IR congress news

CIRSE 2006 - Rome
Saturday, September 9, 2006

Roberto Passariello
Meeting Chairman

Giovanni Simonetti
Meeting Co-Chairman

Dear Colleagues,

It is our great pleasure to welcome you to the CIRSE 2006 Annual Meeting and Postgraduate Course - the highlight of the scientific year for Interventional Radiology in Europe.

At this year's event you will be able to choose from:
- 29 special sessions;
- 45 workshops;
- more than 130 lectures;
- 3 interactive case discussions;
- 160 free papers;
- 264 scientific exhibits;
- 18 satellite symposia and
-the largest dedicated technical exhibition in the field.

However, CIRSE 2006 will not only be memorable for its excellent scientific content. Rome's countless cultural and culinary delights will certainly also contribute to making your stay in the Eternal City an unforgettable experience.

After the outstanding 2005 congress in Nice, Michael Lee's task to further improve the meeting's scientific value was a daunting challenge. However, when looking at the 2006 programme, we can certainly say that he exceeded his mission and that the Programme Planning Committee is indeed spoiling us with choices.

We are sure you will agree that apart from the scientific programme one of the most interesting aspects of our congress is exchanging experience with our colleagues from around the world. Our team has put together a number of social events which will provide the perfect opportunity to do so.

We look forward to seeing you at the Opening Concert and the CIRSE Foundation Party, which hopefully will give you a little taste of la dolce vita.

Benvenuti a Roma, benvenuti al CIRSE 2006!

Roberto Passariello
Meeting Chairman

Giovanni Simonetti
Meeting Co-Chairman

The Bravo Orchestra

Welcome to CIRSE 2006

Join us for a memorable ceremony and concert
16:30, Aula Magna

Opening Concert

For the first time in the history of our meeting the award ceremony will be followed by a concert open to all congress attendees, exhibitors and accompanying persons. Don't miss the Bravo Orchestra performing an outstanding show featuring the all-time classics of Italian and international music!

CIRSE Awards

CIRSE 2006, the most important European meeting in Interventional Radiology, will be officially inaugurated with a ceremony honouring this year's CIRSE laureates. We are happy to announce that Professor Barry T. Katzen, the founder and Medical Director of Baptist Cardiac & Vascular Institute, Miami, Florida, will receive the CIRSE Gold Medal for outstanding achievements in Interventional Radiology. Professor Alexander Rosenberger, one of the founding members of CIRSE and president of its congress in Jerusalem in 1986, will join the ranks of Distinguished CIRSE Fellows. The same honour will go to Giovanni Simonetti, one of the pioneers of Interventional Radiology, who is Professor of Radiology and the Director of the Faculty of Radiology at the School of Medicine and Surgery of the University of Rome Tor Vergata.

Barry T. Katzen
CIRSE 2006
Gold Medallist

Johannes Lammer
CIRSE President

Promoting UFE through patient information, education and research

Jean-Pierre Pelage
Department of Radiology
Hôpital Ambroise Paré
Boulogne, France

Fibroids of the uterus were first treated with UFE in France and the U.S. in 1989. Since then, the procedure has become widely available and is now routinely performed in most European countries. In parallel to the growth of UFE, there has been a steep increase in scientific research and literature dedicated to UFE as a safe and effective medical procedure. Today, an estimated 10 percent of patients treated for fibroids in France undergo UFE and numbers are increasing year on year. If current trends continue, UFE is set to become the treatment of choice for myomas of the uterus in 10 years time. This would be good both for patients and public health care budgets, since UFE is both less invasive and less expensive than the established treatment methods of myomectomy and hysterectomy.

However, for a number of reasons, this change in treatment preferences might take longer than hoped for. The principal reason for this is the lack of direct patient access by interventional radiologists performing UFE and the refusal of many gynaecologists to accept mounting evidence that many of their patients undergoing surgical treatment would be better off with UFE. Better informed patients are already asking their gynaecologists about UFE but these remain a minority and most are unlikely to seek a second opinion.

Unless asked, many gynaecologists will not even refer to UFE as a possible treatment option. When challenged, gynaecologists routinely point to a perceived lack of scientific evidence clearly demonstrating UFE superiority over surgery. In addition, those who do accept UFE as a better treatment option in certain cases often quite rightfully point out that there are simply no facilities offering UFE treatment in their area. Whilst the relationship with gynaecologists can be a difficult one, there is no sensitive alternative to co-operation with gynaecologists who, after all, exercise close to 100 percent patient control.

In order to address some of the issues raised above, CIRSE has established a Taskforce to provide advice on how best to promote UFE. The CIRSE UFE Taskforce intends to become active in three areas: public and patient information, support for IR colleagues already practicing or wanting to specialize in UFE, and collaborative research involving both interventional radiologists and gynecologists.

Public and Patient Information
In many countries it is forbidden to advertise medical therapies. However, through the participation in radio shows, articles and/or interviews in newspapers and in other popular publications, UFE can be promoted quite effectively. Feedback received from the media and the public have demonstrated a great interest in UFE.

Support for IR colleagues
CIRSE has already produced "Quality Improvement Guidelines for Uterine Artery Embolisation for Symptomatic Leiomyomata." Further, similar guidelines might be developed and best practice may be shared by means of brochures, and perhaps training, for interventional radiologists already performing UFE or such wanting to specialize in UFE. Such information could convey experience as to what kind of patients respond best to which treatment but also offer advice on how to develop good collaborative relations with gynecologists as well as pass on basic knowledge of gynecological conditions which are essential if a meaningful partnership is to develop. A course on gynecological disease might be suggested within the framework of the ESIR (European School of Interventional Radiology).

Collaborative Research
Many good studies on UFE already exist and more data will become available in coming years. To take one example, the CIRSE Foundation UFE Registry has already enrolled over 450 patients and first results are expected in three years time. However, much of the research is not finding the echo it deserves within the medical community and particularly amongst gynecologists. In view of this, a prospective study on post-myomectomy vs. post-embolisation fertility in young multi-fibroid women sponsored by CIRSE and the main European society of gynaecologists, and other partners, is suggested. In order to achieve above goals, leading gynaecologists will be invited to join the taskforce.

Session 5	**UAE: Where do we stand?** *Saturday, September 9, 10:15-11:30, Aula Magna*
Free Paper Session 24.1	**Uterine Artery Embolization** *Sunday, September 10, 17:00-18:30*
Special Session 52	**Uterine Fibroid Embolization** *Wednesday, September 13, 08:30-09:45*

Radiofrequency Ablation and Osteoplasty in the Treatment of Bone Osteolytic Metastases

Salvatore Masala
Department of Diagnostic Imaging, Molecular Imaging, Interventional Radiology and Radiotherapy
Policlinico University of Rome "Tor Vergata"

The skeleton represents the most common site of metastases. Approximately 70% of patients with cancer have evidence of metastatic disease at the time of their deaths. The spine is the most common location among osseous sites for metastatic deposits, the thoracic spine being its most commonly affected part (70%), followed by the lumbar spine (20%) and the cervical spine (10%). Other frequent skeletal localizations are the ribs, pelvis and proximal long bones. Approximately 50% of metastases arise from one of these primary types of cancer: breast, lung, prostate or melanoma. They cause spinal metastases in 74.3%, 44.9%, 90.5% and 54.5% of patients, respectively, and are followed by renal cancer, gastrointestinal cancer, thyroid cancer, sarcoma and the lymphoreticular malignancies: lymphoma and multiple myeloma.

Possible mechanisms that may cause pain from bone metastases include: stimulation of nerve endings in the endosteum resulting from the release of chemical agents from the destroyed bone tissue such as prostaglandins, bradykinin, substance P or histamine, stretching of the periosteum by increasing size of the tumour, fractures, tumour growth into surrounding nerves and tissues. Few of these mechanisms are supported by definitive data. Stimulation of nerve endings in the endosteum by chemical agents released from the destroyed bone tissue is probably the main cause of bone pain from small metastases. As metastases enlarge, stretching of the periosteum additionally contributes to the pain (1).

Pain management in terminally ill patients with metastases involving bone can be challenging. Painful bone metastases commonly occur in advanced cancer patients and are difficult to manage because of reduction in mobility and performance status. The treatment of osteolytic bone metastases is palliative and relies mainly on the elimination of pain. Conventional therapeutic options for symptom control include radiation therapy and/or chemotherapy, surgery and the use of oppioid and other analgesics. These conventional therapies with their well known drawbacks and side-effects provide reasonable pain relief obtaining variable success rates. Due to significant risk caused by comorbid conditions common in this elderly population, as well as technical difficulty related to adequate hardware fixation within weak bone, surgical intervention has been limited to few selected cases. Radiation therapy, able to block the tumour's growth, normally determines a partial or complete resolution of the pain in about 10-14 days.

Unfortunately in some patients radiation therapy may not be an option because of radiation insensitivity of the neoplasm or limitations to the radiation dose to normal structures. In these cases the outcome is insufficent relief of symptomatology or recurrence of the tumour after therapy associated to an intolerance to the new cycle. Moreover radiation therapy determines recuperation of the bones' resistance only minimally and delayed by 2 to 4 months, which does not allow a patient with multiple osteolytic lesions to sustain his weight. Chemotherapy may also not be beneficial because of poor therapeutic response or toxicity of the chemotherapeutic agents. Intolerable analgesic-related side effects may develop with increasing analgesic doses. Failure of these therapies to provide adequate pain relief may markedly decrease the quality of life for these patients.

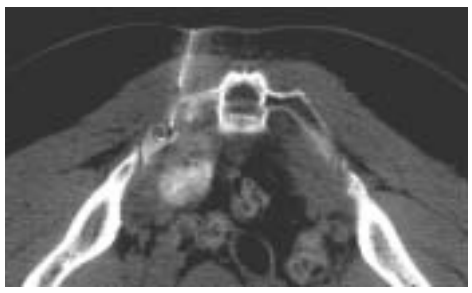


Figure 1a

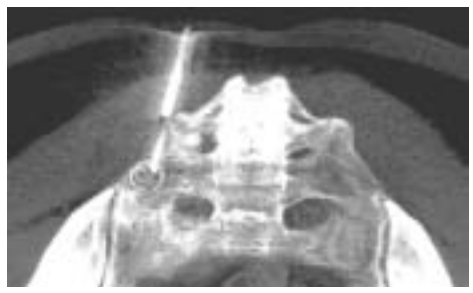


Figure 1b

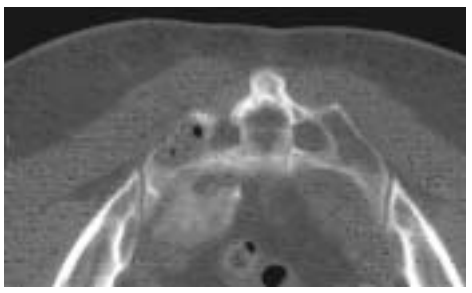
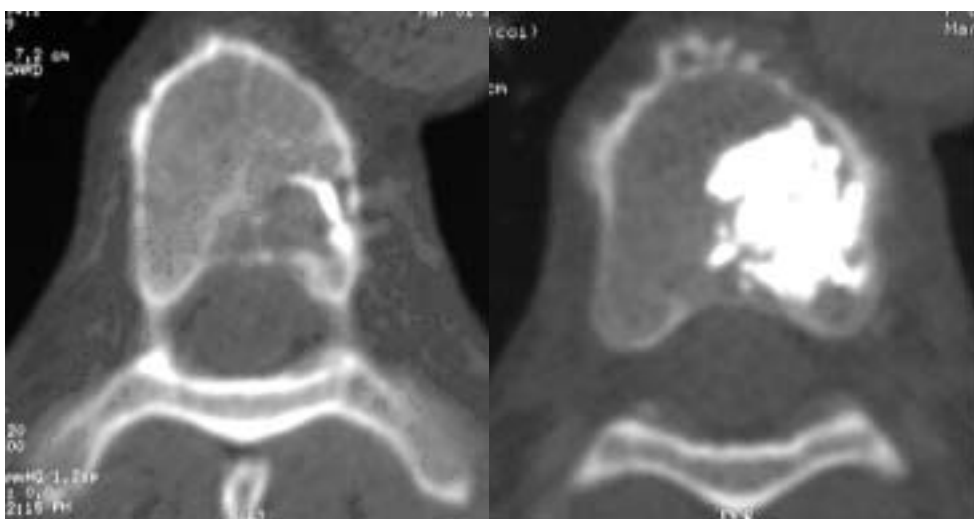


Figure 1c



Figures 2a,b

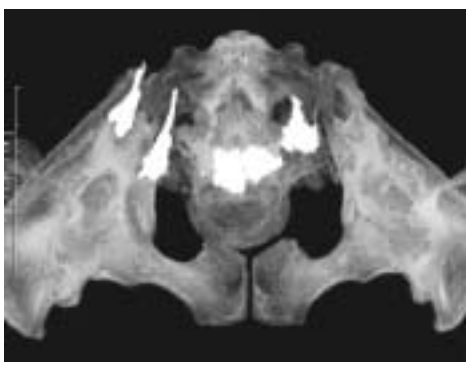


Figure 3

Recently, minimally invasive surgical techniques (MISS) have been added, as an alternative option, to the therapeutic armamentarium in the treatment of intractable debilitating pain. The aim of radiofrequency heat ablation is to destroy the tumour tissue before stabilizing the bone lesion through the intrasomatic injection of cement. Radiofrequency ablation is one of the most promising thermal ablation techniques for the treatment of nonresectable tumours. The use of radiofrequency ablation was first reported in 1990 for the treatment of hepatic tumours. An alternating electric current operated in the range of radiofrequency can produce a focal thermal injury in living tissue. Shielded needle electrodes are used to concentrate the energy in selected tissue. The tip of the electrode conducts the current, oscillating in the range of high frequency (200-1.200 kHz), which causes local ionic agitation, subsequent frictional heat and with that localized coagulation necrosis.

Schematically, a closed-loop circuit is created by placing a generator, a large dispersive electrode (ground pad), a patient and a needle electrode in series. The aim of performing radiofrequency heat ablation before osteoplasty was to destroy tumour tissue and to thrombose the paravertebral and intravertebral venous plexus and, thereby, minimize procedure related complications (2). Major benefits of radiofrequency heat ablation are immediate cell death, accurate control of lesion size with an imaging-guided procedure and the thrombosis of venous drainage of the highly vascularised metastasis. Necrotizing tumour tissue by radiofrequency heat ablation optimizes cement distribution, facilitated by changes in tumour consistency as a result of thermal alterations.

The purpose of osteoplasty is then to stabilize the osteolytic lesion. The mechanism of pain induction in osteolytic lesions of the spine and other skeletal segments is believed to rely on the activation of pain receptors of the periendostium. Stabilization of the lesions leads to pain relief by stopping the stress on the periendostium. In order to explain the analgesic effects of PMMA, the most accredited hypotheses postulated in literature are the neurotoxic effect of monomer PMMA and the exothermic reaction produced during cement polymerization, causing peri-endosteal denervation. Percutaneous osteoplastic treatment of metastatic osteolytic lesions of the spine and other skeletal segments (pelvic region and femur) as a highly efficient palliative therapy for pain has been previously described.

Percutaneous injection of PMMA bone cement into an osseous lesion was first described by Galibert et al. in 1984 as "vertebroplasty", successfully applied to the treatment of C2 aggressive hemangiomas and subsequently also used on vertebral fractures secondary to osteolytic tumours. The procedures were successfully performed in our patients, whose improvements were swift. All symptoms were reduced, decreasing from an average of 8.6 points of VAS to 2.6 (VAS of Huskisson = Visual analogue scale, pain score with points assigned subjectively from patient pre- and post-procedure in a range between 0 absence of grief and 10 maximum pain). Resistance of bone involved was increased considerably. We did not find any condition of thermal damage or extravasations of PMMA with compression of nervous structures.

The entire procedure of Radiofrequency (RF) Heat Ablation and Osteoplasty is performed under CT-fluoroscopy guidance and after administration of local anaesthesia. A bone biopsy needle of 13 Gauge is introduced percutaneously within secondary bone lesions. Once the exact position of the needle had been verified, a 19 Gauge needle electrode and a thermocouple were introduced coaxially through the inserted cannula into the central core of the osteolytic lesion. After unsheathing the spiral electrode tine, which opened to a maximum diameter of 9 mm and length of 10 mm in the metastasis, the needle was connected with a radiofrequency generator. The radiofrequency heat ablation started at an energy level of 15 W. The deployed energy was increased by 5W every 2 min, up to 25 W (Figure 1a,1b,2a). Control CT scans revealed microbubble formation in the treated area, indicating tumour necrosis (3) (Figure 1c).

The Polymethylmethacrylate (PMMA) was loaded into a dedicated device and injected through the bone needle into the lesion under continuous fluoroscopic guidance.
Control CT scans revealed a homogeneous distribution in the tumour necrosis (Figure 2b,3). Patients were instructed to remain in bed supine positioned for the following 4 hours and dismitted on the following day. The injection of PMMA can be done before or after the radiotherapy , thus having a synergic analgesic action upon the pain after the failure of radiotherapy, or in case of local recurrences. We treated patients with unremitting pain over spine, pelvis and proximal long bones, in absence of neurologic deficits and refractory to conventional therapeutic options such as radiation therapy, chemotherapy, surgery and use of analgesics. The procedure demonstrated to be an effective, simple and safe treatment for secondary skeletal localizations in obtaining swift pain relief associated with an evident augmentation in the weight-bearing resistance.

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Interventional radiology simulation: quis custodiet custodes?

Derek Alan Gould
Consultant Interventional Radiologist,
Royal Liverpool University Hospital,
Prescot Street, Liverpool L7 8XP.
Honorary Reader, Department of Medical Imaging, Johnston Building,
University of Liverpool, Brownlow Hill, L69 3GB.

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Imaging guided, catheter-based interventions have been developed by radiologists for nearly half a century. Yet with the demise of invasive diagnostic imaging, and concerns over patient safety, difficulties training technical skills are beginning to emerge. While there are a number of alternatives to learning on patients, it can be daunting to consider how these should be incorporated into curricula. In particular, how can we be sure we are quicker on the draw than Billy the Kid?

To perform interventional radiology (IR) requires specific knowledge, cognitive and technical skills and professionalism (attitudes, behaviour) [1]. These are gleaned and assessed in a carefully designed curriculum, with certification dependent on satisfactory attainment of a series of performance objectives. Basic technical skills in IR involve the manipulation of needles, wires and catheters using imaging guidance. These core skills must first be practiced until automated to allow full attention to be given to more complex technical and cognitive tasks [2]: these must be capable of being performed competently in challenging situations and under stress.

Once learnt, skills need to be maintained by practise, yet varying case mix and a large commitment to training others might leave even the expert with poorly maintained skills. With reduced time to train and changing patient perceptions, further pressure is applied to the creaking apprenticeship model [3]. Yet there are alternatives to training in patients which use procedure simulations based on models, animals and computer generated virtual environments (VE). The latter allow an operator to realistically perform a procedure in a virtual patient, derived from medical imaging data, using a human-computer interface device to provide 'feel' (haptics). While these interface devices are available in a range of ingenious configurations, they have yet to emulate all the mechanisms and degrees of freedom possible in modern IR instruments. A range of methods of simulation will therefore be required for some time to come.

Computer-based simulation, however, holds a trump card: a facility to automatically evaluate and record an operator's performance, providing feedback and, at least in theory, evidence for a certification [4]. To legitimately provide such evidence for a statutory body, the content of an assessment process should follow the discipline's curriculum [5]. Assessment also needs to be unbiased, reproducible, cost effective, feasible and objective [6]. Whereas objective methods (e.g. checklists, global scoring systems, standardised patients) have been used in assessing surgical proficiency [7-15], assessment of IR skills frequently depends on a logbook record to show procedure experience. This method falls short of reliably indicating proficiency. It is subjective, fails to account for differing rates of learning and is susceptible to the variability of case mix and experience between centres. To address such deficiencies, computer based simulation has been used successfully used in surgery, with automated assessment of specific measures (metrics) of performance [16-19].

The computer games industry uses metrics to test performance. If we outgun Billy the Kid in a simulator, does this mean we are indeed the better shot? Are we happy to take him on for real, or might we be concerned about the validity of this assessment? Unless the simulation's design is appropriate and the metrics are correctly replicated and relevant to the real world, our real pistol may feel heavier than we had thought, and Billy may actually be the better shot and quicker on the draw! We would have been misled by design compromises and imprecise assessments of our performance, perhaps fatally so. With appropriate levels of fidelity, however, and relevant content and metrics, modelling and assessment of tasks is more likely to be valid, with a reduced risk of training inappropriate or incorrect skills (negative training).

To find out what a medical simulator should let us do and should be able to measure, we need detailed information on what is happening in the real world task. One way to do this is to first determine best practice in the procedure to be simulated using a literature search. This is then modified to show the skills required and their relationship to each other during an interview of subject experts by a psychologist. The interview uses video recorded procedures as a prompt with further breakdown identifying the cues used, decisions made and psychomotor actions performed (a Cognitive Task Analysis). Subject experts then determine which of these steps are most critical and most prone to error. These data are now the metrics which are used to evaluate the learner's proficiency [20-23], for example in observer based scoring systems or by incorporating them into simulators.

It is, however, arguable that no simulator-based or other tools for training and assessing technical proficiency have yet been validated for use in IR curricula [24]. There are a number of validation studies that can be performed to prove the effectiveness, or validity, of a simulation's training tasks and test items. For training purposes, the simulation should accurately replicate the procedure or process it claims to model (content validity), appearing to test takers to resemble the real world task (face validity). Its training effectiveness can be investigated by comparison with a gold standard (e.g. apprenticeship) in a randomised study (concurrent validation).

For assessment, the test should be able to evaluate those metrics that are relevant and important to acquiring the skills of the target procedure (construct validity). It should, therefore, be possible for the simulator to distinguish the performance of experts from that of novices. Training is, however, about more than improving performance in a machine: the results of assessment should predict future competence in patients as confirmed in a subsequent clinical study (predictive validation) [25]. Ultimately there should be proof that, not only do the skills acquired by simulator training transfer to procedures performed in patients (transfer of training), but that they are then maintained over time.

How reliable are the assessments that are provided in current endovascular simulators? These are generally measures of overall performance, such as the time taken to perform a procedure, fluoroscopy time, 'C' arm handling or contrast volume used. While providing some indication of proficiency, these metrics give little information on detailed skills or errors relevant to IR curricula. This might reflect their selection by those outside the speciality of IR, or simply that these are the only metrics that can currently be utilised by a particular simulation. Metrics that reflect the detailed performance objectives of an IR curriculum would represent more specific measures of proficiency and would be more likely to discriminate between experts and novices. While this discrepancy may, in part, explain the current lack of successful validation of endovascular simulators [25], there are a number of ongoing predictive validation studies of some of these simulators, the outcomes of which are awaited with interest.

It is possible that the reliability and reproducibility of a computer based assessment might be enhanced by using higher visual and tactile fidelity to present a more natural and realistic task to the learner. High fidelity and complexity, however, carry a trade off of financial and computational expense and the latter can introduce difficulty performing in real time. Lower fidelity could therefore be a cost-effective option when developing simulations to train and master the fundamental core skills of IR [2]. High fidelity could then be reserved for trained operators to obtain and maintain more complex skills; experts might also plan and rehearse difficult cases in a VE created from their patient's own imaging data ('mission rehearsal').

Much of the impetus to develop medical simulation has been through concerns regarding patient safety. The great promise of the simulation industry in this respect has rightly placed it centre stage in the skills training arena. Stage left is the more affluent, medical device industry, keen to adopt simulation which might be used to train a range of specialities to use its products [e.g. 26-28]. Often this lies outside the remit of statutory, training organisations' curricula, where ironically it is even more important (and difficult) for validity to be proven. Stage right are the training authorities themselves, seeking to train and certify within their own, well defined curricula. While they have limited financial resources, they are keen to cautiously adopt simulation and to be involved in its collaborative development and careful validation (Fig 1). In this climate, the training organisations must show the way, setting standards, including validation standards, for the use of medical simulation within their curricula.

The Cardiovascular and Interventional Radiological Society of Europe, the Society of Interventional Radiology and the Radiological Society of North America have recognised the need for many factors to be taken into account in order for simulation to form a part of training and assessment. In this respect they have established individual medical simulation task forces and a joint task force which has set out recommendations [24]. Contemporary simulators are considered suitable for gaining certain aspects of procedural experience, such as learning the correct sequence of procedural steps and selection of appropriate tools, though the utility of simulators to acquire catheter manipulation skills was considered as yet unproven, and therefore experience on a simulator could not yet be regarded as equivalent to training on patients.

The Joint International Task Force has since set out a strategy for using simulation to train and assess IR and to realise specific organisational goals. Current curricula require redefining to determine where simulation is best inserted to meet training and performance objectives and the relationship of simulation to patient-based training. Also to be considered are standards for adoption of medical simulation [29], for metrics, efficacy and validation, and how to relate to the industries involved.

The vision of the societies is that by 2010, a growing number of validated IR simulation training modules will:
1) have been shown to transfer skills and reduce procedural error,
2) be delivering clinical benefit to patients
3) have been integrated into a standardized IR training curriculum and certifying examinations
Indeed, the newly formed American Board of Radiology Foundation is planning on a major role for simulation in its early initiatives. At the time of writing, the joint strategy is under consideration by the Executive Councils of the Societies and if ratified, it is hoped to make this available on the CIRSE website. It could then be considered by all involved, including the statutory organisations responsible for certification in the various countries represented.

Despite claims purporting successful validation, no endovascular simulator model has yet been shown to improve IR technical skills in patients [30-32]. There seems little doubt, however, that further development and successful evaluation in curricula will bring an opportunity to supplement the deficient apprenticeship model, reducing reliance on patients for learning. There is, however, a risk that simulation can be used outside or in place of statutory curricula in a potentially unregulated fashion. As this revolutionary and exciting technology is extended from industry and academia into clinical practice, the implementation of agreed standards could help to maintain the quality of training outcomes.

Figure 1: Could this be the interventional radiology classroom of the future? (Aknowledgement: Abbott, Mentice and The Institute for Therapy Advancement, Brussels.)

Virtual Reality Hands-on Workshops

Carotid Stenting
Sunday, September 10,
11:30 - 13:30
Carotid Stenting
Monday, September 11,
10:00 - 12:00

Renal Artery Intervention
Tuesday, September 12,
10:00 - 12:00
Intervention in the Lower Limb
Wednesday, September 13,
10:00 - 12:00

All workshops will take place in the Simulator Gallery on the ground floor.

You can also visit the Simulator Gallery during the exhibition opening hours.

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CIRSE Foundation Party
Tuesday, September 12, 20:00

Enjoy an exquisite dinner accompanied by an outstanding entertainment programme at the fund raising party in aid of the CIRSE Foundation. The yearly event has become one of the social highlights of our meetings, providing the perfect opportunity to get together with old friends and meet new colleagues.

This year's Foundation Party will take place at Villa Miani, a wonderful mansion in Victorian style on the slopes of Monte Mario. It is immersed in a beautifully kept garden and offers a unique panorama overlooking the city of Rome all the way to St. Peter's Cathedral.

If you are interested in joining us for the Foundation Party, please contact the Kuoni booth in the registration area. Since the number of tickets is limited, we recommend early booking.

EPOS™

EPOS™ is a pioneering system for an all-electronic scientific exhibition. The state-of-the-art database, which was developed by the European Congress of Radiology and generously made available to CIRSE, currently comprises more than 4,250 electronic presentations. EPOS™ offers much greater flexibility than traditional scientific exhibits and provides better options for scientific communication.

The possibility to use moving images, link to related websites, search the scientific exhibition for specific topics in minute detail and e-mail entire exhibits are just some of its many advantages. The EPOS™ area is located on the first floor, where 30 computers will be available to view approximately 260 electronic exhibits.

EPOS™ Opening Hours

Saturday, September 9	07.30 - 18.00
Sunday, September 10	07.30 - 18.00
Monday, September 11	07.30 - 18.00
Tuesday, September 12	07.30 - 18.00
Wednesday, September 13	07.30 - 13.00

Onsite EPOS™ staff will be glad to assist you during these hours.

The Angiotech & InterV merge:
Next generation of medical devices and combination products

Angiotech Pharmaceuticals (NASDAQ:ANPI; TSX:ANP) is a world leader in the emerging field of drug-eluting medical devices and biomaterials. The company is pioneering the science of adding drugs to medical devices and biomaterials to dramatically improve their performance and solve some of medicine's most vexing problems.

Recently Angiotech acquired American Medical Instruments, the former owner of the InterV group, including the medical device manufacturers of MD TECH, Florida, and PBN MEDICALS Denmark A/S - founded 25 years ago in Scandinavia.

As Dr. William L. Hunter, President and Chief Executive Officer of Angiotech says "The acquisition of American Medical Instruments (hence InterV) represents a transformational event for us. The convergence of Angiotech's exceptional research and development efforts and InterV's expertise in operations, manufacturing and sales uniquely positions the combined company to develop and commercialize the next generation of medical devices and combination products. We are very excited about working with InterV's talented employees to achieve continued growth and long-term success in the marketplace and to offer physicians and patients the best available products and treatment opportunities in the industry."

Thomas Bailey, Chief Financial Officer of Angiotech, adds, "This exciting and strategically important acquisition is the culmination of our efforts to establish a platform to commercialize our product candidates and R&D initiatives. The addition of InterV is a cost-effective solution to accelerate our strategy and brings significant commercial resources in manufacturing facilities and specialty sales forces. We anticipate a rapid and smooth integration of our two businesses."

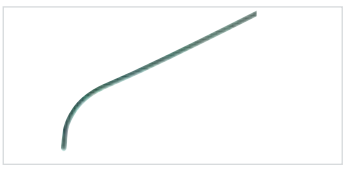
The InterV brand combines a broad portfolio of clinical products, widely accepted by interventional practitioners - radiologists, urologists, oncologists and gastroenterologists. PBN MEDICALS Denmark A/S is responsible for distributing all InterV, MD TECH and PBN brands to markets within Europe, Middle East, North Africa and Asia; either directly or through carefully selected excellent distributors in these areas. The US team of InterV is responsible for North America, South America, Australia, New Zealand and South Africa.

Angiotech and InterV have initiated mutual R&D efforts to bring new technology to products like the CanaliZer® guidewire and InterV's comprehensive assortment of SKATER® drainage catheters.

The new united R&D efforts are also concentrating around InterV's considerable range of biopsy devices, such as Tru-Core® and BioPince®.

Angiotech expects that the combination of its various biomaterials and drug technologies with InterV's devices will provide for numerous new product opportunities. Many of these new product iterations have the potential to be rapidly developed and launched.

Inter V CanaliZer Straight



Inter V CanaliZer Angled

CanaliZer® is a brand new hydrophilic guidewire developed by InterV. It has a highly radiopaque polyurethane sleeve and excellent hydrophilic coating. The pre-angled tip secures stability during long-term manoeuvrability. The super elastic nitinol core offers kink-resistance and atraumatic path finding, due to 1:1 torque and an outstanding coating. CanaliZer comes in both angled and straight versions.

SKATER pigtail

The SKATER® catheter is made of soft polyurethane for optimal kink resistance and perfect configuration memory. The catheter is hydrophilic coated for minimal friction during insertion - only the distal part is coated to ensure a firm grip for optimal handling and control.

SKATER single step

You will meet the Asian and European staff of InterV at booth no. 11. Don't miss the opportunity to experience our interventional devices for radiology, cardiology, drainage, biopsy, oncology and mammography.

The SKATER® Single Step Catheter with Choice Lock is suitable for a variety of applications. Single step procedures are simple and safe with this unique catheter. The Choice Lock needle ensures easy single-handed catheter/needle snap lock. The cannula is used as a catheter stiffener and only the pointed tip of the stylet is used for tissue penetration. The special tip construction prevents the catheter from being caught on the catheter during insertion.
Applications: Percutaneous drainage of abscesses, ascites, hematomas, pleuracentesis, cholecystostomies, nephrostomies and other fluid collections.

Portal Vein Embolization: How I do it

Alain Roche
Department of Medical Imaging,
Institut Gustave-Roussy, Villejuif, France

One of the prerequisites for partial hepatic resection is the presence of enough remaining functional liver parenchyma to avoid life-threatening postoperative liver failure. Therefore, the possibilities of curative resection of liver tumors are strongly dependent on the volume of the future remnant liver (FRL). In clinical practice, these possibilities are frequently limited if an extended right hepatectomy has to be carried out, since the left lobe is small, or when major liver surgery is indicated in patients with impaired liver function, whatever the cause (cirrhosis, cholestasis, non cirrhotic fibrous disease or severe fatty steatosis).

It is well-known in clinical practice that liver trophicity strongly depends on hepatic portal blood perfusion. The aim of portal vein embolization (PVE) is to selectively induce hypertrophy of the FRL during the preoperative period. This is achieved by embolization of the intrahepatic portal branches of the future resected liver, therefore leading to a distribution of the entire portal blood flow (containing hepatotrophic factors) exclusively towards the FRL. This technique is applied to selected patients with hepatocellular carcinoma, hilar cholangiocarcinoma or liver metastasis, in whose cases PVE extends the indications for curative surgery.

1. Indications

Liver function is obviously a predominant factor for determining whether a resection is safe or not. Liver function is considered to be normal if there is no jaundice and indocyanin green clearance at 15 minutes is <10%. Presence of jaundice or ICG clearance 10% to 20% indicates mild liver dysfunction. ICG clearance above 20% indicates a more severely compromised liver, also meaning that PVE should not be followed by a dramatic increase in FRL volume. We consider PVE when FRL/total functional liver ratio is expected to be less than 25% to 30% in patients with normal liver function and less than 40 % in patients with liver dysfunction.

It is widely accepted that tumors do not contain functional hepatocytes and tumor volume must be subtracted from that of the liver. When preoperative radiofrequency ablation (RFA) is planned for treating a tumor located in the FRL simultaneously to the hepatectomy, one should subtract the supposed volume of the future RFA lesion (tumor volume + safety margin) from the total FRL volume.

Usual contraindications or high risk conditions for a percutaneous transhepatic approach (massive ascites, severe blood coagulation disorders) are contraindications or limits to liver surgery as well. Patients who need PVE prior to cholangiocarcinoma resection frequently require an access through a future remnant liver with bile dilatation. It is then necessary to drain the corresponding sector prior to PVE.

2. Technique

The procedure may be performed under intravenous sedation and analgesia, but we prefer general anesthesia which provides more comfort for the patient as for the surgeon. When the goal of PVE is the occlusion of the right branches, the preferred access of the portal vein is usually the anterior subxyphoid left route which allows antegrade catheterization of all right branches to be occluded and free flow embolization, thereby providing greater safety for the maneuvers. The puncture is achieved under sonographic guidance with a 27 cm 5F-needle catheter (Cook) or with a 20 cm 18G-Echotip needle (Allegiance). When branches to segment IV do not require to be occluded, the entry point in portal veins can be the Reix recess.

If the PVE affects segment IV, we recommend entering the segment III branch upstream from the recess in order to facilitate the catheterization of the segment IV branches. Retrograde catheterization of the portal vein for performing a portography is the first step of the procedure in order to identify individual intrahepatic branches and anatomical variations. In patients with a known or suspected compromised liver portal pressure must be measured prior to embolization as it is a prognostic parameter. Cut-off for portal pressures is 16 cm and 25 cm of saline, measured before and immediately after PVE respectively (8). Consequently, high initial portal pressure and an important elevation after PVE both indicate limited resection. Initially elevated pressure should be considered a poor indication for PVE.

Catheterization of every branch to be embolized is then performed with the 5F catheter of the needle catheter device with the help of a J shaped 0.035 glide wire (Boston Scientific) or on demand with a 0.035 shapeable glide wire (Terumo). In case of a left approach and very tightened portal bifurcation, catheterization of the right portal vein may require extemporaneous shaping of the catheter tip. Depending on individual anatomy, a 1 to 2 cm length and 30° to 90° angulated tip is then shaped under steam to make further maneuvers easier.

Every main trunk to be occluded is selectively catheterized in order to perform a distal and free flow embolization. The degree of selectivity (sectorial, segmental or subsegmental) before each embolization depends on individual anatomy and local hemodynamics. It is chosen for each vein individually to ensure a stable selective positioning of the catheter, providing best conditions for free flow embolization and preventing inadvertent reflux of embolic material. We mostly perform embolization with a mixture of cyanoacrylate (Histoacryl® 0.5 mL vials, B. Braun) and Lipiodol (Lipiodol Ultrafluide®, 10 ml, Guerbet).

Safe use of this embolic agent necessitates following a very strict technique, but to our point of view presents multiple advantages; it permits to achieve complete and durable occlusion and its radio-opacity increases safety at the time of embolization. Histoacryl and Lipiodol are mixed in a ratio of 1 part of Histoacryl for 1 to 3 parts of Lipiodol; the more Lipiodol in the mixture, the longer the polymerization time of the glue. Consequently it allows distal embolization in every case, since the polymerization time can be adapted to individual and instant haemodynamic variations. Furthermore, the cyanoacrylate induces a very strong inflammatory reaction, involving vessels as well as bile ducts, which is thought to increase the production of hepatotrophic factors (Figure 2).

The mixture (Histoacryl/Lipiodol ratio close to 1/2) is prepared in an insulin syringe, immediately prior to the first embolization. If needed during the procedure, it is possible to increase the dilution by adding Lipiodol. The mixture is pushed through a 3-way stopcock resistant to Lipiodol (Cook) with isotonic glucose following the "sandwich technique": the volume of every injection of mixture being lower than the catheter content. This is repeated as many times as necessary in order to obtain a distal and complete occlusion (Figure 1). The total dose of Histoacryl will be 1 to 3 ccs, administered in 4 to 6 successive injections of mixture.

A risk of this technique is catheter occlusion during the repetitive injections, which can be minimized by pushing the 0.035 glide wire through the catheter still in position immediately after each injection. By means of this technique the inner wall of the catheter is cleaned from residual glue/Lipiodol mixture, which is gently pushed out into the embolized vein under fluoroscopic control. The 3-way stopcock also needs to be cleared from residual glue after each injection. Either way both, the 3-way stopcock and the catheter, must be exchanged in time before occlusion, at least every 3 to 5 injections.

Caution should be exercised to avoid reflux into left lobe veins when occluding segment IV pedicles. Due to this potential risk, segment IV portal veins are occluded first to increase safety, sometimes even with particulate embolic agent (Embogold® 700-900?m, Biosphere Medical) instead of cyanoacrylate. A control portography is performed at the end of the procedure and postembolization portal pressure is registered. In our experience, the transhepatic tract does not need to be embolized.

Post-procedure and Follow-up care

Clinical tolerance is generally excellent with only mild abdominal pain or discomfort and slight fever which disappears in less than 3 days. A flush syndrome may occur in the post embolization period in patients with carcinoid primary and should be prevented systematically. During the post PVE period, prothrombin time remains above 70% of the baseline value. Serum aspartate transaminase and alanine transaminase slightly increase and may reach a maximum value of 3 times the normal value on the first day post PVE, except when using ethanol which induces a greater cytolysis. Alterations in the total bilirubine level are insignificant. Normally, the total duration of hospitalization for the procedure does not exceed 3 days.

3. Controversies

Approaches

Prior to complex hepatectomies PVE may concern left and right portal branches. A right transhepatic access can then be chosen, preferably entering a vein not to be occluded. Some authors advocate a right transhepatic approach in all cases, using double- or triple-lumen balloon catheters for embolization. The transjugular approach has been successfully used in cases in which the conventional transhepatic technique could not be applied due to tumor interposition or severely impaired hemostasis.

Distal or proximal Occlusion?

Distal embolization is achieved with particulate agents, cyanoacrylate or other liquid agents. Proximal ligation is surgically performed or may be done percutaneously with steel coils or detachable balloons. Considering that the intrahepatic portal vasculature was classically considered as terminal type, interest of performing a distal embolization rather than a proximal surgical ligation has been contested. Therefore, nowadays there are strong arguments for preferring a distal occlusion and the efficacy of PVE vs. right portal vein ligation before extended right hepatectomy has been demonstrated (3).

Choice of the embolic agent

There is no definitive argument in the literature in favor of one specific type of embolus, excepted that the embolic agent must provide a distal occlusion. Among particulate and liquid embolus, the actual tendency is to favor agents inducing complete, distal and durable occlusion as well as a strong inflammatory reaction. Most of teams actually seem to prefer Histoacryl/Lipiodol mixture. Absolute ethanol has also been experimentally assessed and clinically used by some but its clinical and hepatic biological tolerance appeared to be much poorer than that of cyanoacrylate and one should be very careful in using this embolic agent, especially in patients with compromised liver

4. Results

Complications

In the literature from experienced teams, complication rates rarely exceed 1.5%, without any reported mortality. The main complications reported include pneumothorax, subcapsular haematoma and arterial pseudoaneurysm after inadvertent arterial puncture and portal vein thrombosis. The risk is higher in patients with portal hypertension and/or blood coagulation disorders. In patients who have undergone a duodenopancreatectomy and suffer from a chronically infected biliary tree, the PVE can be done without risk of hepatic abcess, unlike after intra-arterial chemoembolization or radiofrequency ablation.

Induced hypertrophy

Nowadays it has been clearly demonstrated by the mean of many different techniques that volume increase parallels function increase. After PVE we have reported a mean increase of 70% in the volume of the FRL and a ratio of FRL/Total liver that measured 32% four weeks after PVE (4), after having increased by 12.4%. Main series report similar increases in the volume of FRL/Total liver ratio. Almost all patients with a normal liver experience hypertrophy after PVE. Only 86% of patients with chronic liver disease develop hypertrophy (6). Furthermore, hypertrophy is milder and slower (35% to 40% increase in volume of the FRL after 1 month) than in a normal liver.

Delay to surgery

Delay between PVE and surgery should be as short as possible in order to preclude any tumor growth. In our experience all patients reached the critical FRL/total functional liver volume ratio of 25% after 4-5 weeks. As several other teams we consequently consider a 4 to 5 weeks delay before surgery to be a good compromise between hepatic hypertrophy and tumor dissemination. Other teams consider the hypertrophy gain negligible after 2 to 3 weeks and prefer to perform the resection earlier.

Does PVE accelerate growth rate of liver metastases?

It is well-known that partial hepatectomy accelerates local tumor growth. Some of the cytokines and growth factors involved in liver regeneration or hypertrophy may also be involved in tumor burden. Together with other authors we have demonstrated that PVE may increase proliferative activity of colorectal metastases. In order to overpass this potential adverse effect, some have proposed a two-stage hepatectomy, PVE being performed after a primary resection of metastases that are present in the FRL. Radiofrequency ablation of lesions located in the FRL prior or simultaneously to PVE is also an alternative option. Further studies are still needed, but it seems logical that PVE accelerates tumor growth in some patients and some tumors. However, clinical experience demonstrates that this rare and probably limited adverse effect remains negligible when compared to advantages of PVE in widely extending indications for curative surgery.

Long term results and survival

We have reported 5-year survival and 5-year disease-free survival of 34% and 24% in respectively 60 patients who underwent PVE for liver metastases. A comparison with long term results from the literature showed that in specific groups of patients with liver metastases from colorectal primary (1,5) or with hepatocellular carcinoma (2,7) there is an equivalence in 5-year survival and 5-year disease-free survival between subgroups of patients who were preoperatively treated by means of PVE and those who were not.

>>

>> Summary : Key points for preoperative portal vein embolization

Indications
Indications of PVE are based on future remnant liver (FRL) volume / Total functional liver volume ratio and depend on liver status: Normal liver: ratio < 25-40% ; Compromised liver: ratio < 40-50%

Total functional liver volume = Total liver volume - Tumor volume in the future resected liver

When complementary RF ablation of a lesion located in FRL is foreseen during surgery, don't forget to subtract the supposed volume of the future necrotic RF lesion

PVE is not indicated in patients with portal hypertension above 20 cm of saline

Technique
It is preferable to access the portal system through a segment you do not have to embolize

When segment IV embolization is required, access the portal system through a segment III vein, upstream to the Reix recess, for allowing easy catheterization of segment IV pedicles

Prefer distal embolization to proximal occlusion and use an embolic agent inducing a strong inflammatory reaction (mainly Histoacryl ® glue mixed with Lipiodol ®)

Embolize step by step with Histoacryl/Lipiodol mixture, following the sandwich technique

Results
Four weeks after PVE mean increase of FRL volume is 70% and FRL/Total liver ratio generally increases by 12% in patients with a non compromised liver

Long term survival of patients who can be resected after PVE is comparable to survival of those who do not need PVE prior to surgery

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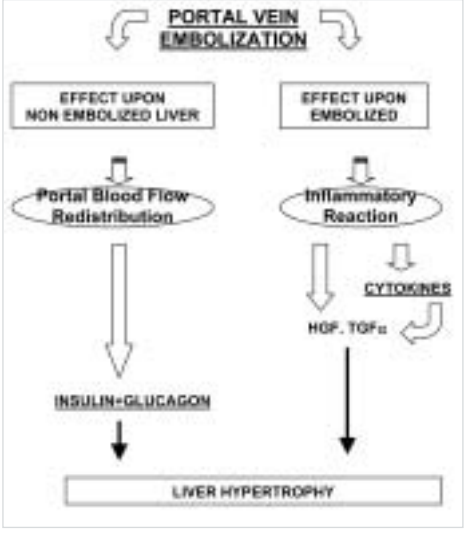
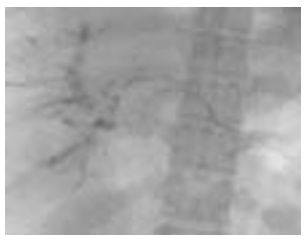


Figure 2: Main mechanisms inducing hypertrophy after portal vein embolization

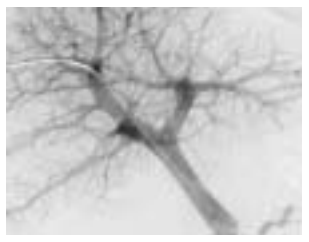
Puncture	5F-needle catheter, 27 cm (Cook)- on demand Echotip needle, 18 G, 20 cm (Allegiance)
Catheter	5F catheter from the needle catheter- on demand: shaping of the tip
Guide wire	Kayak 0.035 J glide wire (Boston Scientific) on demand: 0.035 shapable glide wire (Terumo)
Embolic agent	Cyanoacrylate : Histoacryl® 0.5 mL vials (B. Braun) Lipiodol Ultrafluide®, 10 ml (Guerbet) (Embogold® m) (Biosphere Medical))?(700-900)
Embolization technique	3-way stopcock resistant to Lipiodol (Cook) isotonic glucose solution- two 1ml syringes (Terumo) 20 ml syringe

Table 1: Key equipment

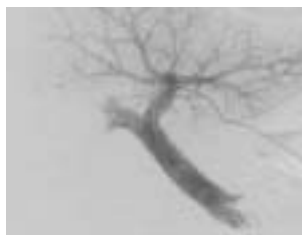
Figure 1: Preoperative portal vein embolization prior to right hepatectomy for metastases



1a: Portography under unusual right approach prior to embolization



1b: Glue cast of Histoacryl occluding the right portal veins after embolization



1c: Control portography showing complete redistribution of portal vein flow towards the left liver

Abbott + Guidant: What does it mean for interventional radiology?

Advertorial

StarClose®: Extravascular clip closure device

Annette Brüls, Vice President EMEA Marketing, Abbott Vascular, sees the new Abbott Vascular advancing the future of vascular care through its commitment to innovation, dedication to service and singular focus on vascular care

The recent acquisition by Abbott Vascular of Guidant's Endovascular Solutions (ES) and Vascular Intervention (VI) businesses has created a new global leader in vascular care. The combined business offers a broad line of leading endovascular and coronary products including innovative technologies and devices such as the broadest range of carotid devices and the StarClose® vascular closure system.

We sat down with Annette Brüls, Vice President EMEA Marketing at Abbott Vascular to discuss how the integration will benefit the radiology community. Ms. Brüls previously led Guidant's endovascular business as Marketing Director in Europe.

Q: What does the combination of Abbott and Guidant bring?

Annette Brüls: For the past several years, Abbott has built a competitive vascular business through acquisitions, licensing agreements, and internal scientific and commercial development. With the addition of Guidant's vascular business, Abbott offers physicians, catheterization labs and clinics a complete line of products and technologies for interventional procedures including: a comprehensive line of endovascular and coronary stents; a full offering of guide wires, catheters and balloons; and innovative vessel closure devices. On the endovascular side, the combination of the two companies has strengthened our offering significantly. We are a worldwide leader in carotid stenting systems and balloon expandable stents, and our partnership efforts are leading the way into new therapies with unique self-expandable stent systems under investigation for lower limb treatment.

Q: What's different about Abbott Vascular?

AB: I think that our singular focus on vascular care is a strong differentiator compared to many competitors. Secondly, we have the largest global vascular sales force devoted to customer solutions. Our goal is to provide our customers with breakthrough products and the very best service.

And, Abbott Vascular enjoys a position as a division of Abbott - a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics.

Q: Will Abbott Vascular invest in research and development?

AB: Absolutely. The legacies of Abbott and Guidant were fuelled by a strong commitment to research and development and to groundbreaking clinical trials; the success of this new partnership will be driven by innovation. Our investment has a purpose: finding new solutions to unmet clinical needs, for example superficial femoral artery (SFA) disease. Pioneering work with emerging technologies in development such as bioabsorbable stent platforms, vulnerable plaque solutions and cell therapy will continue at an even faster rate. Future advances will leverage the best in medical device technology and pharmaceutical research.

Q: You mention SFA disease. Do you have a peripheral drug-eluting stent (DES) program to address it?

AB: Yes, we have a program in development. Actually, we are very excited about our entire drug-eluting stent portfolio. With Guidant, Abbott now has two drug-eluting stents in development in the coronary area. More specifically to target SFA disease, we are actively developing a program based on everolimus, one of the drugs used in our coronary DES program.

The combined organization also is leading the industry with a number of next-generation research programs in development including an investigational stent that elutes two drugs targeted for difficult-to-treat patients such as diabetics, and an investigational bioabsorable drug-eluting coronary stent designed to be fully absorbed by the vascular tissue following the restoration of blood flow. We anticipate that these developments will also help advance our work in our peripheral DES program.

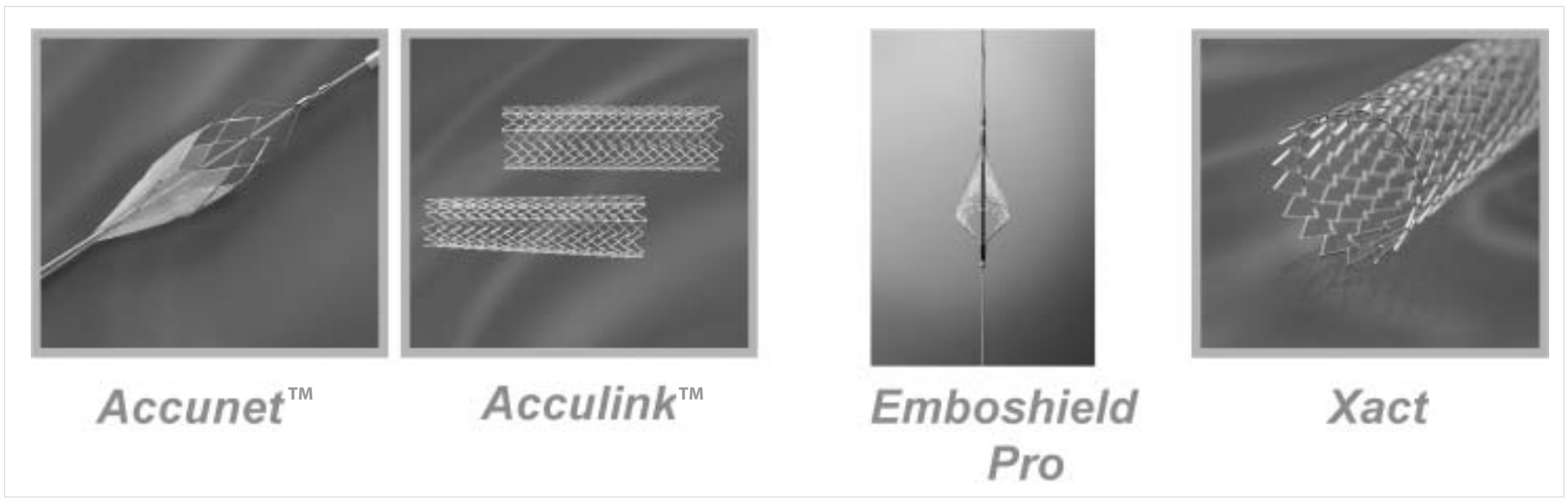
Q: Are you backing up your products with an evidence-based approach?

AB: Yes, we strongly believe in the evidence-based process. For example, in the carotid arena, we have conducted significant clinical trials such as ARCHER, CAPTURE and PROTECT. Our ABSOLUTE self-expanding stent is also under evaluation in the ASSESS trial as an investigational treatment for superficial femoral artery disease.

Q: What about medical education and training? Will Abbott continue the Institute in Brussels?

AB: The training institute remains a top priority. We're investing more into this well-known facility, and not only in Brussels. We've also opened a satellite facility in Johannesburg, South Africa, in partnership with Baroque Medical. We intend to bring training to many countries and congresses. In fact, here at CIRSE this year, our Institute is hosting six workshops on renal and carotid artery stenting.

In summary, our team is committed to becoming the world's leading vascular care company. I know that many might say that, but we are doing it and that is what I am very excited about. With Abbott Vascular's commitment to innovation, dedication to service and focus on vascular we are confident that we can work together to truly advance the future of vascular care.



Abbott Vascular: the worldwide leader in carotid stenting offering two carotid stents and two embolic protection devices

SFA stenting-problem resolved?

Jos C. van den Berg
Head of Service of Interventional Radiology
Ospedale Regionale di Lugano, sede Civico
Lugano, Switzerland

The vascular territory that traditionally has been most difficult to deal with by endovascular means is the superficial femoral artery (SFA). Results of endovascular treatment of atherosclerotic stenotic and occlusive disease of the SFA using balloon angioplasty have been disappointing, with poor outcome in the mid- and long-term. Additional stenting of the lesions in the SFA did not increase patency rates, and several randomized trials using old stent technology (either balloon-expandable or self-expandable delivery systems) have proven that stenting, although yielding higher initial luminal gain and better angiographic success, does not have a positive effect in the long-term.
Recent developments in nitinol stent engineering have however dramatically changed the results of SFA-stenting. The first indication that the use of nitinol stents in the
SFA could improve outcome came from a randomized trial that compared drug-coated nitinol and bare-metal nitinol stents. The results of bare-metal stenting were unexpectedly positive, and no significant additional effect of adding drug-coating could be demonstrated. The same study also revealed a possible downside of placement of nitinol stents in the SFA, namely stent fracture, which has been associated with restenosis. The occurrence of stent fractures that are caused by the hostile environment of the SFA which exerts continuous forces of contraction/extension, torsion, compression and flexion, can be reduced by optimization of stent design and manufacturing while paying special attention to surface etching. With this in mind, recent publications demonstrate that the incidence of stent fractures can be below 2%.
Below you can find an update on the data of the RESILIENT trial that further supports the evidence of improved results of SFA stenting. This is followed by a brief review of another application of this new stent technology, namely in patients with critical limb ischemia. The current developments will pave the way to a more endovascular approach of SFA disease (as most probably will be reflected in the new TASC-guidelines).

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Duda SH, Bosiers M, Lammer J, et al. Sirolimus-eluting versus bare nitinol stent for obstructive superficial femoral artery disease: the SIROCCO II trial. J Vasc Interv Radiol 2005;16:331-338.
Scheinert D, Scheinert S, Sax J, et al.Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol 2005;45:312-315.
Schillinger M, Sabeti S, Loewe C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med 2006;354:1879-1888.

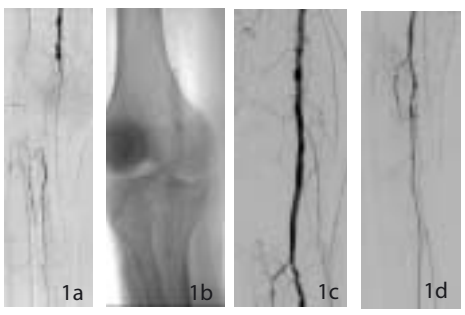
The endovascular approach in critical limb ischemia

Jos C. van den Berg, Head of Service of Interventional Radiolog, Ospedale Regionale di Lugano, sede Civico, Lugano, Switzerland

Critical limb ischemia is a condition characterized by the presence of rest pain and/or the presence of ulceration/gangrene of the lower limb. Most of the patients have multiple co-morbidities and a limited life-expectancy. In patients with critical limb ischemia the vascular territory involved can be either aorto-iliac, femoral, popliteal or crural, or a combination of the above. Aim of treatment is to reverse the vicious circle of inflammation, infection and/or tissue loss that leads to an increased oxygen demand, which can not be provided by the diseased vascular bed and therefore will lead to deterioration of disease. This can be accomplished by treating the complete vascular tree where needed. The majority of patients presents with atherosclerotic occlusive disease of the SFA/popliteal artery and/or crural arteries. The BASIL-trial, the only randomized trial in patients with critical limb ischemia published thus far, comparing endovascular therapy (using balloon angioplasty alone) with surgical bypass demonstrated equal outcome in both treatment arms at 2 years. The advantage of endovascular therapy lies mainly in shorter in-hospital stay and less mortality and morbidity in the early follow-up. The same problem of high restenosis rates that is seen with endovascular treatment of patients with intermittent claudication caused by occlusive disease of the SFA can occur in patients with critical limb ischemia. Therefore dedicated stents that can cope with the forces being exerted in the SFA and popliteal artery are needed in this category of patients as well. Results as obtained with new stent technology, using nitinol stents with mechanical properties specifically designed for the SFA territory indicate that higher patency rates as compared to balloon angioplasty alone and "old" stent technology can be achieved, and these results are likely to be applicable to the group of patients with CLI as well.

Case study
An 84-year old man presented to our institution with rest pain of the right lower limb, and severe trophical disturbances of the right foot. Duplex ultrasound revealed an occlusion of the popliteal artery and significant stenotic disease of the distal superficial femoral artery. The patient was scheduled for an endovascular procedure, and diagnostic angiography from an ipsilateral femoral approach confirmed the Duplex findings, and demonstrated single vessel run-off through a fibular artery (fig 1a).
After successful recanalization of the occlusion a balloon angioplasty was performed using a 4x80 mm balloon. Control angiography (not shown) demonstrated suboptimal result, and subsequently 2 self-expandable nitinol stents (Lifestent NT, 8x80 mm and 4x80 mm) were placed from the distal SFA up to the popliteal bifurcation (fig 1b).

Post-dilation was performed using a 5x40 mm angioplasty balloon proximally and 4x40 mm distally. Control angiography demonstrated no residual stenosis, without signs of distal embolization (fig 1c-1d).
The clinical course was uneventful, with disappearance of rest pain, and increased ABI.



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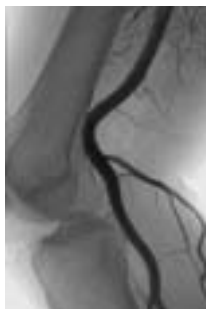
2.Kudo T, Chandra FA, Ahn SS. The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: a 10-year experience. J Vasc Surg 2005;41:423-435.
3.Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicentre, randomized controlled trial. Lancet 2005;366:1925-1934.

The Edwards LifeStent and the RESILIENT Trial: a new treatment option for the challenging SFA anatomy. Preliminary clinical results.

Prof. Maria Schoder, Dept. of Angiography and Interventional Radiology, Medical University of Vienna, Vienna, Austria, on behalf of RESILIENT investigators.



High mechanical constraints in the SFA

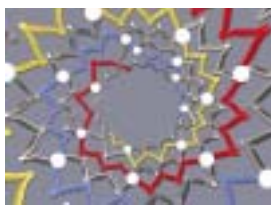
It is now well accepted to selectively use stents to improve patency rates after balloon angioplasty with flow-limiting dissections, residual stenosis or elastic recoil. Although nitinol is now considered as a credible alternative to stainless steel for SFA stenting, the fracture issue has been increasingly recognized.
In the SIROCCO I study, systematic x-ray follow-up after long segment SFA stenting revealed a prevalence of 18.2% stent fractures with no related clinical impact (1). However, Scheinert and colleagues (2) demonstrated that depending on stent design, fractured stents could lead to a significant increase of restenosis and reocclusion rates, compared to non-fractured ones. In both study groups stent fractures were more frequent in long-stented SFA segments and when several overlapping stents were used.

The SFA is exposed to repetitive mechanical forces such as extension/contraction, torsion, compression and flexion that can generate important material fatigue. Not only the material and the surface finish seem to have an impact on stent fracture but also the design itself.

Edwards LifeStent shows less structural tensions vs. zigzag design

Traditional stent designs are based on laser cut, welded or interconnected zigzag rings. The Edwards LifeStent NT is a self-expanding Nitinol stent with a unique triple helical structure which behaves in a similar way to zigzag stents during radial deformation, like compression, but has a better ability to absorb axial deformations such as torsion, flexion, extension and contraction, while being adaptable to almost any type of shape, this with an excellent apposition to the arterial wall.

There are very few randomized studies comparing SFA stenting vs. PTA alone and data on long-term durability of stents in the SFA and in the proximal segment of the popliteal artery are lacking.
To evaluate the safety and efficacy of the LifeStent NT, the RESILIENT trial (Principal investigators Dr. John R. Laird, Cardiovascular Research Institute, Washington Hospital Center and Dr. Barry T. Katzen, Baptist Cardiac and Vascular Institute, Miami, Florida) a prospective, randomized, multicenter trial was initiated in 2004 (3). Inclusion criteria include a lifestyle-limiting claudication defined as Rutherford category 1 to 3. Target lesion(s) characteristics are de novo or restenotic (non-stented) stenosis or occlusions, with a less than 15cm single or tandem lesion length, located within the native SFA and/or proximal popliteal artery, 3cm above the knee joint and 1cm below the origin of the profunda femoris artery. At least one patent run-off vessel to the foot is required.



Helical distribution of mechanical stress all over the Edwards Lifestent structure

To evaluate the feasibility and the safety of a treatment using Lifestent in SFA and proximal popliteal artery lesions, 20 patients were enrolled in the initial non-randomized phase of the study. Baseline clinical and lesion characteristics of Phase I patients are shown in table 1. The 12-month follow-up data has shown promising results with a remarkable improvement of the target limb ankle-brachial index (ABI) and of the Rutherford category patient classification. The clinical patency rate was 90% and none of the stents presented a fracture (Table 2). Furthermore, the Quality of Life measures, WIQ and SF-8 Scores improved significantly. Over 200 patients were randomized in the phase II (Pivotal) of the study in a 2:1 stent/PTA ratio, and data are expected to be presented next year.

Characteristics	**Phase I**
Male, % (n)	75 (15)
Mean Age, Mean ± S.D.	70.5 ± 9.9
Hypercholesterolemia, % (n)	90 (18)
Hypertension, % (n)	85 (17)
Smoker, % (n)	80 (16)
Diabetes, % (n)	50 (10)
Rutherford Category	
Category 2, % (n)	70 (14)
Category 3, % (n)	30 (6)
Target limb ABI, Mean ± S.D. (n)	0.76 ± 0.26 (19)
Mean lesion length (mm), Mean ± S.D. (n)	83.7 ± 28.6 (20)
Calcified lesion, % (n)	66.7 (14)
Total occlusion, % (n)	23.8 (5)
Mean number of stents	1.8

Table 1: Baseline clinical and lesion characteristics

Effectiveness Measures	**Baseline**	**6 Months**	**12 Months**
Target limb ABI (mmHg), Mean ± S.D., (n)	0.76 ± 0.26 (19)	0.93 ± 0.11 (18)	0.86 ± 0.13 (17)
Rutherford Category			
Category 0, % (n)	0.0% (20)	73.3% (15)	66.7% (18)
Category 1, % (n)	0.0% (20)	20.0% (15)	11.1% (18)
Category 2, % (n)	70.0% (20)	6.7% (15)	22.2% (18)
Category 3, % (n)	30.0% (20)	0.0% (15)	0.0% (18)
Clinical success, % (n)	N/A	100% (15)	94.4% (18)
TLR/TVR rate, % (n)	N/A	0.0% (20)	10.0% (20)
Stent fracture rate, % (n)	N/A	0.0% (17)	0.0% (17)

Table 2: Baseline, 6- and 12-month follow-up data

References:
1.Schillinger M et al, CIRSE 2005
2.Scheinert D, Scheinert S, Sax J, et al. J Am Coll Cardiol 2005;45:312-315
3.Laird JR. The RESILIENT Trial update: Endovascular Today 2005;October:29

Legends of Rome

People say that it would take more than a lifetime to really get to know Rome, its secrets, legends and hidden stories. But since you are here for only a few days, we have put together the most unusual and untold legends of the Eternal City!

Nero's Pregnancy

Who hasn't heard of Nero's folly? The emperor was feared by his subjects for his eccentricities and his fits of violence. At one point, he wished to experience pregnancy, so he summoned two court doctors and ordered them to solve the matter. The poor unfortunates prepared a mildly soporific concoction and made the emperor swallow it along with a tiny frog. The little creature stayed alive for a few moments and moved around in Nero's belly, giving him a feeling that seemed to suggest a state of advanced pregnancy. The doctors were nonetheless aware that the trick would not last, so they did not wait to receive the emperor's thanks and ran as fast as their legs could carry them.

Orlando's Sword

Perhaps not everybody knows that during his innumerable travels, the legendary knight Orlando came to Rome. Nobody knows what brought him to the city, but whoever doubts that he was actually here can go to one of the alleys in the historical centre, just behind Piazza Capranica. The mark left by his sword on the wall during a brawl with Roman knights is distinctly visible on the only rock projecting from one of the buildings. It is not a coincidence that the alley itself is called "Via della spada di Orlando"- "The Street of Orlando's Sword".

Pasquino

Behind Piazza Navona in the Parione district, on the little square by the same name, stands the statue of Pasquino, worn by time and controversy. He was the voice of satirical sneering, cruel and ruthless, always willing to expose the clergy and powers that be. The ancient Greek torso was found where the Palazzo Braschi stands today and placed where we can see it today by cardinal Carafa in 1501. The name Pasquino was attributed to it at the same time, when it started being used by the people to vent their resentment towards abuses of power, attaching satirical and provocative notes on its base.

In this custom originated the "pasquinades", a popular tradition fed by numerous writers who invented infinite variations on this theme. It also gave life to a series of legends. Among them, the version that imposed itself; it identified Pasquino as a tailor from the Parione district, whose tongue was as sharp as the scissors of his trade. As he worked on papal vestments, he came to know the foulness of the goings-on at the papal court and was unable to keep them to himself. Over the centuries, caustic spirits great and small have given Pasquino their voices, including the poet Trilussa.

Pope Joan

Legend has it that around the year 1000 the papal throne was occupied by a woman. Joan left England to study at Mainz and her love of learning made her decide to dress up as a man and become a Benedictine monk. She graduated in theology and became famous all over Europe for her knowledge which enabled her to enter the papal court and to be elected cardinal. Her brilliance also led to her election as pope. Some time later she became pregnant by her servant and gave birth during a procession in the area of St John Lateran. Upon discovering the truth, the outraged people lynched her and the baby. This episode led to the introduction of the gestatorial chair which is used by the cardinals before each election to directly check the sex of the pope.

The Angel of Castel Sant' Angelo

At the top of the Castel Sant' Angelo, the archangel Michael stands mighty and proud, sheathing his sword. The bronze statue was created in the mid 1700s and erected in memory of Pope Gregory the Great's vision in the 6th century AD. Tradition has it that a terrible epidemic raged in Rome and that the pope was desperate. He ordered a great expiation procession from St. John Lateran to St Peter's to invoke the end of the plague. At the end of the procession the pope had a vision: a radiant angel appeared at the top of the tomb of the Emperor Hadrian, bearing a sword that he placed back in its sheath. The message was clear: the sword at rest meant that the plague was over. The Lord had listened to their prayers. In memory of this event and perhaps as an offering on the part of Gregory the Great himself, the magnificent angel of Castel Sant'Angelo was erected on the monument.

The Mouth of Truth

Has someone ever dared you to prove that you were being perfectly sincere? If it should ever happen to you in Rome, you can go to the portico of the church of Santa Maria in Cosmedin on Piazza della Bocca della Verità and insert your hand in the "mouth of truth", repeating what you have been accused of lying about. If you are guilty, your hand will be neatly chopped off; if what you said is true, you will have irrefutable evidence of your good faith.

According to tradition, la Bocca della Verità was used in the Middle Ages to discourage liars, who were punished by a sword wielded behind the wall. Legend has it that on one particular occasion the trial of the mouth of truth was imposed on a woman of aristocratic rank, accused by her husband of adultery. The crowd parted to allow the outraged woman to reach the great stone mask, when suddenly a handsome young man rushed forward and kissed her passionately. Faced with the crowd's anger, he justified his action by claiming that he could not resist offering one last Christian tribute to the poor woman, who was certainly innocent. The woman herself placed her hand in the slit of the stone face and declared: "I swear no man but my husband and the youth who just kissed me, has ever touched me!" As she was able to retrieve her hand, people believed her and she was acquitted. Nobody had realized the cunning and artfulness of the Roman woman who was kissed by her lover in public.

The Cunning of Sixtus V

Tradition tells that Cardinal Felice Peretti, who came from a family of poor farmers compensated his humble origins with the wealth of his shrewdness and his intelligence. At the death of his predecessor, he saw that for political reasons the college of cardinals intended to elect a pope whose rule would not last long. He consequently appeared at the conclave on crutches and looking feverish. When he was elected, he could not contain his joy and threw his crutches up in the air with such strength that he scratched the ceiling of the Sistine Chapel with them, the marks of his enthusiasm staying for quite some time.

The Tarpeian Rock

At the time of Romulus, Tarpeia, the young and beautiful daughter of Spurius Tarpeius, the custodian of the Capitoline hill, betrayed Rome. She promised to show the Sabines and their leader Tatius the way up to the citadel in exchange for what they wore on their left arms: precious torques and gold rings. When they reached the top of the Capitoline, the Sabines interpreted the agreement quite differently, crushing her with the shields they carried on their left arms and throwing her from the precipice on the south-west corner of the hill, which was later named after her. During centuries it was used to fling convicted murderers and traitors to their deaths.

The Pope's Cherries

Legend has it that on the 25th of April, the day of St. Mark, a pope had a strong craving for cherries. Unfortunately they were not yet in season, but fervent prayers convinced St. Mark to make the cherries ripen before their time on one of the trees in the Vatican. This legend is at the origin of the Roman saying "Ar papa la voja, a Sammarco la noja", meaning "the pope's wishes are Saint Mark's bother". Was it a miracle or the product of pure imagination? Whatever the truth may be, popular wisdom reminds us that saints themselves must bow to the whims of men of power.

The Holes in the Colosseum

Have you ever noticed that the exterior of the Colosseum is covered with holes? The truth about their origin is that the blocks of travertine used for the exterior of the building were held together by iron clamps that were taken out in later times and reused for other purposes. Nonetheless innumerable explanations have been elaborated over the centuries. Among them the Visigoths' and Vandals' attempt to tear down the structure in the 5th century AD and the bombing of the archeological area during World War II. Yet the Colosseum is still there and confirms the popular saying coined by the Venerable Bede that "as long as the Colosseum stands so will Rome".

The Palace of the Monkey

If you happen to stroll down via dei Portoghesi, near Piazza Navona, beware of the mischievous monkey of the ancient Scappucci Palace! Legend says that the owner of the palace kept a tame monkey as a pet. When his son was born, the monkey probably grew jealous and snatched the crying baby from its crib, carried it to the top of the tower and hid in the most inaccessible spot. The nurse and the servants tried desperately to recover the baby, but every attempt failed and the poor people resorted to praying to the Virgin Mary for help. At that moment, the baby's father arrived on the scene and whistled to the monkey in the usual way. It meekly came down from the tower with the baby safe and sound. Since that day the palace has been known as the "Palace of the Monkey" and a lamp always shines on the image of the Virgin on the tower.

The Splendour of the Chigi Family

While strolling along the Lungotevere avenues you may notice a strange glimmer on the surface of the river. There is in fact a rather humorous story regarding the dining habits of Agostino Chigi, the famous Renaissance banker. In order to keep up his reputation as the richest man in the world, he used to offer lavish dinner parties to high ranking guests in a loggia overlooking the Tiber. At the end of the meal, he ordered his servants to throw the silver cutlery and dishes used by the guests into the river. Obviously nobody knew about the deal the banker had made with the monks from a neighboring convent who, in exchange for alms, spread nets beneath the surface of the water and each night returned the silverware to the shrewd banker.

Good Clinical Research Awareness Programme

All sessions of the
Good Clinical Research Awareness Programme
will take place in
Room I.

Good clinical trials are essential for the future of Interventional Radiology and although we see more and more good research, many of the current studies and publications are not performed according to internationally accepted standards for Good Clinical Practice.

In order to get one's work published in high ranking journals, the implementation of good clinical practice is indispensable. It is essential to be aware of all the regulations and pitfalls in clinical research before starting a trial.
European and a growing number of local healthcare authorities are introducing Good Clinical Practice in their regulations concerning clinical trials as well.

Therefore it is essential to know about all of this before starting to research.
CIRSE gives you the opportunity to learn more about this topic with a Good Clinical Practice Awareness Programme. Registration for the programme is free of charge for all CIRSE 2006 attendees. A certificate of attendance will be provided after the programme.

I would urge all of those interested in clinical research in Interventional Radiology to attend this unique course.

J. A. Reekers
CIRSE Vice-President

Saturday , September 9
09:45 - 10:15
Background of Good Clinical Practice
At the end of this session the participant will
- understand the impact of history on our current laws and guidelines
- development and current status of the laws and guidelines
- have a basic understanding of the applicable guidelines

Saturday , September 9
11:30 - 12:00
EU guidelines and responsibilty
At the end of this session the participant will
- understand how compliance with GCP ensures that clinical trials are scientifically sound and allowing accurate reporting, interpretation and verification-
- understand the importance of confidentiality
- have a basic understanding of the possibility and consequences of FDA and EMEA inspections

Sunday , September 10
09:45 - 10:15
Investigator & sponsor responsibilities according to Good Clinical Practice
At the end of this session the participant will
- have a basic understanding of the investigator & sponsor responsibilities in clinical research projects related to:
  - documentation
  - products / devices
  - protection of the safety and well being of the involved patients

Monday , September 11
09:45 - 10:15
Good Clinical Practice - Common findings
Documentation and reporting
Informed Consent Process
At the end of this session the participant will
- recognize the importance of obtaining informed consent
- understand the importance of documentation and reporting responsibilities
- have a basic understanding of how inspectors / auditors will look and document possible findings

Tuesday, September 12
09:45 - 10:15
Common findings 2: Protocol deviations/Device accountability
At the end of this session the participant will
- understand the need for a protocol and what happens when deviations occur
- understands the need for device accountability and the consequences if this is not performed correctly

Wednesday, September 13
09:45 - 10:15
Common findings 3: Major adverse events vs. serious adverse events
At the end of this session the participant will
- understand the difference between Adverse Events, Serious Adverse Events and Major Adverse Events
- understand the need for reporting this according to the laws, guidelines and protocol

This programme has been made possible by an educational grant from CORDIS, J&J

Technical Exhibition

Official Name	Country	Booth #
AB Medica	Italy	1
ArthroCare Spine	Sweden	40
Abbott Vascular	Germany	36
ALN Implants Chirurgicaux	France	23
AngioDynamics	United States	37
Atrium Medical	Netherlands	50
Barco	Belgium	42
Bard Peripheral Vascular	United Kingdom	9
Baylis Medical	Canada	56
Biba Medical	United Kingdom	49
Biosphere Medical	France	16
Biotronik GmbH & Co. KG	Germany	34
Boston Scientific International S.A.	France	6
Bracco	Switzerland	2
Cardinal Health, Inc.	United States	28
Celon AG medical instruments	Germany	24
CeloNova BioSciences Inc.	United States	61
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CIVCO Medical Solutions	United States	69
COOK	Denmark	12
Cordis, Johnson & Johnson	Belgium	38
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Diomed Ltd.	United Kingdom	67
Edizioni Minerva Medica	Italy	47
Edwards Lifesciences SA	Italy	18
Ekos Corporation	United States	65
Elastrat Sarl	Switzerland	62
Endovascular Today	United States	48
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eucatech AG	Germany	54
ev3 Europe	France	35
GE Healthcare	United Kingdom	8
H.S. Hospital Service Spa	Italy	29
IDev Technologies Inc.	United States	72
Innomedic GmbH	Germany	14
InterV / PBN Medicals Denmark A/S	Denmark	11
Invatec Srl	Italy	60
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Lombard Medical Technologies Limited	United Kingdom	25
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Medax	Italy	58
MedComp	United States	30
Medrad Europe BV	Netherlands	70
Medtronic International Trading Sàrl	Switzerland	26
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Tyco Healthcare GmbH	Germany	3
Vascular Solutions, Inc.	United States	22
Vital Images, Inc.	United States	71
W.L. Gore & Associates GmbH	Germany	17
Wisepress Online Bookshop Ltd.	United Kingdom	36 a
Ziehm Imaging GmbH	Germany	31

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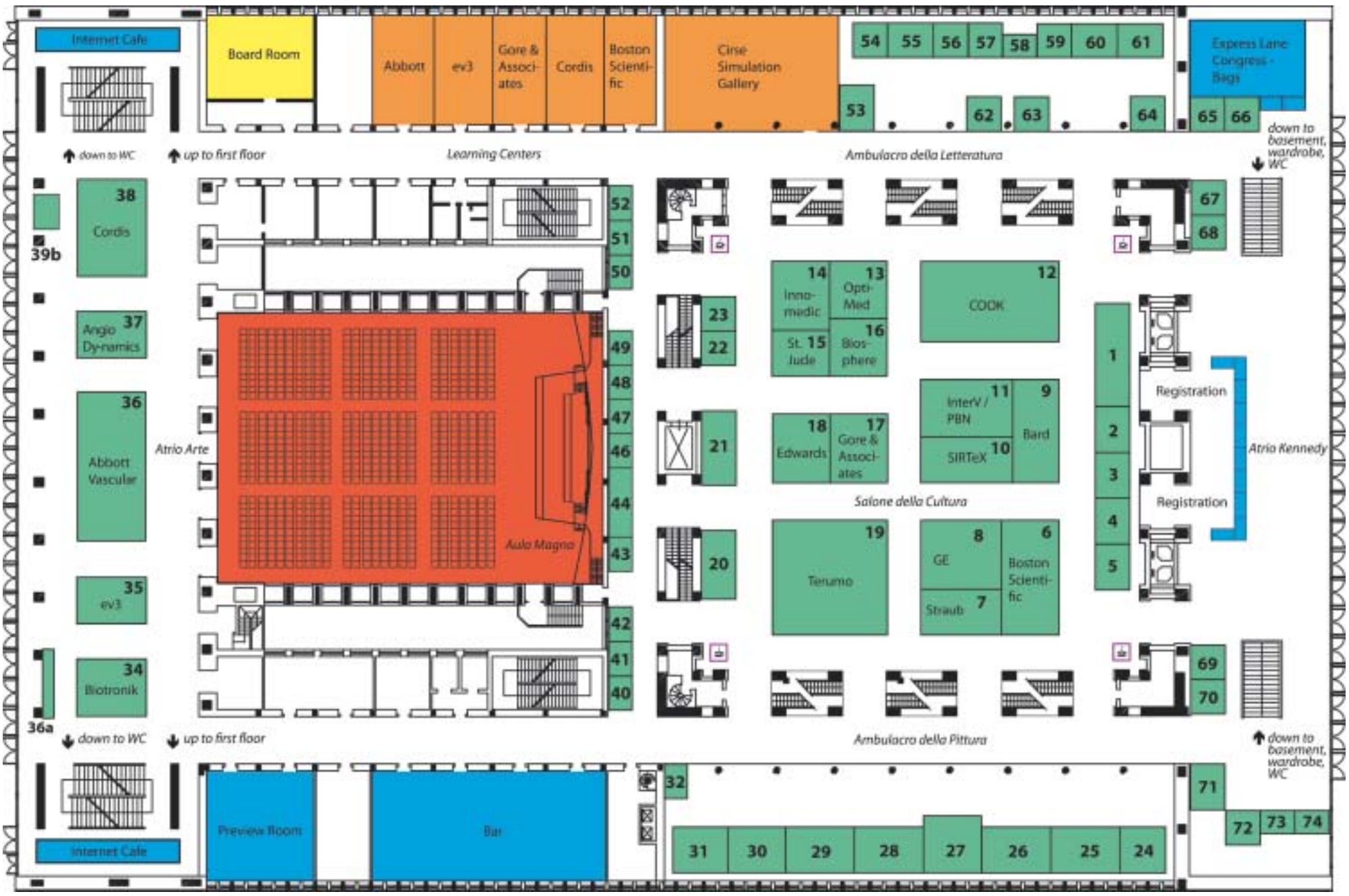

INTRODUCTION

Since its inception in 1963, Cook has embodied an innovative spirit and the highest level of integrity in an uncompromising drive to do what is in the best interests of the most important constituent in the medical device delivery chain – the patient. It is the commitment to these principles that has, for 43 years, served as the cornerstone of the company's success and helped to save and improve countless lives around the world.

Today, Cook maintains its unrelenting dedication to researching, developing and delivering the most beneficial minimally invasive medical devices to the healthcare industry. For example, Cook now delivers state-of-the-art vascular stents, such as the Formula 414 Rapid-Exchange Balloon-Expandable Renal Stent, to the European market. It is not available for sale in the U.S. at this time.

This particular stent was the focus of a recent discussion with Cook Diagnostic & Interventional Products division Senior Product Manager, Michael Schafer:

What are the major advantages you have heard from physicians who have implanted the Formula 414 Rx Balloon Expandable Renal Stent?

There are three main responses I've heard from our clinical cases early in the launch of this new rapid exchange stent system. First, there have been some excellent impressions with the extremely low-crossing profile of the stent system and its ability to cross very tight lesions. Secondly, the uniqueness of the shaft design has translated to providing very good trackability and pushability especially with highly angulated renal arteries. Last, we've been told that the Formula stent's flexibility and ability to conform to the renal artery is also very notable.

What is built into Formula's design that provides clinical advantages and consequent advantageous outcomes?

There are a number of design aspects that potentially result in features that may translate into improved outcomes. The low-crossing profile is a key advantage that has been facilitated through improvements in the stent's balloon pleat or fold design and the unique method we use for crimping the stent down on the balloon. The balloon tip of our delivery system is also optimally tapered to cross highly stenotic lesions. The Formula 414 shaft is one-of-a-kind and is basically made of a specially designed wire coil configuration that facilitates an excellent balance between trackability and pushability of the delivery system. This unique design also provides kink resistance that can be important with highly angulated renal arteries where many rapid exchange systems are compromised. Last, the flexibility and conformability of the stent is a function of the unique hybrid cell design with very good scaffolding. Our stent system is composed of both open and closed cells that provide good structural support to the vessel along with the conformability to the renal artery.

How does the new Formula 414 rapid exchange system compare to other balloon expandable stents on the market?

Formula has many elements that distinguish it from other rapid exchange balloon expandable stents on the market. The shaft design is this system's most unique attribute differentiating it from other stent delivery systems. Again, this balloon on-a-wire design can provide an optimized delivery system for trackability and pushability along with kink resistance unsurpassed by other rapid exchange systems. The improved, precision-oriented attributes, such as the no-shortening design, minimal amount of balloon overhang, ultra low-crossing profile, and highly tapered atraumatic balloon tip , are all attributes unique to the Formula 414 stent system. Our goal with these stent system attributes was to improve the ability to more accurately place the stent at the ostium of the renal artery along with decreasing procedural time. Additionally, the stent has a more circular shape than most other stents, which may enhance its ability to structurally support the vessel and decrease potential irritation to the vessel wall. This improved circularity is a function of increasing the number of crowns or crests to the stent which also reduces sharp edges of the stent cells. Formula also is one of the first stents on the market to include a hybrid cell design providing both closed and open cells.

ABOUT COOK

The world's largest privately held manufacturer of medical devices with international headquarters in Bloomington, Ind., COOK® (www.cookmedical.com) is a leading designer, manufacturer and global distributor of minimally invasive medical device technology for diagnostic and therapeutic procedures.

COOK®

Learning Center Courses

At CIRSE 2006, Abbott Vascular offers procedure skill training on the most advanced simulator currently available:

Sunday 10 September	09.00-11.00: Introduction to CAS 14.00-16.00: Introduction to CAS
Monday 11 September	09.00-11.00: Introduction to RAS 14.00-16.00: Introduction to CAS
Tuesday 12 September	09.00-11.00: Introduction to CAS 14.00-16.00: Introduction to CAS

- Personal coaching by experts
- Step-by-step procedure training on CAS & RAS
- Real patient anatomies
- Unbiased quantitative evaluation
- Complication prevention

Register at the Abbott Learning Center registration desk on the Groundfloor