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Quality Control Effect on Determination of Gestational Age by Ultrasound

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Abstract

The aims of this study were to evaluate the ultrasound Quality Control (QC) testing in Najran, Saudi Arabia and to derive an accurate Gestational Age (GA) formula based on the errors of QC tests.

Using Gammex RMI and CIRS phantoms for twenty four ultrasound systems in the five hospitals the results of penetration depth, distance accuracy, image uniformity, dead zone and axial resolution were reported in this study. On the other hand, a dataset of 35 pregnancies were studied to assess the accuracy of GA during the first and second-trimesters.

Most QC results in all hospitals were found to be within the baseline levels and the best performance derived formula was found a combination of Biparietal Diameter (BPD), Femur Length (FL) and distance accuracy. Periodic QC evaluation should be carried out to motivate the optimization of accurate dating of pregnancy.

Introduction

QC program is necessary even for the modern ultrasound machines which are very reliable and rarely break down. QC can identify degradation in image quality before it affects patient scan [1]. Therefore, there is worldwide interest in QC of ultrasound machines and this was reflected on the guidelines cited by many international organizations such as the American Institute of Ultrasound in Medicine (AIUM) [3], the American Association of Physicists in Medicine (AAPM) [2] and the International Electro-technical Commission (IEC) [4]. This study refers to criteria formulated by the AAPM and relied heavily on report of Ultrasound Task Group No. 1 [2].

The need for more frequent QC evaluations could be attributed to the incompetent servicing, or lack of qualified and experienced ultrasound sonographers. However performing QC tests every six months, can reduce the number of repeated examinations, unless discovering serious problems, it is recommended that certain tests of short duration be performed more frequently [5]. The AAPM [2] recommends performing quick scan tests every three months in the case of the notice serious problems for mobile and emergency room systems and every six months for others ultrasound systems.

The routine ultrasound QC tests performed by a medical physicist based on measurements of the instrument's peak performance for a particular Image Quality Indicators (IQIs). The line of peak performance known as the baseline test and should be performed immediately after the instrument has been installed and accepted or after preventive maintenance and service by a qualified engineer [2]. The action level indicates the IQI value at which corrective action should be taken and to ensure the IQIs never actually reach the defect levels. The values of action level should be less than defect levels with ±75% or ±50%. Further details for action levels, defect levels and baseline values can be found in AAPM report No. 1 [2].

It is not recommended to start testing the IQIs before starting the routine evaluation of physical and mechanical inspection. These inspections include checking cables, housings, and transmitting surfaces for cracks, separations, discolorations, cracks and damage in power cord, dirty of controls or broken switches and knobs, cleaning of video display monitor and free of scratches, wheels and wheel unit locks, and dust filters. Subsequently, the baseline tests and display monitor setup can be carrying out and followed by IQIs tests which divided to quick scan and less frequent tests. The quick performed QC tests include the display monitor fidelity, image uniformity, visualization depth, photography fidelity, and distance accuracy. The less frequent QC tests include anechoic object (cyst), axial resolution, lateral resolution, and dead zone.

On the other hand, the accurate predicting of GA is critically important for pregnancy management from the first trimester to delivery. Ultrasound gave clinicians a method to measure the fetus and there for to estimate the GA [6]. Numerous authors [6-11] agree that when performed with precision, ultrasound alone is more accurate for determining GA in the first or second trimesters (≤ 23 weeks) and is the best method for estimating the delivery date. However, lack of attention of serious problems and ignoring ultrasound scan tests, will lead to erroneous calculations of the GA and estimation of delivery date.

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Table 1: Action and defect levels values for quick and less frequent tests.

IQI and phantom IQI	Defect level	Action level
Image uniformity	Serious nonuniformities (rating of score three [a]) in misc.artifacts, vertical or horizontal banding	Noticeable nonuniformities (rating of score two [a]) in misc. artifacts, vertical or horizontal banding
Depth of visualization	Change ≥ 10 mm from base line	Change ≥ 5 mm from base line
Vertical distance accuracy	Change ≥ 2 mm	Change ≥ 1 mm
Horizontal distance accuracy	Change ≥ 3 mm	Change ≥ 1.5 mm
Axial resolution	> 1 mm	2 mm if f < 4 MHz
		1 mm if f > 4 MHz
Dead zone	10 mm if f = < 3 MHz	5 mm if f = < 3 MHz
	7 mm for 3 MHz < f <7 MHz	3.5 mm for 3 MHz < f <7 MHz
	4 mm if f ≥ 7 MHz	2 mm if f ≥ 7 MHz

[a]Misc. artifacts, vertical or horizontal banding score: 1 = None 2 = Noticeable 3 = Serious.

The purpose of this study was to evaluate the ultrasound QC testing in Najran, Saudi Arabia. Furthermore to study the impact of QC on determination the GA by ultrasound.

Materials and Methods

This work was carried out in five main governmental hospitals in Najran province, Saudi Arabia. Twenty four ultrasound systems and 54 transducers of varying types, models and frequencies, were included in the study. The hospitals that participated in the study were Maternity and Children Hospital (MCH), National Guard Health Affairs (NGHA), Najran University Hospital (NU), King Khalid Hospital (KKH), and Najran General Hospital (NGH). These hospitals were chosen for the study because they are the largest hospitals in Najran in terms of workload. As an example MCH has a room with an average workload of 110 patients per day.

The majority of the QC tests were performed using Gammex phantom model 403GS LE (Gammex RMI, WI, USA) constructed from evaporated milk based gel, weighing 2.8 kg with dimension of 23.2×8.25×18.5 cm and provides combination of anechoic cyst, grey scale and pin targets to permit a wide range of measurements [12]. Additional CIRS phantom model 040GSE was used for validation of distance accuracy tests [13]. Both Gammex and CIRS phantoms have speed of sound equal 1540 ± 10 m/s at 22 °C and attenuation coefficient equal 0.5-0.7 dB/cm/MHz.

The transducers used in this study were convex-array (3.5 MHz central frequency), linear-array (7.5-13.5 MHz central frequency) and endocavity (6.5 MHz central frequency) transducers. Overall, the assessment involved 28 transducers with a frequency of 3.5 MHz, 16 with a frequency of 7.5 MHz, 4 with a frequency of 13.5 MHz and 6 with a frequency of 6.5 MHz. Sector and 3D transducers were excluded from this study.

This study was carried out during 16 months and the majority of the baseline tests were performed immediately after preventive maintenance or after next service call. The guidelines suggested by AAPM [2] for defect and action levels were used to establish appropriate levels for our particular application. It should be pointed out that most of ultrasound machines used in this study are new and this encourage us for reducing the action levels used to be less than defect levels with ±50% as presented in Table 1 for IQI and phantom IQI.

The QC tests were carried out in the following order: (a) physical and mechanical inspections, (b) machine control settings, (c) baseline tests, and (d) quick scan and less frequent tests. The physical and mechanical inspections that performed were mention early in the introduction. With regard to machine control settings, the video monitor's brightness and contrast settings were recorded for all machines under "clinical" room lighting conditions. The recorders of other machine control settings include the dynamic range, gray level map, power level, gain level, and Time Gain Compensation (TGC). It should be pointed out that some QC tests required different settings for image and focal zone depth.

Most ultrasound units that participated in this study have internally stored grayscale test patterns such as the SMPTE test pattern. As baseline and first stage we recorded the noted number of grayscale steps displayed in pattern and realized that no change with hardcopy image. Later in the follow-up procedures, the patterns were used again to verify the displaying of the baseline number of steps on the TV monitor and in the hardcopy image. These steps should not decrease by more than 2 from the baseline value.

Following are the quick scan and less frequent tests performed during baseline and follow-up procedures.

QC tests (quick scan and less frequent)

Ultrasound machines data (model, serial number, etc) and technical parameters (frequency, dynamic range, and gain) were recorded at the time of the baseline tests and checked during routine measurements. For each QC test, a separate graph sheet including the baseline value was used to graphically represent the data and to record important data and events such as equipment failures and repairs.

The quick scan tests performed in this study was completed in the following order: (a) image uniformity, (b) depth of visualization, and (c) distance accuracy. The less frequent QC tests carried out include the axial resolution and dead zone test. The cyst imaging, lateral resolution, and slice thickness tests were ignored in this study.

Descriptions of the quick scan and less frequent tests used in this study are beyond the scope of this document. Further information on description of ultrasound QC tests can be found in other documents [2,5]. However, evaluation of some QC tests such as image uniformity was subjective. Scale from one to three was used for image uniformity

Table 2: Results of depth of visualization tests for frequencies range from 3.5 to 7.5 MHz for depth of 180 mm.

Hospital Code	MCH	NGHA	NU	KKH	NGH
Baseline (mm)					
Mean	180	181	180	180	181
Max	183	182	181	182	183
Min	176	177	176	178	179
SD	2.5	2.4	2.1	2.3	2.2
Sample Size	13	8	9	10	14
Monitor Reading (mm)					
Mean	180	181	180	182	181
Max	189	188	185	187	190
Min	173	174	173	171	172
SD	3.9	4.8	3.3	3.6	4.2
Sample Size	65	40	45	50	70
Hard copy Reading					
Mean	180	182	180	181	181
Max	189	183	185	184	190
Min	173	171	173	169	172
SD	3.8	3.9	3.3	4.3	4.2
Sample Size	65	40	45	50	70

evaluation. The image was rated good and scored one was used if echoes of the same size and depth showed equal luminosity on the monitor. If image have noticeable non-uniformities it was rated by score two. Score three was given if there was discontinuity in the area of interest (serious non-uniformities). Most images were evaluated by two sonographers, and one radiologist. The Mean Opinion Scores (MOS) obtained are revealed that subjected viewer have arrived at a reasonable agreement on the perceptual quality of the retargeted image.

Table 3: Results of vertical accuracy tests for actual targets depth of 120 mm at Gammex phantom (GP) and CIRS phantom (CP).

Hospital Code	MCH		NGHA		NU		KKH		NGH	
	GP	CP	GP	CP	GP	CP	GP	CP	GP	CP
Baseline (mm)										
Mean	120	120	120	120	120	120	119	119	120	120
Max	121	121	120	120	121	121	121	121	120	120
Min	119	119	120	120	119	119	119	119	120	120
SD	0.6	0.6	0	0	0.5	0.5	0.6	0.6	0	0
Sample Size	13	13	8	8	9	9	10	10	14	14
Monitor reading (mm)										
Mean	121	121	119	119	121	121	120	120	121	121
Max	124	124	122	121	126	126	125	125	123	123
Min	118	117	116	116	117	117	119	119	120	120
SD	1.7	1.7	1.4	1.4	1.8	1.8	1.7	1.7	1.5	1.5
Sample Size	65	65	40	40	45	45	50	50	70	70

Gestational age based on the QC

An additional purpose of the study was to examine the impact of the implementation QC tests on the estimation of GA. The most accurate way to determine the GA is using the first day of the woman's last menstrual period and confirming this age with the measurement from an ultrasound exam. The essential method used by sonographers to estimate the GA is to measure the biometric parameters based on the distance measurements in the fetus. Many authors [9,15-17] have created regression equations using various combinations of biometric parameters such as BPD, FL, and abdominal circumference (AC), to improve the accuracy. However, it's not clear which method is superior in determining GA. Randomly we calculate the GA using one of these methods based on use the following equation [17]:

$$GA\ (days) = 50.5 + 1.21\ BPD + 1.00\ FL \qquad (1)$$

The GA calculated using Eqn (1) was corrected using Eqn (2), assuming that the most important factor impact on the estimation of the GA using ultrasound exam was based on the errors of distance measurements in the fetus.

$$GAc\ (days) = 50.5 + 1.21\ (BPD \pm E_{QC}) + 1.00\ (FL \pm E_{QC}) \qquad (2)$$

Where GAc is the corrected gestational age and E_{QC} is the difference between the baseline and routine measurements for distance accuracy.

The GAc was calculated in the period between last performed QC tests and before calling the service engineer in the next QC tests. Data on total of 35 pregnancies were collected from one ultrasound unit at the MCH. The GA at the time of scanning ranged from 14 to 22 weeks, with mean of 19 weeks. These scans include measurements of BPD and FL. Ethical committee approval was obtained, and written maternal consent was given in each case before any data were released for analyses.

The systematic (E_s) and random (E_r) errors were calculating for formula in days:

Table 4: Results of horizontal accuracy tests for shallow and deep targets from phantom surface. The actual distance for horizontal targets is 30 mm for GP and CP.

Hospital Code	MCH		NGHA		NU		KKH		NGH	
	GP	CP	GP	CP	GP	CP	GP	CP	GP	CP
Baseline (mm)										
Mean	30	30	30	30	31	31	30	30	31	31
Max	31	31	31	31	32	32	31	31	32	32
Min	29	29	29	29	29	29	29	29	29	29
SD	0.8	0.8	0.5	0.6	0.7	0.7	0.6	0.6	0.9	0.8
Sample Size	26	26	16	16	18	18	20	20	28	28
Monitor Reading (mm)										
Mean	29	29	32	32	31	31	31	31	30	30
Max	31	31	35	36	32	32	33	33	31	31
Min	28	28	28	28	28	28	29	29	30	30
SD	1.8	1.7	2.3	2.3	1.9	1.9	1.2	1.2	0.9	0.9
Sample Size	130	130	80	80	90	90	100	100	140	140

Table 5: Results of image uniformity for misc artifacts, vertical and horizontal banding. Scale from 1 to 3 used to grade the image (1 = none, 2 = noticeable non-uniformities, and 3 = serious non-uniformities).

Hospital Code	MCH	NGHA	NU	KKH	NGH
Vertical Banding					
Mean of baseline	1	1	1	1	1
Mean of readings	1	1	2	1	1
Max of readings	1	3	2	2	2
Min of readings	1	1	1	1	1
Horizontal Banding					
Mean of baseline	1	1	1	1	1
Mean of readings	1	2	1	1	1
Max of readings	1	3	2	2	2
Min of readings	1	1	1	1	1
Misc Artifacts					
Mean of baseline	1	1	1	1	1
Mean of readings	1	1	1	1	1
Max of readings	1	3	3	2	2
Min of readings	1	2	1	1	1

Table 6: Results of dead zone for target depths of 1, 4, 7 and 10 mm in GP using transducer frequency range between 3 and 7 MHz (F_1) and frequency ≥ 7 MHz (F_2).

	Hospital Code									
	MCH		NGHA		NU		KKH		NGH	
Transducer frequency (MHz)	F_1	F_2	F_1	F_2	F_1	F_2	F_1	F_2	F_1	F_2
Baseline Mean (mm)	3.4	0.9	3.4	1	3.3	0.9	3.4	0.9	3.5	1
Reading Mean (mm)	3.4	0.9	3.4	1	3.3	0.9	3.4	0.9	3.5	1

Table 7: Results of axial resolution for filament targets that are displaced in Gp axially by distances of 0.25, 0.5, 1.0 and 2.0 mm using transducer frequency smaller than 4 MHz (F_1) and frequency ≥ 4 MHz (F_2).

	Hospital Code									
	MCH		NGHA		NU		KKH		NGH	
Transducer frequency (MHz)	F_1	F_2	F_1	F_2	F_1	F_2	F_1	F_2	F_1	F_2
Mean of baseline (mm)	1	0.25	0.5	0.25	1	0.25	1	0.25	0.5	0.25
Mean of reading (mm)	1	0.25	0.5	0.25	1	0.25	1	0.25	1	0.25

$$E_d = GA - GAc \quad (3)$$

$$E_s = \overline{E}_d \quad (4)$$

$$E_r = \sigma (E_d) \quad (5)$$

Where E_d is dating error, $\overline{E}_d$ is the mean of dating errors and σ is the standard deviation.

Results

The mechanical inspection results for all ultrasound machines in the five hospitals were classified as sufficient and following are descriptions for the results of quick scan and less frequent tests and GAc.

Table 2 shows the depth of visualization and baseline results for depths scanned at a distance of 180 mm and analyzed for frequency transducers range from 3.5 to 7.5 MHz using Gammex phantom. These results include the fidelity of the photographic recording and show negligible change in hard copy with 2.1% and 1.8% at the NGH and KKH respectively.

Table 3 presents the results of baseline and vertical accuracy measurements carried out for vertical column of filament targets having known distance of 120 mm in Gammex and CIRS phantoms. The results using both phantoms show mean variation between baseline and routine measurements estimated by 0.7% in the five hospitals.

In regard to the horizontal distance accuracy, Table 4 shows the results of baseline and routine measurements carried out for horizontal columns of shallow and deep filament targets having known distance of 30 mm in the Gammex and CIRS phantoms.

Table 5 shows the results of image uniformity for misc artifacts, vertical and horizontal banding in Gammex phantom. Table 6 shows the results of dead zone (or ring down) for filament targets at depth of 1, 4, 7 and 10 mm from Gammex phantom surface. Transducers frequency used for dead zone results were distributed between two ranges as shown in Table 6.

Table 7 shows the results of axial resolution for filament targets that are displaced in Gammex phantom axially by distances of 0.25, 0.5, 1.0 and 2.0 mm. Transducers frequency used for axial resolution were distributed in Table 7 between transducers having central frequencies equal or greater than 4 MHz, and for transducers having central frequencies less than 4 MHz.

Table 8: GA and GAc (days) for the vertical distance accuracy.

Pregnancies #	E_{QC} (mm)	BPD (mm)	FL (mm)	GA (days)	GAc (days)	E_d (days)	E_r (%)	E_s (days)
3	1	19	20	93.5	95.7	2.2	0	2.2
4	2	32	18	107.2	111.6	4.4	0.1	4.3
2	2	39	34	131.7	136.1	4.4	0	4.4
3	2	40	28	126.9	131.3	4.4	0.1	4.3
4	-1.5	43	27	129.5	126.2	-3.3	0	-3.3
2	1	45	25	130	132.2	2.2	0	2.2
4	2	48	24	132.6	137	4.4	0.1	4.3
5	2	41	26	126.1	130.5	4.4	0.1	4.3
2	2	46	29	135.2	139.6	4.4	0.1	4.3
3	-1.5	46	22	128.2	124.8	-3.3	0	-3.3
3	-1.5	45	25	130	126.6	-3.3	0	-3.3

Table 9: GA and GAc (days) for the horizontal distance accuracy.

Pregnancies #	E_{QC} (mm)	BPD (mm)	FL (mm)	GA (days)	GAc (days)	E_d (days)	E_r (%)	E_s (days)
3	2	19	20	93.49	97.91	4.42	0.01	4.41
4	2	32	18	107.22	111.64	4.42	0.01	4.41
2	1	39	34	131.69	133.9	2.21	0.01	2.2
3	1	40	28	126.9	129.11	2.21	0.01	2.2
4	-2	43	27	129.53	125.11	-4.42	0.13	-4.35
2	1	45	25	129.95	132.16	2.21	0.01	2.2
4	-2	48	24	132.58	128.16	4.42	0	4.42
5	1.5	41	26	126.11	129.43	3.32	0.13	3.24
2	2	46	29	135.16	139.58	4.42	0	4.42
3	1.5	46	22	128.16	131.48	3.32	0	3.32
3	2	45	25	129.95	134.37	4.42	0.01	4.41

On the other hand, Table 8 and 9 show the QAc using E_{QC} values for vertical and horizontal distance accuracy respectively. The BPD measured was found range from 18 mm to 60 mm with mean of 45 mm. While, the FL was range from 18 to 34 mm with mean of 25 mm.

Discussion

QC tests

It should be pointed out that the results of baseline values and routine measurements shown in Table 2 and all subsequent QC tests are not truly comparable, because baseline values for some machines could be change after preventive maintenance. However, 44/50 (87%) of the transducers were rated sufficient in the evaluation of visualization depth comparing with baseline values for frequency range between 3.5 and 7.5 MHz. NGH and NGHA show negligible variation from baseline values estimated with 8% and 5% respectively. In evaluating visualization depth our results was relatively more sufficient comparing with values reported by Cozzolino, et al [14]. In that work 4/48 (8%) 3.5-MHz transducers, and 16/44 (36%) 7.5-MHz transducers were classified as sufficient.

With regard to distance accuracy (see Table 3 and 4), similar to the results of Cozzolino, et al [14], transducers proved to be less accurate in the vertical direction than in the horizontal direction. It's recommended [2] to use a little pressure as possible when perform these tests and applying the transducer to the scanning membrane, where pressing too hard can displace the filaments in the phantom resulting in measurement errors. Furthermore, aligning the scan head so that the scan plane is perpendicular to the filaments and parallel to the long side of the phantom certainly will decrease measurement errors.

With regard to horizontal distance accuracy, the transducers show variation less than 0.9% comparing with the baseline values in the five hospitals. On the other hand, velocity of both phantoms used were known to us, however, bad storage of phantom under varying temperature conditions can be one reasons of changing velocity of ultrasound in the phantom. The second phantom used in this study was helpful in determining the source of the incorrect velocity of ultrasound in the phantom. Comparing transducers results for distance accuracy using both phantoms in the five hospitals show negligible mean variation estimated with 0.3%.

Image non-uniformities were evaluated and observed if we used new gain. It's considered a problem on account of they can mask subtle variations in tissue texture and increase the risk of false negatives [2]. Results of serious non-uniformities observed at NGHA were corrected immediately. Even results of noticeable non-uniformities, have been seen as a potentially large problem and were corrected if consistently present. Evaluation of image uniformity was varied from one hospital to another, however, estimation of scores given by mean opinions of two sonographers, and one radiologist help us to estimate the appropriate results for noticeable non-uniformities. In this study 2/54 (4%) 7.5 MHz transducers were show serious non-uniformities and rated poor comparing with 5/44 (11%) 7.5-MHz transducers rated poor as reported by Cozzolino, et al [14].

With regard to dead zone (or ring down), it is know that no useful scan data are collected in this region. The results show that as frequency was increased, the depth of the dead zone decreases (see Table 6). No variation from baseline values were observed in all hospitals, but probably if such variation observed it will reflects the changes in the transducer and/or pulsing systems. Specifically, deeper dead zones can be attributed to a cracked crystal, a broken lens, or a longer excitation pulse [5].

Most results presented in Table 7 for all hospitals show axial resolutions were remain stable over time of measurements. As expected, axial resolution proved to be greater in high-frequency transducers. There is a difference between these results and axial resolution that is expected in clinical scans, since other factors such as organ and vessel motion and volume averaging will degrade the clinical results. Only in the NGH, deviation was observed for transducer frequency smaller than 4 MHz on account of broken electrical connection in two transducers.

Gestational age

With regards to the second purpose of this study and evaluating the GAc, the results of E_d values range between -3 to +4 days, E_r not exceed 0.1% and E_s range between -3.3 to 4.4% (see Table 8). Similar range of E_d was observed in Table 9. Accordingly the GAc can be obtained using E_{QC} for vertical or horizontal distance.

The error range between -3 to 4 days from delivery date cannot be considered negligible. Furthermore, the correlation between E_d and

E_{QC} are positive and this reflects the importance of implementation the QC tests for ultrasound machines regularly. Eqn (2) can help the sonographers to calculate the accurate GA, if the E_{QC} was provided and during the delay of maintenance service. Furthermore, the difference between values of action level and defect levels used in the QC tests will impact in the dating errors.

This study was not including evaluation other IQIs such as depth of penetration and image uniformity to estimate the GA. This study is expected to encourage further ultrasound QC surveys that will eventually lead to the possible establishment of reference level to correct the GA during first or second trimester and during the delay of service maintenance.

Conclusion

Our study has been useful in providing a snapshot of the functional state of transducers used in the five hospitals at Najran, Saudi Arabia. The main factor that contributed to the lower deviation from baseline levels in most hospitals could be the equipment performance, as relatively new equipment are in use and rarely break down. However, the results show wide variation from baseline levels are certainly caused for concern. In particular, a significant and accurate GA can be calculated if we consider the error of vertical or horizontal distance accuracy in our calculations with biometric parameters. Therefore, periodic QC evaluation should be carried out to motivate the optimization of accurate dating of pregnancy.

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