Author’s response to reviews

Title: A prospective, observational cohort study of patients presenting to an Emergency Department with acute shoulder trauma: The Manchester Emergency Shoulder (MeSH) project

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A prospective, observational cohort study of patients presenting to an Emergency Department with acute shoulder trauma: The Manchester Emergency Shoulder (MeSH) project.

RESPONSES TO REVIEWERS:

Robert J. Neviaser (Reviewer 1): While I agree that there are a significant number of shoulder injuries that cannot be seen on routine x-ray, the sample size of 20 patients is too small to draw any conclusion. If this unit sees over 900 patients a year with shoulder injuries and 67% of those are soft tissue, it seems strange that they would select only 20, even prospectively, for inclusion.

RESPONSE: The sample size was dictated by the funding available for Gadolinium enhanced MRAs conducted in the adjacent research facility scanner. Due to the higher costs of MRA for research purposes in our country, funding was available for about 20 participants.
Rotator cuff tears are seen in patients over the age 50, with a few over the age of 40. In the current color, only 7 patients are over age 50, 5 are between 40 and 50, and 8 are under age 40. Their youngest patient is age 20 and was alleged to have a partial rotator cuff tear on MRA. I have treated over 10,000 patients with rotator cuff tears and have never seen a patient with even a partial tear at age 20. MRA tends to distort soft tissue findings and most shoulder surgeons on this side of the pond use MRI without contrast because it is less distorting and more accurate, despite what the Cochrane base states.

RESPONSE: We agree that a degenerative cuff tear is unlikely in a 20 year old. But this patient suffered severe trauma on an outstretched shoulder playing rugby which in this case led to a partial tear of the cuff. We have attached the MRA report for this individual from Professor Charles Hutchinson for your consideration.

The MRA with contrast is not necessarily distorting nor more accurate, rather it is just different. There will always an argument about MRAs versus orthopaedic direct visualisation. Did the radiologists overcall the imaging diagnosis or did the surgeons not see it? Actually, without autopsy it cannot be answered and is probably not relevant to the fact. Contrast agents will not affect the bone marrow signal changes that we saw. However, whilst it is thought that full and partial thickness tears are better visualised on contrast MRA, in the routine clinical practice they are not routine. They were costed for this study so we might have the gold standard diagnosis and be able to diagnose small glenoid labral lesions, or small capsule tears.

In the cases where the occult, undisplaced fracture of the greater tuberosity was seen on x-ray at 2 weeks, an MRI is unnecessary and expensive in this country where we do not have a national health service.

RESPONSE: The intention of this study was not to investigate (or recommend) that a MRA should become routine clinical practice for all shoulder trauma and to help diagnose occult fractures not visible on plain film. Its aim was to have a gold standard measure from which a firm diagnosis of all structural abnormalities could be made. This scan was performed 2 weeks after the initial X-ray (which had no abnormal findings). The finding of an occult fracture on MRA was unexpected, and as such was actually quite informative. But the primary purpose of the Gadolinium enhanced MRAs was to evaluate soft tissue injury.
I do think that this project might produce some useful information if it changed focus. If limited to patients over age 50 and directed toward assessing the incidence of traumatic rotator cuff tears in a large number of patients, it would provide useful documentation of what that incidence is.

RESPONSE: Changing the focus of this study would be unhelpful at this stage. It was designed to answer a certain research question and to test the feasibility of formulating a future clinical decision rules study. We decided to take ALL those who presented to ED, hence our decision to take a consecutive presentation of patients which would eliminate selection bias. Although the suggestion to limit the results to those over 50 years has merit, our study would have n=5. The reviewer has already commented that the sample size on n=20 was too small. We believe that the age range is, in itself, informative as it reflects real life clinical practice from a truly consecutive cohort of patients.

In the present form I do not feel that it helps define much except that soft tissue injuries do occur. That is not new.

RESPONSE: We feel that this study reflects real life clinical practice. The idea of the project is to develop an emergency shoulder rules. This feasibility study has paved the way for a future predictive rules study in which all ED staff disciplines can apply one simple physical test to predict the likelihood of the patient having a potentially serious soft tissue injury to the shoulder.

Marcel Émond (Reviewer 2):

The authors address the important topic of "what is underneath that shoulder strain diagnosis in ED?" This is a pilot study assessing the capacity of MRA to diagnose significant soft tissue injuries and alter traditional care.

Significant question/suggestion to be address by authors:
The enrollment of the subject is consecutive, convenient. In the Methods section, the authors should detail the subject selection process. The authors mentioned that their EP treat about 600 soft tissue injuries to the shoulder. How was their cohort selected. How do they compared to the missed? If this pilot study only selected the sicker, the results may look "more significant".

RESPONSE: Thank you for allowing us to make this clearer. We have adjusted the manuscript accordingly (Lines 41-44) to describe the selection process better. In essence this was a snap shot of the patients seen at the ED over the period of time for which funding for the gadolinium enhanced MR arthrograms was available. The patients were selected in a true consecutive method from those who presented to ED with a painful shoulder as a direct result of trauma. The only exclusion criteria were a fracture, dislocation or patients who at presentation in ED could already actively abduct the shoulder above 90 deg.

We made a clinical decision which patients had ‘significant’ injury based, in part, on the clinical recovery of patients at 2 weeks. As the flow chart shows (and lines 75-76), 4 patients had made sufficient improvement to satisfy the examining clinician that they were recovering sufficiently not to have significant soft tissue injury. We agree that it is possible that some patients might have’ slipped through the net’ (i.e. have a significant injury on MRA and yet be functioning well) but the limited funding for our study meant that we had to make pragmatic decisions based on our clinical expertise to judge the likelihood of MRA detected injury.

Please explain the rationale for the 2 weeks follow-up. Is this a standard of care. Most shoulder injuries we see at our institution will be f/up by a GP after ED discharge.

RESPONSE: Our ED has a shoulder review clinic. We calculated that a review at 2 weeks would give us the best chance of distinguishing clinically those who would be spontaneously resolving and likely to have a relatively less significant injury from those who were likely to have a more significant soft tissue injury. Previously, (prior to setting up our review clinic) all patients with shoulder trauma had been discharged from our ED directly to their GP.

The authors should define apriori the significance of the outcome.

The actual main outcome is broad. Could "significant lesions" be described and categorized.
RESPONSE: Thank you for pointing this out. There is now new text (lines 70-72) describing and categorising more fully a priori the lesions which we might expect on MRA.

Shoulder surgery is an important outcome in this study: how was the decision made? Was this a surgeon-based decision or a criteria based decision? If decision was based on well-defined criteria can the authors provide them.

RESPONSE: Thank you for allowing us to clarify this. The decision to proceed to surgical repair was purely a surgeon based decision. There were no a priori criteria made (Line 85).

Table 2 should probably be transform in Figures. Difficult and heavy to read as it stands.

RESPONSE: We agree that table 2 is heavy in detail, but this seems the best way to provide the reader with a full description of each injury mechanism and the Imaging diagnosis. We are not certain if this essential detail could be adequately replicated in a set of figures. We would be happy to discuss this further.

>Minor corrections:

>Page 3 line 3 remove a ":" 

RESPONSE: Corrected