The need for education in evidence-based orthopedics

An international survey of AO course participants

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Background **As evidence-based practitioners, surgeons need to understand study methodology to critically appraise and conduct research.**

Objective **To determine current understanding of study methodology and critical appraisal among participants at an international educational meeting.**

Methods **We surveyed participants attending the 76th and 77th AO Course (December 2002) in Davos, Switzerland. We obtained information regarding participant age, gender, clinical and research experience, subspecialty area and respondents' roles in the AO course. The survey questions were formatted into three areas: evidence-based orthopedics, randomization and blinding issues.**

Results **532 participants completed the questionnaire. They represented 78 countries, the majority of which (31%) were from German-speaking countries. A greater proportion of participants trusted randomized controlled trials (89%) and meta-analyses of randomized trials (81%) when compared with case series and case reports. 60 respondents (11%) had never heard of the term "randomization" as a study design method to limit bias, and 114 respondents (21%) had never heard of the term "blinding" as a method of reducing bias in surgical research. When those who had heard of blinding were asked to define the term "double-blind", 20 different definitions resulted. Having completed the survey, nine-tenths of the respondents endorsed the need for training of surgeons in research methodology.**

Adoption and practice of evidence-based medicine require understanding of key concepts such as hierarchy of evidence, and important terminology such as randomization and blinding. Previous reports have demonstrated that 3 factors are critically important in limiting bias in clinical trials: randomization, concealment of treatment allocation, and blinding (Bhandari et al. 2001, Meakins 2001). No previous studies have examined the perceptions of surgeons, trainees and allied health professionals regarding their understanding of these concepts. Thus, we conducted a survey of participants at the Annual AO course in Davos, Switzerland (December 2002).

Methods

Questionnaire design

We developed a questionnaire to evaluate current understanding of key principles in critical appraisal of the published literature using key informants, and previous literature (Kitzinger 1995). Orthopedic surgeons and epidemiologists participated in the development of the questionnaire.

We obtained information regarding participant age, gender, clinical and research experience, subspecialty area and respondents' roles in the AO course. The survey questions were formatted into three areas: evidence-based orthopedics, randomization and blinding issues.

Respondents were asked to provide their opinion on the hierarchy of research designs, definitions of randomization, concealment of allocation, and blinding. The final questionnaire framed the response options in one of two ways: 5-point Likert

scales (i.e., definitely acceptable, probably acceptable, unsure, probably unacceptable, definitely unacceptable) or nominal scales. We also asked whether individuals completing the questionnaire supported additional training in critical appraisal and research methodology.

The questionnaire was prepared in 2 formats, English and German, to ensure that the main language of participants would be represented. There were no differences in the format or questions between the English and German surveys. We pre-tested the questionnaire on an independent group of two orthopedic surgeons and two epidemiologists in order to evaluate the following: 1) whether the questionnaire as a whole appeared to adequately address the question of key issues in critical appraisal of the literature (face validity), and 2) whether the individual questions adequately reflected the three broad areas of evidence-based orthopedics, randomization and blinding (content validity). These surgeons also commented on the clarity and comprehensiveness of the questionnaire. A copy of the questionnaire is available from the first author on request (beate.hanson@aoasif.ch). All 4 pre-test participants agreed that the questionnaire had face validity, content validity, clarity and comprehensiveness. The reliability of the questionnaire was not assessed.

Questionnnaire administration

We identified all participants attending the 76th and 77th AO Course (December 2002) in Davos, Switzerland. During the course, a special booth with a representative from the survey was available at the entrance of the meeting hall to ensure a high profile. We actively encouraged participation and to improve the response rate, we offered participants a small gift as an incentive.

Statistics

We summarized categorical and dichotomous variables with percentages and continuous variables with means and standard deviations. We performed cross-tabulations to identify associations between variables. The Chi-square test (or Fisher's exact test for small sample sizes) was used to compare proportions. We considered $p < 0.05$ to be statistically significant. All tests were two-tailed.

Results

Characteristics of respondents

Of 1064 who received the survey at the AO meeting, 532 completed the questionnaire (50%). The respondents represented 78 countries, one third of which were from German-speaking countries. 14% of respondents resided in English-speaking countries. 84% were men with a mean age of 44 (22–77) years. 19% were junior doctors (1–3 years of experience), 19% were senior residents (> 3–6 years of experience), 25% were chief surgeons and 24% were consultant surgeons. 75% of respondents worked in a teaching hospital. Trauma surgeons were most frequent (68%) followed by maxillofacial surgeons (11%) and spine surgeons (9%). Of the respondents, only 15% reported previous research training in evidence-based medicine.

Hierarchy of evidence

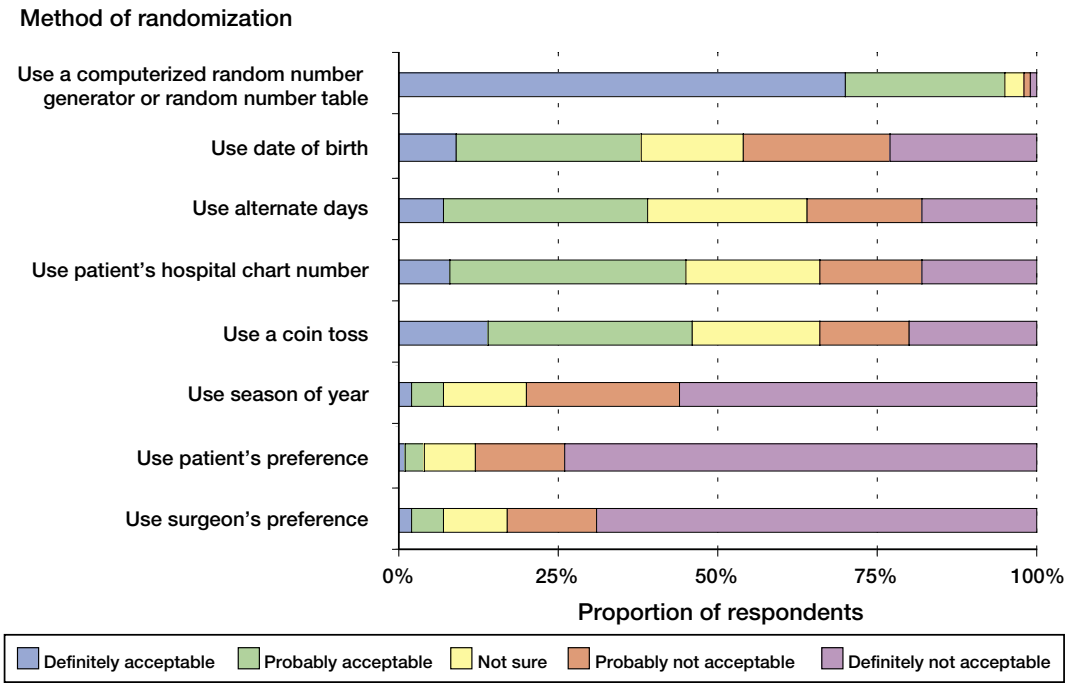
When asked about the validity of various forms of evidence, respondents were most distrustful of case reports (30%), case series (24%), and surgeon opinion (23%) (Table 1). A greater proportion of participants trusted randomized controlled trials (89%) and meta-analyses of randomized trials (81%) when compared with case series and case reports ($p < 0.05$). A large proportion of respondents (range 7–45%) remained unclear about the relative validity of various study designs, from case series to randomized trials (Table 1).

Randomization

60 respondents (11%) had never heard of the term "randomization" as a study design method to limit bias. Of those who had heard of randomization, 74% correctly believed that it was a process to ensure that both known and unknown prognostic factors (predictive factors) are equally balanced between treatment and control patient groups. However, several alternative and incorrect definitions were also endorsed: 1) a process to ensure that patients receive the treatment or control that surgeon's prefer the most (3%), 2) a process to ensure that outcomes between treatment and control groups are the same (7%), and 3) a process to ensure that patients in treatment and control groups are followed an equal amount of time and that their treatments are the same (11%).

Table 1. Pariticipants' belief regarding the validity of various study methodolgies

	Definitely trust	Probably trust	Not sure	Probably not trust	Definitely not trust
Surgeon's opinion	32 (6%)	133 (25%)	239 (45%)	96 (18%)	27 (5%)
Case report	37 (7%)	133 (25%)	202 (38%)	112 (21%)	48 (9%)
Retrospective case series	32 (6%)	165 (31%)	202 (38%)	112 (21%)	16 (3%)
Prospective case series	43 (8%)	298 (56%)	138 (26%)	48 (9%)	5 (1%)
Observational study (i.e. cohort study, case control)	48 (9%)	261 (49%)	170 (32%)	48 (9%)	0
Randomized controlled trial	192 (36%)	287 (54%)	37 (7%)	11 (2%)	5 (1%)
Meta-analysis of randomized controlled trials	176 (33%)	255 (48%)	80 (15%)	16 (3%)	5 (1%)



Methods to randomly assign patients to different tratment groups.

Most respondents (95%) believed randomization was best achieved through a computerized randomization schedule or random numbers table (Figure). Incorrect methods of random assignment such as patient or surgeon preference was endorsed to a lower extent (4% and 7%, respectively, $p < 0.01$). Concealing randomization (i.e. preventing investigators from discovering the treatment allocation of the next eligible patient) was most often believed to be achieved with remote telephone randomization (70%) or opaque envelopes (79%); however, 28% of respondents incorrectly believed that randomization was best concealed by only disclosing this information to the operating surgeon (Table 2).

Blinding

114 respondents (21%) had never heard of the term "blinding" as a method of reducing bias in surgical research. When those who had heard of blinding were asked to define the term "double-blind" from a series of non-exclusive proposed options, 29 different definitions resulted. The most common definitions were as follows: 1) patients and surgeons

Table 2. Techniques that may be used to ensure that investigators will not be able to determine the next group to which a patient will be randomized

	Definitely acceptable	Probably acceptable	Not sure	Probably not acceptable	Definitely not acceptable
Call a separate center via telephone to obtain the next patient allocation	202 (38%)	170 (32%)	80 (15%)	59 (11%)	27 (5%)
Use opaque envelopes that contain the next treatment allocation	229 (43%)	192 (36%)	53 (10%)	32 (6%)	32 (6%)
Only tell the research assistant/study nurse what the next allocation will be	43 (8%)	149 (28%)	117 (22%)	122 (23%)	101 (19%)
Post the randomization schedule on a board in the operating room	5 (1%)	80 (15%)	90 (17%)	133 (25%)	218 (41%)
Only tell the operating surgeon what the full randomization schedule is	37 (7%)	112 (21%)	112 (21%)	144 (27%)	128 (24%)

blinded (51%), 2) surgeons and outcome assessors (25%), and 3) patients and outcome assessors (15%).

Training in methodology

91% of respondents endorsed the need for surgeon training in research methodology. Moreover, 66% of participants believed that a half-day course in parallel with orthopedic educational courses (such as AO courses) would be of significant benefit. One-quarter of participants believed that even more training in the form of longer workshops (1–3 days) or formal research fellowships was needed.

Discussion

Our findings suggest that an appreciable proportion of survey respondents (range 4%–39%) have misconceptions concerning important aspects of evidence hierarchy and common terminology in study design.

The validity of our results has been strengthened by 1) the inclusion of surgeons and epidemiologists in the development of the questionnaire items, 2) a comprehensive sampling of surgeons, trainees and allied health professionals across 78 countries with an interest in caring for trauma patients, and 3) a good survey response rate (at least 50%) limiting non-responder bias (Kellerman et al. 2001). The results may not, however, be generalizable to individuals who do not represent participants at the Annual AO course in Davos, Switzerland. We did not identify language, age, or subspecialty differences among respondents.

Clinicians should know that in the hierarchy of primary research design, the results of randomized controlled trials are considered to carry the highest level of evidence. Unfortunately, not all studies in orthopedic surgery can be randomized. In such circumstances, surgeons and researchers should make use of other important designs, such as prospective cohort studies. Nevertheless, it should be noted that randomization is the only method for controlling for known and unknown prognostic factors between two or more comparison groups (American Medical Association 2001, Bhandari et al. 2001).

More important than randomization itself is the concealment of randomization. When the allocation to treatment is not concealed, the actual participation in a trial may be influenced by the knowledge of the treatment applied. Non-concealed allocation, such as alternate assignment of consecutive patients, for example, can lead to important imbalances in baseline factors between treatment and control groups. Clearly, readers would agree that the extent to which a surgeon can "guess" the treatment group to which his/her next patient will be allocated can be limited by using random numbered assignment in sealed, opaque envelopes (or better still, a centralized telephone randomization system). It is almost impossible to conceal randomization when strategies based on alternate assignment (even/odd days, alternate patients to emergency, even/odd year of birth) are used. Our finding that 28% of respondents misun-

derstood how concealment is achieved in research reinforces the need for increased awareness and education.

Blinding terminology led to 20 definitions and confusion among respondents. While it is believed that surgical trials cannot be double-blinded due to the relative impossibility of blinding surgeons, Devereaux and colleagues (2001) have recently challenged the "classic" definition of double-blinding. In a survey of 91 internists and researchers, 17 unique definitions of "double-blinding" were obtained. Surgical trials can always blind the data analyst, almost always blind the outcome assessor, occasionally blind the patient and never blind the surgeon. In a review of randomized trials, outcome assessors were blinded only 44% of the time and data analysts were never blinded (Bhandari et al. 2002).

Evidence-based medicine is not an end in itself, but rather a set of principles and tools that help clinicians to distinguish ignorance of evidence from real scientific uncertainty, to distinguish evidence from unsubstantiated opinions, and ultimately to provide better patient care. The core foundation of becoming an EBM practitioner mandates a working knowledge of common principles of critical appraisal and study methodology. While surgeons and trainees continue lifelong education in clinical skills, similar training is also needed in critical appraisal and study design (Bhandari 2002a, b). Not all surgeons need to be researchers, but all should understand the principles of research design to help their day to day appraisal of the published literature.

No competing interests declared.

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