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SPECIAL REVIEW – EVIDENCE BASED CARDIOLOGY

Health technology assessment (HTA) in cardiac field

Mahmoud Elbarbary

National & Gulf Center for Evidence Based Health Practice, Department of Critical Care Medicine – College of Medicine, King Saud Bin Abdulaziz University of Health Sciences, P.O. Box 22490, Riyadh 11426, Mail Code #1413, Saudi Arabia

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1. Introduction

Rapid developments in new health care technology in the cardiac field have become almost daily events. The technological development involves a wide range of applications of diagnostic modalities such as cardiac MRI, PET, CT angio or genetic screening for cardiac risk factors. It also covers countless therapeutic interventions, e.g., new anti-platelets, new pulmonary vasodilators, implantable cardioverter-defibrillators (ICD) drug-eluting stents, off pump coronary bypass, ventricular assist devices and robotic surgery. The term "technology creep" describes a phenomenon in which a certain technology first gets approved for a high-risk population in which there's a proven benefit and its use then expands to lower-risk groups, changing the calculus of clinical and financial risk and reward. The ICD was first used for people who had survived cardiac arrest and are now "*recommended*" for primary prevention in patients with low ejection fraction (Epstein et al., 2008). The estimated cost per QALY for each device ranges between $50,300 and $70,200 (Health Technol Assess, 2006). Cardiac centers compete to attract doctors and patients by buying advanced tools. If Hospital A has a PET scanner and cardiac MRI and Hospital B does not have them, Hospital B loses in reputation and volume. This is regardless of the degree of need or priority of the presence of these technologies in certain community.

Unfortunately, adopting these new technologies can put a huge burden in the health systems costs. The annual medical cost of a CVD in USA is exceeding $403.1 billion (Patel and et al., 2005). This is true not only at the individual patient management but also at the nationwide level decisions to adopt such technology. Since available resources are limited, delivering health services involves making decisions. Decisions are required on what interventions should be offered, the way the health system is organized, and how the interventions should be provided in order to achieve an optimal health gain with available resources, while, at the same time, respecting people's expectations.

2. Health technology assessment (HTA) as a continuum of evidence-based medicine (EBM)

The practice of EBM depends on the strength of evidence (level of evidence) and strength of recommendation (grade of

E-mail address: mahmoud_barbary@yahoo.com

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Evidence Based Medicine is as simple as 1-2-3-4-5

1. MAJOR AIM	Best patient's Care
2. MAJOR PRINCIPLES	Evidences are not equal (evidence hierarchy) are not enough (the 3 Es)
3 .COMPONENTS	3 Es Evidence- Expertise-Expectations
4 .PILLARS for appraisal	RVRA system Relevance-Validity-Result clinical significance-Applicability
5.STEPS	5 As • Assess your patient • Ask structured answerable clinical questions • Acquire the best evidence • Appraise the Evidence • Apply the best Evidence

Figure 1 EBM concepts.

recommendation). This practice is based on two types of analyses which are analysis of evidence and analysis of outcome. The HTA process can be considered as an extension of the EBM process with the addition of two more types of analyses which are value analysis (cost/effectiveness) and appropriateness analysis (ethical–legal and societal). These dimensions are shown in Fig. 4.

2.1. Stage of evidence analysis – quality of evidence

The newest isn't always ''the best,'' and the latest isn't always the right answer. It is now clear that interventions once thought to be beneficial have, in the light of more careful evaluation, turned out to be at best of no benefit or harmful and counterproductive to the system. The famous hormonal replacement therapy HRT ''recommendation'' was adopted to reduce cardiac risk in postmenopausal females based on several observational studies. Later after better research quality by RCT in Women's Health Initiative (2002), this recommendation proved to be harmful. This illustrated the importance of practicing ''Evidence-Based Medicine or EBM,'' which argues that the information should be based on rigorous research to the fullest extent possible (Guyatt and et al., 2008). Fig. 1 shows the major concepts of EBM and the concept of best available evidence. This concept implies a ''hierarchy'' of evidence. Since the evidence comes from research, it is important to consider (Fig. 2):

1. The hierarchy of research designs.
2. The quality of the research execution.

Some research studies are considered to be better than others. Evidence from good research is considered to be better than evidence resulting from research of a lesser standard. This was very clear in HRT trials. The first is an evidence analysis—a systematic evaluation of evidence for a technology and a requirement of good evidence for such things as coverage, placement on formularies, and affirmative guidelines. This stage corresponds to the evidence-based guidelines (EBGs) part of EBM.

2.2. Stage of outcome analysis – grade of recommendation and benefit/risk ratio

In general the strength of recommendations is related to the strength of evidence and it was accepted that strong evidence

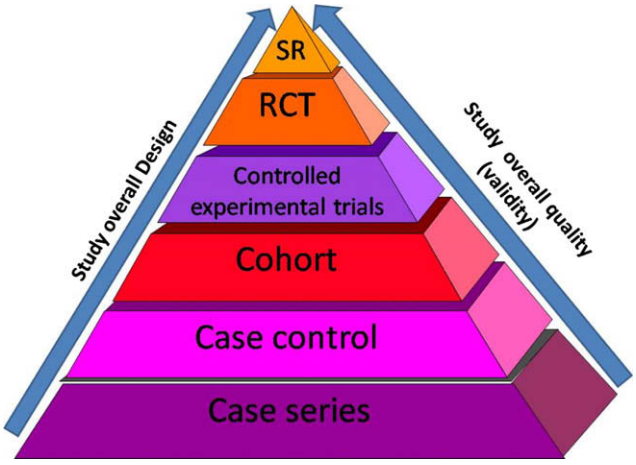

Figure 2 Hierarchy for level of evidence (in intervention).

on the effects of an intervention (positive or negative) allows for strong recommendations for or against the use of it. Weak evidence only supports weak recommendations. For several years, many systems established to link between the strength of the evidence and the grade of recommendation and typically using letters (for instance A, B, C, etc.) to describe the strength of a recommendation. Over the last two decades it has been realized that a recommendation based on the two elements of study design and validity frequently is inadequate. The GRADE system suggests that study quality should go beyond validity to include other factors that can increase or decrease its overall quality. In addition to the presence of any type of bias (that reduces the validity), GRADE considered other factors that if present should reduce the quality namely inconsistency, impression, indirectness and small magnitude of effect.

On the other hand, GRADE considered the presence of certain factors (beyond validity) should increase the overall quality (namely; presence of dose–response, strong association or all plausible confounders would result in an underestimate of the treatment effect). The major addition of the GRADE system is in its methodology in moving from evidence to recommendation. Since interventions may have both positive and negative effects at the same time, GRADE system proposed a framework to make explicit the trade-offs between harms and benefits (GRADE Working Group, 2004). Fig. 3 shows a diagram explaining the GRADE system. The second stage of outcomes analysis is an estimation of the magnitude of the effects of the technology on the desired clinical outcomes (the ''benefits'') and on potential harms such as side effects and risks (the ''risks''). This stage also includes a comparison of benefits and risks, to determine if the ''benefit–risk ratio'' is sufficiently high to justify the technology.

2.3. Stage of value analysis

Here the researcher estimates the effect of the technology on costs and compares the clinical effects against the costs to determine if the ratio is sufficiently high. In this stage there will be cost analysis and cost-effectiveness analysis. If this is combined with the previous two analyses then a decision tree can be plotted. The decision tree basically is a plot that contains the various treatment options with the calculation of two factors (a) probability factor and (b) utility (or disutility) factor.