Knowledge of the bio-effects of ultrasound among physicians performing clinical ultrasonography: Results of a survey conducted by the Italian Society for Ultrasound in Medicine and Biology (SIUMB)

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KEYWORDS

Biological effects;
Safety;
Survey;
Ultrasound.

Abstract *Introduction:* Safety issues should always be kept in mind when using diagnostic ultrasound, which is associated with potentially hazardous bio-effects, especially with the introduction of new technologies.

Aim: To assess the level of awareness and knowledge of safety issues related to the clinical use of ultrasound among physician-members of the Italian National Society for Ultrasound.

Materials and methods: A questionnaire with 11 multiple-choice questions was sent to members of the Italian Society for Ultrasound in Medicine and Biology. The answers were forwarded from the Society's Secretariat to the investigators, who statistically analyzed the data.

Results: The mean age of the 105 respondents was 44 years. The most frequent kind of ultrasound examinations (in addition to conventional B-mode) were: Doppler (74%), contrast-enhanced US (43%), and pediatric studies (43%). Only 50–60% of the responders knew the correct definitions of the terms *thermal index* and *mechanical index*. Almost all respondents understood the bio-effects reflected by the thermal index, but only a minority knew the most likely organ target of bio-effects related to the mechanical index and what do indicate the units in which the thermal index is expressed. The majority knew that fetuses are at higher risk of damage. Few respondents were able to identify the correct safety statements included in the recommendations of the International Ultrasound Societies.

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Conclusion: In conclusion, the present findings indicate that greater efforts of National Ultrasound Societies are warranted in disseminating knowledge of the bio-effects of diagnostic ultrasound modalities among operators.

Sommario *Introduzione:* La sicurezza nell'uso degli ultrasuoni va sempre considerata in campo ecografico, in quanto gli ultrasuoni sono in grado di indurre effetti biologici potenzialmente dannosi, soprattutto con l'introduzione di nuove tecnologie.

Scopo dello studio: Valutare il livello di consapevolezza e di conoscenza dei medici italiani soci SIUMB sulla sicurezza nell'uso dell'ecografia nella pratica clinica.

Materiali e metodi: Un questionario contenente 11 domande a risposta multipla è stato inviato per e-mail a soci SIUMB (Società Italiana di Ultrasonologia in Medicina e Biologia). Le risposte sono state inserite in un database elettronico ed analizzate statisticamente.

Risultati: Sono tornati questionari da 105 soci, di età media di 44 anni i cui esami ecografici più frequentemente eseguiti, in aggiunta all'ecografia B-mode standard, erano l'ecoDoppler (74%), l'ecografia con mezzo di contrasto (43%) e l'ecografia pediatrica (43%). Solo il 50–60% conosceva la definizione corretta dell'Indice Meccanico e dell'Indice Termico. Quasi tutti i partecipanti comprendevano gli effetti biologici espressi con Indice Termico, nonostante che solo una minoranza sapesse in quale organo gli effetti biologici, in relazione all'Indice Meccanico, potevano, con più probabilità, verificarsi; analogamente solo una minoranza conosceva l'unità di grandezza per l'Indice Termico. La maggioranza era a conoscenza di come i tessuti del feto siano più suscettibili ai potenziali effetti di quelli adulti. Pochi partecipanti conoscevano le raccomandazioni delle Società Internazionali di Ultrasonologia in campo di sicurezza.

Conclusioni: Lo studio ha fatto emergere come sia necessaria una maggior diffusione delle conoscenze sugli effetti biologici degli ultrasuoni tra gli ecografisti italiani.

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Introduction

Diagnostic ultrasound (US) has been widely used in several different clinical fields for many years, and thus far there have been no proven negative effects. However, there is ample evidence and a considerable body of scientific literature dealing with the interaction between US waves and biological tissues, where these waves can produce heating, pressure changes, and mechanical disturbances. The bio-effects of US are conventionally divided into two categories: thermal effects and nonthermal effects. To describe the former effects, a thermal index (TI) has been introduced. The TI is proportional to a calculated or estimated rise in temperature for model exposure conditions and is represented by the ratio of the ultrasonic power emitted by the transducer to the ultrasonic power required to raise tissue temperature by 1 °C under model exposure conditions. It is directly proportional to the frequency of the US beam, and it is tissue-specific, so there is a thermal index for soft tissue (TIS) and a thermal index for bone (TIB).

In obstetric US, the TI may underestimate the actual increase in intracranial temperature produced in the fetus during a pulsed Doppler examination. This is particularly important for the brain tissue, which is very sensitive, because the cerebral blood flow is unable to eliminate the heat produced [1]. Thermal effects are caused by the conversion of the mechanical energy of US into thermal energy.

The acoustic outputs associated with modern B-mode imaging are hardly capable of producing harmful rises in temperature. However, biologically significant temperature increases, especially at bone soft tissue interfaces, have been demonstrated with certain Doppler scanners [2].

The nonthermal effects of US are caused by mechanical stress, and they occur without any alteration in temperature. The most important is unstable cavitation in gas-containing tissues. It is triggered by the energy released following the rapid collapse of microbubbles that have been expanded as a result of their interaction with the US beam. A substantial amount of experimental and theoretical evidence suggests that diagnostic ultrasound scanners are able to produce cavitation in vivo [3].

Several national and international US societies, including the American Institute of Ultrasound in Medicine (AIUM), the World Federation of Ultrasound in Medicine and Biology (WFUMB), and the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB), have appointed safety committees to address issues related to the bio-effects and safety of US in different clinical situations and provide regularly updated safety statements. In its most recent executive summary, the Bio-effects Committee of the AIUM examined the literature on this subject and developed conclusions and recommendations related to diagnostic US [4]. The European Committee of Medical Ultrasound Safety (ECMUS), in its latest Clinical Safety Statement, issued recommendations regarding the use of diagnostic US, in general and particularly during pregnancy.

Many experiments have revealed evidence of US damage to tissues containing gas (lung and gut) [5], but these investigations were conducted in animal models and with US intensities significantly above the range commonly used in human clinical diagnostic settings.

The effects of US on organogenesis have also been studied in animals [6]. Significant adverse effects like abortion, malformation, or neuropsychic problems were

reportedly absent when the intensity of US was maintained below the recommended values used in the clinical setting (since this precaution prevents temperature increases, which could be teratogenic), but, in some cases, small, yet statistically significant, reductions in birth weight were observed.

As far as the uses of US in humans are concerned, one of the most important is the use of Doppler technology during pregnancy. In particular, considerable research has focused on the use of pulsed Doppler, which exposes tissues adjacent to bone structures to a high-intensity US beam for a considerable amount of time, and such exposure could lead to a significant increase in temperature in the soft tissues. Numerous epidemiological studies have been conducted to assess the risk of repeated US examinations in humans, especially during pregnancy. For example, one study revealed a slight increase in left-handedness and dyslexia in children exposed to US during pregnancy compared with those who were not exposed [7]. These findings were not confirmed, however, in a recent randomized trial [8], which assessed body weight and neuropsychic development at 1 and 8 years of age in two groups of children who had been examined in utero with US: one group had had 5 B-mode examinations plus 1 pulsed Doppler examination, the second had had only 1 B-mode examination. There were no substantial differences between the two groups in this study. It should also be pointed out that in most studies, the US examination has been performed using out-dated equipment, which produced lower US energy levels than those produced with current Doppler technology. In an article published in 2003 regarding live scanning at ultrasound scientific conferences and the need for a prudent policy, Barnett [9] stated that detailed examination of this issue by the World Federation for Ultrasound in Medicine and Biology might be appropriate.

In summary, the published literature indicates that the bio-effects of US do not reach clinically relevant levels, and to date their existence has been documented only in vitro or in animal models. Nonetheless, physicians performing US examinations need to be aware of the theoretical hazards of US in order to minimize the risk of provoking adverse effects. This problem has become even more important since the introduction of US contrast agents containing gas-filled microbubbles, which increase the likelihood clinically relevant biological effects [10].

The aim of the present study was to assess the level of awareness and knowledge of safety issues related the clinical use of US among physician-members of the Italian Society for Ultrasound in Medicine and Biology (SIUMB).

Materials and methods

In 2006 the Secretarial Office of the SIUMB sent out a questionnaire (Appendix 1) to all society members for whom an e-mail address was available. The questionnaire was composed of two parts:

- Part 1: A form to be filled out by the member providing demographic data and information about his/her experience in the clinical use of US.

- Part 2: A multiple-choice quiz with eleven questions (Q) concerning the safe use of US in everyday clinical practice, in which only one answer would be correct.

At that time, e-mail addresses were available for only 915 members, fewer than half the total number of members. Thereafter, the Society devoted more attention to creating a well-organized, updated database. An invitation to take part in this project was sent to members by e-mail. The message specified that a reply to the questionnaire was required within 48 h to avoid answers based on the consultation of textbooks on the topic.

Physicians interested in participating in this initiative were asked to e-mail their answers to the SIUMB Secretarial Office. The questionnaire was sent at the beginning of a work week to allow working time to reply within 48 h. In all probability, this limited time frame for replies considerably reduced the number of responders, since most members have substantial routine workloads, but it was deemed important by the authors.

The SIUMB Secretariat forwarded the completed questionnaires without the respondents' names to the investigators, who entered them into a database and arranged them for statistical analysis. The questionnaires that were returned were considered valid for analysis only when answers were provided for at least 10 of the 11 questions.

Results

Overall, 105 questionnaires were returned, and 97 of these were considered valid. The mean age of physicians who completed valid questionnaires was 44 years (range 26–59 years), and the mean time physicians had been performing US examinations was 13 years (range 1–29 years).

The majority of these respondents (33%) dedicated 30–70% of their working time (Table 1) to ultrasonography, and a similar percentage (32%) dedicated 1–30%; another 29% dedicated 70–100%, and only a few (6%) dedicated 100% of their working time.

As far as the workplace was concerned (Table 2), some physicians worked in more than one place. The most common settings (70% of respondents) were public hospitals belonging to the National Health Care System or a general medicine practice outside the hospital environment. Overall, 12% of the workplaces reported were semi-private structures connected to the National Health Care System (healthcare providers offering services reimbursed by the National Health Service or paid for directly by private patients), and 18% were totally private.

Table 1 Percentage of professional activity dedicated to ultrasonography reported by questionnaire respondents.

Percentage of time dedicated to US	Number (%) of physicians Total number is 97
100%	6 (6.1%)
70–100%	28 (28.9%)
30–70%	32 (33.0%)
1–30%	31 (32.0%)

Table 2 Work settings reported by respondents.

Type of health-care facility	Number (%) of physicians
Public	68/97 (70.1)
Semi-private	12/97 (12.4)
Private	17/97 (17.5)

After conventional ultrasonography, the most frequent US modalities or specialties used by respondents were general Doppler US (74%) (Table 3), contrast-enhanced ultrasound (43%), and pediatric ultrasound (41%). Ophthalmologic ultrasonography and obstetric and transcranial Doppler studies were performed by a minority of the participants.

The percentages of correct answers to each question are reported in Table 4. Only 50–60% of the responders identified the correct definitions of *thermal index* and *mechanical index* (Q1, Q2, Q5). Almost all understood the bio-effects expressed by the thermal index (Q4), but only a minority knew the most likely organ targets of bio-effects related to the mechanical index (Q3) and what the thermal index actually means (Q6). The majority knew that fetuses are at higher risk for US damage (Q7, Q9) and correctly identified the limitations regarding the acoustic emission of US scanners set by the FDA (Food and Drug Administration) (Q8). At last less than half of the respondents were able to identify the correct safety statements included in the recommendations of the International Ultrasound Societies (Q10, Q11).

Discussion

The responding physicians appeared to know the general definitions of the principal safety parameters, such as those concerning the mechanical and thermal indexes found in questions 2 and 4 (which were answered correctly by 61.9% and 93.8% of respondents, respectively). The same was true for the definitions of TIS and TIB (question 5, correctly answered by 61.9%).

Analysis of the answers regarding the biological effects of ultrasound revealed that general knowledge about the

Table 4 Correct answers to the multiple-choice questions.

Question	Correct answer	Number of physicians providing correct answers	%
Q1	B	52/97	53.6
Q2	A	60/97	61.9
Q3	A	38/97	39.2
Q4	A	91/97	93.8
Q5	A	60/97	61.9
Q6	C	34/97	35.1
Q7	A	78/97	80.4
Q8	C	70/97	72.2
Q9	C	85/97	87.6
Q10	B	41/97	42.3
Q11	A	47/97	48.5

% indicates the percent of correct answer out of total answers for each question (one answer = one physician).

use of ultrasound in obstetrics was good (question 7, correctly answered by 80.4%, concerning the use of US during the first trimester), despite the fact that only 7% of the participants performed obstetric ultrasonography. Physicians also knew that adult tissues are less sensitive to temperature increases (question 9, correctly answered by 87.6%).

At the same time, however, respondents were far less knowledgeable about the biological effects of US. In fact, fewer than 40% provided the correct answer to question 3 (39.2%) and question 6 (35%). These questions concerned not only the damage to the lung vasculature produced by US scans with high mechanical indexes but also the temperature increases in the body area lying beneath the transducer at different thermal indexes.

Although only 42.3% of respondents displayed up-to-date knowledge of the AIUM statements (question no. 10), many physicians (72.2%) correctly answered question no. 8, which concerned the regulation of acoustic emission suggested by FDA. Again, knowledge of the guidelines dealing with contrast media was unsatisfactory: the percentage of correct answers to question no. 11 was only 48.5%.

The present survey suggests that physicians using US in Italy are probably aware of the general definitions and parameters related to US safety. However, they do not appear to be adequately informed and updated on international recommendations, and they are not fully aware of the potential for tissue damage associated with high exposure times or intensity. Therefore, these results indicate that National Ultrasound Societies and Medical Universities - at least in Italy - need to increase their efforts to educate US operators on the bio-effects of diagnostic ultrasound modalities. This conclusion is in keeping with those that emerged from similar surveys conducted by Marsal [11] and more recently by Sheiner et al. [12], mainly among physicians, ultrasonographers, nurses and midwives in the field of obstetrics and gynecology. Marsal conducted a questionnaire-based survey among professionals using ultrasound for fetal examinations and found that the users supposedly responsible for

Table 3 Types of ultrasonograph performed by respondents.

Type of ultrasound	Number (%) of physicians ^a
Obstetric	7/97 (7.2)
Ophthalmic	9/97 (9.3)
Doppler	72/97 (74.2)
Contrast enhanced	42/97 (43.3)
Transcranial	7/97 (7.2)
Pediatric	40/97 (41.2)

^a Some respondents performed more than one type of ultrasound examination, so the sum of the percentages exceeds 100%.

controlling fetal exposure to ultrasound had very poor knowledge of certain basic safety aspects of US. Sheiner and Abramowicz [13], similarly, in a recent survey, concluded that US end users are poorly informed regarding safety issues related to the use of US during pregnancy and that further education and training initiatives would be needed to improve end-user knowledge of the acoustic output of scanners and safety issues. Our study included different types of physicians employing diagnostic US in different fields.

There are several limitations to our study, which do not, however, change the significance or implications of our findings. First of all, the responder rate was rather low. This problem may have been caused by various factors. We were told informally by various members that they did not consider the topic important enough to justify the time spent answering the questionnaire; others did not answer because they were unable to guarantee a rapid reply (as requested) due to a high routine workload. A certain number of e-mail addresses were incorrect or no longer consulted. However, while the number of respondents was relatively low, the ultrasound applications used by these members were advanced (74% employed Doppler US and 43% contrast-enhanced US), indicating that those who did answer are fairly active in the field of ultrasound. Their replies are much more likely to overestimate rather than underestimate the knowledge of US operators in Italy. This brings us to a second potential bias, that is, that those who answered the questionnaire are probably not statistically representative of the Society as a whole, in terms of levels of expertise. In addition, the Society itself may not be representative of all physicians who perform US scans in Italy. However, it would be difficult to find a sample that truly represents the knowledge of all Italian US operators, since occasions to meet a wide variety of operators are rare, except perhaps at large congresses. However, surveying a large number of would be respondents, at any one time, is not feasible. Even if hundreds of participants were present at a congress, each respondent would have to answer without consulting other colleagues, and this could hardly be guaranteed in the usual congress venues. Moreover, congresses are usually attended by the most active and most enthusiastic operators. Furthermore, replies to questionnaires are made on a voluntary basis, which again would tend to involve a relatively enthusiastic subset. In addition to the points raised above, it is impossible to exclude the possibility that some respondents in the present study consulted textbooks or information on the internet before answering the questionnaire, and this also suggests that the present findings are more likely to be an overestimate of operator knowledge. The risk is very low that our findings are an *underestimation* of the safety knowledge of Italian ultrasound operators, which would be the real threat to the significance of our study.

In conclusion, the possibility that we have overestimated the knowledge of our members does not alter the implications of the present findings in any way: greater efforts by National Ultrasound Societies are clearly needed to increase members' knowledge of the bio-effects of diagnostic ultrasound.

Conflict of interest statement

The authors have no conflict of interest.

Appendix 1 Questionnaire

Part 1 (demographic data and description of experience with ultrasonography)

Age: _____

How long you have been performing ultrasonography? _____ (years)

Percentage of working time dedicated to ultrasonography:

- A. 100%
- B. 70–100%
- C. 30–70%
- D. 1–30%

Kind of healthcare facility:

- A. Public or general practitioner
- B. Semi-private
- C. Completely private

Which type(s) of ultrasonography do you usually perform? Write "yes" or "no" beside each type.

- 1) Obstetric ultrasound _____
- 2) Ophthalmic ultrasound _____
- 3) Doppler ultrasound _____
- 4) Contrast-enhanced ultrasound _____
- 5) Transcranial ultrasound _____
- 6) Pediatric ultrasound _____

Part 2 (11 multiple-choice questions)

- 1) The Thermal and Mechanical Indices are shown:
 - a. in the handbook of an ultrasound machine
 - b. continuously in real-time on the screen during scanning
 - c. onscreen at the beginning of a new scan
- 2) The Mechanical Index MI refers to
 - a. the probability that a phenomenon of cellular cavitation might occur
 - b. the intensity with which contrast agents could be used
 - c. the probability that the mechanical effect is greater than that of thermal effect
- 3) During an experiment involving exposure of mice to a high mechanical index exposure experiment conducted on murine model, hemorrhage occurred in which of the following organs?
 - a. Lung
 - b. Kidney
 - c. Liver
- 4) The Thermal Index TI reflects:
 - a. the probability of a rise in temperature in the area being scanned
 - b. the probability of a rise in temperature at the transducer surface
 - c. the probability of a rise in temperature in the handle of the transducer

- 5) The Thermal Indices are
 - a. TIS (Thermal Index at Soft tissue), TIB (Thermal Index at Bone)
 - b. TIS (Thermal Index at Soft tissue), TIB (Thermal Index at Bone) and TIC (Cranial Bone Thermal Index)
 - c. TIS (Thermal Index at Soft tissue), TIC (Cranial Bone Thermal Index) and TID (Time Intensity Diagram)
- 6) If the TI = 2, the tissue temperature has theoretically:
 - a. doubled with respect to the initial temperature
 - b. decreased by 2 degrees Celsius with respect to the initial temperature
 - c. increased by 2 degrees Celsius with respect to the initial temperature
- 7) The Thermal Index is of primary importance during the ultrasound scan in:
 - a. obstetrical examination in the first trimester
 - b. vascular examination
 - c. liver examination
- 8) The acoustic emission of ultrasound equipment is limited, in accordance with the FDA policy, as follows:
 - a. mechanical index < 1.9 and thermal index < 4.0
 - b. intensity $< 720 \text{ mW/cm}^2$
 - c. intensity $< 720 \text{ mW/cm}^2$ and mechanical index < 1.9
- 9) Which of the following tissues are less sensitive to increases in body temperature caused by ultrasound?
 - a. fetal tissues
 - b. neonatal tissues
 - c. adult tissues
- 10) "Although there are no confirmed biological effects on patients caused by exposure to present-day diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future." This statement was released by the AIUM (American Institute of Ultrasound in Medicine) in 1999. Which of the following three statements does not belong to the AIUM Official Statement on Clinical Safety and Prudent Use of ultrasounds, and hence is not true?
 - a. Diagnostic ultrasound should be used in a prudent way to bring medical benefit to the individual; when used for educational and research purposes the subject should be informed of the anticipated exposure conditions.
 - b. Diagnostic ultrasound could be used freely to examine the organs, even in healthy subjects, as long as the provided TIS and TIB are respected and the examination of each organ is carried out in less than five minutes, unless there is some other medical indication.
 - c. The use of either two-dimensional (2D) or three-dimensional (3D) ultrasound only to view the fetus, obtain a picture of the fetus, or determine the fetal gender, without a medical indication, is inappropriate and contrary to responsible medical practice.
- 11) Which of the following statements is correct and is found in the Guidelines of the EFSUMB (European Federation of Societies for Ultrasound in Medicine and Biology) for the use of contrast agents in ultrasound?
 - a. Caution should be considered for the use of ultrasound contrast agents in tissues where damage to microvasculature could have serious clinical implications, such as in the brain, the eye, and the neonate.
 - b. caution should be considered in contrast-enhanced echocardiography when studying the perfusion of the myocardium where as the examination of the internal side of the ventricle does not imply arrhythmia risk for the coronary arteries are not directly involved.
 - c. In the use of ultrasound contrast agents, the level of the mechanical index (MI) should always be borne in mind while the thermal indexes (TIS and BIS) and exposure time do not appear to have any important effect on this field as the risk is limited to cavitation with no thermal effects.

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