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ORIGINAL RESEARCH

Coronary Angioplasty and Stenting in Acute Coronary Syndromes Using Very Low Contrast Volume and Radiation Dosage Improves Renal and Cardiovascular Outcomes

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ABSTRACT

Aim: To demonstrate that in patients with acute coronary syndrome (ACS), using Cordis 6F Infiniti diagnostic catheters for angioplasty may represent a safe alternative associated with lower contrast volume and radiation dosage, improving cardiovascular and renal outcomes. **Material and Methods:** In 1,800 patients with ACS (2,331 lesions/2,603 stents), angioplasty was performed with Cordis 6F Infiniti Thrulumen diagnostic catheters. Primary angioplasty was performed in 545 cases, and only balloon angioplasty in 67 patients. All procedures were performed through the femoral route, and switch-over to the radial route was made in 5 cases due to associated aortic/iliac obstructive lesions. Iodixanol was used in 76% of cases, and tirofiban in 99% of cases with adjusted dosages based on creatinine values. The mean contrast volume used per patient was 28 mL (± 6 mL) including the angiogram prior to the angioplasty. **Results:** The median fluoroscopy time was 4.4 min (IQR 3–6.8), the mean fluoroscopy time was 5.59 min (± 0.28), the median dose-area product or kerma-area product was 1,507 µGym^2 (IQR 918–2,611), median total or cumulative dose including backscatter was 2,702 µGym^2 (IQR 1,805–4,217), and the median cumulative skin dose was 468 mGy (IQR 296–722). Groin hematoma was seen in 7 cases, proximal mild edge dissection in the deployed stent in 3 cases, and acute in-hospital stent thrombosis in 7 cases. In total, 33 deaths were registered and 19 of these patients had cardiogenic shock, of which 11 subjects were late presenters. Three patients died after discharge due to possible acute stent thrombosis. **Conclusions:** Angioplasty and stenting can be performed safely in patients with acute coronary syndromes using Cordis 6F diagnostic catheters. The procedure was associated with a very low volume of contrast and radiation dose, leading to improved clinical outcomes..

Keywords: coronary angioplasty, acute coronary syndrome, contrast volume, radiation

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INTRODUCTION

Acute coronary syndromes (ACSs) are common in clinical practice and are associated with high mortality, which could reach 15% including prehospital mortality.[1] In-hospital mortality could be about 5%, or approximately 2% after excluding cardiogenic shock.[2–5] Reducing fluoroscopy times and thereby procedure times in angioplasty or percutaneous intervention (PCI) may have favorable effects during the therapy of ACS,[6] as longer procedural times are associated with coagulation-related complications,7 as well as more frequent bacteremia.[8–10] Reduced fluorosco-

The study is dedicated to the memory of my mother, Mrs. Susaiammal Arokiaraj.

py times are also associated with lesser stochastic effects, though the benefits are not clearly known.[11] Leukemia and radiation-induced risks are present during interventional procedures for both the patient and the operator.[12] Hence, minimizing radiation can prevent stochastic complications in the future. The reduction of contrast volumes is also associated with improved clinical outcomes in ACS. The contrast volume can be reduced to a certain extent by intravascular ultrasound (IVUS)[13–15] and optical coherence tomography (OCT) imaging techniques.[16] However, these modalities can be used for selected patients and in a few centers only.

The primary purpose of the study was to investigate the potential reduction in mortality and morbidity parameters in patients with ACS, as well as the secondary benefits resulting from the reduction of contrast volume and radiation times.

METHODS

PATIENT AND PROCEDURAL CHARACTERISTICS

A retrospective analysis was performed after the completion of angioplasties in 1,800 patients with ACS using standard 6F Cordis Infiniti Thrulumen diagnostic catheters, between April 2016 and January 2022. Before this period, i.e., in mid-2015-early 2016, this technique has been used only when difficulty in the engagement of guide 6F catheters was observed.[17] Standard Judkins right or left 6F diagnostic catheters and, whenever required, suitable Cordis 6F Amplatz diagnostic catheters for angioplasties with stenting were used. The angioplasty procedures were performed by the author. Fluoroscopy times, fluoro air-kerma, dose-area product or kerma-area product, total or cumulative radiation dose, cumulative skin dose, and contrast volumes were studied. A variety of drug-eluting stents from various companies were used during these procedures; bare-metal stents were not used. Standard PTCA wires (Allstar, BMW, and run through) were used for the procedures, and Allstar was the workhorse wire. Pre-dilatation was performed in one third of cases. Direct stenting was the preferred technique whenever feasible. When balloons were used to cross the lesion, dilatation was performed in the distal edge of the lesion to look for distal visibility. Whenever coronary balloons were used, small profile balloons were used in length as well as in thickness. Stent deployment was performed at usual pressures of 14–16 atm and typically with two inflations of 7–9 s each, sequentially after transient deflation. High-pressure deployment of >16 atm was used in <1% of patients. For a brief period of time, when Cordis 6F diagnostic catheters were not available due to short logistic supply, Terumo and Boston Scientific 6F diagnostic catheters were used (for angioplasty in 20 cases).

Figure 1 shows angioplasty performed in the left main coronary artery, Figure 2 shows angioplasty in the anomalous origin of left circumflex artery from the right cusp, Figure 3 shows angioplasty in the posterior origin of the right coronary artery, and Figure 4 shows angioplasty in a patient with acute left anterior descending artery occlusion with cardiogenic shock.

In 1,800 patients (2,331 lesions/2,603 stents) with ACS, angioplasty and stenting was performed with Cordis 6F diagnostic catheters. In another 67 patients, balloon angioplasty (POBA) was performed. Primary angioplasty was performed in 545 cases. In 76% of cases iodixanol was used, and all the procedures were performed via the femoral route. A regular follow-up of patients was performed 30 days after the procedure. Tirofiban was used in 99% of cases with adjusted dosages based on creatinine values. COVID-19 was positive in 27 cases by RT-PCR. Left main angioplasty was performed in 45 patients using single stents. Ninety-one patients had cardiogenic shock at presentation, and 77% of the cases had diabetes.

The mean age of the patient population was 58.4 ± 8.1 (median 58) years; 4% of patients were <40 and 16% were >70 years. Baseline renal failure or elevated creatinine >2 mg/dL was seen in 114 cases. N-acetylcystine was given p.o. for 2 days when creatinine was >1.3 mg/dL. Antibiotic therapy was guided by clinical symptoms, total leukocyte counts, and urine evaluation.

All procedures were performed through the femoral route only, using 6F Cordis Infiniti Thrulumen diagnostic catheters. The primary route was via the right femoral artery, and if it failed (in less than 1% of cases), the left femoral artery was used. Switchover to the radial route was seen in 6 cases, primarily due to associated aorto-iliac disease or severe peripheral vascular disease. In 82% of cases, 3.5 cm curve diagnostic catheters were used. In 8 patients 5 cm JL curve catheters, in 2 patients a 6 cm curve catheter, and in the rest of the cases 4 cm curve diagnostic catheters were used. In 10 patients, who were very young or short, the procedures were performed with 3 cm curve 6F JL guide catheters.

Fluoroscopy times were calculated from the catheterization lab (Siemens Axiom Artis) after the procedures, from the exam protocol settings. In late 2019, Siemens Artis-one was used. Fluoro air-kerma, dose-area product or kerma-area product, cumulative total dose (including backscatter), and the cumulative skin dose were calcu-

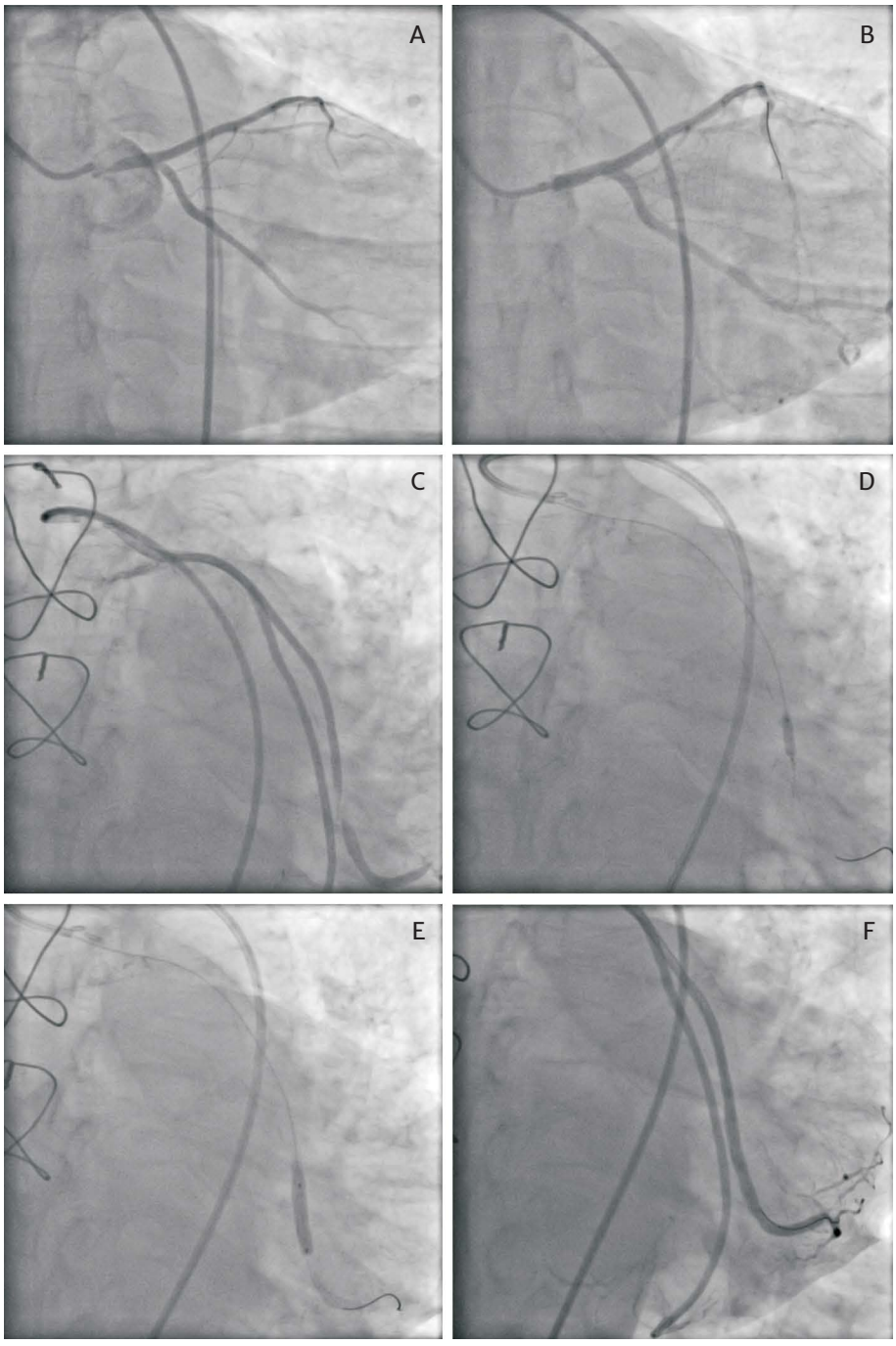

FIGURE 1. **A, B** – Pre- and postangioplasty pictures in a patient with ostial LMCA disease; **C–F** – Angioplasty with stenting in a patient with venous graft stenosis

lated by machine-derived parameters, which were available from the study protocol for each patient. The decision to use coronary stents was at the discretion of the author, with minimal stents whenever possible by number and dimensions. IVUS was used in 2 only patients. Also, thrombus aspiration catheters were used in 4 patients. Whenever thrombus aspiration was considered, 6F guide catheters were used for angioplasty. Vasovagal symptoms were treated with atropine injections and transient infusions of normal saline. Left ventricle (LV) ventriculography was not performed in any of the patients. Temporary pacemaker insertions during procedures were performed in 61 cases.

Predilatation was performed in 33% of patients, and postdilatation was performed in 3.2% of patients. Predilatation was preferably done with smaller balloons.

By using this method, coronary stents up to 4.5 mm were used in 6F diagnostic catheters. Five-mm coronary

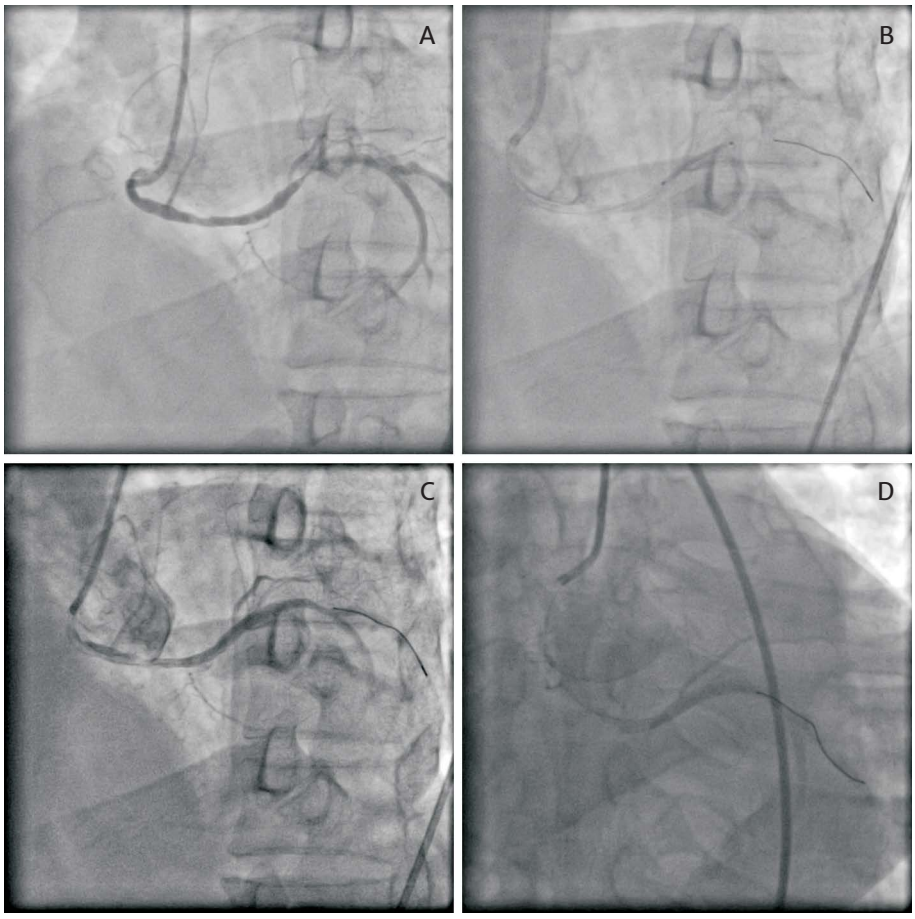

FIGURE 2. Angioplasty in a patient with anomalous origin of left circumflex artery from right coronary cusp (**A**) and stent positioned across the lesion (**B**); **C, D** – Final results

stents were used in 6F diagnostic catheters for renal ostial stenting as an off-label use in 6 patients with 5 mm to 5.5 mm-sized renal arteries (Figure 6). In a few cases, post-dilatation was performed using 5 mm Accuforce (non-compliant) coronary balloons. After postdilatation, the noncompliant Accuforce balloon may not be brought inside the diagnostic catheter since the postdilatation profile is larger, and hence the balloon-wire-catheter has to be removed in-toto. Whereas the standard stent balloons are semi-compliant, Onyx is made of semi-compliant fulcrum material, and the stent balloons can be drawn into the 6F diagnostic catheters after stent deployment.

FEMORAL SHEATH REMOVAL

Sheath removal was typically performed by the nursing staff 6 hours after the procedure, irrespective of the activated clotting time, following the infiltration of local anesthetics. Simple manual compression was the procedure used in all cases. After sheath removal, limb movement was restricted mildly for the next 12 hours. If any hematoma formation was observed and deemed significant, sheath removal was performed at the earliest, from 15 min up to 3–4 hours after the angioplasty procedure. In these cases, simple manual compression was applied for a prolonged duration of about 30–45 min. Pseudoaneurysms were seen in 7 cases, which were diagnosed with murmurs/bruit and by color Doppler evaluation. All 7 femoral pseudoaneurysms were closed by probe compression in a single setting. Post-procedural femoral motor neuropathy was seen in 1 patient who improved with physiotherapy.

All study procedures were performed according to good clinical practice, and ethical approval was obtained from the institution where the study was conducted.

RESULTS

Baseline characteristics of the patients are shown in Table 1. In the age distribution, age <40 years was seen in 3.8% of our cases, >70 years was seen in 16.2% of cases, and the rest of the patients (82%) were in the 40–70 years age group. Figure 5 shows the fluoroscopy profiles of the 6F

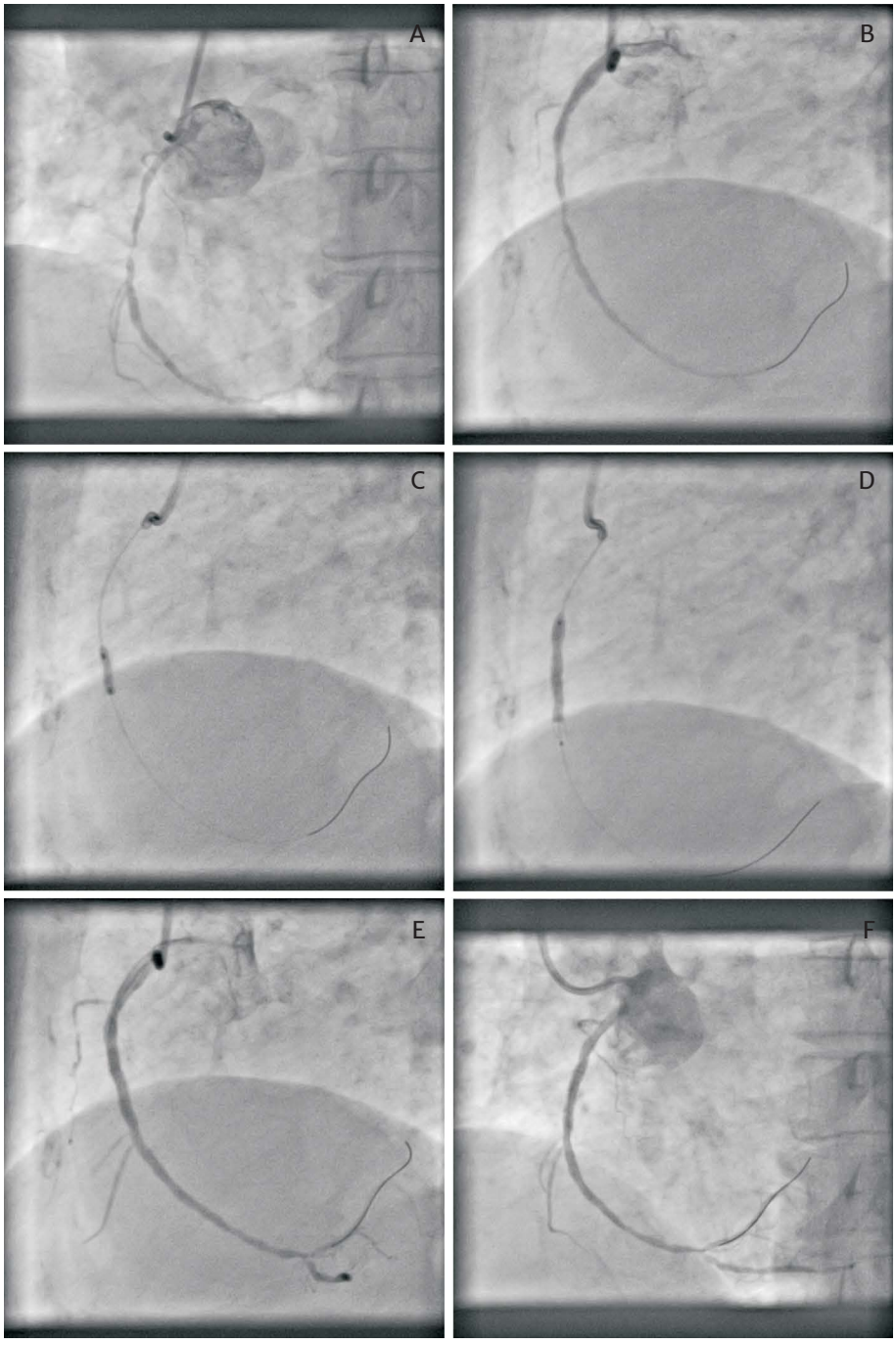

FIGURE 3. Angioplasty using 6F Amplatz AL1 diagnostic catheter for posterior origin of right coronary artery. **A** – 95% stenosis of mid right coronary artery. After 014 wire insertion (**B**), predilatation (**C**) and stenting was done (**D**). **E, F** – Final results

Cordis Infiniti Thrulumen diagnostic catheters and 6F Cordis Vista Brite-tip guide catheters at various magnifications in the cath lab. Figure 6 shows renal angioplasty and stenting wherein a 5 mm diameter stent was used in renal ostial stenosis in a 6F right Judkins diagnostic catheter.

Fluoroscopy times, dose area product or kerma-area product, total or cumulative dose, and cumulative skin dose results for 725 consecutive patients who underwent angioplasty and stenting are shown in Table 2 and Figure 7. The median fluoroscopy time was 4.4 min (IQR 3–6.8), the mean fluoroscopy time was 5.59 min (± 0.28), the median dose-area product or kerma-area product was 1,507 µGym^2 (IQR 918–2,611), median total or cumulative dose including backscatter was 2,702 µGym^2 (IQR 1,805–4,217), and the median cumulative skin dose was 468 mGy (IQR 296–722).

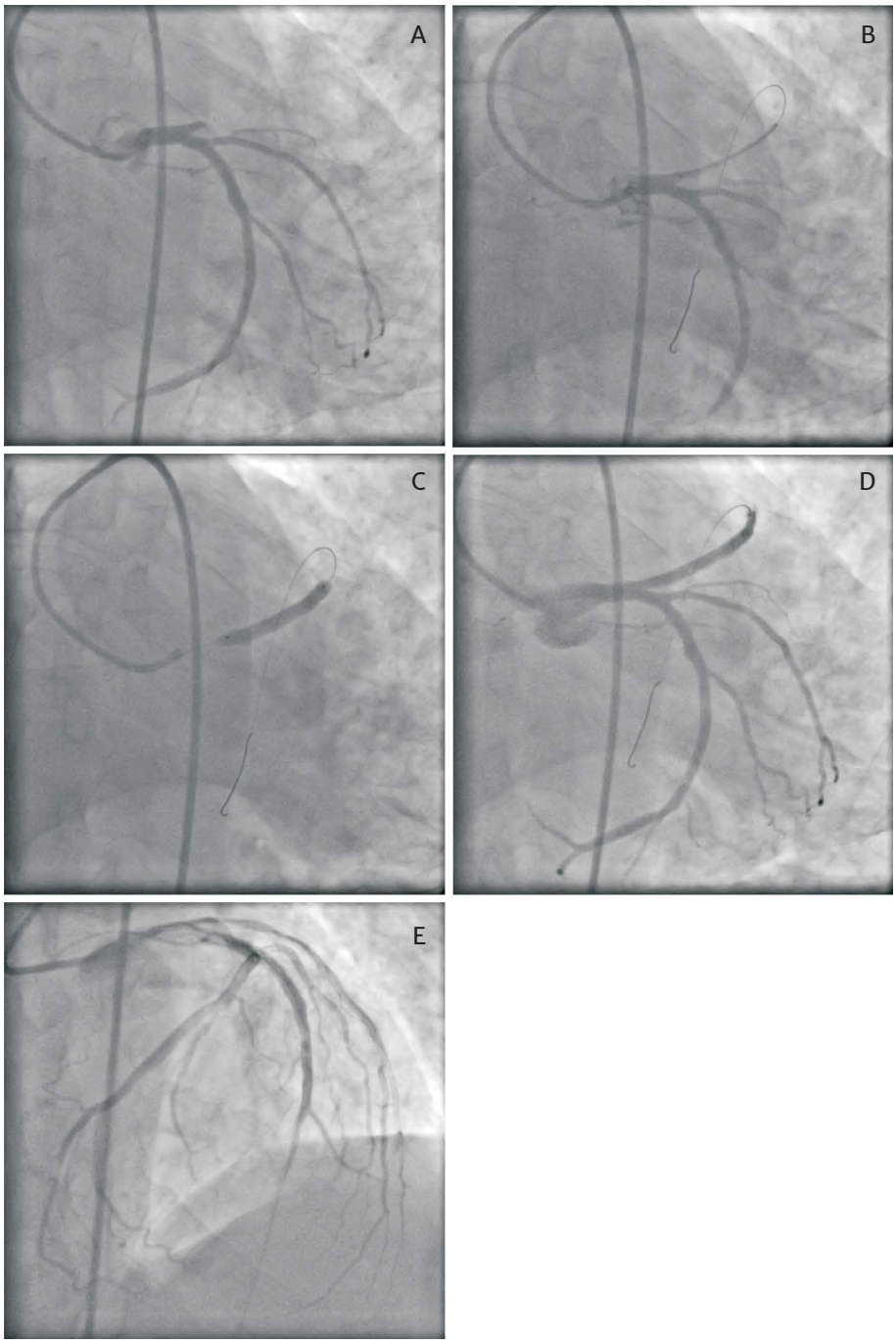

FIGURE 4. Complete occlusion of proximal LAD (**A**). A stent was positioned (**B**) and direct stenting was performed (**C**). **D, E** – Final results

Mild reversible nephropathy (CIN) was observed in 7 patients. Six patients were already on dialysis, which was continued thereafter. In 2 patients who had chronic renal failure with high creatinine values, temporary dialysis was performed. Thirty-three deaths in total were observed in this series; 19 of these patients had cardiogenic shock (11 late presenters), and 3 patients died after discharge due to possible acute stent thrombosis. Groin hematoma was seen in 7 cases requiring 1 unit of blood transfusion. Proximal mild edge dissection in the deployed stent was seen in 3 cases. Distal stent edge dissection was seen in 4 cases, which was treated with an additional stent. Acute in-hospital stent thrombosis was seen in 7 cases, which were managed with balloon dilatations and stents. Higher doses of antibiotics were required in 9.27% of cases. Congestive heart failure was seen in 32 cases, which were treated with early BIPAP ventilation and furosemide injections and infusion.

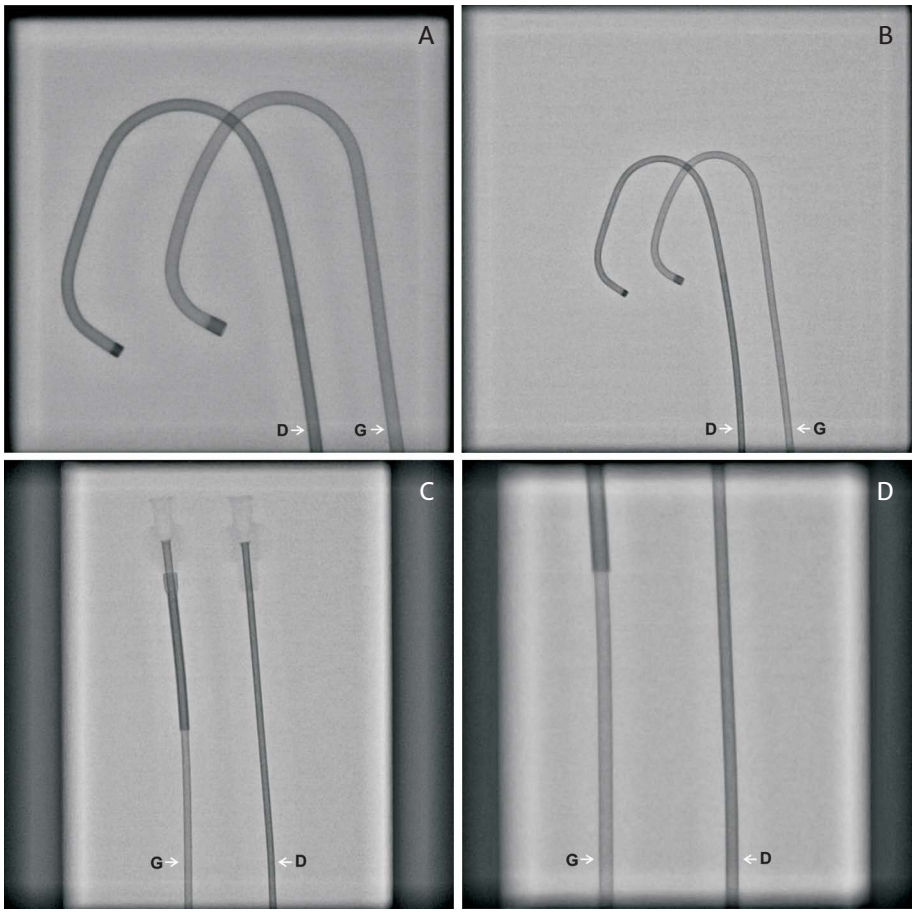

FIGURE 5. Fluoroscopic comparison of Cordis 6F diagnostic Infiniti-Thrulumen catheters (D) and Cordis 6F guide catheters (G) at various magnifications. **A** – ×11 magnification; **B** – ×20 magnification; **C** – proximal end of catheters in ×11 magnification; **D** – the proximal end of catheters in ×20 magnification

Vasovagal symptoms during the procedures were observed in 27 cases during sheath removal, and 20 patients had transient vasovagal symptoms. One unit of blood transfusion for large hematomas was required in 7 patients. Significant iron deficiency anemia not requiring blood transfusion for any reason was treated with iron carboxy-maltose injections.

Wire breakages were not seen. For bifurcation lesions, only provisional stenting method was performed. Wire-induced mild perforation, which was clinically insignificant, was seen in 1 patient, without any pericardial effusion. Coronary perforation or ruptures at the stent site were not seen. Dressler's syndrome with large pericardial effusion was seen in 3 cases and treated with pericardiocentesis and small doses of prednisolone (10–20 mg); these patients recovered subsequently. Post-procedural cerebrovascular intravascular bleeding was observed in 1 patient; post-procedural cerebrovascular ischemia was not recorded. Minor transient ischemic attacks with either lacunar infarcts or normal CT scan during hospital stay were seen in 3 cases. Major gastrointestinal bleeding was noticed in 2 patients in the post-procedural period: one patient, who had other comorbidities, died, while the other recovered with conservative management.

LONG-TERM RESULTS

The study was not focused on long-term results. However, follow-up was completed at one month. Repeated admission to our center after PTCA was recorded in 1% of cases and target vessel or target lesion revascularization in less than <1%.

DISCUSSION

This study shows reduced fluoroscopy times, radiation dosage, contrast volumes, and mortality during interventional therapy of ACS. The mean fluoroscopy time during the angioplasty was 4.4 min, including the angiographic time. Radiation exposure has many side effects, such as

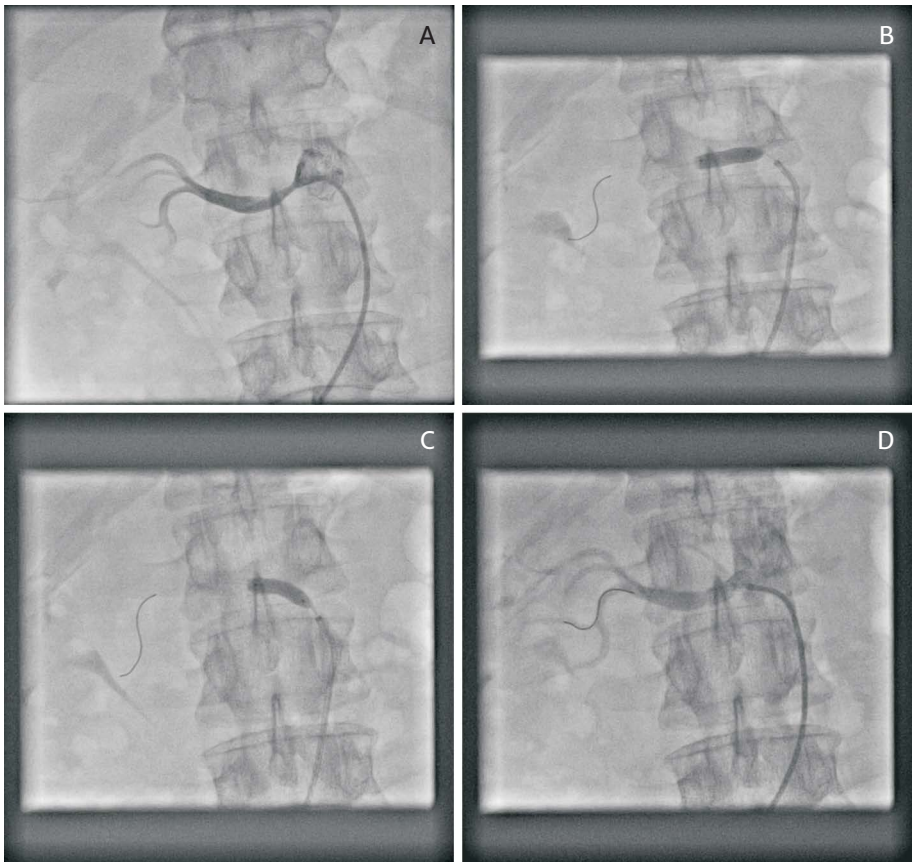

FIGURE 6. Renal angioplasty using drug-eluting Onyx 5 mm stents through 6F Judkins right diagnostic catheter. **A** – significant ostial stenosis; **B** – shows direct stenting; **C** – shows ostial flaring; **D** – final results

cataract, alopecia, and malignancies, and reducing the radiation dose is beneficial to both the operator and the patient.[18] The average dose of radiation per head has been reported at 5 mSv/year.[19] Acquiring angulated views leads to more radiation exposure,[20] and annual exposure to cardiologists is about 5 mSv/head/year.[21]

Biplane angiography can reduce the contrast volume to a certain extent,[22] but it is associated with higher radiation doses for the operator.[23] Hence, biplane cine-fluoroscopy should be considered only in selected cases. Also, it is not available in all centers. Reducing fluoroscopy times can be associated with long-term benefits such as preventing radiation-induced or stochasticity complications.[24]

The procedures in this study were performed through the femoral route. Some studies indicate a shorter procedural time in radial interventions, whereas some studies have shown equal timing through both routes.[25,26] Fractional flow reserve (FFR) was not used in our study, and the recent FLOWER-MI trial also showed similar results with FFR-guided angioplasty and conventional angiography-guided angioplasty.[27]

Currently, IVUS for ST-elevation myocardial infarction (MI) is used only in 5.5% of acute myocardial infarction (AMI) patients, and studies claim lower mortality and similar in-hospital complications.[28] The use of IVUS in ACS angioplasties is difficult, especially when the patient presents ongoing chest pain or Killip class III or IV. A study has shown increased fluoroscopy times when combined with IVUS/OCT.[29] Though many operators are aware of IVUS, many are not comfortable with its frequent use in ACS. Since time is an important factor in ACS, the inadvertent use of imaging modalities tends to overdiagnose normal variations, which could lead to more stents, balloon usage, and risk of coronary spasms during the procedures. Especially in cardiogenic shock, this would result in more complications.

Contrast volume reduction in acute setting would translate into better clinical outcomes. This could lead to a reduction in renal failure requiring dialysis and also a decrease in congestive heart failure; the need for ventilation would also be lower. Also, the incidence of acute respiratory distress syndrome (ARDS) is decreased by a reduction in micro- and macropulmonary hemorrhages. Hemoptysis in congestive heart failure results in severe hypoxemia

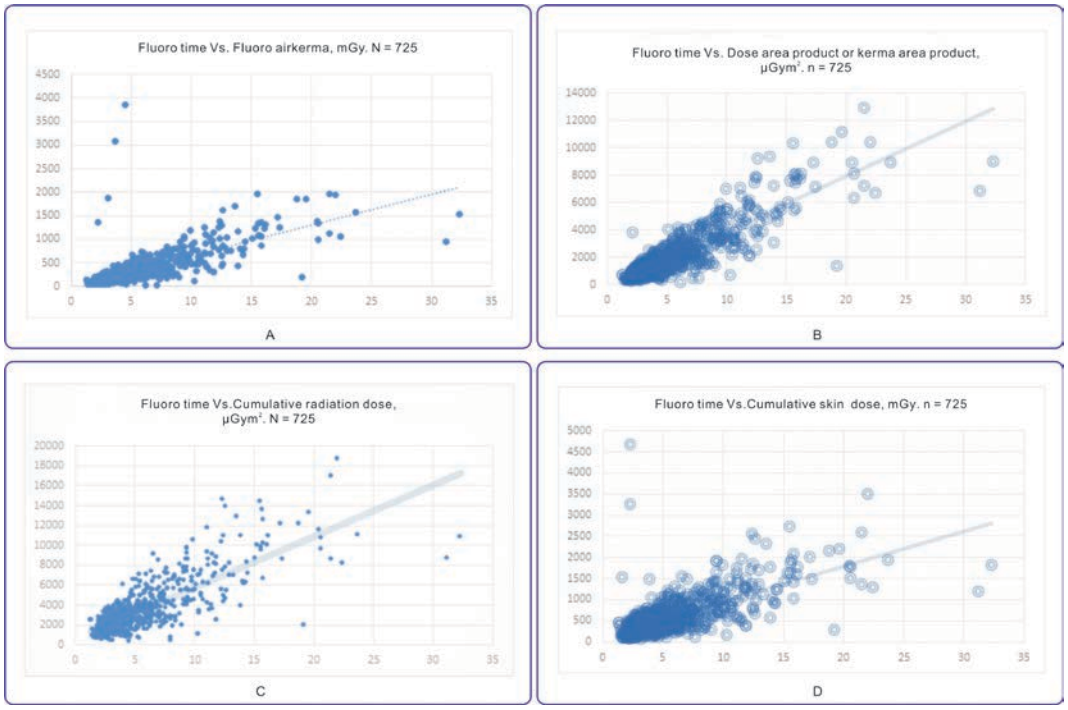

FIGURE 7. Fluoro air-kerma (**A**), dose area product or kerma area product (**B**), cumulative total dose (**C**) and cumulative skin dose (**D**) of 725 consecutive cases of ACS with angioplasty and stenting

with the resultant ARDS, which requires prolonged and tedious respiratory care.[30,31]

MANAGING GROIN HEMATOMAS

The femoral route is often criticized for groin hematomas and significant bleeding complications. This is the primary apprehension to use this route. One of the key techniques to prevent or treat hematomas is to remove the femoral sheath and apply simple manual compression at the puncture site for a prolonged duration irrespective of the anticoagulation status or the time after the procedure. In our center, the routine practice is to remove the femoral sheath 6 hours after the procedures. Whenever groin hematoma was noticed, the sheath was removed earlier, simple manual compression was applied, and tirofiban infusion was stopped for 1–2 hours. In our clinical practice, activated clotting time was not performed, though it is routine practice in many centers.[32] Blood transfusion rates are about 3% in AMI patients. However, in our series it was significantly less.

It is advisable to perform the femoral puncture below the femoral crease, typically at 1–2 cm below, at an angle ranging from 30 to 45 degrees. This results in easier manipulation of the vascular sheath and catheters. More angulation, i.e., 45–90 degrees during puncture, can lead to more groin hematomas and difficulty in manipulation of catheters. The SAFARI trial has shown that the results of the femoral route were similar to those of the radial route in the setting of ACS.[33] The MATRIX trial has shown better

TABLE 1. Baseline characteristics of the patient population

Parameter	n = 1,800
Age, yrs	58.4 ± 8.1
Sex, male %	77.5
Diabetes, %	77
Hypertension, %	36
Primary PCI, n	545
Rescue PCI, n	468
NSTEMI, n	684
Unstable angina, n	103
Baseline chronic renal failure with Cr >2.0	114
Ticagrelor, n	203
Groin hematoma, n	15
Blood transfusion, n	7
Higher doses of antibiotics, n	167
Mortality, n	33
LMCA, %	1.7
LAD, %	45.1
LCA, %	23.3
RCA, %	27.4
Ramus, %	1.6
SVG graft, %	0.93

TABLE 2. Fluoroscopy time, dose-area product, fluoro air-kerma, total radiation, and total air-kerma of 725 consecutive ACS cases treated with angioplasty and stenting

n = 725	Fluoroscopy time, min	Dose-area product or kerma-area product, µGym²	Fluoro air-kerma, mGy	Total or cumulative dose, µGym²	Cumulative skin dose, mGy
Mean	5.59	2101.3	361.1	3480.8	601.7
SD	0.28	598.2	70.7	1186.5	145.2
Median	4.4	1507	249	2702	467.5
Quartile 1	3	918	150.9	1805.5	295.6
Quartile 3	6.8	2610.5	441.6	4217	721.7

outcomes using the radial route compared to the femoral one, with a note of caution regarding its use by inexperienced operators.[34] Also, the switchover rate from radial to femoral route was 8.3%. The incidence of radial artery spasm has been reported at 15% in transradial procedures, and it could be even higher in ACS.[35]

In our study, groin hematomas were less frequent with the use of diagnostic catheters. The outer wall of the diagnostic catheters is thicker than the guide catheters; hence, the torque transmitted to the femoral artery at the puncture site is smaller compared to guide catheters. The lumen of the 6F diagnostic catheters is similar to the lumen of 5F guide catheters. However, the force-displacement curve presents better characteristics with 6F diagnostic catheters compared to 5F guide catheters.[17,36]

The long-term prognosis after ACS in patients with a mean age of 73 showed that age and creatinine levels were the only indicators of prognosis. Hence, preserving renal function in coronary artery disease patients should be considered a priority.[37]

The intracranial bleeding rate was low, being seen in 1 patient. This patient improved after the evacuation of the clot by a neurosurgeon and subsequently came for follow-up. However, several patients who were unstable over the course of hospitalization could have presented an intracranial bleeding that was not obvious or detected (they were too unstable to be shifted for a CT scan) and eventually died. Ischemic cerebrovascular events were not documented within the first 2–3 days after the procedure. Reported rates of strokes after cardiac catheterizations (SCCs), including both ischemic and hemorrhagic types, typically within 36 hours of the procedure, range widely from 0.07% to 7.0%.[38] Low contrast volume has advantages in reducing cerebrovascular events. Ischemic or intracranial bleedings and cerebral microemboli are more common in the transradial approach.[38]

Mortality rates were reduced in our patient population. The lesser use of contrast media, direct stenting, shorter stents (mean total stent length 18 mm, median 15 mm), and reduced procedural and fluoroscopy times were the possible contributing factors. Left main coronary artery or right coronary artery ostial dissections were not present in our study population.

Cardiogenic shock is a unique scenario with multisystem involvement and complex clinical manifestations. Reduced cardiac output to vital tissues can release inflammatory cytokines and further trigger a vicious cycle that induces vital tissue damage.[39,40] The perpetuation of renal and cardiac failure is associated with very high mortality. Low contrast and fluoroscopy times can be associated with reduced damage to renal and cardiac tissues and can improve outcomes. Shorter stents are associated with better long-term results, which are validated in other studies as well.[41] Shorter procedure times are also associated with fewer complications in heparin cohorts.[42,43] Coronary vasospasms tend to occur in 15% of cases during PCI, and this rate can even be higher in ACS and more concerning in cardiogenic shock when trying to work on the non-culprit vessel.[44]

The reduction in fluoroscopy times and procedure times with low contrast usage in myocardial infarctions/ACS have significant advantages. The femoral route is easy to cannulate in emergencies, and the Cordis 6F diagnostic catheters have excellent engagement characteristics in the coronaries.

CONCLUSIONS

Angioplasty and stenting is feasible and safe when performed with Cordis 6F diagnostic catheters. By using this technique, a significant reduction of contrast and radiation dose can be observed in appropriate clinical scenarios.

CONFLICT OF INTEREST

Nothing to declare.

SUPPLEMENTARY MATERIALS

Materials and Methods
Discussion
References (45–61)

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