Exceptional Medicine

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"Those cardiovascular surgeons who have maintained an active interest in managing thoracic aortic pathology have a unique perspective and the potential to be able to provide truly all encompassing care for patients."

—Riyad Karmy-Jones, MD
Southwest Medical Group
Thoracic & Vascular Surgery

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As technologies become refined, and more followup data is accrued, endovascular repair of the thoracic aorta (TEVAR) has evolved to be an accepted third option, along with open repair and medical management, in the treatment of thoracic aortic pathology, including aneurysm, dissection and trauma. Cardiothoracic surgeons are now faced with the issues that vascular surgeons had to deal with as endovascular procedures matured, including a delay to embrace these emerging approaches.

Methods

Recent Advancements in the Treatment of Breast Cancer

Leslie A. Cagle, MD, FACS; Paul Dally, MD, FACS; Allen Gabriel, MD

In the state of Washington, breast cancer has become the most frequently diagnosed cancer among women. The incidence of breast cancer has doubled in the past 60 years. There have been some major recent advances in both the diagnosis and the treatment of this disease. In addition, advances in reconstruction techniques have contributed to significant improvements in cosmetic results.

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Skin is a very robust organ with complex mechanisms for self-healing. However, there are patients whose hurdles to healing are high, and who are at risk for amputation, with all the psychological, medical and financial costs involved. In the past ten years, there has been an enormous amount of research into products, techniques and basic science, all aimed at healing wounds in high-risk patients.

Clinical Practice

Improving the Health of Diabetic Patients Through Resident-Initiated Group Visits

Chris Wheelock, MD; Judith A. Savageau, MPH; Hugh Silk, MD; Scott Lee, MD

Reprinted with permission from the Society of Teachers of Family Medicine, www.stfm.org; Fam Med 2009;41(2):116-9

Our objective was to implement resident-run diabetic group visits that would improve patient education and help patients become more involved in their care. A standardized progress note was developed to encourage patient goal setting and to track relevant laboratory test results. To evaluate our program, we conducted surveys to determine patients' behavioral changes and satisfaction levels. We also assessed the effect on group visit participants' glycated hemoglobin (HBA1c) and low-density lipoprotein (LDL) levels.

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Endovascular Credentialing and Assembling the Endovascular Team

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As cardiac surgery evolves to embrace TEVAR, there has been a seeming diversion from their colleagues in cardiology, interventional radiology and vascular surgery. Cardiac surgery emphasizes the importance of operative skills, years of clinical experience in managing a wide variety of thoracic pathologies, understanding the biology and natural history of thoracic aortic disease, as well as interpreting radiographs. The other specialties, while not dismissing these factors, place more emphasis on broad-based "catheter and wire" skills.

Central to the argument is the question of whether or not it is possible to obtain a skill set that is limited to aortic interventions. Underlying these arguments is the rarely stated, but ever present, concern about losing control, reimbursement and case volume.

In fact, we will argue that the two camps are actually very close, and that the arguments are more perceived than real. Much, if not all, of the debate disappears if one considers credentialing the team, rather than focusing on any individual.

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As technologies become refined, and more followup data is accrued, endovascular repair of the thoracic aorta (TEVAR) has evolved to be an accepted third option, along with open repair and medical management, in the treatment of thoracic aortic pathology, including aneurysm, dissection and trauma. Cardiothoracic surgeons are now faced with the issues that vascular surgeons had to deal with as endovascular procedures matured, including a delay to embrace these emerging approaches.[1]

In 2001, with specific reference to infra-renal abdominal aortic aneurysm (AAA), Choi et al noted that between 1995 and 2000 at their institution there was a marked reduction in open repair, complemented by an increase in EVAR.[2] Between 2000 and 2005, the average vascular fellow's experience in any interventional procedure increased from 15 to >200, and nearly ½ of the overall procedures were interventional rather than open surgical repair or reconstruction.[3]

One of the concerns raised was whether or not there was sufficient clinical material to allow proper training in fellowship programs, although some of the experience was made up by restricting cases given to general surgery residents. Endovascular requirements for training have now been established to some degree internationally, whether vascular surgery is an independent or subspecialty certification process.[4] In the United States, since 2004, specific guidelines for endovascular training within vascular fellowships have been put in place.[5, 6] There have also been specific recommendations for how senior surgeons, who have extensive operative skills but did not have the opportunity to get exposure to interventional/endovascular training in their fellowships, can obtain such training and certification in these methods.[5]

While some vascular surgeons have extensive experience in the management of thoracic aortic pathology (just as some cardiovascular surgeons manage AAA and peripheral vascular disease), in the main, management of the thoracic aorta has been the purview of cardiothoracic surgeons. Even within the community of cardiothoracic surgeons, there is generally a degree of sub-specializing, with some surgeons or centers taking a lead in the repair of complex pathologies. As TEVAR becomes increasingly accepted, the question of how to organize a team that is both capable and credentialed has assumed increasing importance.

Ironically, cardiac surgery as a specialty is facing the same dilemma that our vascular surgery colleagues faced almost a decade ago. As White and colleagues noted in 1999, "Their (i.e., vascular surgeons)

skills have been developed through years of experience in treating patients with severe vascular disease and in performing complex vascular reconstructions. Surgeons are experienced with the anatomy, pathology, and natural history of atherosclerosis and with the patient's response to a variety of treatment methods. For these reasons, surgeons have a valid perspective on the role of endovascular methods. They also have experience with the corrections of many of the complications encountered during the endovascular procedures."[6]

As cardiac surgery evolves to embrace TEVAR, there has been a seeming diversion from their colleagues in cardiology, interventional radiology and vascular surgery. Cardiac surgery emphasizes the importance of operative skills, years of clinical experience in managing a wide variety of thoracic pathologies, understanding the biology and natural history of thoracic aortic disease, as well as interpreting radiographs.[7] The other specialties, while not dismissing these factors, place more emphasis on broad-based "catheter and wire" skills.[8]

Central to the argument is the question of whether or not it is possible to obtain a skill set that is limited to aortic interventions. Underlying these arguments is the rarely stated, but ever present, concern about losing control, reimbursement and case volume.

In fact, we will argue that the two camps are actually very close, and that the arguments are more perceived than real. Much, if not all, of the debate disappears if one considers credentialing the team, rather than focusing on any individual. While a cardiac surgeon may (and in certain centers does) have the ability to perform TEVAR and manage all aspects (including any complication) independently, we would argue that a collaborative approach is in the best interests of the individual patient, and in terms of program development, of the institution.

How this team is assembled depends on local needs and available skill set. With this in mind, we will review the following:

- What is required to perform TEVAR and manage potential complications
- What the various specialties require for certification
- How to obtain this training if not achieved during fellowship training
- Examples of how specific institutions have evolved their teams/programs

Finally, it is our contention that, while cardiac surgeons who have experience in managing thoracic aortic pathologies must be involved in TEVAR, and can perform these procedures independently, it is optimal to develop an inclusive program, working out any reimbursement, intervention and programmatic issues.

Performing TEVAR

Assessing risks and benefits

The primary, and most critical, decision is whether or not TEVAR is appropriate treatment for a specific thoracic aortic pathology. An appropriately experienced judgment is required to balance the risk/benefit of TEVAR vs. medical management and/or open repair. This is not simply an assessment of acute risk, but also risk of requiring late, and potentially more complicated, interventions.[9] For example, while TEVAR in the management of acute complicated type B dissection with malperfusion is becoming accepted as the predominant therapy, utilizing endovascular stents in the management of uncomplicated or chronic dissections has not. Discussions with the patient must include the fact that long-term data is still being accrued for each pathological entity.

Finally, the perceived surgical risk varies between regions and institutions. Centers with large clinical experience with thoracic aortic surgery report mortality of <3% with descending aortic repair, increasing to 6-11% if the entire thoracoabdominal aorta needs to be replaced, with paralysis/paraplegia ranging from 3.8-7.3% depending on the extent of aorta that needs to be replaced and the clinical setting.[10, 11] Moreover, these repairs appear to be durable, with 5 year survival in the 75-80% range.[11] However, it is also clear that with increasing age and urgency, the risks of major complications (death, stroke, paralysis) increases substantially.[11]

A major component of this decision-making process is the ability to interpret imaging in the specific clinical context. With specific reference to TEVAR, this includes:

- The ability to correctly determine the diameter of the device(s) required
- The optimal path of access
- The likelihood of "successful" apposition
- The risk of endoleak, collapse and/or migration
- The determination of whether or not major branch vessels (left common carotid, left subclavian and/or celiac arteries) will need to be or are at risk for coverage by the endograft (Figure 1).

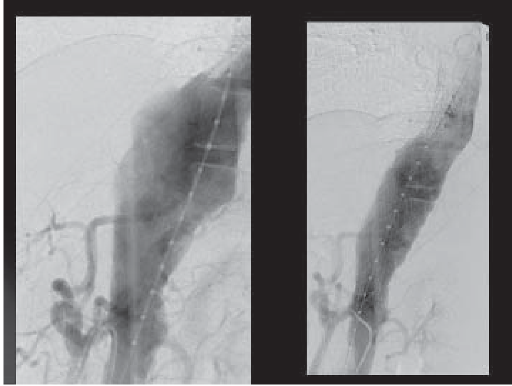

Figure 1. *75 year old woman with lower thoracoabdominal aneurysm. A catheter has been placed in the celiac artery to allow precise endograft deployment while protecting the celiac.*

This assessment is usually obtained by CT angiography, supplemented with intra-arterial angiography either as part of a planning procedure or at the time of TEVAR. Intravascular ultrasound (IVUS) may be particularly invaluable, especially in the management of dissection cases. In addition, IVUS can assess the degree of thrombus and/or calcification at landing zones.[6]

Assessing access

Access remains a critical issue. Because of the diameter of the delivery systems (ranging from 20F to 28F typically), and because many patients have diseased iliac and femoral arteries, up to ¼ of patients undergoing TEVAR will require iliac conduit or even transabdominal access.[8] Additional procedures such as angioplasty may be required (Figure 2).

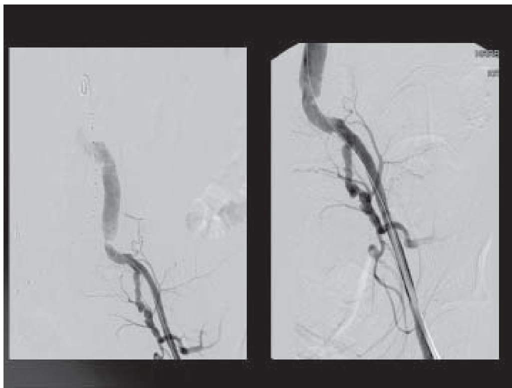

Figure 2. *The same patient as Figure 1. This lady had undergone emergent open repair of free rupture of the abdominal aorta with an aorto-bi-iliac graft. The retroperitoneal dissection of the right iliac limb was difficult, and was aided by placement of ureteral stents. The left iliac was noted to have a tight anastomotic stricture. This was dilated both to manage the stricture and to provide access for pigtail for imaging as well as a route for balloon occlusion should the need arise.*

Although increasingly performed percutaneously, a significant number of patients, particularly those with severe atherosclerotic changes, (as high as 30% in some series) will require open femoral exposure for many of the same reasons, or to repair injury or treat limb ischemia.[9]

In not an inconsiderable number of cases, the access planning is further complicated by "stiff" calcified vessels, significant thrombus, and/or severe tortuosity that may make delivering the endograft, or even gaining wire access, problematic. In some cases, through and through access must be obtained by "body flossing," in which a wire advanced from the right arm is snared via femoral access12 (Figure 3).

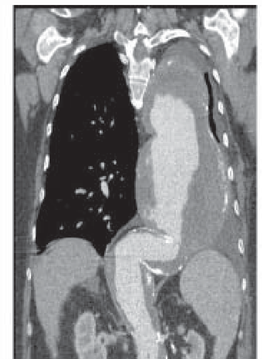

Figure 3. *Extreme tortuosity of the lower thoracic aorta with a large degree of thrombus. Careful wire manipulation is required because of the risk of creating embolization and some degree of catheter direction to obtain access across the curves with a stiff wire can be anticipated.*

Some patients require TEVAR to incorporate significant portions of the arch of the aorta, either due to anatomic requirement, to obtain a reliable landing zone, or to treat extensive disease. A variety of thoracic "hybrid" approaches have been described, including utilizing distal TEVAR at the time of repair of type A dissection ("modified elephant trunk") or pre-TEVAR or simultaneous "debranching" (either directly from the aorta or utilizing a variety of extra anatomic bypass strategies) of the great vessels, and subsequent TEVAR.[13-16]

Assessing potential complications

There must be a plan in place to prevent, recognize and treat potential immediate complications. These include need for immediate conversion to an open procedure because of rupture or proximal dissection, endograft collapse, iliac rupture, stroke, mesenteric ischemia, renal failure and paralysis.

The need for acute conversion due to rupture and/or dissection is generally described as being <1%, although procedures for aortic dissection are at increased risk for this.[8] Management usually requires the ability to institute immediate cardiopulmonary bypass and operative repair. In select cases which are deemed at relatively in-

creased risk, this mandates that a surgical team capable of performing these steps not only be available, but be involved in the decision making from the start of case planning.

"Acute endovascular collapse is similarly rare, although the risk is increased in young trauma patients and those with chronic type B dissection where there is evidence of a chronic membrane and distal false lumen thrombus.[17] "

Acute collapse may mandate immediate open repair, but in some instances has been treated by covered or bare proximal (Palmaz) stent extension.[18]

Iliac rupture, manifested as an acute drop in pressure as the sheath is removed and the "case is over" can be managed by direct open repair, or by proximal control with a balloon through a contra-lateral femoral access followed by open repair/grafting or iliac covered stenting.[9]

Overall, stroke affects between 1-6% of patients, particularly cases involving atherosclerotic aneurysms.[9] However, the incidence can be as high as 28% in patients who have had a prior stroke and require coverage in the proximal descending aorta.[19] The etiology can be due to emboli at the time of wire/catheter manipulation across the arch or posterior circulation deficits related to impinging left vertebral perfusion when the left subclavian artery origin is purposely or inadvertently covered.[20] The risk of the former can be anticipated by assessing the degree of arch atheroma, and reduced, although not eliminated, by meticulous wire/catheter and device maneuvering when in the arch.[19]

Should an embolic event occur and be recognized, there may be an option to perform immediate thrombus extraction. The latter can be assessed pre-operatively with the use of cerebral angiography, CTA, MRA and/or transcranial doppler. If maintaining flow to the left subclavian is felt to be of critical importance (due to risk of stroke or patent internal mammary graft), either pre-procedure carotid-subclavian transposition or bypass can be performed, or selective catheterization of the left subclavian to protect and mark its origin can be utilized.[21-23] If the origin is impinged, a stent can in many cases be placed. Symptomatic left upper extremity ischemia is uncommon when the left subclavian artery origin is occluded, and when it occurs can be managed electively with bypass.[24]

Selective catheterization is also a critical adjunct to avoid critical mesenteric insufficiency in cases where the thoracoabdominal aorta is to be treated. Selectively accessing the celiac artery can also protect it, mark the lowest most place of endograft deployment, and be used for "salvage" stenting.

Renal failure is uncommon, as the amount of contrast required for TEVAR is usually <60 cc. However, in complicated cases (requiring many grafts or if anatomy makes visualizing difficult or endoleak likely) significantly larger volumes may be used. In patients with borderline renal function, pre-procedure protocols with hydration, use of sodium bicarbonate and Mucomyst® have been used. Avoiding deliberate "hypotensive" therapies once the endograft is deployed is also useful. IVUS can provide excellent visualization and permit the procedure to be performed with smaller volumes.

"Patients with pre-existing renal artery stenosis and evidence of increased renal artery resistance may benefit from renal artery stenting."

Paralysis occurs in <1% of cases but can be as high as 10% in certain settings. This includes patients who have undergone prior AAA, require extensive thoracic aortic coverage (>20 cm), or lesser amounts but require coverage of the left subclavian origin.[25-27] In these cases, or any other cases judged to be at higher risk, prophylactic or selective spinal cord drainage and/or using motor or sen-

sory evoked potentials monitoring has been utilized to reduce the risk. Revascularizing the subclavian artery in patients who require extensive thoracic coverage (Extent C) may also reduce the risk of paralysis.[19] If spinal neurological damage does occur, or evoked potentials suggest that some cord injury is occurring, increasing spinal drainage and increasing the blood pressure can ameliorate or reverse the insult in approximately ½ of cases.[28, 29]

Endoleaks occur in approximately 10% of cases, and perhaps 2/3 require some re-intervention, predominantly using endovascular or catheter techniques.[27] The majority of proximal endoleaks can be managed by interventional approaches. Type II endoleak originating from retrograde flow from the excluded left subclavian artery can be managed by coil or device occlusion of the proximal subclavian, with or without carotid-subclavian bypass depending on the clinical circumstances, or subclavian transposition to the carotid.[22]

Credentialing and Training of Physicians for TEVAR

It has been argued that the guidelines laid out by each specialty should be used as benchmarks by hospitals to determine whether or not an individual in that specialty can appropriately perform specific endovascular procedures. In addition, one specialty's guidelines should not be the basis for determining the appropriateness of credentialing an individual in another specialty who has achieved the goals set by his/her particular guidelines.[6] There has been a plea that parity in the total number of cases is reasonable.[6]

As with any infra-renal or peripheral intervention, the team and physician directing the treatment plan "must understand the natural history of specific vascular diseases and be knowledgeable about the utility, accuracy, and limitations of diagnostic approaches, and be cognizant of the advantages, disadvantages, potential outcomes, and complications of all relevant diagnostic and therapeutic procedures."[5]

In simplistic terms, there are two schools of thought regarding training and credentialing physicians for TEVAR: The Society of Thoracic Surgeons/American Association of Thoracic Surgery guidelines representing the cardiothoracic surgeons and the joint statement of the Society of Vascular Surgery/Society of Interventional Radiology/ Society of for Cardiovascular Angiography and Interventions/Society for Vascular Medicine and Biology representing the non-cardiovascular surgery specialties.[7, 8]

"Where the difference emerges [regarding training and credentialing physicians for TEVAR] is in the relative emphasis on operative knowledge vs. catheter skills."

Similarities

Both papers support the need for board certification in the respective specialty, continued documentation of continued medical education in the field, the ability to perform retroperitoneal iliac and open femoral exposure, experience with passing large bore sheaths through vessels, and thoracic great vessel bypass or transposition procedures. Both require a knowledge base of thoracic pathology, including diagnosis, natural history and management options. In addition experience with the recognition and treatment of common complications is required.

Differences

Where the difference emerges is in the relative emphasis on operative knowledge vs. catheter skills. Reviews of case series have been published supporting both perspectives.[30, 31]

Cardiovascular surgeons consider TEVAR an operation. In the majority of programs it is the cardiac surgeon who can determine the relative risk benefits of open repair, medical management or TEVAR. Thus the cardiac guidelines stress an active experience with "evaluation and management of a minimum of 20 patients with diseases of the thoracic aorta in the two-year period immediately prior to application for privileges to perform these procedures (TEVAR)".[7]

In addition, the STS/AAST guidelines ask for documentation with at least 10 open thoracic aortic repairs in the two years prior to requesting privileges. The rational behind this is two-fold: First, to ensure that only surgeons (including cardiac) who truly have been involved in thoracic aortic pathologies and are current in management options participate; and second, that any potential

acute or chronic complication can be anticipated and managed. These guidelines include:

- Documentation of 25 catheter placements involving guide-wire technology and/or steerable catheters in the two years prior to application for privileges
- Participation in successful placement of 10 abdominal or 5 thoracic endovascular stent grafts
- Completion in at least one STS, AAST or SVS sponsored on thoracic stent-grafting

Of note, many centers which are headed up by cardiovascular surgeons not only have extensive open and TEVAR experience but have obtained advanced catheter/wire skills.[32]

The other specialties argue that TEVAR is predominantly an endovascular procedure and emphasize catheter based skills.[8] Thus, there is no requirement for documenting prior experience with open repair of the thoracic aorta. The experience in thoracic aortic pathology and its management could be documented by board certification in either vascular or thoracic surgery with an additional 20 hours of continued medical education in thoracic aortic diseases (10 of which include endovascular options).

The SVS/SIR/SCAI/SVMB recommendations argue that, in many cases, even simply passing a stiff wire up into the thoracic aorta can be complicated and that, in addition, relatively sophisticated catheter and wire skills are required to manage endoleak, branch vessel compromise, embolism, etc. The criteria for achieving competence is based on a prior 2004 set of guidelines put forth by the combined societies (Table 1).[5]

These are guidelines for achieving competence within an approved residency program, after completion of core training, over a 12-month period. These guidelines also include a recommendation that the case mix be equally divided among the four major vascular beds (aortoiliac and brachiocephalic; abdominal visceral and renal; infrainguinal; cerebral). In addition, a minimum of 5 catheter-directed peripheral thrombolytic/thrombectomy cases should have been performed.

This, for vascular surgeons, is a change from 1999, when it was argued that no specific requirement for thrombolytic case experience was needed because the principle technical skills involved vascular access and selective catheter locations and it would be expected that vascular surgeons be familiar with pharmacotherapy.[6] Documented experience with specific interventions was encouraged but not required. In terms of endovascular repair prior to obtaining privileges, the current SVS/SIR/SCAI/SVMB guidelines call for successful performance in EVAR as primary operator in 25 endovascular repairs of AAA or 10 TEVARs in the previous 2 years.

There are potential flaws and worst case scenarios in both documents.

- Theoretically, according to the STS/AAST guidelines, a cardiovascular surgeon who has minimal catheter skills and limited experience in great vessel bypass, could encounter a complication (stroke, mesenteric occlusion, tortuous aorta etc) that he/she is not equipped to deal with.
- Similarly, if one follows the SVS/SIR/SCAI/SVMB recommendations, a patient could be counseled to have TEVAR by a team that has never managed or operated on the thoracic aorta.

Table 1
ACC/ACP/SCAI/SVMB/SVS Clinical Competence Statement:
Formal training to achieve competence in peripheral catheter-based interventions[5]

Cardiovascular physicians	• Diagnostic coronary angiograms: 300 (200 as primary operator) • Diagnostic peripheral angiograms: 100 (50 as primary operator) • Peripheral interventional cases: 50 (25 as primary operator)
Interventional radiologists	• Diagnostic peripheral angiograms: 100 (50 as primary operator) • Peripheral interventional cases: 50 (25 as primary operator)
Vascular surgeons	• Diagnostic peripheral angiograms: 100 (50 as primary operator) • Peripheral interventional cases: 50 (25 as primary operator) • Aortic aneurysm endografts: 10 (5 as primary operator)

- An acute major complication (endograft collapse, aortic rupture, conversion to type A dissection) or delayed complication (persistent endoleak or aortic dilation) that requires open repair that, because of the placement of the endograft, increases operative difficulties, would require the attention of a cardiovascular surgeon who was unaware of the case until the complication arose.

However, careful reading of both documents reveals that, while supporting their respective specialties roles in TEVAR, the recommendations are based more on ensuring patient safety rather than trying to provide ammunition for any local, institutional, politics. To this end, while stressing the value of obtaining "individual" credentialing, both papers encourage the concept of credentialing a team as a whole. Assembling the team, as will be discussed later, is affected by the institution's needs, and should be considered as part of program development.

Anecdotally, but increasingly across the country, if a complication occurs and requires involvement of another clinician who was not at least involved in the planning, and this complication could have been reasonably anticipated to occur, then the team or individual performing the TEVAR could be found liable for breaching standard of care in not properly planning out the case.

Alternative Routes to Certification

The guidelines outlined above were largely derived with the assumption that the skill sets described would be primarily obtained during residency. Many surgeons and other interventionalists have completed their training in the pre-TEVAR (or indeed pre-endovascular AAA) era, and did not have exposure to these modalities, and yet bring years of valuable insight and clinical skills to the field.[6]

The basic definition of a person who is capable of training such an individual includes board certification in the primary specialty and having active credentials in the area of training at the institution that the training is taking place.[5, 6, 33]

- In terms of "catheter-based skills" the ACC/ACP/SCAI/SVMB/SVS clinical competence statement recognizes that cerebral interventions are an evolving field, and separates out this vascular bed from the three other areas.
- To achieve "balanced experience required for competence" at least 20 diagnostic/10 interventional supervised cases in each of the aortoiliac/brachiocephalic, abdominal visceral/renal and infrainguinal regions should have been performed.[5]

The ACC/ACP/SCAI/SVMB/SVS paper does note that some physicians may seek credentialing/competence in only one area. They recommend that as a minimum, the first area, for safety reasons, be in the aorta and iliac distribution, and that 30 diagnostic/15 interventional procedures be the minimum.[5] Intriguingly, this is not significantly different from the 25 cases required by the STS/AAST guidelines for TEVAR.[7]

These procedures should be performed over no more than 24 months to ensure that the physician is current. However, whether they are obtained in a "mini- fellowship" or by sequential experiences at one's home institution or as a "guest" at another institution, is not deemed relevant, as long as the preceptor meets the fundamental criteria laid out earlier, namely board certified in their primary specialty **and** credentialed in the procedures to be taught.

Maintenance of Certification

The STS/AAST paper does not specifically address maintenance of certification as a separate issue. However, it does stress the importance of involvement in an approved regional or national database.[7] The ACC/ACP/SCAI/SVMB/SVS paper recommends participation in 10 hours of CME devoted to TEVAR every 2 years, and for the "program as a whole" successful performance of at least 10 TEVAR procedures over the same 2-year period.

This paper does note that an active endovascular AAA program could reduce TEVAR requirement "because of the similarity of the two procedures."[8] This latter assumption could conceivably be a bone of contention at any given institution, but it is reasonable to give some credit for AAA cases.

Assembling the Team and Developing the Program

How a TEVAR program gets developed will depend on the institutional needs. Although not specifically stated in the STS/AAST guidelines, one underlying philosophy is that TEVAR represents simply one treatment method in managing thoracic aortic pathology. It should not be used as a "stand-alone" intervention, and centers that do not have the capability of medical or operative management should not attempt TEVAR in selected cases if they are going to transfer non-TEVAR cases out. We recognize that there may be individual emergency exceptions, but this should be the exception rather than the rule.

There are two basic stimuli to developing a TEVAR program and coordinating a team. There may be a specific need to manage a subset of aortic pathologies (such as traumatic injuries in centers that see a high volume) and to integrate TEVAR into the management stratagem.[34] This can evolve into a broader based program. The other, and more common approach, is to recognize that a large volume of diverse aortic pathologies are being managed, and to incorporate TEVAR as part of a comprehensive program, often in conjunction with an existing AAA program. The advantages of a multidisciplinary approach are many (Table 2).

Where the TEVAR is performed

The first issue is where the TEVAR is performed. The minimum requirement is a room with surgical standards of sterility (including laminar flow) and lighting that will permit at least retroperitoneal exposure as a minimum. These procedures can be done in an operating suite with portable fluoroscopic monitoring.[30] However, dedicated "hybrid" rooms, which allow rotational angiography, provide a higher degree of resolution, and in some cases this resolution is critical.[27]

As noted previously, in the majority of cases involving atherosclerotic aneurysms, the need for acute thoracotomy/sternotomy is <1%.[8] If the case is a hybrid case (e.g., arch debranching with TEVAR); or is felt to be at remarkable risk for rupture (e.g., acute type B dissection with possible retrograde involvement); or has difficult access with a high risk for failure to get the device in place and thus necessitating thoracotomy; then it is reasonable to do the procedure in the standard cardiac operating suite or at least have it on standby. However, most centers now are utilizing the hybrid room for all cases.

Who is on the team

- The often not recognized but vital members of the team include the nurses and radiology technicians.
- The nurses include those who are based in the cath lab, as well as operating suite nurses/technicians. The cath lab nurses generally are required to have a minimum of a 2 year (RN) degree, and have been certified and credentialed in conscious sedation.
- The radiology technicians also have a 2 year associate degree, and usually have undergone a specific year of further credentialing in the specific institution for each core procedure.

Table 2
Benefits of a Multi-Disciplinary Team Approach

Processes and procedures	• Clinical protocols can be refined, including use of lumbar drain, neurological monitoring, hypertensive agents, post-op follow up, pre-op imaging, transport teams, etc. • Pre-op evaluation can be done in a multi-disciplinary fashion with greater ease (e.g., evaluating a patient with renal stenosis, hypertension and thoracic aneurysm). • Screening protocols can be developed and shared with referral centers. • Exposure to research and new devices can increase. • Credentialing issues can be mutually agreed upon.
Training and education	• Education can include nurses, ER, referral centers. • Sharing and cross-fertilization of ideas and skill sets can enhance all participants' practice and sense of ownership. • There can be increased incentive to cross-train each other and to share valuable training opportunities for the involved residents (e.g., cardiac surgery residents scrubbing on major vascular cases and vascular residents scrubbing on thoracic; or interventional radiology residents learning how to perform pre-procedure assessments and gain experience in post-procedure management; or a cardiac surgeon scrubbing with a vascular surgeon on carotid-subclavian bypass, and the vascular surgeon scrubbing on thoracic debranching cases).
Financial considerations	• Marketing can be shared. • The process of setting up a multi-disciplinary center will force a discussion of revenue sharing so that it is dealt with up front.

- The operating nurses/technicians should ideally have experience in vascular surgery as a minimum. Most programs institute a series of weekly in-services on procedures, devices, etc., and monthly rounds on relevant topics.

The anesthesiologist ideally will have experience at least with open vascular procedures, and preferably with cardiac anesthesia.

As far as the clinicians involved, reviewing the possible interventions required and complications that may arise, it is fairly easy to define what skill set is required for a given case. At a bare minimum, surgical expertise at all forms of access is required. This includes the ability to repair iliac rupture, treat limb ischemia, and perform complex retroperitoneal exposure of the iliac artery. A surgeon with experience in operative repair of the thoracic aorta should be involved at least in the planning stage to make sure that TEVAR is the appropriate procedure, to define parameters of deployment (i.e., to indicate when a proximal deployment would be associated with unacceptable increase in risk of any subsequent repair) and to be available should an operative conversion be required (either acutely or in a delayed fashion).

At the same time, while some basic catheter and wire skills are usually sufficient to perform TEVAR, a number of cases require advanced skills. Thus, in the simplest terms, the ideal team includes advanced operative skills, including the ability to perform open repair, and advanced catheter skills, including the ability to perform branch vessel interventions.

This could be encompassed by a single cardiovascular surgeon, or by credentialing the team as a whole. However, even if one cardiovascular surgeon can fulfill all the requirements, on every case, in most centers there is still a benefit to the patient and the program not to be exclusive. As noted at the University of Pennsylvania, "We (CT & Vasc) have very substantial cross-referral patterns and a long history of working together….it would be a shame to jeopardize this robust relationship" and "TAA stenting is a small part of overall practice in dollar and volume terms—why not work together?"[35] At other institutions these sentiments may apply to interventional radiology or cardiology as well.

Conclusion

Cardiovascular surgeons are coming to realize, like their vascular colleagues over the past few years, that endovascular approaches to thoracic aortic pathology are becoming more relevant and prevalent. Those cardiovascular surgeons who have maintained an active interest in managing thoracic aortic pathology have a unique perspective and the potential to be able to provide truly all encompassing care for patients.

The big difference between the two main credentialing papers relates to the relative importance of operative and clinical experience with thoracic aortic disease vs. what constitutes adequate and appropriate catheter/wire skills. Ultimately, based on the experience that vascular surgeons have had, it is likely that the best and most durable manner to overcome these differences is for cardiac surgery training programs to incorporate catheter and endovascular training, to meet at least the volume criteria spelled out for vascular surgery (100 diagnostic/50 therapeutic interventions, the majority being arterial and ½ of each as primary operator).

In the meantime, we encourage cardiovascular surgeons to obtain credentialing as laid out by the STS/AAST guidelines. Having obtained these, developing a "credentialed team" is the safest for the patient and the most robust manner to develop a program. Even if a cardiovascular surgeon or group achieves credentialing both in and in peripheral interventions, it is still reasonable, in most centers, to continue a multidisciplinary team approach. The program should be based at a center that is capable of performing elective and emergent open procedures, and be part of an overall institutional service, not a stand-alone therapy.

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Recent Advancements in the Treatment of Breast Cancer

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Breast cancer remains the number one diagnosed cancer among women. Recent advances in screening have contributed to earlier diagnosis. At the same time, advances in reconstruction techniques have contributed to significant improvements in cosmetic results.

When screening suggests a potential problem, several diagnostic and treatment options are now available at the new Kearney Breast Center at Southwest Washington Medical Center. Diagnostic modalities include:

- *Breast mammography*
- *Breast MRI*
- *Sentinel lymph node biopsy*
- *Tissue oncotyping*
- *Breast oncoplastic surgery*

The Kearney Breast Center, Southwest Medical Group Surgical Specialists and Southwest Medical Group Plastic Surgery are committed to taking advantage of these new modalities and reporting results back as quickly as possible to providers and patients.

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In the state of Washington, breast cancer has become the most frequently diagnosed cancer among women. The incidence of breast cancer has doubled in the past 60 years. There have been some major recent advances in both the diagnosis and the treatment of this disease.

Mammography

Current guidelines are that women age 40 and above should have screening mammography. Tests should be continued until the woman no longer has a 10 year life expectancy. Digital mammography (available at all mammographic locations in Vancouver) offers an advantage for women younger than 50 and for women with dense breasts.

When screening mammography suggests a problem, additional views and/or an ultrasound will probably be recommended. The new Kearney Breast Center at Southwest Washington Medical Center is committed to obtaining these films on the day of the original mammography. This will make the frightening "call back for more films" a worry from the past.

MRI

The use of breast MRI is still evolving. Breast MRI is only recommended for screening in women with a greater than 20% lifetime risk of breast cancer. These patients might carry the BRCA mutation, have a strong family history of breast cancer, have a previous breast malignancy, or have received mantle radiation for a previous lymphoma.

While nearly all invasive breast cancers images are enhanced on contrast MRI studies, breast MRI is quite expensive ($2,400) and is not covered by many insurance carriers. In addition, false positives continue to be a problem. Nonetheless, breast MRI may be particularly useful in patients with breast cancers that are difficult to see on mammography. MRI will find additional disease 16% of the time on the ipsilateral side and 5% of the time on the contralateral side in patients with a newly diagnosed breast cancer.

Sentinel Lymph Node Biopsy

Sentinel lymph node biopsy has replaced axillary lymph node dissection as the procedure of choice for newly diagnosed breast cancer. It can be performed in conjunction with either a lumpectomy or a mastectomy. Use of axillary ultrasound and fine needle aspiration (FNA) can identify patients who need a full axillary dissection at the time of original surgery.

In patients with tumors less than 1 cm in size, axillary lymph nodes will be negative 80% of the time. Sentinel lymph node biopsy can help identify the small percentage of patients needing a full axillary dissection. Given that a full dissection may cause lymphedema and shoulder dysfunction, less is clearly more for most patients. If the sentinel node is positive, traditionally a full nodal dissection is required, but even that surgical rule may be changing recently.

Breast Oncoplastic Surgery

Breast reconstruction has evolved from a rarely performed surgical venture to a daily occurrence. It is an important part of rehabilitation following either mastectomy or lumpectomy. The aesthetic quality of reconstruction fostered by technical advancements has changed what was a tissue mound to a nearly normal appearing symmetrical breast.

Southwest Medical Group Plastic Surgery offers advanced oncoplastic techniques for even the most severe radical mastectomy defects. Nipple-sparing mastectomy and immediate reconstruction can be offered to appropriate candidates.

Tissue Oncotyping

Less than 40% of lymph node negative breast cancer patients develop distant metastasis. Current estimates are that 40% of breast cancer patients may be over-treated with adjuvant chemotherapy. Molecular markers represent a new way to better select those patients who will benefit from adjuvant chemotherapy.

"Recent advances in screening have contributed to earlier diagnosis. Recent advances in reconstruction have contributed to a marked improvement in cosmetic results."

Using actual tumor mRNA, Oncotype DX classifies patients into low, intermediate and high risk. While this test assays 21 genes, MammaPrint™ (available in Europe) tests 70 genes and separates patients into high and low risk. Using a gene signature to stratify patients for adjuvant chemotherapy is clearly a major recent advancement.

Breast cancer still affects our friends, our families and our patients. Recent advances in screening have contributed to earlier diagnosis. Recent advances in reconstruction have contributed to a marked improvement in cosmetic results. The Kearney Breast Care Center, Southwest Medical Group Surgical Specialists and Southwest Medical Group Plastic Surgery are coming together to take advantage of these recent advances.

What's in a Name? The Rationale behind the Lobular and Ductal Intraepithelial Neoplasia Terminologies

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In this article I review several studies that have highlighted the interobserver variability in distinguishing atypical hyperplasia from carcinoma in situ of the breast and its impact on patient management. I also describe the rationale behind the adoption of the lobular and ductal intraepithelial neoplasia terminologies in the 2003 World Health Organization Classification of Tumors of the Breast.

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The concept of atypical hyperplasia was introduced decades ago within the continuum of both lobular and ductal intraepithelial proliferations of the breast, a continuum that encompasses the benign proliferations of usual hyperplasia to high-grade carcinoma in situ[1-6]. Among the lobular lesions, different degrees of atypical intraepithelial proliferation were designated as atypical lobular hyperplasia (ALH) and lobular carcinoma in situ (LCIS). However, later studies showed that the histopathologic features used to distinguish ALH and LCIS had no prognostic significance[7,8]. It was therefore recommended to unify these two non-invasive lobular proliferations under the umbrella designation of lobular intraepithelial neoplasia (LIN)[9].

Similarly, the term atypical ductal hyperplasia (ADH) was initially coined to include a vaguely defined group of lesions that had "some but not all of the requisite features of ductal carcinoma in situ"[10]. Given the morphologic (qualitative) similarity of ADH to low-grade ductal carcinoma in situ (DCIS), arbitrary size (quantitative) measures were later introduced in the hope of more reliably separating ADH from DCIS[10,11]. However, this artificial separation resulted in significantly different management approaches in the 1980s, i.e., mastectomy for those diagnosed as DCIS and followup for those with a diagnosis of ADH.

Even now with widespread use of conservative surgery, patient management differs depending on whether a lesion is diagnosed as ADH or DCIS. Therefore, the ductal intraepithelial neoplasia (DIN) terminology has been introduced to lessen the impact of such artificial distinctions in the spectrum of intraductal proliferations of the breast.

Lobular Intraepithelial Neoplasia (LIN)

Breast pathologists have traditionally described a spectrum of lobular intraepithelial proliferations that exceed the normal resting lobular architecture. These have been vaguely divided in order of severity into lobular hyperplasia (LH), atypical lobular hyperplasia (ALH), and lobular carcinoma in situ (LCIS). Given that the individual cells and the histologic architecture in most lobular proliferations appear similar under the microscope (Figure 1), the distinction between these three categories has been based on mostly quantitative features:

- A proliferation of lobular cells in the zone closest to the basement membrane is designated as LH.
- Progressive filling of the ducts by the same cells characterizes ALH.
- Distention of the ducts by the proliferation is typical of LCIS[13].

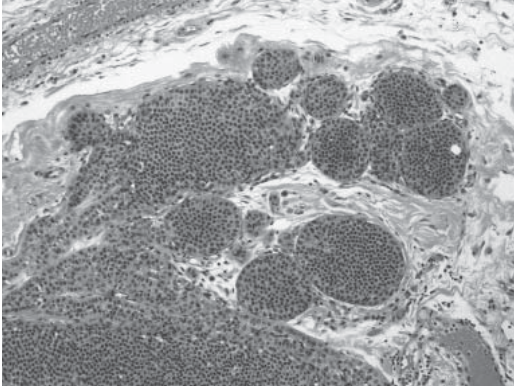


Figure 1. *Most lobular intraepithelial proliferations demonstrate similar low grade cytologic and architectural features and used to be subclassified based on vague and clinically irrelevant quantitative criteria.*

As early as 1978, however, Haagensen et al found this arbitrary distinction — at least the distinction between ALH and LCIS — to be clinically irrelevant[7]. In a review of 5,560 epithelial lesions of the breast, they found 211 cases of lobular proliferation initially occurring alone without coexisting infiltrating carcinoma. These cases were examined for several parameters, including patient age, laterality of the breast affected, length of followup, and interval between the initial diagnosis and frank carcinoma, which eventually developed in 17% of the patients.

The investigators found no relationship between microscopic qualitative and quantitative variations in the lobular proliferations and the subsequent development of invasive carcinoma. Given that the features used to distinguish ALH from LCIS were not found to have any value in predicting subsequent carcinoma, the authors suggested the umbrella designation of lobular neoplasia, which was later adopted in the 2003 World Health Organization Classification of Tumors of the Breast[12].

Some authors recommended a slight modification by naming these lesions lobular "intraepithelial" neoplasia (LIN) to emphasize the non-invasive nature of the proliferation[9]. Under this classification, cases of LIN are graded as LIN 1, LIN 2 or LIN 3, with LIN 3 encompassing lobular intraepithelial proliferations with the highest grade of cytologic and/or architectural atypia, including the pleomorphic, necrotic, signet ring, and macroacinar variants. In a further refinement of the terminology, given the different management approaches adopted for LIN 3 compared to lower grades of LIN, many breast pathologists prefer a two-tier grading system in which LIN lesions are designated as either "classic" LIN (LIN 1-2) or "high-grade" LIN (LIN 3).

Ductal Intraepithelial Neoplasia (DIN)

Similarly, ductal intraepithelial lesions have been traditionally classified as usual ductal hyperplasia (DH), atypical ductal hyperplasia (ADH) and ductal carcinoma in situ (DCIS), with cases of ADH having significant cytologic and histologic overlap with low-grade DCIS. For pathologists, the two most popular approaches for defining the minimum requirement for low-grade DCIS have been:

(a) The definition by Page et al[10], introduced in 1985, that requires complete involvement of at least two duct spaces by a proliferation that cytologically and architecturally resembles DCIS; and
(b) The definition of Tavassoli and Norris[11], published in 1990, that requires complete involvement of one or more ducts that exceed 2 mm in aggregate diameter.

According to either of these two definitions, any intraductal proliferative lesion that demonstrates the qualitative cytologic and architectural features of low-grade DCIS but fails to pass the defined quantitative threshold should be designated as ADH (Figure 2). Since then, no reliable molecular, ultrastructural, immunohistochemical, or morphometric feature has been introduced to aid in the reliable distinction of ADH from low-grade DCIS[5,14-18]. Therefore, separating the two continues to be based solely on application of the arbitrary criteria mentioned above.

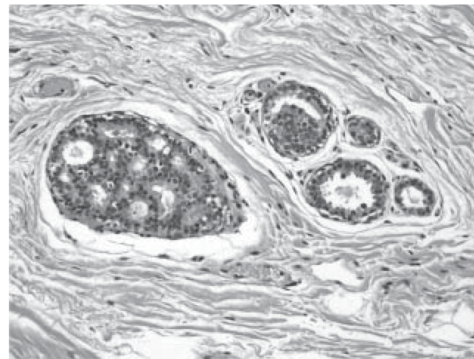


Figure 2. *This intraductal proliferation has the cytologic and architectural features of a low-grade cribriform ductal carcinoma in situ, but because it does not meet the minimum size criteria, it is designated as atypical ductal hyperplasia in the older terminology.*

In a survey done by Rosai in 1991, 17 ductal and lobular proliferative breast lesions were distributed among five experts in breast pathology[19]. The participants were asked to categorize such lesions, which had already been circled on glass slides, as either hyperplasia, atypical hyperplasia, carcinoma in situ, or "other" (to be

specified) based on the diagnostic criteria they used in their daily practice.

In that study, there was not a single case in which all five pathologists agreed on the diagnosis, and there were only three cases (18%) in which four of the five pathologists agreed. Also, some pathologists tended to make more malignant diagnoses than others. In his report, Rosai considered this interobserver variability to be unacceptably high and suggested the adoption of a terminology such as mammary intraepithelial neoplasia with a grading system similar to that which was being used for the uterine cervix.

A possible explanation for such a high degree of interobserver variability set forth in that report was that the pathologists were not using a standard set of criteria. Therefore, a year later, Schnitt et al tried a different approach to assess interobserver variability in the diagnosis of intraductal proliferative lesions of the breast[20]. In their 1992 survey, they asked six experts in breast pathology to evaluate 24 proliferative ductal lesions.

In this survey, the six participating pathologists agreed to review and adhere to the criteria of Page et al regardless of what they used in their daily practice. Fifteen teaching slides representing classic examples of usual ductal hyperplasia, atypical ductal hyperplasia, and noncomedo DCIS were circulated among the pathologists to foster concordance before initiation of the study. The specific area of interest on each study slide was indicated by masking all the surrounding tissue except the duct(s) in question so that all the participants focused on the same lesion, and to prevent any bias that may result from assessment of changes in the surrounding breast tissue.

Despite all these efforts, there was complete agreement among all six pathologists in only 14 (58%) of the 24 cases and among five or more pathologists in 17 cases (71%). The most common diagnostic problem was the distinction of atypical hyperplasia from DCIS in six cases.

Although this study showed a significant improvement in interobserver agreement compared to Rosai's survey, the persistence of significant differences among expert breast pathologists even under optimal and highly artificial conditions conveyed a more widespread problem in the pathology community with potential impact on patient management.

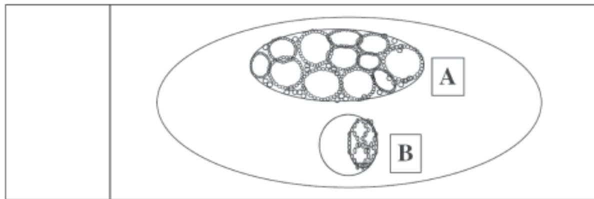
"The persistence of significant differences [in interpretation of intraductal lesions] among expert breast pathologists even under optimal and highly artificial conditions conveyed a more widespread problem in the pathology community with potential impact on patient management."

In 2006, results of a survey conducted among a larger number of pathologists was published that showed almost two decades after the introduction of the aforementioned definitions, a significant degree of discrepancy continues to exist in the histopathologic interpretation of intraductal lesions and how it may potentially impact patient management[21].

A questionnaire was prepared with diagrammatic representations of five potentially problematic scenarios in breast pathology dealing with intraductal proliferative lesions (Figure 3). The authors decided to use diagrammatic representations rather than glass slides to facilitate distribution of the survey among a greater number of pathologists and to ensure that the participants focused on the same diagnostic issue.

As shown in Figure 3, one of the questions addressed whether respondents considered a partially involved duct adjacent to unequivocal cribriform DCIS as ADH or DCIS and, depending on their response, whether they would recommend re-excision if this partially involved duct was less than 0.1 mm from the excision margin. While the sole, partially involved duct described in the question would not qualify as DCIS according to the criteria set forth by either Page et al or Tavassoli and Norris, 43.5% of the 230 respondents diagnosed it as DCIS, 28.0% of whom would not recommend re-excision even though the lesion was close to the excision margin. The remaining 56.5% considered this partial cribriform

proliferation as ADH but, nevertheless, 37.7% of them recommended re-excision of the ADH since it was close to the excision margin. Although pathologists who made a diagnosis of DCIS were significantly more likely to recommend re-excision compared to those who made a diagnosis of ADH, the final impact on patient management was that, regardless of the diagnosis, about half (50.4%) of the respondents would recommend re-excision while the other half (47.0%) would not.



"A" is a single duct with unequivocal cribriform grade 1 DCIS
"B" is a duct with partial involvement by a cribriform pattern located <0.1 mm from the margin.
1. What is your diagnosis for duct "B"?
____ DCIS
____ ADH
2. Would you recommend re-excision?
____ Yes
____ No

Figure 3. *A survey composed of diagrammatic representations of controversial areas in breast pathology once again highlighted the interobserver variability in diagnosing intraductal breast proliferations (From: Ghofrani et al "Discrepancies in the diagnosis of intraductal proliferative lesions of the breast and its management implications: results of a multinational survey." Virchows Arch 449:609-616, 2006)*

In his 1991 survey, Rosai lamented the fact that there were no known morphometric, ultrastructural, immunohistochemical, or molecular features to distinguish ADH from low-grade DCIS[19]. Unfortunately, this issue continues to be the case[5,14-18]. Pathologists must assign lesions within the ADH-DCIS continuum to one end of the spectrum or the other based on the morphologic features present on an H&E-stained slide and an arbitrary set of quantitative criteria that cannot be applied to every lesion encountered.

As Arpino et al commented: "… arbitrary size limitations do not always provide precise definitions. Since ADH and DCIS exist along a continuum and the distinction can be semisubjective, pathologists may disagree on the diagnosis of these atypical proliferative lesions. The clinician should be aware of these issues when interpreting pathology reports that describe these lesions, especially when a second opinion is not consistent with the original diagnosis."[22]

"Not only the subjective nature of interpreting the morphologic findings but also the existence of different and in some cases conflicting diagnostic criteria create considerable interobserver variability in distinguishing ADH from low-grade DCIS."

This diagnostic variability in turn leads to confusion regarding the optimal management approach to such intraductal proliferative lesions because a diagnosis of low-grade DCIS is automatically associated with a significantly worse prognosis and usually requires a more drastic treatment approach compared to ADH. Furthermore, the negative impact of the diagnosis of "carcinoma", albeit in situ, on patients' psychological well-being (i.e., depression and anxiety) has been well documented[23,24], and such a diagnosis will most likely also have a negative impact on patient insurability. These issues must be definitely considered in choosing an optimal terminology.

A further development that provides support for adopting a better terminology in the spectrum of intraductal breast lesions is the recent increased recognition of another form of atypical proliferation called flat epithelial atypia (FEA)[25]. Flat epithelial atypia is presumed to represent one of the earliest morphologically recognizable neoplastic alterations of the breast in which native duct epithelial cells are replaced by 1-5 layers of cytologically monomorphic or mildly atypical cells without significant architectural abnormality. Evidence from studies on the morphology, immunohistochemistry, and molecular genetics of FEA suggest that it represents an early stage in the development of low-grade carcinoma and, therefore, its recognition is important for early detection of intraductal neoplasia[26].

Although the biologic significance of finding pure flat atypia is not yet well-established, studies have suggested that patients with a core needle biopsy diagnosis

Table 1. The Ductal Intraepithelial Neoplasia (DIN) Terminology

DIN Terminology	Older Terminology
Low-risk DIN	Usual ductal hyperplasia (DH)
DIN 1a	Flat epithelial atypia (FEA)
DIN 1b	Atypical ductal hyperplasia (ADH)
DIN 1c	Ductal carcinoma in situ, low grade (DCIS grade 1)
DIN 2	Ductal carcinoma in situ, intermediate grade (DCIS grade 2)
DIN 3	Ductal carcinoma in situ, high grade (DCIS grade 3)

of FEA will have a greater than 20% incidence of subsequent upstaging to DCIS and/or invasive carcinoma on resection, which is not statistically different from the incidence of upstaging associated with a diagnosis of ADH on core biopsy[27]. Therefore, it would seem prudent that patients with FEA found by core biopsy undergo followup excision similar to patients diagnosed with ADH. FEA should be included in the spectrum of intraductal proliferations to at least prevent its misinterpretation as a normal control in future studies, since the presence of unrecognized flat epithelial atypia may explain a portion of the 20% recurrence rate of breast carcinomas excised with reportedly "negative" margins.

For these reasons, the 2003 World Health Organization Classification of Tumors of the Breast has adopted the ductal intraepithelial neoplasia (DIN) terminology to include the full spectrum of intraductal proliferations recognized to date[28,29]. The DIN system has a one-to-one correlation with the designations in the old system (Table 1), so it does not claim to reduce interobserver variability or suggest changing the established management approach to different intraductal proliferations. It does, however, have the added benefit of minimizing the effect of designations as drastically different as hyperplasia and carcinoma applied to histologically similar lesions.

Conclusion

In *Romeo and Juliet* (II, ii, 1-2), William Shakespeare claims:

> "What's in a name? That which we call a rose
> By any other word would smell as sweet."

However, that is not the case for intraepithelial breast proliferations. Whether an atypical breast lesion is diagnosed as hyperplasia or carcinoma will have significantly different implications for the patient's management, psychological well-being, and insurability. Nevertheless, interobserver variability in this area of breast pathology has been recognized for decades.

As early as 1916, Joseph Colt Bloodgood (a Johns Hopkins surgeon who made significant contributions to surgical pathology) commented: "I have submitted over sixty borderline cases to a number of pathologists, and have found that in not a single one has there been uniform agreement as to whether the lesion was benign or malignant. … This is no reflection on the diagnostic abilities of the pathologists; it is simply evidence that at the present time there are certain lesions of the breast about which we apparently do not agree from the microscopic appearance only."[30]

Adapting to change is difficult, and there is even less motivation to change if the undesirable consequences of clinging to an old way of doing things are not readily apparent. Pathologists and clinicians in the United States have for years accepted the intraepithelial neoplasia terminology for other organs including the pancreas (PanIN), prostate (PIN), cervix (CIN), vulva (VIN), and vagina (VaIN). Hopefully, as benefits of the LIN and DIN terminologies become more evident in studies of intraepithelial proliferations of the breast, pathologists and clinicians in this country will join the rest of the world in adopting them in their day to day practices.

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Hyperbaric Oxygen and Other Advances in Wound Healing

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This article will provide an overview of some of the advances in the treatment of chronic, non-healing skin ulceration. Specifically, it will review:

- *The diagnoses contributing to poor wound healing*
- *Basic science at the cellular level*
- *Fundamentals of local wound care*
- *Advanced bioactive dressings*
- *Hyperbaric oxygen therapy*
- *Limb preservation*

This information also was recently presented at the Physician Grand Rounds at Southwest Washington Medical Center on October 1, 2009.

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Wound care has long been a neglected step-child in the medical community. Typically the surgical resident with the least seniority was sent to care for wound patients, and learned from the habits and preferences of the nurse who was in charge. This model works reasonably well for the vast majority of patients, since skin is a very robust organ with complex mechanisms for self-healing. However, there are those patients whose hurdles to healing are high, and who are at risk for amputation, with all the psychological, medical, and financial costs involved. In the past ten years, there has been an enormous amount of research into products, techniques, and basic science, all aimed at healing wounds in these high-risk patients.

Diagnoses

Healthy skin heals. There are powerful and robust mechanisms to make this happen. When there is an ulcer that is not healing, there are usually several factors combining to overwhelm the skin's innate ability to repair itself. A thorough and aggressive investigation is warranted.

Diabetes

High blood sugars inhibit the activity of the immune system.[1,2] It is important to verify the presence or absence of this disease, and when present, to get an A1C test to determine how well controlled their diabetes is. Diabetes also increases the likelihood of other impediments to wound healing, such as vascular disease and pressure from foot deformities.

Peripheral arterial disease

Effective wound healing is dependent on good circulation. Physical examination can give you some clues; poor pulses, cool shiny skin, and a lack of hair can indicate poor arterial supply. However, physical examination is not very sensitive at detecting every case of arterial blockage, so the treating physician should have a low threshold for ordering diagnostic tests.

Ankle brachial index testing, which compares the blood pressures at the ankle and arm, is a quick screen for blockages in the major vessels. Followup testing can be done with ultrasound or angiogram. These tests all focus on large-vessel disease, and they may miss or underestimate patients with significant small-vessel disease.

There are two additional testing modalities available at the Wound Healing Center that can assess for these small-vessel problems.

- **Skin perfusion pressure** detects the pressure with which the capillary beds are perfused in the areas next to the wound.
- **Transcutaneous oxygen measurement** directly measures the partial pressure of oxygen in the tissues adjacent to the wound. This number can give us a valuable ability to predict whether the wound is likely to heal without aggressive intervention.[3]

Venous insufficiency

Venous insufficiency is often the result of leaky valves in the deep veins or in the perforating veins that connect to the superficial system. The end result is fluid retention. The tissues swells, which leads to the capillaries being further apart, and a resulting decrease in oxygen in the tissues in the middle.[4]

Compression with stockings or wraps can be very helpful, but care must be taken if the patient also has arterial disease. If the arterial circulation is poor, too tight a wrap can occlude these vessels.

Ultrasound evaluation can detect significant reflux through the valves. This reflux can sometimes be corrected surgically, which these days is usually done by either laser or radiofrequency ablation of the superficial veins, or of sclerotherapeutic injection of incompetent perforating veins.

Excessive inflammation

Excessive inflammation in the wound environment is fueled by cytokines and proteases, and these factors are difficult to remove from the tissues when the venous and lymphatic systems are overwhelmed. Proper dressing selection and regular wound debridement are important tools to reduce inflammation.

Pressure

Lying or sitting in the same position will lead to pressure on the small blood vessels over boney prominences such as the ankle or the sacrum. These tissues can become chronically ischemic and ulcerate. Foot deformities can also create pressure points, and the repetitive trauma of walking can lead to skin breakdown.

Wounds will fail to heal unless the pressure is relieved. Total contact casting, custom shoes, and wheelchair cushions are among the options available.

Nutrition

Wound healing takes a lot of protein. Structural components like collagen and cytokines that regulate the healing process are some of the important roles played by proteins. A heavily draining wound will lose a lot of protein into the bandages. Between increased protein needs and significant protein loss, many patients end up depleting their protein stores.

Pre-albumen is a more sensitive test than albumen for impending protein deficiency. Dietary education and supplementation are sometimes necessary.

Other

There are a host of other factors that can contribute to poor wound healing. Rheumatological diseases, medications, depression[5], skin conditions, and skin cancers can all be complicating factors. When a wound is not healing as it should, the treating physician may need to go back to the drawing board to broaden the scope of investigation. Skin biopsies can sometimes lead to diagnoses that might otherwise have been missed.

Microenvironment

Traditionally, wound care has focused on large scale, tangible issues, such as the diagnoses listed above. In recent years, however, there has been a growing body of knowledge about the microscopic environment. Our enhanced understanding of what is happening on the cellular level has led to several improvements in the tools and the techniques employed to heal stubborn wounds.

> "There has been some fascinating research done by Dr. Brem which demonstrates that the cells around the margin of a chronic wound look and act differently than cells that are located just a few millimeters back from the wound edge."

Matrix metalloproteases

These protein-degrading enzymes are a normal part of wound healing. Their levels rise moderately in the early stages of healing, presumably to help remove foreign contaminants. Their levels quickly fall in a wound that is healing normally. In a chronic wound, the levels rise very high and stay high, leading to breakdown of structural proteins, growth factors, and cytokine receptors. Thorough debridement can reduce the level of these proteases, and the addition of collagen-containing wound products can help mitigate their effects.

Cytokines and growth factors

These proteins interact with each other, various kinds of cells, and structural proteins in the extracellular matrix. The levels rise and fall in an orderly fashion in normally healing wounds. They are easily degraded by matrix metalloproteases, and thus their levels are low in chronic wounds. There are different topical wound products that can enhance the levels and activity of these proteins.

Cell senescence

There has been some fascinating research done by Dr. Brem[6,7] which demonstrates that the cells around the margin of a chronic wound look and act differently than cells that are located just a few millimeters back from the wound edge. These marginal cells have different sets of genes that are activated, whereas the genes in the cells that are back from the wound edge are similar to normal controls.

Fibroblast cells can be cultured into sheets in the lab and given a “wound” by scratching some of the cells off. Fibroblasts cultured from normal skin, and those from the skin a few millimeters back from the wound edge, will rapidly reproduce and migrate to repair the damage. In contrast, fibroblasts cultured from the wound edge will be slow and ineffective. While it may seem counter-intuitive to take a chronic, non-healing wound and make it bigger, these studies make a compelling argument for trimming back the skin at the margins.

Fundamentals

Through the years, there has been a lot of misinformation about the best way to treat wounds. Various folk remedies and traditional techniques have persisted, in part because skin is so good at healing that even a toxic and counterproductive strategy will succeed most of the time. For those wounds that are not responding to traditional techniques, evidence-based improvements in basic topical wound care can be very effective.

Antiseptics

Alcohol, peroxide, iodine, and various other antiseptics are effective at decreasing a wound’s bacterial load. Unfortunately, they can also be toxic to fibroblasts and keratinocytes.[8] A brief course of antiseptics to help get a dirty, infected wound under control may be helpful, but ongoing use will add another obstacle to wound healing.

Moisture level

For optimum wound healing, the wound bed should be warm and moist.[9] Wounds that are left uncovered get too dry and too cool, and wounds that are washed regularly or that are draining heavily can be too wet. Wet to dry dressings have been in use for many years, but are now considered to be suboptimal — the wound bed should be neither wet nor dry, and the frequency of dressing changes is labor-intensive and also too cooling to the wound bed.[10, 18]

The optimal dressing is one that can absorb the drainage that the wound is producing while being left in place for a number of days. Wound vacuum systems can also be effective at removing excessive drainage.

Debridement

Sharp debridement of wounds is very important for good local wound care. Wound healing centers that debride more often have better healing rates.[11] Removal of necrotic tissue and fibrinous slough in the wound bed removes habitat for bacteria and decreases the inflammation in the wound. Trimming back the wound edges removes poorly functioning cells, allowing the healthier cells behind them to drive the healing process forward. Routine maintenance debridement, often done on a weekly basis, removes bacterial biofilm and stimulates the release of growth factors in the wound bed.[17]

Infection control

Open wounds are prone to developing cellulitis or osteomyelitis. Quantitative cultures can help differentiate bacterial colonization from significant infection requiring antibiotics. Thorough debridement is important, as noted above.

There are a variety of topical products containing silver or Cadexomer Iodine (milder on the skin cells than Betadine®), which can decrease the bacterial load. Topical antibiotic ointments can lead to excessive moisture retention and to allergic reactions.

Bioactive Dressings

There are different kinds of biologically active topical products that can accelerate the body's healing process. Each is unique — in the interest of clarity and brevity, I will refer to each by its trade name, rather than its lengthy and confusing descriptor. No specific product endorsement should be inferred. There are a couple of things they all have in common.

Firstly, they are expensive. Generally, they are used when more conservative treatment, as outlined above, fails to make significant progress. Failure of a wound to heal 50% of its volume in four weeks is a poor prognostic sign[12], and consideration must be made for using more advanced techniques.

Secondly, these products function poorly in an acutely infected or actively inflamed environment. Preparing the wound bed with good local wound care is essential for these products to succeed.

OASIS®

OASIS is manufactured from pig intestine, processed to remove all the cells but to leave behind the original architecture of the extracellular matrix proteins: collagen, elastins, proteoglycans, and glycoproteins. These serve several purposes. They inhibit matrix metalloprotease activity, and they interact with cytokines to enhance their activity. It comes as a dried sheet which expands in the moist wound to form a three-dimensional scaffolding to facilitate cell migration.

Apligraf®

This is a two-layered product comprised of a lower portion of bovine collagen and human fibroblasts, and an upper layer of human keratinocytes. This structure mimics that of normal skin. The live cells are cultured from human foreskins. The collagen and cells do not act like a skin graft; they are gradually broken down and reabsorbed over a period of weeks. But while they are present, the fibroblasts and keratinocytes actively (and interactively) generate their cytokines and growth factors. In contrast to OASIS, the collagen is not in a structured and organized matrix, but the presence of the extra collagen helps to neutralize the activity of the matrix metalloproteases in the wound.

Dermagraft®

The manufacture of this product starts with a fine mesh of vicryl, the same material used to make absorbable sutures. Human fibroblasts are seeded onto this mesh, and as they grow and multiply, they secrete structural proteins including collagen and elastin. The end product is a continuous sheet of fibroblasts and extracellular matrix proteins, which is cut to fit and placed in the wound bed. The vicryl is gradually reabsorbed, and similar to Apligraf, the cells and proteins interact with the patient's tissues and are gradually broken down and reabsorbed.

Hyperbaric Oxygen Therapy (HBO)

Oxygen is essential for adequate wound healing, and some patients' circulatory systems are inadequate to deliver enough oxygen to the wound bed. The addition of extra oxygen can be helpful.

What it is

Patients are placed in chambers where they breathe 100% oxygen at two to two and a half atmospheres of pressure. There are multi-place chambers which can accommodate several patients as well as a technician, and there are monoplace chambers which allow the treatment protocol to be tailored to the patient's needs. Most wound healing centers use monoplace chambers.

> To view videos of wound healing options at Southwest, including hyperbaric oxygen therapy, go to **www.swWoundHealing.org**.

The patient's plasma becomes supersaturated with oxygen, increasing the partial pressure of oxygen from around 90 up to 1800. Treatments are given five days a week, with a course of treatment lasting two to three months, depending on the diagnosis.

Each treatment takes ninety minutes, plus the time involved in gradually raising and then decreasing the pressure. Clearly, hyperbaric treatment involves a large commitment in time and money, so patients should be selected carefully.

How it works

As the oxygen is breathed into the lungs, the patient's plasma becomes supersaturated with oxygen. This increases the radius around the capillaries within which the oxygen can be delivered. In marginally perfused tissues, this enhanced delivery of oxygen allows the immune system to function normally. The killing enzymes of phagocytes require oxygen to function, and these same cells are much more mobile and active when hypoxia is reversed.[13, 14]

Very poorly perfused tissues benefit from hyperbaric treatments through an additional mechanism. Well perfused tissues become hyperoxic, while the poorly perfused tissues remain relatively hypoxic. This oxygen gradient acts as a stimulus to building new blood vessels.[15] As new vessels grow, oxygen is delivered further and further into the hypoxic tissues, with resulting improvements in cellular activity.

When to use it

Any hypoxic wound that is not healing with standard therapy is potentially a candidate for hyperbaric oxygen treatment. Medicare has a specific list of diagnoses that they will cover, which includes the issues below:

- **Soft tissue radionecrosis:** Radiation results in progressive devascularization of the exposed tissues over a period of three to five years. This can result in bleeding problems (radiation cystitis, radiation proctitis) or poor healing of surgical wounds. Hyperbaric treatment can lead to significant re-vascularization and successful healing.
- **Refractory osteomyelitis:** Bone infections can be very stubborn to treat, in part because of the hypoxic environment that is created by the infection. When such an infection fails antibiotic therapy, hyperbaric oxygen can be added as an adjunct to surgical and antibiotic treatments.
- **Diabetic foot ulcers:** Wagner grade 3 (abscess, osteomyelitis, or tendonitis) and Wagner grade 4 (gangrene) diabetic foot ulcers also qualify for hyperbaric treatment under Medicare guidelines. Many of these patients will have co-existing arterial problems.
- **Failed flap or graft:** A skin graft, a muscle flap, or an amputation site that is failing also qualifies for hyperbaric oxygen treatment. Treatment can also be given in preparation for a flap or graft in compromised tissue.
- **Other:** Other Medicare-approved diagnoses include decompression sickness, air embolism, carbon monoxide poisoning, smoke inhalation, gas gangrene, crush injury, acute traumatic ischemia, compartment syndrome, severe anemia, burns, necrotizing infection, and osteoradionecrosis.

Who not to treat

Like any medication or procedure, hyperbaric oxygen is not without the potential for complications. Care must be taken when considering treatment for patients who are at higher risk of complications. (Refer to Table 1: Potential Complications with HBO.)

> "It is my personal opinion that, in the absence of an emergency, all patients who are being considered for amputation should be evaluated for hyperbaric oxygen treatment."

Prevention of Amputation

Keeping limbs attached to their owners has many benefits. Amputation can have significant ramifications on patients' self image and on their ability to care for themselves, and most of these patients will have a few risk factors for surgical complications. The expense of surgery, rehabilitation, managing complications, and providing prosthetics is considerable. Thorough, aggressive wound care can prevent amputations in a cost-effective manner.[16]

When an amputation is needed, a thorough evaluation can help to identify the most conservative site for amputation. Transcutaneous oxygen measurements can identify whether a patient is likely to heal at the proposed site of amputation.[19] When perfusion at the chosen site is marginal, a pre- and post-operative course of hyperbaric oxygen can help increase the likelihood of healing the incision, avoiding the need for a second surgery.

Sometimes a more distal site can be chosen, for instance, losing a toe rather than losing the forefoot. And sometimes, in the course of preparing a patient for amputation, the wound will begin to heal on its own. It is my personal opinion that, in the absence of an emergency, all patients who are being considered for amputation should be evaluated for hyperbaric oxygen treatment.

Conclusion

Wound healing is a growing field of study. There have been significant advances in the basic science of chronic ulceration, resulting in a wide array of new products and techniques. Physician-led wound healing centers use an aggressive diagnostic and therapeutic approach, covering all the factors that led to impaired healing. Remarkable outcomes and significant improvements in quality of life can be achieved with collaboration between the wound healing specialist and the referring physician.

	Table 1 – Potential Complications with HBO
Barotrauma	An isolated pocket of air will contract as the pressure rises, and expand as the pressure is released. Air trapped in a sinus or under a filling will cause pain, and the patient will need to have the underlying problem addressed. Air trapped in the ear can cause pain, and if the pressure is great enough, the eardrum can burst. Treating allergy problems can reduce the likelihood of ear problems, and tubes can be put through the eardrums if needed. The most dangerous form of barotrauma is pneumothorax, which is caused when a pocket of air trapped in the lungs expands and causes a tear. Air then escapes to fill the lung cavity, partially collapsing the lung on the affected side. This is a very rare event, but steps can be taken to reduce the risk. Patients with COPD or asthma should optimize their treatment to reduce the risk of air trapping, and a chest x-ray can help to find blebs that might rupture under pressure. A history of a spontaneous pneumothorax is generally a contraindication to hyperbaric treatment. A high-risk patient who must be treated due to a life-threatening diagnosis should be sent to a center that has a multiplace chamber, where the physician could do an emergency needle decompression if needed.
Oxygen toxicity	Oxygen toxicity is another risk of HBOT, and seizure is the most dramatic manifestation of that. Other symptoms can include nausea, anxiety, and muscle twitches. These symptoms, while uncommon, can happen to anybody at any point in their treatment, but there are some risk factors for oxygen-related seizure that we can keep an eye on. People who need to be treated at higher pressure are at higher risk, and obviously, someone with a history of seizures is at higher risk. Fever, hyperthyroidism, and hypoglycemia are correctable risk factors. There are a number of drugs that increase the risk, such as insulin, steroids, and narcotics. These seizures are not terribly dangerous since the patient is already hyperoxygenated, but they are dramatic, and there are some steps we can take to prevent them. Premedication with a benzodiazepine drug like Lorazepam reduces the likelihood of seizure, and can also help with any claustrophobia issues. Air breaks can also prevent seizure and abort some of the other symptoms like nausea or anxiety. The patient has a mask in the chamber which provides room air, and breathing through this mask for ten minutes allows the oxygen to wash out of the system.
Fire	While there are no specific patients that are at more risk than others, fire remains an ongoing safety issue. Fire requires three components: fuel, an ignition source, and oxygen. Since there is an overabundance of oxygen, we need to be abundantly careful about the other two components. No fuel may go into the tank, including books, ointments (petroleum-based), and perfumes (alcohol-based). No ignition sources may go in either, including electronic devices and metals. Any jewelry that cannot be removed is taped over. Specific cotton-only scrubs are provided at the time of treatment, which reduces the chance of static discharge, and also reduces the risk of proscribed items being left in pockets.

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Improving the Health of Diabetic Patients Through Resident-Initiated Group Visits

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Group visits have the potential to benefit patients with chronic illnesses. Our objective was to implement resident-run diabetic group visits that would improve patient education and help patients become more involved in their care. We developed systems to promote, coordinate, and lead the visits. A standardized progress note was developed to encourage patient goal setting and to track relevant laboratory test results.

To evaluate our program, we conducted surveys to determine patients' behavioral changes and satisfaction levels and assessed the effect on group visit participants' glycated hemoglobin (HbA1c) and low-density lipoprotein (LDL) levels.

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Group visits for chronic illness have been used in primary care for 30 years, but the process of establishing visits and the structuring of their content has not been clearly described.[1] The group visit model has emerged as a solution to some of the difficulties of caring for patients with chronic illness, who often require complex and ongoing interventions that are difficult to achieve with standard office visits. With a complex disease, such as diabetes, the group visit can offer advantages to patients and providers because of increased health education and through a unique combination of encouraging increased self-management[2-4] and use of peer support.[5]

Group visits have been used for a variety of medical issues, including diabetes, asthma, and prenatal care. Numerous outcomes have been tracked from health care utilization measures such as emergency department visits and medical costs, to clinical measures such as weight loss and peak-flow scores.[6,7] While evidence continues to emerge about the benefits of group visits,[1,5] what has not been discussed is the process of initiating and sustaining resident-run group visits and evaluating their effects.

This paper attempts to address those issues for a resident-run diabetic group visit by providing a guide on how to establish and run such visits and sharing lessons learned. We also anticipated that the group visit model would give patients a deeper understanding of the disease process and that this increased knowledge would lead to lifestyle changes and greater adherence to treatment regimens. To evaluate the initial response to this intervention we followed glycated hemoglobin (HbA1c) and low-density lipoprotein (LDL) values and conducted surveys to assess patients' lifestyle changes.

Methods

Setting

The group visits began as a resident practice improvement project at the Hahnemann Family Health Center in Worcester, Mass. The center is an urban community-based residency site with a diverse patient population. There are 12 residents and 11 faculty.

Visit design

We wanted to integrate several tenants of the new model of family medicine as outlined by the Future of Family Medicine Project, including group visits, chronic disease management, a team approach, and outcome analysis.[3] A group of six, including residents, faculty, and nurs-

es, reviewed what components of group and individual visits would benefit diabetics and integrated them into a comprehensive group visit. The visits were designed to educate patients about their illness; work with them to set meaningful, achievable individual goals; and provide support infrastructure through behavioral strategies for change, peer interactions, and physician follow-up.

PROCESS:

- Group visits
- Individual physician visits centered around patient-selected goals, medications, lab results, etc.
- Informal group discussions and peer support with practical presentations

Sample

Through our laboratory database, all clinic patients over 18 years of age who had ever had an HbA1c drawn and given a diagnosis of diabetes were identified and invited to participate in group visits. As initial response was low, we engaged providers to invite their patients to increase participation. Verbal and e-mail reminders were sent to faculty and staff, and invitations were placed on the chart of diabetics so that providers could invite patients during office visits. Resident group visit coordinators called all invited patients. As a practice improvement project, this evaluation was reviewed and granted an exemption from formal review by the University's Institutional Review Board for the Protection of Human Subjects.

Enrolling providers

Other resident-run practice improvement projects had faltered when the championing resident graduated, and we wanted to motivate our residents to adopt the group care concept to ensure it was integrated into the culture of the health center. This would improve sustainability by making group visits a health center-wide initiative. So, first- and second-year residents were involved to increase continuity. A diabetes nurse was identified who took part in all group visits. Additional providers included one to two faculty members and two to three residents at each visit to see patients individually and participate in group discussions.

Process

Six group visits were conducted from June 2006 to June 2007. Visits occurred every 2 months in the evening. Patients could attend as many visits as they desired but were encouraged to attend them all. Group visits lasted 2 hours and included a 30-minute presentation on a diabetes topic followed by a question and answer session and group discussion. This was followed by individual physician visits.

Informal group discussions continued during the patients' individual visits, and these discussions covered a range of issues such as adhering to a diet, handling the stress of coping with diabetes, and sharing exercise ideas. Discussion was facilitated by residents asking patients to relate personal experiences and by questions asked of an expert speaker. A local health food restaurant donated a nutritious meal for each visit.

Presentation topics were selected based on patient need and American Diabetes Association (ADA) standards of care[9] and included exercise, nutrition, foot care, eye care, medications, and behavioral interventions. Expert speakers included an ophthalmologist, a podiatrist, a sports medicine family doctor, a pharmacist, a psychologist, a diabetic nurse educator, and a nutritionist. We encouraged speakers to provide practical information that patients could directly implement. For example, the podiatrist addressed when and how to examine the feet, how to cut nails, and appropriate footwear for people who have diabetes.

The physician one-on-one interaction was done privately and centered around patient-selected goals, such as diet or exercise modification. Goals were reviewed, and a new measurable goal was made at each visit, such as losing 5 pounds or receiving a diabetic eye exam. The goal was often triggered by the presentation or discussion. Medications and lab results were reviewed. An HbA1c graph was discussed so patients could track their progress. Participants were asked about ophthalmology screening, podiatric screening, and nutrition counseling.

This process was facilitated by a diabetes progress note we developed in accordance with ADA standards of care.[9] The note was co-signed by the patient to stress the importance of co-management.

In addition to peer support, participants had access to other forms of support integrated into the visit. For example, many patients were uncertain about how to use a glucose meter. To address this, we invited a local diabetic supply company representative to provide testing supplies and instructions on their use at the visits. He then followed up with patients to ensure they were

testing at the suggested frequency. Prior to this, it was found that many patients were not testing at all or were testing less often than suggested.

Transition

The leadership transition to a new resident group was started early so residents in the new leadership group had time to observe and gradually take over some functions with the support of the outgoing leadership team. A series of "how to" documents, including a timeline delegating responsibilities to prepare for the visit, were generated for use in future years. This served to systematize the program so that its sustainability would not be dependent on a particular individual.

Outcome measures

HbA1c measurements were taken at baseline and every 3 months, and LDL measurements were taken at the beginning and end of the year. All patients who attended at least one group visit were included in our analysis. We compared, in aggregate, participants' changes in HbA1c and LDL data with a randomly selected and matched (by age and gender) comparison group of diabetic patients seen in our clinic over the same 12-month period who had not attended group visits and had completed all recommended laboratory tests.

In addition, self-administered surveys were collected from patients at the end of 1 year. Patients answered yes/no and short-answer questions pertaining to what they liked or disliked about the visits and commented on personal changes they made as a result of these visits.

Data analysis

The data were entered into an Excel spreadsheet and transferred to SPSS V15.0 for analysis. Frequency counts, percentages, and means were calculated for all appropriate variables. Bivariate statistics were computed using t tests to compare the change in HbA1c and LDL values between the first and last group visit dates for group visit patients compared to the comparison group. Because of the small samples, non-parametric Mann-Whitney U tests were also calculated comparing mean ranks of the two outcome values (HbA1c and LDL levels) between the intervention and comparison groups.

Results

The program was initiated and led by residents with faculty collaboration. Patients and providers were committed to this model of care as indicated by consistent faculty and patient participation.

Of the 143 patients invited, seven initially responded. Reasons given for not attending included visits being held at a time when the patient could not attend, group visits being too long, aversion to groups, and difficulty hearing or seeing that precluded participation. Some patients from the original invitation list could not be reached due to outdated contact information. Additional enrollment strategies, as outlined in the methods section, increased participation to a total of 25 patients out of the 143 initially invited patients.

Patient ages ranged from 34 to 70, with a mean age of 60. Females made up 52% of the visit population (Table 1). We averaged 15 patients per visit, and participating patients on average attended 75% of the visits.

All participating patients completed a survey. Results showed that 72% of the patients reported making a lifestyle change as a result of attending visits. Eighty-eight percent reported that the visits helped them achieve better control of their diabetes. When asked what they liked most, 40% stated that the visit provided a support group. Fifty-two percent participated because they were asked to by their primary care doctor. All respondents stated they would come to a group visit again. On average, 68% of patients at any given group visit were repeat visitors.

HbA1c results were missing for two of the 25 patients, and LDL results were missing on four patients due to the patients not having their blood drawn as instructed. Group visit patients demonstrated an HbA1c reduction

Table 1

Patient Characteristics

Variable	*Group Visit Participants*	*Comparison Group Participants*
Number of patients	25	25
Gender (% female)	52	52
Age (mean years)	60	60
Age range (years)	34–70	34–70
Insurance (%)		
Private	36	40
Medicaid	16	28
Medicare only	16	4
Medicare/supplemental	28	28
Self pay	4	0

Table 2

Baseline and 1-year Follow-up HbA1c and LDL Scores for Group Visit Patients and Age- and Gender-matched Comparison Group Patients (n=25 per group)

	Group Visit Patients	*Comparison Group Patients*	t *Test*$_{(df)}$*	P *Value*
Baseline HbA1c	8.23%	7.85%	$0.69_{(47)}$	0.49
Follow-up HbA1c	7.34%	7.82%	$-1.18_{(46)}$	0.24
Delta HbA1c	0.90%	0.03%	$1.63_{(46)}$	0.11
Baseline LDL values (mg/dl)	100.75	86.44	$1.35_{(47)}$	0.18
Follow-up LDL values (mg/dl)	90.86	85.60	$0.65_{(39)}$	0.52
Change in LDL values (mg/dl)	4.71	-3.50	$0.94_{(39)}$	0.35

* Degrees of freedom (df) may not total to the full n because of sporadic missing data.

of 0.90% compared to a decrease of 0.03% for the control group. This difference, however, was not statistically significant (P=.11). The LDL reduction was 4.71 mg/dl for the group visit patients compared to an increase of 3.50 mg/dl for the control group, also not a significant difference (P=.35) (Table 2).

Discussion

One of the most important findings of our study was that our resident-directed group visit program could be implemented and sustained, despite anticipated challenges. Some of these challenges included recruiting patients and providers, finding time to organize and sustain the visits, making visits cost-effective, and establishing criteria to evaluate the success of these visits.

The group visits led to the residents taking an increased leadership role in the health center and increasing their disease-specific knowledge. The visits created a structure around an illness so that disease management steps were not missed. It stimulated team building by bringing residents and office staff together to work toward a common goal.

Jaber et. al. state in their review of group visit research that future reports could benefit from clearly defining the structure, process of care, content of visits, and appropriate outcome measures.[1] In reviewing our implementation process, we hope to stimulate further thought and discussion on these issues as they apply to group visits being integrated into a residency-based practice.

"The group visits led to the residents taking an increased leadership role in the health center and increasing their disease-specific knowledge ... [a structure so that] disease management steps were not missed ... [and] team building."

However, despite both patients and clinicians having a positive experience with the group visits, and despite patients reporting that they made lifestyle changes, we were unable to demonstrate statistically significant changes in HbA1c or LDL levels. The lack of significant change in these parameters may have been due to our small sample size and lack of sufficient statistical power, insufficient length of followup, or it may have represented a true lack of benefit of the group visits on measurable diabetes outcomes. Further study with a larger group of patients over a longer period of time will be required to determine if resident-run group visits can result in improvement in diabetic control or LDL levels.

Limitations

In addition to the small sample size, an additional limitation of our study methods is the possibility of selection bias. Only 25 patients chose to participate from a pool of 143 eligible patients, and these 25 individuals may not have been representative of the population of patients with diabetes at our health center as a whole. Further, the comparison group consisted of patients who chose not to come to group visits rather than being randomly sampled from all health center patients and assigned to this group, further raising the possibility that our participants may have been more motivated and not typical of our overall patient population.

Finally, much of our data relies on patients' self-reporting and is thus subject to self-report biases. And, since this project was conducted at one residency training site in Massachusetts, the results may not be generalizable to other residency practices or to non-residency sites.

Conclusions

Residents successfully overcame challenges and implemented a group visit program for patients with diabetes. Patients reported making lifestyle changes as a result of participation, but we were unable to demonstrate significant changes in objectively measured parameters (HbA1c and LDL levels). Thus, the long-term benefit of resident-run group visits for patients with diabetes is uncertain. Outcome data could be strengthened by a formal intervention study in which patients are randomly assigned, upon recruitment, to standard care or group visit model and then followed more rigorously over time. Additional areas for study include assessing patient and physician satisfaction with the group visit model, as well as following other clinical outcomes such as blood pressure and weight changes.

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