Smoking neglected in patients with PAD

BY MARK S. LESNEY
MDEdge News
From the Journal of the American Heart Association

Patients with claudication consulting a peripheral arterial disease provider are often active smokers, rarely receive evidence-based cessation interventions, and frequently relapse if they do quit, according to a report published online in the Journal of the American Heart Association.

More than one-third of patients with claudication consulting PAD specialists are active smokers, as seen in a data analysis of an international registry, wrote Krishna K. Patel, MD, of the department of cardiology, University of Missouri–Kansas City, and her colleagues.

The authors assessed 1,272 patients consulting PAD specialists who were 50 years of age or older and were considered high enough risk to be referred to a PAD specialist.

The authors reported an overall smoking prevalence of 34.3% and smoking prevalence of 39.4% for those who consulted a PAD specialist.

The study showed that patients with PAD who consult a PAD specialist are significantly less likely to quit smoking than the general population.

Vascular emergencies on the rise, but more patients surviving

BY KARI OAKES
MDEdge News
Reporting From Midwestern Vascular 2018

ST. LOUIS – A patient with a nontraumatic vascular emergency is significantly less likely to die today than a decade ago, with few exceptions, according to a new national analysis looking at 10 years of data. Unsurprisingly, endovascular surgery rates climbed over the study period, as did rates of acute limb ischemia, said Todd Vogel, MD, who discussed the study at the annual meeting of the Midwestern Vascular Surgical Society.

With an objective of evaluating trends for management of nontraumatic vascular emergencies in the United States, Dr. Vogel, who is chief of vascular and endovascular surgery at the University of Missouri–Columbia, and his colleagues examined frequencies of vascular emergencies, mortality rates, and how open versus endoscopic procedure technique affected the data.

To do this, the investigators used the U.S. National Inpatient Sample from 2005 to 2014 to identify nontrau-See Surviving page 7
FROM THE EDITOR

Death of a sales pitch

The EHR and our troubled health care system, Part 1

BY MALACHI G. SHEAHHAN III, MD
MEDICAL EDITOR, VASCULAR SPECIALIST

In 2000, the Institute of Medicine published “To Err Is Human,” a landmark study that warned that as many as 98,000 people die annually as a result of medical errors. One conclusion of the report stated, “When patients see multiple providers in different settings, none of whom has access to complete information, it becomes easier for things to go wrong.” Government and public reaction to the study resulted in the rushed integration of electronic health records into the U.S. medical system. EHR vendors promised solutions that included a dramatic reduction of preventable errors, a simplified system of physician communication, and the consolidation of a patient’s salient medical information into a single transferable file. Now, almost 20 years later, these promises remain mostly unfilled. How did we get here?

Systems of medical records have been in place since 1600 B.C. For thousands of years, they consisted mainly of the patient’s diagnosis and the physician’s treatment. In 1968, the New England Journal of Medicine published the special article “Medical Records That Guide and Teach” by Lawrence L. Weed, MD. In the report, Dr. Weed advocated for the organization of medical records by problems rather than by a single diagnosis. This was the birth of our modern system. Medical records would now include lists of symptoms, findings, and problems that would organize the physician’s planning and allow third parties to confirm the initial diagnosis. Nearly concurrent with this publication, the next major innovation was developing in a very unusual location.

In 1999, Fortune magazine labeled Jack Welch “Manager of the Century” for his innovative work as CEO of General Electric. His techniques involved cutting waste and streamlining his workforce. While these methods were somewhat controversial, GE’s market value increased dramatically under his watch. The publishers at Fortune became interested in finding similar innovators in other fields. In this pursuit, they sent journalist Philip Longman to find the “Jack Welch” of health care.

Mr. Longman had recently lost his wife to breast cancer and was becoming obsessed with medical errors and health care quality integration. He set out to discover the best health care system in the United States. After months of research, Mr. Longman reached a startling conclusion. By nearly every metric, the Veterans Affairs system produced the highest quality of care. The key factor in upholding that quality appeared to be the EHR system VistA (Veterans Information Systems and Technology Architecture).

The development of VistA was a grassroots effort begun in the 1970s. Using Tandy computers and Wang printers, the VA “hardhats” sought to develop an electronic system for medical records and communication. This effort was initially opposed and driven underground by the central bureaucracy. Laptops were confiscated, people were fired. Still, development continued, and in 1978, the Decentralized Hospital Computer Program was launched at 20 VA sites. The national rollout occurred in 1994 under the name VistA.

VistA was developed by doctors, for doctors, and it routinely enjoys the highest satisfaction rates among all available EHRs. VistA also is an open-source model; its code is readily available on the VA website. After seeing the evidence of VistA’s efficacy, Representative Pete Stark (D-CA) introduced HR 6898 on Sept. 15, 2008. The bill would establish a large federal open-source health IT system that private hospitals could leverage. The bill also mandated that only open-source solutions would receive federal funding. As opposed to proprietary systems, open-source models allow for rapid innovation, easy personal configuration, and incorporation of open-source apps from unlimited numbers of contributors.

HR 6898 never passed, despite initial bipartisan support. By relying on lobbyists, marketing, and money, the proprietary EHR vendors killed the Stark bill. After a 4-month scramble, the Health Information Technology for Economic and Clinical Health Act (HITECH) passed, with EHR vendor support. HITECH established a certification system for EHRs. While the Stark bill envisioned a single, open-source network, there were soon hundreds of certified EHR systems in the United States.

Death continued on page 17
Peripheral arterial disease

Smoking from page 1 with PAD and new or worsening claudication who were enrolled at 16 vascular specialty clinics from 2011 to 2015 in the PORTRAIT (Patient-Centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease: Investigating Trajectories) registry (clinicaltrials.gov: NCT01419080).

In-person interviews obtained smoking status from patients and information on cessation interventions at baseline and at 3, 6, and 12 months. At baseline, 474 (37%) patients were active, 660 (52%) were former, and 138 (11%) were never smokers.

Among active smokers, only 16% were referred to cessation counseling, and only 11% were prescribed pharmacologic treatment.

At 3 months, the probability of quitting smoking was 21%. Those who kept smoking had a probability of quitting during the next 9 months that varied between 11% and 12% (P less than .001). The probability of relapse was high, with more than one-third of initial quitters (36%) resuming smoking, and at 12 months, 72% of all original smokers continued to smoke, according to the authors.

The high level of initial smoking and the failed efforts at attempting cessation are clinically important because cigarette smoking is the most important and modifiable risk factor for PAD, and patients with PAD who smoke have higher rates of disease progression, according to Dr. Patel and her colleagues.

“Few patients receive formal cessation interventions. The dynamic nature of these patients’ smoking practices also underscores the need for ongoing assessment of smoking, even among those who report that they have quit, and consistent offering of evidence-based cessation support. Future research should focus on identifying optimal strategies for implementing consistent cessation support,” the researchers concluded.

The study was funded by grants from the Netherlands Organization for Scientific Research and an unrestricted grant from W. L. Gore. One of the authors owns the copyright for a Peripheral Artery Questionnaire used in the study and serves as a consultant to United Healthcare, Bayer, and Novartis, with research grants from Abbot Vascular and Novartis. Another author is supported by an unrestricted research grant by Merck and Boston Scientific. The remaining authors reported having no disclosures.


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Peripheral arterial disease

Less common were rTAAs, which occurred at a rate of about 12 per 10 million individuals at the beginning of the study period and at slightly less than 15 per 10 million by the end.

Looking at hospital resource utilization, length of stay dropped significantly (P less than .004), but costs, unsurprisingly, increased over the study period, from about $25,000 to about $30,000 per occurrence (P less than .0001). “The overall frequency of vascular emergencies has significantly increased over time,” Dr. Vogel said, “but in subgroup analysis ruptured abdominal [aortic] aneurysms are decreasing.” As endovascular procedures have increased, “The overall mortality has decreased, so we actually are doing better.” Some of this drop “may be due to improved perioperative care” as well as the increase in endovascular utilization, he noted.

In sum, though mortality has generally improved as endovascular procedures have become more common in vascular emergencies, “increased implementation of endovascular repair may not always improve outcomes,” Dr. Vogel said, especially in the context of an increasingly complex and aging patient population.

Dr. Vogel reported no conflicts of interest and no outside sources of funding.

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November Is Diabetes Awareness Month

A new flier on diabetes and vascular disease is now available in English and Spanish as an instant download. This is the second new flier produced by the SVS Foundation as part of its awareness and prevention mission. Please download and share this important information. (See p. 13).

VEITHsymposium

The 2018 VEITHsymposium was held Nov. 13-17 in New York. The symposium featured the latest pharmacologic, radiologic, surgical, and endovascular techniques and technologies, updates on clinical trials, and discussions of when treatments modalities are justified and indicated and when they are not. Follow our coverage at mdedge/vascularspecialistonline.com and in upcoming issues of Vascular Specialist.

Upcoming Meetings

(See https://vascular.org/meetings for details)

World Federation Vascular Societies Congress 2018 XXXII
Latin-American Congress of Vascular Surgery

The Congress is being held in Montevideo, Uruguay Dec. 5-8, 2018.

International Vein Congress

The Congress is being held at, Miami Beach, Fla., on April 25-27, 2019.
Rivaroxaban gains indication for CAD/PAD

BY CATHERINE HACKETT
MDEdGE NEWS

The direct oral anticoagulant rivaroxaban is now approved for prevention of major cardiovascular events in patients with chronic coronary or peripheral artery disease when taken with aspirin, Janssen Pharmaceuticals announced on October 11.

The Food and Drug Administration’s approval was based on a review of the 27,000-patient COMPASS trial, which showed last year that a low dosage of rivaroxaban (Xarelto) plus aspirin reduced the combined rate of cardiovascular disease events by 24% in patients with coronary artery disease and by 28% in participants with peripheral artery disease, compared with aspirin alone. (N Engl J Med. 2017 Oct 5;377[14]:1319-30)

The flip side to the reduction in COMPASS’s combined primary endpoint was a 51% increase in major bleeding. However, that bump did not translate to increases in fatal bleeds, intracerebral bleeds, or bleeding in other critical organs.

COMPASS (Cardiovascular Outcomes for People Using Anticoagulation Strategies) studied two dosages of rivaroxaban, 2.5 mg and 5 mg twice daily, and it was the lower dosage that did the trick. Until this approval, that formulation wasn’t available; Janssen announced the coming of the 2.5-mg pill in its release.

The new prescribing information states specifically that Xarelto 2.5 mg is indicated, in combination with aspirin, to reduce the risk of major cardiovascular events, cardiovascular death, MI, and stroke in patients with chronic coronary artery disease or peripheral artery disease.

This is the sixth indication for rivaroxaban, a factor Xa inhibitor that was first approved in 2011. It is also the first indication for cardiovascular prevention for any factor Xa inhibitor. Others on the U.S. market are apixaban (Eliquis), edoxaban (Savaysa), and betrixaban (Bevyxxa).

COMPASS was presented at the 2017 annual congress of the European Society of Cardiology. At that time, Eugene Braunwald, MD, of Harvard Medical School and Brigham and Women’s Hospital in Boston, commented that the trial produced “unambiguous results that should change guidelines and the management of stable coronary artery disease.” He added that the results are “an important step for thrombocardiology.”

First major change for added PAD medication in over 2 decades

BY MARK S. LESNEY
MDEdGE NEWS
FROM PRIMARY CARE DIABETES

Six different clinical tests used to identify peripheral arterial disease (PAD) were found to be significantly different in their ability to detect PAD in a population of 50 patients with diabetes, according to a report published online in Primary Care Diabetes.

This study assessed the same group of participants with each of the following six tests: Doppler Waveform, followed by TBPI (72%), ABPI (57%), ATP (35%), TcPO2 (30%), and pulse palpation (23%). The difference between these percentages was significant at P < .0005. “Use of only one screening tool in isolation could yield high false results, since it is clear that these tests do not concur with each other to a large extent.”

“The reported observations suggest that use of only one screening tool in isolation could yield high false results, since it is clear that these tests do not concur with each other to a large extent,” the authors stated. Dr. Azzopardi and her colleagues pointed out that the use of more specialized tools, such as duplex scanning, could be compared with these six modalities to detect PAD but that such methods were unlikely to be routinely available to primary care physicians who are at the front lines of making the determination of PAD in patients with diabetes.

“The authors advocate for urgent, more robust studies utilizing a gold standard modality for the diagnosis of PAD in order to provide evidence regarding which noninvasive screening modalities would yield the most valid results. This would significantly reduce the proportion of patients with diabetes who would be falsely identified as having no PAD and subsequently denied beneficial and effective secondary risk factor control,” Dr. Azzopardi and her colleagues concluded. The authors reported that they had no conflicts of interest.

PAD AND CLAUDICATION

Obesity tied to improved inpatient survival of patients with PAD

BY MARK S. LESNEY
MDEDGE NEWS
FROM CLINICAL NUTRITION

The obesity paradox appears alive and well in the treatment of peripheral arterial disease (PAD), according to the results of a 10-year, 5.6-million patient database study.

The study found that coding for obesity is associated with lower in-hospital mortality in PAD patients relative to normal weight or overweight. This obesity survival paradox was independent of age, sex, and comorbidities and was seen in all obesity classes, wrote Karsten Keller, MD, University Medical Center Mainz (Germany), and his colleagues.

In total, 5,611,827 inpatients aged 18 years or older with PAD were treated between 2005 and 2015 in Germany, 5,611,484 of whom (64.8% men) were eligible for analysis. Among these, 500,027 (8.9%) were coded with obesity and 16,620 (0.3%) were coded with underweight; 5,094,837 (90.8%) were in neither class, wrote Keller and his colleagues.

Among eligible patients relative to normal weight or overweight, this association remained stable after multivariate adjustment. However, major amputation rates were significantly lower in obese patients (2.6% vs. 3.2%; P < .001), compared with the reference group (6% vs. 5.1%; P < .001), and this was consistent throughout univariate analysis.

Obese patients had lower mortality (3.2% vs. 5.1%; P < .001), compared with the reference group, and showed a reduced risk of in-hospital mortality (odds ratio, 0.617; P < .001). Univariate logistic regression analyses showed the association of obesity and reduced in-hospital mortality was consistent and significant, even with adjustment for age, sex, and comorbidities.

In contrast, underweight patients were significantly more likely to die than those in the reference group (6% vs. 5.1%; P < .001), according to the researchers. Underweight was associated with an increased risk for in-hospital mortality (OR, 1.18; P < .001), and this was consistent throughout univariate analysis.

Underweight PAD patients also had significantly higher frequencies of cancer and COPD but lower rates of diabetes mellitus, hypertension, coronary artery disease, and heart failure, compared with the reference group. Both obese and underweight PAD patients stayed longer in the hospital than the PAD patients who were not coded as underweight/obese.

Obese PAD patients had slight but significantly higher rates of MI (3.9% vs. 3.4%; P < .001) and venous thromboembolic events and more often had to undergo amputation surgery (8.3% vs. 8.1%; P < .001), including a higher relative number of minor amputations (6.3% vs. 5.5%; P < .001). However, major amputation rates were significantly lower in obese patients (2.6% vs. 3.2%; P < .001), with univariate analysis showing a significant association between obesity and a lower risk of major amputation (OR, 0.82; P < .001), which remained stable after multivariate adjustment.

Limitations of the study reported by the researchers included a lower than expected percent obesity in the 10-year database, compared with current rates, and the inability to follow tobacco use or the socioeconomic status of the patients.

“Obesity is associated with lower in-hospital mortality in PAD patients relative to those with normal weight/overweight… Therefore, greater concern should be directed to the thinner patients with PAD who are particularly at increased risk of mortality,” the researchers concluded.

The authors reported they had no disclosures.

Updated AHA recommendations favor adding nonstatin therapy for cholesterol control for some

BY GREGORY PALKO, MD, AND NEIL SKOLNIK, MD

Importance
While statins remain the foundation for treating high cholesterol in order to reduce cardiovascular risk, new evidence has led to important revisions in the American Heart Association’s recommendations for treatment of hypercholesterolemia in patients at very high cardiovascular risk (secondary prevention) with the addition of specific nonstatin agents. We will briefly review the AHA 2013 guideline recommendations, the relevant new information, and the updated AHA recommendations.

American Heart Association 2013 guidelines
The 2013 American College of Cardiology/AHA cholesterol guidelines recommend either high- or moderate-intensity statin therapy for patients in the four statin benefit groups:

1. Adult patients older than 21 years of age with clinical atherosclerotic cardiovascular disease (ASCVD).
2. Adults older than 21 years of age with low-density lipoprotein cholesterol (LDL-C) above 190 mg/dL.
3. Adults aged 40-75 years without ASCVD but with diabetes and with LDL-C 70-189 mg/dL.
4. Adults aged 40-75 years without either ASCVD or diabetes, with LDL-C 70-189 mg/dL and an estimated 10-year risk for ASCVD of over 7.5% as determined by the Pooled Cohort Equations.

At the time of the 2013 guidelines, there was little evidence to recommend the use of medications other than statins.

Recent evidence
The IMPROVE-IT trial was a double-blind, randomized trial involving 18,144 men and women who were older than 50 years and hospitalized for an acute coronary syndrome within the preceding 10 days. They were randomized to either simvastatin plus ezetimibe or simvastatin plus placebo. The primary endpoints were a composite of death from cardiovascular disease, a major coronary event (nonfatal MI, unstable angina requiring admission, or coronary revascularization), or nonfatal stroke. At 1 year, the mean LDL was 69.9 mg/dL in the simvastatin-monotherapy group and 53.2 mg/dL in the simvastatin-ezetimibe group (P under .001), representing a 24% decrease in LDL between the two groups. The rate of the primary endpoints was significantly lower in the simvastatin plus ezetimibe group with a hazard ratio of 0.936 (P = .016). The risk of MI was significantly decreased with an HR of 0.87 (P = .002), and the risk of ischemic stroke significantly decreased, with an HR of 0.79 (P = .008). Prespecified safety endpoints showed no significant difference between the two groups.

The FOURIER trial examined the PCSK-9 inhibitor, evolocumab. FOURIER was a randomized, double-blind, placebo-controlled study involving 27,564 patients with atherosclerotic cardiovascular disease and LDL levels of 70 mg/dL or higher who were receiving statin therapy (at least atorvastatin 20 mg or equivalent with/without ezetimibe). Patients were between 45 and 80 years old with a history of history of MI, nonhemorrhagic stroke, or symptomatic peripheral arterial disease. Patients were randomized to receive subcutaneous injections of evolocumab or matching placebo. The primary endpoints were similar to that of IMPROVE-IT: a composite of cardiovascular death, myocardial infarction, stroke, unstable angina hospitalization, and coronary revascularization. The median LDL on entry was 92 mg/dL for both groups.

At 48 weeks, the evolocumab group showed a 59% decrease in LDL, compared with placebo, with a decrease in median LDL from 92 mg/dL to 30 mg/dL. The primary endpoint occurred in 9.8% of the evolocumab group and 11.3% in the placebo group, for a total risk reduction of 13.2%. The risk of MI or stroke and need for revascularization were significantly lower values in the evolocumab group, compared with placebo. Cardiovascular death did not show significant changes. There was no significant difference in rate of serious events.

The ODYSSEY trial reported on another PCSK-9 inhibitor, alirocumab, in a randomized, double-blind, placebo-controlled trial involving 18,924 patients who had acute coronary syndrome in the prior 12 months. At the median follow-up (2.8 years), the LDL of the alirocumab group was 53.3 mg/dL, compared with 101.4 mg/dL in the placebo group. The primary endpoints for cardiovascular risks were similar to those in the FOURIER trial: a risk of 9.5% in the alirocumab group and 11.1% in the placebo group, for a total risk reduction of 14.4%. This suggests the class of PCSK-9 inhibitors have a strong correlation with reducing LDL levels 54%-59% and reducing major cardiovascular events by 13%-15%.

Recommendations
The American College of Cardiology released a focused update that integrated the new evidence regarding the use of nonstatin therapy. The current focused update recommends an overall 30% or greater reduction in LDL for patients with clinical ASCVD. If this reduction is not achieved, ACC suggests that one consider the addition of nonstatin therapy with either ezetimibe or a PCSK-9 inhibitor. If a patient requires less than 25% additional LDL reduction, consider ezetimibe; if a patient requires more than 25% additional LDL reduction, consider a PCSK-9 inhibitor. Specifically, the guidelines state: “If the patient still has less than 30% reduction in LDL-C (and may consider LDL-C above 70 mg/dL or non-HDL-C above 100 mg/dL), the patient and clinician should enter into a discussion focused on shared decision making regarding the addition of a nonstatin medication to the current regimen.”

The other group that is mentioned in the recommendations, with an acknowledgment that the evidence for benefit in primary prevention is not available, is individuals who have an LDL above 190 mg/dL even while compliant with a maximally effective statin regimen. The guidelines make further but less strong recommendations about a number of risk groups, but the largest and strongest change, based on strong evidence, is the recommendation to consider nonstatin therapy in individuals with established ASCVD, as described above.

Bottom line
Recent trials show significant reductions in LDL, leading to significant reductions in cardiovascular endpoints, with ezetimibe and PCSK-9 inhibitors. This has led to an additional ACC recommendation to consider the use of nonstatin therapy in addition to maximal statin therapy in selected patients with established cardiovascular disease.

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Veteran’s Vietnam Registry Contributions Still Resonate Half-Century Later

(Not: Veterans Day is celebrated every November. The day, created to commemorate the end of World War I, now honors all those who have served in the United States armed forces, in times of peace and in times of war. In honor of our many SVS veterans, we highlight the story of Dr. Norman Rich. He served in Vietnam, retired from the Army as a colonel, headed up the Uniformed Services University of the Health Sciences for a quarter-century, was a professor of surgery for 42 years and also created and sustained the Vietnam Vascular Registry for more than 50 years.)

Dr. Norman Rich decided his career path early in life, listening to the doctor who delivered him relay the horrors of the amputations of World War I. “Someday, blood vessels will be repaired,” he told me,” said Dr. Rich of his early mentor, Dr. Otto Utzinger of Ray, Ariz. “And I thought, ‘I’d like to be involved with that.’ It set my career!”

He perhaps never dreamed as a young boy and man just how closely he would come to be associated with vascular injuries as well as treatments that would save a leg savaged by vascular trauma, avoiding the amputation that had so disturbed Dr. Utzinger.

Dr. Utzinger was just one of Dr. Rich’s mentors. Others include some of the giants of vascular surgery: Drs. Michael DeBakey, Carl Hughes, Frank Spencer, Emile Holman and others. From them Dr. Rich was exposed to some of the groundbreaking treatments of vascular trauma drawn from necessity on the battlefields of World War II and Korea. These ranged from Mobile Army Surgical Hospital units close to battlefields, quick evacuation via helicopters and abandoning ligation in favor of arterial repairs, saving many legs from amputation.

Dr. Hughes had, while serving in Korea, cataloged on a large piece of cardboard the vascular cases he treated. Dr. Rich himself cataloged his own vascular trauma cases and later created the Vietnam Vascular Registry, a formal database of vascular injuries surgeons in Vietnam saw over the course of approximately eight years. Developing and maintaining the Vietnam Vascular Registry of injuries for more than 7,500 people, said Dr. Rich, is one of his proudest achievements.

Each person treated for arterial and, eventually, venous injuries received a registry card. Within the registry, individual records included the progression from injury through treatment through evacuation until point of discharge or entry into the VA system; many records even include notes from the original battlefield doctors.

“A Marine Corps general told me, in the middle of the mud, in the middle of the monsoons, ‘If you can make something good out of this horrible mess, go to it,’” said Dr. Rich. “He told me the Vietnam Vascular Registry was my chance.”

Dr. Rich’s goal was to:
• Document the details of the injury as closely as possible
• Obtain and add long-term follow-up to each entry “to see if what we did worked.”

Beyond arterial injuries, the VVR also cataloged venous injuries. “No one had had much interest in that,” Dr. Rich said. “But I kept saying, ‘Blood flows in a circle. It goes back to the heart through a vein.’” This addition led to some significant surgical treatments and saves. “I felt very good about that contribution,” he said.

He served at Walter Reed, including as head of the vascular surgery service at Walter Reed Army Medical Center, and then was tapped to found and chair the surgery department of the Uniformed Services University of the Health Sciences in Bethesda, Md., a kind of academy for military physicians. This long-term posting – unusual for military personnel who tend to move around a great deal – enabled him to maintain the VVR.

The registry has had a lasting impact. During the first Gulf War, Dr. Rich was told, “You know, that database might be of value. Weapons haven’t changed that much, and treatments haven’t either.” Interest in his registry increased.

Dr. Rich teamed with Dr. Frank Spencer, whose work in Korea revolutionized treatment of vascular injuries, to write “Rich’s Vascular Trauma,” which included VVR statistics collected up to that point. Two editions have followed, with additional statistics; the second with Ken Mattox and Asher Hirshberg of Houston and the third, by Todd E. Rasmussen, MD, FACS, and Nigel R. M. Tai, QHIS, MS FRCS (GEN), includes civilian and international statistics as well. “It makes me very glad that there has been some legacy to the registry,” said Dr. Rich.

He downplayed his own overall role, saying, “I was merely a scribe for 600,000 young American physicians who served during an eight-year period in Vietnam.”

Beyond technical information on injuries, treatments and results, Dr. Rich’s registry has accomplished important human connections as well. The records have led to more than half-a-dozen soldier reunions. For example, not long ago a U.S. Department of Defense article related the wish of a former Army Specialist to thank the surgeons who had treated him in Vietnam in 1969. John Fogle had kept his VVR registry card through the decades, and with it, Dr. Rich was able to access Fogle’s medical records, including the names of his doctors. Fogle and one of his surgeons met up in May.

Dr. Rich is now retired from the Army and from his career. His registry remains a passion. “My remaining job, is to pass my knowledge on to someone else who would be interested.”

Pivotal Long-Ago Moment To Be Retold on PBS

Reporter Ann Curry highlighted Dr. Rich’s registry on the Nov. 13 PBS show “We’ll Meet Again.” The show helps “people find someone whose actions changed the course of their lives,” according to its website, and features reunions of people whose lives crossed at pivotal moments.

The reunion shown that night is just one of at least six or seven the registry has facilitated, said Dr. Rich. The show airs at 8 p.m. Eastern and 7 p.m. Central time. Be sure to check local listings and the PBS website for repeat showings.
NEWS FROM SVS

Download Diabetes Patient Information Flier

The SVS Foundation is releasing its second new patient information flier – on diabetes and vascular disease – just in time for National Diabetes Month in November.

The fliers are great for sharing with your patients and other physicians or for anytime you provide information to the public. The SVS Foundation is producing a total of nine new fliers in English and Spanish on common topics for vascular patients. A flier on PAD was released in September.

Each flier is available in several formats – low-resolution digital for email and web use, and high-resolution for professional printing of larger quantities. The new fliers come in two versions, one with a personalization area for your name and contact information and the other with a link to the SVS “Find a Surgeon” web page.

Visit vsweb.org/FoundationFliers to access all versions of the fliers, including both high- and low-resolution versions.

FROM JVS:

Obesity Complicates OAR Recovery

Obese patients undergoing elective open aortic repair face an increased risk of renal failure and wound infections, according to a study published in the December issue of the Journal of Vascular Surgery. However, no similar findings of major adverse outcomes were found in obese patients undergoing endovascular aneurysm repair. Read more at vsweb.org/JVS-Obese.

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The SVS Executive Board has announced that all SVS Active Members in good standing will now be considered Fellows of the Society of Vascular Surgery™ (FSVSTM). The trademarked designation is one of the benefits of SVS membership and is a public acknowledgement that a surgeon has met the high standards SVS requires of its members and has shown a professional commitment to the field of vascular surgery.
Active members in good standing may add the initials FSVSTM after their name in any usage, such as signature lines, letterhead and door signage. For example:
• Dr. Mary Smith, MD, FSVS
• Dr. John Jones, DO, PhD, FSVS, FACS
This applies to vascular surgeons in the United States or Canada who have been approved for membership by the Society and are up-to-date on their dues. Such members can begin using the designation immediately.
If your dues have lapsed or you aren’t yet an Active Member, please contact membership@vascularsociety.org to reinstate your Active membership or to apply before using the designation. The final membership application deadline for 2018 is Dec. 1 (with the first 2019 deadline set for March 1, 2019). Get application information at vsweb.org/JoinSVS.

Distinguished Fellow of the Society of Vascular Surgery™ (DFSVSTM)
SVS has long recognized Distinguished Fellows™, members who have distinguished themselves in a sustained manner by making substantial contributions in two of three categories: research, service or education. In addition to referring to themselves as Distinguished Fellows, these honorees can now use the distinctive mark, “DFSVSTM.”
Current Senior, Active and International SVS members are eligible to apply for Distinguished Fellow status. (The annual deadline is typically March 1, with Distinguished Fellows recognized at the Vascular Annual Meeting.) The process is rigorous; upon approval, Distinguished Fellows may list the initials after their name in any usage, such as signature lines, letterhead, door signage, etc. For example:
• Dr. Mary Smith, MD, DFSVS
• Dr. John Jones, DO, PhD, DFSVS, FACS
Members must be up-to-date on their dues to use the designations. If your dues have lapsed or you aren’t yet a Distinguished Fellow, please contact membership@vascularsociety.org to reinstate your Active membership or apply for Distinguished Fellow status before using the designation.

A Summary of Advanced Business Degrees for Vascular Surgeons, from the SVS Community Practice Committee

BY SCOTT S. BERMAN, MD, MHA, FACS
SVS COMMUNITY PRACTICE COMMITTEE

The dynamic environment in which vascular surgeons are currently practicing has created abundant opportunities for physicians to move into administrative leadership positions across the spectrum of healthcare. An advanced business degree teaches a surgeon the “language” of health care business. Moreover, the degree can provide the surgeon an important level of credibility in dealing with non-physician business contemporaries working in the healthcare space. This article summarizes features of the common advanced business degrees sought by practicing surgeons through online or executive programs.

Master of Business Administration (MBA)
The MBA curriculum generally consists of a foundation of core classes divided along the traditional business verticals of strategy, operations, finance, marketing, leadership and human resource management. Elective courses delve into industry or country/region-specific topics such as health care operations, provider strategy and medical device commercialization. The electives develop both analytical and soft skills, such as model and simulation building and negotiation, respectively. An MBA’s cost ranges from approximately $10,000 for an exclusively online program to more than $150,000 for the executive program at the University of Pennsylvania’s Wharton School of Business. The usual course of study is 12 to 16 months with complete online or combined online and limited in-residence options.

Master of Health Care Administration (MHA)
Accredited MHA programs of study typically require students to complete applied experiences as well as course work in areas such as population health, healthcare economics, health policy, organizational behavior, management of healthcare organizations, healthcare marketing and communications, human resource management, information systems management and assessment, operations assessment and improvement, governance, leadership, statistical analysis and application, financial analysis and management, and strategy formulation and implementation. Costs range from $10,000 to more than $50,000 and, like MBA programs, the degree can be earned completely online or through an executive program that requires some time in residence at the parent institution. Degree completion typically takes 16 to 28 months.

Master of Medical Management (MMM)
The MMM is targeted towards physicians with leadership potential who are already in administrative positions or plan on taking on an administrative role. MMM programs consist of courses (e.g. health policy, organizational management, health economics, operations management, health finance, quality management, health care law) that are very similar to those offered in other health/business administration masters programs such as the MHA or MBA. MMM programs are currently offered at two universities: the University of Southern California and Carnegie Mellon University. Both consist of a combination of traditional and online courses. A degree at USC will cost $61,000 and take 12 to 18 months; tuition for Carnegie Mellon was not available online.

References
Please Give on #GivingTuesday, and During the Holiday Season

The turkey has been reduced to sandwiches and a wishbone and the mashed potatoes are just a memory. And between the frenzy of Black Friday and Cyber Monday shopping promotions, you’ve put a dent in your holiday shopping.

#GivingTuesday – and a contribution to the SVS Foundation – give you the chance to do something for others. #GivingTuesday is a global day of giving to kick off the charitable season, when many people focus on holiday and year-end giving. It is celebrated annually on the Tuesday following Thanksgiving, coming closely on the heels of Black Friday and Cyber Monday.

The SVS Foundation makes it easy to give, online or by check. Donations can include cash, stocks and an IRA rollover, plus through such sources as a will, life insurance, revocable trusts, a charitable gift annuity.

Donors may direct their dollars to specific areas of interest. For some, that is research that can unlock cures and treatments for circulatory disease. Others may prefer funding community health initiatives or disaster relief, or the unrestricted Greatest Need fund, known as the Annual Fund.

Why give? Simply put, “because:”

– Because research today can lead to breakthroughs tomorrow.
– Because the SVS Foundation provides resources to improve community health and raise awareness.
– Because patients need information on important aspects of vascular health.
– Because a vascular surgeon’s care today means a patient might live to see many more beautiful tomorrows: a grandchild’s wedding, a baby’s first steps, more family holidays.
– Because all of life’s moments matter.

Read more about the SVS Foundation’s efforts, plus more “Because” answers, in the SVS Foundation Annual Report, at vsweb.org/SVSF_Annual_Report_2018.

On Thanksgiving, enjoy family, football, turkey and the trimmings. Take advantage of weekend and Cyber Monday sales to start your holiday shopping.

And on #GivingTuesday, think of the patients you treat and who have more life to live BECAUSE of you and the work you do; then donate to the SVS Foundation at vsweb.org/GIVE.

SVS Creating Private Online Community

The Society for Vascular Surgery is creating a private online community, SVSConnect, with a number of resources for SVS members and their peers. This new collaborative online community will let members connect and engage with, and learn from, fellow members and peers on an infinite number of topics. It is expected to launch by late 2018.

Members will enjoy:

Member Directory Search: Locate colleagues by name, location, practice or area of interest
User-Friendly Forums: Connect and communicate with fellow members on topics large and small via computer, phone or table.
Mentor Match: Share resources and experiences as a mentor or mentee, and work together to achieve professional and personal goals.

Resource Sharing: See attachments posted to discussions, archived in a dedicated Resource Library. Members can add documents to share at any time.

SVS will tell members more about this exciting addition via Pulse, the SVS website, email and Vascular Specialist. Be on the lookout for more information about this new community!

Submit Abstracts for VRIC, VAM

Get ready to submit research for two SVS annual meetings in 2019, the Vascular Research Initiatives Conference and the Vascular Annual Meeting.

VRIC: The submission site for VRIC opened Oct. 30 and will close Jan. 15, 2019. The conference focuses on emerging vascular science and will be held May 13, 2019, in Boston. The theme is “Hard Science: Calcification and Vascular Solutions.” VRIC is held in conjunction with the American Heart Association’s Vascular Discovery Scientific Sessions, May 14 to 16, 2019.

Visit vsweb.org/VRIC19 for more information.

VAM: The VAM abstract submission site opens Monday, Nov. 12 and will close Jan. 16, 2019. Abstract guidelines are now available.

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Visit vsweb.org/VRIC19 for more information.

VAM: The VAM abstract submission site opens Monday, Nov. 12 and will close Jan. 16, 2019. Abstract guidelines are now available.

Submission categories include: aortic disease; cerebrovascular (including Great Vessels); complications; dialysis access; educational/training credentialing; peripheral arterial disease; practice management; renal/visceral disease; vascular laboratory and imaging; vascular medicine; vascular trauma: aortic, arterial, venous; venous disease; and basic research (poster competition only).

See the guidelines at vsweb.org/Guidelines19. Learn more about VAM at vsweb.org/VAM19.

The meeting will be held June 12-15, 2019, at the Gaylord National Resort & Convention Center in National Harbor, Md., outside Washington, D.C. Scientific sessions will be held June 13 through 15 and exhibits will be open June 13 and 14. Housing and registration will open in early March.
Check out the latest news online at www.mdedge.com/vascularspecialistonline

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RENAL ARTERIES

Ultrasound denervation tops RF ablation for resistant hypertension

BY M. ALEXANDER OTTO
MD EDGE NEWS
REPORTING FROM TCT 2018

SAN DIEGO – Denervation of the main renal arteries with ultrasound is more effective than radiofrequency (RF) ablation at lowering blood pressure in patients with resistant hypertension, according to a single-center, randomized trial from Germany.

Dubbed RADIOSOUND-HTN, it was the first time the two emerging technologies have been pitted against each other. At 3-month follow-up, the 42 patients randomized to ultrasound ablation with the Paradise catheter (ReCor Medical) had a mean systolic daytime blood pressure reduction of 13.2 mm Hg on ambulatory monitoring, vs. 6.5 mm Hg among 39 patients randomized to RF ablation with Medtronic’s Symplicity Spyral catheter ($P = .043$).

Meanwhile, 39 patients randomized to both main artery and side branch ablation with the Spyral had a mean reduction of 8.3 mm Hg, slightly better than RF ablation of the main renal arteries alone, but the difference was not statistically significant, and “no definite conclusion on the value of an additional side branch ablation can be drawn,” said senior investigator Philipp Lurz, MD, PhD, a cardiologist at the University of Leipzig, Germany, and his colleagues (Circulation. 2018 Sep 25. doi: 10.1161/circulationaha.118.037654).

Denervation was probably more complete with the Paradise catheter, which might explain the results. Ultrasound energy penetrates about 6-7 mm from the lumen, reaching up to 90% of sympathetic nerve fibers, while RF energy penetrates 3-4 mm; indeed, the idea of going into the branches with RF ablation is because nerve fibers are closer to the lumen surface, Dr. Lurz said at the Transcatheter Cardiovascular Therapeutics (TCT) annual meeting, where he presented the study, which was simultaneously published in Circulation.

Also, the Paradise catheter – an endovascular balloon device inflated to fit the lumen – delivers fully circumferential, ringlike ablations with each application, while the Spyral catheter delivers four ablations simultaneously in a spiral pattern, and requires more ablations to create a similar effect, said Dr. Lurz.

About two-thirds of patients in all three arms responded to treatment, meaning at least a 5 mm Hg drop in systolic blood pressure. Among the nonresponders, it’s possible that their hypertension wasn’t caused by sympathetic overdrive. “Future trials should focus on identifying these patients to avoid futile” procedures, and define “specific anatomic predictors associated with a more effective” renal denervation, Dr. Lurz and his team said in their study report.

The researchers noted that “the present study included patients with larger renal arteries” – at least one renal artery 5.5 mm or greater in diameter – “based on the assumption that sympathetic fibers are in greater distance from the lumen than in smaller arteries, and therefore … higher penetration depth would be more relevant … Results might have differed in a cohort of patients with smaller renal artery diameters.”

Both Paradise and Spyral are in pivotal trials for Food and Drug Administration approval.

The subjects were an average of 64 years. The majority were men, and there were no significant differences in baseline characteristics between the arms. The mean baseline daytime blood pressure was 153/86 mm Hg despite treatment with three or more classes of antihypertensives dosed to at least 50% of their maximum. There was no drug testing to confirm patients were taking their medications, but their general practitioners vouched for their adherence.

One patient in the ultrasound arm group developed a pseudoaneurysm treated successfully by compression. One of the RF subjects developed a postprocedural intracapsular and retroperitoneal hematoma that resolved spontaneously. No renal vascular complications or stenoses were detected at follow-up.

There was no industry funding for the work. Dr. Lurz is a speaker and consultant for both ReCor Medical and Medtronic.

Death

continued from page 6

Before the HITECH Act, many EHRs existed, but several barriers blocked full implementation. Early systems were essentially electronic filing cabinets. Their developers had not anticipated the lack of standardization among physicians and hospital systems. The need for custom EHR bases frustrated the vendors.

The question of marketing was omnipresent. Who was the actual customer? An economic model developed in which clinicians would bear the time and even financial costs as the benefits would be passed on to insurers, hospitals, and, presumably, the patients.

EHRs needed to become practical, affordable, and interoperable, but who was demanding this? Where was the financial motivation? In the beginning, vendors of EHRs had to convince doctors, the public, and the government of their worth. Now, essentially mandated by the HITECH Act, they only had to sell themselves to hospital administrators, who often had a different motive. Profits. Many of today’s EHRs are simply modified billing platforms, and doctors are paying the price. The Meaningful Use standards were meant to provide financial incentives for EHR adoption. Stage 2 required EHRs to be able to transport clinical information from one system to another. Looking at our actual practices can provide a master class in the gap between “be able to” and “actually doing.” Again, who does the EHR vendor see as the customer? Certainly not the physician. My patients can list every type of inferior vena cava filter (or at least those with pending legal action), but most of them have never heard of an EHR. Just like “service lines,” EHRs can make it very difficult for patients to seek care outside of their primary system. Who would see this barrier in communication as a perk and not a deficiency? Hospital administrators. The free transfer of medical records is bad for business. Therefore, hospitals don’t prioritize it in their EHRs. The EHR vendors also benefit since an easy transfer of records would simplify a hospital’s transition from one EHR...
Death continued from previous page to another. So, as with most deficiencies in the EHR, physicians are left to find ways around these problems. Sometimes, we need to go to comical lengths.

Two months ago, a patient pointed to a large machine behind our check-in desk. “What is that?” he asked incredulously; it was a fax machine. While my competence with this apparatus is marginal (my office staff has taken to yelling “doctor faxing!” to alert one another that I am about to inadvertently copy or scan my documents into oblivion), faxes remain a mainstay of medical care. Abandoned by modern business practices as a relic of the 1980s, why are we constantly faxing medical information? Because we are not the customer.

Disruption is now a favorable term in business. Doctors are busy people. BUSY people. Most of us walk a tightrope, a razor-thin timeline. Will we see the next patient in time, the next surgery? Will we get the medical records done today? Will we get the dictations done before being suspended? Will we make the commitment meeting, the conference call, the next clinic across town? Will we have dinner with our spouse or see our kids today? Will we make it to the parent-teacher conference inexplicably scheduled for 10:45 a.m. on a Tuesday?? When deciding between work commitments and family, we side with work overwhelmingly (and depressingly). Explaining this to a layperson is an impossible feat. I have stopped trying, stopped making excuses. Only we know how catastrophic “disruption” can be. Disruption in a 40-patient clinic. Disruption in the trauma bay. I have seen physicians reduced to tears by this disruption. Some activities need disruption. Typing with your back to the patient. Onerous documentation to facilitate billing. Faxing medical records. Will these be disrupted? Who is the customer?

In 1999, the Institute of Medicine started this process, telling us, “To err is human.” I now respond with another Alexander Pope quote, “The same ambition can destroy or save.” The money and influence of EHR vendors destroyed the chance to nationalize the most successful EHR our country has ever seen. What happens now? EHRs are incontrovertibly associated with burnout. Burnout is incontrovertibly associated with outcomes ranging from early retirement to suicide. EHRs cause physicians harm. Major vendors can follow the Big Tobacco playbook and deny the obvious, but the burden of proof is shifting to them. With their billions of dollars in profits, what have they done to study this problem? To help?

Who is their customer?

References


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**Indications**

The MISAGO® RX Self-expanding Peripheral Stent is indicated to improve luminal diameter in symptomatic patients with de novo or restenotic lesions or occlusions of the Superficial Femoral Artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4 to 7 mm and lesion length up to 150 mm.

**Important Safety Information**

Do not use this device in pregnant patients or patients who may be pregnant, patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty (PTA) procedure, patients with contraindication to antplatelet and/or anticoagulation therapy, patients with known allergy to nickel-titanium alloy, gold or contrast media, vessels in which there may be a residual stenosis of 50% diameter or larger in the target vessel after the planned intervention, a lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion, a lesion through which a guide wire cannot pass. This device should only be used by a physician who is familiar with, and well trained in, Percutaneous Transluminal Angioplasty (PTA) techniques and stent implantation.

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PAD AND CLAUDICATION

Lower-limb atherosclerosis predicts long-term mortality in patients with PAD

BY MARK S. LESNEY
MDEDGE NEWS
FROM THE EUROPEAN JOURNAL OF VASCULAR AND ENDOVASCULAR SURGERY

The location and extent of lower limb atherosclerosis predicts long-term mortality in patients with peripheral arterial disease (PAD), according to the results of a retrospective cohort study performed in England.

Comprehensive infrapopliteal arterial imaging that used duplex ultrasound to determine the overall and site-specific burden of atherosclerotic disease predicted long-term outcomes in this patient group, according to a report published online in the European Journal of Vascular and Endovascular Surgery.

“Not only does such imaging provide anatomical information to guide intervention, but it may also provide information to further risk-stratify patients with regard to long-term cardiovascular risk,” wrote Paul J.W. Tern, MD, of Addenbrooke’s Hospital, Cambridge, England, and his colleagues.

A retrospective cohort study was performed on a consecutive series of 678 patients undergoing a lower limb arterial duplex scan during October 2009–June 2011 at Addenbrooke’s Hospital. Patients had a median age of 74 years and were followed for a median of 70 months.

A total of 307 patients died, which was the primary end point. Independent predictors of all-cause mortality included total Bollinger score (odds ratio, 1.11; P less than .001), femoropopliteal Bollinger score (OR, 1.34; P = .05); and crural Bollinger score (OR, 1.03; P = .03).

The Bollinger score has been found to be a validated tool when used to determine overall lower limb atherosclerotic burden, the authors stated.

Dr. Tern and his colleagues also found that mortality was significantly associated with age, a history of ischemic heart disease, a history of congestive cardiac failure, and chronic renal failure (chronic kidney disease), although statin and antiplatelet therapy were found to be protective.

“This study has shown that infrapopliteal atherosclerotic site and burden are independent predictors of poor outcome in patients; it is straightforward to determine and as such could be used to further risk-stratify patients and influence the intensity of cardiovascular risk modification,” the researchers concluded.

The authors reported that they had no conflicts of interest.


Canagliflozin approved for cardiovascular event risk reduction

BY LUCAS FRANKI
MDEDGE NEWS

The Food and Drug Administration has approved canagliflozin (Invokana) as a way to reduce the risk of major adverse cardiovascular events in patients with type 2 diabetes and cardiovascular disease, according to Janssen Pharmaceuticals.

The sodium–glucose cotransporter 2 inhibitor was first approved in 2013 to improve glycemic control in adults with type 2 diabetes.

FDA approval was based on results from the CANVAS (Canagliflozin Cardiovascular Assessment Study) trial, which included more than 10,000 adults with type 2 diabetes who either had cardiovascular disease or were at risk for cardiovascular disease. Overall, patients who received canagliflozin had a 14% lower risk of experiencing a major cardiovascular event over the control group, and patients with established cardiovascular disease had an 18% lower risk.

The most common adverse events associated with canagliflozin include female genital mycotic infections, urinary tract infection, and increased urination. Notably, canagliflozin also increases the risk of lower-extremity amputation, especially in those with a history of amputation.

“Americans living with type 2 diabetes are two to three times more likely to die from heart disease than adults without diabetes. With this approval, Invokana now plays an even more important role in the overall treatment mix with its demonstrated ability to reduce the risk of potentially devastating cardiovascular events,” Ralph A. DeFronzo, MD, professor and division chief of medicine and diabetes at the University of Texas, San Antonio, said in the press release.

The new indication applies to all formulations of canagliflozin.

Find the full press release on the Janssen website.

lfranki@mdedge.com

FDA NEWS

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INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm, in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 mm, and in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts.

CONTRAINDICATIONS The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is contraindicated in compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and adverse events. R4502

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* Heparin Bioactive Surface is synonymous with the CBAS Heparin Surface.

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