-resuscitate order in place	320	31.7
BMI, ^b kg/m²		
<18.5 (Underweight)	119	11.8
18.5–24.9 (Normal weight)	438	43.3
25.0–29.9 (Overweight)	236	23.3
≥30 (Obese)	143	14.1
Smoking status		
Ex-smoker	334	40.3
Current smoker	36	4.4
Mobility^c		
Bedridden (RMI = 0)	224	22.2
Significantly reduced mobility (RMI = 1–6)	369	36.5
Mobile (RMI = 7–15)	417	41.3
Care home		
Type		
With nursing	691	68.3
Without nursing	320	31.7
Size, number of beds		
<30	236	23.3
30–49	294	29.1
≥50	481	47.6
Ownership		
For profit	739	73.1
Not for profit	272	26.9

^aData were missing for five patients. ^bData were missing for 75 patients. ^cData were missing for one participant.

BMI = body mass index. RMI = Rivermead Mobility Index.

Participants had been in the present care home for a mean time of 2.8 years (SD 8.2), with a median time of 1.5 years. Of the participants, 68.3% (691 out of 1011) resided in care homes with nursing and 31.7% (320 out of 1011) in care homes without nursing; overall 31.7% (320 out of 1011) had a do-not-resuscitate order in place.

Baseline VTE risk

When the Department of Health VTE risk assessment tool²¹ for hospitalised patients was applied to baseline data, 58.7% of

participants (593 out of 1011) were classed as high risk and eligible for consideration of either mechanical or pharmacological prophylaxis in the hospital setting (Table 3). The QThrombosis risk tool,²² a risk prediction model designed for primary care, indicated that participants had an increased 1-year risk of VTE with 96.0% (971 out of 1011) having an absolute risk of ≥0.3, three times the general risk.

VTE prevention strategies at baseline

Prompted by a recent VTE or hospitalisation, 0.7% of participants (7 out of 1011) were on heparin, and another 5.5% (56 out of 1011) were on oral anticoagulants, mainly for atrial fibrillation. Compression stockings were used by 5.0% (51 out of 1011). There was no evidence in any participant's records of VTE risk assessment.

Identification of VTE events during follow-up period

Data for 989 participants in the follow-up analyses were reviewed by the internal adjudication team. There were 991 events: 246 deaths, 574 hospital admissions (relating to 345 patients), and 171 GP consults involving symptoms suggestive of VTE. Out of these, the internal adjudication process identified 132 potential VTE events; there was insufficient information to make a judgement on six events. Finally, independent adjudication confirmed 21 VTE events (6 definite, 1 probable, 14 possible).

Incidence of VTE

Table 4 shows the number of VTE events according to diagnostic certainty and associated incidence rates. The incidence of definite VTE was 0.71 per 100 PY (95% CI = 0.26 to 1.54), definite and probable VTE was 0.83 per 100 PY (95% CI = 0.33 to 1.70), definite, probable, and possible was 2.48 per 100 PY (95% CI = 1.53 to 3.79). The incidence of definite and probable VTE varied according to type of care home (care home with nursing: 0.70 per 100 PY, care home without nursing: 1.10 per 100 PY). Table 5 shows supplementary data according to the type of VTE. Most of the definite and probable VTE events were DVTs (71.4% [5 out of 7]), and PE accounted for 16.6% (1 out of 6) of definite VTE compared with 57.1% (8 out of 14) of possible VTE. The incidence of VTE-related deaths was 0.12 per 100 PY for definite VTE as well as definite and probable VTE, and 0.35 per 100 PY definite, probable, and possible VTE. The rate of hospital admissions caused by VTE was 0.34% (2 out of 574) for definite VTE, 0.52% (3 out of 574) for definite and

Table 3. Department of Health VTE risk assessment

Risk assessment criteria	n	%
Mobility		
Significantly reduced mobility	593	58.7
Thrombosis risk (based on 593 patients with reduced mobility)		
Active cancer or cancer treatment	69	11.6
Age >60 years	587	99.0
Dehydration	NM	NM
Known thrombophilias	2	0.3
Obesity (BMI >30 kg/m ²)	83	14.0
One or more significant medical comorbidities ^a	425	71.7
Personal history of VTE	60	10.1
Use of hormone replacement therapy	1	0.2
Use of oestrogen-containing contraceptive therapy	0	0.0
Varicose veins with phlebitis	2	0.3
Pregnancy or <6 weeks postpartum	0	0.0
Number with at least one thrombosis risk factor	593	100%

^aHeart disease; metabolic, endocrine, or respiratory pathologies; acute infectious diseases; inflammatory conditions. BMI = body mass index. NM = not measured. VTE = venous thromboembolism.

Table 4. Incidence of VTE according to diagnostic certainty

Characteristic	Number of events	n	Person years	Incidence rate per 100 person years	95% CI
Diagnostic criteria					
Definite VTE	6	989	847.52	0.71	0.26 to 1.54
Definite and probable VTE	7	989	847.52	0.83	0.33 to 1.70
Definite, probable and possible VTE	21	989	847.52	2.48	1.53 to 3.79

VTE = venous thromboembolism.

probable VTE, and 1.21% [7 out of 574] for definite, probable, and possible VTE.

Table 6 compares the event rates across age groups, sex, mobility, type of care home, length of residency, previous VTE event, and presence of one or more significant medical comorbidities. In summary, the data suggest that the risk of a recurrence is increased with having a previous VTE [relative risk [RR] 3.17 95% CI = 1.16 to 8.66], $P = 0.02$ and with having one or more significant medical comorbidities [RR 4.87 [95% CI = 1.64 to 14.49], $P = 0.004$]. Although the risk of VTE is likely to be increased with

being female, aged ≥ 85 years, resident in a nursing home, and resident in care home for <1 year, the confidence intervals are wide and include the possibility of reduced risk.

DISCUSSION

Summary

This is the first prospective study to determine the incidence of VTE in care homes and evaluate incidence of VTE in UK care homes. There was an incidence of 0.83 per 100 PY for definite and probable VTE, significantly higher (seven times) than the community incidence of 0.117 per 100 PY,¹⁸

Table 5. Incidence of VTE according to type of VTE and diagnostic certainty

Characteristic	Definite VTE (n = 6)		Definite and probable VTE (n = 7)		Definite, probable, and possible VTE (n = 21)	
	n (%)	Incidence rate (95% CI)	n (%)	Incidence rate (95% CI)	n (%)	Incidence rate (95% CI)
DVT	5 (83.3)	0.59 [0.19 to 1.38]	5 (71.4)	0.59 [0.19 to 1.38]	11 (52.3)	1.30 [0.65 to 2.32]
PE	1 (16.6)	0.12 [0.003 to 0.66]	2 (28.6)	0.24 [0.03 to 0.85]	10 (47.6)	1.18 [0.57 to 2.17]
Fatal PE	1 (16.6)	0.12 [0.003 to 0.66]	1 (14.2)	0.12 [0.003 to 0.66]	3 (14.2)	0.35 [0.07 to 1.03]
Recurrent VTE	2 (33.3)	0.24 [0.03 to 0.85]	2 (28.6)	0.24 [0.03 to 0.85]	5 (23.8)	0.59 [0.19 to 1.38]

DVT = deep vein thrombosis. PE = pulmonary embolism. VTE = venous thromboembolism.

Table 6. VTE event rates according to selected participant characteristics

Characteristics		Number of events ^a / person years	Relative risk (95% CI) ^b	P-value
Sex	Male (reference)	4/240	1	–
	Female	17/608	1.67 [0.56 to 4.99]	0.350
Age, years	<75 (reference)	2/106	1	–
	75–84	1/258	0.21 [0.02 to 2.27]	0.200
	≥85	18/483	1.98 [0.46 to 8.51]	0.360
Rivermead Mobility Index	0 (reference)	3/183	1	–
	1–6	8/301	1.62 [0.43 to 6.11]	0.480
	7–15	10/364	1.68 [0.46 to 6.09]	0.430
Length of stay since admission	<1 year	9/306	2.74 [0.35 to 21.59]	0.340
	1 to 5 years	11/448	2.28 [0.29 to 17.69]	0.430
	>5 years (reference)	1/93	1	–
Type of care home	With nursing	17/575	2.02 [0.68 to 6.00]	0.210
	Without nursing (reference)	4/273	1	–
Previous VTE	Previous VTE	5/76	3.17 [1.16 to 8.66]	0.024
	No previous VTE (reference)	16/772	1	–
Malignancy	Malignancy	3/114	1.07 [0.32 to 3.64]	0.910
	No malignancy (reference)	18/733	1	–
Obesity, body mass index	>30 kg/m ²	3/125	0.99 [0.29 to 3.41]	0.990
	≤30 kg/m ² (reference)	16/663	1	–
Significant medical comorbidities ^c	0 (reference)	4/453	1	–
	≥1	17/395	4.87 [1.64 to 14.49]	0.004

^aDefinite, probable, and possible VTE. ^bPoisson exact CI. ^cHeart disease; metabolic, endocrine, or respiratory pathologies; acute infectious diseases; inflammatory conditions.

VTE = venous thromboembolism.

rising to 2.48 per 100 PY when including possible VTE. The incidence of definite and probable VTE is also twice as high as the rate of VTE in people aged ≥70 years (0.44 per 100 PY).²³ The study population was classed as high risk according to conventional available VTE risk assessment tools; however, there was no demonstrable use of VTE risk assessment.

Strengths and limitations

The current study has several strengths; the clear definitions for VTE according to diagnostic certainty and independent adjudication of study endpoints minimised bias in the ascertainment of VTE events. Data collection comprised complete notes review of both care home and GP records; GP records in UK contain the complete medical history including all hospitalisations, investigations, results, and medications, therefore providing a robust data source for identification of VTE events. Furthermore, HSCIC cause of death data provided reliable data for adjudication on deaths. The study sample is drawn from a mix of care homes across Birmingham and Oxford, and reflects a considerable proportion of care home residents without mental capacity. Nevertheless, the small number of definite

and probable VTE events meant that there was insufficient data to develop a reliable clinical prediction model for estimating the probability of the occurrence of VTE in a care home population.

Comparison with existing literature

The incidence rate of definite and probable VTE in the present study is lower than that found in previous studies; however, if possible VTE is included the rate is much higher.^{24–27} Gomes and colleagues found an incidence of 1.30 events per 100 PY,²⁴ Gatt *et al* found an incidence of 1.4 to 1.6 per 100 PY,²⁵ and Leibson and colleagues found an incidence of 1.2 to 1.5 per 100 PY.²⁶ These studies, however, relied on nursing home administrative data and diagnostic codes, and were, therefore, subject to diagnostic uncertainty and misclassification. Furthermore, Gomes *et al* and Leibson and colleagues were unable to disentangle VTE events that occurred during nursing home residence from those that occurred before admission, as conditions were recorded as active at time of assessment. This is important, as Reardon *et al* found that 1 in 25 patients admitted to care homes had a current diagnosis of VTE.²⁷ On the other hand, the present study included only VTE events

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Ethical approval

Ethical approval for the study was granted by the National Research Ethics Service (NRES) committee West Midlands – Black Country (reference 13/WM/0118). Informed consent was obtained for all study participants.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

Carl Heneghan has received expenses from the World Health Organization (WHO) and holds grant funding from the NIHR, the NIHR SPCR, the Wellcome Trust, and the WHO. He is also a member of the advisory group of the WHO International Clinical Trials Registry Platform and also organizes the EvidenceLive conference with the *BMJ*. The other authors have declared no competing interests.

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that occurred during participants' time in the study. Patients were also excluded with life expectancy of <6 months, and this group may have had a higher likelihood of developing a VTE.

A more recent study found a higher incidence of 3.68 per 100 PY.²⁷ This again may be a result of methodological differences, although the authors attributed this to possible consequences of differences in the pool of nursing homes studied, and improved diagnostics for asymptomatic VTE such as the portable Doppler ultrasound. Portable Doppler was not available to care home residents in the current study. Nevertheless, incidence rates found in this and previous studies are likely to underestimate the real incidence of VTE in the care home population as death caused by PE is underdiagnosed while post-mortem-proven fatal PE rate in hospital inpatients is 2.5%.²⁸ Additionally, a post-mortem study of 234 nursing home residents found undiagnosed VTE to be the cause of death in 8%, while 40% of PE events were not suspected before death.²⁹ In the present study, only one out of the 246 deaths had objectively confirmed PE as the cause of death, giving a fatal PE rate of 0.4%. Moreover, the studies are subject to under-recognition of VTE as symptoms may be nonspecific and masked by comorbidity in older patients.^{30–34} Also VTE is often silent,^{35–37}

and a previous study found prevalence of 13.5% DVT by ultrasonography screening of institutionalised older individuals.³⁸

Implications for practice

Despite robust standards for ascertainment of VTE events, the incidence in care home residents in this study is high compared with incidence in the community overall, as well as incidence in older people. The substantial VTE rate in care home residents requires consideration by clinicians responsible for their care; this has implications on national health care in terms of the UK's ageing population, particularly as none of the residents in the present study had been risk assessed for VTE.

Current guidelines have no provision for care home residents; further evidence is needed to inform guideline development. Zarowitz and colleagues developed a VTE risk stratification tool for care homes,³⁹ although this has not been validated. Many of the characteristics of care home residents are also associated with adverse events from pharmacological thromboprophylaxis. Although it is difficult to argue for formal risk assessment in care homes at this stage, there is a need to explore risk stratification and the benefit of VTE prophylaxis in this population.

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