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Quality measures for total ankle replacement, 30-day readmission and reoperation rates within 1 year of surgery: a data linkage study using the NJR data set

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ABSTRACT

Objective: To report on the rate of 30-day readmission and the rate of additional or revision surgery within 12 months following total ankle replacement (TAR).

Design: A data-linkage study of the UK National Joint Registry (NJR) data and Hospital Episodes Statistics (HES) database. These two databases were linked in a deterministic fashion. HES episodes 12 months following the index procedure were isolated and analysed. Logistic regression was used to model predictors of reoperation and revision for primary ankle replacement.

Participants: All patients who underwent primary and revision ankle replacements according to the NJR between February 2008 and February 2013.

Results: The rate of 30-day readmission following primary and revision ankle replacement was 2.2% and 1.3%, respectively. In the 12 months following primary and revision ankle replacements, the revision rate (where implants needed to be removed) was 1.2% with increased odds in those orthopaedic units preforming <20 ankle replacements per year and patients with a preoperative fixed equinus deformity. The reoperation other than revision (where implants were not removed) in the 12 months following primary and revision TARs was 6.6% and 9.3%, respectively. Rheumatoid arthritis, cemented prosthesis and high ASA grade significantly increased the odds of reoperation.

Conclusions: TAR has a 30-day readmission rate of 2.2%, which is similar to that of knee replacement but lower than that of total hip replacement. 6.6% of patients undergoing primary TAR require a reoperation within 12 months of the index procedure. Early revision rates are significantly higher in low-volume centres.

Strengths and limitations of this study

- World's largest cohort of ankle replacements from a joint registry.
- Data-linkage methodology reduces biases that are present in single surgeon, single centre reports of ankle replacement.
- Limited by linkage rate of 73%.

INTRODUCTION

Nearly 9 million people in the UK have sought treatment for osteoarthritis,[1] a huge burden to the National Health Service (NHS) which spends ~£10 billion (US$ 14.6 billion, €13.6 billion) annually on musculoskeletal care.[2]

Joint replacements have been available since the 1960s,[3] and hip replacement is one of the most common orthopaedic interventions carried out globally and is recognised as one of the most cost-effective interventions in medicine.[3] However, the proliferation of implants with little outcome data led to the creation of Joint Registries to capture real-world data. Indeed, the UK now has one of the most advanced National Joint Registry (NJR) programmes in the world[4] and has captured more than 2 million records since its inception in 2003.[5] The NJR now captures data on all hip, knee, ankle, shoulder and elbow replacements carried out in England and Wales. The data of ankle replacements have been captured on the NJR since April 2010, and although an ankle replacement is a less common procedure compared to a hip or knee replacement, the UK registry that consists of 2554 ankle replacements makes this the largest database of its kind in the world.[5]

The burden of ankle arthritis is growing, and, in the UK, ~29 000 patients with symptomatic ankle arthritis present to ankle specialists every year.[6] If non-operative interventions have failed, two main surgical treatment options are available, ankle arthrodesis (fusion) or total ankle replacement (TAR). At present, ~3000 procedures are performed each year by the NHS;[7] of which the ratio of fusion to replacement is approximately 2:1.[6]

TAR has been shown to provide patients with an improved functional outcome,[8] and an increasing patient demand, coupled with evidence of the TAR's cost-effectiveness,[9] is likely to see a rise in the use of this technology over the coming years. However, there are more than 15 types of prostheses available on the market with published survival rates of TAR varying between 65% and 96% at 10 years and a cumulative annual failure rate of 1.2%,[8] which is a significantly higher failure rate than that of hip replacements (which is about 0.76%).[5]

Patients with ankle arthritis need to have access to quality and outcome data to enable informed decision-making,[10] and the aim of the current study was to report on the reoperation and revision rate within a year from the index TAR by linking the UK NJR to the Hospital Episodes Statistics (HES) database, which captures data on all NHS admissions and operations.

In addition, 30-day readmission rates are used in the UK and internationally as a marker of quality of care,[11] and in the UK the data are published by the Health and Social Care Information Centre (HSCIC) routinely for hip and knee replacements[12] but not for TAR. Using similar methodology, we, therefore, also aimed to define the 30-day readmission rate following TAR.

METHODS AND MATERIALS

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 data sets in order to say that they are from the same patient. This is in contrast to the probabilistic linkage, which estimates the likelihood that two records are for the same individual, even if they disagree on some fields.[13] The linkage was conducted by the HSCIC. This was in line with best linkage practice with application of the 'separation principle' to allow the most ethical workflow.[14] This principle is used to protect patient data with patient-identifying components, and clinical components of a data set are kept separate. Identifying data are used by a group to perform data linkage, whereas non-identifying data are used by the research group to perform the analysis. As there was an exact deterministic linkage between the common fields in data sets, all of these revision and reoperation procedures from the HES data set had a linked A1 (Primary TAR) NJR form that contained the demographic data for analysis from the patient's primary procedure.

A total of 1627 NJR records had more than 12 months of time following the index procedure and hence were linked. The 1627 NJR records were linked to 5 years of HES records. The NJR-HES linkage was based on a hierarchy of deterministic criteria on the basis of nine fields (figure 1). NJR data were captured on minimal data set

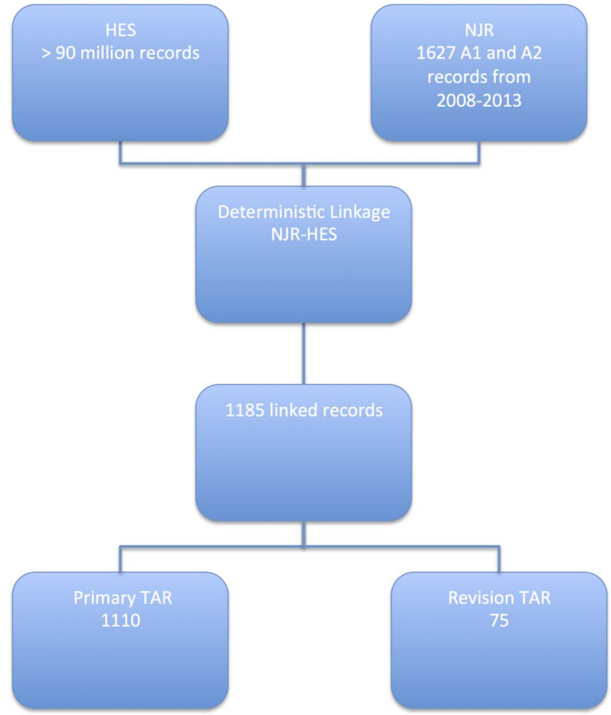

Figure 1 Flow chart to illustrate the linkage process.

forms that were 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, the form is entitled an A2 form.[15] Patient demographics such as patient age, gender and body mass index (BMI) are captured in these forms. The unit where the surgery is performed is also captured with details of the grade of surgeon who performed the surgery. The grade of surgeon is subdivided into a consultant surgeon and trainee. Indications for surgery and details of preoperative deformity and range of motion are also included in these forms. Furthermore, the prosthesis type, surgical approach, associated procedures, intraoperative complications and prophylaxis against venous thromboembolic disease are recorded.[16 17]

Prosthesis type

The data included 10 brands of ankle prosthesis. The most frequently used ankle prosthesis was the Mobility (DePuy Synthes, UK) (56%) followed by the Zenith (Corin, UK) (20%). Mobile-bearing prostheses were the most frequently used with fixed bearing use in <1% of cases (figure 2). The Mobility implant was withdrawn from the market in June 2014.

Identification of concurrent procedures

Concurrent procedures that took place at the time of primary or revision TAR were identified from the NJR data alone as they capture the details on the A1 and A2 forms. Concurrent procedures then formed part of the regression analysis of reoperation and revision. The

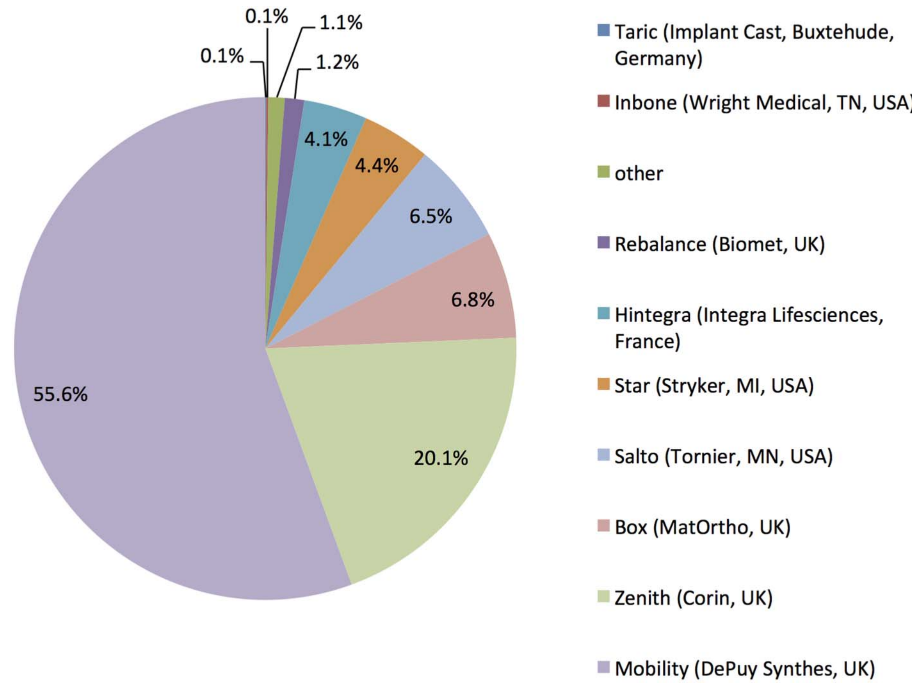

Figure 2 Frequency of use of ankle prosthesis brands in the UK.

frequency of concurrent procedures with primary and revision TARs was 31% and 57%, respectively. The most frequent procedure was Achilles lengthening followed by a calcaneal osteotomy (figures 3 and 4).

Identification of 30-day readmssion

From the linked data set, all the index procedures with an HES entry within 30 days of the index procedure were isolated. These were examined for the ICD-10 diagnostic codes and determined the rate and reason for readmission.

Definition of revision and reoperation

In this study, we used the definition of revision accepted by the NJR, which is "any operation leading to exchange or removal of any of the prosthetic components with the exception of incidental exchange of the polyethylene insert in a mobile bearing (three-component) ankle replacement".[18] Other surgeries such as joint debridement, washout or adjacent joint surgery would constitute a reoperation other than revision. The rate of reoperation used in this paper included all revisions.

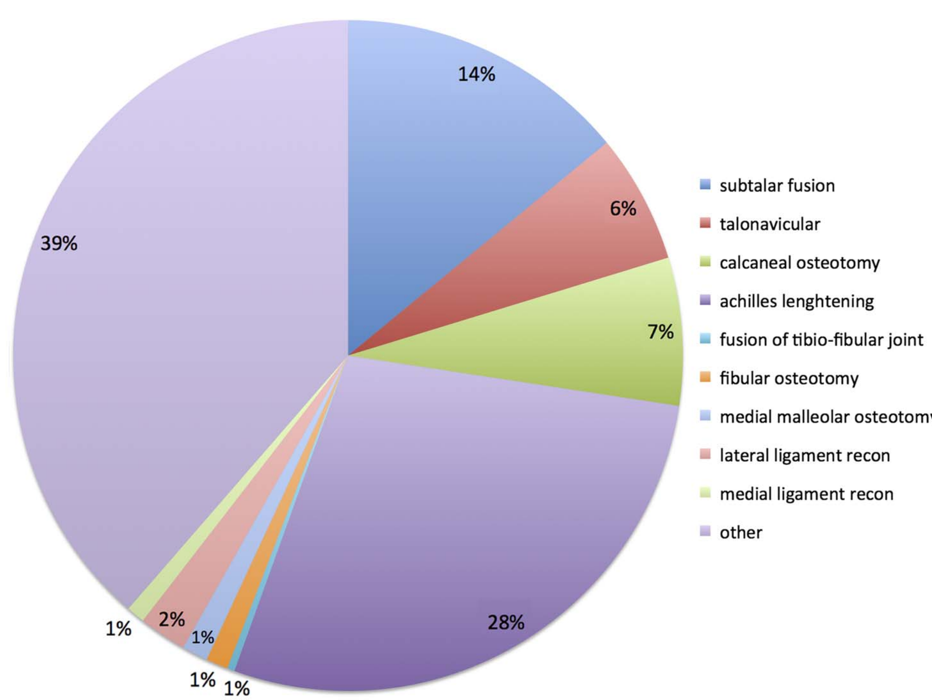

Figure 3 Frequency of concurrent procedures performed with primary TAR. TAR, total ankle replacement.

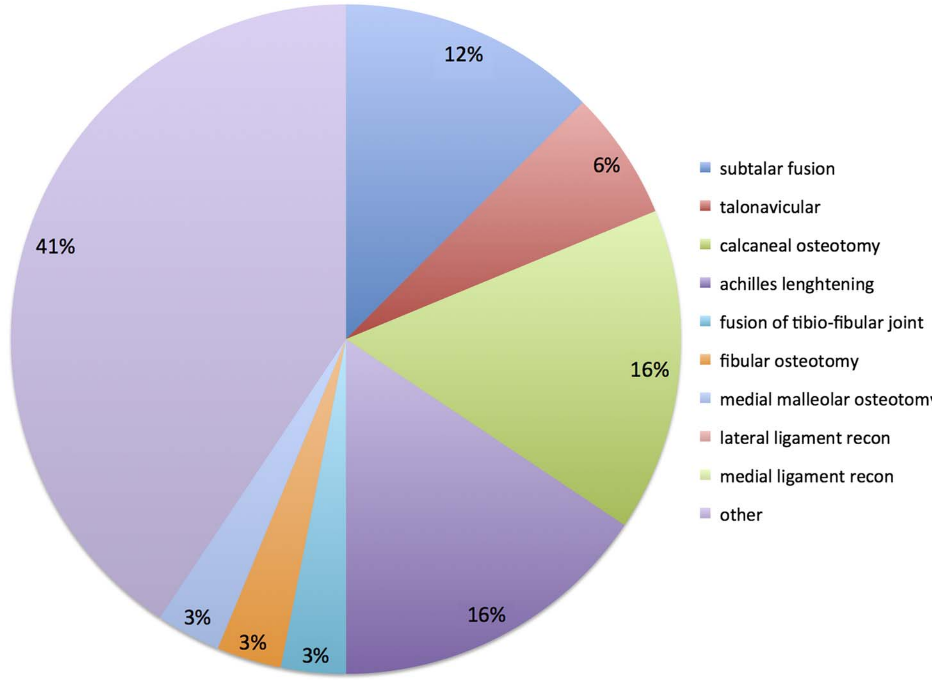

Figure 4 Frequency of concurrent procedures performed with revision TAR. TAR, total ankle replacement.

Identification of reoperation and revision

Reoperation and revision were identified using the linked NJR-HES data set. OPCS-4 (Office of Population Censuses and Surveys Classification of Interventions and Procedures V.4) is the procedural classification used by clinical coders within NHS hospitals in the UK. OPCS codes were used to identify arthroscopy, bone debridement, calcaneal osteotomy, soft tissue operations, wound-related operations, removal of metalwork and subtalar fusion in the 12 months following the index operation. Removal of metalwork pertained to all metalwork unrelated to the implant (that was not the tibial or talar component of the TAR).

Statistical methods

Analysis was performed using R V.3.0.2 (R Foundation for Statistical Computing, Vienna, Austria). Initially, univariate analysis was performed with primary ankle replacements and revision data set to analyse reoperation as a whole. The Shapiro-Wilk test was used to establish whether data were normally distributed. In the case of descriptive statistics, Mann-Whitney or independent sample t-test was used for continuous variables. For categorical data, χ^2 or fisher exact test was used.

Logistic regression was used to model predictors of specific reoperations and was only used with the primary ankle replacement data set. Every model was adjusted for patient characteristics including age, BMI, comorbidity and ASA grade. Multiple regression models were conducted in stepwise forwards and backwards fashions. We used the Akaike information criterion (AIC) to calibrate the model, which is a robust and objective way to determining which model is most parsimonious.[19] [20] 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.[21]

For the purpose of analysis, age was divided into three groups: <65, 65–75 and >75. The BMI was divided into three categories. A BMI of 18.5–25 was classified as normal, and if patients' BMI values were lower and higher than these values, we classify them as underweight and overweight, respectively. Reoperation was

Table 1 OPCS codes used to identify reoperation for the HES data set

Reoperation type	OPCS (Office of Population Censuses and Surveys) codes
Arthroscopy	Y767, Y223, W881, W833, W822, W843, W848
Bone debridement	W815, W082, W712, W801, W803, Y055, W336
Calcaneal osteotomy	W132, X251
Soft tissue operations	T558, Z872, O271, T705, A661, W784, T963, W768, T691, W725, T705, T644, T748
Wound/infection related	S571, S577, S573, S279, S274, S352, T761
Removal of metalwork	W283
Subtalar fusion	W043, W041
Revision	W443, W444, W453, W455, W432, W641, W621, W611, W613, W450, W603, Y032, W433, W434, W444, W453

Table 2 Rate and mean time to reoperation following primary and revision ankle replacements

Operation	n	Rate within 12 months	Mean time to re-op (days, SD)
Primary TAR			
Bone debridement	6	0.54% (95% CI 0.5% to 0.6%)	112 (98)
Calcaneal osteotomy	4	0.4% (95% CI 0.3% to 0.42%)	200 (72.6)
Ligamentous	4	0.4% (95% CI 0.3% to 0.42%)	179.5 (135)
Wound/infection related	5	0.45% (95% CI 0.41% to 0.51%)	89.7 (83.12)
Removal of metalwork	10	0.9% (95% CI 0.87% to 0.96%)	200 (55.6)
Revision	13	1.2% (95% CI 1.1% to 1.23%)	181.9 (124.9)
Arthroscopy	12	1.1% (95% CI 1% to 1.14%)	208.8 (99.4)
Subtalar fusion	3	0.3% (95% CI 0.23% to 0.33%)	251 (174.5)
Other	16	1.44% (95% CI 1.4% to 1.5%)	178.6 (111)
Total	73	6.6 (95% CI 6.5% to 6.64%)	
Revision TAR			
Ankle fusion	2	2.7% (95% CI 2.2% to 3.6%)	242.2 (164)
Removal of metalwork	5	6.7% (95% CI 6.2% to 7.6%)	197.2 (126)
Total	7	9.3% (95% CI 8.8% to 10.3%)	

BMI, body mass index; CI, confidence interval; F, female; n, number in group; NHS, national health service; OR, odds ratio; n, Number of patients; re-op, reoperation; Ref, reference value; SD, standard deviation; TAR, total ankle replacement.

also analysed in the context of unit volume. We classified the units into high volume units where 20 ankle replacements or more per year were carried out and low volume units where <20 ankle replacements per year were performed. The reason for this classification was that, in a primary analysis, we identified that those units performing more than 20 ankle replacements per year (19 units) accounted for half of all ankle replacements performed and those that did <20 ankle replacements per year (163 units) accounted for the other half.

Indications for TARs on the NJR data set are divided into 'osteoarthritis', 'rheumatoid arthritis', 'other inflammatory arthropathy' and 'other'. Inflammatory arthropathy includes psoriatic arthritis, pseudogout, ankylosing spondylitis, juvenile idiopathic arthritis and systemic lupus erythematosus.

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. Using the OPCS codes (table 1)[22] for different types of reoperation, we searched linked episodes for occurrences after the index procedure.

30-Day readmission rate

The rate of 30-day readmission following primary and revision TARs was 2.2% (95% CI 2.1% to 2.3%) and 1.3% (95% CI 0.9% to 2.3%), respectively. There were 25 readmissions; of which, 9 (36%) were for wound infections, 6 (24%) were for medical issues (including cardiovascular and respiratory issues), 5 (20%) were for reoperation, 3 (12%) were due to fractures around the prosthesis and 2 (8%) were due to pulmonary embolism.

Reoperation rate

The rate of reoperation within 12 months of the primary and revision TARs was 6.6% (95% CI 6.5% to 6.64%) and 9.3% (95% CI 8.6% to 10.6%), respectively (table 2). A total of 73 primary ankle replacements had 83 reoperations and 7 revision ankle replacements had 8 reoperations. The odds of reoperation with a primary TAR were increased with rheumatoid arthritis, cemented operations and increasing ASA grade (table 3). With revision operations, no risk factors were shown to be significant (table 4).

Arthroscopy post-primary TAR

The rate of arthroscopy (n=12) was 1.1% (95% CI 1% to 1.14%) at a mean of 209 days (SD ±99.3) with the significant risk factors being preoperative fixed equinus and preoperative reduced plantar flexion (to only 5–15°) (table 5).

Bone debridement post-primary TAR

The rate of bony debridement (n=6) post-TAR was 0.54% (95% CI 0.5% to 0.6%) at a mean of 112 days (SD ±98.3) (table 2). Rheumatoid arthritis was the only significant predictor with an increase in odds of 2.5 (table 5).

Calcaneal osteotomy

The rate of a calcaneal osteotomy (n=4) following TAR was 0.4% (95% CI 0.3% to 0.42%) at a mean of 200 days (SD ±72.6) (table 2). There was a fivefold increase in risk for having this with a concurrent lateral ligament reconstruction (table 5).

Soft tissue operations

The rate of soft tissue operations was 0.4% (95% CI 0.3% to 0.42%) at a mean of 180 (SD ±135) days. Six

Table 3 Univariate analysis of comparing reoperation versus no-reoperation within 12 months following primary ankle replacement surgery

12 months following primary total ankle replacement	Reoperation	No-reoperation	
Age	n (proportion)	n (proportion)	OR (95% CI, p value)
<65	31 (0.43)	395 (0.38)	Ref
65–74	21 (0.29)	376 (0.36)	0.7 (0.4 to 1.3, p=0.24)
>75	20 (0.28)	267 (0.26)	0.9 (0.5 to 1.8, p=0.87)
Length of stay	Mean (range)	Mean (range)	
	4.6 (0–46)	3.8 (0–41)	p=0.25
BMI	n (proportion)	n (proportion)	OR (95% CI, p value)
Underweight	1 (0.03)	4 (0.006)	5 (0.1 to 62, p=0.2)
Normal	6 (0.18)	122 (0.2)	Ref
Overweight	16 (0.47)	258 (0.42)	1.3 (0.5 to 4, p=0.6)
Obese	11 (0.32)	237 (0.38)	0.9 (0.3 to 3.2, p=0.9)
		Missing=455	
Gender/F	42.5%	43.1%	
Indications	n (proportion)	n (proportion)	OR (95% CI, p value)
Osteoarthritis	52 (0.72)	891 (0.86)	Ref
Rheumatoid arthritis	13 (0.18)	95 (0.09)	2.3 (1.2 to 4.6, p=0.008)
Inflammatory	3 (0.04)	20 (0.02)	2.6 (0.5 to 9, p=0.12)
Other	4 (0.06)	32 (0.03)	2.1 (0.5 to 6.4, p=0.16)
Operation	n (proportion)	n (proportion)	OR (95% CI, p value)
Uncemented	69 (0.96)	1023 (0.99)	Ref
Cement	3 (0.04)	12 (0.01)	3.7(1.2 to 14, p=0.03)
Hybrid	0 (0)	3 (0.002)	–
Approach	n (proportion)	n (proportion)	OR (95% CI, p value)
Anterior	69 (0.99)	1000 (0.98)	Ref
Lateral	1 (0.01)	7 (0.01)	2.1 (0.05 to 16, p=0.42)
Ant-lateral	0 (0)	10 (0.01)	–
		Missing=23	
Organisation	n (proportion)	n (proportion)	OR (95% CI, p value)
NHS	64 (0.88)	918 (0.88)	Ref
Independent hospital (NHS funded)	4 (0.06)	71 (0.07)	0.8 (0.2 to 2.3, p=0.68)
Independent treatment centre (NHS funded)	4 (0.06)	49 (0.05)	1.2 (0.3 to 3.4, p=0.77)
Grade of surgeon	n (proportion)	n (proportion)	OR (95% CI, p value)
Consultant	69 (0.96)	975 (0.94)	Ref
Other	3 (0.04)	63 (0.06)	0.7 (0.1 to 2.2, p=0.8)
ASA	n (proportion)	n (proportion)	OR (95% CI, p value)
1	4 (0.05)	155 (0.15)	Ref
2	53 (0.73)	722 (0.7)	2.8 (1.1 to 11, p=0.04)
3	15 (0.21)	157 (0.15)	3.9 (1.2 to 16, p=0.01)
4	0 (0)	4 (0.004)	–
Charlson	n (proportion)	n (proportion)	
0	73 (1.0)	1090 (0.98)	
1	0 (0)	18 (0.02)	
2	0 (0)	4 (0.004)	

ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; F, female; n, number of patients; NHS, National Health Service; OR, odds ratio; Ref, reference value; SD, standard deviation.

procedures were performed in four patients to address the gastrocnemius, peroneal tendons, tibialis posterior, tibialis anterior and the joint capsule. Cemented TAR and having a fibular osteotomy during the initial procedure increased the odds of these procedures (table 5).

Wound-related operations

A total of 13 wound-related operations were performed in 5 patients. The rate of these procedures in 12 months following TAR was 0.45% (95% CI 0.41% to 0.51%) at a mean of 38 days (SD ±19.4). Each of three patients had a single procedure, and two patients had two procedures. Two patients had vascularised skin flaps, and three had the application of a Vacuum Assisted Closure (VAC) dressing. The odds of this type of reoperation were significantly increased in patients with rheumatoid arthritis, cemented prosthesis or concurrent subtalar or talonavicular fusion (table 5).

Table 4 Univariate analysis of comparing reoperation versus no-reoperation within 12 months following revision ankle replacement surgery

12 months following revision ankle replacement	Reoperation	No-reoperation	
Age	n (proportion)	n (proportion)	OR (95% CI, p value)
<65	2 (0.29)	34 (0.5)	Ref
65–74	4 (0.57)	19 (0.28)	3.5 (0.4 to 40, p=0.2)
>75	1 (0.14)	15 (0.22)	1.1 (0.01 to 22, p=0.1)
Length of stay	mean (range)	mean (range)	
	3.6 (1-6)	4.3 (1–12)	p=0.78
BMI	n (proportion)	n (proportion)	OR (95% CI, p value)
Underweight	1 (0.25)	0 (0)	–
Normal	1 (0.25)	5 (0.14)	Ref
Overweight	2 (0.5)	30 (0.86)	0.3 (0.02 to 24, p=0.41)
			Missing=36
Gender/F	43%	44%	
Operation	n (proportion)	n (proportion)	OR (95% CI, p value)
Uncemented TAR	2 (0.5)	38 (0.78)	Ref
Hybrid	1 (0.25)	9 (0.18)	2.1 (0.3 to 44, p=0.5)
TTC nail	1 (0.25)	2 (0.04)	9.5 (0.1 to 250, p=0.2)
			Missing=22
ASA	n (proportion)	n (proportion)	OR (95% CI, p value)
1–2	2 (0.29)	14 (0.21)	Ref
3–4	5 (0.71)	54 (0.79)	0.7 (0.1 to 11, p=0.64)
Charlson	n (proportion)	n (proportion)	
0	7 (1.0)	67 (0.98)	
1	0 (0)	1 (0.02)	
2	0 (0)	0 (0)	

ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; F, female; n, number of patients NHS, national health service; OR, odds ratio; Ref, reference value; SD, standard deviation; TTC, Tibio-Talar-Calcaneal.

Removal of metalwork

The rate of metalwork removal (n=10) was 0.9% (95% CI 0.87% to 0.96%) at a mean of 200 days (SD ±96) (table 2). Rheumatoid arthritis was the only significant predictor for this procedure (table 5).

Subtalar fusion

Subtalar fusion was carried out in three patients, and the rate of subtalar fusion was 0.3% (95% CI 0.23% to 0.33%) at a mean of 251 days (SD ±175) (table 2). No predictors emerged for this procedure (table 5).

Revision

The revision rate in the 12 months following TAR was 1.2% (95% CI 1.1% to 1.23%) (table 2). Three of these were full revisions of the ankle replacement and had the corresponding record for revision on the NJR (an NJR A2 form was submitted), four were converted to ankle fusions (but a corresponding NJR A2 form was not submitted) and six were revisions of just one component (again without the NJR A2 form). Therefore, 10 of the 13 (77%) revisions were identified only through the HES linkage and would not have been identified if reliance were only on the NJR forms being submitted. Fifty-four per cent of the revisions were performed as result of loosening or fracture of any of the three components. The odds of revision were significantly higher in those orthopaedic units performing <20 ankle replacements per year and patients with a preoperative fixed equinus deformity (table 5).

DISCUSSION

This paper constitutes the first output from the world's largest database of ankle replacements (the UK NJR) and has shown 30-day readmission rates following primary and revision TARs to be 2.2% and 1.3%, respectively. The 30-day readmission rate is a proxy measure for quality of care used by the NHS, and this rate for TAR is comparable to the reported 30-day readmission rate following knee replacement (2%)[23] but lower than the reported rate for hip replacement (5.3%).[24] These results support the cause for TAR to be offered as readily as any other lower limb arthroplasty from a quality of care point of view.

The reoperation rate within 12 months following a primary TAR was 6.6%. This rate is lower than those for hip[25] and knee replacements,[26] which have reoperation rates, within 12 months of the index procedure, of 12.3% and 8%, respectively.

We identified three significant predictors for TAR: rheumatoid arthritis, cemented operations and increasing ASA grade. Although rheumatoid arthritis and high ASA grade seem straightforward, it is not clear whether

Table 5 Logistic regression of predictors of reoperation following primary total ankle replacement

	Revision		Arthroscopy		Bone debridement		Calcaneal osteotomy		Ligamentous operation		wound related		removal of metal work		subtalar fusion	
	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value
Indication																
Osteoarthritis	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
Rheumatoid	1.2 (0.5 to 2.5)	0.11	1.3 (0.5 to 3.2)	0.51	2.5 (0.8 to 6)	0.007	4.2 (0.3 to NA)	0.99	0.024 (NA)	0.99	2.2 (1.1-4.3)	0.028	2.2 (1.2-3.9)	0.006	1.7 (0.6-3.8)	0.23
Inflammatory	2.2 (0.6 to 5)	0.78	0.02 (0.001 to 7.3)	0.98	0.04 (0.001 to 82)	0.99	2.6 (0.1 to NA)	0.99	0.025 (NA)	0.99	0.04 (NA)	0.99	2.6 (0.8-6.4)	0.07	0.05 (NA)	0.99
Other	0.03 (NA)	0.99	0.03 (0.01 to 5.30)	0.97	1.3 (0.5 to 2.7)	0.5	2.6 (0.1 to NA)	0.99	0.026 (NA)	0.99	1.6 (0.9-2.8)	0.08	2.1 (0.7-5)	0.11	0.05 (NA)	0.99
Operation type																
Uncemented	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
Cemented	0.05 (NA)	0.99	1.8 (NA)	0.99	0.04 (NA to 77)	0.99	2.3 (NA)	0.99	4.5 (1.1 to 14)	0.02	6.1 (1.3-31)	0.01	0.03 (NA)	0.99	0.05 (NA)	0.97
Hybrid	2.4 (0.7 to 6.1)	0.11	1.5 (NA)	0.98	0.04 (NA to 77)	0.99	6.4 (NA)	0.99	0.03 (NA)	0.99	0.02 (NA)	0.99	0.02 (NA)	0.99	0.05 (NA)	0.95
Approach to ankle																
Anterior	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
Ant-lat	0.03 (NA)	0.99	1.04 (0.02 to 4.4)	0.99	0.9 (0.02 to 7.3)	0.99	7 (0.1 to NA)	0.99	0.3 (NA)	0.99	0.07 (NA)	0.99	0.22 (NA)	0.99	0.42 (NA)	0.99
Lateral	0.03(NA)	0.99	1.7 (NA)	0.99	0.02 (0.001 to 68)	0.99	1.45 (0.1 to NA)	0.99	0.3 (NA)	0.99	1.2 (1.01-7.6)	0.025	0.22 (NA)	0.99	0.42 (NA)	0.94
Organisation																
NHS	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
Ind. hosp	1.02 (0.4 to 2.1)	0.96	1.9 (0.6 to 4)	0.18	1.5 (0.05 to 3.3)	0.4	0.99 (0.1 to NA)	0.99	1.5 (0.5 to 3.3)	0.99	0.02 (NA)	0.99	0.23 (NA)	0.99	0.035 (NA)	0.94
ITC	1.1 (0.4 to 2.4)	0.76	2 (1.01 to 4.4)	0.05	0.02 (0.001 to 23)	0.99	1.1 (0.6 to NA)	0.99	0.03 (0.001-15)	0.99	0.01 (NA)	0.99	0.22 (NA)	0.99	0.035 (NA)	0.95
Unit volume																
>20	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
<20	1.6 (1.1 to 2.5)	0.04	1.2 (0.7 to 2.1)	0.6	0.9 (0.5 to 1.7)	0.716	0.47 (0.01 to 9.6)	0.99	0.9 (0.5-1.6)	0.69	1.1 (0.7-1.6)	0.74	0.52 (0.2-0.9)	0.062	0.03 (NA)	0.91
Pre-op deformity																
Neu	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
Valgus	0.03 (NA)	0.99	0.16 (0.001 to 13)	0.99	0.03 (0.001 to 14)	0.99	7.8 (0.5 to NA)	0.99	0.33 (NA)	0.99	0.03 (NA)	0.99	1.8 (0.8-3.6)	0.14	1.9 (0.6-5.3)	0.2
Varus	1.2 (0.4 to 2.6)	0.66	0.6 (0.3 to 4.4)	0.71	0.03 (0.004 to 45)	0.99	1 (0.1 to 74)	0.99	0.33 (NA)	0.99	1.6 (0.8-2.8)	0.14	1.2 (0.4-2.7)	0.63	1.7 (0.6-4.8)	0.3
Pre-op dorsiflexion																
5–10	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
Neu	1.7 (0.7 to 4.8)	0.23	1.02 (0.6 to 1.7)	0.922	0.03 (0.002 to 15)	0.99	1 (0.2 to 51)	0.99	1.1 (0.4 to 2.2)	0.89	0.9 (0.5 to 1.4)	0.6	0.5 (0.2 to 0.9)	0.06	0.03 (NA)	0.99
Fixed eq	3.53 (1.1 to 12)	0.026	1.9 (1.3 to 3.3)	0.03	1.7 (0.8 to 4.7)	0.23	1 (0.4 to 43)	0.99	0.6 (0.2 to 1.2)	0.22	0.91 (0.3 to 1.8)	0.81	0.8 (0.3 to 1.6)	0.54	0.8 (0.3 to 1.8)	0.61

Continued

Table 5 Continued

	Revision		Arthroscopy		Bone debridement		Calcaneal osteotomy		Ligamentous operation		wound related		removal of metal work		subtalar fusion	
	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value
Pre-op plantarflexion																
16–45	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
5–15	1.04 (0.3 to 4)	0.95	2.1 (1.1 to 4.9)	0.037	4.5 (0.8 to 45)	0.99	1 (NA)	0.98	3.6 (0.6 to 6.8)	0.25	3.04 (0.8 to 20)	0.16	0.8 (0.5 to 1.3)	0.35	0.34 (0.01 to 3.5)	0.4
Number of associated procedures																
0	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
1	0.6 (0.2 to 1.2)	0.2	0.1 (0.02 to 5.4)	0.99	0.9 (0.1 to 32)	1	1.4 (0.6 to 3.3)	0.4	1.4 (0.7 to 12)	0.9	0.9 (0.1 to 5.6)	0.9	1.6 (0.8 to 3)	0.1	0.8 (0.01 to 16)	0.9
2	1.5 (0.1 to 7.2)	0.9	0.2 (0.1 to 7.4)	0.99	0.9 (0.1 to 23)	1	2.4 (0.2 to 22)	0.9	2.3 (0.6 to 6.9)	0.1	5.2 (1.5 to 36)	0.9	1.8 (0.4 to 5)	0.8	0.7 (0.1 to 9.6)	0.9
3	0.2 (NA)	0.9	0.1 (0.01 to 13)	1	1.1 (0.3 to 15)	1	2.9 (0.4 to 4.4)	0.8	1 (0.1 to 9.8)	0.9	6.6 (0.4 to 9.1)	0.9	1.2 (0.4 to 3.1)	0.9	1.1 (0.7 to 6.8)	0.9
Type of associated procedure																
None	Ref		Ref		Ref		Ref		Ref		Ref		Ref		Ref	
Subtalar fusion	0.2 (0.1 to 14)	0.95	0.02 (0.01—14)	0.99	1.5 (0.01 to NA)	1	0.2 (0.1 to 6.7)	0.97	0.03 (0.01 to 78)	0.99	2 (1.1 to 3.8)	0.04	1.7 (0.8 to 3.3)	0.1	0.04 (NA to 26)	0.99
Talonavicular fusion	2 (0.1 to 4.6)	0.97	0.02 (0.001 to 17)	0.96	1.1 (0.01 to 23)	0.89	0.2 (0.01 to 12)	0.98	0.04 (NA to 35)	0.98	2.8 (1.2 to 5.8)	0.01	0.04 (NA to 9.4)	0.98	0.05 (NA to 35)	0.99
Calcaneal osteotomy	0.5 (0.1 to 12)	0.97	0.01 (0.001 to 9)	0.99	1.4 (0.7 to 25)	0.9	1.9 (0.1 to 16)	0.98	1.5 (0.5 to 3.3)	0.36	1.7 (0.5 to 3.9)	0.3	0.03 (NA to 24)	0.99	0.04 (NA to 27)	0.99
Lengthening of achilles	1.1 (0.4 to 2.5)	0.8	0.02 (0.01 to 11)	0.97	0.8 (0.4 to NA)	1	2 (0.4 to 32)	0.96	1.2 (0.6 to 2.2)	0.5	1.1 (0.4 to 2.1)	0.96	0.9(0.4 to 1.9)	0.89	0.03 (NA to 13)	0.99
Fusion distal tibiofibular joint	1.8 (0.2 to 19)	1	0.01 (NA to 23)	1	0.1 (NA)	1	0.2 (NA)	1	0.06 (NA to 31)	0.99	0.02(NA to 21)	0.99	0.09 (NA to 57)	0.99	0.09 (NA to 19)	0.99
Fibula osteotomy	0.2 (0.01 to NA)	0.99	0.02 (0.001 to 31)	0.93	0.9 (NA)	1	0.2 (0.01 to NA)	0.99	5 (1.3 to 18)	0.02	0.06 (NA to 11)	0.98	0.05(NA to 44)	0.99	0.07 (NA to 43)	0.94
Medial malleolar osteotomy	0.03 (0.002 to 15)	0.99	0.01 (NA to 12)	0.99	0.9 (NA)	1	0.2 (0.03 to NA)	0.99	3.3 (0.9 to 9.8)	0.06	0.03 (0.001 to 13)	0.97	0.04 (NA to 38)	0.99	0.06 (NA to 20)	0.99
Lateral ligament recon	0.3 (0.1 to 22)	0.7	0.02 (0.01 to 34)	0.99	1.3 (0.01 to NA)	1	5 (1.2 to 17)	0.017	0.04 (0.01 to 35)	0.98	0.05(0.01 to 35)	0.98	0.04 (NA to 19)	0.99	0.06 (NA to 25)	0.94
Medial ligament recon	1.7 (0.6 to 11)	0.99	0.01 (NA to 23)	1	1 (0.01 to NA)	1	0.2 (0.01 to NA)	0.99	0.05 (NA to 13)	0.98	0.05 (0.01 to 55)	0.92	0.04 (NA to 10)	0.99	0.06 (NA to 98)	0.99

Adjusted for age, gender and comorbidity.
ITC, Independent Treatment Centre.

emented procedures increase complications or whether surgeons elect to use cement in more complicated procedures,[27] explaining the higher reoperation rate. Indeed, the majority (>95%) of TARs reported in the NJR are uncemented.

The reoperation rate following revision was 9.3%, but numbers were small, and no predictors emerged. Previous studies with longer follow-up have shown age to be a predictor of reoperation with increased risk at the extremes of age, but there was no indication of this from our data.[28]

We found that the reoperation rate related to wound complications within 1 year of the index primary TAR was 0.45%, with rheumatoid arthritis being a significant risk factor. This is a similar finding to that found in the study of Raikin *et al*[29], which showed a 14-times increase in wound complications requiring reoperation in patients with rheumatoid arthritis.

In our paper, we have defined revision as being "any operation leading to exchange or removal of any of the prosthetic components with the exception of incidental exchange of the polyethylene insert in a mobile bearing (3 component) ankle replacement".[18] All other procedures are referred to as reoperations other than revision. The revision rate within 1 year of primary TAR was 1.2%. The majority of these were change in only one component. A meta-analysis of joint registry data from Sweden, Finland, Norway and New Zealand[8] has shown the yearly failure rate to be 3.2%, almost double that from the UK thus far, although numbers in the UK registry are much greater. Scandinavian registries contain a higher proportion of rheumatoid patients compared to the UK registry, ~36% and –10% (from current work), respectively, which might explain the difference in the yearly failure rate.[30]

A major strength of this study was that we used another database (HES) to identify revision procedures. We could have used the intradatabase linkage by trying to link all the primary procedures on the NJR to revision procedures; however, this would have greatly underestimated the revision rate as not all revisions were captured on the NJR resulting in reporting bias.[8]

TAR performed in a low-volume centre (ie, <20 TAR operations per year) was found to be a risk factor or an early implant failure. The reason for the cut-off of 20 was that the analysis identified that those units performing more than 20 TAR operations per year (19 units) accounted for half of all ankle replacements performed and those that did <20 TAR operations per year (163 units) accounted for the other half.

This finding contrasts with a Norwegian registry study that examined 257 TARs and found no difference in survival by unit volume.[31] This difference may be attributable to the greater power of the current study as a result of significantly larger numbers of TAR included.

Limitations

This study had a limited power to detect risk factors for specific reoperations owing to small numbers of patient end points. Despite this, we retained the conventional threshold for a statistical significance of p=0.05, which was in keeping with other publications of this type. Some estimates (eg, cemented prostheses) are based on small numbers and need to be treated with caution. A further limitation was the dependence on OPCS-4 procedural coding systems as any errors in coding may have misrepresented an event. In orthopaedics, 19% of procedures have been shown to be inaccurately coded, but training and education combined with continued national audit of coding have resulted in improvement.[32]

In this study, we are unable to divide the osteoarthritis group into primary and post-traumatic osteoarthritis as these data are not captured in the NJR; however, this distinction is, in practice, very subjective as it is possible that patients have a combination of primary and post-traumatic arthritic changes. Hence, we believe that any papers that classify primary versus post-traumatic osteoarthritis are likely to also be subject to similar errors.

The linkage rate of the NJR data to the HES data was 73%. Of the unlinked data, 22% (365 ankle replacements) were carried out in the independent (private) sector and there were no relevant HES records to interrogate. Since there are very few emergency admission units in the private sector, we believe that complications in the main are picked up in the public sector. However, we cannot be certain that complications were not dealt with in the private sector, where no HES record would be recorded and hence the 30-day readmission rates and the 1 year reoperation other than revision rates could be higher as described in this paper.

As with any paper reporting on large national data sets, data incompleteness can be an issue. With respect to primary TARs, there were missing data regarding the BMI and surgical approach (table 3) and the revision BMI and operation type (table 4). We did not consider these data had a major impact on the study results.

Compliance with completion of NJR forms is also an issue. Compliance is the percentage of all TARs that have been entered into the NJR within a 12-month period. Compliance for completion of primary TARs in the NJR has risen from 64% in 2012 to 77% in 2013.[5]

CONCLUSIONS

The TAR has a 30-day readmission rate of 2.2%, which is similar to that of a knee replacement but lower than that of a total hip replacement. Of the patients undergoing primary TAR, 6.6% require a reoperation within 12 months of the primary procedure, and of which 1.2% will require a revision procedure. The leading patient factors that increase the risk of reoperation and revision are rheumatoid arthritis, preoperative deformity and high ASA grade. In terms of hospital/surgeon factors, early revision rates are significantly higher in low volume centres.

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Contributors RZ, AG and AJM were all involved in the conception of the study. RZ and AG were responsible for obtaining the linked data. AJM was involved in gaining approval for all the data used. RZ and AJM did the data analysis and logistic regression analysis. AG was involved in data interpretation. RZ, AG and AJM involved in drafting, revising and final approval of the version to be published.

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