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Misconceptions about practicing evidence-based orthopedic surgery

Rudolf W Poolman¹, Brad A Petrisor¹, Rene K Marti², Gino M Kerkhoffs³, Michael Zlowodzki¹ and Mohit Bhandari¹

¹Division of Orthopedic Surgery, McMaster University, Ontario, Canada, ²Department of Orthopedics, Orthotrauma Research Center Amsterdam, Academic Medical Center, University of Amsterdam, the Netherlands, ³Department of Orthopedic Surgery and Traumatology, Kantonsspital, St. Gallen, Switzerland
Correspondence RWP: Poolman@trauma.nl

Since its inception in the early 1990s, evidence-based medicine (EBM) has been gaining recognition in the literature of both general and orthopedic surgery (Sauerland et al. 1999, Hurwitz et al. 2000, Bhandari and Tornetta, III 2003, Ubbink and Legemate 2004). There has been a proliferation of EBM symposia in many orthopedic journals, and it has been suggested that there is a need for further education in aspects of EBM and study methodology amongst orthopedic surgeons (Bhandari and Sanders 2003, Bhandari et al. 2003c, Fingerhut et al. 2005, Bhandari and Giannoudis 2006, Petrisor and Bhandari 2006).

Most of these “evidence-based orthopedic surgery” articles were written to help readers understand the practice of EBM. However, a number of authors have written criticisms and skeptical reports on different aspects of EBM, ranging from study methodology to its implementation in clinical practice (Sauerland et al. 1999, Cohen et al. 2004, Miles et al. 2006). In this article, we review the history of EBM and discuss the current myths and misconceptions, illustrating them with practical examples.

Overview

One could argue that doctors have always tried to practice evidence-based medicine. The origins of “evidence-based medicine” span over 30 years, however, Gordon Guyatt, a Canadian internist at McMaster University coined the term at the beginning of the 1990s (Guyatt et al. 2002). Evi-

dence-based medicine was initially described as an attitude of “enlightened skepticism” towards the application of diagnostic, therapeutic, and prognostic technologies. Stated in another way, evidence-based medicine is: “the conscientious, explicit, and judicious use of the best current evidence in making decisions about the care of individual patients”. Recently, some authors have discussed a “paradigm shift” away from eminence-based teaching practices (opinions and experience of experts) towards evidence-based teaching practices (Bhandari and Tornetta, III, 2003, Hurwitz et al. 2006). These are not mutually exclusive concepts, and clearly the opinions and experience of experts are an important part of the decision-making process when treating patients. Indeed, the practice of evidence-based medicine integrates individual clinical expertise and patient preferences with the best available external clinical evidence (Guyatt et al. 2002). It does this by fostering the ability to ask a pertinent clinical question, search the literature, appraise it, and apply the findings to patient care within a clinical setting. These principles have recently been promoted in orthopedic surgery and have resulted in a “User’s Guide” series in the American Journal of Bone and Joint Surgery (Bhandari et al. 2001a).

Evidence-based medicine has been implemented in some surgical residency programs and has been found to be beneficial in many cases (Bazarian et al. 1999, Edwards et al. 2002, Bhandari et al. 2003b, Grant 2005, Nicholson and Shieh 2005). It may be

that residents who have an appreciation for asking pertinent clinical questions and critical appraisal may integrate evidence and new technologies more carefully into their clinical practice. Orthopedic surgeons have classically embraced innovations or new techniques on the basis of limited evidence (Hurwitz et al. 2000). With the increase in health-care costs due to new techniques and an aging population, it may be necessary to move towards using interventions that are based on high-quality clinical research with patient-important outcomes and demonstrated cost-effectiveness (Bhandari and Tornetta, III 2003).

Misconceptions about evidence-based orthopedic

Current criticisms and limitations of EBM can be grouped into six main arguments (Sauerland et al. 1999, Guyatt et al. 2002, Cohen et al. 2004, Hannes et al. 2005, Miles et al. 2006): (1) EBM ignores clinical expertise, (2) EBM is not possible without randomized controlled trials (RCTs), (3) EBM is all about statistics and numbers, (4) the usefulness of applying EBM to individual patients is limited, (5) keeping up to date and finding the evidence is impossible for busy clinicians, and (6) EBM is not evidence-based. Most of the criticisms have their roots in a misunderstanding of the concepts of EBM and are discussed point-by-point below.

Misconception 1: EBM ignores clinical expertise

With the increasing amount of evidence-based guidelines, surgeons are afraid to lose autonomy in clinical decision making. Following these guidelines has been referred to as “cookbook medicine”, which prevents surgeons from using their own “recipe” (Sackett et al. 1996, Guyatt et al. 2002). This myth stands in contradiction with the definition of EBM, which is the integration of individual clinical expertise and patient preferences with the best available evidence (Guyatt et al. 2002). The practice of EBM needs to foster within the surgeon an attitude of empowerment, not managing patients according to “the way we’ve always done it”, but based on the best evidence currently available. This requires understanding of different study designs, hierarchies of evidence, how to find the literature, and how to incorporate it into practice.

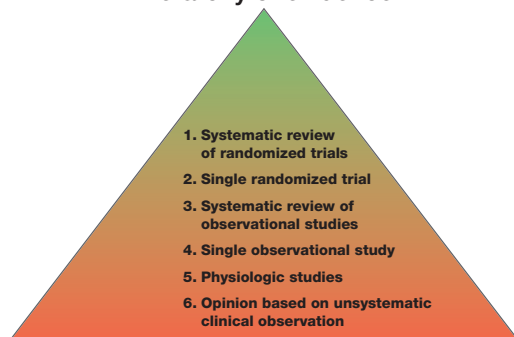
Furthermore, applying evidence directly is only applicable to the patient population that it is derived from. Thus, it is necessary to understand issues of applicability and generalizability of study results to a specific patient or patient population. Let us take the example of a patient with a displaced intertrochanteric hip fracture who also has dementia. It may be that the best available evidence on a specific treatment includes those patients without dementia, or only those with undisplaced fractures. It would then be necessary to extrapolate the results from those studies to our patient, if possible. While we may have some evidence to suggest what treatment to use in study patients, clinical expertise helps in making decisions regarding the generalizability of those results (Hannes et al. 2005, Tonelli 2006). As pointed out clearly by Petersen et al. in this issue of *Acta Orthopaedica*, results from an RCT apply only to the cohort of patients that consented (Petersen et al. 2007). We are often uninformed about the patient characteristics of the “non-consenters”. The findings of Petersen’s study caution the generalizability of even level I studies. Indeed, it was Sackett who said “Without clinical expertise, practice risks becoming tyrannized by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient.” but goes on to say “Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients.” (Sackett et al. 1996).

Misconception 2: EBM is not possible without RCTs

Evidence-based orthopaedic surgery posits the use of the best available evidence in clinical decision making. The term “best evidence” assumes that a hierarchy of evidence must exist. Sackett and colleagues proposed a hierarchy with large randomized trials at the top and opinion at the bottom (Sackett et al. 2000, Guyatt et al. 2002, Petrisor et al. 2006) (Figure). Orthopedic surgeons have modified this initial description for use in journals such as the *Journal of Bone and Joint Surgery* (American Edition) and *Clinical Orthopaedics and Related Research* (Brighton et al. 2003, Wright et al. 2003).

But what is the best available evidence? Data derived from RCTs is considered to be the highest

Hierarchy of evidence



Hierarchy of evidence (Sackett et al. 2000, Guyatt et al. 2002, Petrisor et al. 2006).

level of evidence, mainly because randomization is the best way to balance known—and the only way to balance unknown—prognostic factors within both treatment and control groups in a therapeutic study (Sackett et al. 2000, Guyatt et al. 2002). Although rated as Level I, an RCT can still have methodological flaws (Poolman et al. 2006). Surgical trials, for example, have several important issues that differentiate them from trials of drug therapies. Common questions raised in orthopedic trials include: Were all surgeons equally skilled at performing the techniques in the study? Were the techniques “specialized”, or are they techniques that general orthopedic surgeons should be able to perform? If technique A is better than technique B, and a surgeon uses technique B, is he now required to learn and use technique A? These questions can threaten how the results of these studies are interpreted by surgeons, and subsequently how they are integrated or not integrated into clinical practice (Devereaux et al. 2005).

It is also important to recognize that not all clinical questions can be answered with an RCT. While randomization in RCTs can be stratified based on prognostic factors, in some cases it would be unethical to actively randomize patients to certain types of prognostic or risk factors. For example, it would clearly be unacceptable to randomize consecutive patients to smoking or to no smoking to determine whether smoking has a negative effect on fracture healing. Prognostic factors of a disease or intervention can be assessed with a cohort study design, which then provides the highest level of evidence without being an RCT (Bhandari et al.

2001b). There are other situations where an RCT may not be feasible. For example, when the sample size required is too large or the follow-up requires many years.

In orthopedic surgery, “lesser” forms of evidence have provided many insights that would not have been possible with RCTs (Tovey and Bog-nolo 2005). Some investigators argue that a well-designed non-randomized study can effectively provide the same results as randomized trials (Benson and Hartz 2000, Concato et al. 2000, Hartz et al. 2003). However, it has been shown in the orthopedic literature that observational studies can over- or underestimate treatment effect (Bhandari et al. 2004). Secondly, there are examples in the literature where clinical practice has been changed because of a high-quality RCT or meta-analysis (Boxma et al. 1996, Juni et al. 2004). As a final point, observational series or case reviews can generate highly significant hypotheses. While not providing definitive answers for clinical practice, they can most definitely set the stage for further experimental work. A classic example of an observation study of case-control design would be the assessment of the effect of smoking or other potential prognostic factors on the incidence of lung cancer (rare outcome, needs years to develop). In this case, one would identify patients with lung cancer and a control group without lung cancer and retrospectively assess the patients’ exposure to smoking and other risk factors in both groups (Doll and Hill 1964). This aids in further research and has provided information in a relatively short time with low cost. These points illustrate the continued value of experimental and observational design. Unfortunately, there is the reality of publication bias, which is the tendency of investigators, reviewers, and editors to submit or accept manuscripts for publication based on the direction or strength of the study findings (Simes 1986, Dickersin 1990, Callaham et al. 1998, Sterne et al. 2001). At times, this makes finding all available evidence difficult, which can influence clinical decision making. Published reports describing complications, adverse events, technique or hardware failure, and mistakes in concepts can prevent repetitive studies of unsuccessful procedures, thus protecting patients (Nilsen and Wiig 1996, Poolman et al. 2002).

Misconception 3: EBM is all about statistics and numbers

Being an EBM practitioner does not mean that one has to be a statistician. However, understanding basic terminology is an important step towards the effective use of orthopedic literature. Common terminology necessary for the practice of EBM is provided in Table 1 (Guyatt et al. 2002, Bhandari et al. 2003c).

Studies with a positive treatment effect and significant p-values are often seen in the literature. At times, this statistically significant treatment effect can be confused with a clinically important treatment effect. This may or may not be true. For example, a randomized trial of 1,000 patients may report a statistically significant improvement in patient functional scores (a 3-point difference on a 100-point scale) following operative vs. nonoperative treatment of calcaneal fractures. However, many would argue that this difference is not clinically relevant and may not affect surgical practice. Significant p-values have been shown to influence the perception of surgeons regarding the importance of a paper (Bhandari et al. 2005). More importantly, it may be necessary to think in terms of the confidence interval. The confidence interval overcomes the limitations of the p-value by providing information about the size and direction of the effect, and the range of values for the treatment effect that remain consistent with the observed data (Bhandari et al. 2005).

Despite the incorrect “over-emphasis” of statistics in EBM, Guyatt and Sackett, the forefathers of EBM, remind us that practicing evidence-based medicine starts with the patient and ends with the patient (Sackett et al. 2000, Guyatt et al. 2002).

Misconception 4: The usefulness of applying EBM to individual patients is limited

A fundamental principle of EBM tells us that evidence from the orthopedic literature alone can never guide our clinical actions; we always require the inclusion of patients’ values or preferences (Sackett et al. 2000, Guyatt et al. 2002). Individual patient preferences may differ from the evidence available in the literature. A relatively new concept is “evidence-based patient choice” (Parker 2001, Salkeld and Solomon 2003). It describes two movements in western healthcare systems: (1) the increasing

Table 1. Common terminology requisite to the practice of EBOS (Bhandari et al. 2003c)

Term	Explanation
Study power	In a comparison of two interventions, the ability to detect a difference between the two experimental conditions if one in fact exists.
Alpha error	The probability of erroneously concluding that there is a difference between two treatments when there is no difference. Typically, investigators decide on the chance of a false-positive result that they are willing to accept when they plan the sample size for a study.
Beta error	The statistical error (said to be “of the second kind” or type II) made in testing when it is concluded that something is negative when it is actually positive. Beta error is often referred to as a false negative.
P-value	The probability that results as or more extreme than those observed would occur if the null hypothesis was true and the experiments were repeated over and over.
Confidence interval	Range of two values within which it is probable that the true value lies for the entire population of patients from whom the study patients were selected.
Effect size	The difference in the outcomes between the intervention and control groups divided by some measure of the variability, typically the standard deviation.
NNT	The number of patients who need to be treated during a specific period to prevent one bad outcome. When discussing number needed to treat, it is important to specify the treatment, its duration, and the bad outcome being prevented. It is the inverse of the absolute risk reduction.
Relative risk	Ratio of the risk of an event among an exposed population to the risk among the unexposed.
Odds	A ratio of probability of occurrence to non-occurrence of an event.
Odds ratio	A ratio of the odds of an event in an exposed group to the odds of the same event in a group that is not exposed.

Table 2. Numbers of RCTs published in leading orthopaedic journals

	1975–1980			1981–1985			1986–1990			1991–1995			1996–2000			2001–2005		
	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N
Acta	7	1.0	732	9	1.3	686	36	4.7	774	49	5.4	909	51	6.3	807	44	6.3	697
CORR	4	0.2	2140	8	0.4	2083	20	0.8	2441	57	2.3	2443	61	2.7	2267	58	2.3	2543
JBJS Am	8	0.5	1456	9	0.7	1215	21	1.6	1312	37	3.1	1199	44	3.6	1230	101	4.7	2133
JBJS Br	3	0.5	651	12	1.8	649	19	1.8	1067	69	5.4	1275	64	5.1	1262	98	7.1	1388
Total	22	0.4	4979	38	0.8	4633	96	1.7	5594	212	3.6	5826	220	4.0	5566	301	4.5	6761

n = number of RCT; % = n in percentage of N; N = total number of publications

demand for evidence-based information, and (2) the centrality of individual patient choices and values in medical decision making (Parker 2001, Salkeld and Solomon 2003). Nowadays, surgeons are not the only ones overloaded with information. Patients also have an abundance of information from a variety of resources, most commonly the internet. An evidence-based approach to surgery limits patients' options to choosing from "proven" therapies (Salkeld and Solomon 2003). Newer therapeutic options, the effectiveness of which is not backed up by evidence in the literature, might therefore not be presented to the patient. To help patients in making the "right" decision for them, surgeons must be able to both know and critically appraise the literature. As Haynes believes: "Evidence does not make decisions, people do." (Haynes et al. 2002). For example, a recent meta-analysis on intracapsular hip fractures showed that there was a significant re-operation rate with internal fixation compared to arthroplasty (relative risk 0.23; 95% CI: 0.13–0.42) (Bhandari et al. 2003a). However, there was a trend (relative risk 1.3; 95% CI: 0.84–1.9) toward an increase in mortality with hemiarthroplasty. This trend has been disputed by a subsequent meta-analysis (Rogmark and Johnell 2006). While this evidence suggests that arthroplasty would be the preferred choice for treating patients with displaced femoral neck fractures because of a lowered re-operation rate, patients may have compelling personal reasons and values that favor internal fixation devices. For example, they may fear a potentially increased risk of mortality with arthroplasty (a patient-important outcome) or have had previous personal experience leading them to one decision or the other. A particular patient may not fit the profile of those

studied in a meta-analysis. This illustrates the importance of patient values, clinical acumen, and best evidence (Bhandari and Tornetta 2004).

Misconception 5: Keeping up to date and finding the evidence is impossible for busy clinicians

Opponents of EBM argue that practicing EBM is not easy (Bhandari et al. 2003b). This is true. The number of publications in the orthopedic literature is growing (Table 2). Textbooks are still frequently used by orthopedic surgeons as standard references, although the information presented is often out of date by the time the book has gone to press (Hurwitz et al. 2000). As a result of the volume of literature in orthopedics, several resources have been developed and promoted to assist busy clinicians in finding the best evidence available.

Database resources such as the Cochrane database of systemic reviews (www.cochrane.org) or "clinical queries" in PubMed preferentially identify systematic reviews and have built-in filters to help the visitor find randomized trials.

To prevent too many irrelevant hits, the "clinical queries" feature in PubMed uses evaluated search strategies (Haynes et al. 2005). The standard PubMed search for "hip AND fracture* AND arthroplast*" might result in some 2,300 citations. The "clinical queries" feature limits the search to 66 articles. To remain up-to-date, one can register for the "my NCBI" feature at no cost. This includes an e-mail service in which all new trials in your search area are sent on a daily, weekly, or monthly basis to your email address. These strategies can dramatically reduce the time required to identify high-quality research. The same "clinical queries" feature can be used to find relevant sys-

Table 3. Some websites relevant to practicing evidence-based orthopedic surgery

Name	Website
Bandolier	http://www.jr2.ox.ac.uk/bandolier/booth/booths/bones.html
BestBETS	http://www.bestbets.org
Cochrane Collaboration	http://www.cochrane.org
Centre for Evidence-Based Medicine, Oxford	http://www.cebm.net
Evidence-Based On Call	http://www.nelh.nhs.uk/eboc.asp
PubMed Clinical Queries	http://www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml
Post-publication clinical peer review system	http://plus.mcmaster.ca/raters/stellar.asp

tematic reviews and to keep up-to-date with them. Recently, a post-publication clinical peer review system was introduced to help busy clinicians identify relevant and newsworthy publications (Haynes et al. 2006).

Pre-appraised resources such as EBM reviews in the Journal of Bone and Joint Surgery (American edition), the Journal of Orthopaedic Trauma, and the Canadian Journal of Surgery are just a few options for surgeons. Additional pre-appraised resources include the ACP Journal Club, Evidence-Based Medicine, Up to Date, and Bandolier. These resources have conducted the searches, summarized the results and provided “user-friendly” summaries and bottom-line conclusions for orthopedic surgeons. Table 3 shows websites relevant to the practice of evidence-based orthopedic surgery.

Misconception 6: EBM is not evidence-based

Critics of EBM cite the lack of evidence that EBM-based approaches actually improve patient outcomes. While this is partially correct, several reports do suggest that EBM education instills greater satisfaction and good retention skills in trainees (Nicholson and Shieh 2005). Also, practicing evidence-based medicine is perceived to be helpful in structuring daily clinical decision making (Kellum et al. 2000, Edwards et al. 2002, Korenstein et al. 2002, Ismach 2004, Fingerhut et al. 2005, Kuhn et al. 2005, Nicholson and Shieh 2005, Petrisor and Bhandari 2006). While it may be difficult to ascertain the effectiveness of evidence-based medicine as a whole, it is not so difficult to see how some of the parts that make up evidence-based medicine play a role in patient care.

The effective and timely implementation of key clinical research that is, finding and understanding the best available evidence, has been shown

on more than one occasion to affect patient outcomes. In some cases, the implementation of evidence from RCTs and meta-analyses has helped to differentiate successful therapies from ineffective or even harmful treatment modalities where previous observational studies (or in some cases studies lacking significant methodological rigor) had failed to show this (De Vries et al. 1983, Juni et al. 2004). Results of randomized controlled trials made surgical interventions, such as vagotomy for treatment of peptic ulcer disease, obsolete (De Vries et al. 1983)—and found the basis for what are now routine interventions, such as antibiotic prophylaxis in surgical treatment of closed fractures (Boxma et al. 1996).

In the realm of medical education, increasing use and understanding of critical appraisal is an essential tool for the surgical resident as the amount to learn in a given time is growing rapidly. Focusing on relevant high-quality literature, “foreground” questioning can only augment background knowledge and sound surgical principles (Petrisor and Bhandari 2006). In this respect, aspects of EBM can be viewed as epistemology and a resident or trainee can begin to ask the question “how do we know what we know?”. There is also some evidence to suggest that incorporation of the principles of EBM into resident journal clubs and education not only enhances self-assessment abilities but also the perceived educational value of these events (Sanderfer et al. 1996, Simpson et al. 1997, Carley et al. 1998, Khan et al. 1999, Letterie and Morgenstern 2000, Cramer and Mahoney 2001, Gibbons 2002, Dirschl et al. 2003, Goodfellow 2004).

These are but some examples of how the individual parts of practicing EBM—asking answerable questions, finding, appraising, and applying the evidence—make the practice of EBM a systematic

clinical utility that may affect clinical practice and thus patient-orientated outcomes. Attempts have been made to evaluate this influence of research on society in general (Smith 2001) and more specifically, the effect of evidence-based practice on the quality of life of patients (Dobre et al. 2006). To measure the effects of EBM on quality of life remains complicated and would require an evaluation of all individual aspects of the practice of EBM (Smith 2001).

Evidence-based orthopedic surgery is part of the evolution of science; only time will tell if we are on the right track. To reach the highest possible evidence and guarantee excellent patient care, the practice of evidence-based orthopedic surgery must be subjected to ongoing evaluation.

Conclusion

Most criticisms of evidence-based orthopedics are rooted in myths and misconceptions. Evidence-based orthopaedic surgery should be perceived as a guide to help in clinical decision making in busy clinical practices. It must be reinforced that one can practice evidence-based orthopedic surgery without the availability of RCTs. In such instances, decision making will be based on other sources of evidence (Guyatt et al. 2002). The effects of evidence-based orthopaedic surgery should be the subject of ongoing evaluation.

Discussion between Prof. Per Aspenberg (co-editor in *Acta Orthopaedica*) and the authors on "Misconceptions about practicing evidence-based orthopedic surgery"

Per Aspenberg: This paper is about myths and misconceptions, and I fully agree with it. However, it would also be interesting to discuss why these misconceptions are sometimes deliberate, and why they may perhaps become harmful to scientific development.

1. Healthcare authorities can misuse EBM to reduce short-term expenses. There is a tendency to use the absence of level I evidence to hinder the introduction and evaluation of new therapies. All new ideas are originally evidence-less! It is often necessary to do a short series of a new treatment to learn and get experience, before designing a proper (often randomized) study. Hospital directors can use the absence of evidence to enforce a stan-

dardized healthcare production, similar to industrialized production, which they can more easily control. Although evidence-based and valuable in the short term, this environment may become very conservative in the long run.

Authors' response: This is an important issue. It is thought that healthcare authorities may indeed misuse the absence of level I evidence in a way that could hinder the introduction and evaluation of new therapies. However, absence of findings of RCTs may not restrict future development and testing of new techniques; most new ideas are based upon a biological rationale or clinical experience (albeit lower levels of evidence) and those ideas that merit further investigation are often the subject of case series, cohort studies and ultimately clinical trials.

2. EBM can be misused to reduce the merit of people's clinical experience in the struggle for power over the healthcare system. Especially in surgical disciplines, the need for extrapolation (and intrapolation) from available data is very large. This requires, as the authors point out, a high degree of expertise and experience. However, the rightly low formal grading of expert opinion in EBM is misused to reduce the value attributed to people expressing expert opinion in the struggle for influence over the healthcare system. I do not say this as an argument for a hierarchic system, where age and influence is labeled "expertise".

Authors' response: This is also a good point. Lack of evidence does not mean lack of clinical expertise. Readers must be warned that this misconception about EBM can be misused to reduce the merit of doctors' clinical experience. Recently, knowledge translation, defined as the "exchange, synthesis, and ethically sound application of knowledge" has been proposed as a tool in closing the gap between evidence and practice (Davis et al. 2003). It focuses on the integration of evidence-based methods with not only the physician, but also the healthcare team. Also, it makes it a mandate to address barriers to change, not just information transfer to the physician (Davis et al. 2003). The theory is such that this will lead to more "improved health, more effective services and products, and a strengthened healthcare system." (Davis et al. 2003).

3. Randomization fundamentalism may reduce clinical creativity. EBM is, rightly or wrongly,

thought to be very closely associated with randomized controlled studies. As the authors point out, this can lead to an unjustified disregard for uncontrolled studies. The emphasis on randomized controlled studies also has another problem, in that the concept of clinical knowledge can be (incorrectly) reduced to the sum of all such studies available. However, the most important part of doing research is to formulate creative hypotheses. This must be based on a mixture of clinical experience, basic science, and intuition. Once a good hypothesis is formulated, testing it in a clinical study is just a matter of resources and technicalities. However, I believe that very few good hypotheses are being formulated in the clinics today, and there may be a lack of literature coverage and knowledge of basic science. One reason is that doing science has become increasingly distant from clinical work. EBM is associated with a seemingly rigid system of grading scales and rules, which discourage people from trusting their own eyes and wanting to find out what they are actually doing in their everyday work. A rather loosely controlled clinical experimentation is probably an important requirement for creating an environment in which different ideas are circulating and good hypotheses are being formulated (and then tested, of course!). In the long run, the designation of randomized studies as the only “real science” may reduce clinical creativity.

Authors' response: Again, this is an interesting thought. However, we do discuss this in less detail under misconception 3. Although creativity will create new hypotheses and is therefore important, medical science is different from, for example, alternative or complementary medicine in that the hypotheses or hunches are tested and are often found to be unsuccessful. Creativity has brought us much in the past, but creative hunches have also been found to harm patients and therefore need to undergo rigorous testing in the best trial design available before being advocated for widespread use.

4. The power to decide which hypotheses are to be tested is gliding away from the clinics to the companies and politicians. Because the experienced clinician often cannot afford to do a randomized controlled study, or force the formalistic obstacles associated with it, clinical science is often

occupied with research questions aimed at earning money or votes, rather than helping sick people. EBM is misused in this context to hype large, technically perfect studies of minimally improved drugs, and to direct our interest towards doing such studies, thereby abandoning lower evidence-grade studies of perhaps life-saving procedures.

Authors' response: This comment is strongly related to the misconception that EBM is only possible with RCTs—a misconception we try to counteract. However, Professor Aspenberg raises an important concern about the funding of large scale RCTs. We as clinicians must be careful not to “hand over the wheel” to “money makers”. Conflicts of interest are of concern in medical science indeed. Thus, clinicians must be in control of the study question, the study design, the results and interpretation, and should have full freedom in publishing the final manuscript without any influence from the funding agency. These ethical considerations, which are very important, were not within the direct scope of our manuscript and warrant discussion in detail in a future manuscript.

5. To summarize, EBM is no doubt a basis for good and economic healthcare. However, we also need scientific development within the healthcare system, and science needs a balance between creativity and discipline—the creativity to formulate ideas and the discipline to test them. I fear that the powerful tool of EBM may be misused as a weapon to enforce discipline. This may be good for clinical care, but bad for new ideas.

Authors' response: We agree. This is exactly why EBM is just part of the evolution of science and needs to be under continuous evaluation. EBM is not a fundamentalist religion, but just one tool in the toolbox of knowledgeable clinicians.

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