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Performance Evaluation of Diagnostic X-Ray Equipment Regarding the Hospital Size in the Republic of Korea

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ABSTRACT

Introduction: The Republic of Korea has developed a national standard based on which diagnostic X-ray equipment must be tested every 3 years. Accordingly, the performance of X-ray equipment used in all hospitals is evaluated by national certification bodies in compliance with the safety management regulations for X-ray equipment. However, if the equipment is non-compliant, its use must be stopped until it satisfies the accepted standards.

Material and Methods: In compliance with the safety management regulations for diagnostic X-ray equipment, hospitals in this study were divided into two groups, namely the general hospital group and the clinic group with diagnostic X-ray equipment. The samples in this study were composed of 11 and 18 machines selected randomly from general hospitals and clinics, respectively, which satisfied the acceptance standards since last year in both groups. The evaluation of diagnostic X-ray machines was based on the results obtained from X-ray tube voltage, tube current, exposure time accuracy, and the X-ray dose reproducibility.

Results: The X-ray machines of the general hospital group followed all national standards. However, those of the clinic group failed to satisfy the requirements of tube voltage, tube current, exposure time accuracy, and X-ray dose reproducibility.

Conclusion: Clinics require their own quality control to reduce unnecessary medical radiation exposure due to the poor X-ray equipment performance. Moreover, it is suggested that the test period of the safety management regulations on diagnostic X-ray equipment need to be shorter than three years.

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Introduction

Although X-ray imaging of patients is necessary to detect a disease, care must be taken with their use because even small doses of radiation can harm patients. Diagnostic X-ray equipment has a limited life span. Therefore, it needs to be checked and replaced with parts that might adversely affect the performance of X-ray equipment performance. The possibility of malfunctioning needs to be anticipated and prevented by regular quality management [1, 2]. For this reason, the Republic of Korea has developed a national standard, stating that diagnostic X-ray equipment must be retested every 3 years [3]. In compliance with the safety management regulations on diagnostic X-ray equipment, the national certificate authority evaluates the performance of X-ray equipment. If the machines are non-compliant, their use must be stopped until they satisfy the acceptance standards. Large medical institutions, such as general hospitals, try to overcome this problem by checking and testing the performance of X-ray machines regularly to determine if there is any probable chance of future problems. On the other hand, most small-sized medical institutions need to purchase expensive invasive-type measuring instruments that require a professional workforce. Consequently, this may affect the performance management of X-ray equipment. The performance of X-ray equipment can be measured in two ways, namely invasive type measuring instruments with high accuracy but with electrical risk, and non-invasive type measuring instruments with low electrical risk and convenience.

The results of tube voltage measurements show no significant difference between invasive type measuring instruments and non-invasive type measuring instruments regarding accuracy [4]. On the other hand, non-invasive type measuring instruments have low accuracy in measuring the tube current. This means that invasive type measuring instruments can be assigned as a standard in safety management regulations on diagnostic X-ray equipment [3].

A recent study introduced a new method to measure the tube current, which uses clamp meter connected to a high-voltage cable. This allows the transformation of the size of the magnetic field into an

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electric current [5]. The MagicMaX Universal device is a type of non-invasive type measuring instrument that can measure the tube current without electrical risk. The difference in accuracy between Dynalyzer Ⅲ and the proposed method is within 4.2%, which explains the reason of applying this method for measuring the tube current of X-ray equipment without any electrical risks [5]. Kang et al. (2012) confirmed that the performance of X-ray equipment was dissatisfying when used for a long time, even though it met the criteria of the safety management inspection of the diagnostic X-ray equipment [1].

This study compared the differences in accuracy of X-ray equipment that had satisfied the safety management regulations for diagnostic X-ray equipment for over a year ago with regard to the size of the hospital in the metropolitan area. Moreover, the current study addressed X-ray machines that had previously satisfied the safety management regulations, and had an adequate time left until the next test to determine if they have any problems with their performance.

Materials and Methods

In the metropolitan area of the Republic of Korea, 11 and 18 X-ray machines that had previously satisfied the safety management regulations for diagnostic X-ray machines were randomly selected from general hospitals and clinics, respectively. According to the Article 3 (3) of the Medical Law No. 15540 (Mar, 2018) [6], medical institutions with more than 100 beds and 7-9 medical departments and medical specialists are designated as general hospitals. However, clinics are divided into smaller sections, compared to general hospitals.

The X-ray tube voltage accuracy, X-ray tube current accuracy, X-ray exposure time accuracy, were measured 3 times each. In addition, the calculated percentage average error (PAE) was determined (*Equation 1*).

The measuring conditions (reference: IEC60601-2-54)[7] were as follows: 1) for the X-ray tube voltage accuracy, lower of 50 kV, 300 mA, 0.1 sec, higher of 120 kVp, 50 mA, and 0.1 sec; 2) for the X-ray tube current accuracy, lower of 50 mA, 120 kVp, 0.1 sec, higher of 300 mA, 70 kVp, and 0.1 sec; and 3) for the X-ray exposure time accuracy, shortest of 0.01 sec, and longer of 2.0 sec. All experimental conditions were the same. In addition, the X-ray dose reproducibility was calculated 10 times each using the coefficient of variation (CV) (*Equation 2*) under the following conditions: 50 kVp, 300 mA, 0.1 sec and 120 kVp, 50 mA, and 0.1 sec.

$$\text{Percent Average Error} = \frac{X_p - \bar{X}}{X_p} \times 100\ (\%) \qquad (1)$$

Where, X_p denotes experimental value, and $\bar{x}$ signifies the average of measured values.

$$\text{Coefficient of variation} = \frac{SD}{\bar{X}} \qquad (2)$$

Where, SD is standard deviation, and $\bar{x}$ refers to the average of measured values.

The measuring instrument was MagicMaX Universal (IBA Dosimetry Co., USA, and Calibrated in October, 2016) and a clamp meter connected to a high-voltage cable was used when measuring the X-ray tube current.

The data were analyzed using SPSS, version 18.0. The accuracy and significant difference of the mean percentage error were analyzed at the significance level of 0.05 using a Mann-Whitney U test between the general hospitals and the clinics.

Results

Measurement of X-ray tube voltage accuracy

At the X-ray tube voltage of 50 kVp, the results showed 47.7~50.9 kVp and 47.3~51.7 kVp in the general hospital and clinic groups, respectively. The mean percentage average error was 4.6~-1.8% and –0.1~-5.3% in the general hospital and clinic groups, respectively. They both satisfied the safety management regulations on diagnostic X-ray equipment (±10%).

At an X-ray tube voltage of 120 kVp (higher tube voltage), the result showed 120.1~126.4 kVp and 117.6~133.8 kVp in the general hospital and clinic groups, respectively. In addition, the mean percentage average error was –0.1~-5.3% and 2.0~-11.5% in the general hospital and clinic groups, respectively. In the clinic group, one X-ray machine was found to be non-compliant. In addition, there was a significant difference between the two groups in terms of mean percentage average error (Table 1).

Table 1. X-ray tube voltage accuracy regarding the hospital size

Variable		N	kVp Mean±SD	P-value	Percent average error Mean±SD	P-value
50 kVp at 300 mA	General hospital	11	50.05±0.83	0.259	-0.10±1.66	0.242
	Clinic	18	49.90±1.07		0.19±2.14	
120 kVp at 50 mA	General hospital	11	123.98±1.92	0.051	-3.33±1.59	0.044
	Clinic	18	125.82±3.93		-4.86±3.28	

Table 2. X-ray tube current accuracy regarding the hospital size

Variable		N	mA Mean±SD	P-value	Percent average error Mean±SD	P-value
50 mA at 120 kVp	General hospital	11	49.99±3.60	0.250	2.01±7.21	0.255
	Clinic	18	45.66±11.20		8.67±22.40	
300 mA at 50 kVp	General hospital	11	317.30±18.32	0.072	-5.77±6.12	0.071
	Clinic	18	294.32±51.39		1.88±17.12	

Measurement of tube current accuracy

There was no significant difference in accuracy and mean percentage error between the two groups, regarding measurements of lower and higher tube current (Table 2). In the general hospital group, all diagnostic X-ray machines satisfied to the regulations on safety management by Korea safety management regulations on diagnostic radiation machines and the regulations on accuracy by IEC 60601-2-54 (within ±15% and ±20%, respectively).

However, in the clinic group, the lower and higher tube current were tested and 6 and 5 of those machines (33.0% and 27.0%, respectively) were not passed of the safety management regulations. In addition, 5 and 3 of those (27.0% and 16.0%, respectively) failed to pass the accuracy regulations.

Measurement of X-ray exposure time accuracy

All the hospitals in the general hospital group satisfied the X-ray exposure time accuracy. On the other hand, 3 (16.0%) and 1 (5.0%) X-ray machines in the clinic group were non-compliant with 0.01 sec and 2.0 sec, respectively. However, there was no significant difference in the X-ray exposure time accuracy and mean percentage average error between the two groups (Table 3).

Experiment on X-ray dose reproducibility

In X-ray dose reproducibility, the general hospital group satisfied the requirements in terms of coefficient of variation under the two experimental conditions while 1 X-ray machine (5%) in the clinic group was non-compliant under the conditions of a higher tube voltage and lower tube current (120 kVp, 50 mA, 0.1 sec). A significant difference in standard deviation and coefficient of variation of X-ray dose reproducibility was observed between the two groups ($P<0.05$) (Table 4).

Table 3. X-ray exposure time accuracy regarding the hospital size

Variable		N	Exposure time Mean±SD	P-value	Percent average error Mean±SD	P-value
0.01sec	General hospital	11	0.0099±0.0003	0.263	0.39±3.33	0.289
	Clinic	18	0.0098±0.0014		2.50±14.24	
2.00sec	General hospital	11	1.95±0.09	0.394	2.18±4.75	0.483
	Clinic	18	1.96±0.15		1.88±7.51	

Table 4. X-ray dose reproducibility regarding the hospital size

Variable		N	SD Mean±SD	P-value	CV Mean±SD	P-value
70 kVp, 300 mA, 0.1sec	General hospital	11	0.0013±0.0013	0.075	0.2749±0.9037	0.266
	Clinic	18	0.0023±0.0023		0.0035±0.0029	
120 kVp, 50 mA, 0.1sec	General hospital	11	0.0031±0.0038	0.025	0.0067±0.0108	0.024
	Clinic	18	0.0097±0.0137		0.0165±0.0197	

Assessment of dosimetric effects by comparing the treatment plan

Table 3 shows the results of 360 treatment plans as the sum of 180 cases before the correction and 180 cases after correcting the rotational setup errors for 30 treatment fractions after selecting 6 patients randomly. The CBCT images include the ROIs of the brain, brainstem, and both eyes because the quality of the CBCT images for the ROIs was lower than that of the CT simulation images due to the nature of the CBCT image. Based on the comparison of the doses of the treatment plans, the highest dose difference was observed in patient number 2. The variation of the dose difference before and after correcting the rotational setup error of the Brain_max was 4.47-9.21 Gy, while the Brain_mean was 0.48-1.07 Gy. The maximum of the Brain_stem was -7.58 to -15.95 Gy, while the mean of the Brain_stem was -9.35 to -19.02 Gy. There was a large difference between patient number 2 and 3. On the other hand, the dose difference in the rotational setup error was small in the other patients (Table 3). The mean difference for each ROI was 2.17 Gy for the Brain_max and 0.28 Gy for the Brain_mean. In addition, the maximum and mean of the Brain_stem were -3.58 Gy and -4.43 Gy, respectively. The Lt_eye_max and Rt_eye_max were 1.34 Gy and -0.71 Gy, respectively. The analysis of results by Spearman's correlation coefficient showed that there was a significant linear relationship among the mean values of the remaining ROIs after subtracting the difference of the Brain_mean ($P < 0.05$).

Discussion

Most general hospitals perform quality management for their equipment on their own. However, clinics suffer from the lack of self-quality management program to conduct a constant and continuous evaluation of their X-ray equipment, which can lead to degraded performance of their equipment. Performance degradation can be a direct cause of an increase in exposure dose which implies the need for continuous management [8]. The AAPM report No. 74 [9] assessed the X-ray tube voltage, X-ray tube current, X-ray exposure time, and X-ray dose reproducibility of a general X-ray machine and concluded that these requirements are important to maintain the performance of the devices [10].

The results of a study conducted by Park et al. [11] showed that clinics tended to have more X-ray machines that did not satisfy all the requirements, such as the X-ray tube voltage accuracy, X-ray tube current accuracy, X-ray exposure time accuracy, and X-ray dose reproducibility. In the same vein, the obtained results of the current study differ significantly with that of the national standard in terms of the assessment of the X-ray tube voltage accuracy and X-ray dose reproducibility at a higher tube voltage. Similarly, You et al. [12] reported that clinics do not have sufficient power to provide more electricity as tube voltage is increased. According to IEC 60601-2-54, the standard for the tube current accuracy is ±20%, while the national standard of the tube current accuracy is ± 15%, which is even stricter, in the Republic of Korea.

The tube current accuracy was not significantly different according to the hospital size. However, the general hospital group satisfied all the standards of the IEC 60601-2-54, and the safety management regulations on diagnostic X-ray machines. In contrast, the clinic group failed to satisfy the safety management regulations on the diagnostic X-ray machines. This is supported by the fact that 6 (33%) and 5 (27%) X-ray machines were non-compliant with a low and high tube current, respectively.

The current study evaluated 29 X-ray machines. However, it should not be forgotten that future research is required to assess more X-ray machines with the changes to the relevant regulations. This study also revealed that some diagnostic X-ray machines, previously satisfying the safety management regulations, no longer meet the national standards even after a year.

Conclusion

Clinics also need their own quality control to reduce unnecessary medical radiation due to poor X-ray equipment performance. Moreover, the test period of the safety management regulations on diagnostic X-ray equipment needs to be shorter than three years.

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