Randomized Controlled Trial of Radiation Protection With a Patient Lead Shield and a Novel, Nonlead Surgical Cap for Operators Performing Coronary Angiography or Intervention

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Background—Interventional cardiologists receive one of the highest levels of annual occupational radiation exposure. Further measures to protect healthcare workers are needed.

Methods and Results—We evaluated the efficacy of a pelvic lead shield and a novel surgical cap in reducing operators’ radiation exposure. Patients undergoing coronary angiography or percutaneous coronary intervention (n=230) were randomized to have their procedure with or without a lead shield (Ultraray Medical, Oakville, Canada) placed over the patient. During all procedures, operators wore the No Brainer surgical cap (Worldwide Innovations and Technology, Kansas City, KS) designed to protect the head from radiation exposure. The coprimary outcomes for the lead shield comparison were (1) operator dose (µSv) and (2) operator dose indexed for air kerma (µSv/mGy). For the cap comparison, the primary outcome was the difference between total radiation dose (µSv; internal and external to cap). The lead shield use resulted in a 76% reduction in operator dose (mean dose, 3.07; 95% confidence interval [CI], 2.00–4.71 µSv lead shield group versus 12.57; 95% CI, 8.14–19.40 µSv control group; \( P < 0.001 \)). The mean dose indexed for air kerma was reduced by 72% (0.004; 95% CI, 0.003–0.005 µSv/mGy lead shield group versus 0.015; 95% CI, 0.012–0.019 µSv/mGy control group; \( P < 0.001 \)). The cap use resulted in a significant reduction in operator head radiation exposure (mean left temporal difference [external–internal] radiation dose was 4.79 [95% CI, 3.30–6.68] µSv; \( P < 0.001 \)).

Conclusions—The use of a pelvic lead shield and the cap reduced significantly the operator radiation exposure and can be easily incorporated into clinical practice.

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Key Words: cardiology  ■  coronary angiography  ■  coronary angioplasty  ■  percutaneous coronary intervention  ■  radiation

Use of radiation for medical examinations and tests is the largest artificial source of radiation exposure.\(^1\) Radiation for medical use has increased 3-fold since 1980s.\(^2\) Interventional cardiology procedures are only 12% of all radiological procedures but contribute about 48% of the total collective dose in the adult cardiology patient.\(^3\) In contrast to other radiation-based imaging and therapeutic modalities, these fluoroscopic-based procedures are unique in that healthcare workers also receive meaningful radiation doses. Radiation exposure is well known for its stochastic effects (eg, risks of inducing malignant diseases\(^4\)) and deterministic effects (eg, skin damage as well as cataract formation\(^5,6\)).

Although these risks are difficult to quantify, there is increasing awareness in the literature of the ALARA (as low as reasonably achievable) principle and the need to protect the operator and the laboratory staff.\(^7\)

A recent case series of predominantly left-sided brain tumors in interventional cardiologists further highlights a potential dose–risk relationship.\(^8\) Healthcare workers using fluoroscopy wear lead but the head is not covered typically. Data suggest that interventional cardiologists’ cranial radiation
WHAT IS KNOWN

• Interventional cardiologists receive one of the highest levels of annual occupational radiation exposure.
• Radiation exposure is well known for its stochastic effects (eg, risks of inducing malignant diseases) and deterministic effects (eg, skin damage as well as cataract formation).

WHAT THE STUDY ADDS

• We evaluated the efficacy of a custom-made pelvic lead shield and a novel surgical cap in reducing interventional cardiologists’ radiation exposure.
• We found that the use of the pelvic lead shield and the cap reduced significantly the operator radiation exposure.
• These protective measures can be incorporated into clinical practice and increase operators’ safety.

The study had 2 objectives. We sought to determine the efficacy of (1) a specialized lead shield draped over the patient and (2) the nonlead surgical cap worn by the operator (No Brainer, 9100-Y RADPAD, lead equivalency 0.125 mm, weight 53 g, list price $6.50 USD; Figure 1A). Lead shields were placed in sterile bags. The top lead drape was placed on the patient after the patient was prepped underneath sterile drape and placed below the femoral arteries with semicircular cut outs at the level of the femoral arteries. The top lead drape was placed on top of sterile drapes to facilitate rapid removal in case imaging of iliac and femoral arteries would be needed. This design allows operators to take postfemoral access sheath angiograms.

The cap used was a novel, paper thin, nonlead surgical cap (No Brainer, 9100-Y RADPAD, lead equivalency 0.125 mm, weight 53 g, list price $6.50 USD; Figure 1B). It contains bismuth and barium to block radiation and is lead free. The cap was disposable but could be used repeatedly by the same operator over multiple procedures. The operators were given new caps whenever their caps were noticed to be damaged. The cap is to be worn as far down forehead as possible to maximize protection.

Operator radiation exposure was measured using 3 direct readout digital dosimeters (radiation dose in μSv was recorded using Unfors...
Educational Direct Dosimeters (EDD-30). One dosimeter was placed on the left side of the operator’s chest outside the lead apron to measure overall radiation exposure because of scatter radiation. The other 2 dosimeters were placed on the left temporal region of the operator’s head (1 external and 1 internal to the cap to assess the efficacy of the cap). Characterization of the performance of the EDD-30 dosimeters in an interventional radiology suite was performed before the study and the results were published separately. The EDD-30 dosimeters responded to increase intensity of radiation with a high degree of linearity \((R>0.99; P<0.001)\) and had high degree of accuracy \((R>0.99; P<0.001)\) when compared with a gold-standard ion chamber. The detection limit of each probe was estimated to be 0.6 µSv with an associated uncertainty of 5%. The dosimeters were reset before every procedure and the operator radiation dose was recorded at the end of each procedure by a trained study coordinator. Similarly, the air kerma at the interventional reference point and fluoroscopy time were recorded at the end of each procedure. Dose area product was not available on the current equipment used in the study.

### Trial Outcomes

For the first (lead shield) objective, there were 2 coprimary outcomes: (1) the difference in operator radiation dose (µSv) measured at left breast outside of operator’s lead and (2) the difference between operator dose indexed for air kerma (dose/air kerma in µSv/mGy) between the 2 groups. Indexing operator dose for air kerma allows an estimate of benefit for operator after adjusting for dose delivered to patient and therefore would be valuable in case of baseline differences in the procedures. Because air kerma at the interventional reference point is an equipment generated number and not a measurement performed in the laboratory, there is no impact because of shielding. For the second (radiation protection cap) objective, the primary outcome was the difference between total radiation doses as measured by the 2 dosimeters (µSv) at left temporal region of the head of the interventional cardiologist (ie, external dosimeter versus internal dosimeter to the cap).

Operators were also asked to rate the comfort of the cap on a scale of 0 to 10 with 10 being most comfortable after each procedure. This was important as caps that are heavy and uncomfortable are unlikely to be adopted in clinical practice.

### Statistical Analysis

#### Sample Size

Based on mean radiation exposure during femoral PCI of 21 µSv±14 SD in a control sample13 and assuming normality of distribution for the outcome and a 1-sided \(\alpha\) of 5%, 226 patients were required to have 80% power to detect a 25% reduction in the mean operator radiation dose. The Bonferroni correction to control type I error in the context of multiple comparisons (2 coprimary outcomes) was applied, so that \(P\) values <0.025 were considered significant for coprimary outcomes.

With a total of 226 patients, we calculated that we would have 98% power with a significance level of 5% to detect a 25% reduction in the mean radiation dose/air kerma ratio (based on a 1-sided \(t\) test, mean 0.0317 microSv/mGy±SD of 0.0144 in pretrial mock runs group). Furthermore, assuming the same distribution for the mean radiation dose at the left temporal region of the head (ie, 21±14 µSv), 226 patients would provide 98% power to detect a 25% reduction in the mean radiation dose inside the cap when compared with the dose outside the cap. For the 3 outcomes, reliable estimates of the intra-class correlations (ICC) because of operator were unknown. For the purpose of sample size calculation, they were assumed to be low and with no substantial effect on the study power.

The baseline characteristics were reported as mean (SD) or median (first quartile [Q1], third quartile [Q3]) for continuous variables and count (percent) for categorical variables. The results were

### Table 1. Baseline Characteristics of the Patients*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Lead Shield (n=113)</th>
<th>Control (n=115)</th>
<th>Total (n=228)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>64.73±11.33</td>
<td>66.59±11.62</td>
<td>65.67±11.49</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>38 (34)</td>
<td>36 (31)</td>
<td>74 (32)</td>
</tr>
<tr>
<td>Median body mass index†</td>
<td>27.71 (24.84–32.470)</td>
<td>28.32 (22.99–33.26)</td>
<td>29.69±7.12</td>
</tr>
<tr>
<td>Previous CABG, n (%)</td>
<td>10 (9)</td>
<td>22 (19)</td>
<td>32 (14.06)</td>
</tr>
<tr>
<td>Inpatients, n (%)</td>
<td>78 (69)</td>
<td>74 (64)</td>
<td>132 (67)</td>
</tr>
<tr>
<td>Indication for procedure, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSTEMI</td>
<td>54 (48)</td>
<td>47 (41)</td>
<td>101 (44)</td>
</tr>
<tr>
<td>Staged PCI</td>
<td>39 (35)</td>
<td>49 (43)</td>
<td>88 (39)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>11 (10)</td>
<td>11 (10)</td>
<td>22 (10)</td>
</tr>
<tr>
<td>Stable angina</td>
<td>7 (6)</td>
<td>6 (5)</td>
<td>13 (6)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>1 (1)</td>
<td>2 (2)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>STEMI</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>1 (0)</td>
</tr>
</tbody>
</table>

CABG indicates coronary artery bypass grafting surgery; NSTEMI, non-ST-segment–elevation myocardial infarction; PCI, percutaneous coronary intervention; and STEMI, ST-segment–elevation myocardial infarction.

*Plus or minus values are mean±SD.
†Body mass index is the weight in kilograms divided by the square of the height in meters.
using a mixed effects linear regression model. Operator effects were included in the analyses of the primary outcomes as a clustering effect because each physician performed this intervention for multiple randomized patients. Subgroup analyses were also performed using mixed effects linear regression. Consistency of the treatment effect was evaluated in 5 clinically relevant subgroups: (1) CTO versus non-CTO, (2) PCI including rotablation versus coronary angiography only, (3) femoral versus radial access, (4) tertiles of patient body mass index, and (5) cardiologist attending versus cardiology trainees (residents and fellows) as the primary operator. For the radiation protection cap objective, the difference between the internal and external radiation doses was analyzed using a mixed effects linear regression model, with operator included as a random effect. The analysis was adjusted for treatment group (lead shield group versus control group). The intraoperator correlation coefficients of the 3 outcomes were estimated using the mixed effects model. The least-squares mean estimates derived from linear mixed models were back transformed.

**Results**

Between November 2013 and May 2014, 230 patients undergoing coronary angiography or percutaneous coronary intervention at the Hamilton General Hospital, Canada (Figure 2) were enrolled. Two patients were excluded because of technical and logistic issues related to the dosimeters. There were 10 operators and each operator treated 1 to 53 patients. Characteristics of the enrolled patients who underwent randomization were similar in both treatment groups (Table 1); 74 (32%) were women, mean age of 66±11.49 (SD) years, and mean body mass index of 30±7.12 (SD) kg/m². The lead shield group had 10 (9%) patients with a previous history of coronary artery bypass grafting surgery compared with 22 (19%) patients in the control group.

Characteristics of the procedures performed were similar in both treatment groups (Table 2); PCI with stenting was performed in 163 (71.5%) of cases, whereas diagnostic angiography only in 60 (26.0%) of cases. Radial access was performed in 172 (75.4%) of procedures, and 18 (7.9%) of procedures were planned chronic total occlusion PCI. Fluoroscopy time, air kerma, and contrast volume were similar in both treatment groups (Table 2).

**Lead Shield**

Lead shield use resulted in a 76% reduction in operator radiation exposure in the lead shield group (mean left chest radiation, 3.07 [95% confidence interval (CI), 2.00–4.71] μSv versus 12.57 [8.14–19.40] μSv, P<0.001; ICC=0.078; Table 3). The mean left chest radiation dose as a function of air kerma was reduced by 72% (0.004 [95% CI, 0.003–0.005] μSv/mGy versus 0.015 [95% CI, 0.012–0.019] μSv/mGy, P<0.001; ICC=0.028). The lead drape was well tolerated by patients. Only 1 patient who weighed 52 kg asked to remove the drape because she felt that it was heavy.

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**Table 2.** Details of Procedures*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Lead Shield (n=113)</th>
<th>Control (n=115)</th>
<th>Total (n=228)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator being a clinical fellow, n (%)</td>
<td>64 (57)</td>
<td>69 (60)</td>
<td>133 (58)</td>
</tr>
<tr>
<td>Vessel on which PCI was performed, n (%)†</td>
<td>33 (29)</td>
<td>27 (23)</td>
<td>60 (26)</td>
</tr>
<tr>
<td>No. of stents inserted, n (%)†</td>
<td>0</td>
<td>2</td>
<td>22 (10)</td>
</tr>
<tr>
<td>1</td>
<td>52 (65)</td>
<td>50 (57)</td>
<td>102 (61)</td>
</tr>
<tr>
<td>≥2</td>
<td>26 (33)</td>
<td>35 (40)</td>
<td>61 (36)</td>
</tr>
</tbody>
</table>

CABG indicates coronary artery bypass grafting surgery; IQR, inter quartile range; LAD, left anterior descending artery; PCI, percutaneous coronary intervention; and RCA, right coronary artery.

*Plus or minus values are mean±SD.
†Proportion out of PCI performed.

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**Table 3.** Trial Outcomes for Lead Drape Comparison*

<table>
<thead>
<tr>
<th>Outcomes for Lead Drape Comparison</th>
<th>Lead Shield (n=113)</th>
<th>Control (n=115)</th>
<th>Percentage of Reduction (95% CI)</th>
<th>P Value</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator dose, μSv</td>
<td>3.07 (2.00–4.71)</td>
<td>12.57 (8.14–19.40)</td>
<td>76 (66–83)</td>
<td>&lt;0.001</td>
<td>0.078</td>
</tr>
<tr>
<td>Operator dose indexed for air kerma, μSv/mGy</td>
<td>0.004 (0.003–0.005)</td>
<td>0.015 (0.012–0.019)</td>
<td>72 (65–78)</td>
<td>&lt;0.001</td>
<td>0.028</td>
</tr>
</tbody>
</table>

CI indicates confidence interval; and ICC, intraclass correlations.

*Group means, percentage of reduction, and corresponding 95% CI are back-transformed least-squares mean estimates derived from linear mixed model with lead shield as fixed effect and operator as random effect.
Table 4. Trial Outcomes for the Cap Comparison∗

<table>
<thead>
<tr>
<th>Outcomes for Cap Comparison</th>
<th>Difference, External–Internal (95% CI)</th>
<th>P Value</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>4.79 (3.30–6.68)</td>
<td>&lt;0.001</td>
<td>0.027</td>
</tr>
<tr>
<td>Lead shield</td>
<td>2.73 (1.76–4.00)</td>
<td>&lt;0.001</td>
<td>...</td>
</tr>
<tr>
<td>Control</td>
<td>7.69 (6.64–10.19)</td>
<td>&lt;0.001</td>
<td>...</td>
</tr>
</tbody>
</table>

CI indicates confidence interval; and ICC, intraclass correlations.
∗Difference and corresponding 95% CI are back-transformed least-squares mean estimates derived from linear mixed model with lead shield as fixed effect and operator as random effect.

Nonlead Surgical Cap

The surgical cap use showed a significant reduction in operator head radiation exposure (mean left temporal difference [external–internal] radiation dose was 4.79 [95% CI, 3.30–6.68] μSv, P<0.001; ICC=0.027; Table 4). Significant reductions of head dose with cap occurred in both lead drape group (2.73 with 95% CI, 1.76–4.00; P<0.001) and nonlead group (7.69 with 95% CI, 5.64–10.19; P<0.001).

Median operator comfort level with cap during the procedure on a 1- to 10-point scale was 9.

Subgroup Analyses

There were consistent reductions in operator radiation exposure in the lead shield group compared with the control group within all prespecified subgroups (Table 5). There appeared to be a greater reduction in dose among femoral cases (P=0.002 for interaction). There were also consistent reductions in operator head radiation exposure within all prespecified subgroups (Table 6).

Discussion

The Radiation Protect study clearly demonstrates that a specialized lead drape placed over the patient reduces operator radiation dose to the left chest by 76% and simple lightweight cap can significantly reduce cranial dose. These simple interventions can reduce lifetime radiation dose to the primary operator by almost 3 quarters which is important for health professionals over a 30- to 40-year career.

Recent case series of predominantly left-sided brain malignancies in interventional cardiologists or electrophysiologists have raised concern. Furthermore, the finding of primarily left-sided tumors is of interest because tumors should be equally distributed between right and left. The finding of the disproportionate left-sided head malignancies is important because the left-side of the operator head is as twice as exposed when compared with the right, as the cardiologist stands during the procedure on the right of the patient with the radiation source to the left. The National Cancer Institute estimates an annual incidence of 0.2% of brain and other nervous system cancer in the general population. However, the true incidence or lifetime risk of healthcare worker working with radiation is currently unknown.

With regard to a protective cap, a prior observational study assessed a lead cap that is 1.14 kg in weight and provides 0.5-mm lead equivalent protection showed a significant reduction in operator radiation exposure with the cap. The cap tested in our study is <1/20 the weight (53 versus 1140 g) and so is likely to be much better tolerated by healthcare workers as demonstrated in our survey.

Lange et al randomized 210 patients undergoing coronary angiography alone to a 1-piece lead drape with a central cut out for femoral access. The trial demonstrated significant reductions in operator dose for both radial and femoral access consistent in magnitude with the results of our study. However, our design builds further on this study with a 2-piece drape that is reusable and can be easily covered in sterile bags and the top drape can be rapidly removed if imaging of iliac or femoral arteries are needed. Given that the lead shields are reusable, the costs are minimal per case.

Reducing dose is still important and so measures to reduce overall dose, including coning in (collimation), reducing extreme angles, reducing frame rate, and using fluoroscopy save, should be used whenever possible. Orthopedic injuries remain an important cause of disability in healthcare workers.

Table 5. Radiation Dose (in μSv) for Lead Shield and Control Groups by Prespecified Subgroups∗

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Lead Shield (n=113)</th>
<th>Control (n=115)</th>
<th>Percentage of Reduction (95% CI)</th>
<th>P Value</th>
<th>Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTO, n=18</td>
<td>6.74 (2.76–16.45)</td>
<td>36.57 (13.96–95.77)</td>
<td>82 (38–95)</td>
<td>0.648</td>
<td></td>
</tr>
<tr>
<td>Non-CTO, n=210</td>
<td>2.82 (1.88–4.24)</td>
<td>11.41 (7.52–17.33)</td>
<td>75 (65–83)</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>PCI including rotablation, n=152</td>
<td>3.60 (2.37–5.46)</td>
<td>14.56 (9.50–22.30)</td>
<td>75 (63–84)</td>
<td>0.855</td>
<td></td>
</tr>
<tr>
<td>Coronary angiography only, n=60</td>
<td>1.84 (1.11–3.05)</td>
<td>6.92 (4.00–11.97)</td>
<td>73 (49–96)</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>Femoral, n=56</td>
<td>2.12 (1.20–3.74)</td>
<td>22.43 (13.21–38.08)</td>
<td>91 (81–95)</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>Radial, n=172</td>
<td>3.37 (2.22–5.10)</td>
<td>10.20 (6.67–15.59)</td>
<td>67 (52–77)</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>BMI tertile 1, n=76</td>
<td>2.19 (1.29–3.69)</td>
<td>9.67 (5.80–16.14)</td>
<td>77 (60, 87)</td>
<td>0.517</td>
<td></td>
</tr>
<tr>
<td>BMI tertile 2, n=76</td>
<td>3.22 (1.93–5.36)</td>
<td>16.03 (9.49–27.07)</td>
<td>80 (64–89)</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>BMI tertile 3, n=76</td>
<td>4.06 (2.42–6.82)</td>
<td>12.81 (7.63–21.49)</td>
<td>68 (43–82)</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>Fellow, n=133</td>
<td>3.55 (1.66–7.60)</td>
<td>13.48 (6.28–28.93)</td>
<td>74 (59–83)</td>
<td>0.619</td>
<td></td>
</tr>
<tr>
<td>Attending, n=95</td>
<td>2.67 (1.51–4.75)</td>
<td>12.06 (6.71–21.68)</td>
<td>78 (62–87)</td>
<td>...</td>
<td></td>
</tr>
</tbody>
</table>

BMI indicates body mass index; CI, confidence interval; CTO, chronic total occlusion; and PCI percutaneous coronary intervention.
∗Group means, percentage of reduction, and corresponding 95% CI are back-transformed least-squares mean estimates derived from linear mixed model including lead shield, each grouping variable, and the interaction term between lead shield and the grouping variable as fixed effects, and operator as random effect.
suggest that a drape across a patient does not adversely affect dose reductions with a lead drape over the patient, this simple intervention should be adopted as standard of care in accordance with the ALARA principle.

Limitations

The primary limitation of this study is that we did not directly measure the patients’ radiation exposure. Modeling studies suggest that 2 independent randomized trials have shown substantial dose reductions with a lead drape over the patient, this simple intervention should be adopted as standard of care in accordance with the ALARA principle.

The subgroup analyses from Radiation Protect showed clinically significant reductions in all of the prespecified subgroups, including diagnostic coronary angiography. This data suggest that the lead drape should be used in all cases and not in just high-dose cases (eg, CTO-PCI). Furthermore, given that 2 independent randomized trials have shown substantial dose reductions with a lead drape over the patient, this simple intervention should be adopted as standard of care in accordance with the ALARA principle.

The primary limitation of this study is that we did not directly measure the patients’ radiation exposure. Modeling studies suggest that a drape across a patient does not adversely affect patient dose. However, another study has shown reductions in operator dose but increase in patient exposure. Based on this, it is possible that the dose for the patient is increased with lead drapes. It is therefore important to also attempt to minimize patient dose using improved software upgrades designed to provide minimum possible dose and to use 7.5 frames/s instead of 15 frames/s when possible. The net result of these multiple interventions is likely same or lower dose for patient and markedly reduced dose for healthcare workers.

Further studies to assess the potential increase in patient doses should be performed. The second limitation is that there was a higher rate of patients with prior coronary artery bypass grafting in control group. However, the reduction in operator dose indexed for air kerma suggests that there is >70% reduction in operator dose when indexing for dose delivered to patient. The third limitation is that this was a single-center randomized trial. However, given the consistent findings with a previous independent randomized and the simplicity of the intervention, we think that the results have external validity.

Conclusions

The use of a specialized lead shield atop the patient and the cap significantly reduced operator radiation dose each independently. These protective measures can be incorporated into clinical practice and increase operators’ safety.

Sources of Funding

The study was sponsored by Division of Cardiology, McMaster University, Hamilton, Canada. Lead drapes provided by UltraRay Medical, Oakville, Canada and caps provided by Worldwide Innovations & Technologies, Kansas City, KS.

Disclosures

None.

References


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