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

Dongjun Jang¹, Sungchul Kim ¹°

1. Department of Radiological Science, Gachon University Medical campus, Incheon 21936

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**Abstract**

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**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 the 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.

*Corresponding Author: Tel: +82-32-820-4361; Email: ksc@gachon.ac.kr*
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).

Equation 1

\[
\text{Percent Average Error} = \frac{X_o - \bar{x}}{X_o} \times 100\%
\]

Where, \( X_o \) denotes experimental value, and \( \bar{x} \) signifies the average of measured values.

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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 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

<table>
<thead>
<tr>
<th>Variable</th>
<th>kVp</th>
<th>Mean±SD</th>
<th>P-value</th>
<th>Percent average error</th>
<th>Mean±SD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 kVp at 300 mA</td>
<td>General hospital</td>
<td>11</td>
<td>50.05±0.83</td>
<td>0.259</td>
<td>-0.10±1.66</td>
<td>0.242</td>
</tr>
<tr>
<td></td>
<td>Clinic</td>
<td>18</td>
<td>49.90±1.07</td>
<td>0.002</td>
<td>0.19±2.14</td>
<td>0.000</td>
</tr>
<tr>
<td>120 kVp at 50 mA</td>
<td>General hospital</td>
<td>11</td>
<td>123.98±1.92</td>
<td>0.051</td>
<td>-3.3±1.59</td>
<td>0.044</td>
</tr>
<tr>
<td></td>
<td>Clinic</td>
<td>18</td>
<td>125.82±3.93</td>
<td>0.001</td>
<td>-4.86±3.28</td>
<td>0.000</td>
</tr>
</tbody>
</table>

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

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 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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