

CIRSE 2014 - Glasgow
Sunday, September 14, 2014

Radiation Exposure: Do You See the Risk?

The Radiation Protection Campaign launched at last year's CIRSE meeting has been met with considerable enthusiasm, encouraging further co-operation between CIRSE's Radiation Protection Subcommittee and industry partners, which has culminated in the introduction of its most exciting feature

so far: the Radiation Protection Pavilion, which is making its debut here in Glasgow.

The Pavilion will be open for visitors in the Exhibition Hall until Tuesday, offering practical tips and information materials, as well as industry exhibits showcasing products

tailored to providing tangible solutions. Eye check-ups will be performed from 09:30 to 14:30 on Sunday through Tuesday. While invitations were sent to CIRSE delegates in advance, members may still be able to register for check-ups on-site. Come see for yourself!

Standard clinical guidelines for interventional oncology: where are we at present?

Philippe Pereira (EBIR)

Medicine, in some instances more so than other fields, undergoes a constant development process, making guidelines and standard operative procedures an important tool for the medical community. This is especially true in oncology, a discipline for which multidisciplinary and combined therapies are essential for optimised patient care and better outcomes. The principles of clinical guidelines should be based on current scientific evidence, with participants coming from different medical societies, and by default, on the consensus of medical experts, also called "good clinical practice".

Moreover, high-quality guidelines are necessary not only for a structured knowledge transfer, but they also find their place in the structures of the health system, increasingly becoming a reference for discussions with reimbursement institutes and insurance companies. Finally, evidence-based guidelines serve as a basis to define quality indicators that will be used for the certification process of comprehensive cancer centres, as well as for creating and updating disease management programmes for all medical practitioners.

The current situation

If we refer to the number of papers, lectures and conferences that focus on interventional radiology, we are forced to admit that interventional oncology occupies an important place in interventional radiology. A major reason is that over the last 30 years, interventional oncology has not only developed effective palliative monotherapies, such as transarterial chemo-

embolisation (TACE) and radioembolisation for hepatic tumours, but has also achieved curative ablative treatments for select patients presenting with kidney, liver or lung cancer.

Nevertheless, the international recommendations of expert societies do not seem to recognise the real value of interventional oncology. Thus, the role of interventional oncology is accepted and established almost exclusively for the treatment of patients presenting with non-cirrhotic HCC and in some palliative clinical situations. But even still, if you look carefully at different national and international guidelines for the treatment of HCC, you will note that significant discrepancies and inconsistencies relating to the exact role of interventional therapies exist.

The European Association for the Study of the Liver (EASL)-European Organisation for Research and Treatment of Cancer (EORTC) still recommend percutaneous ethanol injection (PEI) for early-stage HCC nodules and resection for very early HCC only, although meta-analyses have reported the superiority of RFA over PEI for HCC < 3 cm, and similar results for ablation and surgery have been reported for HCC lesions smaller than 2 cm in size, and with survival being comparable even for larger HCC in several reported studies.

Further, the European Society for Medical Oncology (ESMO) recommendations for stage A patients (up to 3 tumours < 3 cm) in 2010 were resection or transplantation, with local therapies being limited to intermediate HCC. More recently,

in 2012, a consensus paper from ESMO and the European Society of Digestive Oncology (ESDO) recommended resection, ablation or transplantation for HCC up to 5 cm in diameter. One year later, German guidelines, conducted by the German Cancer Society with the active participation of the German IR society, DeGIR, recommended both RFA and resection for HCC up to 5 cm in size, with liver function being the deciding factor (and with the recommendation to combine RFA with TACE for HCC > 3 cm). Due to the lack of comparative studies with survival data for TACE with drug-eluting beads and for radioembolisation, only conventional TACE has been mentioned.

In the USA, the National Comprehensive Cancer Network (NCCN) prefers resection or even transplantation for all patients who are surgical candidates, strictly limiting indications for local therapies to patients who are ineligible for surgery or transplantation. Surprisingly, even in patients with major vascular invasion, surgery is considered (Fig. 1). In Asia, Japanese evidence-based guidelines suggest resection or TACE instead of ablation for HCC > 3 cm, with resection or ablation being recommended for smaller tumours (< 2 cm), whereas the Asian Pacific Association for the Study of the Liver reserves TACE for patients with HCC larger than 5 cm.

Although the algorithms and indications differ around the world, reflecting the divergent interpretations of the scientific data reported in the literature, as well as the influence of some medical societies, nevertheless: interventional radiological therapies are largely present in the HCC guidelines.

Don't miss it!

Standard clinical guidelines for interventional oncology: where are we at present?

Andreas Gruentzig Lecture

Sunday, September 14, 14:30-15:00
Main Auditorium



Philippe L. Pereira
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Prof. Pereira is the director of the SLK Clinic for Radiology, Minimally-Invasive Therapies and Nuclear Medicine. He is an active CIRSE Member, currently serving as Chairperson of the EBIR Task Force and as a member of both the Research Committee and the Oncology Alliance Subcommittee. He also served as Chairperson of the Rules Committee from 2011 to 2013. A specialist in interventional oncology, Prof. Pereira is also on the ECIO Scientific Programme Committee and has represented CIRSE at joint sessions with ESTRO in Geneva and Budapest. He is a co-opted member on the Executive Committee of the German Society of Interventional Radiology (DeGIR), and a reviewer for multiple journals, including CVIR and Nature Reviews Clinical Oncology. Prof. Pereira's work has been published in over 220 publications, and recognised with numerous awards, including from the RSNA, ECR and ISMRM.

Room for improvement

At the same time, it is deeply regrettable that recognition of interventional oncology is radically different to other areas of oncology. In 2011, the Société Française de Chirurgie Digestive (SFCD) and the Association de



Chirurgie Hepato-Biliaire et de Transplantation Hépatique (ACHBT) published their recommendations for patients with synchronous liver metastases from colorectal cancers: thermal ablation and intra-arterial therapies were not mentioned. In 2014, an expert panel from European medical societies, the European Registration of Cancer Care (EURECCA), published a consensus statement on the "multidisciplinary" approach in patients with colorectal cancer, including patients with liver metastases. The aim of this consensus conference was "to define core treatment strategies and to develop a European audit structure in order to improve the quality of care for all patients with colon and rectal cancer". In this report, references leading to the assumption that RFA is not effective derive from the results of a Markov analysis comparing RFA

and surgery, based on theoretical outcomes necessary for RFA to demonstrate equivalence to resection or from biased results mostly in patients with non-resectable liver metastases. Transarterial treatments, including radioembolisation, are not mentioned.

The German guidelines published in 2013 allow thermal ablation only in patients with non-resectable liver metastases, in patients with comorbidities, and in patients with relapse after resection, though with a low level of evidence (3a). The UK guideline development group, the National Institute for Health and Care Excellence (NICE), cites RFA as a possible adjunct treatment to chemotherapy in unresectable metastatic disease, and invites clinicians to consider these patients for entry into approved studies on

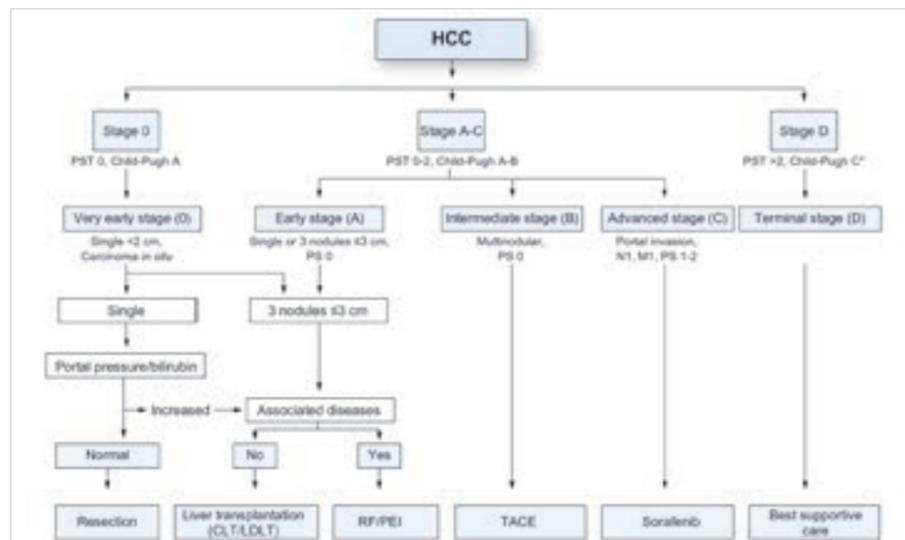


Fig. 1a: Clinical Practice Guidelines from EASL-EORTC.

Stage	PST	Tumour status Tumour stage	Okuda stage	Liver function status
Stage A: early HCC	0			
A1	0	Single, <5 cm	I	No portal hypertension and normal bilirubin
A2	0	Single, <5 cm	I	Portal hypertension and normal bilirubin
A3	0	Single, <5 cm	I	Portal hypertension and abnormal bilirubin
A4	0	3 tumours <3 cm	I	Child-Pugh A-B
Stage B: intermediate HCC	0	Large multinodular	I-II	Child-Pugh A-B
Stage C: advanced HCC	1-2*	Vascular invasion or extrahepatic spread ^a	I-II	Child-Pugh A-B
Stage D: end-stage HCC	3-4 ^b	Any	III ^b	Child-Pugh C ^b

Stage A: liver resection or transplantation; Stage B: TACE or RFA or PEI; Stage C: sorafenib; Stage D: best supportive care.

Fig. 1b: Clinical Practice Guidelines from ESMO.

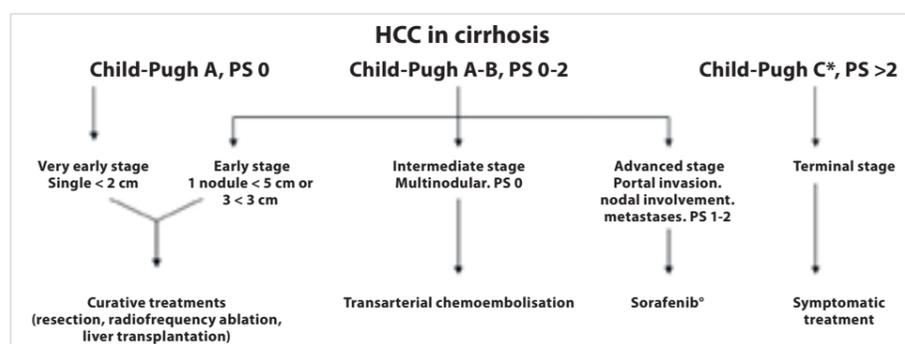


Fig. 1c: Clinical Practice Guidelines from ESMO-ESDO.

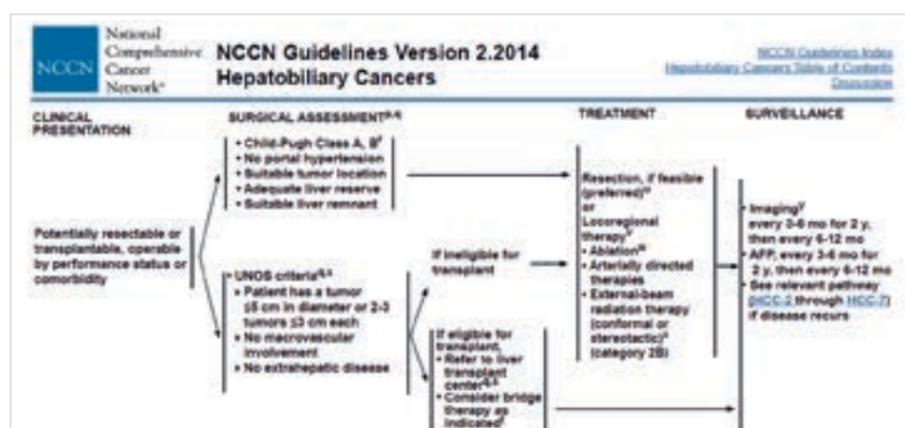


Fig. 1d: Recommendations from the NCCN in resectable patients

Recommendations	GR
Due to the low quality of the available data no recommendation can be made on radiofrequency ablation and cryoablation.	C
In the elderly and/or comorbid patients with small renal masses and limited life expectancy, active surveillance, radiofrequency ablation and cryoablation can be offered.	C

Fig. 2: EAU guidelines for the treatment of renal cell carcinoma

local ablative therapies. The ESMO clinical practice guidelines published in 2010 ignore local interventional therapies, whereas for the NCCN, ablation of liver metastases may be considered alone or in conjunction with resection if all original sites of disease are amenable.

It should be noted a) that the large majority of systematic reviews favourably comparing resection with thermal ablation for colorectal liver metastatic disease gather information from retrospective or observational studies, which are very vulnerable to different types of bias, and b) that no randomised studies have compared resection outcomes with no treatment or other therapeutic modalities in patients with resectable liver disease, as it is generally considered unethical not to offer surgery for resectable metastatic disease.

Since the first publication of Zlotta et al. describing the use of thermal ablation (using radiofrequency energy) as the primary treatment for small renal tumours in 1997, RFA has become the most commonly used percutaneous ablative technique for renal cell carcinomas (RCC). Thus, a large number of studies addressing middle-term survival have reported results similar to those obtained with nephron-sparing surgery in patients with T1a renal cancer, even in patients with poor renal reserve, multiple bilateral tumours, or in those who are poor surgical candidates. Tumour factors predicting RFA failure include large tumours (larger than 4 cm) and tumours in the hilum or the collecting system.

In 2012, the Japanese Urological Association published an update of its evidence-based clinical practice guideline for renal cell carcinoma. RFA and cryoablation are recommended as percutaneous local treatments for small RCC (T1a) only when curative treatment would be impossible because of the patient's general condition or complications. The recommendation grade was classified as C1, i.e. RFA may be implemented but has insufficient evidence!

The European Association of Urology Guideline Group for RCC reported an evidence-based update in 2014. In symptomatic patients unfit for surgery, embolisation can be a beneficial palliative approach. Otherwise, RFA and cryoablation are placed on the same level as active surveillance for patients that are not surgical candidates, with microwave and laser ablation being considered as experimental modalities. The EAU concludes that, due to the lack of prospective comparative studies with nephron-sparing surgery, percutaneous ablation could not be currently recommended for the treatment of renal cell carcinoma, due to the fact that surgical series have shown that a portion of solid enhancing renal masses, particularly when small (< 4 cm), are in fact benign and may be left alone. No interventional radiologist was on this panel.

In the USA, NCCN considers ablative techniques in non-surgical candidates presenting with T1a suspicious renal mass or active surveillance in selected patients, partial nephrectomy being preferred. Individual literature searches were conducted separately for each update question, and in most instances the search was conducted up to the end of November 2013.

And finally for lung cancer, clinical practice guidelines from ESMO, endorsed by the Japanese Society of Medical Oncology (JSMO) (and similar to the NCCN guidelines version 4.2014), recommend stereotactic ablative radiotherapy as a non-surgical treatment of choice for stage I NSCLC, and concomitant chemoradiotherapy for SCLC, a surgical approach being justified only for a small subset of patients after ruling out mediastinal lymph node involvement.

Percutaneous thermal ablation is not even mentioned. References to RFA in the Interdisciplinary Guideline of the German Respiratory Society and the German Cancer Society are limited to the treatment of endoluminal tumour of the bronchi, combined with cryotherapy. Only in the Chinese guidelines is RFA mentioned as alternative to radical radiotherapy or drug therapy in surgery-ineligible patients with stages I and II lung cancer.

What can be the reasons for the restricted presence of interventional oncology in national and international clinical practice guidelines?

The major reason for the restricted representation of interventional oncology is the relatively low level of evidence of our clinical studies. Studies in interventional oncology are often feasibility studies, case series or observational studies, sometimes comparative – and often retrospective – studies, with levels of evidence that remain less robust than those usually encountered in oncology, whereas the benefit of treatments is currently assessed through controlled trials and meta-analysis. However, performing large clinical studies remains challenging without the support of national or international scientific societies, or even financial support from the industry, similar to those provided by powerful pharmaceutical companies.

Another reason is that the number of IO experts is still limited. Few hospitals under 600 beds have a radiology department that can offer the entire spectrum of interventional oncology, which is necessary to be a regular partner for oncologists, surgeons, hepatologists and radiation therapists. Moreover, it is necessary to have consultations with in-patient care, as well as to perform the follow-up of treated patients. An interventional oncologist must be present as a therapist at the same level as the other specialists.

Finally, a certain level of competition between medical disciplines may restrict the development and the establishment of interventional treatments in standard clinical algorithms. Even if cancer treatment strategies should be personalised for each patient – thus reducing the impact of guidelines if expertise is present – insurance companies and reimbursement institutes refer more and more to guideline recommendations, underlining the necessity for IO to perform studies with a high level of evidence and also to be present in all decision steps. As they say, "if you do not sit at the table, then you are on the menu!"

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Sustained Embolic Protection*



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Sunday September 14th

TERUMO BOOTH 54
at CIRSE

13:00-14:00 Auditorium 2

>> Sustained embolic protection -
shifting paradigms in carotid artery stenting?

Moderator: Prof. Dr. Patrick Haage (Wuppertal, DE)
Prof. Dr. S. Müller-Hülsbeck (Flensburg, DE)

*Data on file

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Don't miss it!

**Controversies in BTK treatment
Special Session**
Sunday, September 14, 10:00-11:00
Main Auditorium

 e-voting



Duncan F. Ettles
(EBIR)
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Duncan Ettles is a consultant radiologist at Hull and East Yorkshire Hospitals NHS Trust and honorary clinical professor in radiology at the University of Hull. He is a member of the Local Host Committee for CIRSE 2014. Prof. Ettles currently serves as president of the British Society of Interventional Radiology, through which he has been involved in the development of IR for over 20 years. He has also been active in training IRs throughout his career, including roles as former head of training, regional adviser and examiner for the Royal College of Radiologists. Prof. Ettles is chairman of the NHS specialised commissioning group for Interventional Radiology and served as independent reviewer on the reorganisation of vascular services in England and the provision of thoracic aortic stenting in Scotland.

Angioplasty has been around in one form or another for over fifty years now, thanks to the foresight of the founders of our specialty and the successive waves of followers who made interventional radiology what it is today. The lives of millions have been transformed by the introduction of techniques to combat occlusive arterial disease in virtually every organ system of the body. Even the most complex of endovascular procedures are now performed with impressively low morbidity and vanishingly

low complication rates. This is the case even for those interventions carried out in below-the-knee vessels of high-risk patients.

So, how can this have happened without the routine use of distal embolic protection devices during below-the-knee angioplasty? The answer is very simple – we don't actually need them.

Interventional radiology has seen numerous innovations and technological developments since the early days of arterial intervention. Those innovations that have added value to patient safety or led to improved outcomes have undergone rapid uptake and assimilation into our everyday practice. With the arrival of useful new technology, a widely shared experience develops within the IR community and we can quickly move forward with it. On the other hand, we have witnessed numerous attempts to introduce modifications to standard procedures that range from the "bright idea" at one end of the spectrum, to the frankly ludicrous at the other. Many of these concepts have proved to be of little or no practical value and soon disappear from the radar. So whether the motivation to introduce practice innovation is scientific, financial or something else, we will soon decide as a group whether it stays or makes an early exit from the party.

The use of distal embolic protection devices has its genesis in cardiological and carotid intervention, where the risks of embolisation during intervention are arguably very much more significant than in the peripheral circulation. But interestingly, the evidence to support the use of such devices even in these high-risk patients is contradictory. What has followed

are continuing attempts to transfer the concept of routinely using anti-embolic devices into mainstream peripheral intervention. The major push for this change seems to have come as a result of the increasing involvement of cardiologists in the treatment of peripheral arterial disease, particularly in the USA. What might lie behind the motivation to add unnecessary and undoubtedly expensive additional complexities to a straightforward procedure is itself a fascinating topic for discussion.

Of course, we all know that distal embolisation is a predictable and not infrequent event during arterial angioplasty and stenting procedures. There is ample experimental evidence to confirm that showers of micro-emboli occur during balloon inflation and that filter systems can trap this atherosclerotic debris. What is much more important is whether this knowledge has any real bearing on daily practice in a real-world setting.

It is quite clear that the routine use of embolic protection devices cannot be justified.

Firstly, the incidence of clinically significant or symptomatic embolic episodes during below-the-knee (BTK) interventions remains very low and is difficult to predict. Even when this complication does occur, there are well tried and tested techniques to restore the distal circulation. Admittedly, this might not have been the case twenty years ago, but modern endovascular practice has moved on in leaps and bounds since then. Nowadays, the scenario of transferring a patient to theatre for emergency embolectomy or bypass following BTK intervention is virtually unheard of in experienced units.

It has always stood to reason that the highest efficacy and safety of interventions are achieved by using the minimum number of steps to complete a treatment in as short a period of time as possible. The use of distal protection devices in crural angioplasty not only adds to procedural time and complexity, but is associated with well-documented complications related to retrieval. Given the low incidence of significant embolic episodes in BTK angioplasty, it therefore becomes even more difficult to support the routine use of these devices.

Whether we like it or not, some mention of cost-risk benefit is required when we start to think about the proposal that distal embolic protection devices should come into routine use for BTK interventions. There is, at present, no evidence to suggest that early outcomes, amputation rates or quality of life are influenced by the use of this technology. Although there may be some parts of the European Union where treatment cost is not a major concern, for the rest of us the luxury of using such unjustified and unproven technology doesn't exist and is likely to come under even further scrutiny as national economies struggle.

As I mentioned earlier in this article, helpful innovation and useful technology speak for themselves in interventional radiology. The fact that we will be debating the use of embolic protection devices later today makes it quite clear that even years after these devices were made available, most of us remain convinced that they represent nothing more than technology desperately looking for an application.

To find out who will win the debate, join us in the Main Auditorium at 10:00!

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

FP 1405

Biliary interventions

Bioabsorbable biliary stent in the treatment of benign biliary strictures: follow-up of more than two years

C. Michelozzi, V. Pedicini, F. Melchiorre, D. Poretti, M. Tamarin, E. Lanza, G. Mauri, G. Brambilla, G. Cornalba; Milan/IT

Auditorium 9

FP 1406

GI interventions and biopsies

Effect of bariatric embolization on various appetite-driving hormones of obesity

C.R. Weiss¹, A. Arepally², T. Moran¹, C. Hu¹, J. Singh¹, H.-Q. Mao¹, T.-H. Wang¹, D.L. Kraitchman¹;
¹Baltimore, MD/US, ²Atlanta/US

Auditorium 10

FP 1407

TEVAR and EVAR

Aortic reconstruction with fenestrated and branched stent grafts after previous open or endovascular aortic surgery

A. Katsargyris, K. Oikonomou, R. Wolfgang, E. Verhoeven; Nuremberg/DE

Auditorium 5

FP 1408

Combined therapy (ablation and embolisation)

Local hepatic tumor control in patients undergoing transarterial lipiodol embolization followed by microwave ablation

R. Seidel, A. Massmann, P. Fries, G.K. Schneider, A. Buecker; Homburg/DE

Auditorium 6

FP 1505

Clinical practice

Impact on patient safety and satisfaction of implementation of an outpatient clinic in interventional radiology (IPSI-POLI study)

J. Lutjeboer, M.C. Burgmans, A.R. van Erkel; Leiden/NL

Auditorium 8

FP 1506

Special vascular IR oncology

Tumor degradation after complete tumor response following transarterial ethanol ablation for hepatocellular carcinoma

S.C.-H. Yu; Hong Kong/HK

Auditorium 10

Distal embolic protection devices are reasonable

Stefan Müller-Hülsbeck (EBIR)

Distal embolisation during endovascular procedures typically results when atherothrombotic material dislodges during wiring, device manipulation, or device actuation. The micro- or macro-emboli resulting from plaque or thrombus may cause organ ischaemia following percutaneous peripheral interventions. The incidence and clinical significance of particulate embolisation during percutaneous superficial femoral artery (SFA) and below-the-knee (BTK) intervention can be monitored with continuous Doppler ultrasound. The rate and timing of embolisation will definitely vary during different phases of interventions, such as guidewire crossing, balloon angioplasty, stent deployment or directional atherectomy.

According to CIRSE's Standards of Practice for SFA and popliteal artery angioplasty and stenting, distal embolisation is reported at 1.6% to 2.4%, and rises from 3.8% to 24% in case of thrombolysis [1]. Before looking more closely at these variable embolisation rates, one has to distinguish between micro- and macro-embolisation. Micro-embolisation consists of small emboli (consisting of an aggregation of platelets) that block an arteriole or the terminal part of an artery. This should be prevented with heparinisation as well as with antiplatelet therapy (single or dual). Both micro- and macro-embolisation can and should be prevented. The therapeutic options for microembolisation are especially limited. They include the use of intra-arterial verapamil (100-200 µg bolus) or adenosin (24-96 µg) in the coronary vasculature [2,3]. An additional preventative option is the use of an embolic protection device. It should be noted that treating micro-embolisation is rather difficult, whereas macro-embolisation is often successfully treated with the use of endovascular techniques such as aspiration, mechanical thrombectomy, angioplasty and fibrinolysis, as well as with open surgery. Let's have a closer look at the incidence of embolisation during peripheral endovascular procedures.

Lam et al. evaluated sixty patients who underwent SFA interventions (including PTA, PTA with stenting, atherectomy, excimer laser). A 4-MHz Doppler probe was used for continuous monitoring, and distal embolisation was registered by reference to embolic signals (ES). ES were quantitatively assessed during critical portions of the procedures including guidewire crossing, balloon angioplasty, stent deployment and/or atherectomy. ES were recorded at each step of the SFA interventions; the frequency was greatest during stent deployment. Despite the frequency, only one patient developed angiographically and clinically significant embolisation. Based on their findings, the authors do not support the routine use of protection devices during percutaneous SFA interventions [4].

Similar findings were reported by Shrikhande et al. In 2,137 lesions treated in 1,029 patients, distal embolisation (DE) was a rare event that occurred more often with thrombectomy and atherectomy devices. In-stent and complex native lesions entailed a higher risk of DE. DE was typically reversible with endovascular techniques, and had no effect on patency rates and limb salvage [5].

With these two publications in mind, one has to ask whether embolic protection devices (EPDs) are worth using. Using a protection device during femoropopliteal interventions potentially prevents debris migration, which may be important for high-risk patients with limited distal run-off. The PRO-RATA study included 29 patients suitable for PTA. Macroscopic debris was found in 27 of the 30 filters of distal protection devices used in these patients. Debris particle size ranged from 90 to 2000 µm (1200 ± 640) [6]. The same findings were reported in the PROTECT registry. Macro-embolisation was very frequent in patients undergoing lower extremity interventions, particularly with atherectomy [7]. In case of peripheral emboli, patients required more re-interventions (20% vs. 3%; $P < .001$) and major amputations at

30 days (11% vs. 3%; $P = .02$). There was no difference in hospital stay (2.4 ± 4 days vs 1.6 ± 2 days; $P = .08$), reintervention (2% vs. 4%), and major amputation (1% vs. 4%) among patients treated with or without EPDs, respectively [8]. The two patients who developed embolisation with EPDs had no clinical sequela and required no re-intervention. Most emboli were successfully treated with catheter aspiration or thrombolysis, but 8 patients (24%) treated without EPDs required prolonged hospital stays, 7 (21%) had multiple re-interventions, 1 (3%) underwent unanticipated major amputation, and 1 (3%) died from haemorrhagic complications of thrombolysis. Median follow-up was 20 months. At 2 years, primary patency and avoidance of re-intervention was similar for TASC A/B and TASC C/D lesions treated with and without EPDs. However, even if there was no difference at 2 years, it seems justifiable to identify patients groups who have a high risk of emboli.

Distal embolisation is rare in regular peripheral procedures such as PTA and stenting. Clinical data has shown that applying embolic protection devices in lower limb arteries is safe. More prospective and, ideally, randomised trial data is necessary to justify the increased use of filters in lower extremity interventions, despite the obvious benefits these devices provide. Currently, the clinical relevance of distal embolisation in the lower extremity remains unquantified [9].

Therefore, the use of embolic protection devices should be limited to procedures that entail a high risk of developing emboli downstream. Procedures prone to producing emboli include atherectomy and lesions with an unclear thrombus burden.

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Don't miss it!

Controversies in BTK treatment
Special Session
Sunday, September 14, 10:00-11:00
Main Auditorium

e-voting



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(Diako Flensburg)
Flensburg, Germany

Prof. Müller-Hülsbeck heads the Department of Diagnostic and Interventional Radiology/Neuroradiology at the Academic Hospitals Flensburg (Diako Flensburg). He is a full professor of radiology since 2004. Prof. Müller-Hülsbeck joined the Executive Committee in 2013, and presently holds the position of Membership Committee Chairperson. He served as Chairperson of the Vascular Division of the Foundation Advisory Council from 2007 to 2011, and as a member from 2011 to 2013. He has also served as a member of the Oral Examination Division of the EBIR Committee. Prof. Müller-Hülsbeck is a board member of the German Society of Interventional Radiology (DeGIR).



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› **Subintimal angioplasty for the SFA in 2014**

J. A. Reekers – The Netherlands

› **The evidence for drug coated balloons in the SFA**

F. E. Vermassen – Belgium

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Prostate artery embolisation: technique

Miguel Angel de Gregorio (EBIR)

Benign prostatic hyperplasia (BPH) is one of the most common benign diseases in men over the age of 40, affecting more than 40% of men in their fifties and as many as 90% in their seventies and eighties. Lower urinary tract symptoms (LUTS) are common complaints resulting from BHP; approximately half of all men with histologic diagnosis of BPH have moderate to severe LUTS. Symptoms include nocturia, urinary frequency, urgency, decreased urine flow rates, hesitancy, and incomplete bladder emptying. Over time, urine retention may cause an increase in urinary infections (UTIs), bladder or kidney damage, bladder stones or incontinence. Symptoms are evaluated on a personal basis, with the International Prostate Symptom Score (IPSS) dividing patients into those with mild, moderate and severe LUTS.

Classical treatments

The preferred management strategy for patients with mild symptoms is watchful waiting; the patient is monitored by his physician but receives no active intervention for BHP.

The first-line treatment in the rest of patients is pharmacological, with alpha-blockers, 5-alpha-reductase inhibitors and combination therapy. However, these medications do entail side effects, with orthostatic hypotension, dizziness, tiredness, retrograde ejaculation and nasal congestion being the most common.

If symptoms are refractory to, or the patient is intolerant of, medication, surgical intervention is an appropriate treatment option for patients with moderate to severe LUTS, and for those who have developed acute urinary retention (AUR) or other BPH-related complications. Trans-urethral resection of the prostate (TURP) is the standard and preferred treatment for small prostates, and open prostatectomy is typically performed on patients with prostate volumes greater than 80-100 g. TURP complications include TUR syndrome, a dilutional hyponatraemia that occurs when irrigant solution is absorbed into the bloodstream, erectile dysfunction, ejaculatory disorders, irritative voiding symptoms, bladder neck contracture, blood transfusion, UTI haematuria, early urinary incontinence, stenosis of the urethra and symptom recurrence. In comparison to TURP, open prostatectomy entails greater risks of blood loss, transfusion, and longer hospital stays.

The condition is highly prevalent amongst the elderly, and these patients usually present an increased surgical risk (ASA III-IV of the American Society of Anesthesiologists classification) and face a higher risk of complications, so are often not candidates for surgical treatment. What can we offer these patients? Is there an alternative? Or are they bound to suffer from LUTS for the rest of their lives?

Prostatic artery embolisation

Although embolisation has been used in many other contexts, it wasn't until 2000, when DeMerrit et al. published the first case on the potential benefits of prostatic artery embolisation for BHP, that the door to endovascular treatment was opened. Since then, publications addressing the promising benefits of

prostatic artery embolisation (PAE), led mainly by Dr. Carnevale in Brazil and Dr. Pisco in Portugal, have helped this treatment become recognised as a feasible option and promising treatment alternative for BPH.

However, PAE can be a technically challenging and time-consuming procedure. Small vessel calibres, difficulties with identifying prostatic arteries, tortuosity, anatomical variations and atherosclerosis associated with elderly patients are the main variables in a technically difficult intervention that demands the skills of a well-trained interventional radiologist.

In our experience, the most important factor for avoiding potential complications and reducing X-ray exposure is the clear identification of prostatic arteries, using the PROVISIO technique described by Dr. Carnevale in 2008 (Fig. 1). A well-trained team of interventional radiologists and profound knowledge of anatomical variations are essential for a successful outcome.

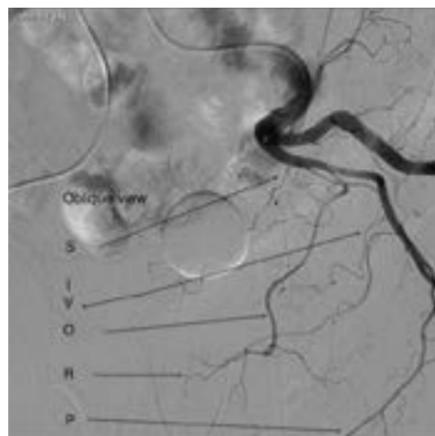


Fig 1: PROVISIO acronym for hypogastric anterior branches, P: internal Pudendal, R: middle Rectal, O: Obturator, VI: Vesical Inferior, S: Superior Vesical under Oblique view.

Technique

A very time-consuming aspect of the procedure is the identification of the branches of the anterior internal iliac artery and the relationship of these vessels with the prostate. Placement of a Foley balloon is an important landmark for that aim, with those vessels situated immediately below the balloon and anterior in the oblique view considered prostatic vessels. Posterior branches below the balloon correspond to rectal arteries; their embolisation must be avoided, using proximal coils if necessary.

We start evaluating the iliac vessels: localisation, vessel occlusion, atherosclerotic stenosis or tortuosity. After crossing the aortic bifurcation, a selective digital subtraction arteriogram of the internal iliac artery is performed in the 25°-55° ipsilateral oblique view with a 4-5 Fr. glide cobra-2 catheter (12 ml; 4 ml/s). The oblique view is mandatory for a correct identification of the five anterior branches of the internal iliac artery. The prostate branches can be identified in this position as being anterior and situated immediately below the Foley balloon. The PROVISIO acronym (internal Pudendal, middle

Rectal, Obturator, Vesical Inferior and Superior under Oblique view) described by Carnevale is very useful for the purposes of remembering the branches of the anterior division of the internal iliac artery.

The inferior vesical artery is the one mainly responsible for prostate vascularisation (Fig. 2). It usually arises as the second or third branch of the anterior trunk of the internal iliac artery; one main prostatic artery is generally found on each side in that position. The main prostatic artery or additional prostatic branches arising from the superior vesical, internal pudendal, obturator and middle rectal arteries also can be found in some patients.

Using small-diameter hydrophilic micro-catheters is mandatory in this intervention because of the small calibre of the vessels and their tendency to spasm.

As embolic agent we prefer to use calibrated 300-500 µm particles. To each 2 ml syringe of microspheres, we add 10 ml of iodinated

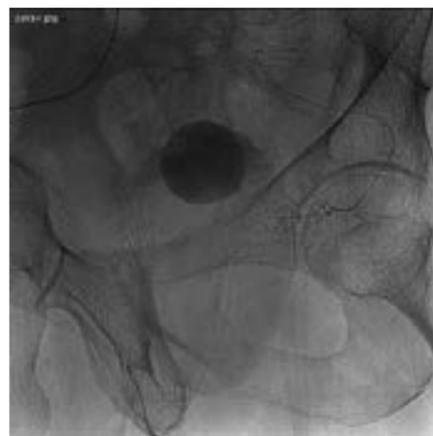


Fig 2: Imaging of the prostatic vascularisation depending on the inferior vesical artery.

contrast medium and 10 ml of saline to get a high dilution and avoid early proximal occlusion (Fig. 3). After achieving a good endpoint, we must search for additional prostatic branches. If any accessory prostatic branches are not embolised, poor long-term clinical results may occur, including reduced prostate shrinkage and return of LUTS symptoms.

The Foley catheter is removed in the first 24 hours in patients without AUR. Patients with AUR who use long-term indwelling catheters are instructed to return within 15 days for removal of the indwelling catheter to attempt spontaneous voiding. If the catheter cannot be removed, another attempt is made every week. We consider a case to constitute a clinical failure if the patient cannot urinate spontaneously after 2 months, and plan another intervention in order to review possible non-embolised prostatic collaterals.

We have noticed that embolisation in the prostate is much less painful than in other parts of the body, so analgesics are necessary only infrequently.

Don't miss it!

Treatment options for BPH

Special Session

Sunday, September 14, 10:00-11:00

Auditorium 4



Miguel Angel de Gregorio
University of Zaragoza
Zaragoza, Spain

Prof. de Gregorio, a CIRSE Fellow, is a Full Professor of Radiology at the University of Zaragoza and Chief of Interventional Radiology at the University of Zaragoza's hospital clinic. He is Principal Investigator of the Research Group of the Government of Aragon in minimally invasive techniques (GITMI). He has also been a visiting professor at the University of Louisiana, and is an instructor for the ESIR course on prostate embolisation.

Prof. de Gregorio served as a member of the National Committee for CIRSE 2004. Twenty-three of his national and four of his international publications have been recognised with awards, including his scientific poster on massive pulmonary embolism, which was awarded a prize at CIRSE 1999.



Fig 3: Proximal arteriography from the inferior vesical artery after embolisation.

Evidence

There are few studies on PAE, and only one controlled multi-centre randomised prospective study by Gao Y. et al. Notably, this study found no clear advantage to PAE versus TURP. Although PAE is shown to be an effective treatment for BHP in serial case publications, the lack of long-term results make touting this treatment as a real alternative to TURP controversial.

Currently, we consider PAE as an alternative treatment option to TURP for patients who would be at high risk with surgery or whose prostates exceed 100 g.

Future

PAE appears to have an exciting future but, as with every new technique, we need more evidence before it can become an alternative treatment not only for patients with high surgery risk, but for all patients who are candidates for BHP surgery. We must aim to obtain enough high-grade scientific evidence via randomised prospective clinical trials. Given that this is a very challenging intervention, it is essential that teams of PAE experts conduct these kinds of studies.

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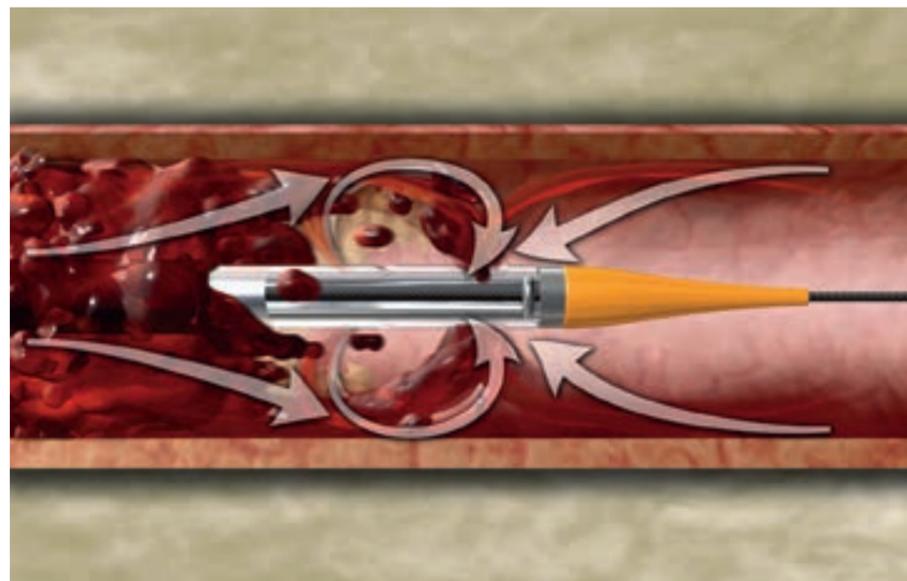
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² Zeller T et al. One-year outcome of percutaneous rotational atherectomy with aspiration in infrainguinal peripheral arterial occlusive disease: the multicenter pathway PVD trial. J Endovasc Ther. 2009 Dec;16(6):653-62.

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JETSTREAM Atherectomy Systems

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4405-014 G.RI.07.2014.0263 7/2014

Radioembolisation for intermediate-advanced HCC

José Ignacio Bilbao (EBIR)

According to the Barcelona Clinic Liver Cancer (BCLC) staging method, "intermediate-stage" (BCLC-B) is defined as a multi-nodular tumour (> 3 lesions – or two or more if one of them is > 3 cm) in an asymptomatic patient. "Advanced-stage" (BCLC-C) includes patients with portal vein invasion or with nodal (N1) and/or distant metastases (M1). For both stages, the underlying liver function must be scored as Child-Pugh A or B [1].

These definitions cover a heterogeneous group of clinical presentations for which it is complex to establish unique and uniform therapeutic recommendations. It seems obvious that, even where similar tumours are involved, the recommended treatment should not necessarily be the same in a well-compensated case (A5) and in a patient with compromised liver function (B9). The therapeutic approach can also vary if tumours are found just in one lobe or if they are widespread. According to the guidelines, any patient with radiological signs of portal thrombosis should be classified as advanced-stage (BCLC-C). The way to proceed, however, will differ if there is segmental portal vein occlusion and associated haemodynamic changes due to underlying cirrhosis (non-tumoural thrombus), or if there is a tumoural thrombus that progresses within the main portal vein lumen and with hepatofugal portal flow. Moreover, some patients with "just" one large tumour (> 7 cm) with limited liver function (Child-Pugh B or BCLC-A) may not be good candidates for curative treatment, such as surgery, and they are "migrated" towards the next stage, thus receiving palliative treatment [2].

There are several therapeutic possibilities for this heterogeneous group of patients, including percutaneous (ablative) techniques, endovascular treatments (chemo-, radio- or bland embolisation; chemotherapy), and systemic therapies (sorafenib or other new agents) [3]. Another interesting strategy is to combine some of these (for example, ablation of a single nodule in one lobe and radioembolisation of several lesions in the contralateral lobe). According to the BCLC guidelines, the recommended treatment for BCLC-B patients is chemoembolisation, while for patients in the BCLC-C stage, systemic treatments are recommended. Several papers have, however, demonstrated that these recommendations cannot be easily applied. Different panel consensus recommendations have raised the issue of establishing different sub-groups for BCLC-B, which would allow a more personalised approach to different clinical circumstances [2,4]. Similarly, some BCLC-C patients with minor (segmental) or moderate (lobar) thrombosis may benefit from selective endovascular treatment, either alone or in combination with systemic therapies.

Chemoembolisation

There is no consensus on what is included in the definition of chemoembolisation (TACE). Therefore, some panels decline to recommend the broad use of this term in order to avoid confusion [5]. "Conventional TACE" (cTACE) consists of administering Lipiodol, mixed with one or more drugs (doxorubicin, cisplatin or others), and subsequent arterial embolisation with particles. The administration of Lipiodol and drugs without embolisation is not considered chemoembolisation. The embolisation is usually performed with gelfoam, particularly in Eastern countries, or with other, more permanent, particles, such as PVA. The aim of the procedure is to combine the delivery of a tumouricidal drug, vehiculated with Lipiodol, with ischaemia, to achieve tumoural necrosis. Drug-eluting beads for chemoembolisation have been introduced to improve the delivery of the drug both by targeting tumoural vessels more selectively and prolonging exposure [6,7]. The

procedure consists of the delivery of non-degradable particles, already loaded with a drug (mostly doxorubicin), as selectively as possible within the afferent tumoural artery or arteries. The size of the particles is an important issue and its selection requires a careful evaluation of several parameters, including the size of the tumour, the possible presence of arteriovenous shunting, and the degree of desired selectivity. Generally the most appropriate size is 100-300 µm, although some small tumours may require 70-120 µm, and, rarely, others may be treated with 300-500 µm. The use of drug-eluting beads will enable standardisation of the procedure, facilitating comparisons of series through more uniform technical methodology. Results obtained with TACE have been satisfactory in select groups, mainly in patients with Child A or B7 with solitary or unilobar tumours [8], as was the case for most of the patients covered in the seminal articles that demonstrated the advantage of TACE for BCLC-B [9, 10].

Radioembolisation

Radioembolisation (RE), also called selective internal radiation therapy (SIRT), consists of the selective delivery of small particles (25-35 µm) into the afferent vessels of a tumour [11,12]. These carry a radioisotope (Yttrium-90) that delivers beta-radiation to the particles' surroundings. The therapeutic effect is based exclusively on the tumouricidal dose of the radiation delivered within the tumoural volume [13]. Particles have a non-ischaemic effect since they micro-embolise the treated volume, a completely different consequence than that obtained with the use of bigger particles (100-500 µm), which will produce ischaemia due to their macro-embolic effect. The tumouricidal benefits of TACE are based on the possibility of delivering the drug into the surroundings/proximity of the tumoural cell; however, it has not been completely demonstrated that it will "enter" the tumoural cell. Several barriers, such as the cell membrane, the interstitial peri-cellular space (with its specific elevated pressure) and the different (acidotic) metabolism of the tumoural cells inhibit the effectiveness of the drug [14]. This is not the case with Y-90 micro-particles, given that, if these are delivered within the selected liver volumes, they will produce coagulative necrosis in most of the cells that are closer than 2 mm and those that receive enough radiation. Ischaemia should be avoided since a decrease in oxygen levels may interfere with the radiation effect on the tumoural metabolism (DNA replication).

In sum, TACE and RE demonstrate some clear similarities, in that they are performed through an endovascular approach and require special skills and thorough knowledge of liver anatomy and function; but they differ in their method of action and in terms of their consequences to the liver parenchyma and surrounding tissues. Thus, the experts' consensus in the published literature is that while TACE has a clear role in some specific sub-groups of BCLC-B HCC (as the guide claims), it may be contra-indicated in some others, in which RE, thanks to its differentiated effect, has a definitive advantage.

Thus theoretically, and as several series have demonstrated, RE can be administered in multi-nodular tumours, both unilobar and bilobar, and in big single tumours, where patients are not candidates for curative treatment. In these circumstances, RE is not only effective but also safe due to the absence of a macro-embolic (carrier exclusively and non-ischaemic) effect. RE has a unique tumouricidal effect given that, if it is selectively delivered at a high dose, it will produce complete necrosis, comparable to resection (radiation segmentectomy), but without the need for surgery [15]. In these cases, RE has the added advantage of "maintaining" the

dead tumoural cells in the liver. This circumstance triggers both an increase in the hyperplasia of the non-target, spared liver volumen (as portal vein embolisation does) [16] and the activation of immunological mechanisms against any tumoural cells that may be active in the body. Just like TACE, RE may then have an intense local effect, provoking a down-staging of the clinical status and allowing the inclusion of patients as liver transplant candidates. Regarding this particular aspect, some series have shown that results obtained with RE are better than those observed with TACE [17, 18].

Since the delivery of Y-90 particles does not provoke ischaemia, RE can safely be administered to patients with portal vein thrombosis (PVT), providing a good alternative to systemic treatments for advanced-stage (BCLC-C) patients with non-deteriorated liver function [19, 20]. Finally, RE can be administered to patients with tumoural recurrence in whom TACE or Sorafenib have failed or been ineffective, achieving an overall survival rate similar to those obtained when RE is administered as a first-line treatment.

From 2010 to 2011, three series involving a total number of 700 cases provided support and evidence of the above-outlined advantages of RE in BCLC-B and BCLC-C HCC cases [21-23]. Published results were consistently similar with both commercially available microspheres (glass and resin). A retrospective analysis of 325 patients treated in different European hospitals showed an overall survival rate (median) of 14.5 (12.8-18.4) months [23]. Median survival was 15.3 months in patients with patent portal vein, 10.7 months in branch PVT and 9.7 for main PVT. There were no statistical differences in survival between the group without PVT and the group of branch PVT. There were significant differences in the survival of patients with different Child-Pugh scores, being 16.8 months for group A and 10.3 months for group B. The benefit of prolonged survival was lower for cases with a high tumour burden, extra-hepatic disease and higher levels of bilirubin.

A recent paper published by Mazzaferro et al. describes a group of 52 patients (BCLC-B and C), prospectively recruited, amongst whom the median time to progression (TTP) was 11 months, with no significant difference between PVT versus no PVT. The median overall survival was 15 (12-18) months, with a non-significant trend in favour of non-PVT versus PVT patients. According to Mazzaferro, "on multivariate analysis, tumor response was the sole variable affecting TTP (P < 0.001) and the second affecting survival (after Child-Pugh class)" [24].

Several on-going trials that have already recruited a large number of HCC patients treated with RE will help clarify the specific role of this treatment and its inclusion in the guidelines.

Complications related to RE are low and most patients are discharged within the first 24 hours after Y-90 administration. Complications are mainly related to the extra-hepatic deployment of Y-90 in the lungs, through arteriovenous shunting, which leads to radiation pneumonitis (<1% of the cases); or to the passage of particles through gastro-enteric arterial branches that may inadvertently be left open. Gastrointestinal complications are also infrequent (lower than 3%) [25]. In cirrhotic patients, liver parenchymal complications are related to over-radiation of the non-tumoural liver and due to a form of sinusoidal obstruction syndrome, which appears 4-8 weeks after the treatment and manifests itself with jaundice, mild ascites and a moderate increase in gamma-glutamyl transpeptidase and alkaline phosphatase. The syndrome has been described as radio-embolisation-induced liver disease [26, 27].

Don't miss it!

Basic principles of intermediate-advanced HCC management
Foundation Course
Sunday, September 14, 10:00-11:00
Auditorium 2



José Ignacio Bilbao
(EBIR)
University Clinic of Navarra
Pamplona, Spain

Prof. José Ignacio Bilbao heads the University Clinic of Navarra's Interventional Radiology Department, which he co-established. He has been an active member of CIRSE since its beginnings.

Prof. Bilbao was awarded a Gold Medal at CIRSE 2013. He was the Josef Roesch Lecturer for CIRSE 2010, speaking on TIPS. That same year, he was also awarded the CVIR Editor's Medal for a paper on non-radioactive resin microspheres, of which he was the primary author. He has served on a number of CIRSE committees over the years, and currently leads CIRSE's Registry for SIR-Spheres Therapy (CIRT).

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Don't miss today
Covidien Symposium on:
**Sophisticated SFA
Treatment Decisions:
Let Evidence be your Guide**



Sunday,
Sept. 14th, 2014
Auditorium 5

07:20 - 08:20

CHAIRMAN
Dr. R. Langhoff

This interdisciplinary symposium will discuss trends in the treatment of the SFA and will give insight into the actual evidence level for DCB and stenting.

Topics will span from clinical science to health economy and will assess possible treatment algorithms in the near future.

DETAILED PROGRAM

07:20 - 07:25

Introduction by the chairman

07:25 - 07:35

Advancing treatment in highly complex lesions
Dr. K. Stavroulakis

07:35 - 07:45

Evaluating Economic Value of 5F systems for Outpatients
Prof. Y. Goueffic

07:45 - 08:00

DCB Evidence Moving the Paradigm
Prof. G. Tepe

08:00 - 08:15

Insight into Drug Coated Balloons: what's the difference
Dr. A. Micari

08:15 - 08:20

Discussion and closing remarks by the chairman

**Visit
our
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Direct distal thromboaspiration combined with stentriever

Gyula Gál

The first thrombolytic agent, streptokinase, was isolated in 1933 (produced from the bacterium *Streptococcus*), and was subsequently used in the treatment of acute myocardial infarctions (AMIs) to dissolve the thrombus blocking the flow in the coronary arteries. Urokinase, isolated from human urine in 1947, has become widely used in the treatment of deep venous thrombosis, pulmonary embolism and also AMI. These two drugs have also been injected into the cerebral arteries to dissolve clots.

Since the introduction of rTPA in 1995 for the treatment of ischaemic stroke in the cerebral vessels, it has long been the only available treatment option, administered as an intravenous infusion, approved by the health authorities worldwide for this disease entity. However, interventional neuroradiologists started to treat thromboembolic occlusions of the brain arteries – arising during ongoing endovascular procedures – by endovascular means a couple of years earlier.

Following the introduction of electrically detachable coils in the treatment of intracranial aneurysms in 1991, the number of these procedures grew quickly in Europe, and after its approval by the FDA in 1995, also in the USA and the rest of the industrial countries. Due to this, early detection of thromboembolic complications of this method has led to attempts of chemical thrombolysis with the aforementioned drugs and/or mechanical removal of the clots by different methods, like retrieving them with a snare, and/or destruction of them with a microguidewire or a balloon. The first mechanical device, the Merci retriever, a corkscrew-like clot remover, specifically developed for this purpose, was introduced 2001. Since then, more than 10,000 patients have been treated with this device, achieving vessel recanalisation in ~25% of cases.

Stentriever

The first stentriever (a contracted form of “stent-retriever”), Solitaire, was originally designed as a self-expandable stent for temporary use, to support the endovascular treatment of wide-necked intracranial aneurysms with detachable coils, acting as a scaffold during the placement of the coils. It was introduced in Europe around 2006, and has subsequently been increasingly used to mechanically remove the clot from the cerebral arteries instead. Since it proved to be more efficient than the Merci, it has been widely used, and was later followed by several similar devices from different companies, acting in more or less the same way: a microcatheter is navigated beyond the clot on a microwire, which is replaced by the stentriever. On withdrawal of the microcatheter, this expands and engages the clot within a couple of minutes. After that, the stentriever is withdrawn,

removing the clot out of the vessel (optimally in one go, but the procedure can be repeated). During the original trial, SWIFT (2012), the rate of recanalisation using the Solitaire was > 60%. Other investigators later reported even higher recanalisation rates using similar devices, with significantly improved clinical outcomes at 90 days.

Current status

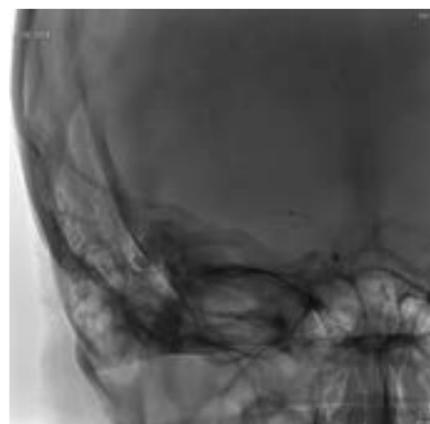
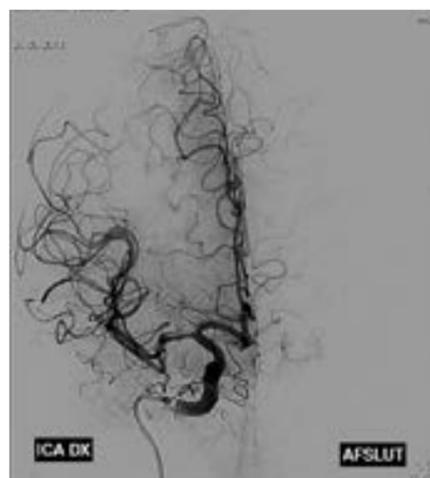
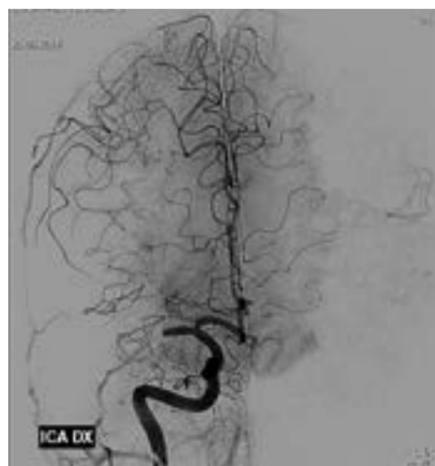
The distal thromboaspiration technique, ADAPT, was described in April 2013, and consists of the following steps:

1. A 6 Fr. long sheath – preferably with a soft tip, such as the NeuronMax (Penumbra, ID 0,088”) – is placed as high as possible without provoking vasospasm in the ICA or VA.
2. A large ID aspiration catheter, such as the 5MAX or 5MAX ACE (Penumbra), is navigated over a long microcatheter up to the level of the clot.
3. Aspiration with the large bore catheter and the Penumbra aspiration pump is applied for at least 90 seconds.
4. The aspiration catheter is slowly removed, and the vessel’s patency is evaluated by angiography.

If the aspiration fails, the procedure can be repeated, or additional devices – i.e. stentriever – can be used.

This technique is based on the special properties of the aforementioned recently developed aspiration catheters, that have variable softness and < 5,4 Fr. OD at the tip, making them suitable to navigate up to the MCA, ACA and PCA, and at the same time, large enough ID to engage the whole clot and aspirate it in one piece. The previous strategy of the Penumbra company was to degrade the clot with a soft tip wire, and aspirate it through microcatheters with three different diameters, all of them smaller than the new ones. The degradation and aspiration should be performed simultaneously, to avoid thromboembolic contamination of the branches distal to the clot. The efficacy of this previous method was in the range of the one performed with the stentriever, but smaller parts of the clot could escape aspiration, causing occlusion of the smaller branches downstream.

The new method is technically easier to perform, quick, and less traumatic to the smaller cerebral arteries, without the mechanical stress



Don't miss it!

Acute stroke: diagnostic and therapeutic concepts

Special Session

Sunday, September 14, 08:30-09:30

Auditorium 4



Gyula Gál

Odense University Hospital
Odense, Denmark

Dr. Gyula Gál is an interventional neuroradiologist and senior consultant in the Department of Radiology of Odense University Hospital, where he has worked since 2008. He was previously a senior consultant at the University Hospital Uppsala in Sweden. Dr. Gál has contributed to articles in various publications, including the first report on simultaneous successful treatment of a large ruptured saccular aneurysm and stenotic parent artery with a single flow-diverting stent; on spontaneous subarachnoid haemorrhage; and on the Cerebral Aneurysm Multicenter European Onyx Trial. He is a member of the International Andreas Gruentzig Society.

the stentriever with a necessary radial force to engage the clot can cause. The operator, however, should have good knowledge of the anatomy of the cervical vessels to start with and be able to successfully navigate the sheath and the aspiration catheter in a telescopic fashion to achieve good support at the neck. The next challenge is the proper understanding of the anatomy of the supracervical vessels, in order to get the aspiration catheter to the clot, without disintegrating it, using the microcatheter and the microwire as a guide. In the author's experience, it can safely be done up to the level of the M1, A1 and P1 segments. Due to the OD of these catheters, more distal positioning of them may harm the vessels, with no benefit to the patient.

In case of a clot distal to these vessels, a stentriever can still reach it through the same microcatheter and aspiration catheter, and it can be removed with the same technique as described before, retrieving it partially in the aspiration catheter, with significantly less harm to the vessel. However, in the author's experience, this is a rare situation, unless the thrombus was located in these distal vessels from the beginning.

Summary: The introduction of the ADAPT technique has caused a fundamental change in the thrombectomy paradigm at the author's institution. During the past year, the rate of recanalisation with aspiration alone was ~85%, and with the additional use of a stentriever > 90%. This is far better than the previous results and lead to significant improvement of the clinical outcome of the patients, as well.

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At this session, acclaimed IR experts will present brief overviews of their most unexpected and challenging cases, showing how fast thinking and flexibility can save the day. This fascinating session will highlight innovative ways in which interventional radiologists can solve difficult problems and get out of trouble – it's a session that is not to be missed!

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Panellists:

Anne-Marie Cahill (Philadelphia, PA/US)

Thierry de Baère (Villejuif/FR)

Afshin Gangi (Strasbourg/FR)

Gerard O'Sullivan (Galway/IE)

William Rilling (Milwaukee, WI/US)

Bien Soo Tan (Singapore/SG)

Richard Tippett (Dorchester/UK)

Otto van Delden (Amsterdam/NL)

Renal sympathetic denervation in resistant hypertension: The current evidence

Tarek Antonios

Hypertension is the most important risk factor for cardiovascular diseases, which include strokes, myocardial infarctions, heart failure, aortic diseases and peripheral vascular disease, and renal failure. Suboptimal blood pressure (BP) control is the most common attributable risk for death worldwide, being responsible for 62% of cerebrovascular disease and 49% of ischaemic heart disease [1]. Hypertension affects 1 in 3 individuals worldwide, and the prevalence of the disease is expected to increase to 1.6 billion in 2025 [2]. Most individuals with hypertension require treatment with 2-3 different anti-hypertensive medications to control their high BP. The British Society of Hypertension and the National Institute for Health and Care Excellence (NICE) in the UK recommend the combination of a calcium channel blocker, an angiotensin-converting enzyme or an angiotensin receptor blocker, and a diuretic for the treatment of hypertension. The majority of individuals with hypertension will have their BP controlled on this combination [3]; however, a significant proportion of around 14% will have difficult-to-control or resistant hypertension.

Resistant Hypertension

Resistant hypertension (RH) is defined as uncontrolled BP above target goal (>140/90 mmHg in non-diabetic patients and >130/80 mmHg in diabetic patients) despite the concurrent use of optimal or best-tolerated doses of three or more different anti-hypertensive drugs including a diuretic [4]. The definition also includes patients with controlled BP who are treated with 4 or more anti-hypertensive medications. Patients with RH have a higher incidence of target organ damage and are at a higher risk for cardiovascular events [5]. The pathophysiology of RH is intricate and varied, and may include: non-concordance with anti-hypertensive medications; the use of drugs that can increase BP, such as non-steroidal anti-inflammatory drugs, steroids, cocaine, liquorice and anti-angiogenic drugs; a high salt diet; alcohol excess; obesity; and presence of secondary causes of hypertension such as hyperaldosteronism, renal artery stenosis, and obstructive sleep apnoea [6]. Patients with RH have also been found to have increased sympathetic activation and outflow as evidenced by increased renal noradrenaline spillover [7].

The sympathetic nervous system and in particular, sympathetic cross-talk between the kidneys and the brain, appears to play an important role in hypertension [8]. Increased efferent sympathetic outflow to the kidneys causes elevation of BP via release of renin, with subsequent activation of the renin-angiotensin-aldosterone system, increased sodium retention by the renal tubules, and reduced renal blood flow [9]. Furthermore, surgical sympathectomy has been used as a treatment for severe hypertension [10]. More recently, endovascular catheter-ablation technology has allowed selective denervation of the human kidney using radio-frequency (RF) energy delivered via the renal artery lumen [11]. Renal denervation (RDN); also known as renal sympathetic denervation, or RSD) is a novel endovascular interventional procedure aimed at treating RH. Initial studies

have shown significant improvement in BP control up to 36 months post-procedure.

Symplcity HTN-1 Trial

Symplcity HTN-1 was the first-in-human proof-of-concept open-label cohort study in 50 patients with RH [12]. The baseline office BP was 177/101 mmHg whilst on a mean of 4.7 anti-hypertensive drugs. 45 patients underwent the RDN procedure and 6 months later, their office BP was reduced by 22/11 mmHg and by 27/17 mmHg at one year [13]. Ambulatory BP monitoring was not done in every patient and some patients (13%) had little, if any, BP reduction. The initial cohort was subsequently expanded from 45 to 153 patients. Office BP was reduced by 32/14 mmHg at 24 months [14]. At 36 months, results were available for 88 patients and showed a reduction in BP by 32/14 mmHg. One new renal artery stenosis requiring stenting and three deaths unrelated to RDN occurred during follow-up [15].

Symplcity HTN-2 Trial

As there was no control group in Symplcity HTN-1, a subsequent trial (Symplcity HTN-2) was initiated as an international, multicentre, randomised but not blinded second study of the safety and effectiveness of RDN in patients with RH [16]. Patients aged 18-85 years with a systolic BP ≥ 160 mmHg (≥ 150 mmHg in patients with type 2 diabetes) were included. RDN was performed in 52 patients, whereas anti-hypertensive medications were continued in 54 patients. BP improved significantly in the first month in the active RDN group, but BP reduction was much greater at 6 months (32/12 mmHg) whereas in the control group, BP change was minimal (1/0 mmHg). BP reduction was significantly less in a smaller group of 20 patients who underwent ambulatory BP measurement (11/7 mmHg) [16]. Ambulatory BP monitoring was not mandatory in Symplcity HTN-1 and HTN-2.

At the 6-month visit, patients in the control group became eligible to be treated with RDN, and 35 out of the 51 patients underwent RDN. Patients in the initial RDN group and the crossover patients receiving the RDN procedure at 6 months were followed to 12 months. BP was reduced by 28/10 mmHg at 12 months in the original RDN group. In the crossover group systolic, BP was reduced by 24 mmHg [17]. The authors reported 1 renal artery dissection, and 1 hypotensive and 2 hypertensive episodes requiring hospitalisation. At 36 months, BP was reduced by 33/14 mmHg for the initial RDN group [18].

Symplcity HTN-3

Very recently, the results of the Symplcity HTN-3 trial were published [19]. Symplcity HTN-3 was the first prospective, single-blind, randomised, sham-controlled trial. All patients were blinded to randomisation using sedation, sensory isolation, and lack of familiarity with the procedure. Furthermore, all patients had a renal angiography, and eligible subjects were randomly assigned at a 2:1 ratio to either the

RDN or the control group. The primary efficacy end-point was the change in office systolic BP at 6 months; a secondary efficacy end-point was the change in mean 24-hour ambulatory systolic BP. A total of 535 patients underwent randomisation. The study was negative, as it did not show a significant reduction in office or ambulatory systolic BP in patients with RH at 6 months after RDN as compared with the sham control. The systolic BP was reduced by 14 \pm 24 mmHg in the RDN group, compared with a reduction of 12 \pm 26 mmHg in the control group ($p = 0.26$). The 24-hour ambulatory systolic BP decreased by 7 \pm 15 with RDN and by 5 \pm 17 mmHg in the control group ($p = 0.98$). At first glance, renal denervation seems not to be effective in reducing SBP in patients with severe RH.

However, several investigators have raised concerns about the results of this trial and asked for caution in the interpretation of the results. A major concern was that less effective RDN interventions were the result of the large number of interventionalists ($n = 111$) and centres ($n = 88$) with a lack of intensive teaching and previous experience with the procedure [20]. Furthermore, optimisation of background anti-hypertensive therapy was commanded but up-titration was allowed to continue potentially up to only two weeks before the RDN procedure. It is possible that BP stability had not been achieved in a proportion of Symplcity HTN-3 patients at the time of the procedure, which may have contributed to the significant BP-lowering observed in the sham group [21].

Symplcity HTN-3 study underscores the need to better identify the characteristics of patients who might derive the greatest benefit from RDN, and to conduct well-executed randomised studies. A major difficulty with RDN is that it is a blind procedure, with no practical biomarker of the efficacy to indicate successful denervation or for the prediction of treatment response. Our experience with RDN at the Blood Pressure Unit, St. George's Healthcare Trust in London in the small number of patients with severe RH who underwent the procedure is varied. Some patients had significant reduction in their systolic BP, while others had little if any effect at all.

The Joint UK Societies (British Hypertension Society, British Cardiovascular Society, British Society of Interventional Radiology and the Renal Association) recommend a temporary moratorium on RDN procedures for all cases as part of routine care in the NHS and private practice in the UK. Prospective randomised properly controlled trials are urgently needed to assess the future role of RDN in the treatment of resistant hypertension [22].

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Don't miss it!

Renal denervation Special Session

Sunday, September 14, 08:30-09:30
Auditorium 2



Tarek F. Antonios
St. George's, University of London & St. George's Healthcare NHS Trust London, UK

Dr. Tarek Antonios is a senior lecturer and consultant physician in cardiovascular and general medicine at the Cardiovascular and Cell Sciences Research Institute, St. George's, University of London, and the Head of the Blood Pressure Unit at St. George's Healthcare NHS Trust. His interests include the management of severe and resistant hypertension, secondary hypertension, malignant hypertension, pregnancy-associated hypertensive disorders including pre-eclampsia, and hypertensive heart failure. Dr. Antonios is accredited as a clinical hypertension specialist by the European Society of Hypertension, and has delivered lectures on microcirculation research around the globe, including in France, the Czech Republic, South Korea, Egypt and Yemen.

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Advertorial

Challenges and Opportunities of treating VCFs in the thoracic spine.

An Interventional Radiologists Perspective.



Vertebral compression fractures (VCF) are the most common type of fracture in patients with osteoporosis, and 1.4 million Europeans¹ each year suffer from one. These fractures can result in significant back pain, spinal deformity and physical limitation. Most VCFs occur at the thoracolumbar junction (T11-L1) and mid-thoracic region (T6-T8).



Andrés González Mandly

Sección de Neurorradiología Hospital Universitario Marqués de Valdecilla Santander

The management of these fractures usually begins with medical treatment, including analgesics and activity modification, and this is sufficient for a proportion of patients². However, a number of these patients continue to experience persistent pain regardless of the use of analgesics, including oral and/or transdermal opioids. Furthermore, medical treatment on its own does not address the spinal deformity caused by the fracture. It is in this setting where minimally invasive vertebral augmentation techniques, and, particularly, Balloon Kyphoplasty (BKP), play an important role, by improving both pain and deformity. Spinal deformity is not only an aesthetic concern. Kyphotic deformity is known to increase the incidence of new vertebral fractures³, and changes in posture derived from the deformity cause uncertain gait and increase the risk of falls. But even more important, kyphosis in the mid thoracic region reduces both the vital capacity and volume of the lungs, which can cause worsening of the condition in patients with chronic obstructive pulmonary disease⁴. Obviously, the impact on the thoracic deformity is much larger in patients with multiple thoracic vertebral fractures. An advantage of BKP is that it allows one to treat multiple fractures in the same patient, optimizing the height and angle restoration of the vertebral body (see pictures).

Occasionally, treating VCFs in the mid thoracic region with BKP can be challenging due to the smaller size of the vertebrae and pedicles. In many cases, transpedicular access cannot be used in thoracic vertebrae as the access tools are larger than the vertebral pedicles. It is in these cases where Medtronic's Kyphon® Express™ system for BKP makes a difference. It consists of a selection of 10-gauge bone access tools and 14-gauge inflatable bone tamps available in multiple lengths and volumes. The smaller diameter of the Osteo-introducer (the 10G bone access tool) allows for a direct, one



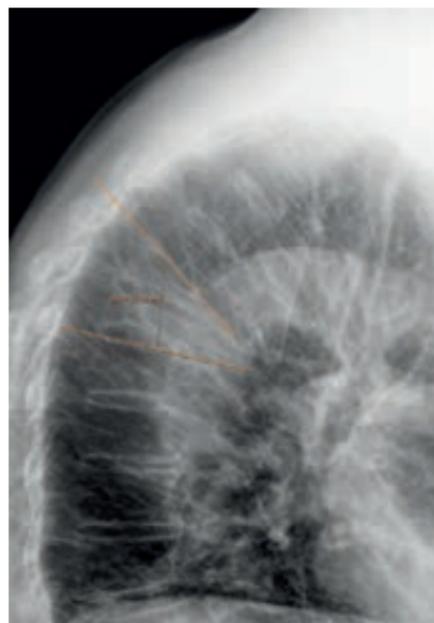
step access to the vertebral body without exchange maneuvers, for both transpedicular or extravertebral approaches in mid and upper thoracic vertebrae.

A new generation of the Express™ system (the Express II™ system) has been recently launched, bringing some interesting improvements: First of all, the balloon tamps have been designed with a "less-compliant" material⁵, which makes the balloon less likely to enter into the path of least resistance, offering a predetermined shape with more control during inflation. They can also be inflated up to 700 psi which could prove useful in moving older, sclerotic bone. The new material is resistant to PMMA-based cements' chemical reaction, which allows the interventionalist to keep one balloon inflated during contralateral cement fill. With this, a theoretical loss of height after balloon deflation and before cement injection could be minimized. This resistance to cements' chemical reaction could also be very useful when using the "egg-shell" technique (creation of a cement lining of a vertebral wall defect by inflating a balloon in a previously created cavity in which a small quantity of cement has been injected). Finally,

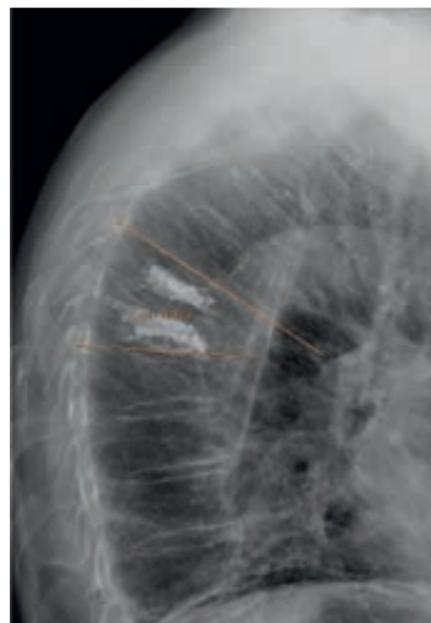
the new Express II™ system is available in three different balloon sizes (10, 15 and 20 mm, with a capacity of 3, 4 and 5cc respectively), so that vertebrae of all sizes can be treated.

The Express II™ system also allows for the possibility of obtaining excellent samples for bone biopsy during the BKP procedure. A bone biopsy device can be inserted through the osteo-introducer as many times as necessary and multiple samples can be obtained, increasing the yield of the biopsy. The results have been so good in our experience that most of the vertebral biopsies in our department are now being performed with this system, even if no BKP is intended.

A major concern for the interventionalists performing vertebral augmentation techniques is the dose of radiation received by the operator during the intervention. Radiation dose to the hands and eyes of the operator are increased during the cement deposition when the operator stands very close to the radiated area. Together with the Express™ and Express II™ systems, a new cement delivery system can be used. It is called Kyphon® CDS™ and it consists of a cement delivery gun attached to a long, flexible plastic tube that connects to a cement cartridge attached to the bone filler devices. By pressing the lever in the delivery gun, the physician performing the BKP sends pressure to the cement cartridge and the cement is injected through the bone filler. There is a safety button at the base of the gun that drops the pressure inside the system to zero when pressed in order to immediately stop the flow of cement. With this set, the operator can stand more than one meter away from the patient, and this system has been clinically proven to reduce radiation by 80%⁶. In summary, BKP is a valid and safe technique for the treatment of VCF in the mid thoracic regions⁷. The thinner design of the access tool for the Kyphon® Express™ system makes it possible to offer this technique even to patients with small vertebrae and narrow pedicles, and the new delivery systems allows the interventionalist to perform this procedure with reduced radiation exposure. Time will tell if the new features in the Express II™ system help us get even better results, but early experience seems promising.



Picture A: 81 y.o male with severe chronic obstructive pulmonary disease with long term medication with corticoids who suffered two VCF (T6 and T7) with secondary increase of the dorsal kyphosis and marked worsening of the respiratory functional tests since the time of the fractures. T6 and T7 fractures are depicted in the upright lateral thoracic spine plain X-Ray.



Picture B: Lateral upright X-ray after BKP with the Express™ system of T6 and T7, showing a 6° restoration. The patient experienced a very significant improvement in pain (VAS 8 to VAS 2) and in the respiratory functional tests.

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Tumour ablation: Current role in the treatment of osteoid osteoma and osteoblastoma

Afshin Gangi (EBIR), Georgia Tsoumakidou, Julien Garnon, Fabrice Bing, Georgios Metaxas

Osteoid osteoma (OO) and osteoblastoma (OB) are benign neoplasms of childhood and adolescence with limited growth potential (85% of patients with OO are between 5 and 24 years old). OOs consist of a small oval or round mass, commonly called a nidus, and a surrounding zone of reactive bone sclerosis [1]. OB are four times less frequent than OO. Histologically, they have striking similarities with OO, which is why they have been termed "giant osteoid osteoma". In general, any tumour > 15 mm is called OB, and < 15 mm is called OO.

Patients with OO typically present with pain of gradually progressive severity that is worse at night and responds to salicylates [2]. Pain is thought to be due to nerve fibres on the margins of the nidus, as well as local inflammation with increased tumoral expression of prostaglandins. More than half of OOs occur in the femur and tibia, while spinal OOs account for 7-20%. The lumbar segments are most commonly involved and there is a predilection for the posterior elements [1,2]. Symptoms of spinal OO and OB include severe pain, painful scoliosis (due to muscle flexion contractures) and radiculopathy [3].

The management of patients with OO has changed dramatically in recent decades. The majority undergo percutaneous image-guided thermoablation [4-6], while conservative treatment and surgical excision (resection or curettage) is mainly reserved for cases where thermoablation is considered inappropriate for technical reasons, i.e. proximity of nerves. Goto et al. found that up to 92% of patients treated conservatively with NSAIDs were pain-free at a mean interval of 18 months after treatment initiation [7]. But NSAIDs, when administered for long periods and at high doses, have potential side effects, such as renal impairment and peptic ulcers. On the other hand, surgical treatment (resection, curettage) is largely invasive and often requires additional bone-grafting.

Percutaneous radiofrequency ablation (RFA) for the treatment of OO was first introduced in 1992 by Rosenthal et al. [6]. Since then, a new era has evolved on the treatment of these small, benign bone tumours. Our team in Strasbourg published the first series of patients with OO treated with laser photocoagulation in 1997 [5]. Laser and RFA have similar success rates, which range between 80-100% [4,8,9], and are nowadays considered the gold-standard treatments.

Recently, there have been several articles published introducing cryoablation (cryoA) for the treatment of OO and OB [10]. The advantage of cryoA over the other thermal ablation techniques is that the operator can easily monitor the soft tissue extent of the ablation zone (ice ball) and thus minimise the unintended damage to the collateral structures. Compared to laser, cryoA can produce larger ablation zones with one single probe, which is usually demanded in cases of OB. In some cases of OB > 2 cm, we further propose performing pre-ablation arterial hyper-selective embolisation. The embolisation procedure reduces tumour vascularity, decreases the loss of thermal energy due to the heat-sink effect, and thus can increase the technical and clinical success rate. The arterial embolisation should be performed on the same session, or a few days before the ablation.

No matter which ablation method is to be used, the technical approach is more or less the same. When determining the needle-puncture trajectory, different anatomical considerations need to be taken into account. Knowledge of the regional anatomy is particularly important. Percutaneous access to the tumour nidus can be achieved with a bone-access device, though in cases of strong cortical bone or excessive perinidal sclerosis, we advise the use of a power bone drill. For laser and cryoA, grounding pads are not needed, as they are in RFA. Extra attention should be paid when treating tumours in locations with thin overlying subcutaneous tissue (i.e. anterior cortex of the tibia) to avoid thermal skin damage and to avoid frostbite lesions around cryoprobes during cryoA. When treating lesions near the articular surface, cartilage thermal protection (with intra-articular fluid injection) is mandatory. Always bear in mind that hydrodissection with N/S 0.9% should never be used with RFA, and dextrose should be preferred in the above cases.

In cases of OO and OB near vital neural structures (i.e. spinal lesions) further protective measures should be taken. The existing active (hydrodissection with continuous slow injection of fluid) and passive (CO2 dissection with no cooling/warming properties) should be advocated whenever necessary. The presence of thick bone restricts thermal energy transmission but cannot be taken as a "guarantee". The temperature can be directly measured with the placement of thermocouples in contact with the neural structure in danger. The temperature should be strictly kept between 10 and 45°C, as temperatures outside this range are neurotoxic. Finally, electrostimulation and neurophysiologic control (MEPs, SEPs) offer a continuous neurological monitoring and can help avoid complications.

Spinal OO and OB are challenging cases both for surgeons and interventional radiologists [11-13]. In our department, we have treated more than 60 patients with spinal OO and OB in the last 10 years. More than 60% of OOs had a minimum distance of < 6 mm from the closest neural structure. We used laser ablation in most cases, and cryoablation combined with pre-ablation arterial embolisation in two cases of spinal OB. For spinal OO, the technical and primary clinical success rate (complete pain relief, return to daily activities and no need for NSAIDs at 1-month follow-up) was 100% and 98.2%, respectively. Two patients presented with recurrence at 4- and 7-month follow-up, and one patient with a second nidus in a different location. All recurrences were re-treated percutaneously. Secondary treatment success rate was 100%; no major complications were noted.

To conclude, we would like to emphasise the role, efficacy and safety of percutaneous image-guided thermal ablation for the treatment not only of the peripheral "easy-to-treat" osteoid osteoma and osteoblastoma, but moreover, for the treatment of the so-called "challenging" cases. OO and OB located in the spine or near thermosensitive neural structures can be addressed percutaneously. Accurate needle positioning in the nidus is essential. Protection of the surrounding vital neural structures is mandatory. Pre-ablation selective arterial embolisation can be helpful in the ablation of OB by reducing the heat/cool-sink effect.

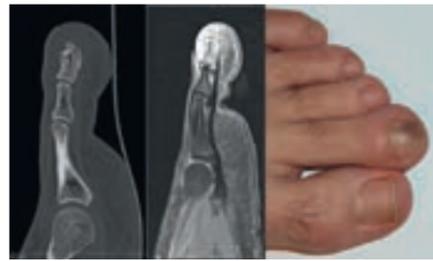


Fig. 1a: Osteoid osteoma of the second toe

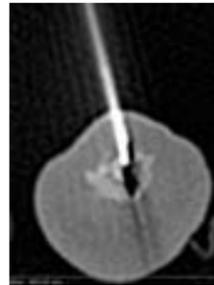


Fig. 1b: Laser ablation: In this case laser, is the best ablation method, with a 400µ fibre inserted and 18 gauge needle inserted through the nail



Fig. 2a: 18-year-old boy with painful scoliosis: osteoid osteoma of the superior articular process of L5

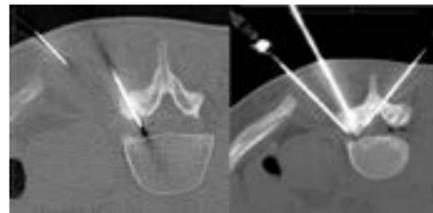


Fig. 2b: Thermal ablation with epidural and foraminal thermal monitoring and cooling

Don't miss it!

Spine interventions
Special Session

Sunday, September 14, 08:30-09:30
Auditorium 5



Afshin Gangi

(EBIR)

University Hospital of
Strasbourg
Strasbourg, France

Prof. Afshin Gangi is the Head of Radiology and Nuclear Medicine and a Professor of Radiology at the University Hospitals of Strasbourg. He is a long-standing member of CIRSE's Executive Committee, and currently serves as its Research Committee Chairperson. Prof. Gangi is also a member of the Scientific Programme Committee for CIRSE 2014, the ESIR Programme Committee for Non-Vascular IR, and the Media Committee. In addition, he serves on the Ethical Compliance Task Force. An expert in musculoskeletal interventions, Prof. Gangi delivered the Andreas Gruentzig Lecture at CIRSE 2012, addressing new frontiers in musculoskeletal tumour management. His renowned team in Strasbourg includes co-authors Dr. Georgia Tsoumakidou, Dr. Julien Garnon, Dr. Fabrice Bing, and Dr. Georgios Metaxas.

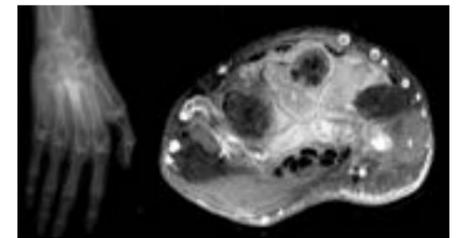


Fig. 3a: Osteoblastoma of the third metacarpal bone

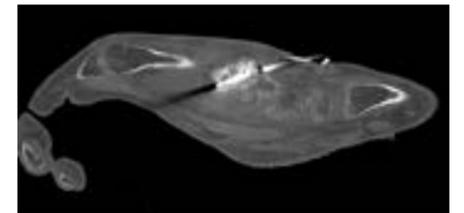


Fig. 3b: Cryoablation of the calcified tumour: Excellent visualisation of the ice ball covering the tumour.

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Embolisation and BRTO for gastric or ectopic varices: technique and results

Hiro Kiyosue

Gastric varices (GV) and ectopic varices are serious complications of portal hypertension, which is often associated with liver cirrhosis. Most of these varices arise on a large portosystemic collateral pathway such as gastrorenal shunt. The gastric varices are roughly divided into two types, according to their drainage routes: the azygos venous system (gastro-oesophageal varices) and the phrenic venous system (isolated gastric varices) [1,2]. The majority of gastric varices are supplied by multiple afferent veins, tributaries of the left gastric vein, the posterior and/or the short gastric veins, and drain through the phrenic venous system into the left renal vein and/or the inferior vena cava [3].

Risk of bleeding from GV is relatively low (16-36% within 3 years). However, the bleeding from GV is usually massive, and is difficult to control due to the large size and rapid blood flow of the varices. Although acute haemostasis of GV bleeding can be achieved in most cases by endoscopic injection of cyanoacrylate, the rebleeding rate is still as high as 15-30% within 1 year [4]. TIPS is accepted as the second-line option for the treatment of GV bleeding, and the rebleeding rate of gastric varices after TIPS is around 15% [5, 6]. Although percutaneous transportal obliteration (PTO) coils, gelatin sponge and ethanol used to be common techniques for the treatment of bleeding from the varices in the '70-80s, these have been replaced by other options due to the high rebleeding rate. Recently, modified PTO technique using cyanoacrylate injected in the variceal lumen to fill whole varices has been used for select cases without a catheterisable draining vein with retrograde transvenous approach [7], or is used in combination with other techniques such as BRTO and more often with TIPS via the TIPS route.

Balloon-occluded retrograde transvenous obliteration (BRTO) developed as a technique for the treatment of isolated gastric varices with a large portosystemic shunt in the '90s, and since then, has rapidly spread in Japan because of its reliability in controlling or preventing variceal bleeding (rebleeding rate: 0-10%) [8]. BRTO is becoming gradually popular around the world. The concept of BRTO is complete thrombosis of the varices by filling of sclerosant in whole varices with retrograde approach. GV are often supplied by multiple gastric veins and drain into a single drainage vein of the inferior phrenic vein as described before, therefore, complete filling of whole GV with sclerosant can be more easily obtained by retrograde injection with balloon occlusion (Fig. 1). The original BRTO technique employed retrograde injection of the sclerosant EOI (5% ethanolamine oleate-iopamidol: the same amount of 10% ethanolamine oleate and iopamidol) via the balloon catheter positioned at the outlet of the gastrorenal shunt to the left renal vein, and stagnation of the sclerosant in the varices for 30 minutes with balloon occlusion. Several modifications of BRTO technique have been made by physicians in the last decade, which include devascularisation techniques of collateral drainage using coils and/or balloon, selective BRTO technique (Fig. 2), combination with antegrade balloon occlusion, prolonged balloon occlusion time (overnight occlusion), and use of alternative sclerosing agent (foam with polydocanol or sodium tetradeceyl sulfate with or without lipiodol) [9-11]. More recently, use of the Amplatzer vascular plug and gelatin sponge instead of balloon and sclerosant, has also been reported [12].

Although many papers have demonstrated the efficacy and safety of BRTO for both management and prevention of GV bleeding, the number of cases is relatively small and follow-up periods are limited. Furthermore, there are potential drawbacks of worsening portal hypertension, resulting in aggravation of oesophageal varices and ascites. In order to evaluate the safety and long-term efficacy of BRTO in a large number of patients, the Japanese Society of Interventional Radiology (JSIR) conducted a retrospective survey of the clinical results of BRTO performed between 2007 and 2009 by certified interventional radiologists at 21 Japanese IR centres.

Results of JSIR's BRTO survey

A total of 314 cases were registered. There were 124 cases diagnosed as liver cirrhosis, 196 cases with co-existence of HCC, 189 cases with oesophageal varices, and 63 cases with bleeding from gastric varices. Adjunctive techniques

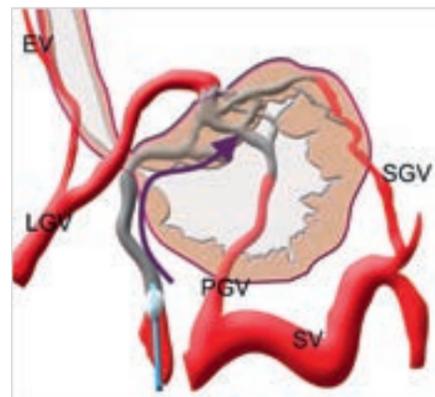


Fig. 1: Schematic drawing of concept of BRTO. Sclerosant (grey color) injected via a balloon catheter at the draining vein fills in the whole gastric varices.

including embolisation of collateral drainage, selective BRTO and double balloons were used in 141 cases (45%). Short-term results (within 1 year) show complete obliteration, regression, and unchanged GV in 78.4%, 20.2%, and 1.4%, respectively. Long-term results (mean follow-up periods 42 months) demonstrated disappearance, regression, stable remnant and recurrence of GV in 80.1%, 4.3%, 5.2%, and 10.4%, respectively. Among the 22 cases of recurrent GV, 12 cases were newly developed GV at another location. (Re)bleeding after BRTO was observed in 2 cases. Cumulative probability of recurrence and (re)bleeding of GV were 1.7% and 0.4% at 1 year, 6.8% and 0.6% at 3 years, and 16.2% and 1.4% at 5 years in all cases, and those of ruptured GV were 2.5% and 0% at 1 years, 5.5% and 0% at 3 years, and 13.3% and 3% at 5 years. Cumulative probability of aggravation and bleeding of oesophageal varices after BRTO were 27% and 9.4% at 1 year, 33% and 13% at 3 years, and 51% and 23% at 5 years in all cases. Complications related to BRTO were encountered in 11 cases (3.5%), including 6 cases of aggravation of ascites, 2 cases of retroperitoneal haematoma, 1 of abdominal pain, and 1 acute hepatic failure. Except for the cases of acute hepatic failure, the other cases fully recovered spontaneously or following medication. The patients developing acute hepatic failure died within 1 month after BRTO, and the mortality rate was 0.3%. No other serious complications such as pulmonary embolism were observed. From the results of this survey and previous reports, BRTO is thought to be safe and the most reliable technique for preventing (re)bleeding of GV.

Ectopic varices are often located at the duodenum and rectum, but can be located anywhere in the intestine and biliary tree, accounting for approximately 1-5% of all variceal bleedings [13]. Risk of bleeding from these ectopic varices is unknown due to their low incidence. However, bleeding from the ectopic varices can be as severe and fatal as GV. Ectopic variceal bleeding is usually more difficult to manage with endoscopic techniques. Although many case reports and small cases series showed the efficacy of various interventional techniques including PTO, BRTO and TIPS for the treatment of the ectopic varices [14,15], there are no guidelines for the management of bleeding ectopic varices. The most adequate techniques depend on the anatomical features and haemodynamics (location, afferent vein and draining veins, and conditions of the associated portosystemic veins), and should be selected for each individual case.

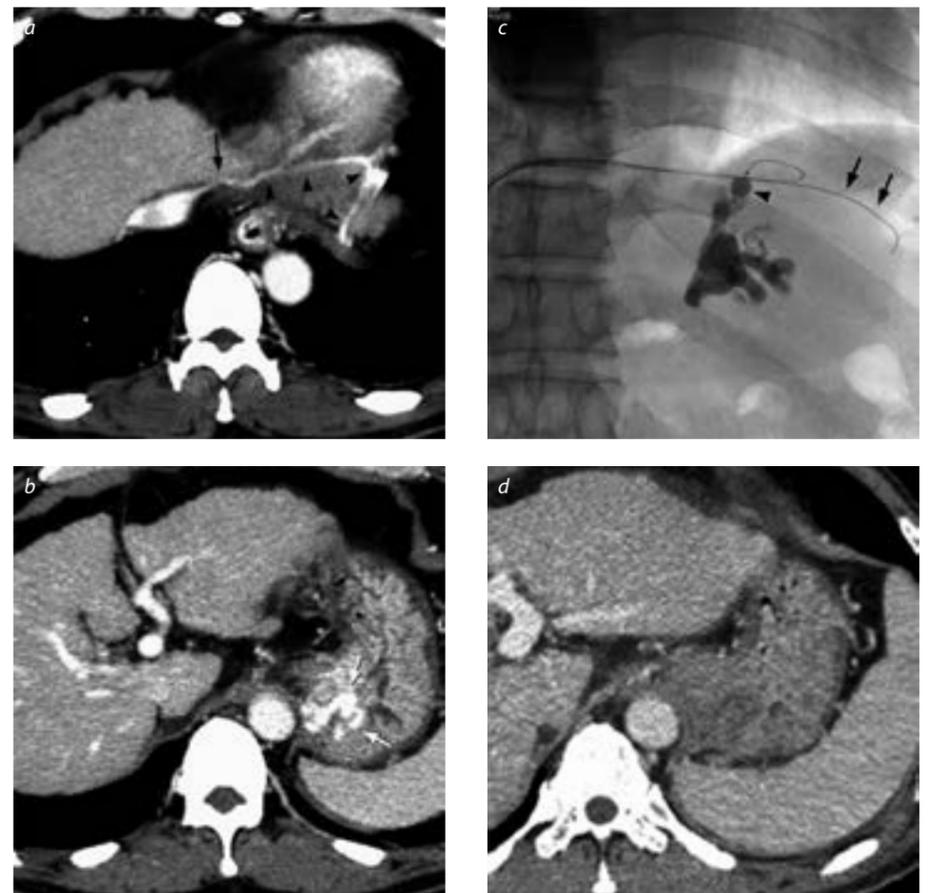


Fig. 2: Gastric varices treated by BRTO technique. (a, b) Axial CT images show the gastric varices (white arrows) which drain through the left inferior phrenic vein (arrowheads) into the IVC. A stenotic portion of the left inferior phrenic vein (arrow) is also noted. (c) Fluoroscopic image during BRTO shows a microballoon catheter (arrow head) selectively advanced into the draining vein via the left inferior phrenic vein. Sclerosant (5% EOI) fills sufficiently in the varices. Arrows indicate a support guidewire inserted into the peripheral branch of the inferior phrenic vein. (d) Contrast-enhanced CT 1 week after BRTO shows complete obliteration of the varices.

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Bleeding: hepato-splenic-GI tract
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Auditorium 3

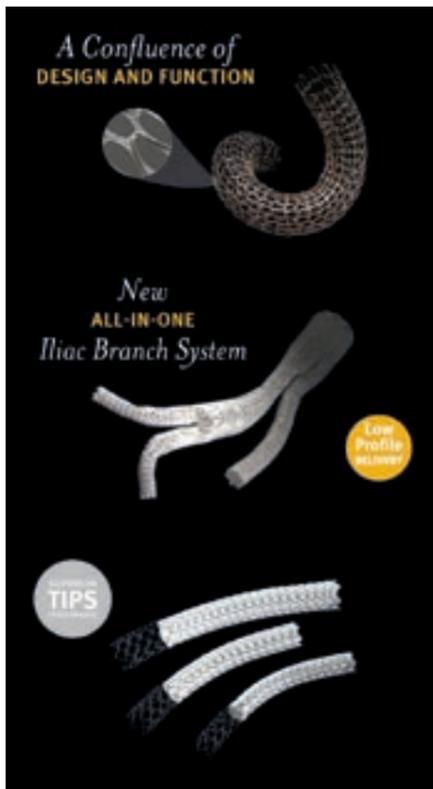


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Dr. Hiro Kiyosue is an associate professor in the Department of Radiology at Oita University Hospital, where he has been on the faculty since 2002. He previously directed the Department of Radiology at Nagarami Neurosurgical Hospital. Dr. Kiyosue has extensive research experience in the field of neurointerventions, focusing on dural arteriovenous fistula. His work has been published in over 100 articles in domestic and international journals, and has been recognised with many awards, including from the RSNA and WFITN. Dr. Kiyosue joined the editorial board of *Neurointervention* journal in 2012.

Advertorial

Gore Scientific Programme



**Sunday, September 14, 17.30-18.10,
Auditorium 5**

Innovative technologies for challenging peripheral and aortic anatomy: What's new?
Chairman: J. P. Schäfer, Kiel, Germany

- Stenting challenging peripheral anatomy.
G. Pratesi, Rome, Italy
- First clinical experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis: what have we learned so far?
M. Hamady, London, UK

**Monday, September 15, 17.30-18.10,
Auditorium 6**

Monitoring, managing and reducing post-TIPS HE
Moderator: G. Richter, Stuttgart, Germany

- Managing portal pressure and TIPS stent diameters reduces post-TIPS HE. Results from a CT based Italian multicentre trial.
F. Schepis, Modena, Italy
- What can the radiologist do in case of refractory post-TIPS HE.
G. Maleux, Leuven, Belgium

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Sharing challenges and experience in TIPS cases to treat portal hypertension complications.

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Treatment of DVT and PE: paradigm shift?

Uta Melzer, CIRSE Office

Deep-vein thrombosis (DVT) and pulmonary embolism have long presented serious challenges for healthcare providers. Although they are vascular conditions, they affect a truly broad range of patient groups, including the young and the old; the healthy and the unwell; and those suffering from seemingly unrelated complaints, such as cancer patients, in whom the altered blood chemistry and need for bed rest dramatically increase the risk of blood clots, with approximately 5-10% affected.

Moreover, factors such as smoking, using oral contraceptives, taking long-haul flights, obesity and a sedentary lifestyle are contributing to the conditions' increasing prevalence. In the USA, which has a population comparable to that of all of Europe, roughly 200,000 new cases of DVT are diagnosed each year. While the causes are diverse, the results are all too often similarly devastating: after stroke and heart attack, venous thromboembolism is the third biggest cause of cardiovascular mortality.

Post-thrombotic syndrome (PTS) is also a common problem, with different sources estimating that this affects between 20 and 70% of DVT patients. The condition arises when a clot is left in place, increasing pressure within the vein and leading to pain, swelling, cramping and skin discolouration. Symptoms can occur for up to two years following DVT, and PTS develops into painful and difficult-to-treat ulcers in 5 to 10% of DVT patients [1]. Several long-term studies have shown that PTS markedly interferes with everyday activities, such as standing or working, and entails significant medical costs. Since the 1950s, DVT has widely been treated with anticoagulants and bed rest, but this fails to prevent PTS in over 70% of ilio-femoral DVTs.

Role of IR – Paradigm Shift?

It is clear that managing blood clots is an essential skill for all IRs, even those with predominantly non-vascular caseloads, and that more sophisticated treatments are needed. DVT and pulmonary embolism can currently be managed with a number of image-guided approaches, and new interventional techniques have already broadened treatment options. However, in the absence of level 1 evidence, it remains unclear which treatment methods are best employed, including with respect to particular patients.

Can it truly be said that the newly-available interventional techniques have led to a rethinking of best clinical practice? Four of the foremost experts in the endovascular treatment of blood clots will tackle this question, addressing different aspects of modern practice before

taking part in a round-table discussion and inviting input from the audience.

Emerging therapies for pulmonary embolism



Nils Kucher (Bern/CH) will discuss image-guided therapies available for treating acute pulmonary embolism, a major medical emergency that results in death in about 30% of cases if left untreated.

While treatment initially entails providing haemodynamic support for hypotensive patients and administering anticoagulants, additional therapies, such as thrombolytic drugs or embolectomy, are often called for, and can be delivered under image-guidance. Dr. Kucher will detail the possible benefits of doing so in his presentation, which will also examine the role of IVC filter placement.

Aggressive Treatment of DVT: what trials have taught us



Stephen Kee (Los Angeles, CA/US) will present the latest evidence on treating PTS with thrombolysis. He notes:

"DVT is associated with significant short-term mortality (PE) and long-term morbidity (PTS). The standard treatment for acute DVT remains anticoagulation. While anticoagulation has proven beneficial for preventing PE and the propagation of thrombus, this treatment method has not been shown to reduce the development or severity of PTS.

"Randomised controlled trials (covering 1109 patients in 17 studies) have demonstrated that patients treated with thrombolysis suffered from significantly less PTS than those treated with anticoagulation alone. The former patient group experienced significantly higher bleeding rates (9% as opposed to 4%), but most

bleeding complications occurred in earlier (pre-1990) studies, and many of these could have been prevented by adopting current thrombolysis guidelines. Similarly, of the two randomised controlled trials that have specifically compared catheter-directed thrombolysis (CDT) to anticoagulation, one (the Norwegian Cavent study) demonstrated significantly lower PTS with CDT ($p=0.047$) based on the treatment of 209 patients.

"Despite such data, widespread reluctance to change the paradigm of DVT treatment remains. However, an ongoing, NIH-sponsored randomised control trial comparing pharmacomechanical thrombolysis to anticoagulation alone could prompt a change in standard practice. The trial, which includes 692 patients and has almost completed enrolment, targets a 33% reduction in PTS with CDT and is aiming for a low incidence of bleeding complications."



Catheter-directed thrombolysis for DVT: tips, tricks and pitfalls

Ken Thomson (Melbourne/AU) will outline recommendations for a successful thrombolysis, as well as potential pitfalls:

"First, where a thrombosis has been present for 6 weeks and has become sufficiently severe to prompt a haematologist to seek help, it is not thrombolysis the IR will be offering, but a recanalisation. Thrombolysis alone will not guarantee blood flow, and an isolated segment without both inflow and outflow will thrombose again after thrombolysis. Anticoagulation and thrombolysis are complementary. When faced with a long segment of thrombosis, the treatment needs to cover substantially all of the thrombus.

"Most mechanical thrombolytic devices are somewhat small for big veins; using an angled guide catheter allows interventionists to sweep the device they are using across the vessel. Moreover, a larger sheath allows IRs to inject contrast as they go, which allows them to direct the device towards the more persistent thrombus. Where a retrievable IVC filter is used, the IR must see the patient in their clinic to follow the filter and remove it as soon as it is no longer required. The aim of ilio-femoral thrombolysis is to preserve as many venous valves as

Don't miss it!

Treatment of DVT and PE: paradigm shift?
Hot Topic Symposium
Sunday, September 14, 15:00-16:00
Main Auditorium

possible. Deep venous reflux is as debilitating as thrombosis in terms of calf venous congestion.

"Finally, interventional radiologists should collect data in order to show medical administrators that catheter-directed thrombolysis is a cost saving measure with a high patient satisfaction index."

Single session therapy for DVT: devices and patient selection



Gerard O'Sullivan (Galway/IE) will address the option of performing a single session therapy (SST) lasting less than three hours, an alternative way of actively and safely dispersing or destroying a thrombus:

"Although this method is initially more labour intensive, once carried out, it is complete, and also requires fewer blood tests, fewer venograms and fewer transfusions than CDT.

"An IR's daily schedule may play a role in which method to choose. SST may be a better choice when access to monitored beds is difficult, given that performing venous CDT is possible but potentially difficult in a regular ward. Ideally patients can hold still for up to 3 hours, preferably on their abdomen. For SST to be appropriate, the popliteal vein needs to be patent, and the thrombus needs to be less than 3 weeks old. By contrast, CDT may be able to treat slightly older thrombus and can be administered into a thrombosed popliteal vein or through a smaller calf or ankle vein.

"The choice of device is personal. The presentation will include a brief description of currently commercially available devices – including the Treorotola, Trellis, AngioJet, AngioVac, and Rotarex – as well as my own views on who might benefit from a filter."

CIRSE President Anna-Maria Belli (London/UK) and Dr. O'Sullivan will lead a round-table discussion following these presentations, further scrutinising the emerging evidence and how it can improve treatment paradigms.

References:

1. Venous Disease Coalition

Horizon 2020 Expert Meeting and Reception

Internationally recognised experts from CIRSE, EIBIR and KOWI will provide you with IR-specific recommendations for successfully competing for European grants and share their insider knowledge to help your future application!

Sunday, 14 September, 16:30-17:30 in Meeting Room 1,
followed by an informal meet-and-greet reception

Please be aware that only a limited number of seats will be available, so early arrival is advised for any interested delegates who have not already confirmed their attendance.



LEADERS IN ONCOLOGIC INTERVENTIONS

ECIO 2015

**Sixth European Conference
on Interventional Oncology**

including a
joint session with the
**European Society for
Medical Oncology
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**Join us for ...
Multidisciplinary tumour boards,
new horizons sessions and
lots of tips and tricks for
local tumour management**

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**April 22-25, 2015
Nice, France**

CIRSE

Cardiovascular and Interventional Radiological Society of Europe

Advertorial

New Product Launches

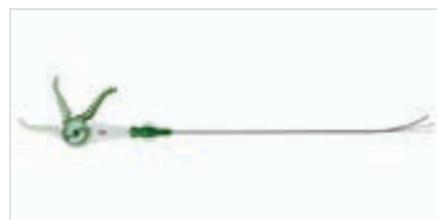
APRIOMED

Morrison Steerable FNA Needle

AprioMed's Morrison Steerable Needle™ is the first steerable fine-needle aspiration (FNA) needle enabling active guidance around objects inside the body. During image guidance, the needle can be steered with live feedback allowing precise needle placement. The 21-gauge FNA needle enables soft tissue biopsy as well as aspiration and injection. With the needle's enhanced control it is possible to:

- Make **major** adjustments around bones, organs or other structures
- Make **minor** adjustments near target
- Make **multiple** adjustments as the needle is advanced

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BOSTON SCIENTIFIC

Boston Scientific releases new data and launches next-generation Vessix™ Renal Denervation System at CIRSE 2014

Boston Scientific announces release of latest data of REDUCE-HTN study* demonstrating a significant reduction in ambulatory and office-based blood pressure at 18 months in patients treated with the Vessix™ Renal Denervation System. This is one of the largest Renal Denervation data sets collected to date using ambulatory blood pressure monitoring. The data release coincides with the launch of the next generation 7F (2.67 mm) Vessix™ Reduce™ renal denervation system. "The Vessix System is the only technology designed to combine bipolar energy and a balloon-based platform, enabling consistent and complete renal denervation treatment across a variety of anatomies," said Dierk Scheinert, MD, Director, Center of Vascular Medicine, Angiology & Vascular Surgery at Park Krankenhaus in Leipzig, Germany. "The new Vessix Reduce Catheter, Generator and Guide Sheath offer an outstanding operator experience and take what was already an exceptional system and make it even better."

* Schofer J, MD. REDUCE-HTN Clinical Study Interim12- and 18-month Data. Presented at EuroPCR; May 2014. All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. PI-256613-AA JUL2014



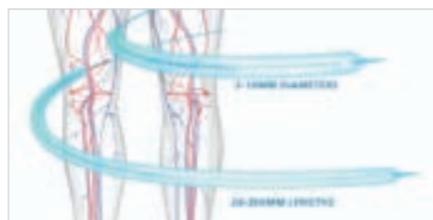
CORDIS

Cordis introduces SABER™ PTA Dilatation Catheter

Cordis is proud to introduce the new SABER™ PTA Balloon Dilatation Catheter.

Developed to complement the Cordis Leg Solutions Portfolio as a next-generation, high-performance workhorse .018" PTA balloon, the SABER™ Balloon Catheter is approved to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries as well as for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Catheter is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

The SABER™ Catheter is available in diameters of 2-10 mm and lengths of 20-300 mm. It combines a durable dual-layer hydrophilic coating with a low-profile body and new molded tip design to enhance crossability. In addition, this new Catheter has exceptional rated burst pressures – up to 18atm – and low compliance due to its construction with Cordis' proprietary DURALYN® Balloon Material.



COVIDIEN

Trellis™ Peripheral Infusion System

Treatment for DVT Redesigned to Improve Thrombus Isolation, Lytic Drug Delivery and Removal of Blood Clot

<http://www.covidien.com/trellis/pages.aspx> Post Thrombotic Syndrome (PTS) is a long-term effect of deep vein thrombosis (DVT). PTS occurs in almost half of patients within two years after DVT,¹ and up to 33% of patients with PTS develop ulcers and skin deterioration.²

The Trellis™ system provides a way for physicians to dissolve acute thrombus and intervene on DVT¹ before it advances to PTS². The system is composed of: an over-the-wire catheter with two occlusive balloons to close off the treatment area and block the release of the drug to other areas of the body. Compared to the previous version, the latest Trellis™ system features enhanced drug delivery a 129% larger aspiration window, which allows for better removal of the drug and the dispersed clot.

¹ Kahn, S. et al. Determinants and Time Course of Postthrombotic Syndrome After Acute Deep Vein Thrombosis, *Annals of Internal Medicine*. 2008; 149: 698-707.2
² Kahn, S. et al. The post-thrombotic syndrome: current knowledge, controversies, and directions for future research, *Blood Reviews*. 2002; 155-165 doi: 10.1016/S0268-960X(02)00008-5
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COVIDIEN

Emprint™ Ablation System and Emprint™ Procedure Planning: The future of ablation from Covidien

The Emprint™ ablation system with Thermosphere™ technology provides clinicians three kinds of spatial energy control – thermal, field and wavelength – to create predictable and spherical ablation zones regardless of target location, tissue type, or changes in tissue properties during a procedure¹.

Come and learn more about the Emprint™ ablation system with Thermosphere™ technology and planning for powerful predictability at booth number 3, at the symposium on Monday, September 15th at 11.30, Auditorium 3 and in the Covidien learning centre.

¹ Covidien "In Vivo Performance Testing of the Emprint Microwave Ablation System in a Porcine Model" – R0043973 Rev A; Emprint Instructions for Use (IFU).

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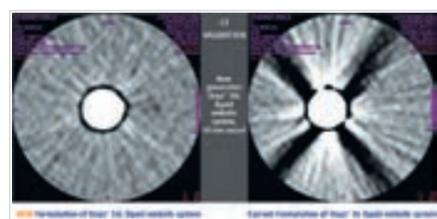
COVIDIEN

Next generation of Onyx™ 34 liquid embolic system has received CE mark

In 2013 Covidien funded the project ORCA as an answer to a request from the market, that preferred a new formulation of PV Onyx™ liquid embolic systems, a formulation that gives less artifacts on CT scanning follow up. Artifacts on follow up CT scanning after treatment with PV Onyx™ liquid embolic system represent a challenge for the physician in identifying anatomical structures, especially after treatment of Endoleaks Type I and II and large peripheral AVMs. **The new formulation of Onyx™ 34L liquid embolic system has less streak artifacts on CT compared to the current version of Onyx™ liquid embolic system¹**

¹ CT artifact Validation *in vitro* using a water phantom tank to simulate body tissue and synthetic vessel Document TR_NV 11300 RevA 2013-08-20

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HANSEN MEDICAL

Magellan™ Robotic Catheter 6Fr – Robotic Control in Smaller Vessels

The Magellan™ Robotic Catheter 6Fr extends the benefits of robotic precision, stability and control to peripheral vascular procedures in smaller vessels.

Designed to deliver:

- Independent control of dual bending sections
- Lower profile and smaller diameter access site
- Streamlined procedural workflow
- Remote navigation, away from radiation

Discover the next big Intravascular thing at www.HansenMedical.com/StayAhead. Visit booth #47 for a test drive.



Product Launches at CIRSE 2014

To find out more about the products being officially launched during CIRSE 2014, please visit the company booths in the Exhibition Hall. A full list of exhibitors and a floor-plan can be found in your pocket guide.

Information can also be found on our website: www.cirse.org/cirse2014

Advertorial

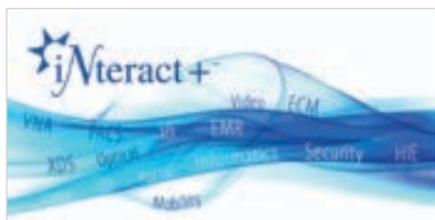
New Product Launches

TERARECON

iNteract+

iNteract+ is TeraRecon's new 'ingeniously informed' image viewer that works in combination with any of TeraRecon's medical image viewers and image sharing and storage solutions to provide unmatched intelligence, powerful interoperability and simplified integration capabilities.

iNteract+ solutions enhance the clinical end-user experience provided by PACS, VNA, EMR and other mission-critical image processing and image acquisition systems. Often, it can eliminate the need for many disparate image transport, viewing and storage systems while facilitating a smooth transition toward centralized administration of imaging resources. From the sharing time-sensitive imaging data, to expanding the clinical tools available when and where physicians are working, iNteract+ stands alone as the only solution capable of also achieving collaborative remote access with image sharing, DICOM and non-DICOM viewing and incorporation of relevant clinical information all within one viewer.



TERUMO

AZUR® CX

AZUR® CX Peripheral Detachable Coil system

New! TERUMO is pleased to announce the launch of AZUR CX. This soft .018" detachable coil has been optimized to deliver Best-in-Class, cross-sectional coverage. It is a complex-shaped, bare platinum coil with an inner core of hydrogel that expands from the inside out. The unique design creates a solid coil without any open spaces in the center. The three-dimensional shape with variable diameter loops creates a stable anchor and promotes conformity to different morphologies. AZUR CX is excellent as a first coil – it provides a stable stopper for control in high flow areas and subsequent coil placement. The detachment system delivers precise positioning and placement.

By matching PROGREAT double marker with AZUR detachable coils, TERUMO Peripheral Coiling Solution offers you the precision of neuroradiology procedures in the peripheral vessels.



TERUMO

PROGREAT® Double Marker

PROGREAT® Double Marker Micro Catheter system

New! TERUMO is pleased to announce the launch of PROGREAT double marker, available in 2.4Fr and 2.8Fr version. PROGREAT double marker has the unique navigability and torquability of the usual PROGREAT, plus two markers that provide excellent visibility. PROGREAT is now available in an extensive range, to allow a perfect match to your needs: PROGREAT 2.0Fr simple marker, PROGREAT 2.4Fr with double marker, PROGREAT 2.7Fr coaxial, PROGREAT 2.8Fr coaxial simple marker, PROGREAT 2.8Fr double marker. PROGREAT are available in 130 cm or 150 cm.

By matching PROGREAT double marker with AZUR detachable coils, TERUMO Peripheral Coiling Solution offers you the precision of neuroradiology procedures in the peripheral vessels.



TERUMO

MISAGO® 5mm

TERUMO extended the size mix of the MISAGO® SX stent system with a 5mm version for the treatment of fem-pop vessels.

The clinically distinguished MISAGO Nitinol Stent Portfolio (6Fr, 0.035") has been expanded to include a 5mm diameter stent. Like the other sizes of the MISAGO stent, they offer optimal flexibility, long-term patency and excellent durability for femoral-popliteal lesions due to "spineless" stent architecture. The versatile Rapid Exchange delivery system with an ergonomic one-hand delivery handle can be used with short and with long wires to facilitate accurate and successful stent implantation.

Features:

MISAGO is available in stent diameters of 5.0-10.0 mm and lengths of 40-150 mm. Clinically proven patency rates, exceptional balance between flexibility and radial force, and the industry's lowest fracture rates provide reliable clinical results. Three radiopaque gold-markers at each stent edge provide full deployment control and post-procedural visibility.



TERUMO

TERCROSS™

TERUMO introduces a new workhorse PTA Balloon (0.014", OTW) for BtK vessel treatment

TERCROSS is the name of TERUMO's recently launched 0.014" OTW PTA-Balloon catheter that offers enhanced pushability, kink resistance and fast deflation time for BtK lesions due to extreme support of the OTW seamless polymer shaft. Available in a variety of broad sizes with long shaft design, TERCROSS enables the treatment of a wide range of BtK lesions. Additionally, TERCROSS has two crossing sizes of 1.25 and 1.5 mm balloon diameters, designed specifically to facilitate the passage of extremely tight subocclusive lesions.

Features:

TERCROSS is available in balloon diameters of 1.25-4.0mm and lengths of 20-200mm. The lowest balloon crossing profile and the hydrophilic coating provide reliable crossability. With an exceptionally high RBP of 20 atm. and fast deflation times it matches all requirements for an efficient and successful recanalization. Two different shaft lengths of 100 and 148cm enable antegrade and contralateral approaches.



TERUMO

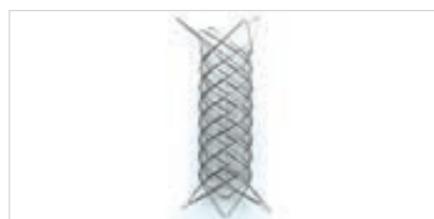
ROADSAVER®

The ROADSAYER® Carotid Artery Stent System for Sustained Embolic Protection

The ROADSAYER Carotid Artery Stent, a double layer micromesh stent is indicated for use in patients with carotid arterial atherosclerotic disease, by combining these unique features:

- It is made of a dual-layer micromesh scaffold with the smallest cell size. The ROADSAYER is designed to sustain embolic protection, much like a metallic covered stent, allowing for side branch patency.
- The braided Nitinol design allows the stent to adapt to most carotid anatomies.
- The very flexible stent delivery system can recapture up to 50% deployment length and can be repositioned for accurate placement. Due to its flexibility the stent delivery system perfectly tracks through tortuous anatomies towards the lesions, minimizing the risk of access sheath/guide catheter dislodgement.

These features set ROADSAYER apart as the latest technology and establish ROADSAYER as the next generation in carotid artery stents.



CIRT, CIRSE's new registry, gets ready to launch

Niels de Jong, CIRSE Office

The first CIRSE-initiated, multinational observational study – the CIRSE Registry for SIR-Spheres Therapy (CIRT) – is making excellent progress. CIRSE is excited to announce that, at this point, hospitals have been invited to participate in the study, and all research elements are ready to be used.

CIRT is a CIRSE-initiated European-wide observational study that aims to collect extensive data on the real-life application of radioembolisation with Yttrium-90-loaded SIR-Spheres in patients with primary or secondary liver tumours. The vast body of observational data expected to be gathered will contribute to a better understanding of the procedure in real-life clinical situations, and allow for the exploratory analysis of an unprecedented volume of radioembolisation data.

Preparations for its launch are in full force. The CIRT Registry Protocol has been approved by the multi-disciplinary CIRT Steering Committee, a group of highly-qualified radioembolisation experts chaired by eminent CIRSE Member Prof. José Ignacio Bilbao (Clínica Universidad de Navarra), and all the documents have gone through an appropriate legal review. With palliative care playing an increasingly important role in interventional oncology, the Steering Committee decided to include a quality-of-life



questionnaire developed by experts at the European Organisation for Research and Treatment of Cancer (EORTC) – the QLQ-C30 – a multi-lingual, verified base questionnaire, together with its HCC Module, which was developed to capture liver-cancer-specific quality of life elements.

The Steering Committee carefully determined minimum selection criteria, which medical centres must fulfill in order to be eligible for an invitation to participate in CIRT. In order for the study to be as sensitive as possible to the expected diversity of medical environments in which radioembolisation is performed, the criteria for including medical centres were kept to a minimum.

With the launch of CIRT, CIRSE aims to bolster the evidence-based approach to interventional radiology, and hopes to initiate further research projects relating to interventional radiological procedures.

ESIR 2014 Courses

Apply now for the ESIR autumn courses!

Don't miss your chance to benefit from the first-rate education programme offered by the European School of Interventional Radiology.

Fundamental Courses

An excellent fit for doctors just beginning their IR career, or those looking to broaden their portfolio or prepare for the EBIR exam.

Genitourinary Interventions

Prague (CZ), October 17-18

Venous Access and Dialysis

Marseille (FR), December 11-12

Expert Courses

Best suited to those familiar with theoretical aspects of interventional procedures, but looking to strengthen their practical skills.

Management of Resistant Hypertension: Renal Artery Denervation

Paris (FR), October 27-28

Stroke Intervention

The Hague (NL), November 14-15

For more information, please visit www.cirse.org/esir2014.

Fundamental Courses are an excellent means of preparing for the EBIR (European Board of Interventional Radiology)



CIRSE foundation

A new and improved resource for patients

IR has many benefits for patients; however, there is a lack of reliable, up-to-date information on the specialty which is aimed at the general public. CIRSE has hosted a patients' section on our website for many years, but the material was in need of an update, and so the Patient Information Task Force was convened.

Over the last year, the task force has been hard at work updating and expanding the content and tailoring it so patients will find it easy to

understand. The most common IR procedures are outlined clearly and comprehensively, anticipating questions readers may have, such as what to expect during the procedure. Each description of an IR procedure also includes explanations about why the procedure may need to be performed and possible complications that may arise.

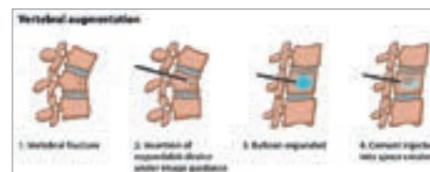
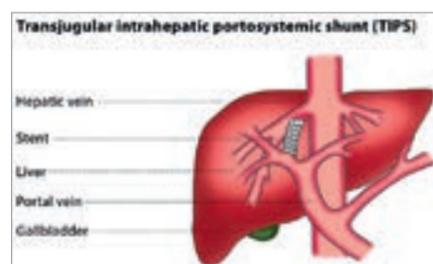
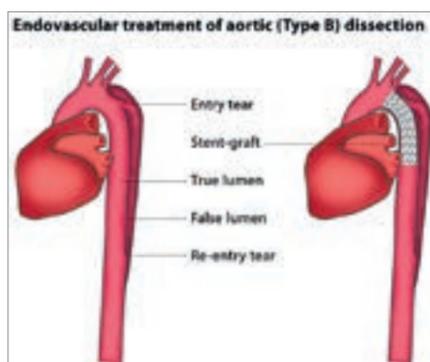
In addition, task force members provided sketches of the procedures, from which our in-house graphic designer created images to show how procedures work in practice. This makes it even easier for patients who do not have a medical background to understand how a particular procedure works.

The task force also updated the material on common medical conditions that may be treated with IR. These are categorised according to the body parts and systems in which they occur, and are accompanied by easy-to-understand diagrams.

This project presents patients with clear and up-to-date information. This means that patients undergoing IR procedures, and their families, can be reassured by a thorough explanation of what will happen, addressing the normal worries they may have before a procedure. It may also help to inform prospective patients, who can use this material to request that they be referred to an IR for a particular procedure.



Dr. Dimitrios Filippiadis,
Chairperson of the Patient
Information Task Force



We would like to heartily thank all Patient Information Task Force Members for their hard work and commitment to this important project. Particular thanks must be given to the Chairperson of the Task Force, Dr. Dimitrios Filippiadis, for his dedication in driving the project forward.

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DOES YOUR STENT GO THE DISTANCE?

Treating PAD patients can be more like a marathon than a sprint. That's why we went the extra mile with our DURABILITY II study. We put the EverFlex™ self-expanding peripheral stent to the test with long, complex lesions at 12, 24 and 36 months.

At each milestone, the results are clear: The EverFlex™ stent demonstrates long-term, proven performance in the SFA and best-in-class fracture rates.¹



Visit Covidien at CIRSE to learn more about DURABILITY II



¹ Rocha-Singh K. DURABILITY II 36-month results. VIVA 2013.

Indication: The EverFlex™ Self-Expanding Peripheral Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 180 mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 – 7.5 mm.

Contraindications: Use of the EverFlex™ Self-Expanding Peripheral Stent System is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Arterial dissection/perforation, Bleeding disorders (including GI, lymphatic), Infection (local or systemic including bacteremia or septicemia), Pseudoaneurysm, Restenosis, Stent/Vessel Thrombosis, Surgical or endovascular intervention. See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events and device information.

Important: Indications, contraindications, warnings and instructions for use 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 the EU.