Rise in Intracranial Pressure by application of a Rigid Cervical Collar: A pilot study in healthy volunteers.

Rigid Collar's effect on ONSD (running head)

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Abstract

Objective: Rigid cervical collars are known to increase intracranial pressure (ICP) in severe traumatic brain injury (TBI). Cerebral blood flow (CBF) might decrease according to the Kellie Monroe doctrine. For this reason, the use such as the collar in patients with severe TBI has been abandoned from several trauma protocols in the Netherlands. There is no evidence on the effect of a rigid collar on ICP in patients with mild or moderate TBI or indeed patients with no TBI. As a first step we tested the effect in healthy volunteers with normal ICPs and intact autoregulation of the brain.

Methods: In this prospective blinded cross-over study, we evaluated the effect of application of a rigid cervical collar in 45 healthy volunteers by measuring their optical nerve sheath diameter (ONSD) by transocular sonography. Sonographic measurement of the ONSD behind the eye is an indirect non-invasive method to estimate ICP and pressure changes.

Results: We included 22 male and 23 female volunteers. In total 360 ONSD measurements were performed in these 45 volunteers. Application of a collar resulted in a significant increase in ONSD in both the left (Beta=0.06, 95%CI 0.05-0.07, p<.001) and right eye (Beta=0.01, 95%CI 0.00-0.02, p=0.027)

Conclusion: Application of a rigid cervical collar significantly increases the ONSD in healthy volunteers with intact cerebral autoregulation. This suggests that ICP may increase after application of a collar. In healthy volunteers, this seems to be of minor importance. Based on our findings the effect of a collar on ONSD and ICP in patients suffering mild and moderate TBI needs to be determined.

Keywords

Intracranial pressure, ICP, traumatic brain injury, immobilization, rigid cervical collar, extrication collar, optical nerve sheath diameter, ONSD, neurotrauma, TBI. Ultrasound / Sonography.

Introduction

Often, patients with head-injuries suffer from additional cervical spine injury. For decades, trauma victims have been routinely immobilized when cervical injuries could not be ruled out at the scene. Rigid cervical collars and spine boards were used during transportation in prehospital trauma care. As advocated in advanced trauma life support (ATLS) and prehospital trauma life support (PHTLS) protocols, immobilization is continued until cervical spine injury is excluded.[1,2] To minimize secondary damage to the spinal cord, in-line immobilization will be continued during transportation and examination.[3] Several devices to help immobilize the cervical spine such as the Stiffneck®(Laerdal Medical AS, Stavanger, Norway) are commercially available.

The application of rigid cervical collars increases the intracranial pressure (ICP) of brain-injured patients in ICU settings.[4-6] This rise in ICP is attributed to compression of the internal jugular veins.[7,8] According to the Kellie Monroe doctrine, impaired venous drainage causes volume expansion inside the skull, which can raise ICP and lead to neurological deterioration.[1] Besides a raised ICP, local pressure of the collar may exacerbate discomfort and agitation in patients suffering mild or moderate TBI resulting in undesirable movement of the neck and an additional rise of ICP. More information about the effects of the cervical collar on the ICP is mandatory. However, outside of the intensive care unit, it is not feasible to measure ICP directly.

Sonographic measurement of the optical nerve sheath diameter(ONSD) is a non-invasive, rapid method for indirect ICP-monitoring.[9-11] The meninges around the brain are in continuum with the optical nerve sheath, and cerebrospinal fluid percolates freely from the cranial cavity into the optical nerve sheath.[12,13] Previously, we demonstrated that any change in ICP results in a simultaneous change of the ONSD in both eyes.[9]

In this study, the effects of the application of a rigid cervical collar on the ONSD were measured in healthy volunteers. We hypothesize that a rigid cervical collar increases the ONSD (through a raised ICP) in healthy volunteers with intact cerebral autoregulation.

Methods

This blinded cross-over study was a single-center prospective research study. Volunteers were recruited in the medical library of the Erasmus University Medical Center. The volunteers were at least 18 years of age and did not have any self-reported medical history of ocular or intracranial disease. Both eyes were intact and functional. Every individual volunteer gave a written informed consent after reading the patient information form which was approved by the ethical committee of the Erasmus Medical Center, Rotterdam. (MEC-2015-460)

Rigid Collar and ONSD

ONSD was measured simultaneously in both eyes by two experienced sonographers (IM and RK) who were blinded as to whether a collar was applied to the neck or not. Both sonographers are senior e-FAST instructors since 2010 and working as helicopter emergency medical service (HEMS) physicians since 2012. Both performed over 25 ONSD examinations previous to our study. Sonographers were also blinded for each other's measurements (Figure 1A,1B). The upper part of the volunteer's head (from the nose up) was presented to the operators through a narrow opening in the center of a room dividing screen. Between every session, the sonographer was not allowed to see the participant, while a collar was being applied or not as per randomization. All four sessions of measurements were performed with the volunteers in a supine position on a table: two with and two without application of a Stiffneck® rigid cervical collar. Measurements were performed within two minutes after application of the collar. Volunteers were instructed to breathe normally-, and not to talk or cough during the measurements. If coughing occurred, measurements were repeated. Randomization was achieved by rolling a dice in one of six "collar regimes."(Table 1) A third researcher (BV) on the other side of the screen adjusted the size of the adaptable Stiffneck® and applied it to the participants' neck as prescribed in the user manual (version and year). The cervical collar Velcro was opened and closed again before every measurement, independent of application to the volunteer's neck or not. This was done to blind the observers to audible clues as to the application or absence of the collar. During every session, heart rate, blood pressure, and blood oxygen saturation (SPO_2) were monitored noninvasively (Infinity M540, Dräger, Lübeck, Germany).

Images of the ONSD in the left and right eye were taken simultaneously with two identical M-Turbo ultrasound machines (7.5MHz linear probe; ocular setting, mechanical index = 0,2: FUJIFILM SonoSite Inc., Bothell, WA, USA). Axial measurements were carried out in B-mode. The images were frozen at the same time and ONSD's were measured by each sonographer on their machine with the internal calliper 3mm behind the retina as suggested before (Figure 2).[9-13] One sonographer measured all left eyes and the other all right eyes throughout the study.

Statistical analyses

Categorical variables are presented as numbers and percentages. Continuous data is presented with ranges and as mean ± standard deviation (SD) when normally distributed or as median values and corresponding 25th and 75th percentiles when data were skewed. The intra-observer variability is calculated as the mean difference between two measurements for each eye/observer with and without application of a collar and reported as mean ± SD. To evaluate the effect of a collar on ONSD, linear mixed models were fitted. This method of analysis takes into account the correlated nature of repeated measures of the same subject. The models included *volunteer* as a random factor and *collar*, *eye* and *collar by eye* as fixed within-volunteer effects. IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA) and R (version 3.2.5) were used.

Results 22 male and 23 female volunteers were included. Age ranged from 18 to 31 (mean 20.3 ± 1.9) years of age. None used vasoactive medication of any kind. Systolic blood pressure (131.8 ± 8.7 mmHg), diastolic pressure (77.2 ± 5.6 mmHg), pulse (78 ± 10.8 min^{-1}), and peripheral oxygen saturation (98 ± 1 %) were within normal limits. In total, 360 ONSD measurements were performed in 45 volunteers. Intra-observer variability varied between 0.001 ± 0.05 and 0.005 ± 0.05.(Table 2)

The application of the collar resulted in a significant overall increase in ONSD (5.5±0.7mm vs control 5.2±0.6, p<.001) (Figure 3). However, a significant effect of eye (left vs right) and the interaction of eye and collar was observed (Table 3). Stratification on eye revealed a rise of ONSD of 0.6mm (p<.001) in the left eye and 0.1mm (p=.027) in the right eye after application of the collar.

Discussion

We demonstrated in this study that application of a rigid cervical collar in healthy volunteers results in a statistically significant increase of the ONSD. This suggests that ICP will rise when a rigid cervical collar is applied. In healthy volunteers, this is probably clinically irrelevant due to maintained cerebral blood flow (CBF) by autoregulation mechanisms. When pressure compensation mechanisms, as described by Kellie and Monroe, are exhausted, and autoregulation is impaired after traumatic injury, a rise in ICP will compromise CBF and worsen secondary brain injury. [14]

It is assumed that the ICP in healthy volunteers is equal throughout the entire cranial cavity. [1,12,13] Toscano et al. suggested no difference in ONSD distention in the left and right eye of heavily sedated and mechanically ventilated patients with increased ICP.[15] For practical reasons the positions of the sonographers were not changed during our experiment. One was seated on the left and one on the right side of the table each with their own ultrasound machine. (Figure 1A,1B)

ONSD distention due to collar application was statistically significant in both eyes but we found an unexpected difference in effect in the left and the right eye.

To our surprise the discrepancy between the left and right ONSD increased to 0.6 mm when a cervical collar was applied. This may be caused by unequal pressure effects on the neck or in the brain due to the asymmetrical design of the collar. As pressure equilibration in the head may need more time than we assumed, we might have measured too short after application of the collar (<2minutes). An asymmetrical jugular diameter might contribute to the difference found as well. [16]

Furthermore, this left-right difference might be due to a systematic measurement error (bias) between the sonographers or the ultrasound machines. However the ultrasound machines are identical.

Although both examiners used the technique as described in the method section, a structural difference in performance might have occurred due to a difference in experience of the two sonographers. One examiner (IM) has done previous research on ONSD, for the other(RK) this test was relatively new. However, the learning curve performing ONSD measurements is reported to be as short as 10 examinations for experienced physicians. [17] Both examiners had done over 25 ONSD measurements prior to this study in previous research or their work in the field. There was a structural difference in measurements of 0,2 mm between the results of the two examiners. Inter-observer variability has been reported to be as little as 0.2 mm (range 0.1-0.5 mm) in experienced sonographers. [11] Measuring structures this small might introduce a standard variation due to pixel density or software limitation of the ultrasound machines. Although Sonosite machines do not have to be calibrated periodically a small difference in firmware might have introduced a systematic measurement error. (User manual Sonosite, M turbo) In future research the sonographers should regularly switch sides to prevent this type of possible bias.

As we described before, the optical nerve sheath's response to ICP depends on its elasticity. The sheath contains the fewest trabeculae three millimeters behind the retina. This explains the hyper elasticity at this part of the sheath.[12] The cut-off point for ONSD for an increased ICP (>20mmHg) is still under debate.[9,10,13,15,17,19] Goeros et al. suggest a difference in ONSD between sexes and advocates a different cut-off for males and females.[18] Maude et al. suggest possible differences between ethnicities.[20] In our previous study we found a cut-off point of 5.0 mm representing increased ICP (>20 mmHg) in sedated and intubated head-injured Dutch patients (67% males). Since sheath elasticity varies between individuals ONSD measurement is rather a qualitative than a quantitative assessment of ICP.[9,19] Because of this we can state that the increased ONSD during collar application does represent an increase of ICP but it is not possible to calculate the exact increase without knowing the elasticity coefficient of the sheath of that individual. The main question that remains, is whether or not this increase in ICP impairs CBF. If ICP compensation mechanisms described by Kellie Monroe are exhausted, the slightest increase in venous volume in the head might result in a rise in ICP and a compromised CBF.

In daily clinical practice, let alone in a prehospital setting, CBF cannot be measured easily and reliably. CBF is directly related to cerebral perfusion pressure (CPP). CPP can be calculated as the mean arterial pressure (MAP) minus the ICP.[1] When autoregulation is disturbed after trauma CPP should be kept between 60 and 70 mmHg to prevent ischemia of the brain and cardiorespiratory complications of induced hypertension.[14] The slightest compromise of venous drainage from the head after application of a rigid cervical collar might impair CBF in TBI patients and may be counterproductive whenever ICP lowering strategies are indicated.[21] In a healthy brain, cerebral autoregulation maintains CBF when systolic blood pressure fluctuates or venous blood temporarily pools in the head. In an injured brain, autoregulation might be altered or entirely dysfunctional which makes the brain vulnerable to arterial pressure fluctuations and venous stasis.[21] This possible harmful effects of the collar and local pressure pain might explain the exacerbation of discomfort and agitation we sometimes observe after application. [22]

Since 2016 Dutch prehospital trauma protocols differ from international ATLS and PHTLS protocols on the subject of cervical spine immobilization. Practise in the Netherlands is based on the evidence that the application of a rigid cervical collar increases ICP in severely brain-injured patients and the use of the collar is of questionable benefit in patients immobilised on a spine board or vacuum mattress.[4-7,24] Alternative strategies are used, such as manual in-line stabilization (MILS) during extrication and vacuum mattress, and head blocks fixed with Velcro straps to a spine board during transportation. [1,2,4-6,23,24]

Conclusion

Application of a rigid cervical collar significantly increase the ONSD in healthy volunteers with intact cerebral autoregulation. This suggests that ICP may increase after application of a collar. In healthy volunteers, the effect is limited and seems to be of minor importance. If baseline ICP is increased or autoregulation is impaired in a head injured patient, this mechanism might worsen CBF. Based on our findings the effect of the collar on ONSD and ICP in patients suffering mild and moderate TBI needs to be determined.

Disclosure

The authors declare no conflicts of interests.

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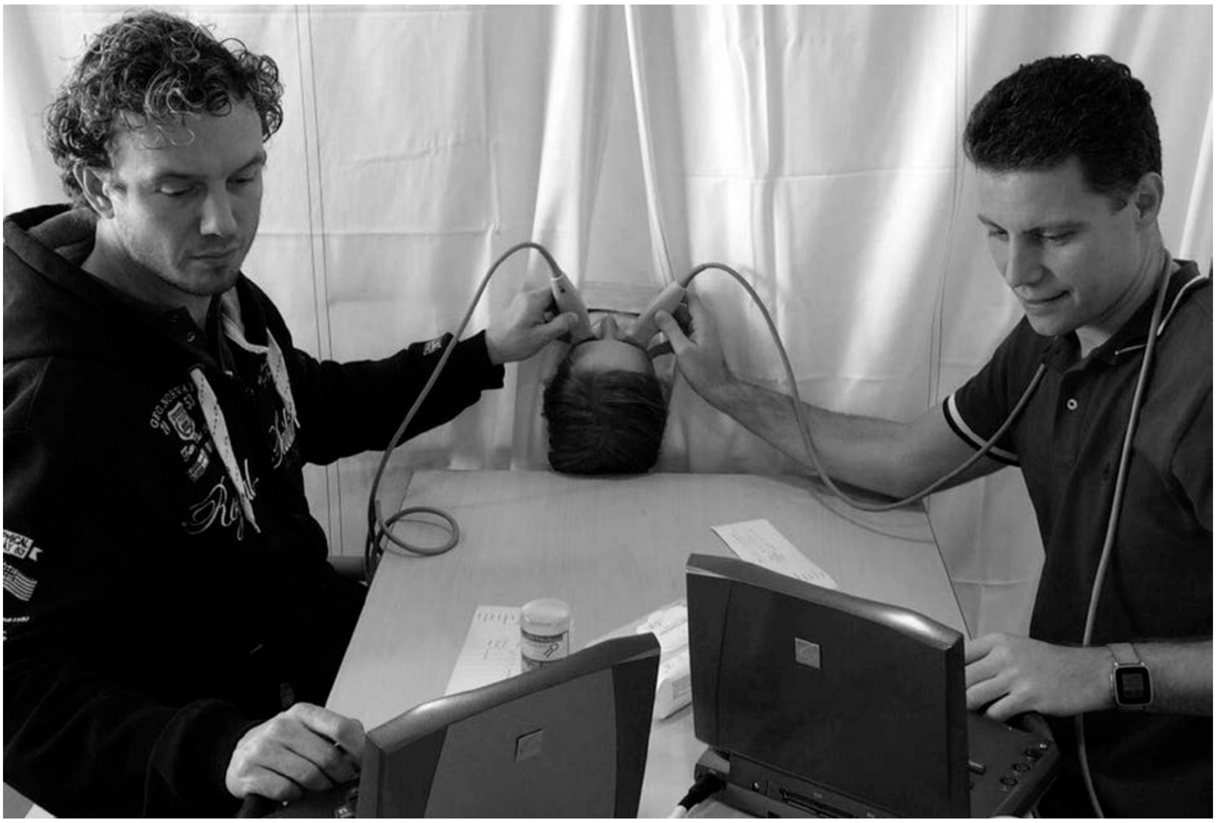

Figure 1A research set-up

Figure 1B research set-up

Figure 2

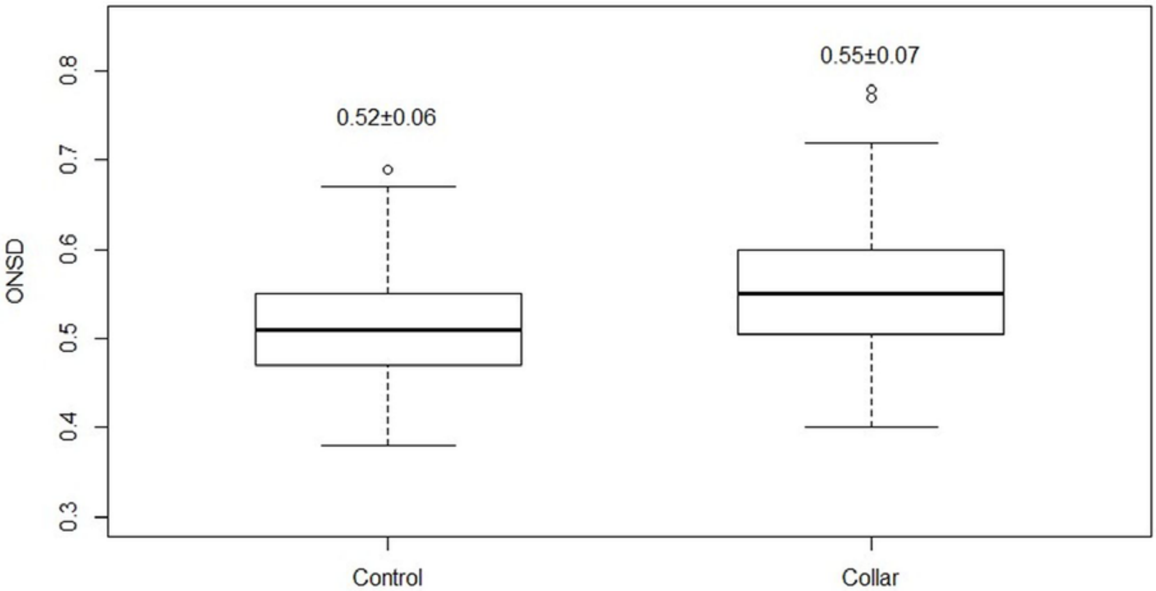

Figure 3

Table 1: Rigid Collar Regime. 0 = no collar, 1 = collar applied.

Dice result	Session one	Session two	Session three	Session four
1	0	0	1	1
2	0	1	0	1
3	1	0	0	1
4	1	0	1	0
5	1	1	0	0
6	0	1	1	0

Table 2. Intra and inter observer variability

	Range ONSD (mm)	Average ONSD (mm)	Intraobserver variability
Left eye (Observer 1)	0.38-0.78	0.54 ± 0.07	
Collar	0.40-0.78	0.57 ± 0.07	0.001± 0.05
No Collar	0.38-0.69	0.51 ± 0.06	-0.005± 0.05
Right eye (Observer 2)	0.40-0.69	0.53 ± 0.06	
Collar	0.40-0.69	0.54 ± 0.07	0.003± 0.05
No Collar	0.42-0.66	0.53 ± 0.06	0.005± 0.05
Interobserver variability			
(Obs1 vs Obs2)			
Collar		-0.03 ± 0.07	
No Collar		0.02 ± 0.06	

Table 3: Estimates of linear mixed effect regression analyses on ONSD

	Overall			Left eye			Right Eye		
	B	**CI**	**p**	**B**	**CI**	**p**	**B**	**CI**	**p**
(Intercept)	0.53	0.51 - 0.54	<.001	0.51	0.49 - 0.52	<.001	0.53	0.51 - 0.54	<.001
Collar	0.01	0.00 - 0.02	.047	0.06	0.05 - 0.07	<.001	0.01	0.00 - 0.02	.027
Left eye	-0.02	-0.03 - 0.01	.001						
Collar*Eye	0.05	0.03 - 0.07	<.001						
Observations	360			180			180		