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Pulmonary embolism and mortality following total ankle replacement: a data linkage study using the NJR data set

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ABSTRACT

Objective: To determine the mortality rate following total ankle replacement (TAR) and incidence of 90 day pulmonary embolism (PE) along with the associated risk factors.

Design: Data-linkage study of the UK National Joint Registry (NJR) data and Hospital Episodes Statistics (HES) database. Linkage was performed in a deterministic fashion. HES episodes 90 days after the index procedure were analysed for PE. Mortality data were obtained pertaining to all the index procedures from the NJR for analysis.

Participants: All primary and revision ankle replacement patients captured on the NJR between February 2008 and February 2013.

Results: The 90-day mortality following TAR was 0.13% (95% CI 0.03 to 0.52) and 1-year mortality was 0.72% (95% CI 0.40 to 1.30); no deaths were as a result of PE. The incidence of PE within 90 days following primary TAR was 0.51% (95% CI 0.23 to 1.13). There was only one PE following revision surgery. Patients with an Royal College of Surgeons Charlson score greater than zero were at 13 times greater risk of PE (p=0.003).

Conclusions: There is low incidence of PE following TAR, but multiple comorbidities are a leading risk factor for its occurrence.

Strengths and limitations of this study

- The world's largest cohort of ankle replacements.
- Data-linkage methodology reduces biases that are present in single surgeon, single centre reports of pulmonary embolism.
- Limited by a linkage rate of 73%.

INTRODUCTION

Total ankle replacement (TAR) provides patients with an improved functional outcome that is maintained at 10 years with a cumulative annual failure rate of 1.2%.[1] The National Institute for Healthcare and Clinical Excellence (NICE) risk assessment tool categorises TAR as a high-risk procedure for pulmonary embolism (PE),[2] but the true incidence of venous thromboembolism (VTE) following TAR is largely unknown, with several papers reporting a wide variation in incidence ranging from 0% to 4.8% (table 1).[3–14] These studies demonstrate ambiguity of definition of VTE; methodological flaws; and small single centre retrospective reviews.

An estimated 25 000 people die from hospital acquired VTE in the UK every year.[15] Indeed, mortality is a key quality of care indicator outlined by the Keogh Report and its reduction a vital ambition of the UK National Health Service (NHS).[16]

VTE events are rare and difficult to capture in a single centre, but can be detected in sufficient numbers by large-scale national registries. It has been mandatory to input every TAR into the NJR since 2010. A further advantage to using registry data for analysis is the diversity regarding the patient population, surgeon and implant choice. It is therefore representative of real-world practice.

In England, any patient admitted to an NHS hospital is recorded on the Hospital Episode Statistics (HES) database; currently, more than 125 million records are captured each year. Almost all suspected PEs are admitted to hospital and should be recorded on the HES database. Between April 2012 and April 2013, 23 257 patients were admitted to NHS hospitals in England with PE.[17]
The aims of our study therefore were to answer the following research questions using linked NJR-HES data:

1. What is the rate of mortality following TAR?
2. What is the 90-day incidence of PE and associated risk factors?

METHODS

Data linkage

Data from the NJR were linked to HES data in a deterministic fashion. Deterministic linkage requires an exact match of the fields being linked from both data sets in order to say that they are from the same patient. NJR

Table 1 Studies reporting on thromboembolic events post-TAR

Study	Source	Number in study	Total VTE events Number and percentage	Deep vein thrombosis Number and percentage	Pulmonary embolism Number and percentage
Barg, *et al*[4a]	SC/MS	655	26 (3.97)	26 (3.97)	NA
Haskell *et al*[4b]	MC/MS	187	2 (1.07)	NA	NA
Hobson, *et al*[5]	SC/SS	123	0 (0)	0 (0)	0 (0)
Jameson, *et al*[6]	HES database	1633	1 (0.06)	0 (0)	1 (0.06)
Karantana, *et al*[7]	SC/SS	52	0 (0)	0 (0)	0 (0)
Knecht, *et al*[8]	SC/SS	67	1 (1.49)	0 (0)	1 (1.49)
Kumar, *et al*[9]	SC/SS	43	0 (0)	0 (0)	0 (0)
Lee, *et al*[10]	SC/SS	50	0 (0)	0 (0)	0 (0)
Rippstein, *et al*[11]	SC/MS	233	3 (1.29)	3 (1.29)	0 (0)
Rodrigues-Pinto[12]	MC/MS	119	0 (0)	0 (0)	0 (0)
Saltzman, *et al*[13]	SC/SS	42	2 (4.76)	2 (4.76)	0 (0)
Schweitzer, *et al*[14]	MC/MS	67	1 (1.49)	0 (0)	1 (1.49)

HES, Hospital Episode Statistics; MC, multicentre; MS, multiple surgeons; NA, not applicable; n, number; SC, single centre; SS, single surgeon; VTE, venous thromboembolism; TAR, total knee replacement.

records for primary and revision procedures (From February 2008 to February 2013) (1627 records) were linked to 5 years of HES records (which equates to 90 million records) (figure 1). This is in contrast to probabilistic linkage which estimates the likelihood that two records are for the same individual, even if they disagree on some fields.[18] Linkage was conducted by the Health & Social Care Information Centre. This was in line with best linkage practice with application of the 'separation principle' to allow the most ethical workflow.[19] This principle is used to protect patient data, with patient identifying components and clinical components of a data set kept separate. Identifying data are used by a group to perform data linkage, while the research group uses non-identifying data to perform the analysis.

A total of 1627 NJR records were linked to NJR data that were captured on minimal data set forms completed by the surgeon at the time of surgery and submitted by the performing hospital. This is a mandated requirement in the UK NHS. For a primary ankle replacement, the form is entitled an A1 form and for a revision ankle replacement, an A2 form.[20 21] The forms capture patient demographics such as patient age, gender and body mass index (BMI). The unit where the surgery is performed is captured with the grade of surgeon performing the surgery. The grade of surgeon is subdivided into a consultant surgeon or trainee. Indication for surgery, details of preoperative deformity and range of motion are also collected. Further to this, the prosthesis type, surgical approach, associated procedures, intraoperative complications and prophylaxis against venous thromboembolic disease are recorded.[20 21]

Identification of PE

The ICD-10 (International Classification of Disease V.10) codes were used to search the linked data for episodes of PE after the index procedure.[22] Deep vein thrombosis (DVT) was excluded from our analysis as these patients are not admitted to hospital but instead are treated in the community and hence are not recorded on the HES database.[6]

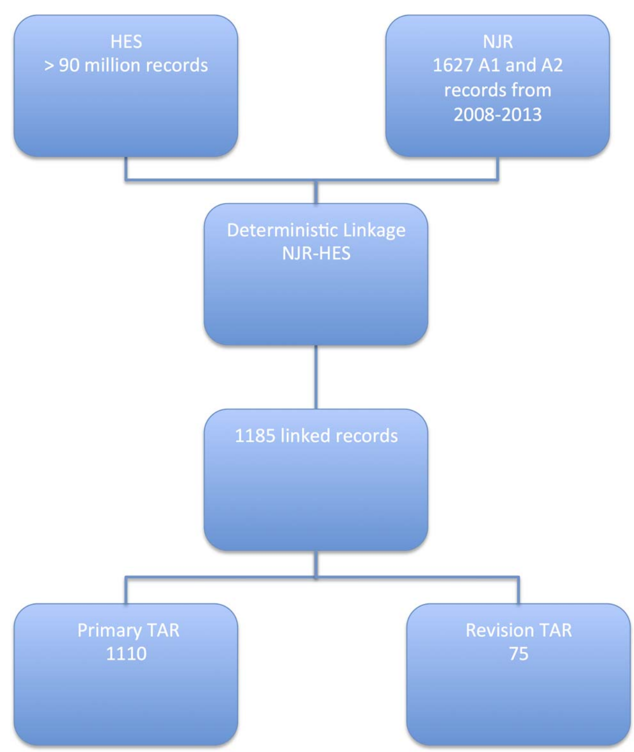

Figure 1 Flow chart showing the linkage of the NJR and HES databases. Twenty-seven of the records remained unlinked due to non-consent and the procedures being carried out in non-NHS institutions where no HES record is created. HES, Hospital Episode Statistics; NHS, National Health Service; NJR, National Joint Registry.

Identification of deaths following TAR

Mortality data were obtained separately from the NJR. The NJR tracks mortality via its link with the Office of National Statistics and automatically flags deaths at 90 days, 1 year, 2 years and 3 years.

Analytical approach

Factors related to increased risk of PE following primary TAR were assessed. Several variables were investigated including: age, sex, BMI, length of stay, indication for surgery, implant type and fixation, thromboprophylaxis, preoperative range of motion and deformity, where the implant was performed (NHS vs independent sector) and comorbidities.

Comorbid conditions were defined using the Royal College of Surgeons Charlson score applied to HES records in the 12 months preceding the index operation for every patient. This is a validated tool that is a count of chronic comorbid conditions that may affect the outcome of surgery.[23] We combined the comorbidity count to form two groups for analysis; this was due to the small numbers of PEs in each group.

An assessment of the similarities between the background characteristics and surgical factors of the PE and no PE patient groups was conducted. The normality of each continuous factor when broken down by the PE or no PE patient groups was assessed using the Shapiro-Wilk test. Student's t-test were used to test whether there was a difference in the means between the two groups when normality was upheld. Mann-Whitney tests were used to test whether the medians of the distributions were different for skew distributions. The χ^2 or Fisher's exact tests were used to test whether there was an association between a categorical factor and patient group membership. Since the number of PE outcome events was small, the ratio of outcome events per factor was not sufficient to enable multivariable analysis of the effect of multiple factors on PE.

For the purpose of analysis, age was divided into three groups: <65, 65–75 and >75. BMI was divided into three categories: a BMI of >18.5 is underweight; 18.5–25 was classed as normal, and a BMI of >25 was classified as overweight, with no further breakdown for obesity. PE rate was also analysed in the context of unit volume. We identified that those units performing more than 20 per year (19 units) accounted for half of all ankle replacements performed and those that did <20 per year (163 units) accounted for the other half. We therefore classed high volume units as those carrying out 20 ankle replacements or more per year and low volume units as those that performed <20 per year.

Owing to the low occurrence of PE, we combined American Society of Anesthesiologists (ASA) grades to form two groups. Analysis was conducted using R V.3.0.2 (R Foundation for Statistical Computing, Vienna, Austria). Estimates of mortality rates were derived by the Kaplan-Meier method using Stata/IC V.14.0 (StataCorp, College Station, Texas, USA).

RESULTS

There were a total of 1627 NJR records comprising 1522 primary operations and 105 revisions. The overall match rate with HES was 73% with 1110 matched primary procedures and 75 revisions.

The mean patient age of patients undergoing primary TAR was 66.6 (SD 10.4). Forty-two per cent of these patients were female. A total of 795 of the 1522 NJR records gave details on patient BMI: the mean BMI was 29.1 (SD 5). Eighty-five of the primary procedures were performed as a result of osteoarthritis with 10% having rheumatoid arthritis as the indication; 98.5% were uncemented operations with 96% being performed via an anterior approach.

The mean age of patients undergoing revision operation was 65 (SD 11.5). Forty per cent of these patients were female. Fifty-two per cent of the 105 NJR records gave details on patient BMI: the mean BMI was 27.7 (SD 9.8). The main indication for revision was infection (26%) followed by persistent pain (17%) and aseptic loosening of the tibia (15%). Fifty-four were uncemented revisions to another ankle replacement; whereas 11.5% involved fusion of the ankle joint from a TAR.

Mortality rate

Survival data were available for 1522 primary procedure patients. The median follow-up time was 46 months (range 2–88), during which 14 patients died. The 90-day mortality following TAR was 0.13% (95% CI 0.03 to 0.52) and 1-year mortality was 0.72% (95% CI 0.40 to 1.30) (table 2). None of the deaths were as a result of PE. When compared to the ONS age and sex standardised death rates in the UK for 2013, the 90-day death rate was 15 times lower and 1-year death rate was 2.8 times lower for patients who had a TAR. No deaths were observed among the 105 revision patients who had a median follow-up time of 44 months (range 30–65).

PE rate

Of the 1110 linked primary procedures, 5 had a PE within 90 days of surgery, giving an incidence rate of

Table 2 Kaplan-Meier estimates of the cumulative percentage probability of mortality at 90 days, 1, 2 and 3 years postoperation (95% CI)

	Number of deaths	Rate (95% CI)	SMR
90 days	2	0.13 (0.03 to 0.52)	0.07
1 year	11	0.72 (0.40 to 1.30)	0.36
2 years	13	0.85 (0.50 to 1.47)	0.42
3 years	14	0.92 (0.55 to 1.55)	0.46

Standardised Mortality Ratio was calculated using the age and sex adjusted mortality data from the ONS.[31]
SMR, Mortality rate in TAR/age+sex adjusted mortality rate in the general population in 2013.
ONS, Office for National Statistics; SMR, Standardised Mortality Ratio; TAR, total knee replacement.

0.51% (95% CI 0.23 to 1.13) at a mean of 56 days. All patients with a PE had an uncemented prosthesis via an anterior approach and received both mechanical and chemical thromboprophylaxis. Only 1 of the 75 revision procedures was recorded as having a PE.

There were no fatal PEs. Although no statistical significance was noted (p=0.09) the 90-day rate of PE was greater among the 65–74 years age group (0.80%), and over 75s (0.74%) in comparison to the under 65 years age group where no PEs occurred (table 3). All the patients who had a PE were overweight. No occurrences of PE were found in patients with a BMI of <25 (p=0.9).

Seventy-three per cent of the patients who did not suffer a PE (no PE Group) had received both mechanical and chemical prophylaxis. Three per cent of patients received no thromboprophylaxis and yet none of them suffered a PE (table 3). Distribution of ASA Grade was similar in patients who suffered and did not suffer a PE (table 3).

Patients with an Royal College of Surgeons (RCS) Charlson score greater than zero were at 13 times

Table 3 Analysis of patients that had PE versus no-PE 90 days post-primary TAR

	PE	No PE	PE rate (%)	Significance test, p value
Age	n (proportion)	n (proportion)		
<65	0 (0)	463 (0.42)	0.00	0.09
65–74	3 (0.6)	373 (0.34)	0.80	
>75	2 (0.4)	269 (0.24)	0.74	
Length of stay	mean (range)	mean (range)		
	3.2 (1–9)	3.8 (0–46)		0.26
BMI	n (proportion)	n (proportion)		
Underweight	0 (0)	4 (0.01)	0.00	0.9
Normal	0 (0)	122 (0.2)	0.00	
Overweight	3 (1)	487 (0.79)	0.61	
Missing data	2	492		
Gender	percentage	percentage		
Female	20	43		0.3
Indications	n (proportion)	n (proportion)		
Osteoarthritis	5 (1.0)	938 (0.849)	0.50	0.9
Rheumatoid arthritis	0 (0)	108 (0.098)	0.00	
Inflammatory	0 (0)	23 (0.028)	0.00	
Other	0 (0)	36 (0.033)	0.00	
Operation	n (proportion)	n (proportion)		
Uncemented	5 (1.0)	1087 (0.98)	0.46	0.9
Cement	0 (0)	15 (0.014)	0.00	
Hybrid	0 (0)	3 (0.003)	0.00	
ASA	n (proportion)	n (proportion)		
1–2	4 (0.8)	931 (0.84)	0.43	0.58
3–4	1 (0.2)	174 (0.16)	0.60	
Charlson	n (proportion)	n (proportion)		
0	4	1085	0.4	0.003
>0	1	20	5.0	
Prophylaxis	n (proportion)	n (proportion)		
Both	5 (1)	809 (0.73)	1.0	0.73
Chemical only	0 (0)	209 (0.18)	0.0	
Mechanical only	0 (0)	54 (0.05)	0.0	
None	0 (0)	33 (0.03)	0.0	
Deformity	n (proportion)	n (proportion)		
Neutral	2 (0.5)	451 (0.73)	0.44	0.3
Valgus	1 (0.25)	75 (0.12)	1.30	
Varus	1 (0.25)	92 (0.15)	1.10	
Missing data	1	487		
Dorsiflexion	n (proportion)	n (proportion)		
5–20	2 (0.4)	582 (0.53)	0.34	0.5
Neutral	2 (0.4)	421 (0.38)	0.47	
Fix equinus	1 (0.2)	102 (0.1)	0.97	

Continued

Table 3 Continued

	PE	No PE	PE rate (%)	Significance test, p value
Plantarflexion	n (proportion)	n (proportion)		
16–45	1 (0.25)	376 (0.4)	0.30	0.9
5–15	3 (0.75)	574 (0.6)	0.50	
Missing data	1	155		
Unit volume per year	n (proportion)	n (proportion)		
>20	3 (0.6)	643 (0.58)	0.46	0.9
<20	2 (0.4)	462 (0.42)	0.43	
Organisation type	n (proportion)	n (proportion)		
NHS Hospital	3 (0.6)	979 (0.89)	0.3	0.1
Independent hospital	1 (0.2)	74 (0.07)	1.3	
Independent treatment centre	1 (0.2)	52 (0.05)	1.9	
Previous operation	n (proportion)	n (proportion)		
None	3 (0.75)	397 (0.54)	0.75	0.9
Fusion	0 (0)	7 (0.01)	0.0	
Ankle ORIF	0 (0)	59 (0.08)	0.0	
Tibial osteotomy	0 (0)	4 (0.005)	0.0	
Other	0 (0)	69 (0.09)	0.0	
Previous fracture	1 (0.25)	204 (0.28)	0.5	
Missing data	1	365		

ASA, American Society of Anesthesiologists; BMI, body mass index; n, number of patients; NHS, National Health Service; ORIF, open reduction and internal fixation; PE, pulmonary embolism; TAR, total knee replacement.

greater risk of PE (p=0.003). When looking at ankle deformity and range of motion, we found a higher rate of PE with varus deformity and fixed equinus, but the differences were not statistically significant (table 3).

DISCUSSION

The 90-day mortality rate following TAR is 0.13%. This is lower than that reported for hip replacement (0.5%) and knee replacement (0.34%).[24]

The incidence of PE within 90 days of ankle replacement surgery is 0.51% (95% CI 0.23 to 1.13), with a mean event time of 56 days after surgery. A review of the literature suggests the published rate of PE to be 0.17% (table 1), which is significantly lower than the incidence revealed by this study. This may represent reporting bias in that, in other reported series, patients were admitted under medical teams and not picked up by the surgical team. The strength in our methodology is that it has the ability to capture readmissions anywhere in the UK under any clinician, regardless of where the TAR was performed, and hence meets one of our key aims to use registry data to determine a true incidence of PE following ankle replacement.

A previous study used HES data only to determine PE rates following TAR determined by a search of a series of relevant treatment codes (ICD) and reported a PE rate of 0.06% post-TAR.[6] The current study used a more robust data linkage methodology to identify several more PEs. This highlights the advantage of using one data set to validate another to ensure that data are not lost.

A national audit of a large UK trust into clinical coding revealed that in orthopaedics 20% of diagnosis and 19% of procedures are coded inaccurately.[25] Therefore, although we employed a robust method to identify ankle replacement more accurately, the actual identification of PE was still limited by accuracy of clinical coding.

All patients who suffered PE had both mechanical and chemical prophylaxis. Other studies have shown similar rates of PE in foot and ankle surgery and argued that evidence for routine thromboprophylaxis use is weak.[26 27] It is difficult to argue that thromboprophylaxis is not warranted, based on negative findings in a treated group; however, this study showed that in the 3% of patients who received no routine thromboprophylaxis, none of them suffered a PE (table 3).

Comorbidity surfaced as the leading predictor of PE in patients undergoing TAR with a comorbidity count >0, leading to increased risk of PE by a multiple of 13. The RCS Charlson score looks at 14 disease categories developed by a consensus group.[23] Until now, the existing literature has focused on the PE rates in foot and ankle surgery as a whole, mostly including trauma cases due to the higher volumes compared to elective surgery. Some have shown that the presence of any comorbid conditions doubles the rate of PE,[28] and Jameson *et al* found that a Charlson score of 2 or more significantly increased the risk of PE in ankle fractures treated operatively. Other groups have shown specific comorbidity, such as diabetes double the risk of PE.[29] The existing body of work is supported by this study in that it emphasises the importance of comorbidity and PE risk.

We showed a trend towards increased risk of PE with age over 65 years and by being overweight. This is similar to the finding of Shibuya *et al*[28] who found a significant increase in PE risk with increasing age and BMI when looking at lower limb trauma. Our findings, however, did not reach statistical significance.

A limitation of this study is that we were unable to record DVT as well as PE to give an overall VTE rate. This is largely because the HES database only records admissions to hospital, whereas DVTs are invariably treated in the outpatient setting and hence not admitted.[6] As a result, the national rate of VTE associated with TAR is unknown. Nonetheless, the PE rate is more accurate as PEs and expected PEs are invariably admitted to hospital. Another limitation was that only 73% of the NJR records were linked to the HES database. This 27% of non-linked records includes both patients who did not sign their consent to enable data linkage, and also patients where the surgery was carried out in the independent sector where no HES record is kept.[30] Despite these limitations, this still represents data from the largest cohort of ankle replacements until now.

A further limitation is not having available data on the duration of surgery and tourniquet use, which are possible factors that might influence VTE. None of this data is captured on the NJR nor the HES database.

Owing to the small number of PE events, it is possible that a type II error occurred and that risk factors existed but did not reach statistical significance with the cohort size in this study. These risk factors will become clear as the number of NJR records increase over time. Increasing patient consent and ability to link records from the independent sector will also increase the power of any future analysis.

CONCLUSION

This study demonstrates that the rate of PE following TAR is low (0.51%) and that within the initial 3-year period of the UK National Joint Registry, no fatal PEs occurred. The 90-day mortality rate following TAR is 0.13%, which is lower than that reported for hip replacement and knee replacement.

Multiple comorbidity is the leading risk factor for PE and must be taken into account in the treatment and informed consenting process for patients undergoing TAR.

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Contributors RZ, AG and AM were all involved in the conception of the study. RZ and AG were responsible for obtaining the linked data. AM was involved in gaining approval for all the data used. RZ and SC carried out the data analysis. AG, SC and RZ were involved in data interpretation. RZ, AG, SC and AM were involved in the drafting, revision and final approval of the version to be published.

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