SCOPE

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President's Message *Col. Richard Satava. M.D.*

Quality Assurance and Outcomes Analysis in the Era of Advanced Technologies

COL. Richard Satava, M.D.

This is a time of cataclysmic changes in Medicine, not of slow and gradual alteration. The changes are broad and sweeping, not localized to a single arena. No matter which sector is scanned—administration, financial, educational, technical or even doctor-patient relationship—there are no simple transitions, there are wrenching differences occurring over short time frames. There are a number of root causes: 1) Medicine is BEING changed (often by opportunists) from a profession to a business. Management practices of quality assurance, i.e. total quality improvement, performance measurements, cost-benefit ratios are replacing the Hippocratic Oath as true determinant of quality for the patient (ref #1) 2) There is an unprecedented call for oversight by someone (and often anyone will do) other than the physician or even the patient (following Ralph Nader's philosophy of "...the consumer must be protected at all times from his own

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INSIDE

Newsletter of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES)

Patient Information Packet in the Works

SAGES Patient Information Task Force is developing educational pamphlets about endoscopic procedures for patients. While there are several excellent publications currently available that touch upon other procedures, few address the specific types of surgeries most commonly performed by SAGES members. Therefore, the Task Force has undertaken to create eight SAGES patient information brochures. These official SAGES publications will describe the most common endoscopic techniques and answer the most frequently asked questions in accessible language easily understood by the layperson.

To aid in the prioritizing of topics for the eight brochures, please indicate which of the following topics you would be interested in SAGES producing for use by your patients. Please indicate by a "yes" or "no" response the attractiveness or usefulness of a SAGES publication to you and your patients on the attached topic list and fax it back to the SAGES office.

TOPICS LIST:

Yes	No	
❑	❑	EGD
❑	❑	ERCP
❑	❑	Flexible Sigmoidoscopy
❑	❑	Colonoscopy
❑	❑	Laparoscopic Cholecystectomy
❑	❑	Laparoscopic Hernia
❑	❑	Laparoscopic Colectomy
❑	❑	Laparoscopic Anti-reflux Surgery

Laparoscopic Aortic Surgery

View

a critical look at endoscopic surgery

Reported by:
Carlos R. Gracia, M.D.
Yves-Marie Dion, M.D.

Laparoscopic surgery has been recognized as beneficial in the performance of a growing number of surgical procedures. Advantages include shorter hospital stays and decreased hospital costs. More importantly, they are associated with less pain, less scarring, improved cosmeses, earlier return to activities and productivity, as well as a decrease in morbidity. Many of the advances thus far in therapeutic laparoscopy have centered around gastrointestinal, gynecologic, urologic, and general thoracic procedures. One of the newest is increasing interest in the application of minimally invasive vascular surgery.

Present minimally invasive vascular techniques include angioplasty, stent placement and angioscopy. All represent efforts to minimize morbidity in patients well-known for their high risk cardio-vascular status and significant comorbidity. Vascular surgeons have been slow in progressing toward laparoscopy, largely due to the technical challenges of the fundamentals of vascular surgery, including: 1) exposure, 2) vascular control, 3) vascular occlusion, 4) anastomoses of vessels and/or grafts, and, 5) hemostasis. The remote, hands-off operating system of laparoscopy is a difficult, not to mention stressful, process to apply to these necessary tasks of vascular surgery. Although in its infancy, laparoscopic vascular procedures have been performed on patients.

The first application of laparoscopy to major vascular surgery in humans was performed in March 1993 by a surgical team led by Dr. Yves Dion of Quebec. The infrarenal aorta was dissected and controlled. Retroperitoneal tunnels were constructed and a knitted Dacron prosthesis was inserted. Finally, by mini-laparotomy, an end-to-side anastomosis was completed, and the distal anastomosis constructed to finish a complete aortobifemoral bypass. The patient did well. Five more patients were completed over the ensuing months with consistently improving clinical courses when compared to open operations.

Four further patients were reported by Berens and Herde in July 1995. They noted the "exceedingly difficult" nature of performing a running vascular anastomosis with conventional laparoscopic instruments. They also pointed out the concerns of being able to maintain a working space under insufflation if continuous suctioning was required. They concluded that "current laparoscopic devices do not provide the security to clamp a calcified aorta or the dexterity to sew a difficult arterial wall". They also suggested a gasless laparoscopic approach to allow the insertion of retractors, laparotomy sponges, and combined conventional and laparoscopic instrumentation, particularly for the construction of anastomoses (all of which were done with end-to-side techniques). This experience highlights the difficulty in translating the technical challenges of open surgery to laparoscopy. However, the successful completion of several patients with good outcomes reinforces the conclusion that laparoscopic vascular surgery is technically feasible.

The common feature of each experience is that they were laparoscopically-assisted in order to deal with the technical challenges. Many experienced laparoscopists recognize that "lap-assisted" or "mini-lap" procedures are potentially very difficult in and of themselves, particularly in patients where the abdominal wall becomes very thick and the intraperitoneal fatty mass increases, making retraction and exposure very difficult. In this respect, a totally laparoscopic procedure offers advantages. Based on our early experience, it became obvious that two problems had to be solved before totally abdominal laparoscopic bypass could be performed. The first is the ability to consistently, safely, and easily do an end-to-end anastomosis (which has been our preference in the standard open bypass). The second obstacle was to provide adequate exposure, especially with retraction of the small bowel.

We undertook a series of animal experiments to resolve these obstacles. A retroperitoneal approach solved many of the exposure and retraction difficulties. Practice with the techniques and skills to perform the end-to-end anastomosis were required. Although the pig aortas do not have atheromata, their smaller size (6-7 mm) is more technically challenging than a human aorta. Some basic vascular instrumentation was adapted with laparoscopic handles. Ultimately, consistent exposures and anastomoses could be constructed in the laboratory animal model of bypass surgery without excessive blood loss (<550 cc), excessive surgery times (<4.5 hours), or

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Ultrasound Course in Philadelphia

The SAGES Pre-Meeting Post Graduate Course "Ultrasound for the General Surgeon," to be held March 12, 1996 sold out early. Sparked by the growing interest in laparoscopic ultrasound, the SAGES Program Committee has brought together expert surgeon ultrasonographers from around the globe to provide a practical course on ultrasound for surgeons. Attendees will learn the basic physics of ultrasound as well as ultrasound terminology. anatomy and technique. The clinical uses of ultrasound in laparoscopic and open surgery will be discussed as wells as endoscopic ultrasound and percutaneous ultrasound. Participants will also obtain "hands on" practice with ultrasound in animate and phantom models covering the neck, breast, abdomen, upper GI endoscopic and rectal ultrasound.

Those interested in future courses should contact the SAGES office.

Announcing: A New SCOPE Column — The Book Corner

Since so many of our SAGES members publish books, we have created a venue through which to announce such publications to the general membership. **The Book Corner** will appear regularly to highlight member-authored books. If you have recently authored or edited a book, submit the title, subject matter, publisher, publication date, and locations where the book is available to the SAGES office. In the next issue of SCOPE, your publication will be featured. You'll gain visibility for your work, and other SAGES members will have the opportunity to learn about the continuing scholarship and achievements of their colleagues.

Support your State Chairmen

Help your State Chairmen help you! One way in which SAGES is increasing its visibility and educating colleagues is a Speakers Bureau. SAGES experts are currently preparing six "turnkey" topics about endoscopic surgery and procedures. These presentations are designed to be of general interest to surgeon and non-surgeon physicians as well as allied health professionals. Some of the first groups that may be interested in engaging a SAGES speaker are local medical societies. Consider the affiliations you have with societies in your area and which ones might enjoy a SAGES speaker. Help your State Chairmen to identify these societies as well as other organizations you feel might utilize SAGES experts. A list of State Chairpersons is in your membership book. Contact the office of your State Chair with suggestions for Speakers Bureau venues.

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operative mortality.

As a result of our laboratory experience, clinical feasibility of a retroperitoneal approach to aortobifemoral bypass was evaluated by human cadaver work. This involved performing the necessary exposure and dissection in the cadaver model. Ultimately, we offered three of our patients totally laparoscopic bypass for aorto-iliac occlusive disease. Two patients underwent aortobifemoral bypass. One was performed totally laparoscopic with a gasless approach and the second totally laparoscopic with pneumoretroperitoneum. Although the procedures were long (>6 hours), the cross-clamp times were acceptable (the second patients' total clamp time was 72 min). The third patient underwent ilio-femoral bypass with pneumoretroperitoneum. All anastomoses were end-to-end and intracorporeally performed. All bypasses are patent and patients two and three rapidly returned to activities and work, after abbreviated hospital stays of 4 and 2 days, respectively. The first patient had developed a compartment syndrome for which he received proper treatment. No other complications or problems were noted. We believe at this time that laparoscopic aortic surgery is feasible, and can be safely performed with

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"off the shelf" instrumentation.

There is enthusiasm from members of the vascular community towards a minimally invasive surgical approach to aortobifemoral bypass and other vascular procedures as a viable alternative to endoluminal procedures. Cikrit et al has reported an average of 2.5 stents placed per patient with the maximum in one patient being 7 stents. Multiple stents were placed in 24 of 38 limbs receiving stent placement. Stenting procedures are also expensive.

In aortic aneurysmal disease, endoluminal graft placement has been plagued by difficulties, including the attachment of a graft in the pulsatile, dynamic, and changing environment of a pulsating aorta. In addition, lack of exclusion of the aneurysm from antegrade pulsatile flow, or significant flow from other branches, such as the IMA, raises the issue of the risk of rupture despite the graft placement. A combined approach whereby control of the neck of the aortic aneurysm laparoscopically along with endoluminal deployment of a graft may turn out to be a better approach. It is a simple process to control, expose, and operate on occlusive disease first, as the presence of the pulsatile mass generates obvious additional technical difficulties.

Despite the enthusiasm for the further application of laparoscopic aorto-iliac surgery, additional developments are necessary. Vascular surgeons have a wide variety of exposure and experience in laparoscopy, ranging from none to extensive (in those who do laparoscopic general surgery). Over the next several years, laparoscopic skills are likely to become more uniform as many of tomorrow's vascular surgeons come out of training programs having had laparoscopic training. Also with understanding the importance of laparoscopic suturing, increasing skills and experience will be more prevalent. Many specific maneuvers will require improvement.

Instrument design is critical. Standard vascular instruments need to be adapted for laparoscopy. Occlusion devices need to be designed and/or adapted to work laparoscopically, either with external handles or as detachable intracorporeal clamps (e.g., bulldogs). An improved ability to provide rapid and consistent exposure of the retroperitoneum, and maintain it, is needed. The issue of a gas or gasless approach is certainly not resolved. The former allows for better exposure because of the 3-dimensional push of the gas under pressure. However, a gasless approach allows the placement of unique instrumentation and the ability to suction. The risk of gas embolism has been well studied by Dion et al. It was shown that only 18% of euvolemic dogs with up to a 1 cm incision in the vena cava demonstrated any gas bubbles in the right heart, under carbon dioxide insufflation. Perhaps a combination of the two approaches (gas and gasless) will become the preferred approach. Finally, the anastomosis will require instrumentation that allows consistent construction of safe and durable anastomosis. A number of technologies are under evaluation for this express purpose.

In conclusion, the growing amount of animal experience continues to support the feasibility of videoendoscopic vascular procedures. Our early patient experience has demonstrated that lab work can be translated into the operating room. Further definition and development of the technology is necessary to make it more readily available in the near future for patients.

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Yet another reason to "get online!"

President's Message
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indiscretion and vanity") to justify every expenditure or validate every physician decision. 3) An unacceptable national budget deficit has resulted in a mandate for reduction of costs - at all costs 4) the "zero defect" mentality calls for low or no risks taking, and assignment of blame whenever there is not a perfect result and 5) The medical community has awakened to the Information Age and the true benefits of information technology.

Recent attempts to improve the quality of health care through Quality Assurance (QA), Total Quality Improvement (TQI) or other performance measurements such as outcomes analysis have mainly been advocated by non-scientists (social scientists, administrators, insurance regulators, policy makers and politicians). They point to success in industry (especially manufacturing) as a model which has shown significant improvement. However this is not translating into success in the medical field. While there are many behavioral, social, economic and business explanations for this, one interesting explanation comes from basic scientific and engineering principles referred to as the "rigid body problem". Assembly line components are comprised of rigid, inanimate objects and materials which do not change (e.g., a steel sphere does not change shape, weight, form or size. A steel sphere can be made to exacting specifications to fit exactly in an assembly line). On the other hand, Medicine is a biologic system with "non-rigid bodies" with opposite attributes (spherical cells change shape, position and composition from minute to minute and no two cells are exactly alike nor are any two "assembled" animals or humans alike). Thus applying management techniques, performance measures or outcomes based upon tried and true "rigid body" principles will not work. Scientific equations made for a spherical steel ball are not likely to work on the same sized spherical biologic cell. This observation does negate the attempt to improve the quality of medical practice, but rather acknowledges the significant differences and redefines what we mean by quality - principally based upon the needs of the patient - and seeks to discover a system of evaluation that is non-putative, constructive and implementable.

There is no single system to date, including "common business practices", which has made a nation-wide impact upon the quality of health care, although there are a small number of focused local successes in specific areas for improved quality. Why? In part, Medicine is undergoing a fundamental change from a technical perspective. While Medicine is moving into the Information Age, we are assessing our performance using Industrial Age standards and tools. I should like to paint, in broad brush strokes, one perspective of this change which could provide a different point of view, a fresh approach to the problem in assessing quality and performance, and could open new horizons for the practice of Medicine.

The key is information technologies. This includes not only traditional tele-radiology, information management systems and electronic medical records, but advanced technologies that acquire, process and display information over an interactive, collaborative, distributed network.

The importance of the information technologies cannot be overemphasized. This is the means by which the critical data for performance measures and outcomes analysis is derived - this is the method that automatically, continuously, unobtrusively and transparently provides quantifiable measurements. The measurements include all physiologic parameters, voluntary and involuntary actions and processes in a form that can be automatically entered into intelligent databases with knowledge engines that autonomously perform complex analyses and generate simplified reports regarding performance and outcomes. Data that previously was too difficult to capture, too voluminous to enter into a database, or too complex to describe or sort can now be acquired, processed, archived and displayed. The question will no longer be "Do I have the data necessary to determine if a certain outcome can be obtained?", The challenge will be to determine what questions to ask in order to get a meaningful answer regarding the outcome.

In addition, there are new issues which will arise with future technologies. Rather than wait for these innovations to establish themselves, and then retrospectively try to craft performance standards or outcome analysis tools, we must be proactive and plan for their arrival.

It is essential to remember that the technology is neutral - it is neither good nor evil; therefore, it is the implementation of the technology that determines the quality of utilization. Rather than address a specific technology, it is the functionality that provides

(continued on page 7)

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which needs to be assessed. The purpose is not to critique the technologies, but to attempt to understand the impact which the technology could have on the manner in which we perform outcomes analysis.

A few of the current trends deserve attention because of their potential for huge changes in the practice of medicine and surgery. While not all inclusive, these areas do provide such promise: 1) enhanced human (physician) performance, 2) remote access, 3) point-of-care data acquisition, 4) autonomous (closed- loop) control, 5) enormously powerful computational engines, 6) knowledge agents and 7) genetic algorithms. By enhancing the physicians capabilities and allowing access to health care where never available before the quality will increase. Point-of-care data acquisition allows the collection and review of information about the patient at the time the information is needed, reducing costly return visits or repeated laboratory studies. The remainder are computer enhancements to information processing which makes information available to the physician in a timely manner, reducing the delay, inaccuracy and repetition of various tests. Understanding these technologies and leveraging their strengths provides the tools to implement meaningful outcomes research.

There are enough difficulties in determining appropriate performance assessments to make your head spin, but if we do not rise to the challenge, others will do it for us, leaving us with nothing but a headache.

References

1.Fischer JE. Ethical Dilemmas in Managed Care. Bull. Amer Coll. Surg. 80:21-25, 1995

Research Mentors Sought

Important clinical research is often carried out by those unaccustomed to writing abstracts, manuscripts and grants. Many of our members engaging in such research have indicated that it would be helpful to have an "academic partner" to shepherd him/her through the research grants and publications process. In response to that need, the Research Committee is launching a mentor program.

The object is for the academic partner to provide guidance and advice to the mentee through such processes as: development and review of research protocols, grant application, manuscript preparation and submission.

SAGES members familiar with the process of writing abstracts, manuscripts and grants are sought to be paired with those physicians and surgeons in need of assistance. Prospective mentors and mentees are requested to return the interest "card" below to the SAGES office.

SAGES Mentor/Mentee Interest Card:

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❑ Yes! I am willing to serve as an Academic Mentor to a clinical colleague.

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MEMBER NUMBER:

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EMAIL (IF APPLICABLE)

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AREAS OF EXPERTISE

Would be interested in working with resident or fellows ❑ yes ❑ no

Interested in/able to provide guidance in:

❑ designing research protocols
❑ grant writing
❑ manuscript publication
❑ abstract writing & submission

MENTEE:

❑ Yes! I am interested in being paired with a SAGES Academic Mentor.

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SAGES Calendar–Future Events

SAGES SCIENTIFIC SESSION & POSTGRADUATE COURSE
5TH WORLD CONGRESS OF SURGICAL ENDOSCOPY
March 13-17, 1996
Philadelphia Convention Center • Philadelphia, Pennsylvania

SAGES SCIENTIFIC SESSION & POSTGRADUATE COURSE
March 19-22, 1997
San Diego Convention Center • San Diego, California

SAGES SCIENTIFIC SESSION & POSTGRADUATE COURSE
April 1-4, 1998
Washington State Convention Center • Seattle, Washington

WORLD CONGRESS OF ENDOSCOPIC SURGERY
SIXTH INTERNATIONAL CONGRESS OF THE E.A.E.S.
June 3-6, 1998 • Rome, Italy

E-mail Update:

Question: What do all 200+ of the SAGES members on page 4 have in common?

A. They no longer have to spend money on faxes to contact each other.

B. They can immediately send documents or messages back and forth.

C. They are on the cutting edge of communication technology.

D. They are cute.

Answer: All of the above—all of the SAGES members listed on page 4 have e-mail and can surf the net, stroll down the Information Highway, and communicate with each other without moving from their desk! While future membership directories will contain the e-mail addresses, we thought we'd congratulate the following pioneers. ALSO—don't forget that FREE American On Line get on line disks will be available at the World Congress in Philadelphia. Get On Line disks provide all the software you need to get your modem-equipped hardware hooked up to the Internet, International e-mail and a host of other services. Each AOL disk comes with ten free hours of time on the net. Additionally, SAGES now requires all committee members to have e-mail.

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