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Letters

Fluoroscopy Save Only Protocol Compared With Conventional Fluoroscopy and Cineangiogram in Percutaneous Coronary Intervention

Feasibility and Safety

Conventionally, a combination of both fluoroscopy (FS) and cineangiography (CA) are used during percutaneous coronary intervention (PCI). CA involves higher radiation dosage exposure than regular FS (1). However, FS-guided PCI has not been studied in terms of safety and effectiveness in the past in a randomized, controlled fashion versus conventional CA-guided PCI.

We compared the procedural feasibility, safety, radiation exposure, and short-term clinical outcomes using FS alone with conventional FS- and CA-guided PCI. This was a prospective, randomized controlled trial. Between February 2013 and August 2013, 197 patients with 227 lesions underwent PCI. Patients were randomized in a 1:1 ratio to a protocol of either exclusive FS-guided PCI or combined use of FS and CA guidance.

FS-guided intervention entailed significantly lower radiation exposure compared with CA guidance, both in terms of air kinetic energy released per unit mass (785.19 vs. 2,190.87) and dose-area product (5,798.46 vs. 9,165.24). Procedure time trended toward a lower time required for PCI in the FS group (36.7 min) compared with the CA group (41.75 min), whereas FS time was significantly lower in the FS group (6:52 min) than in the CA group (7:58 min) (Table 1).

There were no significant differences in the incidences of immediate procedural success, periprocedural myocardial infarction, and procedural death. Major adverse cardiac events (MACEs) at 6 months were also similar in both arms. The mean follow-up period was 6 months. The MACE rates were 2% and 3% in the FS and CA groups, respectively

TABLE 1 Comparison Between Fluoroscopy- and Cineangiography-Guided Percutaneous Coronary Intervention

Radiation Dosage	Fluoroscopy-Guided (n = 97)	Cineangiography-Guided (n = 100)	p Value
Fluoroscopy time, min	6:52 ± 2:58	7:58 ± 4:27	0.03*
Median	6:4	7:55	
25th percentile	5:16	4:09	
50th percentile	6:4	7:55	
75th percentile	8:02	10:33	
Procedure time, min	36.70 ± 18.55	41.75 ± 24.30	0.07 (NS)
Air KERMA, mGy	785.19 ± 67.50	2,190.87 ± 96.09	<0.01*
Median	557.30	1,019.98	
25th percentile	317.30	573.26	
50th percentile	557.30	1,019.98	
75th percentile	1,157.00	1,597.12	
Cumulative DAP, μGym^2	5,798.46 ± 959.58	9,165.24 ± 120.83	<0.01*
Median	3,927.20	5,517.55	
25th percentile	2,229.10	3,334.58	
50th percentile	3,927.20	5,517.55	
75th percentile	6,040.50	10,261.70	

Values are mean ± SD and n (%). *Significance was accepted at $p < 0.05$.

AE = adverse events; BMS = bare-metal stent; CAD = coronary artery disease; CSA = chronic stable angina; DAP = dose-area product; DVD = double vessel disease; EES = everolimus-eluting stent; Hb = hemoglobin; KERMA = kinetic energy released per unit mass; LAD = left anterior descending artery; LCx = left circumflex artery; LVEF = left ventricular ejection fraction; MACE = major adverse cardiac events; MI = myocardial infarction; NSTEMI = non-ST-segment elevation myocardial infarction; PES = paclitaxel-eluting stent; RCA = right coronary artery; STEMI = ST-segment elevation myocardial infarction; USA = unstable angina; ZES = zotarolimus-eluting stent.

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(p = NS). There was no difference in reported adverse events.

In conclusion, compared with conventional CA guidance, FS alone was found to be an equally safe and effective protocol, with similar immediate procedural and 6-month MACE rates, as well as similar clinical outcomes for PCI, and had a significantly lower radiation at the source.

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REFERENCE

1. Shah B, Mai X, Tummala L, Kliger C, et al. Effectiveness of fluorography versus cineangiography at reducing radiation exposure during diagnostic coronary angiography. Am J Cardiol 2014;113:1093–8.

Risk of New-Onset Diabetes and Cardiovascular Risk Reduction From High-Dose Statin Therapy in Pre-Diabetics and Non–Pre-Diabetics

An Analysis From TNT and IDEAL

Statins reduce coronary and cerebrovascular events in primary and secondary prevention. More intensive statin therapy compared with moderate-intensity statin therapy decreases risk even further (1). Therefore, the 2013 American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommend high-intensity statin therapy in high-risk patients. This recommendation is partly on the basis of the documented safety of higher doses. However, meta-analyses have reported a slight increase in the risk of new-onset diabetes (NOD) with statin therapy over placebo; this risk increases by an additional 12% with high-intensity therapy (2).

Fasting blood glucose (FBG) >100 mg/dl is a strong predictor of NOD; however, the incidence of NOD during statin therapy in patients with pre-diabetes (PD), which is defined as a FBG of 100 to 126 mg/dl, compared with those with normal glucose levels, has not been previously reported. We describe the incidence of NOD in patients with and without PD at baseline from the TNT (Treating to New Targets) and IDEAL (Incremental Decrease in Clinical Endpoints Through Aggressive Lipid Lowering) randomized clinical trials.

We pooled patients without diabetes at baseline from both the TNT and IDEAL trials (3,4). The TNT study randomized 10,001 patients with documented coronary heart disease to atorvastatin 10 or 80 mg/day and followed them for a median of 4.9 years (3). The IDEAL study randomized 8,888 patients with a previous myocardial infarction (MI) to simvastatin 20 to 40 mg/day or atorvastatin 80 mg/day with a median follow-up of 4.8 years (4).

The primary endpoint of our analysis was the composite of coronary heart disease death, nonfatal MI, resuscitated cardiac arrest, and stroke. NOD was defined prospectively as at least 2 post-baseline FBG measurements ≥126 mg/dl or at least 1 post-baseline FBG ≥36 mg/dl above baseline (5). FBG was measured at each 12-month visit in TNT and at randomization and at the end of study in IDEAL. We also included patients who had NOD identified through adverse event reporting or patients who received new concomitant diabetic medication.

Of the total 15,056 patients from both trials without diabetes at baseline, 5,924 (39%) had PD, and 9,132 (71%) patients did not. PD and non-PD patients were evenly balanced across the statin treatment arms. Compared with those without PD, PD patients were more likely to be older, to be men, to have metabolic syndrome, to have higher baseline blood pressure, and to have a history of hypertension. PD patients also had, on average, a higher body mass index, higher FBG, higher triglyceride levels, and lower levels of high-density lipoprotein cholesterol.

During the mean 5-year follow-up, 14.2% of PD patients developed NOD compared with 2.9% of patients without PD (hazard ratio [HR]: 5.29, 95% confidence interval [CI]: 4.6 to 6.1; p <0.001). As shown in **Figure 1**, the incidence of NOD was not time-dependent, and occurred at the same rate throughout the trial. In patients with PD, the risk of NOD was higher in the high-intensity statin group (HR: 1.20, 95% CI: 1.04 to 1.37; p = 0.010). In patients without PD, the difference between the high- and moderate-intensity treatment groups was not statistically significant (HR: 1.08, 95% CI: 0.85 to 1.38; p = 0.527).