A DARFI Study
Into

Identifying the incidence of Distal RadioUlnar joInt Dislocations (**UK-DRUID)**

A UK National Collaborative retrospective multi-centre observational study

Study lead: Mr Joseph Fennelly & Mr Howard Stringer

Protocol Version: 1.0.0

Protocol Date: 26/06/2024

Table of Contents

Background

Study Management Group

Mr Joseph Fennelly, MBChB, MRCS, BSc (Hons)

Trauma & Orthopaedic Specialty Registrar, Liverpool University Hospitals.

Mr Howard Stringer, MBChB, MRCS, BSc (Hons).

Trauma & Orthopaedic Academic Fellow, Liverpool University Hospitals.

Mr Lysander Gourbault, MBBS, MRCS, MRes

Trauma & Orthopaedic Specialty Registrar, Southmead Hospital, Bristol

Dr Craig Wyatt, MBBS

Trauma & Orthopaedic Senior House Officer, Liverpool University Hospitals.

Mr Thomas Rogers

R&I Department, Liverpool University Hospitals.

Mr Daniel Brown (via the research fellow) will ensure that LUHFT's local research governance committee is regularly updated with the study's progress.

Final approval for new study sites to commence data collection and upload will be authorised by LUHFT's R&I once all site has issued confirmation of capacity and capability.

Scientific Advisory Group

Mr Daniel Brown FRCS (Eng) FRCS (Tr & Orth) MA (Clin Ed)

Consultant Orthopaedic Hand Surgeon, Liverpool University Hospitals.

Collaborative Partners

Collaborative sites and associated local PIs to be listed following expression of interest for involvement in study which can be initiated here: https://bit.ly/DARFI-EoI

Study Delivery Timeline

Advertisement of study: July and August 2024

Data collection window: 1st September 2024 – 31st August 2025

Analysis period: October – November 2025

Dissemination of results: December 2025

Executive Summary

Aim: The primary aim is to determine the incidence of Distal Radioulnar Joint (DRUJ) dislocations

Primary outcome measure: To assess the number of radiographically confirmed DRUJ dislocations presenting to UK hospital across a 12-month period

Secondary outcomes measure: The initial management of the DRUJ injury

Hospital eligibility: Any UK hospital with a Virtual Fracture Clinic (VFC) service

Inclusion Criteria: All patients sustaining a traumatic DRUJ dislocation

Team: Individual hospitals made up of **up to two junior doctor / allied healthcare professionals** and **one Consultant Project Supervisor**. Patients will be identified in VFC and data collected.

Validation: Diagnosis should be confirmed by the senior clinician assessing the images in VFC. Any uncertainty in diagnosis can be confirmed with local Musculoskeletal Radiologists or shared with the national steering committee for independent evaluation

About DARFI

The Database of Atypical and Rare Fractures and Injuries (DARFI) is a collaborative platform for the study of atypical and rare fractures and injuries on a national scale to better understand their epidemiology and improve their outcomes.

Introduction

Isolated distal radioulnar joint (DRUJ) dislocation is a relatively uncommon but potentially debilitating injury that can significantly impact upper limb function (Garrigues & Aldridge, 2007). Many cases of isolated DRUJ dislocation are identified late and delayed presentation often requires surgery (O'Malley et al., 2023; Paley D, 1986). The literature suggests dorsal dislocation is more common than volar, however, there is no convincing evidence base to support this.

DRUJ injuries are also seen alongside fractures, more commonly associated with the Galeazzi fracture pattern (Ciminero M, 2020; Xiao et al., 2021). There are also reports of DRUJ dislocation with associated ulna head and distal radius fracture (Samy D, 2023; Sonohata et al., 2012; Xiao et al., 2021).

Whilst there are many retrospective case reports and some small case series documenting the identification and management of such injuries, there are no complete large cohort studies. A number of systematic reviews of these series and studies have been identified, however, they comment on the incomplete nature of the data and subjective results (O'Malley et al., 2023). This makes it difficult to form convincing conclusions, or identify the relative incidence of volar and dorsal DRUJ dislocation with or without an associated fracture.

Study Aims

The aim of this study is to identify the UK incidence of DRUJ dislocation and its subtypes. Secondary outcome is to gain insight into the current practice of initial DRUJ management.

Methods

Study Design

An exploratory national multi-centre prospective observational study

Setting

All centres signing up require a named Consultant Project Supervisor and up to two Junior doctor / allied healthcare professional collaborators. All patients presenting to VFC, fracture clinic or on acute take with a DRUJ dislocation will be recorded.

Project Timeline

Advertisement of study: July and August 2024

Data collection window: 1st September 2024 – 31st August 2025

Analysis period: October – November 2025

Dissemination of results: December 2025

Inclusion Criteria

All participants will be adults (aged 16 and above) and have a diagnosis of a DRUJ dislocation, with or without associated fracture.

All participating centres must have a virtual fracture clinic.

Exclusion criteria

Patients that are excluded via the National Data opt-out scheme

Incomplete data

Children <16

Patient Identification

All patients will be identified prospectively at the point of presentation to VFC, fracture clinic or on acute take with a DRUJ dislocation will be recorded. Patients will not be added to the centralised database until a 28 day short-term outcome has been confirmed. The total number of patients and distal radius fractures presenting to each units VFC during the 12 months also needs to be collected and submitted.

Data Points

Patient demographics will be collected alongside direction of dislocation, associated fracture in either ulna or radius, other injuries, date and mechanism of injury and date of diagnosis of DRUJ dislocation. Data will be collected on the initial management of DRUJ injuries within 28 days of presentation. Collaborators in each participating trust will collect and record data anonymously.

Follow Up

Patients will only be added to the centralised database once a 28-day short-term outcome period has passed. There will not be any long-term follow up of these patients.

Using the patient cohort identified, we may develop a secondary study specifically looking into the treatment and outcomes for the management of these patients.

End of Study

End of study will be defined as data collected by 31st July 2025.

Data Collection and Storage

Data will be collected using an encrypted, password protected Excel spreadsheet and stored on REDCap in line with DARFI's SOP. No patient identifiable data will be gathered centrally. All data will be handled in accordance with the Data Protection

Act 1998. The data will be held by Liverpool University Hospitals Foundation Trust (LUHFT) which will act as the data controller.

Statistical Analysis Plan

The study will use convenience sampling since the national incidence of this injury remains unclear. The statistical analysis plan for this study involves conducting descriptive analyses to summarise the characteristics of patients with DRUJ dislocations, calculating incidence rates of DRUJ dislocation overall and stratified by age, gender, and hospital site, comparing incidence rates by direction of dislocation and associated fractures.

Local Governance and Ethical Approval

Agreements are in place between Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department and participating organisations, covering all associated DARFI studies.

Ethical approval for DARFI was obtained on 1st February 2024 from the NHS HRA South West - Central Bristol Research Ethics Committee (REC reference: 24/SW/0015, IRAS ID: 331288), covering all associated DARFI approved sub-studies. Permission is given via REC approval to collect this data retrospectively without individual patient consent.

Indemnity for this study is via the NHSLA.

Quality Assurance

Design:

UK-DRUID is a retrospectively reported national multi-centre observational study. This allows for identification of all DRUJ dislocation through VFC and subsequent collection, allowing for capture of a comprehensive dataset.

Any DRUJ dislocation which are reported at local hospitals are to be confirmed by lead consultant, and in the case of any ambiguity to be confirmed by local

musculoskeletal radiologist or shared with the national steering committee for independent evaluation.

Systematic reviews have been completed reviewing the types and direction of DRUJ dislocation. This has allowed identification of key data points for inclusion.

Data completeness:

To ensure completeness, participating centres are required to have a named Consultant Project Supervisor and one junior doctor / allied healthcare professional for patient identification and data collection. Patients presenting with DRUJ dislocation are recorded at point of presentation to VFC, fracture clinic or acute care settings. Further to this, a 28-day short-term outcome confirmation period is implemented before submitting patients to the centralised database, ensuring all relevant data are captured before inclusion.

Validation:

Diagnosis confirmation is performed by a Consultant Trauma & Orthopaedic Surgeon assessing images in VFC, with the option to consult local musculoskeletal radiologists or the national steering committee for independent evaluation in cases of diagnostic uncertainty. This validation process aims to minimise errors in diagnosis and data entry.

Authorship and Mini-teams

The Consultant Project Supervisor should be a substantive consultant in Trauma and Orthopaedics that can support collaborators in the local set up of the project and in identifying DRUJ dislocations. It is expected that sites will require up to two additional collaborators (junior doctor or allied healthcare professional) who will set up the identification of patients at their hospital VFC and clinics through the use of local department advertisement and information sharing. When a patient is identified, the collaborator will record the required data on the data collection sheet.

Collaborators will be issued with a confirmatory certificate after close of project as evidence for their portfolio. All collaborators that have met the required rules of engagement will be eligible for collaborative authorship. The final manuscript(s) will be published with headline authorship for the writeup group followed by all individual collaborators named and PubMed indexed under a single collaborative author, “The DRUID Collaborative”. Collaborator roles will additionally be listed in the appendix. This will ensure all collaborators will be able to demonstrate evidence for their part in the study and will be PubMed citable. This is in keeping with the current guidelines on standardising authorship in collaborative research.
(NationalResearchCollaborative, 2018)

Patient and Public Involvement

Patient and public involvement was undertaken throughout all stages of the design, development, and delivery of DARFI.

Expected Outputs

This study will help identify the national incidence of DRUJ dislocation, through creating the largest database of DRUJ dislocations. This will allow the formation of more robust conclusions to help guide management of these patients. The results of this research will provide valuable insight into the incidence of DRUJ dislocations, including associated injuries and their early management, clarifying gaps in current knowledge regarding DRUJ injuries.

Overall results will be shared with each participating unit. It is intended that the findings of this project will be submitted to a peer-review journal and presented at meetings to disseminate the findings of this project at a national and international level.

Acknowledgements

We thank the **Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department** for kindly hosting DARFI on their REDCap servers.

Website: https://www.liverpoolft.nhs.uk/about-us/research

References

Ciminero M, Y. N., Garofolo-Gonzalez G, Choueka J. (2020). Isolated Distal Ulna Fracture With Distal Radioulnar Joint Dislocation: A Novel Fracture Pattern. . *Hand (N Y). 15*(4), 57-62. https://doi.org/10.1177/1558944719856116

Garrigues, G. E., & Aldridge, J. M., 3rd. (2007). Acute irreducible distal radioulnar joint dislocation. A case report. *J Bone Joint Surg Am*, *89*(7), 1594-1597. https://doi.org/10.2106/JBJS.F.01566

NationalResearchCollaborative. (2018). Recognising contributions to work in research collaboratives: Guidelines for standardising reporting of authorship in collaborative research. *Int J Surg*, *52*, 355-360. https://doi.org/10.1016/j.ijsu.2017.12.019

O'Malley, O., Brown, O. C., Duncan, L., Cheung, G., Stevenson, H. L., & Brown, D. J. (2023). Isolated volar dislocation of the distal radioulnar joint: a case series and systematic review. *Ann R Coll Surg Engl*, *105*(3), 196-202. https://doi.org/10.1308/rcsann.2022.0023

Paley D, R. J., McMurtry RY. (1986). Irreducible dislocation of distal radial ulnar joint. *Orthop Rev*, *15*(4), 228-231.

Samy D, J. H., Pe E, Brown D. (2023). Ulnar Head Fracture with Volar Dislocation of the Distal Radioulnar Joint: A Case Series and Systematic Review. *Journal of Wrist Surgery*. https://doi.org/10.1055/s-0043-1777019

Sonohata, M., Mine, H., Tsuruta, T., & Mawatari, M. (2012). Traumatic volar dislocation of the distal ulna with a fracture of the ulnar styloid. *Hand Surg*, *17*(3), 383-386. https://doi.org/10.1142/S0218810412720379

Xiao, A. X., Graf, A. R., Dawes, A., Daley, C., Wagner, E. R., & Gottschalk, M. B. (2021). Management of Acute Distal Radioulnar Joint Instability Following a Distal Radius Fracture: A Systematic Review and Meta-Analysis. *J Hand Surg Glob Online*, *3*(3), 133-138. https://doi.org/10.1016/j.jhsg.2021.02.005