VASCULAR LITERATURE HIGHLIGHTS

BASIL-2 Study Finds Better Amputation-Free Survival With Endovascular-First Treatment Strategy Versus Vein Bypass in CLTI Patients Requiring Infrapopliteal Revascularization

In the BASIL-2 study, patients with chronic limb-threatening ischemia (CLTI) requiring infrapopliteal revascularization who received best endovascular treatment had better amputation-free survival (AFS) as compared with those who received surgical vein bypass. Limb-related outcomes were similar between groups. Results of BASIL-2 were presented by Bradbury et al at the 2023 Charing Cross Symposium and were simultaneously published in *The Lancet*.[1]

BASIL-2 was an open-label, pragmatic, multicenter, randomized, phase 3 trial of patients who presented with CLTI to hospital-based vascular surgery units in the United Kingdom (n = 39), Sweden (n = 1), and Denmark (n = 1) between July 22, 2014 and November 30, 2020. Patients were included if they required an infrapopliteal (with or without an additional more proximal infrainguinal) revascularization procedure to restore limb perfusion; had a life expectancy > 6 months; were judged to require and be suitable for both infrapopliteal vein bypass or infrapopliteal endovascular intervention by at least two consultants (each of whom could perform the procedures), including having adequate aortoiliac inflow to support either procedure; had no previous vascular intervention to the target infrapopliteal artery within the previous 12 months; and were able to complete health-related quality of life (HRQOL) and health economic questionnaires. Exclusion criteria included presence of ischemic pain or tissue loss not primarily caused by atherosclerotic peripheral artery disease.

A secure online randomization system was used to randomize patients 1:1 to either vein bypass or best endovascular treatment. Age, presence or absence of type 2 diabetes and/or chronic kidney disease, disease severity, previous intervention in the trial leg, and intention to use a hybrid procedure were used as minimization variables to balance trial group assignments. Procedures were performed using the interventionalists' preferred equipment, devices, and technique. Patients were followed at 1-month postprocedure; 6, 12, and 24 months after randomization; and then annually until the last recruited participant had completed 24-month follow-up.

The primary outcome measure was AFS, defined as time to major amputation of the trial leg or death from any cause, whichever occurred first. Safety was evaluated by monitoring serious adverse events up to 30 days after initial revascularization.

KEY FINDINGS

- Major amputation or death occurred in 63% of patients in the vein bypass group as compared with 53% in the best endovascular treatment group.
- Fewer deaths in the best endovascular treatment group was the main driver for the difference in AFS.
- The 30-day postprocedural morbidity and death were not significantly different between the two groups.
- Cardiovascular and respiratory events were the most common causes of death in both groups.

Of 345 patients (280 men, 65 women; median age, 72.5 years), 172 were randomized to vein bypass (139 male, 33 female) and 173 were randomized to best endovascular treatment (141 male, 32 female). Two hundred primary outcome events occurred by the end of follow-up (median, 40 months [IQR, 20.9-60.6 months]). Adherence to treatment allocation was high (84% for vein bypass and 95% for endovascular treatment).

Major amputation or death occurred in 63% (108/172) patients in the vein bypass group versus 53% (92/173) in the best endovascular treatment group (adjusted hazard ratio [HR], 1.35; 95% CI, 1.02-1.80; $P = .037$). Median AFS was 3.3 (IQR, 2.1-4.3 years) and 4.4 years (IQR, 3.4-5.9 years) for the vein bypass and best endovascular treatment groups, respectively. Death from any cause occurred in 53% (91/172) in the vein bypass group and 45% (77/173) in the best endovascular treatment group (adjusted HR for overall survival, 1.37; 95% CI, 1.00-1.87). Major amputation occurred in 20% (35/172) in the vein bypass group and 18% (32/173) in the best endovascular treatment group (adjusted HR, 1.23; 95% CI, 0.75-2.01).

Thirty-day morbidity and death, major adverse limb events (MALE), major adverse cardiovascular events, relief of ischemic pain, and HRQOL did not differ between groups. Cardiovascular and respiratory events were the most common causes of death in both groups (vein bypass group, 61 and 25 deaths, respectively; best endovascular treatment group, 49 and 23 deaths, respectively).

Investigators noted that further analyses of the BASIL-2 data set and similar CLTI patient cohorts is required to understand the differences observed in this study.

1. Bradbury AW, Moakes CA, Popplewell M, et al. A vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb-threatening ischemia who required an infra-popliteal, with or without an additional more proximal infrra-inguinal revascularisation procedure to restore limb perfusion (BASIL-2): an open-label, randomised, multicentre, phase 3 trial. Lancet. Published online April 25, 2023. doi: 10.1016/S0140-6736(23)00462-2

INTERPRETING BASIL-2 AND BEST-CLI

Experts discuss the biggest takeaways from the BASIL-2 study, how to apply the results of BEST-CLI and BASIL-2 to real-world practice, most important differences between the two studies, and key remaining questions.

What are your biggest takeaways from the BASIL-2 trial and data publication?

Dr. Dua: My biggest takeaway is that we are approaching lower extremity revascularization incorrectly. To clarify, we are so focused on getting a "right answer" for a disease process, we keep trying to put these very complex patients into a box to say "endo first" or "open first" when, in reality, especially given the heterogeneous mix of patient disease patterns, operator skills, and postoperative anticoagulation measures, these types of studies will persistently arrive at the same confusing conclusions because all variables cannot be accounted for properly. Some patients need endovascular treatment, some need an open approach, some need a hybrid approach, and some patients need nothing—and it is absolutely more than just an angiogram that makes this determination.

Dr. Secemsky: My primary conclusion from the BASIL-2 trial is that there is no one-size-fits-all treatment for patients with CLTI. In this second randomized trial published within 6 months of BEST-CLI, BASIL-2 demonstrates an opposite signal, now favoring an endovascular-first approach for CLTI patients with infrapopliteal artery disease. Although the findings from BASIL-2 are supportive of endovascular treatment, there are important limitations that shouldn't move us to recommending one approach for all patients. For instance, there remains a greater need for repeat intervention among patients treated with endovascular treatment, and avoiding further interventions may be a priority for a patient. But similarly, we know surgical bypass results in longer hospital stays, higher risks of complications (infection), and in BASIL-2, worse short-term prognosis, and this may sway a patient to consider endovascular treatment first. Thus, we have now been presented critical high-level data that are supportive of each of our treatment strategies. Now, it is our job to integrate this evidence into our clinical practice.

Prof. van den Berg: The big surprise for me was the fact that endovascular therapy for CLTI was associated with significantly better AFS as compared with bypass surgery. What was also surprising was the high failure rate of the open approach, whereas the technical failure rate of endovascular treatment was comparable with what we saw in BEST-CLI (and this, in my opinion, is still too high). These results also show that there is still a lot of room for improvement in procedural success for both the open and endovascular approaches. Like BEST-CLI and other randomized controlled trials evaluating patients with CLTI, BASIL-2 has shown that patient enrollment is a major issue. Part of this was due to the concurrent COVID-19 pandemic, but because we have seen this in the past (eg, Lutonix BTK), there is probably more to it.

Prof. Varcoe: We've always known that endovascular therapy is less invasive, more easily repeatable, cost-effective, and preferred by patients compared with surgical bypass. We've now learned that an endovascular-first approach to the treatment of infrapopliteal disease in CLTI patients will reduce the incidence of AFS. This supports an endovascular-first approach to most patients with CLTI.

The lower extremity interventional field now has two contemporary level 1 data sets, but with discordant findings. What is your advice for how BASIL-2 and BEST-CLI should be viewed in total to enable the practice of evidence-based medicine?

Dr. Secemsky: Overall, I feel the take home of these studies is that treatment decisions for CLTI should first be about the patient and second about local treatment patterns. Breaking this down, how I intend to bring this into my clinic is by considering (1) the patient's individual risks (surgical, mobility, etc), (2) the patient's preferences, and (3) the strengths of the providers at the center the patient is receiving care. Time to revascularization, access, and costs are also critical here, and these all need to be considered when making a recommendation to a patient.

Prof. Varcoe: In many ways, these were two very different trials. However, some of their findings were consistent. Both showed that CLTI patients have a dismal prognosis, with an annual mortality rate of 10% to 15%, a number that has not changed over the last 25 years since BASIL-1. In well-selected, fit, and healthy patients, both endovascular treatment and bypass are safe and effective. They have similar rates of major adverse cardiovascular events and are equally effective at avoiding major amputation.

The major difference was that BASIL-2 showed that endovascular treatment had higher rates of AFS, driven by lower rates of death, which was observed over the entire follow-up period. BEST-CLI had higher rates of major surgical reintervention in the endovascular group, with similar AFS. This reintervention observation is explained by the high technical failure in the endovascular arm of BEST-CLI (15% in cohort 1; 20% in cohort 2) and the low threshold for converting those failures to surgical bypass (in cohort 1, 61% of those failures went on to bypass within 30 days; 70% in cohort 2). Unfortunately, such high rates of technical failure and low threshold for conversion do not represent current best practice in endovascular treatment for CLTI and illustrate two important limitations of that trial. First, it is likely that the most proficient endovascular centers and operators were underrepresented, either refusing to participate or enrolling very few patients due to lack of equipoise. Second, MALE is a subjective endpoint with surgical conversion left to the discretion of the operator. This was particularly relevant as 73% of interventionalists were vascular surgeons. These factors have exposed the BEST-CLI primary endpoint to significant bias, undermining its legitimacy and giving additional weight to the findings of BASIL-2.

Prof. van den Berg: Given the apparently discordant outcomes, it is important to look into the reason why there were differences. This all comes down to the definition of endpoints and inclusion and exclusion criteria. For example, BEST-CLI did not show a difference in mortality, because all patients had to be good-risk surgical candidates, which was not required in BASIL-2. This, in combination with the different endpoint definition, can explain the differences in outcome. It is important to get this question answered to avoid physicians using data from one trial or another, depending on what suits them best in their practice.

Dr. Dua: I do not think these are conflicting studies in the classic sense—it appears that the BASIL-2 trial looked at what a subset of the BEST-CLI trial encompassed (sicker patients). This brings up its own issues, namely that there is debate around what we should consider as an endpoint for patients with CLTI. Some say AFS, but patients with CLTI typically die of cardiopulmonary issues, so it does not say much about limb salvage itself, and this is an obvious confounder. Others say the endpoint should be wound healing and progression to that endpoint, but there are so many factors that contribute to wound healing, and blood supply is only one. Both are good studies with appropriate power and evaluated methodology, but from an eagle-eye view, it seems they were done in different populations and hence have differing results.

Do you feel the conflicting results of this trial reset the field to the time just before BEST-CLI data became available, or do the two trials provide some key answers while opening entirely new questions?

Prof. Varcoe: Both trials are likely to have enrolled a tiny subgroup of the entire CLTI population. As evidenced by only 2.3 and 1.3 patients per site per year enrolled in BEST-CLI and BASIL-2, respectively. This is the nature of randomized controlled trials, which attempt to keep the cohort homogenous by employing strict inclusion/exclusion criteria. Clinicians must be careful to only generalize these data to patients who fit the trial criteria specifically. Therefore, I would conclude that bypass remains a good treatment option for patients with a

suitable great saphenous vein (GSV) conduit who are fit for surgery and have a good life expectancy. An endovascular approach is a safer, less invasive alternative that can be applied to most patients as a primary strategy. Both are effective at the primary goal of treatment, which is to avoid amputation and keep people alive. Yes, this has reset those same opinions widely held in the field of limb salvage prior to both trials releasing their results.

Prof. van den Berg: I think we now actually have more answers to the questions we deal with in daily clinical practice, and the results may not be as conflicting as they seem at first sight. BEST-CLI has clearly demonstrated that in patients with available GSV graft and a good surgical risk, open procedures are the preferred treatment, while both treatment options are valid in patients without GSV graft but still at good surgical risk. BEST-CLI did not answer the question what to do with CLTI patients with an elevated surgical risk, which is oftentimes the case in real-world practice. This question is probably answered by BASIL-2 (where surgical risk was not a factor that influenced inclusion) by showing that the endovascular approach is preferred irrespective of surgical risk status. In this sense, both studies can be considered complementary.

Dr. Secemsky: These trials are critical and help move our field forward. First, this demonstrates that we can generate level 1 randomized trial data for vascular treatment, which has been a glaring deficit in our field. Second, I think we see the strengths and limitations to our procedures. I was reminded from BEST-CLI that venous bypass is a great conduit and can be a safe option in appropriately selected patients with CLTI. Third, this is a reminder that we can work together in this field across specialties. All vascular specialties in their respective countries participated in these trials, and there is no reason this shouldn't happen in daily clinical practice. Hopefully this brings the field of physicians together to try and address this highly morbid and fatal disease as a collective group.

In your opinion, what are the most impactful differences in the two trials' designs and enrolled populations?

Dr. Secemsky: First, AFS was the primary endpoint for BASIL-2, whereas BEST-CLI included major intervention (defined as surgical bypass, surgical revisions, or thrombectomy/thrombolysis). I think the very early difference in major reintervention in BEST-CLI biased the primary results against endovascular, in particular due to the early crossover. Nonetheless, we still see the consistent need for reintervention in both trials that is important in any patient discussion. Second, BASIL-2 required all patients to undergo infrapopliteal artery intervention, whereas only around 60% of patients in BEST-CLI had infrapopliteal intervention. Most advanced CLTI patients have infrapopliteal or multilevel disease, so this is a notable difference. Last, procedural specialties differed between groups. In BEST-CLI, vascular surgeons performed the majority of endovascular procedures, whereas in BASIL-2, interventional radiologists performed the majority of endovascular procedures. It is unclear if/how this made a difference, but it is worth noting.

Prof. van den Berg: As previously noted, there was a difference in enrollment regarding surgical risk, where the BASIL-2 study can be considered more of an "all-comers" study. Also, there was a difference in endpoint definition, where the endpoint of AFS as used in the BASIL-2 is probably more relevant (at least from a patient's perspective): the patient wants to stay alive without amputation, even if this would need reinterventions.

It is also interesting to see that the sample size calculation ended up with completely different numbers needed to enroll, although (in theory) both studies are evaluating the same type of patients. Finally, BASIL-2 included more patients in the open arm who underwent a true distal bypass, whereas in the BEST-CLI, a significant number of femoropopliteal bypasses was performed, which are known to provide better patency and are less technically demanding.

Prof. Varcoe: There were several, but the most important was the primary endpoint used in BEST-CLI was MALE-free survival. This included major surgical reintervention (in addition to AFS), which was a subjective endpoint left to the discretion of the operator, without being conditional on worsening symptoms, hemodynamics, or imaging and was not independently adjudicated until after the event had occurred. Some would say that it has no place as a primary efficacy endpoint in a CLTI trial, as it is not the goal of treatment to avoid reintervention; the goal is to save the leg/life. Furthermore, its subjective nature and the potential for the endovascular operator to be relatively inexperienced

(≥ 12 below-the-knee interventions in 24 months were required; one every 2 months!) have undermined the major findings of the trial, which should have been that both treatments are safe and effective in well-selected patients.

Reviewing the BASIL-2 trial and its data, what do you feel are the most important questions to be explored in subsequent analyses?

Prof. van den Berg: It is important to wait for planned subgroup analyses from the BEST-CLI trial. I am not sure whether this is also going to be done with the BASIL-2 trial (the cohort may be too small to perform such an analysis). It would also be of interest to analyze the data from BEST-CLI with the criteria and endpoint definition of BASIL-2 and vice versa. This may prove to be difficult given the surgical risk difference mentioned previously.

Prof. Varcoe: I would like to know why mortality was higher over the entire follow-up period in the bypass group. This might be expected in the short term, but it is harder to explain that difference persisting and consistently increasing over the entire follow-up period. So far, the limited data have not supported any one cause of death over another, and a more detailed examination may provide clues.

I would also like to see a deep dive into the anatomic patterns of disease treated in the entire BASIL-2 cohort compared to BEST-CLI. They may have included very different CLTI patients. We also need to specifically compare the endovascular groups between the two trials, their disease patterns, how patients were treated, and a detailed analysis of the technical failures between the two trials. That will give us insight into the generalizability of the data and may provide clues as to why so many in BEST-CLI went on to surgical conversion, a glaring inconsistency between the trials that demands further scrutiny.

Dr. Secemsky: A lot of questions remain. Do patients with just infrapopliteal artery intervention in BEST-CLI look similar to those of BASIL-2? What does BEST-CLI data look like in an as-treated population (only limited data have been revealed), both regarding the primary endpoint and AFS? What does BASIL-2 results look like if we reproduce the primary endpoint from BEST-CLI (amputation, death, major intervention)? And most importantly, how generalizable are these findings to the full community of CLTI patients?

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Community Distress Associated With Risk of Mortality and Major Amputation After Peripheral Vascular Intervention

In a retrospective review of prospectively collected data from the Vascular Quality Initiative (VQI) linked with Medicare claims data, Schenck et al found that high community distress is associated with increased risk of 24-month mortality and major amputation after peripheral vascular intervention (PVI). The study was published online in *Journal of Vascular Surgery*.[1]

Using the PVI module of the Vascular Quality Initiative (VQI) registry linked with Medicare claims data, Medicare beneficiaries were identified who were aged ≥ 18 years and underwent femoropopliteal PVI of the index limb for claudication or chronic limb-threatening ischemia (CLTI) between January 2017 and December 2018.

Patients were assigned a Distressed Communities Index (DCI) score, a composite metric of community distress measured at the zip code level and ranging from 0 (lowest community distress) to 100 (highest community distress). DCI score was then linked with clinical data using zip codes, which were ranked as prosperous (DCI quintile 1), comfortable (quintile 2), mid-tier (quintile 3), at-risk (quintile 4), or distressed (quintile 5).

Primary outcomes were 24-month mortality and major amputation. A time-dependent receiver-operating characteristic curve analysis determined the optimal DCI value to stratify patients into risk factors for the primary outcomes, and mixed Cox regression models estimated the link between DCI and the primary outcomes.

Of the 16,864 patients included in the study, 3,672 patients were in DCI quintile 1; 3,512 in quintile 2; 3,452 in quintile 3; 3,207 in quintile 4; and 3,021 in quintile 5. High community stress was classified as DCI ≥ 70.

KEY FINDINGS

- At 24 months post-PVI, rates of mortality and major amputation were both elevated in patients living in communities with high distress levels.
- Adverse outcomes in patients with high community distress persisted even after adjusting for demographic and clinical characteristics.

Mortality and major amputation at 24 months were both higher in patients with high versus lower community distress (30.7% vs 29.5%; $P = .020$ and 17.2% vs 13.1%; $P < .001$, respectively). A 10-point DCI increase was associated with both higher mortality and higher major amputation at 24 months and remained robust after adjustment for demographic characteristics, medical comorbidities, and disease severity.

Investigators concluded that future research must consider how the individual components of community distress affect risk in this patient population, as well as how individual- and policy-level interventions can address this distress and improve patient outcomes.

1. Schenck CS, Strand E, Smolderen KG, et al. Community distress and risk of adverse outcomes following peripheral vascular intervention. J Vasc Surg. Published online March 19, 2023. doi: 10.1016/j.jvs.2023.03.027

ENDOVASCULAR TODAY ASKS…

Carlos Mena-Hurtado, MD, and Kim G. Smolderen, PhD, with Yale School of Medicine in New Haven, Connecticut, provide insights into implications of the study results and future areas of research.

What did this study reveal about how community distress leads to worse outcomes after PVI?

This study highlights that increased exposures to community distress are associated with a higher risk of long-term amputation and mortality after undergoing a PVI. Community distress was measured based on patient zip code, which was then converted to an index called the DCI, which summarizes information derived from United States Census data on the percentage of adults aged ≥ 25 years without a high school diploma, poverty rate, percentage of adults aged 25 to 54 years not working, housing vacancy rate, median household income, change in unemployment rate, and change in number of business establishments. We documented these associations in the VQI registry, which was linked with Medicare outcomes data.

What would policies or interventions aimed at reducing this community-level socioeconomic distress look like?

There is an urgent need for policymakers to learn, understand, and implement changes at the reimbursement level, make investments in revitalizing local communities, and, along with partners at health system levels, work together to understand, evaluate, and redesign policies that impact social determinants of health in such a way that appropriately allocates resources in areas of need and development.

From the physician's perspective, what changes are needed when it comes to the management and follow-up of patients from communities with high DCI scores?

Awareness, recognition, and understanding of why social determinants of health affect clinical outcomes and what the mechanisms are is critical. It should be part of the risk stratification process because it tremendously impacts outcomes, and interdisciplinary care should accommodate the needs of the patients who are treated. In addition, barriers in access to care and medications need to be recognized and addressed. As an example, guideline-directed medical therapy rates are low in patients with high neighborhood distress; not being able to get access to these medications further predisposes them to increased cardiovascular risk. Concerted efforts to improve access to care and medications are therefore needed.

What questions should be addressed in future studies of this population? How do these study results inform your group's other research projects?

How can we design care to address the diverse needs that individuals with peripheral artery disease (PAD) have—not only focus on the blockage in the leg arteries? Revascularization efforts, although important, are just the tip of the iceberg. In an effort to make a dent in the increasing numbers of amputation and mortality in patients with PAD, there needs to be a paradigm shift, and this work demonstrates the need for it.

Study Explores Lead-Dust Contamination in Protection Apparel

In an occupational health safety study evaluating the presence of surface lead-dust contamination on radiation protection apparel (RPA), Manocchio et al found that 60.9% of RPA sampled were contaminated with surface lead dust, with a significantly higher prevalence of surface lead dust found on thyroid collars versus lead aprons. Results were published in *Journal of Vascular and Interventional Radiology*.[1]

Investigators undertook a survey of surface lead-dust contamination on RPA located on wall-mounted racks outside the angiography suite and emergency department of a tertiary care university hospital, the largest academic center in Canada. RPA were tested on three separate occasions from June to December 2021.

A rapid qualitative test (Leadcheck, 3M) was performed on-site to evaluate the presence of surface lead-dust contamination. Swabs were taken of a 15- X 15-cm region in the middle of the right anterior surface of both lead aprons and thyroid collars.

A total of 69 RPA were tested for surface lead-dust contamination during the study period, including 11 full-length front lead aprons, 25 full-length frontal lead aprons with 25 thyroid collars, and eight thyroid collars alone, all from a single manufacturer. Per inspection by one study investigator, 11.6% of RPA were found to be in worn or poor condition, and one RPA failed the annual quality control check and was disposed of.

KEY FINDINGS

- Approximately 60% of 69 RPA samples were contaminated with surface lead dust.
- 11.6% of RPA were found to be worn or in poor condition.
- Significantly higher surface lead-dust contamination was found on thyroid collars as compared with lead aprons.

On-site qualitative testing found an overall prevalence of surface lead-dust contamination of 60.9% (95% CI, 49.1%-71.5%). There was a significantly higher prevalence of surface lead-dust contamination on thyroid collars as compared with lead aprons (78.8% [95% CI, 62.2%-89.3%] vs 44.4% [95% CI, 29.5%-60.4%]; $P = .0035$).

The high prevalence of surface lead-dust contamination found on RPA in this study is consistent with the results of previous studies, noted the investigators. Health risks of lead exposure from RPA should be further investigated. ■

1. Manocchio F, Ni T, Pron G, et al. Lead-dust contamination on radiation protection apparel. J Vasc Interv Radiol. 2023;34:563-567. doi: 10.1016/j.jvir.2022.12.030

ENDOVASCULAR TODAY ASKS…

Study investigators Kieran Murphy, MD, FRCPC, FSIR, Professor of Interventional Neuroradiology, with University of Toronto, University Health Network and Toronto Western Hospital, and Gaylene Pron, PhD, with Dalla Lana School of Public Health, University of Toronto, were asked about the motivations behind the study, factors that might affect lead-dust contamination, and their recommendations for quality control testing of RPA.

What first motivated you to look into lead-dust contamination as a possible concern?

Dr. Murphy: I have been concerned about occupational hazards to physicians and staff radiology departments for some years. I have developed an antioxidant formulation, DNA halo, that decreases DNA damage from X-ray exposure. I became aware of the issue of elevated lead levels in the hair of x-ray technologists who worked in the angio suites. This implies they ingested lead powder by direct contact. This is not found in the hair of technologists using ultrasound, and I wanted to learn how common it was to find free lead dust on the aprons worn at University Health Network.

Your findings included higher prevalence of contamination on thyroid collars than aprons; what factors might lead to this variance between locations?

Drs. Murphy and Pron: The thyroid collars are exposed to more forces, folding, sweat, and humidity and may break down quicker than the flatter surfaces of mid chest or torso plastic coverings on lead aprons.

What is currently known about how protective apparel is tested, including long-term durability?

Drs. Murphy and Pron: There are no checks on the barrier protectiveness of lead aprons once they are sold. The lead aprons usually are x-rayed annually for cracks in the lead, but the plastic covering is not checked.

Your paper concludes with a push for frequent monitoring of physical defects but also lead-dust contamination. How frequently should facilities test their protection apparel and by what means? How will your findings affect your practices?

Drs. Murphy and Pron: These checks should be performed at least once a year. In our review, we also found there did not appear to be any effective or validated system for cleaning these garments, and this area should be investigated further. In either case, contaminated aprons should be replaced. There is no safe lead level in the body. Lead is more toxic than asbestos. ■