心房細動に対するカテーテルアプレーションにおける fluoroscopy image integration module 導入前後の放射線被ばくと手技時間の比較

学位論文

Comparing radiation exposure and procedure time before and after a fluoroscopy image integration module installation for atrial fibrillation ablation

琉球大学大学院医学研究科　医学専攻

矢島　真知子

Title: Comparing radiation exposure and procedure time before and after a fluoroscopy image integration module installation for atrial fibrillation ablation

Running Head: Fluoroscopy image integration module for AF ablation

Names of Authors:

Machiko Yajima [1) 2)], Shinya Shiohira [3)], Shoichiro Yamazato [3)], Kojiro Furukawa [1)]

Affiliations:

1) Department of Thoracic and Cardiovascular Surgery, Graduate School of Medicine, University of the Ryukyus

2) Department of Clinical Engineer, University of the Ryukyus Hospital

3) Department of Cardiovascular Medicine, Nephrology and Neurology, Graduate School of Medicine, University of the Ryukyus

Name and address of the author responsible for correspondence: Machiko Yajima

207 Uehara, Nishihara, Okinawa, 903-0215, Japan

TEL/FAX: +81(98)895-1363 / +81(98)895-1489

E-mail Address: yajiyajime@yahoo.co.jp

Abstract

Catheter ablation (ABL) for atrial fibrillation (AF) remains a complex procedure and may require long fluoroscopy time. Further time reduction is necessary. We conducted a retrospective, observational, cross-sectional, single-center study to compare procedure time and radiation exposure before and after fluoroscopy image integration module (IIM) installation for AF between April 2018 and October 2020. We reviewed 236 consecutive patients who underwent ABL at University of the Ryukyus Hospital. We performed ABL for AF for 81 patients (before IIM installation), 67 patients (after IIM installation). We analyzed 68 patients as non-IIM group, 56 patients as IIM group who underwent pulmonary vein isolation (PVI) and cavotricuspid isthmus (CTI) ABL for AF after the exclusion of patients with additional ABL. The procedure time, fluoroscopy time, and radiation dose were considered between both groups. The median PVI procedure time (1.50 [interquartile range {IQR} 1.20–1.83]h vs. 1.33 [IQR 0.91–1.50]h; $P<0.05$), total fluoroscopy time (36.6 [IQR 24.2–55.8]min vs. 24.0 [IQR 18.0–35.4]min; $P<0.05$), and radiation dose (125.73 [IQR 73.92–217.04]mGy vs. 77.58 [IQR 48.62–122.90]mGy; $P<0.05$) in the IIM group were significantly lower than those in the non-IIM group. The use of IIM resulted in shorter procedure time and less radiation exposure in ABL for AF.

Key Words: Radiation exposure, Procedure time, Atrial fibrillation, Pulmonary vein isolation, cavotricuspid isthmus

INTRODUCTION

Atrial fibrillation (AF) is the most common clinically significant arrhythmia in clinical practice[1]. The estimated number of patients with AF in Japan is one million[2]. In AF treatment, catheter ablation (ABL) has become a standard therapy. Pulmonary vein isolation (PVI) is considered the standard procedure for ABL of AF in symptomatic patients[3].

Paroxysmal AF (PAF) is mainly triggered by focal firing originating at the ostium of the pulmonary vein (PV). The success rate after PVI for PAF was reported to be 80%–90%[4, 5], and PVI also exerts a beneficial effect on persistent AF (PEF) with light processing remodeling[6]. Moreover, atrial tachycardia involving cavotricuspid isthmus (CTI) often occurs after PVI for AF[7, 8]. Therefore, we have been simultaneously performing PVI and CTI block line in ABL for AF, regardless of clinically documented right atrial flutter.

The procedure time and radiation exposure during ABL for AF has gradually decreased because of the advancement of ABL technology and development of ABL techniques[9-14]. Recently, several studies have addressed the efficacy of the reduction of radiation exposure in ABL for AF using a three-dimensional electro-anatomical mapping system (3D-EAM) with fluoroscopy image integration module (IIM)[15, 16]. However, to our knowledge, no clinical studies have investigated cases simultaneously performed PVI and CTI block line for AF.

This study aimed to evaluate radiation time and dose and procedure time before and after IIM

installation for AF.

MATERIALS and METHODS

Study design and Patient

We conducted a retrospective, observational, cross-sectional, single-center study to compare procedure time and radiation exposure before and after IIM installation for AF. We reviewed 236 consecutive patients who underwent ABL at University of the Ryukyus Hospital. Between April 2018 and October 2020, information about the ABL data and patient characteristics was obtained from a review of records. We performed ABL for 116 patients before IIM installation (April 2018 - August 2019), and for 120 patients after IIM installation (September 2019 - October 2020). Of the 116 patients who underwent ABL before IIM installation, 81 were performed ABL for AF because of the diagnosis with PAF or PEF. PAF was defined as episodes that return to sinus rhythm within 7 days after onset, and PEF was defined as episodes that last longer than 7 days. Of the 120 patients who underwent ABL after IIM installation, 67 were who performed ABL for AF because of the diagnosis with PAF or PEF. We analyzed 68 patients as non-IIM group who simultaneously underwent only PVI and CTI ABL in the ABL for AF, 56 patients as IIM group who simultaneously underwent only PVI and CTI ABL in the ABL for AF. Patients with additional ABL (superior vena cava isolation, left atrium (LA) roof line, etc.) were excluded in both groups (Fig 1).

This study complied with the guidelines of the Declaration of Helsinki and was approved by the ethics committee of University of the Ryukyus for Medical and Health Research Involving Human Subjects (certificate number: 1660).

Outcome measure

We considered the following items between the IIM group and non-IIM group: 1) procedure time: preparation time (time from sheath insertion to ABL initiation), LA mapping time (time from post transseptal puncture [TP] to ABL initiation), PVI time, CTI time, total ABL time (PVI+CTI time), and in-out time (time from entering to exiting the catheter room); 2) fluoroscopy time: PVI fluoroscopy time (including the time of catheter insertion and TP, IIM registration, LA mapping), CTI fluoroscopy time, and total fluoroscopy time (PVI+CTI fluoroscopy time); and 3) radiation dose: PVI radiation dose (frontal, lateral), CTI radiation dose (frontal, lateral), and total radiation dose (frontal, lateral).

System

The 3D-EAM used was CARTO® 3 version 6 (Biosense Webster Inc., Irvine, CA, USA). The polygraph used was RMC5000 (Nihon Kohden, Tokyo, Japan). IIM was provided by the CartoUnivu™ module. The fluoroscopy system used was the Allura Xper FD10/10 biplane (Royal Philips, Eindhoven, the Netherlands). Pulse fluoroscopy rates were preprogrammed at 3.75 frames per second and programmed at 15 frames per second during TP for LA. A temperature probe (SensiTherm, Abbott Laboratories,

Chicago, IL, USA) in the esophagus at the level of the LA was used with the alert of limit 41°C.

ABL was performed by two operators (the second and the third author) with different levels of clinical experience. Their experience for ABL was 5 years and 10 years, respectively. The operation of CARTO® 3 was performed by only one operator (the first author) with 15 years of experience.

Operative procedure

SensiTherm was inserted under fluoroscopy before sterilization. All catheters were inserted via the right femoral vein, with the internal jugular vein used for difficult coronary sinus (CS) cannulation. Moreover, 4-Fr sheath was inserted via the right femoral artery to continuously monitor atrial pressure during allover procedures. The CS catheter used prior to TP was the BeeAT (Japan Lifeline Co., Ltd., Tokyo, Japan). TP was performed with 8.5-Fr long SL1 sheath (Abbott) and 8.5-Fr Agilis™ NxT steerable introducer (Abbott) with a BRK needle (Abbott). Furthermore, TP was performed with live X-ray and AcuNav™ ultrasound catheter (Biosense Webster). ABL was performed with the patient under sedation using continuous propofol infusion.

If AF was present in the beginning, electric cardioversion was performed to obtain sinus rhythm. Registration was conducted to introduce the ABL catheter and PENTARAY® (Biosense Webster) each into the right and left superior PVs with multiple view (Antero posterior, right anterior oblique 30 degree, left anterior oblique 55 degree) (Fig. 2). LA bipolar voltage amplitude was acquired using PENTARAY®. The reconstructed LA anatomies were merged with the reconstructed computed tomography model of

the LA using CartoMerge (Biosense Webster).

All patients underwent point-by-point circumferential ABL of the left and right PVs using radiofrequency (RF) energy delivered through an irrigated catheter (CARTO SMARTTOUCH™ SF, Biosense Webster). Power was maintained at 30 W, 20–30 s by force-time integral (FTI) in the non-IIM group, while power was maintained at 40 W on the anterior surface and 30 W on the posterior surface, at 25 W in front of the esophagus by ablation index (AI) in the IIM group. AI targets were 400 for the posterior wall and 450 elsewhere. All lines were validated with bidirectional block and non-excitability during local pace capture using a deflectable decapolar circular mapping catheter of variable diameters (Lasso® 2515 NAV Eco, Biosense Webster).

CTI block line was performed after PVI. Gap detection and line verification were performed using a decapolar catheter (Livewire™, Abbott). Power was maintained at 30 W, 20–30 s by FTI in the non-IIM group, while power was maintained at 40 W by 450 AI in the IIM group.

Statistical analysis

For baseline characteristics, continuous and categorical variables were expressed as mean ± standard deviation and absolute number (percentages), respectively. Procedure time, fluoroscopy time, and radiation dose were presented as median and interquartile range (IQR). The Mann–Whitney U test was used to compare the non-IIM and IIM groups. A P-value < 0.05 was considered statistically significant. All data were analyzed using JMP® 15 statistical software (SAS Institute Inc., Cary, NC, USA).

RESULTS

Patient characteristics

The clinical characteristics of the IIM group were as follows: mean age, 68.1 ± 10.7 years; 19 women (33.0%); 24 patients (42.3%) with symptomatic PAF. The baseline characteristics are summarized in Table 1. Although the PAF rate in the IIM group was significantly higher than it in the non-IIM group and number of women in the non-IIM group was significantly higher than it in the IIM group, there were no significant differences in patient characteristics between both groups, except for these variables.

Procedure-related complications were observed in one patient in each group. The two patients developed hematoma at the puncture site. There were no other complications (cardiac tamponade, air embolism, transient ischemic, attack, and arteriovenous fistula) between both groups.

Procedure time

PVI time (1.50 [IQR 1.20–1.83] h vs. 1.33 [IQR 0.91–1.50] h; $P<0.05$) and in-out time (4.01 [IQR 3.44–4.73] h vs. 3.50 [IQR 3.17–4.15] h; $P<0.05$) in the IIM group were statistically significantly shorter than those in the non-IIM group. However, there were no significant differences in preparation time (0.85 [IQR 0.72–65–1.10] vs. 0.75 [IQR 0.67–0.93]; $P = 0.05$), LA mapping time (0.53 [IQR 0.43–0.63] vs. 0.50 [IQR 0.43–0.63]; $P = 0.74$), and CTI time (0.40 [IQR 0.25–0.55] vs. 0.33 [IQR 0.21–0.58]; P =

0.17) between IIM and non-IIM group (Fig. 3).

Fluoroscopy time and radiation dose

The total fluoroscopy time (36.6 [IQR 24.2–55.8] min vs. 24.0 [IQR 18.0–35.4] min; P<0.05), PVI fluoroscopy time (24.6 [IQR 16.8–35.4] min vs. 17.4 [IQR 13.8–23.4] min; P<0.05), total radiation dose (frontal and lateral), PVI fluoroscopy time, CTI radiation dose (frontal and lateral), and PVI radiation dose (frontal and lateral) in the IIM group were statistically significantly lower than those in the non-IIM group. There was no significant difference in CTI fluoroscopy time between both groups. Detailed data are presented in Table 2.

DISCUSSION

Main findings

There was a significant decrease in the median PVI time from 1.50 to 1.33 h and PVI fluoroscopy time from 24.6 to 17.4 min, while there were not significant differences in CTI time and CTI fluoroscopy time between IIM and non-IIM group. This difference of PVI and CTI is thought to explain that PVI is higher ABL technique and more necessary of fluoroscopy than CTI. It is our firm belief that the result of this study indicates that ABL for AF using IIM could shorten the PVI time.

Despite reduction of CTI radiation dose in the IIM group, CTI time was not statistically significantly

shortened. This result can be attributable to the fact that CTI time is shorter than PVI time, while this result may show exposure reduction in CTI with IIM.

These results demonstrate a clinically significant reduction in radiation exposure of patients and staff, although we did not evaluate the learning curve that might affect procedure time and fluoroscopy time.

Previous studies

Huo et al.[15] reported that the median procedure time decreased from 1 h and 39 min to 1 h and 37 min and the fluoroscopy time decreased from 10 min and 42 s to 1 min and 45 s. Akbulak et al.[16] reported that the mean ablation time increased from 140.7 ± 27.8 to 140.8 ± 39.5 min but the fluoroscopy time decreased from 11.9 to 7.4 min. They addressed that the IIM technology could simply be integrated into the workflow of the electrophysiological procedure without prolonging the procedure time. The use of IIM also led to a significant overall reduction of the fluoroscopy time.

In this study, the overall procedure time in the IIM group shortened, although it was almost the same in the non to IIM group in previous studies. IIM is able to display the fluoroscopy information and 3D-EAM on the same monitor with a short registration process after initialization. Given the operator's eyes moving from monitor to monitor, we obtained the result of the shortened procedure time. Furthermore, it may be responsible for RF by AI. Several studies have recently addressed that PVI was achieved safely and RF by AI had shorter procedure time and fluoroscopy time compared to RF by FTI[17, 18].

According to the survey of the Japanese Catheter Ablation Registry of Atrial Fibrillation in 2017 in

Japan, the mean fluoroscopy time was 40.5 ± 26.3 min, and the mean in-out time was 3.1 ± 1.2 h. The Swedish Catheter Ablation Registry showed that the median procedure time was 3.0 h and the fluoroscopy time was 21 min in ABL for AF[19]. Casella et al.[20] reported that the median fluoroscopy time was 16 min in large-volume laboratory. Taken together, fluoroscopy time tended to be longer in Japan. Although the fluoroscopy time in our study was shorter than the average in Japan, we must put in a great deal of effort to significantly reduce radiation exposure.

Greater reduction in radiation exposure

There are three points for safe reduction of radiation exposure in fluoroscopy: 1) as low as reasonably achievable, 2) to avoid blind procedure, and 3) thinking before use fluoroscopy. On the contrary, considering why the operators use fluoroscopy, it can be accounted for in part by unreliability of the alternative system. In fact, the location of catheters was incorrect in the case of the longest fluoroscopy time due to the patient's extensive movements. Moreover, the case of the longest procedure time had the same reason. This indicates the most common weakness of 3D-EAM.

Despite the use of IIM, ABL requires live X-ray to determine the location of structures, except catheters (sheath, bone, heart shadow, etc.). We encountered a case of long fluoroscopy time where it was an extremely difficult for TP without live X-ray. This case had the longest preparation time in our study. Furthermore, there were some tricky cases with long fluoroscopy time for CS catheter insertion. Several studies have described the technique and technology for TP with near zero fluoroscopy, positioning

catheters, and ABL[21-24]. Furthermore, Miwa et al.[25] demonstrated that awareness on radiation exposure led to a significant reduction in fluoroscopy time and radiation dose. It could be still possible that the use of IIM will lead to a further reduction in the overall fluoroscopy burden by improvement of the procedure and provision of lectures to promote awareness of the technique.

Limitations

This study has several limitations. First, we only compared radiation exposure and procedure time, while we did not evaluate other factors (learning curve etc.) that might have affected to radiation exposure and procedure time. Second, this was a retrospective, observational, cross-sectional, a single-center study without long-standing experience on AF ABL. A relatively small number of patients were included. Third, we did not report dose area product. A more accurate evaluation of radiation dose could require dose area product.

CONCLUSION

The use of IIM resulted in shorter procedure time in ABL for PVI, and less radiation exposure in ABL for PVI and CTI.

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Legends for Tables and Figures

Table 1 **Patient characteristics**

Note: Values are given as mean ± SD or number (%). BMI: body mass index; PAF: paroxysmal atrial fibrillation.

Table 2 **Fluoroscopy time and radiation dose**

Note: Values are given as median (interquartile range). IIM: group with fluoroscopy image integration module; non-IIM: group without fluoroscopy image integration module; PVI: pulmonary vein isolation; CTI: cavotricuspid isthmus; F: frontal fluoroscopy; L: lateral fluoroscopy.

Fig. 1 **Flowchart of patients analyzed in the study**

ABL: catheter ablation; IIM: fluoroscopy image integration module; AF: atrial fibrillation; PVI: pulmonary vein isolation; CTI: cavotricuspid isthmus.

Fig. 2 **Registration**

Registration was conducted to introduce the ablation catheter and PENTRAY® each into the right and left superior pulmonary venous with multiple view. (A) Antero posterior view. (B) Right anterior oblique 30 degree. (C) Left anterior oblique 55 degree.

Fig. 3 **Procedure time differences between the IIM and non-IIM groups**

For PVI time, total ABL time, in-out, procedure time in the IIM group was statistically significantly shorter than those in the non-IIM group. IIM: fluoroscopy image integration module; LA: left atrium; ABL: catheter ablation; PVI: pulmonary vein isolation; CTI: cavotricuspid isthmus.

略語対応表

略語	
ABL	catheter ablation
AF	atrial fibrillation
AI	ablation index
CS	coronary sinus
CTI	cavotricuspid isthmus
FTI	force-time integral
IIM	fluoroscopy image integration module
IQR	interquartile range
LA	left atrium
PAF	paroxysmal atrial fibrillation
PEF	persistent atrial fibrillation
PVI	pulmonary vein isolation
RF	radiofrequency
TP	transseptal puncture
3D-EAM	three-dimensional electro-anatomical mapping system

Table 1 **Patient characteristics**

	non-IIM (n=68)	IIM (n=56)
Age (years)	65.3±12.0	68.1±10.7
Gender: female	16 (23.5%)	19 (33.0%)
Height (cm)	163.6±9.4	162.9±8.8
Weight (kg)	69.4±15.9	64.6±13.2
BMI	25.7±4.3	24.2±3.8
Diagnosis: PAF	38 (55.9%)	24 (42.3%)

Table 2 **Fluoroscopy time and radiation dose**

		non-IIM (n=68)	IIM (n=56)	*P*
Fluoroscopy time (minutes)	Total	36.6 (24.2-55.8)	24.0 (18.0-35.4)	< 0.05
	PVI	24.6 (16.8-35.4)	17.4 (13.8-23.4)	< 0.05
	CTI	7.2 (3.0-10.8)	4.8 (3.0-9.0)	0.13
Radiation dose (mGy)	Total (F)	125.73 (73.92-217.04)	73.73 (48.17-122.92)	< 0.05
	Total (L)	150.36 (76.36-251.54)	80.43 (38.84-150.95)	< 0.05
	PVI (F)	93.73 (59.98-165.72)	56.52 (42.39-91.71)	< 0.05
	PVI (L)	95.35 (57.31-182.08)	52.59 (31.09-98.28)	< 0.05
	CTI (F)	17.62 (7.11-30.41)	8.01 (5.12-18.44)	< 0.05
	CTI (L)	23.59 (10.66-61.43)	9.89 (4.83-24.10)	< 0.05

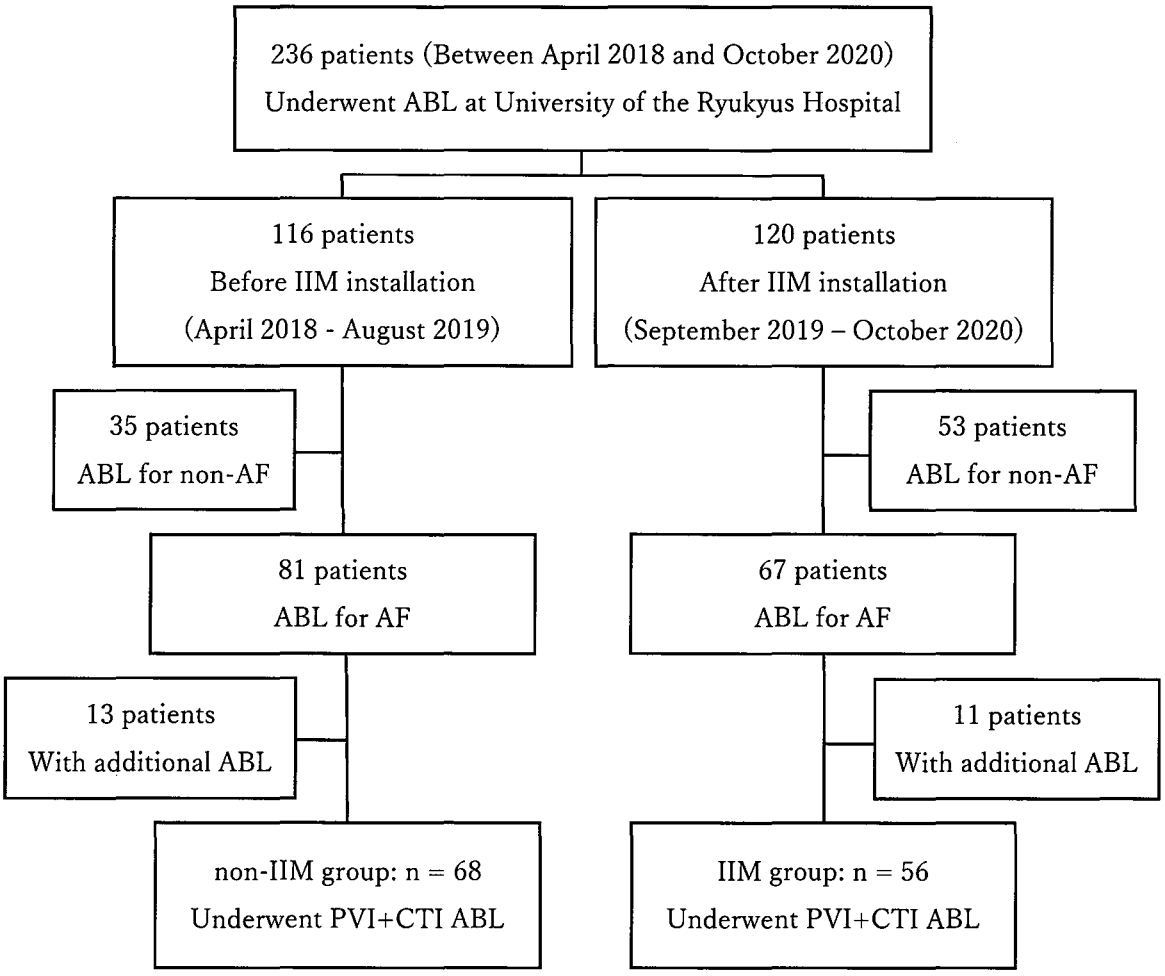

Fig.1 **Flowchart of patients analyzed in the study**

Fig. 2 **Registration**

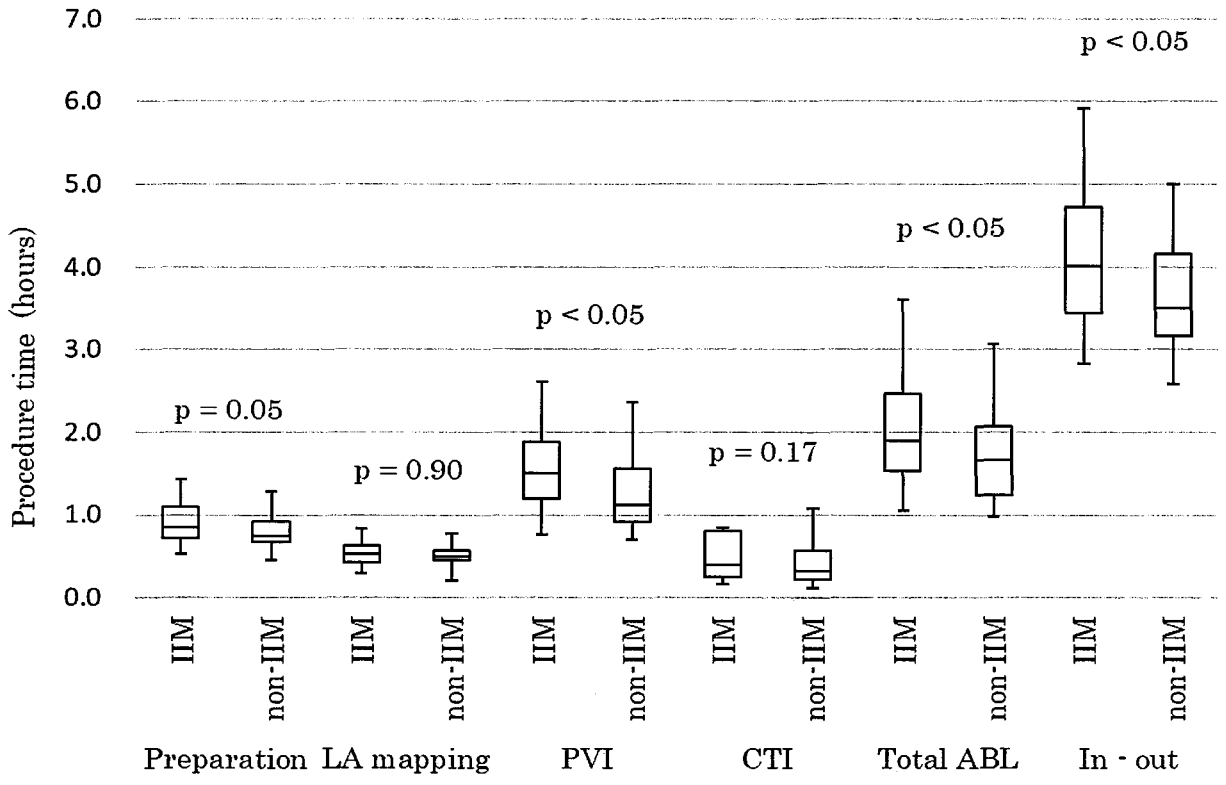

Fig. 3 **Procedure time differences between the IIM and non-IIM groups**