ISRCTN Trial registration details

Public title:

Does a neck collar keep the head and neck still when carrying an injured football player off the pitch on a stretcher?

Scientific title:

The effect of a cervical collar on head and neck movement during emergency spinal immobilisation and extrication procedures in elite football (soccer) players.

Acronym: The Range of movement Evaluation using Stabilisation Techniques during extrication In Cervical Trauma (**RESTRICT**) study

Study Hypothesis: a cervical hard collar used as part of a spinal immobilisation and extrication procedure will show a reduction in head and neck movement measures compared to the same procedure without a collar.

Ethics Approval: sought from University of Salford

Study design: within subjects random order design

Primary study design: interventional

Secondary study design: random ordered design

Trial setting: a training facility at an elite football club in the English Premier League.

Trial type: treatment

Patient information sheet: available on request using PI contact details

Condition: healthy participants simulating acute neck injury requiring cervical immobilisation and extraction from the field of play.

Intervention: each participant (assuming the role of an injured player) will adopt a supine lying position on artificial turf and a standardised immobilisation and extraction procedure will be applied. This will be divided into 12 components to facilitate the analysis and ensure a consistent protocol throughout.

1. Manual In Line stabilisation (MILS) will be applied
2. A cervical collar will be measured and fitted
3. Participant will be log-rolled 15^0 to the left to allow a split scoop device to be slid underneath the right side of the participant, who will then be returned to supine
4. Participant will be log-rolled 15^0 to the right to allow a split scoop device to be slid underneath the left side of the participant who will then be returned to supine
5. Body straps will be applied

6. Head blocks will be applied

7. Chin and forehead straps will be applied

8. The immobilised participant will be lifted by 5 practitioners into a basket stretcher.

9. The stretcher will be lifted and walked off the field a distance of 10 metres

10. The stretcher will be lowered to the ground.

11. The stretcher will be tilted to the right side 90^0 and returned to supine to simulate the airway clearing procedure should vomiting occur while the athlete is immobilised.

12. The test will finish

The procedure will take approximately 15 minutes for each condition for each participant (total time 30 minutes). Participants will act as their own controls. Each will receive in a random order a 'cervical collar' or 'no collar' as part of the simulated exercise. Therefore stage 2 of the above procedure will be omitted when the participant is randomised to the 'no collar' condition. Measures of head and neck movement will be taken during the procedure using sensors placed on the head and chest.

Primary Outcome Measure: The difference in head and neck movement with and without the use of a hard collar. Outcomes will be taken during the entire procedure and will include 3 dimensional movement of head and neck in flexion, extension, rotation, side flexion, yaw, pitch and tilt and acceleration.

Secondary Outcome Measures: nil

Overall trial start date: April 2021

Overall trial end date: August 2021

Eligibility: elite football players under contract at an English Premier League Football Club.

Participant type: Healthy

Age group: Adult age range will be > 18 years

Gender: male

Target number: 34

Final enrolment number: 34

Exclusion criteria: Any player who is being treated for a head or neck injury or ongoing cervical pain or radiculopathy.

Recruitment start date: April 2021

Country: United Kingdom of Great Britain & Northern Ireland.

Sponsor Organisation: University of Salford

Sponsor details:

Sponsor type; University

Funders: Internally University and private sector football club

Dessemination Plan: 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 (MJC) and those who will be processing the data (RKJ) and performing data analysis (TH). Regardless of negative or positive outcomes, findings will be published in peer-review journals and presented at scientific conferences. We will use several approaches for dissemination of the

results including social media platforms and podcasts). These will be used to disseminate and communicate results to medical staff within the football club, to other medical staff and also to the key stakeholders delivering the advanced trauma and management in football (ATMMiF) courses.

PLAIN ENGLISH SUMMARY:

In sport, a severe neck injury is rare but potentially very serious. Many sporting bodies provide mandatory emergency care training for medical staff, which includes how to assess and safely remove an athlete with a suspected neck injury from the field of play with either minimum head and neck movement or no movement at all. This widely accepted procedure to keep the neck still includes fitting a neck collar, but it is debatable whether the collar is necessary to provide sufficient head and neck support. Indeed, it has been suggested that fitting a collar to an injured player may result in an undesirable increase head and neck movement. This study will see whether there is any difference in head and neck movement from using a collar or not, when a player is removed from the field of play using a standard immobilization procedure. The results from this study will inform clinical practice in this important area of athlete care.

Strengths and Limitations

Strengths:

First study to quantify the in-vivo effects of an immobilisations and extrication procedure in football (soccer). It follows standardised ATMMiF procedures as part of the FA medial regulations and will be generalisable to the RFU and RFL.

All clinical practitioners were qualified through ATMMiF to undertake the procedure.

Limitations: All participants are healthy without spinal injury. Therefore the constraints and added difficulties of dealing with an injured player cannot be accounted for in this study.

The study will place in an indoor facility and although environmental factors are standardised these are often unpredictable in a real live match environment.

PROTOCOL

The effect of a cervical collar on head and neck movement during emergency spinal immobilisation and extrication procedures in elite football (soccer) players: The RESTRICT study

BACKGROUND

Major traumatic cervical spine injuries in sport are rare, but 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 onto a long spinal board or orthopaedic scoop 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 are said to safeguard the cervical spine from adverse motion[1] and are recommended in many pre-hospital care guidelines [1 2 5-7] and Level 5 Advanced Trauma and Medical Management in Football (ATMMiF) in the UK.[8]

Despite this widespread use, recent Danish guidelines present weak evidence that the use of collars should be avoided altogether.[9] This reflects the consensus statement from the Faculty of Pre-Hospital Care highlighting the growing concerns of using these devices.[3] The lack of high quality evidence has made it difficult to establish the efficacy of rigid cervical collars as part of

the immobilisation procedure.[7 9] Few studies support their beneficial effects on neurological and survival outcomes, compared to the mounting evidence of adverse effects,[9] such as airway compromise, increased intracranial pressure and patient distress.[7]

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

This has been addressed by only two studies, both of which used simulated road traffic collisions (RTCs) using healthy adults. 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 compared to a participant self-extricating without a collar. However, these data are RTC-specific, so there is a clear need for studies that simulate head and neck trauma management scenarios that are encountered in sport.

Therefore in this study we will use inertial measurement units (IMUs) and motion capture techniques to measure head and neck movements during a simulated spinal immobilisation and extraction scenario from the soccer field of play. We will compare the variability of movements during these procedures with and without a rigid cervical collar in situ. The study hypothesis will be that a cervical collar used as part of a spine immobilisation protocol will reduce cervical movements compared to the same procedure without the collar.

Aim and Objectives

To measure head and neck movements during a spinal immobilisation and extraction procedure from a soccer field of play.

To compare the head and neck movements during the procedure with and without a rigid cervical collar.

To provide guidance and recommendations about the usefulness of a cervical collar during this procedure.

METHODS

Design

A prospective cohort within subjects design will be used to compare present practice (immobilisation with a cervical collar) to the same procedure without a collar. The order of collar *versus* no collar will be randomised.

Sample Size.

G* Power v 3.1.9.6 for MacOS [16] was used to calculate the sample size with data from the study by Dixon et al[15] comparing collar versus no collar in a vehicular extraction procedure. We anticipate a mean difference of 1.6^0 with an expected population SD of difference of 2.1^0, 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). For a within subjects study we will invite 34 healthy subjects to participate. We anticipate no study attrition as all participants are acting as their own controls, and attend the elite training facility daily.

Population and setting

All the practitioners performing the procedure will be ATMMiF level 5 trained. The lead practitioner during the procedure is a senior FA tutor on the ATMMiF course. All practitioners are all full time members of the medical staff working at the elite training facility at an English Premier League Football Club. Participants acting in the simulated role of an injury player will be a convenience sample selected from a cohort of 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 who is currently being treated for a head or neck injury or ongoing cervical pain or radiculopathy will be excluded. The football club grants permission to use these data. The study has an application submitted to the Research Ethics service at University of Salford.

Equipment

The following equipment will be used during the procedure:

Inertial Measurement Units (IMUs). A Wireless 8 channel Delsys Trigno EMG unit (Delsys Inc, Natick, Massachusetts, USA) will be utilised. This device has 9 axis inertial measurement capability allowing acceleration, rotation and magnetic field information. The acceleration data has a span of +- 2g to +-16g.

A three camera motion analysis system (Qualisys OQUS 300) will be used to collect three-dimensional range of motion of markers placed on the head and torso of the individual.

Laerdal Stifneck Select Cervical collar (Laerdal Medical, Stavanger, Norway) will be used to immobilise the neck and head.

Ferno Scoop 65 EXL stretcher with head blocks (Ferno, Bradford, UK) will be used to lie the participant on.

Spider-strap immobilization body straps (Emergency Products and Research, Kent, USA) will be used to provide constraint and support for the participant on the stretcher.

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 stretcher.

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

Movement of the head will be measured in two ways: a) The Delsys IMUs will be utilised to recorded three dimensional acceleration profiles of the head and torso during the movements. The IMUs which have integrated triaxial accelerometers (+-2g), maximum acceleration peaks will be extracted for the collar and no collar conditions; b) The three-dimensional motion capture system (consisting of three markers per cluster) on the sternum and head, will collect positional data of the participant. The relative angle between the head and the torso will be calculated and the maximum angle between these two segments reported as the primary outcome. As well as calculating range of motion, the acceleration of these markers during the task will also allow quantification of the maximal accelerations recorded with and without a cervical collar.

Procedure

Test sessions will be performed over a period of 21 days in an indoor elite sporting facility. Each participant will act as their own control. Each participant (assuming the role of an injured player) will adopt a supine lying position on artificial turf. IMUs will be attached using double sided tape to the middle of the participant's forehead and the centre of the sternum. Markers for motion capture will be placed with small clusters (consisting of three markers per cluster) on the sternum and head. Anatomical markers will be placed on the participant's head and the torso to define the rigid body. 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 randomized order using the Research Randomizer online tool (www.randomizer.com).

The immobilisation procedure used will be according to the Level 5 ATMMiF procedure[8]. Clinical practitioners will form the immobilisation and extrication team. To ensure consistency for each participant's immobilisation and extraction procedure, the same members of the team will be used throughout the study and their roles within the procedure will be consistent. The full procedure for each participant will be approximately 15 minutes (5 minutes with cervical collar application; 5 minutes without cervical collar application and 5 minutes with repositioning of equipment and people). The timings have been established from regular in-service training practice scenarios amongst the medical staff.

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 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. Measurements will be taken from the trapezius and aligned will transect 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 and by the ability of opening and closing the player's mouth.

3. The participant will be log-rolled to 15 degrees to the left. The team of clinical practitioners will adopt positions on the right of the participant at the chest, hips and legs using the 3 over 3 under hand positions. This will allow the split scoop device to be slid underneath the right side of the participant, who will then be returned to supine.

4. Participant will be log-rolled 15 degrees to the right. The team of clinical practitioners will adopt positions on the right of the participant's at the chest, hips and legs using the 3 over 3 under hand positions. This will to allow the split scoop device to be slid underneath the left side of the participant who will then be returned to supine.

5. Body straps will be applied to secure the participant to the board.

6. Foam blocks to the left and right side of the participant's head will be applied with 2 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 scoop device will be elevated to 1m above the pitch by the practitioners to enable a basket stretcher to be slid underneath. The scoop device will then be lowered into the basket stretcher.

9. The basket stretcher will be lifted by the same practitioners, who will walk off the field carrying the basket stretcher to a distance of 10 metres.

10. The basket stretcher will be lowered to the ground.

11. The stretcher will be tilted to the right side 90^0 and returned to supine to simulate the airway clearing procedure.

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.

DATA ANALYSIS

Delsys IPA and Qualysys motion capture data will be transferred wirelessly, saved to a computer and retrospectively processed with a 2-tap averaging filter by the same researcher (RKJ), in Matlab (Matlab, R2016A, MathsWorks, Natrick, MA, USA) using custom written code.

STATISTICAL METHODS AND ANALYSIS

Data will be tested for normal distribution. Values for point measures and measures of variability will be presented and analysed. Within subject differences between each condition (collar *versus* no collar) will be assessed with parametric or non-parametric inferential statistics accordingly. Statistical significance will be set at $p < 0.05$. Statistical analysis will be completed within STATA 14 (StataCorp LLC, Texas, USA).

PATIENT AND PUBLIC INVOLVEMENT

Player participants were not involved in planning, design or conduct of the RESTRICT study. Club medical staff and expert biomechanists were involved in all stages of the design and planning of this protocol by way of formulating the research question, designing and writing the protocol.

DISCUSSION

Debate currently exists within practitioners who manage spinal injury in sport regarding the use of a rigid cervical collar as part of the immobilisation and extrication process. This novel study, the first to examine the spinal immobilisation and extrication procedure in professional football (soccer), will be undertaken by medical practitioners who have appropriate qualification in emergency care of spinal injury from The English Football Association (The FA). The findings of this study will help inform the way spinal injury is managed on the field of play in football in particular and sport in general. We hope the study's results will help advise the optimum way to immobilise a player with a suspected spinal injury and extricate them from the field of play.

ETHICS AND DISSEMINATION

Ethics Approval is being sought from the University of Salford. Any information we collect which may identify players will remain confidential, and this will be maintained at all times. All data will be made anonymous by using a unique study identifier code. 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 (MJC) and those who will be processing the data (RKJ) and performing data analysis (RKJ, TH). Informed consent will be required in written form from all

participants. Regardless of negative or positive outcomes, findings will be published in a peer-review journal and presented at scientific conferences. We will use several approaches for dissemination of the results including social media platforms and podcasts). These will be used to disseminate and communicate results to medical and academic staff internal and external to the Club, and also to the key stakeholders delivering ATMMiF or equivalent sports trauma management courses. These approaches will include utilisation of social media platforms, podcasts in addition to the presentation and publication of the results as stated above.

REFERENCES

1. Gandham S, Annis P. The principles of the advanced trauma life support (ATLS) framework in spinal trauma. *Orthopaedics and Trauma* 2020;34(5):305-14. doi: 10.1016/j.mporth.2020.06.008
2. Swartz EE, Del Rossi G. Cervical spine alignment during on-field management of potential catastrophic spine injuries. *Sports health* 2009;1(3):247-52. doi: 10.1177/1941738109334211 [published Online First: 2009/05/01]
3. Connor D, Greaves I, Porter K, et al. Pre-hospital spinal immobilisation: an initial consensus statement. *Emergency Medical Journal* 2013;30(12):1067-69.
4. Mays B. Is full pre-hospital spinal immobilisation best for the patient? A review of current controversies. *Journal of Paramedic Practice* 2016;8(4):176-83.
5. Berry K, Christmas D, Foster J, et al. Spinal injury: assessment and initial management - Clinical Guideline. Methods, evidence and recommendations: National Clinical Guideline Centre: National Institure for Health and Care Excellence 2015.
6. Brown S, Kumar D, Millins MBCP. UK Ambulance Services clinical practice guidelines 2016. Bridgewater: Class Publishing 2016.
7. Kornhall DK, Jorgensen JJ, Brommeland T, et al. The Norwegian guidelines for the prehospital management of adult trauma patients with potential spinal injury. *Scand J Trauma Resusc Emerg Med* 2017;25(1):2. doi: 10.1186/s13049-016-0345-x [published Online First: 2017/01/07]
8. Hodgson L. The FA Level 5 Advanced Trauma Medical Management in Football (ATMMiF) Manual. Burton Upon Trent: The Football Association 2020.
9. Maschmann C, Jeppesen E, Rubin MA, et al. New clinical guidelines on the spinal stabilisation of adult trauma patients - consensus and evidence based. *Scand J Trauma Resusc Emerg*

Med 2019;27(1):77. doi: 10.1186/s13049-019-0655-x [published Online First: 2019/08/21]
10. Chandler DR, Nemejc CN, Adkins RH, et al. Emergency cervical spine immobilisation. *Ann Emerg Med* 1992;21(1):1185-88.
11. Pryce R, McDonald N. Prehospital Spinal Immobilization: Effect of Effort on Kinematics of Voluntary Head-neck Motion Assessed using Accelerometry. *Prehosp Disaster Med* 2016;31(1):36-42. doi: 10.1017/S1049023X1500552X [published Online First: 2015/12/18]
12. Graziano A, Scheidel EA, Cline J, et al. A Radiographic Comparison of Prehospital Cervical Immobilization Methods. *Ann Emerg Med* 1987;16(10):1127-31.
13. Holla M. Value of a rigid collar in addition to head blocks: a proof of principle study. *Emerg Med J* 2012;29(2):104-7. doi: 10.1136/emj.2010.092973 [published Online First: 2011/02/22]
14. Dixon M, O'Halloran J, Cummins NM. Biomechanical analysis of spinal immobilisation during prehospital extrication: a proof of concept study. *Emerg Med J* 2014;31(9):745-9. doi: 10.1136/emermed-2013-202500 [published Online First: 2013/07/03]
15. Dixon M, O'Halloran J, Hannigan A, et al. Confirmation of suboptimal protocols in spinal immobilisation? *Emerg Med J* 2015;32(12):939-45. doi: 10.1136/emermed-2014-204553 [published Online First: 2015/09/13]
16. Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, 2007;*39*, 175-191.

t tests - Means: Difference between two dependent means (matched pairs)

Analysis:	A priori: Compute required sample size		
Input:	Tail(s)	=	Two
	Effect size dz	=	0.5
	α err prob	=	0.05
	Power (1-β err prob)	=	0.80
Output:	Noncentrality parameter δ	=	2.9154759
	Critical t	=	2.0345153
	Df	=	33
	Total sample size	=	34
	Actual power	=	0.8077775