TRAUMA AND EVIDENCE - BASED MEDICINE: A FEW HOT TOPICS

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How do we learn about <u>new</u> developments in medicine?

- **Pharmaceutical Industry**
- **Consultants**
- **CME**
- **Grazing through the Medical Literature**
  - **Requires a large memory capacity with excellent retrieval functions**
  - **Very time consuming**

Medical publishing

- **Annually:**
  - **20,000 journals**
  - **17,000 new books**
- **Medline:**
  - **4,000 journals**
  - **6 Million references**
  - **400,000 new entries yearly**

JASPA

(Journal associated score of personal angst)

J: Are you ambivalent about renewing your JOURNAL subscriptions?

A: Do you feel ANGER towards prolific authors?

S: Do you ever use journals to help you SLEEP?

P: Are you surrounded by PILES of PERIODICALS?

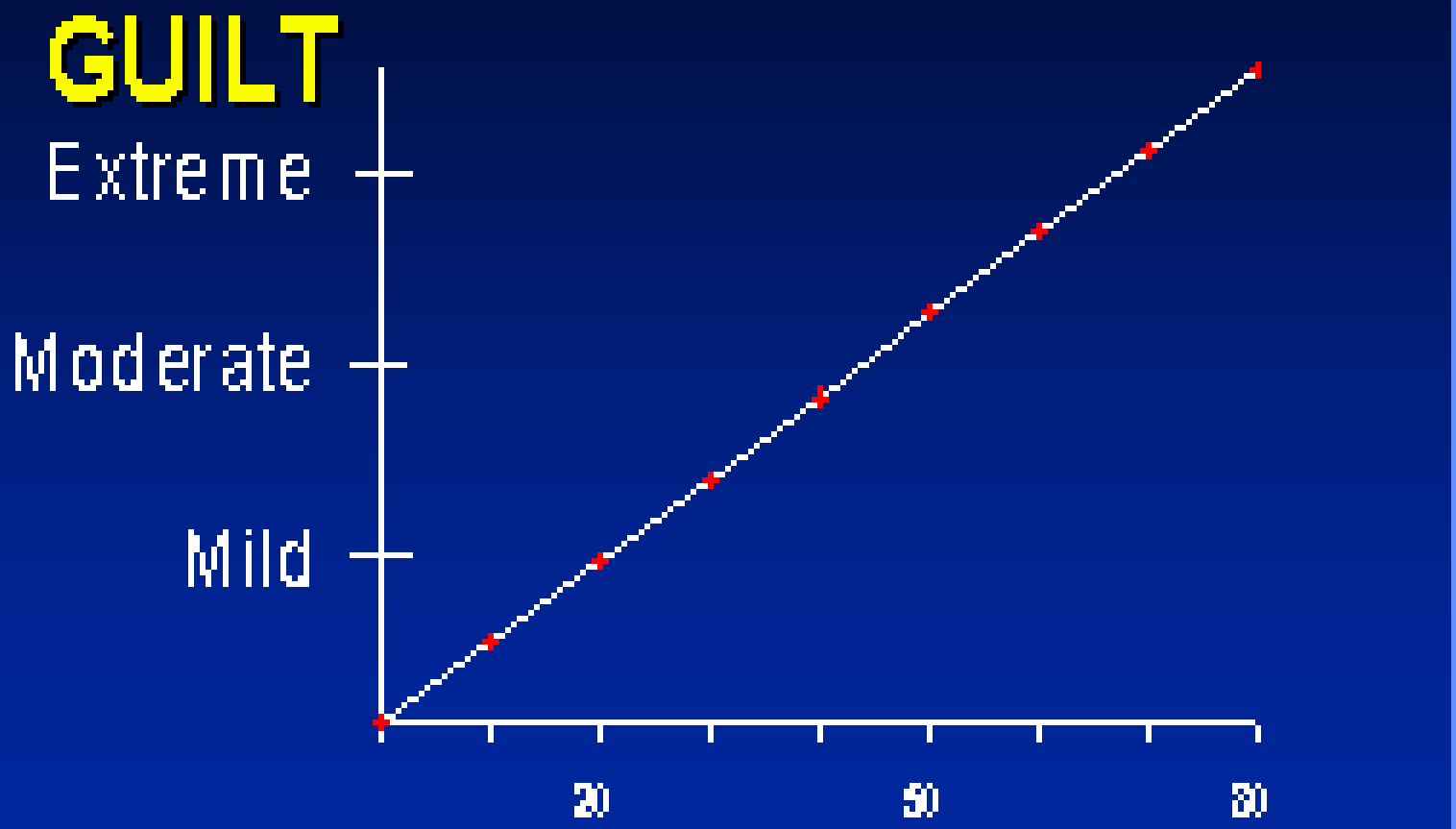
A: Do you feel ANXIOUS when journals arrive?

BMJ 1995;311: 1666-1668

WHY READ THE LITERATURE?

- **To answer a specific patient-related question**
- **To keep up with new clinical developments**
- **To review previously learned information**
- **For enjoyment; to keep up with an interest**

Reasons to Read the Medical Literature



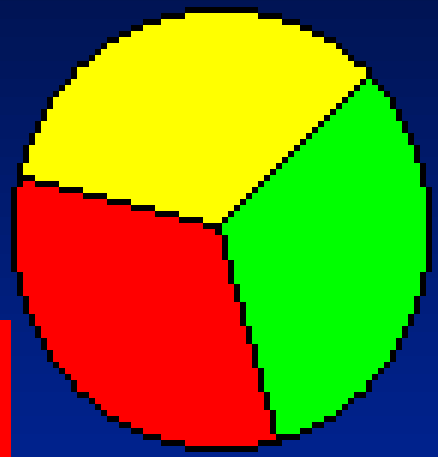
A PARADIGM SHIFT FOR PHYSICIANS

- **From Memory Repositories**
- **To Information Managers**

- **From "How do I keep up with new developments in medicine?"**
- **To "What developments in medicine do I need to keep up with?"**

Clinical Decision Making

Patient circumstances



Evidence from research

Preferences, values and rights

EVIDENCE-BASED MEDICINE: A DEFINITION

- **The conscientious, explicit, and judicious application of the current best evidence in making decisions about the care of individual patients**

Introduction to EBM

- **Ongoing growing interest in the use of Evidence-based medicine (EBM) to develop clinical practice guidelines as a means of:**
  - **Reducing inappropriate care**
  - **Controlling geographic variations in practice patterns**
  - **Making more effective use of health care resources.**

Introduction to EBM

- **Such guidelines can contribute as an aid in clinical decision making, a research tool, and an educational resource.**
- **The Agency of Health Care Policy and Research (AHCPR) has led the way in guideline methodology. There initial work has led many others to develop an evidence-based approach to care**

Introduction to EBM

- **Evidence continues to accrue that guidelines improve clinical practice.**
  - **Brain Trauma Foundation**
  - **ACS COT**
  - **SCCM, AAST, EAST**

Guideline development

- **Step-by-step process**
  - **Development**
  - **Implementation**
  - **Measurement**
  - **Revision**

STEP 1: TOPIC SELECTION

- **With respect to trauma, topics usually selected based on volume, associated hospital costs, and implications for QI/QA.**
- **In general, guidelines will be *disease*, *problem* or *process* specific**

STEP 2: SELECTION OF A PANEL

- **May include:**
  - **Physicians**
  - **Mid level Providers**
  - **Nurses**
  - **Pharmacologists**
  - **Methodologists**
  - **Health Economists**
  - **Mutlidisciplinary**

STEP 3: CLARIFICATION OF PURPOSE AND SCOPE OF THE GUIDELINE

- **Must have clearly and concisely defined objectives**
- **Appropriate inclusion and exclusion criteria should then target the patient population and the clinical setting in which the guideline should be used**

STEP 4: LISTING OF THE GOALS

- **Prior to the lit search the panel should identify the goals**
- **Identification of anticipated health outcomes such as:**
  - **Lowering morbidity**
  - **Changing practice behavior**
  - **Lowering costs**

STEP 5: ASSESSMENT OF SCIENTIFIC EVIDENCE

- **Literature search from 1966 to today using multiple databases and cross checking of citations**

- **Class of Evidence:**
  - **Class I: Prospective, randomized controlled trials**
    - **The GOLD standard**

STEP 5: ASSESSMENT OF SCIENTIFIC EVIDENCE

- **Class of Evidence: (cont.)**
  - **Class II: Studies in which data is collected prospectively with retrospective analyses**
    - **Observational studies**
    - **Cohort studies**
    - **Prevalence studies**
    - **Case control studies**
  - **Class III: Retrospective studies**
    - **Clinical series**
    - **Case reviews and case reports**
    - **Expert opinion**

STEP 5: ASSESSMENT OF SCIENTIFIC EVIDENCE

- **Class of Evidence: (cont.)**
  - **Technology assessment**
    - **Devices evaluated in terms of accuracy, reliability, therapeutic potential, and cost-effectiveness**

STEP 5: RECOMMENDATION

- **Level 1: Convincingly justifiable based on the available scientific information alone**
  - **Usually based on Class I data or a preponderance of Class II evidence**
- **Level 2: Reasonably justifiable by the available evidence and strongly supported by expert critical opinion**
  - **Class II data or preponderance of Class III**

STEP 5: RECOMMENDATION

- **Level 3: Supported by available data but adequate scientific evidence is lacking.**
  - **Class III data**
  - **Useful for educational purposes and in guiding future studies**

STEPS 6 THROUGH 10:

- **Step 6: Drafting and Validation of the document**
- **Step 7: Presentation**
- **Step 8: Implementation**
  - **Extensive education and inservicing**
- **Step 9: Evaluation**
  - **Updated every 3 – 5 years**
- **Step 10: Research**

LIMITATIONS

- **Paucity of prospective randomized Class I data**
  - **Gordon et al " Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomized controlled trials**
  - **Conclusion: Individuals who insist that all interventions need to be validated by a randomized controlled trial need to come down to earth with a bump**

BMJ 2003; 327: 20-21

Eastern Association for the Surgery of Trauma

- **900 members throughout the US**
- **PMG committee formed in 1996**
- **24 published guidelines,**
  - **5 in press, 8 in progress**
- **4000 website hits/day with 1900 downloads/day**
- **Implementation**
  - **State of Washington**
  - **Sydney, Australia**

PRACTICE MANAGEMENT GUIDELINES FOR BLOOD TRANSFUSION IN THE TRAUMA PATIENT

EAST Practice Management Workgroup for Blood Transfusion

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The workgroup

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Rovinder Sandhu, MD
Jay A. Yelon, DO

Scope of the problem

- **The indication for packed red blood cell (prbc's) transfusions in the critically ill patient remains controversial**
  - **Historically, the decision to transfuse has been guided by the hemoglobin concentration "transfusion trigger"**
  - **A re-evaluation of this practice was prompted by the fear of transfusion-related infections, ever-decreasing blood supply, possibilities of allergic reaction, and the immunosuppressive effects of transfusion**

Scope of the problem

- **Another important concern is that anemia may not be well tolerated by certain critically injured patients**
  - **Those with preexisting coronary, cerebrovascular, and pulmonary disease**
- **Finally, belief that certain conditions may require higher Hgb concentrations:**
  - **ARDS**
  - **Sepsis**
  - **MSOF**

Scope of the problem

- **Multiple causes of anemia in the critically ill**
  - **Excessive phlebotomy**
  - **Ongoing blood loss**
  - **Underproduction**
    - **Blunted erythropoietic response to low hemoglobin**
    - **Negative influence of cytokines (TNF)**
    - **Inflammatory responses (IL-1, and IL-6)**
  - **Underlying disease state**

Scope of the problem

- **More than 85% of patients with an ICU LOS of greater than one week receive at least one transfusion of PRBC's**
  - **Mean 9.5 units**
  - **Two-thirds of transfusions are not associated with with acute blood loss**

Scope of the problem

- **Benefits of PRBC infusions:**
  - **Increase DO_2 to tissues**
  - **Increase cell mass/blood volume following acute blood loss**
  - **Alleviate symptoms of severe anemia**
    - **Dyspnea, fatigue, diminished exercise tolerance**
  - **Relief of cardiac effects of severe anemia**

Our questions?

- **What are the risks/benefits of transfusing critically ill trauma patients?**
- **What are the indications for transfusion?**
- **Are there alternatives to transfusions?**

Process

- Medline search from 1966 through January 2004
  - English language
- 140 articles identified and classified
- Literature reviews, case reports and editorials were excluded. Pediatric (<16 yo) excluded
- Trauma surgeons and a trauma nurse

RECOMMENDATIONS - RISK VERSUS BENEFIT

- **Level 1: There is insufficient data to support Level 1 recommendations on this topic**

- **Level 2: Transfusion of PRBC's are associated with increased nosocomial infection rates independent of other factors (wound infection, pneumonia, and sepsis)**

RECOMMENDATIONS - RISK VERSUS BENEFIT

- **Level 2: Filtered, leukocyte-depleted PRBC's should be utilized when available to reduce transfusion related infectious complications**

- **Level 2: Using the freshest stored PRBC's will reduce the incidence of multisystem organ failure.**

RECOMMENDATIONS - RISK VERSUS BENEFIT

- **Level 2: The number of PRBC infusions is independently associated with longer ICU and hospital LOS, more complications, increased mortality**

RECOMMENDATIONS - INDICATIONS FOR TRANSFUSION

- **Level 1: There is insufficient data to support Level 1 recommendations on this topic**

- **Level 2: The decision to transfuse should be based on the patients intra-vascular volume status, duration and extent of anemia, cardiopulmonary reserve and atherosclerotic risk**

RECOMMENDATIONS - INDICATIONS FOR TRANSFUSION

- **Level 2: A "restrictive" transfusion strategy (Hgb < 7.0 g/dL) for patients without active myocardial ischemia is as effective as a "liberal" transfusion policy (Hgb < 10 g/dL) and should be utilized**
  - **Restrictive group maintained between 7.0 g/dL to 9.0 g/dL**
  - **Liberal group maintained between 10 g/dL to 12 g/dL**

RECOMMENDATIONS - INDICATIONS FOR TRANSFUSION

- **Level 2: No benefit of a liberal transfusion strategy in mechanically ventilated patients, those with ARDS, sepsis or multisystem organ failure**

RECOMMENDATIONS - ALTERNATIVES

- **Level 1: Recombinant erythropoietin (Epoetin alfa) administration improves reticulocytosis and hematocrit, decreases overall transfusion requirements but does not affect LOS or mortality**
  - **Supplemental iron**

Discussion

- Transfusion trigger
- The decision to transfuse needs to be based on the patients physiologic status and athero-sclerotic risk.
- Recombinant erthyropoietin improves reticulocytosis and hematocrit

Future direction

- **Propose a prospective randomized trial to the MIT committee**
- **Further investigation of epoetin alfa**
  - **EPO 3 trial**
- **Possibility of massive transfusion and transfusion of blood components guideline**
- **Blood substitutes show promising results in phase 2 trials**

PRACTICE MANAGEMENT GUIDELINES FOR VTE PROPHYLAXIS IN THE HEAD INJURED PATIENT

EAST Practice Parameter Workgroup for DVT Prophylaxis in the Head Injured Patient

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Scope of the problem

- Mobilization
- Graduated compressive stockings
- Intermittent pneumatic compression devices
  - Calf vs. thigh high, vs. sequential vs. foot pumps
- Combination therapy
- Anticoagulant therapy
  - LDH, LMWH, Coumadin, Dextran, Aspirin

Our questions?

- **Are head injured patients at an increased risk of developing DVT?**
- **If so, which modality shows most benefit?**
- **In what time period is it safe to start anticoagulation?**

Process

- Medline search from 1966 through December, 2000
  - English language
- 70 articles identified
- Literature reviews, case reports and editorials were excluded
- 58 selected for classification
- Trauma surgeons, trauma nurse and neurosurgeon

Risk

- **Overwhelming evidence that head injured trauma patients, within both the acute post-injury period and over the longer rehabilitation period, are at increased risk of developing DVT**
  - **Prolonged immobilization is a key component**
  - **DVT rates of 20 - 40%**

RECOMMENDATIONS

- **Graduated compressive stockings**
  - **Level 1: There is insufficient data to support Level 1 recommendations on this topic**
  - **Level 2: Graduated compressive stockings should be used in combination with SCD's in the head injured trauma patient**
  - **Level 3: There is insufficient data to support Level 3 recommendations on this topic**

RECOMMENDATIONS

- **Intermittent pneumatic compression devices**
  - **<u>Level 1</u>: Head injured patients should receive sequential compression devices for prophylaxis against DVT**
    - optimally placed and worn
  - **<u>Level 2</u>: Sequential compression devices should be used in combination with graduated compressive stockings**

RECOMMENDATIONS

- **Intermittent pneumatic compression devices**
  - **<u>Level 3</u>:**
    - In head injured patients in whom the lower extremity is inaccessible to place SCD's, foot pumps may act as an effective alternative to lower DVT formation
    - In severe head injured patients with ICP monitoring, SCD's should be used for prophylaxis

RECOMMENDATIONS

- **Low Dose Heparin**
  - **<u>Level 1</u>: There is insufficient data to support Level 1 recommendations on this topic**
  - **<u>Level 2</u>: In the head injured patient that is high risk (lower extremity fx's, pelvic fx's, spinal cord injury) Low Dose Heparin may be administered after 48 hours**
    - Frequent neurologic exams and head CT's should be performed
  - **<u>Level 3</u>: There is insufficient data to support Level 3 recommendations on this topic**

RECOMMENDATIONS

- **Low Molecular Weight Heparin**
  - **Level 1: There is insufficient data to support Level 1 recommendations on this topic**
  - **Level 2: There is insufficient data to support Level 2 recommendations on this topic**
  - **Level 3: There is insufficient data to support Level 3 recommendations on this topic**

Discussion

- **In the high risk patient, LDH can be started as early as 2 days post injury provided initial coagulation parameters are normal and the hemorrhagic lesions have stabilized**
  - **Prospective randomized controlled studies of LDH use are needed.**
- **Other anticoagulants such as Dextran, ASA, and NSAIDS show no benefit in DVT prophylaxis.**

Discussion

- Aventis' Traumenox study - cancelled
- Various LMWH compounds have variable safety and efficacy profiles; therefore, extrapolation is not acceptable
- It is essential that the therapy be continued until patient is mobilized, regardless of the prophylaxis regiment utilized

PRACTICE MANAGEMENT GUIDELINES FOR TIMING OF TRACHESOTOMY

EAST Practice Management Workgroup for Timing of Tracheostomy

The workgroup

- Michele Holevar, MD
- Michael Dunham, MD
- Robert Brautigan, MD
- Thomas Clancy, MD
- John Como, MD
- James B. Ebert, MD
- Maggie Griffen, MD
- William Hoff, MD
- Stan Kurek, DO
- Susan Talbert, MD
- Sam Tisherman, MD

Statement of the Problem

- Ideal time for tracheostomy not clearly established
- Literature recommends three days to three weeks
- Tracheostomy can be performed with low complication rate
- Risks of prolonged ETT recognized
- Percutaneous tracheostomy has added convenience of bedside procedure

Statement of the Problem

- **Different subgroups may benefit from tracheostomy at different times**
  - **Single organ failure**
    - **Head**
    - **Respiratory**
  - **Multiple injuries**
- **Without clear guidelines local practice preferences guide care**

Process: Questions Generated

- **Does performance of an “early” tracheostomy provide a survival benefit for the recipients?**
- **What patient populations benefit from an “early” tracheostomy?**
- **Does “early” tracheostomy reduce the number of days on MV & ICU LOS?**
- **Does “early” tracheostomy influence the rate of ventilator-associated pneumonia?**

Process: Identification of References

- Computerized Medline search 1966 - 2004
- Search words “tracheostomy” and “timing”
- Search limited to human studies published in English language
- 87 articles identified
- Case reports, review articles, editorials, pediatric series excluded
- Master reference list of 24 citations

Process: Identification of References

- Articles distributed among subcommittee members for formal review
- Data sheet completed summarizing purpose of study, hypothesis, methods, main results, conclusions
- Reviewers classified each reference by methodology established by the Agency for Health Care Policy & Research (AHCPR) of the U.S. Department of Health & Human Services

Process: Quality of References

- Class I: **Prospective randomized controlled trials** (7 references)
- Class II: **Clinical studies in which data collected prospectively but analyzed retrospectively. Included observational studies, cohort studies, prevalence studies & case control studies** (5 references)
- Class III: **Studies based on retrospectively collected data** (12 references)

Level I Recommendations

- **There is no mortality difference between patients receiving early tracheostomy (3 to 7 days) and late tracheostomy or extended endotracheal intubation.**

Level II Recommendations

- **Early tracheostomy decreases the total days of mechanical ventilation and ICU LOS in patients with head injuries. Therefore, it is recommended that patients with a severe head injury receive an early tracheostomy.**

Level III Recommendations

- **Early tracheostomy may decrease the total days of mechanical ventilation and ICU. LOS in trauma patients without head injuries**
- **Early tracheostomy may decrease the rate of pneumonia in trauma patients.**
- **Therefore, it is recommended that early tracheostomy be considered in all trauma patients anticipated to require mechanical ventilation for > 7 days.**

Future Investigations

- **Ideally prospective, randomized studies with sufficient number of patients within a homogenous group**
- **Consensus as to what constitutes “early” versus “late” tracheostomy should be established so various studies can be compared.**

Future Investigations

- As blinding is unrealistic, systematic weaning protocols should be used to reduce the effect of different approaches toward weaning
- Given current conditions of shrinking resources, future studies should routinely include cost-effectiveness analysis

Thank you!

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