0.997; 95% CI, 0.83 to 1.20; p = .98). The absence of additional benefit was consistent for each of the individual end points and among the subgroup of participants who underwent PCI (the majority but not all trial subjects).

Although relatively infrequent, there was a doubling of TIMI major bleeding among subjects who received the 30-mg prasugrel preload (HR, 2.0; 95% CI, 1.3 to 3.1; p = .002).

Dr. Cohen concluded that in patients with NSTEMIs undergoing invasive management within 48 hours of admission, pretreatment with prasugrel (compared with treatment started only at the time of PCI) does not decrease major ischemic events but increases major bleeding complications. It is unknown whether these findings apply to patients with longer waiting times or to those treated with other agents (eg, clopidogrel, ticagrelor). Thus, the results showed no benefit of pretreatment, and reexamination of the current guidelines may be warranted.

Operator Radiation Exposure Reduced by One-Third With Bleeper Sv Radiation Monitoring Device

Written by Toni Rizzo

Radiation exposure during cardiac catheterization can result in injury to both the operator and the patient. Operator exposure has been associated with cataract formation [Ciraj-Bjelac O et al. *Catheter Cardiovasc Interv* 2010] and implicated in brain tumors [Roguin A et al. *EuroIntervention* 2012]. Skin injury and cancer in patients have been linked to radiation exposure during catheterization as well.

Georgios Christopoulos, MD, Veterans Administration North Texas Health Care System and University of Texas Southwestern Medical Center, Dallas, Texas, USA, presented results of the Effect of a Real Time Radiation Monitoring Device on Radiation Exposure During Cardiac Catheterization trial [RadiCure; NCT01510353]. The study objective was to examine the effect of the Bleeper Sv radiation monitoring device on operator and patient radiation exposure during cardiac catheterization. The Bleeper Sv device provides real-time operator dose reporting through auditory feedback. Device feedback enables the operator to take protective measures, such as using radiation only when necessary, repositioning the camera, stepping farther away from the source, or adjusting the lead shielding.

The study included patients undergoing clinically indicated coronary angiography or percutaneous coronary intervention (PCI). A total of 505 patients were randomized to the Bleeper Sv (n = 253) or to the control group (n = 252). The primary end point was operator radiation exposure. Secondary end points were patient radiation exposure, fluoroscopy time, and contrast volume.

Similar proportions of patients in both groups received diagnostic, PCI, and diagnostic + PCI procedures. There were no significant differences in procedural characteristics between the 2 groups (p = .852).

The first operator radiation exposure in the Bleeper Sv group was reduced compared with control for diagnostic procedures (0.7 vs 1.0 millirem [mrem]; p < .001), PCI (1.1 vs 1.4 mrem; p = .323), and both (0.9 vs 1.4 mrem; p < .001), for a 36% relative reduction in overall radiation exposure. The second operator radiation exposure in the Bleeper Sv group was reduced versus control for diagnostic procedures (0.4 vs 0.7 mrem; p < .001), PCI (0.4 vs 0.6 mrem; p = .197), and both (0.5 vs 0.07 mrem; p < .001), for a 29% relative reduction in overall radiation exposure.

There were no significant differences between the Bleeper Sv and control groups in patient air kinetic energy released per unit mass (kerma) for diagnostic procedures (p = .189), PCI (p = .631), or both (p = .153). Nor were significant differences observed between the Bleeper Sv and control groups in patient dose area product radiation dose for diagnostic procedures (p = .269), PCI (p = .511), or both (p = .125). No significant differences were observed in procedural outcomes between the 2 groups.

The Bleeper Sv effect on the first operator exposure remained consistent in various subgroups. The device effect during consecutive periods across the study was consistent, showing that a learning curve was not required.

Limitations of the study included that it was conducted in a single center and that there was no blinding. Additionally, the trial was not adequately powered for differences in patient radiation exposure and did not include a formal protocol for reducing radiation exposure apart from Bleeper Sv use. Dr. Christopoulos concluded that use of the Bleeper Sv device during cardiac catheterization resulted in a 29% to 36% decrease in operator radiation exposure.

Similar Rates of Lesion Misclassification With Nonhyperemic Indices of Stenosis Severity (iFR and Pd/Pa)

Written by Toni Rizzo

Stuart Watkins, MD, Golden Jubilee National Hospital, Glasgow, Scotland, United Kingdom, presented the results of the Verification of Instantaneous Wave-Free Ratio and Fractional Flow Reserve for the Assessment of

Coronary Artery Stenosis Severity in Everyday Practice trial [VERIFY-2] comparing the performance of non-hyperemic indices of stenosis severity (instantaneous wave-free ratio [iFR] or resting distal coronary pressure / aortic pressure ratio [Pd/Pa]) with fractional flow reserve (FFR) for assessing coronary stenosis severity. Lesion-level decision making was evaluated with both a hybrid strategy and a binary cutoff value of iFR and Pd/Pa compared with FFR.

Pressure wire–derived FFR is a validated coronary lesion–level index of functional significance. However, FFR is not widely used, owing to cost, extra procedural time, and the inconvenience of intravenous or intracoronary adenosine administration. The VERIFY [Berry C et al. *J Am Coll Cardiol* 2013] and RESOLVE [Jeremias A et al. *J Am Coll Cardiol* 2014] studies confirmed that iFR and Pd/Pa have a similar diagnostic accuracy of ~80% compared with FFR. Researchers of the ADVISE II study [NCT01740895; Escaned J et al. TCT 2013] reported that with a hybrid iFR-FFR strategy, they correctly classified lesions in 94.2% of cases while avoiding adenosine administration in 65.1% of patients.

The prospective VERIFY-2 trial comprised 97 near-consecutive patients with chest pain and moderately severe coronary artery stenoses. Following diagnostic angiography, the Volcano Prestige Pressure Wire was inserted into the distal third of the coronary artery beyond the lesion. Resting Pd/Pa and iFR were recorded. Intravenous adenosine was administered, and FFR was recorded at stable maximal hyperemia.

A total of 120 lesions were studied. The mean Pd/Pa was 0.93 ± 0.06; mean iFR was 0.90 ± 0.08; and mean FFR was 0.82 ± 0.09. Assessment of the concordance of hybrid strategies based on FFR ≤ 0.8 as the gold standard showed that 10.1% of lesions were misclassified with iFR and 6.3% were misclassified with Pd/Pa (Table 1).

Based on this analysis, the rates of inappropriate percutaneous coronary intervention (PCI) and incomplete revascularization would be 8.7% and 10.9% with hybrid iFR-FFR and 0.0% and 7.7% with hybrid Pd/Pa-FFR, respectively.

Use of iFR and Pd/Pa with a predefined cutoff value compared with FFR showed that 18.3% of lesions were misclassified with iFR and 15.0% were misclassified with Pd/Pa (Table 2).

Based on this analysis, the rates of inappropriate PCI and incomplete revascularization would be 8.3% and 10.0% with iFR < 0.9 and 4.2% and 10.8% with Pd/Pa < 0.92, respectively.

Receiver operating characteristic (ROC) curves comparing iFR and Pd/Pa to FFR ≤ 0.8 showed an area under the curve (AUC) of 0.873 (95% CI, 0.805 to 0.941) for iFR and 0.889 (95% CI, 0.82 to 0.958) for Pd/Pa. ROC curves comparing iFR and Pd/Pa to FFR ≤ 0.75 showed an AUC of 0.936 (95% CI, 0.886 to 0.986) for iFR and 0.946 (95% CI, 0.899 to 0.993) for Pd/Pa.

These results showed that using a hybrid strategy with Pd/Pa-FFR or iFR-FFR provides similar levels of misclassification compared with FFR. Using a binary cutoff level for Pd/Pa or iFR results in similar levels of misclassification compared with FFR. VERIFY-2 confirmed that the diagnostic accuracy of iFR is no better than that of Pd/Pa. Whether used as part of a hybrid or binary algorithm, neither resting index is sufficiently accurate to be used as a guide to the need for revascularization.

Table 1. Assessment of Concordance of Hybrid Decision-Making Strategies Based on FFR ≤ 0.8 as the Gold Standard

Modality: Value	Lesions (n)			Misclassification (%)
	Total	Concordant	Discordant	
iFR[a]				10.1
< 0.86	23	21	2	
> 0.93	46	41	5	
Pd/Pa[b]				6.3
< 0.87	12	12	0	
> 0.94	52	48	4	

FFR=fractional flow reserve; iFR=instantaneous wave-free ratio; Pd/Pa=distal coronary pressure to aortic pressure ratio; iFR vs Pd/Pa:χ^2=0.66; *df*=1; p=.42. [a]Lesions outside the iFR adenosine zone (0.86 to 0.93). [b]Lesions outside the Pd/Pa adenosine zone (0.87 to 0.94).

Table 2. Sensitivity Analyses for iFR and Pd/Pa Based on Defined Cutoff Compared With FFR

Modality: Value	Lesions (n)		Misclassification (%)
	FFR ≤0.8	FFR > 0.8	
iFR			18.3
< 0.9	32	10	
≥0.9	12	66	
Pd/Pa			
< 0.92	31	5	15.0
≥0.92	13	71	

FFR=fractional flow reserve; iFR=instantaneous wave-free ratio; Pd/Pa=distal coronary pressure to aortic pressure ratio; iFR vs Pd/Pa: χ^2=0.48; *df*=1; p=.49.