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Effect of a cervical collar on head and neck acceleration profiles during emergency spinal immobilisation and extrication procedures in elite football (soccer) players: protocol for a randomised, controlled cross-over trial

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ABSTRACT

When immobilisation after a cervical spine or head injury is required, the role of the rigid cervical collar is unclear and controversial. There is a need for further studies investigating the use of a rigid cervical collar when head and neck trauma occurs in sport. This study will compare present practice (immobilisation with a cervical collar) to the same procedure without a collar during a simulated spinal immobilisation and extraction scenario from the field of play to the side-line in football (soccer). It will use a prospective cohort within-subjects cross over randomised, controlled trial design. Healthy participants will assume the role of players with a head or neck injury. Clinical practitioners will perform the immobilisation and extrication procedure according to current clinical guidelines. Three dimensional linear and angular acceleration profiles of the head and torso will be measured and the time taken to complete the procedure. The interventions will be a 'cervical collar' or 'no collar' in random order. Data from the IMUs will be transferred wirelessly to a computer for analysis. Accordingly, within-subject differences between each condition (collar vs no collar) will be assessed with parametric or non-parametric inferential statistics. Statistical significance will be set at $p<0.05$.

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Key messages

What is already known?

- A rigid collar is used to restrict head and neck movement immediately after application during an immobilisation and extrication procedure from the sports field of play to the side-line.

What are the new findings?

- Provide knowledge whether any stabilising effect of a collar is maintained throughout this procedure in sport.
- Provide information if the immobilisation procedure without the collar provides sufficient head and neck motion restriction.
- This study will have high clinical relevance in elite sport in the UK. The clinical practitioners who have appropriate qualifications in the Football Association Level 5 Advanced Trauma and Medical Management in Football course will conduct this study.

INTRODUCTION

Major traumatic cervical spine injuries in sport are rare. Still, they can have potentially devastating sequelae, such as spinal cord injury (SCI) with associated neurological impairment and premature mortality.[1 2] If a destabilising cervical injury is suspected, the whole spine should be immobilised using external supporting devices[3] to reduce the likelihood of further or secondary SCI injury due to hypoperfusion and hypoxia.[1] Consequently, it is vitally important that practitioners involved in training and match day medical care are familiar with the appropriate acute management of cervical trauma.

The most effective methods of spinal immobilisation are unclear,[4] but they typically include transfer and stabilisation of patients along a spinal board or an orthopaedic split device stretcher, as well as the selective application of a rigid cervical collar and head blocks and tape or straps.[3] The use of rigid collars is said to independently safeguard the cervical spine from adverse motion to a limited extent,[5] so are recommended in many prehospital care guidelines[1 2 5–7] and the Football Association (FA) Level 5 Advanced Trauma and Medical Management

in Football (ATMMiF) course in the UK.[8] Despite this widespread use, recent Danish guidelines suggest that the use of collars should be avoided altogether, although this recommendation is based on weak evidence.[9] This reflects the consensus statement from the faculty of prehospital care highlighting the growing concerns of using these devices.[3] These differing approaches may be because few studies support the beneficial effects of rigid collars on neurological and survival outcomes, compared with the mounting evidence of adverse effects,[9] such as airway compromise, increased intracranial pressure and patient distress.[5] However, the lack of high-quality evidence has made it difficult to establish the independent efficacy of rigid cervical collars as part of the immobilisation procedure.[5 9]

The effects of rigid collars on cervical motion during immobilisation have been investigated with other devices such as spinal boards[10–12] or head blocks.[13] Crucially, these studies evaluated motion immediately after collar application, rather than over the whole immobilisation and extrication procedure, so it is unknown whether any stabilising effect of rigid collars is maintained throughout the whole process.

With three-dimensional motion analysis, Dixon *et al*[14 15] showed that immobilisation with a rigid collar and long spinal board resulted in greater cervical movement than a participant self-extricating without a collar. Their studies used simulated road traffic collisions with healthy adults. In the context of sport and specifically football in the UK, there is a need for studies that simulate head and neck trauma management scenarios encountered and the immobilisation extrication methods taught in advanced trauma and life support courses such as ATMMiF.

Therefore, in this study, we will use inertial measurement units (IMUs) to measure three dimensional linear and angular acceleration profiles of the head and torso of healthy, uninjured conscious players during a simulated spinal immobilisation and extraction scenario from the football (soccer) field of play to the sideline. We will strictly follow the stipulations and protocols taught in ATMMiF courses. We will compare the variability of movement acceleration during these procedures with and without a rigid cervical collar in situ.

Study hypothesis

The study hypothesis is that a cervical collar used as part of a spinal immobilisation and extrication technique on conscious, healthy players from the field of play to the side-line will reduce head acceleration movements compared with the same procedure without the collar.

Aim and objectives

First, to measure three dimensional linear and angular acceleration profiles of the head and torso during a spinal immobilisation and extraction procedure from a soccer field of play to the sideline.

Second, to compare the head and neck profiles with and without a rigid cervical collar.

METHODS

Design

The Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines for a randomised controlled trial were followed for this protocol.[16] A prospective cohort, within-subjects cross over design will be used to compare present practice (immobilisation with a cervical collar) to the same procedure without a collar. The collar versus no-collar order will be randomised using the Research Randomizer online tool (www.randomizer.com). Due to the nature of the intervention, neither the clinical team nor the participants will be blinded to the allocation. However, the person performing the data analysis will be blinded to the allocation.

Population and setting

The study will take place at an indoor elite training facility at an English Premier League Football Club. Every clinician performing the procedure will be FA ATMMiF level 5 trained, including a senior FA tutor on the ATMMiF course (JD). All are full-time members of the club's medical staff. Participants acting in the simulated role of an injured player will be a convenience sample from a cohort of healthy elite football players under contract at the same English Premier League Football Club. The participants' age range will be ≥18 years and ≤23 years. Any player currently being treated for a head or neck injury, ongoing cervical pain, or radiculopathy will be excluded.

Equipment

Two wireless eight channel Delsys Trigno Avanti IMUs will be applied (27×37×13 mm; mass 14 g—Delsys, Natick, Massachusetts, USA). Each device has a nine-axis inertial measurement capability which captures acceleration, rotation and magnetic field information. The IMUs have integrated triaxial accelerometers (±2 g), so maximum acceleration peaks will be extracted for the collar and no collar conditions. The acceleration data has a recording span of between 2 g and 16 g; we will record at 16 g. The sensor sampling rate is 1000 Hz. Separate investigations have demonstrated the reliability of the IMU sensor-based system on the spine with intraclass correlation coefficient ranges of 0.93–0.96[17] and 0.94–0.97.[18]

A Laerdal Stifneck Select Cervical collar (Laerdal Medical, Stavanger, Norway) will be used to immobilise the neck and head. A Ferno scoop 65 EXL stretcher with head blocks (Ferno, Bradford, UK) will be the split device to lay the participant supine. Spider-strap immobilisation body straps (Emergency Products and Research, Kent, USA) will be used to provide constraint and support for the participant on the stretcher. A Bound Tree Head Immobiliser (blocks and straps) (Bound Tree Medical Europe, Telford, UK) will be used to provide support to the head and neck on the split device stretcher. A Model 71 Series basket stretcher (Ferno, Bradford, UK) will be

used as the final vehicle to extract the participant from the field of play.

Measurement parameters

The primary outcome will be the head and torso's three dimensional linear and angular acceleration profiles during each task. The secondary outcome will compare the time taken to complete each procedure with and without a cervical collar.

Procedure

Test sessions will be performed for 21 days. Participants will act as their controls. Each participant (assuming the role of an injured player) will adopt a supine lying position on artificial turf. The standard cervical spine immobilisation procedure will be applied to each participant with the two conditions —'cervical collar' and 'no cervical collar' applied in a randomised order. The immobilisation procedure used will be according to the level 5 FA ATMMiF procedure.[8] Consistent with the current approach of minimal handling, we will use a split device primarily designed to minimise the amount of movement required to place a player onto a spinal immobilisation device. Its use eliminates the need for a 'logroll' manoeuvre (if the player is already supine), significantly decreasing movement of the spine and theoretically reducing the risk of further iatrogenic injury. Clinical practitioners will form the immobilisation and extrication team. To ensure standardisation, the same team members will be used throughout the study for all participants' immobilisation and extraction procedures, and their roles within the procedure will be consistent. The full procedure for each participant will be approximately 15 min (approximately 5 min to position the IMUs; approximately 5 min of the procedure, and approximately 5 min with data saving, repositioning of equipment, participants and practitioners). The approximate timings have been established from regular in-service training practice scenarios among the medical staff, ensuring familiarisation with the extrication equipment and procedure.

The trial procedure will commence with one IMU attached to the top of the participant's head at the most proximal location (between the parietal bones). It will be firmly attached to a skull cap (swimming cap) using double-sided adhesive tape. This is to ensure that the sensor is not disturbed by the movement of the hair on the head and thus will allow a rigid placement for measurement. The second IMU will be attached to the skin over the centre of the sternum using double-sided tape; chest hair shaving will be done if needed to ensure IMU fixation.

Once the IMUs have been secured in position, the immobilisation and extraction procedure will be divided into 11 stages to facilitate the analysis and ensure a consistent protocol throughout and will be as follows:

1. Manual In-Line Stabilisation (MILS) will be applied by one practitioner kneeling behind the participant's head and with one hand on each side of the head. This will be in place during the procedure until stage 7 is complete.
2. A cervical collar will be measured using a line from the trapezius extending anteriorly and transecting the chin; the collar will be sized accordingly. The collar will be fitted by sliding the rear portion of the collar under the neck and fastening the front portion of the collar under and around the chin. The collar will be tightened using the velcro strap. Correct parallel and central fitting will be observed. Opening and closing the player's mouth will also be assessed with the collar in situ to maintain the simulation. This is required in a real trauma situation so that an airway adjunct can be used if required.
3. The participant will be tilted 15° to the left using the ATMMiF minimal handling technique. The clinical practitioners will adopt positions on the participant's right at the chest, hips and legs using the 3 over and 3 underhand positions. This will allow the split device stretcher to be slid underneath the participant's right side, who will then be returned to supine.
4. Participants will be tilted 15° to the right. The clinical practitioners will adopt positions on the right of the participant's at the chest, hips and legs using the 3 over 3 underhand positions. This will allow the split device stretcher to be slid underneath the participant's left side and locked in place with the right side of the split device stretcher before being returned to supine.
5. The Spider body straps will be applied to secure the participant to the split device stretcher.
6. Foam blocks to the left and right side of the participant's head will be applied with two practitioners co-ordinating hand positions to ensure MILS is maintained.
7. Chin and forehead straps will be applied with equal pressure by one practitioner to secure the participant's head to the blocks; MILS will then be released.
8. The immobilised participant attached to the split device stretcher will be elevated to 1 m above the pitch by the practitioners to enable a basket stretcher to be slid underneath. The split device stretcher will then be lowered into the basket stretcher.
9. The basket stretcher will be lifted by the practitioners, who will walk off the field carrying the basket stretcher to a distance of 10 m.
10. The basket stretcher will be lowered to the ground.
11. The basket stretcher will be tilted 90^0 to the right side and returned to supine to simulate the airway clearing procedure in response to a participant vomiting.

After stage 11, the procedure will end. Note that stage 2 of the above procedure will be omitted when the participant is randomised to the 'no collar' condition.

Sample size

Acceleration data from McDonald *et al*[19] analysed peak head-neck kinematics during individual phases of pre-hospital care in patients receiving spinal precautions from the scene of an accident with a suspected spine injury. This study allowed us to perform a sample size calculation using acceleration data. With a mean of 2.8 m/s^2 (95% CI 10.6=1 SD±3.42), a within-subjects effect size of 0.5, with power set at 0.8 (the probability of a type-II error) and an alpha level of 0.05 (the probability of a type-I error) the sample size would be n=15. We anticipate no study attrition as all participants act as their own controls and attend the elite training facility daily as part of their playing contract.

Data capture

Delsys IPA data will be transferred wirelessly, saved to a computer and retrospectively processed with a two-tap averaging filter by the same researcher (RKJ) in Matlab (Matlab, R2016A, MathWorks, Natrick, Massachusetts, USA) using custom-written code. Data will be checked for artefacts due to loss of skin contact from the sensors. Any substantial loss of data from a procedure will require a repeat of the procedure.

Statistical methods and analyses

Data will be tested for normal distribution. We will use the software to time stamp the stages listed above to assess if head acceleration movement occurs more in one stage than another. We will also analyse the time to complete each scenario to compare with and without fitting a cervical collar. Values for point measures and measures of variability will be presented and analysed. Within-subject differences between each condition (collar vs no collar) will be appropriately assessed with parametric or non-parametric inferential statistics. Statistical significance will be set at $p<0.05$. Statistical analysis will be completed within STATA V.16.1 (StataCorp).

DISCUSSION

A debate currently exists regarding using a rigid cervical collar as part of the immobilisation and extrication process following cervical spine injury. This novel study, the first to examine this part of the full spinal immobilisation and extrication procedure in professional football (soccer), will be undertaken by clinical practitioners who have an appropriate qualification in ATMMiF from The English FA. The findings of this study will help determine if adding a cervical collar to the immobilisation and extrication technique provides more cervical stability to conscious players being disengaged from the field of play to the sideline, which has relevance to football in particular and sport in general.

Dissemination

Regardless of negative or positive outcomes, findings will be published in a peer-reviewed journal and presented at scientific conferences. Our findings will be disseminated and communicate results to medical and academic staff internal and external to the club and the key stakeholders delivering ATMMiF or equivalent sports trauma management courses. These approaches will include utilising social media platforms, podcasts and the presentation and publication of the results as stated above.

Twitter Tom Hughes @dt_hughes and Daniel Torpey @dantorps

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study has been approved by the Research Ethics service at the University of Salford (reference number 1403). Once the study has commenced, any amendments to the protocol will be communicated in the first instance to the ethics committee and then amended on the clinical trials registry. Informed consent will be required in written form from all participants. If there are any important protocol modifications (eg, changes to eligibility criteria, outcomes, or analyses), we will communicate these to the Research Ethics Service and seek an appropriate amendment. All data will be made anonymous by using a unique study identifier code. However, any information we collect that may identify players will remain confidential, which will be maintained at all times. Access to raw data will be restricted to those directly involved in the administration of the project. This is expected to be limited to the principal investigator (MC) and those who will be processing the data (RKJ) and performing data analysis (RKJ and TH). The football club grants permission to use any data acquired for this study.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data sharing not applicable as no datasets generated or analysed for the protocol. An anonymised summary of the dataset to be analysed during this study may be available from the corresponding author on reasonable request.

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