Literature Evaluation I

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Outline

- Structures of research articles
- Criteria for evaluating a clinical trial

- Evidence-Based Pyramid
- Types of Study Designs
  - Observational study
  - Experimental study

Objectives

- After the current lecture you should be able to
  - Tell the difference of the three levels of literature
  - Write out the structure of original articles in a reasonable consequence
  - Tell a general figure of what information is in each of the section of research articles and how to evaluate their quality

Categories of Literature

Category	Definition	Example	Advantage	Limitation
Primary literature	Original research reports	Original publications	Current and original information	Knowledge is needed to interpret the information
Secondary literature	Database of primary literature search	PubMed, Ovid Medline	Efficient access to original publications	Users need to be adept at searching electronic databases
Tertiary literature	Collection of data and concepts drawn from primary literature	Reference books, drug monograph collections, review articles	Convenient and easy to use; established information	Information may be dated due to gap between when resource is written and published

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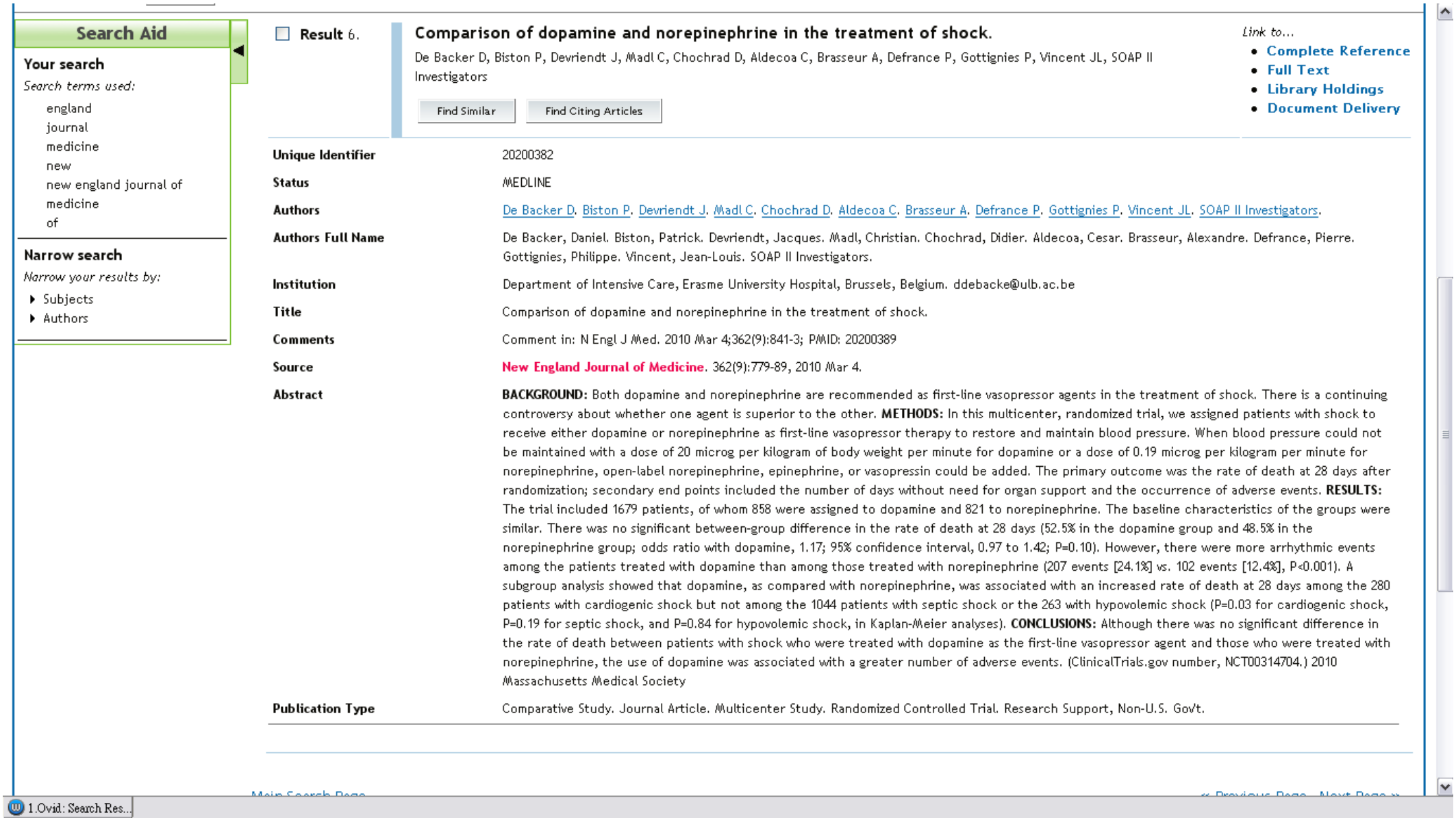

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Result 6.

Comparison of dopamine and norepinephrine in the treatment of shock.

De Backer D, Biston P, Devriendt J, Madl C, Chochrad D, Aldecoa C, Brasseur A, Defrance P, Gottignies P, Vincent JL, SOAP II Investigators

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Unique Identifier	20200382
Status	MEDLINE
Authors	De Backer D. Biston P. Devriendt J. Madl C. Chochrad D. Aldecoa C. Brasseur A. Defrance P. Gottignies P. Vincent JL. SOAP II Investigators.
Authors Full Name	De Backer, Daniel. Biston, Patrick. Devriendt, Jacques. Madl, Christian. Chochrad, Didier. Aldecoa, Cesar. Brasseur, Alexandre. Defrance, Pierre. Gottignies, Philippe. Vincent, Jean-Louis. SOAP II Investigators.
Institution	Department of Intensive Care, Erasme University Hospital, Brussels, Belgium. ddebacke@ulb.ac.be
Title	Comparison of dopamine and norepinephrine in the treatment of shock.
Comments	Comment in: N Engl J Med. 2010 Mar 4;362(9):841-3; PMID: 20200389
Source	New England Journal of Medicine. 362(9):779-89, 2010 Mar 4.
Abstract	**BACKGROUND:** Both dopamine and norepinephrine are recommended as first-line vasopressor agents in the treatment of shock. There is a continuing controversy about whether one agent is superior to the other. **METHODS:** In this multicenter, randomized trial, we assigned patients with shock to receive either dopamine or norepinephrine as first-line vasopressor therapy to restore and maintain blood pressure. When blood pressure could not be maintained with a dose of 20 microg per kilogram of body weight per minute for dopamine or a dose of 0.19 microg per kilogram per minute for norepinephrine, open-label norepinephrine, epinephrine, or vasopressin could be added. The primary outcome was the rate of death at 28 days after randomization; secondary end points included the number of days without need for organ support and the occurrence of adverse events. **RESULTS:** The trial included 1679 patients, of whom 858 were assigned to dopamine and 821 to norepinephrine. The baseline characteristics of the groups were similar. There was no significant between-group difference in the rate of death at 28 days (52.5% in the dopamine group and 48.5% in the norepinephrine group; odds ratio with dopamine, 1.17; 95% confidence interval, 0.97 to 1.42; P=0.10). However, there were more arrhythmic events among the patients treated with dopamine than among those treated with norepinephrine (207 events [24.1%] vs. 102 events [12.4%], P<0.001). A subgroup analysis showed that dopamine, as compared with norepinephrine, was associated with an increased rate of death at 28 days among the 280 patients with cardiogenic shock but not among the 1044 patients with septic shock or the 263 with hypovolemic shock (P=0.03 for cardiogenic shock, P=0.19 for septic shock, and P=0.84 for hypovolemic shock, in Kaplan-Meier analyses). **CONCLUSIONS:** Although there was no significant difference in the rate of death between patients with shock who were treated with dopamine as the first-line vasopressor agent and those who were treated with norepinephrine, the use of dopamine was associated with a greater number of adverse events. (ClinicalTrials.gov number, NCT00314704.) 2010 Massachusetts Medical Society
Publication Type	Comparative Study. Journal Article. Multicenter Study. Randomized Controlled Trial. Research Support, Non-U.S. Gov't.

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Literature Evaluation Example

- Authors
  - De Backer D, Biston P, Devriendt J, Madl C, Chochrad D, Aldecoa C, Brasseur A, Defrance P, Gottignies P, Vincent JL, SOAP II Investigators.
- Title
  - Comparison of dopamine and norepinephrine in the treatment of shock.
- Source
  - *New England Journal of Medicine* 2010;362(9):779-83

Structures of the Research Articles

Major Structures

Sections	Other names
Abstract	Summary
Introductions	
Methods	Materials and methods, patients and methods, subjects and methods, population and methods
Results	
Discussion	May include conclusion
Conclusion	
Acknowledgement	
Reference	

Structure of Research Articles

Abstract

- An overview of the study
  - Brief statement to the whole work
  - General idea
  - About 250 words
- Structural abstract
  - Objective (purpose, background)
  - Methods (setting, design)
  - Results (finding)
  - Discussion (conclusion, interpretation)

Structure of Research Articles

Introduction

- Background information
  - History
  - Etiology: prevalence, incidence, mortality
  - Pathophysiology
  - Clinical presentation
- Review of the work of others
  - “Standing on the shoulders of giants”
- Rational for present study
  - Something still unclear
  - Purpose of the work

Methods

- Study design
- Subjects
- Intervention or comparison
- Measurements
  - Outcome and data collection
- Description of analytic techniques
  - Statistical analysis

Results

- Findings of the study
  - Text
  - Table
  - Charts
  - Figures

Discussion and Conclusion

- Major findings
- Comparison with work of others
- Critique of study (limitations, strengths)
- Conclusions
  - Interpretation

Evaluation Questions for Assessing Clinical Research Reports

Before Doing the Evaluation

- No study is perfect

- Selection of Subjects
  - Did not representing the nature population
- Patients enter analysis must finish all doses
  - How about finish 80% of doses?
- Large sample size study
  - May be funded by a pharmaceutical manufacturer

Criteria of Literature Evaluation

Article Component	Number of Questions
Overall	5
Title / Abstract	2
Introduction	6
Methods	13
Results	12
Discussions / Conclusions	3
References	1

Drug Information: A Guide for Pharmacists, 2001

Overall Assessment

- Was the article published in a reputable, peer-reviewed journal?
- Were the investigators qualified to conduct the study?
- Did the authors contribute substantially to the research effort?
- Did the research site have appropriate resources and patients for the study?
- Was study funding obtained from an unbiased source?

Title and Abstract

- Was the title of the article unbiased?
- Did the abstract provided a clear overview of the purpose, methods, results, and conclusions of the study?

Introduction

- Did the authors provide sufficient background information to demonstrate the study was important and ethical?
- Were the study objectives clearly explained?
- Were planned sub-group or covariate analyses indicated?
- Were the research and null hypotheses stated?
- Was the study approved by an institutional review board (IRB)?
- Was the study ethical?

Criteria for Literature Evaluation

Methods (1)

- Was an appropriate study design used?
- Did the inclusion and exclusion criteria represent an appropriate patient population for the study?
- Was the sample size large enough to detect a statistically significant difference between treatment groups?
- Was the study sample representative of the patient populations to which the study results were interned to be generalized?

Methods (2)

- Was the study controlled? Were the controls appropriate?
- Were the outcome variables relevant, clearly defined, objective and clinically and biologically significant?
- Was methodology used to measure outcome variables described in detail? Were outcome variables measured at appropriate time intervals?

Methods (3)

- Was the study randomized using an appropriate method? After randomization, were demographics for the treatment and control groups similar?
- Were subjects, investigators, outcomes assessors, and data entry personnel blinded? Were these individuals unable to determine whether treatment or control was administered before the blind was broken?
- Were data collected appropriately?

Criteria for Literature Evaluation

Methods (4)

- Was patient compliance with the study medication measured?
- Were patient and investigator compliance with the study protocol monitored?
- Were appropriate statistical tests used?

- *Was the duration of treatment and follow-up adequate?*

JAMA 1993;270(21):2598-601

Criteria for Literature Evaluation

Results (1)

- Were dates for study initiation and completion provided? Is the study current and relevant?
- Were the numbers of patients screened, enrolled, administered study treatment, completing, and withdrawing from the study reported?
- Were reasons for withdrawal reported?
- Were demographics for treatment and control subjects similar at baseline?

Results (2)

- Were data presented in a clear and understandable format? Were data for both efficacy and safety clearly reported?
- Was an intent-to-treat analysis conducted?
- Were exact p-values and confidence intervals reported?
- Was the study power calculated?
- Could a Type I (false positive) or Type II error (false negative) have occurred?

Criteria for Literature Evaluation

Results (3)

- Were the study results valid?
- Can study results be generalized to patients in clinical practice?
- Were the results both statistically and clinically significant?

- *Were all outcomes reported?*

JAMA 1993;270(21):2598-601

Discussions and Conclusions

- Did the authors compare their study results to those of a systematic review or all previously published data?
- Were the study discussions consistent with the results and did they relate to the study conclusions?
- Did the study results support the conclusions?

Criteria for Literature Evaluation

References

- Is the current literature well represented?

Evaluation of Applicability

Biological Difference

- Are there pathophysiologic differences in the illness under study that may lead to a diminished treatment response?
- Are there patient differences that may diminish the treatment response?

Social and Economic Difference

- Are there important differences in patient compliance that may diminish the treatment response?
- Are there important differences in provider compliance that may diminish the treatment response?

- *Are the likely treatment benefits worth the potential costs?*

Drug Information: A Guide for Pharmacists, 2001
JAMA 1994;271(1):59-63

Evaluation of the Applicability

Epidemiological Difference

- Do my patients have comorbid conditions that significantly alter the potential benefits and risks of the treatment?
- Are there important differences in untreated patients' risk of adverse outcomes that might alter the efficiency of treatment?

- *Are the likely treatment benefits worth the harm?*

Drug Information: A Guide for Pharmacists, 2001
JAMA 1994;271(1):59-63

Reference

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Thank You!