Enhanced stent visualization system for percutaneous coronary intervention in patients with chronic kidney disease: effects on contrast media volume and radiation exposure

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Research Article

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Abstract

Objective

We aimed to assess the impact of using enhanced stent visualization (ESV) systems on contrast media volume and radiation dose in percutaneous coronary intervention (PCI), especially for patients with chronic kidney disease (CKD).

Background

Coronary heart disease (CHD) is associated with chronic kidney disease (CKD) as they share the similar pathological pathway. In addition, the iodinated contrast media used for angiography is a risk factor for contrast-associated acute kidney injury (CA-AKI), which could aggravate the progression of CKD. We hypothesized that ESV systems have the potential to reduce the use of contrast media as well as radiation dose, however, few study reported the impact on contrast media with use of ESV systems.

Methods

We retrospectively collected 124 patients with acute coronary syndromes underwent PCI from May 2020 to July 2021. Patients were divided into ESV-guided group (n = 64) and angiography-guided group (n = 60). Procedural parameters including contrast media volume, radiation exposure (in Air Kerma), number of cines, cine frames, fluoroscopy and procedure time were recorded and analyzed.

Results

Groups were comparable for patient characteristics. A significant reduction in contrast media volume (174.7 ± 29.6 ml vs. 132.6 ± 22.3ml, p = 0.0001), radiation exposure (907.62 ± 534.94 mGy vs. 1316.11 ± 768.14 mGy, p = 0.002) and procedure time (53.06 ± 21.20 min vs. 72.00 ± 30.55min, p = 0.01) with the use of ESV systems. Similar results were observed in the subgroup analysis for the patients with CKD.

Conclusion

This study suggested that the use of ESV is associated with reduced contrast media usage, radiation dose and procedure time during PCI. The same results were observed in subgroup analysis in patients with CKD, which is of great significance in decreasing the occurrence of contrast-induced nephropathy and mitigating the progression of CKD and CHD.

Introduction

With the rapid development of urbanization, dramatic lifestyle changes and the accelerated aging of the population, the prevalence of coronary heart disease(CHD) in China has been continuously increasing annually, rising from 4.6‰ in 2003 to 10.2‰ in 2013(1). It is estimated that about 11 million patients are suffering from CHD in China, according to epidemic report of cardiovascular diseases in 2018 (2). To improve the survival rate and life quality for these patients, percutaneous coronary intervention (PCI) has been widely used in the treatment of CHD as a primary method of revascularization(3). Although patients benefit tremendously from this interventional treatment, iodinated contrast media, inevitably used for x-ray-based imaging, is typically associated with a risk of contrast-associated acute kidney injury (CA-AKI) (4). Additionally, hypertension, diabetes, dyslipidemia, and other risk factors for CHD are also common contributing factors for chronic kidney disease (CKD) as both CHD and CKD share the similar pathological pathways such as arteriosclerosis(5). CA-AKI, a risk modifier leading to the progression of CKD, may cause impaired outcomes in CHD and increased risk of prolonged hospitalization and early mortality(6, 7). On the other hand, radiation exposure has been a concerning problem for invasive cardiac procedures in last decade(8, 9). Reports showed that interventional cardiac procedures may lead to a high radiation dose for the patients and physicians, which potentially cause deterministic effects on their skin(10, 11). Therefore, how to reduce the need for contrast media and radiation exposure while ensuring surgical safety and image quality is critical at procedure of PCI Recently, an enhanced stent visualization (ESV) system (CLEARstent and CLEARstent Live; Siemens Healthineers, Germany) has been developed and deployed, providing a clear display of stent deployment by fade in/ fade out imaging (CLEARstent) and real time stent enhancement (CLEARstent Live). Several studies have demonstrated the feasibility, utility and efficacy of this system in facilitating PCI procedures and associating with better clinical outcomes(12–16). However, there is limited study on the contrast media usage with use of ESV technique during PCI for the patient with complication of CKD. In this study, we aim to evaluate the impact of ESV system on contrast media usage and radiation dose in PCI procedure, especially for CHD patients with CKD.

Material And Methods

1.1 Study population

The present comparative, retrospective study collected a total of 124 patients with acute coronary syndromes (ACS) who underwent PCI in the department of cardiology of Tianjin First Central Hospital from May 2020 to July 2021. One interventional cardiologist, with over two-year experience in ESV systems, has performed stent implantation for all these patients. Patients were eligible for enrollment if: (1) age < 80; (2) coronary angiography confirmed at least a significant stenosis (> 75% stenosis) requiring PCI; (3) with diagnosis of unstable angina, ST elevate acute coronary syndromes (STEACS) and non-ST elevate acute coronary syndromes (NSTEACS); (4) patients who have ability of cognizance and cooperation, are willing to participate in postoperative follow-up, and sign informed consent voluntarily.

Patients were excluded if they were: (1) left main or multi-branch lesions with valvular disease or ventricular aneurysm requiring surgical bypass surgery; (2) referred for PCI without stenting or non-

coronary interventions; (3) with diseases of the blood system, coagulation disorders or neutropenia; (4) with chronic total occlusion treatment; (5) patients underwent intravascular ultrasound and/or pressure wire during procedure; (6) under PCI with hemodynamic instability requiring implantable temporary pacemaker and/or intra-aortic balloon pump; (7) not willing to sign informed consent; (8) occurrence of any complications during PCI (e.g., no-reflow, slow-reflow, or dissection); (9) contrast agent allergy. Patients were withdrawal if they were: (1) failed to complete the study and follow-ups; (2) participating in other clinical studies, which may affect the results of this study; (3) incomplete patient data, affecting efficacy or safety evaluation. This study was approved by the institutional review board of the institution in which the procedures were performed.

1.2 Procedures

All PCIs were performed under the radial arterial approach in accordance with the normal routine using Artis Q.zen x-ray system (Siemens Healthineers, Germany), which is equipped with ESV systems (CLEARstent and CLEARstent Live, Siemens Healthineers). Patients were received coronary angiography (CAG) though right radial access using standard Judkins method with 4–5 ml iso-osmolar contrast agent to check the left and right coronary artery. The result of CAG was evaluated by two independent cardiovascular radiologists. The operator would determine the size and type of the guidewire, wire and pre-dilation balloon according to these CAG results. After injecting nitroglycerin, the evaluation of target vessel and lesion was then obtained from another angiography. The operator would select the size of stent based on the diameter of the vessel. Normally a post-dilation would perform after the stent was deployed correctly. All patients regularly took aspirin 100mg/d, clopidogrel 75mg/d (or ticagrelor 180mg/d), statins, β -blockers, ACEI, nitrates, etc. after procedure.

1.3 ESV system-guided stent implantation

ESV system was registered and processed based on a balloon catheter with radiopaque markers in the region of interest. During the procedure, fluoroscopy or cine images exceeds 25 frames could be used for post-processing by ESV systems for better visualization of deployed stents. Besides, it allows real time visualization of stent placement with 45–60 frames of cine images at the rate of 30 frames/s. ESV images were immediately showed on the screen and no other interactions needed.

1.4 Data collection

All patients received interventional treatment based on coronary angiography and they were divided into two groups: an ESV-guided group (n = 64) and an angiography-guided group (n = 60). The use of ESV systems was decided by the certain operator. Patients in ESV-guided group used ESV systems to evaluate stent connection, positioning, and expansion during the intervention. In angiography-guided group, stent implantation and expansion were evaluated using conventional x-ray images. As a subgroup analysis, patients with serum creatinine greater than 104 μmol/L in two groups were selected for CKD analysis in two groups.

Patient characteristics were collected, including age, sex, body mass index (BMI), location of the target vessel, and other detailed characteristics related to the complexity of the procedure. Procedure related data were also collected: radiation exposure, number of cines, cine frames, fluoroscopy and procedure time, as well as contrast media volume. Radiation exposure was recorded in Air Kerma (AK) during fluoroscopy and in total, respectively. In addition, number of cines, cine frames, fluoroscopy time and procedure time were collected from the dose report. The procedure time was recorded from the point of patient on table.

1.5 Statistical analysis

Patient characteristics and all these intraoperative parameters were analyzed and compared between two groups accordingly. SPSS 22.0 statistical software was used for data analysis. Categorical data were summarized as frequency and percentile, using chi-square test or Fisher's exact probability method. For continuous variables, data were presented as mean ± standard deviation (SD). Normally distributed continuous variables were compared using 2-sided Student t test, and the Mann-Whitney U test was used for nonparametric variables. Statistical significance was set to 5%.

Results

2.1 Patient characteristics

During the study period, a total of 124 patients underwent PCI were included. Of these 124 patients, 64 (51.6%) patients received ESV-guided PCI and 60 (48.4%) patients were received standard PCI under guidance of angiography. The mean age of the ESV-guided group was 61 ± 11 years and 62% were male, while the mean age of the angiography group was 62 ± 10 years and 70% were male. Patient characteristics were comparable between two groups in age, gender, BMI, lesion types and other vascular parameters (see Table 1).

Table 1
Comparison of patient characteristics between the two groups

Characteristics	ESV-guided Group (n = 64)	Angiography-guided group (n = 60)	p value
Age	61 ± 11	62 ± 10	0.242
Male	37 (58%)	42 (70%)	0.158
BMI	26.2 ± 2.9	25.8 ± 2.7	0.387
No. of lesions treated every PCI	1.2 ± 0.4	1.1 ± 0.3	0.206
Location of target vessel			
LM	1 (1%)	0	0.753
LAD	31 (46%)	30 (49%)	
LCX	17 (25%)	13 (21%)	
RCA	19 (28%)	18 (30%)	
B2/C lesions			0.760
B2	26 (41%)	26 (43%)	
C	38 (59%)	34 (57%)	
Multivessel PCI	35 (55%)	42 (70%)	0.079
Ostial PCI	2 (3%)	4 (6%)	0.358
Bifurcation PCI	5 (8%)	2 (3%)	0.280
Post-dilatation	55 (86%)	51 (85%)	0.439
No. of stents per PCI	1.3 ± 0.5	1.4 ± 0.6	0.882
Overlapping stents	17 (27%)	18 (30%)	0.671

2.2 Procedural characteristics

A statistically significant reduction was demonstrated on contrast media analysis in ESV-guided group, compared to angiography-guided group (132.6 ± 22.3ml vs. 174.7 ± 29.6 ml, p = 0.0001). With the use of ESV systems, radiation exposure (in air kerma) was significantly decreased for fluoroscopy alone (697.98 ± 472.20mGy vs. 1060.94 ± 698.07mGy, p = 0.002) and for total amount of fluoroscopic and angiographic imaging exposure (907.62 ± 534.94 mGy vs. 1316.11 ± 768.14 mGy, p = 0.002). in addition, a significantly shorter procedure time was observed in ESV-guided group by 30% decreased (53.06 ± 21.20 min vs.

72.00 ± 30.55min, p = 0.01). No significant difference was shown in fluoroscopy time, No. of cine runs and cine frames (see Table 2).

Table 2
Comparison of procedural characteristics between the two groups

Characteristics	ESV-guided group	Angiography-guided group	p value
Air Kerma – fluoro (mGy)	697.98 ± 472.20	1060.94 ± 698.07	0.002 *
Air Kerma – total (mGy)	907.62 ± 534.94	1316.11 ± 768.14	0.002 *
Fluoroscopy time (min)	13.00 ± 8.14	14.54 ± 7.30	0.289
Procedure time (min)	53.06 ± 21.20	72.00 ± 30.55	0.01 *
No. of cine runs (n)	21.75 ± 5.53	23.28 ± 8.21	0.185
Cine frames(n)	821.36 ± 299.93	821.88 ± 294.90	0.924
Contrast media (ml)	132.6 ± 22.3	174.7 ± 29.6	0.0001 *

2.3 Subgroup analysis for patients with CKD

For the subgroup analysis, a similar result as the overall analysis was observed. The patient data was also comparable between two groups. In the ESV-guided group, contrast media was significantly reduced by 36% (179.41 ± 16.76 ml vs. 114.5 ± 13.56ml, p = 0.0001). Except for a significantly half reduction in radiation exposure in fluoroscopy alone (526.14 ± 330.36 mGy vs. 1159.75 ± 882.34 mGy, p = 0.001) and total amount of fluoroscopic and angiographic imaging (693.99 ± 351.04 mGy vs. 1439.45 ± 973.01 mGy, p = 0.001), number of cine runs was also decreased significantly in ESV-guided group. Additionally, angiographic-guided group showed a longer procedure time than ESV-guided group (47.75 ± 15.43 min vs. 65.88 ± 23.81 min, p = 0.029). No significant difference was observed in fluoroscopy time and cine frames (see Table 3,4).

Table 3
Comparison of patient characteristics between the two groups of patients with CKD

Characteristics	ESV-guided Group (n = 20)	Angiography-guided group (n = 17)	p value
Age	58 ± 8	61 ± 11	0.243
Male	13 (66%)	14 (82%)	0.236
BMI	26.1 ± 3.4	26.1 ± 1.6	0.721
No. of lesions treated every PCI	1.1 ± 0.2	1.1 ± 0.3	0.157
Location of target vessel			
LM	0	0	0.063
LAD	10 (50%)	9 (53%)	
LCX	5 (25%)	0 (21%)	
RCA	5 (25%)	8 (47%)	
B2/C lesions			0.402
B2	11 (55%)	7 (41%)	
C	9 (45%)	10 (58%)	
Multivessel PCI	11 (55%)	12 (71%)	0.330
Ostial PCI	0	1 (6%).	0.272
Bifurcation PCI	2 (10%)	1 (6%).	0.674
Post-dilatation	17 (85%)	13 (76%)	0.509
No. of stents per PCI	1.1 ± 0.3	1.5 ± 0.8	0.083
Overlapping stents	3 (15%)	7 (41%)	0.074

Table 4
Comparison of procedural characteristics between the two groups in the subgroup

Characteristics	ESV-guided group	Angiography-guided group	p value
Air Kerma-fluoro (mGy)	526.14 ± 330.36	1159.75 ± 882.34	0.001 *
Air Kerma-total (mGy)	693.99 ± 351.04	1439.45 ± 973.01	0.001 *
Fluoroscopy time (min)	9.95 ± 5.83	13.52 ± 7.64	0.309
Procedure time (min)	47.75 ± 15.43	65.88 ± 23.81	0.029 *
No. of cine runs (n)	19.10 ± 4.41	25.35 ± 9.22	0.026 *
Cine frames(n)	686.40 ± 158.51	857.94 ± 357.89	0.102
Contrast media (ml)	114.5 ± 13.56	179.41 ± 16.76	0.0001 *

Discussion

The present study retrospectively evaluated the impact of ESV systems on contrast media volume and radiation exposure for patients underwent PCI procedures. To best of our knowledge, we firstly reported the comparative results of contrast media usage between the group guided by an ESV system and group guided by standard angiography. It was shown that a significant reduction in contrast media volume, radiation exposure (in Air Kerma) and procedure time with the use of ESV systems. Similar results were observed in the subgroup analysis for the patients with CKD.

ESV system is a fluoroscopic based technique, which could provide enhanced visualization of stents with adequate imaging for diagnosis and guidance. Studies showed that it increases the amount and quality of information during PCI to facilitate the identification of bifurcation stenting, precise stent positioning, stent underexpansion and defining stent-vessel wall relationship in case reports(12, 13, 17, 18). Biscaglia et al.(15) demonstrated a novel timing of intraoperative stent fracture identification during the index PCI with the systematic application of ESV. In addition, ESV system was proved an effective assistance in reducing the excessive overlap in implantation of bioresorbable vascular scaffold(14). Furthermore, the results in the study of McBeath et al.(16) showing a significantly improved correlations of an ESV system and clinical outcome. Jin et al.(19) pointed out that the use of an ESV system (Stentboost, Philips) can be performed with comparable radiation dose with conventional x-ray fluoroscopy imaging and suggested that the operator's experience have an important impact on radiation dose. However, there is a paucity of research that looked at the contrast media usage during PCI of using such a technique.

The current reliable way to perform PCI in minimum or even without contrast administration is guided by intravascular ultrasound imaging (IVUS), which helps to identify the lesion and its length(20). Nevertheless, due to its time-consuming, expensive and requiring for specifically trained personnel, this technique is not routinely used in daily practice(21). In contrast, as an alternative option, ESV systems such as CLEARstent technique only require a few seconds of fluoroscopy or cine images and immediately

provide a real time visualization of the stent. With an enhanced visualization, stent positioning, deployment and overlapping could be performed under a clear and intuitive way without repeated contrast needed, thereby greatly lowering the use of contrast media. Especially for complex cases, such as bifurcation lesions, the relationship between stent and wire and detection of re-crossing wire could be evaluated and facilitated with only one fluoroscopy image, omitting repeated enhanced acquisitions to make confirmation. Furthermore, underexpansions could also be detected without contrast injected, which helps physician to perform proper post-dilation in a minimum of contrast medium. As a result, in this study, the use of ESV systems was demonstrated a significantly reduction on contrast media usage compared with the traditional angiography-guided procedure for preventing the occurrence of contrast-induced nephropathy. In the subgroup analysis, for the patient with existing CKD, a similar result on contrast media suggested that ESV-guided PCI has the potential to reduce the damage to renal and mitigate the progression of CKD, which is of great significance for these patients.

Unlike the result of non-significant impact on patient radiation dose in study of Jin et al.(19), who also noted a learning curve of Stentboost imaging and radiation protection, our study found a significant reduction on radiation dose and procedure time in ESV-guided group, maintaining high quality visualization with an optimization of stents. In traditional angiographic procedures, several cines are required to obtain adequate stent visualization while less cine shots are needed for ESV-guided procedures as enhanced visualization of stent deployment eliminates unnecessary radiation exposure. In addition, since fluoroscopy images could also be post-processed using ESV system developed by Siemens Healthineers, radiation dose could be reduced greatly in terms of replacing the regular cines with fluoroscopy. Not only the reduced radiation dose could provide a relatively radiation protection for patients and operators, but also the shortening procedure time could reduce heart failure from prolonged surgical trauma, especially for patients with CKD.

Studies(19, 22) pointed out that operators' sufficient experience on using the similar technique has an important impact, however we found a steep learning curve for Siemens ESV technique. On the other hand, despite an inevitable learning curve of ESV systems, it could shorten the overall learning curve of percutaneous coronary intervention procedure for especially junior operators. Additionally, it offers some obvious advantages as follows. (1) ESV systems improved visualization of drug-eluting stent. In recent years, the appearance of some new drug-eluting stents has made it more difficult to locate and deploy by traditional angiography methods due to their low relative thickness and x-ray impenetrable materials. ESV systems could significantly improve the positioning and imaging of this self-dilating stent (see Fig. 1). (2) ESV systems enhanced identification of stent underexpansion (see Fig. 2). Incomplete or uneven expansion of stents is the main risk factor affecting short-term and long-term efficacy, as is the case in the era of drug-eluting stents. Timely identification of incomplete expansion of stents is the prerequisite to avoid risks. At present, IVUS is the gold standard for the evaluation of stent structure and dilation level. Under angiographic-based method, contrast media is required to acquire adequate evaluation of stents. As an additional option, ESV systems require no additional contrast media or hardware and provide instant information about its structure. (3) ESV system provided real time guidance for bifurcation lesions (see Fig. 3). On treatment of bifurcation lesions, the use of distal cell when re-wiring was recommended

by The European Club to improve procedural outcomes. Angiography and IVUS are unreliable at detecting the site of wire re-crossing. Optical coherence tomography (OCT) has its own advantage in assessing re-wiring, however, additional contrast is also required. ESV systems can enhance the signal of stent struts and increase the visibility of stents to estimate the wire location, with no additional contrast needed. (4) ESV systems increased identification of vascular calcification. Coronary calcification hinders the placement of stents because of potential inadequate stent expansion and difficult transition. However, it is usually difficult to distinguish the stent struts and calcification under standard angiography. ESV systems could identify distribution of calcification with or without a stent being present and distinguish stents from wall calcification. As a result, the reason for insufficient stent expansion could be confirmed immediately to prevent vascular rupture in case of overexpansion (see Fig. 4).

We should acknowledge some limitations. First, this is a single-center retrospective study with a small sample size and thus a larger, multicenter prospective study will be needed in the future. Second, automatic marker detection may misidentify other objects as markers, and this may need additional step of magnification to improve visualization. Third, further studies demonstrating clinical outcomes with a longer follow-up under ESV guidance for especially patients with CKD are also needed.

Conclusions

This study suggested that the use of ESV is associated with reduced contrast media usage, radiation dose and procedure time during PCI. The same results were observed in subgroup analysis in patients with CKD, which is of great significance in decreasing the occurrence of contrast-induced nephropathy and mitigating the progression of CKD and CHD.

Declarations

Ethics approval and consent to participate

The study received approval from the institutional review board of Tianjin First Center Hospital. The authors confirm that their study was performed in accordance with the Declaration of Helsinki. Oral informed consent was obtained from each patient.

Consent for publication

Not applicable.

Competing interest

The authors declare that they have no competing interests.

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Authors' contributions

YT, XZ, and C. Lu designed the study. YT, YY, LJ collected and processed the data. X. Cai, SG and DX implemented the analysis. YT, X. Chen, C. Li, QG, BC and C. Lu wrote and revised the manuscript. All authors read and approved the final manuscript.

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Availability of Data and Materials

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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Figures

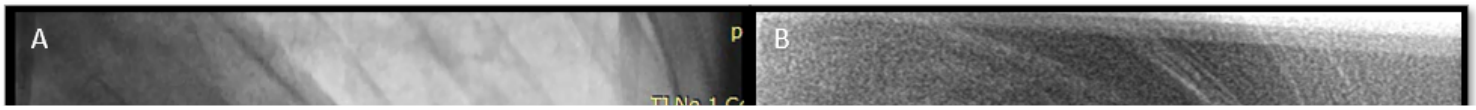

Figure 1

ESV system to visualize drug-eluting stent. (A) drug-eluting stent deployment under conventional fluoroscopy; (B) Clear visualization under guidance of ESV system

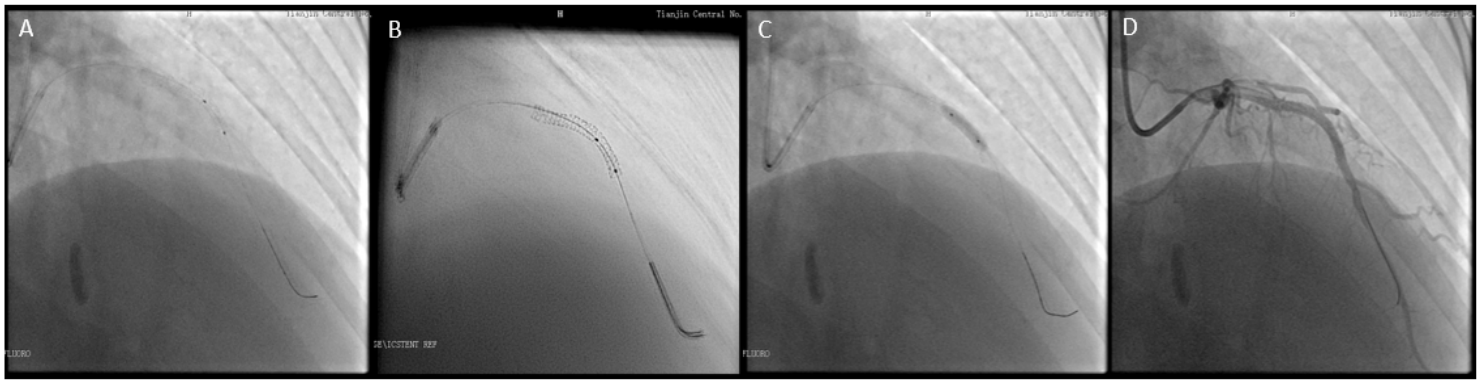

Figure 2

ESV system to detect stent underexpansion and guide post-dilation. (A) stent deployment under conventional fluoroscopy; (B) ESV system help detect the underexpansion of stent and assist align the marker of balloon with margin of stent; (C) post-dilation under fluoroscopy; (D) angiography confirmation after deployment

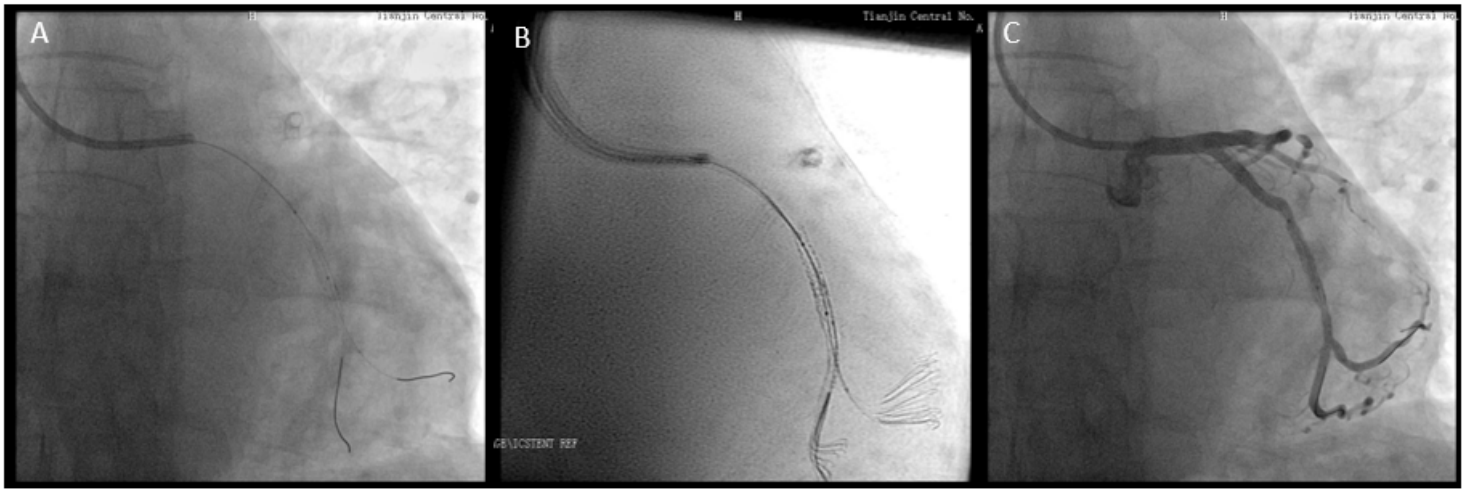

Figure 3

ESV system to guide stent deployment for bifurcation lesion. (A) stent deployment under conventional fluoroscopy; (B) stent deployment under guidance of ESV system to help ensure the wire re-crossing the distal cell; (C) angiography confirmation after deployment

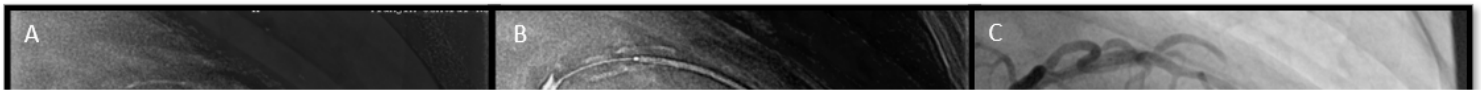

Figure 4

ESV system to identify vascular calcification. (A) identification of calcification to guide pre-dilation under ESV images; (B) ESV system assists stent positioning with visualization of severe calcification; (C) angiography without enhanced visualization when calcification is barely distinguished.