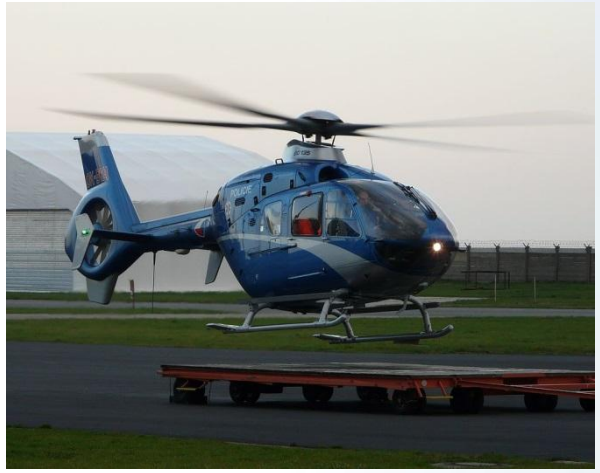

Fibrinogen Concentrate and Perspectives of Prehospital Care in Emergency Medical Services Prague

David Doubek, Karel Štěpánek, Ondřej Franěk, Petr Kolouch, Jaroslav Valášek

Trauma

- One of the main causes of death or disability worldwide
- **Hemorrhagic shock and coagulopathy**
- hypothermia, tissue damage, (tissue) hypoxia

- To improve the prognosis of these patients, it is advisable to initiate therapy for bleeding and coagulopathy as soon as possible, ie still in the pre-hospital phase of care

Our way around bleeding ...

not just to fibrinogen

The last years are an important topic of expert actions of urgent medicine the treatment of bleeding that arises as a result of serious trauma ...

- What are we doing now
- Blood products … yes or no?
- Sources of information, web, etc
- Internal rules / regulations of the Prague EMS
- Discussions with Traumacentres in Prague
- Negotiations with health care insurers
- Putting into practice
- Feedback

Our routine

The current prehospital procedure in Prague EMS for severe traumatic patients

- **Safety** for the patient, us and the environment
- **Speed** = trying for the most appropriate target health facility in the shortest possible time

- **Checking the lethal triad**

  (acidosis, coagulopathy, hypothermia)

- **cABCDE** procedure

What can be done more ...?

What are the novelties in dealing with massive bleeding in pre-hospital

- Full blood, erythrocytes, plasma and thrombocytes
- (calcium), cryoprecipitate, fibrinogen, prothrombin complex,

rF VIIa...

- There is no clear definition in the world of what is best in the civilian sector

Blood products

Administration of blood / transfusion products in prehospital care

Problems:

- legislative
- technical
- medical

Blood products … legislative limits

- The EMS does not have a blood bank
- Temporary "depo" is not clearly defined
- It is not possible to return to a clinical use once-given product from blood bank
- Payment in prehospital care is not settled
- (special conditions)

- There is no internal regulations for the administration of blood products
- Risk of possible complications - (post) transfusion reactions etc.
- Limited experience of staff with routine blood supply

Blood products … technical limits

- It can not be stored only in the fridge ... defined conditions- SÚKL
- Transport case ... ISO 9001
- Heating of the product, Heater / pump
- Time factor – flight time with patient up to 30 minutes (mostly 20min.)

- Time factor – for ambulance up to 15 minutes to the Traumacenter

Blood products … medical limits

What to choose? What do I really want to solve? How to measure it?

- Can we "measure" what we want to heal under prehospital conditions?
- Coagulation status and level of hemoglobin

- Only EBM?

Our approach is influenced by the clinical state of the patient, our practice, our experience

Blood products … medical limits

What to choose?

- Full blood? - (yet) does not exist in the Czech Republic
- Thrombocytes? - how to store (shaker), price, expiration, number of units
- Frozen plasma - frozen ...
- Dried plasma? - (yet) does not exist in the Czech Republic
- Red blood cells / erythrocyte concentrate - is it the winner?
  - Does not solve the coagulopathy (or very remotely - viscosity)
  - **Level of Hb** / Htk - Indication for transfusion?
  - transfusion is **not risk-free and contains citrate**

Sources

Česká lékařská společnost J. E. Purkyně
Společnosti urgentní medicíny a medicíny katastrof

Ošetření pacienta se závažným úrazem v přednemocniční neodkladné péči (PNP)

Aktualizace: 10. 2. 2018

A. Úvod

Úrazy zůstávají – přes veškerá preventivní opatření – nadále jednou z významných příčin úmrtí. Ve věkové skupině do 45 let jsou ve vyspělých zemích vedoucí příčinou úmrtí. V případě trvalých následků mají i nezanedbatelné závažné sociální a ekonomické důsledky jak pro samotného postiženého a jeho okolí, tak pro celou společnost.

Přestože ošetřování každého pacienta se závažným úrazem je dlouhodobý a složitý proces, vyžadující individuální přístup a souhru všech zúčastněných, lze identifikovat některé obecné zásady, které by měly být dodržovány. V současnosti jsou k dispozici data, která potvrzují, že dodržování těchto zásad může významným způsobem zlepšit prognózu postižených jak z hlediska přežití, tak z hlediska zmírnění případných závažných trvalých následků úrazu.

SPOLEČNOST URGENTNÍ MEDICÍNY a MEDICÍNY KATASTROF

Česká lékařské společností Jana Evangelisty Purkyně

aktualizace: 10.4.2018

Novinky na webu:

Zápis z 25. schůze Výboru

ODBORNÉ AKCE S GARANCÍ SPOLEČNOSTI UM a MK ČLS JEP

Dostálovy dny 2018 - 20 let urgentní medicíny v ČR

ČLS JEP Společnost urgentní medicíny a medicíny katastrof

XXV. Dostálovy dny urgentní medicíny

OSTATNÍ ODBORNÉ A VZDĚLÁVACÍ AKCE

PODMÍNKY PRO UDĚLENÍ ODBORNÉ GARANCE

ČLENOVÉ, VÝBOR, STANOVY	ZÁPISY ZE SCHŮZÍ VÝBORU

Recommended procedure – SUMMK

1. Primary examinations and life-saving procedures

- Procedure "cABC"
  Stopping of serious external bleeding in any way.

3. Secondary examinations and providing other priority procedures

- Bleeding control:
  - Compression of the extrenal bleeding.
    - Restriction of internal bleeding by immobilizing fractures of pelvis and long bones
    - (preferably by total immobilization)

Sources
Rossaint, 2016

Rossaint et al. Critical Care (2016) 20:100
DOI 10.1186/s13054-016-1265-x

Critical Care

RESEARCH Open Access

The European guideline on management of major bleeding and coagulopathy following trauma: fourth edition

Rolf Rossaint[1], Bertil Bouillon[2], Vladimir Cerny[3,4,5,6], Timothy J. Coats[7], Jacques Duranteau[8], Enrique Fernández-Mondejar[9], Daniela Filipescu[10], Beverley J. Hunt[11], Radko Komadina[12], Giuseppe Nardi[13], Edmund A. M. Neugebauer[14], Yves Ozier[15], Louis Riddez[16], Arthur Schultz[17], Jean-Louis Vincent[18] and Donat R. Spahn[19*]

Abstract

Background: Severe trauma continues to represent a global public health issue and mortality and morbidity in trauma patients remains substantial. A number of initiatives have aimed to provide guidance on the management of trauma patients. This document focuses on the management of major bleeding and coagulopathy following trauma and encourages adaptation of the guiding principles to each local situation and implementation within each institution.

Methods: The pan-European, multidisciplinary Task Force for Advanced Bleeding Care in Trauma was founded in 2004 and included representatives of six relevant European professional societies. The group used a structured, evidence-based consensus approach to address scientific queries that served as the basis for each recommendation and supporting rationale. Expert opinion and current clinical practice were also considered, particularly in areas in which randomised clinical trials have not or cannot be performed. Existing recommendations were reconsidered and revised based on new scientific evidence and observed shifts in clinical practice; new recommendations were formulated to reflect current clinical concerns and areas in which new research data have been generated. This guideline represents the fourth edition of a document first published in 2007 and updated in 2010 and 2013.

Results: The guideline now recommends that patients be transferred directly to an appropriate trauma treatment centre and encourages use of a restricted volume replacement strategy during initial resuscitation. Best-practice use of blood products during further resuscitation continues to evolve and should be guided by a goal-directed strategy. The identification and management of patients pre-treated with anticoagulant agents continues to pose a real challenge, despite accumulating experience and awareness. The present guideline should be viewed as an educational aid to improve and standardise the care of the bleeding trauma patients across Europe and beyond. This document may also serve as a basis for local implementation. Furthermore, local quality and safety management systems need to be established to specifically assess key measures of bleeding control and outcome.

Conclusions: A multidisciplinary approach and adherence to evidence-based guidance are key to improving patient outcomes. The implementation of locally adapted treatment algorithms should strive to achieve measureable improvements in patient outcome.

Sources

Mizobata *Journal of Intensive Care* (2017) 5:4
DOI 10.1186/s40560-016-0197-5

Journal of Intensive Care

REVIEW Open Access

Damage control resuscitation: a practical approach for severely hemorrhagic patients and its effects on trauma surgery

Yasumitsu Mizobata

Abstract

Coagulopathy observed in trauma patients was thought to be a resuscitation-associated phenomenon. The replacement of lost and consumed coagulation factors was the mainstay in the resuscitation of hemorrhagic shock for many decades. Twenty years ago, damage control surgery (DCS) was implemented to challenge the coagulopathy of trauma. It consists of three steps: abbreviated surgery to control the hemorrhage and contamination, resuscitation in the intensive care unit (ICU), and planned re-operation with definitive surgery. The resuscitation strategy of DCS focused on the rapid reversal of acidosis and prevention of hypothermia through the first two steps. However, direct treatment of coagulopathy was not emphasized in DCS.

Recently, better understanding of the pathophysiology of coagulopathy in trauma patients has led to the logical opinion that we should directly address this coagulopathy during major trauma resuscitation. Damage control resuscitation (DCR), the strategic approach to the trauma patient who presents in extremis, consists of balanced resuscitation, hemostatic resuscitation, and prevention of acidosis, hypothermia, and hypocalcemia. In balanced resuscitation, fluid administration is restricted and hypotension is allowed until definitive hemostatic measures begin. The administration of blood products consisting of fresh frozen plasma, packed red blood cells, and platelets, the ratio of which resembles whole blood, is recommended early in the resuscitation.

DCR strategy is now the most beneficial measure available to address trauma-induced coagulopathy, and it can change the treatment strategy of trauma patients. DCS is now incorporated as a component of DCR. DCR as a structured intervention begins immediately after rapid initial assessment in the emergency room and progresses through the operating theater into the ICU in combination with DCS. By starting from ground zero with the performance of DCS, DCR allows the trauma surgeon to correct the coagulopathy of trauma. The effect of the reversal of coagulopathy in massively hemorrhagic patients may change the operative strategy with DCS.

Keywords: Damage control resuscitation, Acute traumatic coagulopathy, Massive transfusion protocol, Damage control surgery, Balanced resuscitation

Background

Massive bleeding following injury remains the main cause of death in trauma patients. Uncontrolled hemorrhage is reported to be responsible for 40% of trauma deaths [1]. The central measure for controlling such bleeding incorporated physical hemostatic approaches, such as surgery or interventional radiology. Coagulopathy had been thought to be a resuscitation-induced phenomenon, and replacement of the lost and consumed coagulation factors was the mainstay in the resuscitation of hemorrhagic shock. Recently, better understanding of the pathophysiology of coagulopathy in trauma patients has led to the logical opinion that we should directly address coagulopathy during major trauma resuscitation. Damage control resuscitation (DCR) is a strategic approach to the trauma patient who presents in extremis. In this review article, the pathophysiology of the coagulopathy in trauma patients, the theoretical and practical aspects of DCR, and the revolution of damage control surgery (DCS) incorporated with DCR are discussed.

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Yasumitsu, 2017

- Although the 30-day mortality was comparable, the 6-hour mortality was significantly lower in fibrinogen-treated patients.

- Fibrinogen concentrations could delay the cause of death from early haemorrhagic collapse / shock directly leading to death until later organ failure.

Sources

Notfallmedizin

Anaesthesist
DOI 10.1007/s00101-017-0350-0

H. Lier[1,8] · M. Bernhard[2,3] · J. Knapp[4,5] · C. Buschmann[6] · I. Bretschneider[7] · B. Hossfeld[7,8]

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Ansätze zur prähospitalen Gerinnungstherapie

Aktuelle Übersicht für die zivile Notfallmedizin

Hintergrund

Bei Schwerverletzen ist die Hämorrhagie verantwortlich für 30–40 % der Todesfälle; bis zur Hälfte dieser Patienten verstirbt bereits prähospital, insbesondere nach penetrierendem Trauma [32, 37]. Während das Verbluten im zivilen Bereich nach dem Schädel-Him-Trauma (SHT) an zweiter Stelle der Todesursachen steht, rückt die Exsanguination im militärischen Bereich an die erste Stelle [18]. Bereits vor 10 Jahren konnten Maegele et al. [49] an Daten des Traumaregisters der Deutschen Gesellschaft für Unfallchirurgie (TraumaRegister DGU®) zeigen, dass die frühe Gerinnungsstörung deutliche Folgen für das weitere Schicksal der Patienten hat und ein gutes Drittel der Patienten bereits bei Ankunft im Schockraum eine Koagulopathie aufweist. Diese traumainduzierte Koagulopathie (TIK) wird aktuell als eigenständiges Krankheitsbild angesehen [2]. Eine anhaltende TIK korreliert mit einer Aggravation des Schockgeschehens und der Acidose sowie einer Zunahme der Laktatkonzentration [48]. Während

tritt und oft keine therapeutische Intervention ermöglicht, ist das Verbluten ein Prozess der ersten 2–6(–12) h [4]. Vor diesem Hintergrund muss die initial kritische Zeitphase, die die prähospitale und frühe innerklinische Schockraum-, operative und intensivmedizinische Versorgung umfasst, therapeutisch zur Stabilisierung auch der Blutgerinnung genutzt werden. Aus diesem Grund erscheint eine bereits prähospital einsetzende Gerinnungstherapie sinnvoll und ist derzeit Zielsetzung einer Vielzahl internationaler Studien (Tab. 1).

Es ist ausdrücklich nicht Ziel dieser Übersichtsarbeit, über das substanzbasierte prähospitale Gerinnungsmanagement beim Traumapatienten hinaus die zahlreichen Ansätze zur mechanischen Blutungsreduktion (u. a. „pelvic binder", Resuscitative Endovascular Balloon Occlusion of the Aorta [REBOA] [19, 41, 71], ggf. rare Einzellösungen wie Ballonkatheter für anatomisch nichtkomprimierbare Blutungslokalisationen [17]) oder gar Präventionsaspekte (z. B. https://www.berlin.de/polizei/aufgaben/

te, die entweder gar nicht erst auftritt bzw durch mechanische Maßnahmen oder die Kombination aus mechanischem und substanzbasiertem Therapieregime zumindest an der Aggravation gehindert werden kann.

Therapieoptionen

Rahmenbedingungen der Gerinnung

Gemäß der überarbeiteten und 2016 publizierten S3-Leitlinie „Polytrauma/Schwerverletzten-Behandlung" [2] sollten folgende zentrale Punkte in der initialen Schocktherapie berücksichtigt werden:

- unmittelbarer Stopp einer aktiven und anatomisch komprimierbaren Blutung,
- Vermeidung einer Auskühlung des Patienten (Ziel: Normothermie),
- Vermeidung einer Acidämie,
- Vermeidung einer Hypokalzämie <0,9 mmol/l (Ziel: Normokalzämie).

Lier, 2017

- Many publications show that pre-hospital transfusion of blood products (eg red blood cells and plasma) and coagulation factors (eg fibrinogen) are feasible and safe, but needed only <5% of polytraumatic patients in civilian sector.

- **Preliminary data from a prospective, double-blind, randomized, multicenter fibrinogen study in traumatic-induced coagulopathy (FinTIC) indicate that fibrinogen prehospital administration is possible and can be achieved in the first 3-9 hours of improvement in ROTEM results and laboratory values.**

What's left ...?

… treatment of massive bleeding in prehospital care :

(calcium), cryoprecipitate, fibrinogen, prothrombin complex,
rF VIIa…

- Nowhere in the world is it clear the definition of what is best ...!
- For Prague HEMS we still choose fibrinogen!

Internal regulations of the Prague EMS and stakeholders

- 1. Document
  - Possibilities of administering blood and blood derivatives in prehospital under conditions of Prague HEMS
    (a brief summary of available information and recommendations)
- 2. Document
  - Indication of the administration of fibrinogen for Prague HEMS
- 3. Negotiations
  - in all Prague traumacenters with a positive result, support pre-hospital treatment in a selected group of patients and promised to participate in feedback (availability of coagulation results, etc.)
- 4. Negotiations
  - with the health insurance companies on the payment have been successfully concluded

Our indications for the administration of fibrinogen

1. **First Exacyl** / TxA !!!

- prior to administering fibrinogen, give Exacyl at a dose of 1g iv / io

2. **Indications**: (each point is an indication)

- Pacient is in the class III a IV classifications ATLS of the blood losses
- Patient with a visible / demonstrable blood loss of 1500 ml or more
- Patient with signs of hypovolemic shock due to an injury
- Patient with suspected or confirmed severe hemothorax / hemoperitoneum
- Patient with suspected or proven pelvic fracture
- Patient with suspected or proven fractures of both femurs

Why YES to fibrinogen?

Useful =

- Patients after severe trauma have an entry level below the standard
- It is a basic coagulation element
- Helps to stop the primary source of bleeding
- Administration allows to reduce the number of transfusion products (FFP)
- Managing coagulopathy and / or managing DIC resp. Fibrinolysis
- Reduces mortality in patients after severe trauma (?)

Why YES to fibrinogen?

- It is simply stored, prepared and handed.
- Standard use with increasing frequency in hospitals with a large clinical experience with bleeding (cardiac surgery‘s, transplantation center‘s, ED‘s, ICU‘s, ...)
- Minimal side effects and contraindications
- So far there are no data that would exclude its use in prehospital settings
- Rather, its use in prehospital care seems to be meaningful ...

Why NOT to fibrinogen?

Does it have a "minuses"? Unfortunately…yes:

- Price 12000,- Kč za 1g, resp. 20000,- Kč za 2g (euro 460/770)
- It's not a daily use medication for a Prague (H)EMS crew
- Risk of infection – minimal, but exists
- Prague EMS does not have a "bed-side" monitoring of the level or function of fibrinogen, respectively haemocoagulation examination.

Why NOT to fibrinogen?

Does it still have some minuses?

- Time factor ... preparation and giving
- (problematic in case of introduction into practice on the vehicles / car ambulances of the Prague EMS)

Feedback I

- Revision of data in patients who received fibrinogen
- Entry value of fibrinogen level on Emergency departement
- Entry ROTEM on Emergency departement
- The number of blood or blood products transfusions in 24 hours
- The number of blood derivatives in 24 hours
- Mortality

Feedback II

- Control group…? Will be…? (we have 4 patients from february)
- Initial examination of coagulation parameters before administration of TxA and fibrinogen ...?

Cooperation:

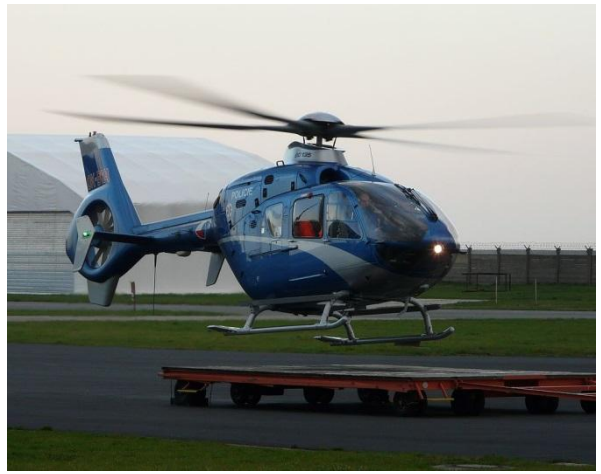
- TC UVN, TC FN Motol, TC FNKV
- Health insurance companies including VZP, consent to reimbursement

Conclusion

- There is plenty of positive data for the use of fibrinogen already in the prehospital care in terms of administration to a selected group of patients.
- We are grateful to all the participants, but especially to the leading doctors from three Prague Traumacenters, with whom we started the project.
- We believe that the correct indication and administration of fibrinogen at the site of an accident or disaster in selected patients will provide them with a better management of the critical situation and thereby improve survival.

Perspectives

- Administration of blood / transfusion products may be another good way to resolve massive bleeding
- In the future (near?) we may be able to choose between full blood and dried plasma and add these to our options for treatment of the massive bleeding
- The Secret Tip: Do not forget about Calcium!



Thank you for your attention.

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