Nigerian Journal of Medical Imaging and Radiation Therapy

PHYSICAL AND MECHANICAL INSPECTION OF ULTRASOUND EQUIPMENT AS A QUALITY CONTROL ASSESSMENT MEASURE: A CASE STUDY OF ANAMBRA STATE, NIGERIA.

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ARTICLE INFO

Keywords:
Equipment, Quality control, Safety, Ultrasound

ABSTRACT

Background: Usage and aging can cause deteriorative changes in ultrasound equipment which affects its performance. Physical and mechanical inspection is a quality control (QC) tool employed to detect presence of physical defects in order that relevant corrective action can be taken.

Objective: To demonstrate the relevance of physical and mechanical inspection measures as an ultrasound quality control measure.

Methods: This was a descriptive cross-sectional study carried out on 25, functional, clinically-used, ultrasound equipment located in accredited ultrasound facilities in Anambra State, Southeast Nigeria. The transducer, power cables, mains cables, plugs, monitor, and control console, wheels and wheel locks were systematically inspected for their physical integrity. Data obtained was analysed using IBM SPSS version 22.0. Results were expressed using descriptive and inferential (Pearson's correlation) statistics.

Results: Majority 76% (n=19) of the problems, which included cracked knobs, worn out knobs, cracked surfaces, cursor problems, gel stains and dust were seen on the ultrasound machines' control consoles. There was a positive and statistically significant correlation ($r = 0.456$, $p = 0.009$) between the age of the ultrasound equipment and the appearance of defects on the ultrasound control console.

Conclusion: Physical and mechanical inspection is a QC tool that can detect and characterize physical defects in ultrasound equipment in order that relevant corrective action can be taken.

Introduction

The ultrasound scanner is an assemblage of physical components with their corresponding electronics designed to interrogate the human body and produce images of corresponding human anatomy for medical diagnosis. The diagnostic accuracy of ultrasound in medicine is a function of the image, which in turn is a function of the imaging performance of various components of ultrasound equipment. Gradual deterioration

occurs in the various components of the equipment over time, which affects their performance and thus the image and may lead to diagnostic error. Workload and age of ultrasound equipment are major factors that cause such deterioration, including physical and mechanical defects [1]. In addition, ultrasound systems contain delicate parts that can be physically damaged by improper use and handling [2]. It is expected that the person handling an ultrasound scanner takes special care in handling and protecting the equipment at all times, however, this may not always obtain as transducers may be accidentally dropped, wheels may be run over cables, dust or fluid may accumulate on the machine and its electrical boards, connecting ports may become loose, cracks may appear on the knobs due to pressure of touch etc. These defects are part of quality control issues that account for most of performance failures on ultrasound scanners [3] and which if not detected, is a factor for wrong medical decisions [4]. Performance failures cause staff inconvenience, increased patient exposure, and increased patient waiting time. Quality control (QC) is therefore an essential element needed if superior patient care is desired because it eliminates or minimizes diagnostic inaccuracies that may arise from faulty equipment. Physical and mechanical inspection of the scanner should be routinely carried out periodically to identify faulty components or those with compromised performance. It also assures the mechanical integrity of the equipment, and the safety of patient and operator [5,6]. This study was aimed at demonstrating the relevance of physical and mechanical inspection measures as a quality control measure.

Materials and Methods

This was a descriptive cross-sectional study carried out on 25 ultrasound equipment's located in Onitsha, Awka, and Nnewi of Anambra State, Southeast Nigeria. Ethical approval (NAUTH/CS/66/VOL.11/035/2018/031) for the study was obtained from the Human Research and Ethical Committee of the Nnamdi Azikiwe University Teaching Hospital, Nnewi, Anambra State, Nigeria. The procedure of the study was adequately explained to the managers of the accredited ultrasound facilities and their consent was duly sought and obtained. They were assured that the study was for academic purposes only and not in any way connected to assisting any government agency in monitoring. Only functional ultrasound machines which were still being put to clinical use were included. Physical and mechanical inspection was carried out using the recommendations of the AAPM [6], a procedure which was also corroborated by other ultrasound bodies like the AIUM [5], BMUS [7] and EFSUMB [8]. It involved systematic visual inspection of the physical components of the ultrasound equipment, viz, transducers, monitors, control consoles, power cords, wheels and wheel locks. The transducer casing, scanning surface, cables, and connectors were thoroughly inspected for signs of wear, crack, discoloration, texture change, separation and damage. Any loose pins at the connecting surface were noted. The main cables, plugs and other cables to peripheral attachment were carefully inspected for cuts, abrasions, twisting, or deformation. The monitors were inspected for dirt and abrasions. The movement and locking mechanism of any moving parts were checked. The controls/knobs were checked for their functionality. Does the control fail to respond, stick, or responds intermittently? The wheels were checked for functionality and stability. Do they rotate freely and are secure? Do they lock properly? A pre-designed proforma was used to record data obtained. Information obtained was treated with confidentiality as the names of the facilities were not recorded but codes which were known only to the researcher were used to represent the facilities. Data was analyzed using IBM statistical package for social sciences (SPSS) version 22.0. Results were expressed using simple descriptive statistics. Correlation between the age of the equipment and presence of physical problems was evaluated using Pearson's correlation test. The level of statistical significance was set at a p-value 0.05.

Brand	Type	Number	Manufacture date	Age at 2019 (years)
Siemens	Sonoline SL-400	3	1993	26
	Sonoline SL-450	1	1993	26
	Sonoline Omnia -	1	2001	18

	Sonoline Versa Pro	1	1996	23
	Sonoline Prima	1	1999	20
	Sonoline Sienna	2	1998, 1999	21, 20
Toshiba	Corevision pro	3	1997	22
	Nimeo	1	2003	16
Edan	DUS 3	2	2011	8
	DUS 60	1	2015*	4
Mindray	DP-1100+	1	2014	5
	DC N3	1	2014	5
Chison	Chison 600M	1	2009	10
GE Healthcare	Logic 3	1	2011	8
Sonostar	Sonostar	1	2013	6
Aloka	Prosound	2	2008	11
Sonoace X8 Medisone	Samsung	1	2007	12
Esaote MyLab	Esaote	1	Unknown	

Table 2: Frequency Distibution for Age of Ultrasound Equipment's Studied

Age (years)	Number of scanners	Percentage (%)
1-5	3	12
6-10	5	20
11-15	3	12
16-20	3	12
21-25	6	24
>25	4	16
Unknown	1	4
Total	25	100

Table 3: Parts of Ultrasound Equipment and Presence of Physical Problems.

Part inspected	Number of scanners	Nature of problem
Transducer	0 (0%)	Nil
Power cord	0 (0%)	Nil
Control panel	19 (76%)	*Cracked knobs, worn out knobs, cracked surfaces, cursor problem, gel stains, dust.*
Video monitor	16 (64%)	Dusty and crack
Wheels and locks	0 (0%)	Nil

Table 4: Correlation between age of ultrasound equipment and presence of physical problems

	Age of ultrasound equipment	
QC Issue	p-value	R
Control panel defects	.009	.469
Video monitor defects	.357	.077
Transducer defects	-	-
Power cord defects	-	-
Wheels and locks defects	-	-

*p is significant at 0.05

Figure 1: Caked gel stains on control panel

Image 2: Erased knobs and cracks on the control console

Discussion

We discovered that most of the ultrasound equipment (76%, n =19) in our work had physical QC issues on their control-panel, viz, worn-out knobs, cracked knobs, cracked console surfaces, cursor-button-movement problems, gel stains, and dust accumulation in different combinations. Cracked knobs and cracked surfaces are routes for fluid, gel or dust accumulation on sensitive electronic parts of the machine which can lead to malfunction. Erased and cracked knobs make identification of the affected knobs difficult and can impair their use. Cursor-button problems presented in the form of frozen cursor, unresponsive cursor, and erratic cursor movement, all which contributed to measurement difficulty. Balbis et al.,[1] demonstrated that a significant number (35.3%) of scanners they studied showed mostly problems detectable by physical and mechanical inspection. The machines in our work were still actively used for patients' imaging despite the presence of defects. This agrees with Russel [9} who observed ultrasound equipment having serious physical defects that were still being put to clinical use.

We noted poor hygiene of the scanners studied, evidenced by caked gel stains and dust accumulation on the control panel. Caked gel stains on some of the buttons were likely part of the reason for the difficulty in manipulating the buttons and results when gel stains are not cleaned off immediately. Russel [9] also noted controls contaminated with gel. Poor hygiene in terms of dust accumulation was also the major issue on the video monitors. Dirty equipment is a major source of infection for both personnel and patients; therefore, clean and hygienic equipment is a mandatory requirement before using it on any patient, even when the equipment is in standby [8]. Ultrasound practitioners may be busy with scanning patients and not commit time to cleaning their equipment. However, equipment cleanliness is an indication of good clinical practice and is one of the QC practices carried out multiple times a day as an infection control measure. We recommend that a cleaning staff be assigned the duty of daily general cleaning of the ultrasound scanner to ensure overall daily cleanliness of the ultrasound equipment to minimize or eliminate possible nosocomial infection. Covering of ultrasound equipment when not in use will also help to reduce dust accumulation on them.

Power cords, wheels and wheel locks showed no physical defects in our work. This may likely be because the machines we studied were stationed permanently in the ultrasound rooms, thus eliminating or minimizing the likelihood of damage to these parts. The transducers with their cables did not show any visually identifiable physical defects. This disagrees with Martensson *et al* [4] who found 39.3% transducer error, inclusive of break in transducer cables. Our finding did seem inconsistent with the fact that most of the scanners we studied were relatively old. The ACR-AAPM [10] stated that transducers are a weak link in the ultrasound imaging chain due to ease of dropping and kinking cables, however, we believed that carefulness in handling of the transducer can protect them from physical defects, which may be the case in our study. In addition, new transducers could be fitted into old scanners, thus eliminating evidence of any previous defect.

Majority of the scanners (68%) we studied were more than 10 years, the oldest machines being 26 years old at the time of this study. The RCR and SCoR [11] suggests that equipment review be undertaken between four to six years in order to identify a machine which has shown significant evidence of change in the scanner performance. Age therefore is a risk factor for change in scanner performance, but the changes are discernible through QC checks as demonstrated in this work. Use of equipment for extended period of time as observed from our study does not stop the clinical usefulness of a scanner, however, periodic physical and mechanical inspection when applied can detect physical scanner issues which when corrected, will ensure that equipment performance is not compromised.

Correlation analysis in our work showed a fairly moderate, positive and statistically significant relationship between the age of the scanners and control-panel problems (r = .049, p = 009). In other words, as equipment age increases, the control-panel defects increase. The panel is the part that contains most of the knobs used for measurements, image post-processing and optimization. It is therefore usually frequently touched during clinical use, and thus tends to develop more wear and tear as a result of friction.

Conclusion

This work has demonstrated that physical and mechanical inspection is a quality control tool useful in detecting physical defects that can impair the performance of ultrasound equipment in order that relevant corrective action can be taken. Majority of ultrasound scanners we studied in Anambra state showed physical defects mostly on their control consoles, relatable to many years of use, as some of the scanners were up to 26 years of age. We also observed poor hygiene in the form of caked gel and dust accumulation on the scanners which indicated poor equipment cleanliness.

Recommendation

We recommend that repair or replacement of the defective parts should be effected to restore the performance of the affected machines. In addition, daily targeted and general cleaning of the equipment will ensure clean equipment to ensure safety of patient and staff.

Conflict of interest: None declared among the authors

Funding sources: None

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