The Real World: How Integrated data can be used to improve patient care?

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Outline of the Presentation

- Importance of EBM
- Pitfalls of EBM
- Solution: Data-Based Medicine
- Advantages and Challenges of DBM
- Integration of DBM and EBM
History of Decision-Making in Medicine

Ancient medicine
- Religious and spiritual theories

Individual preference-based medicine
- Highly subjective decision making

Experience-based medicine
- Based on individual or group observations

Evidence-based medicine
- Followed the introduction of epidemiological methods
Quality of Evidence in EBM

Randomized Clinical Trials: the Heart of EBM

- RCTs are defined as scientific experiments where the people being studied are randomly allocated one or other of the different treatments under study

- Considered the gold standard for a clinical trial

- Form the basis of:
  - Systematic reviews
  - Meta-analyses
  - Treatment guidelines
Pitfalls of EBM

EBM hinges on RCTs: to the point of overreliance

• EBM ‘dogmatically refuses to acknowledge’ other valid sources of health data
• Results may not be relevant for all treatment situations


RCTs are expensive

• There will be always a higher demand for RCTs than supply
• Priorities are influenced by the interests of sponsors


Certain populations are usually excluded from RCTs

• Patients with comorbidities, extremes of ages, racial minorities etc
• Restricts generalizing


Other Pitfalls

• Publication bias: not all studies are published
• Not all conditions have RCTs, especially rare conditions
• Lack of access to clinical trial data
• ‘Statistically significant’ benefits may be ‘marginal’ in actual clinical practice
EBM does not permit generalization of data into a ‘Real-World setting’

Its most prominent pitfall
Data-based Medicine

Data-based Medicine (DBM) is an emerging concept

- It depends on the analysis of the extensive health records that are available across a particular geographic data from all possible sources (often termed as ‘Big data’) for taking healthcare decisions.

Big data analysis can provide multiple forms of health-related information about any condition:

- Natural history of disease
- Effectiveness of any treatment modality
- Impact of an intervention on any objective parameter
- Cost-effectiveness of any treatment modality
Latest Entry: Data-Based Medicine

Ancient medicine
- Religious and spiritual theories

Individual preference-based medicine
- Highly subjective decision making

Experience-based medicine
- Based on individual or group observations

Evidence based medicine
- Followed the introduction of epidemiological methods

Data based medicine
- Depends on the analysis of ‘Big Data’
How is DBM Different from EBM?

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<tr>
<th>DBM relies on Real World Data</th>
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<td>• Outcomes of analyses will be relevant for most treatment situations in the real world: generalization is easy</td>
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<th>Conflicts of interests are less</th>
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<td>• Unlike RCTs, investment not needed for data collection</td>
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<th>No question of excluded populations in DBM</th>
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<td>• Health data of all patient sub groups are available</td>
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<th>Others</th>
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<tr>
<td>• Minimal risk of publication bias</td>
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<tr>
<td>• Larger sample size → better generalization</td>
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<td>• No question of lack of access to clinical data</td>
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Sources of Data for DBM

- Patient registries
- Disease registries
- Insurance claims databases
- Hospital records
- Private practitioners who record data electronically
Integration of EBM and DBM

Real World Data
A retrospective glance at what actually happened

Randomized Controlled Trials
How a treatment will work in an ideal situation

RWD and RCT Data
Complement One Another
Integration of EBM and DBM Contd

Real World Evidence: DBM

Randomized Controlled Trials: EBM

Better Patient Care
DBM in India: Challenges

First and foremost is the availability of data in a country like India:

- Electronic recording is not very popular
- Doctor-shopping is a widely prevalent practice among patients
- Cross-systems practice
- Poor penetration of health insurance → insurance claims data also not promising
- Concepts of disease registry and patient registry not popular

Management of the huge data requires significant experience and expertise

Analysis of huge data requires expertise, and can be expensive

Privacy and confidentiality issues
Conclusions

- Evidence-based Medicine (EBM), considered gold standard of clinical practice, depends heavily on randomized controlled trials (RCTs).
- RCTs have certain disadvantages which forbid proper generalization of results into the population.
- Most of these disadvantages may be overcome by implementation of Data-based medicine (DBM), which depends on the analysis of Real World Data (RWD).
- RWD and RCT data provide complementary information.
- Best outcomes can be obtained by integrating DBM and EBM.
References

Thank You!
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