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Designer's Corner

Evidence-Based Pain Management: The Need for Change

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Current Problems in the Management of Pain

Major advances in the management of pain, over the last 40 years, have been made through extensive research, rapid technological growth, and pharmacological advancements. Together, these factors have contributed to enhanced medical knowledge, the development of new theories, a better understanding of pain mechanisms, and the widespread introduction of new pain-relieving interventions.

Despite all these advances for pain, as with advances in other areas of health care, we have little knowledge about how different treatments compare in terms of overall effectiveness and safety. Treatment regimens are often based on prescriber preference, or on traditional, ritualistic, non-evidence-based practice, rather than on scientific fact. It has been estimated that only 15% of medical interventions currently in use are based on solid evidence (Smith, 1991). Textbooks, which are perceived as reliable sources of information, may be inaccurate and they quickly become outdated (Antman et al., 1992). It is difficult for clinicians to keep up with current research findings, because of the growing number of biomedical journals. There appear to be discrepancies between the recommendations of so-called experts and information from up-to-date systematic reviews, which suggests that the "experts" need improved access to up-to-date information (Milne & Chambers, 1993). With all this, it is hardly surprising that pain continues to be underestimated, inadequately assessed, and poorly controlled.

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The Importance of Systematic Reviews and Meta-Analyses

Evidence-based health care is based on the following principles: to do good rather than harm, to identify and critically appraise all of the existing evidence in an unbiased and systematic way, and to apply these findings to clinical practice (Sackett & Rosenberg, 1995).

Randomized controlled trials (RCTs) are now widely recognized to be the gold standard in assessing outcomes of health-care interventions (Chalmers, Dickenson, & Chalmers, 1992; Sackett, 1991), including treatment of pain. However, RCTs often have conflicting results, which causes confusion when research findings are applied to clinical practice. Adding to the conundrum, poor methodology and the use of inappropriate outcome assessments may result in either false positive or false negative results; similarly, studies of small sample size may be another important source of bias (Guyatt et al., 1986; Larson, Ellsworth, & Oas, 1993). Guidelines for assessing review articles and published reports are now available (Milne & Chambers, 1993; Oxman & Guyatt, 1988; Standards for Reporting of Trials Group, 1994).

Meta-analyses and systematic reviews may help clinicians to become better informed and to participate in decision-making processes – by combining the results of all the available RCTs on a given intervention to make statistical conclusions on their appropriateness, effectiveness, and safety. The main difference between a meta-analysis and a systematic review is that a meta-analysis uses statistical methods to combine data from individual trials, whereas a systematic review does not involve the use of formal statistical tests – either because it is inappropriate or because there is insufficient data in the published primary trials to make meta-analysis possible. The purpose of a systematic review is to gather existing research reports on a topic and summarize the results in a clear, unbiased, and systematic way. It should be noted that the quality of meta-analyses and systematic reviews is itself dependent on the quality of the primary studies (Oxman & Guyatt, 1988). Therefore in areas in which there are few studies, and in which primary studies are methodologically flawed or have small sample size and inappropriate outcome measures, it is unlikely that a high-quality systematic review with full meta-analysis will be possible. Written procedures and guidelines are now available to help health professionals undertake systematic reviews (see Cochrane Library under **Other Useful Sources of Information**).

The Review Process

The process of undertaking a systematic review is similar in approach to that of conducting a primary study, and the methods in a review must be equally rigorous. The actual undertaking of a systematic review should not be underestimated in terms of time, cost, and resources, and the review should be written up in such a way that the methods can be replicated by others. The review process is summarized in Table 1; some practical aspects of stages 1, 2, and 3 will be discussed in relation to systematic reviews in pain relief.

Table 1
Summary of the Review Process

1. Identify a clear and focused research question

- keep it as simple as possible – i.e., How effective is TENS in relieving post-surgical pain?

2. Identify a target sample

- with clear inclusion criteria – i.e., randomized controlled trials

3. Identify source of data

- electronic databases – i.e., MEDLINE, Cinahl, Pain Database, PsychLIT
- grey literature – i.e., unpublished data
- others – i.e., reference lists, textbooks
- identify all relevant papers by developing an adequate search strategy

4. Data analysis

- present data clearly, without misrepresentation or bias
- aims, design, sample size, treatment groups, methodological quality, main outcomes, results, conclusions
- statistical analysis (Is it possible? Is it appropriate? Which method?)

5. Conclusions

- make recommendations based on findings
- implications for patient, for clinical practice, for future research

Identifying Relevant Trials for Systematic Reviews in Pain Relief

Identification of all potential trials is not always straightforward and can be costly in terms of time and money (Chalmers et al., 1992). The effort that must go into the initial search, which will provide the data for a review, should not be underestimated.

Developing a research question. The purpose of a systematic review is to study all of the relevant trials in an attempt to answer a specific question. It is essential that the researcher have a clear and focused research question before attempting to search the literature, as this will influence the search strategy. If the question is too broad, the researcher might be overwhelmed with information; if many relevant papers are found, it may be worth narrowing the question. For example, "How effective is TENS?" may identify many RCTs; a more focused question would be "How effective is TENS during childbirth?" which would identify far fewer reports and concentrate on one clinical setting in which TENS is used. A preliminary literature search is always important once the research question has been decided, to prevent duplication of work. The Cochrane Collaboration have a register of systematic reviews that are either completed or in progress (see **Other Useful Sources of Information**).

Finding information. The development of electronic databases such as MEDLINE has made it considerably easier to identify published reports of clinical trials, but such databases do have limitations. It may be necessary for the investigator to use a number of sources of information to obtain relevant trials for a review – for example, reference lists in scientific publications and textbooks. Not all biomedical journals are indexed on electronic databases. Inadequate indexing in MEDLINE is a recognized problem, which means that by relying on Mesh Terms the researcher may miss important and relevant trials. Identifying relevant trials from an electronic database requires considerable skill and careful selection of appropriate Mesh Terms and free text words (Jadad & McQuay, 1993). To maximize yield, the investigator is advised to consult with a trained librarian before proceeding with complex searches. It is not always possible to determine from a MEDLINE citation whether the report is of an RCT until a hard copy is obtained. Other problems associated with electronic searches have been discussed by Chalmers et al., 1992; Dickerson, Scherer, & Lefebre, 1994; and Duley, 1996.

It is important that the appropriate electronic database be used, in order to detect pertinent trials, and it may be helpful to search more than one database. The Cochrane Database of Randomised Controlled Trials is a useful source of information and may be available through academic libraries; a database of RCTs in pain relief (Jadad, Carroll, Moore, & McQuay, in press) has recently been added to the Cochrane Database of RCTs.

The pain database, which was developed from an extensive MEDLINE search and a manual search of more than 40 biomedical journals, now contains citations for over 14,000 RCTs for pain interventions. The pain database, which is continually updated, was developed to prevent duplication of effort when undertaking systematic reviews in pain relief, recognizing the difficulties of identifying relevant trials. Table 2 outlines the broad structure of the pain database and the many studies in acute, chronic, and cancer pain and the spread of different classes of pain interventions. A sister database is currently being developed from the psychological literature to complement the main database, but it is not likely to be completed in the immediate future.

Table 2
Pain Database of Randomized Controlled Trials (1950-1994)*

Broad Class of Intervention	Acute	Chronic	Cancer	Total (%)
Complementary	112	223	10	345 (2)
Invasive	1697	336	34	2067 (14)
Pharmacological	5390	4978	337	10705 (75)
Physical	402	501	36	939 (7)
Psychological	100	191	10	301 (2)
Total				**14,357**

* Numbers may not always add up, as trials may come under more than one category.

The Future

Systematic reviews and meta-analyses will likely play an important role in the future management of pain. Some systematic reviews in pain relief have been published; others are underway. A recent literature search by the Oxford Pain Research Group identified nearly 200 published systematic reviews or meta-analyses for pain interventions (author's unpublished data), but many more need to be done. Indeed some of these reviews must be updated if they are to continue to be useful, relevant, and informative. Updating and maintaining reviews is an important aspect of evidence-based health care. It is hoped that systematic reviews will provide information for evidence-based clinical guidelines and direction for research. Critical and systematic appraisal of research can only help improve existing research methods and trial design, as well as develop standardized outcome measures for pain, so that it will be easier to combine and compare data from different trials.

For patients in pain it is essential that safe and effective interventions be identified and made widely available, and that ineffective interventions be rejected. New and unproven interventions need to be adequately assessed. If treatments have potential risks, then patients should be informed about them, and they should be involved in decisions on evidence-based treatment options. As resources for health care become increasingly scarce, it is no longer acceptable for ritualistic practices to continue without formal evaluation and justification. It is likely that purchasing decisions will be influenced by the results of systematic reviews in the future; as the public becomes better informed and is encouraged to take a more active role in health care, all health-care professionals will need to be more accountable to patients and be able to justify their clinical decisions.

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Other Useful Sources of Information

Canadian Cochrane Centre, Health Information Research Unit, McMaster University Medical Centre, 1200 Main St. West, Hamilton, Ontario L8N 3ZN. E-mail address: cochrane@mcmaster.ca. Web site home page: http://hiru.mcmaster.ca/cochrane/

Chalmers, I., & Altman, D.G. (1995). *Systematic reviews.* London: BMJ Publishing.

Cochrane Library (containing four databases of reviews and RCTs), available from BMJ Publishing Group, P.O. Box 295, London WCIH 9TE, UK.

Oxford Pain Research Group web site home page: http://www.jr2.ox.ac.uk.80/Bandolier/painres/painres.html

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