Factors Affecting the Patient’s Skin Dose During Percutaneous Coronary Intervention for Chronic Total Occlusion

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Background The aim of this study was to measure the patient entrance skin dose (ESD) during percutaneous coronary intervention (PCI) for chronic total occlusion (CTO), and assess the factors that affect it.

Methods and Results Radiosensitive indicators were used to measure ESDs during 23 procedures. Multiple regression analysis identified the strength of the linear relationship of the dependent variable (the natural logarithm of the maximum ESD) with the set of multiple independent variables (the natural logarithm of both the patient and angiographic data). The methods for estimating the maximum ESD and the estimated ESDs were compared with the actual ESDs. The average maximum ESD for all the patients was 2.7 ± 1.5 Gy (median: 2.6 Gy). The natural logarithm of the maximum ESD correlated well with the natural logarithm of body mass index (BMI; p=0.0112), total fluoroscopic time (TFT; p=0.0002), and Frame Fixation Rate (p=0.0014). For the higher Frame Fixation Rate group, there were significant correlations between the BMI² × TFT value and maximum ESD (r=0.972, p<0.0001), and the TFT and maximum ESD (r=0.968, p<0.0001). There were no significant correlations for the lower Frame Fixation Rate group.

Conclusions In PCI for CTO, the BMI² × TFT value or TFT is a good predictor of radiation skin injury risk, when the beam angulation is not changed frequently. It is important to change the beam angulation to control ESD during a prolonged procedure. (Circ J 2007; 71: 229–233)

Key Words: Angiography; Angioplasty; Catheterization; Dosage

Chronic total occlusion (CTO) has been considered as a relative contraindication for percutaneous coronary intervention (PCI), because of its low success rate and high restenosis rate. The results have improved because of recent advances in technology and increased operator experience.1–7 Recent studies show that successful PCI of a CTO is associated with improved survival;8,9 however, the total fluoroscopic time (TFT) tends to be long in this procedure compared with PCI for non-CTO10 The patient's entrance skin doses (ESD) are higher10,11 and severe skin injury can occur, so the physician must estimate the ESD in order to prevent radiation skin injuries during the procedure. However, there is inadequate assessment of this issue in the literature.

The purpose of this research was to measure the patient's ESD during PCI for CTO, analyze the factors that affect it and assess the methods used to estimate the maximum ESD from both patient and angiographic data.

Methods

Patient Population

This study focused on 23 consecutive patients (6 women, 17 men) who underwent PCI for CTO with evaluation of the ESDs from July 2004 to September 2005. The average patient age was 68.9 ± 7.7 years (range: 53.6–82.2).

Angiography

AdvantX LC and AdvantX LC/LP equipment (General Electric Medical Systems, Milwaukee, WI, USA) were used for angiography. The image intensifiers of both units were renewed in April 2004. Each unit had an undercouch tube and an overcouch image intensifier with 3 fields of view: 9, 6, and 4.5 inches in diameter. A 6-inch field of view was used mainly in this assessment. In both units, the total filtration was equivalent to 2.7 mm aluminum. Procedures were performed using pulse-mode fluoroscopy. The period of use was 9 years for each unit.

PCI and ESD Measurement

The patient wore a jacket with 52 radiosensitive indicators (Nichiyu Giken Kogyo Co, Ltd, Saitama, Japan) placed on the back. Radiosensitive indicators use a functional dye in which the color changes from translucent to red with X-ray absorption. Indicators were arranged in 6 rows (from top to bottom: 1, 2, 3, 4, 5, and 6) and 8 columns (from left to right: A, B, C, D, E, F, G, and H) at intervals of 7 cm. An additional 4 indicators were placed in the 7th row (C7, D7, E7, and F7), except for 2 patients. Four experienced cardiologists performed the procedures using standard tech-
The institutional review board approved the study, and all patients gave informed consent.

Validation Study

The color of the indicators was analyzed with a color-measuring instrument (Chroma Meters CR-300; Konika Minolta Holdings, Inc, Tokyo, Japan) after the procedure. The doses were calculated from the color difference of the indicators, based on the validation study. Allula Xper FD9 (Philips Medical Systems, Cleveland, OH, USA) was used as the angiography equipment. Parameters were 80-kVp tube voltage, and a 25.4-cm field of view. Indicators were placed on the lower surface of Tough Water Phantom WE type (Kyoto Kagaku Co, Ltd, Kyoto, Japan) with 20-cm thickness, and were irradiated. The irradiated doses were calibrated with an ionization chamber (monitor, Radcal Model 9015; ionization chamber, 10×5–6 type X-ray chamber; Radcal Co, Monrovia, CA, USA). With this indicator, the response was almost linear with the natural logarithm of the dose between 0.3 Gy and 7 Gy (Fig 1). The regression equation was $D = \exp(DE^* \times 0.0543 – 2.168)$, where $D$ was the absorbed dose (Gy), and $DE^*$ was the color difference of the indicator.

Patient and Angiographic Data

In each patient, the ESDs in all of the 48 or 52 points, the maximum ESD, and its location were evaluated. In terms of the patient and angiographic data, we assessed age, height, weight, and body mass index (BMI), TFT, total number of cine frames, and the rate of the cine-frame number of the most used view to the total number of cine frames (Frame Fixation Rate). The rotation and craniocaudal skew angles were assessed at intervals of 10° in the assessment of the Frame Fixation Rate.

Statistical Analysis

For the purpose of data analysis, individual patient and angiographic data were compared with the maximum ESD to determine which items showed significant differences. Multiple regression analysis was used to identify the strength of the linear relationship of the dependent variable (the natural logarithm of the maximum ESD) with the set of multiple independent variables (the natural logarithm of the patient and angiographic data). Variable selection was made by using a stepwise technique. Stepwise analysis was performed as a forward-stepping procedure. We used StatView J-5.0 for Macintosh (SAS Institute, Cary, NC, USA). A $p<0.05$ was considered to represent a statistically significant result.

Considering the results of the multiple regression analysis, we assessed methods for estimating the maximum ESD using the significant independent variables. We then compared the estimated ESDs by these methods with the ESDs by the indicators, by means of the Pearson correlation coefficient ($r$).

Results

ESD

In all 23 procedures for CTO (15 stenting, 1 rotational atherectomy, and 7 failures), the average maximum ESD was 2.7±1.5 Gy (Table 1). The maximum ESD of the patients exceeded 1 Gy in 21 procedures, 3 Gy in 10 procedures, and 5 Gy in 2 procedures.

Comparison of the Maximum ESD and Patient and Angiographic Data

Only 3 independent variables (the natural logarithm of BMI, TFT and Frame Fixation Rate) were positively related to the natural logarithm of the maximum ESD with significance ($p<0.0012$, $p=0.0002$, and $p=0.0014$, respectively) in stepwise multiple regression analysis. The multiple correlation coefficient for the maximum ESD ($r=0.858$, Table 1)

![Graph](image1)

![Graph](image2)
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p<0.0001) reached a statistically significant level. The regression equation was ln (Dmax)=1.846×ln (BMI)+0.76×ln (TFT)+0.938×ln (FFR)–7.136, where Dmax was the maximum ESD (Gy), TFT was the total fluoroscopic time (min), and FFR was the Frame Fixation Rate.

Method for Estimating the Maximum ESD

Because the Frame Fixation Rate affected the maximum ESDs, the patient group was divided on the basis of the Frame Fixation Rate into 2 subgroups: lower Frame Fixation Rate group with a rate less than the median (0.54); and higher Fixation Rate group with the median rate and above (Table 2). Considering the regression equation above, we analyzed the relationships between the BMI²×TFT value and the maximum ESD, and the TFT and maximum ESD. For the higher Frame Fixation Rate group, there were significant correlations between the BMI²×TFT value and maximum ESD (r=0.972, p<0.0001; Fig 3), and the TFT and maximum ESD (r=0.968, p<0.0001; Fig 4). The maximum ESDs were less than 3 Gy, when the BMI²×TFT value was less than 17,000 kg²·min·m⁻⁴, or the TFT was less than 35 min. In contrast, there were no significant correlations between the BMI²×TFT value and maximum ESD (r=0.576, p=0.0639), or the TFT and maximum ESD (r=0.416, p=0.2035) for the lower Frame Fixation Rate group.

Discussion

To the best of our knowledge, this is the first study to examine the correlation of both patient and angiographic data to the maximum ESDs in PCI procedures for CTO.

Patient ESD During PCI for CTO

With the increasing number of PCI procedures, radiation skin injuries have been reported more frequently12–16 The International Commission on Radiological Protection recommends that the maximum skin dose and its location should be recorded when the maximum cumulative skin dose is supposed to be 3 Gy or more (1 Gy or more in repeat cases)17 In our assessment of 23 PCI procedures for CTO, the maximum ESDs exceeded 1 Gy and 3 Gy in 21 and 10 procedures, respectively. In the PCI procedure for CTO, TFT is long, and the total number of cine frames is large compared with PCI procedures for non-CTO. According to Suzuki et al, the average TFT and average total number of cine frames during the procedures for CTO were approximately 3-fold higher than those during the procedures for 1 stenosis.10 Therefore, interventionists should estimate the patients’ skin dose and make efforts to prevent radiation skin injuries during PCI, especially for CTO.

Relationship Between BMI and Maximum ESD

As the characteristics of X-rays, the amount of penetration depends on the thickness of the object. This is the reason why the natural logarithm of BMI was positively related to the natural logarithm of the maximum ESD. It should be considered that a patient’s ESD accumulates faster if they are larger.17 The natural logarithm of the maximum ESD correlated well with the natural logarithm of BMI, TFT and Frame Fixation Rate. The coefficient for the natural logarithm of the BMI was 1.846 in the regression equation, meaning that the maximum ESD correlated with the BMI.87 Therefore, we selected BMI²×TFT as a predictor rather than BMI×TFT.
Estimate of the Maximum ESD During PCI

The real-time monitoring of ESD is not available with many types of angiographic equipment, so the fluoroscopic time should be used as information on the level of ESD. Generally, fluoroscopic time is only a very rough indicator of radiation skin injuries because the ESD is affected by such various factors as patient size, the dose rate of fluoroscopy, the distance of the tube from the patient, and the number of acquisitions. Dose–area product (DAP) is another indicator of radiation skin injury. Chida et al. reported that the correlation of the maximum skin dose with DAP ($r=0.724$) was more striking than that with TFT ($r=0.628$) and they regarded DAP as a rough predictor of the maximum skin dose. In contrast, the present study results suggest that the BMI$^2 \times$TFT value or TFT can be used as an estimate for the maximum ESD in PCI for CTO, especially when the beam angulation is not changed frequently during the procedure. When restricted to such procedures, the correlation coefficient between the maximum ESD and the TFT in the present study ($r=0.968$) was larger than that reported by Chida et al. In PCI for CTO, especially in prolonged procedures, the beam angulation is changed less frequently than during PCI for non-CTO lesions, which causes the strong correlation between the maximum ESD and the TFT.

Importance of Altering the Beam Angulation

In prolonged interventional procedures, altering the beam angulation is recommended in order to reduce the patient’s skin dose. In the present study, the maximum ESD was positively related to the Frame Fixation Rate and TFT, which supports the importance of altering the beam angulation to reduce the patient's ESD during PCI for CTO, especially if it is a prolonged procedure. In order to avoid exposure to the same skin area, Mizutani et al. reported in a phantom study that the angle of the X-ray tube should be rotated by more than $40^\circ$. The relationship between the BMI$^2 \times$TFT value and the maximum ESD or the TFT and the maximum ESD is helpful to determine the time at which the beam angulation should be altered. As mentioned before, the International Commission on Radiological Protection regarded 3 Gy as a skin dose standard. In the present study, the maximum ESDs were less than 3 Gy when the BMI$^2 \times$TFT value was less than 17,000 kg$^2 \cdot$min$^{-1} \cdot$m$^{-4}$ or the TFT was less than 35 min. These relationships could be generalized by considering the difference in dose rates among angiographic units.

Study Limitations

First, it is difficult to measure doses of 7 Gy or more with this indicator. Second, the radiation fields may have overlapped in the areas between the indicators, leading to possible underestimation of the ESD. Third, our data did not include DAP, which is a common index for estimating a patient’s ESD and is considered to be a better predictor of skin injury risk. Fourth, the number of cases examined was small, which limits the power of the study. Fifth, we did not assess differences in coronary anatomy, such as the lesion location, length, and morphology, even though they affect the TFT and thus the maximum ESD. The assessment of the effects of these factors on the patient’s skin exposure will be useful for predicting the radiation skin injury risk. Finally, the present study was conducted in 1 institute. Further studies are required in multiple institutions because the exposure dose is affected by differences in imaging equipment, the mode of operation for fluoroscopy and image acquisition, and the protocols used for PCI.

Conclusion

In PCI for CTO, BMI$^2 \times$TFT value or TFT can be a good predictor of radiation skin injury risk, when the beam angulation is not changed frequently. Changing the beam angulation is important to control ESD during a prolonged procedure.

Acknowledgments

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