



Cervical Spinal Splinting; Where's the Evidence?

By:

Martin Rizo Patron

Inventor-Developer, Firefighter-EMT-D,

U.S. ARMY “Deep Sea Diver”

(Underwater Construction Technician)

Thank you for the opportunity !

Analysis of the Management for Potential Spinal Injuries in EMS

- Epidemiology.
- Clinical and empirical evidence:
 - Shortfalls of commonly used tools and techniques.
 - Commonly used protocols and practices.
 - Procedures from a field prospective.
- Cervical Splinting technology basics.
- C-Splinting practical demonstration.
- A New Paradigm publications and evidence.

Epidemiology

- Yearly in the US., EMS providers treat over 5 million patients for potential CSIs. (19, 20).
- Approximately 14,000 CSIs are reported and between 4,000 to 5,000 trauma patients die as a result of these injuries.(1)
- Up to 25% of all CSIs occur after initial trauma; during early stages of patient management or transport, and 40% of these result in neurological deficit. (2, 3, 4, 5, 6, 7)
- Survivors of CSIs with neurological disability and their families must endure substantial physical, psychological and emotional stress.
- Financial burden can rise above \$100,000 during the first year of treatment alone. Estimated cost related to U.S. society is approx. 5 billion dollars per year.(30)

Immobilization Concept Literature

Spinal immobilisation for trauma patients (Review)

Kwan I, Bunn F, Roberts I, on behalf of the WHO Pre-Hospital Trauma Care Steering Committee



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Authors' conclusions

We did not find any evidence that spinal immobilisation reduces mortality, neurological injury, spinal stability and adverse effects in trauma patients remains uncertain. Spinal immobilisation is a major cause of preventable death in trauma patients, and spinal immobilisation, particularly of the cervical spine, can contribute to airway compromise, the possibility that immobilisation may increase mortality and morbidity cannot be excluded. Large prospective studies

Shortfalls Found with the Use of Conventional Tools and Procedures

- Rigid C-Collars (adjustable or multi-size).
- Long spinal boards/straps.
- Head immobilization devices.
- A view as how these relate to the procedures and operations in the field

Clinical Evidence Shows Shortfalls with Conventional Tools Used

1) Shortfalls with C-Collars:

- Conventional c-collars have the tendency to distract (stretch) the cervical spine. (15, 29)
 - This effect occurs due to their wedge like design.
- Creation of a pivot point which makes it more difficult to move patients safely. (36)
- Increased ICP due to venus return blockage.
- Designed to keep the head In-Line ONLY.



Conventional C-Collars Can Do More Harm Than Good!

- Journal TRAUMA, Jan, 2010. Extrication Collars Can Result in Abnormal Separation Between Vertebrae in the Presence of a Dissociative Injury.

EMS Magazine July, 2010

EMS
Innovations 2010

By John Erich,
Associate Editor

Collar Me Bad

Study prompts worries that cervical devices may harm some patients

There's little in EMS more automatic than applying cervical collars to patients with possible neck injuries. That doing this might in some cases harm them is a horrifying prospect. But that's an implication raised by research published earlier this year by the *Journal of Trauma*.

A team led by Baylor University orthopedist Peleg Ben-Galim, MD, found that using extrication collars in the presence of severe dissociative neck injuries can result in abnormal separation within the upper cervical spine. On cadaver models with recreated c-spine injuries, collars produced a separation of 7.3 +/- 4.0 mm between C1 and C2.

"Cervical extrication collars are put on about 15 million times a year... to protect the cervical spine in case of a bad injury," co-investigator John Hipp, PhD, director of Baylor's Spine

Research Lab, said in announcing the findings. "It is known that after a person has a bad injury, you can create a secondary injury very easily. We have discovered that the cervical collar, in

and after application of a rigid collar and some typical patient maneuvers. Distraction was clearly visible—the collar consistently pushed the head up and away from the shoulders. In a living

"The cervical collar, in the case of a really bad injury, not only doesn't protect the spine, but can actually make things a lot worse."

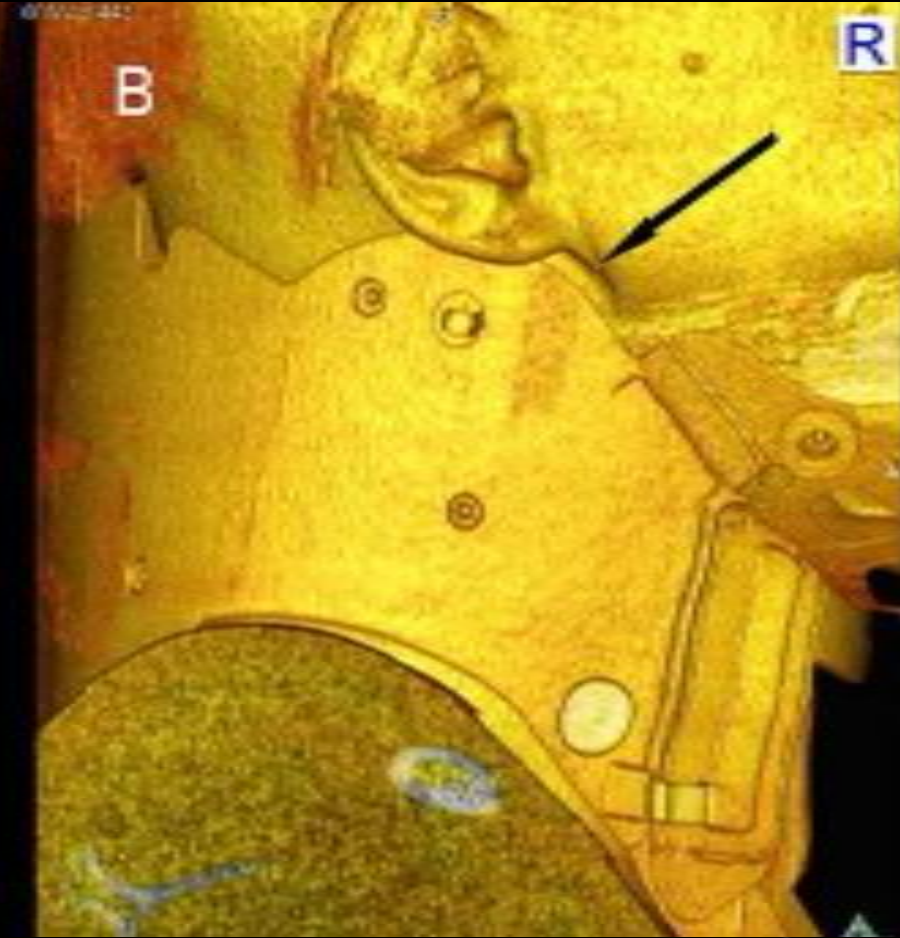
the case of a really bad injury, not only doesn't protect the spine, but can actually make things a lot worse."

The cadaver recreations were based on real cases. Researchers cut the bodies' neck ligaments and membranes but left supporting musculature, then captured images by x-ray, fluoroscopy and/or CT scan before

patient with unstable cervical anatomy, this could contribute to secondary injury—or worse.

What this means for EMS, though, probably isn't all that much yet. It's certainly not enough to send systems out changing standards of care. C-collars remain appropriate and safe for most of the patients on whom they're used. But there are definitely

Distraction Upon C-Collar Application



Another Drawback Against the Use of Conventional C-Collars

Journal TRAUMA, Oct, 2010. Motion Within the Unstable Cervical Spine During Patient Maneuvering: “The Neck Pivot-Shift Phenomenon”.

Head Hinges Upon Collar's Edge

WL: 405 WW: 537



LA

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Effect of Conventional C-Collars on ICP After a Head Injury

R ALPH J. M OBBS , * M ARCUS A. S TOODLEY † AND J OHN F ULLER ‡

*Department of Neurosurgery, Institute of Neurological Sciences, The Prince of Wales Hospital, † School of Surgery, University of New South Wales, Sydney, New South Wales and ‡ Department of Neurosurgery, The Canberra Hospital, Canberra, Australian Capital Territory, Australia

Conclusions: Early assessment of the cervical spine in head-injured patients is recommended to minimize the risk of intracranial hypertension related to prolonged cervical spine immobilization with a hard collar.



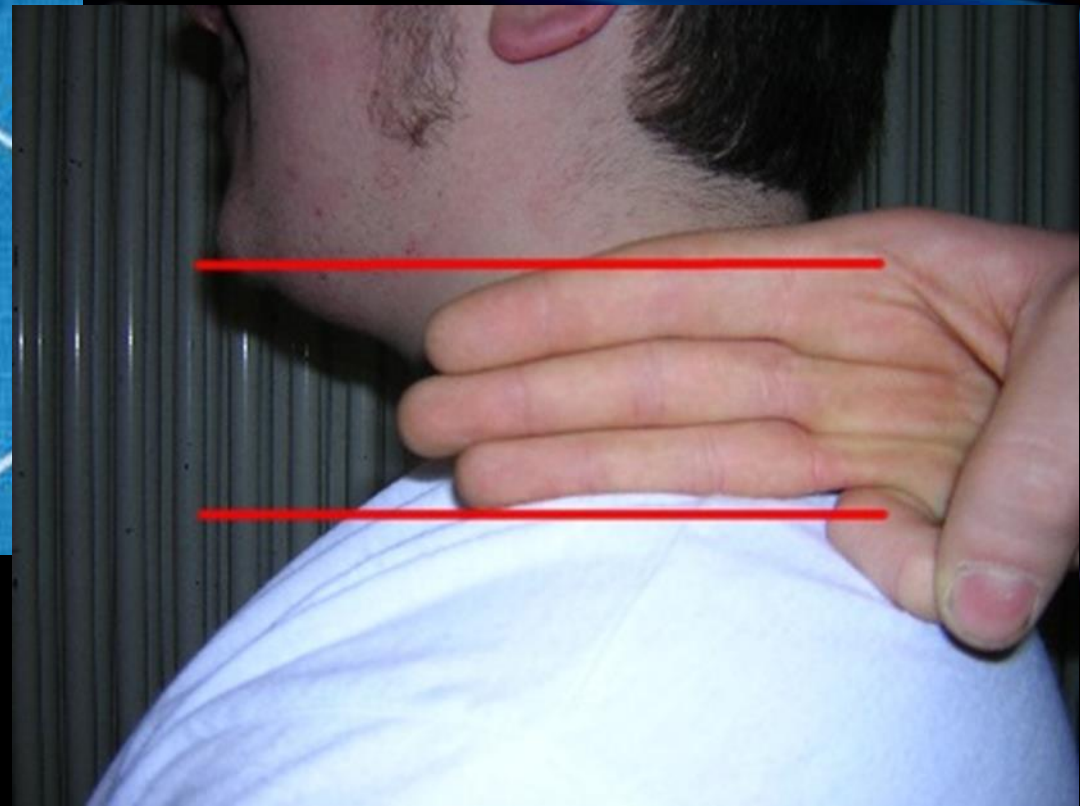
C-Collar Application Techniques

Gross Approximation

GRÖSSENWAHL:

"BABY NO NECK": Kinder ca. 1-4 Jahre

"PEDIATRIC": Kinder ab ca. 4-12 Jahre



2) Long Spinal Boards:

- Due to the rigidity of the surface at the contact points and the time spent laying on these devices, skin ulcers and sores start to develop. (32, 35)
- Tightness of the straps over the thoracic region has been found to limit respiratory function by 15 to 20 %. (11, 18, 33)
- Due to the pain experienced patients tend to move in an attempt to alleviate the pressure points potentially aggravating existing injuries.



3) Head Immobilizers:

- Improper Spine Alignment.
- Occipital support is needed for spine alignment ^(12, 13)
- Over 80% of adults require 1.3 to 5.1 cm. of padding for proper spine alignment. ⁽¹⁴⁾
- Unwanted Manipulation of the Cervical Spine occurs due to dynamic forces during transport. ⁽¹⁹⁾

EMS Spinal Precautions and the
Use of the Long Backboard
Position Statement of the
National Association of EMS
Physicians and the American
College of Surgeons Committee
on Trauma
Mach, 2013



Faculty of Pre-Hospital Care an Initial Consensus Statement. December 2013

- Consensus Statement Outcomes:

1. *The long spinal board is an extrication device solely. Manual in-line stabilisation is a suitable alternative to a cervical collar.*

5. *'Standing take down' practice should be avoided.*



ACEP Management of Patients with Potential Spinal Injuries Position Statement. January 2015

- Encourages local EMS Authorities to develop updated Spinal Management Protocols.
- Stresses the need for discontinuing the use of Long Rigid Spinal Boards for patient transport.



ACEP Statement Extracts

backboards, cervical collars, straps, tape, and similar devices (e.g., sand bags, head wedges). Evolving scientific evidence demonstrates that some of these current out-of-hospital care practices cause harm including airway compromise, respiratory impairment, aspiration, tissue ischemia, increased intracranial pressure, and pain, and can result in increased use of diagnostic imaging and mortality.

EMS medical directors should provide evidence-based spinal motion restriction protocols and procedures that describe specific indications and contraindications for application of spinal motion restriction. The role of adjuncts (e.g., cervical collars) should be specifically addressed. The use of spinal motion restriction procedures and adjuncts should not interfere with critical airway

Backboards should not be used as a therapeutic intervention or as a precautionary measure either inside or outside the hospital or for inter-facility transfers. Spinal immobilization should not be used for patients with penetrating trauma without evidence of spinal injury.



A New Paradigm in Cervical
Spinal Management

Cervical
Spinal
Splinting



The “XCollar” is NOT a C-Collar, It's a Cervical Spinal Splinting Technology

- It is a complete C-Spine Splinting System.
- Designed by looking back at the basics.
- Most effective, least intrusive treatment.
available to protect the Cervical Spine.

The **ONLY ONE**
that splints the cervical spine

ABOVE



&



BELOW

Cervical Splinting System



Position
Found

Pictures: www.xcollar.com

C-Splinting Demonstration

An anatomical illustration of a human spine, viewed from the side. The vertebrae are shown in a light, translucent color. Several vertebrae are highlighted with blue, curved splints that wrap around them, demonstrating the technique of C-splinting. The background is dark, with some blue lines representing nerves or ligaments.

- Timed evolution
- Technique
- Results

University of Pittsburgh

Comparison Study

A COMPARISON OF THREE CERVICAL IMMOBILIZATION DEVICES

David Hostler, PhD, Deanna Colburn, MPT, S, Robert Seitz, MD

ABSTRACT

Objective. Prehospital cervical spinal cord injuries (SCIs) are rare but potentially catastrophic. Although spinal immobilization is resource-intensive, emergency medical services (EMS) personnel commonly immobilize trauma patients to prevent exacerbation of unrecognized SCI during transport. We compared the stabilization properties of a novel rigid, cervical immobilization collar (XCollar) with those of one-piece and two-piece rigid collars commonly used in the prehospital setting. **Methods.** This was a prospective laboratory study of healthy adult volunteers to determine total cervical motion in the horizontal, coronal, and sagittal planes in both seated and supine positions. Goniometric techniques were used to measure head and neck movement after marking anatomic landmarks. Ranges of motion were compared with a one-way analysis of variance (ANOVA). A Bonferroni correction was applied for multiple comparisons, setting significance at $p \leq 0.004$. **Results.** Twenty-five subjects (11 men; 14 women) completed the study. The subject pool represented a wide range of morphometrics. For most measurements, the XCollar permitted 10–15 millimeters of movement when applied without manual cervical stabilization. This was less than the movement permitted by both comparison collars. On average, the XCollar permitted less than 10 millimeters of movement in the sagittal and horizontal planes when the subject was in the seated position. **Conclusions.** The XCollar provided superior cervical stabilization without augmentation by manual stabilization in healthy adult volunteers in both the seated and supine positions when compared with other one-piece and two-piece rigid cervical collars. Although maximal stabilization was achieved only after the subjects were secured to a long spine board with a cervical immobilization device, the XCollar can provide an acceptable alternative to manual cervical stabilization in situations where the number of patients

exceeds the number of EMS providers available to provide care. **Key words:** prehospital; immobilization; cervical; range of motion

PREHOSPITAL EMERGENCY CARE 2009;13:256–260

INTRODUCTION

Cervical spine immobilization is commonly performed in the prehospital setting when treating patients suffering from a traumatic injury.¹ Although spinal cord injury (SCI) is uncommon in the context of total prehospital patient encounters, up to 20,000 cases may occur annually in the United States and Northern Europe.² Exacerbation of SCI during extrication or transport can be catastrophic, typically resulting in overtriage by emergency medical services (EMS) providers and prophylactic immobilization with a cervical collar and long spine board.

Multiple studies have examined prehospital cervical immobilization collars.^{3–6} Although differences in collar effectiveness have been identified, many studies indicate that immobilization with a cervical collar alone is not sufficient and that manual stabilization should be applied until the patient is secured to a long spine board and cervical blocks are applied.^{4,6,9} However, this recommendation requires two rescuers to attend to each patient, one to maintain manual cervical stabilization and one to assess and prepare the patient for extrication. This may not be practical in a mass casualty incident where even a small number of patients can overwhelm the initial responder's resources. This study compared a novel cervical immobilization collar with two commonly used prehospital cervical collars to determine the extent to which the head can be immobilized without manual cervical stabilization in both the supine and seated positions.

METHODS

The University of Pittsburgh Institutional Review Board approved this study. All subjects provided informed consent prior to any procedures being performed.

Subject Population

Subjects were recruited from the local university and medical center community. Eligible subjects were 18 years or older of either gender. Subjects were excluded if they self-reported claustrophobia or a medical

Received August 29, 2008, from the Emergency Responder Human Performance Laboratory (DHD), Department of Emergency Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania; Centers for Rehab Services (DCI), University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania; and the Emergency Medicine Program (SR5), School of Health and Rehabilitation Sciences, University of Pittsburgh, Pittsburgh, Pennsylvania. Revision received September 29, 2008; accepted for publication October 13, 2008.

Supported by an unrestricted grant from Rizo Patron Enterprises, LLC. The sponsor had no input on data analysis, interpretation, or manuscript preparation. The authors have no financial interests in any product tested in this study or in the companies making those products.

Address correspondence and reprint requests to Dave Hostler, PhD, CSCS, Emergency Responder Human Performance Laboratory, University of Pittsburgh, Department of Emergency Medicine, 230 McKee Place, Suite 400, Pittsburgh, PA 15213; e-mail: hostlerdp@upmc.edu

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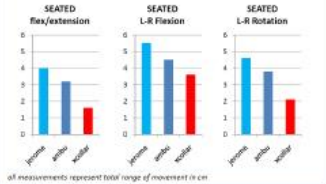
University of Pittsburg Study Analysis



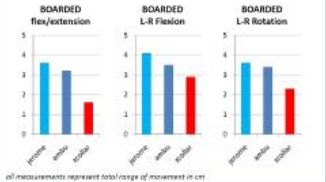
Comparisons of Capabilities & Efficacy: The XCollar & Conventional C-Collars

Range of Motion Allowed:

Patient in Seated Position:
with collar only



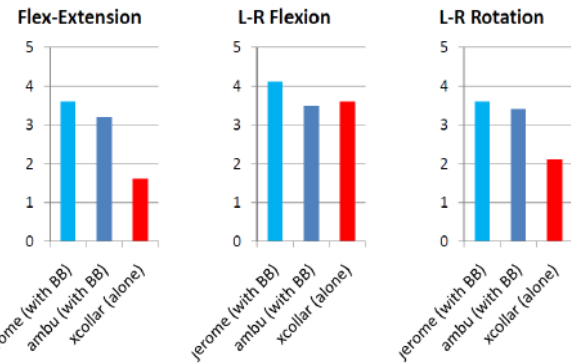
PATIENT FULLY "C-SPINED":
with collar, backboard, and head restraints



Products Comparison Chart			
Product Name	Nec Loc™	Perfit ACE™	XCollar™
Company	Jerome®	Ambu®	Emegear®
Custom-Fitting	No	No	Yes
Adult & Pediatric Application	No	No	Yes
Capability to Immobilize in Position Found	No	No	Yes
Possible Height Adjustment Positions	5	16	24+
Symmetrical & Asymmetrical Adjustment	No	No	Yes
Transparency of Product Material	No	No	Yes
Ergonomic Design	No	No	Yes
Access To Ears	No	No	Yes
Force Multiplier	No	No	Yes



Performance Comparison: XCollar alone vs. others in full "c-spine"



Graph 3: Notice that in the Left-Right Rotation and Flexion Planes the average range of motion measured for patients in the XCollar alone was less than and approximately equal to (within 0.10cm) the average range of motion measured for patients in the other collars with backboards and head restraints. (Measurements for the Flexion/Extension Plane of Motion were not collected when head restraints were utilized.)

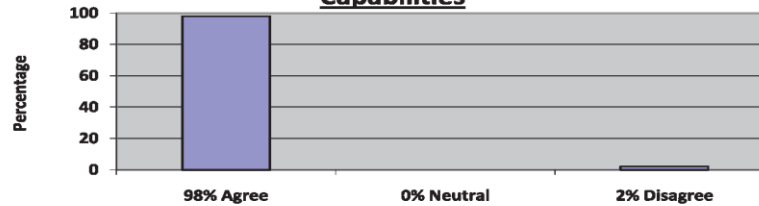
The XCollar, when used alone, offers better immobilization when treating a single patient. The benefits of this technology therefore increase exponentially during multiple casualty incidents. In these cases, the XCollar/NeXsplint cervical immobilization system can effectively liberate a first responder from the obligation of holding manual cervical immobilization. This allows a single rescuer to initiate cervical immobilization to multiple patients in a much shorter time and without compromising patient safety.

Field Trial Dallas Fire-Rescue Dept.

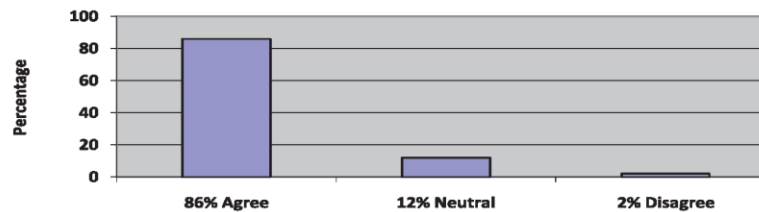


DALLAS FIRE RESCUE DEPARTMENT FIELD TRIAL RESULTS OCTOBER 2010

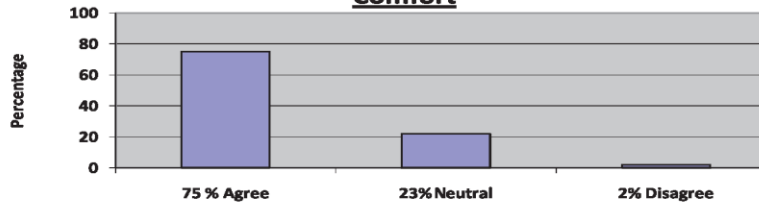
The XCollar Provides Improved Immobilization Capabilities



The XCollar Provides Better Stabilization & Safety



The XCollar Allows for C-Spine in Position of Comfort



The XCollar Provides New & Improved C-Spine Capabilities

Greater patient safety • Fits a greater range of patient sizes (from approx. 22 to over 360 lbs)
Allows application in "Position Found" • Expedites treatment and acts as a force multiplier during MCI

LCEMS Field Trial Results

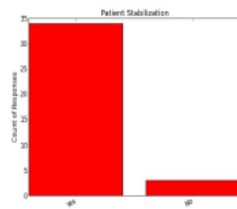
XCollar

Page 1 of 7

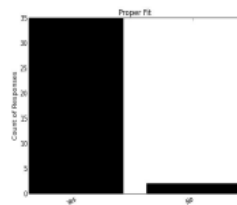
Lee County EMS analysis of the XCollar

23 January 2013

Better Patient Stabilization



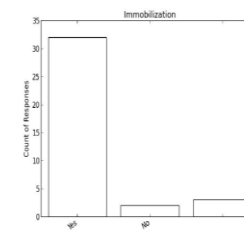
Proper fit for pediatric and adult patients ?



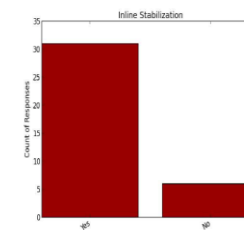
XCollar

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Immobilization in Position of Comfort or Position Found ? (if applicable)



Better inline patient stabilization using the adjustable Head Restraint System (HRS) ?



Opinion Leaders Feedback

2014 RAA Report_Page 3

Medical Director's Report



From a clinical standpoint, 2015 was another exciting, productive year! Some of the most notable highlights include:

The Cervical Spine XCollar

Conventional cervical collars that are commonly placed on patients in motor vehicle crashes or following falls to protect the neck from further injury have significant limitations. They are relatively uncomfortable and, more importantly, they often allow significant movement of the neck which negates their value as a protective device. In the last year, Richmond Ambulance Authority successfully implemented a program deploying a newly designed, highly effective device called the XCollar. This clever device splints the neck in the "position of comfort" and is capable of customizing to fit varying patient body types. It provides unprecedented protection of the spine that is superior to any other device on the market. The XCollar has an oversized opening in the front to allow paramedics to check the patient's pulse. It is made of latex-free materials and allows excellent quality x-rays to be taken with it in place after the patient arrives at the hospital. The device is now used in over 36 countries worldwide. Richmond Ambulance Authority is one of the first agencies in the United States to deploy the device.

EMS Magazine France

March, 2010

Attelle cervico-thoracique X Collar

Une révolution dans l'immobilisation du rachis cervical

Le 3SM du SDIS 25, avec l'appui des instructeurs et moniteurs de premiers secours, teste actuellement un matériel d'immobilisation du rachis cervical qui nous vient des Etats-Unis : l'attelle cervico-thoracique X Collar.

Attelle cervicale

Au total, les colliers cervicaux actuellement utilisés n'offrent une immobilisation efficace que de la partie médiane du rachis cervical dans l'axe antéro-postérieur.

Le système X Collar est une véritable attelle cervicale. Il dispose d'une structure arrière en triangle, pointe vers le bas, qui se positionne entre les omoplates et d'un dispositif réglable à l'avant qui prend appui sur le sternum. Lors de l'étude



d'une attache clip puis ajustée à la taille de la victime. Un dispositif de réglage de la circonférence permet une adaptation aisée à un enfant comme à un adulte. Il faut ensuite régler le dispositif d'appui sternal et finir en fixant les sangles de maintien latéral.

Un système de fixation de l'attelle cervicale sur un plan dur est à l'étude.

Formation préalable

La mise en œuvre de ce nouveau matériel nécessite une formation préalable. La procédure à suivre reste globalement conforme aux prescriptions du référentiel national de secourisme, ce qui ne devrait pas bouleverser les process actuels.

Ce nouveau dispositif d'immobilisation apporte une plus-value indéniable à la qualité de la prise en charge de la victime traumatisée. Seul bémol : la mise en place du triangle dans le dos

Canadian EMS Magazine

May, 2011

C-Spine Splinting:

A New Paradigm of Cervical Spinal Management

Even before Emergency Medical Services were established, rescue personnel have been using their best efforts to save patients by means of current techniques and equipment available. This medical sub-specialty has been evolving thanks to the continued improvement of its methods and tools necessary to meet the needs of critical patients in the hardest conditions.

The need to improve the way C-Spine management has been performed for decades became evident to me after applying hundreds if not thousands of conventional C-collars on patients. As an EMS provider, I always reassured and told our patients "please do not move" and "this



EMS World Publication

June, 2011

6/6/2011

Cervical Splinting Offers a New Paradig...

EMSWORLD

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Cervical Splinting Offers a New Paradigm in EMS

X Collar encourages a new method for practicing c-spine management

Posted: May 24th, 2011 11:53 AM CDT

By Martin Rizo Patron

Even before EMS was established, rescue personnel have used their best efforts to save patients by means of current techniques and equipment available. Since its infancy, emergency medicine has evolved thanks to continued improvements in the methods and tools necessary to meet the needs of critical patients in challenging conditions.

Combat & Casualty Care Magazine

Q3-2011



Cervical Splinting: A New Paradigm in EMS

First responders are today immobilizing casualties with spinal cord injuries without having to wait for traditional equipment to arrive on scene.

By Martin Rizo-Patron, president-founder, Emegear, LLC

JEMS Implementation of New Guidelines. January 2014

DISCRIMINATE SPINAL IMMOBILIZATION

How Lee County (Fla.) EMS implemented a new paradigm of cervical spine management

By Michael G. Hamel, NREMT-P, CCEMT-P, FP-C

As EMS professionals we're obligated to adhere to the principle of *primum non nocere*—"first, do no harm." But as the EMS industry becomes more protocol driven, the ability to think outside the box is often discouraged. Practices that seem like common sense become less common and, for many providers, the notion of doing no harm can be complex. This notion can be magnified when individuals or departments repeatedly accept a lower standard of performance until that lower standard becomes the normal. This behavior is known as *normalization of deviance*. In EMS, normalization of deviance can be defined as performing de facto procedures that appear to be absent of harm or deemed safe by tradition when in fact they are not. Providers end up performing "automatic" procedures that may not be beneficial or may have undesirable patient outcomes.

This is especially true for spinal immobilization procedures. For example, applying a cervical collar (C-collar) and strapping an 85-year-old laryngeal patient to a long spine board, when the only examination finding is a scalp laceration secondary to a ground level trip-and-fall, may not be the best course of action.

Likewise, fully immobilizing an altered mental status patient with a closed head injury who has a stomach full of alcohol and suboptimal airway protective reflexes may also be a poor choice treatment modality. For

more than 30 years, EMS professionals in the United States have settled for spinal immobilization techniques that have been supported by little to no evidence, but now some systems are calling the techniques into question.

IMPROVING IMMOBILIZATION

In late 2011, Lee County Public Safety/EMS (LCEMS) located in Fort Myers, Fla., set out to reduce iatrogenic insult caused by traditional immobilization practices. LCEMS first examined the C-collars used in the system to determine if any weaknesses could

be identified. The agency found that the deployed collar was inadequate in terms of its ability to splint a patient's cervical spine (C-spine) and restrict overall head movement.

A group of experienced paramedics further discovered that patient's lateral head movement, although limited, wasn't rendered immobile. The team also noted the traditional collar created an inadvertent "wedge" space between the patient's head and torso in most cases.

Although the conclusion of this wedge could not be studied thoroughly in the out-of-hospital environment, it was clear to the team the wedge had the potential to create C-spine distraction—obviously counterproductive to the patient suspected of having a vertebral or spinal cord injury.

The agency then examined other collars on the market to evaluate their ability to splint the C-spine. None of them were found to be better than the collar already in use. Discouraged but not defeated, the team continued to research alternatives and eventually discovered the XCollar by Emegear. The XCollar, with its unique C-spine splinting capability, immediately caught the agency's attention. But for various reasons unassociated to the project, the XCollar was not fully appreciated, and was ultimately placed in a drawer.

NEW DEVICE, NEW GUIDELINE

In mid-2012, amid continued pressure from team members determined to continue the quest for clinical excellence in spinal immobilization, representatives from Emegear were asked to visit Fort Myers to present the XCollar. The presentation was well received. The XCollar's ability to splint the C-spine became more impressive to our team.

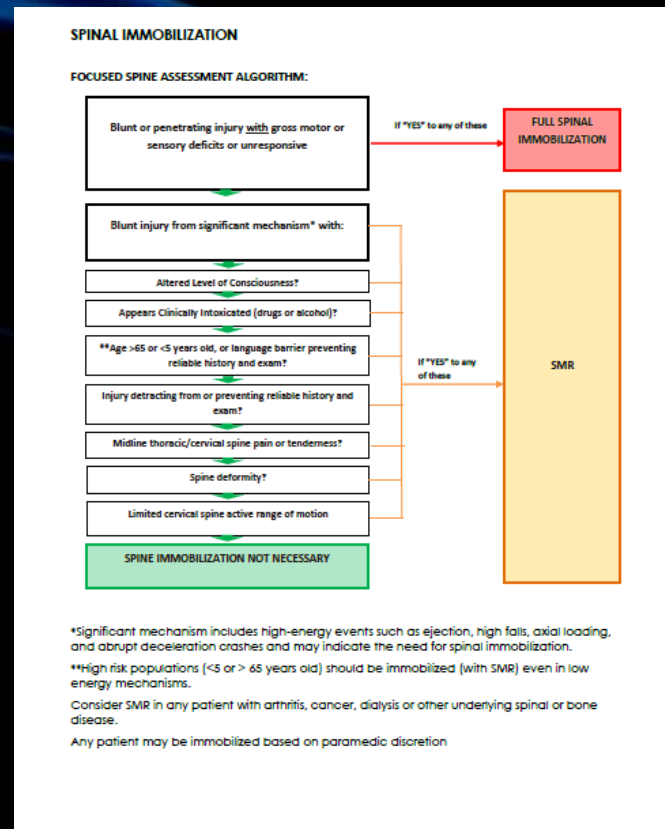
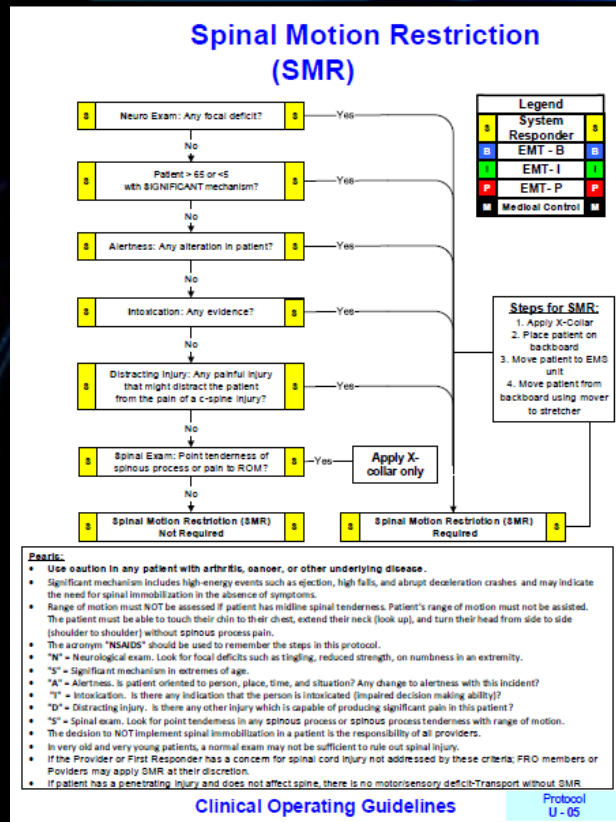


The XCollar secures the patient's head to the torso above C1 and below C7 on two points anterior and posterior. Photo courtesy Lee County EMS.

New Protocols/Algorithm Examples

ETMC Spinal Motion Restriction (SMR)
U - 05

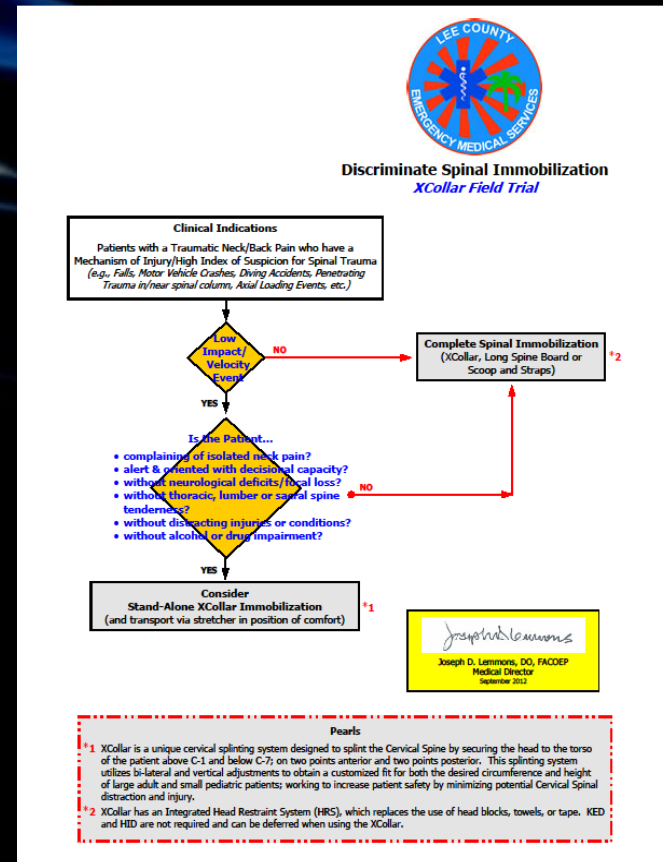
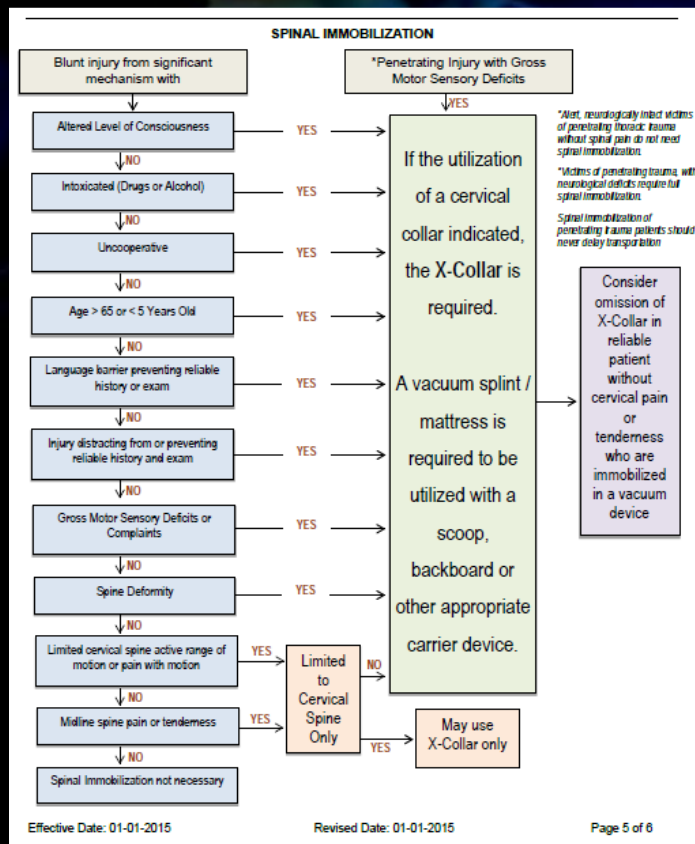
El Dorado Spine Immobilization 2015 Draft



More Examples of Updated Protocols:

Napa County EMS Spinal Immobilization Protocol

LCEMS Discriminate Spinal Immobilization Algorithm (2)



Conclusions:

Cervical Spinal Splinting Technology Allow Providers to:

- Make Updates on their medical guidelines.
- Provide better quality of patient care and safety.
- Provide for early treatment while avoiding further injury.
- “Force Multiplier” as one rescuer can provide treatment for multiple patients.
- Early transport and reduced times on scene.
- Be ready to respond to other emergencies faster.
- Increase provider’s morale.

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