INTERVENTIONAL NEWS

Issue 53 March 2014

Duncan Ettles: Angioplasty
Page 10

James B Spies: Profile
Page 20

Jafar Golzarian: Building evidence
Page 26

Pressing need for evidence on fertility outcomes after fibroid embolization

The latest UK clinical recommendations, jointly issued by the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Radiologists (RCR) find that the early- and medium-term results of uterine artery embolization are good. However, one of the important points of the recommendations, published in December 2013, is that the evidence for fertility and pregnancy outcomes after embolization (and also after myomectomy) is poor. "Similarly, there is no robust evidence comparing embolization to myomectomy for these outcomes," they state

The new college guidelines state that uterine artery embolization "is as effective as surgery for symptom control, with the caveat that about a third of women will require a second intervention by five years. For women with symptomatic fibroids, embolization should be considered as one of the treatment options alongside surgical treatments (such as myomectomy and hysterectomy), endometrial ablation, medical management and conservative measures."

The UK recommendations pinpoint that it is currently impossible to make an evidence-based recommendation about treatment (uterine artery embolization or myomectomy) for women with fibroids who wish to maintain their fertility. Treatments for fibroids in women of child-bearing age who wish, or might wish, to become pregnant in the future should be offered only after fully informed discussion, the document says.

Anna Maria Belli

In the light of this advice, the investigators of the UK FEMME trial hope to spur enrolment in the National Institute for Health Research (NIHR)-funded clinical trial that is designed to measure the changes in the quality of life women experience when their fibroids are treated by either myomectomy or uterine artery embolization.

The FEMME triallists have explained the background to the trial as: "With both myomectomy and uterine artery embolization having their own risks and potential side-effects, many healthcare professionals are uncertain which is the best treatment to offer to women who wish to retain their wombs and this is why the research arm of the NHS have funded the FEMME trial.

Anna Maria Belli, professor of Interventional Radiology and consultant radiologist, St George's Healthcare NHS Trust, London, UK, and CIRSE president 2013–2015, commenting on some of the difficulties of recruiting patients for a trial such as FEMME said, "One of the difficulties is that many women wish to choose their treatment. There may be many reasons contributing to their decision, but they generally prefer to have control. In addition, randomisation between a surgical procedure that may involve open surgery and general anaesthesia, and a minimally invasive procedure performed under local anaesthetic is difficult for many women to accept; although randomisation between uterine artery embolization and laparoscopic myomectomy may be an easier concept."

Both the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) and the Society of Interventional Radiology (SIR) have expressed support for the FEMME trial. A joint letter of support from the two organisations states that "[…]

Continued on page 2

Randomised controlled trial shows negative results for drug-eluting balloon below the knee

Findings from the IN.PACT DEEP clinical trial showed that use of the IN.PACT Amphirion drug-eluting balloon (Medtronic) did not result in a differential treatment effect for patients with below-the-knee critical limb ischaemia as compared to use of a standard percutaneous transluminal angioplasty balloon

The study also showed a safety signal in the drug-eluting balloon arm—specifically, a trend towards an increased rate of major amputation (above the ankle) compared to the angioplasty control. Causality between major amputation and use of the IN.PACT Amphirion drug-eluting balloon could neither be established nor excluded.

The results of the study were presented at the Leipzig Interventional Course (LINC; Leipzig, Germany, 28–31 January) by Thomas Zeller, Universitäts-Herzzentrum, Freiburg-Bad Krozingen, Germany.

Thomas Zeller

Zeller told delegates: "IN.PACT DEEP was the first large, randomised clinical trial of drug-eluting balloons for below-the-knee critical limb ischaemia." He explained that the trial had an independent data safety monitoring board, an independent clinical event committee, an independent angiographic corelab, an independent wound corelab and that external monitoring was done with 100%

Continued on page 2

Pressing need for evidence on fertility outcomes after fibroid embolization

Continued from page 1

the findings of this trial are of utmost importance to women's health and patient choice, and this research trial provides a unique opportunity to answer questions for which there is currently no evidence and no other trial addresses."

Later in this issue of *Interventional News*, James B Spies, professor of Radiology, Georgetown University School of Medicine, Washington DC, USA, and the incoming president of the Society of Interventional Radiology (profiled on page 20 and 21) says: "The biggest questions [on evidence yet to be gathered] relate to those women who would like to become pregnant. When is it better to do myomectomy and when should uterine artery embolization be the first choice? This depends on many factors, including patient age, extent of fibroids, fitness for surgery, prior treatments and others. So it is not a one-size-fits-all answer and we have many gaps in our knowledge."

Jon G Moss, Interventional Radiology Unit, NHS Greater Glasgow and Clyde, Gartnavel General Hospital, Scotland, told *Interventional News* that FEMME is needed because at present neither patients nor healthcare staff know which procedure to recommend in cases of women who wish to maintain their fertility or simply avoid hysterectomy.

"Although myomectomy is seen as the standard option, there is no evidence for this and we need to know whether embolization is superior, inferior or indeed equal to myomectomy. At present what a patient is offered depends on who you see and where you live as much as anything else, clearly a highly unsatisfactory situation. Without FEMME, this situation will prevail," Moss said.

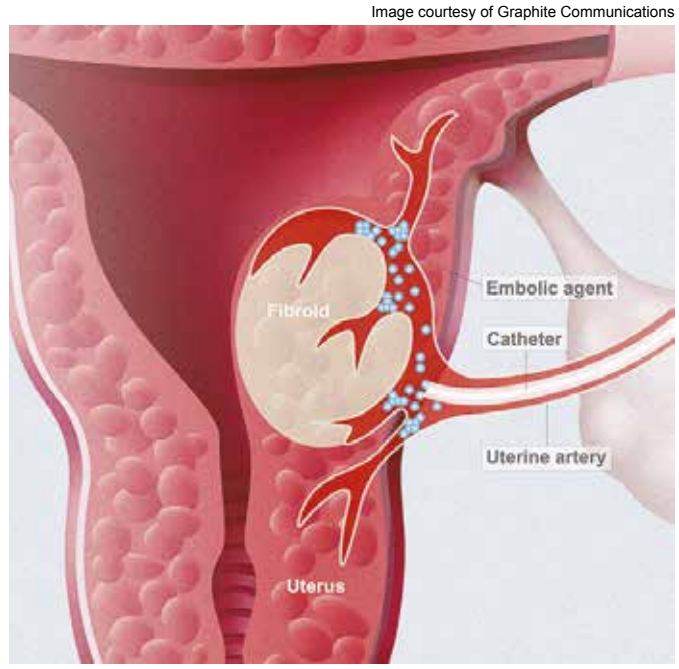
Belli added: "The treating clinician has to be convinced that there is equipoise between the treatment modalities. This has been a particular issue with regard to women desiring pregnancy, particularly as the old college guidelines were very cautious about the role of embolization in women wishing for fertility as the procedure was still a relative unknown. The new college guidelines are much clearer and reflect the lack of evidence for fertility and pregnancy outcomes with both treatment options which should help clinicians accept equipoise in this group of women. I hope we will achieve our target of recruiting 216 women to the trial by the end of October 2014. As of February 2014, we have randomised 160 women which means that we need a further 56. Our high recruitment rate is being maintained, and I am optimistic that we might exceed that figure."

FEMME will follow the progress of 216 women over four years. Half of the women will be randomly allocated to have a myomectomy and the other half will receive uterine artery embolization. Using questionnaires that reflect how well women feel, FEMME will record the quality of life women say they have after they have undergone a myomectomy and this will be compared with the quality of life women report after having embolization. The trial is also going to measure how much blood is lost as well as examine if embolization and myomectomy change the level of ovarian hormones associated with fertility. The triallists explain that ideally, they would like to randomise as many women as possible to FEMME to ensure that any conclusion reached is as robust and reliable as possible.

> ***"The new college guidelines are much clearer and reflect the lack of evidence for fertility and pregnancy outcomes with both treatment options"***
> ***–Anna Maria Belli***

"Quality of life is what matters to patients so that is the primary outcome measure for FEMME. It is a common primary outcome measure in these sorts of trials and was used, for example, in the REST and FUME trials. Pregnancy outcomes are also important but would require a much larger number of subjects as many patients are not desiring immediate pregnancy but simply to keep the option open. Pregnancy data is of course being collected in FEMME as one of several secondary outcome measures," Moss added.

Image courtesy of Graphite Communications



FEMME final findings timeline

The primary outcome of FEMME is to report on the changes in the quality of life two years after the last patient has undergone their procedure. "Since we will be randomising until the end of October 2014, the last patients should have undergone their procedure by the end of February 2015 at the very latest. We should have collected all our final primary outcome data by March 2017. Allowing time for the study results to be analysed and written up and peer reviewed, we would hope to have our results published by March 2018. Secondary outcomes at four years following the procedure should be available and published by March 2020. The results of how each treatment affects anti-mullerian hormone which is a marker of ovarian reserve, should be available for publication around January 2017, as the final sample will be collected one year following treatment by uterine artery embolization or myomectomy," Belli told *Interventional News*.

Randomised controlled trial shows negative results for drug-eluting balloon below the knee

Continued from page 1

source data verification. "This is the highest level of evidence regarding monitoring and oversight in a study," he noted.

The study enrolled 358 patients with Rutherford classification stages 4, 5 and 6 from September 2009 to July 2012 at 13 sites in six European countries: Austria, Belgium, Germany, Italy, The Netherlands and Switzerland.

Patients were randomised 2:1 to treatment with the IN.PACT Amphirion drug-eluting balloon (n=239) or angioplasty (n=119). Baseline clinical, angiographic and wound characteristics were similar across the two groups.

The primary efficacy endpoints at 12 months were clinically driven target lesion revascularisation and late lumen loss for an angiographic subset. The primary safety endpoint at six months was a composite of all-cause mortality, major amputation and clinically driven target lesion revascularisation.

The study failed to meet both of its primary efficacy endpoints. The table on page 4 summarises the primary outcomes of the IN.PACT DEEP trial. On the efficacy endpoint, the drug-eluting balloon was found to be non-inferior, but not superior, to angioplasty. Zeller said: "In terms of primary efficacy, there was no difference in late lumen loss at 12 months, based on angiography, and there was no significant difference in terms of target lesion revascularisation. The results were pretty low in both cohorts. In terms of safety, the non-inferiority margin was met for the composite endpoint; however, there was a trend towards more major amputations in the drug-eluting balloon cohort."

In conclusion, Zeller said that outcomes in the standard percutaneous transluminal angioplasty group were "significantly better than expected." He also commented that the results from this trial were "confirmed with multivariate analysis, and no subgroup was found to have a significantly improved risk/benefit outcome."

He continued, "These findings are limited to a below-the-knee critical limb ischaemia indication and to the IN.PACT Amphirion drug-eluting balloon. Existing randomised clinical trial evidence supports the safety and efficacy of drug-eluting balloons for superficial femoral artery disease in claudication and rest pain."

Other studies show different results

Smaller investigator driven studies of the IN.PACT Amphirion drug-eluting balloon, such as the DEBATE BTK study, also presented at LINC, have shown positive outcomes for the device. When asked the question of why the difference in outcomes, Iris Baumgartner (Inselspital Universitym of Bern, Bern, Switzerland), member of the Steering Committee of the trial, said: "I think we were too ambitious enrolling all comers and there are so many co-factors that we probably missed. In smaller trials, we are more selective with patients. Including all types of patients with critical limb

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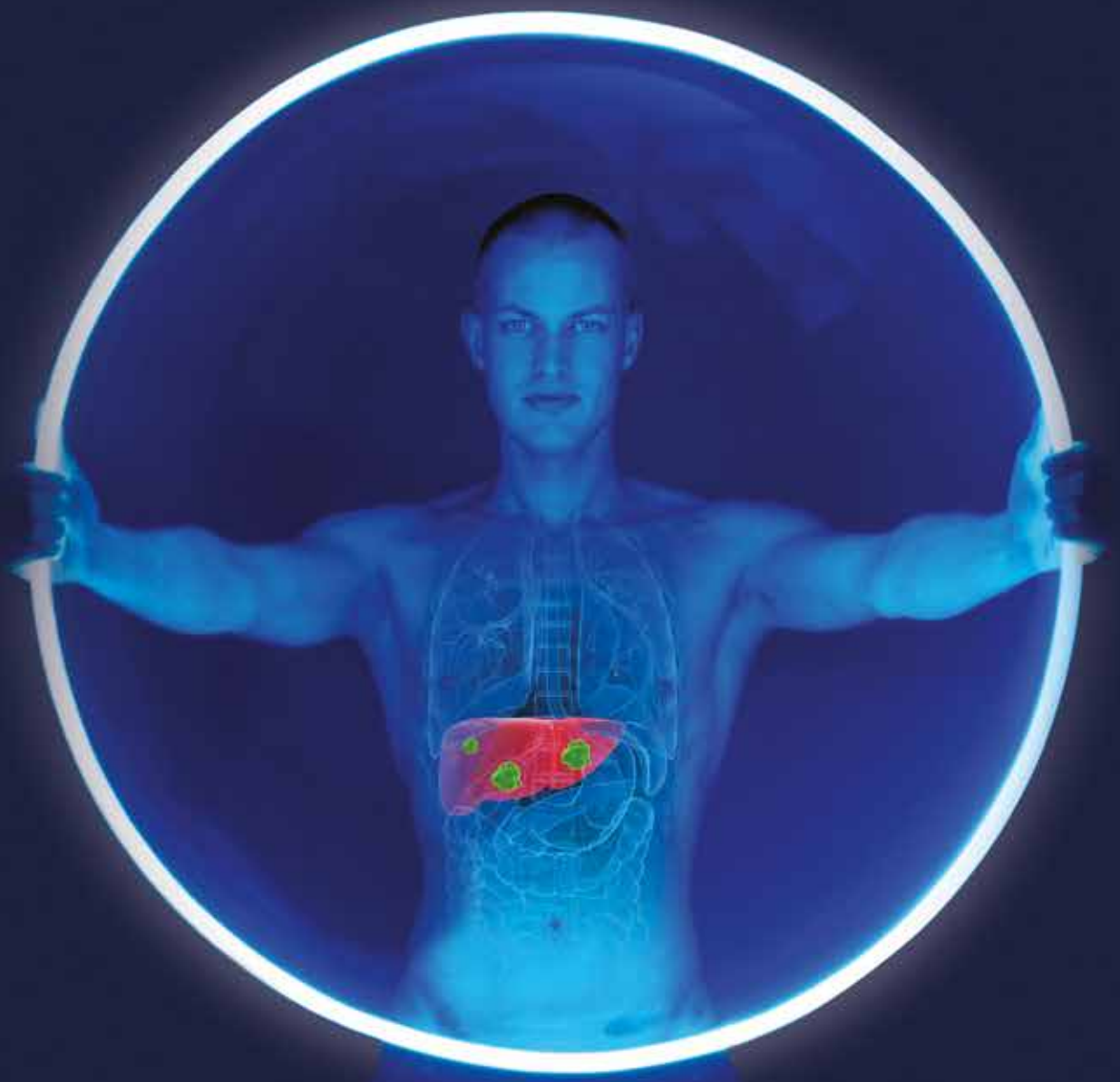

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Sustained reduction in reintervention with IN.PACT Pacific in the superficial femoral artery

Two-year data from the PACIFIER trial, presented at the Leipzig Interventional Course (LINC; 28–31 January, Leipzig, Germany) show that the reduction in target lesion revascularisation and major adverse events observed with the IN.PACT Pacific drug-coated balloon (Medtronic) in the femoropopliteal segment is sustained

Michael Werk (Department of Radiology of the Martin Luther Hospital, Hubertus-Hospital, Berlin, Germany) reported that the PACIFIER study was a proof-of-concept trial that was designed to demonstrate the efficacy of the IN.PACT Pacific drug-coated balloon in reducing restenosis of femoropopliteal stenosis and occlusions compared with standard percutaneous transluminal angioplasty with uncoated balloons.

PACIFIER is an investigator initiated, multicentre study in which patients were randomised in a one-to-one fashion to receive either the IN.PACT Pacific balloon (41 patients; 44 lesions) or standard angioplasty (44 patients; 47 lesions). The primary endpoint was six-month late lumen loss.

At six months, the late lumen loss was -0.01mm in the drug-coated balloon arm and 0.65mm in the standard angioplasty arm (p=0.0014). Werk commented:

Michael Werk

"The significant reduction of late lumen loss was maintained in the three subgroups: restenotic vs. *de novo* lesions; total occlusions vs. stenoses; and long vs. short lesions." Furthermore, there were three cases of target lesion revascularisation reported with the IN.PACT Pacific balloon at six months but 10 reported for standard angioplasty; also while there were no further cases of target lesion revascularisation reported for the device at the 12-month follow-up point, five additional cases were reported for standard angioplasty.

However, at two years, the rate of freedom from target lesion revascularisation was not significantly different between the two groups—84.7% for the IN.PACT Pacific balloon vs. 68.7% for standard percutaneous transluminal angioplasty (p=0.0689). Werk said: "The study was designed as a proof-of-concept, which meant that patients in the standard angioplasty arm who required re-intervention were able to receive the IN.PACT Pacific balloon. This made proving increased efficacy with the device at two years difficult; therefore, this may be why the two-year result just missed significance."

He concluded: "A sustained reduction in major adverse events and target lesion revascularisation was observed with the IN.PACT Pacific balloon vs. standard angioplasty at two years. The rates of 16.7% target lesion revascularisation with the IN.PACT Pacific balloon are consistent with previously reported literature for drug-coated balloon outcomes at two years. Perhaps most important of all, there were no coating-related adverse events noted."

Randomised controlled trial shows negative results for drug-eluting balloon below the knee

Continued from page 2

ischaemia might have diluted the results."

Based on the findings of IN.PACT DEEP, Medtronic voluntarily withdrew the IN.PACT Amphirion drug-eluting balloon from all markets worldwide in November 2013. All of the company's other drug-eluting balloons remain on the market in countries where they have been approved. Multiple studies support positive, consistent outcomes for IN.PACT drug-eluting balloon therapy in the femoropopliteal arteries.

Interventional News spoke to Zeller on the results of IN.PACT DEEP.

Has a possible cause for the negative results of IN.PACT DEEP been established?

The reason for the failure is a lack of biological effect of the IN.PACT Amphirion drug-eluting balloon in this study. However, nobody knows yet what the reason for this phenomenon is. Is it an unstable coating technology specific for this particular balloon resulting in significant loss of drug from the balloon surface before the balloon gets in contact with the vessel wall or is it a specific feature of the vessel wall of tibial arteries?

The efficacy endpoint defined as late lumen loss at 12 months determined by angiography failed. The outcome was that there was absolutely no biological effect of the drug found because lumen loss was absolutely identical in the drug-eluting balloon cohort and in the angioplasty cohort. It was about 0.6mm, which is pretty good for a plain balloon angiographic cohort. It seems as though the drug did not penetrate into the vessel wall to create any biological effect in reducing neointimal hyperplasia. Why has this happened? We do not know. It is completely at odds to previous single-centre trials, where the same balloon technology was used. The investigators in those two trials (Leipzig DEB registry, Schmidt *et al* and DEBATE BTK, Liistro *et al*) found a significant reduction in restenosis rate and late lumen loss. Another important issue is the safety endpoint at six months. This was a non-inferiority endpoint and non-inferiority was met, meaning that there was no significant difference in both study cohorts; however, there was a trend to major amputation rate in the drug-eluting balloon cohort. Now again, it is difficult to understand why this happened.

Considering the results of this trial, what are your views on using drug-eluting balloons in this patient population?

The outcome of the IN.PACT DEEP trial is somewhat opposite to my personal, subjective experience with the use of drug-eluting balloons. The study outcome is specific for a particular drug-eluting balloon, the IN.PACT Amphirion, and cannot be translated to other drug-eluting balloon types. There is no class effect.

What is the future of drug-eluting balloons in this patient population?

The next steps would be to evaluate other drug-coating technologies in terms of safety and efficacy below the knee as has already been done in the superficial femoral artery where almost all the different coatings have shown efficacy and also safety. There have been no reports of major amputations following the use of drug-eluting balloons in the superficial femoral artery.

Each device needs to be specifically tested for this indication. However, before starting another clinical endpoint-driven randomised controlled trial, each single device should be tested regarding its biological efficacy in a pilot trial only including lesions in patients without wounds (Rutherford 2-4).

So we have two further projects: one is to evaluate alternative coating technologies in terms of efficacy, and we have to look for efficacy in terms of reducing restenosis rate or late lumen loss with other coatings in the drug-eluting balloon. If technical efficacy could be shown, the next step is to go again into a clinical endpoint driven study considering what might be the better endpoints for such a trial, besides amputation.

Primary IN.PACT DEEP outcomes

	Drug-eluting balloon	Plain angioplasty	p value
Primary efficacy at 12 months			
Clinically driven TLR*	9.2% (18/196)	13.1% (14/107)	0.291
Late lumen loss (mm)	0.61±0.78	0.62±0.78	0.950
Primary safety at six months			
All-cause mortality, major amputation or clinically driven TLR*	17.7% (41/232)	15.8% (18/114)	0.021 (non-inferiority)/0.662 (superiority)
All-cause mortality	10.1% (23/227)	8.1% (9/111)	0.551
Major amputation	8.8% (20/227)	3.6% (4/111)	0.080

*TLR = target lesion revascularisation

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Haemodynamic depression associated with a higher number of new ischaemic brain lesions after carotid artery stenting

In patients treated with carotid artery stenting, periprocedural haemodynamic depression is associated with an excess of new ischaemic lesions on diffusion-weighted imaging, the randomised International Carotid Stenting Study (ICSS)-MRI substudy has concluded. The findings were published in the January 2014 issue of *Stroke*

Haemodynamic depression was defined as periprocedural bradycardia, asystole, or hypotension requiring treatment.

Aysun Altinbas,from the Department of Neurology and Neurosurgery, Brain Center Rudolf Magnus, University Medical Center Utrecht, Utrecht, The Netherlands, and colleagues write that carotid artery stenting "is associated with a higher risk of both haemodynamic depression and new ischaemic brain lesions on diffusion-weighted imaging (DWI) than carotid endarterectomy." In this substudy, they assessed whether there is an association between haemodynamic depression and new lesions in patients with symptomatic carotid stenosis treated by stenting or endarterectomy.

The number and total volume of new ischaemic lesions on DWI one to three days after carotid stenting or endarterectomy was measured in the ICSS-MRI substudy. The number of new ischaemic lesions was the primary outcome measure. The investigators calculated risk ratios and 95% confidence intervals per treatment with Poisson regression comparing the number of lesions in patients with or without haemodynamic depression.

A total of 229 patients were included (122 allocated to carotid stenting and 107 to endarterectomy). Fifteen patients (12%) treated with stenting and nine (8%) treated with endarterectomy had haemodynamic depression requiring treatment.

In both patient groups, there was no difference in the proportion of patients with ≥1 new DWI lesion between patients who had haemodynamic depression compared with those without haemodynamic depression.

After stenting, patients with haemodynamic depression had a mean of 13 new DWI lesions, compared with a mean of four in those without haemodynamic depression (risk ratio, 3.36; 95% confidence interval, 1.73–6.50).

The occurrence of haemodynamic depression had no effect on lesion count after endarterectomy.

"We found that in patients who were treated by carotid artery stenting, the occurrence of periprocedural haemodynamic depression was associated with a >3 times higher number of new ischaemic brain lesions on DWI compared with patients without this complication. This effect was not observed in patients who had haemodynamic depression after endarterectomy," the authors write. They add that "this finding suggests that avoidance of periprocedural hypotension and bradycardia may reduce the risk of DWI lesions occurring during carotid artery stenting."

Recruitment problems prompt change in SPACE-2 protocol

The protocol of the ongoing SPACE-2 (Stent-protected angioplasty in asymptomatic carotid stenosis vs. endarterectomy) study has recently changed from a three-arm design to a double two-arm design (SPACE-2A and 2B). Study investigator Gustav Fraedrich (director of the University Clinic of Vascular Surgery, University Hospital Innsbruck, Innsbruck, Austria) spoke to *Interventional News* to about the reasons for the change

What are the objectives of the SPACE-2 study?

The aim of the SPACE-2 study is to assess if best medical therapy plus intervention (carotid endarterectomy or carotid stenting) in patients with asymptomatic carotid stenosis is superior to best medical therapy alone. A secondary endpoint will be to compare carotid stenting with carotid endarterectomy.

Initially, SPACE-2 was a designed as a three-arm study in which patients would be randomised to receive best medical therapy alone, best medical therapy plus carotid endarterectomy, or best medical therapy plus carotid stenting. However, in the new two-arm protocol, patients are randomised to receive best medical therapy alone or best medical therapy plus intervention (carotid endarterectomy or carotid stenting).

Why has the protocol of the study changed?

It was very difficult to communicate the three-arm nature of the study to patients and, also, we had to exclude centres that were not able to offer both stenting and endarterectomy. Now in this two-arm study, centres that only offer one of these interventions can participate and it is easier for patients to understand the choices available to them (best medical therapy or intervention) and give their consent to be randomised.

What is the best medical therapy being used in the study?

A combination of antiplatelets, antihypertensives, and statins, but it can be individualised for the patient. If the concept of what constitutes "best medical therapy" changes, the best medical therapy will be changed in both arms as one is best medical therapy alone and the other is best medical therapy plus intervention.

What is the recruitment target for the study?

We need to recruit 3,600 patients and at the moment (after more than two years), we have 400 enrolled. We hope that the recruitment process will be faster now that we have changed the protocol.

What is the follow-up period?

As the rate of stroke is less than 1% per year in asymptomatic patients (treated with best medical therapy alone), the follow-up period needs to be long. Therefore for the primary endpoint (superiority of intervention plus medical therapy vs. medical therapy alone), the follow-up period is five years.

If new centres are interested in being involved in the study, what do they need to offer?

The specialists working at the centre need to be certified, and this means that every interventionalist and every surgeon hoping to be involved in the study needs to have each done 40 documented procedures (carotid stenting or carotid endarterectomy) within the past two years. The information on these procedures is given to the safety committee, who can then certify the interventionalist or surgeon.

Pitavastatin reduces frequency of periprocedural ischaemic complications with carotid stenting

According to the results of a study titled "Effect of pitavastatin on preventing ischaemic complications with carotid artery stenting" (EPOCH-CAS), pretreatment with pitavastatin significantly reduces the frequency of periprocedural ischaemic complications with carotid artery stenting. The findings of EPOCH-CAS were published in *Cardiovascular and Interventional Radiology* in December 2013.


Katsutoshi Takayama

The researchers divided patients with carotid stenosis (symptomatic ≥50%, asymptomatic ≥80%) and at high risk of requiring endarterectomy, but without previous statin treatment, into two groups by low-density lipoprotein cholesterol level. According to Katsutoshi Takayama, department of Radiology and Interventional Neuroradiology, Ishinkai General Hospital, Japan, and colleagues, patients with low-density lipoprotein cholesterol levels (≥120mg/dl) were placed in the pitavastatin-treated group and received 4mg/day of pitavastatin. Those patients with low-density lipoprotein cholesterol levels ≤120mg/dl were included in the group not treated by pitavastatin and received no statin therapy.

After four weeks, both groups underwent carotid artery stenting. Frequencies of new ipsilateral ischaemic lesions on diffusion-weighted imaging within 72 hours of the procedure and cerebrovascular events (transient ischaemic attack, stroke or death) within 30 days were assessed.

Among 80 patients enrolled, 61 patients fulfilled the inclusion criteria. Thirty one of these patients were included in the pitavastatin-treated group and 30 were included in the group not treated by pitavastatin. New ipsilateral ischaemic lesions were identified in eight patients (25.8%) in the pitavastatin-treated group and in 16 patients (53.3%) in the group not treated by pitavastatin. Cerebrovascular events did not occur in any patients in the pitavastatin-treated group. There were cerebrovascular events in three patients (10%) in the non-pitavastatin-treated group.

Multivariate analyses demonstrated the pitavastatin treatment to be an independent factor for decreasing post-carotid artery stenting lesions. The authors conclude that pretreatment with pitavastatin significantly reduced the frequency of periprocedural ischaemic complications with carotid artery stenting.

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* Werk et al. Paclitaxel-Coated Balloons Reduce Restenosis After Femoro-Popliteal Angioplasty. *Circulation*. 2012;5:831-840.

Innovating for life.

A catheter to curb your appetite?

A retrospective study reports that individuals who underwent embolization of the left gastric artery for gastrointestinal bleeding experienced a 7.9% decrease in body weight, three months after the procedure. Could embolization of the left gastric artery be used in the treatment of obesity?

Results of the study were presented at the annual meeting of the Radiological Society of North America (RSNA) in December 2013.

In the retrospective investigation, conducted at Massachusetts General Hospital in Boston, researchers reviewed the records of patients who underwent transarterial embolization for upper gastrointestinal bleeding.

Senior researcher Rahmi Oklu, assistant professor of Radiology, Harvard Medical School, Boston, USA, told *Interventional News*: "The ghrelin literature is very exciting. Although it would be very convenient to have a single target hormone controlling appetite and satiety, there are probably many other undiscovered hormones, proteins and cell-signalling pathways that mediate food intake. When reading from basic science literature, I realised that ghrelin and probably many other unknown hormones were concentrated in the fundus of the stomach, the location of the left gastric artery distribution. Embolization of the left gastric artery is a routine procedure in interventional radiology. My resident, Andrew Gunn, and I began to look at our institution's database to see whether patients who had their left gastric artery embolized lost weight. One important strength of this approach was that there would be no placebo effect, which is an important issue in prospective weight-control related studies.

"Of the 1,213 patients retrieved from our database, the majority were excluded for a variety of reasons such as embolization performed as part of cancer therapy or simply that weights were not recorded. We evaluated 19 patients in the left gastric artery embolization group and 28 patients in the matched control group. Our results showed that the embolized group demonstrated significant weight loss when compared to the control group. Embolic agents used primarily included coils as well as particles and gelfoam.

"We have teamed up with bariatric medicine at our institution to further investigate our retrospective observations in patients as well as at the molecular level in small and large animals.

"Given the significant morbidity and mortality of bariatric surgical interventions, a minimally invasive bariatric interventional approach could become an option, either as a stand-alone procedure or as a bridging therapy to surgery in extreme obesity cases."

Rahmi Oklu

The researchers found that patients who underwent left gastric artery embolization lost an average of 7.9% of their body weight within three months of the procedure. Weight loss within the control group was 1.2% during the same time frame. The post-procedural weight loss of the experimental group was significantly greater than that observed in the control group (p=0.001).

Oklu also pointed out that left gastric artery embolization performed by an interventional radiologist is low risk when compared to more invasive weight loss interventions, such as gastric bypass and laparoscopic approaches. "The effect of left gastric artery embolization will need to be studied in larger populations and eventually in prospective trials," he adds.

Gastric embolization: Is the excitement warranted or premature?

GARY SISKIN

COMMENT & ANALYSIS

There is a lot of excitement within interventional radiology surrounding the potential role of gastric embolization as a treatment option for morbidly obese individuals. Is this excitement justified, or far too early? In my opinion, the answer is both, writes Gary Siskin

Obesity is a significant worldwide public health problem in the USA. The prevalence of adults who are overweight is estimated at >1.6 billion with >400 million considered obese.[1] The World Health Organization predicts that >2.3 billion adults will be overweight and >700 million individuals will be obese worldwide by 2015.[2] The hormone ghrelin, which is produced in the mucosa of the gastric fundus, may be one factor involved in the development of obesity. Ghrelin is a powerful appetite stimulant that is produced in response to hunger. Specifically, it stimulates food intake, gastric acid secretion, and gastric motility, while inhibiting gastric emptying.[3]

Management of obesity is considered essential in order to reduce the incidence of comorbid conditions such as type 2 diabetes, hypertension, and sleep apnoea among others. While lifestyle management and medical therapy are commonly used as initial treatments for obesity, bariatric surgery is considered an effective treatment for morbid obesity. However, many patients are considered high-risk for surgery and while laparoscopic techniques have reduced this number, many patients are still not considered appropriate candidates for surgery. Therefore, there is a gap that leaves many patients without a treatment option beyond lifestyle management and medical therapy.

Since the 1970s, embolization has been employed in the upper gastrointestinal tract as a treatment option for patients experiencing significant upper gastrointestinal bleeding. This procedure controls bleeding with only a minimal risk of ischaemic complications due to the foregut's rich collateral blood supply.[4]

With this background in mind, it has been suggested that embolizing the left gastric artery, which is the principal supply to the gastric fundus, has been proposed to reduce ghrelin levels and potentially affect weight loss.

Four preclinical studies have been performed, providing the background for the excitement surrounding this procedure.

Arepally *et al* initially reported data on this procedure in 2007 and followed this up with an additional study one year later.[5,6] These studies embolized the vascular supply of the gastric fundus in swine using sodium morrhuate. They found that the architecture of the stomach was preserved and that there was decreased ghrelin content in the stomach. In addition, they found that the embolized swine experienced less weight gain than the control animals. More recently, Bawudun and others reported the results of a similar study in dogs after using either a sclerosant (bleomycin and lipiodol) or polyvinyl alcohol particles (500–700 microns).[7] They found more pronounced decreases in ghrelin levels and weight in animals embolized with polyvinyl alcohol and a greater incidence of non-target embolization when a sclerosant was used. In 2013, Paxton and team used 40 micron particles for embolization and also observed weight loss in the embolized animals but they also observed ulcers, gastritis, and oesophageal strictures in treated animals.[8] These four studies clearly highlight the potential risks and benefits of gastric artery embolization.

In March 2013, the results of a first-in-man study, performed by Kipshidze, *et al*. in Tblisi, Georgia, were presented.[9] These authors performed left gastric artery embolization in five patients using BeadBlock microspheres (300–500 microns, BTG). Weight loss was observed in all patients at one month follow-up. The mean initial weight decreased from 128kg to 114kg, and the mean initial body mass index decreased from 42.3 to 37.9. No complications

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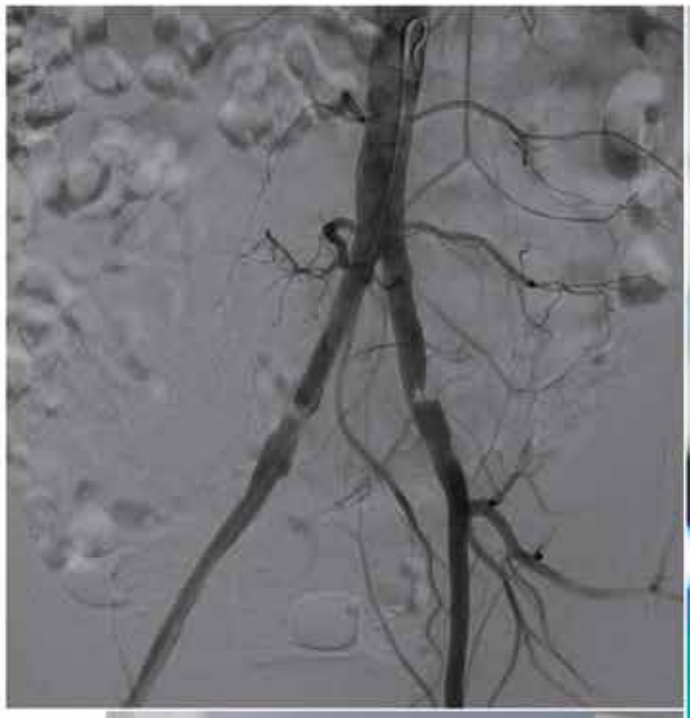

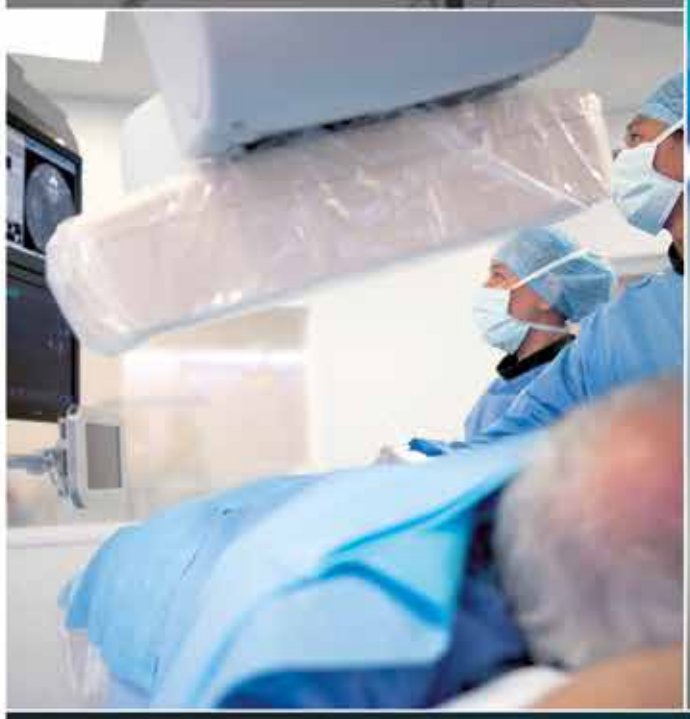

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“The introduction of angioplasty was the beginning of interventional radiology as we know it”

In the historic 50th anniversary year of the first angioplasty performed by Charles Dotter in 1964, Duncan Ettles, consultant Radiologist Hull and East Yorkshire Hospitals NHS Trust, honorary clinical professor in Radiology University of Hull, and president of the British Society of Interventional Radiology (BSIR), tells *Interventional News* how angioplasty is still the technique that underpins so many procedures undertaken by interventional radiologists. “Angioplasty was the simple spark that has evolved in to a wide armamentarium of techniques that can be used in the vascular tree,” he says

“Angioplasty is the fundamental technique that underpins a lot of what we do in interventional radiology. With regard to the use of balloon angioplasty, when Charles Dotter went from using catheters from their original diagnostic use to demonstrating that they could be tools for therapeutic intervention, this was really the birth of interventional radiology as we now know it. The genesis of angioplasty led to all of the other things that we recognise in modern interventional therapy. As it stands 50 years later, the technique has broad applications in terms of peripheral vascular disease and has fundamentally altered the treatment of aortoiliac disease (with or without stenting) and the interventional treatment of critical limb ischaemia. In the UK, critical limb ischaemia has been flagged up as a very important disease entity and there is currently a major focus on raising awareness of the condition and developing strategies to reduce amputation rates.

A recent calculation has suggested that some 50 million angioplasties in all have been performed since that first angioplasty in 1964, which is a pretty impressive total. So it still has a very important place, but is clearly also supplemented by many additional techniques including stenting and more recently, the use of drug-eluting technology.

When we talk about advanced angioplasty, and that would involve stenting, territories in which it is widely used would include the carotid vessels and increasingly the visceral arteries as well. The use of angioplasty and stenting has then morphed to primary stenting and the use of covered stents with further evolution culminating in the introduction of abdominal and thoracic endovascular aneurysm repair.

So angioplasty was the simple spark that allowed the evolution of a wide armamentarium of techniques that can be used in the vascular tree. Whereas, in the beginning, we could only treat large vessels, because of the progressive miniaturisation of devices, we can now treat virtually any vascular territories down to vessels that are less than 2mm in diameter. The scope of treatment has come to involve vascular territories that previously could not be considered for intervention. It is also important to remember that non-vascular intervention such as hepatobiliary work, vertebroplasty and some types of interventional oncology share many of these basic techniques. They are also continuing to rapidly expand and increase treatment options in modern healthcare

What we know about angioplasty:

- We know that angioplasty is a procedure with a high technical success, high efficacy, and low complications rate.
- We understand that the use of angioplasty in certain arterial locations is better than in others and we know that restenosis remains a major problem after the technique.
- We know that angioplasty is a technique that continues to evolve, and we have seen significant technical developments such as the use of drug-eluting balloons and drug-eluting stents.

Duncan Ettles

Research questions that still remain

We still do not completely understand the best strategies to deal with restenosis. We have tackled this problem using mechanical devices, such as stents, but we know that there are also problems with in-stent restenosis. Over the years, we have seen attempts to use other methods, such as cryotherapy, to address this issue. However, restenosis remains the Achilles’ heel of endovascular intervention and we need to know more about the fundamental cellular responses of different arteries to angioplasty. The fact that all arterial beds do not react in the same way means that there are more complex responses taking place than we still understand.

Secondly, what we have struggled to understand is the best patient selection for the procedure, and at the end of the day, it is selecting the appropriate patients for a given treatment that will offer the best guarantee of success. A proportion of the failures that result from angioplasty, and/or stenting, undoubtedly relate to inappropriate patient selection.

Plain old balloon angioplasty vs. drug-elution

There are certain indications and applications for which plain old balloon angioplasty seems to work very well, but in other areas, there is increasing evidence to suggest that the use of additional devices, and more recently, the use of drug-eluting balloons and drug-eluting stents may improve patency and clinical outcomes. However, as yet, we do not have the definitive randomised information with large enough numbers of patients to confirm that these strategies offer a long-term improvement in patient outcomes. Further research will determine whether the improved short-term patency data translates into improved long-term clinical success rates.

In many respects , we still do not understand what the optimum angioplasty technique is and there are fundamental aspects of the procedure that have never been clearly established ,such as selection of the appropriate balloon size; inflation times and the best medical therapy after the procedure. Most operators will work along broadly similar lines, but there are important differences in practice over what constitutes an angioplasty. That may be one of the contributing reasons why different trials have different outcomes when measuring the effects of angioplasty as there are many potential variables. In my opinion, the different basic principles of these techniques are still incompletely understood.

There is a bit of a post code lottery when it comes to critical limb ischaemia

The introduction of interventional radiology techniques has saved countless lives and countless limbs. It is incredibly important that we continue to push minimally invasive intervention, particularly for patients who present with critical limb ischaemia, where we can make a big impact in trying to reduce amputation rates.

This is something that is currently exercising the attention not only of clinicians but many others including an All Party Parliamentary Group which has flagged up the importance of providing adequate services for vascular disease. This is an extremely important area where we must strive to improve the provision of interventional radiology services and have enough trained people to actually cope with the workload. So our objectives are to continue to develop and optimise the best treatment strategies, and strive to improve the provision of interventional services. Looking across the UK, there is evidence to confirm that services are not uniform. There is a bit of a post-code lottery for patients with critical limb ischaemia. One important contributor to this problem is that patients may be referred too late from primary care at a stage when the window of opportunity for endovascular treatment may have been missed. We still have a lot to do to educate the wider medical body and publicise the important role that interventional radiology has in potentially reducing rates of amputations.

What does interventional radiology need to do to survive another 50 years?

I think there needs to be continuing development in training curricula, and this is taking place. As interventional radiology continues to evolve as a specialty, it may be that the old model of interventional radiologist coming from diagnostic radiology and then taking up intervention as a subspecialty needs to change to a more focused approach to training in intervention right from the start. What is most important is that proper training is undertaken and we have to ensure that the highest standards of training are met. In the years to come, it may be that there are different pathways and structures of training for that. At the moment there is a very clear pathway for training through the Royal College of Radiologists with the guidance of the BSIR as a special interest group.

We also need an increase in the number of interventional radiologists who are undertaking these procedures. We know from recently conducted national surveys that we are probably deficient to the tune of about 200–250 consultant interventional radiologists in England in order to preserve the joined up 24/7 services that we would all like to see.

Interventional radiologists also must continue to be engaged clinically, that is fundamentally important for further development of the specialty and to ensure the highest standards of clinical care

Plans for the BSIR

Today, the BSIR is a society that engages with multiple other regulatory bodies to comment on and provide guidance with regard to policy development in healthcare. We have seen a major evolution in the management of conditions such as obstetric haemorrhage and gastrointestinal haemorrhage that are now managed using interventional radiology, but we have to keep pushing to ensure that we provide modern interventional care to patients right across the country. One of my major commitments as BSIR president is to continue to make the case for a significant increase in the numbers of interventional radiologists training in the UK and to change the training syllabus to reflect a more clinically-based specialty.

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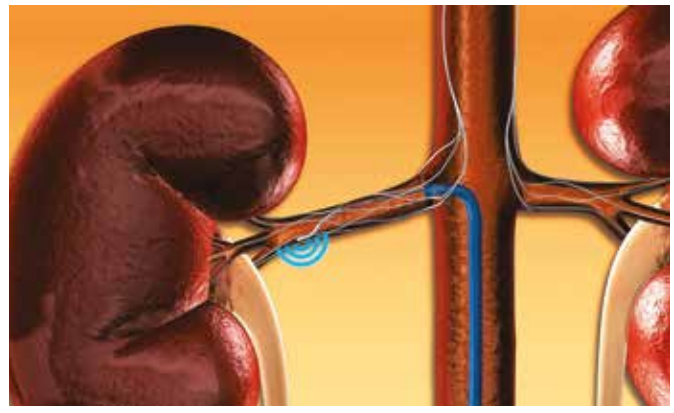
Renal denervation hits SYMPLICITY HTN-3 evidence roadblock

Medtronic has announced that the first sham controlled study of renal denervation— SYMPLICITY HTN-3—did not meet its primary efficacy endpoint of significantly reducing blood pressure in patients with severe resistant hypertension and systolic blood pressure of ≥160mmHg. The company has revealed plans to suspend enrolment in three ongoing regulatory approval trials pending a review of SYMPLICITY HTN-3's findings. Both Covidien and St Jude Medical have also announced plans to halt existing trials with the former exiting its OneShot renal denervation programme completely



Symplicity

Medtronic has stated that it will continue to provide access to the Symplicity technology in all markets where it is currently available and continue the Global SYMPLICITY post-market surveillance registry and renal denervation studies evaluating other non-hypertension indications trial programme. The company is convening a panel of independent advisors to help review the HTN-3 data and the hypertension programme. The full data of Symplicity HTN-3 is scheduled to be presented at 2014 American College of Cardiology scientific sessions (29–31 March, Washington DC, USA).

In SYMPLICITY HTN-3, 535 patients (at 87 US medical centres) with treatment-resistant hypertension and systolic blood pressures of ≥160mmHg were randomised to one of three groups—two renal denervation groups and one sham procedure group. The primary efficacy endpoint was the change in office blood pressure from baseline to six months and the primary safety endpoint was incidence of major adverse events. Although the safety endpoint was met, the efficacy endpoint was not.

Pending the independent review, the company has said it plans to suspend enrolment in the three countries where renal denervation hypertension trials are being conducted for regulatory approvals (SYMPLICITY HTN-4 in the USA, HTN-Japan and HTN-India).

Rick Kuntz, chief medical officer at Medtronic, said: "We believe this course of action is the most prudent and will help us thoroughly evaluate these findings and determine the appropriate next steps for renal denervation therapy."

George Bakris, co-principal investigator of SYMPLICITY HTN-3 and professor of Medicine and director of the ASH Comprehensive Hypertension Center, University of Chicago Medicine, Chicago, USA, noted: "This [SYMPLICITY HTN-3] is the most rigorous renal denervation clinical trial conducted to date, and the first of its kind to include a sham control group. We look forward to advancing these data into the peer-review process."

Melvin Lobo

Wait for full results

Marc Sapoval, professor of clinical radiology and chair of the Interventional Radiology department, Hôpital Européen Georges-Pompidou, Paris, France, and principal investigator of the French DenerHTN randomised controlled trial (Co-principal investigator is Michel Azizi) told *Interventional News*: "The interventional community should not to leap to any conclusions before the results are fully published. We are waiting for the appropriate numbers and relevant information (p values, sub-group analysis, the workflow of patients, the exact number of patients in the denervation group who underwent successful denervation and other important information such as medical treatment). If these findings are confirmed in more detail with the publication of the paper, then this should lead to increased caution when using denervation outside of properly designed clinical trials."

Sapoval also stated that all companies in the field must now be fully conscious of the need for a randomised controlled trial. "This is absolutely mandatory. The French randomised controlled trial, DenerHTN, has completed its recruitment and six months of follow-up with a primary end point on ambulatory blood pressure monitoring, and this data will soon be available," he said.

Melvin Lobo (consultant physician, NIHR Barts Cardiovascular Biomedical Research Unit, William Harvey Research Institute, QMUL, London, UK) also agreed that the full results of SYMPLICITY HTN-3 are necessary to understand why the study failed. "Critical analysis of the full dataset and study design are now imperative," he said. While he does not believe SYMPLICITY HTN-3 spells the end of renal denervation, Lobo does see it as a "major setback" and predicts that other device manufacturers can expect a much tougher climate in which to launch their technologies. He added: "This is probably a good thing given that a number of devices have been CE marked on the basis of weak first-in-man studies with little supportive data to suggest true efficacy in rigorously screened patients with true resistant hypertension and a striking paucity of randomised controlled trials."

Beyond radiofrequency: Technologies in the renal denervation arena

GERARD S GOH

COMMENT & ANALYSIS

The six-month results of the SYMPLICITY HTN-3 trial, when released, will raise much debate over the efficacy of renal denervation using radiofrequency ablation. Several companies have reiterated their commitment to running randomised trials with a sham arm to gather more evidence. Whilst there are other technologies and approaches for renal denervation, any technology still needs to be proven in large trials, writes Gerard S Goh

Ultrasound

Recor Medical's Paradise device is a balloon-based catheter that delivers targeted ultrasound waves in a circumferential manner within the renal artery lumen. Once positioned, the balloon is inflated to achieve catheter stability and the ultrasound transducer is activated. The device is cooled internally with saline circulated by the generator. Ablation times are 30 seconds per treatment, two treatments are recommended per renal artery. The latest generation of device achieves ultrasound ablation in 10 seconds per treatment.

Cardiosonic has created the TIVUS catheter, a 0.014" over the wire catheter that has three separate ultrasound transducers mounted on a catheter with an expandable basket-like configuration. The basket, when expanded, aids the positioning of the catheter within the lumen of the renal artery to ensure the ultrasound probes do not come in contact with the wall of the artery. Once positioned within the lumen, targeted ultrasound waves are produced that perform an ultrasound ablation of the renal nerves.

The Kona Medical SurroundSound system is a high intensity focused ultrasound device that externally delivers targeted ultrasound waves in a non-invasive manner. Currently, the procedure is not entirely non-invasive as targeting of the renal artery does require the placement of a targeting catheter within the renal artery via an endoluminal approach. Trials are currently running that use an

Continued on page 14

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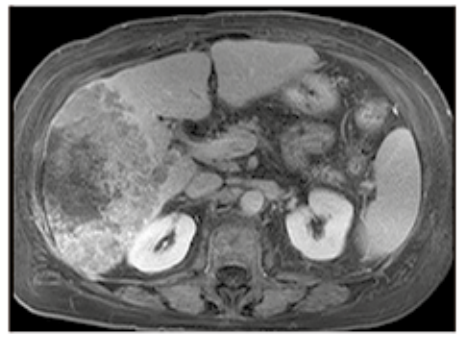
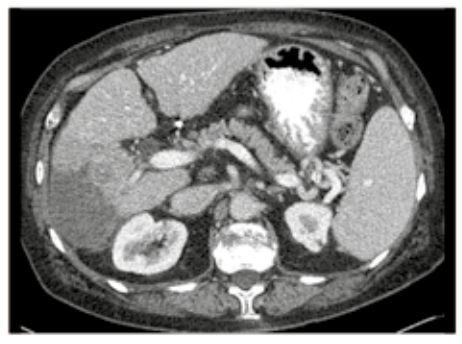


HCC Tumour



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Sato KT, et al. Treatment of Unresectable Primary and Metastatic Liver Cancer with Yttrium-90 Microspheres (TheraSphere™): Assessment of Hepatic Arterial Embolization. Cardiovascular and Interventional Radiology. 2006; 29:522-529.

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1 Refers to high specific activity
2 Hilgard P, Hamami M, Fouly AE, et al. Radioembolization with Yttrium-90 Glass Microspheres in Hepatocellular Carcinoma: European Experience on Safety and Long-term Survival. Hepatology. 2010; 52: 1741-1749
3 TheraSphere™ [US Package Insert] Ottawa, ON; Nordion (Canada) Inc. 2011.

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Identifying pre-procedure predictors of success is critical to furthering renal denervation

KRISHNA ROCHA-SINGH

COMMENT & ANALYSIS

Krishna Rocha-Singh writes about the important factors that need further analysis surrounding the SYMPLICITY HTN trials and renal denervation

I, like many others, am keen to understand why the US pivotal randomised sham controlled SYMPLICITY HTN-3 trial failed to meet its primary effectiveness endpoint. Given the established treatment effect from the SYMPLICITY HTN-1 and HTN-2 trials, I want to know if the failure was due to differences in trial design, patient cohort selection, the catheters used, operator experience or the introduction of a sham arm.

If the introduction of a sham arm resulted in the failure of SYMPLICITY HTN-3, I would like to know more about the veracity of the maintenance of the sham through the entirety of six months prior to and including the primary endpoint analysis. It would also be interesting to understand the duration of the sham effect beyond the six-month primary endpoint assessment.

Is there a class effect?

I would like to know, regardless of the issues of trial design and potential differences in cohorts enrolled in renal denervation trials, whether there is a "class effect" between use of monopolar radiofrequency, bipolar radiofrequency and ultrasound thermal energy sources. Translational medicine models using pigs and human cadaver renal arteries would suggest that a depth of thermal penetration up to 4mm from the renal intima should ablate a sufficient number of renal efferent and afferent nerves, which should translate into a clinical benefit. However, given the ongoing concern of "non-responders" to the mono-polar radiofrequency therapy, it has to be considered whether another energy source (ie, bipolar radiofrequency or ultrasound) may provide deeper or more homogeneous penetration of ablative thermal energy and thereby ablate a larger number of renal nerves which may result in a blood pressure effect. Of course, this issue must be balanced by safety as thermal energy which reaches deeper into the renal vessel wall may also be associated with intimal damage as well.

From my experience…

I know the identification of pre-procedure predictors, beyond simply severe treatment resistant hypertension (>180 mmHg on ≥ 3 anti-hypertensive medication, one being a diuretic) will be critical to the continued growth of the clinical science. This is because there are an apparently growing number of patients deemed "non-responders" (patients who experience <10mmHg reduction in office blood pressure six-month post-denervation) in patients enrolled in single-centre renal denervation registries.

Pre-procedure predictors are especially important because there is no intra-procedural feedback that signals to the operator that a successful and complete anatomic denervation has been performed. This means we must look to potential biomarkers or other surrogates.

Patient referral patterns

Having enrolled patients in both SYMPLICITY HTN-1 and HTN-3, it is my suspicion that the differences in patient referral patterns between the two trials may have resulted in different patient populations selected to undergo renal denervation. In speaking with my European colleagues, I understand that the vast majority of patients referred for renal denervation in both HTN-1 and HTN-2 came from European Society of Hypertension Centres of Excellence that employed a team approach to patient hypertension education and treatment. These patients were essentially "no option" patients in that they had exhausted all pharmacological therapies in treatment of their resistant hypertension and were, importantly, likely on stable and consistent therapy prior to trial enrolment. Importantly, in both HTN-1 and HTN-2, patients were required to be on minimally six weeks of stable therapy ensuring a consistent and stable medication regimen. This is different from the HTN-3 trial where, theoretically, patients could have their medications "up-titrated" in an attempt to "optimise" their medical therapy. Theoretically, this could have selected a very different patient cohort. Importantly, waiting two weeks prior to trial enrolment and subsequent randomisation, as required in SYMPLICITY HTN-3, may have been an insufficient time to fully realise the full pharmacological effect of medication up-titration. This may represent an important variable between these trial designs and has potentially impacted their results.

The role of catheters

Given my experience using the Flex catheter and Arch catheter, I perceive them to be very different in their feel and ability to manipulate in the renal artery. From simple observation, the monopolar electrode appears to be larger on the Arch catheter than the Flex catheter. Additionally, the contact pressure applied by the Arch catheter to the renal intima, in my experience, seemed to be greater and required more facility and caution to avoid potential dissection and spasm. While Medtronic likely performed all appropriate preclinical testing with the two catheters to ensure similar histologic results in a pig model, this may have introduced a potential confounding variable between the SYMPLICITY trials. The impact of the use of these two different catheters may not be resolved unless appropriately powered observational data in similar patient cohorts are examined.

Krishna Rocha Singh is with the Prarie Heart Institute at St John's Hospital, Springfield, Illinois, USA. He is a consultant for Medtronic

Beyond radiofrequency: Technologies in the renal denervation arena

Continued from page 12

external ultrasound probe to perform the targeting instead of the invasive catheter, so making the procedure non-invasive.

Microinfusion and chemical ablation

A balloon-based infusion catheter has been produced by Mercator MedSystems. The Bullfrog micro-infusion device is 0.014" wire compatible and comprises a catheter tipped with a balloon sheathed microneedle. The balloon is inflated in the target region of the artery which inserts the microneedle through the wall of the renal artery. Through this, chemical ablation can be achieved by the injection of various ablative chemicals such as Guanethidine or Vincristine.

Ablative Solution's Perivascular Renal Denervation device uses a catheter with three separate infusion microneedles housed in individual guide tubes. Once deployed, each microneedle perforates the renal artery wall and delivery of chemical ablation can be performed. Ethanol has been used with this catheter. It seems feasible that other ablative chemicals can also be used.

Non-vascular ablation

The Verve Medical device is a non-vascular system that performs ablation of the renal pelvis via a retrograde ureteral approach. Both afferent and efferent nerves are located and intertwined within the layers of the renal pelvic wall. The device is introduced trans-uretherally and guided to the renal pelvis via a retrograde ureteric approach using urological techniques and ablation is performed. Early animal model work and first-in-man results have indicated efficacy and safety in small numbers at this stage.

Other technologies

A carotid baroreceptor stimulator device manufactured by CVRx is the Barostim neo. This device is an implantable device, similar to a pacemaker, within the subcutaneous tissues of the chest that has a lead that is surgically placed on the carotid artery. Activation of the device electrically stimulates the carotid baroreceptors. This causes an increase in parasympathetic and decrease in sympathetic tone, thereby reducing blood pressure.

The ROX medical device is a coupler device that is placed between the iliac artery and vein that creates an arterio-venous fistula. This is a permanent device and the rate of flow is adjustable during implantation. Hypertension is reduced by numerous mechanisms including relieving the arterial pressure directly into the venous system. Should the device no longer be required, it is closed by the covering the opening of the device with a covered stent.

Numerous other technologies are under investigation such as beta radiation, microwave ablation, cryoablation, magnetically charged botox laden particles and intravascular carotid implants.

Clearly there are a number of renal denervation technologies that act in ways different to endovascular radiofrequency ablation. Early results from small first-in-man studies, trials and registries have shown that many of these technologies may be efficacious and safe, but as previously stated, proving the efficacy of the technology in large randomised controlled trials will be necessary.

Gerard S Goh is an interventional radiologist at St George's Healthcare NHS trust, London, UK. He is also an honorary senior lecturer at St George's University of London. He has reported no disclosures pertaining to this article

Leading better patient outcomes—who steps forwards when it is not about devices?

IAIN ROBERTSON

COMMENT & ANALYSIS

Interventional radiologists are always striving for better outcomes. We seek out publications and presentations of new devices and new techniques that offer an improved range of outcomes from more durable patency to improved response rate. We pore over journals and fill conference halls looking for techniques that might make marginal differences to a raft of surrogate outcomes.

We volunteer to learn that new stent graft that can be deployed in 5% more patients. What if the biggest gains for truly improving patient outcomes are much less about specific detailed techniques and much more about behaviours and team-working?

How many interventional radiologists are prepared to spend as much time developing safer and more effective teams as they do on the technical elements of intervention? How many of us feel that our training and skills have equipped us to know where to start improving quality and safety?

If asked to name one element of recently introduced patient safety in interventional radiology, I would guess that the majority would name the WHO surgical safety checklist. It is difficult to imagine a more focused push on a patient safety issue; backed by the WHO, the surgical safety list has been adopted in over 122 countries representing more than 90% of the world's population. Data from pilot studies indicated a 50% reduction in all-cause mortality and a reduction in morbidity of about a third—a truly extraordinary effect. Despite this scale of effect, almost certainly greater than any other interventional paper you will read this year, it proved very difficult to implement the safety list in many centres. Clinicians seemed to miss the message about outcome improvement and were often frustrated at the imposition of a different system or behaviour in their operating room and angiographic suite. In some centres, this meant the checklist was used poorly, or not at all. The effectiveness of adoption of the safety list was critically dependent on the ability of local leaders to be strong advocates and explain, persuade and educate on checklist use and without local persuasive engagement, the risk of failure was much higher.[1] If we do not want safety and quality improvement imposed, how can we get local clinicians engaged and skilled to become the local advocates and build the skills and enthusiasm from the ground up?

In 2012, the British Society of Interventional Radiology (BSIR) working with the Health Foundation and TVC films, produced a patient safety film *The System*. BSIR also developed additional interventional radiology specific material to complement the film and support teams to frame a discussion around key themes such as behaviours and roles. The film follows the journey of a patient with jaundice from initial presentation through a biliary drainage procedure and subsequent complications; focusing on human factors and system errors that contribute to adverse outcomes. The aim is to help teams identify with the story and open up reflection within teams on their local practice. The film was a major success and talking point when displayed at the BSIR conference. It has been used widely and continues to be the most watched video on the BSIR website.

Professional societies can play an important role in driving improvements in safety and quality. They should help bridge the gap between quality improvement structures and the clinician.

Building on the experience of the film, BSIR launched its Safety and Quality group last year: a multidisciplinary group focused on three interlinked areas; quality improvement, patient safety and device safety. The Safety and Quality group is also co-ordinating and developing the BSIR's Quality Improvement Initiative (www.bsir-qi.com), which aims to improve quality and access to interventional radiology services across the UK. The project uses a BSIRQI assessment, which focuses on four key areas: scope of services, 24/7 services, providing good quality care, patient focus and service improvement. A network of exemplar sites has been established and we already have 15 sites established as exemplar sites with several further pilot sites working to improve patient outcomes.

The next area of work for the safety and quality group will be developing a toolkit and guidance for interventional radiology morbidity and mortality meetings. While the majority of sites hold these meetings, the quality of the meetings is variable and identifying the key improvement opportunities requires structure and some core skills. Fortunately, a little like the surgical checklist, we already know how to make morbidity and mortality meetings better based on a standard Situation-Background-Assessment-Recommendation (SBAR) formula and toolkits have already been developed for other specialties such as the Royal College of Anaesthetics. Much of our effort should be in thinking how we can improve the adoption of these techniques.

The challenge for professional societies, conference organisers and individual clinicians is to focus on where greatest improvement in patient outcomes can be achieved. Alluring though they are, that probably is not always in new devices or techniques. We need at least as much leadership in patient safety as we do in new devices and techniques.

Iain Robertson is a consultant interventional radiologist, Greater Glasgow and Clyde, Scotland. He is the immediate past president of the British Society of Interventional Radiology and current chair of the BSIR Safety and Quality Committee. He has reported no disclosures pertaining to this article

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Gastric embolization: Is the excitement warranted or premature?

Continued from page 8

were observed in these patients.

Given the preclinical data and the promising results from an initial clinical study, one cannot help but be excited as to the potential role for gastric embolization as an adjunctive treatment option in patients with morbid obesity. A better understanding of how this procedure leads to hormone reductions and clarity regarding its safety and efficacy are needed. Therefore, well-designed clinical trials are necessary before this procedure can even hope to become part of the daily practice of interventional radiology.

Gary Siskin is professor and chairman, Department of Radiology, Albany Medical College, Albany, USA. He has reported no disclosures pertaining to the article

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Positive results for fully percutaneous EVAR

Endologix has announced the *Journal of Vascular Surgery's* (*JVS*) e-publication of the data from the first prospective, multicentre, randomised clinical trial of a totally percutaneous endovascular aortic aneurysm repair (PEVAR) to endovascular abdominal aortic aneurysm repair (EVAR).

The trial was designed to assess the safety and effectiveness of PEVAR using a 21F endovascular stent graft system and either an 8F or 10F suture-mediated closure system. Nelson *et al*, wrote "Among trained operators, PEVAR with an adjunctive preclose technique using the ProGlide closure device is safe and effective, with minimal access-related complications, and it is non-inferior to standard open femoral exposure. Training, experience, and careful application of the preclose technique are of paramount importance in ensuring successful, sustainable outcomes".

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ULTIMA trial results published in *Circulation*

In patients with pulmonary embolism at intermediate risk, a standardised ultrasound-assisted catheter-directed thrombolysis regimen is superior to anticoagulation with heparin alone in reversing right ventricular dilatation at 24 hours, without an increase in bleeding complications, according to results of the ULTIMA trial

Data from the ULTIMA (Ultrasound accelerated thrombolysis of pulmonary embolism) trial were published in the January 2014 issue of *Circulation*. ULTIMA is a prospective randomised controlled trial of patients with submassive pulmonary embolism treated with either standard of care intravenous anticoagulation or the EKOS EkoSonic Endovascular System (BTG) and rt-PA (Actilyse, Boehringer Ingelheim). EKOS' technology uses ultrasound to accelerate the action of clot-dissolving drugs. Nils Kucher, director of the Venous Thromboembolism Research Group at the University Hospital in Bern, Switzerland, is the lead author and principal investigator of the ULTIMA study.

In the trial, patients treated with the EKOS EkoSonic Endovascular System demonstrated a statistically significant reduction in right heart strain within 24 hours with no adverse effects from the catheterisation, whereas the patients treated only with the anticoagulant heparin showed no significant improvement. In the EKOS group, the mean right ventricle/left ventricle (RV/LV) ratio was reduced from 1.28±0.19 at baseline to 0.99±0.17 at 24 hours ($p<0.001$); in the heparin group, mean RV/LV ratio was 1.20±0.14 and 1.17±0.20, respectively ($p=0.31$). The mean decrease in RV/LV ratio from baseline to 24 hours was 0.30±0.20 vs. 0.03±0.16 ($p<0.001$), respectively. There were no serious bleeding events in either group. There was one death in the non-EKOS group within 90 days for reasons other than pulmonary embolism.

For pulmonary embolism patients at intermediate risk of bad outcomes, the ULTIMA trial demonstrated that EKOS treatment was clinically superior to anticoagulation with heparin alone in reversing right ventricular dilation at 24 hours, without an increase in bleeding complications.

Barry Katzen, medical director, Baptist Cardiac and Vascular Institute, Miami, USA, said, "The outcome and safety data are compelling. This study suggests we should be employing a more aggressive therapeutic approach to these patients with life-threatening pulmonary emboli."

Victor Tapson, professor of Medicine at Cedars-Sinai Medical Center in Los Angeles, USA, commented, "The ULTIMA study targets a patient population that is under-recognised and under-treated. Findings of the study support the role of the EKOS catheter-based technique as a treatment option for these patients in need."

US FDA approves polidocanol injectable foam for varicose veins

The US FDA has approved polidocanol injectable foam (Varithena, BTG) for the treatment of patients with incompetent veins and visible varicosities of the great saphenous vein system.

Varithena is a pharmaceutical-grade, low-nitrogen, polidocanol foam dispensed from a proprietary canister device. In two pivotal, placebo-controlled phase III trials, VANISH-1 and VANISH-2, Varithena achieved a clinically meaningful improvement in the symptoms of superficial venous incompetence and the appearance of visible varicosities and addressed the underlying venous incompetence in the majority of patients treated.

VANISH-1 evaluated the safety and efficacy of a single treatment with Varithena compared with placebo. VANISH-2 allowed for a second optional treatment one week later. The mean baseline great saphenous vein diameter was 7.6mm (range 1.5 to 25.9mm) for patients treated in VANISH-1 and 8.7mm (range 3.1 to 19.4mm) for patients treated in VANISH-2.

In both clinical trials, the primary efficacy endpoint was improvement in patient symptoms as measured by the change from baseline to week eight in the VVSymQ electronic daily diary of varicose vein symptoms. Five patient-reported symptoms were assessed daily and averaged over seven days.

In both VANISH-1 and VANISH-2, treatment with Varithena was significantly superior to placebo in improving symptoms. Significant improvements in appearance were also demonstrated with Varithena compared with placebo, as reported both by patient self-assessment and by physicians in an independent review of photographs ($p<0.0001$ for both measures in VANISH-1 and VANISH-2).

In clinical trials, the most common adverse events (occurring in ≥3% of patients treated with Varithena) were pain/discomfort in extremity, infusion site thrombosis (retained coagulum), injection site haematoma or pain, thrombophlebitis superficial, and extravasation.

Varithena is indicated for a wide range of varicose veins, including incompetent great saphenous vein, accessory saphenous veins and visible varicosities of the great saphenous vein system both above and below the knee.

Complex vena cava filter removal: Much to learn, we still have

WILLIAM T KUO

COMMENT & ANALYSIS

Over the past decade, our knowledge of inferior vena cava filters and filter retrieval has rapidly grown, and we can now help many patients that were previously deemed untreatable, writes William T Kuo

When the United States Food and Drug Administration (FDA) issued an alarming Filter Safety Alert in 2010,[1] it was a wake-up call to the rising epidemic of filter-related morbidity and associated complications. The alert urged all physicians caring for patients with filters to consider removing the filter as soon as protection from pulmonary embolism is no longer needed.[1] However, despite this heightened awareness and improved clinical follow-up, many filters still cannot be removed using standard methods, especially after prolonged implantation.[2] These patients are subjected to all the risks from an indwelling filter and the anxiety of living with a permanent implant.

Over the past decade, our knowledge of inferior vena cava filters and filter retrieval has rapidly grown, and we can now help many patients that were previously deemed untreatable. As we continue exploring the frontier of complex inferior vena cava filter retrieval, how can we further optimise our techniques to achieve the maximum clinical benefit in our patients? To move forward into the future, we must unlearn what we have learned in the past. By convention, we were instructed that retrievable filters could only be removed after a limited window of implantation, required little ongoing maintenance, and could even be used as permanent devices with few consequences. Similarly, we were taught that permanent filters, which had been used for decades, required no routine follow-up. Furthermore, we were convinced that "permanent" filters could not be safely removed percutaneously. Although the medical community has held firmly to these principles, these dogmas are quickly fading; and we must first unlearn them if we wish to begin offering our filter patients the potential benefits of cutting-edge treatment.

Years ago, interventional radiologists began developing a variety of techniques[3–7] to help deal with embedded filters, and once we discovered this new landscape, we began to recognise a growing number of patients suffering from filter-related morbidity and unnecessary indwelling filters. As these challenging cases increased in proportion to rising filter use, we soon exhausted our retrieval methods; and many patients were inadvertently left with a permanent filter with no good explanation. It was a harsh reality that forced us to begin seeing with new eyes, and these patients motivated us to innovate better techniques. As we initiated these pursuits, we began concomitant histologic examinations on retrieved filter specimens.[6,8] All of these studies laid the foundation for advanced tissue ablation. Many patients began travelling vast distances to specialised centres to seek better treatment, and their conditions inspired us to discover photothermal tissue ablation for embedded filter removal. Our first patient treated with laser travelled approximately 2000 miles to reach our centre in Stanford, California; and he became the first human to undergo laser-assisted filter retrieval.[9] At the time, we did not realise the Japanese were experimenting with a similar technique in the canine model,[10] but they were not quite ready to apply their method to humans. However, our prior experience with complex filter retrieval[6,8] in the USA coupled with human histologic data[8] gave us the confidence to proceed with laser tissue ablation in human patients. Based on encouraging preliminary data,[9] we initiated the first-in-man clinical trial on laser-assisted filter retrieval.[11]

We did not realise it, but those years of research were actually preparing us to solve problems that did not yet exist. Sometimes, a problem may go unrecognised or even ignored until there is a solution; and this has been true with embedded and permanent inferior vena cava filters. A patient helped teach us this lesson when she presented with debilitating abdominal pain of unclear aetiology. She had been seen and examined by a number of doctors throughout her life, but no one could explain or alleviate her pain. Many years earlier, she had undergone placement of a permanent inferior vena cava filter; and she was told that it would be safe as a lifelong implant. When she began having pain, the filter was never considered to be a potential source of her symptoms. By the time she presented to us in 2010 with a Titanium Greenfield filter, the device had been embedded for over 18 years. Over time, the filter legs had eroded through her vena cava and penetrated into her duodenum resulting in excruciating pain. If she had presented to us just one year earlier, we would not have been able to treat her; but she arrived to us at just the right time, and she was eager to undergo an experimental procedure. The culmination of our research on filter retrieval and our recent discovery of the laser technique allowed us to percutaneously remove her permanent filter without complication,[11] and we spared her from the morbidity of open surgery. Her pain immediately resolved, and she resumed an active lifestyle for the first time in over a decade. Four years later, the latest results from our ongoing prospective trial have been published.[12] Among the first 100 filter patients treated with laser-assisted removal, success was achieved in 98% with a 3% major complication rate.[12] In our experience, laser-assisted retrieval can be used to alleviate filter-related morbidity, to prevent further risks associated with long-term implantation, and to eliminate the need for filter-related anticoagulation.[12] By removing the obstructing foreign body, the procedure also allows better endovascular treatment of chronic inferior vena cava occlusions to relieve symptomatic venous obstruction. In summary, our preliminary trial data support a new indication for excimer laser use in the venous system to remove a variety of embedded vena cava filters regardless of the dwell time; but more work is needed to refine our protocols in a larger cohort.

What lessons have we learned so far? The safe use of excimer laser requires patience, extensive knowledge of many filter types and their unique characteristics, a deep understanding of venous thromboembolic disease, and a serious commitment to acquiring the proper skills for safe tissue ablation. As a first step, the use of a force gauge is essential[11,12] especially if we are going to teach our colleagues and trainees how much tension is safe to apply before and during tissue ablation. Most interventionalists never realise how little or how much force they are placing on the filter during attempted removal. This is why I insist that all my interventional radiology fellows-in-training handle the force gauge when they are scrubbed with me during our complex retrieval cases. I want these young jedis-in-training to "feel the force" before they can safely wield the lightsabre itself.

The use of excimer laser for filter removal is still under investigation in our ongoing study at Stanford. Although our latest results have been promising in a single centre, the device is not yet FDA-approved for filter removal, and we still need to demonstrate safety across multiple centres. If multicentre studies bear fruition, the procedure could become analogous to laser-assisted pacer lead extraction that is routinely performed everyday around the world.

> ***As a first-step, the use of a force gauge is essential, especially if we are going to teach our colleagues and trainees how much tension is safe to apply. Most interventionalists never realise how little or how much force they are placing on the filter during attempted removal***
> *–William T Kuo*

William T Kuo is associate professor of Vascular and Interventional Radiology, director, Stanford IVC Filter Clinic and director, IR Fellowship Program, Stanford University Medical Center, Stanford, USA. He has reported no disclosures pertaining to the article

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1. Virmani R et. al. Vascular, Downstream, and Pharmacokinetic Responses to Treatment with a Low Dose Drug-Coated Balloon in a Swine Femoral Artery Model *Catheter Cardiovasc Interv.* 2014 Jan 1;83(1): 132-40
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Profile James B Spies

The evolution of embolization over the past decade has been remarkable and it has fundamentally changed our field, James B Spies, professor of Radiology, Georgetown University School of Medicine, Washington DC, USA, and the incoming president of the Society of Interventional Radiology in 2014, tells *Interventional News*. He also highlights the importance of multidisciplinary treatment and multidisciplinary research because "we cannot carry out and ensure quality care in a vacuum"

What drew you to medicine and interventional radiology?

I chose medicine after taking a physiology class in high school, during which I became fascinated with how the body works. I did not really know about interventional radiology until I was an intern. The interventionist in that hospital, John Wok, was doing amazing things even in those days (1980). I was finally sold on it after spending time on interventional at University of California, San Francisco (UCSF) during residency with Ernest Ring and Bob Kerlan. What a great set of role models for our field!

Which procedures in interventional radiology have shaped your career?

Well, since I do mostly uterine embolization, both in clinical practice and in research, that clearly is the first choice. I have loved being a part of the growth of this treatment. It works really well, has a great patient population to engage with and is fun. I would say my interests have broadened over the years and now I am excited about all types of embolization. This whole field has "grown up" during my tenure in medicine and it has been wonderful to be a part of it.

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

Well my first mentors in the field were Ernest Ring and Bob Kerlan, as well as other members of the UCSF group like Anton Pogany. My good friend, Dana Burke, was a year ahead of me in training and he was also a big influence as a friend, mentor and partner. Bob Rosen, who trained me during fellowship, was the other big influence on me early on. He had a great low-key style, outstanding skills and he never got ruffled. Just the type of mentor every fellow needs!

You have contributed significantly to building the evidence base for uterine artery embolization. What clinical questions regarding the procedure would you like to see answered?

The biggest questions relate to those women who would like to become pregnant. When is it better to do myomectomy and when should uterine artery embolization be the first choice? This depends on many factors, including patient age, extent of fibroids, fitness for surgery, prior treatments and others. So it is not a one-size-fits-all answer and we have many gaps in our knowledge.

Could you describe a memorable case?

We have always been careful regarding fertility after uterine artery embolization, but I had a patient who had been trying to get pregnant for nearly 16 years. She had developed fibroids early and had undergone three prior myomectomies by the time I saw her. She had never been able to become pregnant, despite trying after those surgeries. She came to me a week before a hysterectomy was scheduled for her. She was 39 at the time. We did the uterine artery embolization without problem and a hysterectomy was avoided. Eighteen months later she became pregnant and delivered a healthy baby boy. She was the most grateful patient I have ever had and it reminded me that general rules have many exceptions.

What is your message to young interventional radiologists about the available embolic agents for uterine artery embolization?

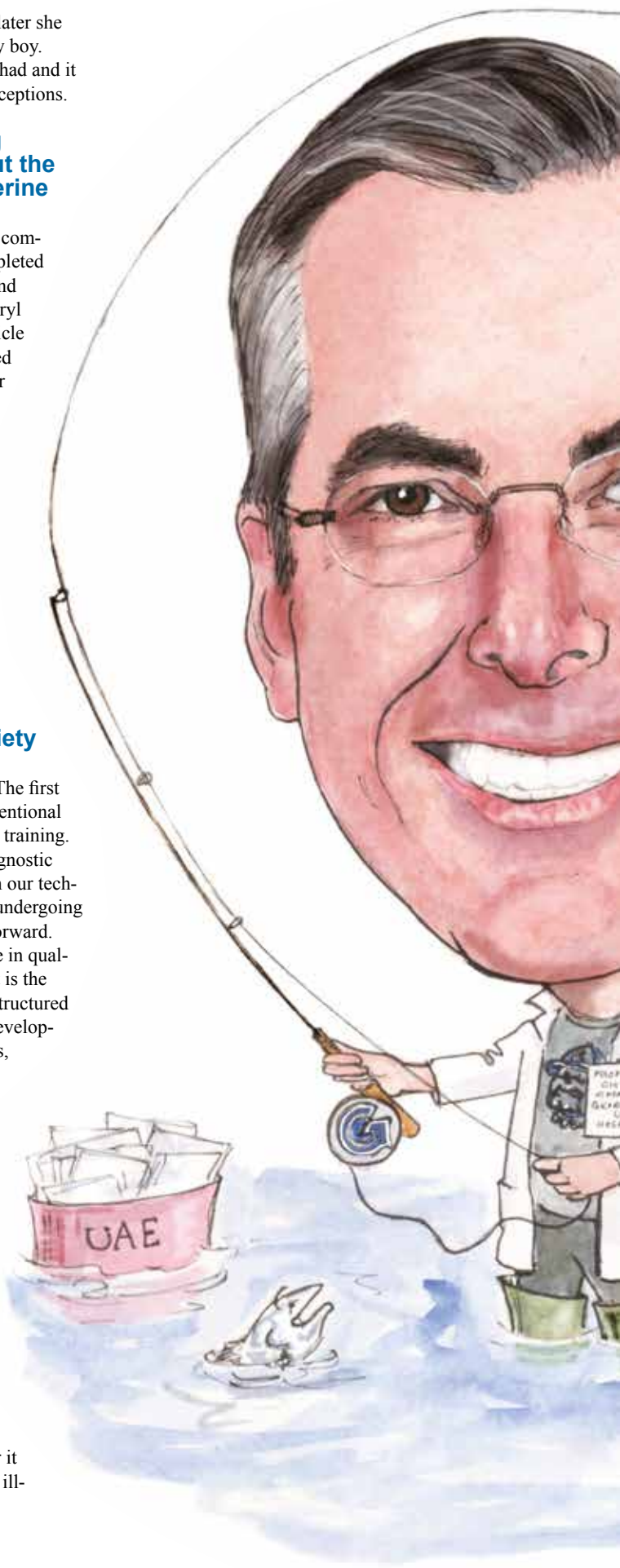
This is one area in which we have substantial comparative data. Several investigators have completed randomised trials comparing these products and our knowledge of them is very strong. Tris-acryl gelatin microspheres (Embospheres) and particle poly vinyl alcohol (Contour) have been studied in comparative trials and are very effective for uterine artery embolization. Spherical poly vinyl alcohol (Contour SE) is not nearly as effective as these other two products and should not be used. There are two additional products: spherical acrylamido poly vinyl alcohol microspheres (Bead Block) and polyzene F-coated poly vinyl alcohol hydrogel spheres (Embozene), for which there is some research to suggest that these are also effective and there are ongoing investigations of these latter products to assess outcomes.

As the incoming SIR President, what are your goals for the society in your presidential term?

We are very focused on two mid-term goals. The first is the successful implementation of the Interventional Radiology/Diagnostic Radiology pathway for training. This new path will continue to ensure our diagnostic imaging skillset, but broaden and deepen both our technical and clinical skills in caring for patients undergoing interventional therapies. This is a huge step forward. The second goal is to advance our programme in quality and safety. The main vehicle for this effort is the ongoing development of a registry based on structured reporting of certain key procedures. We are developing quality metrics related to those procedures, and these will be used for quality reporting purposes under the evolving healthcare reform programme. Our goal here is to provide our members with the tools they need to assess their own practice and to participate in national efforts to improve patient care and outcomes.

In today's healthcare landscape, how important is collaborative and multidisciplinary research for interventional radiologists?

Much of what we do these days is done in the context of multidisciplinary efforts to manage complex medical conditions, whether it is cancer, liver failure or other similar serious ill-



nesses. We cannot carry out and ensure quality care in a vacuum. Quality research is the same—interdisciplinary, which provides for a broader context in any project and ensures a wider audience for the results.

In your view, what are three "general medicine" concepts that interventional radiologists need to think about?

They really parallel the three phases of care—assessment at the time of consultation, care during the procedure and follow-up care and management of outcomes. First, we need to assess patients in the context of their other medical conditions, alternative therapies, and risks for sedation or the interventional procedure. We need to make a recommendation, including recommending something other than an interventional radiology procedure where appropriate, based on this holistic approach. Second, we need to use our medical knowledge to manage the patient during the procedure, particularly related to airway maintenance while providing a comfortable degree of sedation for the patient. After treatment, we need to use our clinical skills to ensure the patient has an uneventful recovery. We also need to provide the follow-up to guide transition of care back to other providers or to make recommendations for additional interventional care. In short, we need provide the continuum of care, not just the intervention. From my perspective, this is the most rewarding aspect of my practice.

What is your proudest achievement in interventional radiology?

I am most proud of the collective effort of all the investigators in our field that has resulted in the acceptance of uterine embolization as a validated treatment for women with symptomatic fibroids. This is not my accomplishment, but the work of hundreds in our field worldwide. It is one of the best examples that we have of the power of quality research to change the recommendations for care for a very large number of patients.

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

Broadly speaking, I think the evolution of embolization over the past decade has been remarkable and it has fundamentally changed our field. The technology has evolved remarkably and its application has been dramatically broadened.

What are your interests outside of medicine?

I am an avid college basketball fan, and get through the winter by following the Georgetown Hoyas. I love photography and I enjoy fly fishing. I am mediocre at the former and not a great threat to the fish with the latter, but both get me away from work.

Fact File

Current appointment
Chairman, Department of Radiology
Georgetown University Hospital,
Washington, USA (2005–present)

Current academic appointments
Professor of Radiology
Georgetown University School of Medicine
Washington, USA (2003–present)

Residency
University of California School of Medicine
San Francisco, USA (1981–1984)

Fellowship
New York University School of Medicine
Vascular and Interventional Radiology
New York, USA (1984–85)

Awards and honours (selected)
Distinguished Reviewer, *Obstetrics and Gynecology* (2009)
Distinguished Fellow, Cardiovascular and Interventional Radiology Society of Europe (2013)
Honorary Fellow, British Society of Interventional Radiology (2013)

Professional society memberships (selected)
American College of Radiology
Radiologic Society of North America (RSNA)
Society of Interventional Radiology (SIR)
American Heart Association
Cardiovascular Radiology Council
American Medical Association
Cardiovascular and Interventional Radiology Society of Europe

Professional committees
Incoming president, Society of Interventional Radiology (2014–2015)
Secretary, Society of Interventional Radiology (2012–2013)
Member, SIR Value Task Force (2011–present)
Member, *Journal of Vascular and Interventional Radiology* (*JVIR*)
Chair, Society of Interventional Radiology Evidence-based Interventional Radiology Committee (2009–2011)

World's largest venous access trial commences in the UK

***Interventional News* has learned that the UK CAVA trial, a four-way randomised controlled trial of long-term venous access devices for the delivery of chemotherapy (Ports vs. tunnelled central lines vs. peripherally inserted central catheters) has begun**

The CAVA (Cancer and venous access) trial seeks to determine which devices—subcutaneously tunnelled central catheters (Hickmans), peripherally inserted central catheters (PICCs) or implantable chest wall ports (Ports)—offer the best outcome from safety, clinical effectiveness and cost-effectiveness perspectives. The trial will randomise 2,000 patients over three years and will be the world's largest venous access trial.

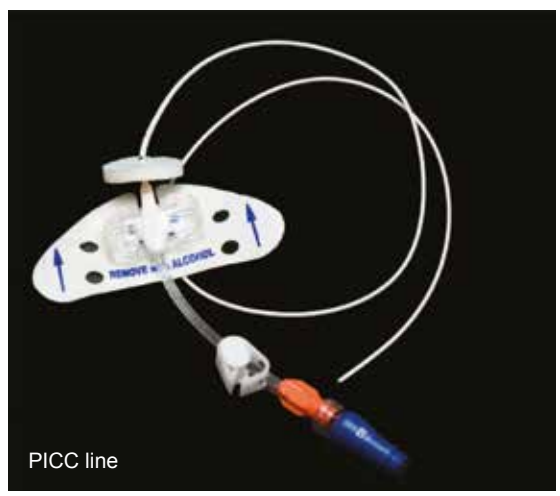
There is currently no evidence-based guidance to help choose between these devices and the decision-making processes behind choice of device, which varies from centre to centre, is poorly understood.

Jon Moss

The four-way randomisation is divided into PICC vs. Port (superiority design) in one arm; PICC vs. Hickman (inferiority design) in the second arm; Port vs. Hickman (superiority design) in the third arm and Port vs. PICC vs. Hickman in the fourth arm. "This covers all eventualities; ie, if a patient is not suitable for one device, (for instance, haematologists generally do not like Ports) then they can still be randomised into one of the other arms," say the researchers.

The investigating team in Glasgow, led by Jon G Moss, Interventional Radiology Unit, NHS Greater Glasgow and Clyde, Gartnavel General Hospital, Scotland, say venous access is seen by many interventionalists as a low key topic increasingly delegated to nurse practitioners and falling well below, for example, aortic stent grafting in the "wow" factor. However, the National Institute of Health Research (NIHR) took a different view and in 2011 put out a commissioned call for research to compare PICCs, Hickmans and Ports in patients receiving chemotherapy of more than 12 weeks duration, they say.

"Interventional radiologists must engage with venous access. Although it is bread and butter stuff, it is a very high activity sport and important to patients and healthcare systems worldwide. Endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR) might make the headlines for doctors and a small number of patients—venous access impacts on millions of patients. In this high-tech world, interventional radiologists must not ignore venous access, it is a duty to millions of patients," Moss told *Interventional News*.



PICC line

The National Chemotherapy Advisory Group estimated approximately 65,000 chemotherapy programmes per year and Hospital Activity Data for England reported 425,000 deliveries of chemotherapy for cancer in the year 2009–2010.

The trial has randomised 32 patients from Glasgow, Manchester, Leeds and Newcastle to date. "Birmingham and Durham will open recruitment shortly and St George's will join as the London site," Moss added. He explained that the centres have all been chosen because of the significant number of venous access devices they use plus their strong commitment to a research ethic and deliverability.

Improving percutaneous gastrostomy: Lessons learned after identifying an unmet clinical need

AKHILESH SISTA

COMMENT & ANALYSIS

Innovation and interventional radiology are for all intents and purposes synonymous. It is not surprising that some of medicine's greatest innovators come from our field. But can we do better? Are there possibilities we are not even considering because we are not formally paying attention? Akhilesh Sista writes on the topic

With this in mind, in the April 2012 issue of *JVIR*, my colleagues and I in the Stanford Interventional Radiology division published our experience finding clinical needs in the interventional suite using the Stanford Biodesign model (biodesign.stanford.edu). Of the needs we identified, the one that caught our eye involved a displaced gastrostomy tube that leaked tube feeds and gastric contents into the peritoneum. After screening the need by looking at the disease state fundamentals, stakeholders, existing technologies, and the market opportunity, we conducted a high level brainstorm for a device to fix the problem. I wanted this to be more than an exercise when I moved to New York City to take my first interventional radiology faculty position at Weill Cornell Medical College. My first tasks were to be more specific about the design and build a prototype. Through conversations and introductions, I found John Cheeseborough, an enterprising and conscientious engineer, who partnered with me to create a 3D printed prototype.

We were proud of this prototype, and felt it could reduce the rate of peritonitis and tube dislodgement. We also knew it required refinements and design iterations, but we needed to conduct essential feasibility testing on an animal model to figure out what improvements were needed. For that, we needed money. Thus, we have applied for non-dilutional grants.

I have known from the beginning that this project has promises and pitfalls. About 200,000 gastrostomies are placed annually in the USA, not a small number. However, most gastrostomies (~90%) are endoscopically placed, and peritonitis and dislodgement seem to be less common (although not absent) with endoscopic placement. The design of the prototype, however, is based on a percutaneous "push" approach employed by interventional radiologists. It could possibly be adapted to the endoscopic method, but would require modifying the endoscopic technique. Next, proving that the device lowers the rate of peritonitis in a clinical study will be challenging. Although peritonitis is devastating, significant peritonitis only occurs in 1–2% of cases, so even with a perfect device, adequately powering the study would require a large number of patients.

Yet, to this day, we as interventional radiologists are frustrated every time a tube falls out. The patient and healthcare system are clearly inconvenienced. Twice in the past year, there has been concern for percutaneous gastrostomies slipping back into the peritoneum. Interventional radiologists place 20,000 gastrostomies per year, and the designs are not changing. At least four companies include percutaneous gastrostomies in their portfolio. I teach a biodesign course to my residents and medical students, and one of the first observations made by Gayle Rudofsky, a first year radiology resident, was: "Percutaneous gastrostomy tubes often fall out or get dislodged leading to unnecessary emergency room visits and hospital admissions". While expanding the technology to other percutaneously placed tubes is slippery, doing so would expand the market opportunity.

So we march on. Our final endpoint is to see the device to its point of failure, whether that be technical or financial. If it continues to pass feasibility tests, however, it has a shot.

My advice to academic entrepreneurs based on my experience: 1) engage your technology transfer office early and often; 2) protect your design as soon as you can; 3) put your prototype in a colleague's hands – watching her or him process your design is invaluable; 4) continue developing your pitch, market analysis, and business plan. If your device passes all the tests, you just might change medicine.

Akhilesh K Sista is assistant professor, Weill Cornell Medical College, Division of Interventional Radiology, New York, USA. He has reported no disclosures pertinent to the article

Bioresorbable vascular scaffold safe with no deaths or amputations at one year

A clinical study has demonstrated the feasibility of using the Esprit drug-eluting bioresorbable vascular scaffold (Abbott Vascular) in patients with symptomatic atherosclerotic disease of the superficial femoral artery or iliac arteries with no deaths or amputations at one year.

The results of ESPRIT I were presented by Johannes Lammer of the Department of Cardiovascular and Interventional Radiology, Medical University Vienna, Vienna, Austria, at the Leipzig Interventional Course (LINC; Leipzig, Germany; 28–30 January).

Thirty five patients with symptomatic atherosclerotic disease of the superficial femoral arteries or iliac arteries were included in the ESPRIT I clinical study. Patients were eligible for inclusion if they had a single, *de novo*, Rutherford category 1 to 3 lesion of the superficial femoral artery or common or external iliac arteries. The lesion length had to be ≤50mm, and the vessel diameter in the range of ≥5.5mm to ≤6.5mm.

At the start of the study, no patients were classed as having Rutherford 0 lesions, 8.6% had lesions that were Rutherford 1, 34.3% had lesions that were Rutherford 2 and 57.1% Rutherford 3 lesions. One month post-procedure, 84.9% of patients were classed as Rutherford 0, 12.1% as Rutherford 1, 3% as Rutherford 2, and 0% as Rutherford 3. After six months, 67.6% of patients were classed as Rutherford 0, 23.5% as Rutherford 1, 8.8% as Rutherford 2, and 0% as Rutherford 3. After one year, 73.5% of patients were classed as Rutherford 0, 11.8% as Rutherford 1, 8.8% as Rutherford 2, and 5.9% as Rutherford 3.

"Safety was demonstrated—there was no death or amputation; there was low occurrence of revascularisation (target lesion revascularisation rate at one year was 8.8%); there was a sustained improvement in Rutherford category (at one year 85% of the patients were classified as Rutherford 0 or 1). Using duplex ultrasound we saw a binary restenosis rate of 12.9%; and what we have learnt when we saw the angiograms, was that it was important that the vascular scaffold matched appropriately with the vessel diameter. Therefore, in the smaller vessels the results were better," said Lammer.

Lammer noted that in patients with smaller vessels, where the average vessel diameter was equal to or less than the median diameter of all 35 patients, there was less in-scaffold restenosis than in those patients with larger vessels. "It is very important that the scaffold is well embedded into the vascular wall after treatment so that the everolimus drug can do its job," Lammer added.

No re-intervention needed for 83.2% of patients treated with Zilver PTX at four years

The most recent ZILVER PTX trial data, presented at the Controversies and Updates in Vascular Surgery congress (23–25 January 2014, Paris, France), demonstrate sustained positive results for the paclitaxel-eluting stent (Cook Medical) vs. bare metal stent in patients with peripheral arterial disease. The four-year results from the ZILVER PTX randomised trial show that Zilvert PTX continues to show superior results when compared to bare metal stents and angioplasty in terms of primary patency, restenosis reduction and re-intervention rates for femoropopliteal disease.

The data confirmed the indications from previous study results at one, two and three years. Patients treated with Zilver PTX demonstrated 75% primary patency in the superficial femoral artery. This compares to 57.9% patency for patients with provisional bare metal stent placement in the study. Four-year restenosis was reduced by 41% with the paclitaxel coating in the head-to-head comparison of provisional paclitaxel-eluting stent placement vs. bare metal stent placement; and 83.2% of patients with femoropopliteal lesions who were treated with Zilver PTX did not require a repeat procedure with a view to revascularise after four years. In comparison, 69.4% of patients treated with acutely successful percutaneous transluminal angioplasty or provisional bare metal stent placement did not require a secondary intervention.

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Why should peripheral IRs know about “neuro” coils?

ANDREW PLATTS

COMMENT & ANALYSIS

Whilst deploying pushable coils, the delivery catheter may move, often backing out of the vessel when the coil is pushed or injected forwards. This can result in non-target vessel occlusion and it is to prevent this that detachable neurocoils are specifically useful, writes Andy Platts

The majority of neurocoils are specifically engineered to pack the sac of an aneurysm. They are usually nested within the sac by serial deployment of coils of diminishing diameter and length. Nearly all neuro coils are detachable and can be withdrawn safely even after full deployment. If an unsatisfactory position has been achieved such as prolapse of part or all of the coil from the target, or deployment of a coil that is clearly unstable, usually because it is undersized and mobile within the sac, it can be retrieved.

Neurocoils use a variety of detachment systems varying from mechanical anchoring systems, electro-thermal and electrolytic detachment to achieve very reliable and safe detachment.

Neuro-microcatherers are specifically designed with double markers to facilitate their safe deployment. These catheters carry two tip-markers, a distal marker and a second marker 3cm proximal to the tip. The detachable coil also carries a marker 3cm proximal from the detachment point and when these two markers align, the coil can be safely deployed. The reason for this is that when a ball of platinum coils builds up around the distal tip marker, it becomes obscured and effectively invisible.

If a coil is detached whilst still within the catheter or if the attached coil and the pusher are advanced too far beyond the catheter tip, each can result in complications such as aneurysm rupture or detachment failure

Most neuro coils are bare metal, mainly platinum, a metal that is densely radio-opaque, easily engineered and stable within the body. They are not resorbed over time. Some coils have coatings to promote healing such as PGLA or hydrogel.

The coils come in an enormous variety of configurations to promote peripheral packing of the aneurysm wall and by concentric deployment of incrementally smaller coil the lumen is filled—the “Russian Doll” technique.

Complete packing of the sac will result in the order of 30% of the volume of the sac being occupied by coil—the remaining space becomes filled by thrombus and this is the reason that the coils may compact over time. Fibred or coated coils attempt to excite an inflammatory reaction to stabilise the thrombus. Hydrogel coils have a dehydrated hydrogel core that expands out of the coil after deployment to fully occupy the sac. The hydrogel is very soft when hydrated, a similar material to soft disposable contact lenses.

These “neuro” coils are extremely easy to use and allow exquisite control during their deployment that cannot be offered by pushable coils.

So, how can they be of use in peripheral intervention?

Neuro coils come in smaller dimensions and can be used to densely pack small vessels or aneurysms. If the target for embolisation is a small vessel, standard coils tend to stretch out along the vessel rather than form their planned shape. Detachable coils can be packed into the vessel by to and fro movements during deployemt.

Whilst deploying pushable coils, the delivery catheter may move, often backing out of the vessel when the coil is pushed or injected forwards. This can result in non-target vessel occlusion and it is to prevent this that detachable neurocoils are specifically useful.

If a clinical case is encountered that matches the geometry neurocoils are designed for, then neurocoils should be used. This is most often seen in renal artery aneurysms that, like intracranial aneurysms, usually arise at vessel bifurcations and renal tissue loss can be avoided by controlled deployment of detachable coils. However, expense is a consideration and currently neuro coils cost in the order of £300 to £800 for each coil.

Andrew D Platts is a consultant Neuro and Vascular Radiologist at the Royal Free London NHS Foundation Trust, London, UK. He is a clinical proctor for Covidien and Microvention

Prostatic artery embolization: Still some burning questions

JAFAR GOLZARIAN

ZIV HASKAL

MARC SAPOVAL

COMMENT & ANALYSIS

In 2014, it appears reasonable to suggest that prostatic artery embolization (PAE) will prove safe and effective and will play a role in the management of patients with symptomatic benign prostatic hyperplasia who fail medical therapy and have either contraindications or reluctance to undergo surgery. However, despite encouraging results, the study of PAE is still in its infancy. There are still many challenges and unanswered questions that need to be addressed and these will form a major talking point at the upcoming Global Embolization Symposium and Technologies US (GEST US; 1–4 May, San Francisco, USA). The need for large multicentre comparative controlled trials is most obvious, write the GEST US course directors Jafar Golzarian, Marc Sapoval and Ziv Haskal

Benign prostatic hyperplasia (BPH) is a common condition, caused by nodular growth of prostatic tissue, enlarging the prostate and narrowing the urethra. It can lead to lower urinary tracts symptoms (LUTS) including a weak urine stream, difficulty in initiating or maintaining steady urination, frequency, dribbling, and excessive straining, nocturia, and urge incontinence. Haematuria and urinary tract infection also occur.

The majority of patients are treated with medical management. However, in many patients, medical therapy is not well tolerated or fails to sufficiently control symptoms. The gold standard of surgical options is transurethral resection of the prostate (TURP). Open surgical prostatectomy is typically reserved for larger than 80–100g prostates. TURP carries a number of important complications, including retrograde ejaculation (relatively common), bleeding, hyponatraemia, and urinary incontinence. Given these adverse events, new surgical techniques have been developed, though a recent systematic review found that there is little evidence for their greater efficacy, and suggested that TURP remains the gold standard. The limitations of current surgical therapies stress the need for less-invasive, safer treatments of medically refractory BPH.

Early research suggests that prostatic artery embolization offers a promising alternative to surgery. In 2000, DeMeritt reported a case describing selective prostatic embolization utilising 150–200µm polyvinyl alcohol particles in a patient with refractory haematuria and severe LUTS secondary to BPH. Embolization led to immediate control of haematuria and resolution of LUTS and led to a 40% reduction in prostate size. Following this paper, Carnevale Pisco, Blihim, Bagla and other investigators, have reported larger series both confirming treatment safety and efficacy of PAE as well as defining technical and anatomic aspects. At the University of Minnesota, Golzarian *et al* retrospectively reviewed the first 15 consecutive patients with symptomatic BPH and found a similar technical and clinical success rate. Two patients developed transient haematuria. Cystoscopy revealed no bladder ulceration or abnormalities.

In 2014, it appears reasonable to suggest that PAE will prove safe and effective and will play a role in the management of patients with symptomatic BPH who fail medical therapy and have either contraindications or reluctance to undergo surgery. However, despite encouraging results, the study of PAE is still in its infancy. The need for large multicentre comparative controlled trials is most obvious.

Most published papers show symptom improvement after embolization based on the International Prostate Symptom Score (IPSS) and Quality of Life Scale scores. However objective measures such as post void residual (PVR) or maximal flow rate (Qmax) improve to a lesser degree. Although the patient perception is the most important factor in the treatment of symptomatic BPH including the medical and surgical therapies, the role of a placebo effect in this group of patient is not well-known and needs to be studied. Of note, the placebo effect of TURP has not been reported.

Another illustrative question is ideal patient selection. Patients with haematuria can benefit from embolization. Other patients who can benefit are those with thrombocytopaenia, very large prostate, and post- surgical/pelvic radiation patients. Prospective studies need to be performed to understand the role of embolization in patients with 'smaller' prostates with median lobe hyperplasia and moderate symptoms. There is a need for comparative studies evaluating the efficacy and safety of embolization not only compared to best surgical treatment, but also to the best medical therapy.

Some patients with early symptom improvement after embolization have had subsequent recurrence of symptoms. There is a need for methodical correlation of imaging outcomes, eg contrast-enhanced MRI, desired degrees of prostate necrosis, shrinkage, and durable symptomatic outcomes.

Importantly, prostatic artery embolization is not the male equivalent of uterine artery embolization. Prostatic artery embolization is far more challenging due to internal iliac and prostatic artery atherosclerosis, small vessel calibres, complex vascular anatomy and variants, risks of non-target embolization, etc. The vascular anatomy alone is described differently by different authors and may add a source of confusion. Based on the recent anatomical and angiographic studies, it is clear that there is dual arterial supply to the prostate that can arise from any of the major pelvic arteries. Further, there is a multitude of anastomoses between prostate, bladder and rectal arteries. Although the incidence of clinically significant ischaemic lesions to these organs has been low, this may change when studied in larger trials or widely offered by interventional radiologists. Equally, there is opportunity to define potentially desirable levels of embolization and respective embolic agents. Thus far, technical and clinical success has been reported with polyvinyl alcohol and spherical particles. The type and sizes of embolic materials may effect the outcome. Material-specific endpoints will differ as well. While the total occlusion of supplying vessels is currently recommended, this has to be confirmed with prospective studies.

There remain many questions and challenges to define the place of embolization in prostate therapy. We need to lead prostatic artery embolization research in collaboration with urologists to create the necessary studies, registries and comparative trials that can provide the evidence required to potentially confirm that this treatment is a viable alternative to current surgical and medical therapies for symptomatic BPH.

Jafar Golzarian is professor of Radiology and Surgery, director, Division of Interventional Radiology and Vascular Imaging at University of Minnesota, Minneapolis, USA. Ziv Haskal is professor of Radiology, University of Virginia School of Medicine, Charlottesville, Virginia, USA and Marc Sapoval is professor of Clinical Radiology and chair of the Interventional Radiology Department at Hôpital Européen Georges-Pompidou in Paris, France. The authors have reported no disclosures pertaining to the article

"There is tremendous development in embolization materials"

GEST 2014 US course directors, Jafar Golzarian, Ziv Haskal and Marc Sapoval, gave *Interventional News* the particulars on some of programme high points scheduled for demonstration and discussion at the upcoming symposium in San Francisco, USA

Highlights of the scientific programme of GEST 2014 US

"There will be phenomenal focus on embolization materials," they said. The directors also point out that the GEST masterclass sessions are an opportunity to discuss the vast variety of materials used in embolization. Experts from across the globe will offer tips, techniques and insights on how to choose the right embolic for each treatment situation. In 2014, there will be major developments in microplugs, detachable coils and new resorbable and drug-eluting particles that attendees will be updated about. "We have decided to bring back the masterclasses, panel discussion and consensus the GEST way. There will be a focus on multidisciplinary discussion, and sessions on imaging," the directors explained.

"The latest data and discussion around embolization of visceral artery aneurysm and the new registry, AVM, are anticipated to be of great educational value and interest to attendees," noted Golzarian. GEST 2014 US will have a "very practical approach" to embolization and embolic materials.

Top tips on the GEST 2014 US programme

New developments in embolization to watch:

- Bariatric artery embolization for weight loss
- Update on prostatic artery embolization for symptomatic benign prostatic hyperplasia
- Embolization for haemorrhoidal bleeding
- There will also be a large interventional oncology focus

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Safety and efficacy of percutaneous cryoablation in renal cell carcinoma in 2014

CHRISTOS GEORGIADES

COMMENT & ANALYSIS

The outcomes from our recent study on the efficacy and safety of percutaneous cryoablation, published recently in *CardioVascular and Interventional Radiology* (*CVIR*), are the result of the most rigorous investigation on the subject to date. These exceptional numbers (97%, five-year oncologic efficacy and 6% complication rate), however, are a double-edged sword. On one hand, they approach those of the gold standard, on the other, we must prove they are widely reproducible, writes Christos Georgiades

The dynamics of introducing a new treatment for a disease are complex and many times unpredictable. This is particularly the case with cancer, especially in the era of multidisciplinary care, advancing technology, burdensome oversight, competing marketing interests and a more educated public. Perhaps it should be this way to avoid introducing procedures/equipment that are not truly beneficial to the patient.

In this complex environment, the option to treat kidney cancer using percutaneous cryoablation was introduced nearly a decade ago.

The usual "growing-pains" plagued this option, including lack of prospective studies, lack of long-term outcomes, lack of standardisation of the technique, etc. The standard of care for kidney cancer is radical or partial nephrectomy, which set a very high efficacy standard. Its five-year oncologic efficacy is reported between 97 and 100% and any new treatment option must have a comparable result, lest it is limited to a tiny subgroup of patients.

Our study confirmed in a rigorous way, (what some previous reports were suggesting) the high efficacy and low complication rate for percutaneous cryoablation. In our prospective study, the long-term efficacy of this option was 97% with a 100% cancer-specific survival at five-year follow-up.

This indeed approaches the numbers reported for more invasive options. What should make percutaneous cryoablation for kidney cancer even more palatable is the low rate of complications, around 6%, the quicker recovery time and, cost-savings.

The high efficacy and low complication rate of percutaneous cryoablation for kidney cancer is not unqualified however. There are factors that are important in achieving and maintaining these results that cannot be quantified or represented scientifically.

First and most important is the creation of a multidisciplinary team involving the relevant specialties, in this case, interventional radiology and urology

We tend to attribute such statements to politics. For those of us who have managed to create such teams and have witnessed the shortcomings of the "go-at-it-alone" mentality, it is an absolutely valid statement.

The experiences and capabilities of the two specialties are complementary and they perform better if a "I-have-your-back" relationship exists instead of a competing one. Such an environment encourages learning, communication, minimises risk and allows for better monitoring and earlier intervention in case of complications. Furthermore, it encourages pushing the limits and allowing for a steeper learning curve, and eventually higher efficacy rates. Equally importantly, the patients easily pick up on such dynamics and feel reassured that they are indeed getting the best care possible.

Of course, cryoablation is not an option for all patients with kidney cancer. The above reported efficacy and complication rates are limited to stage 1 disease, which refers to tumours up to 7cm in size and confined to the kidney. Thankfully most newly diagnosed patients fall within this stage (nearly 70%). Additionally, the location of the tumour is important and anteriorly located tumours and/or near critical structures (intestine, large blood vessels) have a lower efficacy rate.

What is in the future?

As with all new procedures there is a learning curve. The numbers we reported recently, presuppose (in addition to the above) a reasonable operator experience. As a society we need to encourage the training of our younger physicians and provide them with proper oversight, guidance and the wisdom to seek multidisciplinary cooperation. From a societal point of view, if these numbers are achieved only in a few large academic centres, the benefit is only academic.

To summarise, percutaneous cryoablation for stage 1 kidney cancer has been proven to be a great alternative to other more invasive options, but only if certain requirements/selection criteria are met. These are a true spirit of cooperation in a multidisciplinary team; good operator experience and proper patient selection.

Christos Georgiades is with the department of Vascular and Interventional Radiology American Medical Center, Nicosia, Cyprus. He is also adjunct associate professor of Radiology and Surgery, Vascular and Interventional Radiology, Johns Hopkins University, Baltimore, Maryland, USA. Georgiades is a consultant for Endocare and Galil Medical

Nearly all patients report statistically significant decrease in pain after cryoablation of metastatic tumours

Cryoablation provides pain relief to patients whose cancer has spread to the bone and soft tissue, suggests research that was presented at the 6th annual Symposium on Clinical Interventional Oncology (CIO, 18–19 January, Miami Beach, USA), in collaboration with the International Symposium on Endovascular Therapy (ISET 18–19 January, Miami Beach, USA)

Cryoablation has the advantage of being an outpatient, minimally invasive treatment that destroys painful metastatic tumours. Standard treatments for pain relief in these patients include narcotic medications and radiation therapy, which often interfere with daily quality of life and may require interruption of chemotherapy treatments.

"Pain can take over the lives of cancer patients and relief of that pain through this simple, one-day outpatient procedure can significantly and positively impact lives," said J David Prologo, lead author of the study, and interventional radiologist at the Centers for Dialysis Care, Cleveland, USA.

In the study, performed at University Hospitals Case Medical Center, in Cleveland, 51 patients with breast or kidney or skin or lung or prostate, or colon cancer received cryoablation therapy to treat 54 metastatic tumours that had spread to the pelvic bones, skull, foot, chest wall, shinbone, thighbone, chest wall and other areas. Of the 51 patients, 49 (96%) reported statistically significant decreases in pain, scoring an average of eight out of 10 on a pain scale before treatment (with one being the least pain and 10 being the most pain) to an average of three out of 10 after treatment. After three months, 48 patients continued to benefit from pain relief, maintaining the average of three out of 10 on the pain scale. On average, patients decreased the amount of narcotics they took for pain by two-thirds after treatment. Six patients suffered from therapy-related complications, including fractures of treated bones and temporary cryoablation-induced damage to nearby tissues.

Unmet need

"There is a huge unmet need for pain relief in cancer patients that improves rather than interferes with their quality of life," said Prologo. "Cryoablation is quick, simple, safe and effective and patients do not have to miss out on chemotherapy treatments."

Ten-year Spanish experience shows SIRT achieves disease control in over 80% hepatocellular carcinoma patients

The Clínica Universidad de Navarra (CUN), Pamplona, Spain, recently celebrated its 10th anniversary of using Yttrium-90 (Y-90) microsphere radioembolization for the treatment of liver cancer. CUN was a European pioneer in the use of radioembolization, or selective internal radiation therapy (SIRT) with SIR-Spheres (Sirtex) and has treated over 400 patients using the procedure

"From the 400 treated patients, there are very clear data on the efficacy of radioembolization. This technique has in many instances enabled rescue surgery in patients for whom surgery was not initially indicated", Bruno Sangro, director of the CUN's Liver Unit explained. "Over this past decade, we have improved the way we select patients and perform the treatment, and this has enabled us to reduce the side-effects."

Treatment with resin Yttrium-90 microspheres has now become widespread for patients with liver cancer. Although disease control is achieved in a high number of patients, the duration of this effect is very variable. However, it is noteworthy that of the first two patients treated at the hospital ten years ago, one is living with controlled disease and the other is disease free thanks to a transplant which was initially contraindicated, a press release from Sirtex states.

In hepatocellular carcinoma (155 of the 400 patients treated at CUN had this type of tumour), the results show that "the treatment was effective in preventing the growth of treated lesions: it achieved disease control in over 80% of patients, sometimes over prolonged periods of time, and in some very selected patients eradication was even achieved". However, radioembolization does not prevent the possibility of new lesions occurring in the liver or other organs.

Sangro emphasised that "radioembolization is a good palliative treatment, and can be added to other options already available at the CUN for primary tumours. Furthermore, it can open the door to other curative treatments such as liver transplantation, liver resection or percutaneous ablation. It could also enable the complete elimination of the tumour."

The results obtained by the CUN´s multidisciplinary team can be analysed according to tumour type, although in all cases the patients treated had a poor prognosis and advanced disease. Three years after treatment, 18% of patients with hepatocellular carcinoma and 16% of those who had hepatic metastases from colorectal cancer were alive. In the absence of treatment with Y-90 microspheres the expected three-year survival rate is between 1% and 5% of patients.

Results in liver metastases

For patients with neuroendocrine hepatic metastases, the three-year survival rate is 64%, which is not significantly different compared to the survival rate without treatment with microspheres (40–50%). However, the main benefit to these patients lies in improving quality of life by controlling the symptoms.

Patients with hepatic metastases from gastrointestinal and breast cancer have also been treated with this procedure at CUN. The technique is used in certain patients with colon cancer: "either those who have already received all the possible treatment options, used alone or concomitantly with systemic treatments, or as a means of consolidating the response obtained with initial chemotherapy, thus prolonging its effect. Local control of the disease is relatively good because most of the relapses are produced outside the liver", said Javier Rodríguez, of the CUN Oncology Department.

Sangro said: "Radioembolization can be administered in combination with chemotherapy in those tumours that are sensitive to this treatment."

The Clínica Universidad de Navarra team

Interventional oncology gains traction in management of renal tumours

KAMRAN AHRAR

COMMENT & ANALYSIS

Interventional oncology is gaining more of a market share in the management of renal tumours. While thermal ablation remains the core of this activity, embolotherapy continues to play an important role before and after ablation, writes Kamran Ahrar. Ahrar is a member of the GEST 2014 US Scientific Program Committee and writes about the interventional oncology programme at the upcoming GEST US meeting (1–4 May, San Francisco, USA)

For those who are just starting their practice, the "primer" sessions will provide an opportunity to explore practice development options, cancer principles, and the science behind embolization, ablation, and molecular targeted therapies. More advanced practitioners may be intrigued by the concepts of high-risk ablation zone, oncolytic virotherapy, and personalised cancer treatment.

The GEST 2014 US programme will feature small increments of highly-focused didactic presentations, together with extensive interactive educational opportunities through case-based panel discussions, debates, and workshops.

Considering the breath of liver-directed therapies in interventional oncology, a good portion of the programme is dedicated to discussion of hepatocellular carcinoma. A critical appraisal of differences between conventional transarterial chemoembolization (TACE) and TACE with drug-eluting beads, a lively debate on the utility of selective TACE versus radioembolization, and new insights in microcirculation and anti-reflux devices are only some of the highlights in the plenary session on hepatocellular carcinoma.

The treatment of metastatic disease from colorectal carcinoma covers the whole gamut of interventional oncology including ablation, conventional TACE, TACE with irinotecan-loaded beads, and radioembolization. There will also be discussion of more advanced techniques such as portal vein embolization and intrahepatic port placement.

Interventional oncology continues to gain more of the market share in the management of renal tumours. While thermal ablation remains the core of this activity, embolotherapy continues to play an important role before and after ablation.

Liver directed therapies for management of metastatic neuroendocrine tumours have continued to evolve. At the meeting, experts will unravel the mysteries of patient selection, optimal timing of treatment, and choice of therapy.

And finally, evolving interventional oncology therapies and novel application of ablative technologies are presented at GEST 2014 US. Highlights of this programme include ablation of bone metastases, from palliation to local tumour control, and electroporation for pancreatic lesions.

Kamran Ahrar is a professor at the Department of Diagnostic Radiology, Division of Diagnostic Imaging, The University of Texas MD Anderson Cancer Center, Houston, USA. He has reported no disclosures pertaining to the article

Sealing is believing: How effective sealing could be key to successful EVAR

Thomas Nolte, vascular surgeon and director of Vascular Center, Herz und Gefäßzentrum, Bad Bevensen, Germany, recently commented on the importance of sealing in the endovascular treatment of abdominal aortic aneurysm

Nolte stated that there is growing evidence that effective sealing in addition with shielding the aortic wall from radial expansive forces results in prevention of endoleak after EVAR. Successful sealing could explain why the aortic neck after endovascular aortic repair (EVAR) with the Ovation (TriVascular) stent graft shows no further expansion, he explained.

The Ovation Prime graft has innovative polymer-filled proximal rings that allow sealing, even in hostile proximal necks. Sealing is achieved by filling customisable O-rings at low pressure.

"Ovation continues to show durable results regarding safety and effectiveness in the treatment of abdominal aortic aneurysm up to three years. Type II endoleaks are not always benign and are usually the reason for aneurysm sac enlargement in this study population," Nolte told delegates at the Leipzig Interventional Course (LINC; 28–31 January, Leipzig, Germany).

In untreated aneurysms, blood pressure causes a bulge in the aortic wall where the tissue is weak. In self-expanding stent grafts, oversized wire and graft fabric allow the transmission of blood pressure and exert a pressure of their own, Nolte explained. "Blood pressure coupled with outward radial force from the stent contribute to neck dilatation. With the Ovation Prime stent graft, a polymer-filled O-ring insulates the aortic neck from blood pressure resulting in minimal, or no blood pressure and outward radial force from the stent. This could be the explanation why we see no neck dilatation there," he said.

Thomas Nolte

Three years of experience with new approach to sealing

Commenting on the different sealing strategies available, Nolte said that in self-expanding stent grafts, the seal is created by chronic outward force with discontinuous points of wall apposition across a 10–15mm length. "The chronic outward radial force from the stent may result in aortic neck dilatation at the nominal diameter of the stent. The Ovation prime stent graft has a watertight seal created by the O-ring that provides uniform continuous wall apposition. The non-expansive circumferential apposition from the sealing ring creates no chronic outward radial force and no aortic neck dilatation."

The Ovation global pivotal study set out to evaluate the safety and effectiveness of the Ovation abdominal stent graft system, with the primary safety endpoint defined as major adverse events within 30 days of the procedure, as determined by the clinical events committee. The primary effectiveness endpoint was defined as a composite of successful delivery and deployment; freedom from rupture and conversion to open surgical repair, and freedom from type I and III endoleak, migration and sac enlargement as determined by an independent core lab. "The follow-up has been scheduled for one and six months and thereafter annually to five years," Nolte said

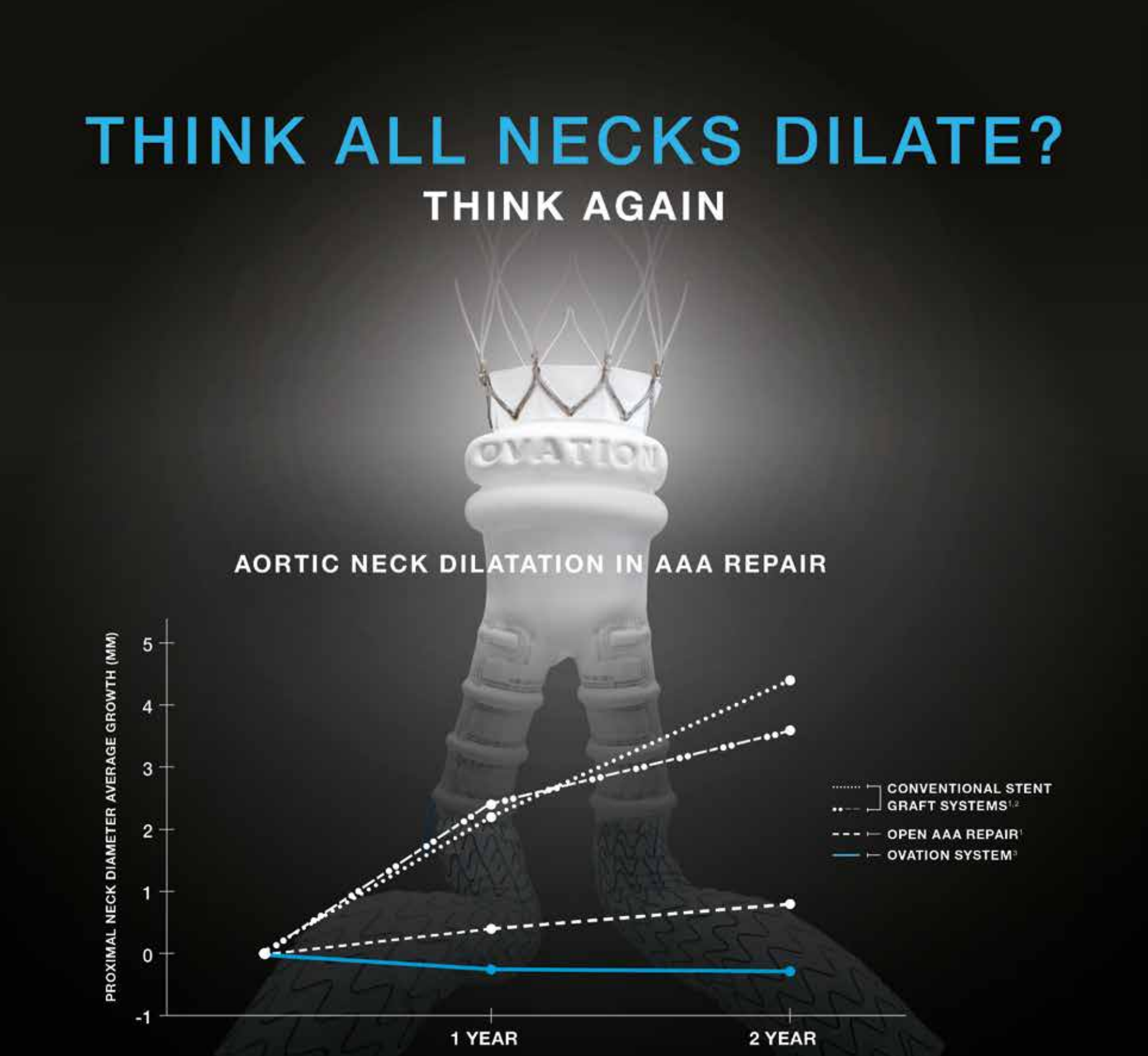
Data from the study showed that patients treated with the Ovation system had no neck dilatation and no late type I endoleak at two years.

In terms of technical success, there were no type I and III endoleak at two years, no migration, no rupture of the aneurysm and no conversion to open repair to two years. In terms of the aneurysm assessment, 3.8% had enlarged more than 5mm at two years. In all those cases type II endoleaks were the driving forces, Nolte said. There was no change in 55.4% of aneurysms at two years and 40.8% had reduced in size at two years.

The European study of 30 patients showed that there were three (10%) major adverse events out to one year with no device-related adverse events. There were no cases of type I, III and IV endoleak to three years and no aneurysm rupture, migration or conversion to open repair in the same time frame.

THINK ALL NECKS DILATE?

THINK AGAIN



Patients treated with the Ovation™ system had no aortic neck dilatation and no late Type I endoleaks at 2 years.[4]

[1] Rodway Eur J Endovasc Surg 2008; 35: 685-93 EVAR: N = 67, Open: N = 56

[2] Monahan JVS 2010: 52: 303-7 N = 46

[3] Core Lab measurements, Ovation Global Pivotal Trial N = 129

[4] Neck dilatation in proximal neck defined as growth > 2mm at renals, 10mm below renals, and 15 mm below renals

INDICATIONS FOR USE: The TriVascular Ovation Abdominal Stent Graft System is indicated for treatment of patients with abdominal aortic aneurysms having vascular morphology suitable for endovascular repair, including: adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories; non-aneurysmal proximal aortic neck: with a length of at least 7 mm proximal to the aneurysm, with an inner wall diameter of no less than 16 mm and no greater than 30 mm, and with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm; adequate distal iliac landing zone: with a length of at least 10 mm, and with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

CONTRAINDICATIONS: The TriVascular Ovation Abdominal Stent Graft System is contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol). Also consider the information in Section 4 Warnings and Precautions of the system's Instructions for Use.

Refer to Instructions for Use at TriVascular.com for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

CE marked. Please refer to current Ovation™ Instructions for Use.

830-0175-01 rA

TRIVASCULAR™

Interventional oncologists begin running US National Cancer Institute cooperative group trial

MICHAEL SOULEN

COMMENT & ANALYSIS

An important opportunity has opened up for interventional oncologists as World Congress on Interventional Oncology (WCIO) leaders take the helm of the E1208 trial. Michael C Soulen writes that the change in the trial leadership from medical oncology to interventional oncology represents a challenge because it rests on the question: can interventional oncologists run a successful cooperative group trial of image-guided therapy?

E1208 is a phase III randomised, double-blind trial of chemoembolization with or without sorafenib in unresectable hepatocellular carcinoma (HCC) in patients with and without vascular invasion.

National Cancer Institute (NCI) cooperative group trials of interventional oncology therapies are few and far between, with a dismal track record; so much so that interventional radiologists have the reputation in the NCI community of being "unable to do trials".

Unfortunately we still lack a clinical trials group for interventional oncology, so to access the resources needed for national multicentre trials requires either industry funding—a rare thing on this scale from the device world—or the national cooperative groups. The NCI (known among cynics as the "National Chemotherapy Institute") cooperative groups are run by medical oncologists with pervasive influence from Big Pharma, who have little interest in interventional oncology studies. Even the radiology cooperative group, ACRIN, was largely unsuccessful in completing the few interventional oncology trials it attempted. (Disclosure: I was the principal investigator of one of the failed trials, though it was six years before I gave up.)

I heard a fascinating talk at an ACRIN meeting years ago on predictors of failure of clinical trials. The number one Achilles' heel was if the two arms were managed by different specialists. This poses a serious challenge for interventional oncologists. Our patients benefit most from integrated multispecialty care. Clinical trials attempting to measure the added value of image-guided therapies usually have some traditional therapy in the control arm, be it systemic, surgical, or radiation. Therefore a medical, surgical, or radiation oncologist controls the flow of patients into a trial. Ironically, in E1208, even though all patients receive chemoembolization as their primary therapy, almost none of the site primary investigators are interventional oncologists.

Anyone with an interventional oncology clinic who is treating hepatocellular carcinoma should be able to prescribe and manage sorafenib therapy. E1208 could be entirely run by interventional oncologists with a research coordinator. One key to resuscitating this trial is for interventional oncologists to take charge of patient recruitment and management.

> ***"Anyone with an interventional oncology clinic who is treating hepatocellular carcinoma should be able to prescribe and manage sorafenib therapy. E1208 could be entirely run by interventional oncologists with a research coordinator"***

Of course, running a trial has a substantial cost associated with it, which brings up another barrier to success in the NCI cooperative groups: money. The per-patient support from Eastern Cooperative Oncology Group (ECOG) is an order a magnitude less than the actual cost of the work. The expectation is that institutions can tap into a pool of coordinators from their NCI-funded cancer centre. Yet at my own institution, despite both myself and one of my medical oncologists being co-chairs of E1208, we were told that our Cancer Center did not have enough coordinator support to open the trial! The solution was to use one of the Radiology research coordinators and run the study at a loss, which did not go over well with the bean counters in my department.

There are some breaths of fresh air from our industry colleagues. Merit Medical, BTG and Sirtex are all running multicentre embolotherapy trials for hepatocellular carcinoma (HCC) and/or liver metastases.

E1208 was activated in October 2009. The primary endpoint is progression-free survival, with a planned accrual of 200 patients in each arm. Jeff Geschwind and I served as the interventional radiology co-chairs for the protocol design, but the trial has been run largely by medical oncologists. Among the 123 sites approved to accrue to the study, only one has a recognised interventional radiologist as the site. Accrual has been a dismal 167 patients over the past four years, less than half of the planned rate. Only three centres in the country have enrolled 10 or more patients. There have been a number of bumps in the road: the interruption in Lipiodol supply in 2010, cessation of production of powdered cisplatin in 2010, and ongoing shortages of powdered doxorubicin all required trial interruption and revision to allow use of drug-eluting beads. Nonetheless, accrual has remained so poor that the ECOG Data and Safety Monitoring Board and the medical oncologists on the steering committee recommended consideration of closing the trial.

In a recent turn of events, the medical oncology principal investigator for E1208 left, and the leadership turned to Peter O'Dwyer, a Penn medical oncologist and interventional oncology enthusiast. He saw the futility in medical oncologists running an interventional oncology trial, and asked us to take it over. In essence, he has thrown down the gauntlet: can interventional oncologists run a successful cooperative group trial of image-guided therapy? This is an historic opportunity; for the first time, interventionalists are running an NCI cooperative group trial. Jeff Geschwind (professor of Radiology, Surgery and Oncology, Johns Hopkins University School of Medicine and director, Vascular and Interventional Radiology, Baltimore, USA) will take over as the principal investigator, with Riad Salem (Medical director of Interventional Oncology, Northwestern Memorial Hospital and professor of Radiology at Northwestern University, Illinois, USA) and myself as the co-chairs.

Call to action

As an interventional oncology community, we need to rise to this challenge. We do not want to be left holding the blame for the failure of the study. Trials of interventional oncology therapies are difficult to accrue. Having treatment arms involving different specialists, instead of the patient being managed by a single doctor, is a major negative accrual factor for any trial. Interventional oncologists doing chemoembolization should be able to prescribe and manage sorafenib; but if you are not comfortable, then team up with a medical oncologist or hepatologist from your HCC team who is. Coordinator support from the cooperative groups is very sparse; your cancer centre should supply a coordinator funded by your group. It is an intergroup trial. Make sure the trial is active at your site, and that your HCC tumour board funnels eligible patients to the trial. See ecog.dfci.harvard.edu/general/E1208info.html for physician and patient information about the trial.

Jeff, Riad and I will be reaching out to centres likely to be able to put patients on the study. We need the concerted effort of the interventional oncology community to prove to our medical oncology, surgical oncology, and radiation oncology colleagues that we can do trials too, and cement our credibility as the fourth pillar of cancer care.

Establishing interventional oncology as the fourth pillar of cancer care requires that we produce clinical research convincing to the oncologists that write the treatment guidelines. In the long run, I do not think the future of interventional oncology cooperative trials lies within the National Cancer Institute (NCI). One item on my professional bucket list is to create an independent interventional oncology trials group. Currently the WCIO is contemplating partnering with industry on a research foundation to meet this critical need.

Michael C Soulen is professor of Radiology and Surgery at Abramson Cancer Center, University of Pennsylvania, Philadelphia, USA and past chair of the WCIO. He has reported no disclosures pertaining to the article.
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"Interventional oncology is evolving so quickly"

"There is gradually increasing awareness in the medical and surgical oncology communities regarding the benefits that interventional oncology can bring to a wide variety of patient populations," William S Rilling, professor of Radiology and Surgery, director, Vascular and Interventional Radiology, Medical College of Wisconsin, Milwaukee, USA and 2014 programme chair of WCIO (11–14 May, New York, USA), tells *Interventional News*

William S Rilling

"We continue to see great advances in the evidence basis for interventional oncology therapies and the integration of local regional image-guided therapy with systemic therapy. These trends are continuing in 2014 and as a result there is gradually increasing awareness in the medical and surgical oncology communities regarding the benefits that interventional oncology can bring to a wide variety of patient populations.

"This year, we wanted to provide content which was attractive to both advanced interventional oncology practitioners as well as early career interventional oncologists and those in training. So we have parallel programmes on the first day of the meeting.

The cornerstone of the WCIO meeting this year, as in the years past, is the up-to-date multidisciplinary disease-focused discussions. In these plenary sessions, attendees will learn the current optimal multidisciplinary treatment of hepatocellular carcinoma, musculoskeletal tumours, renal cancer, lung cancer and liver metastases. Each of these sessions will conclude with a lively multidisciplinary tumour board and will include audience response questions to increase attendee interaction.

Selected highlights from the WCIO programme

- Trends in treatment allocation for early stage hepatocellular carcinoma (HCC) covering transplantation, resection and ablation
- Update on percutaneous ablation for HCC
- New trends in transarterial embolization and radioembolization for HCC
- Debate on locoregional therapy for advanced HCC
- Musculoskeletal and pain palliation session
- Molecular oncology session

Video abstracts

"Some specialties have begun to use video abstracts as a novel way to introduce new technology and techniques. As interventional oncology continues to evolve very quickly, we believe that this format would lend itself very well to demonstrating novel approaches to the wide varieties of problems we face. Since this is a totally new format, the submission rate has been low up to this point, but we hope to increase familiarity and will continue to offer it in the future as it has great potential," Rilling said.

New journal dedicated to the management of liver cancers launched

The journal, *Hepatic Oncology*, published by Future Medicine Ltd, is led by a team of three senior editors, Jordi Bruix (University of Barcelona, Spain), Richard Finn (University of California, Los Angeles, USA) and Ronnie TP Poon (The University of Hong Kong, Hong Kong), along with an international editorial board of experts in the field.

Hepatic Oncology will provide a forum to report and debate all aspects of cancer of the liver and bile ducts. The journal publishes original research studies, full reviews and commentaries, with all articles subject to independent review by a minimum of three independent experts. The scope of coverage includes: studies on all types of primary and secondary hepatic cancers; diagnosis, imaging, prognosis and risk factors; pharmacoeconomics, outcomes and comparative-effectiveness research; therapy (including surgery, chemotherapy, chemoembolization, ablation, radiotherapy, hormonal and biological therapies); translational research and biomarker studies.

Hepatic Oncology will publish original research studies and reviews addressing preventive, diagnostic and therapeutic approaches to all types of cancer of the liver, in both the adult and paediatric populations. The journal will also highlights significant advances in basic and translational research, and places them in context for future therapy.

Product News

Covidien ends OneShot renal denervation programme

Covidien has announced it will exit its OneShot renal denervation programme. The company states that this "voluntary action" is primarily in response to a slower than expected development of the renal denervation market and that the decision resulted from Covidien's regular review of strategic programmes and growth potential for various aspects of its product portfolio.

According to a press release, as a result of this decision, the company will not proceed with its RAPID II randomised study. Additionally, the company expects to record after-tax charges in the range of US$20 to US$25 million as a result of exiting the OneShot programme.

The press release reports that over the next several weeks, the company will collaborate with physicians and the renal denervation community to ensure existing OneShot patients are informed and the currently enrolling clinical trials are transitioned appropriately.

Renlane renal denervation system gets CE mark

Cordis has announced receiving the CE mark for its Renlane renal denervation for the treatment of patients with resistant hypertension and has completed the first successful cases in Europe.

The Renlane system consists of a helical, irrigated, multielectrode ablation catheter with a multichannel radiofrequency ablation system.

The first successful cases were performed by Hannes Reuter, University of Cologne Hospital Cologne, Germany. The treated patients were diagnosed with resistant hypertension and had systolic blood pressures ≥160mmHg, despite undergoing traditional drug therapy with three or more antihypertensive medications. All procedures were performed successfully and patients were discharged after one day.

"The novel technological design of the Renlane catheter with its configuration of five electrodes and irrigated technology, allows for shorter procedure duration, sparing of contrasting dye and likely more protection of the endothelium," said Reuter. "The design of the catheter also makes handling the device very easy."

The catheter features five irrigated electrodes located at the tip of the ablation catheter and is used in conjunction with the multi-channel radiofrequency generator for energy delivery.

Ultrasound renal denervation system receives CE mark

ReCor Medical has announced that it has received CE-mark approval for the latest generation of its ultrasound-based renal denervation system (Paradise). The first patients were treated with the new system in December 2013 at the Universitäts–Herzzentrum, Bad Krozingen, Germany. The company also announced the first use of its new catheter line, called Radiance, which is 5Fr and rapid-exchange compatible, and thus sized to be introduced via the radial artery (as opposed to the femoral artery).

"The initial procedures with the new Paradise System highlighted the new generator's ability to automatically customise energy delivery based on the patient's artery size while maintaining a consistent level of cooling protection," said Thomas Zeller and Elias Noory (both at Universitäts–Herzzentrum, Bad Krozingen, Germany), who performed the first procedures. "Our first patient treated with the new Paradise System was a non-responder of two different radio frequency-based procedures. We are optimistic that the circumferential energy delivery of the Paradise ultrasound system will provide a more reliable treatment."

US FDA approves Valiant Captivia System to treat aortic dissections

Medtronic has received US FDA approval for use of the Valiant Captivia Thoracic Stent Graft System in the treatment of type B aortic dissections.

Supported by the results of the DISSECTION trial, the new indication provides physicians with a minimally invasive alternative to open surgical repair and medical therapy for the condition.

"Acute type B aortic dissection is a potentially life-threatening condition that historically has been treated with either medical therapy or, when necessary, through invasive surgical techniques," explained Joseph Bavaria, professor of Surgery and director of the Thoracic Aortic Surgery Program, University of Pennsylvania, USA, and a national principal investigator for DISSECTION.

Renlane

DISSECTION results

Bavaria presented the results of the trial at the 2014 annual meeting of the Society for Thoracic Surgery. Twelve-month data from 50 patients evaluated in the trial demonstrate safety and efficacy of the Valiant Captivia System in the treatment of dissections, with excellent technical success.

Conducted at 16 US sites, the trial met its primary safety endpoint by achieving an 8% all-cause mortality rate at 30 days, which represents a three- to four-fold mortality improvement over open surgical repair. Additionally, 100% technical success and 100% coverage of the primary entry tear at implant were achieved in the trial.

Rodney White, chief of Vascular Surgery, Harbor-UCLA Medical Center, Torrrance, USA, added: "Data out to one year continue to show positive aortic remodelling of the stented segment, with a 100% increase in true lumen volume and no ruptures."

Option Elite retrievable vena cava filter gets FDA nod for a new over-the-wire delivery technique

Argon Medical Devices has announced receiving clearance from the US FDA to begin marketing the Option Elite retrievable inferior vena cava filter with a new over-the-wire delivery technique.

According to the company, this new clearance enables physicians to safely deliver the filter to a patient's inferior vena cava by following the path of a guidewire. The guidewire assists in keeping the filter centred in the inferior vena cava upon placement. The over-the-wire technique is a standard of care in many endovascular procedures and the Option Elite is the only retrievable inferior vena cava filter that can be delivered by passing the filter's apex over a guidewire.

"Applying the over-the-wire technique to deliver an inferior vena cava filter is a significant development, employing a technique we frequently use during endovascular procedures. It gives a physician more control to accurately position the filter during delivery," said Munier Nazzal, chief of Vascular and Endovascular Surgery at the University of Toledo, USA.

Argon launched the Option Elite filter with the new over-the-wire delivery technique at the International Symposium of Endovascular Therapy (ISET 18–21 January 2014, Miami Beach).

Vela proximal endograft system launched in USA

Endologix has announced the US launch of its new Vela proximal endograft system, a clinical solution for endovascular repair in a broad range of aortic neck anatomies. A press release from the company says the Vela system is specifically designed for the treatment of proximal aortic neck anatomies during an endovascular aneurysm repair procedure using the Endologix AFX endovascular AAA System.

One of the first Vela procedures in the USA was performed by Julio Rodriguez, a vascular surgeon at the Arizona Heart Institute, Phoenix, USA. "The Vela delivery system is very intuitive and the endograft has excellent visibility," Rodriguez said.

John McDermott, chairman and CEO of Endologix said: "Vela's new delivery system and unique circumferential graft line marker provide physicians with enhanced visibility and greater control over the implant procedure. We believe these enhancements lead to better precision and predictability of graft placement when coupled with our proprietary ActiveSeal technology. These features make Vela an attractive clinical solution for endovascular repair in a broad range of aortic neck anatomies."

Gore launches lower profile Gore Excluder components in Australia and New Zealand

Gore has announced the Australia and New Zealand launch of an expanded treatment range, including lower profile components for the Gore Excluder AAA Endoprosthesis. The device is used to treat abdominal aortic aneurysms.

The 31mm trunk-ipsilateral component and 32mm aortic extender will be used with an 18Fr and 17F Gore DrySeal Sheath respectively, reduced from 20F. For the contralateral legs, the reduced profile sizes allow the 12–20mm contralateral leg component to be used with a 12F DrySeal Sheath, the 23mm to be used with a 14F introducer sheath, and the 27mm to be used with a 15F introducer sheath. In addition, a new large diameter 35mm trunk-ipsilateral leg and 36mm aortic extender components will treat 30–32mm vessel treatment range which expands overall treatment range to 19–32mm. The 35mm trunk-ipsilateral component and 36mm aortic extender will be used with an 18F Gore DrySeal Sheath.

A press release from Gore states that no changes have been made to the Gore Excluder device—instead, Gore has implemented an innovative process using ePTFE materials to constrain the device onto the catheter. The lowering of the device profile exemplifies Gore's commitment to improving patient safety while maintaining ease-of-use for the delivery of the Gore Excluder device.

Glasgow, UK
September 13-17

CIRSE 2014

The CIRSE Annual Meeting is by far the largest and most significant platform for minimally invasive, image-guided medicine, welcoming over 6,500 delegates from 94 countries in 2013.

CIRSE 2014 will offer over 250 hours of scientific and educational content transmitted through a range of formats, including special focus sessions, hands-on workshops, interactive case discussions, electronic posters, debates, a state-of-the-art technical exhibition and much more.

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CIRSE Cardiovascular and Interventional Radiological Society of Europe

Product News

"The availability of the expanded treatment range of the Gore Excluder device, in addition to the reduced profile components, provides physicians with a proven and durable option to better treat a broader range of patients diagnosed with abdominal aortic aneurysms," said Stefan Ponosh, a vascular surgeon at Sir Charles Gairdner Hospital, Perth, Western Australia. "Reducing the profile of these devices allows more patients to benefit from minimally invasive access approaches to endovascular aortic repair."

Passeo-18 Lux drug-eluting balloon released in Europe

Biotronik has announced the release of its Passeo-18 Lux drug-eluting balloon in all countries accepting the CE mark, following recent CE approval. The Passeo-18 Lux DRB catheter has shown clinical efficacy in the BIOLUX P-I study. Data collected at six- and 12-month intervals demonstrated that patients treated with Passeo-18 Lux were less likely to require treatment again.

BIOLUX P-I is a randomised, controlled study investigating the safety and performance of Passeo-18 Lux (n=30) vs. an uncoated Passeo-18 angioplasty catheter (n=30) in the treatment of lesions in the femoropopliteal segment of up to 200mm in length. The primary endpoint is late lumen loss in the Passeo-18 Lux arm vs. the uncoated percutaneous transluminal angioplasty catheter arm. Secondary endpoints include the target lesion revascularisation rate and the Rutherford classification. The study enrolled patients at six centres in Germany and Austria.

Six-month primary endpoint data, evaluated by an independent core lab, previously documented significantly reduced angiographic late lumen loss (p=0.038) in the Passeo-18 Lux arm (0.55±0.73mm) vs. the uncoated angioplasty catheter (1.07±1.01mm). Binary restenosis was also reduced (p=0.048) in the Passeo-18 Lux arm vs. the uncoated angioplasty catheter (11.5% vs. 34.6% respectively).

At 12 months, Kaplan-Meier estimates demonstrated a freedom from target lesion revascularisation rate of 84.6% for patients treated with Passeo-18 Lux vs. 58.3% of patients treated with an uncoated angioplasty catheter (p=0.064). Furthermore, patients receiving treatment with Passeo-18 Lux demonstrated greater improvement in Rutherford classification compared to baseline (72%) vs. those receiving treatment with plain angioplasty (65.2%).

FDA nod for MVP-5 micro vascular plug system for peripheral vessel embolization

The MVP-5 system (Reverse Medical) is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature, in 3–5mm vessels. The company also announced the first US clinical case along with the US FDA 510k clearance.

"Our first procedure with the MVP-5 was impressive, and consistent with our prior experience with the MVP-3, resulting in accurate and immediate vessel occlusion upon deployment. The device tracked easily through tortuous anatomy, allowing for more precise control than conventional embolization coils. The MVP product line has become an essential device in my lab. I am particularly excited for its utilisation in my growing Interventional Oncology practice," stated Rahul Patel, assistant professor, Interventional Radiology, Mount Sinai Hospital, New York, USA.

FDA clears Magellan 6F robotic catheter

Hansen Medical has announced it has received US FDA clearance for its smaller diameter Magellan 6F robotic catheter for peripheral vascular interventions.

According to a press release, the Magellan 6F robotic catheter is the latest addition to the growing family of catheters available for use with the Magellan robotic system, and features several important advances. Specifically, the Magellan 6F robotic catheter features novel dual-bend technology, enabling independent robotic control of two separate bend sites on a single catheter, compared to the current Magellan 9F robotic catheter which is designed as a telescoping device with two, independently controlled robotic catheters.

The 6F catheter's


Passeo-18 Lux

Product News

new design provides for precise robotic navigation and control in a single, smaller diameter 6F outer diameter catheter, and enables use of the Magellan robotic system in smaller vessels in the peripheral vasculature and by physicians who may prefer a smaller diameter vessel insertion site.

"This is a major development for Hansen Medical and intravascular robotics," said Barry Katzen, founder and medical director of Baptist Cardiac and Vascular Institute, Baptist Hospital of Miami, USA. "With this lower profile robotic catheter, we can now increase the number and types of procedures we perform with the Magellan robotic system. The new catheter expands the clinical applications to many interventional vascular therapies involving smaller vessels, including cancer treatment, women's health, and lower limb treatment."

Hansen Medical will begin a limited release of the Magellan 6F robotic catheter, collecting clinical and procedure data over a broad set of cases over the next several months, and anticipates a more wide-scale release later in 2014, the press release added.

New crossing catheter launched in Europe

Medtronic has announced the European launch of a new peripheral angioplasty balloon, TOTAL across that targets challenging lesions in the lower-extremity, including below-the-knee arteries associated with critical limb ischaemia.

TOTAL across recently received the CE mark as a tool for improving blood flow through narrowed or occluded lower-extremity arteries, including those below the knee.

With 0.014 inch wire compatibility, the TOTAL across crossing catheter is intended to guide and support a guidewire, including the crossing of a target lesion, during the access of peripheral arteries with obstructive disease and to allow for wire exchanges. The device is also intended to provide a conduit for the infusion of saline solutions or diagnostic contrast agents.

Distinguishing features of the TOTAL across crossing catheter include the device's spiral cut stainless steel hypotube construction and 2Fr tapered tip. The spiral cut stainless steel hypotube construction affords exceptional pushability and unparalleled catheter visualisation, while the tapered tip allows the catheter to cross lesions smaller than the device profile. These features address the specific challenges often encountered in patients with critical limb ischaemia caused by lesions below the knee.

A press release from Medtronic also said the company has submitted an application to the US Food and Drug Administration (FDA) for 510(k) clearance of the new product that is currently under review. At the time of going to press, the FDA has not yet cleared the TOTAL across crossing catheter or approved any of the IN.PACT drug-eluting balloons.

Interim outcomes in Chocolate balloon angioplasty registry demonstrate high rates of procedural success and limb preservation

Interim results from the Chocolate balloon angioplasty registry conducted in the USA demonstrate that use of the TriReme Medical Chocolate percutaneous transluminal angioplasty balloon achieved high rates of treatment success and limb preservation in patients with peripheral arterial disease.

The Chocolate balloon angioplasty registry is a prospective, core lab adjudicated registry conducted at 33 clinical centres in the USA. A broad range of patients with advanced atherosclerotic disease in their legs were treated in this trial, including patients with high risk of amputation (Rutherford 5 and 6, total occlusions, long and calcified lesions). The study included two distinct patient groups: those with atherosclerotic disease mainly in above-the-knee vessels or below-the-knee vessels.

According to a press release, the highlights of the interim data presented at LINC 2014 included: Treatment was completed without major dissection in 98% of all patients; affected limbs were preserved at follow-up in 96% of above-the-knee patients and 97% of below-the-knee patients; and re-intervention of the limb was not required in 89% of above-the-knee patients and 93% of below-the-knee patients.

Jihad Mustapha, Metro Hospital, Wyoming, Michigan, USA, principal investigator for the trial, comments, "In this all-comers registry comprised of a large number of patients with diabetes and some of the most complex lesions including chronic total occlusions and high degrees of calcium, these results with Chocolate are remarkable. Chocolate is an attractive alternative to conventional therapies that often have poor outcomes."

Cordis announces agreement with TriReme

Cordis Corporation has announced entering into an agreement with TriReme Medical that grants the company exclusive distribution rights for the Chocolate percutaneous transluminal angioplasty (PTA) balloon catheter.

According to a press release, the Chocolate PTA balloon catheter, approved in USA in December 2011, is a unique angioplasty balloon that is designed to allow for atraumatic dilatation in treating peripheral artery disease. The Chocolate PTA balloon catheter is indicated for balloon dilatation of lesions in the peripheral vasculature, including

Product News

the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries.

First patient enrolled in Gore TAG Thoracic Branch Endoprosthesis LSA Feasibility study

Gore has announced that Himanshu Patel and David Williams, University of Michigan, USA, enrolled the first patient in the Gore TAG Thoracic Branch Endoprosthesis LSA Feasibility Study, a US-based, multicentre feasibility trial. The FDA approved the investigational device exemption (IDE) trial for the Gore TAG Thoracic Branch Endoprosthesis in the treatment of thoracic aortic aneurysms that require coverage of the left subclavian artery (LSA).

"Thoracic aortic aneurysms that encroach on the left subclavian artery make treating these challenging anatomies very difficult, leaving physicians no choice but to use more invasive surgical techniques or to cover the branch vessel," said Patel. "Using the Gore TAG Thoracic Branch Endoprosthesis, we were able to successfully treat the first patient in the study using endovascular means only. These results demonstrate the feasibility of using branched stent grafts to treat aortic aneurysms that involve the left subclavian artery."

Indigo mechanical thrombectomy system launched in the USA

Penumbra has launched its Indigo percutaneous mechanical thrombectomy system in the USA at the International Symposium on Endovascular Therapy (ISET; 18–22 January, Miami Beach, USA).

The system enables the removal of emboli and thrombi from the vessels of the peripheral arterial system. Unlike thrombolysis, which requires lengthy infusion times, Indigo can provide immediate restoration of flow to thrombosed vessels in the peripheral vasculature, a press release from the company states. It explains that restoration is achieved by means of a catheter with proprietary separator technology for mechanical clot engagement. Once the operator engages the clot, the Penumbra Max pump allows for hands-free aspiration and clot extraction. The release further states that Indigo provides access to tortuous and distal anatomy. This 6F–compatible percutaneous system is available in 6F and 4F catheter diameters with 132–150cm catheter lengths. It has the largest extraction lumen designed for vessels below the knee, with smaller and longer catheter options for hard-to-reach distal extremities. Early cases have shown rapid revascularisation times (<15 minutes), the release adds.

Himanshu Patel and the team at University of Michigan

Calendar of events

22–27 March
SIR—Society of Interventional Radiology's 39th Annual Scientific Meeting
San Diego, USA
San Diego Convention Center
E AnnualMeeting@SIRweb.org
W www.sirmeeting.org

5–8 April
Charing Cross Symposium
London, UK
T +44 (0)20 7736 8788
F +44 (0)20 7736 8283
E info@bibamedical.com
W www.cxsymposium.com

23–26 April
ECIO—5th European Conference on Interventional Oncology
E www.ecio.org
T +43 1 904 2003
E info@cirse.org

1–4 May
GEST 2014 US—Global Embolization Symposium and Technologies
San Francisco, USA
T +1 305 279 2263
E questions@ccmcme.com
W www.gestweb.org

14–17 May
23rd International Congress on Thrombosis
Valencia, Spain
T +34 96 352 48 89
F +34 96 394 25 58
E mltd2014@geyseco.es
W www.thrombosis2014.org

15–18 May
APCCVIR—11th Asia Pacific Congress of Cardiovascular and Interventional Radiology
Singapore
T +65 6346 4402
F +65 6346 4403
E secretariat@apccvir2014.com
W www.apccvir2014.com

20–23 May
EuroPCR
Paris, France
Palais des Congres
W www.europcr.com

28–31 May
SCAI 2014—Society of Cardiovascular Angiography and Interventions
Las Vegas, USA
T +1 202 741 9854/800 992 7224
E info@scai.org
W www.scai.org

29–31 May
CIRA—Canadian Interventional Radiological Association Annual Meeting
Montrèal, Canada
Le Centre Sheraton Montrèal
T +1 514 282 2744
F +1 514 282 4292
W www.ciraweb.org

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