

Five reasons why IRs need to be part of any stroke team

Andreas Mahnken (EBIR)

Stroke is one of the leading causes of death, with an estimated 795,000 strokes per annum and 200,000 deaths annually in the US alone. It has a huge socio-economic impact. Ischaemic strokes represent roughly 80% of the total. Currently, only roughly 10% of patients receive immediate treatment, demonstrating a strong need to build up stroke units and stroke teams. Interventional radiologists with experience in neuro-imaging and intervention should be an integral part of these stroke teams and should be with the patient from the first minute. There are at least five reasons to support this claim:

1) Imaging is an extension of the clinical examination in stroke patients!

Injured but salvageable brain tissue cannot be discerned from irreversibly injured brain by means of a clinical examination. Brain imaging thus became an indispensable extension of the clinical examination. However, imaging in clinically suspected stroke is complex. Although simple unenhanced CT to exclude intracranial haemorrhage suffices to initiate intravenous lysis, diagnostic imaging has more to offer. The multimodal imaging approaches permit the detection of small infarcts and high resolution imaging of the intra- and extracranial vessels.

However, images of the brain and its vasculature need to be interpreted in the clinical context, as there are sometimes only subtle changes indicating critical pathology. Although most institutions have standardised CT and/or MR imaging protocols comprising morphologic and functional imaging aspects, there is a tendency towards individually tailoring specific components of the imaging protocol towards the clinical question.

Modern stroke imaging focusses on the detection of the ischaemic penumbra, the area that can be salvaged by revascularisation therapy. Some groups have even suggested overcoming the strict time windows for initiation of any revascularisation therapy and tailoring any therapy on the volume of brain tissue that might be salvaged by reperfusion. With multimodal imaging being an extension of the clinical exam, presence of a radiologist is mandatory in any stroke team.

2) Interventional radiologists will optimise diagnostic algorithms!

Interventional revascularisation has become a cornerstone in the management of acute stroke. Although only 7-15% of strokes may be suited for interventional therapy, this still holds the potential for 58,000-120,000 interventions per year in the US alone. Optimal decisionmaking on treatment, including the planning of the actual procedure, whether interventional, medical or surgical, is based on dedicated imaging protocols which are tailored on the individual clinical question. In fact, imaging has become an overall approach towards patient management in stroke. The IR is the single person who holds the competence in diagnostic imaging and interventional therapy and therefore is a key player in any stroke team.

3) Interventional radiologists perform best in interventional stroke therapy!

Interventional radiologists are the group with the most extensive and most regular experience in supra-aortic and intracranial interventions. In comparison with other nonradiologist groups of physicians, it has been shown that interventional (neuro)radiologists have the lowest complication rates in

carotid stenting. Were similar principles to be applied to cerebral interventions, similar outcomes would be expected.

Moreover, there are a variety of different techniques and devices available. To achieve optimal results, the right device has to be selected and sufficient experience with that device is needed. Thus IRs, ideally specialised in neurointerventions, need to be part of the stroke team, as they are the ones who most safely provide interventional therapy.

4) Interventional radiologists save brain if part of the stroke team!

"Time is brain" is a well-founded and generally accepted concept in stroke therapy. There are currently time windows of 4.5 hours for i.v. lysis and up to 8 hours for mechanical revascularisation. Still, the sooner therapy is initiated the more brain tissue may be salvaged. Thus early therapy requires rapid decision making based on competent realtime image interpretation and immediate start of therapy. Both of these are key competences in stroke management, which interventional radiologists can best provide. In order to minimise delay, interventional radiologists need to be part of the stroke team starting from the first minute.

5) Radiology is a driver of the future success of any stroke team!

Actively developing diagnostic and interventional methods is a core competency of interventional radiologists. Thus, their value in a stroke team reaches beyond diagnosing stroke and treating selected patients. They are the ones providing and continuously reinventing the basis for any stroke therapy.

Don't miss it!

Intra-arterial stroke management **Hot Topic Symposium** Sunday, September 15, 15:00-16:00 Room 116



Andreas H. Mahnken

Marburg University Hospital Marburg, Germany

Alongside his clinical interest in stroke diagnosis and therapy, Prof. Andreas Mahnken specialises in vascular interventions and tumour therapy. He is currently Chair of Radiology and Director of the Clinic for Diagnostic and Interventional Radiology of the University Clinic of Marburg.

Prof. Mahnken holds both MBA and MME degrees, and has authored or co-authored more than 300 peer-reviewed journal articles and book chapters on diagnostic and interventional radiology, as well as holding several patents. He has served on the CIRSE Standards of Practice Committee and is currently part of the Vascular Division of the ESIRonline Editorial Board.

Considering the huge gap between technical and clinical success in several studies on interventional thrombectomy, scientific advancements (e.g. in terms of patient selection) are needed. Otherwise some promising interventional approaches may prove futile. Therefore, interventional radiologists are a driver not only in the current application, but also in developing stroke teams into the future.

In short, the management of acute stroke is rapidly developing. IRs are an asset to any stroke team as they make the difference in diagnosis and state-of-the-art therapy.

Stroke Therapy Training – how and why CIRSE is involved

Tochi Ugbor, CIRSE Office

Interventional radiologists are playing an increasingly important role in stroke therapy. Indeed, numerous studies have already proven that IR stroke treatments such as intra-arterial thrombolysis and mechanical thrombectomy are both safe and effective when properly implemented. On examining these studies, it becomes clear that proper training is a key determining factor for the efficacy of the treatments, as practitioners require a highly advanced skill-set. CIRSE is dedicated to raising awareness of the need for better training, as well as providing IRs of all levels of expertise with valuable stroke therapy-related sessions during the annual congress.

The need for training guidelines

In a white paper published in CVIR earlier this year, IR experts Michael Lee (CIRSE President), Jim Reekers and Dierk Vorwerk express CIRSE's position regarding stroke therapy. The document highlights the importance of adequate training, emphasising the "... direct correlation between skill level and outcome for intra-arterial stroke therapy" and foreseeing the need for more IRs to be trained to meet increased future demand. The article argues that despite the different stroke therapy guidelines that exist, "...training standards and guidelines have been less rigorously elucidated" and a "European multisociety consensus on training guidelines is highly desirable in the very near future so patients can receive high quality and safe care."

False evidence presented in Stroke journal

Earlier this year, a flawed attempt was made to create a European training charter for interventional neuroradiology by the Neuroradiology Division of the European Union of Medical Specialists (UEMS). The charter, published in the journal Stroke¹, contains numerous anecdotal statements, little concrete evidence and false claims of having been approved by various European societies. In addition, the charter makes no reference to interventional radiology, despite assertions of being an "inclusive document".

CIRSE, along with the European Society of Radiology (ESR) and the European Society of Neuroradiology (ESNR), subsequently wrote a letter of concern to the Editor, which was also published in the journal². While so far only a reply letter has been written in response³, it still remains to be seen which further steps the journal will take to correct the false information presented in the article.

Stroke therapy at CIRSE 2013

Since the introduction of a neurointerventions track at the CIRSE Annual Congress in 2010, interest in the topic has continued to grow and new neurointerventions sessions have been added each year to meet the increasing demand. Neurointerventions will feature at CIRSE 2013 again, with a range of innovative sessions on offer to suit all levels of expertise. Foundation Courses will offer key tips for the novice and experts can get advanced information on topics such as "carotid and vertebral artery intervention" and "preventative stroke management" in the Special Sessions on offer. Workshops and interactive case sessions will provide attendees with a more a hands-on experience in stroke therapy and a Hot Topic Symposium entitled "Intra-arterial stroke management - should this be an IR procedure?" will provoke lively debate.

Access the CVIR white paper on intraarterial stroke therapy, free-of-charge, by logging into myCIRSE on www.cirse.org

- ¹ Flodmark et al., Stroke; 2012:43:2810-2013
- ² Lee et al., Stroke; 2013;44:e46
- ³ Flodmark et al., Stroke; 2013;44:e47-e48

Neurointerventions Track

Saturday, September 14

10:00-11:00, Room 111

SS 203

Special Session

Preventative stroke management Moderators: S. Cekirge (Ankara/TR), T. Engelhorn

(Erlangen/DE)

What we know about atherosclerotic plaques: non-invasive morphologic imaging A.H. Mahnken (Marburg/DE)

Prevention of imminent or recurrent stroke with medical therapy or non-radiologic intervention H.S. Markus (London/UK)

Extracranial stenting: indications and techniques A. González García (Sevilla/ES)

Intracranial stenting: indications and techniques C.P. Stracke (Essen/DE)

16:15-17:15, Room 111

WS 607

Workshop

Revascularisation tools, tips and tricks in stroke management: case-based discussions R. Chapot (Essen/DE), W. Kurre (Stuttgart/DE)

17:30-18:30, Room 132

WS 707

Workshop

Fundamentals of intracerebral aneurysms and AVM treatment

M. Piotin (Paris/FR), C. Cognard (Toulouse/FR)

Sunday, September 15

08:30-09:30, Room 113

FC 901

Foundation Course

Stroke management 1: how I do it

Moderator: A.D. Platts (London/UK)

What do you need to know about imaging in

K.A. Hausegger (Klagenfurt/AT) How to decide when to perform intra-arterial thrombolysis/thrombectomy (IAT)

A. Berlis (Augsburg/DE) Logistics of IAT in acute stroke patients H. van Overhagen (The Hague/NL)

Which devices should I use in which patients? A. Clifton (London/UK)

10:00-11:00, Room 113

FC 1001

Foundation Course

Stroke management 2: how I do it Moderator: S. Cekirge (Ankara/TR)

How I perform thrombolysis and thrombectomy

C. Castaño (Badalona Barcelona/ES) What influences the outcomes of IAT?

T. Engelhorn (Erlangen/DE) Clinical outcomes after IAT – trial update

P. Brennan (Dublin/IE)

How to prevent and manage complications of IAT R. Barranco Pons (Barcelona/ES)

15:00-16:00, Room 116

HTS 1302

Hot Topic Symposium

Intra-arterial stroke management should this be an IR procedure?

Chairmen: M.J. Lee (Dublin/IE), D. Vorwerk (Ingolstadt/DE)

Recent developments regarding the training of neuroradiologists and other specialties for neurointerventions

D. Vorwerk (Ingolstadt/DE)

Intra-arterial thrombectomy should only be performed by dedicated neuroradiologists

T. Andersson (Stockholm/SE)

Intra-arterial thrombectomy can be safely performed by a well trained "general interventionalist" K.A. Hausegger (Klagenfurt/AT)

How much are general IRs involved in stroke therapy across Europe?

D. Vorwerk (Ingolstadt/DE)

A plan for the future involvement of IRs in the provision of acute stroke therapy

J.A. Reekers (Amsterdam/NL)

17:30-18:30, Room 132

WS 1506 Workshop

How to treat epistaxis: case-based discussions

A.D. Platts (London/UK), A.M. Al-Kutoubi (Beirut/LB)

Monday, September 16

08:30-09:30, Room 115

SS 1703

Special Session Carotid and vertebral artery intervention

Moderators: S. Macdonald (Newcastle-upon-Tyne/ UK), K. Mathias (Dortmund/DE)

Current optimal imaging strategy for the assessment and follow-up before and after carotid intervention

P. Brennan (Dublin/IE)

Stenting vs. endarterectomy vs. medical therapy trials update

P.R. Taylor (London/UK)

Which patients benefit from vertebral artery intervention?

A. Clifton (London/UK)

Techniques and outcomes of vertebral artery angioplasty/stenting M. Das (Maastricht/NL)

16:30-18:00, Room 124

ST-HoW 1

Hands-on Workshop Stroke therapy

Co-ordinators: J. Berkefeld (Frankfurt/DE), H. van Overhagen (The Hague/NL)

Instructors: W. Kurre (Stuttgart/DE), J.M. Macho (Barcelona/ES), B. Turowski (Düsseldorf/DE), J.A. Vos (Nieuwegein/NL), J. Weber (St. Gallen/CH)

Tuesday, September 17

08:30-09:30, Room 111

ICS 2505

Interactive Case Session

Ischaemic stroke management - problems and solutions

T. Andersson (Stockholm/SE), T. Liebig (Cologne/DE)

14:45-16:15, Room 124

ST-HoW 2

Hands-on Workshop Stroke therapy

Co-ordinators: J. Berkefeld (Frankfurt/DE),

H. van Overhagen (The Hague/NL) Instructors: W. Kurre (Stuttgart/DE), J.M. Macho

(Barcelona/ES), B. Turowski (Düsseldorf/DE)

J.A. Vos (Nieuwegein/NL), J. Weber (St. Gallen/CH)

Discussion and closing remarks by the moderators

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EVAR 1 Trial and the Dutch DREAM Trial were

significantly lower 30-day mortality for EVAR

well-designed large trials. Both trials showed a

compared to open repair. However, disappointingly, neither trial has demonstrated a long-term

mortality benefit for EVAR with follow-up now

"Achilles heel" recognised by Dr. Collins - a long-

repair. The excessive cost of EVAR compared to

open surgery was also confirmed in these trials.

The complications requiring re-intervention in

occlusion also being significant issues. Since the

RCTs, a number of early devices have been dis-

carded and superseded by modern devices. There

are large industry-sponsored device registries

available to evaluate the performance of these

devices. These registries have shown (as EVAR 1

but at the expense of re-intervention. Although

reduced by improved device fixation, endoleaks

remain a problem, especially Type II endoleaks.

and DREAM did) that EVAR provides excellent

protection from aneurysm-related mortality,

the incidence of device migration has been

those large RCTs were predominantly due to

beyond eight years. The trials confirmed the



Andreas Gruentzig Lecture: Endovascular Sealing for Abdominal Aortic Aneurysms – Evolution or Revolution?

Andrew Holden

When Dr. Juan Parodi, an Argentinian vascular surgeon, performed the first endovascular aneurysm repair (EVAR) in 1989, the interventional world expected that a revolution in aneurysm repair would quickly follow. Dr. Parodi initially treated Type A aneurysms with a surgical tube graft fixed only with a proximal stent. However, he quickly developed a technique to treat aneurysms extending to the aortic bifurcation and even involving the iliac arteries, utilising an aorto-uni-iliac endograft with a femoro-femoral crossover (Fig. 1). Over the next few years, pioneers around the world advanced the technologies and techniques and early commercial endografts became available - most of which were fully supported with self-expanding stents. By 1993, methods to reconstruct the aorta with a bifurcated endograft were being developed; the most effective involved a graft body with a short and long limb, the short limb being cannulated and extended from the contralateral femoral artery.

At this time, in Perth, Western Australia (the most remote city in the world), a project commenced at Royal Perth Hospital (RPH) to develop an endograft and EVAR programme. This was a truly collaborative project between vascular surgery and interventional radiology led by two talented and influential people – vascular surgeon Michael Lawrence-Brown and charge medical radiation technologist David Hartley. Patients were initially, in 1993, treated with a tube graft



Fig. 1: The aorto-uni-iliac endograft first used by Dr. Parodi with femoral-femoral crossover



Fig. 2: The first bifurcated endograft used at Royal Perth Hospital in 1994. This prototype subsequently evolved into the Cook TriFlex device

system, but in June 1994 the first bifurcated endograft was deployed (Fig. 2) - the same week I arrived at RPH as Interventional Radiology Fellow. Over the following years, the team made influential improvements to the procedure and device that would impact on EVAR worldwide, including the use of a bifurcated flow model, fixation hooks on a supra-renal stent, delivery nose cone and integrated safety wire. A close relationship developed between RPH and Cook Medical, resulting in the development of sheaths and haemostatic valves. Eventually, Cook Medical acquired the technology and it became the highly successful Cook TriFlex system.

Although the durability of EVAR was a concern from the start, there was the expectation that such a minimally invasive procedure compared to open abdominal aortic aneurysm repair would result in dramatically reduced morbidity and mortality. However, early registries such as EUROSTAR reported disappointing and disturbing findings, and sceptics soon appeared. In 2001, the lead article in the October edition of the British Journal of Surgery, written by the Chief Editor Dr. Jack Collins, famously declared endovascular treatment of abdominal aortic aneurysm "a failed experiment". His criticism, based on EUROSTAR data, was focused on an unacceptable re-intervention rate after EVAR of 20% in the first year and 10% per year for at least the first four years afterwards! EVAR was also 50% more expensive than open repair.

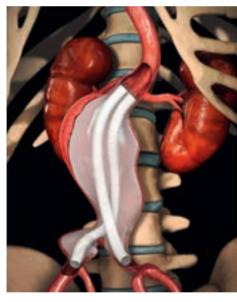


Fig. 3: Cartoon of the Endologix Nellix Endovascular System



Fig. 4: Volumetric CT reconstruction of an AAA and concomitant iliac artery aneurysm treated by the Nellix system

Sunday, September 15, 14:30-15:00 Large randomised controlled trials (RCTs) comparing EVAR to open repair for AAA did not provide reassurance for critics. The British



EVAR for AAA – evolution or revolution? Andreas Gruentzig Lecture



Don't miss it!

Radiology at Auckland City Hospital and term re-intervention rate much higher than open Associate Professor of Radiology at the University of Auckland. He is also lead Radiologist for the Auckland Hospital organ transplant programme. Dr. Holden is a committee member of IRSA (Interventional Society of Australasia) and ARGANZ (Abdominal Radiology Society of Australia and endoleaks with device migration and graft limb New Zealand) and is an examiner for the RANZCR. Dr. Holden is the author of over 60 peer-reviewed articles and three book chapters. He has been the principal investigator in 25 'first-in-man' device trials and has performed over 50 live interventional cases broadcasts from Auckland Hospital to overseas sites such as Germany, France, Hong Kong, the USA and Australia.

> procedures have proved time consuming, expensive and not particularly successful.

Until recently, there has been no EVAR device that directly sealed the aneurysm sac. The Endologix Nellix device has been developed to achieve sealing of the entire aneurysm. Originally planned to consist only of two endo bags, the device has rapidly evolved to a commercial system with CE mark that involves 'kissing' chromium cobalt balloon expandable stents and surrounding endobags (Fig. 3). The endobags achieve aneurysm sealing by being filled by a polymer that quickly cures to the consistency of a pencil eraser. The compliant polymer filled endobags form a cast of the aneurysm blood lumen that potentially prevents endoleaks and device migration. Other potential advantages of this technique include an ability to treat a wider range of adverse proximal neck anatomies, concomitant iliac artery aneurysms (Fig. 4) as well as procedural simplicity. We have been very fortunate at Auckland Hospital to be closely involved in the evolution of the Nellix device from a rudimentary 'first-in-man' device to a commercial product. Clinical experience with this device is still very limited, but no aneurysm related mortality, evidence of a persistent endoleak or device migration has been seen to date.

There is obvious potential to extend the EVAS concept beyond elective repair of AAAs. The simplicity of the EVAS procedure is attractive for the repair of ruptured AAAs and the compliance of endobag sealing is ideal for the parallel graft (snorkel, chimney) repair of juxta-renal aneurysms. Both procedures have already been performed with the Nellix system. There are also concepts to take this technology above the diaphragm into the thoracic aorta.

It is not surprising that other technologies are being developed to achieve aneurysm sealing. Technologies currently under development include injectable haemostatic foam implants capable of filling the aneurysm sac without endangering aortic branch arteries. These implants could be used with conventional EVAR devices to achieve aneurysm sealing. The prospect of a successful endovascular aneurysm sealing (EVAS) technology is exciting and potentially disruptive for current AAA management. If durability can be achieved without significant secondary intervention, the current post-EVAR imaging surveillance protocol can be seriously altered with major cost savings. Patients could be discharged after EVAS without the need for surveillance or secondary intervention! A revolution may have truly arrived!

Another limitation of EVAR devices is an inability to treat the majority of AAA morphologies. This remains a challenge for modern devices. A large percentage of patients are currently being treated by EVAR with devices used outside their company's instructions for use. Infra-renal neck anatomy is the most common limitation, especially in women. The reason that more patients cannot be treated by EVAR is because almost all current devices seal the aneurysm from pressure and rupture risk is by graft-artery wall apposition at the proximal and distal sealing zones. This necessitates a parallel length of artery (typically infra-renal aortic neck and iliac artery) of good length and quality without significant thrombus, angulation or dilatation. Approximately 40% of infra-renal AAAs lacks these features.

Given the persistent re-intervention rate and limited applicability of EVAR, it is not surprising that open surgical repair is still considered the 'gold standard' for AAA repair. Open repair is extremely durable with a very low re-intervention rate and the results in the aneurysm sac being ablated and aortic side branches ligated. Conversely, the aneurysm sac is not directly treated with EVAR, leading to the risks of device migration and endoleaks, especially Type II endoleaks from uncontrolled aortic side branches arising from the aneurysm. There is much debate about the significance of Type II endoleak, but what is beyond debate is that patients with a Type II endoleak have a much higher incidence of aneurysm sac enlargement and re-intervention. It is also clear that current treatment strategies for Type II endoleak (including intra-arterial catheter directed embolisation and percutaneous direct aneurysm sac puncture) are not particularly successful at preventing ongoing aneurysm sac growth.

Since the early days of EVAR, there have been attempts to seal the aneurysm sac at the time of the procedure, preventing complications and the need for re-intervention. In the early days of aorto-uni-iliac endografts, some centres ablated the aneurysm sac via a large sheath introduced from the contralateral groin. Subsequently, the most common techniques have involved pre-procedural branch artery embolisation and a catheter left in the aneurysm sac after the EVAR device has been deployed with subsequent ablation of the aneurysm sac using coils, thrombin or liquid embolic agents such as cyanoacrylate or Onyx. Unfortunately, these



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A chance to learn more about radiation risks to personnel and how to minimise them

Gabriel Bartal, Eliseo Vano

Imagine if there were no radiation required for the real-time imaging during interventional procedures. It could make us "lighter" by some kilogrammes, with no strain on the back or headaches. Unfortunately we are not there yet and we have to live in peace with our protective apparel, treat it very carefully and make sure that it will be replaced if there is any malfunction.

Is low-dose ionising radiation really dangerous for our patients and for us? After all, we only use it for noble purposes, and the dangers do not seem real but instead like the abstract result of some calculations and complex extrapolations based on several theoretical models.

Interventional radiologists are well-educated in all aspects of modern medicine, particularly imaging, but when it comes to the hardware we use daily, there is a gap in our knowledge that needs to be addressed. When buying a new car, the buyer knows almost everything about it, yet basically relies on the vendor and the marketing involved. We can draw a parallel between fuel consumption of a car at the factory as opposed to what we learn when we visit the petrol station. The same could apply to radiation exposure and some other parameters published by vendors compared to what happens in "real life". The difference is that we are usually unaware of the differences. New cars have new technology to reduce fuel consumption and to improve safety to reduce traffic accidents, while new interventional X-ray systems have technology that allows them to reduce the exposure to patients and staff, thus improving radiation safety. IRs have to learn how to master these new technologies and to measure, register and follow dosimetric values.

There are different theories regarding possible dangers of exposure to personnel. Some claim that at low doses the danger is only statistical though the danger of constantly driving through yellow/red traffic lights on street corners is also statistical. It's just a matter of the cumulative chances and when the damage appears.

It is extremely important to adapt our behaviour and our working culture to the powerful

new X-ray machines. We have to fully understand their whole potential and be able to implement it into our daily practice.

Below-the-knee revascularisation procedures are evolving and have better outcomes than ever before. They will ultimately replace most of the distal bypasses, but are time-consuming and require prolonged fluoroscopy time, as well as an unfavourable position for the operator, close to the radiation source in the worst possible angulations of the C-Arm.

Such practice thus requires better and heavier means of personal protection. All of the above will sooner or later cause musculoskeletal problems, as well as potential and cumulative damage to our eyes.

In the era of hybrid rooms with a multidisciplinary team working shoulder-to-shoulder, we also need behavioural adaptation, as we have to orchestrate a small symphony, which comprises diverse staff members and different tools - surgical and endovascular, as well as an imaging chain with fluoro or DSA, C-arm angulations, isocentric positioning of the central beam and more.

Somehow, radiation exposure and exposure doses have become a major issue in diagnostic radiology, mostly in CT and nuclear imaging, and have been more or less neglected and often ignored in interventional radiology. Any IR has to routinely use pre-acquired CTA images, thus avoiding unnecessary DSA runs during the procedure, as well as detailed planning of each and every step of the intervention.

During recent years, CIRSE has taken a very strong position in order to change this paradigm towards safe and skilled use of radiation.

At the CIRSE 2012 General Assembly, a number of Subcommittees were established within CIRSE for permanent consultation with the Executive Committee on specific medical topics. One of the major topics is the radiation protection of patients and personnel. CIRSE as a professional society has emphasised the importance of patient and (particularly) personnel safety. The

issue of personnel safety is usually managed at national levels by relevant governmental authorities and traditionally overlooked by professional societies, which naturally promote the appealing, hi-tech part of the profession.

In an effort to further improve the society's efforts to promote excellence in patient and personnel safety and co-ordinate CIRSE's activities in the field, a permanent Radiation Protection Subcommittee has been established and the first meeting was held during ECR 2013 in Vienna.

The Subcommittee's core tasks are as follows:

- · To provide internal and external consultation on radiation safety measures for the protection of patients and staff in interventional radiology;
- · To co-ordinate all CIRSE activities relating to radiation protection;
- To represent CIRSE in international research consortia dealing with radiation protection;
- To evaluate documents received by CIRSE dealing with radiation protection.

A dedicated group of expert IRs and medical physicists has been appointed. We believe that the activities of this group will contribute to the safe IR practice in Europe.

CIRSE also took an active part in the EU-initiated **Medical Radiation Protection and Training** (MEDRAPET). Following successful completion of the project, a Permanent Multidisciplinary Working Party was appointed in order to draft and maintain European learning outcome inventories for the radiation protection education, training and continuous professional development required for medical professions involved in work with ionising radiation.

Any doctor looking to improve patient and operator safety should be sure to join us today for our session on radiation dose management.

The session comprises four talks that will provide comprehensive state-of-the-art coverage of main relevant topics of radiation protection and dose management issues, including:

1. Understanding the pros and cons of the new X-ray systems in improvement of radiation safety and image quality

Don't miss it! **Radiation dose management Special Session** Sunday, September 15, 11:30-12:30 Room 113



Gabriel Bartal Meir Medical Center Kfar-Saba, Israel

Dr. Gabriel Bartal is an authority on radioprotection and reducing musculoskeletal injuries to IRs, which he has addressed at previous CIRSE meetings. He is an active CIRSE Member who is on the CIRSE Radiation Protection Subcommittee and was a CIRSE delegate for MEDRAPET. His interests include vascular interventions, non-vascular interventions, interventional oncology and transcatheter embolisation.



Eliseo Vano San Carlos University Hospital Madrid, Spain

His co-author, Prof. Eliseo Vano, is a recognised radiation protection authority and like Dr. Bartal is on the CIRSE Radiation Protection Subcommittee. Dr. Vano has presented on the topic of radioprotection at previous CIRSE congresses, such as the workshop at CIRSE 2012 on patient and personnel dose management in interventional radiology.

- 2. What is the real risk of radiation-induced cataracts for interventionists?
- 3. Hybrid systems for IR: how to plan a good radiation safety programme
- 4. Efficient dose management as a result of preplanning image-guided IR procedures

We believe that in the era of turf battles with other image guided specialists, IRs should take a lead in dose management issues, which is one of the major aspects of our mother specialty - radiology.

Today's Featured Papers

will be presented in the Free Paper sessions, taking place from 16:15-17:15

FP 1401

Aortic intervention

The new re-deployable C3 Gore Excluder stent-graft: "real world" results from the **GREAT Registry**

E.L. Verhoeven, A. Katsargyris; Nuremberg/DE **Room 115**

FP 1402

Clinical practice development and radiation safety

Informed consent in interventional radiology: is consent by clinical teams adequate? M.W. McCusker, L. Al Mullah, M.J. Lee; Dublin/IE **Room 129**

FP 1403

Embolotherapy (excluding oncology)

Clinical outcome of prostatic arterial embolization for patients with symptomatic benign prostatic hyperplasia refractory to medical therapy: 365 cases

J.M. Pisco, L.C. Pinheiro, T. Bilhim, H. Rio Tinto, L. Fernandes, M. Duarte, J.A. Pereira, A.G. Oliveira; Lisbon/PT

Room 112

FP 1404

Experimental work in IR

MR-guided periarterial ethanol injection for renal sympathetic denervation: a feasibility study in pigs

F. Streitparth, A. Walter, N. Stolzenburg, L. Heckmann, J. Breinl, J. Rinnenthal, A. Beck, M. de Bucourt, J. Schnorr, B. Gebauer, B. Hamm, R.W. Günther: Berlin/DE

Room 131

FP 1405 **Imaging**

Diagnostic performance of computed tomography angiography and contrastenhanced magnetic resonance angiography in patients with intermittent claudication and critical limb ischemia: systematic review and meta-analysis

S. Jens, M.J.W. Koelemay, J.A. Reekers, S. Bipat; Amsterdam/NL

Room 130

FP 1406

Oncologic intervention 1

Selective internal radiation therapy (SIRT) for hepatic tumors: is gastroduodenal artery coiling always beneficial?

J. Schelhorn, J.M. Theysohn, J. Schlaak, J. Ertle, A. Bockisch, S. Müller, T. Lauenstein; Essen/DE

FP 1407

Peripheral vascular disease intervention 1

Systematic review of nitinol, covered, and drug-eluting stents and drug-coated balloons in the femoropopliteal artery: a hierarchical Bayesian mixed treatment network meta-analysis of randomized controlled trials

K.N. Katsanos¹, S. Spiliopoulos², N. Karunanithy¹, M. Krokidis³, A. Diamantopoulos², T. Sabharwal¹, P.R. Taylor¹; ¹London/UK, ²Patras/GR, ³Cambridge/UK

Room 113

FP 1408

Renal and visceral artery intervention

RADAR: data of a prematurely terminated randomized, multicentre, prospective study comparing best medical treatment versus best medical treatment plus renal artery stenting in patients with hemodynamically relevant atherosclerotic renal artery stenosis T. Zeller; Bad Krozingen/DE

Room 133

FP 1409

Venous interventions and IVC filters

Endovascular treatment of deep vein thrombosis: final report of the prospective multi-center PEARL registry M.J. Garcia; Newark, DE/US

Room 132





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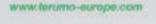
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Irreversible Electroporation (IRE): Pancreatic Applications

Raj Narayanan

Pancreatic adenocarcinoma has the highest case-fatality rate of any malignancy, with a dismal overall 5-year survival rate of 6%. In the United States 44,000 new cases of pancreatic cancer will be detected annually, with 37,400 deaths attributable to the disease. Surgical resection offers the best chance for cure, but only 10-20% of patients will qualify.

Approximately 40% of newly diagnosed patients fall in the locally advanced pancreatic carcinoma (LAPC) category, with disease which is non-metastatic, but still unresectable due to encasement of major vascular structures. Median survival remains at 6-11 months. One third of patients who initially have LAPC may become resectable after neo-adjuvant therapy. Surgery in patients with LAPC has not shown survival benefit. Intra-operative RFA and microwave ablation have been used with limited success, high complication rates and are associated with significant morbidity.

Chemotherapy response in pancreatic adenocarcinoma was published in 1961, utilising single-agent 5-fluorouracil (5-FU). For the next 30 years, there was no significant breakthrough in combination- or single-agent therapy, until gemcitabine became the standard of care in 1996. Combinations with Gemcitabine and Capecitabine (Cunningham et al.), and Gemcitabine with Erlotinib have been tried.

Since 2010, FOLFIRINIX has been used as a firstline treatment option in patients with a good performance status. A Phase 3 randomised trial comparing Gemcitabine and Folfirinox (342 subjects) was conducted by Conroy et al. [1] and demonstrated that Folfirinox was associated with a statistically and clinically significant improvement in the Median Overall Survival compared to Gemcitabine (11.1 vs. 6.8 months), but had more Grade 3 myelosupression, febrile neutropenia, diarrhoea and sensory neuropathy.

Irreversible Electroporation is a technique that involves the use of electrodes to deliver highvoltage direct current (as high as 3kV) to the tumour, creating multiple holes in the cell membrane and irreversibly damaging the cell's homeostatic mechanism, resulting in apoptotic cell death [2,3]. It is cleared by the US Food and Drug Administration under the 510 (k) mechanism for

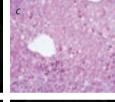
ablation of soft-tissue tumours, and use in the pancreas is considered to represent off-label use.

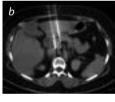
Because of its mechanism of action, tumours in contact with vessels, can be treated with IRE without compromising the vessels or creating a heat-sink effect [2,3]. The preservation of vascular and ductal structures within the treatment field of IRE is hypothesised to result from the supporting connective tissue matrix, which is unaffected by this modality as a result of the lack of thermal effects [2]. IRE has been studied in preclinical and clinical studies in multiple tumour types, including pancreatic cancer, and the preliminary data support its safety and further development [4-12].

Single Centre Experience

We treated our first case of locally advanced pancreatic carcinoma in November 2010 at the University of Miami. Our initial treatment cohort consisted of 14 patients and 15 IRE treatments of the pancreas, all done percutaneously using CT guidance and under general anaesthesia. This preliminary data was presented as an abstract at the Society of Interventional Radiology in 2012 and published in the Journal of Vascular Interventional Radiology the same year [13]. Two patients were down-staged for surgical resection post IRE at 4.3 and 5.3 months respectively, both obtaining negative margins post-resection. One of these cases is illustrated in Fig. 1.







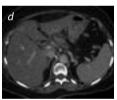


Fig. 1: (a) Pre-IRE CT of patient demonstrating pancreatic cancer with vessel encasement (b) CT-guided percutaneous IRE (c) Pathology specimen during surgery demonstrating fat necrosis (d) Post-surgery CT follow-up

We have continued treating pancreatic cancer patients percutaneously and received IRB approval for a retrospective analysis of 30 patients who underwent 33 irreversible electroporation procedures. Three patients had two treatments each. Male to female ratio was 16:14. 21 patients presented with localised disease and 9 with metastatic disease. The location of the pancreatic lesions included, head (N = 16), uncinate process (N = 2) body (N = 5), neck (N = 3), pancreatic bed (N=4) {between the gastric fundus and body and tail (N = 1), surgical bed in the tail region (N = 1) encasing vessels (N = 2)}. Tumour size ranged from 1.2 cm to 6.8 cm, with a mean of 3.4 cm. All patients received at least one line of chemotherapy prior to IRE and some received up to

From date of diagnosis to IRE procedure, a mean of 13.9 months was calculated. Patients were followed from date of IRE until last followup, which was either a visit to the clinic or date of expiration. The follow-up ranged between 2-837 days (0.06-27.5 months), with a mean of 277.83 days (9.1 months).

five lines, and 60% of the patients also received

Complications included haematoma (N = 3), pneumothorax (N = 1), pancreatitis (N = 4), and pain (N = 5). Overall median survival from the day of diagnosis to last follow-up was 33.8 months (95% CI: 22.3-45.3 months), while the overall median survival from the date of IRE was 10.7 months (95% CI: 2.4-19.4 months).

Conclusion

radiotherapy.

Our initial experience with percutaneous IRE has shown that the procedure can be performed safely in carefully selected patients and with the paucity of treatment options for pancreatic cancer, this presents a new treatment option. The importance of a multidisciplinary approach and a good metastatic work-up cannot be stressed enough, along with the need for a safe access for needle placement. While we have a long way to go before IRE can be incorporated into the management algorithm of the pancreatic cancer, the median overall survival data in our limited series, shows promise that will need to be further validated.

Don't miss it! Irreversible electroporation true revolution? **Special Session** Sunday, September 15, 10:00-11:00



Govindarajan Narayanan University of Miami -Miller School of Medicine Miami, USA

Dr. Raj Narayanan is Associate Professor of Clinical Radiology and Chief of Vascular and Interventional Radiology at the Miller School of Medicine, University of Miami. His work covers both diagnostic and interventional radiology, and he is noted for his interventional oncology work, particularly for his investigations into the clinical uses of new technologies, such as IRE and MWA. His recent papers include Ultrasound-Assisted Thrombolysis in Submassive and Massive Pulmonary Embolism: Assessment of Lung Obstruction Before and After Catheter-Directed Therapy and Transarterial chemoembolisation using DEBIRI for treatment of hepatic metastases from colorectal cancer.

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What do we know about outcomes of prostate embolisation in 2013?

João Martins Pisco

When we start PAE we should have clear inclusion and exclusion criteria. After undergoing patient selection, those patients will have pelvic CT angiography (CTA) or pelvic magnetic resonance angiography (MRA) before PAE. This is because it is important to evaluate the pelvic vessels for tortuosity and atherosclerotic changes of the iliac and prostatic arteries' anatomy.

A specific CT angiography protocol is applied and post-processing using maximum intensity projections (MIP) and volume rendering with 3D reconstructions are obtained. The anatomy and atherosclerotic involvement of the iliac and prostatic arteries, the degree of calcium and stenosis of prostatic origin could by this method be known in advance, before the procedure. CTA avoids catheterisation of all other pelvic arteries and its use will ultimately reduce complications. Patients with advanced atherosclerosis of the iliac and prostatic arteries are excluded on the basis of angio-CT.

With the help of angio-CT, DSA and roadmapping, the prostatic arteries are catheterised with a coaxial micro-catheter. If there is only one prostatic artery, the micro-catheter should be placed before bifurcation in order to embolise both prostatic branches. The end point is the embolisation of prostatic branches, with no reflux to other arteries and opacification of the gland. If there are two prostatic arteries on one side, one should start by the anterolateral or cranial branch as this irrigates the central part of the prostate. So if this branch is well embolised, we should not be worried about the caudal branch. Nevertheless, it is sometimes also embolised by collateral circulation through anastomosis.

Outcomes

In spite of the excellent results of UFE and its similarity to prostatic artery embolisation (PAE), the first case of PAE was performed only in 2000 by DeMeritt in a patient with acute urinary retention and persistent haematuria. The patient stopped bleeding immediately after embolisation, the patient's voiding difficulties improved, the prostate volume reduced 40% and there was no sexual dysfunction. In March 2009, we performed the first PAE in a 76-yearold man on acute urinary retention and bladder catheter who refused surgery after two previous TURP. Five days later, the bladder catheter was successfully removed.

In 2010, Carnevale et al. reported the preliminary results in two patients with acute urinary retention due to BPH successfully treated by prostate artery embolisation. One patient had bilateral PAE and the other unilateral PAE. Both patients could urinate spontaneously after removal of the bladder catheter 15 and 10 days after the procedure, respectively. At the 6-month follow-up, ultrasound (US) and magnetic resonance (MR) revealed a prostate reduction of 39.7% and 47.8%, respectively, for the bilateral PAE and 25.5% and 27.8%, for the patient submitted to unilateral PAE. The patient treated with bilateral embolisation complained of retropubic pain for 24 hours treated with non-opioid analgesic. In 2011, Carnevale et al. reported the midterm follow-up after prostate embolisation in the same two patients with BPH.

Results from Lisbon

At SIR 2010, we presented the preliminary results in the first 12 patients. The procedure was

successful in 11 of the 12 patients (90.9%). The patients did not feel any pain during or after the procedure, except one. Four patients were in urinary retention before embolisation. The vesical catheter was removed 5 days after the procedure in two patients and 10 days in the remaining ones. The symptoms improved in all the patients in whom the embolisation was successfully performed (mean decrease in the IPSS of 8.2 points at 1 month and 9.3 points at 3 months). The mean prostate volume decreased from 96.3 to 74.3 cc (22.9%) at 1 month and an additional 9.95% at 3 months. The peak urinary flow rate increased 3.8 mL/sec at 1 month and an additional 1.5 mL/sec at 3 months. At the third month patients urinated without bladder catheter with a mean IPSS of 6.33 and a peak urinary flow rate of 9 mL/sec.

At SIR 2011, we presented the short and medium-term outcomes of PAE in BPH. PAE was technically successful in 66 of the 67 patients (98.5%) and the embolisation was bilateral in 63 and unilateral in 3. In 62 patients with clinical success, at last follow-up, all the evaluated parameters had significant clinical improvement. The remaining 4 patients improved; however, the changes were not significant, and so are considered clinical failures. There was one case of a major complication, a 1.5 cm²-sized bladder wall ischaemia that was treated by surgical removal. Sixty-two patients were discharged 4-8 hours after the procedure, and the remaining ones were discharged the next morning.

More recent findings

At SIR 2012, Carnevale et al. presented eleven patients treated between June 2008 and November 2010. There was a technical failure (bilateral embolisation) in 75% and clinical success in (10/11 patients) 91%. All patients were in acute urinary retention with bladder catheter. Patients urinated spontaneously between 4-25 days (mean 12.1) after catheter removal. Clinical overall improvement in LUTS at oneyear follow-up was observed by IPSS (mean 2.2) and QoL (mean 0.25). Minimum rectal bleeding (a teaspoon amount) was observed in 3/12 (25%) and focal bladder ischaemia in 1/12 (8.3%) procedures.

Recently we reported the short and mediumterm results of PAE in 89 patients. There were 3 technical failures (3%). PAE was bilateral in 86 patients (92%) and unilateral in 7 patients (8%). At 1-month follow-up, IPSS decreased by 10 points. OoL score decreased by 2 points. peak urinary flow increased by 38%, prostate volume decreased by 20%, post-void residual volume decreased by 30 mL and IIEF score increased by 0.5 (all differences were significant, P<0.01). These changes were sustained throughout the observation period. Seventy-eight of the 86 patients (91%) were discharged from the hospital 6-8 hours after the procedure. The remaining eight patients were discharged the following morning, 18 hours after the procedure. 16 of the 86 patients (19%) had urinary tract infections after embolisation that were treated with antibiotics, and there was transient haematuria in nine of the 86 patients (10%) and transient haemospermia that disappeared spontaneously without any treatment in six (7%). Balanoprostatitis occurred in two of the 86 patients (2%) and inguinal haematoma in six (7%). Two patients had acute urinary retention after PAE, and a temporary bladder catheter was placed for a couple hours. One patient, already mentioned, developed bladder wall ischaemia.

Carnevale et al. recently published the results of PAE in 11 patients with BPH and indwelling urinary catheter. Ten out of eleven patients urinated spontaneously 4-25 days (mean 12.1 days) after vesical catheter removal. Post-embolisation syndrome manifested as mild pain in the perineum, retropubic area and/or urethra. In an asymptomatic patient, there was a hypoperfusion area of bladder suggesting small ischaemia of the bladder that was not detected at 90 days by MR follow-up. After one year, the mean prostatic volume reduction was greater than 30%. There was symptoms improvement of IPSS (2.8 + 2) and Qol (0.4 + 0.5).

Procedure times

The procedure fluoroscopy time of the first 2 patients reported by Carnevale were 160/59 mins and 250/95 mins, respectively. Both patients were discharged 3 days after PAE. At CIRSE 2012, Carnevale reported an average of 2 hours for PAE. In our first reported 15 cases, the PAE procedure lasted between 25 and 135 minutes (mean 85 mins) and fluoroscopy time ranged between 15 and 45 minutes (mean 35 mins). All patients were treated as outpatients; 12 were discharged from the hospital 6-8 hours after the procedure and the remaining 3 patients 18 hours after, the next morning. In our recent publication the PAE procedure lasted 25-185 minutes (mean 86 mins) and the fluoroscopy time was 7-63 minutes (mean 27 mins), 78 of the 86 patients (91%) were discharged from the hospital 6-8 hours after the procedure and the remaining 8 patients were discharged the following morning, 18 hours after PAE. The radiation dose of each patient ranges from 2.121 to 9.766 dGy cm² (mean 3.050 dGy cm²).

Conclusion

In conclusion, it is very important to know the prostatic arteries anatomy through previous angio-CT or angio-MR in order to plan the procedure in advance and reduce the procedure and fluoroscopy time.

Today, more than 500 patients with BPH have been treated with PAE around the world with good and satisfactory results at both short and medium-term follow-up. In Europe, the United States and Brazil there are already several centres performing PAE. As of April 2013, we have treated over 400 patients with BPH, 17 of them with at least 3 years' follow-up. Although we work with urologists, we have a lot of patients coming directly to us to be evaluated due to the results of the technique.

The data available in the literature are still limited and multicentric and more randomised studies are needed. With the results from two centres we can see a real benefit of PAE in selected patients with BPH.

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Don't miss it! **Prostate artery embolisation:** real benefit or myth? **Special Session** Sunday, September 15, 08:30-09:30 Room 115



Joao Martins Pisco Hospital Pulido Valente and St. Louis Hospital Lisbon, Portugal

Dr. João Martins Pisco is a recognised pioneer of IR, with particular focus on vascular interventions, transcatheter interventions and prostate interventions. In his positions as chief radiologist at Hospital Pulido Valente and Director of Interventional Radiology at St. Louis Hospital, he has accepted many residents and trainees, including several under CIRSE's Educational Grant scheme. His current work focuses strongly on the field of prostate artery embolisation for benign prostatic hypertrophy, and in March 2013 he treated his four hundredth patient.

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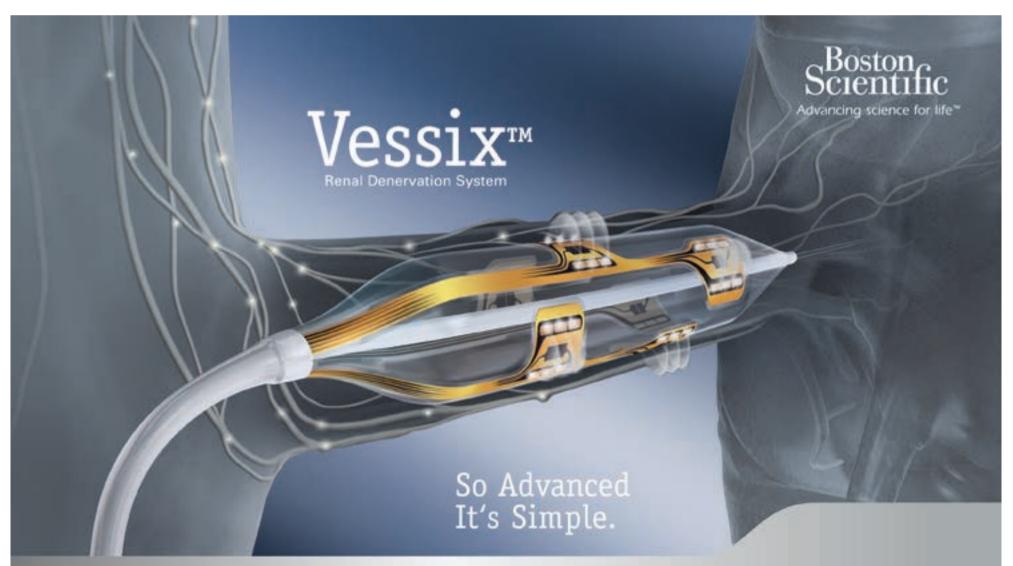
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Hot topics and burning questions - ECIO goes to sizzling Budapest

Ciara Madden, CIRSE Office

At last year's congress, it was announced that ECIO would move from a biennial event to an annual one. 2013 saw the first proper annual occurrence of ECIO, held in June rather than April, due to other fixtures in the CIRSE calendar.

Nevertheless, the meeting proved hugely popular, with over 900 participants from 60 countries making the journey to Budapest in high summer.

Despite the incredible heat outdoors, the congress centre was ideal for our needs, providing a cool and comfortable environment in which to explore the world of interventional oncology. The compact layout of the venue allowed for easy movement between sessions, booths and workshops, while still offering plenty of space and excellent facilities.

Diversity of delegates

The meeting, as always, featured an interesting mix of participants, with many representatives and speakers from other medical fields and from around the globe. This was helped in part by the 'Bring Your Referring Physician' programme, which offers free registration to nonradiologist colleagues and is now in its third year. Also notable were the number of young speakers presenting the research being carried out at their institutions.

Scientific highlights

Amongst the vast array of excellent lectures, workshops and discussion panels were some sessions worthy of particular attention. This year's Honorary Lecture was delivered by Carlo Bartolozzi, a renowned researcher and educationalist from Pisa, Italy, whose career has inspired generations of Italian interventional oncologists. His lecture, Diagnosis and treatment of HCC: from guidelines to clinical practice, was a fascinating overview of the evolution of hepatic cancer therapies, as well as the current best-practice.

The ECIO meets... sessions were similarly captivating. Three were held this year, in conjunction with our partner societies the International Liver Cancer Association (ILCA), the World Conference on Interventional Oncology (WCIO) and our most recently acquired ally, the European SocieTy for Radiotherapy and Oncology (ESTRO).

ECIO meets ILCA featured a number of liver cancer experts, including Peter R. Galle, a hepatologist from Mainz, IR Riccardo Lencioni, Spanish hepatologist Bruno Sangro and ILCA President Josep Llovet.

The joint session with the WCIO was no less fascinating: moderated by WCIO Chairperson Mike Soulen and our own Riccardo Lencioni, the session opened the floor to many young researchers, as well as established IRs from the other side of the globe. The speakers addressed a range of innovative approaches to cancer treatment, including a molecular approach to

chemoembolisation, use of nanotechnology, integrating IO with radiation oncology, Y-90 radioembolisation and the use of embolisation for renal tumours.

This year's final joint session was with ESTRO, and provided fascinating parallels and comparisons between radiation oncology and interventional oncology, focussing on the professional issues that affect both specialties. Insights on how to be a clinician were given from both an IR perspective (Afshin Gangi) and a radiation oncology perspective (Vincenzo Valentini, ESTRO President). Challenges in training and assessment were also discussed, and radiation oncologist and CIRSE-collaborator Lizbeth Kenny gave a fascination talk on Collaboration, not competition, in oncology. The session ended with a panel discussion and questions from the

Variety of formats

The meeting also offered a wide range of session types. Alongside standard sessions, several panel discussions were timetabled in. A new series of multidisciplinary tumour boards was introduced, discussing a variety of clinical cases. Interactive hands-on workshops covering image-guided tumour ablation in a variety of organs were offered, as were interactive sessions devoted to the management of complications, helping IRs to pre-empt, recognise and resolve any complications that may arise during or after image-guided therapy. New to the programme was a series of *How I do* it: tips and tricks from the experts sessions, where leading experts shared their experience with important IO treatments, including transcatheter oncology procedures and imageguided ablation.

Support from industry partners

The congress attracted the support of 26 sponsors, with 24 groups hosting booths in the exhibition area. The exhibition area itself was slightly unusual, due to the layout of the congress centre: it was located in a broad corridor skirting the main auditoria, and was intermingled with the coffee-break stations and tables. This created a particularly ambient and social environment, with much traffic and much interaction taking place between sessions, and plenty of opportunity to examine the latest products while fetching a welldeserved cup of tea.

The interventional oncology meeting of the year

The high quality and success of this year's ECIO affirms the decision to turn the meeting into an annual event. Plans for next year's meeting in Berlin are already underway, and we look forward to hosting another exciting forum for interventional oncology exchange.

The presentations from ECIO 2013 are available on ESIRonline, so be sure to log in and watch any sessions that you missed! www.esir.org











12 Advertisement Sunday, September 15, 2013

Advertorial



Dr. Maneesh C Patel (UK)



Consultant Neuroradiologist and Lead Clinician, Imaging Dept., Charing Cross Hospital, London Honorary Senior Lecturer, Imperial College NHS Trust, London

NICE has recently published a Multiple Technology Appraisal for the use of Percutaneous Vertebroplasty (VP) and Percutaneous Balloon Kyphoplasty (BKP) for Osteoporotic Vertebral Compression Fractures, what is your opinion of this?

It is encouraging that NICE has acknowledged the clinical and cost effectiveness of BKP and VP to treat Osteoporotic Vertebral Compression Fractures (VCF). They have recommended that these treatments should be used in patients who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging.

The recommendation reflects how I have been choosing to treat VCF patients in the past, however, importantly, these guidelines stipulate that the NHS must fund the use of these valuable procedures. NICE has formally acknowledged the impact of vertebral fractures in osteoporotic patients and the consequences on the patient's Quality of Life and mortality risk.

What treatment options do you consider when seeing patients with vertebral compression fractures?

The Charing Cross hospital in London has developed a referral pathway which is established from a Medtronic approach for osteoporotic VCF patients. I am most likely to see patients who have undergone appropriate non-surgical management (NSM) and are referred to me for a surgical procedure as a result of ongoing pain which has not been remedied through their pharmaceutical intervention. I will either select a VP or a BKP depending on the characteristics of the patients fractures, and the patients themselves.

In a recently published paper, a panel of European experts are, for the first time, recommending the use of 'Guiding Principles' to help determine when a BKP or VP is appropriate.

As an example, this publication has recommended that patients with an osteoporotic VCF (time since fracture ≥ 6 weeks), a VAS > 5, a positive MRI, and no spinal deformity should be treated with a VP. Whereas the panel is recommending that a BKP should be performed in patients with ongoing fracture process or with a positive MRI and ≥1 other unfavorable factors* (*impact of VCF on daily functioning, evolution of symptoms, spinal deformity, presence of pulmonary dysfunction, proof of on-going fracture process).

These recommendations are currently in line with my own practice whereby I tend to select a procedure which reduces the impact of kyphosis and improves sagittal alignment (via height restoration) if there is a chance to do so.

It has been debated for long the use of BKP versus VP, what is your opinion?

I believe there is a place for both procedures depending on the patient's characteristics.

It is increasingly understood that both procedures induce a different impact on patients. The NICE multiple technology appraisal acknowledges that BKP may be associated with greater mortality benefit than VP. Indeed, the SAVE trial demonstrated a 23% higher mortality risk reduction for BKP versus VP (p < 0.001).



In my practice, I tend to see older fractures which means it can be more challenging to gain height restoration. I tend to use BKP to create a safe cavity in which to inject cement in higher risk patients. However, it is accepted within studies (such as the recent FREE Surgical trial below) that one can achieve some height restoration.

The FREE Surgical trial (an extension of the FREE results) demonstrated that, at 24 months, the change in kyphotic angulation was significantly improved by an average of 3.1° with BKP (vs baseline), compared to a non-significant improvement of 0.8° with NSM (p = 0.003). Importantly, within the study, this kyphotic correction improvement correlated with an improvement of Quality of Life and functioning, proving that patients with higher kyphotic restoration gain greater clinical benefits.

In my opinion, there is a clear difference between the impact of different types of vertebral augmentation procedures on kyphotic correction capabilities, but there is a place for both VP and BKP depending on the patient and their fracture.



You have been using the Kyphon® Cement Delivery System (CDS). What are the advantages you see with this system?

I could not imagine performing a BKP or VP procedure without Kyphon® CDS gun. There are a number of benefits in using the CDS, but my primary rationale is to gain protection from radiation.

The length of the connecting tube is 120 cm (this is considerably longer than other systems) means that I can keep a safe distance from the fluoroscopy unit during screening, minimizing radiation exposure. A recent publication has demonstrated that, when using the CDS gun, the radiation dose received by the operator's finger, wrist and leg was reduced by greater than 80%, the only trial of its kind.

Furthemore, the control over cement injection is significantly improved with 0.2cc's of cement being delivered with each trigger depression. A further advantage is the ability to immediately stop the flow of cement with the safety button on the device handle which has improved the safety of cement injection and increased my confidence particularly during complex malignant vertebral fractures. It has become my cement delivery device of choice for either BKP or VP.

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To hear more, come and meet Dr. Patel at the Medtronic booth on Sunday, September 15, 2013 – from 11.00 to 13.00 and from 15.00 to 16.00.





Basic and advanced techniques for bronchial artery embolisation

Florian Wolf (EBIR)

Haemoptysis remains a severe medical condition despite advanced medical imaging techniques. It is still a life-threatening respiratory emergency and in many cases needs immediate therapy. Worldwide, the most common cause of haemoptysis remains active tuberculosis; in developed countries, the origin of haemoptysis is more often a chronic inflammatory process due to infection or conditions like cystic fibrosis, bronchiectasis, bronchogenic

In patients with massive haemoptysis, the diagnostic work-up in most cases includes contrastenhanced chest-CT alone or in combination with bronchoscopy. CT is not only able to show the bleeding area, but also to localise the exact site of bleeding in the majority of patients with haemoptysis [2].

carcinoma or congenital heart disease [1].

Anatomical considerations

The anatomy of bronchial arteries is very variable in terms of origin, branching pattern and course. Bronchial arteries can arise directly from the descending aorta between the level of thoracic vertebrae 5 and 6. Alternatively they can arise from the thoracic aorta or arch outside vertebrae 5 and 6. About 20% of the bronchial arteries arise from different thoracic or abdominal arterial branches, such as the subclavian artery, internal mammary artery or coeliac trunk. Cauldwell has defined four different branching types for bronchial arteries which arise directly from the aorta [3]. In the majority of patients, there is one single bronchial artery on the right side with distal branching (intercostobronchial trunk) and two separate bronchial arteries on the left side.

Before the embolisation procedure of a patient with severe haemoptysis, the interventional radiologist should study the CT-angiographic images in detail in order to directly proceed to the site of bleeding without delay. In the vast majority of cases, embolisation is done by femoral access using a 5 or 6 Fr sheath. In rare cases, brachial access can be necessary if the approach to the origin of the bleeding artery cannot be reached or stable catheter position cannot be achieved by femoral access.

How to proceed

Depending on the clinical presentation of the patient and the severity of the bleeding, the intervention is done under local anaesthesia, sedation or general anaesthesia. If the origin of the feeding artery is not completely clear after CT angiography, the embolisation procedure is started with a diagnostic digital subtraction

angiography with a high frame-rate of 4 or 6 images per second using a pig-tail catheter in the descending aorta and a power injector. In all other cases, the radiologist can directly proceed to the bleeding artery using, for example, a Sidewinder or Cobra catheter. The active bleeding can be made visible by angiography only in about 10% of the cases [4]. For that reason, angiographic images should be investigated for signs of abnormality in the terminal vascular bed of the bronchial arteries like vascular hypertrophy, neovascularity, tortuosity, hypervascularity, aneurysm formation or shunting to pulmonary vein or pulmonary artery. A normal bronchial artery in general has a diameter of around 1.5 mm; if it is larger than 2-3 mm in diameter it is definitely pathologic [5]. After selective angiography of the bronchial artery and detection of the origin of the bleeding embolisation, the procedure is started. In most centres this is done with the coaxial technique using a microcatheter, since it is more secure, especially if the position of the macrocatheter is not completely stable. Moreover the embolisation can be done more peripherally, and if the microcatheter is occluded by emboli-

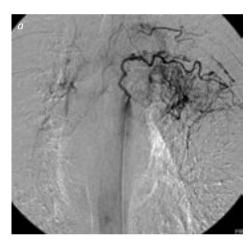


Fig. 1a: 60-year-old female patient with severe life-threatening haemoptysis due to chronic inflammation. Diagnostic selective angiography of a left bronchial artery.

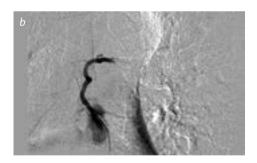


Fig. 1b: Control angiography after embolisation with microspheres between 300 und 700 µm.

sation material it can be removed without losing the arterial access by leaving the macrocatheter in place. Enlarged and more selective diagnostic series are done using the microcatheter.

Embolic agents

For the embolisation procedure, many different agents are available and in different centres different embolisation materials are used. The most important thing in the selection of an appropriate embolisation agent is that the interventional radiologist is used to this agent and knows how it reacts during delivery. A very economical agent is absorbable gelatine sponge [6]; nevertheless, delivery is sometimes not so easy using a microcatheter and moreover it is only a temporary occlusion agent, which might result in recurrent haemoptysis. Polyvinyl alcohol particles are also used in different studies; they provide a permanent occlusion of the vessels and in general are used in sizes larger than 250 µm in order to avoid bronchial necrosis [7]. Microspheres are another possibility, as due to their hydrophilic nature and smooth spherical shape, they are less prone to clumping compared to polyvinyl alcohol particles. For bronchial artery embolisation they are used in sizes of between 500 and 700 μm [8]. In a recent study *n-butyl-2-cyanoacrylate* was used as liquid embolising agent in patients with bronchial artery bleeding and compared to the performance of polyvinyl alcohol particles [7]. It showed higher haemoptysis-free survival rates, without increasing complication rates. Nevertheless the use of this agent needs a high grade of experience in both delivery and especially mixing it with lipiodol in order to achieve the perfect concentration. Another exotic liquid embolisation agent for bronchial artery embolisation is ethylene vinyl alcohol polymer [9] with the only drawback being that it is relatively expensive compared to the other agents. One more possibility is the use of metallic coils – detachable or not. The disadvantage of this method is that the occlusion is achieved relatively proximally in the vascular bed, which may result in recurrent haemoptysis with no more possibility to do the embolisation distal to the coils.

Outcomes

The immediate clinical success rate of bronchial artery embolisation in different studies using different embolisation agents was shown to be between 73 and 100%. In the majority of studies, success rates are around 90%. Clinical recurrence rates are between 10 and 55%, with the majority around 25%. Complication rates are reported between 0 and 27%, with the

Don't miss it! **Embolisation in the thorax Special Session** Sunday, September 15, 11:30-12:30 Room 115



Florian Wolf (EBIR) Medical University of Vienna Vienna, Austria

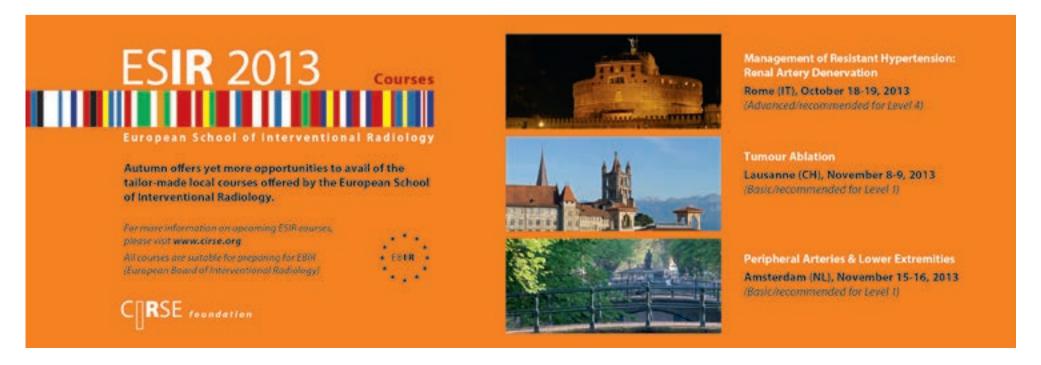
PD Dr. Florian Wolf is an active CIRSE Member who is a Member of the Clinical Practice App Task Force, as well as being on the ESIRonline Editorial Board in the Embolisation Division, and the new Editorial Advisory Board of Intervention IQ. His interests include cardiovascular imaging, vascular interventions, non-vascular interventions, clinical practice and transcatheter embolisation. Dr. Wolf was a co-author of the CIRSE 2010 EPOS cum *laude award-winning paper on CT-angiography* of the supra-aortic arteries.

majority around 10% [10]. In case of recurrent haemoptysis, embolisation can be performed repeatedly.

In the hands of highly experienced interventional radiologists, bronchial artery bleeding embolisation is a safe and very effective method of treating life-threatening haemoptysis. Advanced knowledge of bronchial artery anatomy is necessary in order to ensure a safe and successful procedure. Contrast-enhanced multislice CT is the method of choice for detailed evaluation of haemoptysis and for treatment decision and planning. Many different embolisation agents can be used – the motto in this case should be: use what you are used to using.

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Safety first is safety always "Charles M. Hayes"

CIRSE 2013

13:00-14:00

SY 1202 "MWA: the current and future state of art"

Room 115

Moderator: T. J. Vogl (Frankfurt/DE)

1202.1 "MWA: current experience and advantages"

W. Prevoo (Amsterdam/NL)

1202.2 "How to achieve a good MW ablative margin

(A0): tips and tricks"

B. Gonçalves (Porto/PT)

1202.3 "The science of powerful predictability"

J. Brannan (Boulder CO/US)

September

15

Sunday

Covidien - Satellite Lunch Symposium

"MWA: the current and future state of

art" Room: 115

To get more information about Covidien ablation products please follow the link www.covidien.com/ablation. Or visit us at our booth (52) for all your questions to the Covidien ablation products.





Interventional Oncology in Renal Cancer: Definitive cancer surgery?

David Breen

Don't miss it! **Renal tumour ablation Special Session** Sunday, September 15, 08:30-09:30 Room 111

Interventional oncology (IO) continues to impact many areas of cancer care, including hepatocellular carcinoma, neuroendocrine tumour management and painful bone metastases, both to enhance standard therapies and to offer alternatives in patients declined for other treatments. Nowhere else, however, is IO more set to provide definitive, standard of care treatment than in the management of smaller volume renal tumours. This has come about through stepwise improvements in ablative technologies, image guidance and interventional techniques, but what are the relative merits of the multiple treatment options now being offered to the patient with a small (<5 cm) renal tumour?

First, we need to deal with the debate surrounding active surveillance. Many of these smaller renal cancers are indolent, yet the fact remains that we have no reliable means of predicting their behaviour. Renal cancer remains, on a per capita basis, the most lethal of all urological malignancies. 3-4 cm tumours harbour higher grade disease in 14-25% of cases [1] and the risk of metastatic progression of <4 cm disease ranges in the literature from 1 to 6% [2]. Active surveillance is predicated on the morbidity of the intervention and while, for example, no clinician would usually advocate treating a 20 mm tumour in an 87-year-old patient, many of the tumours now detected incidentally are of 25-30 mm in size and occur in otherwise fit 75-year-olds. The European Association of Urology reckons that 75% of these continue to grow and at least 40% of patients cross over into active treatment. There is no consensus on the necessary frequency or modality of imaging follow-up and of course surveillance of this type carries with it its own expense and morbidity. Is there now a case for earlier, active intervention where a day case therapeutic option has evolved, and what should that treatment be?

In the late-1990s - the early days of radiofrequency ablation (RFA) of renal tumours reasonable results could be obtained for <3 cm tumours, but the poor predictability of treatments - largely as a result of gas obscuration - resulted in unacceptable subtotal treatment rates of 10-20%. This was borne out in 2008 by a retrospective meta-analysis of multiinstitutional data which appeared to suggest that laparoscopic cryoablation (CRA) performed better than image-guided RFA both in terms of primary subtotal treatment rates and unexpected late local recurrence [3]. This data was however plagued by case selection bias and we must be cautious in simply interpreting these findings as suggesting that CRA is better than

More recently, interventional oncologists have realised the merits of image-guided cryoablation as the 'therapeutic' ice ball is so readily visualised using CT or MR [4, 5]. This fundamentally brings control and 'scalability' to the treatment and along with techniques such as retroperitoneal fluid (or gas) hydro-dissection, means that most tumours up to 6 cm are now amenable to image-guided ablation. Of course, microwave brings speed of treatment to the table but, while suitable for <3 cm cortical tumours, this technique still lacks a clear and available method of true periprocedural control and monitoring. The value of multipolar irreversible electroporation (IRE) in this setting remains to be seen.

As <4 cm renal tumours increasingly represent the bulk of renal cancers encountered by the urological tumour board, urologists have likewise been working to finesse their techniques and reduce the morbidity of partial nephrectomy. In particular it was realised that hilar clamping of greater than 20-30 minutes results in unacceptable deterioration of function in the operated kidney, through warm ischaemia.

'Non-ischaemic' techniques such as open parenchymal clamping have reduced this form of injury. Laparoscopic, 'clampless' partial nephrectomy and intracorporeal suturing of the pelvicalyceal system only remain reliably within the routine skill set of a limited number of centres. Extirpative surgery however provides definitive proof of margins and whole specimen histology. This remains a challenge to the interventional oncology community where an in situ treatment such as ablation fails to yield whole specimen histology – in a tumour notorious for grade heterogeneity - and imaging proof of the oncological outcomes is still disputed by some clinical groups.

Will there ever be a prospective, randomised controlled trial of these techniques? This author remains doubtful that in the current environment there is the finance or staying power for such studies which, given the relative indolence of disease, would need to be heavily powered to show differences between the therapeutic groups. Careful registries of complications, costs and procedural outcomes would seem to be a better way forward and CIRSE, along with other bodies, is working on this.

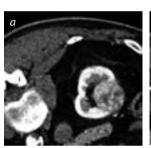


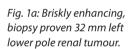
David J. Breen Southampton University Hospitals Trust Southampton, UK

Dr. David Breen is internationally renowned for his work using microwave ablation and cryoablation to treat abdominal cancers, making him very wellsuited to write about interventional oncology in renal cancer. His main interest is in abdominal and interventional radiology, with particular focus on image-guided ablation of small volume cancers. He is past-president of the British Society of Gastrointestinal and Abdominal Radiology, in addition to being a member of the Abdominal Subcommittee of European Society of Radiology, and the Upper Gastrointestinal Clinical Studies Group for the UK's National Cancer Research Network.

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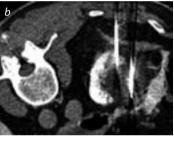
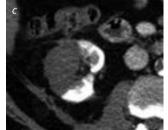


Fig. 1b: The adjacent bowel has been Fig. 1c: CT study at 10 days condisplaced with contrast-tinted fluid injected to the peri-renal retroperitoneum and the therapeutic ice ball can be seen subsuming the target tumour.



firms complete non-enhancement of the tumour, including a subjacent cortical margin. This is now borne out as an effective marker of tumour destruction.



Advertisement Sunday, September 15, 2013

Gore Scientific Program



Sunday, September 15

V 8.00 - 8.20

Gore Satellite Symposium / Room 133

How much does stent design matter in treatment of the peripheral artery?

- Moderator: Eric Verhoeven, Nuremberg, Germany
- Overcoming the unmet needs with the next generation dual component GORE® TIGRIS® Vascular Stent
- Konstantinos Katsanos, London, UK
- Early clinical experience with the GORE® TIGRIS® Vascular Stent Michael Piorkowski, Leipzig, Germany

N 17.30 – 18.10

Gore Satellite Symposium / Room 133

Tips a la carte. Portal hypertension: TIPS is a team approach!

Moderators: Frederik Nevens, Leuven, Belgium Boris Radeleff, Heidelberg, Germany

TIPS patients presented and discussed, using the GORE® VIATORR® TIPS Endoprosthesis. The impact of 'early tips' data. Speakers: Andreas Koops and Daniel Benten, Hamburg, Germany

Monday, September 16

V 8.00 - 8.20

Gore Satellite Symposium / Room 133

Unique technologies for the treatment of aortic disease

Moderator: Jost Philipp Schäfer, Kiel, Germany

- Effect of internal iliac artery interruption: Is preservation a must? Martin Delle, Stockholm, Sweden
- Dealing with acute aortic syndromes, logistic challenges and decision processes Mohamad Hamady, London, UK

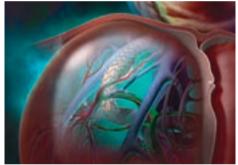


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SURVIVAL on-Covered Sten after TPS placement for refractory excites; covered on-covered stent. The overall survival is significantly better in the cs-TPS patients (p = 0.0071)³ SURVIVAL ryival according Child-Pugh and MELD scores system after scement for refructory ascites. The survival gain in of covered stent occurred in the group of patients with MELD score $< 16 (p < 0.0001)^2$ MELD < 16 or Covenco strat (s = 54)

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INDICATIONS FOR USE UNDER CE MARK: The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the treatment of portal hypertension and its complications such as: variceal bleeding refractory to, or intolerant of, conventional therapies, inaccessible varices, gastropathy, refractory ascites, and/or hepatic hydrothorax. Refer to Instructions for Use at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events. **INDICATIONS FOR USE IN THE US:** The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the de novo and revision treatment of portal hypertension and its complications such as variceal bleeding, gastropathy, refractory ascites, and/or hepatic hydrothorax. Ronly

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GORE® VIATORR® TIPS Endoprosthesis Compared to Bare Metal Stents

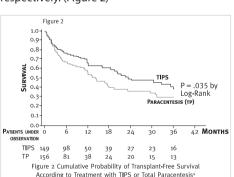
In a randomized prospective trial, Bureau, et al., found the actuarial rates of primary patency in the GORE® VIATORR® Device group and bare metal stent group were 76% and 36%, respectively, at 2 years $(p = 0.001 - log-rank test)^1$. In a retrospective analysis of cirrhotic patients with refractory ascites, Maleux, et al., found that TIPS using the GORE® VIATORR® Device offers better symptomatic control of the ascites at one year follow-up and a better overall survival, compared to bare metal stents². (Figure 1)

GORE® VIATORR® TIPS Endprosthesis Compared to Endoscopic Band Ligation (EBL)

In a randomized, controlled clinical trial with TIPS performed within 72 hours after diagnostic endoscopy and a 1-year follow up, results demonstrated an 86% actuarial survival in the early-TIPS group versus 61% in the pharmacotherapy – EBL group (p < 0.001)³. The 1-year actuarial probability of remaining free of failure to control bleeding and of variceal rebleeding was significantly higher in the early-TIPS group than in the pharmacotherapy – EBL group (97% vs. 50%; absolute risk reduction, 47 percentage points; 95% confidence interval [CI], 25 to 69; number needed to treat, 2.1 patients; 95% CI, 1.4 to 4.0). The conclusion was that patients with cirrhosis who were hospitalized for acute variceal bleeding and at high risk for treatment failure, the early use of TIPS was associated with significant reduction in treatment failure and in mortality.

TIPS Compared to Large Volume Paracentesis (LVP)

Although randomized comparisons of the GORE® VIATORR® Device vs. LVP are in progress, data from bare metal stents provide evidence of the effectiveness of the TIPS procedure compared to continued LVP in ascites patients. In a meta-analysis of individual patient data, it was reported that bare metal stent – TIPS significantly improves transplant-free survival of cirrhotic patients with refractory ascites4. The cumulative probability of developing the first episode of hepatic encephalopathy (HE) was similar between the groups (p = .19). The average transplant-free survival at 12, 24 and 36 months of follow-up was 63.1%, 49% and 38.1% for patients allocated in the BMS-TIPS group and 52.5%, 35.2% and 28.7% for patients allocated to large volume paracentesis (LVP), respectively. (Figure 2)



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Health Economic Benefits

Bureau et al. reported that TIPS with bare metal stents has been less cost effective than other procedures. This is mainly owing to the monitoring and the revisions required to maintain shunt patency. It has been shown that the use of covered stents could result in cost reduction because of decreased clinical relapses and decreased need for shunt revisions1. TIPS is a safe intervention that reduces the need for LVP. Careful calibration allows satisfactory relief of ascites with a low incidence of HE. It has been demonstrated that extremely low complication rates and exceptionally high patency rates can be achieved with the use of GORE® VIATORR® TIPS Endoprosthesis. In the United Kingdom, health economic data favoured TIPS with a cost of £500 per month of patient follow-up for TIPS and £3,500 per month of patient follow-up for paracentesis. Careful patient selection for this procedure has

demonstrated significant health economic benefit in favour of a dedicated TIPS endoprosthesis5.

Conclusion

A large body of published data demonstrate numerous clinical advantages of GORE® VIATORR® TIPS Endoprosthesis in treatment of patients with refractory ascites and variceal bleeding. Furthermore, GORE® VIATORR® TIPS Endoprosthesis may be associated with decreased patient-care costs compared to other therapies. Considering these results, the role of GORE® VIATORR® TIPS Endoprosthesis in the management of portal hypertension should be considered. The improvement of TIPS patency by using ePTFE-covered stents is maintained over time with a decreased risk of hepatic encephalopathy and a decreased risk of death. Furthermore, data demonstrate the clinical advantage of GORE® VIATORR® TIPS Endoprosthesis in treatment of patients with variceal bleeding and refractory ascites. Finally, GORE® VIATORR® TIPS Endoprosthesis has demonstrated a decrease in associated patientcare costs. Considering these results, the role of GORE® VIATORR® TIPS Endoprosthesis in the management of portal hypertension should be considered.



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Haemodialysis: Is shunt surveillance useful?

Miloslav Roček (EBIR)

The monitoring and surveillance of vascular access are an integral part of haemodialysis patient care, as vascular access is the Achilles' heel for a haemodialysis patient.

The Dialysis Outcome Quality Initiative Guidelines (DOQI) and the European Best Practice Guidelines (EBPG) have provided a list of techniques that can be used for the monitoring and surveillance of vascular access. The issue of adequate target-setting can be analysed by using the published works on the clinical impact of access surveillance system introductions (the timely detection of access stenosis and access patency).

The benefits of vascular access surveillance are as follows:

- a) the eradication of unnoticed deterioration of delivered haemodialysis dose caused by access recirculation caused by compromised access;
- b) a higher success rate in correction procedures if performed earlier in a stenosed rather than thrombosed access:
- c) the general prolongation of access patency;
- d) cost savings, or at least cost-effectiveness.

Monitoring strategies include physical examination (thrill, bruit, buzz and pulsations) of the vascular access to detect signs which suggest physical pathology. Access flow measurement, duplex Doppler ultrasound and direct or derived static pressure are the frequently used surveillance tools studied in the literature,

with flow-measurement (QVA) being the most widely used technique.

Early detection of vascular access dysfunction can prevent not only complications related to vascular access, but also those of insufficient

QVA is a parameter that determines the quality of vascular access, with which measurements at regular intervals can allow one to perform early interventions. Indication for a fistulography with possible intervention is recommended at access flow decrease of 25% or more over 4 months and/or at OVA below 350-400 ml/min in arteriovenous fistula (AVF) and below 400-600 ml/min in arteriovenous graft (AVG).

For reliable trend evaluation, the flow should always be measured at the same time during dialysis, preferably during the first hour. Monitoring intervals should certainly be individualised on the basis of access type (longer in AVFs than in AVGs), actual QVA value (longer for higher flows), and QVA history (shorter intervals in new access shunts, longer in known VA with stable flow).

The regularity of the intervals is often chosen according to the current status and history of vascular access. For new AVF/AVG and when decreasing flow-rate once per month, a 1-month interval is also chosen after all interventions for a period of 3 months. Constant flow-measurement interval is 1 month for AVG (DOQI) and 3 months for AVF (EBPG).

All studies on vascular access monitoring and surveillance (VAMS) systems published so far have uniformly demonstrated a significant decrease in thrombosis rates and thus in thrombectomies, regardless of the access type (decrease is apparently more pronounced in AVGs than in AVFs) after introduction VAMS. This decrease is, as a rule, accompanied by a parallel increase in the number of performed prophylactic angioplasties. With the introduction of the access surveillance, the number of surgical interventions decreased from a previous 80% of all interventions to a current 10-15%, which was replaced by balloon angioplasties.

The implementation of VAMS is associated with increase in the number of interventions. VAMS entirely changed the structure of interventions; thrombectomies and surgical procedures now represent less than 10% of all interventions while over 80% are PTAs.

The guidelines of the National Kidney Foundation Kidney Disease Outcomes Quality Initiative recommend that arteriovenous vascular accesses undergo routine surveillance for detection and correction of stenosis. This recommendation is based on the paradigm that surveillance of access blood flow or dialysis venous pressure combined with correction of stenosis improves access outcomes. However, the quality of evidence used to support this paradigm has been widely criticised. Some authors tested the validity of the surveillance paradigm by applying World Health Organization (WHO) criteria for evaluating screening tests to a literature review

Don't miss it!

Sunday, September 15, 08:30-09:30

Haemodialysis Special Session

Room 112

Miloslav Roček (EBIR) University Hospital in Motol Prague, Czech Republic

Prof. Miloslav Roček's interests include vascular interventions, non-vascular interventions and interventional oncology. An active CIRSE Member, he was on the Membership Committee from 2009-2011. He is a member of the Board of Trustees for the Prof. Rösch Foundation and a Committee Member of the Czech Radiological Society, and earlier this year fulfilled the role of Congress President at the historic 50th Anniversary of the Carlsbad Congress. His recent work has addresssed cortical and subcortical atrophy in Alzheimer disease, as well as prenatal diagnosis of congenital epulis by 2D/3D ultrasound and magnetic resonance.

of published vascular access studies. These criteria include four components: undesired condition; screening test; intervention; and desired outcome. The WHO criteria show that surveillance as currently practiced fails all four components and provides little or no significant benefit, suggesting that surveillance is a false paradigm.

Duplex Doppler ultrasonography has been used repeatedly as the surveillance technique for vascular accesses at various populations. The results are also controversial.

A larger multicentric, well-organised and randomised study with hard clinical end points to evaluate the optimal surveillance strategy for both fistula and graft with adequate sample size are required.

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An 82-year-old man with first radiocephalic fistula functioning for 1 year. The flow was decreased below 300 ml/min and fistulography was indicated. Significant anastomotic stenosis and another one 5 cm behind anastomosis were revealed (Fig. 1a). Anastomotic stenosis was treated with 4-mm balloon catheter (Fig. 1b, c) and venous outflow stenosis was then dilated with 7-mm GPS balloon catheter (Fig. 2a, b). The GPS catheter is a new balloon catheter in dialysis access procedures, which combines angioplasty and targeted control angiography through balloon without catheter exchange, removal or adjustment of guidewire. The final fistulography through the GPS catheter demonstrated an optimal finding after the procedure (Fig. 3).

Restaurant and Snacks at CIRSE 2013

At CIRSE 2013, you can take advantage of the Congress Centre's coffee bar and restaurant facilities, located in the exhibition hall.

The restaurant is open **Saturday to Tuesday from 11:00 to 15:00**, serving a range of hot and cold Mediterranean dishes à la carte.

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CIRSE Considers the Evidence – SFA interventions

CIRSE Office

A new session type makes its debut today at CIRSE – the Evidence Forum. To keep pace with the latest developments in interventional medicine, Evidence Forums will see the most up-to-date research summarised and discussed in the context of relevant questions arising in current practice. Today's Evidence Forum will examine the case for superficial femoral artery interventions, asking whether we know the optimal treatment yet.

The rising need for interventions

Peripheral arterial disease is on the rise, and is a cause for great concern. As the traditional response to the ischaemia and non-healing ulcers that arise from this disease is amputation, it can be costly in both economic and social terms. A commonly quoted figure is that somewhere in the world, a leg will be lost to diabetes every 30 seconds. Even with the wealth of IR options available, up to 67% of CLI patients in the USA have a primary amputation as their initial treatment – a staggering figure when one considers that recanalisation techniques can lower the amputation rate in CLI patients from 73-95% down to just 25%. An important contributor to peripheral artery disease is occlusion of the superficial femoral artery.

Today's Evidence Forum

A range of devices and techniques are now available for revascularisation of the superficial femoral artery in peripheral arterial disease. These treatments offer great potential in reducing morbidity and restoring quality of life. However, in light of the latest studies and the volume of data now available there is a need to compare strategies carefully. This is essential if IRs are to offer an optimal and evidence-based approach for each patient.

The results of recent and ongoing investigations are well worth discussion, but comparisons can be challenging if the various differing patient groups and lesion classifications are to be taken into account. To clarify the current state of the evidence, the speakers will present an evaluation of existing data, examining short and long-term outcomes where possible and taking into consideration relevant cost implications alongside the weight of clinical evidence.

A wide spectrum of endovascular options will be compared including stent technologies, where the comparative advantages of drugeluting stents and covered stents as compared to bare metallic stents will be examined. Drugeluting balloons, as well as atherectomy with cutting balloons, will also be discussed.

Bare Metalic Stents

The use of bare metal stents will be discussed by Prof. Stefan Müller-Hülsbeck, who will ask if the received wisdom of endovascular SFA treatment still holds, or if new approaches need to be considered:



"Educated in the philosophy of restricting superficial femoral artery (SFA) stenting to bail-out, and confronted with encouraging data for new generation SFA nitinol stents for almost 10 years, a recent paradigm-shift in endovascular opinion has taken place: 'don't leave any metal behind!' This statement now hangs above our daily decision-making process like a Damocles sword. The decision of when to stay with plain old balloon angioplasty (POBA), subintimal angioplasty or stenting and when to switch to drug-eluting balloon, drug-eluting stent technology or combining POBA with self-expanding bare metal stents and DEB remains unclear. This challenge, however, reflects one of IR's strengths - continual evolution and innovation! At the moment, if PTA fails either in TASC A, B, C or D lesions, implanting a self-expanding stent in the SFA does not seem to be contra-indicated. Bio-absorbable stents seem ready to go for SFA application."

Drug-eluting stents

Drug-eluting stents showed much promise when they were originally conceived. But how has the data fared, and do we know yet when their use is indicated? This will be discussed by Prof. Peter Gaines:



"Simple angioplasty alone in the SFA for complex lesions has an unacceptably high restenosis rate. We know that patency is the main driver of success for endovascular interventions in the SFA. New design bare metal stents have demonstrated better patency than simple angioplasty. Initially, drug-eluting stents (DES) failed to show benefit. More recently, the Zilver DES has shown a significant patency advantage over the bare stent and simple angioplasty in a randomised trial. In addition, the registry data has shown very good patency in diabetics and long lesions. The use of current DES should be considered by anyone wishing to maximise the clinical benefit of endovascular SFA interventions. Whether that drug elution is best delivered by stent or balloon will be debated until suitable trials are constructed."

Drug-eluting balloons

The evolution and merits of drug-eluting ballons will be examined by Prof. Gunnar Tepe, who has been researching this field for many years already:



"After the first promising data with drug-coated balloons, there is increasing evidence that these do indeed increase the long-term patency of endovascular therapy in peripheral vascular disease. Currently these devices are also tested in challenging lesions, such as in-stent restenosis and long occlusions. The principle is to perform a procedure while leaving no foreign material behind. I am confident that this treatment will play a major role in the future of endovascular therapy. Further studies have to find out for which indications the drug-coated balloon should be used and which lesions should be better treated by other devices."

Cutting balloons

Dr. Mo Hamady will be discussing several treatment options, including the rationale of new 'cutting balloons', and how the evidence for their use is accumulating:



"Cutting balloons consists of three to four micro surgical blades imbedded in non-complaint angioplasty balloon. The principle of cutting balloon is to minimise vessel wall trauma by inducing radial micro-incisions in the plaque prior to angioplasty. The indications for CBA include in-stent restenosis, short segment eccentric calcified plaque and graft anastomotic stenosis. CBA has been studied extensively in coronary arteries but scarce of data is available in PVD.

"The evidence from single centre series showed good initial technical success rate with infrequent major complications. In the absence of RCT or direct comparison between CBA and other treatment modalities, it is difficult to draw a clear consensus on guidelines that identify the role and long-term results of this technique. Further studies are needed to define the short and long term outcome, comparing CBA with other surgical and endovascular techniques, taking into account several known confounding factors."

New stent-graft designs

The possibilities raised by stent-grafts in treating SFA lesions will be discussed by Prof. Maria Schoder, who will also evaluate the currently available devices:



"The GORE Viabahn® endoprosthesis may represent an alternative approach for endovascular treatment of long (TASC II C and D) SFA lesions. The original GORE Hemobahn® endoprosthesis was introduced in Europe in 1996 and since then, innovative design enhancements were implemented. The nitinol self-expanding polytetrafluoroethylene (PTFE) lined stent is also the only stent-graft approved by the FDA for the treatment of SFA lesions. The current generation of the Gore Viabahn® device has a heparin bioactive surface to reduce the risk of graft thrombosis and a contoured proximal edge design which may improve flow dynamics resulting in less incidence of proximal edge stenosis. Two recently published singlearm studies reported 12-month primary patency rates of 73% and 76% in mean treated lesion length of 19 cm. In the VIASTAR trial, a prospective, randomised, multicentre study, the 12-month primary patency rate in TASC D lesions was significantly longer in the Viabahn group compared to the bare metal stent group."

Don't miss it! SFA - do we know the optimal treatment yet? **Evidence Forum** Sunday, September 15, 11:30-12:30

Other technologies

Other technologies and techniques are also under investigation, and Dr. Hamady will also address the use of atherectomy devices for SFA lesions: Dr. Hamady will also discuss atherectomy devices:

"Atherectomy devices were first introduced over two decades ago. The main advantages of this modality are to avoid the use of stents in critical levels, such as the groin and the origin of the profunda femoris artery, and to reduce the neointimal hyperplasia. It is particularly suitable for eccentric plaques, heavily calcified lesions, long segment occlusion and femoro-popliteal bypass. Atherectomy has been assessed in small RCTs and in single or multicentres studies. The available data show high recanalisation rates, reduction in need for stenting with no significant improvement over PTA in the main outcomes of limb salvage, and mid- or long-term patency rate. Distal embolisation remains an issue of concern during the use of these devices. Combining atherectomy with drug-eluting balloons is a promising approach, which yet to be properly evaluated. The current NICE guidelines in England and Wales acknowledge the limitations of the current evidence and advise to use this technique under controlled environment or in the context of research projects."

The session will end with a summary of the evidence by Prof. Johannes Lammer, and conclusions will be drawn by the experts in a panel discussion, considering if there is indeed a current "optimal treatment" or if further investigations and longer term trial results are needed in particular areas.

Join us to refine your knowledge of the optimal treatment for SFA, and to hear the views of the other invited speakers!

Today's Evidence Forum: SFA - do we know the optimal treatment yet? 11:30-12:30, Room 116

Moderator: Johannes Lammer (Vienna/AT)

Bare metallic stents Stefan Müller-Hülsbeck (Flensburg/DE)

Drug-eluting stents Peter Gaines (Sheffield/UK)

Stent-grafts Maria Schoder (Vienna/AT)

Drug-eluting balloons Gunnar Tepe (Rosenheim/DE)

Atherectomy, cutting balloons Mohamed Hamady (London/UK)



International Conference on Complications in Interventional Radiology

June 12-14, 2014 Poertschach, Austria

The International Congress on Complications in Interventional Radiology (ICCIR) is a unique event in the IR calendar, giving doctors at all levels of expertise the chance to explore the difficult but necessary subject of procedural complications.

ATMOSPHERE

With a distinguished faculty consisting of renowned interventional radiologists, cases can be viewed through a wide variety of perspectives and experiences. The ICCIR faculty is specially selected to create an atmosphere that is sensitive and professional.

CASE PRESENTATION

At the core of this congress are case presentations and case reports, allowing IRs to be open and honest in discussing the complications they have faced and how these could have been best avoided or managed.

The feedback has been consistently positive, with participants appreciating the chance to improve their understanding of potential downsides through hearing about others' experiences first-hand. A further benefit of the ICCIR is that doctors who have had difficult cases can share their stories with others who have had similar experiences.

CASE SUBMISSION

The ICCIR Scientific Programme Committee cordially invites all authors who wish to present a case at ICCIR 2014 to submit their abstract online by January 27, 2014. The most interesting cases will be selected and accepted for oral presentation.

SUPPORT

For all case presenters, registration fees will be waived and travel support of €120 will be given. Additionally, the JR Foundation is kindly offering a number of Travel Grants to case presenters once again. Submission of your application is possible from now until February 10, 2014. The first ten applicants will receive travel support of up to €500. For detailed information and eligibility criteria, as well as other congress-related information, please visit the ICCIR website at www.iccir.eu.

DON'T MISS IT

We are proud to announce that the ICCIR will once again provide an open forum for the discussion of complications, giving young doctors in particular the chance to learn and benefit from the experience of their elder colleagues in a structured and meaningful way. Participation is limited to 250 participants, so early registration is advised.

We look forward to seeing you in Poertschach, Austria in June 2014!

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Advertorial

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can be found in the product labeling supplied with each device. All claims and descriptions are for CE regulated countries. Availability of these products may vary in countries outside EU. COVIDIEN, COVIDIEN with logo and Covidien logo are US and internationally registered trademarks of Covidien AG. ™ Trademark of a Covidien

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iVascular launches the Luminor Drug Eluting Balloon line to complete its peripheral interventions product portfolio. Based on the Oceanus 14 Balloon and Oceanus 35 platforms, the new Luminor 14 and Luminor 35 provide extra accessibility to most challenging anatomies.

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22 Advertisement Sunday, September 15, 2013

Advertorial

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MicroThermX™ is a powerful, reliable and user-friendly microwave system. Microwaves technology treats tumors faster than RadioFrequency Ablation and there is less impact by heat sink effect.

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New Product Launches

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Did you know that ESIRonline contains more than 6,100 presentations from all areas of interventional radiology?

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Germany Sets New Standards in IR Quality Management

Petra Mann, CIRSE Office

It has been a few years since the German Society of Interventional Radiology (DeGIR) implemented its ground-breaking quality management programme. The objective was to maintain and improve interventional radiology's high standard of care and professional status across the country.

The DeGIR quality management programme addresses two key dimensions of medical professionalism – certification of interventional radiology (IR) specialisation and procedure data collection and monitoring.

Specialisation and Certification

DeGIR's certification in IR is a structured, educational programme that encompasses a basic and an advanced level. It is compatible with similar, Europe-wide programmes (European Board of Interventional Radiology – EBIR) and is fully supported by the German Society for

Radiology's Academy for Continued Education. Thanks to its high standards and official endorsements, the DeGIR certificate guarantees holders recognition of their knowledge, skills and competencies in IR.

DeGIR's educational programme (in full support of EBIR) is complemented by qualification guidelines drafted and published in co-operation with the German Radiology Society (DRG).

Data Collection and Monitoring

In order to provide continuous quality assurance in IR, a state-of-the-art system was developed by DeGIR which allows interventional radiologists to collect and record data pertaining to procedures they have performed throughout their careers.

This unique online system allows its members to enter an array of procedural data, including



quality parameters and treatment outcomes. Users can enter data in real time, evaluate their procedures according to quality assurance parameters and compare them anonymously to all available data.

DeGIR's dedication to this ground-breaking system is shown by the team of specialists continuously reviewing and adapting it to new procedures. This commitment is certainly paying off, with almost 200 hospital and institutes participating in the programme. In 2011, more than 80,000 procedures were entered, making



it the most comprehensive collection of IR quality assurance data worldwide.

Furthermore, registration with and regular use of the system are strict requirements of the DeGIR certification.

Committed to Excellence

To date, there are more than 900 DeGIR certified interventional radiologists and 190 certified IR instructors from 120 educational centres in Germany.

The benefits that such a programme brings to the patient cannot be denied. It has also proven to be an important tool in demonstrating the high standard of IR procedures vis-à-vis more traditional methods and is highly instrumental in discussions on the distribution of resources among the various medical disciplines – which naturally requires supporting data.

Registries in Interventional Radiology

Robert Bauer, CIRSE Office

Medical case-series studies¹, more commonly known as registries, are an important and often overlooked tool in bolstering the evidence base of medical interventions to help improve the quality of service. Registries involve collecting crucial data points of procedures (duration, success, complications, etc.) performed in multiple centres.

Unlike other forms of clinical research, registries do not rely on a randomised sample of patients and the inclusion criteria allow for a wider patient sample.

This straightforward methodology is the greatest advantage of a registry, as Jim A. Reekers, Professor of Interventional Radiology at the

University of Amsterdam points out, "registries give a grosso modo overview of the efficacy, safety, complications and frequency of new procedures. Registry data can also assist in setting up more sophisticated trial studies, helping calibrate how many patients are needed to produce good scientific evidence."

Naturally, registries are not without their challenges, as Prof. Reekers explains, "registries do, however, have an uncontrolled voluntary inclusion and are therefore particularly susceptive to selection bias and must be interpreted carefully."

Owing to their manageable and effective methodology and the relatively modest

setting-up costs, registries are readily applicable enquiries that help better understand and ultimately fine-tune the provision of interventional radiology services.

For examples of IR registries, please refer to www.cirse.org

1 OCEBM Levels of Evidence Working Group. "The Oxford 2011 Levels of Evidence". Oxford Centre for Evidence- Based Medicine, accessed at http://www.cebm.net/index.aspx?o=5653



Angio-Seal

Angio-Seal $^{™}$ registry, 2009, CIRSE registries are conducted electronically, allowing physicians to enter their cases into an online database.

High Volumes, Good Outcomes

Ciara Madden, CIRSE Office

For many years now, it has been accepted, and indeed proven, that a strong link between high volume medical centres and good patient outcomes exists. The first study into this link appeared in 1979, when Dr. Harold Luft of the University of California at San Francisco published a paper in the New England Journal of Medicine, showing 25-41% fewer patient deaths in hospitals performing 200 or more surgical procedures a year, compared with lower volume hospitals. Since then, there have been many such studies conducted, mostly in the surgical field^{1,2}, and all appear to show favourable outcomes in high-volume centres, particularly for rare or difficult cases.

The mechanisms governing such an effect have yet to be fully established, but several possible factors have been identified:

- Regular experience means a hospital and its staff are more primed to deal with such cases, and more familiar with the options and therapies.
- High-volume centres have better resources, such as imaging and diagnostic equipment, which may result in more accurate therapy delivery.
- Surgeon experience may be the underlying cause, and high-volume centres are more likely to provide surgeons with regular opportunities to practice.
- Perhaps good outcomes attract high volumes of patients, and not the other way around.

Whatever the underlying cause, it is clear that high volume, specialised centres can often offer better outcomes, and many medical centres in Europe already reflect this trend, with specialised regional centres widely offered for stroke, cancers and paediatrics, to name but a few.

The Case for Interventional Radiology

There are less data available in the case of interventional radiology (IR), although data on endovascular treatment for stroke do show similar outcomes³. Moreover, it seems logical that interventional radiologists who regularly treat particular pathologies or emergencies will become more adept at treating those cases. It is already the case that interventional radiologists who work in hospitals specialising in trauma, cancer or stroke are emerging as experts in these fields, and are in a position to train and educate their colleagues.

In the same way, centralising IR care, especially for more complex and challenging cases, could greatly contribute to enhanced patient safety – a structure best arranged amongst hospital management, interventional radiologists and medical insurance companies. Given the evi-

dence that exists, hospital administrators would be well advised to capitalise on the resources already available to them. By ensuring that proper referral pathways and collaborative structures exist, hospital managers can ensure that their IR staff treats a regular stream of patients, keeping their hard-won skills up to date and staying abreast of new therapies and technologies – and most importantly, improving the outcomes for patients.

- 1 Vernooij et al, Specialised and high-volume care leads to better outcomes of ovarian cancer treatment in the Netherlands, University Medical Centre Utrecht
- 2 Pasquali et al, Association of center volume with mortality and complications in pediatric heart surgery, Pediatrics, 2012 Feb; 129(2):e370-6
- 3 Speedier treatment and better outcomes for high volume stroke centres, Journal of Neurointerventional Surgery, 9th May 2012



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IR Congress News is published as an additional source of information for all CIRSE 2013 participants. The articles and advertorials in this newspaper reflect the authors' opinion. CIRSE does not accept any responsibility regarding their content.

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Editors-in-Chief: Robert Morgan, Riccardo Lencioni Managing Editor: Ciara Madden, CIRSE Office Editorial Support: Leonora Barclay, CIRSE Office

Graphics/Artwork: LOOP. ENTERPRISES media / www.loop-enterprises.com

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