Safety and Feasibility of Intravascular Ultrasound-Guided Robotic

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Abstract

Purpose

Previous studies have demonstrated the benefit of intravascular ultrasound (IVUS)-guided percutaneous coronary intervention (PCI) for preventing longitudinal geographic miss (LGM). However, it is yet unclear whether IVUS guidance is useful for robotic PCI (R-PCI). This retrospective observational study sought to compare expected stent landing positions between IVUS and angiography.

Methods

A total of 58 consecutive patients with stable angina who underwent IVUS-guided R-PCI was enrolled. The stent landing position was angiographically marked using a balloon marker before stenting followed by measurements of the expected stent length using balloon pullback. Subsequently, pre-stenting IVUS was performed to determine stent landing. All pre-PCI IVUS images were assessed for lesion length and percent plaque volume (%PV) using both IVUS and angiographic marking. LGM was defined as a residual %PV > 50% at either the distal or proximal stent edge, any stent edge dissection, and/or additional stent deployment immediately after stenting. Major adverse cardiac events were assessed at the 6-month follow-up.

Results

The included patients, 41 of whom were male, had an average age of 67.1 ± 10.1 years. IVUS guidance had significantly longer lesion lengths compared to angiographic marking. Based on IVUS-guided stent deployment, 9 cases exhibited LGM immediately after stenting. IVUS-marked landing points had a significantly smaller %PV and significantly larger LA compared to those for angiography. No adverse cardiac events were noted during the 6-month follow-up.

Conclusion

IVUS-guided R-PCI was safe and may be better at preventing LGM compared to angiography-guided R-PCI.

1. Introduction

Robot-assisted percutaneous coronary intervention (R-PCI), an innovative technological development introduced in 2005 [1], can reduce surgeon exposure to radiation given that it allows for treatment from a distance[2] and has been utilized for chronic total occlusions and more complex lesions[3] [4]. Although several reports have highlighted the benefits of R-PCI for surgeons, only a few have focused on its advantages for patients[5] [6]. The robotic PCI system (CorPath GRX, Corindus Vascular Robotics, USA) allows for safe wiring, accurate lesion length measurement using the balloon marker pullback system, and accurate stent deployment with millimeter unit precision. By taking advantage of these features, R-PCI promoted significantly lower incidences of longitudinal geographic miss (LGM) compared to

standard manual PCI, which could potentially improve long-term clinical outcomes through reduced major adverse cardiac events (MACEs) [7]. Considering that R-PCI has shown excellent results in terms of reducing LGM, we hypothesized that intravascular ultrasound (IVUS) guidance would promote even better results. Furthermore, one study showed that precise measurement of robotic lesion length prevented the use of extra stents in 8.3% of the cases [8]. In the era of drug-eluting stents (DES), studies have recommended full lesion coverage to prevent angiographic restenosis and determination of optimal longitudinal stent position associated with clinical outcomes [9]. Accordingly, evidence has shown that IVUS guidance can be expected to reduce target-vessel revascularization (TVR) and myocardial infarction (MI) by reducing LGM and stent underexpansion [10][11][12]. Similarly, R-PCI has been found to be safer and more feasible when combined with IVUS guidance. Unfortunately, only a few reports have been available regarding IVUS-guided R-PCI. Thus, the current study sought to determine whether differences in marking positions exist between IVUS- and angiography-guided R-PCI.

2. Methods

This retrospective, single-center, observational study compared the marking positions of IVUS- and angiography-guidance before stenting. Subjects were selected from 58 consecutive patients with stable angina who underwent R-PCI at our institution between June 2019 and June 2020. Patient inclusion criteria were age ≥ 18 and stable ischemic coronary disease (effort angina or silent myocardial ischemia), which is the clinical indication for PCI with drug-eluting stent. Exclusion criteria were as follows: (1) known severe coronary calcification, (2) acute coronary syndrome, (3) tortuous artery preventing IVUS catheter passage, (4) chronic total occlusion, (5) bypass graft stenosis, and (6) in-stent restenosis treated with drug-coated balloon without stent deployment (two cases). This study was approved by the institutional review board of our hospital, and eligible patients provided written informed consent prior to participation (MH2020-132).

2.1 IVUS and quantitative coronary angiography analysis

IVUS was performed according to Judkin's technique via the trans-radial approach using a 6-Fr system. The present study used the VISIWAVE™ imaging system with the AltaView™ imaging catheter (Terumo Corporation, Tokyo, Japan) or the I-Lab™ imaging system with the OptiCross™ imaging catheter (Boston Scientific, Boston Scientific Way, Marlborough, MA, USA). After inserting a 0.36-mm intervention guide wire, the imaging catheter was carefully advanced distal to the target lesion under fluoroscopic guidance.

Each surgeon visually estimated the lesion length before PCI with reference to the coronary angiography findings (Step 1). Angiographical marking of stent landing position by the robotic system using a balloon marker pullback system was performed before stenting, after which expected stent length was measured (Step 2). Subsequently, the surgeon performed pre-PCI IVUS to determine the stent landing position (Step 3: Figure 1). IVUS measurements were obtained using the conventional manual method and not integrated into the robotic PCI system. The stent length was based on the gold standard for manual IVUS measurements [13]. All pre-PCI IVUS images were assessed for lesion length and percent plaque volume

(%PV) estimated using IVUS marking vs. angiographic marking. Post-PCI IVUS images were assessed for %PV, lumen area at the proximal and distal stent margin, and minimum stent area.

LGM was defined as a residual %PV > 50%, coronary dissection, and/or additional stent deployment immediately after stenting. An average of five frames (estimated landing point $\pm$ 2 mm, proximal and distal, Figure 2) for %PV and lumen area (LA) were used to compare IVUS and angiographic guidance. Estimated landing points were determined by measuring the distance from the ostium and/or major branch using the robotic balloon pullback system and quantitative coronary angiography (QCA) program. An average of five frames were utilized to correct for measurement discrepancies between angiography and IVUS.

IVUS analysis was performed using Echo plaque 4.0 IVUS imaging software (INDEC systems, Santa Clara, CA, USA) by two experienced observers (T.K and Y.K) not involved with PCI. Images were evaluated and interpreted through discussions between both experienced observers. The target lesion was defined using a stent landing segment with a 5-mm addition to both proximal and distal sides.

MACEs [a composite of death, myocardial infarction without creatine kinase-myocardial band (CK-MB) elevation after PCI, and target vessel revascularization] were assessed at the 6-month follow-up after PCI.

The target lesion was analyzed using QCA on a QCA-CMS system version 7.1 (Medis Medical Imaging Systems, Leiden, The Netherlands) using the external diameter of the contrast-filled guiding catheter as the calibration standard. Minimal lumen area, lesion length, percent diameter stenosis, and reference diameter were measured using QCA-CMS. Percent diameter stenosis was calculated from the minimal lumen diameter and reference diameter. However, given that QCA and IVUS analyses were performed by independent core laboratory personnel at our facility, data analysis may not have impeccable accuracy.

2.2 Statistical analysis

All statistical analyses were performed using SPSS Ver. 22 for Windows (Chicago, IL, USA). Continuous values were presented as mean $\pm$ standard deviation. Categorical variables were presented as counts and percentages. The paired-samples Student t-test was used to compare differences in %PVs and minimum lumen areas between angiography- and IVUS-guided PCI. Pearson's correlation coefficient (r) was calculated to determine the relationship between visually estimated, robotically measured lesion length, and finally deployed stent length. Differences were considered significant at $p < 0.05$.

3. Results

Baseline clinical characteristics are summarized in Table 1. Accordingly, the included patients had average age of 67.1 ± 10.1 years, with the majority being male (71%). The prevalence of diabetes was 44%, similar to that reported in other studies [14][15]. Relatively high incidences of hypertension (85%) and dyslipidemia (95%) were observed. The baseline lesion and interventional characteristics are detailed in Table 2. Lesions fulfilling the definition of the American College of Cardiology/American Heart

Association type B2/C were treated in 79% of the patients. The mean number of stents implanted was 1.2 ± 0.4 , with the average stent length and diameter being 25.9 ± 7.8 mm and 3.0 ± 0.4 mm, respectively. The total procedure time was 52.7 ± 24.9 min, and the total contrast media volume was 70.4 ± 21.0 mL. The lesion length measured by the precise robotic balloon pullback system with angiography was 21.0 ± 8.8 mm.

The QCA parameters are provided in Table 3. Thrombolysis in Myocardial Infarction grade 3 flow was achieved in 100% of patients after R-PCI. The angiographic reference diameter was 2.7 ± 0.4 mm after the procedure. The stent length measured via QCA was 25.0 ± 10.8 mm.

The IVUS parameters are summarized in Table 4. The lesion length measured via quantitative IVUS analysis was 25.7 ± 9.40 mm and was significantly longer than that measured via angiographic marking ($p < 0.001$). For pre-stent IVUS parameters, %PV measured at IVUS-marked landing points were significantly smaller than that measured via angiography at both proximal and distal points (IVUS vs. angiography: proximal $45.3\% \pm 9.86\%$ vs. $49.9\% \pm 12.7\%$, $p < 0.001$; distal $40.8\% \pm 8.86\%$ vs. $47.2\% \pm 12.6\%$, $p < 0.001$; Table 4 and Figure 3). However, lumen area measured at IVUS-marked landing points were significantly larger than that measured using angiography (IVUS vs. angiography: proximal 7.02 ± 2.36 mm² vs. 6.05 ± 2.17 mm², $p < 0.001$; distal 5.26 ± 2.50 mm² vs. 4.83 ± 2.44 mm², $p < 0.001$; Table 3 and Figure 4). After stent placement, the minimum stent area was 5.79 mm², with %PV and LA at the proximal margin being larger than those at the distal margin.

Incidences of LGM are presented in Table 4. Accordingly, 6 cases exhibited residual %PV > 50% at the stent landing points, while 3 cases exhibited stent edge dissection detected via IVUS. None of the cases required additional stent deployment after planned stenting. Based on our retrospective analysis, 9 cases (15.5%) developed LGM.

A significant correlation was observed between lesion lengths measured robotically and via IVUS ($r = 0.514$, $p < 0.0001$, Figure 5). A representative case in which a large difference in lesion length was observed between angiography and IVUS measurement (Figure 1) involved a 53-year-old male with effort angina due to proximal right coronary artery stenosis. In the mentioned case, angiography-marked and IVUS-guided lesion lengths were 10.5 and 38 mm, respectively. Angiography-marked landing points had larger %PV (proximal point, 63%; distal point, 64%) and smaller minimum lumen area (MLA) (proximal point, 5.6 mm²; distal point, 5.7 mm²) compared to those marked via IVUS (%PV: proximal point, 42%; distal point, 40%; MLA: proximal point, 8.0 mm²; distal point, 7.8 mm²). No adverse cardiac events occurred during the 6-month follow-up.

4. Discussion

The present study comprehensively examined IVUS and angiography assessment to determine the utility of IVUS guidance for robotic PCI. The following are the remarkable findings obtained herein: (1) IVUS guidance had a significantly longer measured lesion length compared to angiographic guidance; (2) after

IVUS-guided PCI, 9 cases (15.5%) developed LGM immediately after stenting; (3) %PVs were significantly smaller and lumen areas were significantly larger in IVUS-guided landing point. Based on the aforementioned results, IVUS guided robotic PCI might be feasible and useful to avoid LGM.

4.1 Conventional angiography marking versus IVUS marking with R-PCI

Several reports have compared angiography- and IVUS-guided PCI, with their results suggesting that the latter resulted in longer lesion and stent lengths [16][17][18][19], a finding consistent with that presented herein. The results of the TULIP study demonstrated that the IVUS guidance group had significantly longer stent length (IVUS guidance: 45 ± 11 mm; angiographic guidance: 35 ± 11 mm), and higher average number of the deployed stents (IVUS guidance: 1.4 ± 0.6 ; angiographic guidance: 1.1 ± 0.4) [17]. In the current study, majority of the cases (46, 79%) were classified as ACC/AHA type B2/C, a lesion background close to that observed in real-world settings [9][15][20].

With the recent widespread utilization of DES, IVUS guidance can be expected to reduce stent thrombosis and cardiac death in complex lesions [21][22][23]. Furthermore, IVUS guidance has been shown to reduce not only stent thrombosis after PCI but also MI, target lesion revascularization (TLR), and TVR in various patients, including those with ACS [24]. Compared to conventional R-PCI, IVUS-guided R-PCI is expected to provide more accurate stent placement and improve patient outcomes. Notably, a previous study demonstrated that robotic assistance promoted lesser LGM and significantly fewer subsequent MACEs compared to manual PCI [7]. Despite the large number of cases in the previous study, two limitations stand out: (1) all studies were performed with angiographic-guidance and (2) the definition of LGM was not specific and objective, meaning that “the lesion was not entirely covered by the stent”. Although propensity score matching was adopted, the aforementioned study had a relatively shorter mean lesion length (13.4 mm) and slightly lower prevalence of ACC/AHA type B2/C (31.7%) compared to the present study (79.3%), suggesting a fairly low lesion difficulty. In contrast, the present study included cases whose lesion length and difficulty were close to those observed in real-world populations. Moreover, our definition of LGM via IVUS analysis was objective and may be more reliable. Another study comparing MACE between robotic and manual PCI (M-PCI) at 6 months and 1 year in more complex lesions found no difference between both groups [4]. While the forementioned study had a mean lesion length of 22.2 mm and a 79% prevalence of type B2/C cases, which is close to that observed in real-world populations, their MACE at 1 year was 7.8% and 8.1% in the R-PCI and M-PCI groups, which indicated no significant difference. Despite the limited number of patients, the lack of a difference in patient outcomes compared to M-PCI suggests that R-PCI can be used safely for complex lesions.

The CorPath GRX Robotic PCI System (Corindus Vascular Robotics, Waltham, MA) has been reported to require no additional stents in 8.3% (5 of 60) of patients owing to accurate stent positioning [8]. The aforementioned study, which compared the visual stent length estimation with the stent length measured by the robotic system, showed that 35% (21/60) of the visually estimated lesions resulted in accurate stent length selection. The current study also compared the stent length measured visually and robotically. Although the robotically measured stent length was significantly longer than the visually

predicted length (21.8 vs. 19.7 mm, $p < 0.0001$, Table 2), a strong correlation had been noted between both groups ($r = 0.798$, $p < 0.0001$). Moreover, the lesion length measured using the robotic system was the only value that approximated the visual evaluation. We also determined the correlation between lesion length measured via the robotic system and the visually estimated lesion length or the finally deployed stent length based on IVUS measurement. Although both correlations were significant, the correlation coefficient was lower for the stent length after the final IVUS measurement (robotically measured lesion length vs. visually estimated lesion length: $r = 0.798$, robotically measured lesion length vs. deployed stent length based on IVUS measurement: $r = 0.514$). A certain number of plaque landings are inevitable with angiography guidance, regardless of the measurement and implantation accuracy afforded by robotic assistance. This suggests that IVUS guidance will still be needed in the era of robot-assisted PCI to cover occult plaques that may be overlooked with angiography guidance.

4.2 LGM of robotic PCI

Reports have shown that the presence of LGM can cause restenosis and increased TVR and MI after PCI. Accordingly, the STLLR study of the first-generation sirolimus-eluting stent showed that 47.6% of patients developed LGM and that those with LGM had greater TVR compared to those without LGM [10]. Moreover, an optical coherence tomography study of everolimus-eluting stents showed that lipid plaque volume and minimum lumen area immediately after stent implantation were reported to be predictors of stent edge restenosis, suggesting the importance of reducing LGM in second-generation DES as well [25]. Evidence has shown that the device placement accuracy of robotic PCI could be used to reduce LGM. In fact, one report found that LGM was reduced from 43.1% with manual surgery to 12.2% with robot-assisted systems, with a reduction in MACE also being observed [7]. In the present study, 9 cases (15.5%) ultimately developed LGM, a finding comparable to those in previous studies. The landing position estimated using angiographic guidance had a significantly higher plaque volume and smaller minimum lumen area compared to estimated using IVUS guidance. Had the stent been deployed according to angiography guidance, the increase in LGM may have caused subsequent TVR and/or in-stent restenosis. Despite the accuracy of robotic PCI, IVUS guidance may be able to further reduce LGM. Although IVUS measurements are performed manually in the current era of robotic systems, systems with automatic IVUS can be expected in the near future. Moreover, the combination of telemedicine and R-PCI allows the potential delivery of the primary PCI to remote locations, such as in medically depopulated areas, without transfer delays[26] [27].

Limitations

First, given the retrospective observational nature of this study, the findings presented herein should be interpreted with caution, and potential selection bias may be present. Second, considering the relatively small number of patients, the incidence of LGM and MACE may have been underestimated. Third, the single-arm design of the current study does not allow us to definitively conclude that IVUS-guided R-PCI was superior to angiography-guided approaches. Forth, given that the IVUS system has yet to be built into the robotic PCI system, it may not be strictly characterized as an IVUS-guided robotic PCI. Finally,

although detailed IVUS analysis was performed herein, further randomized controlled trial comparing IVUS- and angiography-guided R-PCI is necessary to evaluate the potential advantages of robotic assistance and IVUS guidance.

Conclusion

Intravascular-ultrasound guided robotic-PCI was safe and identified landing areas with smaller percentages of plaque and larger lumen areas, which may reduce the incidence of LGM compared to angiography-guided R-PCI.

Declarations

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Declarations: not applicable

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Tables

Table 1. Baseline clinical characteristics

	N = 58
Age (years)	67.1 ± 10.1
Male (%)	41 (71)
BMI (kg/m ²)	25.4 ± 5.6
Hypertension, n (%)	51 (89)
Diabetes, n (%)	25 (44)
Dyslipidemia, n (%)	56 (95)
Current smoker, n (%)	7 (12)
Previous cerebrovascular disease, n (%)	6 (11)
Atrial fibrillation, n (%)	7 (12)
eGFR (mL/min/1.73 m ²)	68.7 ± 14.4
Hemoglobin (g/dL)	13.4 ± 1.4
LDL-C (mg/dL)	88.4 ± 33.5
HDL-C (mg/dL)	51.8 ± 14.4
HbA1c (%)	6.4 ± 1.0

BMI, body mass index; eGFR, estimated glomerular filtration rate; LDL-C, low density lipoprotein-cholesterol; HDL-C, high-density lipoprotein-cholesterol.

Table 2. Lesion and interventional characteristics

	N = 58
Mean no. of diseased vessels	1.2 ± 0.5
Mean no. of stent use	1.2 ± 0.4
Visual estimated lesion length before PCI (mm)	19.7 ± 7.94
Lesion length measured by angiography (mm)	21.0 ± 8.89
Culprit location	
Left main coronary artery, n (%)	0 (0)
Left anterior descending artery, n (%)	32 (55)
Left circumflex artery, n (%)	14 (24)
Right coronary artery, n (%)	12 (21)
ACC/AHA lesion classification B2/C, n (%)	46 (79)
Total contrast media volume (ml)	70.4 ± 21.0
Total procedure time (min)	52.7 ± 24.9
Total radiation exposure dose (mSv)	0.6 ± 0.4

PCI, percutaneous coronary intervention; ACC, American College of Cardiology; AHA, American Heart Association

Table 3. Quantitative coronary angiography parameters

	N = 58
Pre stent	
TIMI grade n 3/2/1/0	52/5/1/0
Lesion length (mm)	26.6 ± 10.9
Reference diameter (mm)	2.52 ± 0.51
Minimum lumen diameter (mm)	0.88 ± 0.34
% diameter stenosis (%)	65.0 ± 9.8
Proximal margin	
Minimum lumen diameter (mm)	2.60 ± 0.57
% diameter stenosis (%)	8.66 ± 8.49
Distal margin	
Minimum lumen diameter (mm)	1.82 ± 0.55
% diameter stenosis (%)	10.1 ± 11.7
Post stent	
TIMI grade n 3/2/1/0	58/0/0/0
Stent length (mm)	25.0 ± 10.8
Reference diameter (mm)	2.73 ± 0.43
Minimum lumen diameter (mm)	2.42 ± 0.42
% diameter stenosis (%)	11.1 ± 9.1
Proximal margin	
Minimum lumen diameter (mm)	2.74 ± 0.53
% diameter stenosis (%)	12.1 ± 12.0
Distal margin (mm)	
Minimum lumen diameter (mm)	2.03 ± 0.45
% diameter stenosis (%)	11.1 ± 9.3

Table 4. IVUS assessment in IVUS marking vs. angiography marking

N = 58	Angio	IVUS	p
Pre stent			
Lesion length measured (mm)	21.0 ± 8.89	25.7 ± 9.4	<0.001
Proximal % plaque volume (%)	49.9 ± 12.7	45.3 ± 9.86	<0.001
Distal % plaque volume (%)	47.2 ± 12.6	40.8 ± 8.86	<0.001
Proximal lumen area (mm ²)	6.05 ± 2.17	7.02 ± 2.36	<0.001
IVUS guided distal lumen area (mm ²)	4.83 ± 2.44	5.26 ± 2.50	<0.001
Post stent			
% plaque volume at proximal margin (%)	NA	39.6 ± 7.58	NA
Lumen area at proximal margin (mm ²)	NA	7.90 ± 2.36	NA
Minimum stent area	NA	5.79 ± 1.97	NA
% plaque volume at distal margin (%)	NA	36.0 ± 8.57	NA
Lumen area at distal margin (mm ²)	NA	5.98 ± 2.71	NA

IVUS, intravascular ultrasound

Table 5. The incidence of longitudinal geographic miss (LGM)

	N = 58
Residual % plaque volume > 50%	6 (proximal: 2, distal: 4)
Stent edge dissection	3 (proximal: 2, distal: 1)
Additional stent deployment	0
Total LGM, n (%)	9 (15.5%)

IVUS, intravascular ultrasound.

After IVUS-guided PCI, LGM was observed in 9 cases (15.5%) immediately after stenting (% plaque volume > 50%, 6 cases; stent edge dissection, 3 cases; additional stent deployment, none).

Figures

Study flow chart with representative case

Figure 1

Study flow chart with a representative case. Step1: Visually estimated lesion length was determined by each surgeon before PCI with reference to the coronary angiography. Step 2: Angiographical marking of the stent landing position using the balloon marker pullback system was performed before stenting, after which the expected stent length was measured. Step 3: Finally, the surgeon performed pre-PCI IVUS to determine the stent landing position. Given that the IVUS system was not been built into the robotic system, IVUS measurements were performed using the conventional manual method. Representative case of a 53-year-old male with effort angina due to proximal right coronary artery stenosis who showed a large difference in lesion length between angiography (robotic) and IVUS measurements. Step 1, visually estimated lesion length was 10 mm. Step 2, angiography (robotic) guided lesion length was 10.5 mm. Step 3, the IVUS guided lesion length was 38 mm. The landing point estimated with angiographic guidance had a larger %plaque volume (%PV) (proximal point, 63%; distal point, 64%) and smaller minimum lumen area (MLA) (proximal point, 5.6 mm²; distal point, 5.7 mm²) compared to that with IVUS guidance (%PV: proximal point, 42%; distal point, 40%; MLA: proximal point, 8.0 mm²; distal point, 7.8 mm²).

Figure 2

The angiography-guided estimated landing point was measured using the precise robotic balloon pullback system, whereas the IVUS-guided estimated landing point used measured using manual IVUS maker pullback. An average of five frames (estimated landing point ± 2 mm, proximal and distal) for %PV and lumen area (LA) were used to compared IVUS with angiographic guidance.

Figure 3

Percent plaque volume (%PV) of IVUS-guided and angiography-guided robotic PCI. in the IVUS-guided landing point had a significantly smaller %PV (IVUS vs. angiography: proximal 45.3% $\pm$ 9.86% vs. 49.9% $\pm$ 12.7%, $p < 0.001$; distal 40.8% $\pm$ 8.86% vs. 47.2% $\pm$ 12.6%, $p < 0.001$).

Figure 4

Lumen area (LA) of IVUS- and angiograph-guided robotic-PCI. The IVUS-guided landing point had a significantly larger LA (IVUS vs. angiography: proximal 7.02 ± 2.36 mm² vs. 6.05 ± 2.17 mm², $p < 0.001$; distal 5.26 ± 2.50 mm² vs. 4.83 ± 2.44 mm², $p < 0.001$).

Figure 5

Correlation between robotic- and IVUS-measured lesion length ($r = 0.514$, $p < 0.0001$).