

Duration and magnitude of postoperative risk of venous thromboembolism after planned inguinal hernia repair in men: a population based cohort study

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Abstract

Purpose: Little is known regarding the magnitude and timing of the risk of VTE following inguinal hernia surgery. We aimed to determine absolute and relative rates of venous thromboembolism (VTE) following planned inguinal hernia repair.

Methods: We analysed male adults with a first inguinal hernia repair with no prior record of VTE from the Clinical Practice Research Datalink, linked to Hospital Episode Statistics (2001-2011). Crude rates and adjusted hazard ratios (HR) of first VTE were calculated using Cox regression analysis to compare specific time periods following surgery compared to the general population.

Results: We identified 28,782 men who underwent an inguinal hernia repair with 53 (0.2%) having a first VTE in the 90 days following surgery. The overall rate of VTE in the first 90 days following surgery was 7.61 per 1000 person years (pyrs) (95% CI 5.82-9.96) compared with 2.74 per 1000 pyrs (95% CI 2.51-3.00). Increasing age, a body mass index $>30 \text{ kg/m}^2$ and an in-patient procedure were associated with an increased risk of VTE when compared to the general population. The risk of VTE was highest in the first month following surgery with a 2.3 (aHR 2.33; 95% CI 1.09-4.99) and 3.5 (aHR 3.47; 95% CI 2.07-5.83) fold increased risk compared to the general population for both day case and planned in-patient procedures respectively.

Conclusions: Reassuringly the absolute rates of VTE following inguinal hernia repair are low. Patients should be informed that their peak risk of VTE is during the first month following surgery.

INTRODUCTION

Inguinal hernia repair is the most commonly planned general surgical procedure performed with over 750,000 each year in the United States and 70,000 a year in England[1, 2]. The British Hernia Society guidelines suggest patients should be informed about the symptoms and signs of venous thromboembolism following surgery[3]. However these guidelines give no details on how commonly VTE occurs following inguinal hernia surgery. Studies reporting the risk of VTE following inguinal hernia repair have generally focused on individual patient groups such as those having a laparoscopic repair[4-6], are single centre retrospective studies[4, 7], have not reported the timing of events[7] or have reported VTE as part of a composite endpoint[8-10]. To date the largest study reporting on rates of VTE following inguinal hernia surgery reported a 91 day rate of VTE of 0.4% and included 10,263 patients[11]. The study however, did not report hernia specific rates of VTE by age, comorbidity or by mode of surgery (in-patient/day case). There was also no report of the excess risk of VTE associated with surgery compared to the general population. Whilst the overall risk of VTE may be low following inguinal hernia surgery we currently have no population based estimates of how patient factors and the mode of surgery impact on the risk of VTE following hernia repair. Information regarding those at greatest risk and the duration and magnitude of this risk are key to directing appropriate preventative measures and accurately informing patients of their risk of postoperative VTE.

Therefore we have undertaken a population based study using linked primary and secondary health care data to quantify the risk of first VTE among males undergoing inguinal hernia repair during the post-surgical period and compared those to the baseline VTE risk of the general population.

MATERIAL AND METHODS

Patients and data sources

Clinical Practice Research Database (CPRD)

The CPRD contains diagnostic and prescription data for approximately 13 million people of the general population in the UK, with 3.4 million active patients contributing data. Diseases are coded within the CPRD using Read codes[12]. Read codes are a coded thesaurus of clinical terms that have been used by clinicians to record data in IT systems within the primary care setting since 1985.

Hospital Episode Statistics (HES)

HES collect a detailed record for each 'episode' of admitted patient care delivered in England, either by NHS hospitals or delivered in the independent sector but commissioned by the NHS. It has collected data since 1989 with more than 15 million new records added each year. Records are coded using a combination of International Statistical Classification of Disease and Related Health Problems (ICD-10) for primary diagnosis at discharge along with Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures version 4 (OPCS 4) detailing procedures performed.

We also used death certificate data from the Office for National Statistics (ONS). The anonymised patient identifiers from CPRD and HES were linked by a trusted (anonymous) third party by using the National Health Service (NHS) number, date of birth, postcode, and sex. Most patients were matched exactly according to NHS number (over 90% of patients are linked in this way), with the remaining patients linked probabilistically on the basis of postcode, date of birth, and sex. Currently 53% of practices in the CPRD are linked to HES which represents a 3% sample of the UK population. These data have been previously shown to be similar in terms of age, sex, and geographical distribution to data from the UK population published by ONS[13].

Cohort Identification

The cohort was identified from CPRD-HES linked data using OPCS codes for inguinal hernia (Codes T201, T202, T203, T204, T208, T209, T211, T212, T213, T218, T219). A laparoscopic approach was confirmed by the inclusion of an OPCS code for laparoscopy Y508, Y571 and Y752. Men were followed up until they developed

a VTE event, died, left a participating GP practice or 31st Dec 2011, whichever was earliest. Men under the age of 18 years were excluded as the risk of VTE following hernia repair in this group have been reported previously. Female patients were excluded as they only contributed 6.6% of cases of planned inguinal hernia repair (2063/30845).

The population cohort was identified from the CPRD-HES linked data. In order to maximize statistical power, all available controls without a diagnosis of surgery during their CPRD-HES record were eligible. The population cohort were drawn from a larger study of all patients undergoing gastrointestinal surgery in which they were frequency matched in a ratio of 10:1 by 5-year-age bands to those undergoing surgery. They received a pseudo-diagnosis date generated at random between the study start and end date (2001-2011).

Outcome Definition

VTE diagnosis was determined from medical codes in the CPRD and HES (using Read and ICD-10 respectively). These were considered to be a VTE event if supported by either: a prescription for an anticoagulant or other evidence of treatment in an anticoagulation clinic (such as a medical code) between 15 days before and 90 days after the VTE diagnosis, or a date of death within 30 days of the event. Additionally, an underlying cause of death of VTE was included as evidence of VTE diagnosis. Only the first confirmed instance of VTE was included in the analysis. We took the date of diagnosis of VTE's to be the episode start date for VTEs occurring within the same hospital spell as the index operation. Men were excluded if they had a VTE prior to admission for hernia repair or pseudo-diagnosis date. The definition using primary care data alone has been validated previously showing 84% of cases were valid[14] and used in our prior studies of VTE[15, 16].

Exposures

Comorbidity was determined from the CPRD and HES data and classified using the Charlson index prior to admission for surgery and categorised as no comorbidity, 1 comorbidity or 2 or more comorbidities[17]. Body mass index (BMI) was defined from the primary care data and classified as less than 30 kg/m², greater than or equal to 30 kg/m² or missing to assess any systematic differences in those with missing data. Length of stay for each admission was calculated in days. Finally, admission type was defined as in-patient or day case on the type of admission recorded for the surgical procedure.

Statistical Analysis

First, we described the basic characteristics of our cohort using frequencies and percentages. Median ages were calculated and compared using Kruskal Wallis Test. Absolute rates of VTE (per 1000 person years) were calculated for the first 90 days following surgery. These rates were then stratified by age, comorbidity, BMI and admission type. The impact of these factors on VTE risk was assessed in terms of Hazard ratios (HR) using Cox regression model compared to the general population within each stratum. In order to assess the impact of timing in relation to index surgery on the risk of VTE, we also calculated the rate of VTE within hospital admission during which the index surgery was conducted and during the post-discharge period (defined from the date of discharge up to exit from the study defined as death, last data collection or VTE). The post discharge period was further stratified into individual months up to 3 months. We undertook a further analysis by weeks following surgery up to 12 weeks following discharge given the increased risk of VTE following gastrointestinal surgery reported in the Million Women Study[18]. Cox regression analysis was again used to provide HR for each time interval at risk comparing risk of those undergoing in-patient or day case inguinal hernia repair to the general population. Missing data was fitted as a separate category in all analyses. All data management and analysis were performed using Stata 12 (Statacorp, Texas 77845 USA).

The study had approval from the Independent Scientific Advisory Committee approval board which provides scientific advice to the Medicines and Healthcare products Regulatory Agency (MHRA) (Protocol 11-051R).

RESULTS

Demographics of cohort

We identified 28,782 men undergoing an inguinal hernia repair with 53 (0.2%) VTE events occurring within 90 days of surgery. The median age at hernia repair was 61 years (inter quartile range (IQR) 48-71 years). In total 53.8% (15480/28782) of men had their hernia repair performed as a day case procedure. Those men having a day case procedure (median 57 years; IQR 43-66) were younger than those undergoing in-patient repair (median 66 years; IQR 55-76) (Kruskal Wallis, $p < 0.0001$). The median age of the population cohort was 52 years (IQR 38-65). The proportion of men with a Charlson index greater than two was higher in those undergoing in-patient repair compared to those under day case repair (Charlson group ≥ 2 10.5% vs 24.8% chi squared $p < 0.001$). The median length of stay following an in-patient procedure was 1 day (IQR 1-2). Overall 5.5% (1576/28782) of hernias were recurrent. Laparoscopic hernia repair was undertaken in 12.3% (1897/15480) of day case procedures and 12.6% (1678/13302) of in-patient procedures. In total 700 (2.4%) men had a prior prescription of long term anticoagulant but none of these developed VTE.

Overall rates of VTE following inguinal hernia surgery

The overall rate of VTE in the first 90 days following inguinal hernia surgery was 7.61 per 1000 person years (95% CI 5.82-9.96) compared with 2.74 per 1000 person years (95% CI 2.51-3.00) in the control cohort. The rate of VTE increased with increasing age peaking in those over the age of 70 years with a rate of 15.31 per 1000 person years which represented a 2.1 fold (HR 2.10; 95% CI 1.44-3.06) increase in risk compared to the general population (Table 2). A BMI greater than 30 kg/m² was associated with a 3.7 fold increase risk of VTE compared to the general population however those men where BMI was missing also had a 5 fold increase in risk compared to the general population when adjusting for age comorbidity and admission type (Table 2). Those undergoing an in-patient repair had a 2.8 fold (adjusted HR 2.84; 95% CI 2.04-3.95) increased risk of VTE compared to the general population. Those undergoing a day case inguinal hernia repair had a 1.6 fold increase in risk of VTE compared to the general population however this was not significant (adjusted HR 1.57; 95% CI 0.92-2.87).

The absolute rate of VTE was highest in those men with a Charlson score of at least 2 (AR 11.78 per 1000 person years), which did not represent an increase in risk of VTE compared to the general population (HR 1.30; 95% CI 0.76-2.24). The greatest relative risk of VTE was seen in those men with no comorbidity with a 4.3 fold

increased risk compared to the general population (adjusted HR 4.29; 95% CI 2.81-6.56). To explore this relationship further we stratified rates by in-patient and day case procedure which demonstrated that the highest absolute rates were in those men having an in-patient repair with a Charlson score of 2 or more (16.32 per 1000 person years) representing a 1.8 fold increase in risk compared to the general population (adjusted HR 1.76; 95% CI 1.01-3.08) (Table 3). In contrast those men having a day case procedure with a Charlson score of 0 had the highest absolute rates of VTE 4.07 per 1000 person years which represented a 3.2 fold increase in risk (adjusted HR 3.26; 95% CI 1.75-6.06) with those men with a Charlson score of 1 or 2 or more having lower rates of VTE with no associated increase in risk compared to the general population.

Rates of VTE following day case inguinal hernia repair

The absolute rate of VTE was greatest in the first month following day case surgery (5.55 per 1000 person years 95% CI 2.64-11.64). The peak rate occurred in the second week following discharge (10.16 per 1000 person years (95% CI; 3.28-31.51).

Rates of VTE following in-patient hernia repair

The absolute rate of VTE was 29.58 per 1000 person years (95% CI 9.54-91.72) in the in-hospital period. Following discharge the rate remained elevated with a rate of 19.65 per 1000 (95% CI person-years in the first week and 31.62 per 1000 person-years (95% CI; 15.81-63.23) in the second week post discharge giving a combined rate in the first two weeks of 19.65 per 1000 person years (95% CI 8.18-47.21) (Figure 1. Rates of VTE in the in-hospital period and every 2 weeks following).

Relative risk of VTE following hernia repair by mode of surgery compared to the general population

Following a day case hernia repair there was a 2.0 fold increase (Table 4) in risk of VTE compared to the general population and when accounting for age, comorbidity and BMI this increased to a 2.3 fold increased risk of VTE in the first month following surgery (adjusted HR 2.33; 95% CI 1.09-4.99). There was no difference in the rate of VTE between those undergoing day case repair compared to the general population in the time following.

In those undergoing an in-patient repair there was a 5.3 fold increase (Table 5) in risk of VTE compared to the general population in the first month following surgery however this relationship was attenuated when accounting for age, comorbidity and BMI (adjusted HR 3.47; 95% CI 2.07-5.83). The risk of VTE remained

elevated compared to the general population in the second and third month following surgery (Table 5) before returning to the baseline risk in the time following.

DISCUSSION

Summary of findings

The overall rates of VTE following inguinal hernia repair are low. Increasing age, BMI and an in-patient admission were associated with an increased risk of VTE. Day case surgery was associated with a 2.3 fold increase in the risk of VTE in the first month following surgery compared to the general population whilst in-patient surgery was associated with a 3.5 fold increase compared to the general population in the first month following surgery. The duration of this excess risk was limited to the first month following day case surgery but extended to the third month following surgery in those having an in-patient repair. The peak risk of VTE following inguinal hernia repair occurred in the first two weeks following discharge irrespective of whether the procedure was carried out as a day case or in-patient.

Limitations of study

Our study used linked data to identify men undergoing inguinal hernia repair from population based data, with identification of operative procedures from secondary care along with defining VTE in a validated manner from primary[14] and secondary care and in that sense it is uniquely placed to quantify VTE risk accurately. However the utilization of day case surgery is lower than that reported from other Countries[19]. There may therefore be an over estimate of the risk of VTE following hernia surgery from this cohort due to the higher proportion of men having an in-patient procedure as VTE risk is known to increase with hospitalisation independent of other factors[20]. Although we were unable in our analysis to identify those men receiving thromboprophylaxis there were no specific recommendations for extended prophylaxis following hernia repair until the last year of the study. Furthermore rates of VTE prophylaxis use in these patients were low[21]. Nevertheless we cannot exclude the possibility that rates of VTE might be higher in some groups than we observed precisely because they received prophylaxis.

Other literature

Our overall 90 day rate of VTE following inguinal hernia repair of 0.2% is less than that reported by the only other population based reporting on rates of VTE following hernia surgery using data from the California Patient Discharge Data Set from 1992 to 1996 which reported a 0.4% incidence at 91 days[11]. Possible explanations for

this difference include a greater awareness of VTE prevention by surgeons in the current dataset given this study uses more contemporary data. There was also little data given on the type of surgery undertaken and as our results show rates vary by the mode in which hernia repair is performed which may also therefore account for the difference in rates. The prior study also used only secondary care data to identify cases of VTE and this may overestimate rates of VTE[15].

One previous study has suggested that low risk patients could have thrombo-prophylaxis omitted following inguinal hernia surgery as rates of VTE are low[7]. Our findings of a low rate following day case and only a small increase in risk compared to the general population would agree with this. This prior study however did not have the power to risk stratify patients to identify those at increased risk or detail the timing of the risk of VTE following inguinal hernia repair. Given that it has been reported that the majority of surgeons fail to risk stratify their patients undergoing hernia repair it may be that those at high risk of VTE are not being correctly identified[22].

The Million Women study a large cohort study of middle aged women reported an increased risk of VTE following surgery which lasted up to 12 weeks following surgery[18]. However this previous study was unable to detail risk by procedure and the vast majority of patients having an inguinal hernia repair are males. Our study has confirmed an increased risk of VTE lasting up to 12 weeks following an in-patient repair. It also highlighted the peak rate of VTE occurs following discharge suggesting risk stratification at discharge may be appropriate given the short length of stay of patients having an in-patient repair.

Clinical Significance

The overall risk of VTE following planned inguinal hernia surgery in males is low. The risk of VTE peaks in the second week following discharge with the highest absolute rates seen in men following in-patient repair. The risk of VTE is elevated for a month following day case surgery and 3 months following in-patient repair compared to the general population which is important when informing men of the duration for which they may be at increased risk of VTE. Our results suggest that after appropriate risk stratification the majority of men may not need any prophylaxis for VTE following inguinal hernia repair. Further larger studies considering a wider range of prognostic variables could be performed to further characterise those who do not require thromboprophylaxis. Current NICE guidance would recommend that men with associated risk factors for VTE and poor mobility following repair may be considered for thrombo-prophylaxis post discharge from a day case unit[23]. Given our findings of a peak risk of 2 weeks this may be an appropriate duration of prophylaxis however randomised trials

of this intervention may be required. Given the risk is higher in men undergoing an in-patient procedure it may be that this group of men should also be considered for risk assessment for prophylaxis following discharge or greater efforts should be made to undertake these procedures in the day case setting where risks of VTE are lower. These patients may be considered for prolonged prophylaxis of up to one month however further studies would be required to assess the risk benefit of this duration of prophylaxis given the potential for increased complications due to bleeding associated with thromboprophylaxis.

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Table 1. Demographics of those undergoing inguinal hernia repair by method of admission and population controls

	Day case		Elective in-patient		General Population	
	No.	%	No.	%	No.	%
<i>Age</i>						
>=18-59	8,853	57.2	4,489	33.7	501,440	63.5
60-69	3,818	24.7	3,259	24.5	144,176	18.3
>=70	2,809	18.1	5,554	41.8	143,559	18.2
<i>Comorbidity</i>						
0	11,189	72.3	7,054	53	515,705	65.3
1	2,660	17.2	2,951	22.2	133,534	16.9
>=2	1,631	10.5	3,297	24.8	139,936	17.7
<i>BMI (kg/m²)</i>						
<30	10,877	70.3	9,526	71.6	452,773	57.4
>=30	1,258	8.1	1,423	10.7	127,702	16.2
Missing	3,345	21.6	2,353	17.7	208,700	26.4

Table 2. Rates of VTE in first year following inguinal hernia repair by risk factors for VTE. *adjusted for all factors in table

		Absolute Rates Population cohort.				Absolute Rates Following inguinal hernia repair				Univariate Cox Model		Multivariate Cox Model*	
		Events	Time	Rate	95% CI	Events	Time	Rate	95% CI	HR	95% CI	HR	95% CI
Age (years)	>=18-59	125	115	1.09	0.91-1.30	8	3.22	2.48	1.24-4.96	2.29	1.12-4.68	2.45	1.20-5.01
	60-69	114	33.43	3.41	2.84-4.10	14	1.71	8.16	4.84-13.78	2.39	1.37-4.17	2.8	1.60-4.90
	>=70	256	32.07	7.98	7.06-9.02	31	2.02	15.31	10.77-21.77	1.92	1.32-2.79	2.1	1.44-3.06
BMI	<30	298	104.39	2.85	2.55-3.20	29	4.94	5.88	4.08-8.46	2.06	1.41-3.01	1.65	1.12-2.42
	≥30	90	29.56	3.04	2.48-3.74	8	0.65	12.38	6.19-24.76	4.07	1.97-8.38	3.72	1.80-7.69
	Missing	107	46.54	2.3	1.90-2.78	16	1.38	11.58	7.10-18.90	5.07	3.00-8.57	4.99	2.94-8.45
Comorbidity	0	126	118.66	1.06	0.89-1.26	27	4.42	6.11	4.19-8.91	5.78	3.82-8.76	4.29	2.81-6.56
	1	108	30.65	3.52	2.92-4.25	12	1.36	8.84	5.02-15.56	2.51	1.38-4.55	2.04	1.12-3.73
	≥2	261	31.18	8.37	7.41-9.44	14	1.19	11.78	6.98-19.89	1.41	0.82-2.41	1.3	0.76-2.24
Admission	Day Case	495	180.5	2.74	2.51-3.00	14	3.74	3.75	2.22-6.33	1.36	0.80-2.33	1.56	0.91-2.65
	In-patient	495	180.5	2.74	2.51-3.00	39	3.23	12.09	8.83-16.54	4.42	3.19-6.12	2.84	2.04-3.95

Table 3. Rates of VTE by comorbidity following an in-patient procedure.

		Absolute Rates Population Cohort				Absolute Rates In-patient				Univariate Cox Model		Multivariate Cox Model*	
		Events	Time	Rate	95% CI	Events	Time	Rate	95% CI	HR	95% CI	HR	95% CI
In-patient Comorbidity	0	126	118.66	1.06	0.89-1.26	16	1.71	9.34	5.72-15.24	8.82	5.24-14.84	5.33	3.13-9.08
	1	108	30.65	3.52	2.92-4.25	10	0.72	13.97	7.52-25.96	3.96	2.07-7.57	2.78	1.44-5.36
	≥2	261	31.18	8.37	7.41-9.44	13	0.8	16.32	9.47-28.10	1.95	1.12-3.41	1.76	1.01-3.08

Table 4. Rates of VTE following day case inguinal hernia repair compared to the general population by month following surgery and then time following.

	Events (n)	Rates of VTE (per 1000 person years)	Univariate		Multivariate*	
			HR	95% CI	HR	95% CI
<i>1st Month</i>						
General population	168	2.76 (2.38-3.22)	ref		ref	
Day Case	7	5.55 (2.64-11.64)	2.01	0.94-4.27	2.33	1.09-4.99
<i>Post Surgery</i>						
General population	5171	2.39 (2.32-2.45)	ref		ref	
Day Case	120	1.97 (1.66-2.35)	0.84	0.70-1.00	0.89	0.75-1.06

* adjusted for, age, comorbidity, BMI

Table 5. Rates of VTE following in-patient inguinal hernia repair compared to the general population by month following surgery and then time following.

	Events (n)	Rates of VTE (per 1000 person years)	Univariate		Multivariate*	
			HR	95% CI	HR	95% CI
<i>1st Month</i>						
General population	174	2.76 (2.38-3.21)	ref		ref	
In-patient	16	14.72 (9.02-24.02)	5.33	3.19-8.89	3.47	2.07-5.83
<i>2nd Month</i>						
General population	171	2.85 (2.46-3.31)	ref		ref	
In-patient	13	12.10 (7.02-20.83)	4.24	2.42-7.46	2.71	1.53-4.79
<i>3rd Month</i>						
General population	150	2.60 (2.22-3.06)	ref		ref	
In-patient	10	9.39 (5.05-17.46)	3.61	1.90-6.84	2.28	1.20-4.35
<i>Time Following</i>						
General population	5171	2.37 (2.30-2.43)	ref		ref	
In-patient	196	3.31 (2.87-3.80)	1.42	1.23-1.64	0.97	0.84-1.12

* adjusted for, age, comorbidity, BMI

Figure 1. Rates of VTE following in-patient repair by in hospital period and two weeks following discharge to 12 weeks and time after.