

Status of evidence-based medicine in Ukraine

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24.09.08



Background and objectives

Background:

- “My treatment helps to everyone except the hopeless one” (*Physician in England in 18 century (I couldn't find reference)*)
- During the Soviet Union time it was profound deficiency for quality drugs and it was formed “worshipping attitude” to foreign drugs. Someone still believes in “magic bullet”

Objectives:

- to characterize a place and perspectives of the evidence-based medicine in Ukraine
- to formulate a critical approach to actively promoting treatment methods

Approaches to drugs prescription

Traditional Chinese medicine, shamanism in Africa, Extreme North and Amazonian region

- **treatment by herbs and roots that are not passed through controlled clinical studies.**

Approach in post Soviet Union countries:

- **usage of domestic and international pharm companies that were not passed through II and III phases of clinical trials for particular indications and are not registered for them in western countries.**

Approach in developed countries:

- **establishing of permissions for particular indications for usage by Regulatory Authorities on the base of III phases of clinical trials;**
- **limited usage out of label treatment (in clinical research or as exceptions in routine practice);**
- **not using out of label drug cocktails (a couple of drugs not registered for a particular indication).**

Principles of evidence-based medicine

Evidence-based medicine (EBM) is choosing of diagnostics and treatment methods on the basis of the best evidence achieved in quality clinical trials (CTs)

For application of EBM principles in a particular patient it is necessary to establish a clinical question and to find the answer on the basis of the most valuable evidence

In each severe ICU patient it could be dozens of such clinical questions

Hundreds of quality CTs have been conducted in ICU patients, *but several important clinical questions in a particular patient remaining without answers...*

Elucidating of EBM principles in Ukraine

Передерий В.Г., Безюк Н.Н. EBM or empiric intuitive treatment. Укр. кардиол. журн. 2001, № 3. с. 73-78.

Трещинский А.И., Глумчер Ф.С., Гуляев Д.В. Essence of EBM. Біль, знеболювання, ІТ. 2003, № 3. с. 3-15.

Гуляев Д.В. – series of publications about evidence based stroke treatment

Воробьев К.П. – series of publications about EBM in Ukrainian scientific journals.

Сакун М.П. Basics of EBM.

Тернопіль: Укрмедкнига, 2005. -244с.

Frequently published Russian authors
in EBM field:

Бачинский С.Е., Власов В.В., Верещагин Н.В.,
Леонов М.В. и др.



Тернопіль
"Укрмедкнига" 2005

М.П. Скакун
ОСНОВИ
ДОКАЗОВОЇ
МЕДИЦИНИ

Approaches to drugs prescription

Presumption of usage of *potentially* effective drug (common approach in Ukraine):

- if it is registered and promoted;
- if an of its inefficacy is absent.

Evidence of inefficacy is often does not published.

Evidence for inefficacy are available for:

- *glucocorticoids in SHI treatment;*
- *proteases inhibitors in acute pancreatitis;*
- *high doses of epinephrine during cardio-pulmonary resuscitation.*

Presumption of *not-usage* of *potentially* effective drug if reliable evidence of it's efficacy is absent (approach in development countries)

Multicentre (international) studies results analysis and applying for our patients

Questions arise:

- is the cohort of patients in our country belong to patients population where the data of efficacy have been achieved?

Belonging to cohort has to be estimated for age, gender (?), race (?), severity of main disease, quantity and severity of complications

It is important to considering:

- the influence of syndrome is treated in the study course on the main treatment results (attributable mortality).

The high incidence of complications is negatively influences on the value of attributable mortality from main disease

Positive results is achieved on Ukrainian patients population

Backgrounds:

- in Ukraine is published mostly positive study results
- on the small samples one often achieved statistically significant differences in results

Interpretation:

- *reader has no objective reasons to doubt the difference between study group and control groups*
- *reader often can't exclude that effect (difference between groups) could be dependent by (related to) other factors*

Factors associated with positive effects in study group: *selection bias*

Retrospective patients selections for control group

In prospective study:

- inadequate matching of patients for age, severity of status, presence of complications or concomitant diseases (*absence of clear randomization procedure*)
- inadequate matching of patients for concomitant medication; in a control group is often more poor patients with limited possibility to by adequate antibiotics, solutions for infusions, products for clinical nutrition etc. (*absence of randomization and blinding*)

Factors that can influenced to the positive results (continious)

- **inadequate matching of for monitoring (during the absense of standard of ICU bed equipment and deficiency of monitoring devices they are likely to concentrate near patient in main grope; the same as for higer class of ventilators)**
- **inadequate matching of for nursing care (if nurse-patients ration is from 1:3 to 1:6 it is likely to have disproportion in favor to main group)**
- **unconsciousness bias for information collecting**
- **bias during statistic analysis**

Principle “negation of negation” concerning drugs with doubtful efficacy

Without conducting of clinical trials we can't claim about inefficacy of drugs (that are actively promoted in Ukraine but not registered for this indication in developed countries)

We say: “that is not enough evidence to consider their usage...” “We did not perform own studies...”

Medical representatives say a part of truth:

“It a lot of works where is demonstrated efficacy of medicine”

“Here is a copies of articles where is demonstrated effect of this medicine”

List of questions for med reps answers for them can bring you closer for truth

Has the drug completed II and III phases of clinical trials?

If yes:

- has in registered in USA (FDA) and EU (EMA)?
- are the results of corresponding studies available to reveal the size of effect on true outcomes:
 - mortality,
 - quality of live,
 - length of hospitalization,
 - costs of treatment?
- what is the clinical of effect (*don't confuse with statistically significance*)

If drug has not passed II and III phases of CT for such indication (but registered in country for other indications)

What is the level of evidence?

- has investigated true outcomes?
 - *other endpoints is surrogate outcome – can only indirectly indicate efficacy of treatment*
- are the results match the results of high level studies, conducted abroad?
 - *in Ukraine some times works principle “First time in the world and 100-th time in our clinic”.*
 - *key principles of CTs is repeatability of results.*

Яку наукову літературу читати лікарю

Рівень доказів (від вищого – до нижчого):

1. Оригінальні статті, метааналізи
2. Оглядові статті
3. Розділи підручника
4. Клінічні випадки
5. Абстракти

Рейтинг наукового журналу визначається:

- Journal impact factor (журнальний фактор впливу) – міра частоти цитування журналу

На теренах колишнього СРСР більшість журналів з низьким фактором поштовху

Заходи для покращання ситуації з впровадженням медицини, що базується на доказах

Індивідуальний:

- освіта лікаря, навчання принципам критичного підходу до наукових публікацій.

Підвищення вимог вітчизняних наукових журналів:

- застосування до наукових статей принципу відсутності презумпції невинності: *«Що не описано, те не виконано»*.

Колективний/державний:

- розробка протоколів, методичних рекомендацій для основних (найбільш важливих) нозологій.

Впровадження міжнародного досвіду:

- рекомендацій консенсусних конференцій;
- метааналізів (виконаних за високими науковими стандартами)
- оглядових статей (опублікованих у провідних фахових журналах).

**Сподіваємось що Україна зробить свій
венсок у всесвітню наукову спадщину!**



Дякую за увагу!