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ワークショップ

Evidence Based Practice in Electro-Physical Agents *

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Introduction

While the use of electrophysical agents (EPA) is not confined to just physical therapists, it has been demonstrated that physical therapists have been a major contributor to the knowledge base in EPA, as well as being the most active group in terms of their research activities related to EPA[1]. Most of these clinical studies related to EPA were conducted within the last 25 years. A review of these studies and a summary of the evidence for the effectiveness of the various EPA modalities, have already been presented in a previous paper[1].

A summary of the research activities into the various modalities over the last few decades is given in Fig. 1, according to the three eras of professional development described by Ritchie[2].

During the first stage of professional development, the "Era of Physiotherapy Dependency" (1940s to 1976), rehabilitation doctors were mainly responsible for carrying out research into EPA modalities, sometimes in collaboration with physical therapists. However, the number of research studies in this era was minimal (Fig. 1). In addition, most of the studies during this era did not set out to answer questions of specific interests to physical therapists. Hence, many issues such as dosimetry, treatment protocols and treatment effectiveness were not adequately addressed. Nevertheless, most of the studies in this era served as guidelines for future studies, and it was not uncommon to find that they usually concluded with a call for more investigation into the various modalities. Unfortunately, in most of these areas, the call for more studies had gone largely unheeded. In addition, the results of the studies that were meant to serve only as guidelines for future investigations became accepted as "evidence", which by today's standards fell short of the minimum standards specified by a randomized controlled trial or RCT.

During the next phase of professional development, the "Era of Independent intuition" (1976 to early 1990s), physical therapists themselves began in earnest to look for the evidence for the effectiveness of the various modalities. Most of these early studies, however, were marred by poor design, lack of a control group, inadequate sample size, and insufficient data analysis. As a result, many of the results from these studies were contradictory, confusing, and the effectiveness of the treatment modality being investigated remains equivocal till today.

During the present stage of professional development, the "Era of Expert Evaluation" (1990s to present), physical therapists' involvement in independent research into the various EPA modalities increased substantially. The pace of research activities had also increased (Fig. 1). Also, there was a vast improvement in the quality of the research not only in their research designs but also in the quality of the questions asked. These questions were directed at clinical effectiveness of the various modalities, as well as pertinent issues related to application of the modalities. However, because of the problems associated with research prior to this era, researchers are still struggling with most of the basic issues, which have yet to be resolved, and which are pre-requisites to a good clinical study. These issues include dosimetry, treatment protocols, and appropriate outcome measures to assess the effectiveness of the modalities, among others.

From the results of numerous literature reviews conducted over the past few years[3-11], it is evident that in many areas, clinical studies are desperately lacking. There is an urgent need to address this issue, not only in the quality of the research design, but also in the quantity of the clinical trials that are being carried out. However, while more clinical studies into the effectiveness of each of these modalities is desperately needed, it would not serve any purpose to pursue these at the expense of answering more basic and fundamental questions related to the treatment protocol, dosimetry and appropriate outcome measures for quantifying the effec-

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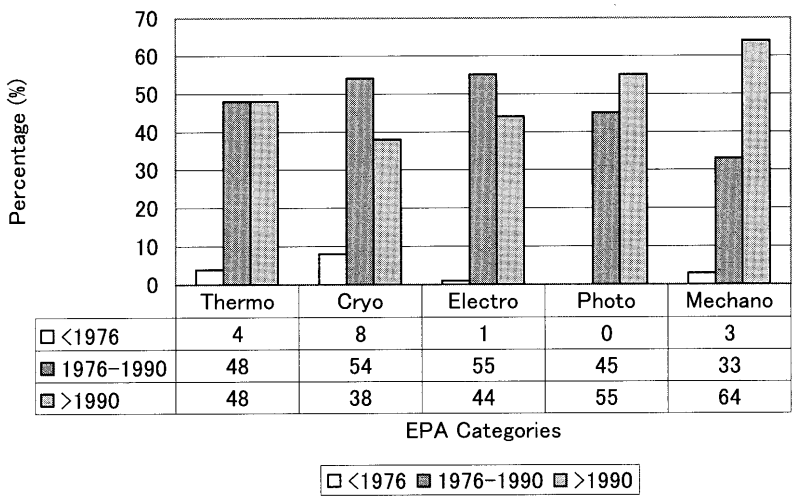

Fig. 1 Relative research activities in the various areas of EPA during the 3 eras of professional development described by Ritchie[2)]

tiveness of the treatment.

From a previous analysis of 331 clinical studies[1)], there is strong evidence that favors mild to moderate recommendation for using EPA in the treatment of various conditions. Admittedly, there are also many areas where the evidence is equivocal[1)]. The implications, nevertheless, are that while EPA does appear to have an evidence base, there is still a lot of work to be done.

Currently, while evidence based practice in EPA is theoretically possible, its acceptance among clinicians remains to be tested. In addition to presenting the evidence to the clinicians, it is also necessary to create a clinical environment that will facilitate the implementation of evidence-based practice in EPA. In making the transition from "presenting the evidence" to an "evidence based practice" environment in EPA, it is necessary to begin by changing the mindsets and practice patterns of more than 3 generations of physical therapists who still rely on "instincts, trial and error, and a blind clinging to tradition"[2)].

The aim of this paper is to identify and discuss the factors which can be considered to be critical for the transition to an evidence-based practice environment in EPA. These factors have been identified as follows:

a. Technical competency in EPA
b. Clinical standards for the use of EPA
c. Adoption of a credible research model for EPA
d. Issues related to dosimetry for the various EPA modalities

Technical Competency in EPA

One of the biggest challenges we face in EPA is the technical competency of its users. Often, it is not the modality itself that is ineffective, but rather the sloppy application of the modality, which renders it useless from the start. In our efforts to educate our students in evidence-based practices in EPA, we may have inadvertently de-emphasized the importance of achieving technical competency, which is a pre-requisite to good practice in the first place. While there are no published papers that have documented this phenomenon, it would probably be quite self-evident to any visitor to a busy outpatient's physiotherapy department. Due to either time constraints or a high patient load, or both, the application of the EPA modality is often hurriedly applied by the physical therapist, or relegated to an assistant or worse still, the patient himself. These poorly applied or inadequately supervised applications of EPA modalities are probably doomed from the start. No amount of good evidence regarding its treatment effectiveness will change the outcome of the particular treatment, resulting in a further general disbelief in the evidence for its effectiveness. In order to make that first step in the transition from "evidence" to "practice", there is a need to return to basics in our education and to emphasize technical competency as a pre-requisite to good practice and successful treatment outcomes. There is also a need to change the attitudes of clinicians who are using EPA in their treatment of patients. While some of these modalities do not require a high level of skill for its application, the effectiveness of the modality depends on its correct and appropriate application in the first place. It is doubtful that unsupervised support staff, and even more doubtful for patients themselves, to be able to carry out treatment on themselves without compromising on its efficacy.

Clinical Standards for the Use of EPA

In 1990, Ide wrote "Concern has been expressed for some time about the practice of electrotherapy within the profession. This concern has focused on the safety of machines and the efficacy of treatment..." (p7)[12]. In response to this "concern", the Chartered Society of Physiotherapists in the United Kingdom published a series of documents that served as safety guidelines for the use of the various EPA modalities[13-19]. A similar effort by the Australian Physiotherapy Association was also published at around the same time[20]. The efforts of both Associations are commendable in their attempts to set the minimum standards of practice in order to prevent injuries arising from unsafe practices.

In light of today's evidence based practice environment, a thorough reading of both documents is highly recommended. However, these clinical standards documents alone, which served more as safety guidelines during the 1990s, are inadequate for today's evidence based practice environment.

It may be appropriate for any future document that deals with clinical standards for the use of EPA, to be divided into the following sections:

1. Clinical safety standards of procedures using EPA modalities

   The current documents by the Australian Physiotherapy Association[20] and the Chartered Society of Physiotherapists[13-19] deals with the issue of safety adequately and with minimum modifications may continue to serve our needs in this area in the new millennium.

2. Clinical effectiveness standards of treatment using EPA modalities

   Clinical effectiveness standards for EPA treatment currently do not exist. It is also probably unrealistic to expect that these standards can be formulated within the immediate future. However, based on the evidence on treatment effectiveness of the various EPA modalities currently available, it is not difficult to compile a database of research studies that could serve as clinical guidelines on treatment effectiveness of the various modalities. This information could be made readily available, using the current Internet technology. An example of such a project is the Physiotherapy Evidence Database or PEDro (http://pedro.fhs.usyd.edu.au/), and the Electrophysical Agents Home Page (http://alps2.shinshu-u.ac.jp/users/PT/electro/index.htm). These guidelines could eventually be evolved into standards as and when sufficient information becomes available.

3. Clinical Performance standards of EPA modalities

   The clinical performance standards of EPA equipment are probably the most overlooked aspect of clinical standards, and yet is a pre-requisite in an evidence-based practice environment.

   Despite the presence of established performance standards for some EPA modalities such as thermotherapy[21-23], and ultrasound[24-26], physical therapists by and large remain unaware of their existence. Also, despite the presence of several studies that have shown sub-standard performance and poor reliability of these equipment[27-33], physical therapists who use these modalities every day still do not see the need to change their practices. Perhaps even more alarming is the fact that many of this sub-standard and unreliable equipment are being used in clinical trials to determine the efficacy of the modality. The effects of these unreliable equipment on the equivocal evidence we have to date on treatment effectiveness using EPA modalities cannot be lightly dismissed or under-estimated.

Adoption of a Credible Research Model for EPA

The pharmaceutical model for testing and clinical research into new drugs begins with either the discovery of new chemical compounds or an accidental discovery that a chemical compound being tested for its effect on an identified disease exhibits potential in the treatment of other unrelated diseases[34]. This discovery usually initiates a chain of events, beginning with initial testing in animals to document the new drug's toxicity, metabolism, excretion and other biological effects (Fig. 2). Often, it is not unusual for a pharmaceutical company to have accumulated at least 2 to 5 years of data on animal tests before approval is given by the FDA or its equivalent in other countries, to begin testing in human

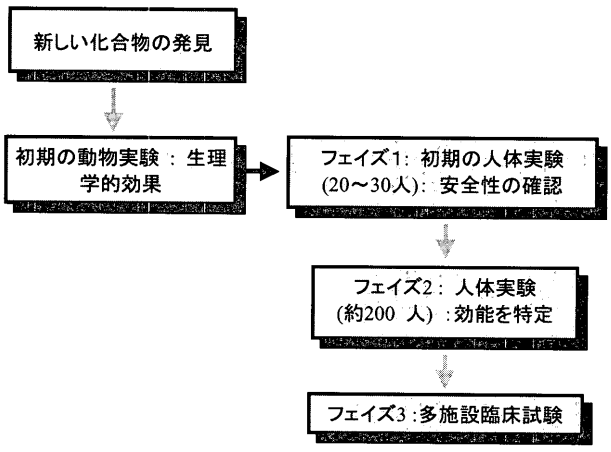

Fig. 2 Pharmaceutical Research Model

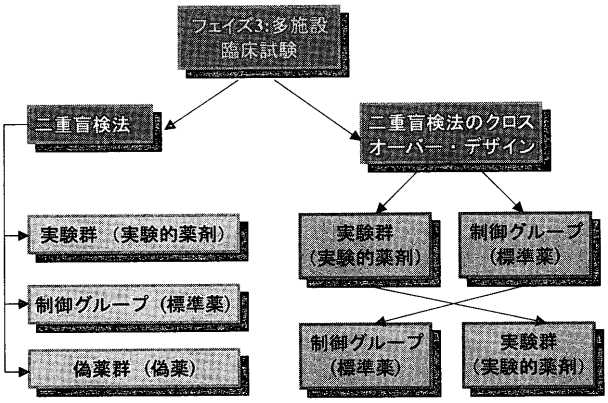

Fig. 3 Phase 3 research design

subjects.

Testing in human subjects is carried out in three phases[34]. Phase I, which is the initial human studies, is carried out under the supervision of expert investigators whereby the drug is administered to one or very few normal individuals (perhaps 20 to 30 subjects) and the results analyzed. The test drug is administered in varying dosages, and biochemical analysis of blood samples are carried out to determine its safety rather than efficacy (Fig. 2).

Phase II involves administration of the drug to a larger group (approximately 200) patients to examine the efficacy of the drug (Fig. 2). Safety studies are also repeated, but not as extensively as in Phase I[34].

Phase III involves field trials in which the drug is administered to a larger group of patients, and approaching conditions of general medical practice (Fig. 2). Phase III testing of a new drug can be carried out through either of two basic experimental designs[34] (Fig. 3).

a. Double blind design (Fig. 3). This design is employed when test subjects are suffering from a transient type of disability. Patients are randomly assigned to one of three groups; treatment by test drug, standard drug or placebo. To evaluate the effectiveness of the drug, group comparisons are made. The consistency of performance of this test system is measured by the group response to the standard drug and not to the placebo.

b. Double blind cross over design (Fig. 3). Test subjects are initially assigned at random to either one of two groups; treatment with test drug, or treatment with standard drug or placebo. They are then crossed over to the alternative treatment without their knowing the identity of either.

In contrast, the research model for EPA usually begins with the development of a new technology, and the possibility of applying this technology to patients. Often the possibility of application to patients is backed up by no more than biological plausibility. Initial animal testing and Phase I and Phase II testing as in the pharmaceutical model are usually bypassed, and small and large scale clinical trials are usually conducted in parallel with widespread application in the clinics even before results of these clinical trials are made known. Often, these trials are even unnecessary as widespread use of the modality usually assures it of general acceptance by the profession. This hardly constitutes a coherent research model, and is more representative of research chaos. Ultimately, the issue of whether an EPA modality is effective remains unanswered, and possibly irrelevant. The system, however, perpetuates the use of the modality, and the physiotherapy profession is left with the dubious credit of using unproven treatment techniques.

The present EPA research "model" resembles a "hit-and-miss" strategy, which is both meaningless and flawed. In today's evidence based practice environment, there is an urgent need for a more credible and coherent research model. Conducting more Phase III clinical trials with larger samples without putting the work initially into animal studies, and Phase I and II clinical trials will not provide us with the evidence we seek.

Dosimetry

In the area of therapeutic ultrasound, it is stated "the physiotherapist shall ensure that the correct intensity is chosen for the treatment to avoid delivery of excess energy to the tissues" (p43)[20]. Current knowledge in this field does not lend support to such a statement. Partridge[35] claimed that "there is little general agreement nationally or internationally about optimum dosages for given conditions" for any of the EPA modalities currently in use.

Therapeutic ultrasound has been claimed to have both thermal and other biophysical effects in in-vitro studies and reviews[36-41]. Young and Dyson[42] suggest that these biophysical effects are intensity dependent; "too low a dose will have no effect, and too high will be damaging" (p594). The question as to what constitutes a low or high dose cannot be answered, however, unless the issue of dosage in therapeutic ultrasound is clarified.

In a recent study by Goh *et al.*[43], a questionnaire survey was conducted to sample opinions on what constitutes an appropriate treatment dosage for various specified conditions. An overwhelming 92% of respondents suggested that there was not enough evidence to guide them in determining treatment dosages. This concern was supported by poor consensus among respondents on treatment dosages for the specified medical conditions.

When respondents were asked their opinions about appropriate treatment dosages for seven specific medical conditions, the majority stated that they considered the pulsed mode to be appropriate for the acute phase and the continuous mode for the chronic phase. The nature of the problem (acute or chronic), the depth of the target tissue (superficial or deep) and the size of the treatment head (small or large) were considered to be the three most important factors when determining the treatment dosage. The respondents' choice of treatment intensity varied from 0.66 Watts/cm^2 (for acute lateral epicondylitis) to 1.03 Watts/cm^2 (for chronic torn quadriceps). In the determination of the treatment intensity, males consistently chose higher treatment intensities than females ($p<0.001$); the geriatric and pediatric practitioners favored higher treatment intensities compared with the other specialties ($p=0.026$); and graduates from the United Kingdom were more conservative, choosing lower treatment intensities than graduates from other countries such as Australia and Singapore ($p<0.001$).

It appears from the results of this survey[43] that the determination of treatment dosages for therapeutic ultrasound requires further clarification. In the absence of concrete guidelines based on experimental data, clinicians' selection of treatment dosage appears somewhat arbitrary and differs according to their gender, clinical specialty, country of training, and educational background[43] rather than being based on clinical information, the aims of treatment and knowledge of the effects of different dosages on the target tissues. The authors concluded, "unless we are prepared to undertake more research into this area, the determination of treatment dosages in therapeutic ultrasound for the various conditions remains in the realm of instinct and guesswork rather than science" (p83)[43].

The issue of dosimetry is tied closely with the adoption of a credible research model. In initial animal studies, issues such as dosimetry can be addressed and confirmed with Phase I and Phase II testing on human subjects. While the example given here deals specifically with therapeutic ultrasound, the issue of dosimetry is still outstanding in almost all the EPA modalities that we currently use. Again, conducting more clinical trials with larger samples will not provide us with the answers we seek in relation to dosimetry.

Conclusion

The behavior and attitudes of our clinicians are usually influenced by their undergraduate education. For too long, the subject of EPA has been taught in the same manner from generation to generation, with emphasis on technical competency and more recently, some exposure to the current research, no matter how flawed and ambiguous. Students learn, from the offset, that while EPA is something that we use quite often in our treatment of patients, it is something that cannot be taken seriously, not even by ourselves. Some even use EPA as a time-filler; something to keep the patient occupied until more "definitive" treatment can be provided. The image of an EPA user is still that of a technician, and the more we strive to improve our professional image, the more we tend to dissociate from EPA.

The problem, though, lies in how we have approached the subject of EPA in our education. In our early days, when the responsibility of the effectiveness of our treatment laid with the medical doctor who referred the patient, EPA was just another treatment modality we carry out as directed by the referring physician. Other than technical competency, very little else was needed in the EPA curriculum. However, now that we have the responsibility for determining the treatment options for the patient, together with the responsibility of producing the evidence for its effectiveness, still nothing has changed in the way we educate our students in EPA to prepare them for this role.

In order to educate a new generation of physical therapists who can develop the subject of EPA to its highest potential, we have to address all the outstanding issues, some of which have been discussed in this paper, in the curriculum we teach.

The issue of evidence-based practice in EPA is more than just producing the evidence. Fundamental issues, as discussed in this paper, need to be addressed if we are to succeed in making the transition.

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