Johannes Lammer

Vascular IR and sailing the ocean

Both vascular IR and ocean-sailing were pioneered by ingenious men and by chance. Christopher Columbus wanted to reach India by sailing westward across the Atlantic Ocean. Both were important first steps, but quite imperfect. The first “Dotter procedures” caused moderate widening of the arterial stenosis; Columbus landed in Newfoundland in 1000 A.D., Werner Porstmann developed the Korsett Balloon in 1969 [11], and Nicholas Volodos achieved the very first aortic stent graft in 1981 [12].

Drug-eluting stents and balloons

In 1992 Lindsay Machan patented the coating of stents with paclitaxel, and in 2002 Stefan Duda published the first results of drug-eluting stents for treatment of peripheral artery disease (PAD) [13]. Thus, local drug-eluting technologies were introduced into vascular IR [14, 15, 16]. Ulrich Speck developed local delivery of paclitaxel together with contrast media on a balloon in 2004 [17] and Gunnar Tepe published the first results of drug-eluting balloons in PAD in the New England Journal of Medicine [18]. Interventional radiologists are those who have done most pioneering works for endovascular treatment of PAD.

Currently, many treatment modalities such as plain balloon angioplasty and bare metal stenting are being replaced by new concepts. It has been demonstrated in many randomised studies that drug-eluting balloon angioplasty is superior to plain balloon angioplasty [18, 19, 20], and drug-eluting stents are superior to bare metal stents [16, 21]. Stenting to treat post-percutaneous transluminal balloon angioplasty (PTA) dissections, residual stenoses and long and calcified total occlusions is still required in many cases. Further developments of stent technologies and drug-eluting stents have improved the one-year patency rates from 70% to >95%. However, permanent implants may cause intimal hyperplasia within the first two years after the index procedure due to foreign body reactions and chronic outward force and fracture, thus reducing the patency rates over time.

Bioresorbable vascular scaffolds (BVS)

In peripheral vascular IR, bioresorbable technologies are likely to replace metal stents in the near future. Magnesium and polylactic acid (PLLA) have been tested so far, and a bioresorbable drug-eluting PLLA stent (Fig. 1) has demonstrated excellent results with freedom from binary restenosis in 89% at one-year follow-up [22]. In TASC A lesions, freedom from target lesion revascularisation (TLR) was almost 90% at 3-year follow-up. Bioresorbable scaffolds combine the advantage of acute luminal gain without residual stenosis, restenosis and dissection, and, after the resorption of the implant, nothing is left behind. More drug-eluting BVS devices for PAD are currently under clinical investigation.

Future of endovascular drug-eluting therapy

New drugs, drug combinations, antibodies and gene therapy for local delivery are on the horizon. Drug combinations with sequential release, antibodies that may prevent proliferation of endothelial cells and neovascularisation, adenosine-mediated gene therapy and selective microRNA-based strategies are currently under investigation for local therapeutic delivery.

Endovascular aortic repair (EVAR)

Since the first publication of tube grafts in thoracic aortic aneurysms (TAA) by Michael Dake in 1994 [23], and of bifurcated stent grafts in AAA by Ulrich Blum in 1996 [24], many device improvements have been achieved. However, new concepts, such as endovascular aneurysm sealing (EVS) [25] (Fig. 2) and low-profile parallel pipe stent grafts (Fig. 3), may replace the bifurcated devices. These new concepts can be adapted to any anatomic variation, are...
Sailing the ocean is always an adventure. In previous times, poor navigation instruments, pirates and stormy conditions were the major risks. Still today the violence of the wind and waves can be a great challenge. In visual IR, the limitation of our instruments and the pirate activities of other disciplines are challenging interventional radiology. However, the inventors should not surrender to irritators. It should be the incentive to work continuously on improving devices, making treatments more effective and, most importantly, our clinical service.

Conclusion

Any endovascular treatment of PAD and aortic disease can be and will be carried out as an out-patient procedure in the near future. This open surgical option, which is already the second choice in almost all cases of non-medical treatment of PAD and aortic disease, will be performed in only a small minority of patients. If IR is not the only provider of endovascular treatment of peripheral arterial and aortic disease, it should be the leading force in developing new treatment concepts in the future, as it has been in the past.
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FROM BENCH TO BEDSIDE: TECHNOLOGY, EVIDENCE AND TREATMENT ALGORITHMS IN PERIPHERAL ARTERIAL DISEASE

Sunday, September 11 at 13.00, Auditorium 2

Medtronic  
Further, Together
Haemorrhoid embolisation – Con

Petr Vávra

Symptomatic patients with haemorrhoids are some of the most frequent visitors of the outpatient surgical department, with a prevalence of 43.5%. Patients experience anal pain, rectal bleeding, anaemia and defecation difficulties. These symptoms are caused by oedematous tissue cushions covered by an anastomotic pleura between the superior rectal artery and rectal veins.

The initial treatment consists of hygiene improvement and higher dietary fibre intake, which helps to improve the microclimate of the anorectal area, possibly alleviating some of the symptoms and, occasionally, even leading to a complete remission of all symptoms. Some patients may benefit from less common types of treatment, such as local anaesthetics, corticosteroids or flavonoid medication. However, a surgical solution is usually the fastest and safest way to treat patients [1, 2]. Many types of surgical procedures have been developed, showing good results in large groups of patients. The new “emborrhoid” technique tackles the problem from an entirely new perspective, possibly bringing new possibilities into the treatment of haemorrhoids. However, the new method raises several important questions which need to be addressed.

Is it safe for the patient?

The complications of the haemorrhoidal treatment may include oedema, bleeding, necrosis of the rectum, pseudoeuano and prolapse and others. Up to 70% of patients experience pain after sclerotherapy treatment, which is often recurring or accompanied by other complications [3]. The percentage of patients experiencing post-operative complications is lower in the most frequent types of treatment. With open surgery, the complication rate is up to 10% for anastomotic leakage, followed by 4.1% for bleeding and up to 5% for continence disorders [4]. Post-operative pain is common, however, usually it disappears within three weeks. The stapled haemorrhoidectomy is less painful compared to open surgery, although less effective with a 7% recurrence rate compared to 2% for open surgery [5]. The most common complications include urinary retention (8-32%) or rectal bleeding (4-17%) [6]. The Doppler-guided ligature is even better tolerated. However, the total recurrence rate is 17.5%. [7] Elastic band ligation shows frequent recurrence: up to 68% in a 5-year follow-up [3]. As the ligation can usually be repeated quickly and safely in the outpatient clinic, the impact of the high recurrence rate is greatly diminished.

The safety of the “emborrhoid” technique has not been well-documented and further research is required to fully evaluate the short- and long-term complication rates. Out of 14 patients, four experienced rebleeding and one experienced painful oedema [8]. During the procedure, it is necessary to embolise all arteries connected to the haemorrhoidal tissue, which may lead to ischaemia and necrosis of the rectum. A common complication is painful oedema, which usually disappears within two weeks [2]. It may also cause a prolapse of the haemorrhoidal tissue. The range of possible complications is extended by a set of catheterisation-specific complications, i.e. an infection of the catheterisation site or pseudoeuano of rectal arteries. Most of these complications require surgical treatment. The patient is also inevitably exposed to a small dose of radiation (averaging 62 Gy/cm² [8]), which can be avoided by a surgical approach.

Is it fast?

The length of the surgery depends largely on the chosen method. From experience in our institution, the majority of haemorrhoids (stages I and II) can be solved by the elastic band ligation, which is usually performed in a couple of minutes, depending on the number of haemorrhoidal cushions (approx. 30 seconds per one ligature). The Longo haemorrhoidectomy is the fastest invasive technique and can be performed in 15-20 minutes. The Doppler-guided ligature requires 20-30 minutes to perform, while open surgery is usually completed in about 40 minutes. The “emborrhoid” technique is usually completed in an average of 69 minutes [8].

Is it necessary?

The initial choice of treatment depends on the clinical findings in the anorectal area. Aside from conservative treatment, ligation is the most frequently used treatment method of stage I or II haemorrhoids [4, 6]. This method is very fast and reliable and can be performed repeatedly, but, on the other hand, it cannot be used to treat external haemorrhoids. In more complicated or severe cases, the circular stapled haemorrhoidectomy is usually the method of choice. In other cases, the Doppler-guided ligation or open surgery (the latter performed in 10% of cases [9]) is usually advised. The latter is very effective with a recurrence rate of only 2% [5]. The “emborrhoid” technique allows haemorrhoids to be treated in difficult terrain, for instance during massive bleeding or oedema. Even in acute cases, it is usually necessary to haemodynamically stabilise the patient first. In these rare indications, the embolisation may prove effective. It needs to be noted that several sources report the occurrence of post-operative complications, including significant anal pain or recurrent bleeding [10]. Further research is necessary in order to compare it to other methods of treating complications.

Who really leads the treatment?

The main question arises while discussing the management of patients. The haemorrhoid treatment has always been performed by surgical departments, as these are best suited for the complex treatment of haemorrhoids. The surgeon takes the medical history, performs a rectoscopy or anoscopy, performs the surgery and treats possible complications. Then patients receive their follow-up in surgical outpatient clinics. This unified concept of care would be interrupted by using the “emborrhoid” method, as the embolisation would be performed by an interventional radiologist. Therefore, the patient would have to be transferred to the department of radiology to undergo the procedure and then returned to the surgical department for post-operative care. The division of the treatment between two departments is not advisable, and it is unlikely for this practice to be accepted by many departments.

Conclusion

The “emborrhoid” technique is a completely different approach to treating haemorrhoids. It is a feasible method for very specific cases, usually in patients with a plentiful history of haemorrhoid surgeries. However, it features many downsides, including radiation exposure and complicated management of the patient. Current methods of treatment are very effective and may be performed safely and repeatedly even in out-patient clinics, and the efficiency and safety of the “emborrhoid” technique is still to be determined.
With a prevalence of 4–35%, haemorrhoidal disease is the most common anorectal condition. One of the main chronic symptoms is rectal bleeding. Its recurrence can alter quality of life and, more rarely, cause anaemia. Pain is less common, only occurring in the event of a complication (congestive exacerbation, external haemorrhoidal thrombosis, fissures). The most common treatment involves hygiene and dietary measures, pharmacotherapy (surgery) or non-surgical outpatient treatment, such as infrared photoagulation or elastic band ligation.

The haemorrhoidal arteriovenous network is a normal vascular formation. There is a clear distinction between the external haemorrhoidal network below the dentate line, under the skin of the anal margin dependent on the pudendal artery (the branch of the inferior rectal artery) and the internal haemorrhoidal network, located in the upper part of the anal canal above the dentate line in the submucosal space, depending on the superior rectal artery.

Internal haemorrhoids are now thought to result from an increase in arterial blood flow from the superior rectal artery into the haemorrhoidal cushion (corpus cavernosum recti) [1]. Replacement of muscle tissue by connective tissue causes an increase of the vascular network of the anorectal submucosa, initiating a negative vicious circle of progressive vascular dilation and venous insufficiency leading to haemorrhoidal hyperplasia. This hyperplasia causes an increase in blood pressure, arterial inflow and anal pressure in the corpus cavernosum recti. The lower part of the rectum and the anal canal are known to be supplied with blood by the inferior and middle rectal arteries, both of which have origins at some distance from the inferior mesenteric artery (the pudendal artery and iliac network, respectively) [2]. By contrast, the mechanical function of the corpus cavernosum recti is dependent on the influx of arterial blood from the branches of the inferior mesenteric artery: the superior rectal artery.

Ten years ago, proctologists developed a new concept of treatment: elective trans-anal Doppler-guided haemorrhoidal artery ligation (DG-HAL). DG-HAL technique consists of the identification and ligation of the superior rectal arteries under trans-anal Doppler guidance. Ligation of the superior rectal arteries provides a significant reduction of arterial blood flow to the haemorrhoidal and is effective in treating haemorrhoidal disease [3].

It was feasible that this concept could be compatible with embolisation. We have suggested that arterial ligation can be performed with coils in the terminal branches of the superior rectal arteries via the endovascular route (Fig. 1) [4].

The advantages of Emborrhoid and DG-HAL compared to surgery are that they maintain the haemorrhoidal tissue in place, preserving anal continence, with no rectal wounds (no local care), significantly less pain and avoid the complications of open surgery, thus allowing a faster return to daily activity. "Emborrhoid" embolisation is performed using a right femoral route. The inferior mesenteric artery is catheterised using a Simmons catheter. The superior rectal arteries are then catheterised with a microcatheter. Coils used for the embolisation are 0.018", from 2 to 3 mm in diameter.

Technical success of the Emborrhoid technique has been reported in up to 90%. Clinical success of the Emborrhoid technique has been reported between 74–83% of patients with no complications [2, 5].

The main advantages of the Emborrhoid technique are:

- Patients have absolutely no pain
- No major complications have been related to Emborrhoid and especially no ischaemic or continence complication
- This technique is available as an outpatient procedure
- Patient can return to activity the day after embolisation
- Embolisation does not close the door to a complementary treatment if required
- The technique is easy to perform in one hour or less

There are many benefits of endovascular treatment, including complete visualisation of all the branches of superior rectal arteries and anastomoses with middle and inferior rectal arteries [6]. Embolisation also eliminates the risk of direct anorectal trauma. With DG-HAL, it is possible that not all arteries are detected, which can lead to incomplete treatment, especially if there are anastomoses.

The latest results of new studies will be published soon and will confirm the same good clinical results of previous studies as well as objectively demonstrating that at one month after embolisation, haemorrhoidal bundles decrease significantly in size, that embolisation particles do not cause ischaemia in histology and that the sphincter has a normal physiology one month after embolisation.

We hypothesise that embolisation will be more effective with particles because it causes a more distal haemorrhoidal plexus embolisation, and it restricts the superior rectal arteries reloads by the middle rectal arteries.

There is a clear need for a randomised controlled study to confirm the real benefits of the technique.

There are many patients who suffer from haemorrhoids but do not complain to physicians because they refuse to have an endorectal treatment. If we can offer a treatment for out-patients without pain, we believe more patients will seek treatment for this condition.

Given the preliminary results reported in our studies, we believe that there is sufficient evidence to include embolisation in therapeutic options for patients with bleeding related to haemorrhoidal disease. We have demonstrated that distal coil embolisation of the superior rectal arteries to stop chronic bleeding is safe and effective.

Our latest results (currently being published) will demonstrate that embolisation of superior rectal arteries with particles does not lead to ischaemia. Particle embolisation is likely related to a complete embolisation of the haemorrhoidal plexus, lower than the anastomoses with the middle rectal arteries, and thus opens a new door in the development of the Emborrhoid technique.
BIOTRONIK Combination Therapy

Symposium

Stent, Drug-Coated Balloon or Both?
Role of DCB and Stent in the treatment of SFA

Date: Sunday, September 11, 2016
Time: 11:30 - 12:30
Room: Auditorium 2

Chairman
Prof. Gunnar Tepe, Germany

Moderator
Dr. Ralf Langhoff, Germany

Speakers
Prof. Marianne Brodmann, Austria
Prof. Claus Nolte-Ernsting, Germany
Dr. Koen Deloose, Belgium

Panelist
Prof. Junmin Bao, China

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**BIOFLEX PEACE** All-comers registry with Pulsar stent 12m data – can we improve the outcomes of Stent or Drug-Coated Balloon alone?
Prof. Claus Nolte-Ernsting, Germany

**BIOLUX P-II** All-comers registry 12m data using Passeo-18 Lux DCB
Prof. Marianne Brodmann, Austria

**BIOLUX 4EVER** trial 12m data - BIOTRONIK Combination therapy: treatment rationale and clinical evidence
Dr. Koen Deloose, Belgium

Visit us at booth #57
With an ageing population, arterial calcification is an increasing problem. The endovascular treatment of calcified arterial lesions remains challenging and is associated with higher complications including dissection and residual stenosis. Calcified plaque also acts as a barrier to drug elution. Several strategies are available for debulking calcified arteries prior to additional treatment, but none of them are without trade-offs, including angiographic complications, prolonged procedural time and expense.

The concept of lithoplasty involves modification of calcified arterial lesions with lithotripsy-enhanced low-pressure balloon dilatation. Lithotripsy is tissue-specific, being hard on calcified tissue but not damaging soft tissue. The lithoplasty-delivered by the Peripheral Lithoplasty Catheter System (Shockwave Medical, Fremont CA) is designed to disrupt both superficial and deep calcification in the arterial wall, normalising vessel wall compliance and thereby facilitating controlled, low-pressure balloon angioplasty. The current catheter system utilises 6 cm-long, 0.014” guidewire-compatible angioplasty balloons of varying diameters combined with multiple lithotripsy sources (Fig. 3). Once the lithoplasty catheter is placed in the target lesion area, the balloon is inflated to 4 atm and lithoplasty treatment is delivered for 30 seconds at one pulse per second. Following lithoplasty, the balloon catheter is inflated to the reference vessel size using the reference balloon compliance chart, typically at 6 atm, and then deflated to restore flow.

Peripheral lithoplasty was initially evaluated in a “first-in-man” study performed at Auckland Hospital. Seven calcified femoro-popliteal lesions in 6 patients were treated. There were no procedural complications and acute technical success, defined as a residual stenosis ≤ 30% diameter loss, was achieved in 70% of lesions. At one month, clinical improvement and freedom from residual stenosis was achieved in 86% of lesions. At one year, there was no recurrence of symptoms, complications or target lesion revascularisation. At 3 years, freedom from target lesion revascularisation was achieved in 83% of patients (Fig. 2). The very positive results from this study encouraged further evaluation of the procedure and device.

The DISRUPT PAD programme has provided further clinical evaluation of Shockwave’s peripheral lithoplasty system in a more challenging cohort of patients with calcified femoro-popliteal disease. The DISRUPT PAD programme is a two-phase, prospective, non-randomised, multi-centre study with independent angiographic and duplex ultrasound laboratory analysis plus an independent clinical events committee.

DISRUPT PAD I enrolled 35 subjects at 3 sites while DISRUPT PAD II enrolled 60 patients at 8 sites. Moderate to severely calcified femoro-popliteal lesions up to 150 mm in length were included. The primary safety endpoint was absence of major adverse events at 30 days. The primary performance endpoint was procedural success defined as the ability of the lithoplasty system to achieve a post-lithoplasty residual diameter stenosis of ≤ 50% (with or without adjunctive PTA therapy) as assessed by quantitative angiography. Secondary effectiveness endpoints included freedom from MAE, TLR, vessel patency defined as freedom from greater than 50% restenosis (as assessed by Duplex ultrasound peak systolic velocity ratio of ≥ 2.5), improvement in Rutherford Category, and ankle-brachial index (ABI) at 30 days and 6 months. A subset of the enrolled cases underwent optical coherence tomography (OCT) imagining pre- and post-treatment (Fig. 3).

In the 95-patient combined DISRUPT PAD trials, the mean lesion length, percent stenosis, and total occlusions were 73 ± 3.7 cm, 77 ± 10%, and 18.9%, respectively. Most lesions had moderate (44%) or severe (55%) calcification. Lithoplasty treatment resulted in an acute procedural success of 100%, a mean residual stenosis of 24 ± 6%, and an acute gain of 3.0 mm (Fig. 4). Minor dissections occurred in 14% overall, post-lithoplasty balloon angioplasty was required in 7.4% of cases and only one stent was placed. There was one major adverse event at 30 days in the dissection case requiring bail-out stenting. Patency, defined as freedom from binary restenosis on duplex ultrasound, was 100% at 1 month (N=95) and 80.4% at six months (N=64). Significant improvement in clinical parameters, including ankle-brachial index and Rutherford score, was seen and sustained at 6 months. Target lesion revascularisation was required in only 2 patients by 6 months. Interestingly, both lesions were easily and effectively treated with drug-coated balloon angioplasty, again suggesting lithoplasty achieves a sustained change in vessel compliance. Analysis of OCT images has also provided some insight into changes in vascular calcium burden achieved by lithoplasty.

The DISRUPT PAD programme has confirmed that lithoplasty has a favourable safety profile, with no major vascular complications. In the studies, acute luminal gain was excellent without a need for significant stent use. This relatively simple angioplasty balloon-based therapy promises to achieve higher patency than traditional therapies for a challenging patient population.

**Fig. 1:** The Shockwave Peripheral Lithoplasty Catheter System.

**Fig. 2a:** Procedural images.
**Fig. 2b:** Post-procedural MRA images before and after target lesion revascularisation with drug-coated balloon angioplasty.
**Fig. 2c:** “First-in-man” case with Shockwave Lithoplasty.
**Fig. 3a:** Angiography and OCT pre-treatment.
**Fig. 3b:** Angiography and OCT post-lithoplasty.
**Fig. 3c:** Challenging, calcified near complete occlusion with an excellent result after Shockwave lithoplasty.

Andrew Holden
Auckland City Hospital
Auckland, New Zealand

Andrew Holden is Director of Interventional Radiology at Auckland City Hospital and Associate Professor of Radiology at the University of Auckland. He is also Lead Radiologist for the Auckland Hospital organ transplant programme. Dr. Holden is a committee member of ISRA (Interventional Society of Australasia) and ARRANZ (Abdominal Radiology Society of Australia and New Zealand), and is an examiner for the RANZCR. Dr. Holden is the author of over 60 peer-reviewed articles and three book chapters. He has been the principal investigator in 25 ‘first-in-man’ device trials and has performed over 50 live interventional cases broadcasts from Auckland Hospital to overseas sites such as Germany, France, Hong Kong, the USA and Australia.
The prestigious “2016 Editors’ Medal” was awarded to: Johannes Lammer et al., “Sustained Benefit at 2 Years For Covered Stents Versus Bare-Metal Stents in Long SFA Lesions: The VIASTAR Trial”

CVIR’s “2016 Awards for Outstanding Service to the Journal” were awarded to the following recipients:


• Most Downloaded Article in 2015* – Anthony James Lopez, “Female Pelvic Vein Embolization: Indications, Techniques, and Outcomes”

• Most Reviews Carried Out in 2015* – Dr. Thomas Kinney

• Best Media Performance in 2015* – Mark C. Burgmans et al., “Percutaneous Isolated Hepatic Perfusion for the Treatment of Unresectable Liver Malignancies”

* Please note that CVIR’s “Awards for Outstanding Service to the Journal” may only be awarded to non-Editorial Board members.
The CIRSE Survey on Anaesthetic Practices for Interventional Radiology in Europe

Alessandra Vari

The CIRSE 2016 Scientific Committee hit a home run by deciding to host the session meaningfully entitled Anesthesia and Interventional Radiology: time to face reality? The idea took place in the framework of the growing interest CIRSE had shown in clinical and peri-procedural care for interventional radiology (IR), which recently culminated in the completion of a dedicated member survey on anaesthetic practices. The session has been cleverly planned to be a unique forum in which the discussion of anaesthetic practices for IR sees interventional radiologists as main actors, and introduces the final presentation of the CIRSE survey results. As the principal investigator, this is the main purpose of my talk.

The panel is made up of prestigious IR experts who will explore the (sometimes) controversial relationship between IR and anaesthesia, the way in which the two specialties could and should successfully integrate, how to face the impending shortage of anaesthetists (unfortunately common in many countries) that appears to affect the practice of IR in several European countries.

Internationally renowned interventional radiologists will be discussing different approaches to routine practices and exchanging opinions on pros and cons of different anaesthesia (NORA), one of IR’s most interesting domains, markedly increased in the last decades with a growing number of procedures being performed in the IR suites have been reported.

The use of propofol by non-anaesthesiologists, notably one of the hottest and most controversial topics at the moment, given many ongoing controversies among professional societies, will be presented by an interventional radiologist practising in Switzerland, one of the few European countries that allows NORA (non-anaesthesiologists administered propofol). The rationale of this initiative is fairly evident: the number and complexity of procedures being performed in the IR suites have markedly increased in the last decades with a consequent expansion of non-operating room anaesthesia (NORA), one of IR’s most interesting and challenging fields of application.

As for specialties with similar practice patterns such as gastrointestinal endoscopy, in a great number of centres, anaesthesiologists are not available to attend all IR cases. Consequently, interventional radiologists are increasingly involved in administering sedative and analgesic drugs and, most importantly, managing complications of pharmacological sedation.

Given the persisting, large variability of IR suite settings in terms of staffing and anaesthetic practices, and the growing debates on sedation administered by non-anaesthesiologists all over Europe, CIRSE has decided to take a deeper and more specific look into the issue of anaesthetic management of IR patients, also in light of potential future initiatives.

The project started in the form of an online anonymous survey distributed by email to all European CIRSE members in March 2015. Responses were collected over the 40-day period during which the survey was online. In addition to several sets of questions investigating specific aspects of anaesthetic practices for interventional radiology, three optional questions were added at the end of the survey to explore the responder’s opinion on issues related to the future of anaesthesia practices in IR and the role of CIRSE. Data were analysed by CIRSE’s Department of Research and Analytics. Notably, results of this survey confirmed several (how)ome investigations predict differences between countries and national regulations, showing how significantly many “local” factors (type and size of centres, availability of dedicated in-patient beds, availability of anaesthesia staff, for example) can affect the routine practice and the expansion of IR as a subspecialty.

All aspects of anaesthetic management for IR have been investigated (assessment, choice of technique, pharmacology, follow-up, paediatric IR, peri-procedural recording and adverse events management) in detail. A particular focus has been placed on analysing the process of peri-procedural care as a whole, with questions on safety louse of checklists, availability of emergency devices and training in cardiopulmonary resuscitation) and pain management in IR.

The survey has shown encouraging data, although there still appear to exist some “conceptual” issues such as the lack of awareness about the services provided by IR and a certain underestimation of cost-benefit outcome and IR as a hospital administration and medical policymaker level (with consequently no allocation of anaesthesia resources to IR in spite of the complexity of procedures and severe co-morbidities of many IR patients). In addition, given the growing involvement of IR in the provision of peri-procedural care (including sedation management and pain control), clinical competencies clearly appear to represent an essential component of the IR Curriculum and a significant portion of the IR community perceives this as an existing gap to be filled with the help of CIRSE.

Unfortunately, significant country variations, confirmed by the survey, represent the most relevant drawback for addressing this issue and certainly pose an additional challenge to potential initiatives at a European level. CIRSE has historically emphasised a multidisciplinary team approach to IR and a strong focus on peri-procedural patient care as the mainstay for further development of the subspecialty.

In the age of multidisciplinary medicine, the interest CIRSE has developed in safe anaesthesia care for IR, of which both the survey and this all-IR anaesthesia session here in Barcelona 2016 are yet further examples, looks extremely promising.

On a closing and personal note, I truly believe this session, which I am thrilled to be an active part of, will be an exciting opportunity for mutual and interactive learning and I look forward to welcoming an even more fantastic audience than usual at CIRSE.
BECAUSE EXPERIENCE MATTERS

Generating Clinical Evidence in Interventional Oncology

Moderator: Prof. K Malagari
Speakers: Prof. T De Baere, Dr. F.G. Gomes, Prof. P.L. Pereira, Prof. M.G.E.H. Lam

- From bench to clinical results: LifePearl in HCC
- Locoregional treatments in HCC pre-transplant patients: LifePearl-100 patients experience
- Growing evidence with LifePearl-TACE in CRC
- CIREL Registry highlights
- New horizons in radioembolisation with QUIREM spheres

Growing number of publications
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Meet CIREL – the CIRSE Registry for LifePearl Microspheres

Birgit Thüele-Bekina, CIRSE Office

In its continuous efforts to push innovation and boost scientific understanding of medi-
cal procedures, CIRSE is proud to announce that it is about to launch the second obser-
vational study to be exclusively sponsored by the society. The CIRSE Registry for LifePearl
Microspheres (CIREL) will prospectively ob-
serve, throughout Europe, the administration of irinotecan-eluting microspheres, a newly
CE-approved transarterial chemoembolisa-
tion (TACE) system for treating patients with
colorectal adenocarcinoma with liver-only or
liver-dominant metastatic disease. CIREL will be
collecting data over an initial period of three
years following enrolment of the first patient,
which is projected before the end of 2016.

Furthering our understanding of TACE in a
real-life setting

CIREL will prospectively capture the broadest
feasible spectrum of data on the delivery of
TACE using LifePearl Microspheres loaded with
irinotecan and related clinical outcomes. The
aim is to improve our understanding of how
drug-eluting microspheres are administered
as part of the treatment of colorectal adeno-
carcinoma with liver only or dominant liver
metastases in Europe.

The primary objective is to ultimately map
exactly at which stage in treatment the device
is being applied, and to assign the real-life
practice of LifePearl Microspheres to categories
including first-line, consolidation, intencifica-
tion and end-stage treatment. Secondary
objectives of CIREL will be to assess the ob-
served treatment outcomes in terms of safety
and efficacy as well as trying to determine any
predictive response factors.

CIREL will use an electronic data-capturing
system to collect all required data points for
measuring the objectives. The primary focus in
terms of data points will lie on baseline patient
characteristics and the precise treatment
delivered. Treatment outcomes, including the
objective tumour response using the RECIST 1.1
criteria, quality of life as well as adverse events
and toxicities will also be measured.

CIREL’s multidisciplinary governance

The study is overseen by a multidisciplinary
Steering Committee which is chaired by Profs.
Philippe L. Pereira (Director Clinic of Radiology,
Minimally Invasive Therapies and Nuclear
Medicine SLK Clinics Heilbronn) and Julien
Taieb (Head of Hepato-Gastroenterology and
Digestive Oncology, Hôpital Européen Georges
Pompidou). CIREL is proud to reveal the list
of leading experts from the fields of inter-
ventional radiology, oncology, hepatology and
surgery, who make up the Steering Committee
for this registry and who are responsible for the
scientific leadership and input of the project.

New features to improve data quality

CIREL will be a new departure for CIRSE, since
the research design will include central image
analysis to be performed by an independent
institution to maximise the validity of clinical
data. The central analysis has the aim of finding
a possible association between RECIST criteria
and other data points and to provide a second
assessment of treatment outcomes. In addition,
this independent assessment shall help reduce
bias and increase data quality.

Ready to launch in 3, 2, 1…

The CIRSE Central Office’s Research and
Analytics Department is project-managing
the registry and will shortly invite European
centres on behalf of the Steering Committee.
In order to approach a representation of the real-
life application of LifePearl Microspheres, the
registry aims to capture the largest number of
patients in hospitals experienced in performing
TACE of liver metastases with drug-eluting
beads and currently using LifePearls, and
centres will endeavour to include all patients
volunteered for TACE treatment.

The Steering Committee agrees that this re-
gistry is not just important in its own right, but
if successful, may instigate further research
projects related to interventional oncology
procedures. Interventional radiology is growing
fast as a clinical discipline, and CIRSE continu-
ously strives to support its evidence-based
approach in every possible way.

CIREL is determined to make sure that CIREL
will be successful in providing scientifically
sound and medically relevant evidence on the
clinical use, safety and efficacy of TACE with
LifePearl Microspheres for the treatment of
colorectal adenocarcinoma with liver-only or
liver-dominant metastases.

How to participate in CIREL

Prospective data collection will be collated
with an electronic data-capturing system (EDC
system). The EDC system will be accessed via
the CIRSE website and will be available in
English, Spanish, and German.

For more information on CIREL, please don’t
hesitate to get in touch with the Research &
Analytics Department at research@cirse.org or
visit our website www.cirse.org/cirel

Interview with the Coordinating Investigators:

What are your expectations regarding what
the CIREL registry will be able to achieve?

Prof. Philippe Pereira: This observational
study will not only provide us with robust,
multicentre data on the precise use, efficacy
and safety profiles of this particular device but
also give some insight into how TACE can fit
into the established lines of standard clinical
practices in Europe.

How would you describe the value of large-
scale, prospective data collection in IOT?

Prof. Philippe Pereira: Continued observation
of interventional oncological procedures once
they are certified for use is very important
practice – and not only for safety reasons.
Oncologists are used to larger sample sizes
than we commonly see in medical device
research. Thus, large-scale, multinational
outcome data can really make a difference in
bolstering an evidence base and can help in
approaching treatment decisions that may not have found space in previous
studies, such as length of hospital stay, tumour
response and quality of life.

As CIRSE’s first TACE registry, how im-
portant do you think it is that this collective
endeavour has a multidisciplinary
approach?

Prof. Julien Taieb: The pathways of patients
with adenocarcinoma and liver metastasis
referred for TACE treatment make communi-
cation and collaboration between different
disciplines a practical necessity in daily clinical
practice. The importance of this good col-
laboration is also reflected in the composition
of the CIRSE Steering Committee. In CIREL,
centres will be asked to assign oncologists as
well as interventional radiologists as Principal
Investigators, to ensure treatment and follow-
up data will be collected and included in the
registry.

As a co-chair of the CIREL Steering
Committee, but also as an active member of
the OAS and the CIRSE Research Committee,
why do you think the research agenda CIRSE
is currently pursuing is so important for the
society?

Prof. Philippe Pereira: I believe it is a great
achievement that CIREL can provide a platform
that brings together these diverse medical
specialties involved in interventional oncolo-
gy and offer to all such a high standard of
outcome research. CIREL will greatly contribute
to the collection of scientific knowledge and
clinical data in one of interventional radiology’s
most dynamic and promising fields and help
us better understand the best way to treat
patients with transarterial chemoembolisation.
The brain is extremely sensitive to both hypoperfusion and embolic complications, and stroke remains one of the most devastating complications of both open and endovascular treatment of arch pathology. The risk associated with intervention is dependent on the atheroma burden which can be subjectively assessed on CTA. Montgomery’s transoesophageal echocardiographic classification [1] is often cited as a more objective grading system, with normal or mild intimal thickening, to a, describing a mobile atheromatous lesion, but this is open to subjective interpretation.

Unlike the descending thoracic aorta (where TEVAR has predominated in the last decade), open surgery remains the gold standard both within the ascending aorta and aortic arch. Despite refinement of techniques for cerebral protection, outcomes from the highest volume centres continue to record major stroke rates of 4% to 8% [2-4]. Not surprisingly, much study time has been invested into the causes and treatment of peri-operative stroke [5].

In an effort to reduce the morbidity associated with open aortic arch surgery (a technique mandating circulatory arrest), less invasive strategies have been investigated. Combining extra-anatomical bypass and endovascular stenting has allowed more frail patients to be treated with no reduction in stroke risk [6]. Chimneys and parallel grafts have also been used within the arch, but, again, no consistent reduction in stroke rate has been observed [7]. The most recent registry data, however, has shown a commendably low stroke rate of 2%, but this group included aortic dissections [8]. The most recent registry data, however, has shown a commendably low stroke rate of 2%, but this group included aortic dissections [8]. The most recent registry data, however, has shown a commendably low stroke rate of 2%, but this group included aortic dissections [8]. The most recent registry data, however, has shown a commendably low stroke rate of 2%, but this group included aortic dissections [8].

In a similar way to carotid filters being used in CAS, clinical pilots are now being undertaken using embolic shields in the arch at the time of stent deployment. The Sentinel Cerebral Protection System is one such embolic protection device. It is a percutaneous dual filter embolic capture device introduced through the right brachial via a 6 Fr. sheath, with 140 μm filters deployed at the origin of the brachiocephalic and left common carotid before stent grafting to protect the brain intra-operatively (Fig. 3, Fig. 4).

It has demonstrated encouraging results with use in TAVI with over 50% reduction in number and volume of cerebral infarction on diffusion-weighted MRI, with a concurrent neurocognitive decline [9].

A pilot trial of this protection device has been conducted with TEVAR in our unit, and has shown a marked reduction in the number of lesions post-operatively (Fig. 5). Histopathological analysis of the embolic debris has shown that all filters captured a combination of arterial wall and thrombus. It is too early to decide how beneficial this method will ultimately be, but it is a potentially promising advance in an area where there has been little success to date.

From a practical perspective, intra-operative monitoring using transcranial Doppler confers little benefit. Although useful as a research tool, it merely detects emboli after they have occurred and is therefore of limited use in preventing adverse clinical sequelae, other than perhaps as a warning to stop whatever manoeuvre is being performed. Once emboli have left the arch, any deficit is related to whether the carotid or vertebral territory is affected. The only therapeutic options are then supportive with maintenance of adequate oxygenation, blood pressure and anti-platelet medication with early physiotherapy for any physical impairment.

Therefore, a “shaggy aortic arch” remains a contraindication for most forms of treatment, as the considerable stroke risk probably outweighs the treatment benefit with current technology.

In conclusion, the arch remains a hostile environment for both open and endovascular treatment and stroke is still the big enemy.

Fig. 1: TCD hits during phases of TEVAR.

Fig. 2: Silent cerebral infarction. Post-operative MRI patient with TEVAR and no clinical stroke.

Fig. 3: Sentinel Cerebral Protection System. Claret Medical. Embolic protection filters deployed at origin of innominate and left common carotid.

Fig. 4: Proximal and distal filters in situ brachiocephalic and left common carotid. TEVAR deployed distal to the left subclavian artery.

Fig. 5: Post-operative DW MRI in patient undergoing TEVAR with cerebral embolic protection.

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Ruptured aneurysms and dissections involving the ascending aorta or the aortic arch are still considered an absolute surgical emergency. In comparison, such pathology involving the descending thoracic aorta is increasingly being treated endoluminally (4–9).

Ruptured thoracic aortic aneurysms (rTAA) are associated with a high morbidity and mortality. Clinical presentation is often induced by acute onset chest pain, often accompanied by hypotension or hypovolemic shock. An associated haemorrhagic pleural effusion may cause respiratory distress. Rupture into the mediastinum may lead to pericardial tamponade and rapid death. Rarely, the creation of an aorto-branchial fistula may give rise to haemoptysis (10).

CT has become the mainstay of imaging in such cases. In addition to its easy availability, it also allows for precise measurements of the relevant aortic dimensions in order to determine correct endograft size. Pre-interventional CT in a rupture setting is, however, a topic of certain debate on account of the possible loss of vital time. Considering the fact that in untreated patients with rupture, the time interval between onset of symptoms and admission is usually greater than 6–8 h, it would appear reasonable to assume that CT, which nowadays requires but a few minutes, would not adversely influence overall outcome.

CT-features of rupture include peri-aortic haematoma, extra-aortic extravasation of contrast, haemorrhagic pleural or pericardial effusion, haemothorax (haemomediastinum) (Figures 1–2). In the endovascular era, the importance of examining the iliac vessels in addition to imaging the entire aorta, cannot be adequately emphasised. Access vessels with diameters less than 7 mm may preclude endoluminal repair, or alternatively, may make a surgical conduit as an access portal to the common iliac vessels necessary.

With the interventionalist becoming increasingly familiar with percutaneous suture-mediated closure under local anaesthesia, thoracic endovascular aortic repair for rupture (rTEVAR) has acquired a new dimension, as the patient is spared the acute haemodynamic changes that may be associated with general anaesthesia and muscular relaxation which may re-activate bleeding at the rupture site. Furthermore, performing the procedure under local anaesthesia facilitates early detection of procedure-related paraplegia, which in turn enables an early institution of CFS-drainage in order to reduce procedure-related morbidity (10, 12).

The technique of permissive hypotension has also altered the management of the ruptured aorta. Normally in hypotensive patients, volume substitution is used, in order to maintain appropriate arterial and venous pressures. This, however, leads to reduced viscosity and dilution of clotting factors, which in turn leads to continued bleeding at the rupture site [10, 13]. As opposed to this, with permissive hypotension, the blood pressure is intentionally maintained at systolic levels between 60 and 80 mmHg, under constant monitoring of the patient’s condition and response to stimuli [14, 15]. Permissive hypotension has been proven to effectively reduce blood loss [13].

It is worthy to mention that hypothermia can adversely affect procedure-related mortality. Consequently, aggressive efforts to combat hypothermia are advisable from the outset (16).

In rTEVAR, adequate proximal and distal sealing has to be achieved with the endograft, which is normally oversized by about 10–15% in relation to the proximal and distal aortic necks. As this, in contrast to rupture in type B dissections, the primary entry of the rupture is cut to off direct blood flow to the ruptured false lumen and thus achieve haemodynamic stabilisation. The endograft is placed over a few millimetres to ensure that the endograft is placed over its entire length in the true lumen. Extreme oversizing of the endograft and post-implantation ballooning of the endograft should be avoided. Due to close proximity of the entry tear to the origin of the left subclavian artery, covering the origin of this vessel may be unavoidable in some cases.

Ever since the first reports regarding the endovascular repair of rTAA appeared in the mid-nineties (4), rTEVAR has been used not only for elective repair, but also for emergency repair of rTAA (5, 6).

Compared to open repair for ruptured descending thoracic aortic aneurysms, rTEVAR is associated with a lower morbidity and mortality, and shows equivalent late outcomes (5, 17). In experienced hands, rTEVAR has a procedural success rate of about 95%. Following stent-grafting however, surgical evacuation of thoracic haematoma may be necessary in some cases. In addition, the surgical team should be prepared to occasionally perform debranching procedures such as cardiopulmonary or cerebral bypass, which are not commonly done otherwise (22).

While the incidence of stroke varies between 3–10%, the incidence of spinal cord injury is markedly lower at between 1–2% (12). It is worth mentioning a procedure-related myocardial infarction rate of 11.1% and a 30-day mortality of 19% (20, 21). Other complications include injury to access vessels and iatrogenic Type A dissections. Especially in the case of aortic dissection, it is important to emphasise that rupture may progress fatally despite successful entry closure; consequently, close vigilance is of importance, and response to open surgical repair may become necessary either in the acute or in the chronic phase. Furthermore, persistent thoraco-abdominal malperfusion may require modified measures downstream to optimise outcome (20).

The above results reflect the start of a paradigm shift in the approach to treating the formidable surgical challenge of ruptured thoracic aneurysms and dissection. Unlike the open surgical approach centred primarily around the surgical team, rTEVAR requires a cohesive team effort that spans several disciplines.

To ensure consistently good results with rTEVAR, certain organisational requirements and infrastructure are mandatory in a clinical setting of severe chest pain, haemorrhagic pleural effusion and/or haemoptysis. These include round-the-clock immediate access to a multi-slice CT, an adequate stock of appropriately sized catheters, guidewires, percutaneous stent devices, endografts (diameters between 24 and 46 mm; lengths up to 250 mm) and bare metal stents, the availability of a hybrid OR as well as a constant 24/7 availability of an experienced endovascular team consisting ideally of interventionalists, surgeons, anaesthesiologists, radiology technicians as well as OR staff (22, 23). It is important to emphasise, that although a hybrid OR is ideal, rTEVAR can function even in its absence if a good understanding exists between the various members of the endovascular team and rapid patient transfer between the cath lab and the OR are properly co-ordinated.

References:
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P. Haage (Wuppertal/DE)

Panellists:
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F.G. Irani (Singapore/SG)  
A. Krajina (Hradec Kralové/CZ)  
P. Minko (Homburg/DE)  
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M. Szczerbo-Trojanowska (Lublin/PL)  
S.O. Trerotola (Philadelphia, PA/US)
The strong surge of minimally invasive treatments in the past two decades has led to an increasing number of young physicians choosing IR as their specialty. However, this rise has not been reflected in the number of women involved in IR, with only about 12.5% of European and 2% of US interventionalists being female.

Spain seems to be the exception to this phenomenon with 26% of its interventional radiologists being female, and the percentage rising to as much as 40% in Catalonia. We spoke to four women working in IR in Barcelona to find out what Spain is doing right on the path to balanced gender representation.

Q: Spain has experienced a strong increase of IR procedures in recent years. Do you think this is due to the population being increasingly aware of IR procedures or has the cooperation and referral system between specialties changed?

Mercedes Perez: I think that both factors have been crucial to the increase of IR procedures in recent years. Multidisciplinary teams and work protocols have led to the recognition of our procedures as absolutely valid treatment options alongside more traditional ones. In fact, some of our procedures have been recognised as first-line treatment options by several specialties. Additionally, today’s patients are much better informed regarding IR and its procedures, mainly through the internet, which is leading to more and more people specifically asking to receive percutaneous treatment rather than traditional open surgery.

Marta Burrel: I agree – the general public has become more aware of the various medical treatments available through the media, mainly the internet. I think that in Spain, patients still very much rely on their referring physicians. I therefore believe that the increase of IR procedures is mainly due to interdiscipli- nary work and good communication between the specialties.

Elena Escalante: It is true that in the last two decades IR has been able to exponentially increase its importance in the treatment and clinical handling of patients, but this development has not been limited to Spain. IR has taken place worldwide. However, in Spain this boom has been so strong that it has brought us to the brink of ‘dying of success’. The diversity of procedures and their applications has increased so strongly that the workload of interventional radiologists is often becoming suffocating. Clinicians from other specialties expect fast replies to their queries, continuously increasing the workload in our ICUs. At the same time, other specialties have taken advantage of our proactive approach and inventiveness, expropriating IR procedures and even accusing us of intrusion. It is hard for IR to maintain a balance between moving the specialty forward while not losing it to others.

Q: Even though women make up 75% of med students in Spain, on a national level only roughly 26% of interventional radiologists are female. What could be done to attract more women to IR?

Marta Burrel: I think one of the most important measures to increase the awareness of IR among med students is by means of internships and seminars, which is already being done in many medical schools throughout Spain. Nevertheless, many students only discover vascular radiology during their residency, either in radiology or another specialty.

Marta Barrufet: That is true. This is why I think it would help to increase the presence of interventional radiologists, women in particular, in undergraduate medical training.

Mercedes Perez: I think that the relative- ly low percentage of women in IR is due to fears regarding ionising radiation exposure and its effects on future pregnancies. However, today’s safety regulations are very strict and many radiologists have become mothers without any problems. Therefore women are slowly joining the specialty in greater numbers. In addition, the number of interventionalists hired per IR unit is increasing, therefore decreasing on-call duties and making the job more family-friendly.

Elena Escalante: Since the year 2000 there have been more female than male university students in Spain. Therefore, there are now more female than male Spanish doctors under the age of 40, their percentage increasing even more the younger they are. Although the situation might be different on a national level, in Catalonia, radiology has actually become one of the most popular specialties among young female doctors and, in the last decade, interventional radiology as well. All major hospitals with well-established IR units in Catalonia have about the same number of male and female IRs. In my hospital, the ratio has been at least 50% women since 1995.

Q: So the situation regarding women in the IR work force in Catalonia is quite different from the rest of Spain. Why do you think that is the case?

Marta Burrel: I am not sure why in Catalonia more female physicians are inclined to become IRs, but I think it might be the result of several factors. In the 90s and 2000s, many women went into radiology and consequently more of them chose to go on IR. Also, seeing other women work in the field – in the late 80s there were already four female IRs in Barcelona – inspired the next generation and the one after to follow suit, as these young women could see that IR is in fact compatible with having a private life.

Elena Escalante: Absolutely. The fact that women started working in IR in Catalonia from an early point on has historic reasons. Interventional radiology within an undoubt- edly started in Barcelona where, thanks to enthusiastic physicians like Dr. Rius and Dr. Montalà, IR departments were established in all major third level hospitals. These units with more than 30 or 40 years of experience have attracted male and female physicians alike. The possibility of being part of the passion and development of this specialty and achieving a deep understanding of it has outweighed taboos like the fear of possible side effects of ionising radiation. Personally, I am not worried about how to attract more women to the specialty, but rather how to get them to lead IR units, which is still our Achilles tendon.

Q: What is your advice to today’s female med students?

Mercedes Perez: Due to its continuous evolution, interventional radiology is a very gratifying specialty. The development of ever-new tools and materials provides us with infinite possibilities. The advancement of the specialty is also leading to better radiation protection for patients as well as the IR team and the reduction of radiation for IRs compared to only a few years ago.

Elena Escalante: Most of all I would tell them not to give in to preconceived notions and to try to find a work-life balance that will let them choose the specialty they find the most fulfilling without losing sight of the search for excellence and leadership. Unfortunately, the percentage of women in leading positions in Spanish hospitals is still very low. They have to rise to that challenge!

Marta Burrel: I would like young women in medicine not to worry about secondary radiation in connection with possibly starting a family one day. Today we have very effec- tive radiation protection measures and strict dosimetry controls. Additionally, a large part of interventional and vascular radiology is diagnostic and non-invasive. In this field of work, radiation exposure is non-existent. During pregnancy, female vascular and interventional radiologists can dedicate themselves to this area as well as procedures carried out with no-radiating image guidance.

Marta Barrufet: I would tell them to strongly consider interventional radiology as a career option, as it is a very attractive, multi-faceted field. IR is always in the spearhead of medical development, using state-of-the-art techno- logy to diagnose and treat a large variety of pathologies. At the same time, it requires a strong relationship with the patient and close cooperation with other specialties. What more can you ask for?
Robotic interventions for the visceral artery?

Dimitrij Kuhelj

There is a long history of using robots in industry. For more than half a century, robots have been used in automobile production. Their use in medicine came later: first in orthopaedics for automatic drilling during arthroplasty [1] and later, in laparoscopic surgery, mainly in urology and gynecology [2, 3]. Upgrading the human hand with motion control and tremor compensation offers precision never witnessed before and is useful in a majority of complex surgical procedures.

Due to their minimal invasiveness, interventional procedures have become more and more frequently used. New tools and approaches offer treatment to patients once considered ineligible for endovascular treatment. Despite these improvements, there are still many issues addressing operators that might be improved by the use of robotic systems:

• Access vessels, especially for larger devices that are mainly affected by tortuosity and calcifications that influence catheterisation at the rate of procedural complications
• Catheter stability, allowing access and implantation of different devices
• Radiation exposure to patients and operators, which is not negligible in this area, even in relatively simple interventional procedures
• The amount of contrast media (CM) necessary for the procedures

To overcome these issues, operators should be provided with new skills over their years of training.

In complex anatomy, the navigation and manoeuvrability of a robotic catheter system (RCS) is meant to be better than those of manual catheterisation, thus RCSs should be safer for patients due to better stability of catheters and a lower amount of radiation exposure and CM.

The number and complexity of percutaneous procedures involving visceral arteries is increasing from endoleaks and stenting, grafting, embolisation, chemobembolisation and coiling to chemoembolisation, snookels, and fenestrated and branched stent grafts. Unfortunately, the current data on the performance of RCS in the visceral arteries, especially clinical data, is limited and sometimes controversial, so it is difficult to draw solid conclusions.

Especially, during the implantation of fenestrated and branched stent grafts, RCSs are supposed to reduce procedure time, radiation dose and the number of catheter movements in order to target the desired vessel and potentially lower the complication rate, especially in combination with current image fusion and 3D imaging technology in the angioplasty [4].

Catheter stabilisation with an RCS offers obvious advantages in difficult anatomy. A randomised study in animal models showed the superiority of a procedure performed with an RCS over a manually performed procedure in the visceral, renal and contralateral iliac arteries. The study included not only catheterisation, but also stent deployment in vivo models. After the procedures, vascular lesions were significantly more common in manually performed procedures (p < 0.01). Overall, the study showed non-inferiority to the established manual technique in tested animals, although the conclusions were drawn from one catheter for a canine model, another reason might be different in presence of pathology encountered in real-life settings [5].

Also, the time-to-target vessel cannulation showed the superiority of using an RCS over the manually performed procedure in complex anatomies, showing cannulation of the renal celiac, and superior mesenteric arteries was significantly faster with an RCS. The greatest differences were in anatomically challenging vessel cannulation, with an overall time reduction of 93% (6). RCSs offer centrelime navigation, producing minimal impact to the vessel wall and reducing the possibility of vessel damage, dissection, or dissection [6, 7]. Catheter stability is another important feature. An RCS allows for the avoidance of deep ostial cannulation (with possible damage), while obtaining a stable road for endovascular therapy, including dilatation balloons and stent delivery at a desired point without difficult curve crossing. There are some reports [8], including our experience, which favour access to the visceral arteries from above due to easier access to the target vessel and a more stable catheter position. A stable ostial catheter position with an RCS allows for a conventional approach instead of the approach from “above” that might be questionable, especially in the use of larger introducer sheaths which are necessary for some complex procedures.

Technical results of RCSs are often similar between highly experienced and less experienced interventional operators [7]. This confirms that robotic therapy is easy to use, and allows fast and greater reduction of catheterisation times for beginners to perform complex procedures.

Radiation doses received during abdominal vascular procedures can be considerable, especially in long-lasting, complex procedures [9]. Radiation dose to the operator is reduced by the use of an RCS, which provides remote control operation of the system. Consequently, the radiation dose for the staff is lower or even negligible when the remote control is located outside the angiography. Although dose reduction mostly affects staff, patient dose can also be reduced due to shorter procedure times [10].

Aortic and iliac tortuosity, excessive calcifications and plaques influence stent graft deployment and represent a high risk for vessel damage and distal embolisation. Remote vascular access can be seriously affected by tortuosity, including visceral branches or contralateral limb cannulation especially in the presence of a large, non-thrombosed abdominal aorta. Considerable iliac tortuosity makes manual target vessel cannulation increasingly demanding, while it does not affect procedures performed by RCS, as functionality was shown to be unaffected by the severity of iliac tortuosity [6, 11]. Also, the robotic catheters are steered by controlling the catheter tip [6], which could result in potentially less traumatic impact to the vessel compared to the conventional catheters that require force and pushing.

In situ stent graft fenestration has been described in animal models, offering the possibility of an endovascular approach to the patients unsuitable for conventional stent grafts, especially in emergency conditions where branched and fenestrated devices are not readily accessible. This technique could also be beneficial in aortic dissections when fenestration between true and false lumens should sometimes be performed, as well as for cannulation of arterial branches in false lumen.

Promising data from in vitro and animal model-based RCSs are not always confirmed by clinical data. In a safety and feasibility study involving 15 patients and 37 vessel cannulations, during branched and fenestrated stent graft implantations, all vessels were cannulated by an RCS in 15 minutes. Manual approach was successfully attempted in all patients, although cannulation time was longer than 30 minutes [4]. Technical encounters were also identified. Catheter steering in a limited space between aortic lumen and fabric was limited, and the diameter of the peripheral catheter (6 Fr.) was unsuitable for delivery of many peripheral stent grafts.

There are other issues to consider, including less contact to the patient and a less friendly environment due to additional RCS equipment, influencing patient comfort. It also decreases tactile and force feedback information, which is very important for the operators. Some systems try to overcome this with force sensors which allow constant catheter force measurement, but, as yet, tactile feeling cannot be simulated [8]. Systems often use expensive and non-standard catheters, raising costs and reducing catheter availability. The size of an RCS is limited: for visceral use, a 6-Fr. or larger than catheters used during manual catheterisation, while for peripheral stent graft implantation, 6-Fr. is often too small and 9 Fr. might cause issues with safe haemostasis.

The major drawback of RCS is still the price. The systems are expensive, and the initial reported cost of more than $600,000 is augmented with high maintenance costs of over $60,000 per year, with additional costs for expensive disposables catheters [12]. Though systems are expected to decrease gradually in size, they are still large and cumbersome, limiting the use in routine work in standard angiographies.

Set-up times for the systems are not negligible, and last from 5 to 15 minutes for each procedure in laboratory and clinical settings [4, 14]. Still, if the rest of the procedure would be performed faster, there could be minimal or no practical impact of an RCS’s set-up time on the procedure duration.

Despite promising initial results, current clinical data show only limited benefit of RCSs. Their use seems safe and radiation dose, especially to the staff, can be significantly reduced. Further clinical studies will provide better insights and define the role of RCSs in the visceral arteries.

The major drawback for the wider use of RCSs is the price of the system, its maintenance and disposables catheters.

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Dr. Kuhelj currently serves as the head of the Clinical Radiology Institute (KIR) at the University Medical Centre in Ljubljana. The KIR is the largest unit in Slovenia for the professional training of staff in radiology, including radiologists, nurses and other staff members. Dr. Kuhelj has authored a number of publications, most recently a case report on aortic pseudoaneurysm associated with a fracture bone Chevloth (2013) and another one following stenting for aortic coarctation, which was featured in Cardiology in the Young.
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IESIR (the Italian-European Society of Interventional Radiology) has been active for around one and a half years, although not without difficulties. Founding the Society was hard and laborious, due to ostracism from many sides. However, all members, especially the youngest, welcomed the birth of a new, independent scientific society of interventional radiology in Italy.

Some crucial issues are not completely solved, many barriers have not been fully overcome and the route is still uncertain, but there are at least ten reasons why IESIR and the idea of an independent scientific society of interventional radiology should exist in Italy.

1. Nowadays, interventional radiology plays a key role in every clinical field, and this contribution is not negligible.
2. There are no longer reasons for keeping IR as a subsector of diagnostic radiology, although the common cultural origin and the still overlapping qualifications cannot be denied.
3. It’s essential to seek appropriate credit for the clinical role of IRs, who personally bear the burden of medical, professional and legal responsibilities for each of their therapeutic interventions.
4. The economic-administrative credits, the full visibility of IR activities and the full traceability of the diagnostic-therapeutic path, cannot be delayed any longer; in other words, the time is coming for when IR centres will no longer be counted as “spending centres” only, but as “income centres”, like any other clinical department.
5. The cultural growth of every IR is based on the university and post-graduate education pathways, but also on the achievement of a full awareness of their role and its importance in daily clinical activities and also on the national and local healthcare planning.
6. The Italian-European Interventional Radiology Society (IESIR) should have the same standing as the other national and European IR scientific societies, through the option of common guidelines, therapeutic protocols, local programming and planning bases as other societies usually do.
7. Based on IR’s specific competences, IESIR should have the chance to establish a direct dialogue, for negotiation and cooperation, with the healthcare organisations and public sector (i.e. national government, local authorities, etc.).
8. As an independent society, all interventional radiologists can democratically express themselves without awe and without opportunism and/or consideration of the interests of the more powerful or of the most numerous.
9. The job opportunities, both for youngest and less young IRs, should be protected and safeguarded: “having the opportunity to work within a defined interventional area” should mean to have career opportunities both in professional and economic terms.
10. Give “hope” to the younger doctors who have recently joined or will join shortly to IESIR.

In order to survive and for the previously listed “10 reasons”, all IESIR Members and its Executive Board ask for the continued endorsement of CIRSE for all the independent European IR societies. These national societies represent the solid roots from which European IR will continue to develop and increase its valuable contribution to modern patient care.

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<td>Freedom from Composite Safety Endpoint</td>
<td>78.9%</td>
</tr>
<tr>
<td>All-Cause Death</td>
<td>7.6% (21/276)</td>
</tr>
<tr>
<td>Target Limb Major Amputation</td>
<td>0.4% (1/261)</td>
</tr>
</tbody>
</table>

In Pre-Clinical Animal Studies

**LUTONIX® 035**
Drug Coated Balloon PTA Catheter

0%² Skeletal Muscle Necrosis in Swine Arterial Tissue at 90 days

0%² Crystalline Material in Swine Arterial Tissue at 90 days

**COMPETITOR**
Drug Coated Balloon

12%² Skeletal Muscle Necrosis in Swine Arterial Tissue at 90 days

5%² Crystalline Material in Swine Arterial Tissue at 90 days

Competitor DCB Downstream Effects

Crystalline material found in downstream aortas in Competitor DCB pre-clinical data.

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1. LEVANT 2 clinical trial data on file. Lutonix, Inc., New Hope, MN. N=476. Primary safety composite endpoint is defined as freedom from all-cause peri-operative death at 30 days, freedom from index limb from amputation (A3K or BTK), re-intervention, and index limb-related death. Composite safety endpoints are by Kaplan-Meier method.

2. Data obtained from two different data sets. Dr. Preru Vermi's pre-clinical data on file, Lutonix, Inc., New Hope, MN. Data presented by Dr. Preru Vermi at TCT 2014. Animal test results may not be indicative of clinical performance. Different test methods may yield different results. Swine were dosed with three times the nominal DCB dosage.

Please consult product labels and instructions for use relevant to your geography for indications, contraindications, hazards, warnings and precautions.

The Lutonix® 035 Drug Coated Balloon Catheter is intended for use as a PTA catheter to dilate stenotic or obstructive vascular lesions in the lower extremities, and native or synthetic arterial bypass grafts, for the purpose of improving limb perfusion and decreasing the incidence of restenosis.

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LUMPRO/0516/008

Lutonix, Inc., a subsidiary of C.R. Bard, Inc. 5438 Science Center Drive, New Hope, MN 55426 USA Tel: 1 763 445 2352 Fax: 1 763 445 2353
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 informational material, interactive tools, ophthalmological check-ups, and opportunities to engage directly with experts in RP matters. Today’s RPP Mini-Talks, which feature short expert presentations, again cover a wide range of topics delving further into various aspects of radiation safety. We hope to see you there!

Prize draw
To help you get started in improving your department’s radiation safety, we’re giving away some great prizes. Taking part is simple: to be in with a chance of winning, all you have to do is complete the sticker that’s been handed out with each copy of Congress News. Visit any of the RP Pavilion exhibitors; they will provide you with the missing part, which you can peel off and add to your sticker; the backing card acts as your ‘ticket’. Simply fill in your name, ID number and email address, and hand it in. Pop the completed sticker on your jacket or congress bag to show that you can ‘handle the risk’.

Today’s RPP Mini-Talks

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:00</td>
<td>There is more than meets the eye (MDT)</td>
<td>D. Janssen (Hilvarenbeek/NL)</td>
</tr>
<tr>
<td>11:15</td>
<td>Last image Hold (LIH) to reduce patient and occupational exposure: control of interventional procedures without radiographs or DSA series</td>
<td>R.W. Loose (Nuremberg/DE)</td>
</tr>
<tr>
<td>12:30</td>
<td>Improving patient follow-up in interventional radiology (GE HealthCare)</td>
<td>F. Gardavaud (Paris/France)</td>
</tr>
<tr>
<td>12:45</td>
<td>DICOM tools help to manage patient radiation exposure (MINI refresh course series)</td>
<td>A. Trianni (Udine/IT)</td>
</tr>
<tr>
<td>13:00</td>
<td>Through the looking glass: Improving radiation safety in the interventional suite through room design, workflow and protection verification (ANRAY)</td>
<td>P. Gilligan (Dublin/IE)</td>
</tr>
<tr>
<td>14:00</td>
<td>Managing radiation metrics with Radimetrics (BAYER)</td>
<td>H. Hauberreisser (Mannheim/DE)</td>
</tr>
<tr>
<td>14:15</td>
<td>Pre-procedural patient-specific simulation of endovascular interventions reduces patient and personnel radiation exposure (BD SYSTEMS)</td>
<td>G. Bartal (Kfar Saba/IL)</td>
</tr>
<tr>
<td>16:00</td>
<td>Radiation-related illnesses in the cath lab (RADPAD)</td>
<td>E. Razhke (Kansas City, KS/US)</td>
</tr>
</tbody>
</table>
TIPS Breakfast Symposium

Monday, September 12, 2016, 7:40-8:20 am
Rooms 114, CIRSE 2016, Barcelona

Why, when and what patients will benefit from TIPS?
Introducing the new Gore TIPS Set and TIPS innovations.

Moderator:
Geert Maleux, Leuven, Belgium

Speakers:
Jonel Trebicka, Bonn, Germany
Roberto Miraglia, Palermo, Italy

Real-time ultrasound guidance for portal vein targeting during TIPS creation.
Effects on radiation exposure of patients and medical staff.
Introducing the new Gore TIPS Set.
Roberto Miraglia

Introducing total patient care in portal hypertension:
Why, when, what patients will benefit from TIPS?
Concept of an optimized TIPS service.
Jonel Trebicka