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

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Scientific summary

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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.

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