Bispectral Index versus Minimum Alveolar Concentration for Prevention of Intraoperative Awareness

Does a Practical Controlled Trial Provide CERtainty?

Approximately half of all medical care provided in the United States is based on insufficient scientific evidence and may even be of "uncertain or questionable value." This realization has spurred interest and extensive government funding in comparative effectiveness research (CER) with the ultimate goal to improve the effectiveness, efficacy, and efficiency of health care. To date, few initiatives to conduct and publish studies guided by principles of CER in perioperative medicine, and specifically in the field of anesthesiology, have been taken. In this issue of *Anesthesiology*, Mashour et al. present a major leap forward in this endeavor to participate in CER and highlight the importance that our specialty can play in answering difficult clinical questions, which will hopefully convince stakeholders to fund more such initiatives.

Multiple studies have already investigated whether bispectral index spectroscopy (BIS) monitoring reduces risk of intraoperative awareness. The authors of this study were unable to find differences in the incidence of awareness or variables of recovery in a randomized trial with more than 18,000 patients when comparing monitoring protocols based on BIS values or anesthetic concentration. By post hoc analysis, the protocol based on BIS monitoring reduced the incidence of definite or possible intraoperative awareness compared with routine care. This study is of particular interest for two reasons. As recently pointed out in an editorial by Devereaux et al., studies of this large size are required to study low-incidence outcomes with sufficient confidence in the statistical significance of results. In addition, this protocol incorporated the high standards demanded for CER, including the assessment of effectiveness, efficacy, and efficiency. First, they performed their study in a large, "real world" patient population in various hospitals undergoing various procedures, thus affording their results a high level of external validity. Second, they compared the impact of various competing strategies on various outcomes, which is in contrast to the typical standard that compares only controls (e.g., placebo) with the intervention for a single outcome. Finally, they assessed economically important outcomes (e.g., recovery variables) to put the outcomes into a wider context.

Performance of CER has specific components outlined by the Federal Coordinating Council for CER that focus on the need for the evolution of research methodology.* Traditional "Gold Standard" clinical study designs, such as randomized controlled trials, may pose limitations (e.g., low external validity of results because of strict protocols and study environments) to the ability of researchers to answer important CER questions. In response, various groups have proposed new approaches, such as practical controlled trials that compare clinically relevant alternative interventions, select diverse populations for study, utilize diverse practice settings, and evaluate a wide range of outcomes without the constraints of a randomized controlled trial with its strict inclusion and exclusion criteria. Thus, practical controlled trials may be better equipped to address the "real world" questions of interest to decision-makers as proposed by the
awareness are critical to anticipating and optimizing patient information, constant vigilance and development of situation “smart” monitoring systems may help prioritize alarm information of alarm values to enhance vigilance without creating

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In conclusion, the present article is proof that anesthesia-related CER is not only feasible, but can play a major role in shaping accountable and evidence-based perioperative care. To maximize efficiency, it is becoming increasingly important to identify the appropriate study design and match it to desired goals of a particular CER study. One has to caution that even extensive population-based CER trials that define the currently available, most effective, efficacious, and efficient intervention to address a problem, may not yield the optimal intervention for individualized care.

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