IR congress news

CIRSE 2006 - Rome
Sunday, September 10, 2006

Michael Lee
Chairman of the
Scientific Programme Committee

Highlights from the CIRSE 2006 Programme

I hope everyone is enjoying and will continue to enjoy CIRSE 2006, in the fabulous City of Rome. I would like to take this opportunity to thank the members of the Scientific Programme Committee (SPC) for their hard work and enthusiasm over the past year. I am indebted to Professor Mark Sapoval, Deputy SPC Chairman, Professor Elis Brountzos, Professor Mario Bezzi, Professor Anthony Watkinson, Dr. Tony Nicholson and Professor Johannes Lammer, President of CIRSE.

I hope you will agree that this year's CIRSE continues to highlight the important issues in the practice of Interventional Radiology. There will be a mini symposium on intermittent claudication, running over three days of the meeting, with experts from vascular surgery and Interventional Radiology discussing the gamut of intermittent claudication from clinical examination to imaging to treatment strategies. There are two special sessions on uterine artery embolisation. One of the sessions will compile all the registry and study results, including the REST study, EMMY study, HOPEFUL study, BSIR registry and CIRSE registry data.

There is a special session devoted to computer and robotic assisted interventions, which are making inroads into the surgical sphere and more recently into Interventional Radiology. A further special session is devoted to the IR/OR suite of the future, which is an important item for those contemplating building or renovating an interventional suite. There are three special sessions on interventional oncology and a number of other sessions on clinical practice development, radiation protection in Interventional Radiology, EVAR and thoracic stenting.

As usual, there will be two foundation courses, one in vascular intervention and one in non-vascular intervention. This year for the first time both foundation courses will be themed. The non-vascular foundation course will be on biliary intervention and the vascular foundation course will be on angioplasty of the superficial femoral artery. Hands-on worksops will include RFA ablation, veretebroplasty and simulation. Please check the CIRSE website and/or your programme for details.

It is important not to forget our junior colleagues during the CIRSE meeting and with this in mind there are a number of basic workshops designed for trainees and/or junior staff starting out on their career in Interventional Radiology. For the first time there will be a special session on basic vascular diagnosis, which is an often overlooked part of radiology training. It will focus particularly on catheter angiography, MRA and CT. Obviously, the foundation courses are also designed for our junior colleagues. The film interpretation panel as well as the morbidity and mortality conferences are also good opportunities to learn the practice of Interventional Radiology.

Finally, I hope you enjoy the educational scientific components of CIRSE 2006. If you have any comments or suggestions I would be delighted to hear from you by email (mlee@rcsi.ie) or indeed during the meeting.

The Future of Interventional Radiology

Giovanni Simonetti
Chairman of the Dept. of Diagnostic Imaging, Molecular Imaging, Interventional Radiology and Radiation Therapy,
University of Rome Tor Vergata

Since its birth in the early seventies, Interventional Radiology has undergone many different stages of development and growth which especially in recent times have become a source of much debate. The world of radiology and particularly young interventional radiologists are wondering what can be expected of Interventional Radiology in the future and in which direction it is going to develop in the future. Since these questions are certainly not easy ones, we have decided to ask it to one of the pioneers of Interventional Radiology; *Prof. Giovanni Simonetti.*

Prof. Simonetti, How do you see the future of Interventional Radiology?

This is definitely not an easy question. I believe that to find an answer we have to take a look at the history of interventional radiologists. As you probably know, Interventional Radiology was born in the mid-70s, when a group of pioneers performed the first endovascular and extra vascular procedures. Those years were both difficult and stimulating. The frantic expansion of the different techniques was regarded with unresponsiveness and indifference by other specialists. I assume that in most cases the potential of Interventional Radiology was simply underestimated.

Was this initial lack of interest from other specialties a problem?

No, on the contrary; we had the chance to grow professionally and technically, thus reaching an undisputable superiority that has allowed us to become the only referring centre for the different interventional techniques. We have certainly struggled, and - allow me to use a strong term - we have fought real battles, both scientific and personal ones, in order for Interventional Radiology to become an acknowledged discipline. As I mentioned before, those were not easy times, but we were driven by great enthusiasm and strengthened by the experience we had acquired in the field. Let's not forget that in addition we enjoyed technological support that in those years was inducing a real revolution in diagnostic imaging. In this contest we obtained one of the most important results in the history of radiology: we became a professional entity which was no longer limited to the role of an interpreter of radiological imaging. Looking back today, it can be said that it was then that we committed the first mistake.

What was that mistake?

We were compared to fine artisans that were able to obtain excellent results, which is why we though that our technical skilfulness could protect us from field invasions. We were not in competition with other specialists, such as surgeons, vascular surgeons or orthopaedics any more, but rather became their allies. We did not understand that affirming our professionalism only within the procedure without any direct control of the patient turned us into secondary figures in the management of the patient. This is why we have been progressively and aggressively invaded by the other specialties.

What should have been done?

We should have assumed an overall management of the patient. We should have been one step ahead and become clinicians instead of waiting for the clinicians to become interventionalists.

This brings us back to the initial question: Where are we going?

Today we are at a crossroad. If we do not want to be confined to a marginal role, we have to learn from our past mistakes and become clinical interventional radiologists. We need to change our mindset and manage the patients from diagnosis to therapy to dismission.

So you think that the future of Interventional Radiology lies in patient control?

Exactly! If interventional radiologist do not begin to exercise patient control, there will be no future for our discipline. In order to gain patient control it is necessary for us and especially the young generation of interventional radiologists to learn how to manage therapies, the clinical chart and everything else concerning the hospitalization of a patient who has to undergo an interventional procedure. We have to regain the lost field and quickly change mentality.

Does this mean that we should somehow detach ourselves from diagnostic imaging?

Absolutely not! Diagnostic imaging is fundamental to our discipline; its crucial importance in the diagnosing of a patient allows us to play a pivotal role in the management of the indications to therapy, which is why tomorrow's interventional radiologist will have to also be a clinician as well as having perfect diagnostic imaging skills.

Is there anything you would like to say to all the young interventional radiologists attending CIRSE 2006?

I would like to invite all young interventional radiologists to maintain the enthusiasm and courage that has always characterized us when facing the challenges ahead. Only by further developing the way we see our work can we achieve the most important step in our professional development and become interventional radiologist of the third millennium.

Andreas Gruentzig Lecture

Sunday, September 10, 14:30-15:15
Aula Magna

Honouring the German radiologist Andreas Gruentzig, who first developed successful angioplasty for expanding lumens of narrowed arteries, CIRSE's yearly Gruentzig Lecture has been given by some of the most outstanding personalities in the field of Interventional Radiology. Over the years these exceptional lectures have become one of the highlights of our meeting's scientific programme.

This year's Gruentzig Lecture has been awarded to Professor Luigi Solbiati, Italy
(see article on page 2).

Interventional Oncology :

The subject of this year's Gruentzig Lecture

Luigi Solbiati
Chairman of the Diagnostic Imaging Department, Busto Arsizio General Hospital, Professor of Techniques and Methods of Diagnostic Imaging at the University of Milan

One of the most significant advancements of Medicine in the last 30 years has been the development of minimally-invasive operative techniques capable of replacing conventional surgery by using imaging modalities (angiography, ultrasound, computed tomography, magnetic resonance, etc .) to guide treatments. This article will review the rapid evolution of this new branch of medicine called 'interventional oncology'.

Intravascular methods have been used for many years for the non-surgical treatment of vascular diseases and subsequently of richly vascularised malignancies. Percutaneous and laparoscopic approaches have been used for "ablation therapies". These are carried out with the help of electrodes or probes inserted into tumours in order to achieve local control of the pathologies by heating, freezing, radiation, occlusion of tumour blood supply or direct injection of caustic agents. The above treatment options can also be combined in various ways. Historically, percutaneous ethanol injection (PEI) was the first percutaneous ablative therapy to be clinically applied in the early 80's, when the capability of 95% ethanol to induce thrombosis and disruption of the endothelium of small blood vessels and to induce cell death due to dehydration was clearly demonstrated.
PEI was initially used for the treatment of renal (1) and hepatic (2) cysts, but it was soon evident that ethanol could also achieve local control of highly vascularised encapsulated solid tumours (e.g. parathyroid adenomas and hepatocellular carcinomas) with high local tumoricidal effect and minimal risk of side effects.
The first papers on PEI of parathyroid hyperplasias in uremic patients with secondary hyperparathyroidism (3) and of small hepatic and abdominal tumours (4) likely mark the official birth of percutaneous interventional oncology. In two subsequent papers, Livraghi et al. (5, 6) and Ebara et al. (7) demonstrated PEI to be safe, effective, low cost and easily reproducible in the treatment of patients with hepatocellular carcinoma (HCC), with survival rates comparable to that of surgery, but dependent on the severity of accompanying cirrhosis.
Similar results were achieved injecting acetic acid under sonographic guidance into HCCs (8).
Additional attempts to use ethanol for the treatment of different types of malignancy (e.g. liver metastases) did not provide effective results because of the minimal tumour vascularity and the lack of peritumoral capsule to contain the injected ethanol. For a similar reason, other injectable agents such as chemiotherapeutic drugs, hot saline, etc. did not provide great efficacy for the treatment of metastatic diseases. Different methods for ablation therefore came into being and were based on the deposition of physical energy. Each method emerged with a different "history", but with the common purpose of enabling the treatment of larger and different (including extrahepatic) malignancies with high reliability and repeatability.
Radiofrequency ablation (RFA) is currently the most widely employed of these methods. While the clinical use of RFA is relatively new, the basic principle was described in 1891 by D'Arsonval (9), who demonstrated that when RF waves passed through tissue an increase in tissue temperature was recorded. This effect was explained only eighty years later with the demonstration of the ionic agitation of the tissues surrounding the RF probe (10). For many years the clinical application of RFA has been limited to the so-called "Bovie knife", an instrument used either for cauterization or for cutting tissue (11). It was not until 1990 that two independent operators (12,13) replaced the Bovie knife with specially designed needles insulated to the distal tip to create coagulation necrosis applicable via the percutaneous route. Through subsequent technological improvements (cool-tip needles, multi-pronged needles, clustered needles, simultaneous intratumoural injection of hypertonic saline, more powerful generators, etc.) (14-17), RFA has reached a high level of reliability for the treatment of HCCs up to 5-6 cm in size, of hepatic metastases up to 3-4 cm and of some extrahepatic malignancies, i.e. lung, kidney and bone neoplasms (18-27) (Fig.1).
Laser hyperthermia for tumour ablation had a different history. Neodymium: yttrium-aluminum-garnet (Nd: YAG) laser system was initially used to treat head and neck tumours through precise surgical dissections and not for tumour destruction. The first experimental application of laser hyperthermia for the treatment of liver neoplasms was reported in 1987 (28). Five years later the percutaneous US-guided technique of laser hyperthermia with a laser fibre introduced through a 19-gauge needle was described (29). Recent improvements in laser-induced thermotherapy allow larger areas of coagulative necrosis than were possible with earlier systems (30,31). However, the clinical acceptance of laser ablation has been limited in part due to the technical complexity of the method which requires many fibre placements compared to the easier-to-perform RFA or cryoablation methods.
Extremely cold temperatures have been used to decrease inflammation and to relieve pain since the time of the ancient Egyptians. In the 19th century an English physician, J. Arnott, used a combination of ice and salt to produce tissue necrosis for tumours of the cervix and breast by topic application (32). Liquid air and carbon dioxide were subsequently employed as cryogens for the treatment of tumours, based on the principle used for air conditioning and refrigeration; atmospheric gases warm when compressed and cool during expansion. Following many experimental studies using liquid nitrogen as cryogen (33,34), the first clinical experiences with the use of cryotherapy were reported by the late 1980s and early 1990s. The key development was the fusing of cryoablation with real-time imaging guidance to verify the extent of treatment and to measure the size of the ice ball created by freezing (35,36). Interstitial hepatic cryosurgery initially started as intraoperative procedure, mostly because of the large size of cryoprobes. Thanks to the subsequent development of argon-based cryoablation systems with much thinner cryoprobes and decreased treatment times, minimally invasive cryoablation techniques, including the percutaneous approach under cross-sectional image guidance, have been introduced, mostly for kidney, lung and bone malignancies (37,38). Important advantages of cryoablation over RFA are: 1) the sharp and predictable margins of the zone of ablation ("ice ball"), 2) high visibility of the ice on CT or MRI during the ablation, thereby allowing greater certainty of tumour destruction and avoidance of damage to adjacent tissues, 3) lower level of pain during the ablation and in the immediate recovery period (39).
Microwave hyperthermia is the most recently introduced method for tumour ablation. Microwave irradiation from a monopolar antenna causes water molecules in the tissue to vibrate at a frequency of 2450 MHz. This generates frictional heat in the water molecules and leads to thermal coagulation of tissue. The first reports about microwave coagulation therapy with percutaneous approach and US guidance for the treatment of unresectable HCC were published in 1994 (40,41). Recently, reports on long-term results and survival rates have been reported mostly for liver malignancies (42,43). However, in spite of significant technological improvements, the major problem of microwave hyperthermia is the limitation on the volume of tissue necrosis achievable with a single probe. Multiple, regularly spaced applicators are needed to achieve sufficiently large areas of necrosis, which increases the technical complexity of this method.
The technical limitations of each of these ablative methods and the concomitant progressive increase of "difficult" lesions sent for treatment (large tumours, multiple lesions, masses in critical anatomical locations) has led to the need of "combining" different cancer treatment methods for more effective therapy. "Combination therapies" originally started in order to compensate for the "heat sink" effect of large vessels within tumours during RFA. The combinations of RFA with transcatheter arterial embolisation (44) and chemoembolisation (45), temporary venous occlusion (46), the Pringle manoeuvre during open surgical application of RFA (47), adjuvant liposomal chemotherapy (48,49), and chemoembolisation (50,51) have been reported to be successful at improving effectiveness over ablation alone.
In most practices throughout the world, it is the interventional radiologist who offers this medical service to the cancer patient. CT and MRI are the most suitable imaging methods for pre-procedural planning and follow-up (52,53). Sonography (particularly contrast-enhanced ultrasound) (54,55) and MRI on the other hand are the best methods for guiding and monitoring treatments. However, fascinating improvements of imaging are currently being introduced in the field of interventional oncology: PET/CT for the assessment of the results of ablations (56), three-dimensional rotational angiography for transarterial chemoembolisation (57) and mostly image fusion for guiding and monitoring ablations (58). Different systems for image fusion are currently under development, but it is real-time imaging that is mandatory for guidance of ablations within most organs of the abdomen or thorax due to their inherent movement. Therefore systems combining a real-time modality such as US with the static images of CT or MRI (with its inherent better global view) will likely be the most suitable for this application. Real-time US and pre-registered CT/MRI images can be matched and either displayed side by side or overlapped. Ablations can be performed following the biopsy line paired on CT/MRI and US scans, but visualising targets on CT/MRI scans (Fig.2). This allows safe and precise treatment of early (small) neoplastic targets, which represent the real challenge for achieving local curability of malignancies.
Continuous technological improvements of imaging methods and interventional devices as well as increasing evidence of the efficacy and the low rate of complications of non-surgical treatments will likely guarantee a bright future for the emerging field of Interventional Oncology.

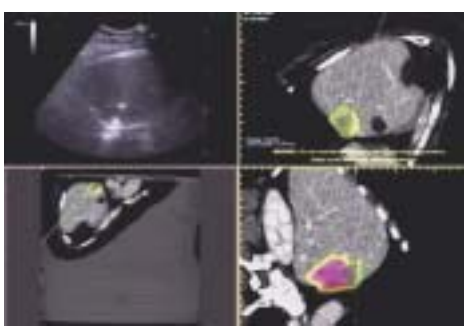

Figure 2: Percutaneous RFA treatment of large metastatic lesion poorly visualized by ultrasound. Treatment is guided using real-time US/CT image fusion. On CT scans the lesion has previously been mapped with colours. The peripheral "safety halo" is marked in yellow. Due to the large size of the mass, treatment requires multiple electrode insertions: after each insertion, the colour map is removed in the corresponding volume of tumour ablated in order to make the still unablated portions clearly visible.

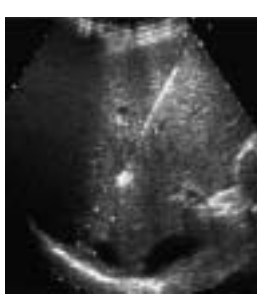

Figure 1: Cool-tip electrode for RFA percutaneously inserted into small hepatocellular carcinoma under ultrasound guidance.

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'Evidence-Based Practice': What is it, where does it fit in and what's in it for Interventional Radiologists?

Session 23.9
Evidence Based Practice in Interventional Radiology
Sunday, September 10, 15:45-16:45, Room D

Dermot E. Malone
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St. Vincent's University Hospital, Ireland

Evidence-Based Practice: What is it?

Since 1990 the original concept of "Evidence-Based Medicine" (EBM) has broadened into "Evidence-Based Practice" (EBP) and been applied to many disciplines, including Radiology. It has spread beyond English-speaking countries and is also known as "Médicine Fondée sur les Preuves", "Evidenz-Basierte Praxis", "la Medicina Basata sulle Evidenze", "Medicina Basada en la Evidencia", etc. These phrases have become the international mantra of healthcare providers and the yardstick by which medical practitioners competing for their attention and their money are judged.

Why has the EBP movement developed internationally? After all, radiologists have, like other doctors, been trained to be analysts and decision-makers. We attend meetings like CIRSE to gain the knowledge that will allow us to update our protocols and learn about the appropriate role of new procedures. We have been taught that individual clinical experience provides the foundation for diagnosis, treatment and prognosis. We trust that traditional medical training and common sense enable an experienced physician to evaluate new tests and treatments and that clinical experience and expertise in a given subject enable an experienced physician to develop and teach clinical practice guidelines. This has been described as the 'Eminence-Based Practice' paradigm (1) and is the traditional foundation of academic practice in many specialties and countries.

As far back as the 1970's concerns began to arise among epidemiologists and those funding healthcare as it became apparent to them that medical experts differed widely in their recommendations based upon identical data. As early as 1979, David Sackett (a Canadian epidemiologist and internal medicine physician) had recognized 35 biases that could arise when researchers were sampling and measuring during prospective and retrospective research studies (2). Gordon Guyatt, another Canadian epidemiologist, has described many problems with the traditional expert review of the literature (3) - after all, every parent loves their offspring and every 'cutting-edge' researcher believes in their project! Slowly, working together and with others in McMaster University, Canada, Sackett and Guyatt developed a bottom-up approach that integrates the best external evidence with individual clinical expertise and patients' choice (4). The aim of this approach is to allow health care professionals who are not epidemiologists to reliably 'decode' various types of medical literature using explicit methods that produce reasonably consistent results. It is somewhat analogous to cardiologists developing a systematic approach to teaching medical students how to examine a patient's cardiovascular system and determine whether it is healthy, minimally flawed or severely diseased.

They developed and taught this way of approaching the medical literature in McMaster University during the late 1980's and early 1990's. It proved to be controversial, but very influential. A series of "User's Guides to the Medical Literature" were written and published in the Journal of the American Medical Association. These were subsequently collated by the Canadian Centre for Health Evidence to allow free online access (5). The development of EBP and the rise of the Internet coincided. The group rapidly realized that modern informatics now potentially allowed in-hospital and even 'point of care' searching of the literature. Accordingly, they integrated literature searching as a fundamental skill of EBP and developed a 5-step approach with which to solve clinical problems using 'Evidence-Based' methods. This can be summarized as 'Ask, Search, Appraise, Apply and Evaluate.' Basic and advanced textbooks followed (6-8).

Sackett spent a sabbatical year in Oxford University and subsequently returned there to help establish the National Health Service/ Oxford University Centre for Evidence-Based Medicine (9). Meanwhile, the McMaster group established their Health Information Research Unit and the Evidence-Based Practice Centre (10, 11). The purpose of these units is to promote research that supports the development, dissemination and application of evidence to clinical practice and policy as well as student involvement and training for better understanding of the role of evidence in health care decision-making (11).

Where does it fit in?
The integration of EBP concepts into Radiology:

Personal Experience

As I had worked in Radiology at McMaster University (Fig. 1), I was aware of EBP when I returned to Ireland from Canada. I attended the McMaster and Oxford University courses in teaching and learning EBP (9, 12) and in 1999 began working on local practice problems with a small group of residents using the 'stepwise process.' We have applied EBP to a variety of scenarios and have found it very useful for decision-making. It is typically used for decisions about commonly encountered problems; those for which there is likely to be high quality evidence; decisions about whether to advise a high risk therapy and decisions about which either patients or referring clinicians care a great deal (13). The implication that physicians must always seek external evidence seriously undermines the effort of promoting the appropriate use of evidence (13).

Figure 1: McMaster University

The EBP concept of 'Levels of Evidence' allows us to rank retrieved abstracts and confine our in-depth analysis to the best studies; for interventional problems the explicit EBP analysis of benefit and harm (which we do with a spreadsheet) is simple, comprehensive and easy to apply clinically and the EBP guidelines on the reliability of evidence about procedural safety, based on study sample size, are very helpful. If the evidence is convincing, the arguments are over. If the best evidence is weak (as is often the case), clinical expertise (the 'eminence-based' paradigm) and patient values define the final decision. A full discussion is beyond the scope of this article, but interested readers can easily access our website (Fig 2; 14) or read one of our recent publications (15) for more detail, basic references, a downloadable spreadsheet etc.

Figure 2: www.evidencebasedradiology.net

International Developments

In North America, complete training and continuing education now require more than technical expertise. The American Boards of Radiology mandate training and certification in six competencies for certification and re-certification (16). These are medical knowledge, patient care, interpersonal and communication skills, practice-based learning and improvement, systems-based practice and professionalism. The Royal College of Physicians and Surgeons of Canada require similar roles to be developed during resident training (medical expert/clinical decision-maker, communicator, collaborator, manager, health advocate, scholar and professional) (17). EBP skills form an important part of many of these roles. They have not yet been incorporated into European training requirements.

What's in it for Interventional Radiologists?

Interventional Radiology (IR) has developed from purely being a part-time activity of diagnostic radiologists into a radiological sub-specialty of its own with the potential to develop into a stand-alone specialty like surgery. IR must, however, compete with surgery, medical oncology and diagnostic radiology for credibility, resources and patients. IR research tends to oversimplify issues and fails to impress policy-makers (18). IR practitioners come under industry and peer pressure to incorporate new procedures with scant regard for the populations studied in the literature or the level of evidence achieved in preliminary reports.

Now imagine for a moment that you must choose between a new IR procedure, an older IR procedure and a surgical procedure as an interventional radiologist, a healthcare manager (or fund holder) and as a patient. As an interventional radiologist, would you like to be able to satisfactorily search the literature, reliably appraise what you have found, integrate the best current evidence with your expertise and local circumstances and then present an authoritative expert decision to all comers? As a healthcare manager, would you like to consult an interventional radiologist who is not only technically trained to a high level of excellence, but who is patient-centred with the goal of improving the patients prognosis or palliation by recommending the most effective technique, regardless of which specialty applies it; who has either produced or located and appraised current best evidence before reaching a decision and who is able to argue his / her point using terminology familiar both to you as a manager / fund holder and to your epidemiological advisors? As a patient or as the relative of a patient, would you like to consult with an up-to-date specialist that you can trust knows when, how and (importantly) when not to employ his/her specialist skills instead of those of another specialist or conservative therapy to get the best achievable clinical outcome?

In the anecdotal experience of our EBP group, the addition of EBP methods to traditional training has helped us as we work towards being the type of interventional radiologist described above. We work successfully in a multidisciplinary team with physicians and surgeons - competing when appropriate - and have no shortage of referrals. I will leave the final word with the Society of Interventional Radiology, as they quote the American Board of Radiology Trustees: "Our profession is becoming increasingly marginalized through the activities of … many … organizations working to determine health policy. Our way out of this problem,… is 'to convince the public that the profession has different, and perhaps loftier goals, than the other players. A primary goal should be to provide patient-centred, evidence-based medicine."

Some key points about EBP and IR will be explored further by Dr. L. Crocetti (University of Pisa) and me during the CIRSE interactive workshop 23. Please join us if you would like to know more about EBP. The following references contain many links to helpful websites, so that you can do some exploring on your own and each annual ESGAR meeting contains a mini-course on EBP that you are welcome to attend.

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Please refer to full national Summary of Product Characteristics (SPC) before prescribing. **PRESENTATION** An isotonic, aqueous solution containing iodixanol, a non-ionic, dimeric contrast medium, available in three strengths containing either 150 mg, 270 mg or 320 mg iodine per ml. **INDICATIONS** X-ray contrast medium for use in adults in cardioangiography, cerebral angiography, peripheral arteriography, abdominal angiography, urography, venography, CT enhancement, studies of the upper gastrointestinal tract, arthrography, hysterosalpingography (HSG) and endoscopic retrograde cholangiopancreatography (ERCP). Lumbar, thoracic and cervical myelography in adults. In children for cardioangiography, urography, CT enhancement and studies of the upper gastrointestinal tract. **DOSAGE AND ADMINISTRATION** Adults andchildren: Dosage for intravascular and oral use varies depending on the type of examination, age, weight, cardiac output, general condition of patient and the technique used (see SPC and package leaflet). **CONTRAINDICATIONS** Manifest thyrotoxicosis. History of serious hypersensitivity reaction to Visipaque. **PRECAUTIONS, WARNINGS, ETC** A positive history of allergy, asthma, or reaction to iodinated contrast media indicates need for special caution. Premedication with corticosteroids or H1 and H2 antagonists should be considered in these cases. Although the risk of serious reactions with Visipaque is regarded as low, iodinated contrast media may provoke serious, hypersensitivity reactions. Therefore the necessary drugs and equipment must be available for immediate treatment. Patients should be observed for at least 30 minutes following administration of contrast medium, however delayed reactions may occur. Non-ionic contrast media have less effect on the coagulation system in vitro, compared to ionic contrast media. When performing vascular catheterization procedures one should pay meticulous attention to the angiographic technique and flush the catheter frequently (eg. with heparinised saline) so as to minimize the risk of procedure-related thrombosis and embolism. Ensure adequate hydration before and after examination especially in patients with renal dysfunction, diabetes mellitus, paraproteinemias, the elderly, children and infants. Special care should also be taken in patients with hyperthyroidism, serious cardiac disease, pulmonary hypertension, patients predisposed to seizures (acute cerebral pathology, tumours, epilepsy, alcoholics and drug addicts), and patients with myasthenia gravis or phaeochromocytoma. Particular care is required in patients with severe disturbance of both renal and hepatic function as they may have significantly delayed contrast medium clearance.All iodinated contrast media may interfere with laboratory tests for thyroid function, bilirubin, proteins, or inorganic substances (e.g. iron, copper, calcium, and phosphate). In diabetic patients metformin should be stopped when contrast media are used. The timing of this should be amended based upon serum creatine/renal function levels. (refer to SPC) An increased risk of delayed reactions (flushe or skin reactions) has been associated with patients treated with interleukin-2 up to two weeks previously. The safety of Visipaque in pregnancy has not been established. The degree of excretion into human milk is not known. Breast feeding should be discontinued prior to administration and not recommenced until at least 24 hours after administration. **SIDE EFFECTS** Usually mild to moderate, and transient in nature, they include discomfort, general sensation of warmth or cold, pain at the injection site or distally.Serious reactions are only seen on very rare occasions.Nausea, vomiting, and abdominal discomfort are rare.Hypersensitivity reactions occur occasionally with symptoms such as rash, urticaria and pruritus (immediate or delayed). Severe reactions such as bronchospasm, angioedema, dyspnoea and fatal anaphylaxis are very rare. Neurological reactions, headache, dizziness, seizures, and transient motor or sensory disturbance (e.g. taste or smell alteration) are very rare. Also reported very rarely; vagal reactions, cardiac arrhythmia, hypertension and 'iodide mumps'. Arterial spasm may follow injection. A minor transient rise in creatinine is common. Renal failure is very rare. Post phlebographic phlebitis or thrombosis is very rare. Gastrointestinal disturbances including diarrhoea, nausea/vomiting and abdominal pain and systemic hypersensitivity reactions occur occasionally (<1:10, >1:100). **OVERDOSE** In the event of accidental overdosing, renal function should be monitored for at least 3 days in addition to supportive measures. Haemodialysis should be considered if needed. **MARKETING AUTHORISATION NUMBER** Visipaque 150 mg I/ml - 60.635, 270mg I/ml - 60.636, 320mg I/ml - 60.637; Visipaque USP 150 mg I/ml - 62.916; Visipaque USP 270 mg I/ml - 62.917; Visipaque USP 320 mg I/ml - 62.918. **MARKETING AUTHORISATION HOLDER** Amersham Health AS, Nycoveien 1-2, Postboks 4220 Nydalen, N-0401 Oslo, Norway. Further information on request from: GE Healthcare Limited, The Grove Centre, White Lion Road, Amersham, Bucks HP7 9LL.
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Fundamentals for Departments of Interventional Radiology

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Many general radiologists perform only a small number of interventional procedures although they would like to increase their patient volume. Especially in small and medium sized hospitals this increase is sometimes difficult to achieve due to many obstacles, including other departments fearing the competition and wanting to prevent the expansion of our activities. In addition they do not know enough about our capabilities or doubt the success of the procedures we are offering. How can we change this situation, which has existed since Interventional Radiology came into being?

First of all it is very important to have a pleasant relationship with our colleagues, with the referring physicians in our hospital and especially with referring physicians outside the hospital. The second group is especially important, since outside physicians sending us patients make us independent of the referring physicians inside our hospitals, who sometimes fight us with unreasonable arguments. Furthermore we should inform our most important referring physicians about our capabilities, i.e. the interventional procedures we are familiar with and which are suited for the hospitals we work in. We should also make sure we have enough time for out-patient visits, since this makes us independent of our in-hospital patients and in-hospital colleagues.

For vascular patients it is extremely important to have your own beds for patient hospitalisation. If you have a difficult relationship with your vascular surgeons, try to find other possibilities and send patients which have been referred to you to other departments which have vacant beds or which are also related to peripheral vascular disease, such as departments of angiology and internal medicine.

It is also very important to organize scientific and educational meetings for your colleagues, especially physicians from outside your hospital. For these events you should invite well known interventional radiologists, the most important of which should give the main lecture. Do not hesitate to present your own work, even though your patient volume might be smaller or you might have less experience. The big interventional companies will give you logistical and financial support in this regard; you should ask them for advice to organize the meeting. Also, you should inform your administrator about your activities. Let him/her know that you are organizing a meeting and, in addition, tell him that your interventional procedures are of no economical risk for the hospital. In some European countries, e.g. Germany, interventional procedures are paid like a corresponding open surgical procedure, for instance chemoembolization of the liver or liver dissection. You should convince your financial administrator of the financial advantages provided by your actions.

Of course it is always important to improve one's own knowledge and skills in Interventional Radiology. Therefore it is not enough to read the special interventional journals and to visit other interventional meetings. It is very important that you and your colleagues visit other departments having more experience in procedures you are willing to perform in the future to see how these procedures are performed. This is especially vital for carotid angioplasty and stenting. CIRSE can give you information about hospitals and departments in which the procedures you would like to learn are performed. Even this can be financially supported by the CIRSE Foundation.

Josef Rösch has repeatedly emphasized the importance of interventional radiologists having a close relationship to their patients. He has always underlined that we are not just physicians sitting in front of a monitor. Before we carry out interventional treatment we have to explain the procedure to our patients, explaining all benefits and risks. We do not only require profound knowledge about the technical part of the procedure, but also about the disease in general, for instance atherosclerosis in peripheral vascular disease. During the procedure we have to monitor our patients thoroughly being capable of reacting to adverse situations like arterial hypertension, coagulation problems or pain. After the procedure we have to give written advice to the physician at the respective hospital ward. Nevertheless we need to continue seeing our patient. Daily visits to the patient in order to see the success of our treatment and detect possible complications are indispensable. Also seeing our patients after the procedure will create a good doctor-patient relationship. The patient will therefore be aware of your capabilities, inform others about IR and in case of recurrent disease come back to you.

Flat panel CT - A new imaging modality for interventional procedures

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With the introduction of flat-panel detectors the acquisition of CT- like images with a rotational CT-arm system, which could not be achieved with conventional image intensifier systems due to poor contrast resolution, has become possible. Flat-panel detectors have a contrast resolution of about 10 Hounsfield units, which is why soft tissue imaging is possible to a certain degree. For Flat-panel CT (FP-CT) a volume data-set consisting of 300 or 600 single projections is acquired during a 200° rotation of the fluoroscopic C-arm. Depending on the acquisition mode, the rotation time is 10 or 20 seconds. The projection data can be displayed as multiplanar reconstructions or in a volume rendering mode.

Since March 2005 we have had the opportunity to work with a new biplane angiographic system which is FP-CT capable. FP-CT was used before or during neuro-interventions, during stent-graft procedures and occasionally as an additional imaging tool during liver embolization and TIPS. In series of 25 patients we were able to compare conventional cranial computed tomography to FP-CT in the diagnosis of intracranial hemorrhage. We were able to demonstrate that FP-CT can show clinically significant acute supratentorial bleeding, which might occur during an interventional procedure. In addition to intracranial bleeding, the supratentorial ventricle system is well shown.

According to our experience, FP-CT can be a valuable diagnostic tool when bleeding is suspected during a neuro-intervention, be it an embolization procedure or acute stroke intervention. In addition to the diagnosis of intracranial hemorrhage, intracranial stents, which are difficult to see on fluoroscopy, can be displayed quite nicely by FP-CT. In the posterior fossa region image quality of FP-CT is hampered by beam hardening and streak artifacts.

In the case of body imaging the value of FP- CT is less clear. We have found FP-CT helpful in some stent-graft procedures, since the stent-graft is nicely displayed and the alignment of the stent-graft in the landing zones can be evaluated (Fig. 2a,b, see also EPOS CIRSE 2006, P21). However, guide-wires, catheters and too highly concentrated contrast-medium may cause disturbing artifacts. Theoretically FP-CT should be especially attractive during tumor embolisations. Nevertheless, we found 2 major problems with this application: Firstly, the field of view is limited to 38x30 cm, which is why it is sometimes difficult to cover the whole ROI. Secondly, the acquisition time is at least 10 sec., preferably 20 sec. Especially in the immediate post-embolisation phase it can be difficult for the patient to hold his/her breath for that period of time and motion-artifact free images are difficult to obtain. For TIPS FP-CT can be useful in complex cases in which orientation by fluoroscopy or ultrasound is difficult.

We also found FP-CT helpful in bone-imaging, although it is only performed occasionally on our bi-plane equipment. We were able to obtain excellent images of the lumbar spine after intra-thecal contrast medium application as well as from the cervical spine, especially in the problematic region of the cervico-thoracic junction (Fig. 3 a,b).

In summary we found FP-CT a helpful additional imaging tool on our fluoroscopic C-arm system. However, it must be kept in mind that FP-CT is not supposed to replace conventional CT in the well established indications.

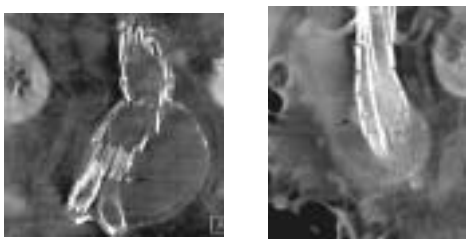

Figure 2a,b: Flat-panel-CT (FP-CT) after endoluminal treatment of abdominal aortic aneurysm.
a.) Non-enhanced FP-CT; coronal MPR: The relation of the stent-graft to the aneuysmal sack is nicely shown.
It can be well recognized that the iliac limb on the left side has been extended with a Wallgraft.
b.) Contrast enhanced FP-CT; coronal MPR: The alignment of the stent-graft in the neck and the relation to the renal arteries is well shown. However, a proximal endoleak can be seen (arrow).

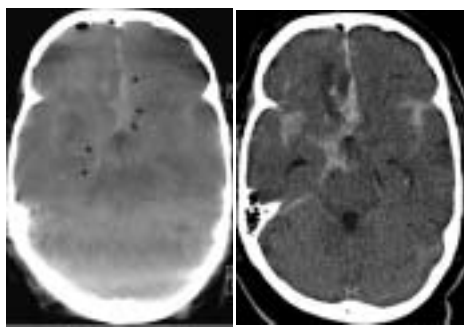

Figure 1a,b: Cranial Flat-panel CT (a) in comparison to conventional cranial CT (b)
in a patient with acute subarachnoid hemorrhage: Note the good correlation of the subarachnoid hemorrhage
in the anterior interhemispheric fissure and also in the parasellar region right (arrows). The hypodense area in
the frontobasal region also can be seen in FP-CT.

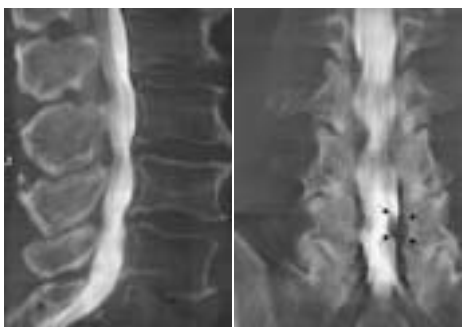

Figure 3a,b: Myelo-Flat-panel CT in a patient with left lateral disc herniation .
The herniated disc is nicely shown in the coronal MPR reconstruction (arrows).
Note the excellent display of bony structures.

Interview with Pascal Girin, President of ev3 International

Can you tell us what type of company ev3 is?

ev3 was founded with the idea to be very responsive to our customers' needs. We do this by meeting the specific needs of Peripheral and Neurovascular device segments, segments that we deem underserved by the large companies as they mostly focus on the coronary DES markets. ev3 aims to offer the coverage and services that customers appreciate from the large corporations to these segments, heavily investing in new product development specific to these underserved markets.
We have made fast progress towards meeting our objectives: In about 5 years we have reached a true global market coverage with a direct presence in the US, Europe, Japan and Canada and a representation through distributors and agents in the rest of the world. We have launched 25 new products since 2004 and 90% of our current revenue growth comes from products developed in the last 2 years. Finally, since June 2005, ev3 has been a public company (NASDAQ: EVVV).

Where does the name ev3 come from?

ev3 was named to signal our intent to work in all three segments of the endovascular market: cardiovascular (heart), neurovascular (brain), and peripheral vascular (the rest of the body). In reality at this stage, ev3 is much more focused on the latter two segments than in the cardiovascular one, for the reasons I just explained.

Do you develop and manufacture your products yourself?

Yes. Although ev3's foundations were built through a number of acquisitions, we have integrated all acquired technologies, and have improved them while rapidly developing our own new products. Today ev3's R&D and manufacturing is concentrated in two facilities, one in Plymouth, Minnesota, and the other one in Irvine, California. I must say that I am constantly impressed by the quality of our R&D team. These guys are really committed to leading innovation in our technology field, and our latest developed products reflect that. As an example, we have developed a 100-150mm stent, the PROTÉGÉ® EverFlex™ for stenting of the Superfical Femoral Artery. This is an artery that is exposed to tremendous compression, elongation and torsion forces. First generation stents are prone to fractures when exposed to these forces. The challenge was to develop a dedicated stent designed to address these specific demands of the SFA. Our development teams responded by designing the PROTÉGÉ® EverFlex™ stent. We tested the stent in rigorous simulated fatigue testing conducted by independent testing facilities and it demonstrated fracture resistance between five to ten times that of any of the other competitive stents tested. We have now also started the DURABILITY study, with Dr. Bosiers and Dr. Scheinert as Principal Investigators to confirm clinically the excellent bench data. Pretty remarkable for a young company!

What products do you offer in the peripheral arena?

You can divide our peripheral product portfolio into stents, embolic protection and procedural support. In fact, we offer a complete stent portfolio for peripheral interventions covering the carotid, renal, biliary, iliac and femoral arteries. Well known brands are the PROTÉGÉ® Rx for the carotid artery, the PRIMUS™GPS™ for the iliac applications and the PROTÉGÉ® EverFlex™ for the SFA. Products for embolic protection and thrombectomy are the SpideRX™ Embolic Protection System, and the X-SIZER Thrombectomy device. Examples of products for procedural support are the NITREX® and Aqwire® guidewires and Amplatz GOOSE NECK® Snares.

What products are most doctors interested in here at CIRSE?

There is a high interest in our products for Carotid Artery Stenting and SFA. For Carotid Artery Stenting, we offer the Protégé® Rx stent in straight and tapered versions with various lengths and diameters, along with the SpideRxTM, the only embolic protection system in the market that allows the operator to use his/her wire of choice to cross the lesion. Clinical studies conducted in Europe and the US (ProCar, CREATE I & II) have proven the outstanding safety and performance of these products.

Of course there is a lot of interest in our new PROTÉGÉ® EverFlex™ stent which I mentioned before. We offer it in 100, 120 and 150mm lengths to improve the long term outcome of treating the diffuse nature of the disease in the SFA. In addition to producing these long SFA stents, we are also working on introducing the EverFlex technology across our self-expandable stent line to include a soon to be released small diameter stent for below the knee applications.

What can we expect from ev3 in 2007?

As I've mentioned already, we are continually expanding our product portfolio in our focus areas. Therefore, organic innovation is the life blood of our company.
In 2007 we will continue to make incremental improvements in our existing products by making them more flexible, or smaller in diameter, so that physicians can treat vessels a little farther down in the leg or farther up into the brain. And of course, we will continue to launch new products. Just count on us in the future!

More curiosities about Rome

Truth and legend blend together in the Eternal City, especially when it comes to stories about masterpieces created by artists such as Michelangelo, Bernini and many others who throughout the centuries worked in Rome and left eternal evidence of their artistic talent.

Bernini and the Papal Altar

Even when it comes to St. Peter's Basilica truth and legend cannot be entirely separated. Of the millions upon millions of people who have seen the Papal Altar in St. Peter's, either in person or on television, only few are aware of the extremely moving human details that Bernini put into his work of art at the behest of pope Urban VIII during the second quarter of the seventeenth century. One documented story concerns a favorite "niece" of the pope, who experienced a difficult pregnancy. Since it appeared that both, mother and child might be lost, Pope Urban vowed that if his niece gave birth to a healthy child and she lived, he would bequeath an altar to the basilica.

The baby was delivered safely and the mother recovered. Commissioned to do the new altar, Bernini told the story of the pregnancy by using the escutcheon of the Pope's family (three bees on a field) as a focal point: The first coat of arms shows the head of the young woman above the field of bees; the three bees represent details of her body, and the ornaments below the field stand for her womb. On the base of the first column is the head of a young and healthy woman with a normal body. On the following coat of arms, Bernini depicted the changes in the pregnant woman and her suffering: her face is distorted with pain and her body has become quite large. The series ends with a coat of arms no longer crowned with the mother's head - instead there is the head of a smiling baby.If you do not believe this story, you should go and check for yourself.

The Broken Bridge

The so called Broken Bridge could be called a left-handed tribute to Michelangelo. In 1550, Pope Julius III asked Michelangelo to fix the span of the bridge, which had collapsed. When the artist explained that this would require an astronomical sum of money, Julius III turned the job over to another architect who had bragged he could do it cheaper and better than Michelangelo. However, in 1598 the bridge fell into the Tiber a second time, much to the Vatican's chagrin. Ever since then the bridge did not get repaired, its remains still standing in the middle of the Tiber river.

The sailor and the Egyptian Obelisk

The great Egyptian obelisk in St. Peter's square is one of Rome's landmarks, although it stands neither in Rome nor in Italy, but about ten yards beyond the Italian border. Back in 1586, when the obelisk was being drawn into St. Peter's Square by hundreds of horses and thousands of workers struggling with beams, ropes, and scaffolding, orders were that any spectator making even the slightest utterance would be sentenced to death. No noise should distract the lifting of the unwieldy 75-foot giant.

Soon the friction began to burn the ropes and it was certain that the obelisk would eventually fall. Suddenly a sailor, aware of what was happening and expert as to what needed to be done, disobeyed the order of silence at the risk of his life, shouting, "Throw water on the ropes! Throw water on the ropes!" This was done immediately and the workers finished the job without a mishap. As for the sailor, instead of being executed, he earned a papal reward - the right to supply St. Peter's Basilica with palms on Palm Sunday. His heirs still have the concession today.

The Bridge of the Four Heads

Ponte Fabricio, one of Rome's oldest bridges (going back over 2,000 years) leads to the Tiber's only island, the Tiberina, which is largely devoted to providing low-cost hospital care. This particular bridge is also known by another name - the 'Bridge of the Four Heads'. Behind that nickname is the true story of Pope Sixtus V (1585-1590) who commissioned four big-name architects to restore the Fabricio Bridges, which had undergone disrepair. During their work, the four men bickered constantly among themselves, a few times even coming to blows. Sixtus kept getting reports of the continuous fighting, but waited until the work was done to punish the querulous quartet. The penalty was severe; Sixtus had all four men beheaded on the bridge. Then, on the very spot where they lost their heads, Sixtus erected a monument to them - four heads carved out of one block of stone. 'Now', he said, 'for the rest of eternity, they are sentenced to a peaceful and quiet unity'.

Giotto's becoming a Vatican artist

The Vatican discovered Giotto because of a circle he drew. When the pope needed some artwork done in the Vatican, he accepted samples of drawings from many painters, but Giotto merely submitted a circle as his sample. He made the circle by dipping his brush into the paint, and then, while keeping his arm tightly against the side of his body, drew a perfect circle by manipulating his wrist. From the sheaf of drawings the artists had submitted, the pope selected Giotto, since he had instantly became aware of Giotto's amazing talent from the way the circle had been perfectly executed.

An artist's insult to a pope

The most lasting insult ever heaped on any pope is very visible in Rome until today. When approaching Porta Pia Square from the Via XX Settembre, you will notice three white relieves; one to the right, one to the left, and one in the center of the arch. Though they look like generic ornaments, they are in reality shaving bowls with a piece of soap inside, each draped with a fringed towel. The artist who created them did not like Pope Pius IV, who had ordered the arch to be built in 1546 following a design submitted by Michelangelo. The subtle joke of the three barbers' bowls was a wry reference to the humble background of the pope, whose ancestors were barbers. This amusing baroque trifle did not come to the attention of the Vatican until almost a century later.

Michelangelo and his joke in the Last Judgment

In the Last Judgment, Michelangelo's masterpiece in the Sistine Chapel, the artist left behind a marvelous private joke. While in the process of finishing the big painting, Michelangelo had been reprimanded by Biagio da Cesena, the papal master of ceremonies, because most of the figures depicted were unclothed. Michelangelo revenged himself by painting da Cesena's own likeness in a corner, showing him not only totally nude, but also with the ears of a donkey.

Bernini's optical illusion

Here's a tip about something 99 percent of the people who visit St. Peter's Square overlook completely: There are two black marble disks imbedded in the pavement, both of which are just a few feet from each of the fountains. Position yourself on one of the disks and cast your eyes on the four rows of Bernini colonnades - and you will only see one row, the front row. The other rows will magically disappear! Step off the disc, and three other rows of columns will suddenly return. This now-you-see-it/now-you-don't optical illusion is a mark of Bernini's mathematical genius.

Michelangelo and the statue of Moses

Due to what he considered two defects in his statue of Moses, Michelangelo did not want to offer the pope a work he personally had ambivalent feelings about. Therefore, the famous Moses masterpiece cannot be found in the Vatican, but in the Church of San Pietro in Vincoli. One of the "defects" is that Mose's head is too small in relation to the rest of his body, a proportion that Michelangelo did not intend. While the master sculptor was working on the head, he accidentally lopped off a large piece of marble and therefore had to fashion the head using the small segment that remained. When he finished the statue, however, Michelangelo was himself overwhelmed by the effect it had on him. So enraptured was he that he began to talk to it. One day he even yelled to it, "Why don't you answer me?". Provoked by the sculpture's silence, Michelangelo struck the statue sharply with his hammer, making a tiny chip in the right knee. Still visible today, it is one of the reasons why many curious tourists pay a visit to Moses.

Michelangelo's only signed sculpture

Michelangelo's famous Pietà marble statue of the dead Christ lying on his mother's knees, which graces the first chapel on the right inside St. Peter's Basilica, is the only work he ever signed. The young sculptor, 22 years old at the time, had overheard two travelers attributing his supreme masterpiece to a third-rate artist from Lombardy. Angered, he sneaked into the church one night and by candlelight chiseled a message on the diagonal band that crosses Mary's torso: MICHAEL. ANGELUS. BONAROTUS. FLORENT. FACIEBAT.(Translation: Michelangelo Buonarroti. Florentine. Made this.)

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Advertorial

HepaSphere™ Microspheres loaded with Doxorubicin - Early experience in Italy.

An Interview of Professor Maurizio Grosso
Azienda sanitaria ospedaliera
Santa Croce e Carle - Cuneo - Italy

Professor Grosso, a registry is being conducted in Italy using HepaSphere that are loaded with Doxorubicin or Epirubicin in the treatment of HCC. From your initial experience, can you tell us what patients are ideal candidates for this treatment?

In the registry we are conducting in Italy, using Doxorubicin-loaded HepaSphere, we have included patients with hepato-cellular carcinoma having less than 3 lesions, smaller than 8 cm in diameter, ideally located in the same lobe. All these patients are not candidates for surgical or percutaneous ablation. As a caution for this study (but it could be used for further evaluation outside of this study), patients with extra-hepatic disease have been excluded, as well as patients with portal vein thrombosis, although this last situation might not be an absolute contra-indication.

Can you describe your protocol and preparation method of the product?

We have preferentially used HepaSphere with size range of dry particles from 50-100 microns. Their expanded size range as indicated by previous in vitro evaluation is 200-400 micrometers.
In our early experience, we have prepared HepaSphere Microspheres using a 50mg Doxorubicin solubilised in 5ml NaCl0,9%. After injecting this solution into the HepaSphere vial, we waited 15 minutes for the spheres to expand and absorb the drug. Then we added 5 ml non-ionic isotonic contrast medium (Iodixanol - Visipaque 270 mg |/ml). The 10ml suspension of Doxorubicin-loaded HepaSphere was then aspirated in a syringe and used as a regular embolic to perform the procedure.
More recently, in order to simplify the mixture process as well as ease the handling of HepaSphere Microspheres this way, we have prepared the Doxorubicin solution directly in non-ionic isotonic contrast medium (Iodixanol - Visipaque 270 mg |/ml), by mixing 50mg Doxorubicin and 5ml of contrast. We inject this solution in HepaSphere vial and wait for 15 to 20 minutes. Then we add another 5ml of contrast and the Doxorubicin-loaded HepaSphere Microspheres are ready to use.
In both cases we have dispersed the Doxorubicin loaded HepaSphere Microspheres using an additional volume of contrast to get a final 20ml suspension. We have also used Epirubicin, which can be handled the same way. HepaSphere Microspheres are easy to prepare and they can be mixed using either a contrast media solution or NaCl0,9% solution. However, it is important to never use pure water for reconstituting the dry HepaSphere Microspheres as their expansion rate would be higher and the microspheres would be difficult to handle.
Embolization is then performed injecting the suspension not too distally and very slowly, to avoid a premature occlusion of the feeding artery of the tumours and to allow the spheres to travel to the hypervascularized tumour. The endpoint is reached when complete embolization of the pathologic vascularisation is obtained.

How many patients have been treated and what are the early results?

From December 2005 to July 2006, four centres in Italy (Cuneo, Milano, Pavia and Pisa) have enrolled 30 patients with HCC, according to the inclusion criteria mentioned earlier. Follow-up has been performed using CT scan and biological examinations at 1, 3 and 6 months following treatment. No major complications have been observed except a mild pancreatitis, which resolved with medical therapy. Although our experience is limited, post-embolization syndrome as well as usual chemotherapy side effects, seem to be less severe than after conventional TACE performed with Lipiodol plus chemotherapeutic agents.
Even though a longer follow-up is mandatory, preliminary data suggest promising results, with complete necrosis in at least 50% of the tumours. In case of non-complete response, additional treatment can be performed without difficulties.

What are the benefits and outcomes for your patients with HCC?

Our early experience of embolisation using Doxorubicin-loaded HepaSphere Microspheres for the treatment of HCC, has demonstrated feasibility, low complication rates as well as promising efficacy.
The prolonged term contact between drug and tumour should bring additional efficacy and reduced adverse effects of the chemotherapeutic agent compared to standard TACE.
In this registry, we used a 50mg Doxorubicin or Epirubicin dose but, based on the results from previous tests, higher doses of drugs can be loaded into the microspheres. Also an advantage of this material is that it can be used with other drugs as demonstrated by previous in vitro studies, although we don't have any clinical experience of this association yet.

Sanjiv Sharma
President of the Indian Society of Vascular and Interventional Radiology

Dear Colleagues,

On behalf of the Indian Society of Vascular & Interventional Radiology (ISVIR), I thank Johannes Lammer and the CIRSE Members for inviting the Indian society to this meeting and making the "CIRSE 2006 meets India" session possible. We, the members of the Indian society, are grateful for this honour. It is my great pleasure to introduce this session and the Indian society.

"CIRSE meets India" will begin with a brief introduction to the Indian society and its activities, followed by presentations on three key areas in interventional radiological practice in regionally relevant disease states, including Takayasu's arteritis, Budd-Chiari syndrome and tubercle-related hemoptysis. The session will end with a short presentation on cutting edge research in Cardiovascular and Interventional Radiology in India. I take this opportunity to invite you all to attend this exciting session, exchange ideas and help develop and strengthen our mutual relationships.

The practice of Cardiovascular and Interventional Radiology (CVIR) in India began in the early 1970s at a few isolated centres providing tertiary care. Non-availability of hardware and trained personnel, lack of familiarity with techniques and mismatched facilities were major obstacles to its growth. The society in its present shape was established on November 7th, 1997 with 28 founder members.

Since then, we have come a long way. Today our society has over 350 members and a nation-wide network of state branches & zonal chapters. It performs many activities, including monthly local, quarterly zonal and annual national level scientific meetings, 2-3 regional CME programs on topics of local interest every year, a quarterly newsletter, public awareness programs on locally relevant subjects in different regions, short-term training fellowships and the maintenance of an interactive website. We are the only national society in the world to conduct a comprehensive, web-based annual national registry of interventional radiological procedures which we initiated in 1999. The society has also been actively working with the industry to address the issues related to availability, pricing and governmental policies for custom clearance of various devices.

CVIR is at a cross-roads in India today. There are perpetual shortages of equipment and hardware which is either not available or mismatches our requirements. Most products are still imported, the prices are steep and do not match to the average per capita income. Indigenization of technology and local production are essential to bridge the above gap. There is also a lack of trained manpower. Furthermore we face turf issues with various other sub-specialists, including those from cardiology, neurology and vascular surgery.

Despite above issues, there is a tremendous scope for the practice of Cardiovascular and Interventional Radiology in India. The number of centres regularly practicing CVIR has grown from 14 at the time of inception of ISVIR to over 50 today. Our members perform all state-of-the-art techniques available anywhere else in the world and participate in cutting edge experimental and clinical research, alone and in collaboration with other national and international institutes. Some key areas of recent research include gene therapy in vascular disease, stem cell therapy in various disease states, synthetic venous valves, newer options in vascular recanalisation and evolving concepts in endovascular reconstruction, among others. CVIR in India is strategically poised for growth.

The ISVIR is honoured to be represented in Rome on this occasion. I take this opportunity to invite all delegates and members of the European and other participating societies to a presentation of work in progress and the cutting edge research in India. On behalf of the Indian society, I express my gratitude to the organizers for this opportunity to share our work with all of you and hope that you enjoy the experience.

CIRSE Meets India

The "CIRSE meets…" sessions, introduced at CIRSE 2005, aim at establishing and further developing relations between CIRSE and IR societies from overseas. After the success of last year's "CIRSE meets Korea", CIRSE will meet the Indian Society of Vascular and Interventional Radiology at this year's meeting.

The ISVIR has put together an extraordinary session which will give an overview of the current status of its work in three especially chosen, regionally relevant, disease states as well as its ongoing research. Sanjiv Sharma, the Indian society's president, who will be the chairman of the session, invites all congress participants to attend this meeting and gain an insight into Interventional Radiology in India.

CIRSE meets India
Sunday, September 10, 12:30-13:30
Aula Magna

ISVIR - Objectives, activities and current status
A.K. Gupta
Current concepts in the management of IVC and hepatic vein occlusion
S. Punamiya
Interventional radiology in the management of tubercle induced hemoptysis
M. Cherian
Endovascular management of symptomatic lesions in nonspecific aortitis
S. Sharma
Current status of IR research in India
J. Venkateshwarulu

The SFA: a problem without solution?

Dierk Vorwerk
Professor and Chairman of the
Department of Radiology,
Klinikum Ingolstadt, Germany

For surgeons, as well as for interventional radiologists, the superficial femoral artery (SFA) is a territory of lost illusions and hopes when a new treatment option is introduced, whether it might be atherectomy, freezing balloons, nitinol stents or laser. With every new technique many interventionists convince themselves that they have found the ultimate solution, neclecting the fact that there has only been limited improvement despite of great technical refinery. They dream of successful and durable treatment of long and calcified occlusions from the groin to the knee, for which some patients have to pay by wearing 20 cm of metal tubes in their legs. Clinical reality is still somewhat frustrating.

Coming back to our topic, the SFA is a peculiar vessel. It is very long, flexible, twisted and stretches thoughout its life. Nevertheless it is not the most important artery in the leg. This title goes to the profound femoral and maybe to the peroneal artery, but certainly not to the SFA. If it is the only occluded vessel, it rarely means any danger for the limb. It is rather discomfort that results from its occlusion. A society that is forced to be careful with its resources probably would not count claudication as a disease, while a society that is life-style-oriented certainly will. One solution to solve the problem would be to ignore the SFA in claudicants, as it does not cause much harm. This attitude of course does not meet the interests of interventionists, who are eager to develop successful concepts for this challenging territory and treat patients who do not only have an occluded SFA, but depending lesions in the subpopliteal arteries or patients in stage IV who need an improved blood supply to a heavily diseased infrapopliteal vasculature.

Endovascular vs. surgical treatment

Endovascular therapy is known to be of low invasiveness, with good technical success and a fair overall patency. In femoropopliteal endovascular interventions (taken from 8 publications reporting on 1469 procedures), the weighted average technical success was 90%, the complication rate was 4.3% and the 3-year patency rate was 51%. Stents did not improve patency showing a 3-year patency of 58% after 3 years (1). Surgery offers acceptable results for distal reconstruction; an average 5-patency of 80% for vein bypasses and 65-75% for ePTFE bypasses has been reported. Combined mortality and amputation risk was calculated to be about 2.2 % for aortobifemoral reconstructions and 1.4% for femoropopliteal reconstructions (1).

Type of lesion

The morphology of a treated lesion will influence the technical outcome, follow-up results and risk of treatment. The TASC document therefore introduced a classification system which tries to categorize lesions with regard to their accessability to either percutaneous treatment or surgery. Type A lesions are those ideal for percutaneous approach. For type B lesions a percutaneous approach is still the preferred technique. In type C lesions a surgical approach should be preferred. Type D lesions should only be treated with surgery.

In the femoropopliteal field, type A lesions are single stenoses up to 3 cm in length not involving the very proximal superficial femoral and the distal popliteal artery. Type B lesions are stenoses 3 -5 cm in length, heavily calcified stenoses, multiple lesions (each up to 3 cm) and lesions with insufficient tibial run-off (the latter are unlikely to meet the criteria of mild or moderate claudication). Type C lesions are classified as stenoses or occlusions longer than 5 cm and multiple mid-size lesions (3-5 cm). Total common femoral, superficial femoral and popliteal occlusions are classified as type D lesions. The definition of type B lesions involved many a discussion, since interventional radiologists represented by CIRSE were of the opinion that even longer lesions of up to 10 cm may be classified as type B rather than type C lesions. They argued that the results reported are mainly due to underdeveloped techniques and instruments which have majorly improved in the meantime and that there is no evidence comparing efficacy of PTA versus bypass surgery for lesions between 4 and 10 cm.

Other than in the iliac area, less femoral lesions will meet the criteria of type A and B lesions especially if they are limited to 5 cm in length. Thus fewer patients with mild and moderate claudications due to femoropopliteal lesions will be considered ideal candidates for percutaneous treatment. The TASC document certainly means a step forward in the joint approach to peripheral vascular disease. Nevertheless it must be said that the morphological classification does not take into account some technical considerations regarding the age and composition of a lesion. Particularly in femoral occlusions the degree of organization of the occluding thrombus or the composition of the lesion with the original stenosis at proximal and distal end or in the middle are factors that are not easily predictable, but may influence the technical outcome of the intervention. They might also have an impact on its complication rate, i.e. distal embolization, which might cause an aggravation of symptoms.

Other than in the iliac arteries, liberal use of stents and stent grafts may help to overcome a failed balloon angioplasty and solve the technical outcome of a procedure. Nevertheless it does not achieve an improved long-term efficacy and might initiate a life-time dependency on recurrent interventional or surgical procedures. These associated potential drawbacks have to be carefully balanced against the potential benefits and need to be discussed in depth with the patient before treatment is performed, especially in association with mild or moderate claudication. These considerations mainly restrict use of endovascular treatment in femoropopliteal lesions to stage II b and II a patients with type A and less pronounced type B lesions.

Assisting forms of treatment

It is widely accepted that well-conducted physical exercise should precede any type of interventional treatment. Furthermore cessation of smoking is mandatory. Nevertheless, it is also true that in many institutions it is most difficult to find an infrastructure allowing to teach state-of-the-art physical exercise in claudicants. As far as smoking is concerned, there is a major difference between wanting to quit and actually doing it. Moreover, even with state-of- the-art exercise young patients will not recover completely from claudications in all of their activities, including sports. The process will be longer and compromise their abilities in their professional lives. It should therefore be discussed whether especially young and active patients should be vigourously put under the axioma of "physical exercise first" or whether in this group of patients invasive treatment should be the first choice.

Treatment options with relation to location and lesion

Treatment of femoropopliteal lesions in claudicants has to be regarded more critically than treatment of the iliac region. The main reasons are less favorable technical success, a higher complication rate and poorer long-term success. There are many more lesions in the femoropopliteal arteries that do not meet the criteria which make them well suited for endovascular treatment. On the other hand, the versatility of endoluminal techniques results in treatment options for many particular lesions. Using clinical symptoms as the only criterion to indicate or to exclude treatment is not appropriate, since depending on the type of lesion a simple and limited intervention could mean a considerable improvement for the patient.

Additional morphological factors (not included in the TASC classfication)

Femoropopliteal occlusions are particularily prone to becoming a source of complications, especially if they are recent. Simple PTA may result in a downward embolization of occlusion material that may aggravate the symtoms and even become limb-threatening. Even in short occlusions PTA may be insufficient to reopen the vessel. Additional treatment might be necessary, such as stent placement. Reobstruction of stents however is more difficult to treat compared to simple restenosis. Eccentric calcified stenosis is often treated insuffifiently. Since stenting is a technical, but not necessarily a long-standing solution to such lesions, alternative techniques such as atherectomy may be considered if available. Unfortunately those niche techniques are difficult to establish on the market due to the costs involved.
Therefore, some well-advanced devices, such as the Simpson atherectomy catheter, have been withdrawn from the market.

Techniques

Balloon angioplasty

Balloon angioplasty remains the working horse in femoropopliteal lesions. Modern angiographic units allow a quite exact measurement of the true arterial diameter. By use of semicompliant balloons, adaptation to the diameter is performed well. We prefer not to grossly overdilate the artery in order to avoid dissection. Preferable dilation times of 1 to 3 minutes are achieved by using pressure gauges.
Balloons with a length of 2 to 4 cm are mainly used. In case of major dissection, the first first thing to try in order to improve the result is prolonged balloon dilatation over 4 to 5 minutes. In many cases the result will be improved by this cost-effective and simple approach.
Analyzing subgroups after femoral PTA, Huninck and Wong found different patencies for patients with stenotic and occlusive femoral lesions (62% versus 48% after 5 years) and good run-off as well as poor run-off (stenoses: 62% versus 43% after 5 years; occlusions: 43% versus 27% after 5 years) (4).

Stent placement

Use of all types of stents should be limited to cases in which balloon angioplasty in all its variations did not achieve sufficient results. This is particularly true for occluding dissections other than in the iliac field, where stents should not be used liberally. The stented segment should be as short as possible. The overall results of femoral stenting were disappointing with older types of stents; other than in the coronaries drug-coated stents did not prove to be superior to uncoated nitinol stents. Surprisingly flexible nitinol stents showed a much better patency as older stent types, which is reason for cautious hope. The results however do not justify a liberal policy regarding the general use of stents in the SFA.

Stent grafts

Stent grafts still play a limited role in the femoropopliteal field. In a multicenter trial ePTFE-covered self-expanding stent grafts like the Hemobahn device (Gore Inc., Flagstaff AZ) yielded promising results even in the femoropopliteal field. This stimulated hopes for a percutaneous alternative, especially for those patients presenting with long femoropopliteal occlusions. Nevertheless there is also a risk of midterm or late rethrombosis. Below the inguinal ligament, only ePTFE covering should be used, since it has shown much less tendency to induce neointimal growth compared to Dacron covering in animal experiments. Other than in extraluminal bypasses, trans-covering growth of tissue has been demonstrated, probably due to the long-segement wall contact between stent graft and the original vascular lumen (2,3). However, a considerable disadvantage of stentgrafts is that often important collaterals have to be covered by the full body of the stent graft. In case of reocclusion, these collaterals will not be available anymore, which might cause an aggravation of symptoms. This is particularly true for the popliteal artery, where the development of compensating collaterals is limited. Therefore we favor limiting their use to the proximal two thirds of the superficial femoral artery, especially in claudicants.

Other treatment modalities

Cutting balloons, freezing balloons and new atherectomy devices have been introduced into clinical practice. Cutting balloons have been used in small series and case reprts and may be an important technical tool in resistant stenoses, which are rare in the SFA, or anstomotic strictures. Freezing balloons and new atherectomy devices have been introduced with a lot of enthusiasm, but no randomized data exist comparing it to PTA and/ or stenting.

Complications

The nature and quality of complications in femoropopliteal arteries do not differ widely from the aortoiliac area. They include dissection, perforation and embolization of occluding material. With stents the risk of early thrombosis was a problem in the very beginning, but became rare since the combined treatment of modern antiplatelet drugs. In occlusions the risk of embolization of occluding material is the most dramatic complication. Aspiration embolectomy in combination with selective thrombolysis is the treatment option of choice. Especially in claudicants, its risks must therefore be proportionate to its potential benefits.

SFA thrombosis

Other than in chronic atherosclerotic disease, whose treatment aims at a durable success, acute occlusion of the SFA asks for a quick and technically convincing result. For this reason, especially mechanical thrombectomy has added a major improvement over the last years allowing relatively safe and timely removal of clots even from long segments of the SFA.

Conclusion

The SFA remains a challenging territory and although many methods exist that allow a good technical outcome even in difficult lesions, we still lack data to prove their durable and long-standing success. Interventional radiologists should therefore be careful when choosing a technique, taking into consideration whether their treatment might complicate a surgical alternative. They should be courageous enough not to treat a patient if the clinical severity of the disease does not justify risking a complication.

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Advertorial

Clinical benefits of flat panel 3D rotational angiography in vascular interventions

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C. Felix, P. Gobert, GE Healthcare, Buc, France

Background
The University La Sapienza in Rome is amongst the first hospitals in Europe equipped with the Innova 4100 digital flat panel angiography system. The Innova 4100 system installed by GE Healthcare has a 40 cm x 40 cm digital detector designed to perform general vascular interventional procedures, and an integrated multi-modality Advantage Workstation.

Flat panel Innova 3D, introduced in 2005, has radically changed the concept of just morphological analysis of vessels and moved closer to CT imaging, with un-subtracted cross-sectional display of soft-tissue, bone, plaque, thrombus and devices as well as the typical volume rendering of vessels.

Case 1 : Bilateral Iliac stenting

Case History
A 45 year old female, with high risk factors including diabetes and smoking, suffers from claudication and is unable to walk more than 50 m without pain. A bilateral stenosis of the common iliac arteries is diagnosed by MRA and Doppler ultrasound.

Procedure details
The patient is programmed in the angio suite for endovascular treatment. A pre-therapeutic Innova 3D angiography is realized in order to enable the optimal choice of the stent. A 5-second 3D rotational angiography is performed with the injection of 40 ml of contrast media at 6 ml/s (fig. 1).

Fig. 1 Volume Rendering showing stenosis

Discussion and conclusion

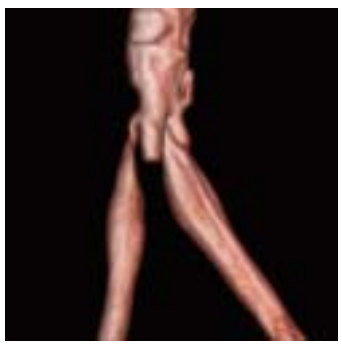


Fig. 2 Volume rendering of aorto-iliac bifurcation

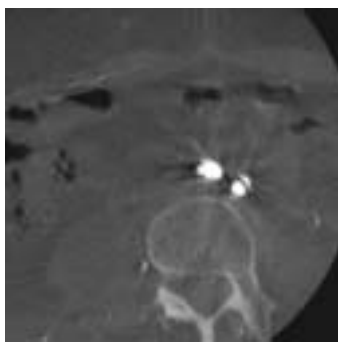


Fig. 3 0.4 mm axial slice showing iliac arteries

The complex morphology of the stenosis on both iliacs at the aorto-iliac bifurcation (fig. 2) is clearly visualized. The stenosis on the right iliac is evaluated at 30% and on the left iliac at 90% (Fig. 3).
The patient undergoes angioplasty with the kissing technique, where two balloon expandable stents are positioned, an Omnilink 8x38 mm in the left common iliac and a Palmaz Genesis 7x29 mm in the right common iliac artery.

Fig. 4 Volume rendered image post-stenting

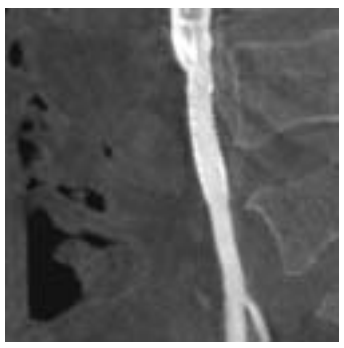


Fig. 5 Curved view of left iliac with stent

At the end of the procedure, an Innova 3D rotational angiography acquisition is performed in order to verify the deployment of stents in both iliac arteries (fig. 4). The reconstructed curved views show that the stents are correctly positioned and well deployed from their proximal to distal parts (figs. 5, 6, 7).

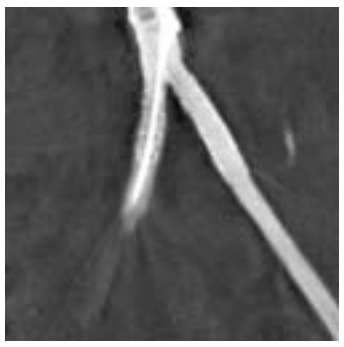


Fig. 6 Curved view showing both iliacs

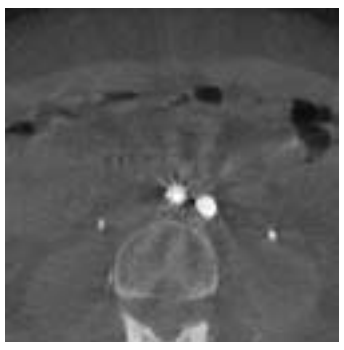


Fig. 7 0.4 mm axial slice of iliacs post-stenting

Innova 3D provides simultaneously high resolution images of complex pathologies and the cross-sectional images showing the relation to soft tissues, bones and devices. This comprehensive clinical information provided is of great use for pre-therapeutic decision on the choice of device and for post-procedure control of stent deployment within the angio suite.

Case 2 : Mesenteric carcinoma

Case History
A 75 year-old female with episodes of blood loss in her medical history. In February 2006, she underwent a colonoscopy that was stopped at 30 cm to anal margin for presence of blood and clots. A couple of days later, she had a new episode of bleeding from the rectum.

Procedure details
The patient is sent for angiography. No source of bleeding is seen, but an area of intense vascularization near to the caecum is detected. An Innova 3D rotational angiography is performed in order to clearly visualize and analyze the complex pathology.

Discussion and conclusion

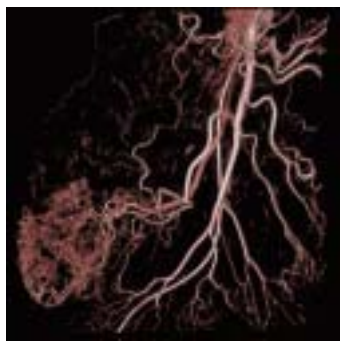


Fig. 1 Volume rendering of mesenteric artery

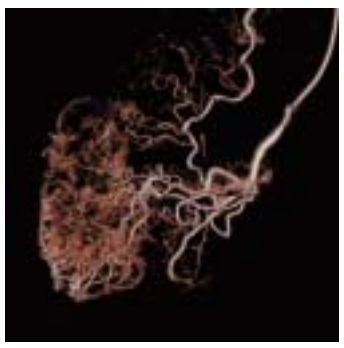


Fig. 2 Volume rendering of tumour

The Innova 3D images clearly show the complex angioarchitecture of what is believed to be a solid tumour in the ileocolic branch of the superior mesenteric artery (Figs. 1, 2). The 3D and the cross-sectional views are used to measure the tumour size and identify the feeding arteries (Figs. 3, 4 and 5).

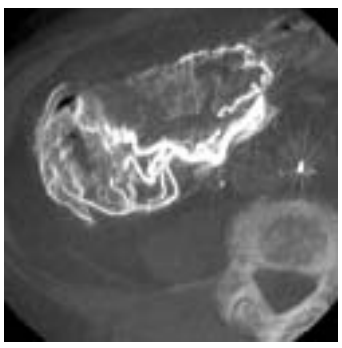


Fig. 3 Axial slice showing tumour

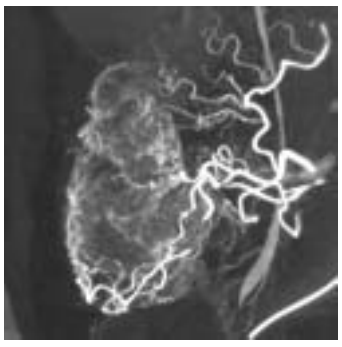


Fig. 4 Coronal slice showing tumour

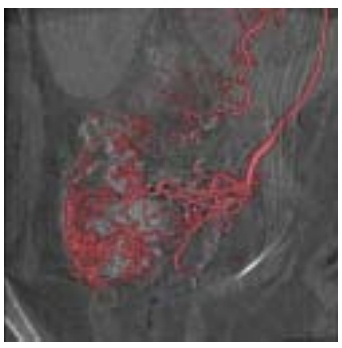


Fig. 5 Fusion of 3D vessels and cross-section

Following this diagnosis, the patient underwent surgery with right emicolectomy and ileo-transverse anastomosis. The histological analysis showed the appearance of colonic adenocarcinomas.

For oncology procedures involving the diagnosis and treatment of carcinomas with complex angioarchitecture, Innova 3D is extremely useful in locating the multiple feeding arteries and evaluating the extent of the tumour with respect to soft tissues visualized in the cross-sections.

Alfimeprase: A key to rapid clot lysis in acute peripheral arterial occlusion?

Advertorial

Dr Steven R Deitcher, Vice President, Medical Sciences, Nuvelo, Inc.

When acute peripheral arterial occlusion (PAO) occurs, rapid intervention is necessary to restore blood flow, ease pain and reduce the threat of compromised limb viability. Acute PAO (also referred to as 'leg attack') occurs after a clot forms in the arteries or in a bypass graft, which blocks blood flow to the limbs. It is usually the result of underlying peripheral arterial disease, in which chronic fatty plaque build-up leads to restricted blood flow and clot formation, which manifests as an abrupt onset of pain. If blood flow is not restored, acute PAO can lead to permanent nerve and muscle damage, gangrene that may necessitate limb amputation, or, in severe cases, death.

Limited treatment options for acute PAO

Approximately 200,000-300,000 people each year suffer from acute PAO worldwide and there are currently no approved pharmacologic therapies for treatment. Open vascular surgery is the standard of care, but is invasive and associated with increased risk of cardiovascular morbidity and mortality.

Although thrombolytics, such as plasminogen activators (PAs) are used, they require prolonged infusions of 24-36 hours on average, thereby delaying the restoration of blood flow and often necessitating admission of patients into intensive care units (ICUs). This delay in clot lysis may lead to increased risk of permanent limb damage and bleeding complications, including intra-cerebral hemorrhage (ICH).

Mechanical devices used to treat acute PAO are invasive, require specialist training and equipment, and can be associated with safety issues such as vessel trauma and distal embolization.

Why another thrombolytic?

Alfimeprase is a novel, recombinant, direct-acting fibrinolytic with a different mechanism of action to that of PAs. By degrading fibrin directly, and thus not requiring activation of plasminogen, it is capable of rapid clot lysis. In vivo studies have demonstrated that thrombolysis with alfimeprase is up to six times more rapid than with selected PAs.

Importantly, alfimeprase can be delivered at the site of the clot, and its activity is localized to the site of delivery. Once alfimeprase enters the circulation, it is rapidly inactivated by alpha-2-macroglobulin, a highly prevalent mammalian protease inhibitor in the blood, which forms a macromolecular complex with alfimeprase. This mechanism of inactivation prevents the development of a systemic "lytic" state.

Importance of this direct mechanism of action?

In a phase II clinical trials, alfimeprase has demonstrated rapid restoration of arterial flow within 4 hours of initiation of administration, and has the potential to be associated with minimal bleeding risks. Therefore, patients may benefit from a reduced length of time in hospital, limited ICU admissions, as well as a more rapid reduction in pain with minimally invasive treatment.

Clinical outlook for alfimeprase

In phase II clinical studies, alfimeprase demonstrated rapid and effective thrombolysis, with up to 60% of patients achieving restoration of arterial blood flow within 4 hours of initial dosing. Alfimeprase was generally well tolerated, with no incidence of ICH at 30 days, and up to 69% of patients avoiding the need for open-vascular surgical intervention.

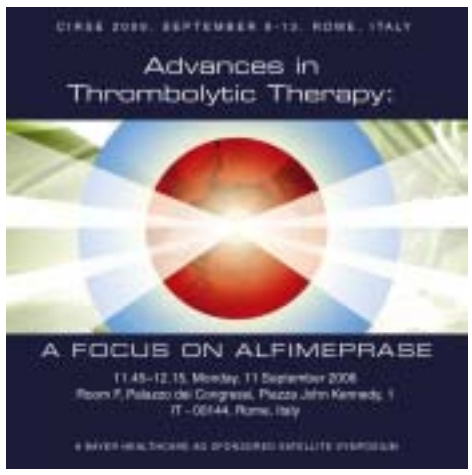
Novel Arterial Perfusion with Alfimeprase (NAPA) is an ongoing phase III clinical development programme in acute PAO, and has received fast-track designation from the FDA. The programme comprises two randomized, double-blind, multi-national trials, comparing 0.3 mg/kg alfimeprase with placebo, in a total of 600 patients. The primary endpoint of these two studies is the avoidance of open vascular surgery within 30 days of treatment.

Alfimeprase is also in phase III development for venous catheter occlusion (CO). Encouraging results from phase II studies in venous CO have been obtained, in which restored patency of occluded catheters was demonstrated in 50% of patients within 15 minutes after the first dose of alfimeprase.

Alfimeprase may also be indicated for the treatment of a wide variety of thrombotic conditions, including stroke, deep vein thrombosis (DVT) and myocardial infarction. Studies investigating alfimeprase are due to be initiated in stroke and DVT patients in 2006 and 2007, respectively.

Future directions

Recombinant, direct-acting fibrinolytic agents capable of rapid clot lysis present exciting potential for the future of acute PAO treatment. Alfimeprase represents the first of a new therapeutic class of fibrinolytics and has orphan drug status in both the US and Europe for acute PAO.



Advances in Thrombolitic Therapy:
A Focus on Alfimeprase
Monday, September 11, 2006
11.45-12.15, Room F