Handbook of Evidence-Based Critical Care

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2nd Edition

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Springer

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ISBN 978-1-4419-5922-5 e-ISBN 978-1-4419-5923-2
DOI 10.1007/978-1-4419-5923-2
Springer New York Dordrecht Heidelberg London

Library of Congress Control Number: 2010921986

Printed on acid-free paper

Springer is part of Springer Science+Business Media (www.springer.com)

To Susan, Ernie and Molly,
who have enriched my life.

Acknowledgments

This book is dedicated to my mentors and students who have taught me everything I know and inspired me to learn even more.

Preface

Learning without thinking is useless. Thinking without learning is dangerous

– Confucius

Since the publication of the first edition of *The Handbook of Evidence-Based Critical Care* in 2001, the landscape of critical care medicine has changed enormously. Numerous randomized controlled studies (RCTs) that have changed the daily practice of critical care medicine have been published. Furthermore, our understanding of the complex pathophysiology of the critically ill and injured has advanced, new therapies have emerged (and some have fallen by the wayside), and we have refined how we monitor and manage our patients. We have also recognized our limitations and improved end-of-life care. In all, we are *wiser* and more attuned to the challenges of providing care to the sickest of the sick. However, the basic guiding principles of critical care medicine have not changed; compassionate, dedicated and thoughtful clinicians, who evaluate the functioning of the "whole" patient, ponder their disease processes and pathophysiology and provide the highest level of *evidence-based* interventions with the goal of restoring the patient to a quality of life which he/she values. The second edition of *The Handbook of Evidence-Based Critical Care* chronicles the remarkable progress made in the last decade and sets the stage for what is yet to come!

The focus of this handbook is on issues that pertain specifically to the ICU. As such the reader is referred to standard medical and surgical texts as well as online resources for more complete information on the wide spectrum of conditions and diseases from which ICU patients may suffer.

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Contents

Part I

Introduction to Critical Care Medicine

1

Evidence-Based Critical Care

There are in fact two things, science and opinion; the former begets knowledge, the latter ignorance.

–Hippocrates (c460–c377 BCE), Greek physician

Before medicine developed its scientific basis of pathophysiology, clinical practice was learned empirically from the events of daily experience in diagnosing and treating the maladies patients presented. Students learned as apprentices to clinicians, observing the phenomena of disease, the skill of diagnosis and treatment, and the outcomes of different remedies. Sir William Osler's classic textbook of medicine was based almost entirely on his *personal experience correlated with the general experience of others*.[1] With advances in our understanding of human physiology and the pathophysiological basis of disease, these remedies fell by the wayside and treatment became based on modalities of treatment that were shown to interrupt or otherwise modify the disease process. Until recently, it was considered sufficient to understand the disease process in order to prescribe a drug or other form of treatment. However, when these treatment modalities were subjected to randomized, controlled clinical trials (RCTs) examining clinical outcomes and not physiological processes, the outcome was not always favorable. The RCT has become the reference in medicine by which to judge the effect of an intervention on patient outcome, because it provides the greatest justification for conclusion of causality, is subject to the least bias, and provides the most valid data on which to base all measures of the benefits and risk of particular therapies.[2] Numerous ineffective and harmful therapies have been abandoned as a consequence of RCTs, while others have become integral to the care of patients and have become regarded as the standard of care.

P.E. Marik, *Handbook of Evidence-Based Critical Care*,
DOI 10.1007/978-1-4419-5923-2_1,

Many RCTs are, however, inconclusive or provide conflicting results. In this situation, systematic reviews that are based on meta-analysis of published (and unpublished) RCTs are clearly the best strategy for appraising the available evidence. While meta-analyses have many limitations, they provide the best means of determining the significance of the *treatment effect* from inconclusive or conflicting RCTs. Furthermore, as a result of publication bias, positive studies are more likely to be published and usually in more prestigious journals than are negative studies. A clinician may base his/her therapeutic decisions on these selected RCTs which may then lead to inappropriate patient care. It is therefore important that common medical interventions be systematically reviewed and the strength of the evidence (either positive or negative) be evaluated. Although over 250,000 RCTs have been performed, for many clinical problems, there are no RCTs to which we can refer to answer our questions. In these circumstances, we need to base our clinical decisions on the *best evidence* available from experimental studies, cohort studies, case series, and systematic reviews.

Every decision that the clinician makes must be based on sound scientific evidence (a collection of anecdotes is not scientific evidence). Science is the continuing effort to discover and increase human knowledge and understanding through disciplined research. Using controlled methods, scientists collect observable evidence, record measurable data relating to the observations, and analyze this information to construct explanations of how things work.[3] Intuition, anecdotes, common sense, personal biases, and clinical experience are not considered "science" and cannot be used to justify clinical decision making or therapeutic policies.

While *Evidence-Based Medicine (EBM)* is frequently criticized as "cookbook" medicine, this is most certainly not the case. Rather, the best scientific evidence should be applied to the unique characteristics of each patient.[2] Each patient is unique, and the "art" of medicine is the ability to integrate and apply the best scientific knowledge to each patient. Checklists may be fine if you are flying an airplane; however, patients are not airplanes and doctors are not pilots.[4,5] While the response to pushing a button or pulling a lever on a Boeing 737-400 is entirely predictable (with the same reproducible result), the response of any given patient to a volume challenge or an injection of a β-blocker is dependent on a myriad of physiological/pathophysiological factors, with the response not being entirely predictable. Furthermore, intensivists evaluate and provide care to the entire patient and are not single-organ physicians that merely adjust the rudder or lower the landing gear and hope for the best![4] Clinical practice guidelines (CPGs), which are evidence-based and up-to-date, are useful in providing the clinician with direction but should never be followed blindly. Rigid protocols and policies, have little place in clinical medicine.

As critical care medicine has evolved into a discreet specialty that crosses anatomical and other artificial boundaries and deals with an enormous array of human conditions, it has become evident that to achieve the best outcomes for our very complex patients, all our clinical decisions should be based on the *best available evidence*. The complexity of the critically ill patient together with the vast armamentarium of therapeutic options available makes it essential that we critically evaluate established and emerging clinical practices. Bone throwing, bloodletting, witchcraft, and other forms of hocus-pocus have no role in modern critical care. However, it is important to realize that critical care medicine can be practiced only by close observation of the patient (at the bedside), by contemplation, and by the integration of a large data base of evidence-based medicine together with a good deal of humility.

The *Handbook of Evidence-Based Critical Care* is not a reference text but presents a practical *evidence-based approach* to the management of critically ill ICU patients. Due to the vast number of therapeutic interventions that ICU physicians make daily, the topics are presented as narrative summaries of the *best available evidence* rather than as systematic reviews of each and every intervention. While all attempts have been made to be current, due to the exponential growth of medical knowledge, some of the information presented may already be outdated when this book comes to print. The reader therefore should keep up-to-date with the current medical literature. In keeping with the goal of providing an evidence-based approach to critical care, references are provided to support the evidence presented.

ALERT

The guidelines presented in the book are not meant to replace clinical judgment but rather to provide a framework to patient management. Individual clinical situations can be highly complex and the judgment and wisdom of an experienced and knowledgeable intensivist with all available information about a specific patient is essential for optimal clinical management.

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2

Classic Critical Care Papers

A limited number of publications have had a dramatic impact on the practice of critical care medicine. These publications are regarded as "compulsory" reading for residents, fellows, and other practitioners of critical care medicine. Surprisingly, although not unexpectedly, those publications with the potential to have the most dramatic positive impact on patient care have been slow to be adopted, while publications of questionable scientific rigor are frequently adopted with an unexplained religious fervor. This chapter reviews those papers which have dramatically altered the practice of critical care medicine (for good or bad) as well as those "classic" papers that have shaped the history of critical care medicine.

Perhaps the most important publication in the history of critical care medicine is that of the ARDSNet low vs. standard tidal volume study.[1] This study demonstrated a significant reduction in 28-day mortality in patients randomized to the low tidal volume group (6 ml/kg PBW) as compared to the traditional tidal volume (12 ml/kg PBW) group. The results of this study are supported by extensive experimental and clinical studies. Furthermore, high tidal volumes are associated with progressive lung injury in patients who initially do not have acute lung injury. A tidal volume of 6–8 ml/kg is therefore considered the standard of care for *all* ICU patients. A follow-up study by the ARDSNet group suggested that a fluid management strategy that aims to keep patients "dry" improves patient outcome (significant increase in ventilator-free days).

Kress and colleagues[2] demonstrated that in patients who are receiving mechanical ventilation, daily interruption of sedative drug infusions decreases the duration of mechanical ventilation and the length of stay

P.E. Marik, *Handbook of Evidence-Based Critical Care*,
DOI 10.1007/978-1-4419-5923-2_2,

in the intensive care. Ely and colleagues[3,4] have demonstrated that a non-physician-directed protocol of spontaneous breathing trials expedites weaning and shortens the duration of mechanical ventilation. Recently, Girard and colleagues[5] demonstrated that a wake up and breathe protocol that pairs daily spontaneous awakening trials (i.e., interruption of sedatives) with daily spontaneous breathing trials results in better outcomes for mechanically ventilated patients than do the "standard approaches." This approach should be considered the standard of care in all ICU patients.

Blood transfusions and the choice of resuscitation fluid have until recently been a controversial issue. In a landmark study, Hebert and colleagues[6] compared a conservative (transfusion for Hb <7 g/dl) vs. liberal (transfusion for Hb <10 g/dl) blood transfusion protocol. In this study the complication rate and 28-day mortality tended to be lower in the conservative group. These results of this study are supported by a meta-analysis of cohort studies, which clearly establishes the benefits of a restrictive blood transfusion strategy.[7] The SAFE study demonstrated the safety of albumin in critically ill patients,[8] while the VISEP study demonstrated an increased risk of renal failure and death in critically ill patients resuscitated with a hydroxyethyl starch solution.[9]

Beginning in the 1960s, Dr. Max Harry Weil[10,11] (the father of critical care medicine) demonstrated the relationship between lactate and the reversibility of shock. Furthermore, in what is now a landmark study, Dr. Weil and colleagues[12] demonstrated a marked difference in arterial and mixed venous acid–base status in patients undergoing CPR. These studies ushered in our current approach to the monitoring of tissue oxygenation in the critically ill patients.

In 1982, Shoemaker and colleagues[13] published a study suggesting that achieving "supranormal" levels of oxygen delivery improved the outcome of critically ill patients. This approach became very fashionable in the late 1980s and the early 1990s and became part of the ICU culture encouraging the (excessive) use of the pulmonary artery catheter (PAC). Subsequent, RCTs were unable to demonstrate the benefit of this approach with the suggestion that driving up oxygen delivery to the "magical" end points proposed by Shoemaker and colleagues may be harmful (this became a popular theme!).[14,15]

The "classic" study by Connors et al.[16] in 1996 raised the possibility that the PAC may be harmful in critically ill patients. Subsequent studies have been unable to demonstrate any benefit associated with the use of the PAC.[17] While the use of the PCWP (pulmonary capillary wedge pressure) as measured using the PAC has fallen into disfavor, the central venous pressure (CVP) continues to be used universally to guide fluid management despite convincing evidence that this measurement is as useful as flipping a coin.[18]

The diagnosis and treatment of ventilator-associated pneumonia (VAP) is an important issue in the ICU. Fagon and colleagues[19] compared a diagnostic approach based on lower respiratory tract sampling and quantitative culture with that of the "standard approach." Compared with the non-invasive strategy, the invasive strategy was associated with fewer deaths at 14 days, earlier resolution of organ dysfunction or less antibiotic use in patients suspected of having VAP. Chastre and colleagues[20] compared 8 vs. 15 days of antibiotic therapy in patients with VAP. There was no difference in outcome between the two groups (with the possible exception of those with pseudomonas pneumonia).

Until recently, the optimal dosing of intermittent hemodialysis (IHD) and continuous renal replacement therapy in the ICU was unclear with data suggesting that more aggressive renal replacement therapy (RRT) was associated with improved renal recovery. The VA/NIH Acute Renal Failure Trial Network randomized 1,124 patients with ARF to receive intensive or less intensive RRT.[21] Hemodynamically stable patients underwent IHD (6 vs. 3 times per week) and hemodynamically unstable patients underwent CVVHD (35 vs. 20 ml/kg/h). There was no difference in clinical outcomes between the two groups of patients.

November the 8th was a dark day in the history of critical care. On that day two "studies" were published in the *New England Journal of Medicine* which changed (overnight) the way critical care was practiced around the world.[22,23] Rivers and colleagues[23] randomized 288 patients with severe sepsis and septic shock to "early goal-directed therapy (EGDT)" or standard care. EGDT was reported to be associated with a 16% absolute reduction of hospital death (35% relative reduction in death). Based on this single study, EGDT became adopted as the "standard of care" around the world and has become the cornerstone of the recommendations of the *Surviving Sepsis Campaign*.[24,25] It is however important to recognize that this was an unblinded, small, single-center study with investigators who were highly "invested" in the outcome of the study. By any stretch of the imagination the results of this study were "too good to be true." Recent evidence questions the validity of the findings of the study (see *Wall Street Journal*, lead report, August 14th 2008).[26] While the concept of EGDT intuitively makes sense, the role of the "central venous oxygen saturation" and a CVP >8 cm H_2O as the end points of resuscitation in septic patients is questionable (and not validated) as is the liberal use of blood and other interventions called for by the EGDT protocol (see Chapters 8, 10, and 51). Stay tuned to this interesting saga; a sequel is in the works! [Protocolized Care for Early Septic Shock (ProCESS); NCT00510835]

On the same day that the EGDT study was published, the *Leuven Intensive Insulin Therapy Trial #1* appeared in the *NEJM*.[22] This study compared the outcome of patients randomized to an insulin

infusion protocol that achieved "tight glycemic control" (blood glucose 70–110 mg/dl) as compared to "standard glycemic control" (blood glucose 180–200 mg/dl). This study demonstrated a significant reduction in morbidity and mortality in the patients randomized to the "tight glycemic group." Similar to EGDT, based on this single-center, unblinded study performed by highly "invested" investigators, "tight glycemic control" became adopted overnight as the standard of care throughout the world.[27] Subsequent studies have failed to reproduce the findings of van den Berghe et al. and "tight glycemic control" should now be abandoned.

The role of corticosteroids in patients with sepsis and ARDS is controversial. Landmark studies by Annane et al. and Meduri et al. suggested that corticosteroids reduced 28-day mortality in ICU patients with septic shock and ARDS (late), respectively.[28,29] The results of more recent studies have further fueled this controversy.[30–32]

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3

Critical Care Medicine 101

Patients in the ICU need to be managed by doctors who can see the "big picture," be able to integrate and understand the patients' complex multisystem disease, and formulate an integrative plan that is evidence based, systematic, and is in keeping with the patients' treatment goals and values while being consistent with reality. Intensivists are realists who provide physiologically based interventions with the goal of limiting disease and improving outcomes; voodoo and other fantasy-based treatments have no role in the ICU. This chapter reviews the concepts and basic interventions which should be addressed when admitting a "generic patient" to the ICU. A number of issues need to be addressed regardless of the type of ICU to which the patient is being admitted and the patient's diagnosis.

It is important to note that no two patients are ever the same and that patients do not read medical textbooks or "policies and procedures." Furthermore, patients respond differently to the same intervention. Each patient's care must therefore be individualized based on the patient's unique demographics, comorbidities, acute disease processes, response to physiologically based interventions, and their values and goals. "Policies and procedures" and "bundles of care" have a limited place in the ICU. Parallels are often drawn between the airline industry and the practice of medicine. In general, this is a dangerous position to take. As Southwest Airlines understands, all 737-300s are build exactly the same and respond exactly in the same way when the same set of knobs and levers are pulled; patients, however, are not 737s (they are infinitely more complex and much more unpredictable).

P.E. Marik, *Handbook of Evidence-Based Critical Care*,
DOI 10.1007/978-1-4419-5923-2_3,

■ HOW AN ICU DIFFERS FROM OTHER AREAS OF THE HOSPITAL

An ICU is a place where patients undergo intensive and continuous physiological monitoring, where the critical care team applies physiologically based interventions and monitors the response to these interventions, which then serves as the basis for further interventions. It is therefore clear that critical care medicine can be practiced only at the bedside; office-based "intensivists" have no place in the ICU.

■ FACTORS TO CONSIDER WHEN A PATIENT IS ADMITTED TO THE ICU

- The patient's age (chronological not physiological)[1] (see Chapter 55).
- Comorbidities, particularly the following:
  - Cardiac disease and ventricular function.
  - Underlying lung disease.
  - Baseline renal function (the baseline and current estimated GFR should be calculated on admission in *all* patients).*
  - Use of immunosuppressive drugs.
- The diagnoses and differential diagnoses.
- Is this patient septic?
- Does this patient have SIRS (leaky capillaries)?
- Does this patient have acute lung injury (ALI)?
- What is the status of this patient's intravascular volume? (see Chapter 8)?
  - Normal.
  - Increased.
  - Decreased.
- Does this patient have evidence of impaired tissue/organ perfusion (see Chapter 8)?
  - Decreased urine output.
  - Cold/clammy skin.
  - Mottled peripheries.
  - Increased lactate concentration.
  - Hypotension.

*Estimated GFR (Cockcroft–Gault equation) = (140–age) × (weight in kg) × (0.85 if female)/(creatinine × 72)

- The patients' code status, preferences for life-supportive therapy, and goals/expectations of treatment *must* be determined when the patients are admitted to the ICU.
- Determine the adequacy of venous access.
- Communicate with the patients' nurse and respiratory therapist.
- Keep the family informed.
- Measure the patients' height and weight on admission (see Chapters 14 and 19).

■ INITIAL "GENERIC" TREATMENT ORDERS

- Fluids:
  - State the type of fluid and the infusion rate.
- Oxygenation
  - Nasal cannula/Venturi mask.
- Initial ventilator settings:
  - AC rate 6–8 ml/kg Ideal Body weight (IBW).
  - Flow rate 60 l/min.
  - FiO_2 100%.
  - PEEP 5–10 cm H_2O.
- ICU patients are at a high risk for deep venous thrombosis (DVT) and therefore *all* ICU patients require DVT prophylaxis. This should be individualized based on the patient's risk of DVT, risk of bleeding, risk of HIT, and renal function (see Chapter 21):
  - Subcutaneous heparin (5,000 U BID, TID).
  - Subcutaneous low molecular weight heparin.
  - Subcutaneous fondaparinux (2.5 mg q day).
  - Sequential compression devices.
  - Combination of SCD and anti-coagulant.
- Routine stress ulcer prophylaxis is not required in patients who are receiving enteral nutrition (see Chapter 32):
  - PPI or H2RB in those who require stress ulcer prophylaxis.
- Nutrition (see Chapter 31):
  - Unless specifically contraindicated or the patient's length of stay in the ICU is expected to be less than 24 h, all patients should be fed enterally once they have been resuscitated.
- All patients require chlorhexidine (or equivalent) mouth wash and regular oral hygiene.[2,3]
- All patients should be nursed head up 30° unless contraindicated for some reason (reduces risk of VAP).[4]
- Ocular lubricant to prevent exposure keratopathy.[5]
- Sedation should be titrated to the RASS score (see Chapter 9).

- All ICU patients should be regularly screened (at least daily) for the presence of delirium using a validated delirium assessment tool (see Chapter 47).
- Sedation with benzodiazepines should be avoided (see Chapters 9 and 47).

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4

House Officers' Guideline 1: Housekeeping

Intensive care units embody the miraculous advances of modern medicine. An ICU provides an environment where high-quality, compassionate, physiologically orientated, and evidence-based medicine can be practiced. The ICU is an exciting and challenging place to work and provides a remarkable learning environment. The keys to a successful rotation in the ICU are (1) teamwork and (2) a systematic, disciplined, and organized approach to patient care.

■ ADMISSION HISTORY AND PHYSICAL EXAMINATION

It is essential that a detailed and systematic history and physical examination be performed on all patients admitted to the ICU. This should include past medical and surgical history, current mediations as well as details of the current illness. The patient's *code status* and the presence of advance directives should be established on admission to the ICU. The initial physical examination frequently serves as the baseline reference, and it should include a basic neurological examination (including reflexes, motor power, evaluation of mental status, and funduscopic examination). Following the history and physical examination, and review of the available laboratory data and chest radiograph, a differential diagnosis and a management plan should be formulated.

The patient's weight and height should be measured directly with a scale and tape measure on admission to the ICU. These values should not

P.E. Marik, *Handbook of Evidence-Based Critical Care*,
DOI 10.1007/978-1-4419-5923-2_4,

be estimated as they are frequently *wrong*[1]; the height and the weight are used in dosing calculations as well as estimating GFR and predicted body weight (PBW); so the correct data should be used.

■ DAILY EXAMINATION

It is essential that the patient's flow sheet (paper or electronic) over the last day be thoroughly reviewed and the major events of the last 24 h be documented. Most ICUs use a 24-h flow sheet which runs from midnight to midnight. Hence when reviewing and documenting the patient's progress over the "last day," the last 24-h period (midnight–midnight) as well as the progress since midnight should be reviewed. The following serves as a guideline for the daily progress note:

ALERT

It is important to be systematic and develop a template for your daily progress notes.

General

Primary and secondary diagnoses, overall condition of the patient, and events of the last 24 h.

Vital Signs (24-h Min and Max and Current)

- Temperature
- Blood pressure
- Pulse (rate and rhythm)
- Respiratory rate
- Arterial saturations

Fluid balance and urine output are *vitally* important in the daily and ongoing evaluation of the ICU patient. The following should be recorded:

- 24 h in.
- 24 h out.
- 24 h urine.
- Output of each drain should be noted.
- *Cumulative fluid balance.*
- 6 h in.
- 6 h out.
- 6 h urine.