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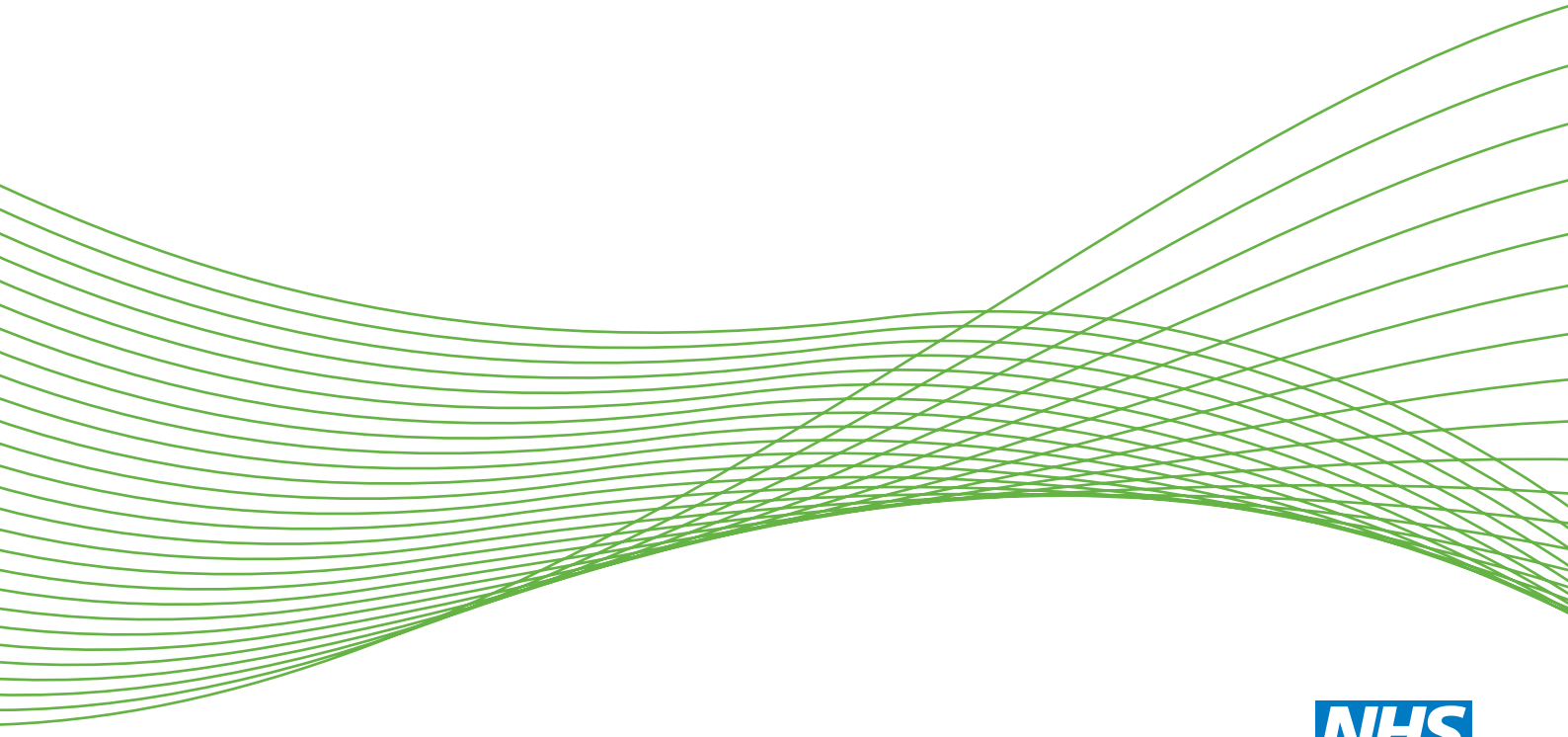

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Treatment of first-time traumatic anterior shoulder dislocation: the UK TASH-D cohort study

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Abstract

Treatment of first-time traumatic anterior shoulder dislocation: the UK TASH-D cohort study

Jonathan L Rees,[1,2]* Anjali Shah,[1,2] Katherine Edwards,[1,2] Maria T Sanchez-Santos,[1,2] Danielle E Robinson,[1,2] Antonella Delmestri,[1,2] Andrew Carr,[1,2] Nigel Arden,[1,2,3] Sarah E Lamb,[1,2,7] Amar Rangan,[1,2,4,5] Andrew Judge,[1,2] Rafael Pinedo-Villanueva,[1,2] Tim Holt,[6] Sally Hopewell,[1,2,7] Daniel Prieto-Alhambra[1,2] and Gary Collins[1,2]

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Background: Shoulder dislocations are the most common joint dislocations seen in emergency departments. Most traumatic cases are anterior and cause recurrent dislocations. Management options include surgical and conservative treatments. There is a lack of evidence about which method is most effective after the first traumatic anterior shoulder dislocation (TASD).

Objectives: To produce UK age- and sex-specific incidence rates for TASD. To assess whether or not surgery within 6 months of a first-time TASD decreases re-dislocation rates compared with no surgery. To identify clinical predictors of recurrent dislocation.

Design: A population-based cohort study of first-time TASD patients in the UK. An initial validation study and subsequent propensity-score-matched analysis to compare re-dislocation rates between surgery and no surgery after a first-time TASD. Prediction modelling was used to identify potential predictors of recurrent dislocation.

Setting: UK primary and secondary care data.

Participants: Patients with a first-time TASD between 1997 and 2015.

Interventions: Stabilisation surgery within 6 months of a first-time TASD (compared with no surgery). Stabilisation surgery within 12 months of a first-time TASD was also carried out as a sensitivity analysis.

Main outcome measure: Re-dislocation rate up to 2 years after the first TASD.

Methods: Eligible patients were identified from the Clinical Practice Research Datalink (CPRD) (1997–2015). Accuracy of shoulder dislocation coding was internally validated using the CPRD General Practitioner questionnaire service. UK age- and sex-specific incidence rates for TASD were externally validated against rates from the USA and Canada. A propensity-score-matched analysis using linked CPRD and Hospital

Episode Statistics (HES) data compared re-dislocation rates for patients aged 16–35 years, comparing surgery with no surgery. Multivariable Cox regression models for predicting re-dislocation were developed for the surgical and non-surgical cohorts.

Results: Shoulder dislocation was coded correctly for 89% of cases in the CPRD [95% confidence interval (CI) 83% to 95%], with a 'primary' dislocation confirmed for 76% of cases (95% CI 67% to 85%). Far fewer patients than expected received stabilisation surgery within 6 months of a first TASD, leading to an underpowered study. Around 20% of re-dislocation rates were observed for both surgical and non-surgical patients. The sensitivity analysis at 12 months also showed little difference in re-dislocation rates. Missing data on risk factors limited the value of the prediction modelling; however, younger age, epilepsy and sex (male) were identified as statistically significant predictors of re-dislocation.

Limitations: Far fewer than the expected number of patients had surgery after a first-time TASD, resulting in an underpowered study. This and residual confounding from missing risk factors mean that it is not possible to draw valid conclusions.

Conclusions: This study provides, for the first time, UK data on the age- and sex-specific incidence rates for TASD. Most TASD occurs in men, but an unexpected increased incidence was observed in women aged > 50 years. Surgery after a first-time TASD is uncommon in the NHS. Re-dislocation rates for patients receiving surgery after their first TASD are higher than previously expected; however, important residual confounding risk factors were not recorded in NHS primary and secondary care databases, thus preventing useful recommendations.

Future work: The high incidence of TASD justifies investigation into preventative measures for young men participating in contact sports, as well as investigating the risk factors in women aged > 50 years. A randomised controlled trial would account for key confounders missing from CPRD and HES data. A national TASD registry would allow for a more relevant data capture for this patient group.

Study registration: Independent Scientific Advisory Committee (ISAC) for the Medicines and Healthcare Products Regulatory Agency (ISAC protocol 15_0260).

Funding: The National Institute for Health Research Health Technology Assessment programme.

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Glossary

Clinical Practice Research Datalink A database that routinely collects observational data in UK primary care.

Clinical Practice Research Datalink Read codes The dictionary of codes used in Clinical Practice Research Datalink.

Hospital Episode Statistics A secondary care database covering the main types of patient-level NHS hospital activity.

Hospital Episode Statistics Office of Population Censuses and Surveys 4.7 codes The dictionary of secondary care operative codes used in Hospital Episode Statistics.

List of abbreviations

BMI	body mass index
CCI	Charlson Comorbidity Index
CI	confidence interval
CPRD	Clinical Practice Research Datalink
EPV	events per variable
GP	general practitioner
HES	Hospital Episode Statistics
HR	hazard ratio
HTA	Health Technology Assessment
IMD	Index of Multiple Deprivation
IQR	interquartile range
ISAC	Independent Scientific Advisory Committee
NEISS	National Electronic Injury Surveillance System
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OPCS	Office of Population Censuses and Surveys
SMD	standardised mean difference
SQL	Structured Query Language
TASD	traumatic anterior shoulder dislocation

Plain English summary

Traumatic anterior shoulder dislocation (TASD) happens when the top of the arm bone is forced frontwards out of the shoulder socket. After a TASD, the shoulder joint can become 'unstable' and keep dislocating. The main treatments are surgery or physiotherapy; however, we do not know which treatment is best at stopping more dislocations.

Two large NHS computer databases were studied to assess this problem. This has allowed us to produce information on the extent of this problem in the UK. We also looked for any differences in the number of people who suffered more shoulder dislocations when treated with either surgery or no surgery.

The results showed that young men aged 16–20 years and women aged > 50 years suffer the most with this problem. In young people, the cause is thought to be due to sports injuries. These findings in women aged > 50 years are new and suggest that further research is needed to discover what puts them at a greater risk of TASD.

When patients who had surgery and those who did not were compared, there appeared to be no difference in the number of people suffering a re-dislocation. Although, overall, this might suggest that surgery after only one dislocation does not have any extra benefit in preventing more dislocations, this research discovered that important information used to help decide on whether or not surgical treatment is needed is not reported in the databases. Some patients may be at a greater risk of more dislocations than other patients based on risk factors, such as sport and occupation, and this information is not recorded in the NHS databases. Therefore, the research question cannot be answered by studying these NHS databases and so other methods, such as a research trial or a custom database built especially for shoulder dislocation patients, would be needed.

Scientific summary

Background

Shoulder joint dislocations are the most common dislocations seen in hospital accident and emergency departments and trauma clinics (8.2–17 cases per 100,000 people per year) (Pope EJ, Ward JP, Rokito AS. Anterior shoulder instability – a history of arthroscopic treatment. *Bull NYU Hosp Jt Dis* 2011;**69**:44–9). Around 80–97% of traumatic glenohumeral dislocations are anterior, wherein the shoulder is forced forward out of the socket. Anterior shoulder dislocation most commonly occurs after traumatic injury in young people, usually resulting in structural problems, such as Bankart and Hills–Sachs lesions. The joint can remain 'unstable' and high re-dislocation rates of 85% or 92% have been reported (Rowe CR. Prognosis in dislocations of the shoulder. *J Bone Joint Surg Am* 1956;**38-A**:957–77).

There are two main approaches to the management of traumatic anterior shoulder dislocation (TASD): surgery and physiotherapy. Surgery is now a common treatment option, especially for sporting athletes, with some surgeons and patients opting for surgery after only one dislocation. Surgical treatment options can involve soft-tissue reconstructions (i.e. Bankart labral repair) or bony procedures (i.e. coracoid process transfer) and can be carried out using arthroscopic (keyhole) or open surgery. Alternatively, non-surgical treatment options include physiotherapy or the use of slings or splints. Currently, there is a lack of evidence regarding the efficacy of surgical versus non-surgical treatment options. Further questions, including when to treat surgically and which surgery method (arthroscopic or open) is more effective for preventing re-dislocation, still remain unanswered.

Previous studies have investigated the incidence of TASD, including a small, well-cited, population-based study in Sweden (Hovelius L. Incidence of shoulder dislocation in Sweden. *Clin Orthop Relat Res* 1982;**166**:127–31). This study observed that 1.7% of the population aged 18–70 years had a shoulder dislocation. In another 25-year follow-up study of patients aged 12–40 years (Hovelius L, Augustini BG, Fredin H, Johansson O, Norlin R, Thorling J. Primary anterior dislocation of the shoulder in young patients. A ten-year prospective study. *J Bone Joint Surg Am* 1996;**78**:1677–84), recurrent dislocation was more common in younger people, with 72% of patients aged 12–22 years suffering another dislocation. This dropped to 27% in those aged 30–40 years. Other studies have reported a high incidence of shoulder dislocation in military and athletic populations, with young men being at greatest risk (Owens BD, Dawson L, Burks R, Cameron KL. Incidence of shoulder dislocation in the United States military: demographic considerations from a high-risk population. *J Bone Joint Surg Am* 2009;**91**:791–6). In Edinburgh, a study of 252 patients aged 15–35 years suffering a shoulder dislocation identified the most common cause (86%) was playing contact sports (Robinson CM, Howes J, Murdoch H, Will E, Graham C. Functional outcome and risk of recurrent instability after primary traumatic anterior shoulder dislocation in young patients. *J Bone Joint Surg Am* 2006;**88**:2326–36). Of these, 60% suffered a repeat dislocation in an average time frame of 13.3 months.

A number of studies report incidences ranging from 11.2 to 26.2 per 100,000 person-years for shoulder dislocations. Zacchilli and Owens (Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am* 2010;**92**:542–9) examined the incidence of TASD in patients of all ages from a random sample of 100 hospital emergency departments across the USA during 2002–6, as recorded in the National Electronic Injury Surveillance System. Seventy-two per cent of dislocations were in men, with the highest incidence among 20- to 29-year-olds [47.8 per 100,000 person-years, 95% confidence interval (CI) 41.0% to 54.5% per 100,000 person-years]. Overall, incidence in men was 34.9 per 100,000 person-years (95% CI 30.1 to 39.7 per 100,000 person-years) and incidence in women was 13.3 per 100,000 person-years (95% CI 11.6 to 15.0 per 100,000 person-years).

In 2014, Leroux *et al.* (Leroux T, Wasserstein D, Veillette C, Khoshbin A, Henry P, Chahal J, *et al.* Epidemiology of primary anterior shoulder dislocation requiring closed reduction in Ontario, Canada. *Am J Sports Med*

2014;**42**:442–50) evaluated the incidence of first-time TASD in patients aged 16–70 years who underwent a closed reduction of the shoulder during April 2002 to September 2010 in Ontario, Canada. The majority (74%) of shoulder dislocations occurred in men, with the highest incidence in those aged 16–20 years (98.3 per 100,000 person-years). The overall adjusted incidences in men and women were similar to figures reported by Zacchilli and Owens.

The incidence rate of first-time TASDs in the UK is unknown, as no large-scale studies of a UK population have been previously undertaken. National computerised databases, such as the Clinical Practice Research Datalink (CPRD) and Hospital Episode Statistics (HES), already contain existing patient data that would allow UK incidence rates for shoulder dislocation to be produced, although they have not previously been used for this purpose.

This report presents first-time age- and sex-specific incidence rates for first-time TASD between 1995 and 2015 for a UK population. It then uses these data to evaluate the effectiveness of management options for TASD by comparing rates of re-dislocation among surgical patients and non-surgical patients following their first dislocation.

Aims

The main aims of this project are as follows:

- to study the association between surgical treatment and re-dislocation rates compared with receiving no surgery following a first-time TASD
- to identify clinical predictors of re-dislocation in a cohort of young adults with TASD for those having surgery compared with those who did not have surgery.

Objectives

To answer the research aims, routinely collected observational data were used from CPRD and HES. These databases provide affordable access to sizeable quantities of routinely collected observational data for UK primary care (CPRD) and secondary care (HES). This allows research studying the effects of uncertainties on treatments for a variety of diseases and conditions.

To address the research questions, a two-stage approach involving two work packages was planned.

Work package 1

To confirm the ability of these data sets to answer the research questions, a validation study was designed to check the quality and validity of coding for TASD and treatments in CPRD.

Work package 2

The main analysis consists of a propensity-score-matched cohort study using CPRD and HES to evaluate the association between surgical treatment (vs. no surgery) and recurrence rates following a first-time episode of TASD in young adults.

Study design

A cohort study was conducted using routinely collected data from CPRD and HES to study the association between surgical treatment and re-dislocation rates, compared with no surgery, in young adults (aged 16–35 years) following a first-time episode of TASD. Further analysis was conducted to identify predictors of re-dislocation in each treatment group.

As there is no previous validation of shoulder dislocation coding in CPRD, the study was designed in two phases (work packages).

Work package 1 consisted of an internal and external validation study of the coding in the CPRD for TASD. A total of 172 general practitioner (GP) questionnaires were sent out using the CPRD questionnaire service to the practices of patients identified from the CPRD (aged 16–35 years with a first-time TASD). The returned GP responses were analysed to check the quality and completeness of the coding for TASD in the CPRD. Age and sex prevalence rates were then produced for the UK population based on the CPRD data set, then externally validated against published rates from other settings (Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am* 2010;**92**:542–9 and Leroux T, Wasserstein D, Veillette C, Khoshbin A, Henry P, Chahal J, *et al.* Epidemiology of primary anterior shoulder dislocation requiring closed reduction in Ontario, Canada. *Am J Sports Med* 2014;**42**:442–50).

Work package 2 consisted of a population-based propensity-score-matched cohort study using CPRD and HES data. This is one of the best designs for minimising the confounding present in observational data sets. The propensity approach allows each surgical patient to be matched to a non-surgical control patient. Included participants were young adults aged 16–35 years with a TASD, with at least 2 years of coding in the CPRD before the first-time entry Read code for shoulder dislocation (washout period) and with at least 2 years of follow-up coding.

Methods

Work package 1

An internal validation study was conducted with the use of a GP questionnaire to confirm first-time TASD and assess the use of shoulder dislocation codes and treatments in the CPRD. Patients in the CPRD who were aged 16–35 years and had been diagnosed with a shoulder dislocation between 1995 and 2015 in the UK were identified. In total, 172 patients were then randomly selected and CPRD services sent the questionnaire to their general practices for completion.

An external validation was conducted, in which the incidence rates for first-time TASD identified in this study were compared with those reported by similar studies in the USA (Zacchilli and Owens) and Canada (Leroux *et al.*).

The GP questionnaire study was designed to internally validate coding in the CPRD before progressing to any main analysis. We compared the responses from the returned GP questionnaires for the numbers of patients who had been correctly coded.

The following criteria had been defined a priori as clear stop–go criteria for progression to work package 2:

- a positive predictive value of at least 75% accuracy for shoulder dislocation coding in the CPRD
- a positive predictive value of at least 75% accuracy for ‘primary’ or ‘first-time’ shoulder dislocation coding in the CPRD
- a similar age and sex incidence pattern between UK CPRD data and published rates for the USA and Canada
- a sample size of 3065 patients with linked CPRD-HES records.

Work package 2

A population-based propensity-score-matched cohort analysis of TASD patients was conducted using linked CPRD and HES data. Eligible participants were young adults aged 16–35 years with a TASD, and with at least 2 years of data entry in the CPRD before first entry of a code for shoulder dislocation and another 2 years of follow-up data. Participants were assigned to the intervention or control group. The intervention group participants were patients with a first-time TASD who underwent shoulder stabilisation surgery after a primary dislocation, and the control group participants were patients who did not receive surgical treatment following a primary dislocation. Events and outcomes for shoulder dislocations and

treatments were collected using a pre-agreed validated list of Read codes (CPRD) and Office of Population Censuses and Surveys 4.7 codes (HES). The 'first dislocation' was defined as the first-entry Read code in CPRD for a shoulder dislocation.

A prediction model was developed using linked CPRD-HES data to identify patients at an increased risk of re-dislocating. Potential risk factors of re-dislocation were defined a priori by expert consensus and informed by the validation study. Multiple imputation by chained equations was used to overcome bias resulting from the cumulative effect of missing data. Cox regression survival models were used to identify risk factors associated with time to re-dislocation, with shrinkage methods to adjust for overfitting. Fractional polynomials were used to examine continuous predictors.

Results

Internal validation

In total, 97 (56%) of the 172 GP questionnaires were completed and returned. The positive predictive value for shoulder dislocation coding in CPRD was 77% (95% CI 69% to 85%). Shoulder dislocation was correctly coded for 89% of patients, with 76% of patients having a confirmed primary dislocation. Within 2 years of having a first-time TASD, 43% of patients had a re-dislocation. Coding for physiotherapy treatment was poor and, overall, physiotherapy treatment was confirmed for only 65% of patients.

External validation

The UK CPRD cohort was similar in age and sex distribution to the USA and Canadian cohorts. Incidence rates in the UK were similar to those in the USA (UK, 6.6 per 100,000 person-years; vs. USA, 23.9 per 100,000 person-years), but higher than those in Canada for all age and sex groups except for 16- to 20-year-old males (UK men, 80.5 per 100,000 person-years; vs. Canadian men, 98.3 per 100,000 person-years). Patterns of incidence between countries were similar, although the peak age in men was more widely spread in the UK than in the USA or Canada (UK, 17–22 years; vs. USA and Canada, 17–18 years). By contrast, the UK shows an increased incidence for TASD in women aged > 50 years.

Propensity score analysis

After the CPRD-HES linkage, there were surprisingly fewer patients than expected in the surgical group, leading to the sample being underpowered for re-dislocation at 6 months after a first-time TASD. Therefore, a further sensitivity analysis was conducted for re-dislocations over 12 months. The cohort was mostly male and aged between 17 and 22 years. There was a considerable number of missing data on body mass index (BMI), smoking, drinking and Index of Multiple Deprivation (IMD) 2004. Many of the predefined risk factors were also not recorded in CPRD. Within 6 months, complete-case analysis showed surgery to have a slightly protective but non-significant effect after a first-time TASD. After 12 months, propensity score analysis did not identify significant differences following surgery. An interaction was found between the quintiles of the propensity score and surgery group. This means that for the propensity score matching to work properly, information on additional unmeasured confounding factors (e.g. mechanism of injury) needs to be included. However, although the actual rates of re-dislocation in both the surgical and the non-surgical groups were observed to be similar, both at around 20% at 12 months, this figure is higher than previously thought and higher than many surgeons and patients might expect after surgical treatment.

Prediction modelling

Prediction models were developed using CPRD data to predict the risk of re-dislocation in the surgical and non-surgical groups. The risk factors used to predict the outcome were limited to the data available in CPRD: age, sex, smoking status, alcohol consumption, BMI, analgesic medication, epilepsy status and IMD score. Alcohol consumption and BMI were particularly affected by missing data. The surgical group shows some capacity to predict re-dislocation, with age, epilepsy and IMD being highlighted as important factors. None of the above variables predicted re-dislocation within the non-surgical group. It was not possible to test the impact of the remaining predetermined surgical risk factors.

Conclusions

The validation study demonstrated CPRD to be an acceptable data set to use for the study of shoulder dislocation patients. The patient sample size available for analysis, the high positive predictive value for overall and first-time TASD (75%), and the similarities in incidence rates and patterns between UK CPRD data and data from the USA and Canada supported progression to the next phase of the study and the main analysis.

The UK CPRD data showed that young males (aged 17–22 years) had the highest incidence of TASD, which may be related to playing contact sports. Unexpectedly, women aged > 50 years showed an increased risk for shoulder dislocation, supporting the need for further research into identifying causes of the increased risk in this group.

Age and sex incidence patterns observed in the UK CPRD data showed similarities with the USA and Canada. A more narrow age peak in young males in the USA and Canada may be caused by high numbers of young men, between 17 and 18 years of age, playing ice hockey and American football at school before discontinuing the sport in college.

There was no difference in re-dislocation rates after a first-time TASD in surgical and non-surgical patients at 6 or 12 months. However, there were many confounders related to surgical decision-making for TASD that were not present in CPRD. There were also minimal data available for physiotherapy and many patients were excluded because they had < 2 years of follow-up data available in CPRD. This probably highlights the limitations of using a primary care database to answer secondary care surgical questions. Finally, as CPRD is a NHS database, there were no data on patients receiving private health care.

Recommendations for research

The primary question asked of this project has been difficult to answer with missing confounding factors. Although a 20% re-dislocation rate (after first TASD, any treatment) indicated that this is an important problem, the data also do not suggest that many patients in the NHS are having surgery after only one TASD, which may surprise some stakeholders. To answer this question, either or both of the following will be needed:

- A randomised controlled trial, taking into consideration the risk factors relevant to this patient group that are not collected routinely through CPRD. However, the low surgical rate observed after one TASD might limit patient and surgeon recruitment to a surgical trial.
- The creation of a carefully constructed registry for shoulder dislocation patients, to enable more granular data to be collected on the outcomes and risk factors associated with decision-making and outcomes in this population group.

Funding

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Chapter 1 Background and study introduction

This study is in response to a research commission from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme and, as such, this avenue of research has already been deemed necessary. Since the commissioned call, no systematic reviews or randomised clinical trials that answer the brief have been published.

The most common joint dislocations seen in hospital accident and emergency departments affect the shoulder (8.2–17 cases per 100,000 people per year).[1] Around 95% of traumatic dislocations of the shoulder occur anteriorly, where the top end of the arm bone (humerus) is forced frontwards out of the shoulder socket.[1] The mobility of the shoulder joint renders it particularly unstable and susceptible to re-dislocation. Traumatic anterior shoulder dislocation (TASD) is particularly common in younger patients and often occurs as a result of injury during contact sports.[2] When it occurs, it is very painful and the shoulder often stays dislocated until it is repositioned. The condition is associated with significant morbidity as, following a first-time dislocation, there will probably be damage to the soft tissue and ligaments that are responsible for stabilising the joint, rendering it susceptible to re-dislocation. The literature reports that recurrent dislocation can occur in 85–92% of cases.[3] However, the most effective treatment for the management of first-time traumatic shoulder dislocation in preventing further dislocations remains uncertain.

Surgery versus conservative treatment

Current options for the management of TASD include surgical or conservative treatment (usually physiotherapy) that aims to restore the stability and function of the shoulder joint.[4] However, there is a lack of consensus and a lack of good-quality evidence in support of a particular treatment regime.[2] Prior to both surgical and non-surgical intervention, closed reduction techniques tend to be used to restore the correct position of the shoulder joint.[4] Subsequent surgical management tends to include either soft-tissue reconstruction (e.g. Bankart labral repair) or bony procedures (e.g. coracoid process transfer).[5] Alternatively, non-surgical treatments involve immobilisation of the arm using slings or splints, followed by physical rehabilitation.[2] It is currently unclear from the literature which treatment approach to use following a first-time TASD to restore the stability and function of the shoulder and to help prevent recurrent dislocations.

The use of traditional conservative management approaches after initial reduction and joint immobilisation has been challenged because of high rates of recurrent dislocation among some population groups. In younger patients, rates of recurrence as high as 92–96% have been reported.[6] An incidence study of shoulder instability among athletes at a US military academy showed that 85% of athletes experienced a recurrent event within a 9-month period.[7] A systematic review showed that there were some limited data to support primary surgery following a first-time TASD among young adults engaged in demanding physical activities (military personnel and athletes).[5] A later systematic review also showed that among younger patients, a significantly lower rate of recurrent instability was identified in a 2-year period following a first-time TASD for those having surgery than for those having no surgery (7% vs. 46%).[8] Consequently, there appears to be some limited evidence for surgical intervention following a first-time TASD among younger and/or highly active patients; however, the literature emphasises that there is no evidence to challenge the use of non-surgical techniques for other patient groups.[5]

Concerning non-operative treatment approaches in the management of first-time TASD, not only is there a lack of evidence for non-surgical over surgical treatment, but there are also uncertainties regarding the type of non-operative treatment used. For example, there is debate over the length of time the arm should be immobilised and the position (i.e. internal or external rotation) in which it should be immobilised.[6]

Some studies have found a lower recurrence rate in patients treated using external rotation (26% recurrence) than in those treated using internal rotation (42% recurrence) methods, and that this technique was also more effective for the younger, < 30 years age group.[9] However, an earlier systematic review did not identify any statistically significant results in re-dislocation rates among patients treated using internal or external rotation methods.[2] The literature has highlighted the absence of and the usefulness of future trials looking at these aspects of non-operative management for TASD.[2]

The use of surgical intervention for the management of TASD goes back to 1923, when Bankart described an anterior labral avulsion of the glenoid during shoulder dislocation.[10] Current approaches involve stabilising the joint using open or arthroscopic (keyhole) surgery; however, the literature is unclear as to which strategy is most effective. No significant differences have been identified between open and arthroscopic approaches in terms of recurrent instability or re-injury.[8,11,12]

Incidence studies

Studies of the incidence of traumatic shoulder dislocation have been conducted outside the UK. An early, highly cited study of the incidence of shoulder dislocation was carried out in Sweden in 1982 by Hovelius.[13] In a random sample of 2092 people aged 18–70 years, it was shown that 1.7% of participants had a history of dislocation, with re-dislocation more common in young adults and with a male-to-female ratio of 3 : 1 overall (although varying with age).[13] In a 10-year follow-up study of 247 Swedish patients aged 12–22 years at the time of their dislocation, 66% of patients had one or more re-dislocations but only 24% had a recurrence between 30 and 40 years of age.[14]

The incidence of shoulder dislocation was again examined in a later (2010) study based on a US population.[15] This study utilised data from the National Electronic Injury Surveillance System (NEISS) and was based on patients of all ages who experienced a shoulder dislocation from 2002 to 2006. Their findings showed an overall adjusted incidence rate of 23.9 per 100,000 person-years [95% confidence interval (CI) 20.8 to 27.0 per 100,000 person-years], a rate that was more than double that originally thought. The majority of dislocations occurred in men (72%), with the highest incidence observed in those aged 20–29 years (47.8 per 100,000 person-years, 95% CI 41.0 to 54.4 per 100,000 person-years). In males, the overall incidence rate was 34.9 per 100,000 person-years (95% CI 30.1 to 39.7 per 100,000 person-years), whereas in females this was 13.3 per 100,000 person-years (95% CI 11.6 to 15.0 per 100,000 person-years).

A further study, by Leroux *et al.*[16] in 2014, also looked at the incidence rate of primary anterior shoulder dislocation in a Canadian population of 16- to 70-year-olds who were diagnosed between April 2002 and September 2010. Compared with the US study, the Canadian data showed a similar rate of dislocations in men (74%), with an incidence rate highest for 16- to 20-year-olds (98.3 per 100,000 person-years). Similar figures for the overall adjusted incidence rate were observed, which in males was 34.3 per 100,000 person-years and in females was 11.8 per 100,000 person-years.

It is unclear in the current literature as to the most effective treatment pathway (i.e. surgery vs. no surgery) in the management of first-time TASD. Regarding conservative treatment, the optimum position for arm immobilisation and the duration of time are still in question. Concerning surgery, it is debated what technique (i.e. open or arthroscopic, soft tissue or bony) is more effective, and when or if surgery is needed following a first-time TASD. The main problem is an absence of data on the natural history of shoulder dislocation, including in the UK where age and sex incidence data have not been published. The literature also highlights the lack of good-quality evidence and supports the need for further research and randomised trials to address these issues.

Aims

The commissioned aims were:

- to study the association between surgical treatment and recurrence rates following a first-time TASD in young adults who had surgery compared with those who had not had surgery
- to identify clinical predictors of recurrent dislocation in young adults with a TASD for surgical and non-surgical patients.

Objectives

To use routinely collected data from two NHS computerised databases [i.e. the Clinical Practice Research Datalink (CPRD) and Hospital Episode Statistics (HES)] to study the association between surgical treatment and rates of re-dislocation, compared with no surgery in young adults with a first-time TASD. Potential predictors of re-dislocation in patients from each treatment group were further investigated.

The research questions were addressed by implementing a two-stage approach using two work packages.

Work package 1

Work package 1 consists of an internal and external validation study to test the quality and completeness of coding in the CPRD for identifying patients aged 16–35 years diagnosed with and treated for a first-time TASD. From these data, age and sex prevalence rates for first-time TASD in the UK were produced and these were externally validated against reported rates published in other settings.

Work package 2

A propensity-score-matched cohort analysis was conducted using CPRD and HES data. The cohort of participants used in the analysis comprised young adults (aged 16–35 years) with a TASD, who had at least 2 years of coding in the CPRD prior to a first-time entry Read code for shoulder dislocation (washout period) and at least 2 years of follow-up coding. The association between treatment strategy (i.e. surgery compared with no surgery) and rates of re-dislocation were then studied. Propensity matching ensured that patients undergoing surgery were matched and compared with a non-surgical control patient. Risk factors that may play an important role in re-dislocation in both the surgical and the non-surgical groups were further investigated.

Methods

Work package 1

The first phase of this project involved conducting an internal and external validation study to test the suitability of using the CPRD data set for identifying patients with a first-time TASD, and then externally validating the findings against published results from other settings. Relevant risk factors that were identifiable in the CPRD were recorded and used to inform the formal analysis regarding future predictors.

Internal validation

An internal validation study was conducted to check the quality of the coding for shoulder dislocations and treatments in the CPRD. A cohort of patients aged 16–70 years who were diagnosed with a shoulder dislocation in the UK between 1995 and 2015 were initially identified from the CPRD, to use as UK incidence data for all age groups. The included patients all had at least 2 years of coding in the CPRD prior to a first-time entry Read code for shoulder dislocation and at least another 2 years of subsequent coding. The internal validation exercise then focused on the planned study cohort of patients identified from the CPRD who were aged 16–35 years and had the same washout period.

A general practitioner (GP) questionnaire was designed with the help of GPs to internally validate the coding of shoulder dislocations and treatments in the CPRD. A random sample of 172 patients was then selected from those identified as meeting the above selection criteria. A questionnaire was sent to the general practice of each patient using the CPRD GP questionnaire service. A clinician at the practice completed the questionnaire by comparing the records on the CPRD with the clinical records of the patient. Written reminders to complete the questionnaire were sent to the general practice by the CPRD every 2 weeks (up to a total of four reminders). The data from returned questionnaire responses were double-entered into a database, and an academic orthopaedic shoulder surgeon was consulted to resolve data input queries.

The following criteria were established a priori to ensure that shoulder dislocation coding in the CPRD was of high quality prior to moving forwards with the main analysis:

- The coding of shoulder dislocation within the CPRD needed to have a positive predictive value of $\geq 75\%$.
- The coding of 'primary' or 'first-time' shoulder dislocation coding in the CPRD also had to have a positive predictive value of $\geq 75\%$.

External validation

The external validation exercise compared the age and sex incidence rates for TASD produced for the UK with those reported in other settings. For this analysis, the original cohort of patients aged 16–70 years who were identified from the CPRD with a shoulder dislocation between 1995 and 2015 were used. The CPRD has a representative coverage of around 6.9% of the UK and includes 11.3 million patients, making it broadly generalisable in terms of age, sex and ethnicity for the UK population as a whole. The external validation study itself produced population-based age- and sex-specific incidence rates for TASD for the UK. Comparing these with the published rates reported from other settings allows for external validation of the UK data.

Work package 2

Propensity-score-matched cohort analysis

The main study is a population-based propensity-score-matched cohort study comparing the association between surgery (vs. no surgery) and rates of re-dislocation in patients diagnosed with a TASD. The cohort of patients used for this analysis consisted of young adults aged 16–35 years with a TASD, with 2 years of coding in the CPRD prior to a first-time entry Read code for shoulder dislocation, and at least another 2 years of follow-up coding after the initial event. A pre-agreed list of Read codes (CPRD) and HES Office of Population Censuses and Surveys (OPCS) 4.7 codes for shoulder dislocation and treatments was used to collect all related outcomes and events; these were further informed by the earlier validation work (work package 1) (see *Appendix 1*). A 'primary' or 'first-time' TASD is defined here as a first-time entry Read code for shoulder dislocation.

Identified patients were allocated to the intervention (surgical) or control (non-surgical) groups. Patients in the intervention group were those who underwent shoulder stabilisation surgery following a first-time episode of TASD (early surgical repair is defined here as a 'decision to treat surgically after a first-time TASD'). Patients in the control group were those who did not receive a surgical intervention following a first-time episode of TASD.

Propensity score matching methods were used to match each patient receiving surgery to a comparable patient in the non-surgical group. Propensity score methods were used because they provide the best approach to handling observational data sets that may be influenced by confounding (e.g. some patients being more likely to have surgery than others). Propensity score methods allow for bias being introduced into the data set through confounding, as the type of treatment received (i.e. surgery or no surgery) was not randomly allocated in this study.

After the process of matching surgical patients to non-surgical control patients, a Cox regression survival model was used to assess the association between surgery and time to re-dislocation over a 2-year period.

Identify clinical predictors of recurrent dislocations by treatment type

In this component, investigated potential risk factors associated with re-dislocation for both the surgical and the non-surgical groups were investigated. Prediction models were developed using linked CPRD and HES data, including any risk factors defined a priori by consensus that were available and those identified through the earlier validation work.

Conclusion

The relevant background information supporting the need for research into the efficacy of management options for patients with first-time traumatic shoulder dislocation has been described. Each of the four key components of the study has been outlined in this chapter and they are described in more detail in *Chapters 2–5*.

Chapter 2 Internal validation study of shoulder dislocation coding within the Clinical Practice Research Datalink

Introduction

The first phase of this study was to carry out an internal validation of shoulder dislocation coding in routinely collected data from the CPRD to confirm the feasibility of using the CPRD to study shoulder dislocations for the main analyses. It also sought to identify which risk factors were relevant to shoulder dislocation and were readily available in the CPRD for use in the main analyses.

Objectives of *Chapter 2*

- Identify patients in the CPRD aged 16–35 years who were diagnosed with a traumatic shoulder dislocation between 1 April 1997 and 31 March 2015 in England.
- Develop a GP questionnaire using a validation algorithm and with input from GPs.
- Take a random sample of patients from those identified in the CPRD and use the CPRD GP questionnaire service to send the questionnaire to the respective patient practices for completion.

Methods

Data source

Population-based primary care data from the CPRD were used to identify a cohort of patients diagnosed with a traumatic shoulder dislocation (aged 16–35 years) in the UK from 1 April 1997 to 31 March 2015. The CPRD covers 11.3 million people from 674 UK general practices and provides a representative coverage of around 6.9% of the UK population, which is broadly representative of the population in terms of age, sex and ethnicity.[18] Patient and practice data are anonymised, but patient-level data are available on age, sex, geographic region, body mass index (BMI), smoking status (i.e. current smoker, ex-smoker, non-smoker) and drinking status (i.e. current drinker, ex-drinker, non-drinker). The CPRD data were linked to data from the Index of Multiple Deprivation (IMD) 2004[19] for English patients and the Charlson Comorbidity Index (CCI) score was calculated using predefined Read codes.

Participants

The Read codes were used to identify patients from the CPRD with a shoulder dislocation. These codes had been established a priori through consensus by specialist shoulder surgeons with clinical experience and experts in epidemiology research (see *Appendix 1*). To ensure that 'primary' or 'first-time' shoulder dislocations were captured, patients were required to have no recorded shoulder dislocations in their CPRD clinical data for 2 years prior to first entry of a shoulder dislocation Read code. The 2-year washout period was defined using the date that the general practice was classified as 'up to standard' and the date that the patient was first registered at the general practice. This first entry of a shoulder dislocation Read code was defined as the primary dislocation.

The patients had to be registered at 'active' CPRD practices. An 'active' practice was defined as a practice that had contributed to the CPRD database in the previous 6 months. No general practices were classified as active in the East Midlands, and so it was not possible to include patients from this region. Following the identification of the shoulder dislocation cohort from within the CPRD data set, a predefined set of patient exclusion criteria was applied to facilitate the validation (*Table 1*).

General practitioner questionnaire design and implementation

The GP questionnaire was designed with the assistance of GPs and based on a developed validation algorithm (see *Appendices 2* and *3*) and a random sample of 172 patients was selected from a list of the 6046 eligible patients. CPRD personnel then sent the questionnaire to each patient's general practice for a clinician to complete by comparing the records on their CPRD computer system with the patient's clinical records. The GPs assessed the use of shoulder dislocation codes for traumatic dislocation, confirmation of first-time shoulder dislocation, subsequent codes used for further events, physiotherapy referral codes and confirmation that physiotherapy took place.

Four written reminders were sent every 2 weeks to the general practices. Data from the returned questionnaires were double-entered into a data set by a statistician and a project manager. Any queries were resolved by an academic orthopaedic shoulder surgeon. In the instance that two questionnaires were received for the same patient with differing answers (on three occasions two questionnaires were sent back for one patient, i.e. three patients and six questionnaires; differing responses were only received for questions 6 and 7), clarification was sought from the general practice via CPRD personnel (clarification was received for one patient).

The following validation criteria were defined a priori to reflect that the coding of shoulder dislocations in the CPRD was of a sufficiently high quality to proceed with the main analyses planned in work package 2:

- a positive predictive value of $\geq 75\%$ accuracy for shoulder dislocation coding in the CPRD
- a positive predictive value of $\geq 75\%$ accuracy in coding 'primary' or 'first-time' traumatic shoulder dislocation within the CPRD.

TABLE 1 Shoulder dislocation exclusion flow chart for patients aged 16–35 years during 1 April 1997–31 March 2015 within the CPRD data in England

Exclusions	*n* (%)
Total number of CPRD shoulder dislocation patients received	63,324 (100)
Unacceptable patients (i.e. CPRD flags that data quality for a patient is insufficient for medical research)	806 (1)
Unacceptable dates (i.e. impossible to find a shoulder dislocation code between the CPRD minimum and maximum acceptable dates as defined by data management standard operating procedures for clinical research)[18]	34,710 (55)
Shoulder dislocation date prior to 1 April 1997	2507 (4)
Shoulder dislocation date after 31 March 2015	823 (1)
< 2-year minimum washout period (i.e. washout period defined using the date the general practice was classified as 'up to standard' and the date the patient first registered at the practice)	3694 (6)
Aged < 16 years	825 (1)
Aged > 35 years	12,125 (19)
Non-resident of England patients	1788 (3)
Patients remaining in cohort	6046 (10)

Results

Cohort

An initial cohort of 63,324 patients with codes for shoulder dislocation was identified from the CPRD database. A database manager and statistician assessed the cohort against clear predefined and important exclusion criteria (see *Table 1*). Unacceptable patients were defined as those whose records had not met quality standards and had been flagged by the CPRD as 'unacceptable'. Unacceptable dates were defined as when it was impossible to find a shoulder dislocation code between the CPRD minimum and maximum acceptable dates, as defined by data management standard operating procedures for clinical research.[18] During this process, the majority of patients were excluded, either because they had a shoulder dislocation diagnosis outside the study time period (55%) or because they were outside the study age limits (16–35 years) (20%). The final cohort included 6046 patients aged 16–35 years who were diagnosed with a shoulder dislocation between 1 April 1997 and 31 March 2015 in England.

Internal validation

Of the 172 patients whose GP received a copy of the validation questionnaire, a response for 95 (55%) patients was received. For two patients, their GPs confirmed that they had transferred out of the practice and that no further information was available for them on the CPRD system.

Table 2 presents demographic characteristics for the following patient groups:

- the cohort of 6046 patients from the CPRD aged 16–35 years and diagnosed with a shoulder dislocation between 1 April 1997 and 31 March 2015 in England
- the 172 patients randomly selected to have their GPs receive a questionnaire
- the 97 patients for whom completed questionnaires were returned by their general practice
- the 75 patients for whom questionnaires were not returned by their general practice.

All four groups were similar with respect to demographic characteristics, including age, BMI and CCI score. The highest response rate (100%) was received from general practices in the South West of England, but otherwise the proportion of responses received reflected the regional distribution of patients included in the cohort. Data on the IMD 2004[19] were obtained and linked after the selection of the 172 records to be validated. There were no missing data on deprivation, as all practices sampled were 'active practices'. A higher proportion of patients had been sampled from category 1 (affluent) and category 4 (somewhat deprived) than in the initial cohort of 6046 patients, but otherwise response rates were similar from all deprivation groups.

The distribution of CPRD Read codes used by GPs to code shoulder dislocations is given in *Table 3*. Codes S41..00, S41z.00 and 14G5.00 for dislocation of shoulder accounted for 82% of all shoulder dislocation coding in the data. Recurrent shoulder dislocation codes only identified another 10% of patients, indicating that the 2-year washout period was a successful approach to identifying primary or first-time shoulder dislocations. Of the seven patients who had a recurrent shoulder dislocation code and for whom a GP questionnaire response was obtained, four were confirmed as having had a primary shoulder dislocation and one was confirmed as not having had a shoulder dislocation at all.

Shoulder dislocation was confirmed as having been coded correctly in 89% (95% CI 83% to 95%) of all patients (*Table 4*). The remaining 11% (10 patients) had been miscoded and the patient had suffered other shoulder trauma or injuries, such as strains or dislocations of the acromioclavicular joint, as confirmed by their GP. Of all patients, a first-time or primary shoulder dislocation was confirmed in 76% (95% CI 67% to 85%) of cases. Subsequent dislocations occurring up to 2 years after the primary dislocation were recorded in the CPRD for 32% of patients. From the GP responses, an additional 11% of patients experienced a re-dislocation during this time that was not recorded in the CPRD.

TABLE 2 Demographic characteristics of shoulder dislocation patients aged 16–35 years recorded within CPRD during 1 April 1997–31 March 2015 in England, and responders and non-responders to the CPRD GP validation questionnaire

	Patient group			
Demographic characteristic	Whole cohort	All GP questionnaires	Responders	Non-responders
Cohort size, (*n*)	6046	172	97	75
Sex, *n* (%)				
Male	4991 (83)	137 (80)	81 (84)	56 (75)
Female	1055 (17)	35 (20)	16 (16)	19 (25)
Median age (years) (IQR)	24 (20–34)	24 (20–29)	24 (20–29)	24 (19–29)
Median BMI (kg/m^2) (IQR)	24 (22–27)	24 (21–27)	25 (22–28)	23 (21–26)
Median CCI score (IQR)	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Region, *n* (%)				
East Midlands	263 (4)	0 (0)	0 (0)	0 (0)
East of England	673 (11)	21 (12)	17 (18)	4 (5)
London	695 (12)	23 (13)	11 (11)	12 (16)
North East	133 (2)	4 (2)	3 (3)	1 (1)
North West	951 (16)	29 (17)	13 (13)	16 (21)
South Central	965 (16)	32 (19)	17 (18)	15 (20)
South East Coast	702 (12)	25 (15)	12 (12)	13 (17)
South West	743 (12)	17 (10)	17 (18)	0 (0)
West Midlands	667 (11)	15 (9)	7 (7)	8 (11)
Yorkshire and the Humber	254 (4)	6 (3)	0 (0)	6 (8)
IMD 2004 quintile, *n* (%)				
1 (affluent)	1279 (21)	53 (31)	28 (29)	26 (35)
2	1077 (18)	35 (20)	20 (21)	15 (20)
3	958 (16)	24 (14)	16 (16)	8 (11)
4	876 (14)	38 (22)	19 (20)	18 (24)
5 (deprived)	624 (10)	22 (13)	14 (14)	8 (11)
Missing	1232 (20)	0 (0)	0 (0)	0 (0)

IQR, interquartile range.

TABLE 3 The CPRD Read codes of shoulder dislocation patients aged 16–35 years recorded within CPRD during 1 April 1997–31 March 2015 in England, and responders and non-responders to the CPRD GP validation questionnaire

CPRD description (Read code)	Patient group (%)			
	Whole cohort	All GP questionnaires	Responders	Non-responders
Total number of patients	6046	172	97	75
CPRD description (Read code)				
Dislocation or subluxation of shoulder (S41..00)	55	55	52	60
Dislocation of shoulder NOS[a] (S41z.00)	10	10	9	11
H/O:[a] dislocated shoulder (14G5.00)	17	19	20	17
Closed reduction of dislocation of shoulder (7K6G300)	3	3	5	1
Closed traumatic dislocation of shoulder (S410.00)	2	1	1	0
Recurrent dislocation of shoulder, anterior (N083A00)	6	6	5	7
Anterior dislocation of shoulder (S410111)	2	1	2	0
Recurrent joint dislocation, of shoulder region (N083100)	2	0	0	0
Recurrent subluxation of shoulder, anterior (N083C00)	2	2	2	3
Closed traumatic dislocation shoulder joint, anterior (subcoracoid) (S410100)	< 1	1	0	1
Closed traumatic dislocation shoulder joint, unspecified (S410000)	< 1	1	2	0
Closed traumatic subluxation, shoulder (S412.00)	< 1	1	2	0

a No definition for abbreviation available. Displayed as the codes appear in the Read code directory.

TABLE 4 Validation of shoulder dislocations coded within the CPRD data set: responses to GP questionnaires ($n = 95$)

Validation of shoulder dislocations	*n* (%)
GP confirmation of shoulder dislocation	85 (89)
Patients who had a confirmed 'primary' shoulder dislocation	72 (76)
Patients who had a further dislocation within 2 years of the primary dislocation[a]	27 (32)
Confirmation that this was a further dislocation episode and not a review of the problem	21 (78)
Patients with further dislocations that have not been noted in the CPRD	9 (11)
Patients who have CPRD Read codes for physiotherapy in the 2 years following the first dislocation code	24 (28)
It is clear that this physiotherapy code indicates that the patient received physiotherapy for their shoulder	15 (63)
Patients who did not have a CPRD Read code for physiotherapy, but for whom documentation exists confirming that they received physiotherapy for their shoulder	17 (21)

a The denominator is 85 because these patients were confirmed to have had a shoulder dislocation and could then potentially have a re-dislocation.

Notes

Two additional questionnaires were received from GPs stating that the patients had transferred out of the practice and that no data were available for them. These two patients have been omitted from the denominator used for this table.

Twenty-eight per cent of patients had been coded as having received physiotherapy within the CPRD, and GPs confirmed that physiotherapy had been given to 63% of these. However, a further 17 patients had received physiotherapy for their shoulder dislocation that was not recorded within the CPRD. Thus, 41% of patients known to be receiving physiotherapy were not recorded within the CPRD.

Conclusion

This validation exercise, carried out, to our knowledge, for the first time for this condition in the CPRD, has demonstrated that the CPRD is an acceptable data set to identify and study shoulder dislocation patients. The validity of GP coding of shoulder dislocations within the CPRD in a subset of patients proved very high, at 89%. Of all patients, 76% were confirmed to have primary shoulder dislocations. All of the CPRD Read codes used to identify shoulder dislocation patients were useful for identifying patients who had a primary shoulder dislocation, including the three codes that are specific to re-dislocations (i.e. N083A00, N083100 and N083C00). There was a small amount of under-reporting of subsequent shoulder dislocations. Physiotherapy treatment coding was of a poorer quality given that it is under-reported, at 41%, and, as such, the effectiveness of physiotherapy cannot be evaluated using the CPRD in any subsequent analyses of shoulder dislocations. Although not all general practices responded to the questionnaire, those that did and those that did not respond to the questionnaire survey were similar by deprivation level, geography and other demographic characteristics.

The strength of the CPRD is that it is a large, population-based primary care cohort that is representative of the UK general population. The positive internal validation result achieved on the correct coding of shoulder dislocations in the CPRD now provides the opportunity to use these codes and study definitions in the main study analysis.

Chapter 3 External validation study of shoulder dislocation data within the Clinical Practice Research Datalink

Introduction

The second phase of this study was to produce, for the first time, the age- and sex-specific incidence rates for shoulder dislocations in the UK. These would then allow the comparison of numbers and incidence rates of shoulder dislocations in the UK with those published from the USA and Canada. The comparison will facilitate an external validation of the data contained within the CPRD on shoulder dislocations.

Objectives of *Chapter 3*

The objectives of this chapter are to produce age- and sex-specific incidence rates for shoulder dislocation for the UK population and to validate UK data by comparing age- and sex-specific incidence rates of first-time TASD with those of similar studies from the USA and Canada.[15,16]

Methods

Data source

The CPRD of population-based primary care data was used to identify a cohort of patients diagnosed with a traumatic shoulder dislocation aged 16–70 years during 1995–2015 in the UK. A description of the CPRD and the potential risk factors available within it was presented in *Chapter 2*.

Participants

The cohort of 16,763 CPRD patients aged 16–70 years with a TASD during 1995–2015 in the UK was used. The patients were identified using predefined Read codes as described in *Chapter 2* (see also *Appendix 1*).

Statistical analysis

Descriptive statistics were used to summarise the epidemiology of primary shoulder dislocations by demographic factors. The incidence rates by age and sex per 100,000 person-years and incidence rate ratios with 95% CIs and *p*-values were calculated for all age and sex groups using Stata® software version 14.1 (StataCorp LP, College Station, TX, USA).

Incidence rate denominators were constructed using the patient-level data from the CPRD. Observation time per patient was calculated between 1995 and 2015 as the sum of total year-time contributed by all subjects, wherein person-years start as the latest of first registration date, practice up-to-standard date and 1 January 1995, and end as the earliest from patient transfer out date, practice last collection date, death date and 31 December 2015.

Results

An initial cohort of 63,324 patients with codes for shoulder dislocation was identified. A predefined set of exclusion criteria was applied (*Table 5*). During this process, many patients were excluded either because they had a shoulder dislocation diagnosis outside the study time period (55%) or because they were outside the study age limits (16–70 years) (8%).

The final cohort produced included 16,763 patients aged 16–70 years who were diagnosed with a shoulder dislocation between 1995 and 2015 in the UK. The numbers of patients identified by CPRD Read codes are given in *Table 6*. *Table 7* highlights the baseline characteristics of the cohort. Most (72%) of the shoulder dislocations occurred in men and the median age for the whole cohort was 36 years [interquartile range (IQR) 24–52 years]. Most patients had a 'normal' BMI (18.5–24.9 kg/m^2) and 88% of patients had no comorbidities.

TABLE 5 Shoulder dislocation exclusion list for patients aged 16–70 years during 1995–2015 within CPRD in the UK

Exclusion	*n* (%)
Total number of CPRD shoulder dislocation patients received	63,324 (100)
Unacceptable patients (i.e. CPRD flags that data quality for a patient is insufficient for medical research)	806 (1)
Unacceptable dates (i.e. impossible to find a shoulder dislocation code between the CPRD minimum and maximum acceptable dates, as defined by data management standard operating procedures for clinical research)	34,710 (55)
Shoulder dislocation date prior to 1 January 1995	1446 (2)
Shoulder dislocation date after 31 December 2015	75 (< 1)
< 2-year minimum washout period (i.e. washout period defined using the date the GP was classified as 'up to standard' and the date the patient first registered at the general practice)	4008 (6)
Aged < 16 years	878 (1)
Aged > 70 years	4638 (7)
Patients remaining in cohort	16,763 (26)

TABLE 6 The CPRD data set dislocation Read codes used to identify shoulder dislocation patients

Description	Read code	Number of patients
Dislocation or subluxation of shoulder	S41..00	9600
Dislocation of shoulder NOS[a]	S41z.00	2066
H/O: dislocated shoulder[a]	14G5.00	2331
Closed reduction of dislocation of shoulder	7K6G300	739
Closed traumatic dislocation of shoulder	S410.00	410
Recurrent dislocation of shoulder, anterior	N083A00	646
Anterior dislocation of shoulder	S410111	424
Recurrent joint dislocation, of shoulder region	N083100	176
Recurrent subluxation of shoulder, anterior	N083C00	168
Closed traumatic dislocation shoulder joint, anterior (subcoracoid)	S410100	64
Closed traumatic dislocation shoulder joint, unspecified	S410000	78
Closed traumatic subluxation, shoulder	S412.00	61
Total		16,763

a No definition for abbreviation available.

TABLE 7 Baseline demographic characteristics of patients with primary shoulder dislocation aged 16–70 years within the CPRD data set during 1995–2015 in the UK

Characteristic	*n* (%)
Total	16,763 (100)
Sex	
Male	12,148 (72)
Female	4615 (28)
Age at shoulder dislocation (years)	
16–20	2561 (15)
21–30	4266 (25)
31–40	3021 (18)
41–70	6915 (41)
BMI (kg/m^2)	
< 18.5	180 (1)
18.5–24.9	3392 (20)
25.0–29.9	3020 (18)
30.0–34.9	1292 (8)
≥ 35.0	768 (5)
Missing	8111 (48)
Smoking	
Non-smoker	6674 (40)
Current smoker	3388 (20)
Ex-smoker	2014 (12)
Missing	4687 (28)
Drinking	
Current drinker	6854 (41)
Non-drinker	1113 (7)
Ex-drinker	188 (1)
Missing	8608 (51)
CCI score	
0	14,834 (88)
1	950 (6)
2	523 (3)
≥ 3	456 (3)
Region	
East Midlands	600 (4)
East of England	1444 (9)
London	1484 (9)
North East	279 (2)
North West	2071 (12)

continued

TABLE 7 Baseline demographic characteristics of patients with primary shoulder dislocation aged 16–70 years within the CPRD data set during 1995–2015 in the UK (*continued*)

Characteristic	*n* (%)
Northern Ireland	602 (4)
Scotland	1626 (10)
South Central	2005 (12)
South East Coast	1572 (9)
South West	1462 (9)
Wales	1591 (9)
West Midlands	1470 (9)
Yorkshire and the Humber	557 (3)
IMD 2004 (quintile of deprivation)	
1 (affluent)	2790 (17)
2	2345 (14)
3	2001 (12)
4	1793 (11)
5 (deprived)	1309 (8)
Missing	6525 (39)

The age distribution of primary shoulder dislocation patients during 1995–2015 in the UK within the CPRD is given in *Figure 1*. A peak of > 500 patients per year of age occurs in patients aged 17–21 years, which then decreases until the age of 53 years. Between 55 years and 70 years, there is a gradual increase in the number of patients with a primary shoulder dislocation.

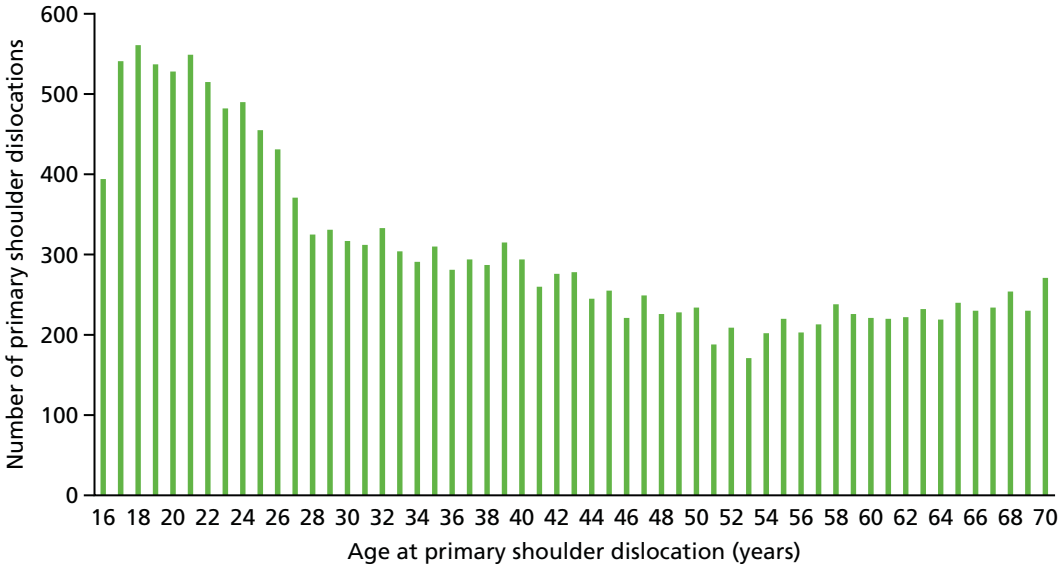


FIGURE 1 Distribution of primary shoulder dislocation patients by age (years), demonstrating the overall distribution within CPRD during 1995–2015 in the UK.

UK incidence rates

The incidence rates and incidence rate ratios by age and sex for primary shoulder dislocation patients in the UK are presented in *Table 8*. The overall incidence rate in males was seen to be 40.39 per 100,000 person-years (95% CI 40.38 to 40.41 per 100,000 person-years) and in females was 15.52 per 100,000 person-years (95% CI 15.51 to 15.52 per 100,000 person-years). The highest incidence observed was in 16- to 20-year-old males (80.55 per 100,000 person-years, 95% CI 80.45 to 80.65 per 100,000 person-years). The incidence in men decreased with an increase in age. A U-shaped pattern of incidence was observed in women. The incidence was 16.36 per 100,000 person-years in those aged 16–20 years. This decreased in women aged 21–50 years and then increased to 28.64 per 100,000 person-years in women aged 61–70 years. Overall, the incidence was significantly higher in men than in women in almost all age groups, with an overall incidence rate ratio of 2.60 (95% CI 2.52 to 2.69). The exception was found in men and women aged 61–70 years, in whom no significant difference in incidence was observed ($p = 0.334$).

TABLE 8 The number, incidence rates and incidence rate ratios of primary shoulder dislocation by age and sex within the CPRD data set during 1995–2015 in the UK

Demographic category	Number of patients	Person-years[a]	Incidence rate[b]	95% CI	Demographic comparison	Incidence rate ratio	95% CI	*p*-value
Sex								
Male	12,148	30,074,078	40.39	40.38 to 40.1	Male vs. female	2.60	2.52 to 2.69	< 0.001
Female	4615	29,741,559	15.52	15.51 to 15.52				
Age (years)								
16–20	2561	5,245,428	48.82	48.78 to 48.87				
21–30	4266	11,006,586	38.76	38.74 to 38.78	16–20 vs. 21–30	1.26	1.20 to 1.32	< 0.001
31–40	3021	12,362,061	24.44	24.42 to 24.45	16–20 vs. 31–40	2.00	1.90 to 2.11	< 0.001
41–50	2472	12,244,890	20.19	20.18 to 20.20	16–20 vs. 41–50	2.42	2.29 to 2.56	< 0.001
51–60	2091	10,583,309	19.76	19.75 to 19.77	16–20 vs. 51–60	2.47	2.33 to 2.62	< 0.001
61–70	2352	8,373,363	28.09	28.07 to 28.11	16–20 vs. 61–70	1.74	1.64 to 1.84	< 0.001
Age (years), sex (male)								
16–20	2137	2,653,062	80.55	80.45 to 80.65				
21–30	3588	5,463,830	65.67	65.61 to 65.72	16–20 vs. 21–30	1.23	1.16 to 1.29	< 0.001
31–40	2316	6,265,348	36.97	36.94 to 36.99	16–20 vs. 31–40	2.18	2.05 to 2.31	< 0.001
41–50	1733	6,243,377	27.76	27.74 to 27.78	16–20 vs. 41–50	2.90	2.72 to 3.094	< 0.001
51–60	1244	5,342,095	23.29	23.27 to 23.31	16–20 vs. 51–60	3.46	3.22 to 3.71	< 0.001
61–70	1130	4,106,366	27.52	27.49 to 27.54	16–20 vs. 61–70	2.93	2.72 to 3.15	< 0.001

continued

TABLE 8 The number, incidence rates and incidence rate ratios of primary shoulder dislocation by age and sex within the CPRD data set during 1995–2015 in the UK (*continued*)

Demographic category	Number of patients	Person-years[a]	Incidence rate[b]	95% CI	Demographic comparison	Incidence rate ratio	95% CI	*p*-value
Age (years), sex (female)								
16–20	424	2,592,366	16.36	16.34 to 16.38				
21–30	678	5,542,756	12.23	12.22 to 12.24	16–20 vs. 21–30	1.34	1.18 to 1.51	< 0.001
31–40	705	6,069,714	11.56	11.55 to 11.57	16–20 vs. 31–40	1.41	1.25 to 1.60	< 0.001
41–50	739	6,001,514	12.31	12.30 to 12.32	16–20 vs. 41–50	1.33	1.18 to 1.50	< 0.001
51–60	847	5,241,214	16.16	16.15 to 16.17	16–20 vs. 51–60	1.01	0.90 to 1.14	0.840
61–70	1222	4,266,996	28.64	28.61 to 28.67	16–20 vs. 61–70	0.57	0.51 to 0.64	< 0.001
Age (years), sex (male vs. female)								
16–20					16–20 vs. 16–20	4.92	4.44 to 5.47	< 0.001
21–30					21–30 vs. 21–30	5.37	4.95 to 5.83	< 0.001
31–40					31–40 vs. 31–40	3.20	2.94 to 3.48	< 0.001
41–50					41–50 vs. 41–50	2.25	2.07 to 2.46	< 0.001
51–60					51–60 vs. 51–60	1.44	1.32 to 1.57	< 0.001
61–70					61–70 vs. 61–70	0.96	0.89 to 1.04	0.334

a Person-years used as the denominator for incidence rates, as obtained for patients aged 16–70 years during 1995–2015 in the CPRD data set.
b The incidence rate per 100,000 person-years.

Comparison of UK incidence data with Canadian incidence data

Incidence rates for TASD in the UK were also compared by age and sex with those reported in Canada.[16] A comparative summary of the characteristics of the UK and Canadian cohorts is shown in *Table 9*. The UK cohort included in the analysis consisted of 15,666 patients aged 16–70 years with a primary shoulder dislocation in the UK as recorded in the CPRD between 1 April 1997 and 31 March 2015. Denominators for incidence analyses were obtained from the CPRD by individual year, age and sex. Data on urban or rural residence were not available in the CPRD, and thus this comparison could not be made.

The demographic data for the UK cohort (*Table 10*) were similar in age and sex distribution to those observed in the Canadian cohort.[16] The median age in both cohorts was 35 years, with a similar IQR. In the UK, 72% of primary shoulder dislocations occurred in men; in the Canadian cohort, this was slightly higher, at 74%.

TABLE 9 Comparison of the characteristics of the data used in the Canadian paper[16] and the UK data

Details	Canadian data (Leroux *et al.*[16])	UK data
Setting	Hospital records of patients having closed reduction of the shoulder	Primary care records of coded shoulder dislocations
Geography	Ontario cohort	UK sample (CPRD)
Dates	April 2002–September 2012	April 1997–March 2015
Patient age (years)	16–70	16–70
Numbers of patients	20,719	15,666

TABLE 10 Cohort demographic data for patients with a primary shoulder dislocation aged 16–70 years between 1 April 1999 and 1 March 2015 in the UK within CPRD, compared with an extract of similar Canadian cohort data[16]

Demographic variable	UK cohort	Canadian cohort (Leroux *et al.*[16])
Cohort size (*n*)	15,666	20,719
Age (years)		
Mean (SD)	38.29 (16.31)	37.99 (16.62)
Median	35	35
IQR	24–52	22–51
Sex, *n* (%)		
Male	11,357 (72)	15,399 (74)
Female	4309 (28)	5320 (26)
Deprivation quintile,[a] *n* (%)		
5 (most deprived)	1224 (8)	3698 (18)
4	1686 (11)	3862 (19)
3	1889 (12)	4071 (20)
2	2188 (14)	4356 (21)
1 (most affluent)	2625 (17)	4732 (23)
Missing	6054 (39)	0 (0)

SD, standard deviation.
a Quintiles for the English IMD are 1 (most affluent) to 5 (most deprived), in contrast with Leroux *et al.*[16] who defined their income quintiles as 1 (most deprived) to 5 (least deprived).

The English IMD 2004[19] is a composite deprivation index at the small-area level, based on seven domains: income, employment, health and disability, education, barriers to housing and services, living environment, and crime. The Canadian measure of deprivation is solely based on income. These two measures are not directly comparable but a similar pattern of deprivation is observed, with increasing numbers of patients linked to increasing affluence. There was a large number of missing data for the UK cohort because the IMD results were available for English patients only, whereas complete data on deprivation were available for the Canadian patients.

Figures 2 and *3* present the percentage of primary shoulder dislocation patients by age and sex in the UK and Canada, respectively. In the UK, the peak in numbers for men is spread over those aged 17–22 years, whereas there is a distinct peak in men aged 17 years in Canada. The pattern in the number of women with shoulder dislocations is similar in both cohorts, with a high percentage in those aged 16 years, which decreases up to the early 30s and then increases until the age of 70 years.

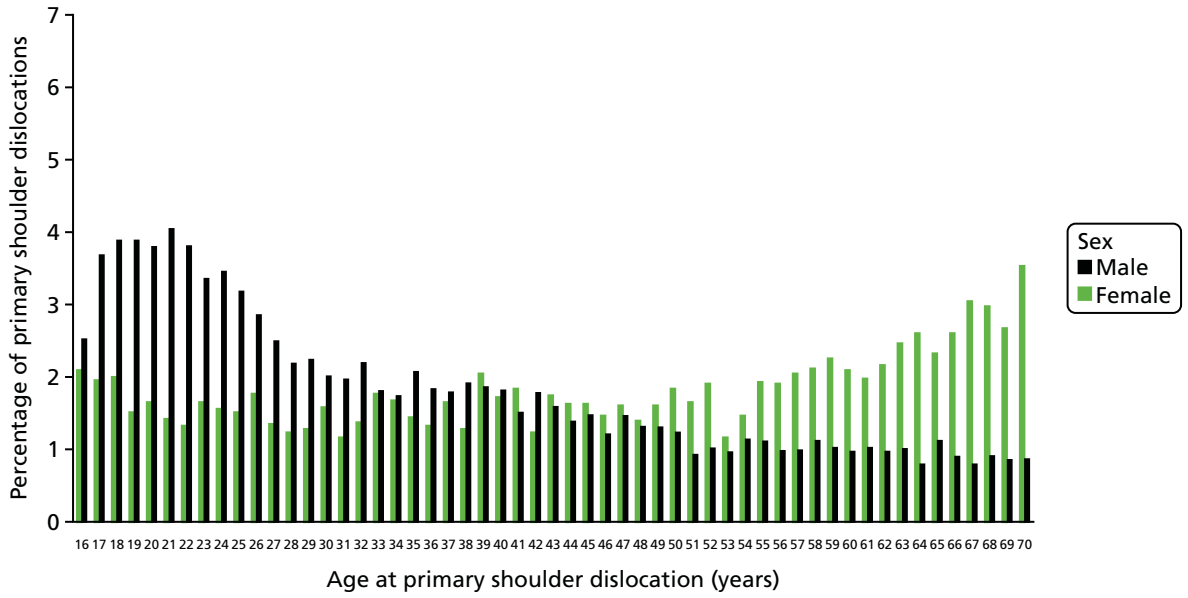


FIGURE 2 The percentage of primary shoulder dislocation patients by age (16–70 years) and sex recorded within CPRD (UK) between 1 April 1997 and 31 March 2015. Reproduced from Shah *et al.*[17] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/.

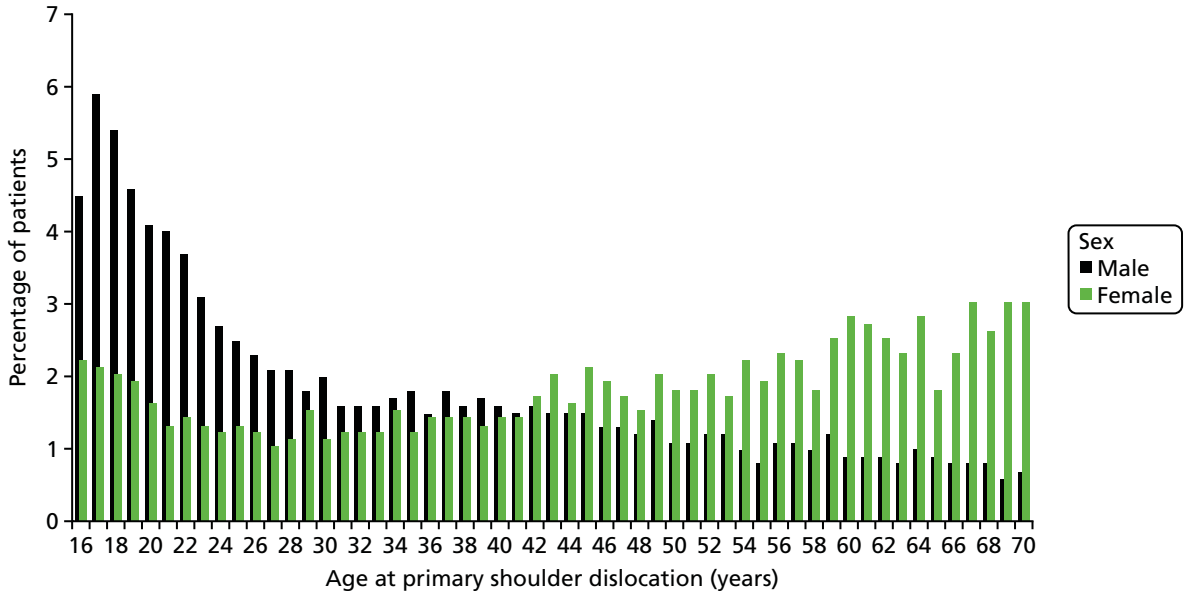


FIGURE 3 The percentage of primary shoulder dislocation patients by age and sex recorded in Canada. Leroux T, Wasserstein D, Veillette C, Khoshbin A, Henry P, Chahal J, *et al.*, *American Journal of Sports Medicine*, vol. 42, issue 2, pp. 442–50, copyright © 2014 by American Orthopaedic Society for Sports Medicine, reprinted by Permission of SAGE Publications, Inc.[16]

The incidence rates by age and sex for primary shoulder dislocation patients in the UK and an extract of similar Canadian incidence data are presented in *Table 11*. The patterns of incidence by age and sex were similar and are also represented in *Figures 4* and *5*. Incidence rates were higher in the UK for all combinations of age groups and sex, except for men aged 16–20 years [UK men (81.6 per 100,000 person-years) vs. Canadian men (98.3 per 100,000 person-years)].

TABLE 11 Incidence rate by age and sex among patients with a first-time TASD aged 16–70 years, recorded within CPRD (UK) between 1 April 1997 and 31 March 2015 and compared with an extract of Canadian cohort data[16]

	UK cohort		Canadian cohort (Leroux *et al.*[16])
Demographic category	Incidence rate[a]	95% CI	Incidence rate[a]
Sex			
Male	40.4	40.4 to 40.4	34.3
Female	15.5	15.5 to 15.5	11.8
Age (years)			
16–20	48.8	48.8 to 48.9	56.6
21–30	38.8	38.7 to 38.8	27.0
31–40	24.4	24.4 to 24.5	16.5
41–70	22.2	22.2 to 22.2	18.8
Age (years), sex (male)			
16–20	80.5	80.5 to 80.6	98.3
21–30	65.7	65.6 to 65.7	46.9
31–40	37.0	36.9 to 37.0	25.9
41–70	26.2	26.2 to 26.2	22.3
Age (years), sex (female)			
16–20	16.4	16.3 to 16.4	13.8
21–30	12.2	12.2 to 12.2	7.5
31–40	11.6	11.6 to 11.6	7.1
41–70	18.1	18.1 to 18.1	15.2

a The incidence rate per 100,000 person-years at risk.

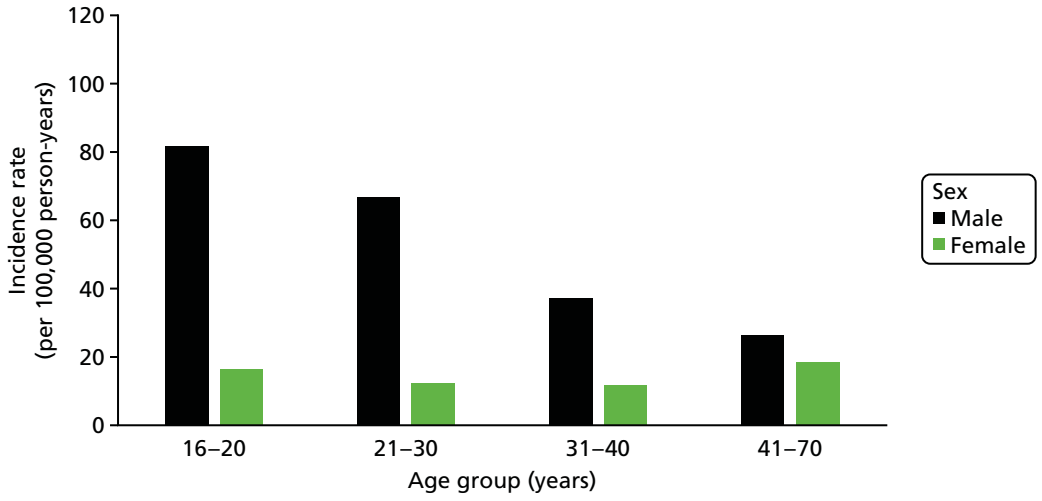


FIGURE 4 The incidence rate of primary shoulder dislocation by age and sex among patients aged 16–70 years with a primary shoulder dislocation recorded within CPRD (UK) between 1 April 1997 and 31 March 2015.

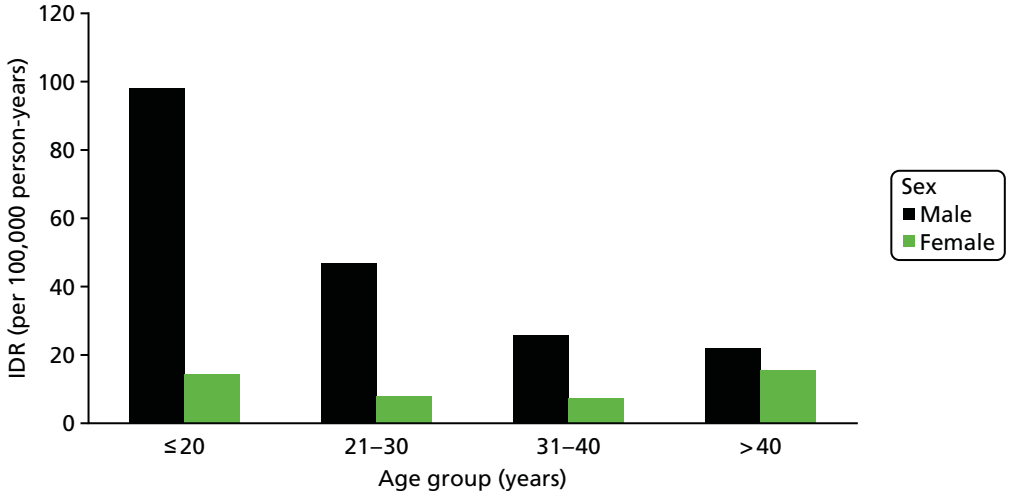


FIGURE 5 The overall IDR of primary anterior shoulder dislocation in Canada requiring closed reduction in accordance with both age and sex. The *y*-axis depicts the IDR per 100,000 person-years and the *x*-axis depicts each age category. IDR, incidence density rate. Leroux T, Wasserstein D, Veillette C, Khoshbin A, Henry P, Chahal J, *et al.*, *American Journal of Sports Medicine*, vol. 42, issue 2, pp. 442–50, copyright © 2014 by American Orthopaedic Society for Sports Medicine, reprinted by permission of SAGE Publications, Inc.[16]

Comparison of UK incidence data with US incidence data

The age and sex incidence rates for primary shoulder dislocation in the UK were also compared with published data from the USA.[15] A comparison of the characteristics between the UK and US cohorts is shown in *Table 12*. The UK cohort included in the analysis comprised 20,784 patients of all ages with a primary shoulder dislocation between 1 April 1997 and 31 March 2015. Data on ethnicity were not available within the CPRD, thus this comparison could not be made. Denominators for incidence analyses were obtained from the CPRD by individual year, age and sex.

The overall incidence rate in the UK was 26.6 per 100,000 person-years (95% CI 26.2 to 26.9 per 100,000 person-years), which was similar to the incidence rate reported in the USA (23.9 per 100,000 person-years, 95% CI 20.8 to 27.0 per 100,000 person-years). The peak incidence occurred in patients aged 20–29 years in the UK (41.8 per 100,000 person-years, 95% CI 40.6 to 43.1 per 100,000 person-years) (*Table 13*), which is similar to the peak in 20- to 29-year-olds observed in the USA (47.8 per 100,000 person-years, 95% CI 41.0 to 54.5 per 100,000 person-years).[15] Significantly higher rates of incidence were observed in the UK among patients aged > 50 years in comparison with those in the USA (see *Table 13*).

In the UK, the incidence of primary shoulder dislocation was significantly higher in men (34.3 per 100,000 person-years, 95% CI 33.7 to 34.9 per 100,000 person-years) than in women (19.0 per 100,000 person-years, 95% CI 18.6 to 19.5 per 100,000 person-years) ($p < 0.001$), which is similar to the pattern observed in the USA (see *Table 13*). Incidence of shoulder dislocation in men was similar between the UK and US cohorts,

TABLE 12 Comparison of the characteristics of the data used in the US paper and the UK data

Details	USA data (Zacchilli and Owens[15])	UK data
Setting	Hospital records of patients presenting to 100 hospital emergency departments with a shoulder dislocation	Primary care records of coded shoulder dislocations
Geography	USA sample (NEISS)	UK sample (CPRD)
Dates	2002–2006	April 1997–March 2015
Patient age (years)	All ages	All ages
Numbers of patients	8940	20,784

TABLE 13 Effects of sex and age on shoulder dislocation incidence and incidence rate ratios in CPRD (UK) between 1 April 1997 and 31 March 2015, compared with an extract of US cohort data from Zacchilli and Owens[15]

	UK cohort data					USA cohort data (Zacchilli and Owens[15])				
Demographic category	Incidence rate[a]	95% CI	Incidence rate ratio	95% CI	*p*-value	Incidence rate[a]	95% CI	Incidence rate ratio	95% CI	*p*-value
Sex										
Female	19.02	18.59 to 19.45	Reference[b]			13.26	11.56 to 14.96	Reference[b]		
Male	34.29	33.71 to 34.88	1.80	1.75 to 1.86	< 0.001	34.90	30.08 to 39.73	2.64	2.39 to 2.88	< 0.05
Age (years)										
0–9	1.23	1.01 to 1.49	0.06	0.05 to 0.08	< 0.001	0.92	0.56 to 1.29	0.07	0.04 to 0.10	< 0.05
10–19	27.34	26.32 to 28.41	1.38	1.30 to 1.46	< 0.001	39.71	34.05 to 45.37	3.07	2.62 to 3.53	< 0.05
20–29	41.80	40.55 to 43.08	2.11	2.00 to 2.23	< 0.001	47.76	41.02 to 54.50	3.70	3.15 to 4.25	< 0.05
30–39	25.05	24.14 to 25.99	1.26	1.19 to 1.34	< 0.001	25.69	21.85 to 29.53	1.99	1.73 to 2.25	< 0.05
40–49	20.66	19.84 to 21.51	1.04	0.98 to 1.11	0.169	17.59	14.22 to 20.96	1.36	0.91 to 1.82	> 0.05
50–59	19.81	18.95 to 20.70	Reference[b]			12.89	10.48 to 15.30	Reference[b]		
60–69	26.71	25.60 to 27.87	1.35	1.27 to 1.43	< 0.001	16.96	14.06 to 19.87	1.31	0.98 to 1.65	> 0.05
70–79	41.12	39.48 to 42.82	2.08	1.95 to 2.20	< 0.001	22.56	17.51 to 27.61	1.74	1.45 to 2.03	< 0.05
80–89	58.03	55.40 to 60.79	2.93	2.75 to 3.12	< 0.001	31.34	25.05 to 37.63	2.43	1.93–2.93	< 0.05
≥ 90	65.55	59.65 to 72.03	3.31	2.98 to 3.67	< 0.001	28.38	17.97 to 38.79	2.20	1.30–3.10	< 0.05

a The incidence rate per 100,000 person-years at risk.
b Reference indicates the reference group for the incidence rate ratio within the demographic category.

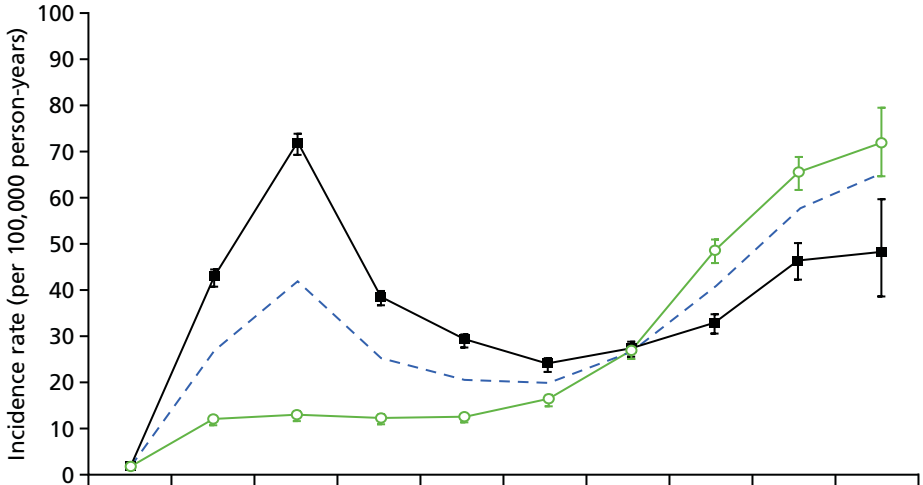
but incidence in women in the UK was much higher than incidence in women in the USA. In the UK cohort, 36% of shoulder dislocations occurred in women, in contrast to 28% of shoulder dislocations in the US cohort.

Figure 6 shows the peak of incidence in men aged 20–29 years in the UK (71.5 per 100,000 person-years), which was similar to the peak in men in the same age group in the USA (79.2 per 100,000 person-years) (*Figure 7*). The peak in women in the UK was observed in those aged > 90 years (71.7 per 100,000 person-years), in contrast with the 38.8 per 100,000 person-years in women aged 80–89 years in the USA. A possible reason for the differences in incidence may be caused by the UK study being based on primary care records and the US study being based on emergency department records.

Conclusion

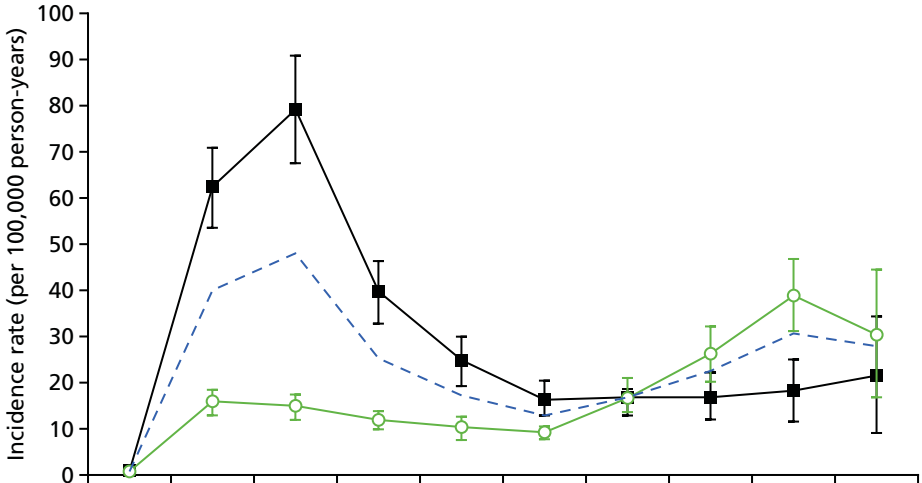
This chapter describes a large population-based cohort of 16,763 patients aged 16–70 years in the UK during 1995–2015 identified in the CPRD data set in relation to shoulder dislocations. Most shoulder dislocations occurred in males (72%), with an overall incidence rate of 40.4 per 100,000 person-years. In females, the overall incidence rate was 15.5 per 100,000 person-years. The highest incidence was observed in 16- to 20-year-old males (80.5 per 100,000 person-years). An unexpected finding was that incidence in women increased beyond the age of 50 years to 28.1 per 100,000 person-years among those aged 61–70 years; this pattern was not observed in men.

The results from the UK cohort were then compared with other cohorts in other countries. The UK cohort was similar in age, sex distribution and incidence patterns to those observed in the Canadian, US and Norwegian cohorts.[15,16,20] Although the incidence patterns were similar between countries, in the UK the peak in numbers observed for men is spread over those aged 17–22 years, whereas there is a distinct peak in men aged 17–18 years in Canada and the USA. Possible reasons for this difference may be the high numbers of young men playing ice hockey and American football at school, aged 17–18 years, of whom not all continue to play at college. In a smaller study of the causes of shoulder dislocations in Sweden, incidence was high (8%) among ice-hockey players.[13] Other explanations might be the under-reporting of



	0–9	10–19	20–29	30–39	40–49	50–59	60–69	70–79	80–89	≥90
All	1.2	27.3	41.8	25.0	20.7	19.8	26.7	41.1	58.0	65.5
Male	1.3	42.5	71.5	38.0	28.8	23.6	26.9	32.5	45.9	47.9
Female	1.1	11.7	12.5	11.8	12.2	15.9	26.5	48.3	65.2	71.7

FIGURE 6 Shoulder dislocation incidence rates and 95% CIs by age and sex in CPRD (UK) between 1 April 1997 and 31 March 2015.



	0–9	10–19	20–29	30–39	40–49	50–59	60–69	70–79	80–89	≥ 90
All	0.9	39.7	47.8	25.7	17.6	12.9	17.0	22.6	31.3	28.4
Male	1.2	62.2	79.2	39.5	24.9	16.6	16.9	17.1	18.3	21.9
Female	0.7	16.0	14.8	11.7	10.4	9.4	17.0	26.5	38.8	30.7

FIGURE 7 Total weighted NEISS estimates of all US shoulder dislocations between 2002 and 2006 by age and sex, demonstrating a bimodal distribution with peaks among men (aged 20–29 years) and women (aged 80–89 years). The vertical bars denote the 95% CIs.[15] Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg* 1992;**3**:542–9. https://insights.ovid.com/pubmed?pmid=20194311. Reprinted by permission of Wolters Kluwer.

shoulder dislocations among college students or a genuine decrease because of better skeletal maturity and shoulder muscle strength and control.

Incidence rates were higher in the UK than in Canada for all combinations of age groups and sex, except for men aged 16–20 years (UK men, 80.5 per 100,000 person-years; vs. Canadian men, 98.3 per 100,000 person-years). These higher incidence rates may be explained by UK data being based on primary care records in contrast to Canadian data, which are based on accident and emergency hospital records.[16]

A study conducted in Denmark identified the same bimodal age distribution of incidence, and also specifically noted that older people most frequently dislocated their shoulders at home by falling on their arm, whereas young people most frequently suffered a shoulder dislocation while playing sports.[21] However, the increasing incidence of shoulder dislocations seen in UK women aged > 50 years is a new finding that is of both interest and concern because the reasons for it are not known. Such injuries in the elderly are usually associated with rotator cuff tears and fractures with subsequent loss of function, as well as instability. However, further work will be required to examine the reasons that may explain this increased risk of shoulder dislocations in ageing women. Possible reasons include biological differences between ageing men and women, including differences in joint proprioception, soft tissue tendon quality and protective muscle bulk. Other possibilities might be a difference in the incidence of falls between men and women. This is of particular importance, given that the population of the UK continues to change to include more elderly people. The increasing population priority needs to be given to increasing the safety of the elderly to reduce falls, dislocations and fractures, as advocated by the National Institute for Health and Care Excellence (NICE),[22] which suggests that this is a finding that needs further investigation and research.

The main strength of this study is its large population-based cohort that uses real-world data from primary care. The CPRD is representative of the UK general population by age and sex and the age- and sex-specific incidence of primary shoulder dislocations observed are similar to those observed in Canada and the USA. Although some differences were observed, the incidence of traumatic shoulder dislocations in these other countries has only been calculated using regional data or hospital data. This is, therefore, the first time,

to our knowledge, that the incidence of shoulder dislocations has been studied using population-based primary care data and the first time, to our knowledge, that results for the UK have been produced. The findings in this chapter and *Chapter 2* support the use of CPRD for the subsequent study chapters and work package 2 studies.

In summary, in the UK most primary shoulder dislocations during the selected time period occurred in young men. An unexpected finding was that incidence increased in women aged > 50 years but not in men of the same age. The reasons for this are unknown. Priority and attention should be directed towards increasing preventative measures for young people playing contact sports, and to the research of the possible causes of the increase in primary shoulder dislocation incidence for women aged > 50 years.

Chapter 4 The impact of surgical treatment within 6 months or no surgical treatment on the rates of shoulder re-dislocations in young people aged 16–35 years with first-time traumatic anterior shoulder dislocation in England

This chapter begins the main analysis of the commissioned research (work package 2). The previous chapters described the internal and external validation of the data to be used in this and the following chapters.

Objectives of *Chapter 4*

To study the effect of surgical treatment on the 2-year recurrent shoulder dislocation rates in young adults in England when surgical treatment took place within 6 months of the first episode of TASD.

Methods

Study design

A population-based propensity-score-matched cohort study to control for confounding at baseline has been conducted. Young adults (aged 16–35 years) who presented with a first-time TASD were selected from two computerised NHS databases (CPRD and HES). *Figure 8* shows a detailed illustration of the study plan, which is described in more detail in the following paragraphs.

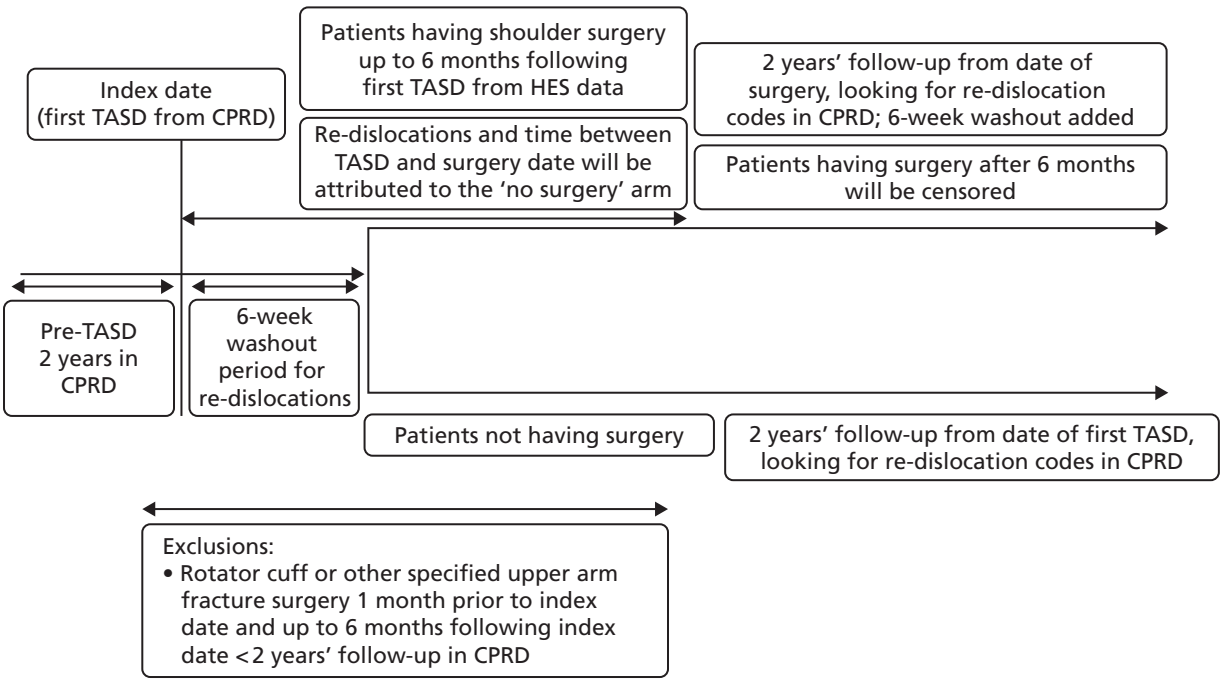


FIGURE 8 The UK TASH-D phase 2 plan design for patients who received surgery or no surgical treatment within 6 months of a diagnosis of a first-time TASD during 1 April 1997–26 April 2014, in England.

Using methodology identical to the internal validation study described in *Chapter 2*, to ensure that only primary dislocations had been captured, all participants had to have 2 years of clinical data within CPRD before their first TASD and at least 2 years' follow-up from the event (re-dislocation). This 2-year washout period is required to ensure that a first dislocation code actually represents a first-time dislocation, as a recurrent dislocation usually occurs within 2 years of the primary event. This period therefore minimises the risk of a code being a second dislocation code. The period was defined using the date that the general practice was classified as 'up to standard' and the date that the patient was first registered at the practice. Patients had to be registered at 'active' practices, as defined in *Chapter 2*, *Data source*. Taking into account this washout period, the first Read code entry in CPRD for shoulder dislocation was then defined as the first dislocation. All events were collected using a pre-agreed validated list of CPRD Read codes (see *Appendix 1*). Patients experienced their first-time TASD between 1 April 1997 and 26 April 2014, allowing at least 2 years of follow-up for each patient to the end of the study on 26 April 2016.

A 6-week washout period for re-dislocation codes within CPRD was applied to all patients following their TASD to avoid duplicate records. Patients were highly unlikely to re-dislocate their shoulder during this period as their arms would be in slings and they would be following rehabilitation protocols, but would probably return to visit their GP for prescriptions for painkillers or referrals to physiotherapy and secondary care.

Surgical group

The surgical group comprised patients in CPRD with a first-time TASD who underwent shoulder stabilisation surgery after their first dislocation. Early surgical repair in this NHS context means 'a decision to treat surgically after the first TASD' (as per the approved study protocol) and receiving surgery within 6 months of injury before any subsequent dislocations. This meant linking HES data to CPRD data in such a way that a HES surgical OPCS 4.7 code was seen to occur after a single first dislocation code in CPRD before that surgical date. The timelines between first dislocation codes and OPCS 4.7 codes were recorded. If a re-dislocation occurred prior to their surgery date, the patient was allocated to the non-surgical arm.

A further 6-week washout period for re-dislocation codes within CPRD was applied to all patients in the surgical group following their surgery date to avoid duplicate records because they would have been asked to immobilise their arm for this period and, thus, a re-dislocation would be highly unlikely to occur. During these 6 weeks, patients would most probably return to visit their GPs for painkillers or referral to physiotherapy. Surgery patients were followed up for at least 2 years from the date of their surgery. Patients who had surgery more than 6 months following their TASD were censored on their date of surgery. The surgery dates for these patients ranged from 25 December 1997 to 18 August 2014.

Non-surgical group

Although the most desirable control group would have been physiotherapy, the internal validation study identified that the referral codes for physiotherapy are lacking and unreliable in CPRD. Thus, conservative care has been defined as 'non-surgical intervention', with no linked OPCS 4.7 surgical shoulder codes, producing a control cohort of patients whose first-time shoulder dislocation has been treated non-operatively. Non-surgical patients were followed up for at least 2 years following the date of their first-time TASD, as illustrated in *Figure 8*.

Outcome

The outcome was time to a shoulder re-dislocation, as defined by the CPRD Read codes given in *Appendix 1*. For the surgical group, the shoulder re-dislocation can occur between 6 weeks and 2 years following the date of surgery. For the non-surgical group, the shoulder re-dislocation could occur between 6 weeks and 2 years following the date of first-time TASD.

Any patients who died during the study were censored on their date of death.

Data sources

The analysis utilised two computerised NHS databases, one from primary care (the CPRD) and the other from secondary care (the HES). The characteristics of the CPRD have been described in *Chapter 2*, *Data source*. For HES data, each time a patient sees a health professional in a hospital, a record or 'episode' is created and added to the HES database. The HES record contains patient details, some diagnosis codes, treatments and lengths of hospital stay.

Clinical Practice Research Datalink has been linked with HES data to provide a HES-linked patient identifier. About 60% of CPRD-contributing practices have been linked to HES data. HES data provide a general patient identifier to facilitate linkage of hospital records belonging to the same individual. Management of the CPRD and HES databases was carried out by a senior data manager with expertise in the use of these data sets. The senior data manager developed an ad hoc code using Python (version 3.6, developed by Python Software Foundation, Wilmington, DE, USA) and Structured Query Language (SQL) (version 5.6.12, developed by the International Electrotechnical Commission and the International Organization for Standardisation; Geneva, Switzerland) to produce a final working data set that was analysed using standard statistical software packages Stata® version 14.1 and R (version 3; The R Foundation for Statistical Computing, Vienna, Austria).

Sample size

The original sample size considerations for this study were based on data from a Cochrane systematic review comparing surgical and non-surgical treatment for an acute TASD.[5] From the pooled results, 3 out of 58 patients in the surgical arm had subsequent further surgery (5.17%) compared with 17 out of 61 patients in the non-surgical arm (27.9%), at a minimum follow-up of 2 years (risk ratio 0.22, 95% CI 0.08 to 0.64). The large effect size is based on the pooled results of three randomised controlled trials with uncertainty around the true size of the effect outside a clinical trial setting in routine general practice. Therefore, values were set to detect a smaller difference in subsequent surgery within 2 years, with a 25% re-dislocation rate in the non-surgical group, compared with a 20% re-dislocation rate in the surgical group (an absolute difference of 5%). A two-sided, log-rank test for equality of survival curves was used, with 90% power at a 5% significance level (alpha) and for which the outcome is time to re-dislocation with an anticipated 25% re-dislocation rate in the non-surgical control group compared with a 20% re-dislocation rate in the surgical group [equivalent to a hazard ratio (HR) of 0.78]. Allowing for a 10% loss to follow-up and assuming equal group sizes meant that the study required a total sample size of 3065 participants, with 656 expected re-dislocations.[5] It was assumed that 35% of the patients would receive surgery within 6 months after one dislocation ($n = 1073$).[23]

Participants

Inclusion criteria

The CPRD records of 6046 patients, aged 16–35 years with 2 years of data in the CPRD before a first-time TASD, identified in the internal validation study (see *Table 1*) were linked to HES records.

Exclusion criteria

The following patients were excluded:

- those aged 16–35 years with a first-time TASD who cannot be linked by CPRD-HES
- those with < 2 years of follow-up in the CPRD
- those with prior shoulder surgery for a shoulder dislocation
- those whose instability was treated with rotator cuff repair surgery or fracture surgery prior to or following a TASD.

Exclusions were made in accordance with the criteria above and are described in *Table 14*. Following linkage to HES, there was a linkage loss of 1234 patients and six duplicates were identified and removed. A substantial number of patients had < 2 years of follow-up within the CPRD ($n = 854$), which may relate to these young people moving away from home to attend university or to start new jobs in new locations, which, in turn,

TABLE 14 Shoulder dislocation exclusions for patients aged 16–35 years during 1 April 1997–26 April 2014, within CPRD in England with the linkage to HES records

Exclusions	Excluded (*n*)	Total (*N*)	%
Eligible patients in the CPRD cohort for the internal validation study, following exclusions made in *Table 1*		6046	100
HES linkage loss	1234		20
Duplicate removal	6		< 1
< 2 years of follow-up within the CPRD	854		14
Prior shoulder surgery for a shoulder dislocation	155		3
Surgery for rotator cuff tear prior to TASD	1		< 1
Surgery for rotator cuff tear in the 6 months following TASD	4		< 1
Surgery for a shoulder fracture prior to TASD	14		< 1
Surgery for a shoulder fracture in the 6 months following TASD	19		< 1
Total exclusions	2287		
Patients included in subsequent analyses		3759	62

requires a change of GP. A very small proportion of patients (3%) were excluded for having shoulder surgery for rotator cuff tears, fractures or prior dislocations. In total, 3759 patients remained available for analysis, which was greater than the minimum number of patients ($n = 3065$) required for a sufficient sample size and power (*Figure 9*).

Statistical analysis

The aim of this study was to investigate the effect of surgical intervention within 6 months compared with non-surgical intervention on the rates of re-dislocation in young patients with a first-time TASD over a 2-year period. In addressing this research question, the exposure is whether or not a patient received surgery, and the primary outcome of interest is the time from date of surgery for surgical patients or date of the first-time TASD for non-surgical patients to having a subsequent re-dislocation within 2 years.

Covariates

Demographic data were available from the CPRD on age, sex, BMI, IMD 2004,[19] smoking status (i.e. current smoker, ex-smoker, non-smoker), drinking status (i.e. current drinker, non-drinker), geographic region, epilepsy and prescriptions for painkillers in the 3 months preceding the first-time TASD and 1 month following the first-time TASD. The CCI score was calculated using a list of predefined CPRD Read codes.

A consensus survey was conducted of specialist shoulder surgeons and shoulder physiotherapists who were all members of the British Elbow and Shoulder Society. The saturation point and a list of predictors was reached rapidly and this list is tabulated in *Appendix 4*. The list highlights the risk factors (and covariates) deemed most important. However, data were only reliably available on the following factors from the list: age, sex, geographic region, deprivation scores, time between first dislocation and surgery.

Missing data

Multiple imputation using chained equations was used to address potential bias and increase precision as a result of missing data on BMI, smoking, drinking and IMD.[24] The imputation equations included all potential factors, including the outcome and length of follow-up time. Fifty imputed data sets were generated and the resulting estimates were combined using Rubin's rules.

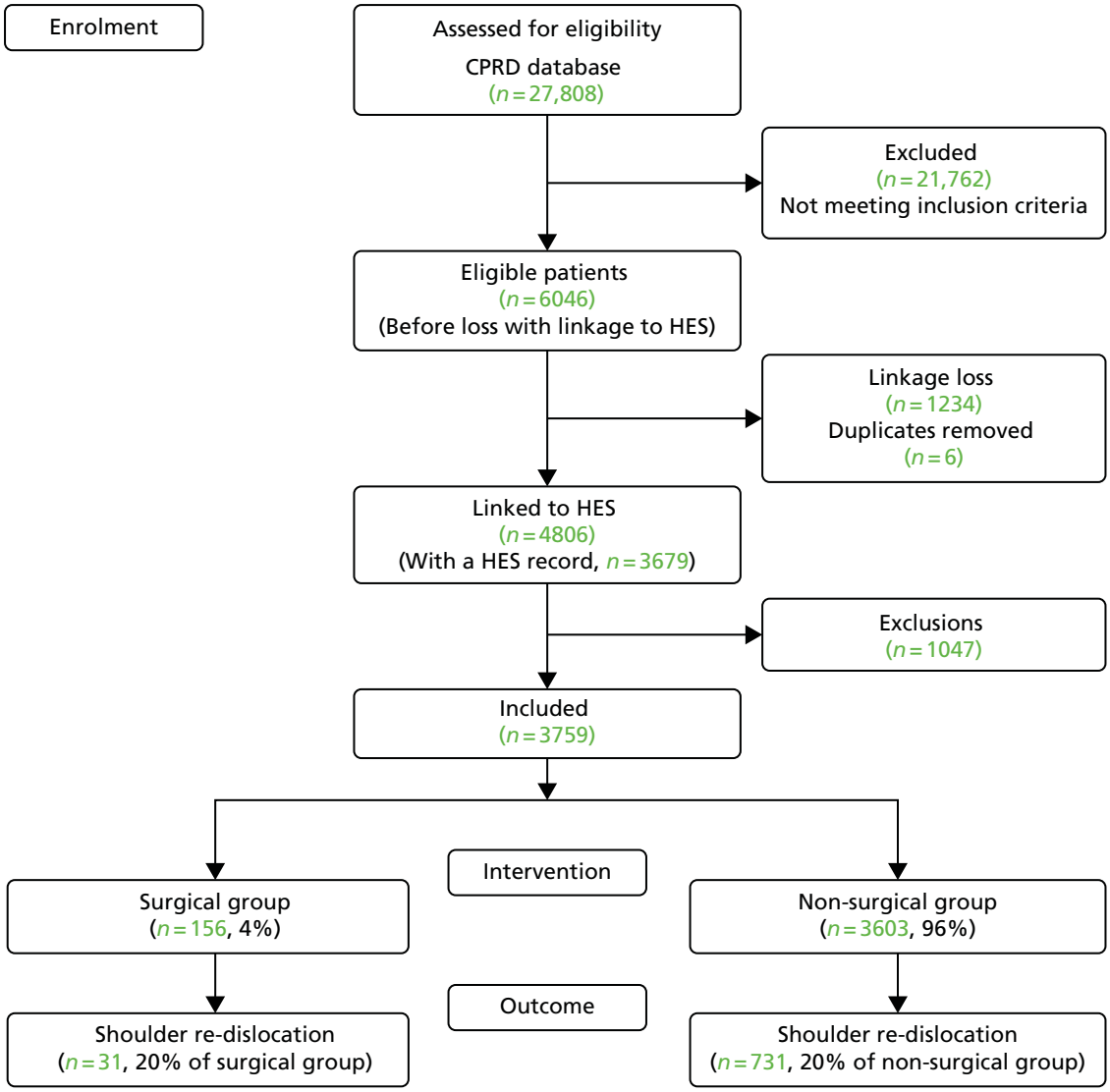


FIGURE 9 Shoulder dislocation exclusions flow chart for patients aged 16–35 years during 1 April 1997–26 April 2014, within CPRD in England with linkage to HES records.

Confounding by indication

In randomised controlled trials, each person has an equal probability of being in the treatment or the control group. Observational study designs, such as the one used for this study, are limited by an inherent imbalance of both known and unknown confounders, making some patients more likely to receive surgery than others. A surgeon typically uses information and risk factors on the patient at baseline to make a decision about whether or not to operate. Whether or not a patient receives surgery is therefore not random in this population-based setting.

As the type of surgery received is not randomly allocated in this study, propensity score matching methods were used to minimise confounding by indication. These propensity score methods were used to achieve comparability of groups with and without the intervention with respect to their observed baseline covariates, thus, controlling for confounding in estimating treatment effects. The use of these methods for the assessment of causality in epidemiological studies has been previously described.[25]

The propensity score represents the probability that a patient received the intervention (surgery) conditionally, based on their covariate values. One feature of the propensity score is that it provides balance, so that at each value of the propensity score, the distribution of the covariates (used to define the score) is expected to be similar in the intervention group and non-surgical-intervention group. Comparing patients with the intervention and those without the intervention with the same propensity score gives an unbiased estimate of the effect of treatment.

A logistic equation was fitted for which the outcome was actually the main study exposure (surgical compared with non-surgical intervention) and an agreed list of covariates were introduced as potential confounders of the study outcome.[26,27] All of the covariates described in *Covariates* were included in the model.

Propensity scores were then used to match each patient receiving surgery to comparable non-surgical controls using a 0.2 standard deviations calliper, as demonstrated in previous simulation studies.[28] Matching was performed without replacement using the MatchIt package in R.[29] Each patient receiving surgery for TASD was matched to three comparable non-surgical controls.

The balance of covariates before and after matching was assessed by calculating the absolute standardised mean difference (SMD) for each covariate. The commonly used boundary for the absolute SMD to indicate acceptable balance is 10%, meaning that a standardised difference of $< 10\%$ is considered a good balance. The distribution of propensity scores before and after matching were also judged subjectively for sufficient overlap following matching using density plots.

If the analysis includes participants outside the boundaries of the overlap, this can lead to biased estimates. Participants outside these boundaries will be patients with very high or very low propensity scores. Thus, the best approach is to trim the patients included in the analysis, removing those with extreme propensity scores. This was carried out by calculating 1% of the extremes of the propensity score tails and removing patients outside the limits.

This is a standard method for minimising confounding by indication that not only provides participants with balanced baseline characteristics in both surgical and non-surgical groups, but also eliminates surgical patients with no comparable controls.[30]

This methodology is now widely used in pharmacoepidemiology and drug safety, and has both strengths and limitations. The main advantages of propensity score matching are:

- Exclusion of non-comparable subjects (e.g. non-surgical participants with a very low propensity score who probably have some contraindication or are not fit for surgery and, therefore, should not be compared with those who actually underwent surgical repair).
- This method produces clearly comparable cohorts in terms of observed confounders and is highly visual and intuitive.

The main disadvantage (when compared with randomised trials) is the lack of adjustment/matching for unobserved confounders. In an observational setting, there is the potential risk that the choice of patient treatment by skilled clinicians is driven by unmeasured patient characteristics and risk factors that are not recorded in the observational data sets. This can affect the precision of the estimate of treatment efficacy and external validity.[31] The performance of a propensity score can be examined for homogeneity at different points on the propensity score scale. If the analysis has worked as anticipated, a similar treatment effect should be observed across the range of propensity score values. Another potential limitation is the potential loss of power if patients cannot be matched as part of the propensity score analysis.

The association between surgery and time to re-dislocation within a 2-year time frame was described using a Cox regression survival model, including the surgical patients and their three matched non-surgical controls. The model was stratified on matched sets, to allow for the correlation between matched pairs of surgical patients and controls. An assumption in the use of the Cox regression model is that of proportional hazards, which was assessed using Schoenfeld Residuals Test. Probability of survival up to 2 years was estimated in the surgical and non-surgical groups using Kaplan–Meier plots.

Immortal time bias

A common issue in epidemiological studies is that of immortal time bias, which describes a form of bias introduced from a period of time when the outcome or event of interest cannot occur by design. It usually occurs in a cohort study with two index dates, when the passing of time from the first date (i.e. inclusion date) to the date when a patient receives the intervention (i.e. exposure/treatment date) is by definition immortal in the exposed group. In the present study, immortal time bias would be introduced in the surgical group, arising in the time following a first dislocation to when they receive surgery, because during this time they cannot have the outcome of interest (otherwise they would have been classified as 'non-surgical'). Although the patient is not truly 'immortal', they had to remain free from re-dislocations prior to receiving surgery, which introduces a bias of offering guaranteed survival time to the surgical group. The surgical patients will be artificially 'safeguarded' from having a re-dislocation until their date of surgery. By not being correctly classified, this immortal time would produce an artificial increase in re-dislocations in the non-surgical group, suggesting that surgery has a better outcome. The effects of immortal time bias have been confirmed and quantified by Suissa.[32]

To address the problem of immortal time bias, time-varying exposures have been used. In the survival analysis, the time prior to surgery for the surgical group has been reclassified as 'non-surgical', and new ('twin') patients have been created and added to the 'non-surgical' group. This is deemed the best available method for the minimisation of immortal time bias.[33]

Results

Descriptive characteristics

A cohort of 3759 patients diagnosed with a first-time TASD during 1 April 1997–26 April 2014 was identified in the CPRD. The CPRD Read codes used to identify these patients can be found in *Appendix 5*.

An unexpected finding at this stage was that only 4% ($n = 156$) of the remaining patients had received surgery for their dislocation within 6 months. This was only 15% of the expected number of surgical patients. In addition, an identical proportion of patients (20%) had suffered a re-dislocation in the surgical and non-surgical groups instead of the anticipated 5% difference. Although this finding is useful for this commissioned study, indicating that surgery after one traumatic dislocation is not common in the general NHS population, it also means that, overall, this study was underpowered for the primary question at 6 months. The analysis was conducted as per the approved protocol, but a protocol amendment was added to carry out an additional sensitivity analysis at 12 months.

For the 156 patients who underwent shoulder surgery within 6 months, the OPCS 4.7 surgical codes identified within HES are given in *Appendix 6*. The descriptive characteristics of patients categorised by receiving surgery within 6 months or no surgery are described in *Table 15*. In the first 4 years, fewer than five patients underwent surgery per year. This increased from 2001 to a maximum of 18 (out of a total of 156 surgical patients) in 2008. More men (83%) were diagnosed with a primary shoulder dislocation than women, and more men underwent surgery within 6 months (40 men vs. 16 women). The majority of patients were aged 17–21 years at the time of their first-time TASD, but similar numbers were operated on among those aged 18–25 years.

TABLE 15 Descriptive characteristics of primary shoulder dislocation patients diagnosed during 1 April 1997–26 April 2014 who had surgery within 6 months or no surgery within CPRD-HES, in England

Characteristic	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 6 months of TASD
Total	3759 (100)	3603 (96)	156 (4)
Year of shoulder dislocation			
1997	62 (2)	61 (2)	1 (1)
1998	106 (3)	102 (3)	4 (3)
1999	120 (3)	118 (3)	2 (1)
2000	143 (4)	139 (4)	4 (3)
2001	192 (5)	185 (5)	7 (4)
2002	226 (6)	221 (6)	5 (3)
2003	270 (7)	262 (7)	8 (5)
2004	276 (7)	269 (7)	7 (4)
2005	258 (7)	252 (7)	6 (4)
2006	280 (7)	270 (7)	10 (6)
2007	303 (8)	290 (8)	13 (8)
2008	297 (8)	279 (8)	18 (12)
2009	275 (7)	261 (7)	14 (9)
2010	294 (8)	279 (8)	5 (10)
2011	265 (7)	249 (7)	16 (10)
2012	212 (6)	197 (5)	15 (10)
2013	159 (4)	149 (4)	10 (6)
2014	21 (1)	20 (1)	1 (1)
Sex			
Male	3115 (83)	2975 (83)	140 (90)
Female	644 (17)	628 (17)	16 (10)
Age at shoulder dislocation (years)			
16	204 (5)	195 (5)	9 (6)
17	257 (7)	251 (7)	6 (4)
18	241 (6)	230 (6)	11 (7)
19	266 (7)	255 (7)	11 (7)
20	254 (7)	241 (7)	13 (8)
21	276 (7)	266 (7)	10 (6)
22	242 (6)	225 (6)	17 (11)
23	212 (6)	203 (6)	9 (6)
24	222 (6)	214 (6)	8 (5)
25	198 (5)	187 (5)	11 (7)
26	180 (5)	173 (5)	7 (4)
27	156 (4)	148 (4)	8 (5)
28	128 (3)	125 (3)	3 (2)

TABLE 15 Descriptive characteristics of primary shoulder dislocation patients diagnosed during 1 April 1997–26 April 2014 who had surgery within 6 months or no surgery within CPRD-HES, in England (*continued*)

Characteristic	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 6 months of TASD
29	145 (4)	138 (4)	7 (4)
30	147 (4)	141 (4)	6 (4)
31	109 (3)	105 (3)	4 (3)
32	137 (4)	133 (4)	4 (3)
33	117 (3)	113 (3)	4 (3)
34	131 (3)	127 (4)	4 (3)
35	137 (4)	133 (4)	4 (3)
BMI (kg/m^2)			
< 25	1285 (34)	1233 (34)	52 (33)
25.0–29.9	646 (17)	617 (17)	29 (19)
≥ 30	309 (8)	296 (8)	13 (8)
Missing	1519 (40)	1457 (40)	62 (40)
IMD 2004 (quintile of deprivation)			
1 (affluent)	987 (26)	959 (27)	28 (18)
2	840 (22)	798 (22)	42 (27)
3	746 (20)	723 (20)	23 (15)
4	691 (18)	656 (18)	35 (22)
5 (deprived)	492 (13)	464 (13)	28 (18)
Missing	3 (< 1)	3 (0)	0 (0)
Smoking status			
No	2029 (54)	1951 (54)	78 (50)
Yes	1137 (30)	1086 (30)	51 (33)
Ex-smoker	314 (8)	301 (8)	13 (8)
Missing	279 (7)	265 (7)	14 (9)
Drinking status			
Yes	1847 (49)	1782 (49)	65 (42)
No	356 (9)	340 (9)	16 (10)
Missing	1556 (41)	1481 (41)	75 (48)
CCI score			
0	3484 (93)	3338 (93)	146 (94)
1	172 (5)	166 (5)	6 (4)
2	66 (2)	64 (2)	2 (1)
≥ 3	37 (1)	35 (1)	2 (1)
Region			
East Midlands	114 (3)	108 (3)	6 (4)
East of England	444 (12)	430 (12)	14 (9)

continued

TABLE 15 Descriptive characteristics of primary shoulder dislocation patients diagnosed during 1 April 1997–26 April 2014 who had surgery within 6 months or no surgery within CPRD-HES, in England (*continued*)

Characteristic	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 6 months of TASD
London	464 (12)	445 (12)	19 (12)
North East	96 (3)	89 (2)	7 (4)
North West	636 (17)	603 (17)	33 (21)
South Central	543 (14)	521 (14)	22 (14)
South East Coast	430 (11)	420 (12)	10 (6)
South West	454 (12)	430 (12)	24 (15)
West Midlands	441 (12)	424 (12)	17 (11)
Yorkshire and the Humber	137 (4)	133 (4)	4 (3)
Epilepsy	130 (3)	118 (3)	12 (8)
Painkiller prescriptions			
Prescribed 3 months prior to TASD	210 (6)	198 (5)	12 (8)
Prescribed 1 month following TASD	446 (12)	420 (12)	26 (17)
Mortality	22 (1)	21 (< 1)	1 (1)

Only 8% of patients were overweight or obese, with missing data on BMI for 40% of all patients. There was a pattern of decreasing numbers of patients by deprivation quintile, but this pattern was not evident for surgical patients. Only three patients did not have a recorded IMD score. Most patients were non-smokers (54%) and there were missing data on smoking for 7% of all patients. Most patients drank alcohol (49%) and there were missing data on alcohol consumption for 41% of all patients. Most patients had no comorbid conditions (93%). Many patients were from the North West ($n = 636$) and South Central regions ($n = 543$), and fewer were from the North East region ($n = 96$). A small proportion of patients had been diagnosed with epilepsy (3%), but a higher proportion of all surgical patients had been diagnosed with epilepsy (8%). A small proportion (6%) of patients were prescribed painkillers in the 3 months prior to their first-time TASD, which increased to 12% in the 1 month following TASD. Of the patients prescribed painkillers, both 3 months prior to and 1 month after their TASD, only 1% of patients were prescribed a different painkiller. Only 22 patients died during the study period.

Multiply imputed data analyses

Multiple imputation by chained equations was conducted for patients with missing data on BMI, smoking, drinking and IMD. *Appendix 7* presents the HRs, 95% CIs and *p*-values for each of these variables using all available data, a complete-case analysis and the multiply imputed data. The HRs are similar for each group, indicating that the multiple imputation process was successful.

Cox survival estimates for complete cases and the multiply imputed data, with the factors that had an impact on re-dislocations, are presented in *Appendix 8*. In total, only 1790 cases had complete data on all factors. For these patients, a protective but non-significant adjusted effect of surgery was observed (HR 0.55, 95% CI 0.29 to 1.04; $p = 0.068$). Year of first-time TASD, younger age at first-time TASD and an epilepsy diagnosis were significant risk factors for a re-dislocation.

Using the multiply imputed data resulted in similar HRs, 95% CIs and the same risk factors. The protective effect of surgery was less marked and remained non-significant (HR 0.76, 95% CI 0.52 to 1.11; $p = 0.151$).

Propensity score analysis

Logistic regression was used to calculate the propensity scores. The distribution of propensity scores in patients receiving surgery within 6 months and in those who had non-operative treatment are presented in *Figure 10*. Prior to matching, the propensity scores tended to be higher in the surgery group, but there was a substantial amount of overlap, indicating that it is possible to proceed with propensity score matching to estimate the treatment effect. Following matching, the propensity score density plots are very similar between the surgery and non-surgery patient groups. The propensity score matching does not include the non-surgical patients in the left-hand peak of the distribution.

Table 16 presents the baseline characteristics of first-time TASD patients who had surgery or non-operative treatment within 6 months. The SMDs, prior to propensity score matching, show that the two groups of patients do differ for most characteristics (SMD > 0.1). During propensity score matching, each surgical patient ($n = 156$) was matched to three non-surgical patients ($n = 468$). In addition to this, the time between the date of the first-time TASD and the date of surgery was allocated to the non-surgical patients for 102 surgical patients, making a total of 570 non-surgical patients. The remaining 54 surgical patients had no time to be re-allocated because the date of their first-time TASD was the same as their date of surgery. Following propensity score matching, the SMDs were much smaller than before (all < 0.1), suggesting that the balancing was successful.

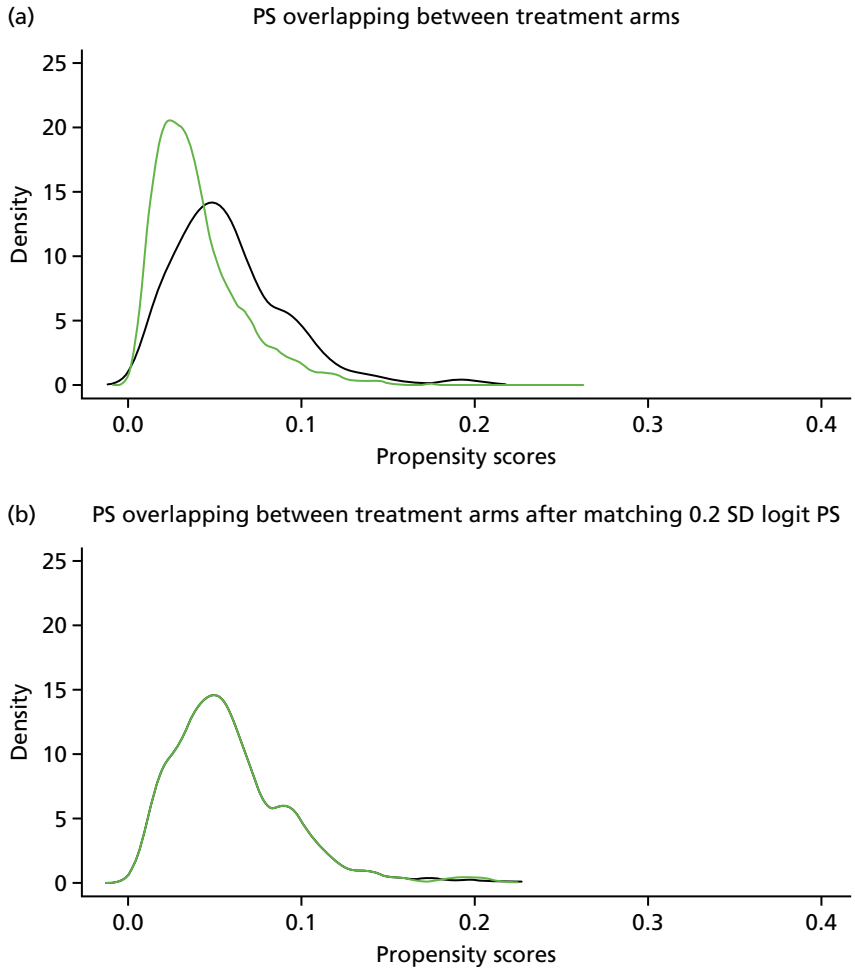


FIGURE 10 Propensity scores for first-time TASD patients diagnosed during 1 April 1997–26 April 2014, who had surgery within 6 months or no surgery within CPRD-HES, in England. (a) Prior to PS matching; and (b) following PS matching. PS, propensity score; SD, standard deviation.

TABLE 16 Baseline characteristics of patients diagnosed with a primary shoulder dislocation during 1 April 1997–26 April 2014, with number of re-dislocations and SMDs stratified by surgery or non-surgery within 6 months of diagnosis, in England

	All eligible primary shoulder dislocation patients ($N = 3784$)[a]					Matched analysis (3 : 1): patients matched on PS ($N = 726$)[a,b]				
	Surgery ($n = 156$)		Non-surgery ($n = 3603$)			Surgery ($n = 156$)		Non-surgery ($n = 570$)		
Characteristic	*n* (%)	Re-dislocation, *n* (%)	*n* (%)	Re-dislocation, *n* (%)	SMD	*n* (%)	Re-dislocation, *n* (%)	*n* (%)	Re-dislocation, *n* (%)	SMD
Re-dislocation	156 (100)	31 (20)	3603 (100)	731 (20)		156 (100)	31 (20)	570 (100)	102 (18)	
Calendar year of shoulder dislocation	156 (100)	31 (20)	3603 (100)	731 (20)	0.344	156 (100)	31 (20)	570 (100)	102 (18)	–0.046
Sex										
Male	140 (90)	26 (19)	2975 (83)	618 (21)	–0.209	140 (90)	26 (19)	500 (88)	89 (18)	–0.064
Female	16 (10)	5 (31)	628 (17)	113 (18)		16 (10)	5 (31)	70 (12)	13 (19)	
Age at shoulder dislocation (16- to 35-year-olds)	156 (100)	31 (20)	3603 (100)	731 (20)	–0.067	156 (100)	31 (20)	570 (100)	102 (18)	0.016
BMI (kg/m^2)										
< 25	86 (55)	20 (23)	2159 (60)	461 (21)	0.114	86 (55)	20 (23)	320 (56)	58 (18)	0.030
25.0–29.9	44 (28)	6 (14)	972 (27)	170 (17)		44 (28)	6 (14)	162 (28)	23 (14)	
≥ 30	26 (17)	5 (19)	472 (13)	100 (21)		26 (17)	5 (19)	88 (15)	21 (24)	
IMD 2004 (quintile of deprivation)										
1 (affluent)	28 (18)	2 (7)	961 (27)	189 (20)	0.196	28 (18)	2 (7)	91 (16)	18 (20)	–0.011
2	42 (27)	7 (17)	799 (22)	168 (21)		42 (27)	7 (17)	169 (30)	33 (20)	
3	23 (15)	8 (35)	723 (20)	139 (19)		23 (15)	8 (35)	78 (14)	8 (10)	
4	35 (22)	8 (23)	656 (18)	133 (20)		35 (22)	8 (23)	130 (23)	21 (16)	
5 (deprived)	28 (18)	6 (21)	464 (13)	102 (22)		28 (18)	6 (21)	102 (18)	22 (22)	

Characteristic	All eligible primary shoulder dislocation patients ($N = 3784$)[a]					Matched analysis (3 : 1): patients matched on PS ($N = 726$)[a,b]				
	Surgery ($n = 156$)		Non-surgery ($n = 3603$)			Surgery ($n = 156$)		Non-surgery ($n = 570$)		
	n (%)	Re-dislocation, *n* (%)	*n* (%)	Re-dislocation, *n* (%)	SMD	*n* (%)	Re-dislocation, *n* (%)	*n* (%)	Re-dislocation, *n* (%)	SMD
Smoking status										
No	85 (54)	19 (22)	2090 (58)	446 (21)	0.051	85 (54)	19 (22)	324 (57)	59 (18)	0.056
Yes	57 (37)	10 (18)	1184 (33)	222 (19)		57 (37)	10 (18)	202 (35)	36 (18)	
Ex-smoker	14 (9)	2 (14)	329 (9)	63 (19)		14 (9)	2 (14)	44 (8)	7 (16)	
Drinking status										
Yes	128 (82)	23 (18)	2985 (83)	597 (20)	0.021	128 (82)	23 (18)	479 (84)	80 (17)	0.053
No	28 (18)	8 (29)	618 (17)	134 (22)		28 (18)	8 (29)	91 (16)	22 (24)	
CCI score										
0	146 (94)	30 (21)	3338 (93)	682 (20)	–0.019	146 (94)	30 (21)	535 (94)	96 (18)	0.010
1	6 (4)	0 (0)	166 (5)	31 (19)		6 (4)	0 (0)	23 (4)	5 (22)	
2	2 (1)	0 (0)	64 (2)	11 (17)		2 (1)	0 (0)	3 (1)	0 (0)	
≥ 3	2 (1)	1 (50)	35 (1)	7 (20)		2 (1)	1 (50)	9 (2)	1 (11)	
Region										
East Midlands	6 (4)	2 (33)	108 (3)	27 (25)	–0.024	6 (4)	2 (33)	24 (4)	6 (25)	–0.003
East of England	14 (9)	2 (14)	430 (12)	84 (20)		14 (9)	2 (14)	44 (8)	11 (25)	
London	19 (12)	3 (16)	445 (12)	85 (19)		19 (12)	3 (16)	76 (13)	10 (13)	
North East	7 (4)	0 (0)	89 (2)	24 (27)		7 (4)	0 (0)	24 (4)	5 (21)	
North West	33 (21)	7 (21)	603 (17)	115 (19)		33 (21)	7 (21)	126 (22)	21 (17)	

continued

TABLE 16 Baseline characteristics of patients diagnosed with a primary shoulder dislocation during 1 April 1997–26 April 2014, with number of re-dislocations and SMDs stratified by surgery or non-surgery within 6 months of diagnosis, in England (*continued*)

	All eligible primary shoulder dislocation patients ($N = 3784$)[a]					Matched analysis (3 : 1): patients matched on PS ($N = 726$)[a,b]				
	Surgery ($n = 156$)		Non-surgery ($n = 3603$)			Surgery ($n = 156$)		Non-surgery ($n = 570$)		
Characteristic	*n* (%)	Re-dislocation, *n* (%)	*n* (%)	Re-dislocation, *n* (%)	SMD	*n* (%)	Re-dislocation, *n* (%)	*n* (%)	Re-dislocation, *n* (%)	SMD
South Central	22 (14)	2 (9)	521 (14)	104 (20)		22 (14)	2 (9)	74 (13)	14 (19)	
South East Coast	10 (6)	5 (50)	420 (12)	73 (17)		10 (6)	5 (50)	42 (7)	4 (10)	
South West	24 (15)	7 (29)	430 (12)	93 (22)		24 (15)	7 (29)	74 (13)	10 (14)	
West Midlands	17 (11)	3 (18)	424 (12)	100 (24)		17 (11)	3 (18)	70 (12)	18 (26)	
Yorkshire and the Humber	4 (3)	0 (0)	133 (4)	26 (20)		4 (3)	0 (0)	16 (3)	3 (19)	
Epilepsy	12 (8)	4 (33)	118 (3)	38 (32)	0.195	12 (8)	4 (33)	42 (7)	9 (21)	0.012
Painkiller prescriptions										
3 months prior to TASD	12 (8)	3 (25)	198 (5)	45 (23)	0.088	12 (8)	3 (25)	48 (8)	10 (21)	–0.027
1 month following TASD	26 (17)	7 (27)	420 (12)	75 (18)	0.144	26 (17)	7 (27)	92 (16)	18 (20)	0.014

PS, propensity score.
a After multiple imputation for missing values of BMI, smoking and drinking. (Only the first imputed data set used for propensity-score-matched analysis.)
b Probability of being exposed given values of potential confounders.

Figure 11 presents Kaplan–Meier estimates of probability of survival in the surgical and non-surgical groups; the hazards were proportional (Schoenfeld Residuals Test; $p = 0.39$). There appears to be a small survival advantage for surgical patients that is not statistically significant.

Table 17 presents the final results of the effect of surgery within 6 months compared with no surgery among first-time TASD patients. The median follow-up in both groups was similar and the rate of shoulder re-dislocations was slightly higher in the non-surgical group [0.36 per 1000 person-years (95% CI 0.29 to 0.43 per 1000 person-years) in the non-surgical group compared with 0.30 per 1000 person-years (95% CI 0.21 to 0.43 per 1000 person-years) in the surgical group], although this was not statistically significant as demonstrated by the wide CIs. Overall, the effect of surgery within 6 months appeared slightly protective, at HR 0.88 (95% CI 0.58 to 1.35; $p = 0.565$), but this was not statistically significant.

Discussion

A population-based cohort of 3759 patients diagnosed with a first-time TASD during 1 April 1997–26 April 2014, with CPRD-HES linked records and 2 years of follow-up in England were identified. In total, only 156 patients in this data set received surgical treatment within 6 months of first-time TASD. Thus, despite the commissioned question, our findings conclude that early surgery after only one shoulder dislocation is uncommon in the NHS.

The overall finding from the propensity-score-matched analysis was that although surgery within 6 months appeared to be slightly protective, it was not a statistically significant deterrent for re-dislocations (HR 0.88, 95% CI 0.58 to 1.35; $p = 0.565$). The wide CI indicates that this study was underpowered. Owing to the unexpected small numbers receiving surgery after only one dislocation and the subsequent loss of study power, we are not able to confirm whether or not surgery within 6 months of a first-time anterior shoulder dislocation has any additional benefit on whether or not a patient suffers a re-dislocation.

This is the first time a large, primary care, national, observational data set has been used to examine the role of surgery on treating shoulder dislocations in England. The main strength of this study is that it uses a population-based cohort using real-world data from linked primary and secondary care databases and these databases are representative of the English population with respect to age and sex. The study also uses the latest statistical methods to account for missing data, confounding by indication and immortal time bias. There was a considerable number of missing data for BMI (40%) and for alcohol consumption (41%); fewer data were missing for smoking (7%) and IMD ($n = 3$). Data were successfully imputed for these covariates.

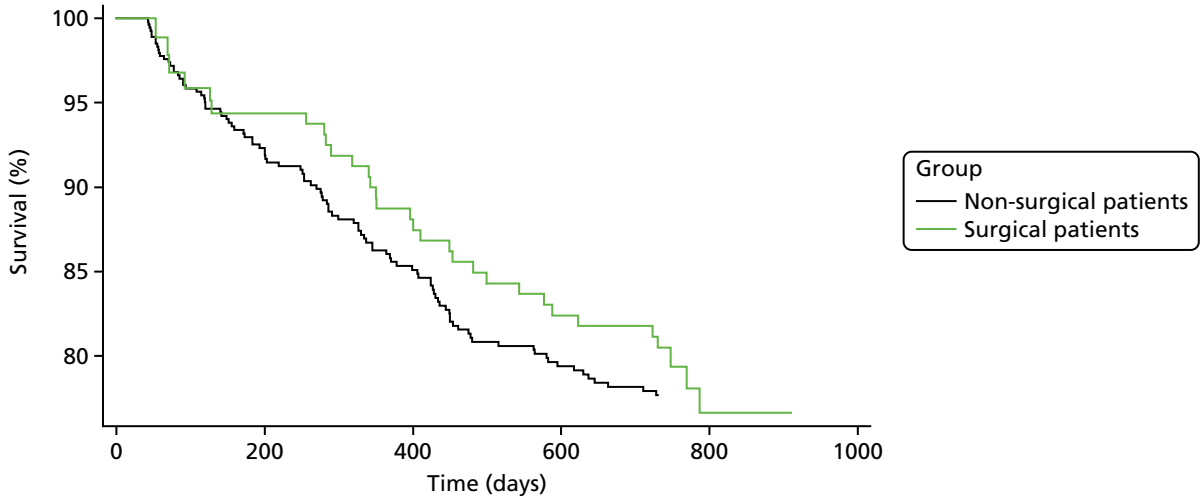


FIGURE 11 Kaplan–Meier survival estimates for first-time TASD patients diagnosed during 1 April 1997–26 April 2014 who had surgery within 6 months or no surgery within CPRD-HES, in England.

TABLE 17 The effect of surgery within 6 months compared with non-surgical treatment on re-dislocations among first-time TASD patients who were diagnosed during 1 April 1997–26 April 2014 within CPRD-HES, in England

	Patient group							
	Surgery			Non-surgery				
N	Events (*n*)	Median follow-up (days) (IQR)	Rate (per 1000 person-years) (IQR)	Events	Median follow-up (days) (IQR)	Rate (per 1000 person-years) (IQR)	HR (95% CI); *p*-value	HR[a] (95% CI); *p*-value
Shoulder re-dislocations	31	731 (731–815)	0.30 (0.21–0.43)	102	731 (495–731)	0.36 (0.29–0.43)	0.84 (0.55 to 1.29); $p = 0.429$	0.88 (0.58 to 1.35); $p = 0.565$

a After trimming 1% off of the extremes of the propensity score tails.

Although the number of patients ($n = 3759$) included in the analysis was greater than the minimum number required for statistical power ($n = 3065$), disappointingly, the main weakness of the study was the unexpected low number of NHS patients having surgery after one dislocation. In total, only 156 patients had undergone surgical treatment within 6 months of the date of their first-time TASD. The lack of surgical patients in the cohort resulted in an overall lack of statistical power. It was also observed that a substantial number of patients in this cohort of 16- to 35-year-olds had < 2 years of follow-up within the CPRD ($n = 854$), which may be related to moving location and changing GPs because of going to university or finding jobs.

The main disadvantage of using propensity score matching methods is that confounders for which no data are available result in a lack of adjustment. Other than age and sex, the risk factors recorded and available in the CPRD were considered less important risk factors. Many factors considered important by surgeons, including original cause/mechanism of shoulder dislocation, imaging findings of structural problems, anterior apprehension, occupation, sports played and level of sports, were not recorded in the observational data. This links with the findings later in *Chapter 6*, *Prediction models*. Finally, in this cohort, 20% of patients in the surgery and non-surgery group had suffered a shoulder re-dislocation. Responses to the GP questionnaire validation study (reported in *Chapter 2*) indicate that about one-third of patients suffered a re-dislocation within that CPRD cohort. It is possible that either shoulder re-dislocations have not been reported to GPs or the re-dislocations were not coded in the general practice's computer system.

Conclusions

Overall, relatively few patients have surgery within 6 months of a first-time TASD in the NHS. This is probably a reflection of many GPs not referring patients with only one dislocation to secondary care and also because of NHS operative waiting times.

This study was underpowered, lacked sufficient follow-up data on many patients and did not include data on many of the important risk factors used by surgeons to make clinical decisions on the best care.

Based on these findings, and in an attempt to maximise the use of this data set to further examine the commissioned question of surgery after first-time shoulder dislocation, a further sensitivity analysis was planned and approved by the HTA programme and Independent Scientific Advisory Committee (ISAC) and is discussed in the following chapter.

Chapter 5 Sensitivity analysis: the impact of surgical treatment within 12 months or no surgery on shoulder re-dislocations in young people aged 16–35 years with first-time traumatic anterior shoulder dislocation in England

In view of the findings in the previous chapter, and to try to maximise the potential conclusions using the data set, a further sensitivity analysis was planned and approved. This analysis included a new sample size power calculation.

Objective of *Chapter 5*

To study the effect of surgical treatment within 12 months of diagnosis of a first-time episode of TASD on recurrence rates in the 3 years that follow the diagnosis, among young adults in England.

Methods

Study design

A population-based, propensity-score-matched cohort study to control for confounding at baseline has been conducted. Young adults (aged 16–35 years) who presented with a first-time occurrence of TASD were selected from two NHS computerised databases: the CPRD and HES. *Figure 12* shows a detailed illustration of the study plan that is described in more detail in the following sections.

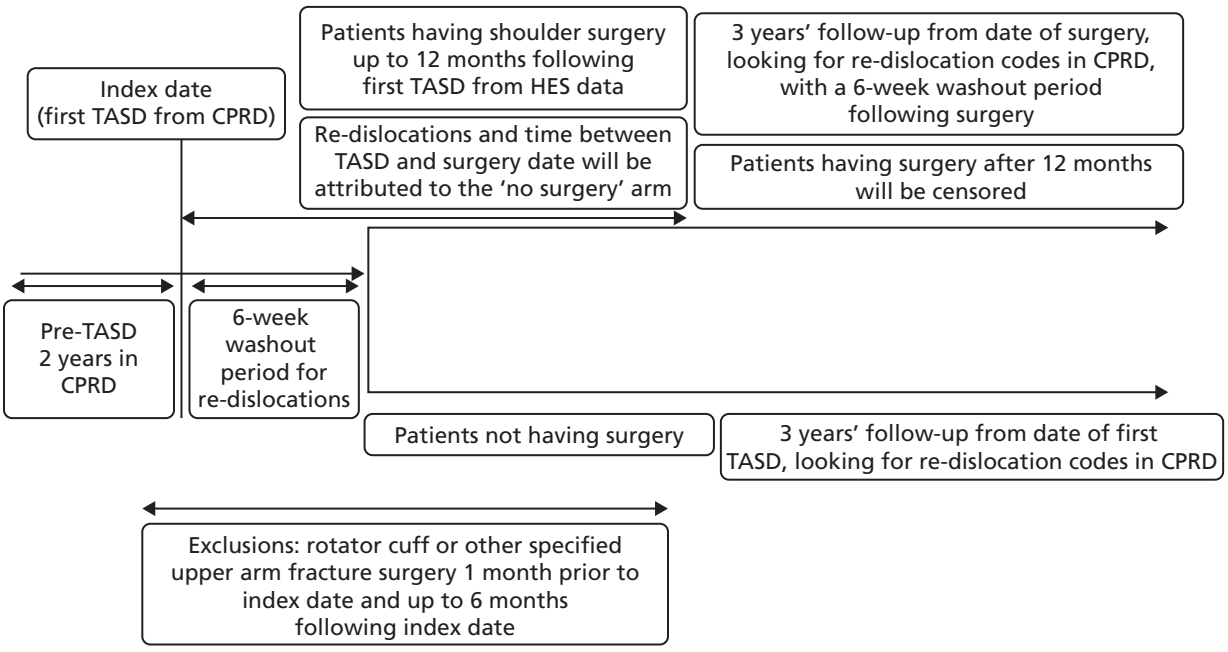


FIGURE 12 The UK TASH-D phase 2 plan design for patients who received surgery or no surgical treatment within 12 months of diagnosis of a first-time TASD during 1 April 1997–31 March 2015, in England.

This study used methodology identical to that described in the internal validation study in *Chapter 2* and the 6-month analysis in *Chapter 4*; all participants had to have 2 years of clinical data within the CPRD before their first-time TASD to ensure that only 'primary' dislocations had been captured. The same rules were followed and the first Read code entry in the CPRD for shoulder dislocation was defined as the 'first' dislocation. All events were collected using the pre-agreed, validated list of CPRD Read codes (see *Appendix 1*). Patients experienced their first-time TASD between 1 April 1997 and 31 March 2015, allowing up to 3 years of follow-up for each patient to the end of the study on 26 April 2016. As in the previous analysis, a 6-week washout period for re-dislocation codes within the CPRD was applied to all patients following their TASD to avoid duplicate records.

The key changes from the previous analysis described in *Chapter 4* were to include:

- patients having surgery up to 12 months from the date of their first-time TASD
- patients with any length of follow-up, rather than at least 2 full years
- follow-up up to 3 years, rather than 2 years.

Surgical group

The surgical group comprised patients in the CPRD with a first-time TASD who underwent shoulder stabilisation surgery after their first dislocation. This meant linking HES data to CPRD data in such a way that a HES surgical OPCS 4.7 code was seen to occur after a single first dislocation code in the CPRD before that surgical date. The timelines between first dislocation codes and OPCS 4.7 codes were recorded. If a re-dislocation occurred prior to their surgery date, the patient was allocated to the non-surgical arm.

A 6-week washout period for re-dislocation codes within the CPRD was applied to all patients in the surgical group following their surgery date to avoid duplicate records. Surgery patients were followed up for up to 3 years from the date of their surgery. Patients having surgery > 6 months following their TASD were censored on their date of surgery. The surgery dates for these patients ranged from 25 December 1997 to 30 September 2015.

Non-surgical group

As in the 6-month analysis, conservative care has been defined as 'non-surgical intervention' with no linked OPCS 4.7 surgical shoulder codes, producing a control cohort of patients whose first-time shoulder dislocation has been treated non-operatively. Non-surgical patients were followed up for up to 3 years following the date of their first-time TASD, as illustrated in *Figure 12*.

Outcome

The outcome was time to a shoulder re-dislocation as defined by the CPRD Read codes given in *Appendix 1*. For the surgical group, the shoulder re-dislocation can occur between 6 weeks and 2 years following the date of surgery. For the non-surgical group, the shoulder re-dislocation could occur between 6 weeks and 2 years from the date of the first-time TASD.

Any patients who died during the study were censored on their date of death.

Data sources

The analysis utilised two computerised NHS databases: the CPRD and HES, as described in *Chapter 4*. The linked databases were managed by a senior data manager using Python and SQL, and statistical analyses were conducted using Stata and R.

Sample size

The sample size calculation in the study plan, described fully in the previous chapter, required a total sample size of 3065 patients with 656 re-dislocations, with 90% power at the 5% significance level and allowing for a 10% loss to follow-up, to detect an absolute difference of 5% between the surgical and non-surgical

groups. It was assumed that 1073 (35% of the total) patients would receive surgery. The 6-month analysis was underpowered on this basis.

A senior statistician reran the sample size calculation, reducing the power to 80%, having unequal groups (1 : 10 ratio), extending follow-up to 3 years from 2 years and looking at surgical intervention up to 12 months (rather than 6 months). To detect a HR of 0.73 (26% surgical re-dislocations vs. 19.5% non-surgical re-dislocations) would require a total of 3456 patients, of whom 314 were surgical patients and 3142 were non-surgical patients, and at least 695 re-dislocations.

Participants

Inclusion criteria

The CPRD records of 6046 patients aged 16–35 years with 2 years of data in the CPRD before a first-time TASD were identified in the internal validation study (see *Table 1*) and were linked to HES records.

Exclusion criteria

The following patients were excluded.

- those aged 16–35 years with a first-time TASD who could not be linked by CPRD-HES
- those with prior shoulder surgery for a shoulder dislocation
- those whose instability was treated with rotator cuff repair surgery or fracture surgery prior to or following a TASD.

Exclusions were made in accordance with the criteria above and these are described in *Table 18*. Following linkage to HES data, there was a linkage loss of 1234 patients and six duplicates were identified and removed. A very small proportion of patients ($n = 193$) was excluded for having shoulder surgery for prior dislocations, rotator cuff tears or fractures.

In total, 4613 patients remained available for analysis, which was greater than the minimum number of patients ($n = 3456$) required for a sufficient sample size at 80% power (*Figure 13*). Of these, 342 were surgical patients (slightly more than the minimum required, $n = 314$) and 4271 were non-surgical patients (much greater than the minimum required, $n = 3142$). Re-dislocations were observed in 912 patients (much greater than the minimum required, $n = 695$). Among the surgical group, 18% of patients suffered

TABLE 18 Shoulder dislocation exclusions for patients aged 16–35 years during 1 April 1997–26 April 2014 within CPRD in England with the linkage to HES records

Exclusions	Excluded (*n*)	Total (*n*)	%
Eligible patients in the CPRD cohort for the internal validation study following exclusions made in *Table 1*		6046	100
HES data linkage loss	1234		20
Duplicate removal	6		< 1
Prior shoulder surgery for a shoulder dislocation	155		3
Surgery for rotator cuff tear prior to TASD	1		< 1
Surgery for rotator cuff tear 6 months following TASD	4		< 1
Surgery for a shoulder fracture prior to TASD	14		< 1
Surgery for shoulder fracture in the 6 months following TASD	19		< 1
Total exclusions	1433		24
Patients included in subsequent analyses		4613	76

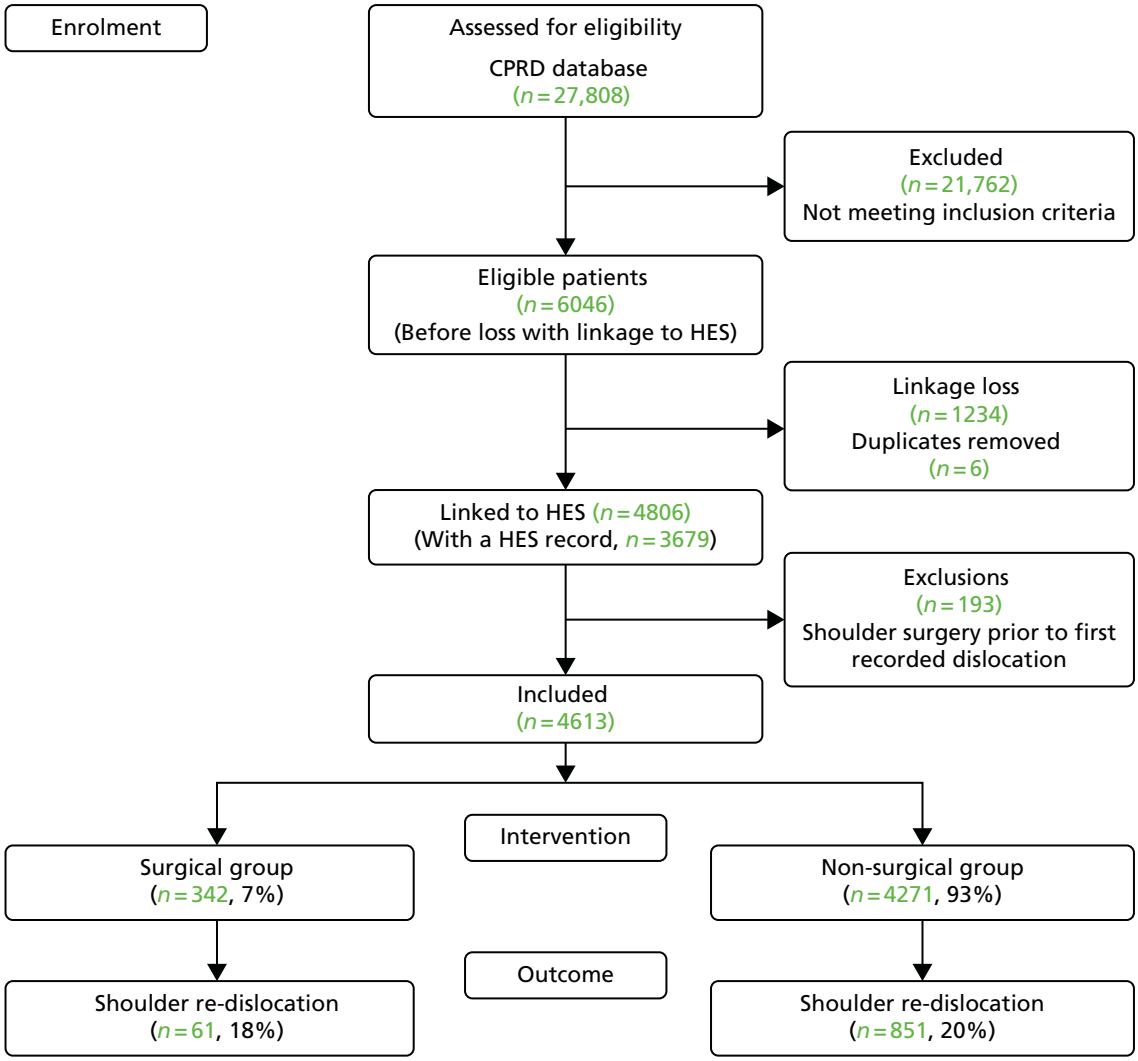


FIGURE 13 Shoulder dislocation exclusions flow chart for patients aged 16–35 years during 1 April 1997–31 March 2016 within CPRD in England, with linkage to HES records.

a re-dislocation, and 20% of patients suffered a re-dislocation in the non-surgical group. The difference in re-dislocation proportions between the surgical and non-surgical groups was only 2%, rather than the 5% difference used in the power calculation, which means that the power is reduced. However, overall, this study of surgical intervention up to 12 months on shoulder re-dislocations should have had sufficient power.

Statistical analysis

The statistical analysis used for this sensitivity analysis was identical to that described in *Chapter 4*, with respect to covariates, missing data, confounding by indication and immortal time bias.

Results

Descriptive characteristics

A cohort of 4613 patients diagnosed with a first-time TASD during 1 April 1997–31 March 2015 was identified in the CPRD. The CPRD Read codes used to identify these patients are listed in *Appendix 9*. Of these patients, 342 underwent shoulder surgery within 6 months. The OPCS 4.7 surgical codes identified within HES are given in *Appendix 10*.

The descriptive characteristics of patients categorised by receiving surgery within 12 months or no surgery are described in *Table 19*. In the first 4 years, < 10 patients underwent surgery per year, but this increased from 2001 to 2010 to a maximum of 34 patients out of a total of 342 surgical patients. More men (82%) were diagnosed with a primary shoulder dislocation than women, and more men underwent surgery within 12 months ($n = 302$ men vs. $n = 40$ women). The majority of patients were aged 17–21 years at the time of their first-time TASD, but similar numbers were operated on among those aged 18–25 years.

Only 8% of patients were overweight or obese, with missing data on BMI for 42% of all patients. There was a pattern of decreasing numbers of patients by deprivation quintile, but this pattern was not evident for surgical patients. Only three patients did not have a recorded IMD score. Most patients were non-smokers (53%) and there were missing data on smoking for 9% of all patients. Most patients drank alcohol (47%) and there were missing data on alcohol consumption for 44% of all patients. Most patients had no comorbid conditions (93%). Many patients were from the North West ($n = 743$) and South Central regions

TABLE 19 Descriptive characteristics of primary shoulder dislocation patients diagnosed during 1 April 1997–31 March 2015 who had surgery within 12 months or no surgery within CPRD-HES, in England

Characteristic	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 12 months of TASD
Total	4613 (100)	4271 (93)	342 (7)
Year of shoulder dislocation			
1997	65 (1)	64 (1)	1 (< 1)
1998	115 (2)	109 (3)	6 (2)
1999	128 (3)	125 (3)	3 (1)
2000	161 (3)	155 (4)	6 (2)
2001	209 (5)	199 (5)	10 (3)
2002	250 (5)	239 (6)	11 (3)
2003	309 (7)	288 (7)	21 (6)
2004	301 (7)	290 (7)	11 (3)
2005	288 (6)	271 (6)	17 (5)
2006	315 (7)	292 (7)	23 (7)
2007	334 (7)	308 (7)	26 (8)
2008	339 (7)	306 (7)	33 (10)
2009	331 (7)	303 (7)	28 (8)
2010	348 (8)	314 (7)	34 (10)
2011	329 (7)	301 (7)	28 (8)
2012	293 (6)	261 (6)	32 (9)
2013	237 (5)	209 (5)	28 (8)
2014	217 (5)	195 (5)	22 (6)
2015	44 (1)	42 (1)	2 (1)
Sex			
Male	3794 (82)	3492 (82)	302 (88)
Female	819 (18)	779 (18)	40 (12)

continued

TABLE 19 Descriptive characteristics of primary shoulder dislocation patients diagnosed during 1 April 1997–31 March 2015 who had surgery within 12 months or no surgery within CPRD-HES, in England (*continued*)

Characteristic	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 12 months of TASD
Age at shoulder dislocation (years)			
16	245 (5)	225 (5)	20 (6)
17	309 (7)	294 (7)	15 (4)
18	308 (7)	281 (7)	27 (8)
19	324 (7)	293 (7)	31 (9)
20	295 (6)	271 (6)	24 (7)
21	315 (7)	298 (7)	17 (5)
22	290 (6)	260 (6)	30 (9)
23	258 (6)	242 (6)	16 (5)
24	277 (6)	262 (6)	15 (4)
25	246 (5)	216 (5)	30 (9)
26	230 (5)	212 (5)	18 (5)
27	207 (4)	190 (4)	17 (5)
28	165 (4)	156 (4)	9 (3)
29	177 (4)	159 (4)	18 (5)
30	178 (4)	169 (4)	9 (3)
31	148 (3)	137 (3)	11 (3)
32	164 (4)	152 (4)	12 (4)
33	149 (3)	143 (3)	6 (2)
34	161 (3)	152 (4)	9 (3)
35	167 (4)	159 (4)	8 (2)
BMI (kg/m^2)			
< 25	1542 (33)	1439 (34)	103 (30)
25.0–29.9	763 (17)	708 (17)	55 (16)
≥ 30	364 (8)	338 (8)	26 (8)
Missing	1944 (42)	1786 (42)	158 (46)
IMD 2004 (quintile of deprivation)			
1 (affluent)	1241 (27)	1173 (27)	68 (20)
2	1028 (22)	949 (22)	79 (23)
3	915 (20)	846 (20)	69 (20)
4	834 (18)	752 (18)	82 (24)
5 (deprived)	592 (13)	548 (13)	44 (13)
Missing	3 (< 1)	3 (< 1)	0 (0)
Smoking status			
No	2461 (53)	2287 (54)	174 (51)
Yes	1335 (29)	1233 (29)	102 (30)
Ex-smoker	392 (8)	362 (8)	30 (9)
Missing	425 (9)	389 (9)	36 (11)

TABLE 19 Descriptive characteristics of primary shoulder dislocation patients diagnosed during 1 April 1997–31 March 2015 who had surgery within 12 months or no surgery within CPRD-HES, in England (*continued*)

Characteristic	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 12 months of TASD
Drinking status			
Yes	2172 (47)	2033 (48)	139 (41)
No	432 (9)	403 (9)	29 (8)
Missing	2009 (44)	1835 (43)	174 (51)
CCI score			
0	4275 (93)	3945 (92)	330 (96)
1	205 (4)	199 (5)	6 (2)
2	84 (2)	80 (2)	4 (1)
≥ 3	49 (1)	47 (1)	2 (1)
Region			
East Midlands	152 (3)	142 (3)	10 (3)
East of England	549 (12)	522 (12)	27 (8)
London	560 (12)	520 (12)	40 (12)
North East	113 (2)	104 (2)	9 (3)
North West	743 (16)	669 (16)	74 (22)
South Central	669 (15)	628 (15)	41 (12)
South East Coast	537 (12)	502 (12)	35 (10)
South West	580 (13)	524 (12)	56 (16)
West Midlands	525 (11)	488 (11)	37 (11)
Yorkshire and the Humber	185 (4)	172 (4)	13 (4)
Epilepsy	156 (3)	134 (3)	22 (6)
Painkiller prescriptions			
Prescribed 3 months prior to TASD	257 (6)	235 (6)	22 (6)
Prescribed 1 month following TASD	542 (12)	499 (12)	43 (13)
Mortality	22 (< 1)	20 (< 1)	2 (< 1)

(*n* = 669), and fewer were from the North East region (*n* = 113). A small proportion of patients had been diagnosed with epilepsy (3%), but a higher proportion of all surgical patients had been diagnosed with epilepsy (6%). A small proportion (6%) of patients were prescribed painkillers in the 3 months prior to their first-time TASD, which increased to 12% in the 1 month following a TASD. Of the patients prescribed painkillers, both 3 months prior to and 1 month after their TASD, only 1% were prescribed a different painkiller. Only 22 patients died during the study period.

Multiply imputed data analyses

Multiple imputation by chained equations was conducted for patients with missing data on BMI, smoking, drinking and IMD. *Appendix 11* presents the HRs, 95% CIs and *p*-values for each of these variables using all available data, a complete-case analysis and the multiply imputed data. The HRs are similar for each group, indicating that the multiple imputation process was successful.

Cox survival estimates for complete cases and the multiply imputed data with the factors that had an impact on re-dislocations are presented in *Appendix 12*. Only 2100 cases had complete data on all factors. For these patients, a protective but non-significant adjusted effect of surgery was observed (HR 0.63, 95% CI 0.40 to 1.00; $p = 0.052$). A younger age at first-time TASD and an epilepsy diagnosis were significant risk factors for a re-dislocation.

Using the multiply imputed data resulted in similar HRs, 95% CIs and the same risk factors. The protective effect of surgery was less marked but was significant (HR 0.73, 95% CI 0.55 to 0.95; $p = 0.022$).

Propensity score analysis

Logistic regression was used to calculate the propensity scores. The distributions of propensity scores in the patients receiving surgery within 12 months and in those patients who had non-operative treatment are presented in *Figure 14*. Prior to matching, the propensity scores tended to be higher in the surgery group, but there is a substantial amount of overlap, indicating that it is possible to proceed with propensity score matching to estimate the treatment effect. Following matching, the propensity score density plots are very similar between the surgery and non-surgery patient groups. The propensity score matching will not include the non-surgical patients in the left-hand peak of the distribution.

Table 20 presents the baseline characteristics of first-time TASD patients who had surgery within 12 months or non-operative treatment. The SMDs, prior to propensity score matching, show that the two groups of patients do differ for most characteristics (SMD > 0.1). During propensity score matching, 295 surgical

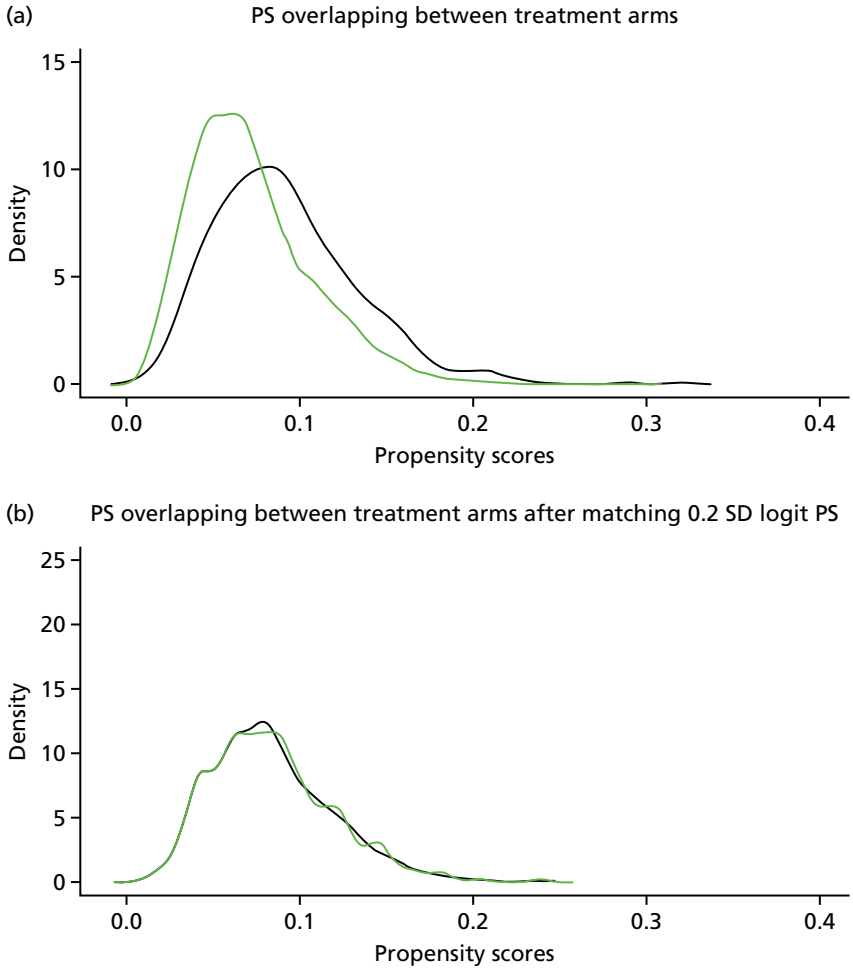


FIGURE 14 Propensity scores for first-time TASD patients diagnosed during 1 April 1997–31 March 2015 who had surgery within 12 months (black) or no surgery (green) within CPRD-HES, in England. (a) Prior to PS matching; and (b) following PS matching. PS, propensity score; SD, standard deviation.

TABLE 20 Baseline characteristics of patients diagnosed with a primary shoulder dislocation during 1 April 1997–31 March 2015 with the number of re-dislocations and SMDs: stratified by surgery within 12 months of diagnosis or non-surgery, in England

	All eligible primary shoulder dislocation patients ($N = 4613$)[a]					Matched analysis (10 : 1): patients matched on propensity score ($N = 3478$)[a,b]				
	Surgery ($n = 342$)		Non-surgery ($n = 4271$)			Surgery ($n = 295$)		Non-surgery ($n = 3183$)		
Characteristic	*n* (%)	Re-dislocation (%)	*n* (%)	Re-dislocation (%)	SMD	*n* (%)	Re-dislocation (%)	*n* (%)	Re-dislocation (%)	SMD
Re-dislocation	342 (100)	61 (18)	4271 (100)	851 (20)		295 (100)	58 (20)	3183 (100)	590 (19)	
Calendar year of shoulder dislocation	342 (100)	61 (18)	4271 (100)	851 (20)	0.347	295 (100)	58 (20)	3183 (100)	590 (19)	0.011
Sex										
Male	302 (88)	52 (17)	3492 (82)	720 (21)	–0.184	258 (87)	50 (19)	2770 (87)	528 (19)	–0.013
Female	40 (12)	9 (23)	779 (18)	131 (17)		37 (13)	8 (22)	413 (13)	62 (15)	
Age at shoulder dislocation (16- to 35-year-olds)	342 (100)	61 (18)	4271 (100)	851 (20)	–0.083	295 (100)	58 (20)	3183 (100)	590 (19)	–0.019
BMI (kg/m^2)										
< 25	184 (54)	35 (19)	2506 (59)	523 (21)	0.035	166 (56)	34 (20)	1835 (58)	367 (20)	0.013
25.0–29.9	106 (31)	21 (20)	1191 (28)	231 (19)		92 (31)	19 (21)	934 (29)	163 (17)	
≥ 30	52 (15)	5 (10)	574 (13)	97 (17)		37 (13)	5 (14)	414 (13)	60 (14)	
IMD (quintile of deprivation)										
1 (affluent)	68 (20)	6 (9)	1173 (27)	225 (19)	0.153	61 (21)	6 (10)	814 (26)	144 (18)	0.058
2	79 (23)	14 (18)	950 (22)	201 (21)		72 (24)	14 (20)	690 (22)	146 (21)	
3	69 (20)	17 (25)	846 (20)	158 (19)		55 (19)	15 (27)	626 (20)	104 (17)	
4	82 (24)	13 (16)	754 (18)	150 (20)		72 (24)	13 (18)	599 (19)	102 (17)	
5 (deprived)	44 (13)	11 (25)	548 (13)	117 (21)		35 (12)	10 (29)	454 (14)	94 (26)	
Smoking status										
No	197 (58)	39 (20)	2521 (59)	528 (21)	–0.010	177 (60)	37 (21)	1888 (59)	365 (19)	–0.002
Yes	112 (33)	17 (15)	1356 (32)	252 (19)		90 (31)	16 (18)	1011 (32)	176 (17)	
Ex-smoker	33 (10)	5 (15)	394 (9)	71 (18)		28 (10)	5 (18)	284 (9)	49 (17)	

continued

TABLE 20 Baseline characteristics of patients diagnosed with a primary shoulder dislocation during 1 April 1997–31 March 2015 with the number of re-dislocations and SMDs: stratified by surgery within 12 months of diagnosis or non-surgery, in England (*continued*)

	All eligible primary shoulder dislocation patients ($N = 4613$)[a]					Matched analysis (10 : 1): patients matched on propensity score ($N = 3478$)[a,b]				
	Surgery ($n = 342$)		Non-surgery ($n = 4271$)			Surgery ($n = 295$)		Non-surgery ($n = 3183$)		
Characteristic	*n* (%)	Re-dislocation (%)	*n* (%)	Re-dislocation (%)	SMD	*n* (%)	Re-dislocation (%)	*n* (%)	Re-dislocation (%)	SMD
Drinking status										
Yes	280 (82)	44 (16)	3506 (82)	677 (19)	0.091	237 (80)	42 (18)	2541 (80)	473 (19)	–0.013
No	62 (18)	17 (27)	765 (18)	174 (23)		58 (20)	16 (28)	642 (20)	117 (18)	
CCI score										
0	330 (96)	60 (18)	3945 (92)	792 (20)	–0.146	283 (96)	57 (20)	3066 (96)	567 (18)	0.014
1	6 (2)	0 (0)	199 (5)	37 (19)		6 (2)	0 (0)	55 (2)	15 (27)	
2	4 (1)	0 (0)	80 (2)	15 (19)		4 (1)	0 (0)	41 (1)	5 (12)	
≥ 3	2 (1)	1 (50)	47 (1)	7 (15)		2 (< 1)	1 (50)	21 (< 1)	3 (14)	
Region										
East Midlands	10 (3)	2 (20)	142 (3)	30 (21)	0.075	10 (3)	2 (20)	103 (3)	20 (19)	–0.012
East of England	27 (8)	5 (19)	522 (12)	98 (19)		26 (9)	5 (19)	268 (8)	46 (17)	
London	40 (12)	6 (15)	520 (12)	102 (20)		37 (13)	6 (16)	396 (12)	70 (18)	
North East	9 (3)	3 (33)	104 (2)	26 (25)		9 (3)	3 (33)	81 (3)	18 (22)	
North West	74 (22)	14 (19)	669 (16)	129 (19)		53 (18)	12 (23)	592 (19)	108 (18)	
South Central	41 (12)	2 (5)	628 (15)	132 (21)		36 (12)	2 (6)	433 (14)	82 (19)	
South East Coast	35 (10)	9 (26)	502 (12)	84 (17)		34 (12)	9 (26)	359 (11)	63 (18)	
South West	56 (16)	10 (18)	524 (12)	110 (21)		47 (16)	9 (19)	459 (14)	88 (19)	
West Midlands	37 (11)	7 (19)	488 (11)	110 (23)		33 (11)	7 (21)	367 (12)	76 (21)	
Yorkshire and the Humber	13 (4)	3 (23)	172 (4)	30 (17)		10 (3)	3 (30)	125 (4)	19 (15)	

Characteristic	All eligible primary shoulder dislocation patients ($N = 4613$)[a]					Matched analysis (10 : 1): patients matched on propensity score ($N = 3478$)[a,b]				
	Surgery ($n = 342$)		Non-surgery ($n = 4271$)			Surgery ($n = 295$)		Non-surgery ($n = 3183$)		
	n (%)	Re-dislocation (%)	*n* (%)	Re-dislocation (%)	SMD	*n* (%)	Re-dislocation (%)	*n* (%)	Re-dislocation (%)	SMD
Epilepsy	22 (6)	8 (36)	134 (3)	42 (31)	0.155	10 (3)	5 (50)	128 (4)	38 (30)	–0.033
Painkiller prescriptions										
3 months prior to TASD	22 (6)	5 (23)	235 (6)	56 (24)	0.039	15 (5)	5 (33)	181 (6)	42 (23)	–0.027
1 month following TASD	43 (13)	10 (23)	499 (12)	89 (18)	0.027	31 (11)	9 (29)	353 (11)	57 (16)	–0.019

a After multiple imputation for missing values of BMI, smoking and drinking. (Only the first imputed data set was used for the propensity-score-matched analysis.)
b Probability of being exposed given the values of potential confounders.

patients were each matched to 10 non-surgical patients ($n = 2950$). In addition to this, the time between the date of the first-time TASD and the date of surgery was allocated to the non-surgical patients for 233 surgical patients, making a total of 3183 non-surgical patients. The remaining 62 surgical patients had no time to be re-allocated because the date of their first-time TASD was the same date as their surgery. Following propensity score matching, the SMDs were much smaller than before (all < 0.1), which suggested that the balancing was successful.

Figure 15 presents Kaplan–Meier estimates of probability of survival in the surgical and non-surgical groups. The hazards were not proportional as shown by the two lines crossing at approximately 750 days and by the Schoenfeld's Residuals Test ($p = 0.003$). We estimated time-varying hazards, which showed that there was no effect in the first year of follow-up ($p = 0.458$). This means that, initially, surgical patients had a similar rate of re-dislocations to non-surgical patients. Between 1 and 3 years of follow-up, the non-surgical group was more likely to re-dislocate ($p = 0.022$). Overall, there appears to be a small survival advantage for surgical patients, but this is not statistically significant.

Table 21 presents the final results of the effect of surgery within 12 months compared with no surgery among first-time TASD patients. The median follow-up was less in the non-surgical group. The rate of shoulder re-dislocations was similar between the surgical and non-surgical groups (0.26 per 1000 person-years, 95% CI 0.20 to 0.33 per 100,000 person-years, compared with 0.26 per 1000 person-years, 95% CI 0.24 to 0.28 per 100,000 person-years, respectively). Overall, there was no difference between the effect of surgery and non-surgery within 12 months on shoulder re-dislocations (HR 1.17, 95% CI 0.88 to 1.55; $p = 0.274$).

To test for residual confounding, the patients were split into quintiles, based on the value of the propensity score, and HRs were produced for each quintile (see *Appendix 13*). The numbers of surgeries were equal in each quintile. HRs were found to differ between quintiles, suggesting that there was unmeasured confounding in the study consistent with the a priori risk factors not available in the CPRD or HES. Quintile 5 was found to have a twofold increase in the risk of dislocation after surgery (HR 2.07, 95% CI 1.23 to 3.46). Some key differences between the characteristics of patients within each stratum are shown in *Appendix 14*. Quintile 5, for instance, included more men, people who had a more recent first-time TASD, fewer alcohol drinkers and more people with epilepsy than the other quintiles.

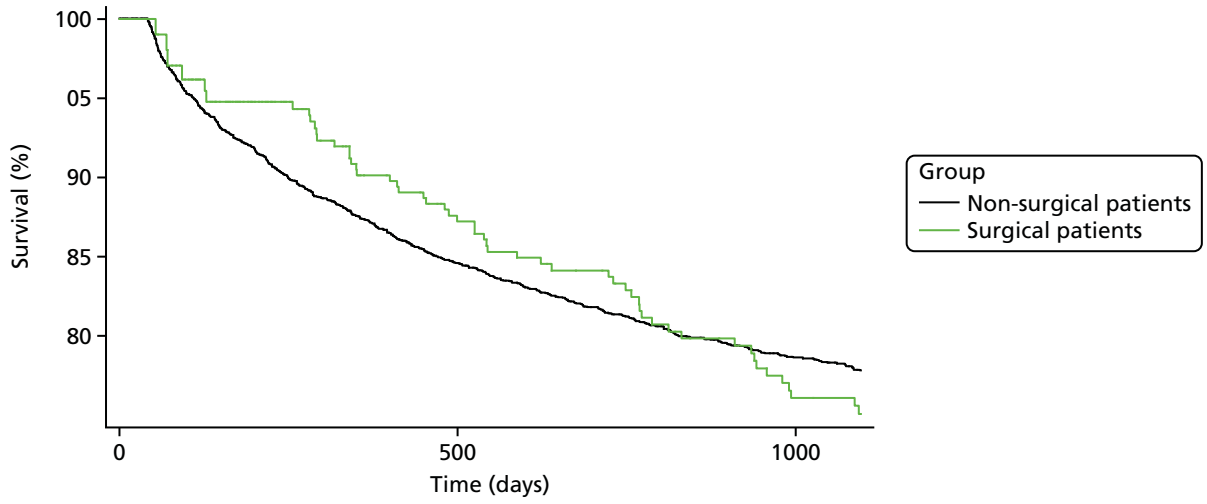


FIGURE 15 Kaplan–Meier survival estimates for first-time TASD patients diagnosed during 1 April 1997–31 March 2015 who had surgery within 12 months (green) or no surgery (black) within CPRD-HES, in England.

TABLE 21 The effect of surgery within 12 months compared with non-surgical treatment on re-dislocations among first-time TASD patients who were diagnosed during 1 April 1997–31 March 2015 within CPRD-HES, in England

	Patient group							
	Surgery			Non-surgery				
N	Events (*n*)	Median follow-up (days) (IQR)	Rate (per 1000 person-years) (IQR)	Events (*n*)	Median follow-up (days) (IQR)	Rate (per 1000 person-years) (IQR)	HR (IQR)	HR[a] (IQR)
Shoulder re-dislocations	58	1096 (558–1214)	0.26 (0.20–0.33)	590	1028 (430–1096)	0.26 (0.24–0.28)	1.18 (0.89–1.56)	1.17 (0.88–1.55)

a After trimming 1% off of the extremes of the propensity score tails.

Discussion

A population-based cohort of 4613 patients diagnosed with a first-time TASD during 1 April 1997–31 March 2015 with CPRD-HES linked records and up to 3 years of follow-up in England were identified. Only 342 patients in this data set received surgical treatment within 12 months of a first-time TASD. This again confirms that, in the NHS, even when extending surgery to 12 months, it is still an uncommon treatment after only one shoulder dislocation. However, extending to 12 months for this sensitivity analysis did provide some more power to the analysis, even though 47 surgical patients were not matched to controls in the propensity score analysis. On this occasion, non-proportionality of the HRs was observed, which suggests that further, more complex, statistical techniques could be considered; however, the issues of small patient numbers in the surgical group, similar proportions of re-dislocations and residual confounding mean that further analysis is unlikely to change any conclusions.

The main finding from this further propensity-score-matched analysis was that surgery within 12 months of a first-time TASD had no obvious beneficial effect compared with non-surgical interventions (HR 1.17, 95% CI 0.88 to 1.55; $p = 0.274$). The lack of association meant that adjusting for clustering at the general practice level and conducting a Rosenbaum bounds sensitivity analysis was inappropriate. However, when the propensity scores were split into quintiles, one quintile in particular (5) was found to be at a significantly increased risk of shoulder re-dislocation. The fact that one quintile had a different risk of the outcome is highly suggestive of the existence of residual confounding. This quintile included more men, people who had their first-time TASD more recently and fewer alcohol drinkers and had most of the people with epilepsy. So although the study now has more power, residual confounding continues. The confounders are likely to be contained within the a priori list of important risk factors, used by surgeons to make clinical decisions on the best care, that could not be identified from the data, and so these confounders could not be taken into account during the propensity scoring.

Chapter 6 Prediction modelling

Introduction

This chapter describes the development and internal validation of a model to predict the risk of re-dislocation. Prediction models using routinely collected data from primary care were developed in the surgical and non-surgical cohorts separately, using the CPRD-HES linked data set.

Methods

Sample

The collated sample comprised patients aged 16–35 years with a first-time TASD who had at least 2 years of data (washout period) before a first-time entry Read code for shoulder dislocation and with up to 3 years of follow-up coding, who were registered at 'active' general practices in England (see *Figure 11*).

Definition of the primary outcome

The primary outcome was re-dislocation following a first-time TASD. We determined an entry date for each participant, which was the date of surgery for the surgical cohort and the date of first shoulder dislocation for the non-surgical cohort. Observation time was calculated from the entry date to an exit date, which was defined as the earliest date of recorded re-dislocation or 3 years after the index date.

Candidate predictors

Potential predictors of re-dislocation were defined a priori by expert consensus and informed by the validation study (see *Appendix 4*). Only eight of these predictors were available in the CPRD and were used as candidate predictors in the multivariable prediction model (*Table 22*). Owing to the sparseness of the CCI score in the surgical cohort, it was not considered in the model building in this cohort.

Continuous predictors

Fractional polynomials were used to explore the presence of non-linear relationships of continuous predictors (e.g. age, BMI); however, a linear relationship was found to be a good approximation.[34]

TABLE 22 Candidate predictors available in CPRD

Candidate predictors (surgical patients)	Candidate predictors (non-surgical patients)
Age (years)	Age (years)
Sex	Sex
BMI (kg/m^2)	BMI (kg/m^2)
Smoking status (non-smoker, current smoker, ex-smoker)	Smoking status (non-smoker, current smoker, ex-smoker)
Alcohol consumption (reference: non-drinker)	Alcohol consumption (reference: non-drinker)
Epilepsy	Epilepsy
Painkillers within 1 month of index date	Painkillers within 3 months of index date
IMD	IMD
	CCI score

Missing data

We assumed that missing data occurred at random and we carried out multiple imputation.[24] Missing values were predicted on the basis of all other predictors as well as the outcome. One hundred imputed data sets were generated with imputed values, reflecting the uncertainty associated with the imputations. Models were fitted on each imputed data set and coefficients combined using Rubin's rules.

Model development

All candidate predictors in *Table 22* were included in the multivariable Cox regression models for predicting re-dislocation. Because predictors were chosen a priori based on clinical consensus, and only a small number of candidate predictors were available in the CPRD, no reduction of predictors was considered.

Assessment of model performance and internal validation

The predictive ability of the model was assessed in terms of discrimination.[35] Discrimination is the ability of the model to differentiate between individuals who have a re-dislocation and those who do not. Discrimination was assessed by calculating the concordance (c)-index; a value of 0.5 indicates no discrimination (equivalent to tossing a coin) and a value of 1 indicates perfect discrimination.

Optimism in the performance was assessed by bootstrap resampling.[35] We drew 200 samples with replacement from the original data, with the same size as the original derivation data. In each bootstrap sample the entire modelling process was repeated. This process was repeated over each of the 100 imputed data sets, and an averaged, optimism-corrected c-index was taken.

The R software environment (version 3.5.0) was used for all analyses. We followed the Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis statement for reporting our analyses.[36,37]

Results

The characteristics of the surgical and non-surgical groups are described in *Table 23*. There were 342 eligible individuals in the surgical cohort, of which 61 (18%) went on to have a re-dislocation within 3 years of the index date. There were 4271 individuals in the non-surgical cohort, of which 851 (20%) went on to have a re-dislocation within the study period. There were large numbers of missing data, most notably for BMI (46% missing in the surgical cohort and 42% missing in the non-surgical cohort) and alcohol consumption (51% missing in the surgical cohort and 43% missing in the non-surgical cohort). Forty-one per cent ($n = 140$) of individuals have no missing information on all eight predictors for the model developed in the surgical cohort, and 46% ($n = 1960$) have no missing information on all nine predictors for the model developed in the non-surgical cohort.

Prediction model: surgical cohort

Eight predictors were included in the model to predict re-dislocation in the surgery cohort (*Table 24*). With an effective sample size of 61 re-dislocation events, this yields an events-per-variable (EPV) number of 5.1 (61 events/12 regression coefficients), which is much smaller than the widely recommended EPV number of 10, indicating the likelihood of overfitting because of a small sample size.

Age and epilepsy were the only statistically significant predictors (at the $p < 0.05$ level). The apparent predictive performance of the model, as measured by the c-index, was moderate, with a c-index of 0.72 (95% CI 0.65 to 0.80), which dropped slightly to 0.67 after correcting for optimism (because of overfitting).

TABLE 23 Characteristics of the surgical and non-surgical cohorts

	Patient group, *n* (%)				
	No surgery		Surgery		
Variable	No re-dislocation	Re-dislocation	No re-dislocation	Re-dislocation	Total, *n* (%)
Total number of participants	3420 (80.1)	851 (19.9)	281 (82.2)	61 (17.8)	4613
Year of shoulder dislocation					
1997	54 (1.6)	10 (1.2)	1 (0.4)	0 (0.0)	65 (1.4)
1998	82 (2.4)	27 (3.2)	5 (1.8)	1 (1.6)	115 (2.5)
1999	101 (3.0)	24 (2.8)	2 (0.7)	1 (1.6)	128 (2.8)
2000	127 (3.7)	28 (3.3)	5 (1.8)	1 (1.6)	161 (3.5)
2001	153 (4.5)	46 (5.4)	7 (2.5)	3 (4.9)	209 (4.5)
2002	189 (5.5)	50 (5.9)	10 (3.6)	1 (1.6)	250 (5.4)
2003	234 (6.8)	54 (6.3)	17 (6.0)	4 (6.6)	309 (6.7)
2004	232 (6.8)	58 (6.8)	10 (3.6)	1 (1.6)	301 (6.5)
2005	213 (6.2)	58 (6.8)	13 (4.6)	4 (6.6)	288 (6.2)
2006	230 (6.7)	62 (7.3)	21 (7.5)	2 (3.3)	315 (6.8)
2007	240 (7.0)	68 (8.0)	20 (7.1)	6 (9.8)	334 (7.2)
2008	239 (7.0)	67 (7.9)	28 (10.0)	5 (8.2)	339 (7.3)
2009	238 (7.0)	65 (7.6)	20 (7.1)	8 (13.1)	331 (7.2)
2010	244 (7.1)	70 (8.2)	29 (10.3)	5 (8.2)	348 (7.5)
2011	251 (7.3)	50 (5.9)	24 (8.5)	4 (6.6)	329 (7.1)
2012	207 (6.1)	54 (6.3)	26 (9.3)	6 (9.8)	293 (6.4)
2013	170 (5.0)	39 (4.6)	22 (7.8)	6 (9.8)	237 (5.1)
2014	174 (5.1)	21 (2.5)	19 (6.8)	3 (4.9)	217 (4.7)
2015	42 (1.2)	0 (0.0)	2 (0.7)	0 (0.0)	44 (1.0)
Age (years), median (IQR)	24 (20–29)	22 (19–26)	24 (20–28)	21 (19–23)	23 (19–28)
Sex					
Male	2772 (81.1)	720 (84.6)	250 (89.0)	52 (85.2)	3794 (82.2)
Female	648 (18.9)	131 (18.9)	31 (11.0)	9 (14.8)	819 (17.8)
BMI (kg/m^2)					
< 25	1132 (33.1)	307 (36.1)	87 (31.0)	16 (26.2)	1542 (33.4)
25.0–29.9	584 (17.1)	124 (14.6)	46 (16.4)	9 (14.8)	753 (16.5)
≥ 30.0	277 (8.1)	61 (7.2)	24 (8.5)	2 (3.3)	364 (7.9)
Missing	1427 (41.7)	359 (42.2)	124 (44.1)	34 (55.7)	1944 (42.1)
IMD 2004 (quintile of deprivation)					
1 (affluent)	948 (27.7)	225 (26.4)	62 (22.1)	6 (9.8)	1241 (26.9)
2	748 (21.9)	201 (23.6)	65 (23.1)	14 (23.0)	1028 (22.3)
3	688 (20.1)	158 (18.6)	52 (18.5)	17 (27.9)	915 (19.8)
4	602 (17.6)	150 (17.6)	69 (24.6)	13 (21.3)	834 (18.1)
5 (deprived)	431 (12.6)	117 (13.7)	33 (11.7)	11 (18.0)	592 (12.8)
Missing	3 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.1)

continued

TABLE 23 Characteristics of the surgical and non-surgical cohorts (*continued*)

Variable	Patient group, *n* (%)				
	No surgery		Surgery		
	No re-dislocation	Re-dislocation	No re-dislocation	Re-dislocation	Total, *n* (%)
Smoking status					
Non-smoker	1795 (52.5)	492 (57.8)	137 (48.8)	37 (60.7)	2461 (53.3)
Current smoker	996 (29.1)	237 (27.8)	86 (30.6)	16 (26.2)	1335 (28.9)
Ex-smoker	295 (8.6)	67 (7.9)	25 (8.9)	5 (8.2)	392 (8.5)
Missing	334 (9.8)	55 (6.5)	33 (11.7)	3 (4.9)	426 (9.2)
Alcohol consumption?					
No	312 (9.1)	91 (10.7)	21 (7.5)	8 (13.1)	432 (9.4)
Yes	1628 (47.6)	405 (47.6)	122 (43.4)	17 (27.9)	2172 (47.1)
Missing	1480 (43.3)	355 (41.7)	138 (49.1)	36 (59.0)	2009 (43.6)
CCI score					
0	3153 (92.2)	792 (93.1)	270 (96.1)	60 (98.4)	4275 (92.7)
1	162 (4.7)	37 (4.3)	6 (2.1)	0 (0.0)	205 (4.4)
2	65 (1.9)	15 (1.8)	4 (1.4)	0 (0.0)	84 (1.8)
≥ 3	40 (1.2)	7 (0.8)	1 (0.4)	1 (1.6)	49 (1.1)
Region					
East Midlands	112 (3.3)	30 (3.5)	8 (2.8)	2 (3.3)	152 (3.3)
East of England	424 (12.4)	98 (11.5)	22 (7.8)	5 (8.2)	549 (11.9)
London	418 (12.2)	102 (12.0)	34 (12.1)	6 (9.8)	560 (12.1)
North East	78 (2.3)	26 (3.1)	6 (2.1)	3 (4.9)	113 (2.4)
North West	540 (15.8)	129 (15.2)	60 (21.4)	14 (23.0)	743 (16.1)
South Central	496 (14.5)	132 (15.5)	39 (13.9)	2 (3.3)	669 (14.5)
South East Coast	418 (12.2)	84 (9.9)	26 (9.3)	9 (14.8)	537 (11.6)
South West	414 (12.1)	110 (12.9)	46 (16.4)	10 (16.4)	580 (12.6)
West Midlands	378 (11.1)	110 (12.9)	30 (10.7)	7 (11.5)	525 (11.4)
Yorkshire and the Humber	142 (4.2)	30 (3.5)	10 (3.6)	3 (4.9)	185 (4.0)
Epilepsy?					
No	3328 (97.3)	809 (95.1)	267 (95.0)	53 (86.9)	4457 (96.6)
Yes	92 (2.7)	42 (4.9)	14 (5.0)	8 (13.1)	156 (3.4)
Prescribed painkillers 3 months after the index date?					
No	3241 (94.8)	795 (93.4)	264 (94.0)	56 (91.8)	4356 (94.4)
Yes	179 (5.2)	56 (6.6)	17 (6.0)	5 (8.2)	257 (5.6)
Prescribed painkillers 1 month after the index date?					
No	–	–	248 (88.3)	51 (83.6)	–
Yes	–	–	33 (11.7)	10 (16.4)	–

TABLE 23 Characteristics of the surgical and non-surgical cohorts (*continued*)

Variable	Patient group, *n* (%)				Total, *n* (%)
	No surgery		Surgery		
	No re-dislocation	Re-dislocation	No re-dislocation	Re-dislocation	
First-time TASD					
14G5: H/O dislocated shoulder[a]	393 (11.5)	84 (9.9)	33 (11.7)	5 (8.2)	515
7K6G300: closed reduction of dislocation of shoulder	58 (1.7)	24 (2.8)	3 (1.1)	2 (3.3)	87
N083100: recurrent joint dislocation, of shoulder region	29 (0.8)	8 (0.9)	5 (1.8)	1 (1.6)	43
N083A00: recurrent dislocation of shoulder – anterior	113 (3.3)	25 (2.9)	25 (8.9)	4 (6.6)	167
N083C00: recurrent subluxation of shoulder – anterior	52 (1.5)	14 (1.6)	7 (2.5)	1 (1.6)	74
S41..00: dislocation or subluxation of shoulder	2081 (60.8)	496 (58.3)	147 (52.3)	36 (53.5)	2760
S410.00: closed traumatic dislocation of shoulder	75 (2.2)	31 (3.6)	4 (1.4)	2 (3.3)	112
S410000: closed traumatic dislocation of shoulder joint, unspecified	21 (0.6)	7 (0.8)	1 (0.4)	0 (0.0)	29
S410100: closed traumatic dislocation of shoulder joint, anterior (subcoracoid)	13 (0.4)	2 (0.2)	2 (0.7)	0 (0.0)	17
S410111: anterior dislocation of shoulder	87 (2.5)	37 (4.3)	11 (3.9)	2 (3.3)	137
S412.00: closed traumatic subluxation, shoulder	18 (0.5)	2 (0.2)	1 (0.4)	0 (0.0)	21
S41z.00: dislocation of shoulder NOS[a]	480 (14.0)	121 (14.2)	42 (14.9)	8 (13.1)	651

a No definition for abbreviation available.

Prediction model: non-surgical cohort

Nine predictors were included in the model to predict re-dislocation in the non-surgery cohort (*Table 25*). With an effective sample size of 851 re-dislocation events, this yields an EPV number of 56.7 (851 events/15 regression coefficients), which is higher than the widely recommended EPV number of 10, indicating a sufficient sample size for model development and the minimal likelihood of overfitting.

Age, sex and epilepsy were statistically significant predictors (at the $p < 0.05$ level). The apparent predictive performance of the model, as measured by the c-index, was low (c-index 0.58, 95% CI 0.56 to 0.60), which dropped to 0.56 after correcting for optimism (because of overfitting).

TABLE 24 Prediction model: surgery-only cohort (after multiple imputation)

Predictor	Coefficient (SE)	HR (95% CI)	*p*-value
Age (years)	–0.1029 (0.0366)	0.90 (0.84 to 0.97)	0.0050
Sex	0.10275 (0.3825)	1.11 (0.52 to 2.34)	0.7887
BMI (kg/m^2)	–0.0777 (0.0606)	0.93 (0.82 to 1.04)	0.2015
Smoking status (reference: non-smoker)			
Smoker	–0.4653 (0.3444)	0.63 (0.32 to 1.23)	0.1767
Ex-smoker	–0.0989 (0.5322)	0.91 (0.32 to 2.57)	0.8526
Alcohol consumption (reference: non-drinker)	–0.3965 (0.4968)	0.67 (0.25 to 1.79)	0.4255
Epilepsy	0.9216 (0.4434)	2.51 (1.05 to 5.99)	0.0377
Painkillers within 1 month of index date	0.5171 (0.3848)	1.68 (0.79 to 3.57)	0.1791
IMD 2004 [reference: 1 (affluent)]			
2	0.7099 (0.5146)	2.03 (0.74 to 5.58)	0.1677
3	1.0641 (0.5029)	2.90 (1.08 to 7.77)	0.0344
4	0.6600 (0.5127)	1.93 (0.71 to 5.29)	0.1980
5 (deprived)	1.0757 (0.5667)	2.93 (0.97 to 8.90)	0.0577

SE, standard error.

TABLE 25 Prediction model: non-surgery-only cohort (after multiple imputation)

Predictor	Coefficient (SE)	HR (95% CI)	*p*-value
Age (years)	–0.0379 (0.0069)	0.96 (0.95 to 0.98)	< 0.0001
Sex	–0.2179 (0.0959)	0.80 (0.67 to 0.97)	0.0230
BMI (kg/m^2)	–0.0122 (0.0094)	0.99 (0.97 to 1.01)	0.1964
Smoking status (reference: non-smoker)			
Smoker	–0.0775 (0.0828)	0.93 (0.79 to 1.09)	0.3496
Ex-smoker	–0.0039 (0.1340)	1.00 (0.77 to 1.21)	0.9770
Alcohol consumption (reference: non-drinker)	–0.0336 (0.1142)	0.97 (0.77 to 1.21)	0.7687
Epilepsy	0.6377 (0.1598)	1.89 (1.38 to 2.59)	0.0001
Painkillers within 1 month of index date	–0.0726 (0.1139)	0.93 (0.74 to 1.16)	0.5242
CCI score (reference: 0)			
1	–0.1202 (0.1687)	0.89 (0.64 to 1.23)	0.4763
2	–0.0464 (0.2616)	0.95 (0.57 to 1.59)	0.8593
3	–0.2470 (0.3804)	0.78 (0.37 to 1.65)	0.5161
IMD 2004 [reference: 1 (affluent)]			
2	0.1178 (0.0975)	1.12 (0.93 to 1.36)	0.2271
3	0.0031 (0.1046)	1.00 (0.82 to 1.23)	0.9766
4	0.0770 (0.1065)	1.08 (0.88 to 1.33)	0.4697
5 (deprived)	0.1619 (0.1169)	1.18 (0.93 to 1.48)	0.1662

Discussion

Main findings

The use of primary care data to predict the risk of re-dislocation following a first-time TASD is limited. However, the performances of the two models were markedly different, with better performance in the surgery cohort. Both models identified age and epilepsy as statistically significant predictors of re-dislocation, but in the non-surgery cohort sex was also identified as a statistically significant predictor.

The model developed in the surgery cohort showed moderate performance, with a c-index of 0.67, suggesting that the information collected has some predictive capacity but that additional information (risk factors) is needed to allow better predictions of re-dislocation. For the model developed in the non-surgery cohort, the predictive ability of the model was poor, with a c-index of only 0.57, and, therefore, has no use for the risk factors available in predicting re-dislocation in this cohort of patients.

Strengths and limitations

This study has several strengths. The models were developed using data routinely collected in electronic health-care records in primary care. Widely recommended statistical methodology was followed to develop and evaluate the models, including the exploration of complex relationships (e.g. non-linearity) in continuous measurements (e.g. age and BMI). Bootstrapping techniques were used to internally validate the models.

There are also some limitations. We were only able to include a small number of predictors, fewer than half of those identified in the clinical consensus. This had a considerable impact on our ability to develop models to accurately predict the risk of re-dislocation. There was also a considerable number of missing data (e.g. BMI, alcohol consumption). However, we followed recommended guidance and increased the number of imputations to 100 to account for the large number of missing data and any uncertainty in the imputation.[24] Despite using a large electronic health records database (CPRD linked to HES), the number of eligible individuals, notably in the surgical cohort, was surprisingly small, with only 61 re-dislocation events during the study period. A small sample size can lead to overfitting. However, to counter the risk of overfitting, internal validation was carried out using bootstrapping to obtain unbiased estimates of model performance. Another limitation was the lack of a separate data set to carry out external validation, particularly to evaluate the model in the surgery cohort, which showed some predictive accuracy in the internal validation.

Conclusion

An insufficient number of data are routinely collected in CPRD and HES to allow for any reliable prediction modelling for shoulder re-dislocations after a first-time TASD in 16- to 35-year-olds.

Chapter 7 Discussion and conclusions

With regard to first-time TASDs, previous research has been limited to small cohort studies, case series and systematic reviews. The relevant background information supporting the need for research into the efficacy of management options for patients with a first-time TASD has been described. It highlighted that the use of traditional conservative management approaches after the initial reduction and joint immobilisation after a TASD seem to result in high rates of recurrent dislocation in some population groups.[3,38–40] In younger patients, rates of recurrence as high as 92–96% have been reported.[6] An incidence study of shoulder instability among athletes at a US military academy showed that 85% experienced a recurrent event within a 9-month period.[7] A systematic review showed that there were some limited data to support primary surgery following a first-time TASD in young adults engaged in demanding physical activities (i.e. military personnel and athletes).[5] A later systematic review also showed that in younger patients a significantly lower rate of recurrent instability was identified in the 2-year period following a first-time TASD for those having surgery than for those having no surgery (7% vs. 46%).[8]

Consequently, there appears to be some limited evidence for surgical intervention following a first-time TASD in younger and/or highly active patients. This research was, therefore, commissioned by the NIHR HTA programme as an ongoing research uncertainty, and probably with concern that this type of surgery is becoming more frequent after a first-time TASD, based on the positive suggestions of the lower-quality evidence described above.

Internal and external validation study

We conducted both an internal and an external validation assessment of the CPRD and found it an acceptable data set to identify and study shoulder dislocation patients. It provided a large, population-based, primary care cohort that is representative of the UK general population. We found the GP coding internally valid for shoulder dislocations and the incidence rates externally valid against data from Canada and the USA.

Our large UK population-based cohort of 16,763 patients aged 16–70 years during 1995–2015 allowed us to identify, for the first time (to our knowledge), the overall incidence rates in the UK. Most shoulder dislocations occurred in men (72%). The overall incidence rate in men was 40.4 per 100,000 person-years, and in women this was 15.5 per 100,000 person-years. The highest incidence was observed in 16- to 20-year-old men (80.5 per 100,000 person-years). Although this was similar to other world data (Canadian, US and Norwegian cohorts[15,16,20]), an unexpected finding was that the incidence in women aged > 50 years increased to 28.1 per 100,000 person-years among those aged 61–70 years.

Our new finding of the increasing incidence of shoulder dislocations among women aged > 50 years is of both interest and concern because the reasons for it are not known. Such injuries in more elderly people are usually associated with rotator cuff tears and fractures, with the subsequent loss of function as well as instability. However, this finding suggests that further work is now required to examine the reasons that may underpin this increased risk of shoulder dislocations in ageing women. Biological differences between ageing men and women in relation to joint proprioception, soft tissue tendon quality and protective muscle bulk and differences in the incidence of falls between men and women are all factors that could be examined. With an increasing ageing population, priority needs to be given to increasing the safety of the elderly to reduce falls, dislocations and fractures, as advocated by NICE;[22] this is a new finding that warrants exploration.

Stage 2: propensity score analysis

One weakness identified during stage 1 of our study was that not all a priori risk factors were identifiable in the CPRD and the impact this would have on the stage 2 propensity score analysis was unclear because linkage to HES did not take place until stage 2 of this study. However, besides this weakness, once CPRD and HES linkage had taken place, a population-based cohort of 3759 patients diagnosed with a first-time TASD during 1 April 1997–26 April 2014 with 2 years of follow-up in England was produced.

Therefore, it was surprising that for a commissioned research question we could find only 156 patients in this large data set who had received surgical treatment within 6 months of a first-time TASD. On the one hand, this information is useful and informative and allows us to conclude that within the NHS early surgery after only one shoulder dislocation is uncommon. It also means that the study would be underpowered to demonstrate any real differences in re-dislocation rates between surgical and non-surgical treatments. Therefore, although the number of patients ($n = 3759$) included in the analysis was greater than the minimum number required for statistical power ($n = 3065$), the unexpected low number of NHS patients having surgery after one dislocation was a disappointing and surprising finding. It was also observed that a substantial number of patients in the young cohort of 16- to 35-year-olds had < 2 years of follow-up within the CPRD ($n = 854$), which may be related to them going away to university or finding jobs in different locations, resulting in the need to change their GP and this, in turn, resulted in a further loss of numbers. Overall, relatively few patients have surgery within 6 months of a first-time TASD in the NHS. This is probably a reflection of many GPs not referring patients with only one dislocation to secondary care and also due to NHS operative waiting times.

Combining this finding with the confounding risk factors not available in either the CPRD or HES had a large impact on the study. Although the overall finding from the propensity-score-matched analysis was that surgery within 6 months was slightly protective, it did not reach statistical significance (HR 0.88, 95% CI 0.58 to 1.35; $p = 0.565$) and the wide CI further indicates that this study was underpowered. With regard to the missing risk factors, the main disadvantage of using propensity-score-matching methods is that confounders for which no data are available result in a lack of adjustment. Other than age and sex, the risk factors recorded and available in the CPRD are considered less important risk factors for this particular condition. Other important factors identified in our expert survey, such as cause of shoulder dislocation, imaging findings of structural problems, anterior apprehension, occupation, sports played and level of sports, were not recorded in the observational data. Outcome data on ongoing instability symptoms without dislocation were also not available and, thus, only the hard outcome of re-dislocation could be used. This is another layer of potential confounding that could not be accounted for.

Sensitivity analysis

Based on the primary analysis findings, and in an attempt to maximise the use of this data set to further examine the commissioned question of surgery after a first-time TASD, a further sensitivity analysis was planned and approved by the HTA programme and ISAC. We looked at surgery within 12 months of a first-time TASD and increased the follow-up to up to 3 years. This produced a population-based cohort of 4613 patients diagnosed with a first-time TASD during 1 April 1997–31 March 2015 in England within CPRD-HES linked records. The overall finding from this propensity-score-matched analysis was that surgery within 12 months had a similar effect to non-surgical interventions (HR 1.17, 95% CI 0.88 to 1.55; $p = 0.274$) and did not seem to offer any additional benefit on whether or not a patient suffers a re-dislocation. However, the number of patients receiving surgery only increased to 342 (from 156 patients) and residual confounding was present.

There are two further observations to note from this analysis. First, re-dislocations in the surgical group seemed to occur later. This is unlikely to be due to any benefits of surgery wearing off but more likely to be related to the return to contact sports, which is a true test of stability. This is often delayed for

> 6 months after surgery as part of the rehabilitation process. Second, the same process tends not to be in place for any non-operative patients; such patients may not even return to contact sports having decided to change their lifestyle instead of considering surgery. Recording such outcome metrics would be important for any future trials on the treatment of this condition. Although risk factors and residual confounding existed and it was not possible to reliably compare surgery with no surgery, it is still worth noting the 20% re-dislocation rate in the surgical cohort. The re-dislocation recurrence rate after surgery is probably higher than many surgeons and patients would expect and will help inform shared decision-making processes with patients.

Prediction models

Although some risk factor data were not available, it was still possible to construct prediction models, but these were limited. A non-surgical and a surgical model were developed and although the performances of the two models were markedly different, with a better performance in the surgery cohort, both models identified age and epilepsy as statistically significant predictors of re-dislocation. In the non-surgery cohort, sex (male) was also identified as a statistically significant predictor of re-dislocation. The modelling study has several strengths, as the models were developed using data routinely collected in electronic health-care records in primary care. Widely recommended statistical methodology was used to develop and evaluate the models, including the exploration of complex relationships in continuous measurements and bootstrapping techniques to internally validate them. The results indicate that using prediction models for this condition holds promise, but more risk factors are needed for more accurate prediction of outcome information for patients and surgeons.

Conclusions

- This study provides the first-time age- and sex-specific UK incidence rates for TASD, with most TASDs occurring in men, but with women aged > 50 years unexpectedly showing an increased incidence.
- Far fewer patients received surgery after a first-time TASD than expected, leading to an underpowered study.
- Surgery after a first-time TASD is not common in the NHS. Re-dislocation rates for surgical patients after a first-time TASD are higher than previously expected (at around 20%).
- A sensitivity analysis at 12 months suggests that there is little difference in re-dislocation rates between surgical patients and non-surgical patients, but important residual confounding risk factors were present and not recorded in NHS primary and secondary care databases.
- Missing risk factor data limited the value of the prediction modelling; however, age and epilepsy were identified as statistically significant predictors of re-dislocation.

A randomised controlled trial and/or a carefully constructed national shoulder dislocation registry documenting all appropriate risk factors and outcome metrics is needed to answer this commissioned research question reliably.

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Patient and public involvement statement

A patient representative was involved in managing the study and sat on the Project Management Board. Although other patient and public involvement activity was planned in the protocol of this study, the findings have been such that widespread dissemination of the results and the development of specific patient decision-making information for patients has not been possible or worthwhile. The research question remains unanswered and is one of the top 20 James Lind Alliance Surgery for Common Shoulder Conditions[41] research priorities.

Contributions of authors

Jonathan L Rees contributed to the conception and design of the study, oversaw the acquisition of data, analysis and interpretation of the findings.

Anjali Shah analysed the study data and contributed to the interpretation of the findings.

Katherine Edwards assisted with the literature review, data access and the internal validation of the study.

Maria T Sanchez-Santos assisted with analysing the data and interpreting the findings.

Danielle E Robinson assisted with analysing the data and interpreting the findings.

Antonella Delmestri contributed to the acquisition, cleaning and management of the data.

Andrew Carr contributed to the interpretation of the study findings.

Nigel Arden contributed to the interpretation of the study findings.

Sarah E Lamb contributed to the interpretation of the study findings.

Amar Rangan contributed to the interpretation of the study findings.

Andrew Judge contributed to the interpretation of the study findings.

Rafael Pinedo-Villanueva contributed to the interpretation of the study findings.

Tim Holt contributed to the interpretation of the study findings.

Sally Hopewell contributed to the interpretation of the study findings.

Daniel Prieto-Alhambra contributed to the interpretation of the study findings.

Gary Collins analysed the study data and contributed to the interpretation of the study findings.

All authors contributed to the drafting of this report or revising its content and have approved the final version.

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Data-sharing statement

All of the available data are included in the report. All queries should be submitted to the corresponding author for consideration.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 Clinical Practice Research Datalink and Hospital Episode Statistics codes

Clinical Practice Research Datalink dislocation Read codes

Description	Read code
Dislocation or subluxation of shoulder	S41..00
Dislocation of shoulder NOS[a]	S41z.00
H/O: dislocated shoulder[a]	14G5.00
Closed reduction of dislocation of shoulder	7K6G300
Closed traumatic dislocation of shoulder	S410.00
Recurrent dislocation of shoulder, anterior	N083A00
Anterior dislocation of shoulder	S410111
Recurrent joint dislocation of shoulder region	N083100
Recurrent subluxation of shoulder, anterior	N083C00
Closed traumatic dislocation of shoulder joint, anterior (subcoracoid)	S410100
Closed traumatic dislocation shoulder joint, unspecified	S410000
Closed traumatic subluxation, shoulder	S412.00

a No definition for abbreviation available.

Hospital Episode Statistics Office of Population Censuses and Surveys 4.7 codes

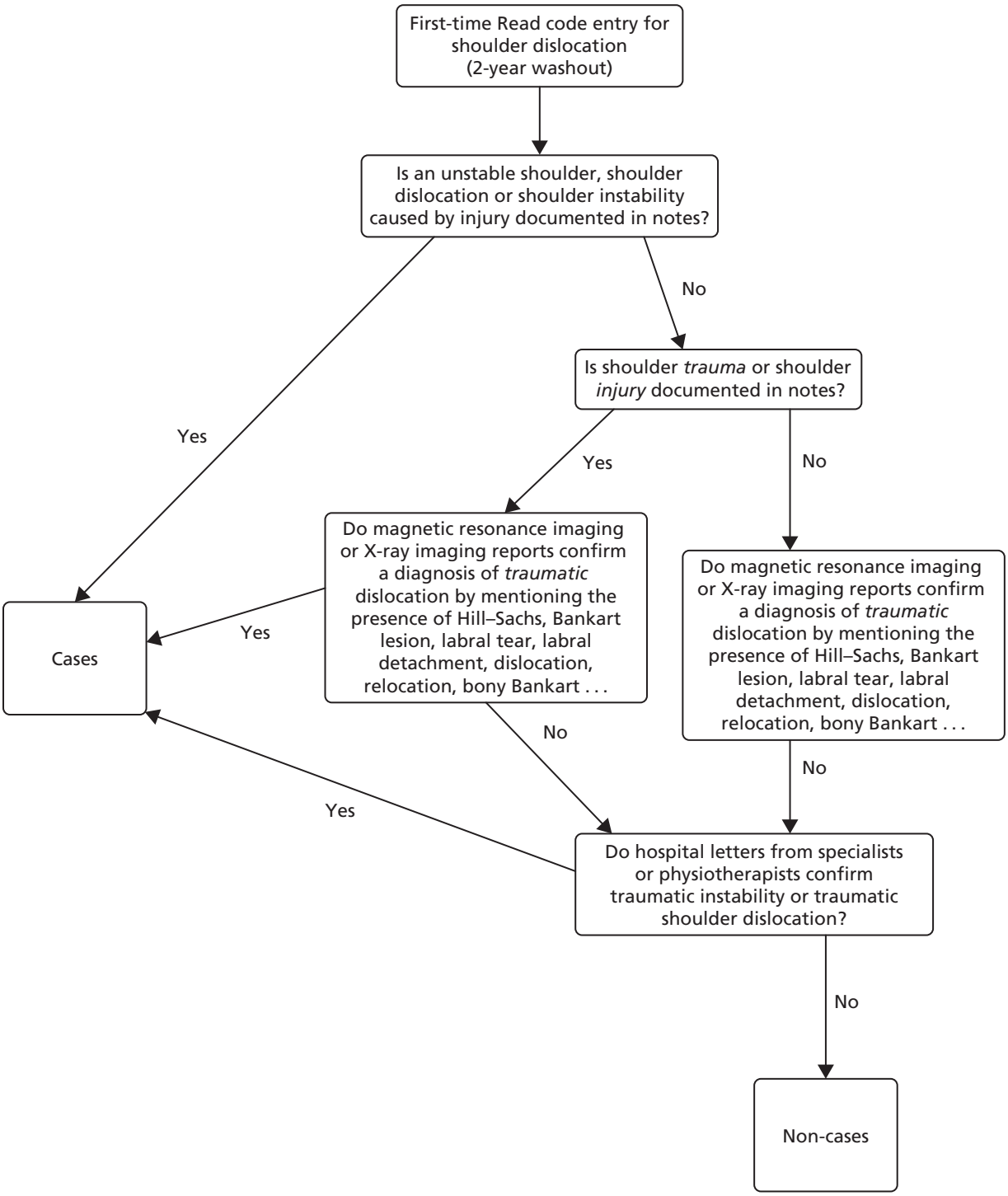
Shown below is a list of the HES OPCS 4.7 codes used to identify shoulder dislocation events and outcomes. These codes have been provided by the expert advisor in orthopaedics to the NHS Digital Clinical Classifications Service and Collaborating Centres for the World Health Organization Family of International Classifications. The codes listed below are based on the following procedures: labral repair, stabilisation, capsular shift, Latarjet procedure, bone transfer, SLAP (Superior Labrum Anterior to Posterior) repair and Bankart repair. The following site codes should be present in cases when the codes do not define the anatomical site: Z81.3 (glenohumeral joint) or Z81.4 (shoulder joint).

Operative description	OPCS 4.7 code
Other bones and joints: primary closed reduction of traumatic dislocation of joint, primary closed reduction of traumatic dislocation of joint and skeletal traction	W66.2
Other bones and joints: primary closed reduction of traumatic dislocation of joint, other specified	W66.8
Other bones and joints: primary closed reduction of traumatic dislocation of joint, unspecified	W66.9
Other bones and joints: secondary reduction of traumatic dislocation of joint, re-manipulation of traumatic dislocation of joint	W67.6
Stabilising operations on joint	W77
Repair of capsule of joint for stabilisation of joint NEC	W77.1
Transposition of muscle for stabilisation of joint	W77.2
Blocking operations on joint using prosthesis for stabilisation of joint	W77.3
Blocking operations on joint using bone for stabilisation of joint	W77.4

Operative description	OPCS 4.7 code
Periarticular osteotomy for stabilisation of joint	W77.5
Transposition of ligament for stabilisation of joint	W77.7
Other specified stabilising operations on joint	W77.8
Unspecified stabilising operations on joint	W77.9
Prosthetic replacement of ligament	W72
Primary prosthetic replacement of multiple ligaments	W72.1
Prosthetic replacement of multiple ligaments NEC	W72.2
Primary prosthetic replacement of intra-articular ligament	W72.3
Prosthetic replacement of intra-articular ligament NEC	W72.4
Primary prosthetic replacement of extra-articular ligament	W72.5
Prosthetic replacement of extra-articular ligament NEC	W72.6
Other specified prosthetic replacement of ligament	W72.8
Unspecified prosthetic replacement of ligament	W72.9
Other stabilising operations on joint	O27
Extra-articular ligament reconstruction for stabilisation of joint	O27.1
Repair of capsule and anterior and posterior labrum for stabilisation of glenohumeral joint	O27.2
Repair of capsule and anterior labrum for stabilisation of glenohumeral joint	O27.3
Repair of capsule and posterior labrum for stabilisation of glenohumeral joint	O27.4
Other reconstruction of ligament	W74
Reconstruction of multiple ligaments NEC	W74.1
Reconstruction of intra-articular ligament NEC	W74.2
Other specified other reconstruction of ligament	W74.8
Unspecified other reconstruction of ligament	W74.9
Other open repair of ligament	W75
Open repair of multiple ligaments NEC	W75.1
Open repair of intra-articular ligament NEC	W75.2
Open repair of extra-articular ligament NEC	W75.3
Other specified other open repair of ligament	W75.8
Unspecified other open repair of ligament	W75.9
Therapeutic endoscopic operations on other joint structure	W84
Endoscopic repair of intra-articular ligament	W84.1
Endoscopic re-attachment of intra-articular ligament	W84.2
Endoscopic repair of superior labrum anterior to posterior tear	W84.7
Other specified therapeutic endoscopic operations on other joint structure	W84.8
Unspecified therapeutic endoscopic operations on other joint structure	W84.9
Capsulorrhaphy of joint	W81.6
Other bones and joints: therapeutic endoscopic operations on cavity of other joint, other specified	W86.8
Other bones and joints: other manipulation of joint, unspecified	W91.9

NEC, not elsewhere classified.

Appendix 2 Validation algorithm



Appendix 3 General practitioner validation questionnaire of the UK TASH-D study distributed by the Clinical Practice Research Datalink questionnaire service

Dear Colleague,

Thank you for completing this questionnaire as a practice connected to the CPRD database.

The UK.TASH-D study has been commissioned by NIHR HTA and will use the CPRD to investigate the treatment of first time traumatic anterior shoulder dislocation. As you know, shoulder dislocations often recur and we are investigating whether surgery makes recurrence less likely after a first episode. Our aim on completing this study is to write national guidelines to help you with referral care pathways for these patients. Your responses will be collected by CPRD and then provided to our university department where the data will be fully protected and managed by our data manager and data analysts.

The study is in two phases and we will be completely reliant in the main second phase on electronic codes to identify recurrent dislocations. Before starting the main phase, we need to know whether we can reliably identify 'New dislocation episodes' or whether these tend to be recorded as a 'Review' of the same problem (without a further dislocation occurring). Conversely, we need to know if codes apparently indicating a 'further' dislocation episode are in fact a 'Review' of the problem. We also need to confirm that codes recorded in primary care as 'dislocation' actually reflect this diagnosis, rather than less specific conditions affecting the shoulder.

We are therefore looking at a national sample of records that indicate a shoulder dislocation. By completing the following questionnaire on your patient, you will help tell us:

1) Was this actually a traumatic shoulder dislocation?

2) Did further episodes occur over the following two years, and if so, how many true recurrences were recorded as 'New' episodes?

3) Were there any examples of 'New' recurrences being recorded as a 'Review' of the original problem?

If the coding proves valid and reliable, then we will link a CPRD dataset to a Hospital Episode Statistics (HES) dataset to compare surgical versus conservative treatment (including physiotherapy) on recurrent dislocation rates. This will allow us to write national pathway guidelines for the management of this condition in primary care.

Thank you in anticipation of your help

Professor Jonathan Rees and the UK.TASH-D study team.

GP CPRD Validation Questionnaire for the UK.TASH-D Study

Number	Question	Response (please tick)	
		Yes	No
1.	Is shoulder dislocation, an unstable shoulder, or shoulder instability caused by INJURY documented in the patient's notes?	*(If YES go to Q5)*	*(If NO go to Q2)*
2.	Is shoulder trauma or shoulder injury documented in the patient's notes?	*(If YES go to Q3)*	*(If NO go to Q3)*
3.	Do MRI or X-ray imaging reports confirm a diagnosis of traumatic dislocation by mentioning the presence of Hill Sachs, Bankart lesion, labral tear, labral detachment, dislocation, relocation, bony Bankart?	*(If YES go to Q5)*	*(If NO go to Q4)*
4.	Do Hospital letters from specialists or physiotherapists confirm traumatic instability or traumatic shoulder dislocation?	*(If YES go to Q5)*	*(If NO go to Q8)*
5.	Is there any record of a dislocation prior to the CPRD first registration date at your practice?	*(If YES go to Q6)*	*(If NO go to Q6)*
6.	Are there any further dislocation codes in the record during the 2 years after the first dislocation code?	*(If YES go to Q6b)*	*(If NO go to Q6c)*
6b.	If YES is it clear (for each one) that this is a further dislocation episode rather than simply a review of the problem?	*(If YES go to Q7)*	*(If NO go to Q7)*
6c.	If NO, have there been any further dislocations recorded during the following 2 years that are not electronically coded?	*(If YES go to Q7)*	*(If NO go to Q7)*
7.	Are there any physiotherapy treatment codes for 2 years after the first dislocation code?	*(If YES go to Q7b)*	*(If NO go to Q7c)*
7b.	If YES is it clear that this physio code indicates the patient received physiotherapy for their shoulder?	*(If YES go to Q8)*	*(If NO go to Q8)*
7c.	If NO, is there any documentation that the patient has received physiotherapy for their shoulder without a code being entered?	*(If YES go to Q8)*	*(If NO go to Q8)*
8.	If your responses to this questionnaire indicate this patient has not had a traumatic shoulder dislocation but your reading of the notes or your knowledge of the patient suggest they might have please tick the YES box, otherwise tick the NO box.	*The end – thank you*	*The end – thank you*

Appendix 4 List of risk factors identified by expert consensus

Risk factors for re-dislocation after first dislocation	Risk factors for re-dislocation after surgery
Age (years)	Age (years)
Sex	Sex
UK region	UK region
Deprivation scores	Deprivation scores
Glenoid and/or humeral bone loss	Glenoid and/or humeral bone loss
Mechanism of injury	Number of dislocations pre surgical repair
Rotator cuff tears	Time between first dislocation and surgery
Imaging findings	Anterior apprehension
Anterior apprehension	Occupation
Occupation	Sport type and level
Sport type and level	Operation type
Neurological injury	Laxity/Beighton score
Laxity/Beighton score	Insufficient physiotherapy/rehabilitation after surgery
Insufficient physiotherapy/rehabilitation after first dislocation	Time at return to sports
Young rugby player (aged < 20 years)	Number of anchors used at surgery
Time at return to sports	Incorrect positioning of anchors
Post-dislocation immobilisation	Not addressing capsular laxity at surgery
	Previous lower limb or back injury

Appendix 5 Clinical Practice Research Datalink Read codes of primary shoulder dislocation patients who had surgery within 6 months or no surgery within Clinical Practice Research Datalink-Hospital Episode Statistics during 1 April 1997–26 April 2014, in England

Diagnosis codes and descriptions for first-time TASD within the CPRD	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 6 months of TASD
Total	3759 (100)	3603 (96)	156 (4)
S41..00: dislocation or subluxation of shoulder	2269 (60)	2187 (61)	82 (53)
S41z.00: dislocation of shoulder NOS[a]	510 (14)	482 (13)	28 (18)
14G5.00: H/O – dislocated shoulder[a]	413 (11)	398 (11)	15 (10)
N083A00: recurrent dislocation of shoulder – anterior	139 (4)	126 (3)	13 (8)
S410111: anterior dislocation of shoulder	111 (3)	104 (3)	7 (4)
S410.00: closed traumatic dislocation of shoulder	94 (3)	90 (2)	4 (3)
7K6G300: closed reduction of dislocation of shoulder	69 (2)	67 (2)	2 (1)
N083C00: recurrent subluxation of shoulder – anterior	64 (2)	60 (2)	4 (3)
N083100: recurrent joint dislocation, of shoulder region	36 (1)	35 (1)	1 (1)
S410000: closed traumatic dislocation shoulder joint, unspecified	22 (1)	22 (1)	0 (0)
S410100: closed traumatic dislocation shoulder joint, anterior (subcoracoid)	16 (< 1)	16 (< 1)	0 (0)
S412.00: closed traumatic subluxation, shoulder	16 (< 1)	16 (< 1)	0 (0)

a No definition for abbreviation available.

Appendix 6 Hospital Episode Statistics Office of Population Censuses and Surveys 4.7 codes for primary shoulder dislocation patients diagnosed during 1 April 1997–26 April 2014 who had surgery within 6 months within Clinical Practice Research Datalink-Hospital Episode Statistics, in England

Surgical codes and descriptions for first-time TASD patients within HES	*n* (%)
W77.1: repair of capsule of joint for stabilisation of joint NEC	49 (31)
W66.9: other bones and joints – primary closed reduction of traumatic dislocation of joint – unspecified	49 (31)
O27.3: repair of capsule and anterior labrum for stabilisation of glenohumeral joint	15 (10)
W77.9: unspecified stabilising operations on joint	8 (5)
W77.8: other specified stabilising operations on joint	7 (4)
W91.9: other bones and joints – other manipulation of joint – unspecified	7 (4)
W66.8: other bones and joints – primary closed reduction of traumatic dislocation of joint – other specified	5 (3)
W84.7: endoscopic repair of superior labrum anterior to posterior tear	3 (2)
W84.8: other specified therapeutic endoscopic operations on other joint structure	3 (2)
W66.2: other bones and joints – primary closed reduction of traumatic dislocation of joint – primary closed reduction of traumatic dislocation of joint and skeletal traction	2 (1)
W67.6: other bones and joints – secondary reduction of traumatic dislocation of joint – remanipulation of traumatic dislocation of joint	2 (1)
W86.8: other bones and joints – therapeutic endoscopic operations on cavity of other joint – other specified	2 (1)
O27.2: repair of capsule and anterior and posterior labrum for stabilisation of glenohumeral joint	1 (1)
O27.4: repair of capsule and posterior labrum for stabilisation of glenohumeral joint	1 (1)
W75.9: unspecified other open repair of ligament	1 (1)
W77.4: blocking operations on joint using bone for stabilisation of joint	1 (1)
Total	156 (100)

NEC, not elsewhere classified.

Appendix 7 Estimated univariate hazard ratios, 95% confidence intervals and *p*-values of patients suffering a shoulder re-dislocation following a primary traumatic anterior shoulder dislocation diagnosed during 1 April 2014–26 April 2014 for variables with missing data, in England

	All available data			Complete-case data ($n = 1790$)			Multiply imputed data ($n = 3759$)		
Variables	HR	95% CI	*p*-value	HR	95% CI	*p*-value	HR	95% CI	*p*-value
BMI (kg/m^2)									
< 25	1.00			1.00			1.00		
25.0–29.9	0.77	0.62 to 0.96	0.021	0.83	0.65 to 1.06	0.128	0.80	0.64 to 0.99	0.039
≥ 30	0.84	0.63 to 1.13	0.247	0.91	0.66 to 1.26	0.579	0.87	0.64 to 1.17	0.353
IMD 2004 (quintile of deprivation)									
1 (affluent)	1.00			1.00			1.00		
2	1.07	0.87 to 1.32	0.501	1.08	0.79 to 1.46	0.633	1.07	0.87 to 1.32	0.503
3	1.03	0.83 to 1.27	0.804	1.06	0.77 to 1.47	0.712	1.03	0.83 to 1.27	0.804
4	1.07	0.86 to 1.33	0.535	1.07	0.77 to 1.48	0.690	1.07	0.86 to 1.33	0.538
5 (deprived)	1.16	0.92 to 1.47	0.206	1.09	0.78 to 1.54	0.609	1.16	0.92 to 1.47	0.208
Smoking status									
No	1.00			1.00			1.00		
Yes	0.86	0.73 to 1.02	0.079	0.92	0.73 to 1.16	0.478	0.87	0.74 to 1.03	0.101
Ex-smoker	0.91	0.70 to 1.19	0.509	0.94	0.66 to 1.35	0.734	0.91	0.70 to 1.19	0.506
Drinking status									
Yes	1.00			1.00			1.00		
No	1.20	0.95 to 1.53	0.129	1.01	0.75 to 1.35	0.971	1.20	0.97 to 1.48	0.087

Appendix 8 Cox survival estimates (hazard ratios), 95% confidence intervals and *p*-values for complete cases and multiply imputed data on primary traumatic anterior shoulder dislocation patients diagnosed during 1 April 1997–26 April 2014 who may have suffered a re-dislocation in Clinical Practice Research Datalink-Hospital Episode Statistics, in England

	Complete-case analysis ($N = 1790$)								Multiply imputed data analysis ($N = 3759$)					
			Unadjusted			Adjusted model			Unadjusted			Adjusted model		
Variables	*n* (%)	Re-dislocations, *n* (%)	HR	95% CI	*p*-value	HR	95% CI	*p*-value	HR	95% CI	*p*-value	HR	95% CI	*p*-value
No surgery	1714 (96)	340 (20)	1.00			1.00			1.00			1.00		
Surgery	76 (4)	11 (14)	0.63	0.34 to 1.18	0.148	0.55	0.29 to 1.04	0.068	0.83	0.57 to 1.21	0.326	0.76	0.52 to 1.11	0.151
Calendar year of shoulder dislocation			1.03	1.00 to 1.05	0.047	1.03	1.00 to 1.05	0.034	1.03	1.01 to 1.04	0.003	1.02	1.01 to 1.04	0.008
Sex														
Male	1359 (76)	265 (19)	1.00			1.00			1.00			1.00		
Female	431 (24)	86 (20)	1.01	0.79 to 1.29	0.917	1.00	0.78 to 1.27	0.970	0.87	0.71 to 1.05	0.151	0.87	0.71 to 1.05	0.153
Age at shoulder dislocation (16- to 35-year-olds)			0.96	0.95 to 0.98	< 0.001	0.96	0.94 to 0.98	< 0.001	0.97	0.95 to 0.98	< 0.001	0.97	0.95 to 0.98	< 0.001
Epilepsy diagnosis?														
No	1708 (95)	326 (19)	1.00			1.00			1.00			1.00		
Yes	82 (5)	25 (30)	1.77	1.76 to 2.65	0.006	1.93	1.28 to 2.91	0.002	1.82	1.34 to 2.49	< 0.001	1.98	1.45 to 2.71	< 0.001

Appendix 9 Clinical Practice Research Datalink Read codes of primary shoulder dislocation patients who had surgery within 12 months or no surgery within Clinical Practice Research Datalink-Hospital Episode Statistics during 1 April 1997–31 March 2015, in England

Diagnosis codes and descriptions for first-time TASD within the CPRD	Patient group, *n* (%)		
	Whole data set	No surgery	Surgery within 12 months of TASD
Total	4613 (100)	4271 (93)	342 (7)
S41..00: dislocation or subluxation of shoulder	2760 (60)	2577 (60)	183 (54)
S41z.00: dislocation of shoulder NOS[a]	651 (14)	601 (14)	50 (15)
14G5.00: H/O – dislocated shoulder[a]	515 (11)	477 (11)	38 (11)
N083A00: recurrent dislocation of shoulder – anterior	167 (4)	138 (3)	29 (8)
S410111: anterior dislocation of shoulder	137 (3)	124 (3)	13 (4)
S410.00: closed traumatic dislocation of shoulder	112 (2)	106 (2)	6 (2)
7K6G300: closed reduction of dislocation of shoulder	87 (2)	82 (2)	5 (1)
N083C00: recurrent subluxation of shoulder – anterior	74 (2)	66 (2)	8 (2)
N083100: recurrent joint dislocation, of shoulder region	43 (1)	37 (1)	6 (2)
S410000: closed traumatic dislocation shoulder joint, unspecified	29 (1)	28 (1)	1 (< 1)
S410100: closed traumatic dislocation shoulder joint, anterior (subcoracoid)	17 (< 1)	15 (< 1)	2 (< 1)
S412.00: closed traumatic subluxation, shoulder	21 (< 1)	20 (< 1)	1 (< 1)

a No definition for abbreviation available.

Appendix 10 Hospital Episode Statistics Office of Population Censuses and Surveys 4.7 codes for primary shoulder dislocation patients diagnosed during 1 April 1997–31 March 2015 who had surgery within 12 months within Clinical Practice Research Datalink-Hospital Episode Statistics, in England

Surgical codes and descriptions for first-time TASD patients within HES	*n* (%)
W77.1: repair of capsule of joint for stabilisation of joint NEC	127 (37)
W66.9: other bones and joints – primary closed reduction of traumatic dislocation of joint – unspecified	69 (20)
O27.3: repair of capsule and anterior labrum for stabilisation of glenohumeral joint	43 (13)
W77.9: unspecified stabilising operations on joint	19 (6)
W77.8: other specified stabilising operations on joint	16 (5)
W84.8: other specified therapeutic endoscopic operations on other joint structure	15 (4)
O27.2: repair of capsule and anterior and posterior labrum for stabilisation of glenohumeral joint	11 (3)
W91.9: other bones and joints – other manipulation of joint – unspecified	8 (2)
W84.7: endoscopic repair of superior labrum anterior to posterior tear	8 (2)
O27.4: repair of capsule and posterior labrum for stabilisation of glenohumeral joint	6 (2)
W66.8: other bones and joints – primary closed reduction of traumatic dislocation of joint – other specified	5 (1)
W86.8: other bones and joints – therapeutic endoscopic operations on cavity of other joint – other specified	4 (1)
W77.4: blocking operations on joint using bone for stabilisation of joint	3 (1)
W67.6: other bones and joints – secondary reduction of traumatic dislocation of joint – remanipulation of traumatic dislocation of joint	3 (1)
W66.2: other bones and joints – primary closed reduction of traumatic dislocation of joint – primary closed reduction of traumatic dislocation of joint and skeletal traction	2 (1)
W75.9: unspecified other open repair of ligament	1 (< 1)
O27.1: extra-articular ligament reconstruction for stabilisation of joint	1 (< 1)
W77.3: blocking operations on joint using prosthesis for stabilisation of joint	1 (< 1)
Total	100 (100)

NEC, not elsewhere classified.

Appendix 11 Estimated univariate hazard ratios, 95% confidence intervals and *p*-values of patients suffering a shoulder re-dislocation following a primary traumatic anterior shoulder dislocation diagnosed during 1 April 2014–31 March 2015 for variables with missing data, in England

	All available data			Complete-case data ($n = 2100$)			Multiply imputed data ($n = 4613$)		
Variables	HR	95% CI	*p*-value	HR	95% CI	*p*-value	HR	95% CI	*p*-value
BMI (kg/m^2)									
< 25	1.00			1.00			1.00		
25.0–29.9	0.80	0.66 to 0.98	0.032	0.88	0.70 to 1.10	0.247	0.83	0.67 to 1.02	0.077
≥ 30	0.82	0.63 to 1.07	0.147	0.93	0.69 to 1.26	0.645	0.81	0.62 to 1.06	0.119
IMD 2004 (quintile of deprivation)									
1 (affluent)	1.00			1.00			1.00		
2	1.11	0.93 to 1.34	0.252	1.10	0.83 to 1.46	0.499	1.12	0.93 to 1.34	0.250
3	1.02	0.83 to 1.24	0.872	1.05	0.78 to 1.41	0.732	1.02	0.83 to 1.24	0.872
4	1.04	0.85 to 1.27	0.712	0.99	0.73 to 1.35	0.969	1.04	0.85 to 1.27	0.712
5 (deprived)	1.18	0.95 to 1.46	0.140	1.06	0.78 to 1.46	0.700	1.18	0.95 to 1.46	0.140
Smoking status									
No	1.00			1.00			1.00		
Yes	0.86	0.74 to 0.99	0.042	0.88	0.71 to 1.09	0.248	0.86	0.74 to 1.00	0.048
Ex-smoker	0.86	0.67 to 1.10	0.221	0.88	0.63 to 1.22	0.438	0.87	0.68 to 1.11	0.255
Drinking status									
Yes	1.00			1.00			1.00		
No	1.25	1.00 to 1.55	0.049	1.14	0.88 to 1.48	0.318	1.22	1.00 to 1.48	0.054

Appendix 12 Cox survival estimates (hazard ratios), 95% confidence intervals and *p*-values for complete cases and multiply imputed data on primary traumatic anterior shoulder dislocation patients diagnosed during 1 April 1997–31 March 2015 who may have suffered a re-dislocation in Clinical Practice Research Datalink-Hospital Episode Statistics, in England

	Complete-case analysis ($N = 2100$)								Multiply imputed data analysis ($N = 4613$)					
			Unadjusted			Adjusted model			Unadjusted			Adjusted model		
Variables	*n* (%)	Re-dislocations, *n* (%)	HR	95% CI	*p*-value	HR	95% CI	*p*-value	HR	95% CI	*p*-value	HR	95% CI	*p*-value
No surgery	1960 (93)	393 (20)	1.00			1.00			1.00			1.00		
Surgery	140 (7)	19 (14)	0.67	0.42 to 1.05	0.083	0.63	0.40 to 1.00	0.052	0.77	0.59 to 1.01	0.059	0.73	0.55 to 0.95	0.022
Calendar year of shoulder dislocation			1.00	0.98 to 1.02	0.833	1.00	0.98 to 1.03	0.816	1.00	0.99 to 1.02	0.845	1.00	0.98 to 1.01	0.952
Sex														
Male	1582 (75)	309 (20)	1.00			1.00			1.00			1.00		
Female	518 (25)	103 (20)	1.02	0.82 to 1.27	0.869	1.02	0.81 to 1.27	0.891	0.83	0.69 to 0.99	0.039	0.83	0.69 to 0.99	0.039
Age at shoulder dislocation (16- to 35-year-olds)			0.95	0.93 to 0.97	< 0.001	0.95	0.93 to 0.97	< 0.001	0.96	0.95 to 0.97	< 0.001	0.96	0.95 to 0.97	< 0.001
Epilepsy diagnosis?														
No	2005 (95)	383 (19)	1.00			1.00			1.00			1.00		
Yes	95 (5)	29 (31)	1.74	1.19 to 2.53	0.004	1.93	1.32 to 2.82	0.001	1.81	1.36 to 2.40	< 0.001	2.00	1.51 to 2.68	< 0.001

A washout period of 6 weeks following a first-time TASD has been applied for subsequent re-dislocations.
Follow-up is up to 3 years following a first-time TASD for non-surgical patients and up to 3 years following date of surgery for surgical patients.

Appendix 13 The effect of surgery within 12 months by stratified quintiles of the propensity score compared with non-surgical treatment on re-dislocations among primary traumatic anterior shoulder dislocation patients who were diagnosed during 1 April 1997–31 March 2015 in Clinical Practice Research Datalink-Hospital Episode Statistics, in England

Propensity score quintiles	HR	95% CI	*p*-value
Overall	1.17	0.88 to 1.55	0.260
1	0.58	0.24 to 1.42	0.233
2	1.11	0.61 to 2.01	0.735
3	0.73	0.32 to 1.67	0.458
4	1.39	0.80 to 2.42	0.247
5	2.07	1.23 to 3.46	0.006

Appendix 14 Characteristics of patients stratified by quintiles of the propensity score among those having surgery within 12 months compared with non-surgical treatment on re-dislocations among primary traumatic anterior shoulder dislocation patients who were diagnosed during 1 April 1997–31 March 2015 in Clinical Practice Research Datalink-Hospital Episode Statistics, in England

	Quintiles of the propensity score				
Characteristic	1	2	3	4	5
Year of shoulder dislocation, median (IQR)	2003 (2001–6)	2006 (2004–8)	2008 (2006–10)	2010 (2007–12)	2012 (2010–13)
Sex, *n* (%)					
Male	471 (68)	589 (85)	641 (92)	651 (94)	676 (97)
Female	225 (32)	107 (15)	55 (8)	44 (6)	19 (3)
Age at shoulder dislocation (years), median (IQR)	25 (20–30)	23 (20–29)	23 (19–27)	22 (19–26)	22 (19–26)
Drinking status, *n* (%)					
Yes	618 (89)	569 (82)	572 (82)	529 (76)	490 (71)
No	78 (11)	127 (18)	124 (18)	166 (24)	205 (30)
Epilepsy, *n* (%)	9 (1)	6 (1)	10 (1)	19 (3)	94 (14)

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