Characterization of the PRAETORIAN score in Japanese patients undergoing subcutaneous implantable cardioverter–defibrillator implantation

（日本人皮下植込み型除細動器植込み患者における PRAETORIAN スコアの特徴）

申請者　弘前大学大学院医学研究科

循環病態科学領域

循環病態内科学教育

氏名　山﨑　堅

指導教授　富田　泰史

Abstract

Background: The PRAETORIAN score was developed to evaluate the implant position and predict defibrillation success in patients implanted with subcutaneous implantable cardioverter–defibrillator (S–ICD). However, usefulness of the PRAETORIAN score for Japanese patients is unknown.

Methods: We evaluated usefulness of this score, which was determined by width of sub–coil fat, sub–generator fat, and anterior positioning of the S–ICD generator by post–operative chest X–ray, in consecutive 100 Japanese S–ICD implanted patients [78 men, median age 59 (IQR 46.5–67.0) years, median body mass index (BMI) 24.2 (21.3–27.2) kg/m^2].

Results: The median PRAETORIAN score was 30 (30–45) and 93 patients were classified as a low–risk of conversion failure. The remaining 7 were as an intermediate risk. Almost all patients were classified as an optimal pulse–generator position in the second and third steps of the PRAETORIAN score. Only the difference was observed in the width of sub–coil fat in the first step. To further evaluate its significance, patients were divided into the Thicker group (sub–coil fat > 1 coil width, n=19) and the Thinner group (sub–coil fat ≤ 1 coil width, n=81). BMI and post–shock impedance were both higher in the Thicker group than in the Thinner group [27.1 (25.6–31.6) versus 23.1 (20.9–25.7) kg/m^2, $p<0.001$, and 75 (68–88) versus 63 (55–74) Ω, $p=0.003$, respectively]. During the median follow–up periods of 888 (523–1,418) days, 7 patients experienced appropriate shock therapy for spontaneous ventricular tachyarrhythmias, who were

all at a low risk. No conversion failure was observed. Inappropriate shock (IAS) occurred in 11 patients, and there was no difference in IAS rate between the Thicker group (n=2) and the Thinner group (n=9) (p=0.747 by Log–rank test)

Conclusions: Most Japanese patients were classified as a low–risk of conversion failure. The PRAETORIAN score may be useful for the evaluation of conversion failure in Japanese S–ICD implanted patients.

Introduction

The subcutaneous implantable cardioverter–defibrillator (S–ICD) system was introduced as a new alternative to the conventional transvenous implantable cardioverter–defibrillator (TV–ICD) in Japan in February 2016. With the introduction of the proctorship at the time of initial implantation of S–ICD, the technique for S–ICD implantation with intermuscular pocket formation between the serratus anterior and the latissimus dorsi muscles has been recommended in Japan. Standardization of intermuscular pocket formation in S–ICD implantation enabled safe S–ICD implantation with low procedure–related complications.[1] The most suitable placement for the S–ICD system, represented by the effectiveness of defibrillation, is determined by deep parasternal tunneling and posterior location of the pulse generator (PG).[2] The existence of adipose tissue between the coil electrode and the surface of the sternum and between PG and chest wall is estimated to increase the defibrillation threshold. Furthermore, the anterior location of the PG is also estimated to affect defibrillation efficacy and to be a risk of inappropriate sensing such as myopotential.

The PRAETORIAN score is a novel radiograph–based method that assesses these determinants of the defibrillation efficacy and has been retrospectively validated to predict the probability of defibrillation success during the acute defibrillation test.[3,4] However, the usefulness of the PRAETORIAN score for Japanese patients who underwent S–ICD implantation by standard implantation method is unknown. In the present study, we evaluated the usefulness of

the PRAETORIAN score in Japanese S–ICD implanted patients and characterized these patients based on this scoring system.

Methods

Study patients.

The 100 consecutive patients who underwent S–ICD implantation between February 2016 and June 2020 at the Hirosaki University Hospital were included in this study. Based on the Japanese Heart Rhythm Society guidelines, S–ICD was selected as an alternative to TV–ICD because these patients had an indication for ICD but did not require pacing therapy.[5] Particularly, S–ICD was selected for patients who had difficulty in accessing veins or who had TV–ICD removed due to device infection, or young patients with a necessity for long–term ICD therapy. The study protocol was approved by the institutional ethics committee (2021–046).

S–ICD implantation procedure.

We performed body surface marking of the S–ICD system position immediately before implantation, and then S–ICD implantation was performed under conscious sedation using continuous intravenous infusion of midazolam or dexmedetomidine hydrochloride with intermittent intravenous administration of fentanyl, and local anesthesia, except for initial 7 cases who underwent the procedure under general anesthesia. The patient's vital sign was monitored continuously during the procedure. Respiratory care was performed using an adaptive–servo

ventilator to prevent respiratory depression and decompensation of heart failure in patients with low left ventricular ejection fraction (LVEF). S–ICD implantation was performed using a three– or two–incision technique (3–ICT or 2–ICT).[6] The 2–ICT does not require a parasternal incision by using a standard 11–Fr peel–away sheath to deliver the lead from the xiphoid incision in a cephalad direction parallel to the sternum. The PG was placed in intermuscular space between the serratus anterior muscle and the latissimus dorsi muscle via a lateral sub–mammary incision in all patients. After the S–ICD system was placed, the optimal vector for sensing was assessed, and the vector with the greatest distinction between the QRS and the T–wave was chosen. Defibrillation test (DT) was performed during procedure and termination of induced ventricular tachyarrhythmias (VAs) by a first 65 joules (J) shock delivered from S–ICD was confirmed. On the other hand, DT was not performed in patients with severe heart failure or intracardiac thrombus, and only the post–shock impedance was measured by simultaneous 10 J shock delivery. The S–ICD was programmed to two zones of tachycardia detection, such as conditional shock zone and shock zone after DT. The tachyarrhythmia detection rate in each of conditional zone and shock zone was determined at the discretion of the physician. Shock energy was set to 80 J for both tachycardia detection zones.

PRAETORIAN score analysis.

Post–operative posterior–anterior and lateral chest X–rays were analyzed in this study. The PRAETORIAN score was calculated according to a three–step approach (Fig. 1).[3] In brief,

the first step assesses the thickness of sub–coil fat, in other words, the width of the adipose tissue between the coil electrode and the surface of the sternum by using the width of the coil as a reference. The second step is to evaluate the position of the generator in relation to the mid–axillary line. The third step determines the amount of sub–generator fat, in other words, the amount of fat tissue between the nearest point of the generator and the chest wall by using the generator width as a reference. Finally, if the calculated PRAETORIAN score is 90 or more and his/her body mass index (BMI) is 25 kg/m^2 or less, 40 points are subtracted from the total score. The risk of conversion failure is categorized based on the final score. Scores less than 90 points are at low risk, 90 to 149 points are at intermediate risk, and 150 points or more are at high risk of conversion failure.

Thicker group and Thinner group.

To evaluate the significance of the width of sub–coil fat in the first step, patients were divided into the Thicker group (sub–coil fat > 1 coil width) and the Thinner group (sub–coil fat ≤ 1 coil width). In other words, patients with ≥ 60 points in step 1 of the PRAETORIAN score were defined as the Thicker group and those with 30 points as the Thinner group. Patients' characteristics were compared between the two groups.

Statistical analysis

Baseline characteristics were shown as median (IQR). Continuous data were compared using the Mann–Whitney U test. Categorical variables were summarized as frequencies

(percentages) and were compared using the Fisher's exact test. Freedom from inappropriate shock rate was analyzed using the Kaplan–Meier method. Data were analyzed using the JMP® 15 (SAS Institute Inc., Cary, NC, USA).

Results

Study population and S–ICD implantation procedure.

Baseline characteristics of the study patients are shown in Table 1. Median age was 59 (46.5–67.0) years, and 78 patients (78%) were male. The underlying heart diseases were coronary artery disease including prior myocardial infarction in 36 patients (36%); hypertrophic cardiomyopathy in 15 patients (15%); Brugada syndrome in 11 patients (11%); idiopathic ventricular fibrillation (VF) in 10 patients (10%); dilated cardiomyopathy in 8 patients (8%); non–ischemic cardiomyopathy in 5 patients (5%); cardiac sarcoidosis in 3 patients (3%); arrhythmogenic right ventricular cardiomyopathy in 3 patients (3%); idiopathic ventricular tachycardia in 2 patients (2%); drug–induced cardiomyopathy in 2 patients (2%), valvular heart disease in 2 patients (2%), and others in 3 patients (3%). Median BMI was 24.2 (21.3–27.2) (kg/m^2). Median LVEF was 47.5 (34.2–62.6) (%). Thirty–six patients underwent S–ICD implantation as primary prevention for sudden cardiac death. Initial 22 patients underwent S–ICD implantation by 3–ICT and the remaining 78 patients (78%) by 2–ICT.

PRAETORIAN score in study population.

The median PRAETORIAN score was 30 (IQR 30–45) points and 93% (n=93) of the patients were classified as a low risk of conversion failure. Only 7 (7%) patients were classified as an intermediate risk (Table 1). The details of the analysis in each step of the PRAETORIAN score were as follows. In the first step, 81 patients scored 30 points, 12 scored 60 points, and the remaining 7 scored 90 points. In the second step, the PG was located on or behind the mid–axillary line in 99 patients and anterior to the midline in one patient. In the third step, 98 patients were classified as having less than one device width of fat between the chest wall and the PG. Notably, almost all patients were classified as an optimal PG position in the second and third step, and only the difference was observed in the first step, that is, the depth of the parasternal tunneling. Final PRAETORIAN score in this study was 30 points in 77 patients, 45 points in 2 patients, 60 points in 14 patients, and 90 points in 7 patients (Fig. 2). There was no significant difference in the PRAETORIAN score between 3–ICT and 2–ICT.

Patient characteristics that define sub–coil fat width.

We compared the differences in patients between the Thicker and the Thinner group (n=19 and n=81, respectively). There were no significant differences in baseline characteristics (age, gender, height, and LVEF) between the two groups (Table 2). Underlying heart diseases and number of incisions also did not differ between the two groups. Body weight and BMI were significantly greater in the Thicker group than in the Thinner group [73.0 (64.6–81.0) versus 65.0 (56.8–71.7) kg, p=0.004, and 27.1 (25.6–31.6) versus 23.1 (20.9–25.7) kg/m^2, p<0.001,

respectively].

Impact of sub–coil fat width on acute DT.

Acute DT was performed in 83 patients (83%) during the procedure. The reasons for 17 cases without having DT were intracardiac thrombosis (n=8), acute cerebral infarction (n=1), severe left ventricular systolic dysfunction (n=7), and non–inducibility of sustained VA (n=1). Induced VAs were successfully terminated by a single 65 J shock in all patients. The negative predictive value of the PRAETORIAN score for conversion failure on acute DT was 100%, with sensitivity and specificity of "undetermined" and 94%, respectively (Table 3).

The patients in the Thicker group showed a significant higher post–shock impedance compared to the Thinner group [75 (68–88) versus 63 (55–74) Ω, p=0.003] (Table 2). There was no difference in time to shock therapy between the two groups.

Impact of the PRAETORIAN score on occurrence of spontaneous VAs and inappropriate shocks.

During the follow–up periods [median 888 (IQR 523–1,418) days], 7 patients (7%) experienced appropriate shock therapy for spontaneous VAs. All 7 patients with appropriate shock therapy were at a low risk in the PRAETORIAN score. Spontaneous VAs were successfully treated by initial shock in all patients. On the other hand, inappropriate shock (IAS) occurred in 11 patients due to cardiac oversensing (n=5), non–cardiac oversensing (n=2), and atrial tachyarrhythmias (n=4). Of them, 10 patients were at a low risk and 1 patient was at an

intermediate risk in the PRAETORIAN score (p=0.569). There was no significant difference in IAS rate between the Thicker group (n=2) and the Thinner group (n=9) (p=0.747 by Log–rank test) (Fig. 3).

Discussion

Major findings.

Evaluation by the PRAETORIAN score in Japanese patients with standardized intermuscular pocket formation showed that most patients had a low risk of conversion failure. Furthermore, the sub–coil fat depth, evaluated in the first step of the PRAETORIAN score, was a risk of conversion failure, which was affected by body weight and BMI. Spontaneous VAs occurred in 7% of patients and all of them were successfully converted by initial shock therapy. There were no significant differences in IAS rate between patients at low risk and at intermediate risk in the PRAETORIAN score, and between those in the Thicker group and in the Thinner group. To our knowledge, this is the first report to examine the characteristics of the PRAETORIAN score in Japanese patients who underwent S–ICD implantation.

Clinical implication of the PRAETORIAN score in Japanese patients with S–ICD.

As expected, the BMI of Japanese patients undergoing S–ICD implantation was lower than that of patients enrolled in Western studies[1,7,8], and the intermuscular pocket formation between the serratus anterior muscle and latissimus dorsi muscle were recommended in Japan in

order to reduce procedure–related complications. Furthermore, placement of the PG behind the mid–axillary line was also instructed to improve the effectiveness of defibrillation by S–ICD. As a result, the device was placed in the optimal position in almost all patients in the present study, which was related to the evaluation of the second and third steps in the PRAETORIAN score. On the other hand, regarding the depth of substernal tunneling evaluated in the first step of the PRAETORIAN score, there were individual differences in the width of sub–coil fat, and in particular, the implementation of optimal substernal tunneling for patients with high BMI was a major concern. In other words, evaluation of the PRAETORIAN score revealed that the sub–coil fat depth was the most important risk determinant of conversion failure for the patients undergoing S–ICD implantation in the present study.

On the other hand, since we did not have cases with defibrillation failure, it was difficult to predict the conversion failure using this score in the present study. The paper describing the original PRAETORIAN score[3] showed that 13% of cases failed DT in the multicenter S–ICD Investigational Device Exemption data, and only 2 of 181 cases failed DT at the Amsterdam medical center. These results indicate that the proper implantation procedure can reduce conversion failure. Since S–ICD was introduced to Japan several years after Europe and the U.S., it seems reasonable that there were no conversion failures in our study.

Impact of the PRAETORIAN score on optimization of S–ICD implantation procedure.

One of the limitations of the PRAETORIAN score is that this score is calculated by

postoperative chest X–ray, which results in difficulty in evaluation of the score during the procedure. Amin et al. reported that suboptimal device position defined as the inferior electrode or electrode coil depth > 3 mm anterior to the sternum was associated with higher post–shock impedance.[9] They also showed that the defibrillation success rate decreases significantly when the post–shock impedance is 90 Ω or more. In the present study, all of the patients had body surface marking for the implantation position immediately before implantation, and the inferior placement of the proximal electrode was avoided under fluoroscopy. Therefore, when the PG is located behind the mid–axillary line and close to the chest wall, and the location of the proximal electrode is optimal, the post–shock impedance within the proper range may be one indicator for successful implantation during the procedure.

Furthermore, we demonstrated that body weight and BMI were significant risk factors for increased post–shock impedance. Although BMI of the Japanese patients is generally lower than Western S–ICD–implanted patients, some Japanese patients with high BMI have an increased risk of conversion failure. Therefore, some alternative parasternal tunneling method is needed to achieve optimal parasternal tunneling. We recently reported the usefulness of the echo–guided parasternal tunneling method for high BMI patients.[10] Further development for a new parasternal tunneling method in high BMI patients may be required.

A potential limitation of the PRAETORIAN score for inappropriate sensing.

The PRAETORIAN score estimates the risk of conversion failure by evaluation of

contact of the coil–electrode with the sternum and position of the PG. However, the position of the electrodes related to subcutaneous sensing is basically not evaluated. In particular, there is a limitation to the optimization of the proximal electrode, which affects the sensing accuracy of the primary vector and the alternate vector. Suboptimal placement of the proximal electrode is a trigger of IAS due to morphological change of subcutaneous electrocardiogram (S–ECG). For example, S–ECG in high BMI patients may easily change according to breathing or body position. Therefore, the optimal placement of the proximal electrode is important for accurate sensing and prevention of IAS. In the present study, there was no significant difference in IAS rate between the patients at low risk and at intermediate risk. Since the PRAETORIAN score only estimates the risk of conversion failure by the device position after the procedure, it should be noted that the PRAETORIAN score does not reflect a risk of IAS caused by inappropriate sensing of the proximal electrode.

Study limitations.

There are several limitations in the present study. First, this is a retrospective observational study and therefore generalization of our results may be limited. However, we studied the consecutive patients admitted during the study period, which seems to minimize the biases caused by the design of the present study. Second, this is a single center study with a relatively small number of patients. Third, the difference in the experience of the physician may have affected the results. Finally, a follow–up period of the patients may not be enough to

provide evidence. Further large–scale prospective study is required to confirm our primary experience.

Conclusions

Most Japanese S–ICD implanted patients with standardized intermuscular pocket formation are at low risk of conversion failure in the PRAETORIAN score, and the sub–coil fat depth evaluated in the first step is a risk determinant. Although the PRAETORIAN score may be useful for the evaluation of conversion failure in Japanese patients, further establishment of a standardized parasternal tunneling method for high BMI patients is highly warranted.

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Fig. Legends

Fig. 1. Each step of the PRAETORIAN score. In step 1, the thickness of the sub–coil fat is assessed on the lateral chest X–ray. The optimal fat width is ≤ 1 coil width, which is calculated as 30 points. The thicker the sub–coil fat, the higher the score. In step 2, the position of the generator is evaluated using the position of the mid–axillary line (red dotted line) as an indicator on the lateral chest X–ray. The optimal position is on or posterior the line. The more anterior the position, the lower the defibrillation efficiency, so the score is calculated as **x 2** or **x 4**. In step 3, the amount of sub–generator fat is assessed on posterior–anterior chest X–ray. The optimal fat width is < 1 generator width, which is calculated as **x 1** . When it is equal or wider than the generator–width, the score is calculated as **x 1.5**. Finally, if total score of steps 1–3 is ≥ 90 points and body mass index (BMI) is < 25 kg/m^2, 40 points are subtracted from the total score. Risk stratification for conversion failure based on the PRAETORIAN score is summarized in the box.

Fig. 2. The PRAETORIAN score in the study patients. The PRAETORIAN score was 30 points in 77 patients, 45 points in 2 patients, 60 points in 14 patients, and 90 points in 7 patients, respectively. Ninety–three patients were classified as low risk, and the remaining 7 patients were as intermediate risk.

Fig. 3. Comparison of inappropriate shock rates between the Thinner (blue line) and Thicker (red

line) sub–coil fat depth groups. There was no significant difference between the two groups.

Table 1. Baseline characteristics of the study patients

Clinical characteristics	
Age, years	59 (46.5–67.0)
Male gender, n (%)	78 (78)
Height, cm	165 (159–171)
Body weight, kg	65.7 (58.6–74.2)
Body mass index, kg/m^2	24.2 (21.3–27.2)
Left ventricular ejection fraction, %	47.5 (34.2–62.6)
Sinus rhythm, n (%)	91 (91)
Primary prevention indication, n (%)	36 (36)
Underlying heart diseases	
Coronary artery disease, n (%)	36 (36)
Hypertrophic cardiomyopathy, n (%)	15 (15)
Brugada syndrome, n (%)	11 (11)
Idiopathic ventricular fibrillation, n (%)	10 (10)
Dilated cardiomyopathy, n (%)	8 (8)
Non–ischemic cardiomyopathy, n (%)	5 (5)
Cardiac sarcoidosis, n (%)	3 (3)

Arrhythmogenic right ventricular cardiomyopathy, n (%)	3 (3)
Idiopathic ventricular tachycardia, n (%)	2 (2)
Drug–induced cardiomyopathy, n (%)	2 (2)
Valvular heart disease, n (%)	2 (2)
Others, n (%)	3 (3)
PRAETORIAN score	
Low risk: < 90	93 (93)
Intermediate risk: 90–149	7 (7)
High risk: ≥ 150	0 (0)

Data are shown as median (IQR) or n (%).

Table 2. Comparison of the characteristics between the Thicker group and the Thinner group

Variable	Thicker group (> 1 coil width) n=19	Thinner group (≤ 1 coil width) n=81	p value
Age, years	59 (52–67)	59 (46–69)	0.089
Male sex, n (%)	15 (79)	63 (78)	0.912
Height, cm	163 (159–168)	166 (160–173)	0.130
Body weight, kg	73.0 (64.6–81.0)	65.0 (56.8–71.7)	0.004
BMI, kg/m^2	27.1 (25.6–31.6)	23.1 (20.9–25.7)	<0.001
LVEF, %	34.3 (28–63)	50 (36.7–62.2)	0.104
Shock impedance, Ω	75 (68–88)	63 (55–74)	0.003
Time to therapy, sec	13.2 (12.4–15.0)	13.2 (12.4–14.8)	0.882

Data are shown as median (IQR) or n (%). BMI indicates body mass index, LVEF; left ventricular ejection fraction.

Table 3. The sensitivity and specificity of the PRAETORIAN score for the conversion failure

	Conversion failure (n=0)	Conversion success (n=83)
Intermediate risk (n=5)	0	5
Low risk (n=78)	0	78

Figure 1

Step 1 : Thickness of sub-coil fat

≤ 1	coil width	**30**
> 1 ≤ 2	coil widths	**60**
> 2 ≤ 3	coil widths	**90**
> 3	coil widths	**150**

Step 2 : Generator position relative to mid-axillary line

On or posterior of the midline	**× 1**
Anterior of the midline	**× 2**
> 1/2 length anterior	**× 4**

Step 3 : Amount of sub-generator fat

< 1 generator width	**× 1**
≥ 1 generator width	**× 1.5**

Step 4 : Total score of Step 1-3 ≥ 90 and BMI ≤ 25 kg/m^2 **-40**

Final PRAETORIAN score	
< 90	Low risk
Between 90 and 149	Intermediate risk
≥ 150	High risk

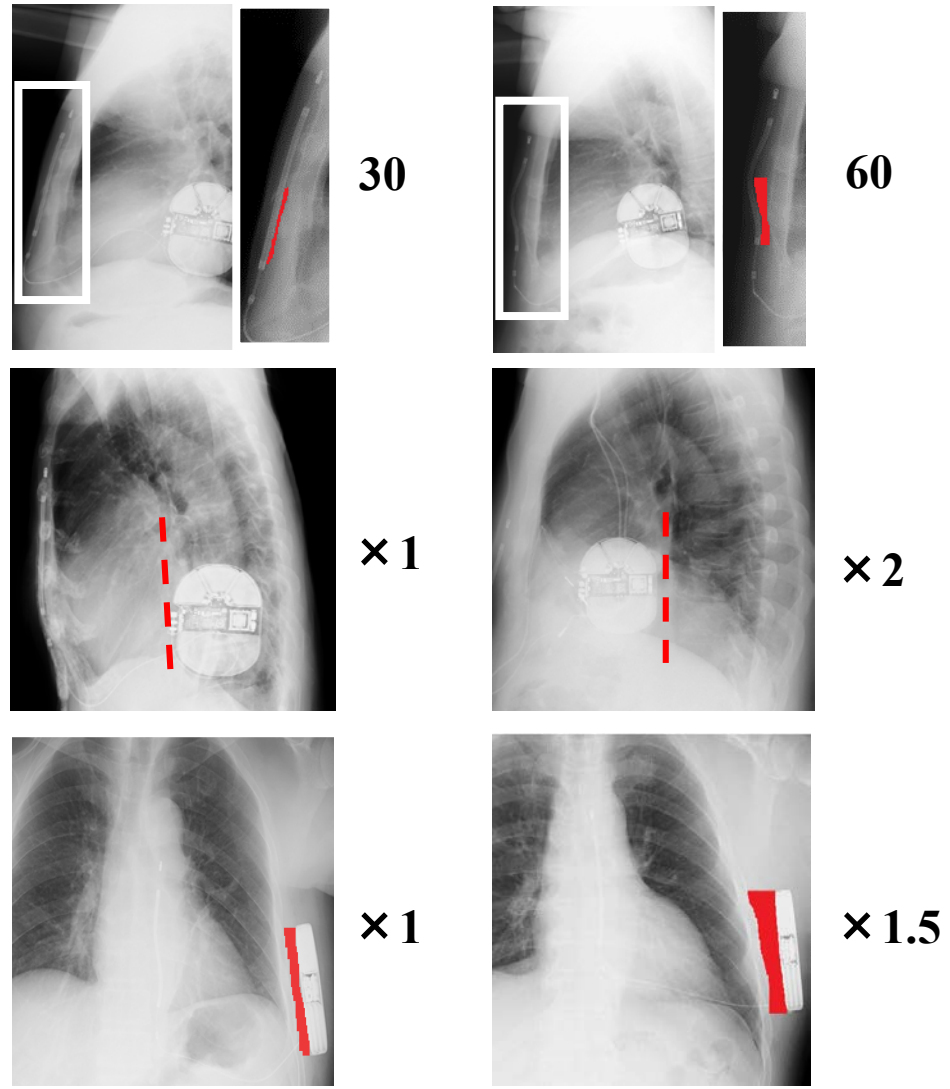
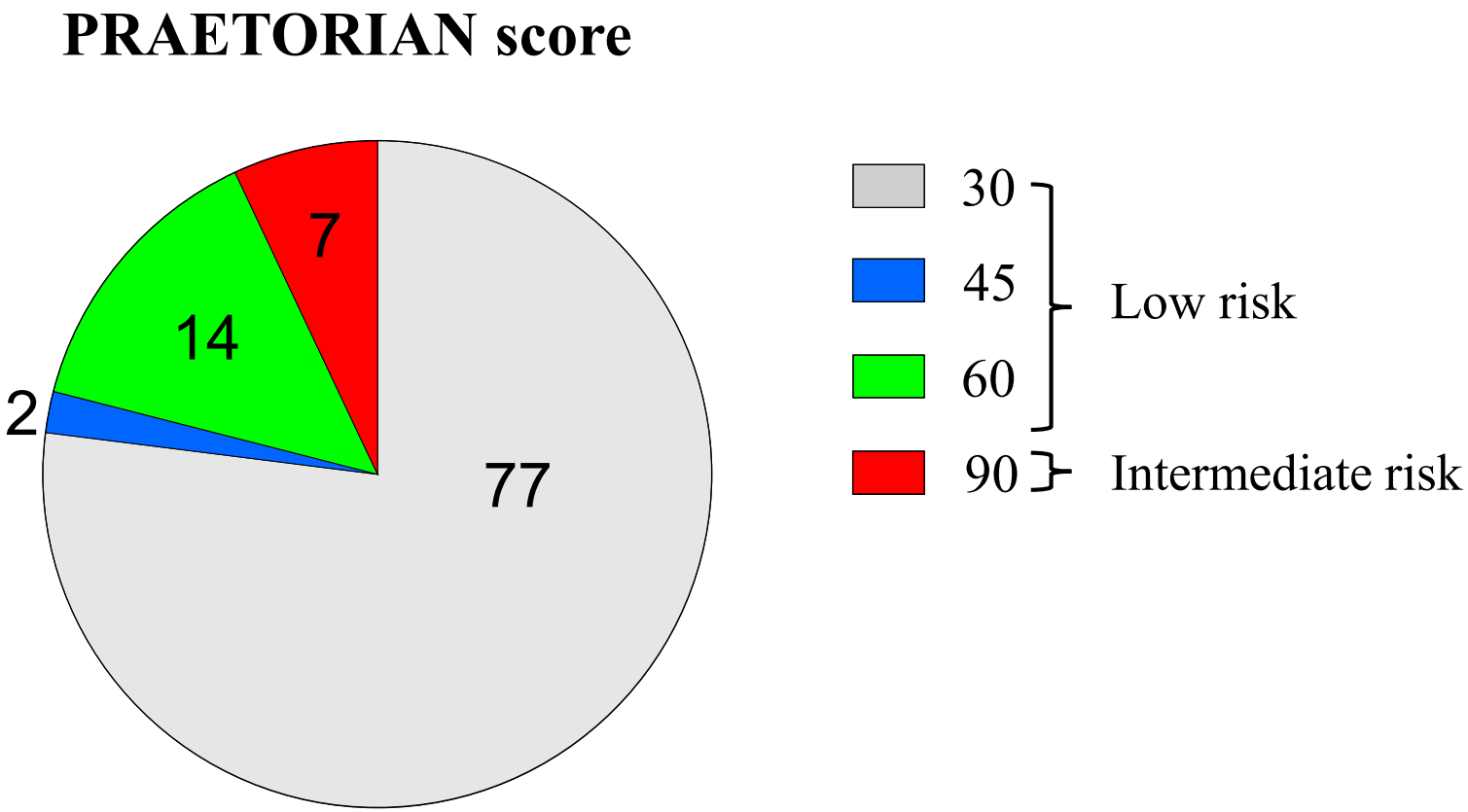


Figure 2


PRAETORIAN score
7
14
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77
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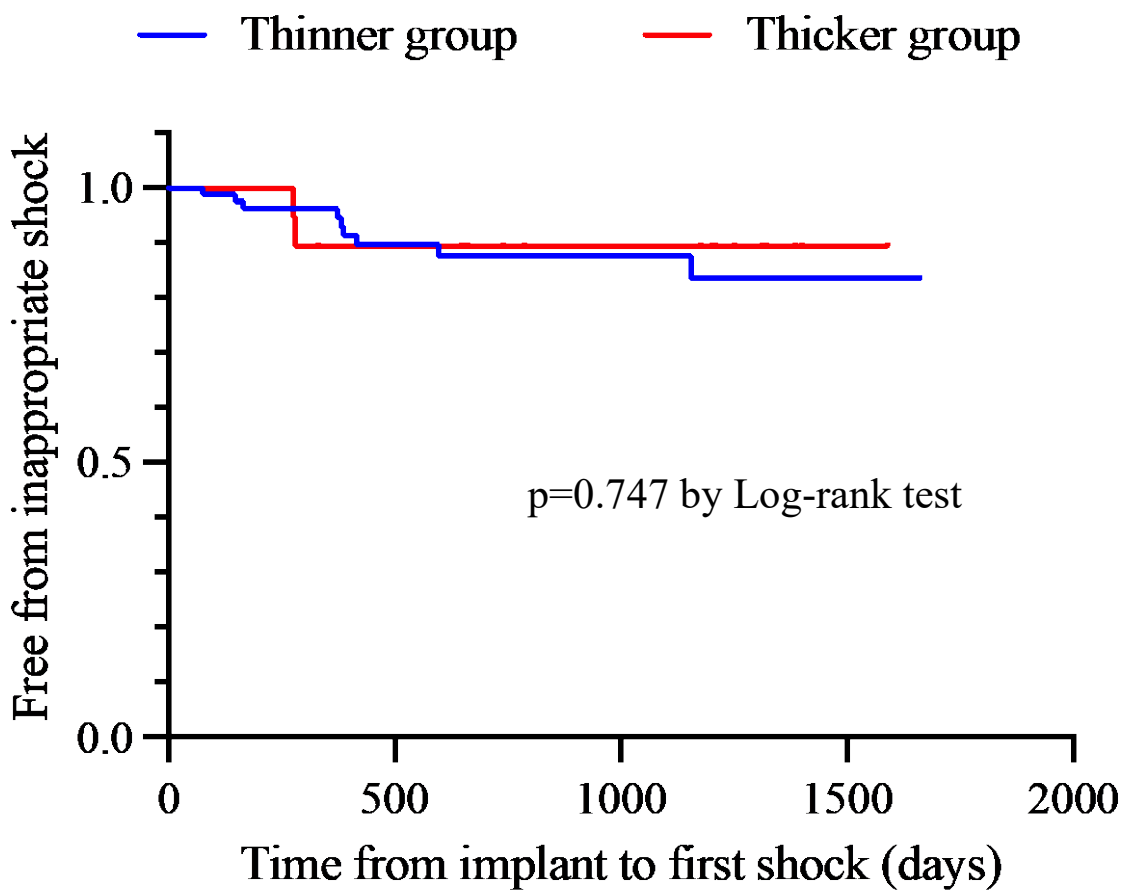
45
60
90
Low risk
Intermediate risk

Figure 3



Number at risk

Thinner group	81	50	32	8	2
Thicker group	19	16	10	2	1