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Right needle, right patient, right time? A national flash-mob audit of thromboprophylaxis in palliative care.

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Abstract

Background

The prevention of hospital associated thrombosis in palliative care remains controversial yet many countries recommend the documented risk assessment and where appropriate pharmacological prophylaxis of inpatients with advanced cancer.

Aim

To audit adherence to national guidelines which require hospitalised patients to be risk assessed and receive appropriate thromboprophylaxis.

Design

A one day “flash-mob” audit across multiple clinical inpatient sites across the United Kingdom.

Setting/ participants

Inpatients receiving palliative care within hospitals, hospices and specialist palliative care units across the United Kingdom.

Results

Data were collected from 1125 patients (514 hospital and 611 hospice/specialist palliative care units). Appropriate thromboprophylaxis was observed in 90% of hospital and 90% hospice/specialist palliative care units. Documented risk assessment was only found in 79% and 71% of patient notes respectively. Pharmacological thromboprophylaxis was contraindicated in 88% of hospice/specialist palliative care unit patients due to bleeding risk or receiving end-of-life care. Twenty-four percent of patients in hospital had contraindications due to receiving end of life care, bleeding risk and thrombocytopenia. Patients in hospice/specialist palliative care units were of poorer performance status prior to admission with a history of gradual deterioration. Hospitalized patients were more likely to have been admitted following an acute deterioration of previous good performance status.

Conclusion

Thromboprophylaxis guidelines were followed correctly for the majority of patients. There were considerable differences in the demographics of patients according to place of admission. Patients admitted to hospice/specialist palliative care units were sicker and had more contraindications to prophylaxis than those admitted to hospital. Thromboprophylaxis focused research data conducted in hospices is unlikely to be applicable to the care of palliative care patients admitted acutely to hospital.

Introduction

The prevention of hospital associated venous thromboembolism (VTE) has been the focus of patient safety programs around the world for several years, with some countries mandating documented risk assessment and, where appropriate, the provision of thromboprophylaxis for all hospitalized patients.(1, 2) The presence of malignancy confers an independent risk for VTE, which will vary according to primary site, stage and cancer modifying therapies used.(3) Consequently pharmacological thromboprophylaxis is recommended as routine practice for cancer inpatients unless there are contraindications.(4) Advanced cancer patients are particularly prothrombotic; the presence of metastases are reported to increase the risk of VTE twenty fold.(5) Symptomatic VTE is experienced by up to 15% of advanced cancer patients and seen in 50% of cancer patients post-mortem.(6, 7) Developments in anticancer treatments have led to people living longer with metastatic disease whilst continuing to receive systemic anticancer therapies (SACT) and this has seen a proportionate increase in rates of VTE.(8) Consequently the prevention and management of VTE has become more relevant to palliative care teams with evidence of changing attitudes and practice.(9, 10)

There are a plethora of clinical guidelines on the prevention and treatment management of cancer associated thrombosis (CAT).(11) However, they are of limited utility in the palliative care setting since the data informing them used end points of little relevance to end of care and these studies excluded patients near the end of life.

Only one clinical guideline has a specific set of recommendations for patients with cancer receiving palliative care; the National Institute for Health and Care Excellence (NICE) Clinical Guideline 89 (CG89) and these are summarized in Figure 1.(12) The evidence base supporting these recommendations is poor; the only prospective thromboprophylaxis study conducted specifically in the palliative care setting closed having enrolled 20 out of an intended 389 participants.(13) Consequently the recommendations are based on consensus and data extrapolated from general medical thromboprophylaxis studies.

Newly published research challenges these guidelines; HIDDEN, a prospective observational study identified a 28% prevalence of femoral deep vein thrombosis (DVT) in patients with cancer admitted to hospice and specialist palliative care units (HSPCUs). Patients with deep vein thrombosis had minimal attributable symptoms and the presence of deep vein thrombosis had no impact on survival.(14) Twenty-nine percent of those originally

screened had been admitted for end of life care and were ineligible for participation, meaning over 50% of patients admitted to HSPCUs are unlikely to benefit from thromboprophylaxis. The presence of DVT was strongly associated with a Modified Australian Karnofsky Performance Status (AKPS) below 50 (considerable assistance and frequent medical care required) and a history of gradual deterioration in clinical condition.(15) This suggests VTE, in this context, is likely to be part of the agonal process and not a terminal event.(16)

Previous data has suggested a reluctance of HSPCUs to offer thromboprophylaxis and charitably funded inpatient services are not mandated to do so.(9, 10) However, the majority of patients with cancer, receiving palliative care, are admitted into the acute setting where they are more likely to be risk assessed.(17) It necessarily follows that the decision to risk assess and offer thromboprophylaxis may be determined by place of admission rather than clinical evaluation. We describe a national flash-mob audit of palliative care cancer inpatients to evaluate compliance with palliative care specific thromboprophylaxis guidelines as outlined in CG 89.

Aims

The overarching aim was to audit the risk assessment and where appropriate, the initiation of thromboprophylaxis in cancer in-patients receiving palliative care. To achieve this, the following data were collected;

- 1) The number of patients with a documented VTE risk assessment
- 2) The number of patients with CG89 compliant thromboprophylaxis (regardless of whether formal risk assessment documented)
- 3) Evidence of non-compliant practice, to identify patterns and areas to focus as part of an improvement program
- 4) Contraindications to thromboprophylaxis

Methods

Design

We undertook a one day multi-site “flash-mob” audit on Tuesday 25th February 2021.(18) The audit tool was developed by members of the audit steering committee based on standards outlined in CG89. It was amended according to feedback from a pre-agreed pilot stage. The protocol was reviewed by the Aneurin Bevan University Health Board Risk Review Committee who categorised the project as an audit as per the NHS Health Research Authority research decision tool 3 and did not require ethics approval.

Setting

The audit was undertaken in the United Kingdom (UK). Patient data were audited in palliative care inpatient units (hospices and specialist palliative care units) where the main clinical decisions are made by palliative care teams and acute hospitals where palliative care teams are more likely to offer a consultancy service.

Population (inclusion and exclusion criteria)

Patients were eligible for inclusion if they were aged 16 or over, had a diagnosis of incurable cancer and were under the care of the palliative care team. Within the hospital setting it was acceptable for patients to be under the care of a primary clinician with palliative care team offering a consultancy service. Patients were ineligible if they were admitted as a day case.

Sampling

The audit was conducted under the auspices of the UK Palliative Trainees Research Collaborative, a group of palliative care trainees, consultants and academic supervisors across nineteen UK training regions.(19) Audit sites were recruited through the collaborative’s regional leads and through social media.

Approvals

To register, sites were required to operate according to standards articulated in the Understanding Practice in Clinical Audit and Registries tool advocated by Health Quality Improvement Partnership.(20) This included gaining approvals through their relevant governance processes including their audit department and Caldicott guardian. Some organisations within the independent sector which did not have a formal process, liaised with their neighbouring statutory sector organisations and took the approval processes through them.

Data collection

Data were anonymised at source to contain no identifying features at the time of collection and recorded on an electronic audit tool designed for the project. The audit tool was then transferred via email to a single purpose email account with Transport Layered Security and Industry standard 128-bit encryption to ensure data security.

The anonymised data were stored as a password protected encrypted file on a secure computer in a locked office in Cardiff University. All data analysis was undertaken on this computer with the exception of logistic regression analysis which was undertaken on a separate university computer within the same department and with identical data security standard operating procedures.

Analysis

Data were analysed as two distinct inpatient environments; the acute sector (i.e. acute medical/ surgical admissions) and the HSPCU setting. This distinction was made for the following reasons;

1. Previous data suggests a resistance to thromboprophylaxis in HSPUs.
2. Within the UK acute hospitals are mandated to document a risk assesses whilst independent HSPUs are not
3. Based on data from the HIDDEN study, it has been hypothesised that patients admitted to HSPUs may differ to those admitted acutely to hospital with respect to performance status, prognosis and disease trajectory.

Where appropriate, logistic regression analysis was applied to relevant data. Since anonymised data had been transferred from the source with no identifiable features, it was not possible to refer back to recruitment sites to account for missing data. The small amount of missing data were therefore managed using multiple imputation. For each multiply imputed dataset, logistic regression was fitted with the outcome "prophylactic low molecular weight heparin" and exposure "setting" (hospital vs hospice/specialist palliative care unit). This was only applied to patients who were not on anticoagulants prior to admission. Bootstrapping was used to obtain standard errors (95% Confidence Intervals) for the derived estimated risk difference, following multiple imputation within each bootstrap sample. The remaining data were presented using descriptive statistics.

Results

Data on 1125 patients were collected from 119 clinical institutions comprising 52 Hospitals (514 patient datasets) and 67 HSPCUs (611 datasets). These are summarised in Table 1.

Patients admitted to hospital or HSPUs had similar male to female ratio and 86% of HSPUs patients were over the age of 65 compared with 60% of hospital patients. The commonest malignancies in both groups were lung, colorectal, prostate, gynaecological and breast cancers, whilst a larger proportion of haematological malignancies (lymphoma, leukaemia, myeloma) were managed in hospital.

With respect to performance status (Table 2), more patients with AKPS of 50 or below were observed in HSPUs (77%) compared with hospital patients (70%) with an even greater difference in those of AKPS of 30 and below (46% and 33% respectively). The majority (69.7%) of patients admitted to HSPUs had experienced a gradual deterioration in contrast to patients admitted to hospital (11.1%). An acute clinical deterioration accounted for 85% admitted to hospital who compared to 28.8% in HSPUs.

Over one third (34.8%) of patients admitted to hospital had received some form of cancer modifying treatment in the previous four weeks (Table 2). This included 4.5% of patients receiving palliative radiotherapy with the remainder having some form of SACT (chemotherapy, targeted therapy, hormones or a combination). The proportion of HSPU patients receiving anti-cancer therapies was half those in hospital (16.2% vs 34.8% respectively). The proportion of patients receiving radiotherapy was similar, at 4.6%.

Compliance with CG89 is summarised in Table 3. A documented risk assessment was completed in 79% of hospital patients and 71% of those managed in HSPUs. However objective assessment concluded that appropriate management was followed for just under 90% of patients in both hospital and HSPUs. Excluding patients already admitted on anticoagulants, only 12% of patients in HSPUs received thromboprophylaxis compared with 76% of those admitted acutely to hospital (Table 3). The main documented contraindications to pharmacological thromboprophylaxis for hospitalised patients were "receiving end of life care" (30.4%), "history of recent bleeding" (33.3%) and "thrombocytopenia" (13%). Similarly

“receiving end of life care” and “history of recent bleeding” were cited as contraindications for 44.7% and 13.6% of patients in HSPUs respectively.

The estimated unadjusted risk difference between recruitment sites was 0.47 (95% CI 0.42-0.52) which suggests that based on initial data, patients in hospital were 47% more likely to receive thromboprophylaxis than in HSPUs.

After adjusting for key patient characteristics (AKPS, age, gender, location of primary cancer, comorbidities and bleed history) the risk difference was estimated to be 0.33 (95% Confidence Interval 0.28-0.39). This means, that assuming the distribution of all the covariates included in the statistical model were hypothetically the same in both settings, (and equal to the overall distribution seen across hospitals and HSPUs in this dataset), then there would still be a 33% greater probability of receiving thromboprophylaxis hospitals compared with HSPUs.

Comparing the 0.33 to the 0.47 risk, revealed that around 29% of the difference in probability of thromboprophylaxis is explained by the variance in measured patient characteristics between the two settings. The 95% Confidence Interval for this estimate is 19%-39%.

Discussion

The use of thromboprophylaxis for palliative care cancer inpatients is still a matter of debate. Nevertheless, current health policy in many countries mandates the documented risk assessment and, where appropriate, administration of primary prophylaxis for all hospitalised patients regardless of disease status or prognosis. A previous multinational cross sectional survey of 358 hospitals in 32 countries, conducted between August 2006 and January 2007, provided data on over 68,000 medical and surgical inpatients, demonstrated poor compliance (39.5% and 58.5% respectively) with guidelines in those considered high risk.(21) Our one day “flash-mob” audit, is, to our knowledge, the largest audit of thromboprophylaxis specific to palliative care. Reassuringly, appropriate clinical practice, as judged by those undertaking the data collection, was recorded in 90% of patients in both hospitals and HSPUs. It is important to note the term “appropriate thromboprophylaxis” in this context is not synonymous solely with the provision of LMWH; it also encompasses the decision *not* to give these medicines to patients when there are contraindications. Within HSPUs, 88% of patients did not receive thromboprophylaxis, mainly due to receiving end of life care (44.7%) or a

history of recent bleeding (13.6%) . In contrast, thromboprophylaxis was administered to 76% of patients admitted to hospital. Once again, a history of bleeding (33%) or end of life care (30%) were the main contraindications to LMWH along with thrombocytopenia which accounted for a further 13% of patients.

The marked difference in practice between HSPUs and hospitals appears best explained by the differences between the patient groups. Whilst both patient groups were well matched for gender and primary cancers, hospitalised patients were generally younger, of better performance status and were more likely to be receiving anti-cancer treatments prior to admission. A larger proportion of patients admitted to HSPUs had a AKPS below 50 with a history of general deterioration prior to admission. This not only represents a sicker patient group who are nearer to end of life but also one similar to the population described in the HIDDEN study.(14)

This audit offers several insights relevant to the improvement of patient care. It is reassuring, that for a vulnerable adult population, we are providing appropriate thromboprophylaxis to those who need it, whilst ensuring it is not given to those at risk of harm from LMWH or who are unlikely to gain any benefit. It also suggests those admitted to HSPUs and hospitals represent two markedly differing populations with respect to thrombotic risk and the potential utility of thromboprophylaxis. The HIDDEN study challenged primary prophylaxis for most patients cared for in HSPUs, but it remains to be demonstrated whether its conclusions and recommendations should be extrapolated across all palliative care patients, regardless of inpatient environment. Hospitalised patients in this audit were fitter, of better prognosis and more likely to experience an acute deterioration prior to admission than those in HSPUs. In theory, they would be more likely to benefit from thromboprophylaxis since a typical admission represented a temporary elevation of thrombotic risk from a potentially reversible cause. A prospective observational study similar to HIDDEN is currently being undertaken in a hospital setting in order to answer explore this view.

Despite appropriate thromboprophylaxis being undertaken in both settings, this practice was not supported by a documented risk assessment in 21-30% of patients. Whilst this is unlikely to have direct clinical impact, in health settings where completion of a documented risk assessment tool has financial implications incentives or penalties, this allows room for improvement. There is also another consideration especially in HSPUs. In an environment

where the majority of patients do not receive thromboprophylaxis, documentation of the reason for not prescribing LMWH may spare teams from inappropriate scrutiny or complex bereavement. From this audit, just under one quarter of HSPCU patients who did not receive thromboprophylaxis had no documented reason given. Even though the majority of these will have been managed appropriately, it may be harder to demonstrate good practice retrospectively without supporting documentation.

This audit and its implications need to be viewed in the context of its potential limitations. Whilst it is admirable to have audited 1125 patient cases, this represents a small proportion of patients under the care of palliative care teams. For example, 611 patient datasets were audited within HSPUs but there are 2760 beds around the UK.(17) However, we believe this is a representative sample since the population was similar to those recruited (and those ineligible to recruitment) to HIDDEN. It is also important to recognise that cancer patients admitted to hospital are rarely under the main care of the palliative care team, which usually adopts a consultancy model of care. They are usually the primary responsibility of medical or surgical teams who will also have the responsibility for risk assessment and thromboprophylaxis. As seen, in the statistical analysis, even when accounting for variance in patient clinical features (AKPS, age, gender, location of primary cancer, comorbidities and bleed history), patients are more likely to receive low molecular weight heparin thromboprophylaxis when admitted to hospital. This is not a complete surprise; previous research has suggested that palliative care physicians are less likely to offer thromboprophylaxis than other specialities including oncology, haematology and intensive care.(22, 23)

As such, lessons learned, including improving the number of documented risk assessments and offering appropriate thromboprophylaxis may not be in the gift of the palliative care team alone. The audit tool developed, reflects the recommendations of Clinical Guideline 89, which is the current accepted standard of care in the UK. However, the publication of HIDDEN has challenged these guidelines suggesting the minority of HSPU patients would benefit from thromboprophylaxis and it is conceivable that some clinicians have already altered their practice. In this audit, six patients were recorded as not meeting the audit standard but their documentation stated their management was informed by HIDDEN results. This suggests an emerging change in practice, prior to any recommendations by professional bodies.

Finally, the implications of this audit may be of limited relevance to teams outside of the UK depending upon the importance attributed to VTE prevention. Also, some healthcare systems, particularly where medical care is self-financed or covered by insurance, may not support funding for pharmacological prophylaxis in patients who are classified as receiving palliative care. This is of even greater relevance where clinical guidelines other than CG89 are used since palliative care is not mentioned in any other published clinical guidelines.

Conclusion

Historically, palliative care teams have based their thromboprophylaxis management on unrepresentative and out of date research. As more relevant data emerges for the specialty, it is likely that practice will continue to change. However, these emerging data are largely from prospective observational studies and unlikely to influence future iterations of CG89 whose recommendations are usually based on health economic analysis of randomized control trials. This audit demonstrates that primary thromboprophylaxis remains a relevant issue within palliative care clinical practice but also highlights the shortcomings in the current evidence-based guidelines. It also illustrates that the definition of a “palliative care patient”, when characterized by “the involvement of palliative care teams”, covers a spectrum of clinical conditions, stage, performance status and prognosis, as well as thrombotic and bleeding risk. In a time of patient centered care, an individualized approach to thromboprophylaxis in advanced cancer patients has never been more relevant. Finally, these data suggest that place of admission will influence the likelihood of thromboprophylaxis predominantly because patients admitted to HSPUs are more unwell but also due to different practices in the acute setting by non-palliative care teams.

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Affiliations

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1.7.1 Consider pharmacological VTE prophylaxis for people who are having palliative care. Take into account temporary increases in thrombotic risk factors, risk of bleeding, likely life expectancy and the views of the person and their family members or carers (as appropriate):

- Use LMWH as first-line treatment.
- If LMWH is contraindicated, use fondaparinux sodium.

1.7.2 Do not offer VTE prophylaxis to people in the last days of life.

1.7.3 For recommendations on shared decision-making in the last days of life, see the NICE guideline on care of dying adults in the last days of life.

1.7.4 Review VTE prophylaxis daily for people who are having palliative care, taking into account the views of the person, their family members or carers (as appropriate) and the multidisciplinary team.

Figure 1. National Institute for Health and Care Excellence Clinical Guideline 89 recommendations for thromboprophylaxis in people receiving palliative care (LMWH=low molecular weight heparin, VTE =venous thromboembolism, NICE= National Institute for Health and Care Excellence).(12)

Table 1. Demographics of patients audited in hospital and hospice/ specialist palliative care units (HSPCU)

	Hospital (%)	Hospice/ Specialist Palliative Care Units (%)
	N= 514	N= 611
Sex		
Male	266 (51.8%)	283 (46.3%)
Female	248 (48.2 %)	328 (53.7%)
Age		
18-24	2 (0.4%)	1 (0.2%)
25-34	12 (2.3%)	5 (0.8%)
35-44	17 (3.3%)	23 (3.8%)
45-54	51 (9.9 %)	52 (8.5%)
55-64	122 (23.7%)	112 (18.3%)
65-74	123 (23.9%)	159 (26.0%)
75-84	120 (23.3%)	165 (27.0%)
85+	66 (12.8%)	94 (15.4%)
Data not recorded	1 (0.2%)	0 (0.0%)
Tumour primary site		
	Hospital	HSPCU
Lung	76 (15%)	102 (16.7%)
Gastro-oesophageal	34 (6.6%)	48 (7.9%)
Hepatobiliary/ pancreatic	36 (7%)	60 (9.8%)
Colorectal	53 (10%)	69 (11.3%)
Small bowel/appendix	2 (0.4%)	6 (1%)
Gynaecological	47 (9%)	47 (7.7%)
Breast	41 (8%)	47 (7.7%)
Brain	13 (2.5%)	24 (3.9%)
Bladder	22 (4.2%)	15 (2.5%)
Head and neck	19 (3.6%)	22 (3.6%)
Myeloma	9 (1.7%)	9 (1.5%)
Prostate	52 (10%)	58 (9.5%)
Renal/Urothelial	22 (4.2%)	18 (3%)
Unknown primary	19 (4.3%)	18 (3%)
Melanoma	8 (1.5%)	11 (1.8%)
Lymphoma	22 (4.2%)	15 (2.5%)
Leukaemia	14 (2.7%)	3 (0.5%)
Other	25 (4.8%)	39 (6.3%)

Table 2. Treatments, Reason for Admission and Performance Status Indices.

	Hospital (%)	Hospice/ Specialist Palliative Care Units (%)
	N= 514	N= 611
Anti-cancer treatments in past 4 weeks		
Yes	179 (34.8%)	99 (16.2%)
None	332 (64.6%)	510 (83.5%)
Data not recorded	3 (0.58%)	2 (0.3%)
Type of anticancer treatment		
Chemotherapy	72 (14.0%)	34 (5.6%)
Combination	20 (3.9%)	1 (0.2%)
Targeted therapies	26 (5.1%)	10 (1.6%)
Hormone	27 (5.3%)	26 (4.3%)
Radiotherapy	23 (4.5%)	28 (4.6%)
Data not recorded	11 (2.1%)	0 (0.0%)
Illness trajectory prior to admission		
Acute deterioration	43 (85.0%)	176 (28.8%)
Gradual deterioration	56 (11.1%)	249 (69.7%)
Elective procedure/ planned admission	19 (3.7%)	9 (1.5%)
Modified Australia Karnofsky Performance Score		
10	25 (4.9%)	28 (4.6%)
20	75 (14.6%)	158 (25.9%)
30	69 (13.4%)	99 (16.2%)
40	87 (16.9%)	94 (15.4%)
50	109 (21.2%)	120 (19.6%)
60	65 (12.6%)	74 (12.1%)
70	42 (8.2%)	26 (4.3%)
80	19 (3.7%)	8 (1.3%)
90	1 (0.2%)	3 (0.5%)
100	0 (0.0%)	0 (0.0%)
Data not recorded	22 (4.3%)	1 (0.2%)

Table 3: Compliance with Clinical Guidance 89 and reasons for not giving low molecular weight heparin

	Hospitals (%)	Hospice/ Specialist Palliative Care Unit (%)
	N= 514	N= 611
Has a documented risk assessment score been completed?		
Yes	406 (79.0%)	436 (71.4%)
No	102 (19.8%)	175 (28.6%)
Data unavailable	6 (1.2%)	0 (0.0%)
In your personal opinion, does the management follow the recommendations of Clinical Guideline 89?		
Yes	457 (88.9%)	548 (89.7%)
No	50 (9.7%)	60 (9.8%)
Data unavailable	7 (1.4%)	3 (0.5%)
Patient currently on prophylactic low molecular weight heparin? (Excluding patients on treatment dose anticoagulants)		
Yes	277 (76%)	64 (12%)
No	138 (24%)	463 (88%)
Main reasons for patients not receiving prophylactic low molecular weight heparin(%)		
End of life care	42 (30.4%)	207 (44.7%)
History of recent bleeding	46 (33.3%)	63 (13.6%)
Thrombocytopenia	18 (13.0%)	7 (1.5%)
Renal failure	3 (2.2%)	4 (0.9%)
Heparin induced thrombocytopenia	0 (0.0%)	1 (0.2%)
Other reason	6 (4.3%)	69 (15.1%)
No reason recorded	23 (16.7%)	112 (24.2%)