QUALITY CONTROL IN ULTRASOUND: AN EXPERIMENT TO ASSESS THE OBSOLESCENCE OF ULTRASOUND PROBES WITH AN AGAR GEL PHANTOM

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■ **KEYWORDS:** Ecografia, ultrasuoni, controlli di qualità, fisica sanitaria, fisica degli ultrasuoni, phantom, sono-

ABSTRACT

The ultrasound scanner is the most installed equipment in the operating realities but it is not part of precise quality control programs like all other radiological equipment. Considering how many examinations are carried out, it seemed essential to set up intuitive and repeatable QCs, using instruments with low economic impact. The objectives were to test low-cost handmade phantoms to assess the uniformity and sensitivity of the ultrasound probes and the global status of the ultrasound scanners, confirm the goodness of the phantom in terms of use, functionality and storage, then compare the data collected between QC and the global status of the equipment looking for obsolescence causes. 25 linear geometry probes and 19 ultrasound scanners in 10 operating realities undergo quality control. To do this, a phantom in 5% agar-agar and a set of specially designed modules are created. The probes studied showed drops in uniformity and sensitivity already after 3 years with an average of 30 examinations and about 10h of power-on per day. In terms of uniformity, 65% of the probes did not reach acceptability. A condition of poor hygiene was detected in 74% of the ultrasound scanners. The phantom used was homogeneous and isoecogenic in almost all applications according to the professionals.

INTRODUCTION

Ultrasonography is a method based on the reception of reflected signals, initially sent to the region of interest in the form of ultrasonic pulses. The images generated are obtained by exploiting the physical properties and biological interactions typical of ultrasounds, not radiation but mechanical vibrations, longitudinal elastic waves of rarefaction and compression that propagate with variable speed in the physical transmission medium as a function of its density and acoustic impedance.

About numbers, the number of ultrasound scanners on Italian soil at the end of 2016 amounted to 37521 operating units, with a growth rate from 2014 of about 17% (+5291 units purchased) and an average age of the installed park compared to the date of first installation of 6.3 years [1]. The data reported represent the massive distribution of ultrasound equipment, making them the most widely installed biomedical imaging instruments. And it is not difficult to imagine how many ultrasound services are provided to patients when compared to the number of equipment in operation.

It is precisely from here that it is essential to set up a control program in ultrasound diagnostics to maintain an acceptable quality standard of ultrasound operation over time. A 2004 SIRM document states that: "planning a quality control program can reduce the number of repeated investigations, make the diagnosis

more accurate and limit the patient's referral to other methods for diagnostic completion, making each ultrasound examination more accurate and informative" [2] - true observation for all equipment performing radiodiagnostic and therapeutic imaging.

The project stems precisely from the need to have periodic, constant quality controls within the reach of qualified healthcare professionals, to go against what is the natural physical deterioration of transducers, connection cables and electronic components. These elements, as well as affecting electrical safety, lead to a gradual deterioration of image quality with a consequent reduction in accuracy and overall diagnostic confidence. In addition, unlike other imaging equipment, the degradation experienced by an ultrasound scanner is often a slow and progressive event, not usually perceived by an operator working continuously with the same equipment.

The work will focus on the technical aspects concerning ultrasound and ultrasound equipment, passing through the physical and technological principles, standard components, the main protocols used in outpatient clinics and those related to quality control, arriving at the on-site testing of a phantom in low-cost agar-agar gel to assess the state of obsolescence of ultrasound probes according to their uniformity and sensitivity, using a form specifically designed in compliance with international guidelines for the safe use of ultrasound waves in the biomedical field.

Fig. 1 – Agar-agar powder from the batch purchased for the creation of the phantom. Consistency and appearance recall those of flour used in cooking, unlike the more pungent and characteristic smell.

METHODOLOGY AND MATERIALS

A crucial part of the experimentation was the creation of a phantom that could be considered as homogenous and durable as possible, that would not be subject to dehydration and the growth of flora on surfaces. The idea was developed starting from an article published in the “African Journal of Emergency Medicine” in 2016 [3], which reported the experimentation of a phantom tissue-equivalent agar-agar hydrogel at different molar percentages, preservable over time without refrigeration and enriched with secondary components (such as flour, PVC and latex tubular structures), designed to offer free and multiple practice of eco-guided procedures to local specialist. Agar-agar, also known more simply by the name of *agar*, is a polysaccharide used in cooking as a natural gelling agent and obtainable from algae; once dehydrated they are

ground to obtain an ivory-coloured powder. Given the high quantity of mucilage and carrageenan (a gelatinous substance also known in pharmacopoeia), agar powder tends to create a compact bond with water; it produces a gelatine certainly denser and more natural than the commercial one. The preparation of agar is simple and involves a short cooking without the need for boiling, followed by a solidification phase that generally does not exceed one hour at room temperature.

The following table shows some essential data to understand the nature of the final phantom used in the trial, how to prepare it and how long it can last.

Considering the purchase of the components for the preparation and the percentage date used to obtain the final phantom, it was possible to calculate the cost, making a quick comparison with the market price of industrial fabric-equivalent phantom. The following table shows the individual expenses and the total below:

The total cost to make a phantom tissue-equivalent agar-agar is around the above price of 4€, with the reasonable exclusion of easily available and considered accessory equipment. If compared with the current price of an industrial phantom (about 2800€) the percentage ratio speaks clearly: the phantom can be considered low-cost with a saving of 99,86%.

To accompany the phantom in the testing phase there was, in the end, the creation of pre-filled modules that would effectively accompany the quality control. The objective set was not so easy: the modules had to accurately respect the AIUM guidelines in the evaluation of some technical image parameters and, above all, of the electrical, mechanical and hygienic safety of the equipment.

Annex A is entitled “US Quality Control Module” and is strictly related to the parameters of uniformity and penetration of the machine, with a final section totally dedicated to the electrical (visual) and mechanical state. The two technical parameters can be evaluated following the guidelines described in italics at the bottom of both boxes; once the transducer has been positioned and the desired image quality has been set on the screen, the image is freeze and compiled. The

Materials

- distilled water (1250 ml)
- 5% Agar powder (62.5 gr)
- 2% benzalkonium chloride
- plexiglass container (approx. 17x12x20mm)
- steel or borosilicate glass kettle
- steel ladle
- microwave or gas cooker

Procedure

The distilled water at room temperature should be mixed with the agar powder until a homogeneous, lump-free mixture is obtained. Pour the mixture carefully into the kettle and light a low flame, stirring constantly throughout: avoid boiling as it is not necessary to obtain a good density. Add the benzalkonium chloride at the end of cooking, which will act as a preservative, protecting the phantom from the growth of aquatic flora. Insert the plexiglass container inside a bowl with cold water and, keeping it firmly anchored to the bottom, slowly pour the mixture avoiding the formation of bubbles. Once the dripping is complete, take the phantom to a cool place, away from sunlight and store it at a temperature between 17 and 25°C out of the fridge. Wait for at least 1h for a maximum of one whole night for effective cooling.

Tab. 1 – Instructions and composition of the final phantom tissue-equivalent in 5% agar-agar hydrogel obtained from the thirteenth attempt onwards. The phantom has all the characteristics sought: compactness, homogeneity to the ultrasound signal and durability.

agar-agar “123 plantes” 500gr	62,5 gr	euro 50 / Kg	3,12 euro
distilled water 3 L	1250,0 ml	euro 1,25 / L	0,77 euro
benzalkonium chloride 1 L	25,0 ml	euro 11 / L	2,75x10 ⁻⁴ euro
			3,89 euro

Tab. 2 – The table shows the costs of the components in their percentages declared in Tab. 1 with the exclusion of the instrumentation considered as an accessory part easy to find.

answers are deliberately made very complete to make the experience more intuitive. The same goes for the generalization in YES and NO bound to the questions related to “electrical, mechanical and hygiene safety of the instrument”.

Annex B is entitled “Transducer Characteristics Module” and is divided into three sections that recall the following fields:

- the first one has been deliberately entitled “Nomenclator” in order to report all the relevant construction characteristics and make them available to everyone without the need to refer to the official documentation of the equipment;
- the second section contains a questionnaire with a response mediated by 4 scoring steps (where 1 is poor and 4 is very good) to assess in more detail the current status of the analyzed transducer;
- the third section ends with “Additional Notes” in which to report observations of particular relevance that could not be recorded in the form due to intrinsic limitations of the pre-filled forms or because they are accessory but undoubtedly worthy of note.

■ **RESULTS**

On october 19, 2018, the phantom and the related quality controls on the ultrasound equipment and its transducers were completed after about nine months. There were seven facilities involved in total:

- Private clinic “F-Medical” (FE);
- Rizzoli Orthopaedic Institute;
- Sant’Orsola-Malpighi Polyclinic;
- Maggiore Carlo Alberto Pizzardi Hospital;
- G.B. Morgagni L. Pierantoni Hospital (FC);
- Private Radiological Studio “San Tommaso” (TA);
- Private D’Amore Hospital (TA).

Within these facilities, 19 ultrasound scanners from various manufacturers and 25 transducers were tested, the majority of which are linear probes with multi-crystal technology - only 4 of these are monocrystal technology and did not require any special care or adaptation to be tested.

As far as the data concerning the penetration index is concerned, it is possible to appreciate its distribution on the following histogram. The area highlighted in red represents an area of theoretical acceptability,

Fig. 2 – From left and clockwise: agar gel phantom in front view, top view and a normo-pattern of the phantom on a probe in good uniform condition.

Graph 1 - Distribution by depth penetration index of the ultrasound probes. The area in red is a threshold of theoretical acceptability valid for linear probes with a frequency range between 13 and 4 MHz. The values represented are entirely expressed in centimeters.

- the value of the latter, on the other hand, is derived from an average obtained orally from information obtained by the various professionals who practice clinics with the single ultrasound scanner, equipment managers and cleaning staff - often unduly engaged in power-offs at the end of the working day. Also of interest are the representations related to the age of the ultrasound probes and their global status. The age of the probes is not an average but a simple difference between the date of first installation and

the current year in which they are checked: This concludes the most important representation in Module B concerning the average of the values that make up the global status of the probes: In order to be able to fill in the “global status” questionnaire appreciable in fig.4 it is essential to have as reference a new probe characterized by an intact acoustic lens, intact gaskets, components in the standard and intact connector both at the level of the body and of the slats present in the multi-pin

Graph 2 - Percentage representation of the disuniformities detected in the ultrasound probes. Disuniformity has been deliberately represented rather than uniformity as it is more consistent with the questions asked in fig.4 and related to module A of the quality control.

Graph 3 - Percentage representation of the acceptability of the electrical, mechanical and hygienic conditions of the ultrasound scanners encountered during the trial period.

Chart 4 - Quantitative representation of examinations and hours sustained relatively by probes and their ultrasound scanners. The former are numerical values in contrast to the latter expressed in hours.

Graph 5 - Graphic representation of probes ages. Where present a value equal to zero indicates a probe purchased in the current year 2018 and currently in use.

Graph 6 - Graphic representation of the average global status of the ultrasound probes. The maximum score is 4 and minimum of 1, which correspond to “excellent” and “poor”.

■ DATA ANALYSIS AND DISCUSSION

The age of the ultrasound probes analyzed, when compared with the global status and the penetration and uniformity indices detected, is only partially a characteristic element of obsolescence. This can be affirmed by observing probes such as #6, #11 and #21 that report a value of the global status significantly lower than the average at the same age of about 3 years for the first two and 2 years for the second. And it is always the #21 along with #17 and #9, which is a good example because their penetration and uniformity indices do not reach the sufficiency even though they were purchased and used from 2016, 2018 and 2015. In particular, the case of #17, a linear Esaote probe with multicrystal technology, is interesting because it was purchased on 6/2018 and is characterized by the presence of visibly broken crystals with consequent presence on the ultrasound pattern of shadow cones in a vertical direction and present at several levels. In detail, it is possible to state that probes #6, #10, #17 and #20 show a clear presence of broken crystals documented in 3 out of 4 cases by the same clinicians, which are being replaced by the installation companies but still in use in outpatient practice with a declared average of 30 daily examinations for each of them. From the images printed by the ultrasound equipment it was possible to obtain a clear pattern of broken crystals in multiple points such as no signal: The data collected concerning the sensitivity of the probes, as well as their depth penetration index, are not in the theoretical acceptability range for about 50% of the total. A superficial observation would admit that the sensitivity of the transducers is close to sufficient. This data, however, cannot be considered strictly reliable because the frequency range of the

probes and the technology of the crystals which, with the same type, can vary considerably for the same number of component crystals, do not allow us to say that all the probes have lost sensitivity. There is no doubt that probes #3, #8, #16, #17#, #20 and #24 (6 probes out of 25 analyzed) do not reach with certainty the threshold of acceptability because their sensitivity stops at a clear ultrasound pattern about 9cm deep against the 10cm declared by the respective installers at the time of the first installation. As regards the area of the module dedicated to the electrical, mechanical and overall hygiene safety of the ultrasound equipment, many ultrasound scanners were found to be unacceptable in several respects. In particular, it was possible to note in 74% of cases a

Fig. 5 – Broken crystals in linear Esaote probe with multicrystal technology. The broken crystal is appreciated in the ultrasound pattern as a vertical line with slight depression near the dead zone.

Fig. 6 – Broken crystals in Siemens linear probe with multicrystal technology.

Fig. 7 – High frequency detail of broken crystals in Siemens linear probe with multicrystal technology.

lack of hygiene on the *display monitors* (including *touchscreen micro-monitors*) with deposits of dust, gels and biological liquids, as well as an almost total lack of cleanliness of the air filters:

No less important is the poor maintenance of the components related to the mains cables and the cleaning of the probes after each single use (37% unacceptable) to which is added the absence in 26% of the cases of all the equipment supplied with the equipment - such as machine book, technical assistance plate, filter cleaning brush etc..

The overall status of the probes falls almost totally in a score higher than 3 (equal to “good” on the scale declared for the questionnaire) although only 3 out of 25 probes have reached full marks - probes maintained quite well, purchased just 2 out of 3 and with a declared daily use significantly lower than the average. In the probes with the lowest score, which is around 3 points, the most recurrent defects were found to be due to the cleaning (evident traces of dried gel near the acoustic lens and the handle body) and the acoustic lens, as well as the seal present between the outer layer and the coupling layer just below (ideal entry point for gel, dust, biological liquids and humidity).

Fig. 8 – Air filters from a Toshiba. Dust sediments in the metal filter are appreciable.

CONCLUSIONS

The absence of any fine planning of quality controls on the ultrasound equipment was clearly perceived throughout the trial period. The professionals encountered, almost all of them, have never witnessed a first-hand control. They recognise the fragility of this aspect when compared with clinical practice and the number of services to be provided on a daily basis. Doing so with an overall unmonitored equipment provides the ideal conditions to generate diagnostic uncertainties at the time of real-time visualization or subsequent reporting, with a propagation of error with the patient undergoing ultrasound examination as the final destination.

The obsolescence assessed in the 25 probes was not particularly influenced by the age reached but by factors such as maintenance and the average of daily examinations carried out, reducing by a couple of years compared to what declared by the installation companies in terms of average operating life - 5 years compared to an average of 3 assessed. Many probes were found to be in questionable hygienic conditions and with an evident lack of care for the cavistics. On numerous occasions, in fact, it has been necessary to sanitize the probe even before carrying out quality control as well as reducing the stress generated on the connector cables, which is the result of the torsion to which they are subjected when the transducer is moved on patients. The same thing was possible with ultrasound scanners, often covered with dust, gel residues and biological liquids, and with air filters weighed down by thick layers of dust deposited by time and carelessness.

A fine maintenance of these aspects could allow an overall increase in the life of the equipment, less overheating of the equipment and a presentability that should naturally be confined to medical equipment for diagnostic purposes. The future aim of the experimentation is precisely that of identifying in a finer way the critical points of a questionable maintenance of the probes and of the ultrasound equipment, staggering the controls with common timing among several operating units, involving as many technical and professional figures typically linked to the world of ultrasonography, with the use of pre-filled modules that can be superimposed on each other and a phan-

Fig. 9 e 10 – From left: polycarbonate air filters from an Esaote echograph and display screen from Esaote HP. In the filter dust sediments are visible in the honeycomb structure; the equipment in question suffers from overheating declared by clinicians.

tom with a reasonably manageable cost-benefit ratio. Finally, it is good to remember that the ultrasonographic method was born as a strongly operator-dependent practice because it is necessary not only a fine knowledge of human anatomy but also a solid experience in the setting of the equipment. If it is pos-

sible to admit that already from the hand of the operator there may be an error propagation, why enrich it with a superficial quality control of the instrument? The re-adjustment of these facts is evidence that must be more carefully analyzed, understood and shared with professionals in the scientific and medical field.

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