

CIRSE 2017 – Copenhagen
Tuesday, September 19, 2017

CIRSE lands in Lisbon

At the end of 4.5 days of innovation, education and science, it is the perfect time to think about what you will take back with you to implement into your daily practice. CIRSE 2017 has seen a number of exciting new sessions as well as long-standing favourites, with a strong theme throughout: **Impact the Future of IR**. So now, it's time to ask yourself, what can you do to impact the future of IR?

We hope you will tell us next September at CIRSE and IDEAS 2018 in Lisbon! This wonderful Portuguese city has hosted several CIRSE congresses, and we are looking forward to another spectacular stay.

Abstract submission will be open from December-February, so mark your calendars, and start planning your contribution to IR.

We look forward to welcoming you in Lisbon!

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Taming the systemic effects of interventional oncology through mechanistic study

Nahum Goldberg

For many of us, one of the most appealing reasons to enter the field of interventional radiology is the ability to adapt and improve upon extant novel technologies that can be creatively applied to solve a host of otherwise intractable clinical problems. A classic example of this paradigm in the sphere of interventional oncology is that of the development of percutaneous ablation devices [1]. Initially, simple monopolar radiofrequency devices were adopted from the neurological setting and used to treat small bone lesions, such as osteoid osteomas. This was rapidly followed by several parallel lines of industrial-academic interaction that resulted in improved multi-tined and internally-cooled devices for the treatment of initially liver, but ultimately lung, kidney, bone and other forms of malignant and benign disease. Proliferation of multiple, varying energy sources to accomplish such tumour ablation, including microwave, cryoablation, ultrasound, and the largely non-thermal irreversible electroporation (IRE), have subsequently followed.

Given the critical importance of device development to our field, parallel to the generation of clinical data demonstrating the efficacy of our transcatheter and percutaneous ablation devices, the primary focus of most translational and basic studies has traditionally been that of development, characterisation and optimisation of new devices (including those for image-guidance), accompanied by elucidation of the biophysical principles governing thermal methods for tumour destruction. Only more recently have there

been efforts to undertake a mechanistic approach to better understand how to best combine tumour ablation with other therapies to maximise efficacy. These include combining tumour ablation with the chemotherapeutic cocktails found in chemoembolisation [2] and nanotherapies, such as liposomal doxorubicin [3].

This trend towards gaining a better understanding of how our therapies affect both the underlying cancer biology and overall patient's health has important consequences. In addition to improving our standing with medical oncologists (whose clinical paradigm is virtually based upon a detailed understanding of the molecular interactions of chemotherapies with tumour cells and their environment), such knowledge will play an ever-increasing role in improving our clinical outcomes. This will likely occur not only by demonstrating increased tumour cytotoxicity and completeness of ablation by combination therapy, but by also eliminating any unintended negative consequences of our therapies. Although we have traditionally assumed that our local, focal interventional oncologic therapies have minimal systemic effects, there is increasing compelling animal evidence that backs up anecdotal clinical reports suggesting that RF and other ablative therapies can stimulate distant tumour growth [4]. Thus, strategies to better understand and ultimately modulate local and systemic pro-oncogenic effects of tumour ablation are urgently required to further improve therapeutic effects and, ultimately, clinical outcomes.

Our research group and others have now established that there are a number of tissue reactions that occur in the peri-ablational zone of non-lethal heating surrounding all RF ablations. On a cellular level, following ablation in the liver, it has been demonstrated that both early transcriptional and secretory activity of hepatocytes leads to the subsequent inflammatory response of increased cellular recruitment of neutrophils, macrophages, and activated myofibroblasts [5]. Using a host of cutting-edge technologies, we have also identified several key cytokine mediators with probable interlinked activity (i.e. IL-6, HGF/c-Met, STAT-3, and VEGF) that likely function as the key components of a mechanistic pathway, driving these pro-oncogenic effects [6]. Moreover, several of these cytokines have been shown to be elevated in patients following ablation and chemoembolisation [7,8]. It is precisely the identification of these targets, using techniques such as gene and protein expression platforms, real-time PCR (polymerase chain reactions), and knockout mouse models that enables the rational selection of drugs that can interrupt and arrest the systemic, pro-oncogenic effects of ablation. Specifically, it has been demonstrated in animal models that targeting this specific pathway, by suppressing IL-6 or inhibiting c-Met, STAT3, or VEGFR, can block hepatic RFA-induced stimulation of distant tumour growth to a varying extent.

Further mechanistic study is clearly warranted, as our current state of knowledge of the systemic effects of our interventional oncologic therapies is far from complete.

Don't miss it!

Josef Roesch Lecture
Honorary Lecture
Tuesday, September 19, 14:30-15:00
Auditorium 1



Nahum Goldberg
Hebrew University
Jerusalem, Israel

Professor Goldberg is an interventional oncologist and Professor at the Hebrew University in Jerusalem, Israel, and Harvard Medical School in Boston, USA. His research interests include over 20 years of experience studying image-guided tumour ablation and imaging studies. His independent Applied Radiology Laboratory in Hadassah, and Minimally Invasive Tumor Therapies Laboratory at Beth Israel Deaconess Medical Center in Boston are dedicated to uncovering methods to improve tumour ablation studies. Prof. Goldberg has authored more than 180 original scientific manuscripts, 25 book chapters and reviews, six guest editorials in Radiology and JVIR, and six patents. Prof. Goldberg has also served on multiple national and international committees, including CIRSE, SIR and the ESR.

HAVE YOU GOT YOUR TICKET?

We can't wait to celebrate with you at the official **CIRSE Farewell Dinner and Party** tonight. Tickets can be purchased at the "Hotels | Social Events | City Information" desk, which is located in the entrance hall of the Congress Centre. **See you tonight!**

>>

There are key questions, which (although subject to intensive study) are currently unanswered:

- 1) Which of these specific cytokines can be most successfully targeted in animal models simulating clinically relevant situations of known distant tumour, residual primary disease, or *de novo* tumorigenesis, and, ultimately, in the clinic to minimise recurrence and increase overall survival?
- 2) Which recruited and/or native cells in the peri-ablational rim are most responsible for cytokine production?

- 3) What is the true prevalence of post-ablation pro-oncogenesis in clinical practice?
- 4) Are certain tumour types more susceptible to RFA-induced pro-oncogenic effects (i.e., is this process linked to cytokine receptor expression and thus amenable to biomarker detection?
- 5) To what extent do these systemic effects vary when treating different organs?
- 6) To what extent do the systemic effects vary by the method of ablation (including energy source and dose) or embolisation used? [9]

Finally, it must also be noted that several studies have reported that tumour ablation can, under poorly defined "favourable" conditions, induce systemic immunologic "abscopal" effects that induce distant tumour regression [9,10]. In all likelihood, there is a balance between pro-oncogenic and pro-immunogenic effects that differs from patient to patient. Thus, our ultimate goal – achievable only through additional mechanistic study – should be to alter the post-ablation milieu to prevent any untoward tumorigenic effects, while simultaneously promoting these abscopic effects.

In conclusion, tumour ablation and other interventional oncologic techniques can potentially have more widespread effects than just eliminating a focal tumour. These effects can potentially influence organ homeostasis, residual tumour growth, and possibly tumour initiation. Systematic mechanistic study will lead to a better understanding of these processes and holds great promise for elucidating the best possible strategies for future pharmacologic manipulation. Optimised therapy will likely require organ-by-organ and device-by-device tailoring, but nevertheless holds substantial potential to improve therapeutic outcomes.

References:

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Optimal logistics for a stroke system of care

Marc Ribó

Intravenous tPA treatment is effective in acute stroke patients, especially those with mild or moderate symptoms [1,2]. The efficacy of IV tPA in terms of arterial recanalisation in the early hours of stroke progressively drops as the burden of the occlusive clot increases [3]. While the recanalisation rate of an M2 occlusion is around 70%, the recanalisation rates of M1 or terminal ICA occlusions drop to 30% and 10%, respectively [4].

The main advantage of IV tPA treatment is that the treatment is readily available in centres that do not need high technological or professional requirements. In fact, in the last decade, the growth of telestroke services has allowed the spread of IV tPA treatment to remote areas that cannot provide an in-house stroke specialist 24/7 [5].

On the other hand, endovascular treatment (EVT) has also recently been shown to be a powerful treatment in moderate to severe stroke patients. In these cases, recanalisation rates after the procedure are often reported above 80%, especially when stent retrievers are predominantly used [6-10]. The catch is that, due to the nature of this treatment, a high level of technological resources and specialised physicians are needed, limiting the availability of this treatment to the biggest comprehensive stroke centres.

Access to EVT, therefore, continues to be very unequal according to the patient's geographical location at stroke onset. Patients living in areas where the primary referral hospital is an EVT-capable stroke centre (EVT-SC) have much higher chances of receiving EVT than patients primarily referred to local stroke centres (SCs) (Fig. 1) [11].

It seems clear that in the coming years, the number of trained interventionalists will grow, and new centres capable of delivering EVT will appear. Yet still, the presence of EVT-capable centres in remote areas with

low population density will not be justified.

At present, we have two different treatments for acute stroke patients with different geographical availability and different efficacy. In both cases, the time to treatment initiation is critical, and the sooner the treatment is started, the higher the chances of clinical recovery. A recent study showed that in the first hours after onset, for each 30-minute delay in EVT initiation the likelihood of regaining functional independence drops by 10-15% [12]. That raises the question of where a patient with a suspected LVO stroke should be primarily transferred (Fig. 2).

Option 1: Transfer to the nearest local SC (immediate care including IV-tPA) offers rapid access to the less effective treatment, and subsequent transfer to an EVT-SC where their status will determine follow-up treatments: a) already recanalised (no further specific treatment needed); b) with a large infarct and no mismatch (no further specific treatment needed); or c) with persistent occlusion and mismatch (will receive EVT with time delay as compared with option 2). The time to admission in the comprehensive SC will be determined by the initial distance to the EVT-SC and the door-in/door-out (DIDO) time at the local SC.

Option 2: Transfer to the nearest EVT-SC (bypassing the nearest local SC) offers access to all effective treatments. The time to admission to the EVT-SC will only be determined by the distance to stroke onset location. As compared to option 1, IV-tPA treatment is delayed, but EVT initiation is advanced.

This question cannot be definitively answered based on the present published scientific evidence. Initially transferring these patients to an EVT-SC seems reasonable since it may increase the number of patients that will benefit from the strong positive effect of EVT, but this, of course, needs to be proven.

Moreover, several other issues should concern us. How safe is it to transfer these patients long distances before they access a hospital? Is there a distance beyond which there is no or very limited benefit from a direct transfer to an EVT-SC? In this case, new EVT-capable facilities will need to be strategically created.

Theoretically, the benefits of a primary transfer to an EVT-SC would only apply to patients with large vessel occlusion (LVO) and may unnecessarily delay treatment in all others. Therefore, the predictive power of initial screening tools to identify patients with suspected LVO is of paramount importance. Several pre-hospital scales have been developed with the aim of rapid assessment of suspected acute stroke patients by paramedics. The RACE scale is a simple and rapid neurological scale designed to evaluate patients with acute stroke at a pre-hospital level to detect cases with a high probability of having an LVO, with candidates to be treated with endovascular techniques in a comprehensive stroke centre [13]. The RACE scale is a simplification of the NIHSS scale using those items with a higher ability to predict the presence of LVO (Fig. 3). The RACE scale evaluates five things: facial palsy, brachial paresis, crural paresis, oculocephalic deviation and aphasia/agnosia, with a total score of 0-9. A score >4 triggers the suspicion of LVO with a sensitivity of 85% and specificity of 69%.

The RACE scale was designed and validated between 2011-2013 in a region of Catalonia in a prospective study with 357 patients [13] and was implemented in September 2014 in the stroke code protocol in Catalonia, following an online training programme for EMTs and other EMS professionals. Currently, the RACE scale is evaluated, registered on the EMS database and given to the receiving stroke centre in 60% of the stroke code activations. More information about the RACE scale can be found at www.racescale.org (Fig. 3). The RACE and other scales are currently being used to make

Don't miss it!

Establishing an acute intra-arterial stroke service

Special Session

Tuesday, September 19, 10:00-11:00

Auditorium 15



Marc Ribó
Vall d'Hebron Stroke Unit
Barcelona, Spain

Dr. Ribó is a Neurology Professor at University Hospital Vall d'Hebron, where he completed his residency in neurology. His PhD was awarded for research on endogenous inhibitors of fibrinolysis in tPA-treated stroke patients. This was followed by a vascular neurology fellowship at the University of Texas in Houston, USA, where he acquired experience in intra-arterial rescue procedures and telemedicine for acute stroke care. He has also served at the University of Pittsburgh Medical Center as a visiting Professor. He has had over 140 articles published in peer-reviewed journals and has been cited over 7,000 times. He is on the Board of Directors of the Society of Vascular Interventional Neurology, and is an active member of the European Society of Minimally Invasive Neurological Therapy.

decisions about which level of care centre acute stroke patients should be primarily transferred.

Transfer protocols are being revised worldwide and novel algorithms are being proposed to improve access to EVT for patients living in geographic areas distant from EVT-SC. Unfortunately, the safety and efficacy of these solutions are not supported by data from clinical studies. Whether a pre-hospital triage system (including the use of a pre-hospital triage scale) to determine the primary destination centre would allow increased efficiency of revascularisation treatments and long-term clinical benefits is the aim of the RACECAT study that is currently in progress in Catalonia [14,15] and aims to generate clinical evidence to answer this matter.

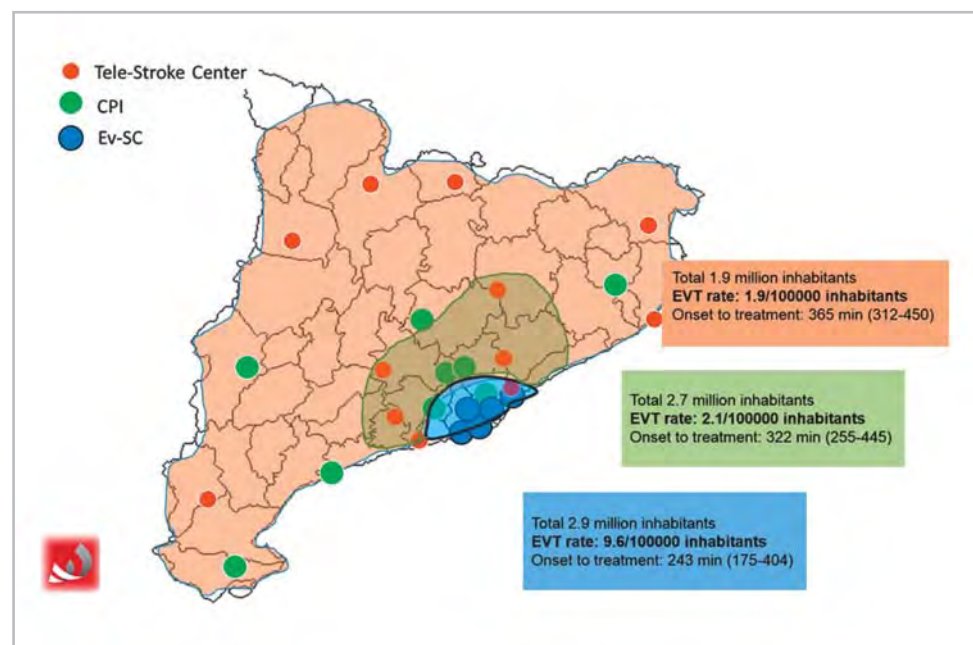


Fig. 1: Distribution of mechanical thrombectomies performed in 2015 by patient's location at stroke onset, according to three geographical areas (inner and outer metropolitan areas and the provinces). (CPI: primary stroke centre, EV-SC: endovascular treatment-capable stroke centre).

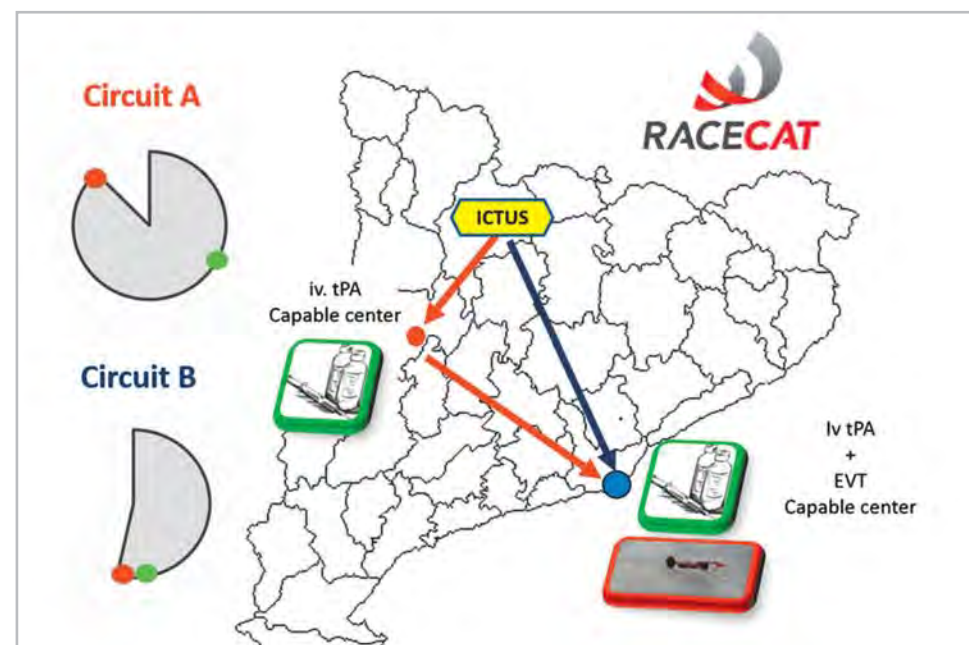


Fig. 2: Different primary transfer options of suspected large vessel occlusion stroke patients, prioritising (a) IV tPA treatment over (b) endovascular treatment.

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Don't miss it!**Treatment of peripheral vascular malformations****Special Session**

Wednesday, September 20, 10:00-11:00
Auditorium 10



Alex M. Barnacle
Great Ormond Street
Children's Hospital
London, UK

Dr. Barnacle is a Consultant in Paediatric Interventional Radiology at Great Ormond Street Hospital, where she is the lead radiologist for the vascular anomalies service. In addition to this, she has a special interest in working with children with complex birthmarks, and provides expertise in the management of paediatric renal stones, thrombolysis and musculoskeletal interventions. Dr. Barnacle is a member of several professional societies, including the Society of Pediatric Interventional Radiology, the British Society of Interventional Radiology and CIRSE.

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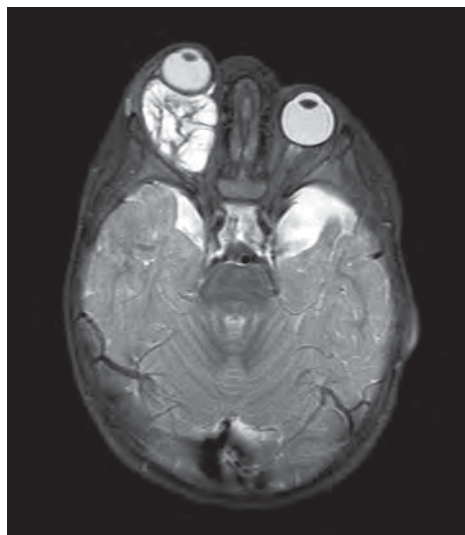


Fig. 1: Axial T2-weighted MRI of a child with a complex lymphatic malformation of the right orbit, treated with percutaneous sclerotherapy.

Complex malformations and associated syndromes

Alex Barnacle

Vascular malformations have always been a niche part of IR practice. They challenge us to be real experts in embolisation as well as sclerotherapy, and complex patients become very well known to us as frequent attenders in our angiosuites. When we talk about vascular malformations, most of us tend to focus on high-flow arterio-venous malformations and the technical challenges they present. Although we may not see them so often, there are also a huge range of other malformations that exist and which merit our attention too.

Most of these complex vascular anomalies involve low-flow venous or lymphatic malformations. They can occur as part of a much wider abnormal growth pattern. A huge array of malformations can co-exist in this way but there are some patterns that are seen much more commonly than others. Historically, vascular malformations with overgrowth have been labelled as various eponymous syndromes, such as Parkes Weber or Klippel Trenaunay syndrome (KTS). These myriad syndromes were often poorly understood or defined when they were first named centuries ago. Indeed, Doctors Klippel and Trenaunay did not include lymphatic malformations as part of their definition in their seminal paper in 1900 [1]. They had recognised a pattern that included a birthmark of a whole limb with associated venous varices and some hypertrophy. They named this constellation "noeuv variqueux ostéohypertrophique", though this unwieldy name soon came to be called Klippel-Trenaunay syndrome. We now know that lymphatic disease is a pretty consistent feature of the constellation of abnormalities that have traditionally been called KTS.

Most complex malformations occur in association with overgrowth, often of an entire limb. Although some patterns occur more often than others, it is now clear that using such labels to group a range of very different conditions is unhelpful and misleading. It is far more helpful to simply classify these conditions as 'complex overgrowth with a vascular malformation' and manage them according to the patient's individual needs [2]. Recently, geneticists have shown that many patients with complex regional overgrowth have mutations in common. Almost all of these are somatic mutations of phosphatidylinositol-

4,5-bisphosphate 3-kinase, catalytic subunit alpha (PIK3CA). They result in segmental overgrowth disorders now designated as the PIK3CA-related overgrowth spectrum (PROS). Recognising this is extremely helpful. PIK3CA and other common gene mutations function in the mTOR signalling pathway, which controls cell growth and metabolism. Such mutations are well known to occur in cancer, but are only now being recognised in benign hamartomatous lesions such as vascular malformations [3]. What is so exciting about this is that drugs targeted at inhibition of mTOR and other signalling pathways are now being developed to modulate overgrowth in many of these complex disorders [4,5]. Formal trials are already underway. I think that in the very near future, scientists will be showing us how, by targeting growth dysregulation at a cellular level, they can control or even prevent overgrowth in these patients.

In the meantime, patients with complex overgrowth require a multidisciplinary approach, with orthopaedic and plastic surgeons to manage the overgrowth, interventional radiologists to manage associated vascular malformations and a host of other specialists to manage functional issues. These include physiotherapists, speech and occupational therapists and, importantly, psychologists to help patients deal with the issues surrounding differences in appearance [5]. These rare and complex conditions challenge us to become more holistic doctors, giving careful consideration to each one of the patient's complex needs.

Complex malformations also give us exciting opportunities to develop novel therapies to manage some aspects of these diseases. Vascular malformations occurring as part of a wider syndrome can be challenging to treat, occurring in difficult-to-reach sites and often presenting late. These can include the urogenital tract, mesentery, airway and orbit. These patients often do not present directly to an IR clinic, and radiologists need to reach out to other specialties to find them. As we have seen in the past in so many other conditions, it often falls to IR to suggest minimally invasive interventions and encourage collaborative and innovative approaches to treatment. This includes endovenous laser therapy (EVLT) to treat malformations with a predominantly

'dysplastic-vein' type anatomy and cryoablation for more solid overgrowth lesions [6,7]. Sclerotherapy is still the easiest way to treat deep-seated low-flow malformations, but you may need the expertise of your colleagues to get you there. Endoscopically guided sclerotherapy of the bladder, mesentery and airway is both effective and extremely attractive to patients, compared to aggressive surgical options. We owe it to these patients to think collaboratively and push the boundaries of what is possible [8-10].

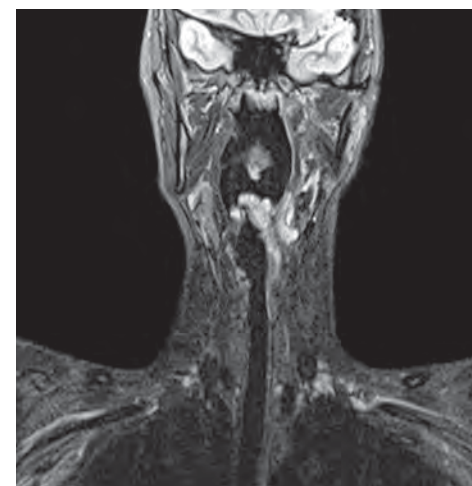


Fig. 3: T2-weighted a) coronal and b) axial MRI images of a venous malformation of the larynx, treated with bronchoscopically-assisted sclerotherapy.

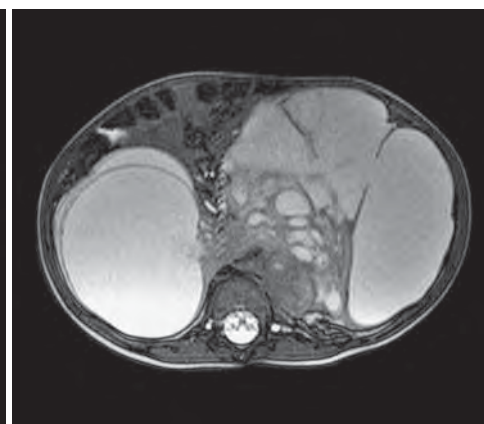


Fig. 2: T2-weighted a) coronal and b) axial MRI images of the abdomen of a 3-year-old child with a complex mesenteric malformation.

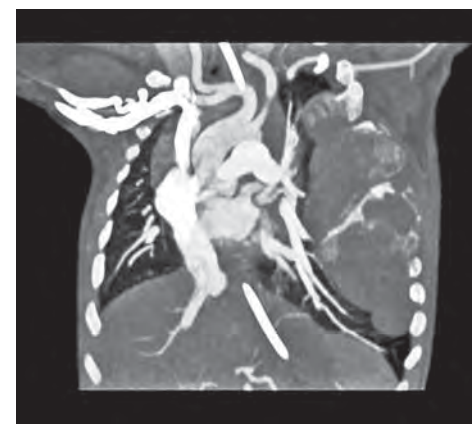


Fig. 4: Coronal CT reconstruction of a complex hamartomatous lesion of the chest in a one-year-old girl, treated with cryoablation.

Time for Super Tuesday!

After a successful inauguration last year, this special Free Paper Session aims to emphasise abstracts that have had the most impact on IR or that should be promoted in our subspecialty. The goal of the Super Tuesday session is to make science more popular and increase the importance of the scientific work in IR. With a broad range of topics included in the session, one of the papers which will be presented covers the results of the ROPE registry, an observational study collecting data on the treatment of LUTS using prostate artery embolisation in order to determine its safety, efficacy and compare it to other treatment options. This is a perfect topic for the Super Tuesday session as it highlights the latest information on a novel treatment. The session is geared toward everyone, IRs young and old, and is not to be missed.

Don't miss it!

Super Tuesday Free Paper Session

Tuesday, September 19, 16:15-17:15

Auditorium 11



News on Stage

The aim of this session format is to allow physicians to showcase the latest results from multi-centric trials, ground-breaking techniques and many more IR hot topics in an informal and open atmosphere. The presentations will be displayed in a dedicated open area next to the exhibition, giving delegates the opportunity to engage in active, lively discussions.

Today at 13:15-14:15, in the News on Stage area

NoS 2804 – Interventional Oncology News on Stage

- 2804.1 Proof of concept of a gene-directed enzyme prodrug therapy with intra-arterial delivery of mesenchymal stem cells in a rabbit VX2 hepatic tumor model
O. Pellerin, I. Amara, P. Beaune, I. de Waziers, C. Déan, M.R. Sapoval; Paris/FR
- 2804.2 Idarubicin-loaded DC Bead® for chemoembolization of HCC: interim analysis of IDASPHERE II (FFCD 1307) multicenter single-arm phase II trial
B. Guiu¹, P. Chevallier², P. Merle³, M.-A. Pierredon Foulongne¹, A. Rode³, A. Bouvier⁴, O. Guillaud³, P.-J. Valette⁵, J. Dumortier³, J.-P. Joly⁶, E. Nguyen Khac⁶, T. Yzet⁶, M. Lartournerie⁷, J.-C. Barbare⁶, M. Boulin⁷, S. Manfredi⁷; ¹Montpellier/FR, ²Nice/FR, ³Lyon/FR, ⁴Angers/FR, ⁵Pierre Benite/FR, ⁶Amiens/FR, ⁷Dijon/FR
- 2804.3 Prospective clinical and pharmacological evaluation of the Delcath System's second generation (GEN2) hemofiltration system in patients undergoing percutaneous hepatic perfusion with melphalan
T.S. Meijer, E.M. De Leede, M.C. Burgmans, C.H. Martini, F.G.J. Tyl, J. Vuyk, A.R. van Erkel, C.J.H. van der Velde, E. Kapiteijn, A.L. Vahrmeijer; Leiden/NL
- 2804.4 Chemoembolization adopting polyethylene glycol drug-eluting embolics loaded with doxorubicin for the treatment of hepatocellular carcinoma
C. Aliberti¹, R. Carandina¹, D. Sart², E. Pizzirani¹, G. Ramondo¹, L. Mulazzani², G. Fiorentini²; ¹Padova/IT, ²Pesaro/IT
- 2804.5 Pharmacokinetic profile of irinotecan in patients with liver metastases from colorectal cancer treated with unilobar or bilobar drug-eluting microsphere chemoembolization
G. Maleux¹, H. Prenen¹, T.K. Helmberger², U. Martens³, P.L. Pereira³; ¹Leuven/BE, ²Munich/DE, ³Heilbronn/DE
- 2804.6 Transarterial chemoembolization of hepatocellular carcinoma with 100±25-µm and 200±25-µm Lifepearl microspheres: short-term follow-up and safety profile
R. Argirò¹, C. Cirelli¹, M. Corona¹, P. Lucatelli², F. Fanelli¹, C. Catalano¹, M. Bezzi¹; ¹Rome/IT, ²Siena/IT

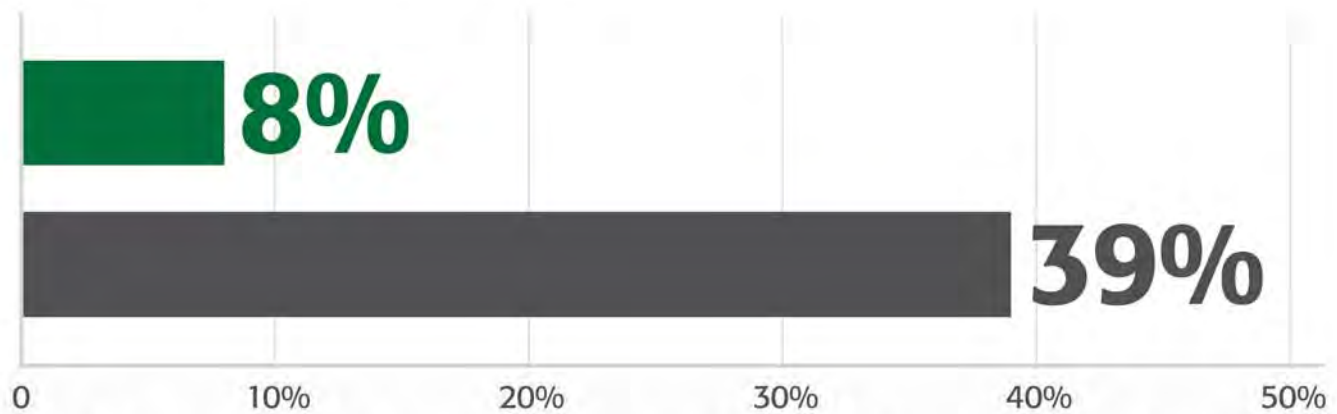
DID YOU KNOW?

PRE-CLINICAL TESTING HAS SHOWN DIFFERENCES IN DOWNSTREAM VASCULAR CHANGES AMONG DCBs.

Study I: Percentage of sections observed with vascular changes in downstream non-target tissue from arteries harvested at 28 days.¹

LUTONIX® 035
Drug Coated Balloon PTA Catheter

DCB BRAND 1



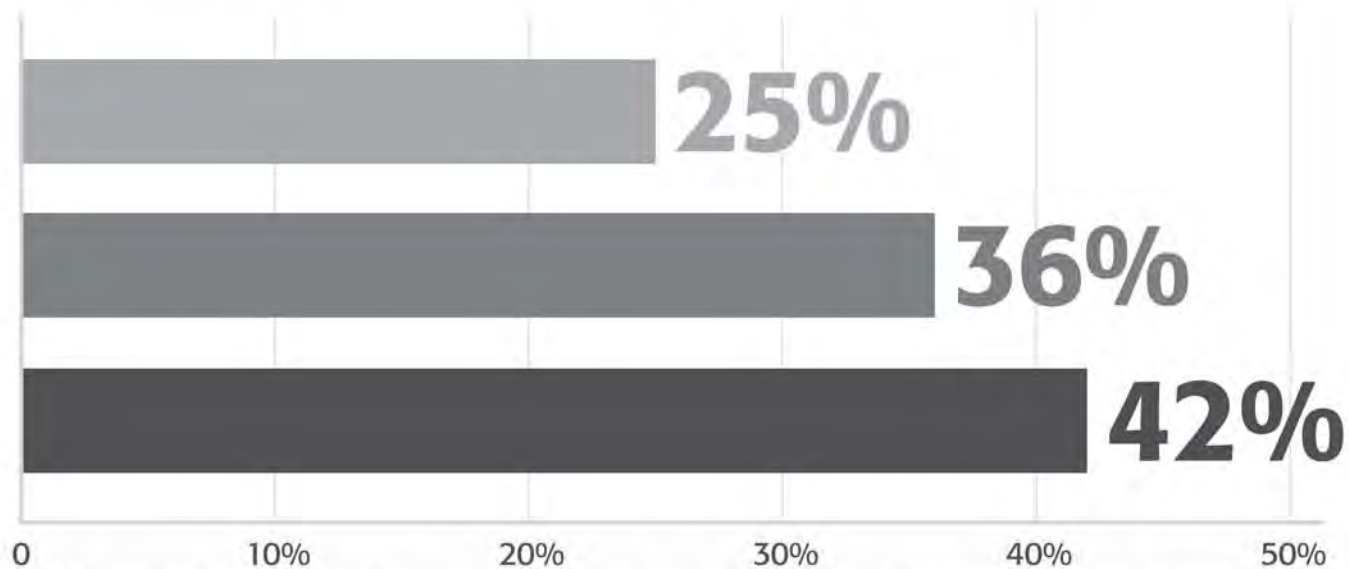
Pre-Clinical head-to-head comparison of vascular changes (inflammation, smooth muscle cell necrosis, fibrinoid necrosis, nuclear pyknosis). 3X Balloons. 30 second inflation.

Study II: Percentage of sections observed with vascular changes in downstream non-target tissue from arteries harvested at 28 days.

DCB BRAND 3

DCB BRAND 2

DCB BRAND 1



Pre-Clinical head-to-head comparison of vascular changes (inflammation, smooth muscle cell necrosis, fibrinoid necrosis, nuclear pyknosis). 3X Balloons. 1 minute inflation. Data on file. LUTONIX, Inc., New Hope, MN, USA.

Advancing Lives and the Delivery of Health Care™



1. Journal of Vascular and Interventional Radiology: Comparison of Particulate Embolization after Femoral Artery Treatment with In.Pact Admiral versus LUTONIX® 035 Paclitaxel-Coated Balloons in Healthy Swine. Limitations associated with this pre-clinical study include: Pathologic findings are limited to healthy swine and do not account for the fact that human PAD presents with co-morbidities; and transferring pre-clinical findings in healthy animal arteries to humans with peripheral arterial disease is complex, as lesions can be complicated by fibrosis, necrosis and calcification. This study was funded by LUTONIX, Inc. (New Hope, Minnesota). Article available at: <http://dx.doi.org/10.1016/j.jvir.2016.06.036>. Kolodgie et al, JVIR D-15-01131R1.

Preclinical results may not be indicative of clinical performance. Different test methods may yield different results.

The LUTONIX® 035 Drug Coated Balloon Catheter is intended for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature and for the treatment of obstructive lesions and decreasing the incidence of restenosis. In addition, the LUTONIX® 035 Drug Coated Balloon Catheter is intended for PTA of native dialysis fistulae or synthetic grafts, opening narrowing and immature fistulae, to improve blood flow, and decreasing the incidence of restenosis.

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0086

Anything left for SFA treatment – new drugs, new tools?

Andrew Holden, EBIR

Over the last decade, two major advances have occurred in the endovascular treatment of superficial femoral artery (SFA) occlusive disease: the concept of drug elution to minimise restenosis and the concept of adequate vessel preparation. Both are intimately related. There have been additional developments in stent, bioresorbable scaffold and debulking technologies. So, is there anything left for endovascular treatment in the SFA?

Head-to-head appraisal

There has been an emphasis shift in device research, from trials that show device and procedural safety and efficacy to trials that directly compare devices head-to-head. For example, the ZilverPass trial provides a direct comparison between two treatment strategies for long SFA lesions: drug-eluting stents versus prosthetic bypass. The Imperial trial provides a direct comparison between two devices for short to medium-length SFA lesions: Cook Zilver PTX versus Boston Scientific Eluvia drug-eluting stents. These head-to-head trials are exactly what clinicians, patients and funders demand, especially if they include cost-effectiveness data.

Drug-coated balloons

The well-designed randomised controlled trials comparing drug-coated balloon (DCB) angioplasty to plain balloon angioplasty have consistently shown superior sustained patency of DCB angioplasty for short to medium-length SFA lesions that respond well to pre-dilatation. The obvious question that has arisen is: are all DCBs the same? Although there is a paucity of prospective head-to-head randomised trials, careful cross-trial comparisons are reasonable given the randomised trial similarities. Most SFA DCB trials were multicentre trials evaluating SFA lesions of similar lesion length and complexity in claudicant and rest pain patients with similar demographics. Many trials used the same independent core laboratories.

There are two ways to compare DCBs – efficacy and safety. Efficacy is usually measured in terms of patency and freedom from clinically driven target lesion revascularisation (CD-TLR) at various time points. The cross-trial studies have clearly shown differences in both patency and freedom from CD-TLR (Fig. 1). With regards to safety, there have been no clear clinical safety differences between current DCBs in terms of local or systemic adverse events. However, there have been differences between DCB devices in particulate embolisation (Fig. 2). This may prove important, especially in patients with critical limb ischaemia.

There is still considerable research and development of DCBs in the SFA. Almost all current DCB devices in the SFA use Paclitaxel with variable dosimetry, choice of excipient and coating technology. With regards to Paclitaxel dosimetry, the most important issue is the dose delivered to the target vessel, rather than the dose on the device. This is an area of ongoing research into new devices with a lower concentration of drug on the balloon, potentially delivering equivalent or higher dose to the vessel. Excipient development that provides more stability with less embolisation is also being evaluated. While there is research into alternative anti-proliferative agents, these have yet to show equivalence to Paclitaxel.

Vessel preparation

The concept of adequate vessel preparation prior to DCB angioplasty really only referred to residual stenosis and dissection in the SFA

randomised trials. This concept is expanding as the clinical importance of drug-eluting technologies develops (Fig. 3). Stents have traditionally had a role in treating residual stenosis and significant dissection after plain balloon angioplasty. However, in the DCB era, devices have been developed to achieve better acute results without the need for permanent stents. Multiple scoring and cutting angioplasty balloons are currently being evaluated. The Trireme Chocolate balloon constrained in a nitinol cage provides an alternative approach, with the drug-eluting version currently being evaluated (Fig. 4).

A new area of interest in vessel preparation is facilitating drug delivery. The anti-proliferative pathway used by drugs such as Paclitaxel requires the drug to be delivered in sufficient quantities to the vessel media and adventitia. There are early indications that atherectomy devices, including directional and rotational atherectomy devices, do achieve superior patency when combined with a DCB. New vessel preparation devices, besides atherectomy, are also being developed. An example is the Cagent Vascular Serrator device that creates serrations or microchannels along the vessel wall (Fig. 5). This may not only provide improved dilatation with less dissection but also facilitate drug delivery to the media and adventitia. There are many alternative developments also attempting to improve drug delivery.

The final component of vessel preparation is altering vessel compliance. The SFA is not only the longest artery in the body but also the vessel subjected to the most deformity, with frequent motion including flexion, extension, torsion and axial compression. The most severe loss of arterial compliance occurs when atherosclerosis is associated with calcification. Arterial calcification in the SFA is a common finding, especially in the elderly and clinical sub-groups such as renal failure and diabetic patients. Most endovascular devices do not cope well with vessel calcification and often result in incomplete dilatation, dissection or even rupture. Significant calcification is a common exclusion criterion for many device trials. Calcification also appears to impair drug delivery. New approaches to calcified SFA occlusive disease include high-pressure, cutting and scoring balloons, atherectomy and lithoplasty. The Shockwave Medical Lithoplasty system combines localised lithotripsy (designed to disrupt calcification in both superficial and deep layers of the vessel wall) with low-pressure angioplasty (Fig. 6). Early results have been encouraging and trials combining lithoplasty with DCB technology are underway.

Scaffolds

Although DCB angioplasty has altered the treatment algorithm for SFA disease, there will always be a need for scaffolds to manage significant residual stenosis and dissection. This is particular relevant with longer and more complex lesions. The high radial-resistant biomimetic Abbott Supera stent has been extensively evaluated and plays an important role, particularly in complex SFA disease. Other biomimetic stents such as the BioMimics 3D stent are also being evaluated. Further stent developments include tack-assisted balloon angioplasty using the Tack Endovascular System in an attempt to provide focal dissection treatment with minimal metal and low radial force. Drug-eluting and covered stent alternatives to existing technologies continue to be developed. Current drug-eluting stent trials include the Imperial trial described above as well as the Xpedite trial

evaluating different Paclitaxel preparations on the Cook Zilver PTX stent. Extra-anatomic transvenous covered stent bypass of long SFA lesions is currently being investigated in the DETOUR studies using the PQ Bypass system.

For many years, the concept of a bioresorbable scaffold has been appealing in the SFA to take advantage of the acute performance of a scaffold but avoid the long-term complications of a permanent stent. However, there have been multiple failed trials in this arterial territory, primarily due to an inability to overcome the inflammation and restenosis associated with scaffold resorption. Despite this, the desire for a bioresorbable scaffold to manage residual stenosis and dissection after DCB angioplasty remains. Fortunately, trials with new devices such as the Elixir DESappear Trial are underway (Fig. 7).

In conclusion, there is still a lack of agreement and many questions around how to manage SFA disease, particularly complex lesions. Continued research and development of devices and procedures is vital as we strive towards consensus.

Don't miss it!

Therapy of claudication (SFA interventions)
Special Session
Tuesday, September 19, 08:30-09:30
Auditorium 2



Andrew Holden
(EBIR)
Auckland City Hospital
Auckland, New Zealand

Dr. Andrew Holden is Director of Interventional Radiology at Auckland City Hospital and Associate Professor of Radiology at the University of Auckland, as well as lead radiologist for the Auckland Hospital organ transplant programme. He is a member of IRSA (Interventional Society of Australasia) and ARGANZ (Abdominal Radiology Society of Australia and New Zealand) and is a former examiner for the RANZCR. Dr. Holden is the author of over 60 peer-reviewed articles and three book chapters, and was the Gruentzig Lecturer at CIRSE 2013. He has been the principal investigator in 25 'first-in-man' device trials and has performed over 50 live interventional case broadcasts from Auckland Hospital to overseas sites such as Germany, France, Hong Kong, the US and Australia.

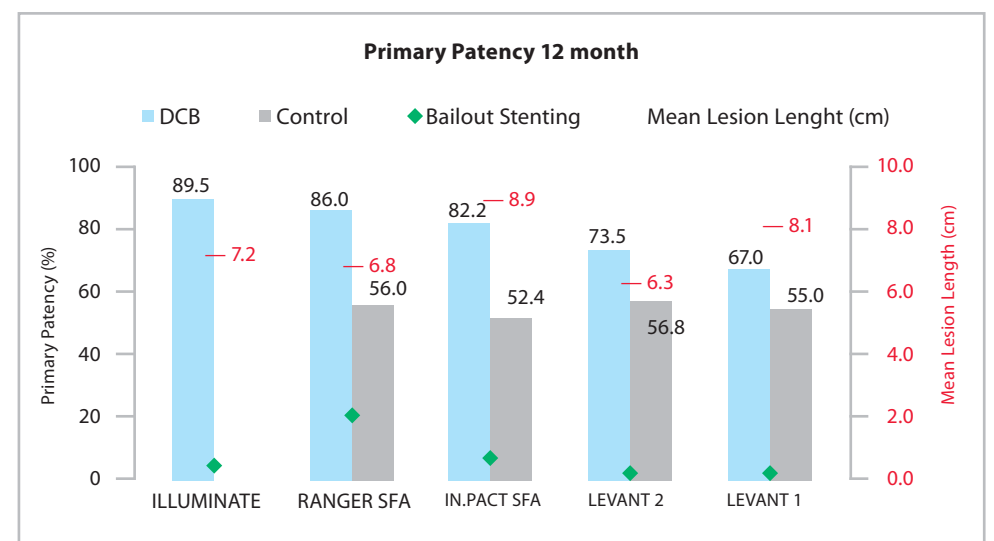


Fig. 1: Comparison of primary patency at 12 months from multiple DCB trials in the SFA.

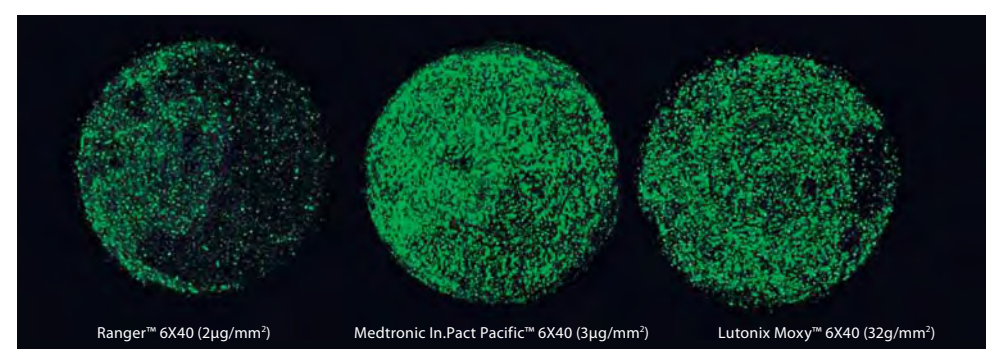


Fig. 2: In-vitro study comparing particulate embolisation amongst several DCB devices.

Adequate Vessel Preparation

- Significant lumen gain (residual stenosis <30%)
- Minimal dissection (< grade C dissection)
- Facilitate improved drug delivery
- Change vessel compliance

Fig. 3: Adequate vessel preparation.



Fig. 4: Trireme Chocolate drug-coated balloon.



Fig. 5: Cagent Vascular Serrator Balloon with microscopic views of vessel serrations.



Fig. 6: Shockwave Medical Peripheral Lithoplasty System.

Don't miss it!**Decision-making in acute stroke revascularisation****Expert Round Table**Wednesday, September 20, 10:00-11:00
Auditorium 15

Dierk Vorwerk
(EBIR)
Klinikum Ingolstadt
Ingolstadt, Germany

Professor Dierk Vorwerk recently stepped down as CVIR's Editor-in-Chief, a position he held since 2003. He is currently Chairman of the Department of Diagnostic and Interventional Radiology at the Klinikum Ingolstadt in Germany. Prof. Vorwerk is the renowned author of over 200 papers and more than 250 abstracts in the field of radiology. He has received numerous awards including the Wilhelm Conrad Röntgen Award (1993) of the German Roentgen Society, and he holds honorary memberships for various medical societies. He delivered the CIRSE 2010 Gruentzig Honorary Lecture, and is the recipient of this year's CIRSE Gold Medal for his services to the society and specialty.

Decision-making in acute stroke revascularisation

Dierk Vorwerk, EBIR

Stroke management has made astonishing progress within the last decade. While local application of thrombolytic drugs delivered via microcatheters, combined with some careful mechanical manoeuvres, remained the only contribution of IR to stroke management in patients refractory to intravenous thrombolysis, mechanical thrombectomy was gradually developed over the years with some devices being more effective than others. Aspiration and stent retrieving were the latest technical developments. However, 2013 was a bleak year for interventional stroke treatment, when three highly cited studies in *NEJM* did not show any benefit over intravenous thrombolysis. After that, interventional treatment of stroke was considered clinically dead, despite the fact that the *NEJM* studies had many weak points and raised more questions than they gave answers. Interventional (neuro)radiologists worldwide were puzzled as their clinical experience told them the opposite: the procedures resulted in high technical, and sometimes astonishing clinical, success.

Nevertheless, the published data brought interventional treatment into question for a while. To the relief of many, the MR CLEAN trial was published in 2014, clearly showing a significant benefit for patients treated by stent retrievers over intravenous thrombolysis alone. This was a milestone study and was quickly followed by several others with comparable results. The results matched the personal experiences of IRs involved in stroke therapy and drastically changed the clinical approach to stroke patients.

Intra-arterial treatment of stroke by mechanical thrombectomy is now a well-accepted part of the stroke workflow and is applied to patients with centrally located occlusions. This development suddenly created the need for experienced IRs and NIRs to be available to perform these procedures on a 24/7 basis.

Questions remain

However, there are still some questions remaining, and the round table is dedicated to examining some of these. There is still some discussion, for example, about the optimal approach to be applied. Key questions, therefore, focus on technical details. There is a trend in the community to apply suction aspiration rather than stent retrieval, at least as a first approach. Technically this is possible, thanks to the development of highly flexible aspiration catheters that allow the carotid T or the M1 segment to be reached quite easily. However, we will ask how well established this approach is and how much it is supported by true scientific data.

Furthermore, some investigators are quite convinced that balloon occlusion is mandatory to achieve the best technical and clinical outcome. Others use non-occluding sheaths for the same purpose and claim equal results. So an important question to be discussed is whether we have enough data to make a proper decision in this matter.

Should our patients undergo full anaesthesia and intubation, or is conscious sedation a better option? Will the patients benefit from

the chosen anaesthesiology protocol? This question surely has practical importance in institutions where full, round-the-clock anaesthesiology support might be an issue.

As intra-arterial stroke treatment for the anterior circulation became accepted just recently, a direct approach has long been accepted for patients suffering from posterior occlusions. Nevertheless, the posterior circulation is technically more challenging and we would like to have a glimpse of the latest requirements here.

Finally, the important question has to be asked: how can a 24/7 service be established to cover a whole country or region sufficiently? While in some communities, neuroradiologists insist on being the only group involved in interventional stroke management, some countries like Norway and Germany have adopted invasive stroke management models that involve both neuroradiologists and interventional radiologists. The beauty of the latter approach is that the NR and IR can together quickly build up a workforce that allows easy organisation of a 24/7 service. This aspect will be discussed extensively, especially in light of contradictory recommendations by national and international scientific societies.

In conclusion, interventional stroke therapy, albeit well accepted and highly desired in the medical community, still offers a number of open questions and challenges that have to be addressed. We hope to see you tomorrow in Auditorium 15 for a frank and informative discussion!

Case 1

77-year-old female patient with acute onset of left-sided hemiplegia. Otherwise in stable condition and coherent. Onset approximately 1 hour earlier. Only anaesthesiological back-up was provided and no intubation performed.

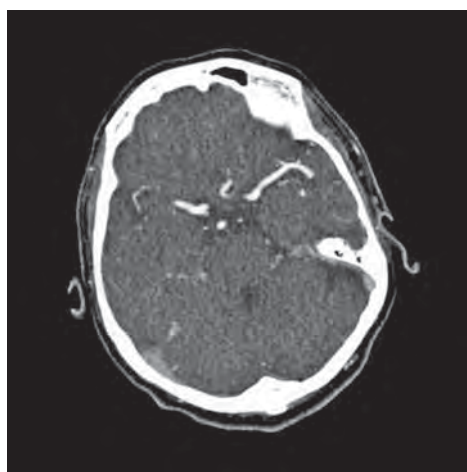


Fig. 1a: CT-angiography shows abrupt ending of the right MCA in the M1 segment.

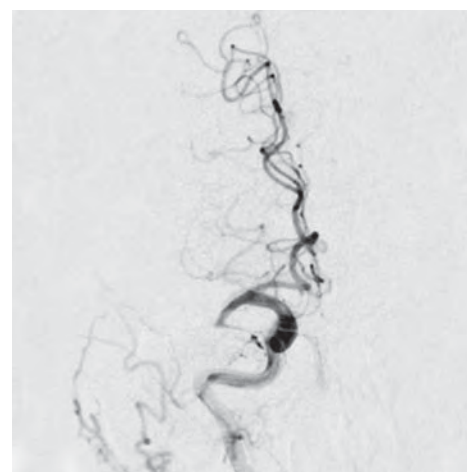


Fig. 1b: DSA of the right carotid artery proves M1 occlusion.

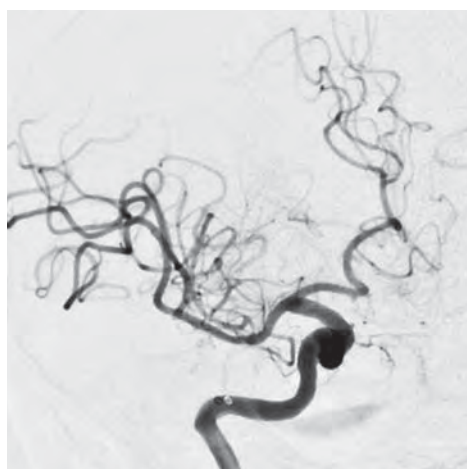


Fig. 1c: Combining aspiration in the M1 segment and two attempts of retrieving combined with continuous suction was successful in recanalising the anterior circulation.

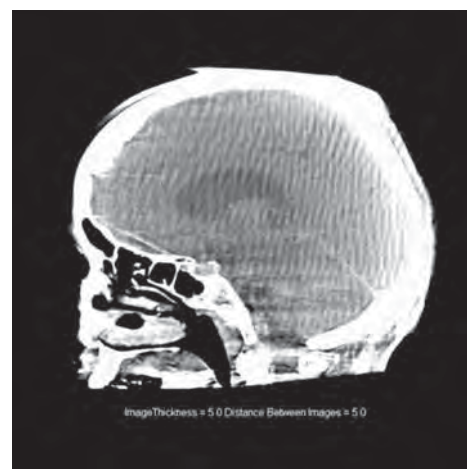


Fig. 1d: Topogram of DynaCT post-intervention proves absence of tube even at the end of the procedure. The patient immediately experienced clinical improvement.

Case 2

85-year-old female patient with severe neurological deficit and insomnia. Clinical signs of posterior infarction.



Fig. 2a: DSA of the posterior circulation via the left vertebral artery shows complete occlusion of the mid-segment of the basilar artery.



Fig. 2b: After a single aspiration manoeuvre, the basilar artery has been recanalised but the posterior cerebral arteries are still occluded.

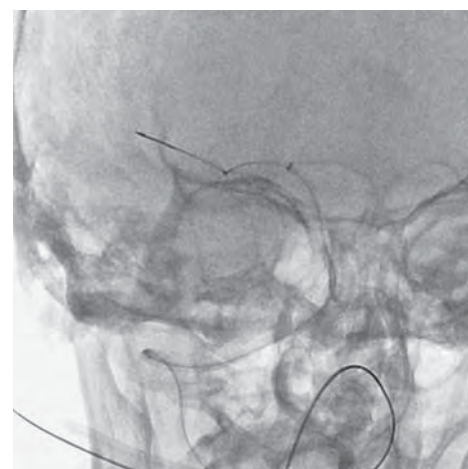


Fig. 2c: Additional manoeuvres using a 4x30 mm Preset retriever were performed.



Fig. 2d: Combined use of suction and retrieving was successful in recanalising the posterior circulation.

PAE: Ready for Prime Time?

Michelle Weiss, CIRSE Office

First performed in 2008 by Francisco Carnevale in Brazil, prostate arterial embolisation therapy has been gradually gaining popularity worldwide ever since. Prostate artery embolisation (PAE) is a procedure used to treat elderly patients who suffer from benign prostatic hyperplasia (BPH). BPH frequently occurs in men over the age of 50, and up to 75% of men develop at least one symptom of BPH by the time they reach their 70s.

By embolising the blood vessels to induce ischaemia and thus shrink the prostate, this procedure relieves the patient of urinary tract symptoms with minimal side effects and offers an alternative to the traditional surgery, a transurethral resection of the prostate (TURP), at a quarter of the cost and without the risk of injuring the bladder neck or disturbing sexual function. This procedure has been proven effective in several studies, but is still quite new and technically highly complex due, in part, to the variations in prostatic artery anatomy, thus adding to the difficulty in differentiating the prostatic arteries alongside the arteries of neighbouring organs.

Although a challenging and time-consuming technique, this new procedure is being taken up by some innovative interventional radiologists in an attempt for it to become an alternative treatment for all patients who are prospective candidates for BPH surgery. To gain significant recognition will take time and many clinical studies will need to be conducted by teams of PAE experts. The publications on PAE have already taken huge steps in gaining recognition for the treatment by showing that it is safe and effective (offering improvements in patients' International Prostate Symptoms Score (IPSS) and quality of life), but much work is left to be done. By conducting more clinical trials and publishing the results, PAE therapy will hopefully gain due credit through scientific evidence and become a feasible option for all patients, not only those with high surgical risk.

As the number of research centres performing PAE continues to grow, greater insights into the procedure are greatly needed. At this year's CIRSE Congress, there are several sessions and many posters which are dedicated to this theme, and one especially important session is the upcoming Hot Topic Symposium *Prostate artery embolisation: ready for prime time?*

During this session, four experts will discuss some of the most pressing questions revolving around the topic of prostate artery embolisation, and you won't want to miss! We spoke briefly with each speaker to get a few insights into this topic:

CIRSE: What current evidence exists for the use of prostate artery embolisation?

Lukas Hechelhammer: PAE has shown promising results in single centre studies in terms of reduction of the international prostate symptom score (IPSS), improvement of quality of life, significant prostate volume reduction, improvement in the urodynamic of the patients as well as a relatively low complication rate. Two randomised controlled trials comparing PAE to transurethral resection of the prostate (TURP), the surgical gold-standard treatment, showed a similar reduction of IPSS and an improvement in quality of life, but urodynamic results for the TURP group were better. TURP has well-known peri- and postoperative complications, including long-term urinary incontinence in up to 2% as well as erectile dysfunction in up to 6.5%, and yet, to compete with the surgical gold-standard, the IR community has to complete more randomised controlled trials with more patients and longer follow-up, and compare this to surgical or medical therapies to reach level 1a evidence. PAE has the potential to become an alternative treatment option to surgical, or perhaps medical, treatment in patients with lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO); it is minimally invasive, can be performed without the need of hospitalisation and has a low rate of complications.

CIRSE: While a number of publications have shown the feasibility of PAE, very few have looked into the patient populations most or least likely to benefit from the procedure. When it comes to patient selection for PAE, who are the most suitable patients?

Jafar Golzarian: Currently, patients with lower urinary tract symptoms who failed with or cannot undergo medical or surgical therapy could be considered for PAE. When starting to perform this procedure, the most suitable patients to treat are those with large prostates (over 80 cc) and patients between 50 and 65 years old. For smaller sized glands and older patients, the technique is more challenging and requires more experienced operators, but can be considered after completing a substantial number of cases.

CIRSE: What techniques are there to perform this procedure and what's the most common method?

Francisco Carnevale: PAE has been performed using two different techniques. The original PAE method (oPAE) is performed via superselective catheterisation and embolisation of the inferior vesicle arteries

and prostate arteries from a single position distal to any bladder or rectal branches, but proximal to individual prostatic branches. The PERFeCTED (Proximal Embolisation First, Then Embolise Distal) technique is performed by embolisation of the inferior vesical arteries and prostate arteries from two microcatheter positions: first from the proximal position used for oPAE, and then distally from individual branches to the prostate. While both procedures were found to be safe, the PERFeCTED technique has been associated with a significantly lower rate of LUTS recurrence. A refined technique and patience are key elements to a good embolisation; patients' symptoms improve in more than 90% of cases, without retrograde ejaculation, sexual disorders or urinary incontinence, from a procedure done under local anaesthesia, which, if necessary, can be repeated in the future to avoid surgery.

CIRSE: What challenges or obstacles still exist and what steps need to be taken for IRs to consider performing this treatment?

Nigel Hacking: PAE is an exciting new development in IR and is set to expand rapidly as evidence grows and national approvals are confirmed. IRs should attend dedicated training courses and/or centres to understand and observe the procedure. They should then undertake formal on-site proctoring for around 5-10 cases before attempting to commence a PAE service. This PAE service must be in conjunction with their urology colleagues, who must see all patients and assess their suitability. With full urological support, many obstacles to setting up a PAE service should dissipate when national and international guidelines are in place. In Brazil and the US, PAE has now been approved, and in the UK, the National Institute for Health and Care Excellence (NICE) has approved PAE for use in trials and cohort studies, including a national registry. The results of that registry, UK-ROPE, will be announced during this congress, and NICE are then planning to review PAE in late 2017.

CIRSE: What skills are necessary for an IR to perform this procedure?

Francisco Carnevale: An excellent and detailed technique from physicians is critical when performing PAE for long-term symptom relief. It requires thorough investigation of all arteries bringing blood to the prostate, many of which are very small, and, as with any new treatment, there is a learning curve. The more cases we perform, the more apparent it has become to us that even small details in

Don't miss it!

Prostate artery embolisation: ready for prime time?

Hot Topic Symposium

Tuesday, September 19, 15:00-16:00

Auditorium 1



Lukas Hechelhammer
Kantonsspital St. Gallen
Sankt Gallen, Switzerland



Francisco Carnevale
University of São Paulo
São Paulo, Brazil



Jafar Golzarian
University of Minnesota
Minneapolis, Minnesota, USA



Nigel Hacking
University Hospital
Southampton
Southampton, UK

the technique can make a difference in the outcomes.

CIRSE: Is there any advice you would give to IRs who would like to begin performing the PAE procedure?

Nigel Hacking: Meet with your urologist. Make sure that they are aware of the evidence and that they will refer patients. Try to get a combination clinic going, and then go to a training centre with your urologist. Don't go on your own. Your urologist needs to come and meet the urologists, because they will have different questions than the interventional radiologist. From there, you should arrange to get one of the proctors to come to your centre so you can ask them what catheter they use, what guidewire, what embolic agent, and what their evidence is for that or if it's just personal preference. Collect the data.

Today's Featured Papers

will be presented in the Free Paper sessions, taking place from 16:15-17:15 and from 17:30-18:30

16:15-17:15

FP 3006 Super Tuesday

Auditorium 11

Four-year results of the IN. PACT SFA trial comparing a drug-coated balloon catheter with an uncoated balloon catheter in femoropopliteal lesions
P. Krishnan¹, A. Micari²; ¹New York, NY/US, ²Cotignola/IT

17:30-18:30

FP 3104 Neuro and carotid intervention

Room 20

Tandem therapy in bilateral intraocular retinoblastoma
S.S. Kulkarni, S.N. Panbude, N.S. Shetty, A.M. Polnaya, R.S. Chivate, S. Qureshi, G. Chinnaswamy, N. Shetty, M.H. Thakur; Mumbai/IN

FP 3105 Oncology 2

Room 19

No-touch multi-bipolar radiofrequency ablation of superficial subcapsular hepatocellular carcinoma within Milan criteria: effectiveness and tolerance
A. Petit¹, O. Seror¹, A. Hocquet², E. Varin¹, O. Sutter¹; ¹Bondy/FR, ²Pessac/FR

FP 3106 TEVAR

Auditorium 12

Initial experience with the transapical access for TEVAR
A.H. Mahnken, M. Irsusi, W. Hundt, R.G. Moosdorf; Marburg/DE

Launching CIREL

Michelle Weiss, CIRSE Office

Over the last ten years, new techniques in transcatheter chemoembolisation (TACE) with drug-eluting beads have been developed in order to treat patients with metastatic colorectal cancer. TACE with drug-eluting beads has become a popular treatment method around Europe, and, as it is a relatively novel treatment modality which has been proven efficient and safe, CIRSE's new registry, CIREL (the CIRSE Registry for LifePearl Microspheres), aims to collect real-life data in order to form evidence-based decisions on optimising the treatment.

CIREL is a multi-centre observational study on patients with liver-only or liver-dominant metastatic disease being treated with transarterial chemoembolisation (TACE) using LifePearl Microspheres loaded with irinotecan. This European-wide study will observe and categorise the use of the device in the context of patients' cancer treatment and will also collect extensive quality of life data to learn more about the palliative aspect of TACE. Alongside prospectively collecting data through an electronic data capture (EDC) system, the registry will also include central image analysis in order to detect possible associations between RECIST criteria and observed outcomes, reduce bias by providing a second reading and ensure quality of the data. So far, the current enrolment progress is off to a great start with 104 hospitals invited across 15 European countries.

CIREL is governed by a multidisciplinary Steering Committee comprised of leading experts from the fields of interventional radiology, oncology, surgery and hepatology. The Committee is co-chaired by the coordinating investigators, Prof. Philippe L. Pereira and Prof. Julien Taieb. In order to capture a broad range of data, the registry aims to enrol 500 patients over an initial period of three years.

With CIREL just getting started, we met with Philippe Pereira, one of the Chairmen of the Steering Committee, to hear about

his expectations for this registry as well as his insights on drug-eluting beads in Europe.

CIRSE: What is your personal clinical experience with drug-eluting beads?

Pereira: In my clinic, we use a lot of different beads from various manufacturers, and I have seen some patients who had problems with the bead treatment, but, fortunately, they weren't long-lasting. My experience has taught me that it's necessary to have high-quality peri-interventional management when treating a patient with bead therapy. When we began using beads, patients often experienced some pain and a slight fever for two days post-op, but now we have developed our peri-interventional management. This means that, before we inject the beads, we may deliver some drugs, like cortisone, to diminish pain; during the treatment, we look at the hydration of the patient; and after the treatment, we give some additional pain treatment or anti-vomiting medication. With adequate peri-interventional management, we are able to manage any secondary effects such as vomiting, pain and fatigue, and we've seen improvement in the last few years.

CIRSE: What do you like about TACE with beads?

Pereira: TACE with beads is especially different from conventional TACE. The advantage of TACE with beads is that the doses of the drug and the timing between applications are both standardised; that's not the case with conventional TACE. Also, conventional TACE never proved its efficacy for colorectal liver metastases, although it was used for a couple of years. But with this new approach with beads, TACE has become more interesting for the treatment of colorectal liver metastases, and it should be studied.

CIRSE: What has been the most interesting piece of research you've seen recently about drug-eluting beads?

CIREL CIRSE Registry for LifePearl Microspheres

Pereira: One very interesting topic that is starting to be explored is the combination of the beads treatment with systemic chemotherapy or immune therapy. This is interesting because, unfortunately, these patients almost always have metastases not only in the liver but often in the bones and lungs as well. With the drug-eluting beads therapy you never treat outside the liver, so combining it with immunotherapy for specific diseases could be a really good option. Currently, we're using only three different drugs, but it's possible to imagine loading the beads with other drugs, maybe even with immune drugs, and then other treatments could be considered. Right now, beads are solely being used for colorectal and HCC, but if a drug like Paclitaxel is used, for example, you can treat liver metastases from breast cancer. The potential is huge, so we shouldn't miss the chance to test new drugs and gather data to find different diseases that we can treat with bead therapy.

CIRSE: Considering CIREL, what are your expectations for the registry? What do you think it will be able to achieve?

Pereira: My only expectation is that we enrol 500 patients, since, currently, we have no studies of beads with more than 150 patients, and even that is an exception; the majority of papers have 30 to 50 patients. Of course, I hope that it will be a fantastic treatment for the patients, but the most important aspect is to see if the beads are relatively safe and effective and for which patients they work best. Our goal now should be to collect a lot of clinical data on the beads treatment in the form of observational studies or large registries, which is what we are doing with CIREL. After we collect the data to see how the beads are used and at which stage of the disease, then we can analyse it to see which patients might benefit from the beads treatment or a combination treatment.

Another point to consider is the outcomes of patients. Right now, I believe we get patients

for bead treatment too late in the course of the disease. It will be interesting to see through CIREL if there are some centres in Europe using beads earlier in the course of the disease. That will be one of the most important results to observe in the data analyses: the patient's benefit in terms of progression-free survival when beads are used as the second- or third-line treatment instead of the fourth-line.

CIRSE: As CIRSE's first TACE registry, how important do you think it is that it has a multidisciplinary approach?

Pereira: By definition, oncology is multidisciplinary. Nobody has the solution alone, neither the surgeon, nor the oncologist, nor the interventional oncologist. All together we are stronger for the patient, so it's extremely valuable to have a multidisciplinary approach. I have learned so much from oncologists, including how they consider study designs, or what should be assessed regarding safety, efficacy, reproducibility, etc. In the new generation of oncologists, they're even thinking a little bit differently about treatment patterns; they know that they rarely cure the patient completely and that is being joined with a new philosophy that patients should learn to live with their cancer. They could live 20 years with their cancer, and if their treatment is compatible with a good quality of life, why not? That's where interventional oncology comes in, because we have so many different methods to treat the patient. One of our major problems is that we need to educate more and more interventional radiologists to have expertise with interventional oncology. In centres where you have good multidisciplinary teamwork and a good interventional oncologist, a lot is possible, and that is the best situation for the patient.

For more information, please contact research@cirse.org.



CIREL Steering Committee

Can embolisation alter the course of knee osteoarthritis?

Yuji Okuno

Osteoarthritis (OA) is the most common degenerative joint disease, significantly affecting quality of life and resulting in direct and indirect costs ranging between 1 to 2.5% of the Gross National Product in Western countries [1]. The most frequent site of OA is the knee, with more than 40% of people older than 70 years old diagnosed with knee OA.

There are currently no curative or effective disease-modifying treatments for OA. Therapeutic options are essentially symptomatic, usually temporary and often ineffective. Major joint replacement surgery remains the most radical treatment in end-stage OA, yet it has a limited durability, carries the risk of complications (a significant factor in the high costs of OA), and is not feasible in a considerable number of patients due to comorbidities and elevated perioperative risk.

Although OA was viewed as a "wear and tear" disease for many decades, it is now generally accepted to be a low-grade inflammatory disease of synovial joints and a biomechanical whole-organ disease [2,3]. It has been suggested that cartilage lesions, bone marrow lesions and meniscus damage are all associated with knee OA symptoms. In contrast to this notion, a study in which a 3T MRI of both knees was performed in 169 patients with knee OA and unilateral chronic knee pain found a high degree of symmetric pathology between both knees for such lesions, as assessed by WORMS [4]. This finding suggests that these lesions are more nonspecific than previously believed. On the other hand, assessment of knee OA using contrast-enhanced MRI has demonstrated that certain post-contrast patterns within the synovium and periarticular adipose tissue are associated with pain symptoms [5,6].

Angiogenesis is believed to contribute to the genesis of inflammation, especially in regards to its maintenance [7]. The new increased vascular network provides inflammatory cells access to the synovium and other joint tissues and promotes hyperplasia and inflammation in other vessels, leading to bone and cartilage destruction [8]. Furthermore, studies on OA have shown that angiogenesis may contribute to chronic pain by enabling the growth of new unmyelinated sensory nerves along their path [9,10].

We have previously reported our experiences with transcatheter arterial embolisation (TAE) in patients with mild to moderate radiographic knee OA that is refractory to conservative treatment [11]. This prospective trial included 95 knees which were followed up to 4 years.

In this study, abnormal neovessels were seen on angiography in all patients. These vessels were located mainly within the periarticular soft tissue (synovium, infrapatellar fat pad, periosteum and joint capsule) and were often observed to be in a location consistent with the sites of tenderness. This suggests that the prevalence of vascular changes in mild to moderate radiographic knee OA is quite high and that OA pain and local tenderness could be related to abnormal neoangiogenesis. Our study demonstrates that TAE improves pain symptoms and knee function for up to 4 years as shown by the follow-up results. No serious adverse event was noted. Minor complications occurred, such as moderate subcutaneous haemorrhage at the puncture site and transient cutaneous colour change on the treated knee, but all of these resolved without treatment.

In the procedures, a femoral artery was punctured in an ipsilateral anterograde fashion under ultrasound guidance. A 3 Fr angiographic catheter was introduced towards the popliteal artery. Selective angiography of the arteries feeding knee joint was performed, as shown in Figure 1. Abnormal vessels appeared as "tumour blush"-type enhancement in the arterial phase, often accompanied by early venous drainage. After identifying the abnormal vessels, embolic material was infused. Imipenem/cilastatin sodium (IPM/CS) was used as the embolic material to 88 knees in 65 cases. Patients who had contraindications to IPM/CS were treated with Embozene 75-µm microspheres instead (n=7 knees in 7 cases). IPM/CS is a crystalline compound that is slightly soluble in water and forms small-sized particles with an embolic effect when it is suspended in contrast agent, and it was selected based on previous reports. We asked patients about their pain level to confirm the decrease in local tenderness several minutes after infusion of the embolic material. The catheter was removed after confirming successful reduction of the number of abnormal vessels on angiography and reduction of local tenderness by palpation.

In this study, patients who had more severe degenerative changes (KL 3) showed a lower frequency of clinical success at 6 months after TAE compared to those with mild changes (KL 1-2). A subset of patients in both groups experienced pain recurrence after initial clinical success. Knee OA is an age-related disease with no prospect for spontaneous recovery; it is thus expected that structural changes and associated inflammation will continue to progress and that pain can recur, especially in patients with severe degenerative changes. Thus, although TAE cannot treat knee OA completely or reverse its natural progression, it seems to be an effective additional option to alleviate pain, decrease the use of pharmacologic painkillers and injection therapies and improve quality of life. Indeed, in the present case series, TAE allowed a reduction in the use of oral NSAIDs and oral opioids and a reduction in the frequency of use of injection therapies.

There may be several concerns about applying embolisation to knee OA, such as the risk of ischaemic events, including osteonecrosis, muscle atrophy, peripheral paraesthesia or neuropathic joint disease such as Charcot joint. Although all patients in the present study were repeatedly asked and encouraged to report symptoms suggestive of these pathologies, none reported any such symptoms. On the MRI evaluation at 2 years after first TAE, no ischaemic findings consistent with osteonecrosis or periarticular soft tissue abnormalities were detected. The absence of such adverse events may be related to the embolic technique used in our study, especially in regards to the small amounts of embolic material used.

MRI evaluation at the 2-year follow-up showed improvement of the synovitis score, which bolsters the hypothesis that abnormal neoangiogenesis is an important factor in inflammation (and thus pain) and that TAE can reduce inflammation by occluding these abnormal vessels.

The TAE procedure remains more invasive than other routinely used minimally invasive treatment for pain management and should be performed by a trained interventional radiologist.

To date, our work represents a solid proof of concept and a sound basis for further studies.

Don't miss it!

Knee osteoarthritis
Special Session

Tuesday, September 19, 08:30-09:30
Auditorium 10



Yuji Okuno
Edogawa Hospital
Tokyo, Japan

Dr. Okuno is the Director of the Musculoskeletal Intervention Center at Edogawa Hospital in Tokyo, Japan. He is an expert in orthopaedic surgery and musculoskeletal topics, and he has published multiple works in various journals, including the *Journal of Vascular and Interventional Radiology*, *Cardiovascular and Interventional Radiology*, and the *Journal of Shoulder and Elbow Surgery*. His recent work on knee osteoarthritis examines the safety and efficacy of using transcatheter arterial embolisation when the disease is resistant to conservative treatment yet not severe enough to warrant joint replacement therapy.

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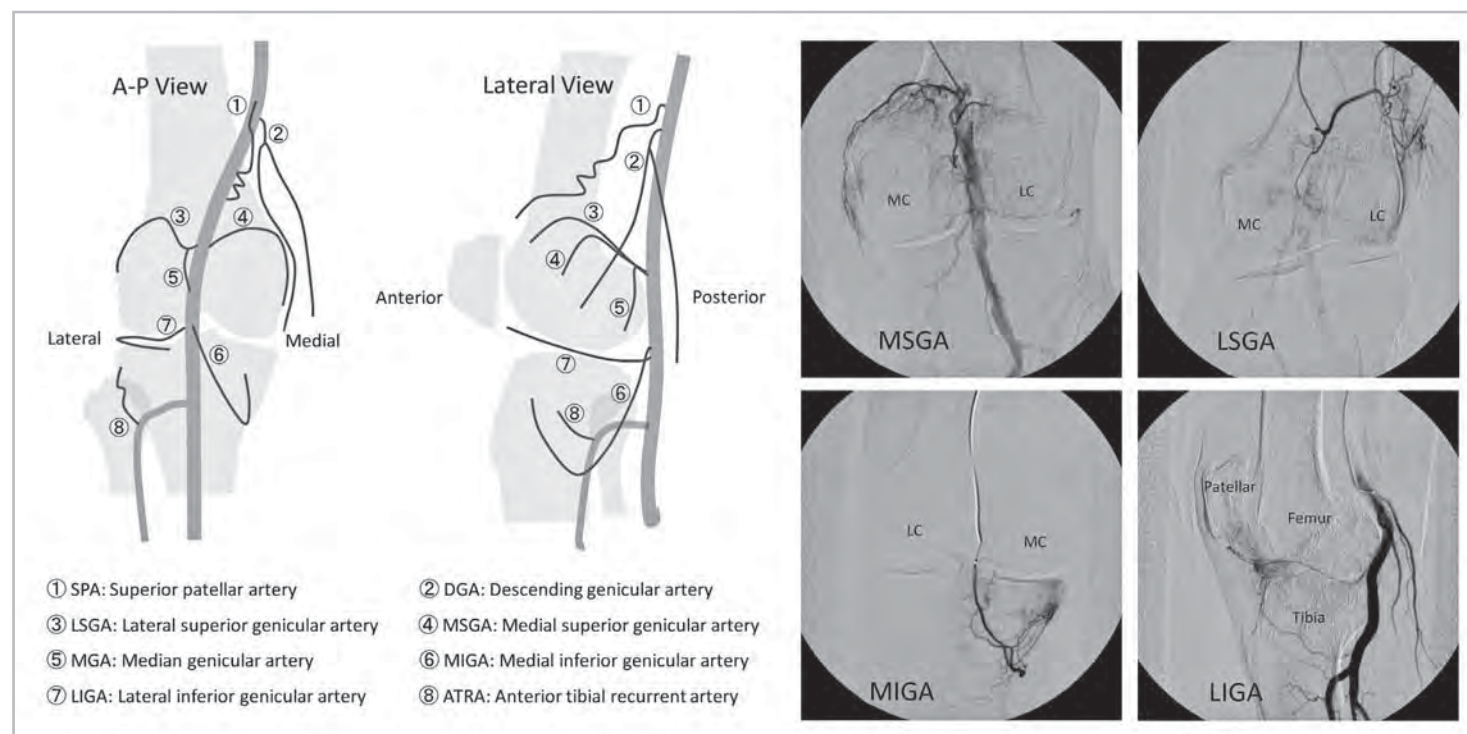
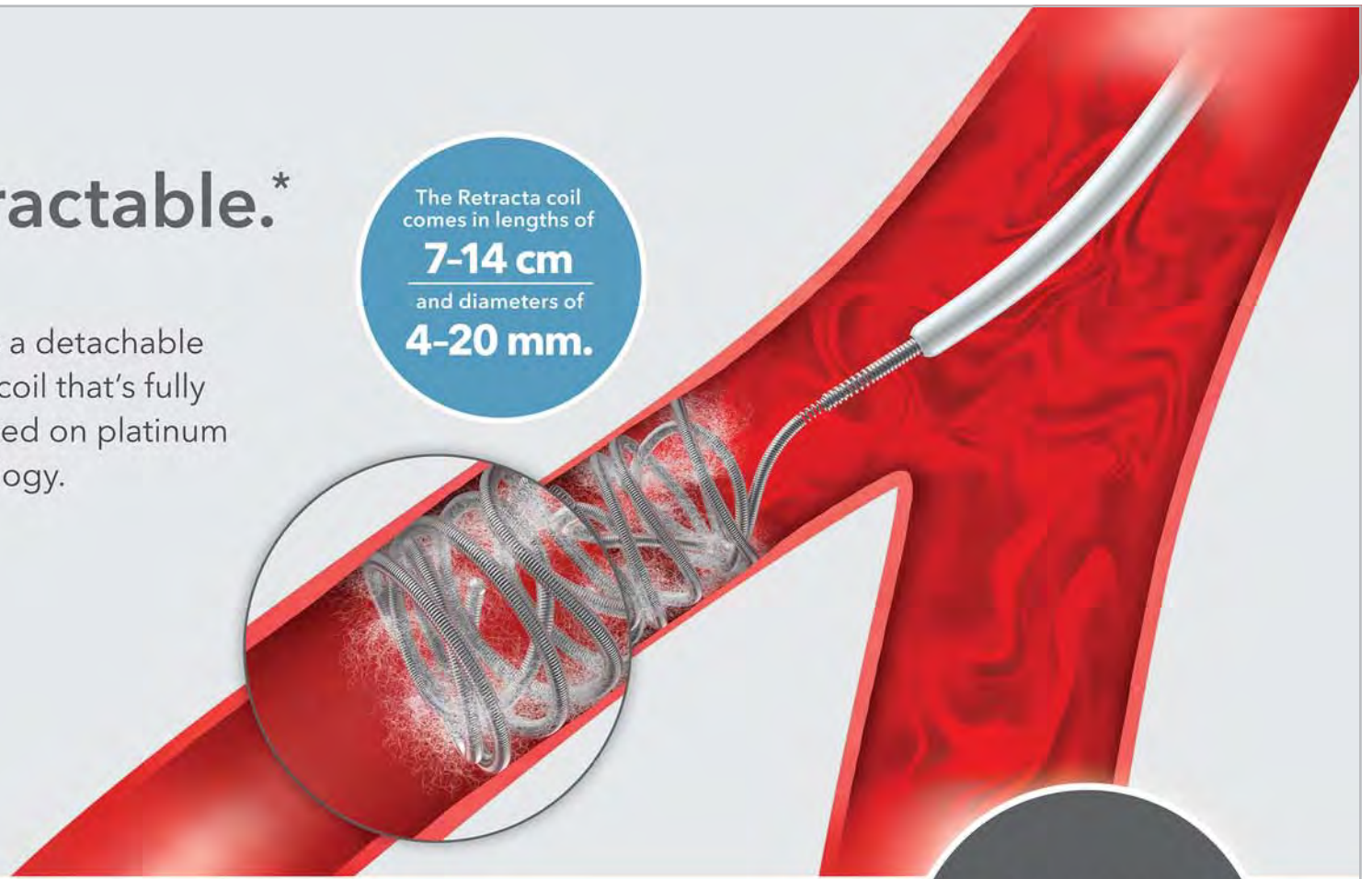


Fig. 1: Anatomical schema of the arteries feeding the knee joint and selective angiography of each artery.

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Ben Raho, CIRSE Office

be inspIRed...

The Interventionalist's Toolbox

At some point, every medical student has to answer the big question: specialise in what?

Interventional radiology has a lot going for it, but what may be most exciting about it is the variety and versatility of its available therapies. An IR has the tools and skills to treat a multitude of diseases of every body part, with a range of different procedures. The variety is so staggering that it is impossible to list all of them here. To illustrate this point, it is enough to go over the first three letters of the alphabet: ablation, angiography, angioplasty, aspiration, balloon angioplasty, balloon stenting, biliary drainage and stenting, biopsies, bio-absorbable stenting, bone ablations, bone augmentations, brachytherapy, bronchial stenting, carotid artery stenting, central venous access, chemoembolisation, closure device placement, cryoablation...

This list perfectly illustrates how, starting from a small puncture in the skin, you can fight some of the most common and deadly diseases, treat conditions all over the body and significantly improve the lives of patients. Furthermore, every one of these procedures

requires a unique set of skills and knowledge. Let's look at three common IR procedures and their applications:

Ablation

Ablation encompasses a range of thermal and non-thermal procedures, including radio-frequency ablation, microwave ablation, high-intensity focused ultrasound, laser ablation and cryoablation. The underlying principle sounds simple enough – the interventional radiologist penetrates the skin with a needle and then destroys tumour tissue – and a growing body of research also clearly supports its efficacy, cost-effectiveness and the fact that it is not as painful as surgery. Ablation can also be used in combination with other oncological treatments, such as chemotherapy, and is used to treat many tumours.

Angioplasty

One of the most common procedures for interventional radiologists, angioplasty has helped millions of patients worldwide by preventing arteries from being blocked by

arteriosclerosis, thus also saving countless lives. Angioplasty involves the mechanical dilatation of any narrowed or occluded vessel by means of a balloon catheter and by placing a metal stent if necessary. This way, an interventional radiologist can prevent possibly lethal consequences of arteriosclerosis.

Embolisation

The term embolisation, again, encompasses numerous different procedures with the goal of obstructing the flow of blood, to either prevent haemorrhage or cut off the blood supply of cancerous tissue or benign tumours, such as uterine fibroids. This is done via minimally invasive access to an artery and the introduction of emboli to restrict the flow of blood to the target area. Embolisation is used in oncology as an effective way of stopping tumour growth – especially when the emboli are coated with either chemotherapeutic chemicals or radioactive material. Such localised chemotherapy or radiotherapy greatly reduces the stress for the patient in comparison with systemic treatments. Embolisation is also used to stop haemorrhage in a variety of cases

such as post-partum bleeding, haemoptysis or even nosebleeds but also in cases when blood flow is to be restricted to vascular malformations or varicoceles.

Here we have only briefly discussed a few select IR procedures. But these examples illustrate the variety of IR procedures and their versatility in providing effective, minimally invasive solutions for patients with all kinds of different diseases, affecting every part of the human body. Regardless of what medical specialty a student ends up choosing, it is very likely that he or she will be working with IRs in one way or another. Because, with their toolkit and their skills, interventional radiologists will be a crucial part of tomorrow's medicine.



Students practising ablation at last year's congress in Barcelona.



Andreas Gruentzig, inventor of balloon angioplasty, at USZ, Zurich on September 16th, 1977.



An embolisation hands-on workshop at GEST 2017.

Your Career in IR

Interventional radiology guarantees an exciting career in the forefront of modern medicine. So it is no surprise that more and more medical students, and radiology trainees choose it for their professional future. However, figuring out the first professional steps can be daunting for someone who has just completed their medical degree or is still a doctor in training.

To address this issue, the European Trainee Forum (ETF) organised the IR Trainee Session *Building an IR Career* for the first time last year. This session was so popular that it is now a regular feature at the CIRSE annual congress, and will again feature a line-up of top notch speakers and leaders of the European IR community:

1. Greg Makris, Chairperson of the ETF Subcommittee, will introduce the work of the ETF, CIRSE's platform for trainees, residents and young IRs and discuss how the ETF can help build your professional network and skills. The ETF will continue to grow over the next year and openly welcomes participation.

2. Malgorzata Szczerbo-Trojanowska, a highly esteemed IR, will offer her unique insights from decades of experience into how an IR can build a successful academic career and how you can become a successful researcher as well as clinical practitioner.

3. One of the most important aspects of any academic career is disseminating your ideas. Klaus Hausegger, *CVIR* Editor-in-Chief, will discuss how to write and publish effectively. His talk will cover basics of academic writing and publishing as well as an overview of some relevant publications for IR.

4. Increasingly, the EBIR Exam is becoming a requirement for many IR positions and an internationally recognised certification of training in interventional radiology. Otto van Delden, Chairperson of the EBIR Council, will outline how taking the EBIR Exam opens doors and boosts your career.

5. The session will then be rounded off by Christoph Binkert, an international authority

on clinical practice in interventional radiology, who will share his insights on what it takes to build a clinic and how to develop an entrepreneurial mind as an IR.

All of the talks will include enough time for questions and discussions, a feature that stimulated dynamic debate last year. For anyone at the start of their career in interventional radiology, this session is an

absolute must. It will also be another excellent opportunity to meet peers from around Europe. Tuesday will include another highlight for trainees, residents and young IRs. For the first time at the CIRSE annual congress, there will be the chance for young IRs to compete in the ETF Quiz and win prizes in a friendly competition against peers. Don't miss this fun event!



Don't miss it!

IR Trainee Session:

Building an IR Career

Tuesday, September 19, 08:30 – 09:30
Auditorium 12



CIRSE Radiation Protection



New radiation safety legislation in 2018!

Visit the Radiation Protection Pavilion

CIRSE's Radiation Protection Pavilion, located in the exhibition hall, is here for you during the entire Annual Meeting, offering information material, interactive tools, and opportunities to engage directly with experts in radiation protection. This year, you can learn more about the impact of European Directive 2013/59/Euratom on safety standards and regulations regarding radiation exposure and how it will affect practitioners and patients.

Today's RPP Mini-Talks, which feature short expert presentations, again cover a wide range of topics delving further into various aspects of radiation safety. We hope to see you there!

Today's RPP Mini-Talks

	Time	Mini-Talk	Speaker
TUE SEPT 19	09:30 - 09:45	Reducing radiation exposure using Procedure Rehearsal Studio's patient specific simulation (Simbionix / 3D Systems)	F. Vermassen (Ghent/BE)
	09:45 - 10:00	Basic safety standards directive: what's new for patients	P. Platoni (Athens/GR)
	11:00 - 11:15	News from EuroSafe Imaging: activities to promote and establish clinical DRLs (EuroSafe Imaging)	W. Jaschke (Innsbruck/AT)
	11:15 - 11:30	Intraprocedural personal dosimetry: The Innsbruck experience	M. Freund (Innsbruck/AT)
	12:30 - 12:45	Developing a strong radiation safety culture using a NEW real-time dosimetry system (Raysafe / Fluke)	A. Shestakova (Eindhoven/NL)
	12:45 - 13:00	Radiation protection of paediatric patients in fluoroscopically guided procedures	A. Ploussi (Athens/GR)

CIRSE Meets... The European Wound Management Association (EWMA)

Petra Mann, CIRSE Office

With diabetes on the rise in the Western world, treatment of the diabetic foot and peripheral arterial disease has become the most prevalent area of chronic wound management in interventional radiology. As it is essential for interventionalists to be fully clinically involved in a multidisciplinary team, the European Wound Management Association is an important common denominator with other specialists involved in the field.

The "CIRSE Meets..." sessions have been an integral part of the Annual Meeting's programme, providing an excellent opportunity to reach out to other associations and national societies to initiate or deepen cooperation and provide the audience with an insight into their work. As interventional radiologists treating acute and chronic wounds are in the forefront of wound management, it makes them key allies of the European Wound Management Association (EWMA) and its work.

The EWMA is an umbrella organisation linking European national wound management societies, individuals and groups with interest in wound care. Founded in 1991, EWMA's main objective is to support the implementation

of interdisciplinary, cost-effective, high-quality wound care. It does so by organising conferences, contributing to international projects and providing information on native epidemiology, pathology, diagnosis, prevention and management of wounds of all aetiologies.

The EWMA cooperates with various national and international organisations in order to achieve their goals of comprehensive data collection, heightened quality of evidence, the dissemination of knowledge and the provision of multidisciplinary, high-quality education regarding wound management.

The annual EWMA congress, which took place this year from May 3-5 in the Netherlands, is complemented by numerous other educational activities organised by the association, including the EWMA University Conference Model, which enables students of wound management programmes from around Europe to attend the congress for specially designed lectures and workshops.

At CIRSE 2017, the dedicated *CIRSE Meets EWMA* session will cover presentations on

basics of wound care for IR, surgical coverage of non-healing ulcers, arterial perfusion to optimise arterial ulcer healing, and clinical and imaging assessment of wounds of the lower extremity.

Read all about it

The EWMA Journal (published in May and October) is primarily designed to be a membership journal, with a specific focus on promoting EWMA's activities, but it also includes peer-reviewed original articles, reviews and clinical information, providing an important platform for sharing wound relevant news among EWMA target groups across Europe. It is distributed free of charge to EWMA members and to members of national wound healing organisations in Europe, as well as to a wider audience via the internet. It can be accessed for free at www.ewma.org.

The EWMA has produced several position statements and recommendations which are also available free of charge on the EWMA website.

Join us at today's session!



Tuesday, September 19, 11:30-12:30,
Auditorium 11

CM 2706 CIRSE meets the European Wound Management Association (EWMA): Standards of wound care – the essentials

Moderators: E. Brountzos (Athens/GR), A. Piaggese (Pisa/IT)

- 2706.1 Clinical and imaging assessment of wounds of the lower extremity
M. Collier (Boston/UK)
- 2706.2 Basics of wound care for IR
M. Collier (Boston/UK)
- 2706.3 Arterial perfusion to optimise arterial ulcer healing
M. Palena (Abano Terme/IT)
- 2706.4 Surgical coverage of non-healing ulcers
A. Jawien (Bydgoszcz/PL)



Don't miss the Morbidity & Mortality Conference Tomorrow at 11:30 in Auditorium 15

As IRs, it is vital to be aware of how to avoid or manage procedural complications as they occur. With this in mind, the Morbidity & Mortality Conference is an important part of each CIRSE Congress, as a group of expert panellists discuss interventional radiology cases, which have led to complications or deaths, that could have been circumvented. This session provides a valuable learning experience for attendees who can benefit from the experience of their colleagues and hopefully avoid the same unfortunate outcomes. This year's session will be dedicated to vascular and non-vascular cases. Once presented with a case, audience members will be asked to vote on their preferred course of action – allowing the chance to see how you might have fared when faced with that difficult decision.

Don't miss this excellent opportunity to learn from a distinguished panel about complications that can arise and how best to react and treat them.

MM 3401 11:30-12:30

Coordinators: D.K. Tsetis (Iraklion/GR) and R. Uberoi (Oxford/UK)

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