MEDICAL ULTRASONICS STANDARDS: PRACTICAL TECHNIQUES AND PRESENT STATUS IN HOSPITALS

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1. Introduction

Almost any generalized discussion about the status of ultrasonic techniques in hospitals, whether of diagnostic procedures, of the sophistication of equipment, or of the status of equipment test procedures is a highly complex discussion which at present defies elegant analysis. The reasons for this are many: the wide range of professional people involved (physicists, engineers, radiographers, physiotherapists, clinical assistants and clinical specialists); the wide range of ultrasonic devices commercially available; the varied local structure and terms of responsibility for ultrasonic devices in the NHS- and the varied level of awareness - even among physicists - of the problems of fundamental biomedical ultrasonics. These all contribute to increasing the scientific distance between the achievements and practice of workers in a few leading centres, and the general level of achievement and practice, e.g. that at a typical District General Hospital. The many different kinds of personnal involved introduces a wide range of differently directed questions or indeed a range of different orders of importance. An overall structure is thus hard to define, but as a first approximation we can identify two distinct scales of judgement; that of the scientific laboratory and that of the clinical situation.

As Dr. ter Haar has indicated in the previous paper, the standardization must derive from scientific work. The justification, however, must derive from the clinical situation; and, as in any situation in which physical insult is deliberately applied to the body, a balance must be found between two inevitable factors: the potential benefit and the potential hazard. These two factors, in specific application to the types of equipment to be found in hospitals (surgical, and physiotherapeutic devices, Doppler devices, A-scanners M-scanners, hand-scanned and real-time B-scanners) provide two useful directions for the discussion.

2. In relation to the potential benefit

The first of them - the potential benefit - gives four contexts for standardization. These are identified by the questions: 'Is the machine doing today what it did yesterday?', 'Is the machine doing today what it did last month (or last year)?', 'Is the machine (in the hands of its operator) doing what it was designed to do as well as it can?', 'Is the machine performing its task(s) as well as other machines that are available?'. (As will be seen from the subsequent discussion, the questions unfortunately have to stop at that point).

The first two of these have led to the suggestion [1], of two levels of testing - simple checks performed by the routine operator, probably performed daily or whenever the machine is used, and more infrequent sophisticated tests based for example on specialist equipment held by a Regional Physics Department. The definition of the test procedures for defining these temporal standards begs

the question implicit in the last two of the four questions above: 'What is the machine supposed to be doing?' or 'How can the performance of the machine be measured?'.

Inadequacy of the author's knowledge may affect the validity of the remarks that follow immediately, but it is his impression that ultrasonic surgery is limited to situations in which there is direct contact with the tissue to be destroyed, and that the probe is applied until the surgeon considers enough tissue has been destroyed. Performance is thus assessed by the direct observation of the experienced surgeon.

Physical medicine appears to base performance on the operator's experience - but it is the operator's experience based essentially on patient expression of satisfaction (or otherwise). Part of the experience may involve measurement of the output of the equipment, but this will be discussed later.

With(diagnostic) Doppler equipment, the essential object appears to be the detection of blood flow. It is related primarily to signal-to-noise problems, and secondarily to specifity of direction. Little appears to have been reported on measures of equipment performance in relation to the clinical situation, and it appears to rest entirely on the subjective assessment of the operator.

Diagnostic scanners rely for their assessment on concepts of registration and resolution - as assessed, for example, by the A.I.U.M. phantom and other devices [1]. These are all implementations of very simple ideas that are not necessarily relevant to the clinical problem because of our ignorance of the acoustical micro-structure of tissue. The increasing use and developmental proliferation of grey-scale scanners has revived the idea of tissue models - inhomogeneous materials of constant properties - for the assessment of the machine's ability to display the scattering of the tissue texture. The assessment remains subjective.

In summary, therefore, as far as machine performance in a clinical context is concerned (from which patient benefit directly derives), standardization appears rudimentary or subjective in almost all applications, and the essential cause in each case is our ignorance of the mechanisms of the interaction of the ultrasound with the tissue.

3. In relation to potential hazard

The other factor to be balanced mentioned in the introduction was the potential hazard, in elucidation of which the ignorance identified at the end of the previous section plays a fundamental role, via the determination of the biological effects of ultrasound. The potential hazard is also the justification for most of the standards-work that has been described in the two papers immediately preceding the present one. These standards are concerned with measurement of various characteristics of the beams that are used to irradiate the body. They are thus concerned with a form of exposure measurement. In addition to the devices already discussed by Mrs. Livett, mention may be made of sensitive calorimeters [2], and radiation force devices sensitive enough to be used on diagnostic machines [3]. Although hydrophones - whether with ceramic or plastic elements - may in certain circumstances be used to obtain an absolute measurement of the field distribution, relative distributions for pulse-echo equipment were previously advocated, the echo being obtained from a scanned spherical target. It is probably fair to say that at present there are no devices that are universally used or even that are used by the majority of hospital workers.

4. A pilot survey

In order to provide more certain information than that of an impression, a small pilot survey was performed. The answers from 8 physicists and 1 doctor covered some 67 hospitals and well over 200 pieces of equipment of various types. Only elements of the detailed results will be given.

Whereas all replies indicated exact knowledge of B-scan devices of both types, only one in three knew exact numbers of physiotherapy and Doppler devices. The estimated numbers - of approximately equal numbers of each of these four categories (at a level of approximately two devices to every three hospitals) - would appear weighted against the physiotherapy devices at least. (One Regional Office has indicated the rates of physiotherapy devices to B-scanners is at least 2:1 for their region). Regular testing was known to be performed on 6 out of 7 surgery devices, on less than one in eleven physiotherapy machines, on more than half the hand-scanned B-scanners, on approximately 7% of the real-time B-scanners and on less than one in three Doppler devices. Overall 30% of diagnostic devices were known to be tested regularly and 18% of therapeutic devices. The testing situation (i.e. availability of skilled personnel, suitable devices of reasonable cost, etc.) was considered adequate for less than 10% of the machines numerically estimated. Only two centres identified beam scanning facilities. No test procedures were commonly used and two thirds of the test equipment is home-built. Unfortunately the questionnaire did not touch the calibration of test equipment or what was specifically measured on each machine. The level of awareness of existing knowledge and devices was, however, extremely varied.

5. Conclusion

The general conclusions are thus that:

(i) there are few objective criteria of machine performance relevant to the clinical situation;
(ii) there is essentially no consensus of procedural usage;
(iii) the awareness of involved clinical physicists is very varied;
(iv) the activities of the standards organizations would appear to have almost no systematic influence on current practice in hospitals.

And the significance of these comments is that the survey was biased heavily to those clinical physicists particularly aware of or involved with the problems of equipment assessment.

One can see the arguments that may be presented: that diagnostic procedures appear to do no harm and thus ill-defined experimental errors of exposure measurement that may lead to several tens of per cent of systematic errors are not worth worrying about. Similarly the relation of exposure measured in water to the related exposure in a particular tissue may be argued to far outweigh any systematic errors in the exposure measurement in water, particularly if the assessment of clinical performance is rather imprecise.

Comfortable as these arguments of ill-defined usefulness are, it is the author's belief that they are dangerous. They militate against a vigorous scientific approach in which systematic errors are quantitatively accounted and which - however difficult it may be - is the only route to understanding the ultrasound: tissue interaction. This understanding is in its own right the only basis upon which standardization (of performance) will have meaning in a clinical context, and indeed in the context of ultrasonic field characterization in relation to a scientifically determined hazard.

While the present situation is allowed to continue, not only will the rather individualistic approach to machine assessment revealed by the survey continue, but also the achievements of leading laboratories whether they are scientific, technological or clinical will continue to remain remote from the scene of basic medicine - the District General Hospital. This will not only be to the detriment of the care of the individual, but also tend to lead to the squandering of public funds on ill-directed, irreproducible empiricism in both testing and developing clinical ultrasonic equipment.

6. References

1. The assessment of ultrasonic scanners. Report TGR 23, Hospital Physicists' Association, London (1978).

2. G. R. Torr and D. J. Watmough (1977). A constant flow calorimeter for the measurement of acoustic power at megahertz frequencies. Phys.Med.Biol. 22, 444-450.

3. M. J. Farmery and T. A. Whittingham (1978). A portable radiation force balance for use with diagnostic ultrasonic equipment. Ultrasound Med. Biol. 3, 373-379.