IR congress news

CIRSE 2018 – Lisbon
Sunday, September 23, 2018

PICK UP CONGRESS NEWS EVERY DAY!

The CIRSE Clinical Registries

CIEMAR CIRSE Emprint Microwave Ablation Registry

CIEMAR (in design) | Objectives:
- Primary: To assess local tumour control of colorectal liver metastatic disease using the Emprint microwave ablation device
- Secondary: To assess safety (AEs and toxicity), effectiveness (PFS, OS, hPFS, time to untreated progression, QoL et al.) and economic factors

CIRT CIRSE Registry for SIR-Spheres Therapy

CIRT (ClinicalTrials.gov Identifier: NCT02305459) | Objectives:
- Primary: To observe the real-life application of radioembolisation using SIR-Spheres (all liver tumours) and associated treatment outcomes
- Secondary: To observe safety and effectiveness of SIR-Spheres treatment in terms of adverse events, OS, PFS, hPFS and QoL

CIRT-FR CIRSE Registry for SIR-Spheres Therapy in France

CIRT-FR (ClinicalTrials.gov Identifier: NCT03256994) | Objectives:
- Primary: To observe the real-life clinical application of radioembolisation with SIR-Spheres (all liver tumours) in France and associated treatment outcomes
- Secondary: To observe safety and effectiveness of SIR-Spheres treatment in terms of adverse events, OS, PFS, hPFS, technical considerations and QoL

CIREL CIRSE Registry for LifePearl Microspheres

CIREL (ClinicalTrials.gov Identifier: NCT03086096) | Objectives:
- Primary: To observe the usage of DEB TACE using LP-IRI for colorectal metastatic disease in the liver and map the exact indications as well as the stage in treatment that the device is being used at
- Secondary: To assess the observed treatment outcomes in terms of safety (AE & tox), efficacy (OS, hPFS, ORR et al.)

The CIRSE Research Infrastructure: our 5-year experience

Robert Bauer, Senior Clinical Project Manager, CIRSE Office

Data on IR therapies is sparse. Speak to most experienced IRs and they will be familiar with the situation of discussing a new treatment with opinion leaders in other medical specialties, insurance or regulatory bodies and having their request rebutted with a "looks promising but we need more evidence". The reasons for this apparent dearth are complex and it would go beyond the scope of this article to explain them. Rather, the intention here is to demonstrate what can be done about it, and what we are doing at CIRSE.

In 2013, CIRSE embarked on the search for opportunities to sponsor, and therefore be fully and independently responsible for the design, execution and quality of clinical studies in IR. The inital aim was:
- to set up a research infrastructure capable of executing high-quality clinical studies
- to conduct a succesful flagship study
- to identify and acquire more opportunities to conduct impactful research into IR procedures

Setting up a high-quality research infrastructure

Following consultation with eminent figures in the field of medical device research, four quality principles were defined, in the context of a broader quality system which forms the indispensible blueprint for our research infrastructure to this day. CIRSE aims to:
- produce high-quality data
- conduct ethical research
- conduct clinical research in an efficient and cost-effective manner
- provide a valuable member service

Reflecting on how to put our quality principles into practice, it became apparent that the scope of the research CIRSE could handle needed to be clarified. While randomised, controlled studies are universally accepted to generate the highest level of evidence, they are limited in terms of how they reflect real-life practice, an important factor in an operator skill-sensitive discipline. They have also demonstrated a high rate of failure in the dynamic field of IR. Randomised trials were deemed to be too costly for CIRSE to run, especially when taking into account their risk of failure and limited generalisability.

Our sights were trained on high-quality observational research that had the potential to yield impactful, "real-life" evidence on sizeable, multi-centre samples, while living up to our quality principles. The assemblance progressed accordingly: electronic data capture systems were evaluated and a network of reputable partners and third-party suppliers sought out. A dedicated team of researchers was set up in the CIRSE Office and certified to conduct clinical evaluations of medical devices in the human body. By the end of 2014, CIRSE had a fully-formed and trained clinical research department, with all the tools at hand and a clear goal to work towards.

Conducting a successful flagship study

Parallel to the setting-up of the infrastructure, early discussions between senior IRs, the CIRSE Office and SIRTEX Medical were being held regarding a possible data collection on their SIR-Spheres device. The interest of physicians in better understanding this innovative therapy and building on the randomised clinical assessments already performed implied that a "real-life" observation of SIR-Spheres would be appropriate. The device was being used to treat CRLM and HCC, but at what stage in treatment? And for which patients exactly? These questions were well-suited to the observational methods that CIRSE could now apply and were soon being considered in the context of a clinical study sponsored by CIRSE and funded by SIRTEX.

A study contract was negotiated, and in late 2014 CIRSE launched CIRT: The CIRSE Registry for SIR-Spheres Therapy. It was the overlap of physician, Society and manufacturer interest in creating actionable clinical data that underpinned CIRT and later drove its progress. Our flagship study was well-chosen, and CIRT has succesfully closed data collection with over 1,000 patients and a 99% completion rate of data collected from 29 centres in eight nations, with the first manuscripts currently being drafted. Although we will only have final conclusion on the study's impact after results have been published, CIRT is considered a proof of concept that CIRSE is able to independently conduct, from protocol to publication, high-quality data collections in the field of minimally invasive, image-guided therapies.

Identifying more opportunities to conduct research

As CIRT slipped into gear, it soon became apparent that the IR community saw substantial value in conducting independent studies through CIRSE: research ideas discussed with the Society can be conceived as multi-centre studies, spanning borders and data collections profit from CIRSE's excellent reputation and network in Europe. By 2017, CIRSE had succesfully entered into another three observational study partnerships (please see the tables above for more information).

As a direct result of the successful running of CIRT, an exclusively French data collection on radioembolisation has been implemented to facilitate the reimbursement of the procedure in France. CIRT-FR's design is based on CIRT but adjusted to meet the heightened requirements of the French national health authorities (HAS). This project is considered a milestone in the development of our research services so far, proving that CIRSE is capable of conducting studies of a quality high enough to satisfy regulatory bodies.

Looking forward, data on IR therapies is becoming less sparse and CIRSE is playing an important part in this. We have set up a high-quality research infrastructure, which now has a succesful study under its belt and is stimulating significant interest in the IR commmunity. The demands to our infrastructure have grown, and we currently face new challenges in developing our service to be able to even better meet the demands for high-quality data collection in the IR community. There is still plenty to be done. And it will be done at CIRSE.

Please visit our Focus Session:
FS 2501 – Clinical trials in IR – what an IR has to know in clinical research
on Tuesday, September 25, 08:30 – 09:30
for more information.

ET2019

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EMBOLOTHERAPY

June 26-29
Valencia | Spain

www.ETconference.org

Cardiovascular and Interventional Radiological Society of Europe

CIRSE

Polytrauma complications and their management

Colin Nice, EBIR

The majority of trauma occurs outside of traditional core working hours [1], when there are typically fewer and less experienced staff available. Management by a trauma team is associated with a better outcome and more unexpected survivors [2]. Complications occur in approximately 30% of seriously injured patients. They cause suffering and are responsible for a long-term reduction in quality of life. Complications are also detrimental to the institution and healthcare system, as the length of hospital stay and hospital costs are both increased in patients experiencing complications.

Men (the majority of serious trauma patients) and elderly patients are more likely to develop serious complications. There is an association with the injury pattern; those with fractures, solid organ injury and head injury all experience a greater rate of complications [3].

Complications affect all organ systems but their aetiology, and therefore opportunities for prevention, can be considered to be:

1. A direct consequence of the initial trauma (e.g. compartment syndrome);
2. Due to haemorrhage and hypoperfusion (e.g. acute lung injury/ARDS/coagulopathy);
3. Treatment-related (e.g. catheter-related blood stream infection or urinary tract infection);
4. Thromboembolic disease, associated with trauma.

Trauma prevention (the best way to avoid complications) is governed by societies using a combination of legislation and public health campaigns to promote objectives such as traffic speed reduction, reducing alcohol consumption and fitting stair gates within the homes of young children.

Haemorrhage

30-40% of early trauma deaths are due to haemorrhage (62% of all hospital deaths within 4 hours of trauma). A 2007 UK report [1] concluded that the "majority of preventable deaths after injury occur from unrecognised and hence untreated haemorrhage, particularly within the abdominal cavity making it perhaps the single most important reversible cause of death in the trauma population".

The aims of circulation management are to avoid hypoperfusion (acidosis), hypothermia and coagulopathy. When successful, this reduces trauma mortality and also the incidence and severity of complications due to organ hypoperfusion and ischaemia. Simple, effective measures include warming intravenous fluids, the patient and their environment.

Rapid haemorrhage control is critical and may be best achieved within a trauma-centre environment with defined transfer protocols, trauma teams, staff call-out, and imaging and treatments protocols. Embolisation techniques must also be appropriately modified to achieve this aim; a hypovolaemic patient with pelvic fractures requires a rapid non-selective embolisation of the internal iliac territory rather than a lengthy super-selective procedure (resulting in longer period of hypotension or larger transfusion requirements).

Pelvic fractures

Arterial haemorrhage due to pelvic fractures is a serious threat to life requiring immediate treatment. Many patients arrive in IR departments with a pelvic binder in place. These reduce the amount of blood loss and may be associated with a shorter hospital and intensive-care stay [4], although inaccurate placement is common and reduces their effectiveness [5]. Pressure damage to the skin may begin as soon as 3 hours after binder application, making definitive haemorrhage control and fracture stabilisation to facilitate early binder removal imperative.

Gluteal muscle necrosis is an infrequent but feared complication of internal iliac artery embolisation [6] and is more likely in patients with high injury severity scores and co-existing buttock soft tissue trauma. This results in sepsis and a high mortality rate. Prompt recognition and surgical debridement may be life-saving. Soft tissue reconstruction utilising a flap with non-embolised arterial supply can be undertaken later as a planned procedure [7].

Urological and sexual function are both compromised by pelvic fractures, but it remains unclear whether embolisation procedures further exacerbate these problems [8, 9].

Splenic injury

Splenic artery embolisation has increased the success rate of non-operative management of splenic injuries (from 77% to 96%), enabling high splenic salvage rates whilst also reducing hospital mortality and hospital stay [10]. Embolisation may be proximal (occlusion of the main splenic artery just beyond the dorsal pancreatic branch) or distal (segmental and sub-segmental branches). A recent meta-analysis [11] suggests that distal embolisation is slightly more effective in achieving haemostasis, but also results in twice as many complications requiring intervention or surgery. Combined proximal and distal embolisation produces a tenfold increase in severe complications!

Treatment-related complications can be minimised by meticulous asepsis and procedural technique and responsible antibiotic usage. Constant vigilance is essential for the early detection and management of other emerging complications.

Logistics

Many of these procedures will be undertaken outside core working hours, and in larger institutions (where major trauma centres tend to be located), the team members may be meeting each other for the first time. Properly implemented surgical safety checklists are invaluable in getting the team communicating effectively and functioning well from the outset and allow an early opportunity to ensure that the resources (personnel, equipment and venue) are appropriate for the patient and that contingency plans are in place ('what do we do when the angiosuite malfunctions?'). Whilst there may be little specific evidence regarding their effectiveness in reducing trauma-related morbidity and mortality, their use is logical and has become mandatory in many countries.

Operator factors

Trauma IR is challenging and there is scope for avoidable operator error or system failures leading to complications and patient harm. Lessons from surgical practice are likely to apply equally to trauma IR: retained surgical swabs and instruments (considered a good indicator of disorganisation or system failure) are nine times more likely to occur in emergency cases and are four times more likely when there has been an unplanned change in procedure [12]. It is rare that a count has not been undertaken; mostly it is simply incorrect. Similar risk factors are frequently encountered in trauma interventions.

As operators we may have the opportunity to influence how we fail:

Consider an 18-year-old patient with a grade 3 blunt thoracic aortic injury at the isthmus requiring emergency stent graft insertion. Even with intentional coverage of the left subclavian artery, there is only a short proximal sealing zone before the graft impinges on the left common carotid artery and with thoracic aortic pulsation, millimetre-perfect graft deployment is not always possible.

An operator concerned by this may deploy the graft too far from the left CCA, compromising exclusion of the transection (potentially remediable with insertion of another appropriately sized graft – but do you have one?) Too proximal deployment and the left common carotid is compromised (Fig. 1) and may require rescue placement of a covered stent (Figs. 2 and 3). In this case it would be reassuring to know that one is immediately available. Even then, unexpected complications may arise; on removal of the surgical drapes, the left foot was observed to be ischaemic due to distal embolisation of thrombus from the thoracic aorta and required aspiration thrombectomy to salvage the limb.

Conclusion

Interventional radiology is a fundamental element of modern trauma management, but even within major trauma centres, the experience may be limited. Effective multidisciplinary working and rigorous monitoring of trauma outcomes is mandatory and problems must be reported under a unit's governance structure, ensuring that the lessons learnt are shared promptly and systematically.

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Don't miss it !

Management of the poly-traumatised patient
Clinical Evaluation Course
Sunday, September 23, 10:00-11:00
Auditorium 8

Colin Nice
(EBIR)
Freeman Hospital
Newcastle-upon-Tyne,
United Kingdom

Dr. Nice is an interventional radiologist at the Newcastle upon Tyne NHS Foundation Trust in Newcastle, United Kingdom. He has recently joined the Freeman Hospital after 11 years as a Consultant in nearby Gateshead. Dr. Nice is a lead radiologist for the North East Abdominal Aortic Aneurysm Screening Programme and a peer reviewer for the National AAA Screening Programme. He is currently the Head of the Written Examination for the EBIR Council.

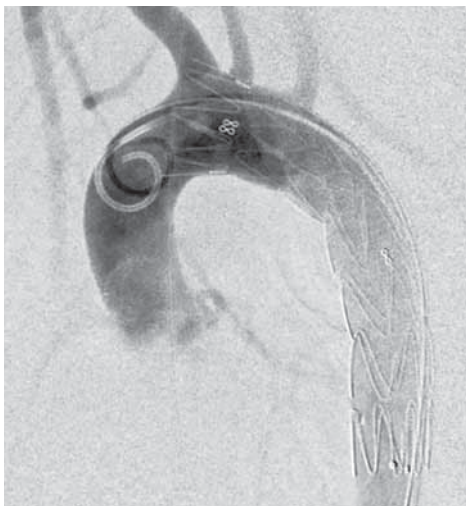

Fig. 1: Partial coverage of the left common carotid artery with a thoracic aortic stent graft.

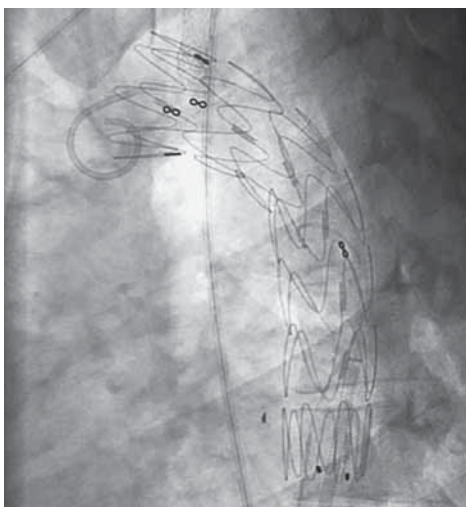

Fig. 2: Covered stent placed to preserve the left common carotid artery.

Fig. 3: Thoracic aortogram following left common carotid artery covered stent placement.

Don't miss it !
Transradial access
Hot Topic Symposium
Sunday, September 23, 15:00-16:00
Auditorium 1

Transradial access: why we need to move from the groin to the wrist

Darren Klass

Darren Klass
Vancouver General Hospital
Vancouver, Canada

Dr. Darren Klass works as an IR at Vancouver General Hospital and is a Clinical Associate Professor at the University of British Columbia, Vancouver, Canada. He obtained his Bachelor's degree of medicine and surgery in South Africa at the University of Pretoria in 2001. He also obtained his doctoral degree from the University of East Anglia in 2011. Dr. Klass is a member of numerous radiology and IR societies in both North America and Europe and serves on the Board of Directors of the Canadian Association for Interventional Radiology (CAIR). He is a Member of the Royal College of Surgeons of England (MRCS), Fellow of Royal College of Radiologists (FRCR) and Fellow of the Royal College of Physicians and Surgeons of Canada (FRCPC).

Percutaneous transradial (TR) access for angiography was first described in 1989. It has been shown to be as efficacious as transfemoral (TF) access, as well as safer, more cost-effective and preferred by patients in cardiology.

Radial access in interventional radiology has many advantages for both the patient and the operator and team. The significant decrease in complications and subsequent mortality demonstrated in cardiology have some relevance to interventional radiology, particularly in patients with poor cardiorespiratory reserve or those patients with coagulopathies. The mortality benefit demonstrated in the MORTAL study will not be replicated in IR literature; however, the MORTAL study provided evidence that a complication from vascular access in a vulnerable patient, requiring transfusion is an independent predictor of mortality. The study demonstrated a number needed to harm (NNH) of 7.4 at 1 year [1].

The IR literature has increasing data demonstrating the safety and efficacy of TR access; since one of the first papers describing the technique in fibroid embolisation [2], the data has strengthened with large retrospective cohorts published from Mount Sinai, New York [3] and Vancouver [4].

Both studies demonstrated TR to be safe in a variety of IR procedures, with low haematoma rates and low radial artery occlusion (RAO) rates (Table 1).

A concern with many IRs has been the perceived increased radiation dose to both the patient and the operator with TR procedures. Much of this concern was without merit and was based on early cardiology studies where procedure time for TR was longer than femoral, but only by 60 seconds [5]. A study by Yamada et al. [6] demonstrated significantly lower operator dose and a trend to lower patient dose in TACE patients in a well-designed randomised trial.

Challenges

Despite the data that has been generated for TR intervention in IR, scepticism continues regarding its adoption as a routine technique.

Groin complications remain an issue despite the belief that they are vanishingly rare in IR. The reality is that although the complication rate is almost certainly lower than in cardiology, the data in IR regarding femoral complications is sporadic, with low-number studies describing major retroperitoneal haematoma rates of 0.1-0.7%. A larger study quoted a 5.3% pseudoaneurysm rate and 1.6% dissection rate [7]. There is no doubt that closure devices have decreased femoral complication rates significantly; however, the rate is not zero and this should be considered when deciding on access sites.

An ongoing debate has been the issue of stroke with TR access. I accept, as do all radial operators, that there is a stroke risk, however it must be borne in mind that a large randomised trial (MATRIX) included an analysis of the incidence of stroke in radial vs femoral coronary procedures (subclinical stroke and ischaemic stroke combined) and demonstrated no difference in incidence. In a study accruing over 500,000 patients [8], a 0.1% incidence of stroke was found in both femoral and radial coronary procedures.

For many operators, even this is a high rate, but there are many factors in IR which decrease the probability of stroke even further: fibroid patients have little or no vascular disease; the number of catheter exchanges is much less in IR procedures; we do not cross the arch; only the left vertebral artery is crossed. All these factors decrease the extremely low rate even further. This should not be used as a reason not to offer radial access to patients.

The most common mistake made by IRs is the belief that no training is required to competently perform radial procedures. The access of the vessel in the wrist is, in my opinion, the least complicated aspect of the procedure; the steps following access will dictate the rate of spasm, thrombosis, technical failure and procedure time, and many of these aspects are not translated from femoral access.

Patients require a cocktail of antispasm medication and heparin to decrease the rates of spasm and RAO. A low RAO rate allows for multiple reaccess procedures through the radial artery (Table 1). Traversing the radial artery requires knowledge of anatomical variants such as radial loops. Catheter selection and wire selection for the procedure can have a significant impact on technical success and procedure time, and the wealth of experience available from around the world should not be ignored. I feel it is mandatory for all operators to undergo some form of training before embarking on radial intervention. It aids in room set-up, patient selection, catheter selection and careful procedural considerations that are unique to radial intervention.

Benefits of TR access

Above all, the benefits of radial intervention lie in reduced bleeding complications, ease of cannulation of visceral vessels from above, decreased radiation dose to the operator and patient, and benefits for trauma; it seems an irrefutable fact that radial is better for the patient. For those who remain sceptical of the benefits regarding bleeding risk mitigation, the ability to discharge a patient so rapidly post procedure and avoid unnecessary hospital admissions or prolonged recovery is in itself enough reason to consider radial access. That is the reason each of us wakes up and goes to work each day – to make the lives of our patients better.

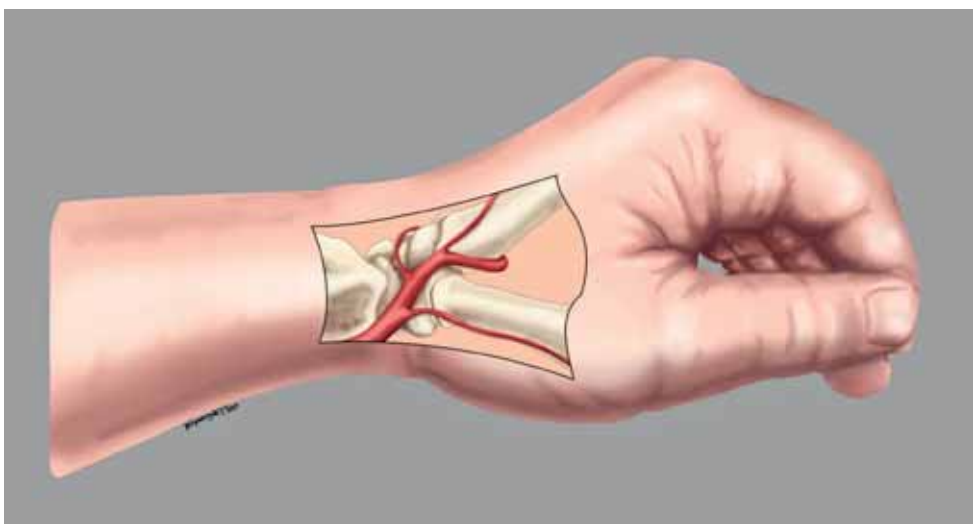

Fig. 1: ldTRA is gaining popularity in cardiology and has many advantages for IR.

Access no.	Patient no.
1	1,428
2	302
3	119
4	42
5	10
6+	12
11	1

Table 1: Radial arteries can be accessed multiple times if good techniques including patent haemostasis are utilised.

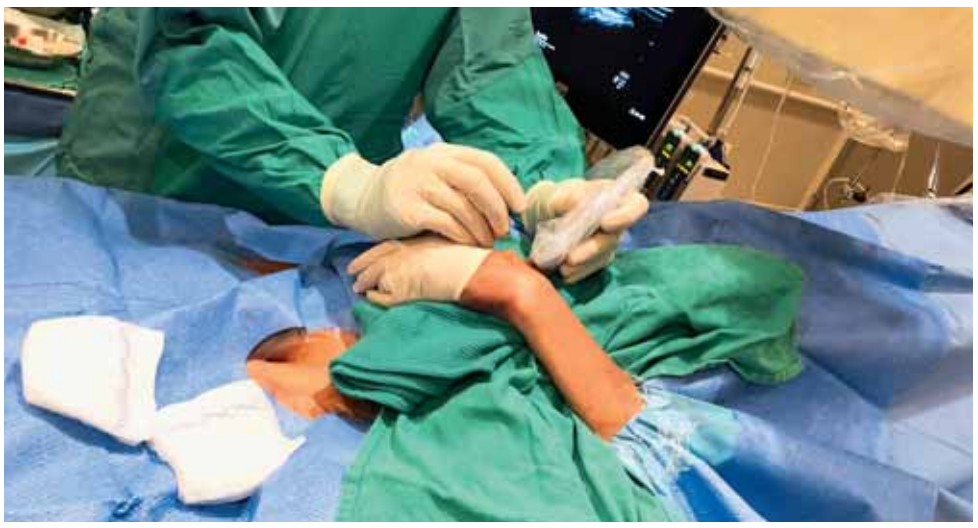

Fig. 2: ldTRA allows for access from the right side of the patient. The groin can be prepped for more complex cases if necessary.

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9. Abstract No. 159 Technical feasibility and safety of left distal transradial access for percutaneous image-guided procedures Hadjivassiliou, A. et al. J Vasc Interv Radiol. 2018;29(4):S71.

In late 2014, I surveyed patients who had undergone both radial and femoral interventions, asking which they preferred and why. The response was an overwhelming preference for radial intervention [4]. The majority of patients felt earlier ambulation and being able to sit up immediately post-procedure were significant benefits. The oncology population unequivocally voiced their preference for TR access, as it allowed them to be discharged almost immediately post-procedure. For many of us, this is not a consideration and it is normal to admit patients for an overnight stay following an intervention; however, for a patient with a prognosis of 3 months, a single night in hospital is one less night spent with their family, purely because of access site choice. This specialty that we all advocate for prides itself on being able to do complex procedures through a pinhole and get patients home faster, yet many do not see the benefit of radial access as part of it.

Radial access has the ability to revolutionise post-procedural care; it decreases nursing intensity post-procedure and allows for safer recovery of patients. Patients require less nursing input because they are ambulant immediately and often will then require less analgesia. A recent comparison of nursing intensity in our department between femoral and radial access demonstrated a four-fold decrease in nursing intensity per patient.

Since the adoption of TR access as a default for almost all of our procedures in our institution, we have saved over CA$600,000 in closure devices alone.

The future

Social media has provided a unique springboard to cross-specialty collaboration and discussion amongst medical professionals.

None is as well-demonstrated as the evolution of left distal radial access (ldTRA) (Fig. 1). The literature on ldTRA prior to 2016 was limited to Russian and Iranian journals. The procedure is well described and used in both of these countries, but little was known in the western world. The father of radial intervention, Dr. Ferdinand Kiemeneij, first performed and then tweeted about the procedure, which has led to an extremely fast adoption of the technique, and for the first time, IR leads together with cardiology in developing this technique. Many unanswered questions remain regarding this procedure, but after performing over 250 cases, I believe that there is definitely a place for it in radiology, perhaps even more so than conventional radial access, given the possibility of access with the patient's arm across their lower pelvis, allowing access from the right side of the patient as for femoral access (Fig. 2). The haemostasis times are faster than for conventional radial access. A purpose-designed haemostasis device is now available (Fig. 3), allowing for even faster haemostasis than femoral access, with very few obstacles once access is obtained. In a recent study, no difference was demonstrated in the size of the radial artery in the wrist, compared to the snuffbox [9]. The data is accruing at a rapid rate and a multi-centre, multi-specialty randomised controlled trial is planned to assess haemostasis (haematoma and RAO rates) using a potassium ferrate haemostatic disc.

Parting thoughts

I am not a radial-only operator, I am a radial-first operator.

I choose radial because I believe it is better for patients; however, if appropriate, I choose femoral access. Radial access skill is essential for all IRs today; the degree of adoption, however, is an individual's choice. That choice should not be clouded by trepidation regarding a new skill or unfamiliarity, as this will only lead to patients not getting the best available care; and that, for an IR, is not acceptable.

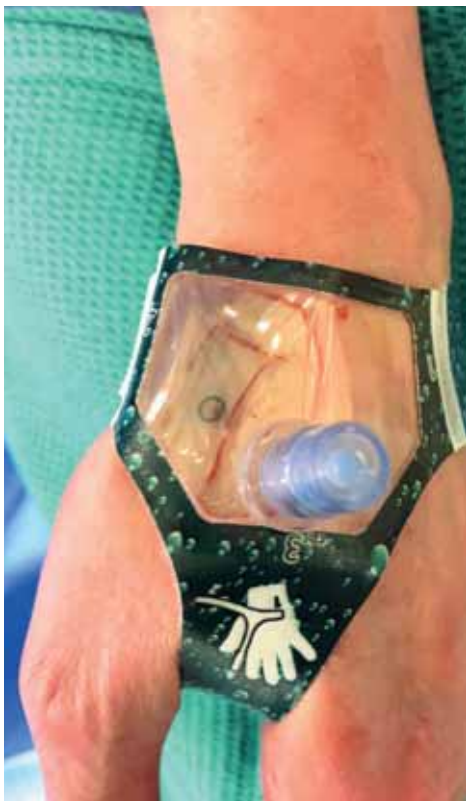

Fig. 3: Purpose-designed ldTRA haemostasis device allows for comfortable haemostasis with free movement of the wrist and hand.

DESIGNED WITH PURPOSE

ACCELERATE AND MAXIMIZE **THROMBIN GENERATION**

241%

HIGHER RATE OF THROMBIN[1]

80%

INCREASE IN PEAK THROMBIN[1]

Achieve mechanical occlusion and support biological response with our fibered Concerto™ detachable coil system

Reference

[1] Girdhar G, Read M, Sohn J, Shah C, Shrivastava S. In-vitro thrombogenicity assessment of polymer filament modified and native platinum embolic coils. *J Neurol Sci.* April 15, 2014;339(1-2):97-101. Percentages are calculated from the average of nylon and PGLA fibered coils.

Medtronic
Further, Together

Lessons learnt from the ATTRACT trial

Rick de Graaf

Patients suffering from acute deep venous thrombosis (DVT) are at higher risk for premature death and long-term disability. Low molecular heparin followed by oral anticoagulants (OAC) has proven efficient in preventing fatal PE, thrombus progression and recurrent DVT. Still, despite adequate anticoagulation, patient morbidity is considerable, with a high rate of post-thrombotic syndrome (PTS). One third of patients do not return to their baseline quality of life (QoL) after DVT. Moreover, the socio-economic impact of PTS is noteworthy. At 10 years after an ilio-femoral DVT, nearly 50% of patients have ulcers; 11 of 12 men are disabled and unable to maintain a steady job because of their leg symptoms, and 7 of 9 women are unable to perform household duties [1]. Over the last two decades, increasing evidence suggests that early thrombus removal may prevent PTS by restoring venous patency, limiting the inflammatory cascade and preserving valvular function.

The Data

The ATTRACT trial was a 56-centre, randomised controlled trial (RCT) that evaluated pharmaco-mechanical catheter-directed thrombolysis (PCDT) for prevention of PTS in patients with acute proximal DVT [2].

However, the ATTRACT trial was not the first RCT. The first RCT investigating endovascular thrombus removal, the Torpedo trial, showed clear superiority of interventional therapy and OAC over OAC alone in the treatment of proximal DVT to prevent PTS [3]. However, this study did not lead to a generally accepted change in treatment strategy.

The CAVENT trial from southern Norway was another prospective multi-centre RCT across 20 hospitals comparing standard OAC with standard OAC plus more aggressive CDT and/or stenting [4]. Initially published in 2011, and more recently with 5 years' follow-up, it demonstrated unequivocal improvements in the rate of PTS; these differences in favour of "intervention" became considerably more impressive at 5 years as compared with the initial 2 years' results. Even after this second positive RCT, the clear benefit of CDT has not been fully appreciated, mainly because "the expectations were higher". Surely, in retrospect, there are some reasons for this suggested discrepancy in CAVENT, including a number of methodological and technical issues, including a very low rate of stent placement (17%), a low incidence of purely ilio-femoral venous thrombosis (~37%) and variable diameters of balloon dilatation and stent insertion. Another argument for criticism amongst conservatives is the risk of bleeding. There was a significant rate of bleeding (20/101) with 3 "major" bleeds in the CDT group vs. none in the standard therapy group. Neither group had any intracerebral bleeds, nor deaths, and no pulmonary emboli. Again, however, even allowing for these issues, it needs to be strongly emphasised that there was a significant improvement in patients' symptoms at 5 years and 2 years in those patients treated with thrombolysis.

Surprisingly, ATTRACT did not show a benefit to the addition of PCDT to OAC to limit PTS. Denoted by a Villalta score of greater than 5, PTS was similar between the two groups (46.7 vs. 48.2%; P= 0.56). Interestingly, the analysis of Villalta and VCSS for continuous data does show a significant difference at every time point in favour of intervention (P values of <0.01). Moreover, ATTRACT data from sub-groups and secondary analyses suggest that catheter-directed thrombolysis may have a benefit in patients who have acute iliofemoral DVT (in contrast to femoropopliteal DVT). The data also showed a trend towards greater treatment effect for catheter-based interventions with patients who present with more severe symptoms.

The Issues

Since its final publication at the end of 2017, ATTRACT has had to endure multiple attacks on its design and execution. Both substantial methodological critique from multiple venous experts and justification from the author's side have recently been published [5, 6]. One major problem the study suffered from is that it was conceived in the early 2000s. Since then, endovascular therapy for both acute and chronic venous obstructions has flourished, while knowledge and experience has been increasing rapidly. With the knowledge of 2018 we would most definitely design a similar study in a different way.

The Lessons

Foremost, catheter-based treatment of femoropopliteal DVT (FP-DVT) patients would not be included. We know that FP-DVT patients do not benefit from endovenous thrombus removal. Including FP-DVT patients in the ATTRACT trial undermined the iliofemoral DVT (IF-DVT) arm and reduced the ability to make statistically significant decisions based upon the reduced IF-DVT sample size.

Secondly, dedicated and targeted imaging is essential to include the right patients, decide on treatment strategy and evaluate treatment success. Magnetic resonance venography (MRV) is excellent to determine the location and extent of the thrombus (indication and treatment approach), estimate the composition and morphology of the venous obstruction (acute vs. sub-acute or old thrombus and acute-on-chronic), and identify underlying causes of DVT, e.g. May-Thurner compression. Acknowledging these aspects may have significant impact on treatment success. This type of imaging should be routinely included in a future trial, however, it was neglected in the ATTRACT trial. This may be one of the reasons that a remarkably low percentage of stent deployment was seen in ATTRACT. It is estimated that more than 90% of DVT patients require stenting after thrombus removal, because of relevant vein compression.

Directly associated is the aspect of dedicated venous stents. The patients who were actually stented received arterial designed stents in the majority of cases and Wallstents in other cases. Although the modern venous stents have not been proven to perform better than the Wallstent, the other stents used in ATTRACT don't come close to either dedicated venous stents or the Wallstent, considering radial force and maximum diameter. Adequate stenting of iliac vein stenosis is essential in DVT treatment. Failing to do so is likely to result in recurrent DVT, i.e. risk of PTS. Another reason for early failure relates to residual thrombus. It is widely acknowledged that residual thrombus induces recurrent DVT and PTS. It is surprising that a scoring system from 1977 [7] was used to evaluate such a significant factor for treatment success. With the knowledge from venous stent studies in the 1990s and early 2000s, it's evident that intravascular ultrasound (IVUS) is superior to venography to evaluate vein stenosis. For thrombus removal estimation, IVUS superiority is even more obvious. Thus, not fulfilling these prerequisites may lead to early re-occlusion of the vein after endovascular therapy. Early recurrence after intervention would of course show no benefit in the treatment arm. Sadly, in ATTRACT (early) recurrence was not evaluated with duplex ultrasound prior to discharge in 500 of 695 patients.

In summary, most lessons in DVT treatment were learned in the last decade and were recently confirmed by ATTRACT results. They include:

- Patients with iliofemoral DVT are likely to benefit from endovenous thrombus removal; patients with femoropopliteal DVT are not;
- Dedicated imaging modalities are helpful to include the right patients, treat all the significant lesions and evaluate treatment success;
- In order to test if open veins prevent PTS after DVT, make sure that the veins are actually open after treatment;
- Dedicated venous devices are likely to perform better than devices manufactured to treat arterial disease and should be favoured in venous recanalisation.

Don't miss it !

Update in venous thrombo-embolic disease
Focus Session
Sunday, September 23, 08:30-09:30
Room 5.A

Rick de Graaf
Clinical Center of Friedrichshafen
Friedrichshafen, Germany

Dr. Rick de Graaf studied medicine at the University of Maastricht, Netherlands and obtained his PhD at the Department of Surgery and Medical Microbiology in the Maastricht University Medical Centre. He received his training in radiology at the same institution and obtained his board license in 2010. After clinical and research fellowships at renowned international institutes, including Montefiore Medical Centre and the Alfred Krupp Clinic, he focused on the minimally invasive treatment of vascular diseases. Dr. de Graaf has published over 60 scientific papers and at the beginning of 2018, acquired the position of Chief of Radiology in the Interventional Radiology and Nuclear Medicine Department at the Clinical Centre of Friedrichshafen, Germany.

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1. TF O'Donnell, NL Browse, KG Burnand, ML Thomas. The socioeconomic effects of an iliofemoral venous thrombosis. J Surg Res. 1977(22);483-488.
2. Vedantham S. , Goldhaber, S.A., Julian, J.A. et al. Pharmacomechanical Catheter-Directed Thrombolysis for Deep-Vein Thrombosis. N Engl J Med 2017. 377:2240-2252.
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SMART AND SAFE!

CIRSE **Radiation Protection**

How to make your angio suite smart and safe!

Visit the Radiation Protection Pavilion

CIRSE's Radiation Protection Pavilion, located in the exhibition hall, is here for you during the entire Annual Meeting, offering information material and opportunities to engage directly with experts in radiation protection. Interventional radiologists are exposed to high levels of radiation in daily practice and therefore face particular health risks. Take a seat in the Radiation Protection Pavilion and learn how to reduce and protect against exposure.

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

Today's RPP Mini-Talks

	Time	Mini-Talk	Speaker
SUN SEPT 23	09:30 – 09:45	The use of real-time dosimetry in optimising radiation protection (Raysafe/Fluke)	J. Williams *(Everett, WA/US)*
	09:45 – 10:00	High dose procedures: how to manage dose in biliary drainage	M. Freund *(Innsbruck/AT)*
	11:00 – 11:15	Peak skin dose: trigger level to implement dose optimisation and patient-oriented best practice (Bracco)	A.G. Rampoldi *(Milan/IT)*
	11:15 – 11:30	High dose procedures: how to manage dose in transradial access	A. Buecker *(Homburg/DE)*
	12:30 – 12:45	X-ray dose reduction in angiography (Kinepict)	S. Osváth *(Budakeszi/HU)*
	12:45 – 13:00	High dose procedures: how to manage dose in prostatic artery embolisation	F.C. Carnevale *(São Paulo/BR)*
	13:00 – 13:15	High dose procedures: how to protect and manage dose – technical solutions	R. Adamus *(Nürnberg/DE)*
	13:30 – 13:45	Radiation protection beyond the cath lab (MAVIG)	M. Schmid *(Munich/DE)*
	13:45 – 14:00	How to optimise your angiographic room	G. Bartal *(Kfar-Saba/IL)*
	14:00 – 14:15	How to recognise overexposures (incidents and accidents) for reporting to authorities	R. Loose *(Nürnberg/DE)*
	14:15 – 14:30	High dose procedures: how to manage dose in paediatric IR	A. Cahill *(Philadelphia, PA/US)*

Radiating Awareness: Prof. Werner Jaschke

We sat down with Prof. Werner Jaschke to discuss the EU directive on radiation protection which came into effect in 2018. Make sure to check out the RPP Programme!

CIRSE: What effect has the new directive had on radiation protection in daily practice?

Jaschke: The new directive has had a great impact on every department in terms of working styles and documenting. I think what became obvious to the public very rapidly was the lowering of the threshold for the dose of the lens. Initially, there was a big concern among the interventional radiology community on how to achieve this goal but there were a lot of indicators that interventionalists stay below the annual threshold if they use lead shields and protecting eyewear. If you keep up with radiation protection recommendations, it's not a problem; even if you do very demanding, long-lasting interventions.

CIRSE: What kind of myths exist surrounding radiation protection among the medical community?

Jaschke: I think there are two myths: one is the risk is irrelevant, so don't bother too much with radiation protection and the other one is, radiation is so dangerous, you better stay away from it! As an instructor, you come across both. There are then people who are neglecting the risks entirely, so we always recommend personal dosimetry. Because as soon as physicians get direct feedback on how to protect themselves, they see that the dose can be decreased by ninety percent without interfering with image quality or handling catheters.

CIRSE: Is there any overview of training in radiation protection and level of implementation of the directive in the EU?

Jaschke: Diagnostic reference levels (DRL) for interventional procedures will hopefully help to harmonise standards of radiation protection and medical practice in the different member states. It has a lot to do with the equipment you use: if you have sophisticated or new equipment, it's much easier to lower the dose for the patient and the staff. If you have, for example, an image intensifier instead of a flat panel system, it's much harder to stay in the range. It also has to do with the training: if you are well trained and have experience with a lot of procedures, it's much easier to fulfil all criteria but if you are in institutions where you don't have support from well-trained interventionalists, it's a different story.

CIRSE: You've recently released a paper with Prof. Anna Belli on radiation myths and how it affects the gender gap in IR. Can you talk to us about this?

Jaschke: Well, first of all, you have national legislation which forces you more or less to do some things. Let's say in Austria: when a woman gets pregnant, usually the recommendation is that she should not perform fluoroscopy or any procedure in which she would be directly exposed to radiation. The risk is handled very differently, for example, in Switzerland, the US or UK, where there is no legislation that the woman has to stay away from the radiation during her pregnancy.

What is very important for us is not only the pregnant interventionalists, but younger females who are concerned that by working in interventional radiology, they might increase the potential risk for genetic abnormalities, cancer or anything like that and I think we have to inform them that, according to our current knowledge, this risk is not higher than the natural risk if you respect certain rules. I myself, for a long time, advised young female doctors that if they wanted to get pregnant, they'd better stay out of interventional radiology because I was uninformed. Now, I always encourage young females to enter interventional radiology. If they get pregnant then we have to deal with the fact that they are out of the field for one year, perhaps a little bit longer.

CIRSE: The Radiation Protection Pavilion (RPP) has been a hit at CIRSE since its establishment; what more can we do to campaign for radiation awareness in the field?

Jaschke: The RPP is a great way of promoting radiation protection issues but we also need to reach the general audience, not only the ones who voluntarily step up to the RPP, listen to talks and gather information. I think that radiation protection issues should be an integral part of every session, either via the speakers themselves or handout materials. We really have to inform the entire community, especially the younger interventional radiologists. If you have a teacher who doesn't take care of radiation protection at all, there is the likelihood that you will neglect all these vital steps.

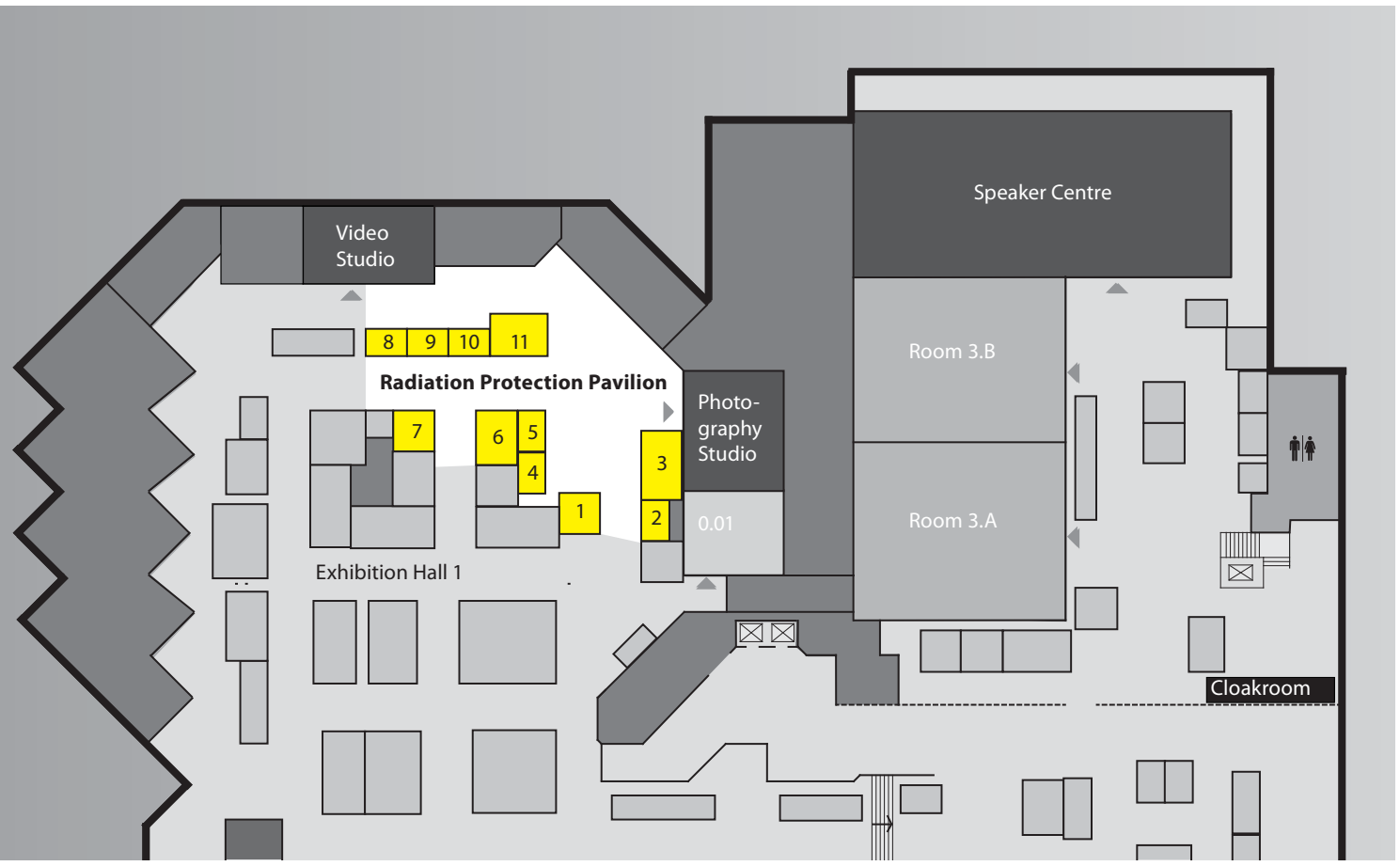
The nice thing about radiation is you can measure it; you have very sensitive tools, like for no other chemical or physical hazard. It's very easy to gain high-quality information on the radiation dose during each procedure. Good indicators of radiation dose are provided by the DICOM dose report which is automatically generated by the angiographic equipment at the end of each procedure. Interventionalists should evaluate it routinely!

Personal real-time dosimetry is very helpful to optimise radiation protection of the staff. If you see your personal dose in real time you can, for example, directly see the protective effect of leads shields, undertable lead shields or the decrease of dose if you change from high resolution and frame fluoro to lower resolution and frame fluoro. Personal real-time dosimetry helps to increase the acceptance of radiation protection measures.

Prof. Werner Jaschke is the Director of Radiology at the Medical University of Innsbruck in Tirol, Austria.

Technical Exhibition RPP
(Alphabetical List)

Official Name	Booth# (RPP Area)
3D Systems Simbionix	8
Bracco Injeneering	4
Ecolab	1
EuroSafe Imaging	9
Kinepict Health	6
Mavig	3
MDT X-Ray	11
Mentice	2
Siemens Healthcare	5
Unfors RaySafe	10
Worldwide Innovations & Technologies	7



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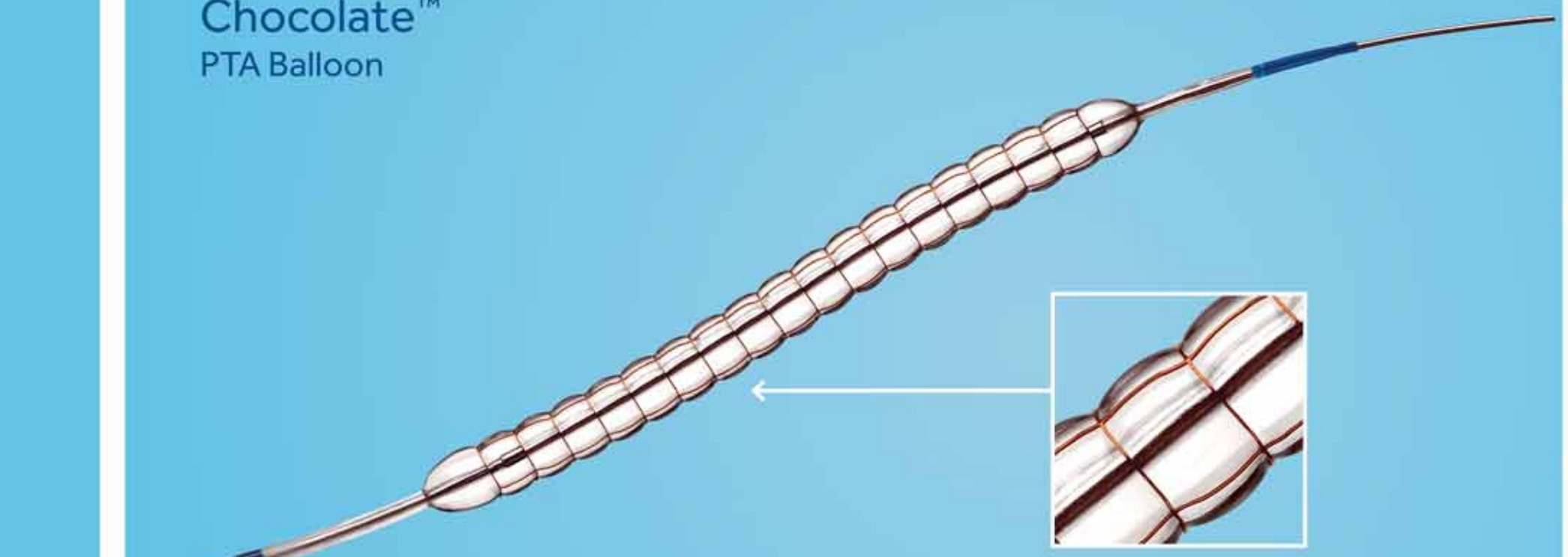

SYMPOSIUM

Strategies and Innovative Solutions for Success in Complex Peripheral Vascular Disease

Monday, September 24 | Auditorium 8		
14:30-14:40	Introduction	F. Fanelli
14:40-14:55	What are the DCB Data from Real-world Global trials telling us?	G. Goyault
14:55-15:10	Calcium: the Achilles Heel of Endovascular Treatments	C. Nolte-Ernsting
15:10-15:25	What are the Consequences of Dissections and How to Avoid Them?	J. van den Berg
15:25-15:30	Closing Remarks	K. Katsanos

LEARNING CENTER

Medtronic Booth,
Exhibit Hall

Saturday, September 22 | 14.00-14.45		
How do you treat calcium? Hands on Directional Atherectomy		M. Treitl
Sunday, September 23 | 12.30-13.15		
RESCUE ME! Must have tools to get you out of complications		Y. Bausback
Monday, September 24 | 12.30-13.15		
Directional Atherectomy with CO2 Angiography: when and how?		T. Bisdas
Monday, September 24 | 15.30-16.15		
How do you minimize dissection? Chocolate balloon from bench to routine clinical practice.		G. Schuetz
Tuesday, September 25 | 11.00-11.45		
Directional Atherectomy with CO2 Angiography: when and how?		T. Bisdas

Medtronic
Further, Together

Treating One of the Biggest Causes of Death Worldwide: How IR Can Help

ESIR

Host of the 2019 course in Dublin, Prof. Mick Lee, tells us why his hometown is the ideal location for an ESIR course.

CIRSE: Why is venous thromboembolism an important focus for IR?

Lee: Venous thromboembolism is probably one of the biggest causes of death and morbidity in the world and healthcare spending on VTE is enormous and rising year to year. There is a novel treatment for patients who have certain types of venous thromboembolism and this is where interventional radiology fits in. IR treatments of DVT and PE are generating a lot of excitement in the worldwide community.

A great example of the interest in VTE is the fact that our biggest ESIR course ever, in terms of attendance, was on this topic. Furthermore, interest in venous thromboembolism also comes from other disciplines, not just interventional radiology.

CIRSE: Is there any other upcoming evidence that we should look forward to in this field?

Lee: Yes, the first trial in this area was the CAVENT trial which demonstrated a significant benefit from thrombolysis over anticoagulation alone, at five years in terms of the post-thrombotic syndrome. Currently, we are waiting on the Dutch trial, CAVA, which is supposed to be reporting either at the end of this year or perhaps next year. It is a study looking purely at patients with iliofemoral DVT.

CIRSE: What can attendees expect to learn from the ESIR course hosted in Dublin?

Lee: This time we are going to have a lot more clinical input in terms of pulmonologists, intensivists and A&E physicians who are going to talk about anticoagulation treatment of DVT and pulmonary embolism. We are also going to provide input into the appropriate treatment in terms of anticoagulation post-stenting and I think that this is an exciting addition.

We will also have many hands-on sessions and there will be a faculty member at each station to explain the use of particular devices to attendees. On top of this, there will be a complications session where the experts are going to show their complications, which should be a valuable learning experience.

CIRSE: What is your personal highlight of next year's course?

Lee: The exciting thing for me is learning what the clinicians have to say about modern anticoagulation treatment for pulmonary embolism and deep venous thrombosis, including the length of treatment, what kind of anticoagulation we should put patients on and for how long. These are all questions that are difficult to reach a conclusion on but it's great having experts who might give us some guidance in that area.

CIRSE: Why is Dublin a good place to host this course?

Lee: The meeting is going to take place in the Royal College of Surgeons which is on St. Stephen's Green in the centre of Dublin. It has easy access to all the hotels in the region and it's a very historic building (taken over by rebels during the uprising in 1916) with a new state-of-the-art medical school and worldclass postgraduate simulation labs. Then there is Dublin itself, a thriving, multicultural city which offers a lot in terms of culture and history, so I am sure attendees will certainly not be disappointed.

CIRSE: How has IR developed since you started your career as a trainee in this field?

Lee: The subspecialty has progressed extensively in terms of breadth and depth of IR treatments and the acceptance of these treatments into daily practice. IRs are also shifting toward a clinical practice model which I think could be much better because there are a lot of places that are still not providing 24/7 cover and that are still not doing clinics. The latter are important for the future of interventional radiology.

CIRSE: In what ways do you think that the CIRSE community has grown?

Lee: It has grown enormously and I attribute this to three main factors. Firstly, things really started to take off when we got the permanent secretariat in Vienna and that was really important in terms of running the day to day business of CIRSE. Secondly, there has been a big improvement in the quality of speakers and presentations at our meetings. Thirdly, CIRSE reached out to other interventional societies in terms of group membership, but you can only do that if you've got the basics right and there's a meeting worth going to. On that note, I actually think that the annual CIRSE meeting is now a premier IR meeting with a global audience.

Exploring IR in Latin America

Kamil Jabarkhel, CIRSE Office

The *CIRSE meets...* programme is an opportunity to reach out to other associations and national societies to initiate or deepen cooperation, while providing the audience with an insight into their work. Over the years, the programme has helped to strengthen the relationship between CIRSE and countless other societies in the field of IR.

This year, we are delighted to welcome the Sociedad Iberoamericana de Intervencionismo (SIDI) to our popular session. SIDI has a rich history in helping to shape and develop the field of IR throughout Latin America and beyond, and CIRSE is very excited to gain its perspectives on different areas of IR. These include discussions on congenital portosystemic shunts, complications in uterine fibroid embolisation as well as CHEVAR, FEVAR and T-Branch stent grafts.

CIRSE meets SIDI

SIDI is a non-profit organisation whose goal is to foster and promote interventional radiology within Spanish-speaking countries. Since its inception in 1994, it has grown to include more than 140 members, all of whom work in the field of image-guided, minimally invasive procedures. While a large proportion of the current members are from Latin America, Spain and Portugal, the scope and influence of the society extends to other countries in Europe and also the USA, fostering international collaboration that extends beyond the Spanish-speaking world. Some of the main activities of SIDI include the organisation of scientific congresses, seminars and other activities as well as the production and publication of the Spanish-language quarterly scientific journal *Intervencionismo*.

The advantages for individuals associating with SIDI are diverse, and include scholarships and training programmes in reference centres, information about IR courses, congresses and other activities, as well as access to content featured in the *Intervencion* magazine.

Presentations on key IR topics

As a part of the programme, three members of SIDI will come and give presentations about three different medical conditions and their IR treatments, with a distinctly local twist. Firstly, Dr. Sierre will share his knowledge of congenital extrahepatic portosystemic shunts. CEPS is a rare disorder characterised by partial or complete diversion of portomesenteric blood into systemic veins via congenital shunts. Type I is characterised by a complete lack of intrahepatic portal venous blood flow due to an end-to-side fistula between main portal vein and the inferior vena cava. Type II, on the other hand, is characterised by partial preservation of portal blood supply to the liver, and a side-to-side fistula between main portal vein or its branches and mesenteric, splenic, gastric and systemic veins. Attendees can expect to not only learn more about this dangerous condition, but also what the diagnosis and treatment options are.

This will be followed by a presentation by Dr. Guerrero-Avendaño on how to prevent and solve complications in uterine fibroid embolisation. UFE is an increasingly popular, minimally invasive treatment option for women with symptomatic fibroid disease. Although UFE therapy is an effective, well-tolerated procedure that offers relief of fibroid symptoms with a low risk of complications in the acute post-procedural period, immediate complications may relate to vascular access, thromboembolic events, infection and pain management. Reported major complications include, but are not limited to, pulmonary embolus, uterine ischaemia, necrosis, sepsis and death. Because of the severity of potential complications, this session can be highly useful for anyone who is either currently performing UFE or is simply interested in learning more about the procedure.

The last session featured in this programme will include Dr. Cruz Vásquez talking about the CHEVAR, FEVAR and T-Branch procedures. The CHEVAR procedure refers to the use of a parallel graft chimney technique that uses covered renal stents with a standard aortic stent graft, whereas FEVAR is used in the para-renal or visceral segment of the aorta for a proximal sealing zone, preserving the visceral perfusion via precisely located windows within the stent-graft fabric. T-Branch multi-branched stent grafts provide a longer overlap between the bridging stent and the attachment site, minimising the risk of disconnections and type III endoleaks. Dr. Vásquez will talk about these procedures in detail, making the session essential for anyone wishing to learn more about aortic interventions.

Sunday, September 23
10:00 – 11:00, Room 3.A

CM 1006 CIRSE meets SIDI

Moderators:
M.A. de Gregorio (Zaragoza/ES),
R.A. Morgan (London/UK)

1006.1 Congenital portosystemic shunts: diagnosis and treatment options
S. Sierre (Buenos Aires/AR)

1006.2 Complications in uterine fibroid embolisation: how to prevent and solve them
G. Guerrero-Avendaño (Mexico City/MX)

1006.3 CHEVAR, FEVAR and T-Branch: the Latin American aorta's puzzle
L.A. Cruz Vásquez (Medellín/CO)

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TIPS SYMPOSIUM
AT CIRSE 2018, LISBON

New evidence using cTIPS with Controlled Expansion to treat portal hypertension.

MONDAY, SEPTEMBER 24, 2018
7:40–8:20 AM • Room 3.A

Moderator
Dr. F. Fanelli, Florence, Italy

Speakers
Prof. R. Loffroy, Dijon, France
Dr. R. Miraglia, Palermo, Italy
Prof. Trebicka, Bonn, Germany

GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion

Topics

Reviewing new guidelines for the treatment of portal hypertension complications. What has changed?
R. Loffroy, Dijon

Initial experience using the GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion and the GORE TIPS Set.
R. Miraglia, Palermo

1-year results of a case control study using cTIPS with Controlled Expansion in patients presented with ascites.
J. Trebicka, Bonn

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East meets West – CIRSE supports IR growth in the Asia-Pacific

Ciara Madden and Genevieve Schmoeker, CIRSE Office

More sophisticated medical devices are not the only benefit of the forward-march of technology: with better communications and travel opportunities, ideas and information can flow freely. We no longer rely on the shoulders of giants to boost us upwards; small, continuous contributions from everyone in the community can result in big steps forward – if, that is, we take the time to meet, share and connect.

The CIRSE meeting, and the CIRSE Society, endeavour to be global platforms to facilitate just such an exchange. We are honoured to be supported in this endeavour by many partner societies around the world, as well as the individual members who valiantly strive to play their part in this global effort to advance the subspecialty.

IR, IR, burning bright...

An area of key growth, in medicine as well as other technological and economic areas, is the Asia-Pacific region – a true "tiger economy" in IR terms. Countries with well-established IR communities, such as Japan and Australia, are increasing their professional interactions with more recently established IR communities, such as China and Malaysia. Combined, they form a formidable block of knowledge, and are mobilising this through the Asia Pacific Society of Cardiovascular and Interventional Radiology, which has just decided to change its biennial scientific meeting to a yearly event.

In March this year, CIRSE was once again thrilled to participate in and support the 13th APSCVIR meeting. This year, the conference took place from March 8-11 in Auckland, New Zealand, and was hosted by the Interventional Radiology Society of Australasia (IRSA). Many current and former CIRSE Executive Committee Members took part in the conference as faculty, most notably at the "APSCVIR meets CIRSE" session, where CIRSE President Robert Morgan, Afshin Gangi, Anna-Maria Belli, Otto van Delden and Raman Uberoi spoke on a range of scientific topics.

The session *Quality Assurance and Clinical Practice in Interventional Oncology* touched upon an increasingly important topic, and speakers, such as radiation oncologist Liz Kenny, emphasised how quality assurance measures benefit not only safe and efficient practice of IO, but ultimately innumerable patients, too.

In a magnificent celebration that followed the successful conference days, conference convenor Andrew Holden led the awards ceremony, with Andy Adam being among the proud recipients of APSCVIR Honorary Membership. This was an exciting opportunity for CIRSE to be represented in Australasia alongside other international interventional societies, and to exchange ideas and strengthen ties with this region.

EBIR – An increasingly global qualification

The partnership between IRs in Europe and the Asia-Pacific doesn't stop there. A mere week after candidates took the EBIR exam in Vienna during the European Congress of Radiology (ECR 2018), the EBIR examiners flew across the globe to Auckland, New Zealand for another sitting on March 7-8, on the occasion of APSCVIR. Excitingly, this Auckland examination was EBIR's fourth round in Australasia, and was overall the twentieth EBIR exam to have taken place. The Auckland examination also set a new record for the total number of candidates to sit an exam in Australasia, with a total of 21 people having participated. Currently, 72 Australasian IRs hold the EBIR certificate - an impressive number that will undoubtedly increase in the coming years.

The high standards that govern the EBIR examinations are constantly under review, and a second edition of the European Curriculum & Syllabus for IR was released in early 2017. The new curriculum now includes updated and new procedures, a separate section on interventional oncology, as well as an explanation of how candidates can use the syllabus to prepare for the exam. By using the syllabus to create balanced examinations, the EBIR exam not only assures a summative assessment but also ensures that candidates are tested in key areas of interventional radiology. It also demonstrates that CIRSE is committed to maintaining the very highest standards of safety and clinical care.

EBIR is expanding its reach across the globe, and many have taken note. Candidates from a total of 45 countries have taken the exam since 2010, when the EBIR examination was first established. Currently, the United Kingdom holds the greatest number of candidates who have been EBIR-certified, while Germany holds a close second. Out of the non-European countries who have participated, Australia and Saudia Arabia have the highest number of candidates to have taken the EBIR. CIRSE applauds all candidates who have taken the EBIR and invites those who have not yet tried the exam to certify their expertise!

To sign up for an EBIR examination or to find out more information, please visit www.cirse.org/ebir.

For questions regarding the exam, please contact us at ***ebir@cirse.org.***

APSCVIR Asia Pacific Society of Cardiovascular & Interventional Radiology

IRSA Interventional Radiology Society of Australasia

Words from an APSCVIR Gold Medallist: Dr. Robert Allen

In conversation with Megan Leahy, CIRSE Office

I lost my left hand making a bomb at the age of 14 – this was not to hurt anyone but to make a big bang. I think if I had had two hands I would have chosen surgery but in 1971 I chose radiology because of the limited number of imaging procedures involved. For me, IR fitted with my manual skills and it also promised the challenge of discovery by presenting many "what if" questions. It has been personally rewarding for me to develop new concepts and design many devices useful in the practise of IR throughout my working life.

It is always good to back a winning horse and in IR I saw the opportunity. It is gratifying that what I was doing 40 years ago has now been consolidated into routine practice. Industry, partnered with clinicians, has been inventive in the design and manufacture of a huge range of high quality catheters, wires and many other tools. Today, I work exclusively in IR with a practice covering vascular, oncology, renal and other pathologies with new devices and techniques emerging in all areas.

It was a surprise and great honour to find out that my colleagues nominated me for consideration. However, I do not see this award as just mine as I have been supported and inspired by many of my colleagues over the years.

In this connected world it is useful to have a standard, such as the EBIR, that gives weight to the specialty, facilitates the distribution of ideas and practice standards that will hopefully be transferable and recognised worldwide. I took the exam myself because I wanted to encourage our young IRs to get up to speed in their Fellowship year in IR with a view to sitting the exam.

There is a lot to learn now and the discipline is maturing. That said, there is enormous scope for improvement in existing practice and in devising and implementing new ideas. Look back and learn from those that have gone before but do not be afraid to explore new paths.

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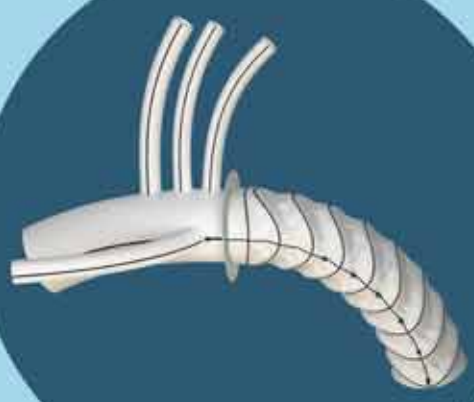

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Collaborating Against Cancer Initiative: Dr. Bargellini and Dr. Depalo

ECIO

As part of a new interview series, we spoke with a number of pairs from around the world who took part in the Collaborating Against Cancer Initiative during ECIO 2018.

Thanks to CIRSE's popular Collaborating Against Cancer Initiative, hundreds of non-radiologist colleagues have received a travel grant and attended ECIO free of charge over the years. This grant option allows the colleague to see the variety of interventional oncology options available and for positive interdisciplinary relationships to be fostered. We caught up with recipients of the grant, Dr. Irene Bargellini and her nuclear medicine colleague, Dr. Tommaso Depalo from the University Hospital of Pisa, in Italy.

CIRSE: How does multidisciplinary teamwork function in your hospital?

Bargellini: In our hospital, we have several multidisciplinary boards for different topics. Regarding the treatment of liver conditions, the multidisciplinary board meets once a week, bringing together experts from surgery, hepatology, interventional radiology and so forth. With regards to radioembolisation, we generally work together twice a week.

CIRSE: Why did you decide to work in cancer care?

Bargellini: The way I was introduced to cancer care was through our liver transplantation programme, which has traditionally been very strong in our hospital. During the programme, we worked a lot on treating hepatocellular carcinoma, often handling the pre- and post-procedures as well. Focus on radioembolisation on the other hand, came as a result of our collaboration with pharmaceutical companies in the area of thyroid cancer. We have a strong multidisciplinary team in our hospital focusing on thyroid cancer and this is how the collaboration came about.

Depalo: Just to add to Irene's point about our thyroid team, we also actively treat patients suffering from thyroid cancers by administering doses of radioactive iodine (I-131). In fact, this is a specific branch of nuclear medicine and we are very happy to have it in our hospital. This particular treatment is offered in our Nuclear Medicine Unit and is performed in collaboration with radiologists, oncologists, clinical physicians and so forth. As pointed out by Irene, we generally meet twice a week.

CIRSE: Why were you interested in taking part in the Collaborating Against Cancer Initiative at ECIO?

Bargellini: A few years ago, I proposed the same initiative to an oncologist. At that time, he was working in our hospital, as a resident. After finishing his residency, the physician in question chose to pursue radioembolisation as an area of focus and I am very happy to say that we now work with him actively in the radioembolisation programme. I think that he is clear example of the fact that it is very beneficial for physicians, especially the younger ones, to attend ECIO and explore all the different options that are available to them. The initiative clearly encourages multidisciplinary collaboration in the field of cancer care and this is great, especially because I feel that many older physicians are not very keen on attending multidisciplinary meetings.

Above all, ECIO is one of the few congresses that concentrates so many different specialists in oncology all under one roof. This means that the congress is an excellent way to educate yourself and stay up to date on very specific topics in IO. Because of its size, delegates have the opportunity to meet like-minded professionals, share ideas and update themselves on new and exciting research.

Depalo: Coming to the conference has been very interesting for me because it allowed me to explore the field of cancer care from an IR perspective. Coming here and attending some of these sessions has proved to me that the scope for multidisciplinary collaboration between interventionalists and experts from other fields such as nuclear medicine can be expanded. I think the Collaborating Against Cancer Initiative is doing a great job of proving this point and I hope that more physicians use it in the years to come.

CIRSE: What do you enjoy most about the ECIO conference?

Bargellini: One thing that immediately comes to my mind is the fact that the sessions are planned very well. What I mean by this is that you are not faced with a dilemma about which sessions to attend and which ones to miss. Furthermore, ECIO is very educational and gives all physicians a great opportunity to update themselves on the latest research and data regarding various studies and trials taking place in IO. I also very much like the size of the congress and the fact that it is not too big, which makes navigating very easy. I am always fortunate to come across old friends and acquaintances which for me, makes the event even more memorable.

Depalo: I agree with what Irene said, particularly about the well-planned sessions. For example, one of the congresses that I attend, which focuses on nuclear medicine is much more confusing because many of the sessions that I want to attend happen simultaneously and this can be frustrating. Luckily, that doesn't happen at ECIO.

CIRSE: Are there any sessions at ECIO this year that you are really looking forward to attending?

Bargellini: There are a number of sessions that I am really looking forward to. The one topic that I particularly want to explore at ECIO is hepatocellular carcinoma. There are going to be a number of sessions focused on this topic throughout the conference so that's definitely something that I am going to follow closely.

Depalo: I will also follow the sessions related to hepatocellular carcinoma, with a particular focus on side effects of different procedures in HCC. I also look forward to attending sessions on radioembolisation as this is a field that I actively work in and it would be great to get some insight into it from an IR perspective.

News on Stage

News on Stage will feature displays on the latest results from multi-centric trials, ground-breaking techniques and many more IR hot topics, shown in a dedicated open area. Large-screen presentations given by the authors during dedicated slots around lunch time will give delegates the opportunity to hear from the experts and engage with them and other key opinion leaders in active, lively discussions.

Sunday, September 23, 13:15-14:15, News on Stage Area

NoS 1204 Scientific News on Stage

Moderators: J.A. Kaufman (Portland, OR/US), O. Pellerin (Paris/FR)

1204.1 Inside interventional radiology: micro CT 3D imaging of angiographic guidewires
T.Q.L. Klaus, G.A. Krombach, E. Alejandre-Lafont, M. Kampschulte; Giessen/DE

1204.2 Design, creation and evaluation of 3d-printed high-detailed vascular models for selective interventional simulation
R. Kaufmann, M. Takes, C.J. Zech, T. Heye, P. Brantner; Basel/CH

1204.3 Application of a biomechanical deformable registration image method for assessing ablation margins in colorectal liver metastases
E.Y. Lin, B.M. Anderson, G. Cazoulat, K. Brock, B.C. Odisio; Houston, TX/US

1204.4 EW-7197, a transforming growth factor-beta type I receptor kinase inhibitor, ameliorates acquired lymphedema in a mouse tail model
S.H. Yoon, K.Y. Kim, J.-H. Park, H.-Y. Song; Seoul/KR

1204.5 WITHDRAWN

1204.6 Comparison of a full-core end-cut biopsy device with a side-notch device: diagnostic valence of the specimen
J. Schaible, B. Pregler, L. Lurken, P. Wiggermann, L.P. Beyer; Regensburg/DE

STUDENT CORNER

Risha Rose, CIRSE Office

Enjoying the Coolest Capital in Europe

Known lately as Europe's "capital of cool", this city's fusion of vintage charm and cultural flair will make for the trendiest congress experience and most student-friendly travel destination backdrop yet. Students can spend their off-hours exploring the city, tasting the local delicacies, sun bathing at the beach, partying until the sun comes up, and much more. While some activities can be rain-checked for a later date, others are a must! Check out the must-dos while in Lisbon.

Kyle_Taylor@Flickr.com

Things Not to Leave Lisbon Without Experiencing

The Nightlife

While you will be immersed in the busy happenings of congress-going by day, the hours after sunset are when you will experience the city come alive. Some of the most popular party spots are Bairro Alto, one of the oldest, most traditional neighbourhoods known for its bohemian and alternative vibes, that gains a new life along its cobblestone streets at night, and Cais do Sodré, the district responsible for transforming a traditional Lisbon into a progressively innovative and liberal hotspot. Both areas are a short ride from the congress centre.

Affordable Feasting

Lisbon is Western Europe's least expensive city, which means you can try all of the best delicacies without blowing your budget. Top of the list is the pastéis de nata, the famed Portuguese custard tart that originated at the Jerónimos Monastery. Seducing from the first bite, this tasty treat can now be found throughout the city. Lisbon's stretches of coastline also offer a wide variety of seafood cuisine, with cod (or bacalhau) being the country's most popular. Try this entrée in one of its many variations at any of the restaurants along the harbour. For a trendier meal experience, join locals at the LX Factory, an old fabric-manufacturing building situated under the bridge in Alcântara, that now buds creativity in its many restaurants, cafes, and artsy shops. Wash any meal down with some sweet ginjinha cherry liqueur, or Portugal's most noted port wine.

The City of Seven Hills

Like Rome, Lisbon was built on seven hills. This means seeing the beautiful sunshine city in all its cultural and fashionable charm from multiple viewing points, or miradouros. Stay an extra day after the congress to hike each steep cobblestone slope for fascinating sights of the city rolling onto the banks of the River Tagus, and, on your way, visit famous city landmarks, such as the iconic Belém Tower, St. George's Castle, Jeronimos Monastery, and historic turned hippest Alfama neighborhood. For those short on time, a ride on the tram 28 makes for a spectacular exploration.

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Students in the Spotlight

We had a chance to speak with some of your peers about their interest in medicine and experiences studying throughout Europe. Meet today's students from Latvia and the United Kingdom.

Anastasija Dergunova
Latvia

Navin Mukundu Nagesh
United Kingdom

CIRSE: Why did you decide to study medicine and why are you interested in interventional radiology?

Anastasija: I decided to study medicine when I was a child, and over the years, this dream has become even stronger. I first learned of IR during my last school year when my mother started working as a nurse in the interventional radiology department of the Riga East University Hospital. Then, during my first year of university, I had the opportunity to participate in a workshop of endovascular aneurism repair. My interest in IR continues to grow; it is relatively new in the medical world and has huge growth potential for practice and research. IR reflects the advanced world we live in!

CIRSE: How did you hear about the CIRSE Annual Congress and Student Programme and why did you decide to attend?

Anastasija: I heard about CIRSE from doctors in my department, who visit it annually. Learning that the congress also offers a programme for students, I decided to attend, especially because this year it is taking place in Lisbon – a city that simply amazes me!

CIRSE: What are the reasons you chose to study medicine in the UK? Did you consider going to medical university in any other countries?

Navin: Studying medicine in the UK was a natural choice for me since I already live there and have my family and friends. I feel fortunate to have the opportunity to study in the UK as I believe there is tremendous support for students and trainees. I have had opportunities to get involved in research projects, attend conferences, author journal publications and more. I am continuously inspired to believe that we are all working together for the benefit of the health of our community and this is highly motivating.

CIRSE: If you could practice medicine anywhere in the world, where would that be and why?

Navin: I would like to complete my postgraduate training within the UK, which will hopefully allow me to have the credentials to work overseas. I enjoy teaching and mentoring and would love the opportunity to use my knowledge and skills to educate students and trainees from other countries to help them provide better patient care. I have previously had elective experiences in Mumbai and Chennai in India and would like to return there one day as a doctor to conduct charitable or fellowship experiences.

be inspIRed...

Fact or Fiction: Shedding Light on Occupational Radiation Hazards for Female IRs

There is no real occupational radiation hazard for female IRs. FACT

The lack of knowledge or misinformation provided by the medical community on radiation risks for pregnant women often leads to undue apprehension and may deter potential female trainees. The risks from occupational radiation exposure during pregnancy, however, are very small compared to other risks that may affect a pregnancy. In fact, the pregnancy outcomes after exposure to radiation levels encountered in the angiography suite are indistinguishable compared to outcomes among those exposed to natural background radiation.

Despite knowing that the risks are small, many pregnant IRs do not wish to accept any risk and often request to be moved away from tasks with radiation exposure. If a pregnant interventional radiologist continues working, it is important to keep the dose to a minimum by wearing appropriate personal protective shielding and practising careful fluoroscopic techniques.

Dr. Clair Cousins, Chair of the ICRP and former IR at Addenbrooke's Hospital in Cambridge, UK

Occupational radiation will harm the foetus during pregnancy. FICTION

Once a pregnancy has been declared, ICRP recommends that the additional dose to the foetus should not exceed 1mSv during the remainder of the pregnancy. The threshold dose for foetal injury is 100mSv. The average dose received by a working pregnant interventional radiologist over the entire gestation is 0.3mSv and to the foetus is approximately 0.09mSv. The risks from occupational radiation exposure during pregnancy are very small compared with other risks that may affect a pregnancy, i.e. a spontaneous abortion rate of 15% and an incidence of major malformation of 2–4%. Pregnancy outcomes after exposure to radiation levels encountered in the angiography suite are indistinguishable from outcomes among those exposed to natural background radiation.

Dr. Clair Cousins, Chair of the ICRP and former IR at Addenbrooke's Hospital in Cambridge, UK

By keeping below the occupational dose limits, the risk of developing radiation-induced genetic defects in a pregnant IR's offspring is negligible. FACT

Women of child-bearing age may have a heightened concern about the long-term genetic risks, or in case of pregnancy, the risks of their unborn child related to exposure of low-level radiation. This issue has been extensively discussed, and presently there is no evidence that foetal exposure below 1 mSv during the whole pregnancy involves an additional risk to the unborn child. For example, according to the Report 174 of the National Council of Radiation Protection and Measurements (NCRP), there is little to no evidence among the offspring for an excess of cytogenetic syndromes, single-gene disorders, malformations, stillbirths, neonatal deaths, cancer, or cytogenetic markers that would indicate an increase in heritable genetic mutations in the exposed parents.

Jaschke, W., Bartal, G., Trianni, A. et al. Cardiovasc Intervent Radiol (2018) 41: 1254. https://doi.org/10.1007/s00270-018-1968-2

QUESTIONS OF THE DAY

Sunday, September 23, 2018

Be in with a chance to win daily prizes by sending your correctly answered questions to **students@cirse.org** by 18:00 tonight!

Answers to the below questions can be found within today's Congress News.

The first three correct responses will win €25 Amazon vouchers. Ready… set… GO!

1. Name at least two current **CIRSE clinical registries.**
2. The **EU Directive 2013/59/Euratom** – what topic does it address?
3. How many Australasian IRs hold the **EBIR certification?**
4. Complications occur in approximately ▮▮% of seriously injured patients. ▮▮% to ▮▮% of early trauma deaths are due to haemorrhage, which is ▮▮% of all hospital deaths within 4 hours of trauma.
5. This condition is probably one of the biggest causes of **death and morbidity** in the world.

Recommended for Students Today!

Mentoring Breakfast
09:00-10:00, Student Lounge

CEC 1004: Management of the poly-traumatised patient
10:00-11:00, Auditorium 8

FC 1003: Musculoskeletal ablation
10:00-11:00, Room 5.A

CEC 1401: Femoropopliteal disease in claudicants
16:15-17:15, Auditorium 8

CBD 1403: Arterial gastrointestinal bleeding
16:15-17:15, Auditorium 7

AI 1406: Amazing Interventions
16:15-17:15, Auditorium 1

IDEAS WS 1502: Fundamentals in TEVAR
17:30-18:30, Auditorium 2

CIRSE Students' Evening
20:00

DON'T MISS THE **STUDENT MENTORING BREAKFAST** TODAY FROM 09:00-10:00 IN THE **STUDENT LOUNGE!**

Coming up tomorrow!

- **Dr. Sara Protto, ETF Subcommittee Member from Finland tells us about what inspired her to study interventional radiology**
- **Meet your peers from Slovenia and Romania**
- **Try your chances at another Questions of the Day challenge**

Crossword puzzle answers from Saturday's Student Corner:
1. CVIR Endovascular 2. Deep vein thrombosis 3. Intervention 4. Anna-Maria Belli 5. Charles Dotter 6. Claudication 7. CIRSE 8. ETF 9. Student Programme 10. RPP 11. IDEAS 12. Hypertension

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[1] LUTONIX Global SFA Real World Registry, n=691. Primary efficacy endpoint is defined as freedom from TLR at 12 months. TLR Free rate by subject counts at 12 months was 93.4% (605/648). The Kaplan-Meier TLR-Free survival estimate was 94.1% at 12 months and 90.3% at 24 months. In the LEVANT 2 IDE Clinical Trial, treatment with LUTONIX® 035 DCB resulted in freedom from TLR rate of 87.7% at 12 months (250/285) and a freedom from TLR rate of 82.0% at 24 months. Data on file, Bard Peripheral Vascular, Inc.

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CE 0086

Stem cell and gene therapy: new frontiers in critical limb ischaemia

Sanjiv Sharma, Mumun Sinha

Don't miss it !
New frontiers in critical limb ischaemia
Focus Session
Sunday, September 23, 08:30-09:30
Auditorium 1

Sanjiv Sharma
All India Institute of Medical Sciences New Delhi, India

Prof. Sanjiv Sharma is the Head of the Department of Cardiovascular Radiology & Endovascular Interventions at the All India Institute of Medical Sciences (AIIMS), New Delhi where he has worked for over 30 years. He completed his radiology training at the Post Graduate Institute of Medical Education & Research at Chandigarh in 1982 and was awarded the highest order of merit at this institute. Prof. Sharma was also a WHO fellow at the University of California, San Francisco. He is past president of the Indian Society of Vascular & Interventional Radiology (2003-2006), of the Asia-Pacific Society of Cardiovascular & Interventional Radiology (2004-2006) and the Chairman of the Research & Education Foundation, Indian Society of Vascular & Interventional Radiology (2009-2014).

Critical limb ischaemia (CLI) represents a severe form of peripheral artery disease (PAD). The management strategies include medical, surgical or endovascular intervention to restore straight-line, pulsatile blood flow to achieve wound healing, alleviate rest pain and prevent major amputation. Below-the-knee lesions pose challenges due to access issues, poor distal run-off, small vessel diameters, extensive calcifications and concomitant multifocal proximal obstructive disease. Often, a strategy for surgical or endovascular revascularisation may not be feasible due to anatomically irreparable disease. Hence, management strategies are constantly evolving.

New endovascular techniques & devices may improve short-term outcomes, but fail progressively with time and, eventually, are not much better than conventional techniques in the long term, despite major treatment cost escalation. Angiogenesis and cell-based therapies have emerged as a new frontier in this treatment and may have the potential to fulfill a crucial clinical need. Therapeutic angiogenesis using recombinant proteins and genes amplifies adaptive neovascularisation and perfusion in tissues compromised by ischaemia. There is growing interest in gene- and cell-based therapy. Many studies have evaluated their safety and efficacy in patients with CLI who are not suitable for revascularisation or when used as additives to endovascular revascularisation.

There is evidence that administration of growth factors can be employed to augment perfusion and collateral flow. Many growth factors, including vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF) and hepatocyte growth factor (HGF) have been shown to demonstrate angiogenic potential to promote angiogenesis and arteriogenesis in revascularising an undersupplied tissue [1]. VEGF, a 45 kDa heparin-binding glycoprotein, is the most extensively studied. With intra-arterial and intramuscular administration, it was reported to increase vascularity and salvage limbs in a clinical study [2]. Two later randomised controlled trials (RCTs) using plasmid DNA and adenovirus vector, respectively, failed to meet primary and secondary endpoints with increased peripheral oedema [3,4]. FGF therapy is safe, but a beneficial effect has been inconsistent thus far, as clinical trials failed to demonstrate consistent beneficial effects on primary or secondary endpoints [5]. An in-human clinical trial (Phase I/IIa) for HGF was initiated using intramuscular injection of naked human HGF pDNA by Morishita et al. [6]. It showed significant improvement in ankle-brachial index, rest pain, wound healing and walking distance at 2 months. No serious adverse event was detected over 6 months' follow up. Powell et al. assessed the safety of intramuscular injection of HGF plasmid to improve limb perfusion (HGF-STAT trial) and concluded that intramuscular injection of HGF plasmid was safe and well tolerated [7]. We conducted a trial on an experimentally induced hind limb ischaemia model in 24 rats, using graded doses of VEGF administered by intramuscular injections under control of CMV promoter in three doses (200, 400 and 800 microgram) or saline in the left thigh. Two weeks later, ischaemia was induced by excision of the left femoral artery. IA-DSA of both limbs was performed two days later. The rats were later euthanised for pathological and immune-cytochemistry studies. We showed that collateral density and distal circulation improved following injection of VEGF and the response was dose-related. This improvement in capillary density was well seen at IA-DSA performed before the animals were euthanised. Many clinical phase 1 and 2 trials have evaluated the safety and efficacy of similar approaches with mixed results.

The concept of using growth factor-eluting stents has also been explored. These coated stents may help the endothelium to grow back over the stent, a process called stent passivation. This serves as a physical barrier to platelet adhesion and thus thrombosis. The capacity of VEGF-coated stents to accelerate re-endothelialisation and reduce restenosis and thrombosis was tested using radio-labelled VEGF absorbed onto the stents deployed into iliac arteries of New Zealand white rabbits [8]. Local delivery via gene-eluting stent of naked plasmid DNA encoding for human vascular endothelial growth factor (VEGF)-2 could achieve similar results on re-endothelialisation, as proposed theoretically. This was practically assessed where phVEGF 2-plasmid coated stents versus uncoated stents were deployed in a randomised, blinded fashion in the iliac arteries of 40 normocholesterolemic and 16 hypercholesterolemic rabbits in a study by Walter et al. [9]. Bilayered stents coated with VEGF plasmid in the outer layer and paclitaxel (PTX) in the inner core have also been investigated, with the rationale that early release of the VEGF gene would promote re-endothelialisation, while slow release of PTX would suppress smooth muscle cell proliferation [10]. This model was successfully tested in the coronary arteries of mini-swine with complete re-endothelialisation and a significantly reduced rate of lumen loss and suppressed in-stent restenosis at 1 month.

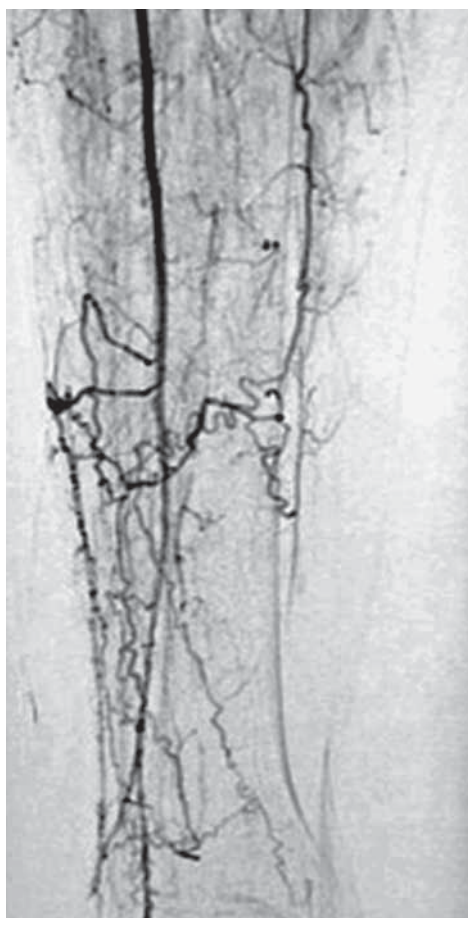
Some studies have shown an improvement in rest pain and limb integrity following therapy with growth factors. In trials in which no statistically significant difference in the amputation rate was observed between the treatment and control arms, significant improvement in clinical symptoms was nonetheless observed in those who received therapy with growth factors. Even though there are potential risks to gene therapy, no significant increase in mortality has been recorded in any angiogenic gene therapy trial. In addition, there is no in-vitro or in-vivo data to suggest that methods of therapeutic angiogenesis increase the risk of neoplastic growth or metastasis. However, longer-term follow-up may be needed to resolve this issue. The doses of VEGF used in human studies have also not shown any risk of angioma formation in the treated limbs. In addition, there is no evidence to suggest that a transient increase in the levels of circulating VEGF and FGF levels achieved during treatment is risky with respect to plaque angiogenesis and atherogenesis. So far, no significant increase in mortality related to athero-thrombotic events has been reported in any angiogenic gene therapy trial.

Therapeutic angiogenesis using stem cells has the potential to rewrite the treatment algorithms in patients with critical or chronic limb ischaemia [11, 12, 13]. These cells have three characteristic properties, including plasticity, homing and engraftment, which make them well-suited for this treatment. Stem cells derived from early human embryos are pluri-potent and can generate all committed cell types. These latter cells are higher in number, expansion potential and differentiation abilities if compared with SCs from adult tissues, but have issues related to adverse effects and ethical concerns. Hence, the clinical experiences are largely restricted to the use of autologous adult stem cells in various disease states. The migration, differentiation and growth of stem cells are mediated by the nature of the tissue, degree of injury and the type of stem cells involved. Damaged tissue releases factors that induce homing of these cells to the site of injury. In ischaemic tissues, endogenous biochemical agents are released stimulating angiogenesis. The angiogenesis is developed by vascular cell proliferation and new capillary formation. Pre-clinical studies have shown that angiogenic growth factors and cell-based therapies promote the development of collateral arteries, a process that is termed "therapeutic angiogenesis".

Stem cells can be extracted from various sites, including bone marrow, peripheral blood and adipose tissue. These can be administered to the affected area by intra-arterial or intramuscular delivery. Both these routes of delivery have shown clinical benefit in multiple studies [14, 15, 16]. We conducted a pilot project using graded doses of stem cells in a group of patients with CLI, and showed that benefit in terms of relief of rest pain and healing of ischaemic ulcers was seen in all patients in the treatment arm, and that this benefit was not dependent on the dose of injected stem cells beyond a threshold dose. While in the control arm, no improvement was seen in any patient, the critical limb ischaemia improved in all patients in the treatment group who received three graded doses of stem cells. No adverse effects related to the treatment were seen in any patient. Subsequently, we conducted a randomised first-in-human placebo-controlled double-blinded clinical trial that included 80 patients with no options: CLI not suited for any form of revascularisation. This trial was recently concluded and the results have established the safety and efficacy of autologous stem cell therapy for limb salvage in these patients, and indicate therapeutic angiogenesis as evidenced by a demonstrable increase in collateral density after stem cell therapy and zero percent amputation rates in the treatment arm (Fig.1).

There is some evidence to suggest that the effect of this therapy may be more pronounced in Berger's disease than in atherosclerosis [14]. The barriers to the development of stem-cell therapy relate to the autologous cell population that is often heterogeneous and may lead to varied responses. Also, to obtain the large cell numbers needed for transplantation, ex-vivo cell expansion may be required, which leads to regulatory concerns and increased cost and time. Advanced disease also has the problem of cytokine resistance. Furthermore, the cell engraftment efficiency is typically low upon transplantation and may require multiple injections.

The therapeutic potential of stem cells can be further enhanced by combining this treatment with gene therapy. In this approach, stem cells can be genetically modified prior to transplantation in such a way that particular cellular processes are strategically exploited to up-regulate expression of intracellular transcription factors or cell surface receptors and overexpress desired therapeutic factors to induce a biological response. This is likely to overcome insufficient paracrine release, poor cell survival upon engraftment, and lack of cell-homing by controlling cell behaviour at an intracellular signalling level [1].



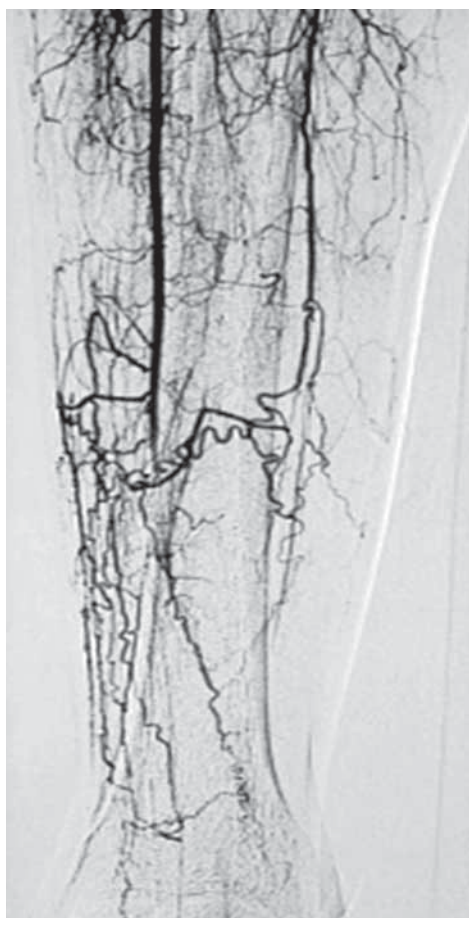


Fig. 1(a): Baseline angiogram of a young smoker with a non-healing ulcer right big toe (1.5x1.8 cm) & rest-pain for 4 months; (b) Follow-up angiogram after 6 months of injection of 60 million stem cells in the proximal stump and collaterals. Clinically, there was healing of the ulcer and relief of rest pain.

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To reduce the occurrence of in-stent restenosis (ISR), stents have been reshaped and improved in many aspects with the development of drug- and growth factor-eluting stents. Bompais et al. used stem cells as a source of seeding cells for coating the stents [11]. In a study by Xue et al., MSCs derived from the bone marrow of New Zealand white rabbits were used as seeding cells. The MSC-coated stents were deployed in the infra-renal abdominal aorta and they observed that intimal hyperplasia and in-stent restenosis were significantly inhibited by the MSCs coated stent. In another study, stents seeded with transfected endothelial cells at different VEGF levels were implanted in the abdominal aortas of New Zealand white rabbits to study re-endothelialisation and inhibition of instent stenosis [12]. It was observed that stents with cells exposed to excess VEGF expression were almost completely covered with cells after stent implantation for one week. Endothelial cells exposed to VEGF overexpression also reduced neointimal hyperplasia, promoted endothelialisation and reduced in-stent restenosis.

Platelet-rich plasma (PRP) may also be used for limb salvage in patients with CLI. PRP is defined as a sequestration and concentration of platelets within the plasma fraction of autologous blood. A milieu of growth factors secreted from the a-granules of activated platelets after injury, specifically PDGF, TGF-b, EGF, VEGF-A and IGF-1, play a critical role in the initiation as well as in the process of bone and soft-tissue healing. Kontopodis et al. sought to investigate the effect of autologous platelet-rich plasma (PRP) on the healing rate of diabetic foot ulcers in patients with diabetes and concomitant PAD. Diabetic patients with foot ulcers presenting with PAD who were treated with local growth factors in a single centre during a 24-month period, from May 2009 to April 2011, were retrospectively reviewed. Overall, 72 patients were evaluated, 30 with CLI. Ulcer area reduction >50% was observed in 58/72 patients, while reduction >90% was achieved in 52/72 patients. There were 14 (19%) major and minor amputations, whereas the limb salvage rate was 89% [13]. The notion that PRP could provide an autologous source of these essential growth factors and directly benefit CLI shows promise, but needs validation by further studies. We are currently initiating a trial to investigate this hypothesis.

Although proof from large randomised trials for the above therapies is still inconsistent, these treatments have shown the ability to improve perfusion by inducing arteriogenesis, angiogenesis or vasculogenesis in selected patients. Pre-clinical studies with a combination of cell and gene therapy have also shown encouraging results. This may be an alternative option to address the limited number and function of progenitor cells in elderly patients, those with co-morbidities and the challenge of cytokine resistance. Further research will define their role in suitable patients. The evidence for cell-based therapies is encouraging. There is a need for optimised trials to define the treatment algorithms in these patients.

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Welcoming the Belgian Society of Radiology to CIRSE!

Ciara Madden, CIRSE Office

In 2017, the CIRSE family acquired several new group members, bringing the number of national and regional societies under the CIRSE umbrella to 38. Amongst these new members, an important partner is the Belgian Society of Radiology, who help close one of the few remaining gaps in the European network of IRs.

The society has an active IR section, headed by two energetic young interventionalists: Dr. Fabrice Deprez, representing the French-speaking community of Belgian IRs, and Dr. Tom de Beule, representing the Flemish-speaking community. CIRSE spoke with both to find out how IR is currently faring in Belgium, and how they hope to advance the specialty further.

CIRSE: The Belgian Society of Radiology has recently become a CIRSE Group Member; how would you like to see these two societies working together?

BSR: The IR section is a very active and growing section of the BSR. We are trying to develop close relations with the other European IR societies (especially with the French and the Dutch societies), and consequently, we want to be an active and innovating member of CIRSE. One of our major goals is to improve IR networking, enhance IR's visibility and recognition in terms of public and politics, and increase professional defence. For this reason, we endorsed and actively support the European Board of Interventional Radiology (EBIR).

CIRSE: How big is the Belgian IR community? Is there a robust network, and if not, what are the hurdles?

BSR: The Belgian IR community is quite small. Probably only half of IRs have a non-vascular daily practice. The main problem is that we still don't have IR title recognition. Consequently, we don't have a specific IR nomenclature, specific IR suites and equipment recognition, or a coherent identified nationwide IR service. The main consequence (and cause) is a noticeable lack of awareness at the government level. The initial problem is probably a relative lack of interest from the general radiological community, and probably a lack of united action by interventional radiologists.

Moreover, with this situation, Belgian IR suffers from a fierce competition with other medical specialties: mainly vascular surgery, but also interventional cardiology, gastroenterology, urology, orthopaedics... Lastly, Belgian IR is largely underfunded, which is why it is difficult to maintain high levels of activity in smaller hospitals.

CIRSE: How is professional IR accreditation handled in Belgium? Is there professional interest in the EBIR certification?

BSR: As mentioned, we don't actually have any IR title recognition in Belgium yet. Consequently, EBIR certification doesn't have any legal value in our country. However, we are fighting for the creation of a Belgian IR title, based on the European Curriculum and Syllabus for Interventional Radiology, and the IR section actively encourages all our members, especially the youngest, to obtain the EBIR certification.

CIRSE: A radiology training curriculum was recently introduced under Belgian law: how is IR addressed under this curriculum?

BSR: We don't yet have any specific IR curriculum in Belgium. The first step of the Belgian Society of Radiology was to modernise the general title of radiologist (the last Belgian definition was written in 1979!), and we included basic IR skills in the new radiology curriculum. However, this new global title is still not published under Belgian law.

CIRSE: Quality assurance is a topic of interest for the Belgian Society of Radiology: what progress is being made? Are any IR-specific measures being discussed?

BSR: These last years, quality measures promoted by the BSR were essentially about radioprotection. For the Belgian IR, future challenges will concern IR title and curriculum legal recognition, and can be based on the European Curriculum and Syllabus for Interventional Radiology. One major concern will be integrating IR in global healthcare missions: for example, everyone actually agrees that a stroke centre cannot exist without an IR unit; it should be the same for an oncology centre, or a trauma centre...

CIRSE: Is IR represented in the recently finalised coordinated stroke units? What impact is this having on patient pathways?

BSR: In Belgium, neurointerventions are a part of general IR activities, and we don't have a specific neurointerventionist title, as we don't have IR title legal recognition. Most of the interventional radiologists who perform neuro-IR (stroke or embolisation) also perform a wide spectrum of IR activities (e.g. vascular IR or interventional oncology). As recognised by EBIR, stroke management is a specific competence of IR, and we have appropriate IR units offering stroke endovascular therapies in all the main cities of the country.

CIRSE: In your opinion, what are the key things that IRs globally could learn from their Belgian colleagues? Conversely, what could Belgian IRs improve?

BSR: Belgian interventional radiologists should really be more federated, in order to promote IR recognition with more efficiency. Belgian general radiologists should understand that IR is an essential part of radiology spectrum, and must be defended. However, as we work in a very competitive and underfunded healthcare environment, we think that Belgian IRs have developed a lot of adaptive skills and some ingenuity that we would be pleased to share!

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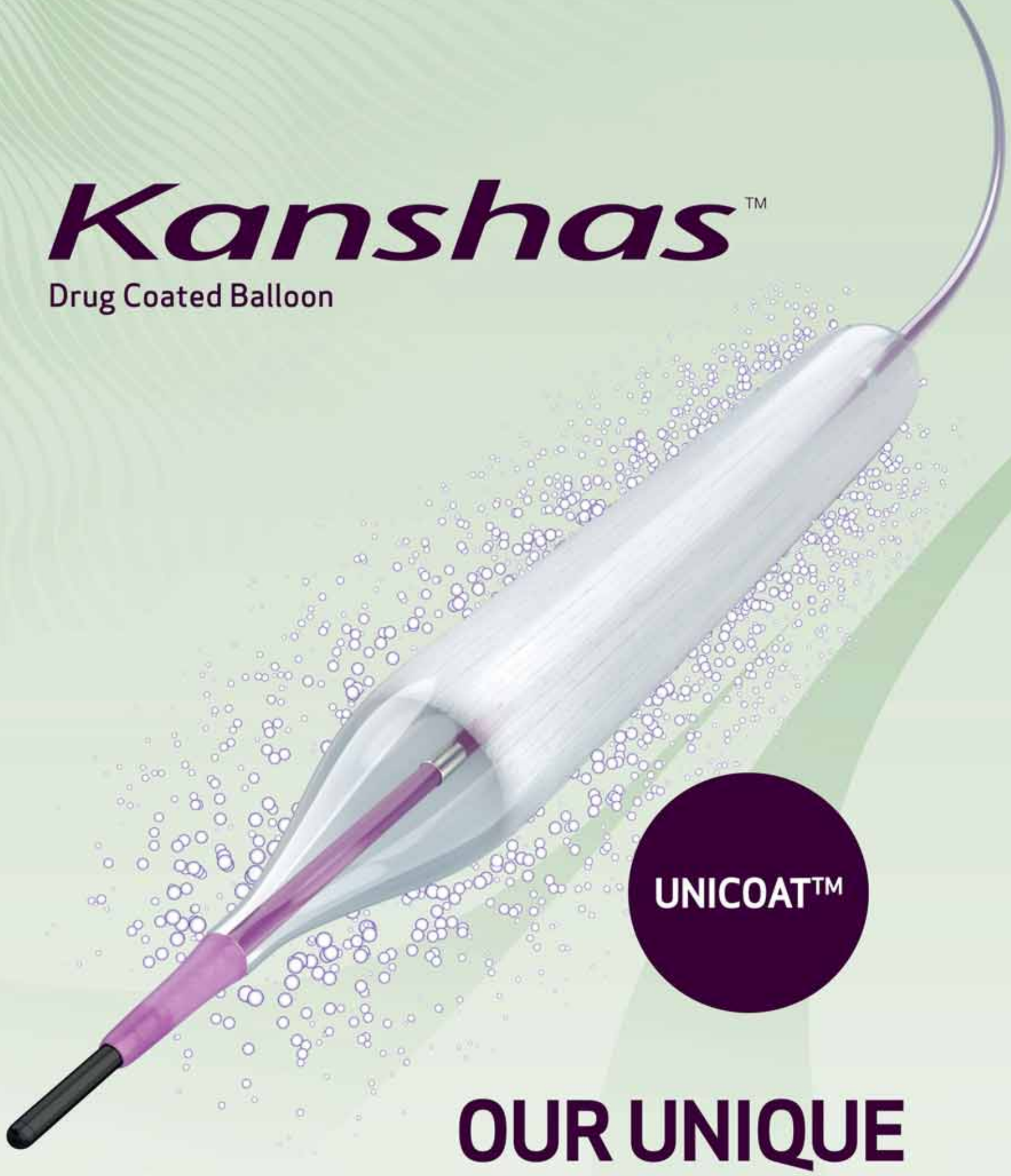

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