Preliminary results for cryoablation in small lung tumours look promising

The initial results from a clinical trial investigating the use of cryoablation for metastatic lung tumours have demonstrated the safety of the procedure. At a median three-month follow-up, the intervention showed 100% control rate in tumours under 3.5cm.

Thierry de Baere, Institut Gustave Roussy, Villejuif, France, spoke to delegates on the results of the ECLIPSE (Evaluating cryoablation of metastatic lung/pleura tumors in patients—safety and efficacy) trial and efficacy of cryoablation. The aim of the study was to assess the safety and efficacy of cryoablation for metastatic lung tumours. The study showed 100% control rate in tumours under 3.5cm.

At median three-month follow-up, the speaker told delegates, the local tumour control rate was 100% but six patients demonstrated new distant tumours. They commented that cryoablation for metastatic lung tumours appeared to be safe but that these were only preliminary results from the ECLIPSE trial and therefore longer follow-up was required to validate the initial findings.

Irreversible electroporation
The new ablation technique irreversible electroporation also showed positive results. Contantinos T Sofoceulous, Memorial Sloan-Kettering Cancer Center, New York, USA, at a press conference, spoke about the “innovative” technique for treating cancers on a cellular level that are near to large vessel structures. He reviewed the advantages and clinical applications irreversible electroporation as a new modality. He discussed different ablation modalities available and devices—radiofrequency, microwave, cryoablation—and said: “All of these modalities use some type of energy to deposit or change the tumour cell. There have been reports of modest median survival benefit of 2.3 months and 2.8 months in patients with advanced stage hepatocellular carcinoma treated with sorafenib compared with placebo.”

Kim et al stated that the aim of their study was to assess the safety and efficacy of TACE with drug-eluting beads for treatment of patients in the advanced BCLC stage.

Two hundred and five patients with hepatocellular carcinoma, 121 patients (52.9%) had advanced stage BCLC C disease, portal vein invasion or portal vein thrombosis in 23.9% of patients. The authors noted that, until the SHARP (Sorafenib hepatocellular carcinoma assessment randomised protocol) trial determined a protocol there was no systemic therapy that had been proven to be effective in treating hepatocellular carcinoma, but recently there have been reports of “modest median survival benefit of 2.3 months and 2.8 months in patients with advanced stage hepatocellular carcinoma treated with sorafenib compared with placebo.”
Preliminary results for cryoablation in small tumours look promising

Continued from page 1

With temperature in the tumour until the cells are dead.” Sofoceleous noted that, comparatively, irreversible electroporation, unlike radiofrequency microwave or cryoablation, does not use a thermal mechanism of ablation. Sofoceleous and colleagues, in their cohort, implemented irreversible electroporation in 40 metastases (25 patients) in the liver, lung, pancreas, thyroid gland, uterus, uterine lining, ovaries and rectum. There were no reported major complications. Sofoceleous noted that these findings proved irreversible electroporation was safe enough to expand investigations into larger clinical trials.

He also spoke about the applications of irreversible electroporation close to the bile duct and reported that patients were free from local recurrence 778 days after the procedure. Sofoceleous presented a rectal tumour case where the patients were local recurrence free 565 days post procedure. He noted that a complication in another case of ovarian cancer was “severe burning and electric shock-like sensations” post procedure, which continued up to one year (managed by pregabalin).

The speaker concluded that, in the study, irreversible electroporation “when in close proximity to bile ducts, major vessels, bladder, rectum, and nerves has an acceptable safety profile in our experience”, but added that longer term follow-up is needed to determine efficacy.

The advantage of irreversible electroporation vs. other modalities, according to the speaker, is that there is little to no scarring, no structural alteration, and there is no “heat sink” effect.

Charles E Ray, University of Colorado, Colorado, USA, and treasurer of SIR, moderated the press conference and commented on Sofoceleous’s and others’ presentations: “this is a nice conglomeration of very interesting topics in the vascular and basic science side of interventions.”

Thermal ablation techniques

On the topic of transcatheter arterial chemoembolization, Michael Ginsburg, University of Chicago, Chicago, USA, presented data for a collaborative approach. He compared transcatheter arterial chemoembolization (TACE) in conjunction with radiofrequency ablation vs. TACE with microwave ablation. The primary endpoint of the study, according to the speaker, was overall disease-free survival and time to transplantation.

The retrospective data of cirrhotic patients with hepatocellular carcinoma who were treated with either radiofrequency ablation (41 patients) or microwave ablation (57 patients) alongside TACE from November 2003 to November 2011 were analysed. The patients had Child-Pugh A or B scores.

According to the results presented by Ginsburg, in the cohort who received radiofrequency ablation and TACE, the one, two and three year overall survival rates were 87.8% (36/41), 53.7% (22/41), and 44.7% (18/41) respectively. For the microwave ablation cohort the survival rates were 86% (49/57), 73.8% (42/57), and 58.9% (34/57) respectively.

The difference between overall survival for microwave vs. radiofrequency ablation was not found to be statistically significant.

“Combined procedures of TACE and percutaneous thermal ablation are both safe and effective for the treatment of hepatocellular carcinoma,” said Ginsburg. “While no statistically significant difference in both overall survival and overall disease free survival were observed between the two cohorts, when controlling for tumour size the radiofrequency ablation cohort had a 43% improved disease free survival compared to the microwave ablation cohort.”

Awards

The majority of awards presented to delegates at SIR were for oncology-based research.

Amongst other research, Ahmad Parvinian, University of Illinois at Chicago College of Medicine, Chicago, USA, received the Dr Constantine Cope Medical Student Research Award for his study “Transarterial sorafenib chemoembolization: preliminary study of technical feasibility in a rabbit model.” Alexander Sheu, Feinberg School of Medicine, Northwestern University, Chicago, USA, also received the award for his research entitled: “Transcatheter intra-arterial delivery of superparamagnetic iron-oxide-labeled natural killer lymphocytes to hepatocellular carcinoma: longitudinal efficacy studies in a rat model.” The recipient of the Gary J Becker Young Investigator award was Joseph P Ermieri, Memorial Sloan-Kettering, New York, USA, for his study “Image guided thermal ablation of tumors increases the plasma level of IL-6 and IL-10”.

The awards listed in the left-hand side box are from the Dr Constantin Cope Medical Student Awards and the Journal of Vascular and Interventional Radiology honours.

“TACE with drug-eluting beads is a safe treatment option”

Continued from page 1

Who did not receive sorafenib, noted Kim and others.

“In conclusion, TACE with drug-eluting beads is a safe treatment option. Promising outcomes were shown in patients with BCLC C advanced stage hepatocellular carcinoma,” said Kim et al. “Patients with Child-Pugh class A without portal vein thrombosis and metastasis benefited most from drug-eluting bead TACE.”

The authors added that randomised controlled trials of TACE with drug-eluting beads vs. systemic treatment may define an optimal treatment strategy for patients at the advance stage of the disease.
I

n the study the authors aimed to evaluate the local efficacy, safety and survival at mid-term follow-up. Dayan said in his presentation that 45 patients with unresectable hepatocellular carcinoma underwent 49 percutaneous computed tomography (CT) microwave ablation procedures. The patients were initially treated, 24 hours before microwave ablation, with transcatheter arterial chemomobilization (TACE) with drug-eluting beads, which, according to the authors, were loaded 100-300 LC Beads (Biocompatibles).

Follow-up was at one month and then three to four months afterwards with CT or magnetic resonance imaging (MRI). The primary endpoints of the study were: rate of complete ablation, local tumour progression within 1cm from ablated site, and 30 and 90 day major and minor adverse events.

Dayan reported a total of 49 tumours were treated (median size 2.1cm) with a procedural success of 100% using standard microwave ablation protocol. Complete ablation, according to the results, was achieved at one-, three- and nine-month follow-up in 38 out of 39 (97.4%), 26 out of 27 (96.3%), 15 out of 16 (93.8%), and 12 out of 12 (100%) of patients, respectively. Minor adverse events included post-procedural pain and transient low-grade fever.

“Combination therapy using drug-eluting bead TACE and percutaneous microwave ablation is a safe and locally effective treatment for unresectable hepatocellular carcinoma as evidenced by high rates of complete ablations and low rates of major adverse events,” concluded Dayan et al in their study.

**Prostatic artery embolization is a safe and effective alternative to TURP, laser and microwave treatments**

At the Society of Interventional Radiology Annual Scientific Meeting (13–18 April, New Orleans, USA) Bagla said that, two million US men avoided transurethral resection of the prostate (TURP), laser or microwave treatment because of the possibility of impotence, urinary leaking, incontinence, bleeding, pain and stricture narrowing, and infection.

The 21 patients enrolled in the study had moderate-to-severe symptoms of benign prostatic hyperplasia, with an average American Urological Association score of 25.5, a mean quality of life score of 5.7, and an average prostate volume of 70cc. The follow-up is expected to be at two years to assess the long-term outcomes.

The early findings of the study, according to Bagla, showed that 13 of 14 men (92%) who had prostatic artery embolization noticed a significant decrease in symptoms after four weeks. None of the men suffered any major complications.

According to the speaker, the potential for prostatic artery embolization is that it can reduce lower urinary tract symptoms. He said it is safe and can improve quality of life and added that the implications for the treatment (based on the results of this cohort) are that it can potentially eliminate the need for daily use of medication.

Enrolment of 30 men for the first prospective US study to evaluate prostatic artery embolization for enlarged prostates is currently underway and is expected to be completed by autumn, said Bagla. The study is intended to examine clinical success and safety and will follow patients for two years.
Presentations were on numerous topics about inferior vena cava filters, the use of permanent vs. retrievable filters, and techniques of removal. At a session focused on inferior vena cava filters, Weiping Wang, Cleveland Clinic, Cleveland, USA, presented a retrospective review of the 143 filter retrievals.

He said that the aim of the single-centre review was to determine the safety and efficacy of the Celect filter (Cook Medical). Six hundred and ninety patients were included in the review. Wang said out of these 690 patients 143 underwent filter removal and 125 filters (87.4%) were removed. The filters that could not be removed and remained in situ (18) were left as such for the following reasons: filter entancstion, caval occlusion, and retained thrombus; large floating thrombus in the inferior vena cava; or tilt of >15 degrees. The speaker noted that six patients developed pulmonary embolism.

“This study showed a high penetration rate for the Celect inferior vena cava filters, including inferior vena cava were symptomatic or involved in the adjacent structures,” Wang said. “Penetration appears to correlate with indwelling time, suggesting the filter should be removed as soon as pulmonary embolism protection is no longer indicated.” He further noted that 5.6% of filter retrievals were unsuccessful because of technical failure.

**Vascular access**

William T Kuo, Stanford University Medical Center, Stanford, USA, spoke to delegates on the excimer laser-assisted removal technique. He said that excimer laser tissue ablation is effective for removing embedded inferior vena cava filters refractory to standard retrieval and high force.

In his prospective, institutional review board-approved study, over a three year period, 100 patients were enrolled. The indications for removal were: symptomatic acute inferior vena cava occlusion; pain from retroperitoneal penetration; and pain from bowel penetration. Laser-assisted removal was employed when standard techniques failed, according to the speaker. It was successful in 98% of patients.

**Filters in interventional oncology**

In a presentation on potentially inferior vena cava filters in oncology, James A Gehl, Northwestern University, Chicago, USA, said that, because cancer leaves patients in a hypercoaguable state, the risk of pulmonary embolism in increased. He presented data on a cohort of cancer patients in which potentially retrievable filters were placed. Gehl hypothesised that there would be a “limited role” for retrievable inferior vena cava filters in cancer patients with metastatic disease because of an “unacceptably low rate of retrieval”.

Gehl told delegates that, in their institutional review board-approved study, 351 filters were placed (41% permanent and 59% potentially retrievable filters). He said that of these patients 27% had metastases at the time of placement. In the subgroup of patients with metastases 66% received permanent filters and 34% received retrievable filters.

According to Gehl, “Patients with metastases at the time of potential retrievable inferior vena cava filters placement have nearly a two-fold risk of not having their inferior vena cava filter retrieved when compared to those who do not have metastases at presentation (44% retrievable rate).” The author also commented that, when compared with overall filter removal (60%), the retrieval rate for metastatic cancer is statistically significantly lower (p=0.0023).

Gehl and colleagues recommended that cancer patients are better served by permanent devices rather than retrievable. However, they noted that larger studies are required to further ascertain the role of potentially retrievable inferior vena cava filters in oncology patients without metastatic disease.

**We found very wide variation in the use of inferior vena cava filters in California hospitals**

Richard H White, UC Davies, California, USA, investigated the variation of vena cava filter use among hospitals in California, USA in his study: “High variation between hospitals in vena cava filter use for venous thromboembolism”, published in JAMA Internal Medicine. He spoke to Interventional News about the implications for the use of inferior vena cava filters globally and how variations could be addressed in the future.

Please could you summarise the findings of your study on the variations in vena cava filter use in Californian hospitals?

Guidelines advocate that, among patients diagnosed with acute venous thromboembolism, an inferior vena cava filter should be used only when standard anticoagulant treatment cannot be given. Although these indications for an inferior vena cava filter apply to 5% to 7% of all patients, we found very wide variation. Looking only at patients who developed acute venous clots, some hospitals put an inferior vena cava filter in 50% of all of these patients whereas other hospitals put a filter in none of these patients! We took into consideration the types of problems associated with not being able to use an anticoagulant, such as presence of acute bleeding or the need for major surgery, and we still found significant variation between hospitals in the use of these devices. We hypothesise that the higher use of an vena cava filters at some hospitals may be due to greater availability of physicians who are skilled at placing them (interventional radiologists or vascular specialists) or that the physicians at these hospitals simply believe that they are useful in sicker patients, despite the absence of any convincing evidence in the literature.

From these results could you determine how this affects patients globally?

There are risks associated with use of a filter. They can break apart, cause local thrombosis, and they can lead to the development of venous thrombosis in the lower extremities. There is no evidence to suggest that use of an inferior vena cava filter saves lives. Although we do not get into a detailed discussion about this point in the paper, we speculate that the term “filter” connotes inherently efficiency in “filtering” the blood. A better term to describe these devices would be an inferior vena cava “vascular metal strut”. These devices are a foreign body, which can lead to local clotting. They may not filter blood clots but, instead, simply dice them or julienne the clots as they flow to the lung.

What indications would you recommend for vena cava filter use?


In an accompanying editorial Vinay Prasad, National Institutes of Health, Bethesda, USA, said: “Given the known harms and the lack of efficacy data for inferior vena cava filters, we need randomised controlled trials. Unfortunately there is little incentive for manufacturers of filters to embark on trials that can only eliminate their products’ market share.”

Do you agree with the statement?

Yes, but the right study will almost be impossible to complete. We could do a study of “elective” use of inferior vena cava filter, but if a patient is bleeding and cannot receive anticoagulation treatment, I cannot imagine coming up to such a patient and talking to them for 30 minutes, going over a consent form and trying to convince them to enter a randomised trial.

How would you propose to combat the variations in filter use in the future?

We can do more sophisticated analyses of high quality observational data, comparing how well patients do with and without insertion of a filter. We can educate doctors about the potential harm associated with inferior vena cava filter, and, finally, we can get the Council on Medical Service [USA] to change the amount of money hospitals are reimbursed for placing a filter—which we noted in the paper is an astronomically higher reimbursement based on the diagnosis-related groups associated with filter placement.
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Results of the RETRIEVE, RAPID and STANCE trials presented at CX35

At the Innovation Showcase (CX35, 6–9 April 2013, London, UK) chaired by Nick Cheshire and Stephen Greenhalgh (both from London, UK), innovations in inferior vena cava filters and devices for the superficial femoral artery were presented. The results of the Crux Vena Cava Filter RETRIEVE clinical trial. The trial was a prospective, single-arm study which enrolled 125 patients with a primary endpoint of clinical success (technical success and freedom from pulmonary embolism, migration, and device-related adverse events at 90 days).

Holden reported the implant technical success, femoral approach and jugular approach in 123 patients (98%), 106 (84.8%), and 19 (15.2%) respectively. Retrieval results were retrieval success (53/54, 98%), femoral access (38/54, 70.4%), and jugular access (16/54, 29.5%), respectively.

He concluded: “Implant and retrieval of the Crux Filter have been performed safely in the RETRIEVE study with high clinical success of 98%. The efficacy results are good with no reported filter migration, tilting or embolization and 2.4% pulmonary embolism rate.”

Legflow drug-eluting balloon

On lower limb interventions, Jean-Paul de Vries, Nieuwegein, The Netherlands, spoke about the Legflow drug-eluting balloon (Cardionovum) for the treatment of superficial femoral artery occlusions.

De Vries said that drug-eluting balloons can be an attractive alternative to stents because they do not leave any inflammatory triggering scaffolds in the artery and can be used in challenging femorocrural arterial segments. He said, however, that drug-eluting balloons vary by coating, formulation of the drug, and the elution excipients. All coatings have an influence on the efficacy of the drug delivery into the arterial wall and on treatment outcome, he added.

De Vries noted that the Legflow drug-eluting balloon has embedded paclitaxel underneath the surface as well as inside its shelliolic acid drug-release matrix, which is coated onto the balloon surface to minimise embolization risk and wipe off.

He said preclinical studies have shown that a short inflation time (60 to 90 seconds) is sufficient to inhibit smooth muscle cell proliferation, with sustained anti-proliferative effects for up to 150 hours according to unpublished data by R. Virmani, Gaithersburg, USA.

Recently, the RAPID trial (Randomized trial of Legflow paclitaxel-eluting balloon with stent placement vs. standard percutaneous transcutaneous angioplasty with stent placement for the treatment of intermediate (>5cm) and (<15cm) and long (>15cm) lesions of the superficial femoral artery) started recruitment. It is intended that this Dutch multicentre, patient-blinded trial will enrol 176 patients.

The primary endpoint of the trial is to assess the difference in absence of binary restenosis rate between the coated and uncoated group after two-year follow-up. De Vries reported that, to date, 30 patients have been randomised and followed by the data monitoring and safety board. No serious adverse events have been documented. Interim analysis is intended to be performed when the first 60 randomised patients have completed six months of follow-up. Follow-up assessments are intended to be performed at one, six, 12, and 24 months and include physical examination, ankle brachial indices, toe pressure measurements, treadmill tests, and duplex ultrasound imaging. First results from the trial are expected at the end of 2013.

Stanza bioresorbable scaffold

In a subsequent presentation, Holden also presented data from the STANCE trial which is a prospective, single-arm, multicentre trial of the Stanza scaffold in patients with symptomatic atherosclerotic disease in the superficial femoral artery. The Stanza scaffold, which fully resorbs in about one year, is the first fully self-expanding bioresorbable technology being developed for treatment of superficial femoral artery lesions, according to Holden. It uses a conventional retrograde sheath delivery system and is currently being tested in the trial in lengths up to 100mm. The primary safety endpoint is major adverse events at six months. Secondary performance endpoints include vessel patency at three, six, 12 and 24 months. In the first cohort of 25 patients, both technical and procedural success were achieved in 24 of 25 subjects with only one subject leaving the procedure with a residual stenosis of greater than 30%. There were no subjects that had a major in-hospital adverse event. The scaffold has demonstrated excellent mechanical integrity with the ability to improve post-percutaneous transcutaneous angioplasty residual stenosis, Holden said.

In the presentation he commented that the STANCE optical coherence tomography (OCT) sub study provided important information on scaffold deployment, structural integrity, and resorption, as well as underlying plaque morphology. The sub study enrolled 16 patients; eight patients have been treated at Auckland City Hospital. Post-procedure OCT demonstrates good vessel wall apposition and tissue encapsulation at follow-up of the Stanza scaffold. Additionally, lumen eccentricity is observed post procedurally and shifts to a concentric lumen, which is sustained through 12-month follow-up suggested favourable remodelling of the vessel.

The STANCE trial is ongoing and is expected to conclude in 2013.

Non-Cardiovascular Imaging Day held at CX35

Delegates had the chance to visit the advanced hybrid suites that were being showcased at CX35 (6–9 April 2013, London, UK) from Philips, Siemens and GE. Later, in the CX Non-Cardiovascular Advanced Imaging Day session, speakers from the respective companies spoke about a hybrid operating room, the financial implications of doing so, and laser-guided hybrid suite

For GE Healthcare, Michel Grimaud, Buc, France, spoke out the GE Discovery OGS 730 (a laser-guided imaging system for the hybrid operating room), how it can be used in different room layouts, and its performance in applications in the liver and plastic surgery (amongst others).

Clemens Bulitta, University of Applied Science, Amberg-Wieden, Germany, spoke on behalf of Siemens and discussed the process of building a hybrid operating room and how to optimise workflows. Georg Nollet, Forchheim, Germany (also Siemens) emphasised the importance of cost effectiveness of a 3D hybrid imaging suite in the various aspects of vascular surgery.

Presenting on behalf of Philips, Koen Noordermeer, Eindhoven, The Netherlands, also spoke about building a hybrid suite. He talked about the business case for the hybrid suite and optimising the use of the suite.

The afternoon session, chaired by John Primrose, president of the association of Surgeons of Great Britain and Ireland, saw presentations on a variety of topics. Amongst others, Dogu Teber, Heidelberg, Germany spoke about laparoscopic partial nephrectomy in kidney cancer guided by Dyna CT/laparoscopy image diffusion which explored using a fusion of preoperative and intraoperative imaging data to “track relative positions of instruments and anatomy during surgery”. He demonstrated the use of an iPAD to track access to the kidney. Alexander Schramm, Ulm, Germany, gave the prentation “First experience of maxillofacial surgery in a hybrid operating room”. He showed a patient with complex orbital wall fracture where a visual implant insertion was performed with anatomic mesh. A fusion of imaging data showed a virtual reconstruction of the eye.

Christian Ratopoulos, Brussels, Belgium discussed the use of the hybrid operating room for neurosurgery. He said that “many neurological procedures are performed in a high quality imaging system to ensure the best possibly accuracy.”

Roger Greenhalgh, Imperial College London, London, UK, post event, posed the question to Interventional News on non-cardiovascular imaging: “Will vascular surgeons learn interventional radiology imaging techniques that will require retraining or will it pass to interventional radiologists?”
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Mobile vs. fixed imaging: Is there an absolute answer?

DAVID H DEATON

COMMENT & ANALYSIS

David H Deaton discusses the pros and cons of installing a state-of-the-art fixed imaging system in hybrid operating suites compared with flexible mobile imaging

Over the last two decades, vascular reconstruction has witnessed a revolution (or perhaps evolution) to catheter-based therapies in most peripheral circulatory beds. While almost every surgeon involved in the development of modern endovascular techniques initially used mobile C-arms in their traditional operating room environments, they now have state-of-the-art fixed imaging in their "hybrid" operating rooms. Should this be the new standard for all endovascular procedures, operating rooms and facilities? Are there any downsides to these advanced systems?

While few can argue against the fact that advanced fixed imaging systems offer the highest image quality, they are expensive (in both initial cost and maintenance), and diminish the options for performing endovascular procedures in different operating room environments and in the conduct of certain combined open and endovascular (ie. "hybrid") procedures. In a world where the cost and efficiency of care is under ever-increasing scrutiny, there is a strong case to be made for using mobile imaging in a significant majority of endovascular cases.

While the C-arms of the mid 1990s offered essentially no specific technologies for vascular imaging (such as subtraction angiography and road-mapping), the current generation of mobile imaging systems can perform the vast majority of imaging modalities and offers features found on fixed systems without the greatly increased cost. The most recent generation of mobile systems allows the operator table-side control of both imaging modality and C-arm position. Combined with mobile “floting” operating room table technology, the traditional operating room can easily be converted into a high-end endovascular environment without expensive renovation of existing infrastructure. Mobile imaging also has the capabilities to be used essentially in any room available. It also preserves the creativity of the modern vascular surgeon to combine advanced open and endovascular techniques in a manner not possible in a room with a fixed fluoroscopic table and imaging system.

At our centre at Georgetown University Hospital, Washington, DC, USA, we employ a hybrid approach to our imaging needs. For most non-aortic outpatient intervention we use a “cath lab” environment refitted with a fixed-imaging system optimised for peripheral procedures (ie. large image intensifier and no traditional cardiac modalities). Outside of our conventional operating room our productivity is maximised with quick turnover and without any formal anaesthesia support. For aortic and more complex and hybrid procedures in the lower extremity or elsewhere, we use the latest generation of mobile imaging in the operating room. We also use the operating room environment for physiologically or psychologically less stable patients. This diverse portfolio of imaging and operating environments allows us to tailor care to the specific needs of patients and are not limited to a simple consideration of imaging equipment.

Essentially, one must ask the question: “Do we need the most expensive and advanced system to do every case?” Of course, the answer is “no”. Advanced imaging systems are best utilised for complex anatomy where fine detail and extreme imaging flexibility are critical elements for optimal outcomes (such as intracranial cerebrovascular procedures, complex distal lower extremity intervention and complex aortic intervention). Many of the more routine endovascular procedures performed can be easily accomplished with mobile systems that offer the economic flexibility to purchase multiple systems that allow higher procedural volume and technical redundancy in the case of imaging system failure.

David Deaton is chief of Vascular and Endovascular Surgery, Georgetown University Hospital, Washington, DC, USA

Proteus embolic capture angioplasty balloon “effective for avoiding embolic events in long lesions”

In a small cohort, Thomas Zeller, Universitäts-Herzzentrum, Bad Krozingen, Germany, and colleagues, investigated the use of the Proteus embolic capture angioplasty balloon for peripheral vascular disease. They reported on their initial experience using the balloon in a study published in the Journal of Endovascular Therapy

To date, no dedicated embolic protection device has been designed for use during lower limbs intervention. The filters currently approved for embolic capture in the carotid arteries are considered expensive, difficult to handle, and time consuming in the lower limb vessels, so they are almost solely used in conjunction with atherectomy procedures,” said Zeller et al.

However, they said that recently a novel peripheral angioplasty balloon with embolic capability has been introduced—the Proteus embolic capture angioplasty balloon which is US Food and Drug (FDA) Administration approved and CE marked. Therefore, the authors aimed to assess the safety and the performance of the balloon in the treatment of peripheral vascular disease. The study was a non-randomised single-arm study that enrolled 15 patients.

The 5x300mm Proteus balloon catheter was implanted as first-line treatment strategy (including as provisional stenting after unsuccessful balloon dilation) and as secondary treatment it was used as adjunctive therapy to post-dilatational stents following direct implantation or following rational thrombectomy.

The primary endpoint of the study was the rate of clinically significant vessel dissections and device-related distal embolisations. Secondary endpoints included: rate of acute serious adverse events; adverse events related to device malfunction; and, procedure success rate.

There were 20 TASC II C (n=4) and D (n=16) lesions, according to Zeller and colleagues, of which 15 were in the superficial femoral artery and, five in the popliteal and superficial femoral arteries. Five of the lesions de novo, five were restenoses, and five were in-stent restenoses. The average lesion length was 21±78mm per lesion.

The procedure was performed using a 7F sheath over a 0.035inch guidewire for all cases. They reported that procedure and device success rate was 100% and there were no device malfunctions, vessel dissections, or distal embolizations. According to the study results, the embolic capture angioplasty balloon was used for predilation in 11 lesions and for post dilation in nine. Four lesions required the use of the angioplasty balloon after rational thrombectomy and 18 target lesions had self-expanding stents applied. According to the results, there were three non-device related complications: pseudoaneurysm, myocardial infarction, and acute renal failure which were resolved without any sequelae at 30 days.

In five cases, the captured embolic material was transferred from the balloon to a filter and stained with violet Davidson tissue marking dye (Bradley Products), which were analysed to determine the overall count and major axial dimension of each particle. The analysis of the particles (although no histopathology was conducted) suggested chronic thrombus and neointima.

“We believe that the Proteus embolic capture angioplasty balloon should be applied especially in cases where the potential risk of distal embolism is high and the need to minimise complications is prominent,” said Zeller et al. “Such cases include lower extremity chronic arterial occlusions, critical limb ischaemia, long and/or thrombotic lesions, stenting, after atherectomy, and/or patients with poor distal runoff.”

“It is, however, important to add that the rationale for using embolic capture angioplasty with the Proteus device needs to be further investigated by large-scale clinical trials,” they concluded.
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Diffusion-weight magnetic resonance imaging in carotid artery interventions

SUMAIRA MACDONALD

COMMENT & ANALYSIS

Following carotid intervention, the number of detectable diffusion-weight magnetic resonance imaging (DWMRI) lesions is an order of magnitude greater than adverse clinical event (stroke/death). This lends credence to the use of DWMRI as a surrogate endpoint allowing comparisons of interventional strategies in studies with reduced sample size, wrote Sumaira Macdonald...

The International Carotid Stenting Study (ICSS) sub-study comparing DWMRI lesions in patients undergoing largely filter-protected carotid stenting and carotid endarterectomy demonstrated significantly fewer DWMRI lesions after carotid endarterectomy, implying superior control of procedural microemboli. Sixty-two of 124 (50%) patients undergoing distal filter-protected transfemoral carotid artery stenting and 18 of 107 patients undergoing carotid endarterectomy (17%) had new DWMRI lesions (p=0.0001). Individual lesions were smaller in the carotid artery stenting group than in the carotid endarterectomy group (p=0.0001). Of the DWMRI positive scans following carotid artery stenting, 25 (34%) resulted from unprotected carotid artery stenting and 37 (75%) resulted from filter-protected carotid artery stenting (p=0.019).

Total lesion volume per patient did not differ significantly between patients undergoing carotid artery stenting and those undergoing carotid endarterectomy. Two small randomised trials compared proximal embolic protection (Medtronic MoMa) with distal filters during carotid artery stenting. There were substantial or significant reductions in DWMRI lesions for the MoMa compared with filter protection. There were significantly fewer DWMRI lesions in the MoMa group ipsilateral to the carotid lesion (p=0.0002) but no difference in the DWMRI lesions in the contralateral hemisphere, implying the embolic penalty associated with catheterisation of the arch/great vessel origins for transfemoral carotid artery stenting. There was also a significant difference in favour of the MoMa system for lesion volume 0 [0 to 0.84] vs. 0.47 [0 to 2.4cm³] (p=0.0001).

The PROOF first-in-man analysis of high flow rate flow reversal via direct common carotid artery access (MICHI System) evaluated 65 patients, 48 of whom had pre- and post-carotid artery stenting DWMRI read by two independent US neuroradiologists. Eight of 48 patients had new DWMRI lesions (16.7%).

Another study examined patients undergoing transcervical carotid artery stenting with flow reversal or distal filter-protected transfemoral carotid artery stenting. DWMRI lesions were found in four of 64 transcervical (12.9%) and in 11 transfemoral (33.3%) patients (p=0.03). In multivariate analysis, age (relative risk, 1.022; p=0.001), symptomatic status (relative risk, 4.109; p=0.001), and open-cell vs. closed-cell stent design (relative risk, 2.01; p=0.001) were associated with a higher risk of lesions in the transfemoral group but not in the transcervical group.

The low rates of DWMRI lesions in studies of carotid artery stenting with flow reversal via direct carotid access are commensurate with carotid endarterectomy, presumably resulting from more effective embolic control and avoidance of catheterisation of the arch. A prospective study of 110 patients undergoing filter-protected transfemoral carotid artery stenting investigated the fate of silent DWMRI lesions. Twelve of 30 DWI lesions persisted, resulting in a lesion reversibility rate of 60%. Seventy-five per cent (12/16) of the cortical lesions disappeared while only 30% (3/10) of subcortical lesions disappeared. Eighty-three per cent (14/17) of lesions measuring 0–5mm disappeared while only 31% (4/13) of lesions measuring >5mm disappeared.

It was concluded that a large number of silent ischaemic lesions visualised on the PWI images post-carotid artery stenting disappear within months and therefore the extent of permanent carotid artery stenting-related cerebral damage may be overestimated.

The most recent analyses of the ICSS sub study data set revealed that patients in the carotid artery stenting group had more acute (relative risk 8.8, 95% CI 4.4–17.5, p<0.001) and persisting lesions (relative risk 4.2, 1.6–11.1, p<0.005) than patients in the carotid endarterectomy group. However, the rate of conversion from acute to persisting lesions was lower in the carotid artery stenting group than in the carotid endarterectomy group (relative risk 0.4, 0.2–0.8, p<0.007).

Systematic reviews have failed to provide consistent data across included studies comparing cognitive outcomes following carotid artery stenting and carotid endarterectomy.

Of 1,713 patients included in the ICSS, 140 of 177 patients enrolled in two Dutch centres had neuropsychometric testing at baseline and 120 at follow-up. Ten domains were examined, including executive function. There were no significant differences in overall cognition between patients undergoing carotid artery stenting and carotid endarterectomy despite the impressive difference in DWMRI lesions counts between carotid artery stenting and carotid endarterectomy.

“Standard” filter-protected transfemoral carotid artery stenting generates more DWMRI lesions than carotid endarterectomy but technical modifications (proximal embolic protection, direct carotid access) allow carotid artery stenting to more effectively compete where microemboli are concerned. Clinical decision-making, with regards cognitive function is poor, implying either that a large number of DWI lesions are clinically irrelevant or that neuropsychometry is a blunt tool. DWMRI is a reasonable secondary endpoint for carotid interventions, but without watertight clinical inference, the use of DWMRI as a primary endpoint remains an unproven convenience.

Sumaira Macdonald is an interventional radiologist at Freeman Hospital, Newcastle, UK.

Want to read a past issue?
Pulmonary embolism protection during the treatment of deep vein thrombosis with the new Capturex PEP device

Straub Medical has launched, at CX35, the Capturex as a pulmonary embolism protection system. The peri-interventional protection system is designed to overcome the limitations of currently available inferior vena cava filters including impossibility to mechanically empty the filter from massive clot load, limited filtration abilities, inability to retrieve, migration, perforation and damage to the caval wall.

Regarding its dimensions and construction, the Capturex PEP device is designed for the use in the central venous system—the vena cava inferior and superior. Key features of the PEP system include:

- Complete filtering emboli from the bloodstream in the vena cava inferior or superior during the thrombectomy procedure
- Self-centering, no tilting
- Total transluminal filtration across the entire lumen of the vessel
- Capturing thrombi and detritus with high efficiency
- Preventing embolism to the lung arteries or paradox embolism to the arterial system
- Save retraction of the captured material, even if infectious, from the central venous system
- Immediate and easy removal of the whole system after the intervention.

The filter catheter consists of a braided shaft providing a working channel with an inner diameter of 6F. It is placed over a 60cm 10F introducer sheath. By slowly pulling back the introducer sheath, the tulip-formed nitinol filter basket opens distally to its full expansion. Capturex PEP then covers the entire caval lumen of diameters from 20–30mm, while simultaneously keeping the vessel patent for the blood flow. After the intervention, clots, which had been trapped in the Capturex PEP system, can be easily removed, either by the use of a Straub Medical 6F AspirexS catheter through the working channel of the Capturex PEP shaft, or by using the same AspirexS catheter, which had been used to remove the thrombotic material of the underlying deep vein thrombosis, by approaching the protection device from its open distal filter basket side.

According to a press release, Capturex PEP offers the physician the highly effective safety net for their percutaneous endovenous deep vein thrombosis treatments they were looking for. It enables an even more aggressive approach to the thrombus load without an increased risk of an acute pulmonary embolism.

The catheters of Straub Medical’s AspirexS family are approved and indicated for use in acute thrombotic or thromboembolic occlusions, especially in veins or dialysis grafts, where the fast and reliable removal of fresh thrombus is necessary: They feature superior properties of high volume continuous aspiration and transport of the aspirated thrombotic material into a collecting bag outside the patient. AspirexS catheters are able to fragment less organised clot without the simultaneous use of thrombolytic drugs.
Catheter-directed thrombolysis and thrombectomy techniques explored

In the CX35 (6–9 April 2013, London, UK) Catheter-directed Thrombolysis and Thrombectomy Course, Miroslav Bulvas, University Hospital Kralovske Vinobrady, Prague, Czech Republic, presented data from a study using the Rotarex rotational thromboembolectomy device (Straub Medical) for the treatment of acute and sub acute ischaemia of lower the limbs.

B ulvas told delegates that thrombolysis and/or surgical approach are therapeutic methods commonly used for treatment of threatening acute and subacute ischaemia of lower limbs but both are associated with mortality and morbidity rates that are “difficult to accept”. He said the aim of their study was to establish whether acute and subacute occlusions of lower-limb arteries can be safely and efficiently treated without thrombolysis and open surgery. In the study, according to the speaker, from April 2009 to March 2013, 171 patients were treated percutaneously for acute (100) and subacute (71) ischaemia of lower limbs caused by occlusions of bypasses and aortoiliac or femoropopliteal arterial segments. He reported that the mean occlusion length before Rotarex therapy was 23cm (4–59) and blood flow was re-established in all patients. Mean length of residual stenosis was 4.3cm (0–40) and mean residual percentage stenosis was 37% (0–90) after Rotarex thromboembolectomy. The number of Rotarex passes was 1.5 and running time of the device was two minutes in average.

Further treatment of residual lesions included percutaneous transluminal angioplasty in 64% and stenting in 36% of patients. Additional therapy of concomitant infrapopliteal lesions was performed in 54% of patients, including 11 patients (6% of 171) with thrombolysis. Open surgery was not necessary, the speaker added.

At six months, there was one death due cerebral bleeding that was not associated with the Rotarex procedure. Relief from ischaemic symptoms occurred in 98% of patients and amputation-free survival was 99%.

The most common minor complication of the therapy was peripheral embolisation after the Rotarex (3.5%) and embolisation after percutaneous transluminal angioplasty or stenting (8%). All peripheral emboli were removed by aspiration or extraction with endomyocardial biopsy device.

“With Rotarex device, we have transformed long acute and subacute occlusions into short residual stenoses accessible to additional endovascular treatment, if necessary. Thrombolysis was applied in a small number of patients to influence lesions in infrapopliteal region where the Rotarex was not used,” said Bulvas.

Chronic ischaemia

In a following presentation, Bulvas addressed the use of the Rotarex device in patients with chronic ischaemia of the lower limbs. He said that Rotarex’s rotational thrombectomy efficacy depends on presence of fragmentable and removable occlusive material.

He presented the results of a study which aimed to show that fragmentable material exists in occlusions that can be easily passed with guidewire without respect to the age of ischaemic symptoms.

In the study cohort, from April 2009 to February 2013, the speaker reported that popliteal artery occlusions were recanalised by Rotarex in 101 patients with ischaemic symptoms lasting longer three months.

The mean occlusion length was 13.2cm, which he said an important condition for therapy with Rotarex was an easy and intraluminal passage of guide wire through the lesion.

With Rotarex, 101 lesions were recanalised with residual percentage stenosis of less than 30% in 54 patients. Adjunctive popliteal stenting was necessary in 25 patients with average stent length 3.5cm (SD 5.8). Percutaneous transluminal angioplasty without stenting was performed in additional 44 patients after Rotarex therapy. One third of patients did not require any adjunctive treatment. Restenosis rate was 13% and amputation free survival was 98% at 12-months follow-up, according to Bulvas.

“Based on our results, Rotarex should be considered in patients with popliteal artery occlusions and chronic ischaemic symptoms to avoid stent insertion in this challenging vascular location,” he concluded.

Deep vein thrombosis

Lubomir Spak, The Eastern Slovak Institute of Cardiovascular Diseases, Kosice, Slovakia, spoke about advantages of mechanical thrombectomy with the Aspirex system in the treatment of acute deep vein thrombosis. Spak told delegates that the technique in the venous system is safe and effective, with shorter hospitalisation time and without the risks seen with thrombolysis.

He speculated whether long-term results will be comparable to those seen with thrombolysis.

Angiojet

Ali Amin, West Reading, USA, spoke about the Angiojet system in the management of deep vein thrombosis and the PEARL registry (Registry of Angiojet use in the peripheral vascular system). He explained the epidemiology of venous thromboembolism and iliofemoral deep vein thrombosis, its pathophysiology, and the indications for endovascular therapy.

In iliofemoral deep vein thrombosis the objective of the treatment is to minimise or eliminate the embolic potential of the existing thrombus, prevent further thrombosis, restore venous penalty (remove obstruction) and preserve venous valvular function.

He told the audience that PEARL is the first prospective registry studying the safety and efficacy of Angiojet catheters for treatment of deep vein thrombosis.

“Among the first 371 patients, there have been excellent immediate results with the majority of patients successfully treated in 24 hours or less,” he said. “The mean catheter-directed thrombolysis drip time of 17 hours was significantly lower than either the Venous Registry or CaVenT trial.” Amin added that 82% of patients demonstrate continued clinical benefit at three month follow-up, and that PEARL II is showing continued clinical benefit at six month of follow-up.

Ultrasound thrombolysis

Nils Kucher, University Hospital, Bern, Switzerland, presented data about the use of ultrasound thrombolysis for submassive pulmonary embolism and also deep vein thrombosis.

For submassive pulmonary embolism, Kucher said that in patients at intermediate risk of death, low-dose, catheter-directed ultrasound-accelerated thrombolysis (up to 20mg rt-PA over 15 hours) appears similarly effective in reversing right ventricle enlargement when compared to the effect seen with systemic full-dose thrombolysis (reduction in right ventricle/left ventricle ratio by 0.3).

“In pulmonary embolism patients at intermediate risk of death, low-dose, catheter-directed ultrasound-accelerated thrombolysis (up to 20mg rt-PA over 15 hours) appears safer as compared with systemic full-dose thrombolysis when comparing with the bleeding rate observed in the PEITHO (Pulmonary embolism thrombolysis) trial,” he told delegates.

In patients with iliofemoral deep vein thrombosis, he said, an early revascularisation strategy using ultrasound-assisted thrombolysis with a fixed low-dose t-PA regimen (20mg/15 hours) with optional stenting of underlying venous lesion is effective and safe, and is associated with late venous patency and freedom from post-thrombotic syndrome in 90% of cases.

“It remains unclear if ultrasound-assisted thrombolysis is superior to conventional catheter-directed thrombolysis in dissolving venous thrombus and the BERNUTIFUL (Ultrasound-enhanced thrombolysis vs. standard catheter-directed thrombolysis for iliofemoral deep vein thrombosis) trial will address this question,” he concluded.
Doxorubicin-eluting microspheres limit progression of hepatocellular carcinoma

Daniel B Brown

Investigators from Thomas Jefferson University published a study in the February edition of the Journal of Vascular and Interventional Radiology, compared the incidence of progression of hepatocellular carcinoma when treated with either doxorubicin-eluting beads or ethiodol-based regimens using either cisplatin/adriamycin/mitomycin-c (CAM) or adriamycin alone. A total of 122 patients were reviewed: 59 were treated with adriamycin, 30 with CAM and 33 with drug-eluting beads. The groups had statistically similar demographics including Child-Pugh status, tumour/node/metastasis staging, and Barcelona Cancer Liver Clinic Scores, writes Daniel B Brown.

Patients receiving adriamycin required significantly more treatments (mean 2.3 +/- 1.4) compared to drug-eluting beads (1.4 +/- 0.6) and CAM (1.6 +/- 0.7). Using modified Response Evaluation Criteria in Solid Tumors (mRECIST) criteria, patients treated with adriamycin were significantly less likely to achieve an objective tumour response (51% of patients) compared to CAM (84%) and drug-eluting beads (82%). Finally, patients were significantly more likely develop progressive disease when treated with adriamycin (37%) compared to CAM (13%) or drug-eluting beads (9%).

The significance of this study relates to the lack of availability of a number of drugs that have been used for chemoembolization over the last several years, including ethiodol, powdered cisplatin, and powdered doxorubicin. Ethiodol is and will be available in the future. However, powdered doxorubicin has been on and off the market and powdered cisplatin has been unavailable for several years. Based on our findings, chemoembolization of hepatocellular carcinoma with CAM performed similarly to drug-eluting beads, both in regards to treatment response and disease control. These benchmarks directly correlate to survival and can improve the opportunity for patients to undergo liver transplantation, which is the best opportunity for cure. Given the lack of availability of powdered cisplatin in the United States, we would recommend drug-eluting beads over adriamycin based on these results if these are the only two options available to an interventional oncologist.

Other findings of note included a similar time to progression among the three treatment groups and similar complication rates. The risk of grade III complications using the Common Terminology Criteria for Adverse Events v3.0 ranged between 2.2% and 3.3% by procedure depending on the regimen. Forty of the 122 patients (32.8%) underwent liver transplantation. Only patients treated with adriamycin had progressive disease at the time of transplant, with nearly one third of patients progressing. However, no patients in any of the three groups developed recurrent hepatocellular carcinoma following transplantation.

We consider liver transplantation to be the ultimate goal of patients treated with chemoembolization. Fortunately, there were no recurrences in the adriamycin patients even in those who progressed. While more research needs to be done to determine the relative risk of local tumor progression prior to transplantation, it is likely that patients with disease control have the best long-term outcomes. Prior research has shown that patients with locoregional therapy prior to transplantation had superior disease-free survival to a matched group not undergoing any neo-adjuvant treatment. This finding suggests that maximising tumour necrosis prior to transplant is essential to ensuring long-term survival.”

Daniel B Brown is a professor of radiology, Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, USA

We would recommend drug-eluting beads over adriamycin based on these results if these are the only two options available to an interventional oncologist.
Iain Robertson is the current president of the British Society of Interventional Radiology (BSIR) and is the co-author of *Interventional radiology: a survival guide*, which he said is “aiming to be the book most often stolen from interventional radiology departments”. He spoke to *Interventional News* about his aims as president of BSIR for 2013, his current research on validated data on interventional radiology outcomes for common procedures, and his love of photography.

**Profile Iain Robertson**

**What drew you to medicine and interventional radiology?**

It was by accident really. I was all set to do a degree in maths and physics and really looking forward to it. By chance I met a teacher from a private school that only sent students in either law or medicine. He persuaded me that there would be lots of science in medicine and everyone was very wealthy—wrong on both accounts.

**Which innovations in interventional radiology have shaped your career?**

Oddly, while I have an addiction to electronic gadgets, I do not get too focused on the latest gadgets in interventional radiology—and there are a lot of them. I am old enough to have seen some of the initial applications of material science, such as nitinol in stents and wires and hydrophilic coatings, which made a huge impact. I remember being told by a senior interventional radiologist colleague that, in his opinion, the invention of the Terumo wire took three to five years off the training of an interventional radiologist. Timing meant that I was lucky to be in the group that benefited from this.

**Who were your mentors and what wisdom did they impart to you?**

I learned most of my early interventional radiology at the Hammersmith, London, with Professor David Allison and Dr James Jackson. There was a real focus on demanding the highest standards from yourself and thinking ahead on procedures to maximise success and minimise time, risk and complications. At that stage we did not have so much kit and success could only be gained by perseverance and really understanding the kit used. A lesson I learned was that, the most common reason for failure in a procedure, was that I had either not planned it through well enough or just did not know how to use the kit to its best. I still have a mental image of never quite being able to match the skill and understanding achieved by David and James, but I certainly learned a lot. I still shudder when I see colleagues try for a few minutes and immediately reach for another catheter and wire.

**As the current president for the BSIR, what are your aims for 2013?**

This is a challenging time for interventional radiology in the UK as we are facing changes in workforce, commissioning and service delivery. The specialty has started the move from a technically-focused group to a more clinical focus. Improving 24-hour services that are available seven days a week will remain an important focus for the society. We have profiled the need to expand the interventional radiology workforce to support this programme and are definitely making progress. Only two years ago, we did not really have an accurate number of interventional radiologists needed in the UK or accurate numbers for current workforce, but we have recognised the size of the gap and I am confident that we will see an expansion in the numbers of interventional radiologists produced in the future.

While interventional radiology only became a subspecialty in 2010, we already need to think about adapting our curriculum and training structures. We plan to develop a clearer clinical focus within the curriculum during 2013. Finally, the society launched a quality and safety group this year, and this will work with key organisations such as the Medical Healthcare Regulatory Authority and NHS Improvement.

**What is your proudest achievement in interventional radiology?**

That is a difficult one but I am hugely proud and honoured to have been president of the BSIR. We are not the biggest society, but through hard work and excellent stewardship from previous presidents, the BSIR council and other members we have become increasingly influential and innovative. The society really punches above its weight.

**What developments in interventional radiology have had an impact on the specialty recently?**

I think oncological intervention in general is going to be huge for interventional radiology. The earlier detection of tumours in more elderly and frail patients will drive the need for minimally invasive treatments. With new evidence and technology it is easy to see the improvements in radiofrequency ablation and other ablative techniques. Embolization treatments for cancer have moved forward as well and in particular selective internal radiotherapy treatment (SIRT) looks very promising. I think the increase in oncology treatments will need to be reflected in changes to our training so that future interventional radiologists have a better understanding of cell biology and more.

**You jointly led the participation in “The system” that was shown at BSIR Annual Scientific Meeting 2012; please could you explain the importance of this?**

Interventional radiologists need to move to being more clinical and less technical, and there can be no better or more important way of demonstrating that transition than by improving patient safety. The system was supported by a grant from the Health Foundation and deals with a whole patient journey for a patient with biliary obstruction from the general practitioner (GP) to rehabilitation and highlights what can go wrong. It was an opportunity for the society to learn from experts in the patient safety area, and we produced a DVD looking at the expertise in the interventional radiology department and provided support and learning materials. The film debuted at the BSIR Annual Scientific Meeting in 2012 and got a fantastic response—so far we have distributed over 650 copies and are having to produce more DVDs. We are just finalising a web-streamed version. BSIR have agreed to continue a programme of work in patient safety, harnessing the whole interventional radiology team, including, vitally, nurses and radiographers.

**You have contributed to many journals and books including *Interventional radiology: a survival guide*, what does your current research focus on?**

Most of my current work is looking at validated data on interventional radiology outcomes for common procedures, and his love of photography.
You were the co-author of “BSIR first biliary drainage and stent report” in 2009, what impact did this have on clinical standards and practice?

This is the largest series of collated records in biliary drainage in the world and shows the effectiveness of the BSIR at collecting data. The in-hospital mortality associated with this procedure is very significant and, gauging from the debates I have had with colleagues, perhaps it is not well recognised. The registry would suggest that we can improve patient selection in this group. After the registry we did a piece of preliminary work looking at risk stratification in Glasgow and the pilot data was so encouraging that it should be possible to develop an effective risk model. There is a useful further project in risk modelling for this procedure just waiting to be picked up.

What advice would you give to interventional radiologists just starting out in the field?

Grab the opportunity to join a rapidly growing field with constant innovation. Move around a bit during your training if possible, getting exposed to different teachers is important. Remember the importance of the interventional radiology team, the radiographer and nurse in the room works with all your colleagues and knows what succeeds and fails—they are invaluable sources of knowledge. Do not be put off by a view that interventional radiology is going to change, that is inevitable and if we focus on providing the best possible service we should be leading that change, not following it.

What are your interests outside of medicine?

I am a very keen photographer—it is the only vaguely artistic thing I can accomplish. I recently managed to complete a 365 project, which is a photo a day for a year published online. It sounds easy but give it a go, it is fun but actually quite hard to do. There is an online community and by looking at other submitted pictures you realise that it is a little like in interventional radiology—getting a great result is often more about the operator than the equipment. I also love swimming (my knees have given out for running) and a bit of cycling stops me from getting too round in the middle.
Paclitaxel-eluting balloons show favourable outcomes in femoropopliteal arterial disease at two years

**Paclitaxel-eluting balloons are associated with favourable functional and clinical outcomes at two years in patients with femoropopliteal arterial disease requiring percutaneous revascularisation**

According to a study published in the *Journal of the American College of Cardiology: Cardiovascular Interventions* in March 2013, paclitaxel-eluting balloons are associated with favourable outcomes after femoropopliteal angioplasty with the IN.PACT Admiral balloon (Medtronic), they said. The Italian Multicentre Registry also included centres in Merseoglio, Cottignola, Lecco, Bari, and Rapallo. Consecutive patients with Rutherford class 2 to 4 disease due to femoropopliteal lesions ≤15mm long and with 3- to 7-mm reference vessel diameter were prospectively enrolled in a multicentre registry. Endpoints included primary patency, major adverse events (the composite of death, amputation, or target lesion revascularisation), changes in Rutherford class, ankle brachial index, absolute claudication distance, and quality of life after ≥24 months. A total of 105 patients (114 lesions) treated with paclitaxel-eluting balloons (135) and provisional stenting were enrolled, and final procedural success was obtained in all. Follow-up after 27±3 months was obtained in 98 (93.3%) patients, showing that primary patency was maintained in 71 (72.4%) and major adverse events had occurred in 17 (17.5%), with death in two (2.2%), amputation in one (1%), and target lesion revascularisation in 14 (14.3%). There were persistently significant benefits in Rutherford class, ankle-brachial index, absolute claudication distance, and quality of life (all p<0.001). Secondary patency rate was achieved in 89 cases (84.7%). The authors concluded that their findings “signal that a stent-less therapy approach with IN.PACT Admiral paclitaxel-eluting balloon and optimal angioplasty provides favourable outcomes and is likely to leave more interventional options open for the future”.

**Plain old balloons and bare metal stents do not reign supreme in the superficial femoral artery**

After listening to the latest data for the Zilver PTX drug-eluting peripheral stent, 81% of delegates at the CX35 (6–9 April 2013, London, UK) stent data session voted against the motion that “plain old balloon and bare metal stents reign supreme in the superficial femoral artery”.

At the session, Frank Criado, Baltimore, USA, reviewed whether plain old balloons and bare metal stents were still the first-line treatment devices for the superficial femoral artery. He said that currently, vascular physicians were “addicted to stents” because they are predictable, easy to use, and widely available. According to Criado, there are disadvantages with this approach and these include monetary costs, the risk of in-stent restenosis, fractures and the possible need for re-intervention. However, with current positive data from the RESILIENT (A randomised study comparing the Edwards self-expanding LifeStent vs. angioplasty alone in lesions involving the superficial femoral artery and/or proximal popliteal artery) trial and the one-year data from the Zilver PTX (Cook Medical) trial, Criado predicted that the use of plain old balloons and bare metal stents—in the next five years—will be replaced by drug-eluting stents, drug-eluting balloons, mechanical and laser atherectomy, and endoluminal bypass.

In a following presentation, Marc Bosiers (AZ St-Blasius, Dendermonde, Belgium) discussed the use of the Zilver PTX in long lesions in the superficial femoral artery (>15cm). He said that stent integrity decreases as lesion length increases, but added that the Zilver PTX “provides better results in long lesions than bare metal stents”. Concluding his presentation, Bosiers announced the launch of the Zilverpass (The Cook Zilver PTX drug-eluting stent versus bypass surgery for the treatment of femoropopliteal TASC C and D lesions) study, which has a primary endpoint of patency at 12 months.

Michael Dake (Stanford School of Medicine, Stanford, USA) then presented the three-year data from the Zilver PTX drug-eluting stent clinical trial. The Zilver PTX, according to Dake, is designed for the superficial femoral artery and is approved in Europe, Japan, and the USA. He reported that the Zilver PTX trial had a primary and secondary randomisation process. According to the results, event-free survival was 83.5% in the 185 patients who received the Zilver PTX stent compared with 72.7% in 189 patients who were treated with percutaneous transluminal angioplasty alone (p<0.01). The rate of freedom from target lesion revascularisation was 84% in the 185 patients and 70.2% in the 189 patients. Dake added that, at three years, the Zilver PTX demonstrated a low fracture rate of 2.1%.

Additionally, the primary patency of the Zilver PTX was 68.7% in 184 lesions vs. 22.8% in 207 lesions with percutaneous transluminal angioplasty. In a comparison between the Zilver PTX stent and a bare metal stent, the primary patency was 79.6% in 44 lesions and 56.3% in 53 lesions respectively. “Three-year results support sustained safety and effectiveness,” he concluded.

**PVTE could be the new standard of care for liver transplant patient with PVT**

“Portal vein thrombectomy/transjugular intrahepatic portosystemic shunt (PVTE-TIPS) is novel pretransplantation approach to re-establish portal flow making liver transplantation possible,” said Riad Salem, Northwestern University, Chicago, USA, in a presentation at the Society of Interventional Radiology’s (SIR) Annual Scientific Meeting (13–18 April 2013, New Orleans, USA). He spoke at the TIPS/BORTO scientific session.

Salem explained that complete portal vein occlusion is a contraindication to liver transplantation and recommended against using intra-operative techniques as they were “suboptimal solutions to this challenging problem.” He added that the aim of their study was to evaluate the feasibility of PVTE-TIPS to re-establish portal vein continuity before liver transplantation. In their cohort, Salem explained, 30 patients underwent successful PVTE-TIPS. He reported that there were no technical failures and none of the patients needed main portal vein stenting. There were two peri-procedural adverse events (one haemoperitoneum and one haemobilia).

Out of the 30 patients, 15 were said to be transplanted successfully. Salem said there was >1.5cm of patent portal vein in all patients with excellent anastomotic flow. At one-month and three-month follow-up the speaker reported that the splenography revealed all portal veins to be patent. “Pre liver transplantation PVTE-TIPS is a novel approach to a challenging, if not untransplantable population,” Salem said. He further noted that as the technique develops the patient selection will have to also in order to identify the optimal candidates for the procedure.

Salem added that with the current advances in PVTE-TIPS, it may become the standard of care in the management of pre liver transplant patients with complete portal vein thrombosis.
Percutaneous radiofrequency ablation safe and effective for treat renal cell carcinomas

FRANÇOIS CORNELIS

Comment & Analysis

The results of a long-term study have shown that percutaneous renal radiofrequency ablation appears to be a safe and effective method in treating primary renal cell carcinomas, with a low morbidity for exophytic or parenchymal tumours writes François Cornelis. He discusses the impact of percutaneous radiofrequency ablation for the treatment of renal cell carcinomas and research in the area over the past decade

Over the last few decades, the increasing use of imaging in many diseases has profoundly modified the diagnosis and the treatment of kidney cancer. These tumours are diagnosed are currently discovered by chance which means earlier detection of often small, renal tumours, in 70% to 80% of cases, while they are still in a non-metastatic stage. These changes in presentation and prognosis have considerably modified the management of renal cell carcinomas, particularly over the last ten years, with the development of nephron-sparing techniques replacing open surgery.

The initial technique of laparoscopic partial nephrectomy has been supplemented by the techniques of laparoscopic thermal ablation, including the use of radiofrequency ablation (RFA) and cryoablation. However, some patients with small kidney cancers cannot tolerate a surgical procedure, because of advanced physiological age, comorbidities, or already precarious renal function. For these patients, a percutaneous approach using thermal ablation is gradually predominating. Particular because the equipment and techniques have developed to be ever more efficient in terms of sparing renal function and being less invasive for these fragile patients.

Many studies have reported the efficacy of radiofrequency ablation on renal cell carcinomas, even though long-term studies were not available. The study entitled: “Ten-years experience of percutaneous image-guided radiofrequency ablation of malignant renal tumors in high-risk patients” published in February 2013 in European Radiology has confirmed these results on a long-term follow-up (mean follow-up was 38.8 months with a range of 18–78 months). This study showed that radiofrequency ablation was technically possible for all patients enrolled in this study which included 62 patients (71 tumours), with a median age of 73.5 years (20–87), consecutively treated with radiofrequency ablation under ultrasound or computed tomography guidance for malignant renal tumours, including 25 patients (40.3%) with solitary kidney and seven cystic cancers. The maximal tumour diameters were between 8mm to 46mm (median: 23mm).

In this study, the primary and secondary effectiveness were 95.2% and 98.4% per patient, respectively and confirmed the results of the literature ranged from 67% to 100%. Moreover, these results agreed on the fact that most recurrences appear during the first year. However, recurrences can occur several years after what was considered to have been complete treatment of the lesion, although after three years they are still rare. In radiofrequency thermal ablation, it is well known that the size and sinus extension of the tumour to be treated can increase the risk of technical failure. In the study, the rates of local tumour progression and metastatic evolution were respectively 3.2% and 9.7% per patient. In univariate analysis, central location appeared as a risk factor of recurrence with a relative risk of 22.41 (95% CI=2.48 to 202.38, p=0.006). In univariate and multivariate analysis, size was the only factor independently associated with the occurrence of residual tumour or in situ recurrence. 100% of tumours less than 4cm were completely processed from the first radiofrequency ablation while only four (57.1%) of the tumours greater than 4cm had a complete initial treatment. For a one centimetre increase the relative risk was 9.35 (95% CI=2.08 to 41.43) (p=0.005). The disease-free survival rates were 88.3% and 61.9% a three and five years, respectively. The recurrence-free survival rate was not influenced by sex, the side or crano-caudal topography of the tumour: no significant difference whether the site of the lesion was exophytic, parenchymal, central or mixed. Tumour size of less than 3cm and a non-central location were considered as independent factors of primary efficacy. Only the non-central site of lesions is described as an independent factor of secondary efficacy.

Moreover, as reported in previous studies, the tolerance was excellent. No significant difference in glomerular filtration rate before and after the procedure was observed (p=0.107) which was one of the main advantages of radiofrequency ablation compared to nephrectomy. The major complication rate was 5.9% per session and in multivariate analysis, only a central location of the tumour was associated with an increased risk of complications (odds ratio: 22.66, 95% CI=2.47 to 208.33, p=0.006).

As a consequence, we can assume that this minimally invasive therapeutic option contributes to the conservation of renal function and subsequently to the improvement of quality of life and life expectancy of patients even in cases of poor surgical candidates. François Cornelis is an assistant professor in the Department of Radiology, CHU Bordeaux, France.

High-intensity focused ultrasound may be an alternative renal denervation approach

Qi-feng Wang and Jing Huang, The Second Affiliated Hospital of Chongqing Medical University, Chongqing, China, and others reported that while renal denervation was associated with “encouraging clinical outcomes” in patients with drug-resistant hypertension, intervention-related complications could occasionally occur. The authors commented: “In addition, vascular wall injury has been observed in a preclinical model and haemodynamic stenosis has been found in clinical case reports due to possibly related complications.” According to Wang et al., HIFU may be an alternative approach to the catheter-based, radiofrequency approach to renal denervation. They explained: “HIFU has been used non-invasively to ablate tissue by extracorporeally delivering focused acoustic energy. This technique is considered the ideal source of energy, especially for the ablation of deep solid tissue.”

In their study, they reviewed the use of a HIFU tumour therapeutic system (Model-JC200, Chongqing Haifu Technology) to ablate the bilateral renal nerves of healthy canines. Wang et al. randomly assigned 18 dogs (of 23 overall) to receive renal denervation through HIFU and five dogs to receive a sham procedure. Using colour Doppler flow imaging as a guide, the investigators placed the foci of the extracorporeal HIFU on the bilateral wall on the proximal, middle, and distal right renal artery, respectively. They wrote: “Therapeutic ablations (250Wx2 seconds) were performed on each set of foci. A total of six emissions of acoustic power were delivered when every segment of the renal artery was visible on an ultrasonographic view. The therapeutic transducer was moved 2mm dorsally or ventrally to initiate the viewing of the next set of ablations.” Throughout the procedure, the abdominal wall of each canine was immersed in a therapeutic chamber filled with degassed water to provide acoustic coupling between the transducer and skin. The sham procedure was similar to the ablation procedure apart from acoustic energy being delivered.

Wang et al. wrote: “On days six and 28 post-ablation, systolic blood pressure (12.3mmHg and 15.9mmHg, respectively; p<0.001 for both) and diastolic blood pressure (11.6mmHg and 13.6mmHg, respectively; p<0.001 for both) significantly decreased relative to the individual baseline blood pressure. Similarly, after ablation, the blood pressure in the ablation group was significantly lower than that of the sham group on both days.” They added that both during and following the ablation procedure, the canines’ vital signs appeared normal and none of them died until they were sacrificed. Furthermore, gross and histological examinations did not reveal significant injuries along the acoustic fibres. According to the authors, unlike the catheter-based strategy, the HIFU-mediated renal denervation technique can be performed “relatively independently” of anatomical variations in renal arteries. They stated: “This technique may be more suitable for certain conditions, such as bifurcated renal arteries and renal arteries that are smaller and shorter than normal” and added that there was some suggestion that the effect of HIFU-mediated renal denervation might be permanent as they said: “The myxoid change and shrinkage of the targeted renal nerve fibres were will present 28 days post-ablation.” Wang et al. concluded: “This new strategy may provide an alternative approach to the clinical treatment of drug-resistant hypertension and other conditions associated with sympathetic overactivity.”
Serious adverse events are rare with coil embolization

LUC DEFREYNE

COMMENT & ANALYSIS

Ever since interventional radiologists started to occlude vessels intentionally, coils have been the workhorse tool of therapeutic embolization. Handmade in 1975, vintage Gianturco “woody tails” coils were soon produced on a large scale by companies as a technology for interventional radiology. Cook was involved in the design of stainless steel coils for treatment of haemorrhage or vascular malformations. Later, Boston Scientific extended its portfolio of small caliber coils, invented for intracranial aneurysm treatment, to 0.018 inch platinum coils suitable for peripheral indications.

Pushable coils are now available from different companies in either soft 0.018inch or stiffer stainless steel 0.035inch (even 0.025 or 0.038) caliber. Coil materials proved or were adapted (Inconel, Cook MReye coils) to be MR compatible. To increase thrombogenicity, most coils have fibres of Dacron or nylon. Creative minds designed different shapes to improve the stability when delivered in the vessel or to increase the occlusive effect. Tornado and VortX coils have loops with incremental diameter ranging from 2mm to 5mm on the one end and from 3mm to 10mm on the other end. Such coils are pushed or injected (0.018inch ones) into a preformed basket of circular or complex coils to achieve dense coil packing. Coils coated with an expanding hydrogel, first introduced to increase filling percentage and packing density of intracranial aneurysms, are now available as well as pushable hydrocoils (Azur, Terumo).

Embolization with pushable coils is most efficient when the goal is blank point occlusion of a damaged or ruptured vessel. If the lesion can be reached, and the artery is an end artery (such as the kidney, lung, and the vasa recta of the bowel) simple placement of appropriately-sized coils will do the job. If a major artery is ruptured or carries a pseudoaneurysm, is should be crossed by the catheter and treated by coil placement in sandwich technique from distal to proximal. A similar technique is employed to treat arteriovenous fistulas, although it will not always be possible to enter the venous side. In pulmonary arteriovenous fistulas, filling of the usually aneurysmal fistula point and the feeder is usually sufficient. Pushable coils can be employed to protect distal or adjacent vascular territory if you need to embolize with liquids. Flow will be diverted to the target lesion, so will highly diluted glue do in spinal dural arteriovenous fistulas. Similarly, contamination of the stomach or duodenum is prevented by coil embolization of the gastroduodenal or right gastric artery in Y90 radioembolization of the liver.

Coil embolization is not a life-long guarantee for permanent vessel occlusion. It is well known that, from pulmonary arteriovenous fistulas even after dense coil filling, years later, vessel remoulding around the coils may cause at least partial recanalisation of the fistula. Coils placed in a pseudoaneurysm without treatment of the parent vessel will be pushed by the blood pressure, ensuing reopening of the aneurysm and high risk of rebleeding. Embolization of a major vessel can be performed safely in the presence of proximal and distal collateral circulation. Although ensuring blood supply to a distal territory is an advantage of coil embolization, it could turn into a disadvantage as well. If protective gastroduodenal artery embolization is performed weeks before the Y90 treatment, then small duodenal collateral branches from the proximal and distal hepatic artery might enlarge and increase again the risk of gastroduodenal contamination.

Arstasis Axera is safe and efficacious at a low angle of entry for neurovascular procedures

Published in the Journal of Vascular and Interventional Radiology, a study led by Manuel Fortes, University of Maryland Medical Center, Baltimore, USA evaluated the safety and efficacy of the Arstasis Axera access device for neurovascular procedures at a low angle.

The study was a single centre, retrospective study which included 94 patients undergoing neurovascular procedures. The authors analysed the data from diagnostic and interventional neuroendovascular procedures between 21 September 2011 and 31 March 2012. 104 procedures in 94 patients were performed and, according to the authors, 87 (83%) were performed using a 5-French sheath and 17 procedures (16%) were using a 6-French sheath. Intravenous heparin was administered in 64 procedures (61%) and 32 patients (31%) were taking antplatelet medications. The Arstasis Axera device, according to the authors, performs two punctures into the vessel to complete access. The first of which is an arterial puncture which is performed with a standard 19 gauge needle. The technique employed by the authors was a modified Soldinger’s technique which was to create a low angle arteriotomy (10 degrees), intended to reduce time manual compression time to haemostasis.

Fortes et al reported that the median time to haemostasis was four minutes with manual compression; mean time to haemostasis was 4.1, 4.9 and 5.7 minutes for patients who did not receive antithrombotic medications, those who receive heparin alone, and those who received only antiplatlets, respectively. Outpatients undergoing diagnostic angiograms were permitted to ambulate at one hour.

According to the results, nine patients underwent arterial access twice and two cases (2%) failed to initially use the device with standard conversion to arterial puncturing.

There were two reported complications in the cohort with the Axera device. Complications were one small haematooma and, in two patients, arterial access was not achieved with the Arstasis device the procedure was changed to standard puncture.

“Our results demonstrated a reduction in time to haemostasis in comparison to historical recommended times of manual compression following a standard arteriotomy,” Fortes and others said.

The authors added that they theorised that, due to the low entry angle created in the artery, arterial blood pressure may have helped seal the arteriotomy. However, they noted that there is no definitive evidence to support this theory.

“In conclusion, our initial experience has shown initial safety and efficacy for the use of this device in the neuroendovascular setting. We believe that the initial experience we describe here represents a retrospective feasibility study which may help to serve as a basis for future prospective research,” said Fortes et al. “While these early results are encouraging, further prospective, controlled investigations should be performed to obtain a better understanding of the device.”
The morning session titled “Electronic Endovascular Education—Edited live cases broadcast online to the Far East” showed delegates three complex below-the-knee procedures from Germany, Italy and France. The participants who watched the session via an online stream reached 702 with participants. They watched from around the world including Europe and Russia, USA, Asia, Australasia and Africa.

The first case was performed by Andre Schmidt in December 2012 in Leipzig, Germany. The second procedure was executed by Roberto Ferraresi in March 2013 in Milan, Italy, and Eric Ducasse undertook the third case in Bordeaux, France, in March 2013. Ducasse said: “In the past decades we have seen major advances in the treatment of below-the-knee lesions with dedicated materials and retrograde approaches to peripheral arterial disease.” For this case, Ducasse showed below-the-knee techniques using Abbott Vascular materials. He showed a retrograde approach through the peroneal artery followed by guide wire proximal recapture and use of successful balloon angioplasty.

After each case, Dierk Scheinert, Leipzig, Germany; Flavio Airoldi, Sesto San Giovanni, Italy; Ferraresi, and Ducasse, answered questions, via video link, from delegates watching in the Far East.

At the end of the session, Greenhalgh told delegates: “This Electronic Endovascular Education session has been a wonderful experience with great educational value. I have to thank the colleagues from Germany, France and Italy for those who trained and for sharing with us all what could be done to save legs.”

Greenhalgh told Interventional News: “In these times of economic difficulties—when flight costs are on the rise—this online educational experience could be a cost-effective way of sharing education. We would like to invite the participants of this experience to share their opinion via twitter or facebook on whether this should be a pattern to be followed in future CX meetings.”

King’s College Hospital Open Access System aims to save diabetic foot The King’s College Hospital Open Access System, London, UK, “includes a multidisciplinary team of podiatrists, nurses, microbiologists, diabetologists, vascular surgeons, orthopaedic surgeons, diabetologists and interventionists dedicated to give an urgent, immediate treatment to patients who are at risk of developing necrosis, gangrene and losing their legs.”

Michael Edmonds, King’s College Hospital, told Interventional News: “The two drivers for this—in diabetic patients—are infection and ischaemia. Rapid diagnosis of infection and rapid treatment will prevent the progression of the necrosis. At the same time, the vascular system should be addressed and we should go forward with revascularisation either with angioplasty or bypass depending on the degree of the circulation problem as soon as possible,” he added. Edmonds presented an update entitled “Rapid referral and treatment within the concept of the diabetic foot attack” at the CX ilegx session.

Physicians with different specialities from the King’s College Hospital Open Access System also gave presentations at the ilegx Collaboration Day on their experience treating diabetic foot as a multidisciplinary team. Jason Wilkins, London, UK, presented a modern interventional approach to the diabetic foot. He told delegates, “The modern interventional approach to the diabetic foot begins with teamwork and recognition of patient centred care being at the forefront of the team approach. Ischaemia with neuropathy or infection is considered an emergency and robust patient pathways are mandatory in providing timely intervention.”

Wilkins highlighted that revascularisation was a basic requirement for successful treatment and amputation prevention. “Revascularisation may be surgical, radiological or a combined approach according to the presentation and nature of disease and distribution,” he commented. According to Wilkins, modern techniques and equipment provide the interventionalist with excellent tools for revascularisation with angioplasty, stenting and recanalisation of multiple long occlusions. He said: “The understanding and availability of modern equipment and techniques along with an effective multidisciplinary and team approach to urgent revascularisation result in improved outcomes for our patients.”

Hisham Rashid, vascular surgeon, London, UK, presented “Distal and ultra-distal bypass: a discussion on the foot angiomes—fact or fiction?” Rashid told delegates that the angiome concept was developed in 2006 by Attinger. He commented on a study—that he undertook to evaluate the impact of the angiome concept in a group of 142 diabetic and non-diabetic patients who underwent distal and ultra-distal bypass surgery for critical limb ischaemia with significant foot tissue loss. Rashid reported: “In this cohort of patients the healing and time to healing was not affected by the angiome revascularised, but was significantly affected by the quality of the arterial pedal arch. In patients with no pedal arch, the healing was significantly slower and inadequate compared to the complete and incomplete pedal arch subgroups. However the amputation-free survival rates were similar in all groups.”

International input to limb salvage As part of the Kings College Hospital Access System programme, speakers from Europe and USA gave their views and experiences on limb salvage.

Carlo Setacci, Siena, Italy, spoke on the latest guidelines on diabetic foot treatment: The Italian consensus document. Carlo Caravaggi, Milan Italy, presented a new integrated surgical approach—based on timing—to reconstruct the diabetic foot. Christopher Attinger, Washington, USA, told delegates about surgical care of the wound with debridement and planning of amputations and reconstruction. An interventional approach to the diabetic critical limb ischaemia patient vs. the non-diabetic was presented by Roberto Ferraresi, Milan, Italy. And David Armstrong, Tuscan, USA, spoke on techniques to correct foot deformity by surgical means.

Revascularisation challenges In the afternoon, Roger Greenhalgh, London, UK, chaired the session on revascularisation challenges on the treatment of critical limb ischaemia.

Frank Vemassen, Ghent, Belgium, highlighted the importance to keep patency in the long run, he said: “Sustained patency of the wound related artery is mandatory to optimise the chance for wound healing, to avoid repeat intervention and to preserve the limb.” Thomas Zeller, Bad Krozingen, Germany, considered: “Patency is necessary but not sufficient for wound healing and ultimate limb salvage.” He added, “Drug-eluting balloons may be the solution to achieve the necessary patency levels within the extensive multivessel arterial disease typical of critical limb ischaemia.”

In the discussion, the question was raised that to achieve the necessary patency in critical limb ischaemia patients more than one balloon would be needed, however, this approach increases costs. Greenhalgh made the point that only patients with insurance companies willing to pay for this and patients who can afford it would receive the treatment.
Ahmad Alomari wrote to dispel common myths about the management and diagnosis of vascular malformations and said that dispelling these myths can “only help in the management of this challenging disorder”

Vascular anomalies can be broadly classified into vascular tumours (eg. infantile haemangioma) and vascular malformations. The two main categories of vascular malformations are slow-flow (venous, lymphatic and capillary malformations) or fast-flow (arteriovenous malformations and fistulas). The interventional management of vascular malformations is the primary minimally-invasive therapy which largely replaced the surgical approach. The use of accurate terminology to describe this heterogeneous, occasionally overlapping group of disorders is crucial for proper management and research. Unfortunately, despite the major improvement in the clinical, genetic and therapeutic management of vascular anomalies, myths and misconceptions about the diagnosis and management of these anomalies continue to be surprisingly pervasive with frequent serious consequences. Dispelling some of these common myths can only help the management of this challenging disorder.

Myth 1. Modern medical practice uses proper terminology for vascular anomalies

Partially correct! The common use of inappropriate terms such as “lymphangioma”, “cystic hygroma”, “cavernoma” or “cavernous haemangioma”, does not attest to this statement. Vascular malformations are not tumours. Old, imprecise tumour-denoting terms (such as the suffix “oma”) should be avoided. “Lymphangioma” and “cystic hygroma” should be replaced by the proper name “lymphatic malformation.” Similarly, the use of “cavernoma” or “cavernous haemangioma” to refer to venous malformations is inappropriate.

Myth 2. Interventional radiology management of vascular anomalies is the only justified practice

Managing patients with vascular anomalies usually requires the collaboration of several experienced specialties, including interventional radiology. The undisciplined approach is hardly justified in modern medicine.

Myth 3. Interventional radiologists are well-trained to manage vascular anomalies

This is correct for only a handful of institutions. A reasonably large volume of patients with vascular anomalies is essential to consolidate such experience. In reality, the current high-intensity interventional radiology fellowship training cannot provide a comprehensive knowledge base and the practical skills necessary for managing these diseases in a one-year period. I advocate further specific training and retraining in this field beyond the fellowship and institutional experience limits.

Myth 4. Surgical management of vascular anomalies is an antiquated practice

Impressive! For some vascular anomalies, successful management can be primarily achieved surgically. In addition, combined interventional radiology-surgical approach is particularly helpful for large vascular anomalies requiring eventual debulking and for cosmesis and solid components of vascular anomalies.

Myth 5. Magnetic resonance angiography (MRA) and magnetic resonance venography (MRV) are standard parts of the protocol for imaging vascular anomalies

Difficult to prove! One of the common mistakes in imaging vascular anomalies is studying local blood vessels with MRA and MRV without standard cross-sectional sequences. For the vast majority of the vascular anomalies, MRA and MRV provide little, if any additional information. Contrary to the common belief, MRA and MRV studies are not essential for the diagnosis of arteriovenous malformations, which can be imaged by standard cross-sectional sequences. Nevertheless, the 3D data can be helpful in characterising and planning the management of some fast-flow anomalies.

Myth 6. Contrast enhancement is essential to differentiate venous from lymphatic malformation

Most of the time, contrast enhancement is not needed for this particular purpose. The classic T2 magnetic resonance imaging (MRI) signal of venous malformations is amorphous mass of very thin septations (malformed venous walls) containing stagnant blood and clots without solid components. Blood stagnation very commonly causes fluid-level fluid. Enhancement of venous malformations is patchy and heterogenous while only septal enhancement is typically seen in lymphatic malformations. Nevertheless, with characteristic T2 features, enhanced sequences are not essential for diagnosis.

Myth 7. Lymphaticovenous malformations are commonly noted on imaging

This myth is expressed far too often. For isolated, non-syndromic slow flow malformations, the common use of “lymphaticovenous malformation” is incorrect. These malformations are composed predominantly of one anomalous vascular lineage and the diagnosis is simply either “venous” or “lymphatic” malformations.

Myth 8. “Klippel-Trenaunay-Weber syndrome” is a proper diagnosis

False! Klippel-Trenaunay syndrome and Parkes Weber syndrome are completely different clinical entities. In fact, there is no such eponym as “Klippel-Trenaunay-Weber syndrome!” Parkes Weber syndrome is characterised by a limb overgrowth with capillary stasis and hyper-vessularity of the soft tissue. In Klippel-Trenaunay syndrome, limb overgrowth is composed of extrafascial fatty thickening, ectatic marginal venous system and lymphatic malformations.

Myth 9. Arteriovenous malformations can be precisely diagnosed with angiography

This is true—to a point. Fast flow, early venous filling and even arteriovenous shunting are not a sine qua non of arteriovenous malformation. Benign hypervascular masses (eg. hepatic infantile hemangioendothelioma) and extensive capillary malformations demonstrate marked hypervascularity, overgrowth and early venous filling without discreta arteriovenous shunting. Arteriovenous malformations by definition are primary lesions with no solid mass component.

Myth 10. “Liver hemangioma” and “vertebral hemangioma” are benign tumours

The so called “liver hemangioma” and “vertebral hemangioma” are not tumours, as the suffix “oma” suggests. These two entities are peculiar slow-flow venous lesions, not tumours.

Ahmad Alomari is an associate professor at Harvard Medical School, Boston Children’s Hospital, Boston USA.
**Embolic agents effective with uterine artery embolization**

Edwin Zhang, University of Alberta, Edmonton, Canada, presented the outcomes of a cohort of patients who underwent uterine artery embolization for the management of post-partum or post-abortion haemorrhage secondary to uterine vascular malformations at the Society of Interventional Radiology’s (SIR) Annual Meeting, which was held from the 13 to 18 April 2013 in New Orleans, USA.

In the study, the authors reported that they used embolic agents to treat 25 patients. Thirty two uterine artery embolization procedures were conducted in the cohort of 25 patients and, according to the study results, microcoils were used in 32% (n=8), microcoils and gelofoam pledget in 12% (n=3), microspheres in 12% (n=3), glue in 2% (n=1), polyvinyl alcohol particles in 48% (n=12), and polyvinyl and gelofoam pledgets in 20% (n=5) procedures.

Zhang et al said that 17 (68%) had no bleeding recurrence but eight (32%) experienced rebleeding post-embolization which was treated supportively or with further intervention such as repeat intervention, D&C or hysterectomy.

At follow-up, on a subjective satisfaction scale of one to 10 the patients score the treatment 8.5. Post-embolization, eight patients became pregnant nine times of which two had elective abortions and six had seven uneventful intrauterine pregnancies. “Uterine artery embolization in patients with post-partum or post-abortion haemorrhage secondary to uterine vascular malformations, with preservation of fertility, and should be considered the first line of treatment” said Zhang et al.

“Uterine artery embolization is effective with a myriad of embolic agents, including microcoils, not just polyvinyl alcohol particles and glue”.

**CCSVI model undecided for multiple sclerosis**

In a late-breaking trial presented at the Society of Interventional Radiology’s Annual Meeting (13–18 April 2013, New Orleans, USA), Albert Scappaticci, Rhode Island Hospital, Providence, USA, reported the findings of a study on a controversial interventional treatment for multiple sclerosis.

According to the study authors, chronic cerebrospinal venous insufficiency (CCSVI) is a “controversial entity proposed in the development and treatment of multiple sclerosis”. Therefore, the study aimed to evaluate autonomic responses to cervical venoplasty and changes in vagus nerve activity with percutaneous transluminal angioplasty.

The experimental model was conducted in rabbits in which 20 treatments were performed under general anaesthesia. The cervical vagi were exposed and hook electrodes were attached.

According to the authors, a BioLab acquisition system was used to obtain whole nerve recordings and spike count analysis was performed post hoc. The results showed that, during venoplasty events, there was increased bilateral vagus nerve activity in comparison to baseline with an average range of six to 15% spikes during treatment. During balloon percutaneous transluminal angioplasty there was an average increase in spikes on the right side in the range of 24.6% to 34.7% compared to 13.7% to 18.7% on the left.

Scappaticci et al said that balloon percutaneous transluminal angioplasty increased bilaterally the vagus nerve tone and differential increase in the response of the experimental right vagus nerve compared to the left.

“These preliminary data suggest further analysis of a unifying theory to explain clinical change in multiple sclerosis patients following jugular percutaneous transluminal angioplasty exclusive or in addition to the current CCSVI model. Specifically, that clinical improvement in multiple sclerosis patients following jugular venoplasty may be due to vagal nerve manipulation,” Scappaticci et al concluded.
Thoracic-length Heili-FX aortic securement system receives the CE mark

Aptus Endosystems announced on 2 April 2013 that it received CE clearance for its thoracic-length Heili-FX System. Similar to the original Heili-FX system that was cleared for European distribution in May 2011 and designed for treating abdominal aortic aneurysms, the new system consists of a longer delivery device with additional tip configurations to bring the innovative helical EndoAnchor technology to the treatment of thoracic aortic aneurysms.

The thoracic-length Heili-FX system allows physicians to deliver Aptus’ novel EndoAnchor technology to the thoracic aortic anatomy. The implantable EndoAnchor enables independent endograft fixation which is designed to replicate the sealing and fixation of hand suturing. Like the abdominal version, the thoracic system can be used during de novo thoracic endovascular aneurysm repair (TEVAR) procedures to enhance an endograft’s inherent fixation and sealing mechanisms. In addition, the EndoAnchor can be used to repair endovascular grafts that have migrated away from the implant site and have developed endoleaks or are at risk of developing these complications. In such cases, augmented fixation and/or sealing is required to regain or maintain effective aneurysm exclusion.

“Patients undergoing repair of their thoracic aortic aneurysms still face many risks and potentially serious complications,” said Eric Verhoeven, chief of Vascular and Endovascular Surgery at Klinikum Nürnberg Süd in Nuremberg, Germany. “With the new Heili-FX system for thoracic aortic aneurysms, we will have the ability to reduce those risks by addressing imperfect apposition of an endograft in angulated thoracic aortic anatomies and secure grafts in anatomies where endograft migration could become an issue.”

“The CE clearance of the Heili-FX system designed for thoracic aortic aneurysms is a major milestone for the Aptus team and our European physician partners,” said James Reinstein, CEO of Aptus Endosystems. “Acceptance of the Heili-FX abdominal technology has grown significantly for use in endovascular aneurysm repair (EVAR) procedures and we expect the utilization in TEVAR procedures will be even higher for standard antegrade vascular access procedures as well,” explained Randy Lyles, vice president of Cook’s Peripheral Interventional clinical division.

The company released that the Advanced Micro 14PTA Balloon Catheter demonstrates a dedicated over-the-wire micro balloon with a low profile. The balloon is small enough to fit through a 3 French introducer and can even be used through the 2.9 French pedal access sheath that is also available from Cook Medical. The device has a tip entry profile as small as a 0.018 inch diameter wire. The Pliaform balloon texture and hydrophilic coating reduce friction during device insertion and retraction compared to uncoated devices. (Pliaform is available on all sizes except the 1.5 mm diameter devices.) The device is available in 50, 90 and 150cm shaft configurations to accommodate a variety of access points.

The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is intended to be made available soon in many European Union markets. The device is not approved for sale in the USA. Schmidt is a paid consultant to Cook Medical and has been involved with this new device.

“This technology provides clinicians with a safe and stable inferior vena cava filter that can be confidently deployed and retrieved while minimizing the risk of migration, penetration and fracture. This product, along with the new Cleaner15 Mechanical Embolization System, and the recently announced acquisition of Angiotech’s Interventional business, is designed to provide the clinician with enhanced ease of delivery and retrieval ability,” said Rex Medical and is intended to provide the clinician with enhanced ease of delivery and retrieval ability.

“Safety and retrievability are without question two of the most vital, and rare, characteristics in a best-in-class retrievable inferior vena cava filter,” Argon Medical Devices. "This technology provides clinicians with a safe and stable inferior vena cava filter that can be confidently deployed and retrieved while minimizing the risk of migration, penetration and fracture. This product, along with the new Cleaner15 Mechanical Embolization System, and the recently announced acquisition of Angiotech’s Interventional business, is designed to provide the clinician with enhanced ease of delivery and retrieval ability," said Rex Medical and is intended to provide the clinician with enhanced ease of delivery and retrieval ability.

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Endurant abdominal aortic aneurysm stent graft shows sustained durability in complex patients

Analysis of the Engage registry found similarly strong outcomes with the Endurant abdominal aortic aneurysm stent graft in endovascular treatment in short and standard neck lengths.

Presented to endovascular specialists at CSX5 (6-9 April 2013, London, UK), a new analysis of clinical data on the Endurant abdominal aortic aneurysm stent graft system (Medtronic) demonstrated that the implanted medical device performed consistently and had a compelling performance in treating abdominal aortic aneurysms across a range of patient anatomies, from relatively straightforward to highly complex, according to a Medtronic release.

The subset analysis of the international Engage registry for the Endurant stent graft compared the influence of neck length on four primary outcomes. The two-year data demonstrated similarly strong outcomes in patients with neck lengths of 10mm to 15mm (short) and greater than 15mm (standard). Historically, shorter neck lengths have been associated with limited eligibility for endovascular repair and higher rates of adverse events, the release stated.

Argon Medical Devices announces launch of Option Elite and the acquisition of Angiotech’s interventional business

Argon Medical Devices has launched the Option Elite retrievable inferior vena cava filter. The Option Elite has been designed to make it easier to retrieve,” said David W Trost, associate professor of Clinical Radiology, Weill Medical College of Cornell University in New York, USA.

Elekta receives FDA 510(k) clearance for Versa HD Therapy System for cancer treatment

Elekta recently received 510(k) clearance from the US Food and Drug Administration (FDA) which allows the company to begin shipping and installation of all components of the Versa HD system within the USA, according to a release. High precision and tumour targeting and radiation dose delivery are three times faster than previous Elekta linear accelerators.

“We are delighted to receive FDA clearance,” says Jay Hoey, executive vice president, Elekta North America. “The potential clinical benefits for patients are significant. Further, the operational benefits for clinicians and providers are eagerly anticipated.”

Fully integrated with the Atrium multileaf collimator, Versa HD provides high-definition, high-speed beam shaping over a versatile 40x40cm field. This unique combination of fast multileaf collimator leaf speed with the new high dose rate
mode empowers clinicians to fully exploit high dose rate delivery and take advanced therapies such as VMAT, SRS and SRT to new levels—with compromising treatment times, according to the company.

Versa HD also features:
- Safety innovations
- Customisable, disease-specific configurations
- Modern patient-friendly ergonomics
- Fewer delays and downtime with real-time remote system monitoring
- Low environmental impact, low energy consumption design

Versa HD is not available for sale or distribution in all regions.

### Medwaves announces the first successful use of hot and cold thyroid nodules with AveCure

**Microwave Ablation System and radioiodine**

In August 2012, the University Hospital in Frankfurt, Department of Nuclear Medicine Germany, performed for the first time a microwave ablation of thyroid nodule on a patient in Europe. The microwave therapy has since been established in Frankfurt. Now the world’s first hospital has treated a patient with hot and cold thyroid nodules by the combined use of radioiodine therapy and microwave ablation. Compared to the usual procedures, the new combination therapy for patients is much safer and more comfortable, the release stated.

The release reported that the microwave ablation of the cold node followed by radioactive iodine treatment of the hot node was for the first time this year performed on a 52-year-old patient. For both procedures, no surgery was needed. With microwave ablation, treatment was performed under local anaesthesia; a probe is passed through the skin to position the antenna in the node with the purpose to apply microwaves directly on the thyroid nodules.

The diseased cells are heated by the waves, and the treated thyroid tissue is then metabolised by the body. The thyroid nodule is reduced to smaller size. Using real-time images from an ultrasonic device, the ablation process is monitored and controlled at all times. The duration of treatment depends on size and number of thyroid nodules and normally requires between 10 and 15 minutes. The microwave treatment is an outpatient procedure, according to MedWaves.

For the subsequent treatment of the patient’s hot node, radioactive iodine in the form of a capsule was administered. The rays cause cell death in the tumour. The node is removed without damaging surrounding tissue. The treatment is very safe and well tolerated. For combination therapy, a hospital stay of a few days is sufficient.

Radioiodine application and microwave ablation are both non-surgical procedures. A big advantage is the fact that the risks of surgery and related anaesthesia are completely eliminated. This is especially important for people who have pre-existing conditions, for example, the cardiovascular system problems and thus have an increased risk during surgery.

“The patient stated that a dental visit was more unpleasant than this treatment. We are pleased to be the first clinic to offer our patients this very gentle combination therapy,” said Hudayi Korkusuz who performed the first treatment.

### Nordion hosts European-based educational and scientific meetings

Nordion hosted two educational and scientific meetings to support the growth and expansion of Therasure® in Europe. On 11-12 April, Nordion hosted its European Therasure User Group Meeting in Vienna, Austria, and on 18 April, Nordion offered a Satellite Symposium at the 3rd Interdisciplinary Treatment of Liver Tumors (ITLT) Meeting in Essen, Germany, according to a company release.

“These meetings provide physicians with an opportunity for interactive, real-time discussions on industry best practices and trends in radioembolization and liver cancer therapy,” said Steve West, Nordion CEO and chief operating officer, Targeted Therapies. “These events help us share the latest developments in radioembolization to a broad physician base from various liver cancer disciplines.”

The 3rd European Therasure User Group Meeting covered a variety of topics over two days with a focus on current and future trends in radioembolization presented by speakers from Italy, Germany, France and the USA.

According to the release, the ITLT Satellite Symposium titled “Clearly targeted! Looking beyond systemic therapies for the treatment of liver cancer” intended to provide attendees with the latest data on radioembolization from Nordion’s three European Therasure Centres of Excellence. The symposium’s chairman, Stefan Plunkte, a medical oncologist from Essen Mitte hospital, Germany, moderated the following sessions from key presenters:

- “Targeted liver cancer therapy in the windy city. The Chicago experience with Therasure”— Jörg Schlaak, hepatologist, Essen University Hospital, Germany
- “The future is clear. The Milan experience with Therasure”— Riccardo Zamboni, interventional oncologist, Northwestern University, Chicago, USA
- “Less lesions from Essen. Latest insights on the use of TheraSphere”— Jörg Schlaak, gastroenterologist and hepatologist, Essen University Hospital, Essen, Germany
- “The lesson from Essen”— Jörg Schlaak, gastroenterologist and hepatologist, Essen University Hospital, Essen, Germany

### BSD Medical announces distribution agreement with Terumo

BSD Medical announced today that the company has signed an exclusive, long-term, multi-million dollar distribution agreement with Terumo Europe, a wholly owned subsidiary of Terumo Corporation, for the MicroThermX Microwave Ablation System. Under the terms of the distribution agreement, Terumo Europe will have the exclusive right to market MicroThermX 100 countries in Europe, Western Asia, and Northern Africa. The potential market size for MicroThermX in these countries is estimated to be in excess of US$1 billion in annual sales, according to the company. This agreement validates the large market opportunity for MicroThermX ablation products and is expected to drive market adoption for the MicroThermXa leading ablation therapy system. Strategically, MicroThermX will benefit from Terumo Europe’s extensive market reach, focus on interventional oncology, and well-established relationships with key interventional oncology opinion leaders throughout Europe, according to a company release.

“Our distribution agreement with Terumo Europe is the result of a collaborative effort between BSD Medical and Terumo. Importantly, it represents one of the most significant milestones in BSD’s corporate history,” said Harold Wolcott, BSD president and CEO. “Revenues from our agreement with Terumo Europe should commence by the end of the third quarter of our fiscal year 2013 and are expected to make a substantial contribution to our overall revenue over the next few years. Longer term, we expect this agreement will make a strong contribution toward our objective of achieving profitability.”

### Nordion to host interactive TheraSphere educational session at SIR

Nordion hosted an educational session called “TheraSphere test flight interactive: How to treat or should I treat?” at the Society for Interventional Radiology’s (SIR) Annual Scientific Meeting (13–18 April, New Orleans, USA).

The session is part of SIR’s new Industry Interactive Program, developed to provide industry partners with the opportunity to host dynamic sessions that showcase the latest Interventional Radiology technologies and research, including TheraSphere, Nordion’s Y-90 microsphere therapy for hepatocellular carcinoma.

“Nordion’s session featured hepatocellular carcinoma case presentations delivered by leading physicians to challenge expert panelists in their thinking, technique, and opinion on how, or if, they would proceed with TheraSphere treatment,” said Steve West, Nordion’s chief executive officer and chief operating officer, Targeted Therapies. “Nordion is always looking at ways to enhance the Therasure learning experience, and this interactive session is a great complement to our physician educational portfolio consisting of our Centers of Excellence.”
First centre in Hong Kong treats patients with CyberKnife and TomoTherapy systems

Accuracy announced that the Hong Kong Adventist Oncology Center, the first centre locally to offer both the CyberKnife Robotic Radiosurgery and TomoTherapy systems, hosted its official opening ceremony last week.

Hong Kong Adventist Oncology Center is a newly built cancer center that was designed to accommodate both systems. Their TomoTherapy System was installed late last year and their CyberKnife System was installed in September 2006.

“We are pleased to offer the most flexible, precise solutions for radiation treatment planning and delivery that enable us to deliver personalised treatments to a wide range of patients,” said Stephen Law, clinical director of Hong Kong Adventist Oncology Center. “The CyberKnife and TomoTherapy systems allow our clinicians to create specialised treatments ranging from high-precision radiosurgery for early-stage and localised disease to image-guided, intensity-modulated radiation therapy (IG-IMRT) for more advanced disease throughout the body.”

“Our two leading-edge treatment solutions—the CyberKnife and the TomoTherapy systems—satisfy all the external beam radiation delivery needs of an oncology department and give clinicians flexible, individualised treatment options to use in their pursuit of optimal treatment outcomes,” said Lionel Hadjadjea, general manager EMIEA and senior vice president of International Business at Accuracy. “The adoption of Accuracy’s versatile systems are constantly proven to provide comprehensive treatment solutions that serve the full spectrum of radiation oncology patients.”

Global clinical study initiated to determine safety and effectiveness of stent for patients

with iliofemoral venous obstruction

Cook Medical has launched the VIVO clinical research study to evaluate the safety and effectiveness of the Zilver Vena Venous Self-Expanding Stent in the treatment of symptomatic iliofemoral venous outflow obstruction. This disease is characterised by leg pain, throbbing, swelling and skin discolouration in the legs. The Zilver Vena venous stent was designed specifically for the dynamic environment of the iliofemoral veins.

The VIVO clinical research study, led by global principal investigators Anthony J Comerota from Josb Vascular Institute in Toledo, USA, and Lawrence “Rusty” Hofmann from Stanford University, is a prospective, non-randomised study that will enrol 243 patients at up to 30 participating sites in the United States and the Asia-Pacific region.

“This is an important trial which is intended to objectively assess the endovascular correction of symptomatic iliofemoral vein stenosis with a stent designed for this specific purpose,” said Comerota. “It is a privilege to be a part of this crucial prospective trial.”

The VIVO clinical research study will enrol adults 18 years and older who have leg pain that limits usual activities, swelling or skin discoloration of the leg, or a healed or active lower leg ulcer. There are additional eligibility criteria for the study. The primary study results will be evaluated one year after stent placement, with patient follow-up through three years after stent placement.

“It is exciting to be a part of the first ever iliofemoral venous stent trial in the US,” said Hofmann. “I look forward to the study initiation.”

The Zilver Vena Venous Self-Expanding Stent is an investigational device that is not approved for sale in the USA.

Significant palliation of spinal tumours with ablation system

Dfne has announced that two studies presented at the Society of Interventional Radiology’s (SIR) annual scientific meeting (13–18 April, New Orleans, USA) have underscored the benefits of targeted-radiofrequency ablation therapy (t-RFA) using Dfne’s Star tumour ablation system for the treatment of painful malignant lesions of the vertebral body, he first presentation—Image-guided t-RFA of spinal tumours using a novel bipolar navigational device: multicentre initial clinical experience”—by Jack Jennings (assistant professor of Radiology and director of Musculoskeletal and Spine Interventions at the Washington University School of Medicine at Washington University in St Louis, USA) noted that the Star system provided a significant clinical advantage by allowing in those vertebrae with pathologic fractures. Lesion aetiology included a wide variety of metastatic tumours throughout the thoracolumbar and sacral spine. Cement augmentation post-t-RFA proved to be sufficient and resulted in predictable cement filling. Pain relief, measured by Visual Analogue Scale (VAS), was rapid, significant and durable monitoring 7, 35, 180 days, 6 months, and 1.75 at six months post-op. Decrease in pain medication usage was recorded post-procedure and no complications or thermal injury were observed.

“The Star system is a highly effective tool capable of providing substantial pain relief and metastatic vertebral body tumours,” Jennings said. “We have found it to be particularly valuable when managing patients whose spinal tumours were unresponsive to traditional radiation and chemotherapy treatments. Now we can easily treat them using t-RFA without significant interruption to their primary cancer treatment regimen.”

In the second study, Robert Ryu, professor of Radiology of the Feinberg School of Medicine at Northwestern University and his co-authors used the Star system to treat 13 lesions in 11 patients that failed conventional chemotherapy and radiation therapy. Now a process to injection of high-viscosity bone cement into the ablated tumour bed. All patients noted clinically significant pain relief, with a decrease in average VAS score from 8.9 pre-procedure to 2.7 four days after treatment. No treatment-related complications occurred during the follow-up period. These data are consistent within the large multicentre
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experience (Jennings et al), demonstrating palliative treatment alternatives for painful spinal metastatic lesions.

**Cook Medical introduces new fully-retractable embolization coil**

Cook Medical has launched a new fully-retractable 0.035 inch embolization coil, intended for peripheral arterial and venous embolization. Cook showcased the Retracta Detachable Embolization Coil at the annual Society of Interventional Radiology Annual Meeting (13–19 April 2013, New Orleans). The new Retracta coil is designed to provide the physician with more controlled delivery of embolization coils. With the Retracta system, the physician can place the coil and detach it with precision when ready. Visibility of the detachment zone allows a clinician to easily identify when the Retracta is ready to be detached. If the physician is not satisfied with the positioning of the coil in the vessel, he/she can fully retract the coil into the catheter and reposition it before detachment. “When trying to control bleeding, precise coil placement is critical in embolization procedures,” said Andrew Conder, senior global product manager for embolization at Cook Medical. “The Retracta is simple and affordable, and gives physicians control over placement.”

Based on the construction of Cook Medical’s Nester coils, the Retracta coils use platinum technology to allow soft packing of the coil. Physicians can confirm placement accuracy under fluoroscopy by seeing the change in radiopacity at the detachment zone. If the physician wishes, he/she can inject a contrast medium to confirm that the coil is correctly placed. Like the Nester coil, the Retracta can be used right out of the package.

**FDA approves FibroScan for non-invasive liver diagnosis**

EchoSens has announced that FibroScan device received 510(k) clearance from the US Food and Drug Administration (FDA) on 5 April 2013 and is preparing to market its technology in the USA. Today, 1800 FibroScan devices are used worldwide both in research and routine clinical practice. The USA is the last major market to approve FibroScan, according to a company release. FibroScan is used in the clinical management of patients with liver disease such as chronic viral hepatitis C and B and fatty liver diseases. Based on a technology called transient elastography, FibroScan assesses liver shear wave speed (expressed in metre per second) and equivalent stiffness (expressed in kilopascal) at 50Hz in a rapid, simple, non-invasive and totally painless way.

Initially introduced in the European market in 2003, FibroScan pioneered the quantitative elastography medical field. It received market clearances in China (2008), Canada (2009), Brazil (2010), Japan (2011) and is currently available in 70 countries. According to the company, the use of FibroScan is also mentioned in guidelines and recommendations in different regions of the world such as the World Health Organisation, European Association for the Study of Liver (EASL), and Asian Pacific Association for the Study of Liver (APASL).
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