Vascular IR and sailing the ocean

Johannes Lammer

Both vascular IR and ocean-sailing were pioneered by ingenious men and by chance. Charles Dotter observed that patients reported a clinical improvement after performing a diagnostic angiogram crossing an arterial stenosis with a large bore catheter [1]. Christopher Columbus wanted to reach India by sailing westward across the Atlantic Ocean [2, 3]. Both were important first steps, but quite imperfect. The first "Dotter procedures" caused moderate widening of the arterial stenosis; Columbus landed at the Bahamas. Initially, both ideas – to cross the Atlantic Ocean on the way to East Asia and to treat arteriosclerotic arterial disease by endovascular techniques – were derided as tomfoolery, and many further steps of development were required. However, the biggest obstacles were the lack of appropriate instruments: sailors in the 15th century had poor instruments for navigation and Dotter only large bore catheters.

History of vascular IR for treatment of peripheral vascular disease (PAD)

Andreas Grüntzig, trained by Eberhard Zeitler in the "Dotter procedure" [1], developed the angioplasty balloon in 1974 [4], which was a big step forward, and further advancement occurred when, in 1985, Julio Palmaz patented his stent. Together with Goetz Richter, he performed the first peripheral vascular, renal and TIPS stenting, and, with Juan Parodi, the first EVAR [5, 6, 7]. All these pioneers had predecessors: Leif Eriksson landed in Newfoundland in 1000 A.D., Werner Porstmann developed the Korsett Balloon in 1973 [8], Charles Dotter completed a coil spring tube graft in 1969 [9], Kurt Amplatz with Andy Cragg developed a spiral stent in 1983 [10], Josef Rösch performed the portocaval shunt procedure 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 (post-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 88% 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, recoil 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 neovasculature, adenovirus 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 (EVAS) [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

Don't miss it!
Andreas Gruentzig Lecture
Honorary Lecture
Sunday, September 11, 14:30-15:00
Auditorium 1

Johannes Lammer
Vienna, Austria

Former CIRSE President Prof. Johannes Lammer completed medical school in Vienna in 1975 before completing his residency in radiology at the University of Graz. From 1992 to 2004, he headed the Department of Angiography and Interventional Radiology at the University of Vienna. From 2004 until his retirement in 2015, he was director of Cardiovascular and Interventional Radiology and Vice-Chairperson of the Department of Radiology at the Medical University Vienna. He has published more than 300 peer-reviewed scientific papers in various international journals.

>>

>> much easier to deliver and enable EVAR to be done as an out-patient procedure.

On the ocean, sudden local storms can cause quite serious conditions. Ruptured aneurysms are a life-threatening situation for patients and a challenging situation for the treating physicians. Mortality and complication rates are usually high. However, despite randomised controlled trials which seem to show no advantage of EVAR over open surgical repair, EVAR is the treatment of choice in ruptured AAAs for most patients.

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. Thus open vascular surgery, 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 diseases. 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.

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 vascular IR, the limitation of our instruments and the pirate activities of other disciplines are challenging interventional radiology. However, the inventors should not surrender to imitators. It should be the incentive to work continuously on improving devices, treatment modalities and, most importantly, our clinical service.

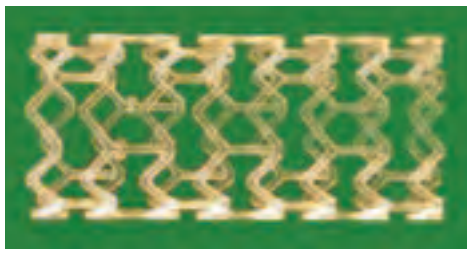

Fig. 1: ESPRIT everolimus-eluting bioresorbable vascular scaffold (Abbott Vascular, CA, USA)

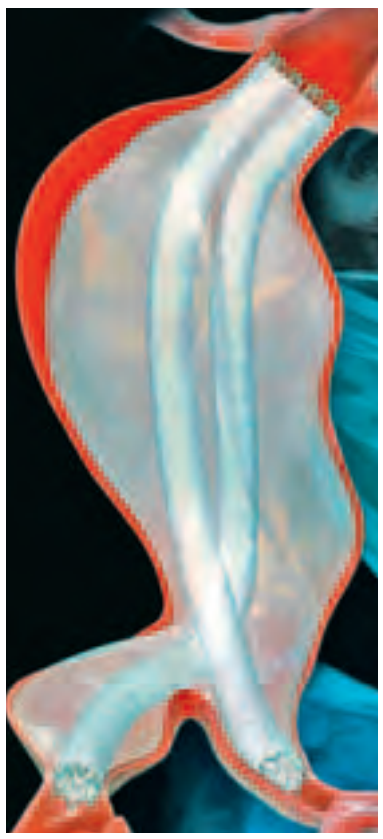

Fig. 2: NELLIX endovascular aneurysm sealing system (Endologix, CA, USA)

Fig. 3: ALTURA endograft system (Lombard Medical, CA, USA)

References:

1. Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction. Description of a new technic and a preliminary report of its application. Circulation 1964 Nov; 30:654-70
2. Colombo C. Cuaderno de bitácora del primer viaje y el descubrimiento de las Indias (Giornale di bordo del primo vaggio e della scoperta delle Indie). 3.8.1492 – 4.3.1493
3. Colon F. Historie del Sig. don Fernando Colombo. : Nelle quali s'hà particolare, & vera relatione della vita, & de' fatti dell' ammiraglio don Christoforo Colombo, suo padre. Et dello scoprimento, ch'egli fece dell'Indie Occide[n]tali, dette Mondo Nuouo, possedute dal potentissimo Rè catolico. By Colón, Fernando, 1506; Pané, Ramón, d. 1571; Ulloa, Alfonso, d. ca. 1580 Published Milano 1614
4. Gruntzig A. Transluminal dilatation of coronary-artery stenosis. (Letter). Lancet 1978 Feb 4; 1(8058):263
5. Palmaz JC, Richter GM, Noeldge G, Schatz RA, Robison PD, Gardiner GA Jr, Becker GJ, McLean GK, Denny DF Jr, Lammer J, et al. Intraluminal stents in atherosclerotic iliac artery stenosis: preliminary report of a multicenter study. Radiology 1988 Sep; 168(3):727-31
6. Richter GM, Palmaz JC, Nöldge G, Rössle M, Siegerstetter V, Franke M, Wenz W. The transjugular intrahepatic portosystemic stent-shunt. A new nonsurgical percutaneous method. Radiologe 1989 Aug; 29(8):406-11
7. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991 Nov; 5(6):491-9
8. Porstmann W. A new corset balloon catheter for Dotter's transluminal recanilization with special reference to obliterations of the pelvic arteries. Radiol Diagn (Berl) 1973; 14(2):239-44
9. Dotter CT. Transluminally-placed coilspring endarterial tube grafts. Long-term patency in canine popliteal artery. Invest Radiol 1969 Sep-Oct; 4(5):329-32
10. Cragg A, Lund G, Rysavy J, Castaneda F, Castaneda-Zuniga W, Amplatz K. Nonsurgical placement of arterial endoprostheses: a new technique using nitinol wire. Radiology 1983 Apr; 147(1):261-3
11. Rösch J, Hanafee WN, Snow H. Transjugular portal venography and radiologic portacaval shunt: an experimental study. Radiology 1969 Apr; 92(5):1112-4
12. Volodos' NL, Karpovich IP, Shekhanin VE, Troian VI, Iakovenko LF. A case of distant transfemoral endoprosthesis of the thoracic artery using a self-fixing synthetic prosthesis in traumatic aneurysm. Grudn Khir 1988 Nov-Dec; (6):84-6
13. Duda SH, Pusich B, Richter G, Landwehr P, Oliva VL, Tielbeek A, Wiesinger B, Hak JB, Tielemans H, Ziemer G, Cristea E, Lansky A, Bérégi JP. Sirolimus-eluting stents for the treatment of obstructive superficial femoral artery disease: six-month results. Circulation 2002 Sep 17; 106(12):1505-9
14. Duda SH, Bosiers M, Lammer J, Scheinert D, Zeller T, Tielbeek A, Anderson J, Wiesinger B, Tepe G, Lansky A, Mudde C, Tielemans H, Bérégi JP. Sirolimus-eluting versus bare nitinol stent for obstructive superficial femoral artery disease: the SIROCCO II trial. J Vasc Interv Radiol 2005 Mar; 16(3):331-8
15. Lammer J, Bosiers M, Zeller T, Schillinger M, Boone E, Zaugg MJ, Verta P, Peng L, Gao X, Schwartz LB. First clinical trial of nitinol self-expanding everolimus-eluting stent implantation for peripheral arterial occlusive disease. J Vasc Surg 2011 Aug; 54(2):394-401
16. Dake MD, Ansel GM, Jaff MR, Ohki T, Saxon RR, Smouse HB, Zeller T, Roubin GS, Burket MW, Khatib Y, Snyder SA, Ragheb AO, White JK, Machan LS; Zilver PTX Investigators. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv 2011 Oct 1; 4(5):495-504
17. Speck U, Scheller B, Abramjuk C, Grossmann S, Mahnkopf D, Simon O. Inhibition of restenosis in stented porcine coronary arteries: uptake of Paclitaxel from angiographic contrast media. Invest Radiol 2004 Mar; 39(3):182-6
18. Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwälder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U. Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med 2008 Feb 14; 358(7):689-99
19. Werk M, Langner S, Reinkensmeier B, Boettcher HF, Tepe G, Dietz U, Hosten N, Hamm B, Speck U, Ricke J. Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. Circulation 2008 Sep 23; 118(13):1358-65
20. Rosenfield K, Jaff MR, White CJ, Rocha-Singh K, Mena-Hurtado C, Metzger DC, Brodmann M, Pilger E, Zeller T, Krishnan P, Gammon R, Müller-Hülsbeck S, Nehler MR, Benenati JF, Scheinert D; LEVANT 2 Investigators. Trial of a Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. N Engl J Med 2015 Jul 9; 373(2):145-53
21. Müller-Hülsbeck S. MAJESTIC Trial 12-month Results. CIRSE 2015
22. Lammer J, Bosiers M, Deloose K, Schmidt A, Zeller T, Wolf F, Lansink W, Sauguet A, Vermassen F, Lauwers G, Scheinert D, Popma JJ, McGreevy R, Rapoza R, Schwartz LB, Jaff MR. Bioresorbable Everolimus-Eluting Vascular Scaffold for Patients With Peripheral Artery Disease (ESPRIT I): 2-Year Clinical and Imaging Results. JACC Cardiovasc Interv 2016 Jun 13; 9(11):1178-87
23. Dake MD, Miller DC, Semba CP, Mitchell RS, Walker PJ, Liddell RP. Transluminal placement of endovascular stent-grafts for the treatment of descending thoracic aortic aneurysms. N Engl J Med 1994 Dec 29; 331(26):1729-34
24. Blum U, Voshage G, Lammer J, Beyersdorf F, Töllner D, Kretschmer G, Spillner G, Polterauer P, Nagel G, Hölzenbein T. Endoluminal stent-grafts for infrarenal abdominal aortic aneurysms. N Engl J Med 1997 Jan 2; 336(1):13-20
25. Holden A. Endovascular aneurysm sealing for abdominal aortic aneurysm repair: evolution or revolution? Cardiovasc Intervent Radiol 2014 Oct; 37(5):1129-36

IDEAS Training Village

This year, to accompany the second Inter-disciplinary Endovascular Aortic Symposium, there will be a special IDEAS Training Village: a special open forum which will allow delegates to get hands-on experience with a number of companies' aortic devices. The six companies will also be hosting their own device training programmes. Stop by throughout the congress and see what's happening at the Training Village located next to Auditorium 2! It will be open Sunday and Monday from 09:00-18:00 and Tuesday from 09:00-19:00.

Bolton Medical

Bolton Medical will be offering 1-to-1 simulation sessions on the treatment of a thoracic or abdominal pathology. One hour slots will be available for 1-2 physicians on three different courses covering either pre-case planning of TEVAR, pre-case planning of EVAR or advanced tips and tricks for Osirix. Each small group course will include product presentation, hands-on deployment, case discussion and a case simulation. To participate, enquire at the welcome desk outside the Training Village.

Sunday, September 11
09:00-10:00 (1 slot) | 14:00-17:00 (3 slots)

Monday, September 12
09:00-10:00 (1 slot) | 14:00-17:00 (3 slots)

Tuesday, September 13
09:00-10:00 (1 slot) | 14:00-17:00 (3 slots)

Cordis, a Cardinal Health Company

Cordis will have experts on hand who will be offering demonstrations of the benefits and simulated use of the low profile AAA Stent Graft System. Personalised demonstrations are welcome during these hours, with no need to pre-register!

Sunday, September 11
09:00-12:00 | 13:30-18:00

Monday, September 12
09:00-12:00 | 13:30-18:00

Tuesday, September 13
09:00-12:00 | 13:30-18:00

JOTEC

Covering endovascular treatment of aorto-iliac and isolated iliac aneurysms, JOTEC will be offering hands-on demonstrations on the E-liac and the E-tegra Stent Graft System. To participate, visit the JOTEC booth in the Training Village.

Sunday, September 11
10:30-11:30 | 14:30-15:30

Monday, September 12
10:30-11:30 | 14:30-15:30

Tuesday, September 13
10:30-11:30 | 14:30-15:30

Maquet/Getinge Group

This partner is offering two special hands-on workshops on "The chimney endovascular technique in the treatment of juxtarenal aneurysms: 'from alpha to omega'". These workshops will be led by Konstantinos Donas and Francisco Azevedo and will walk participants through pre-operative planning and the procedure step by step as well as give tips to optimise clinical outcome. The workshops are free of charge, but pre-registration is required. To sign up, please enquire at the Training Village Welcome Desk.

Sunday, September 11 13:00-15:30
Monday, September 12 13:00-15:30

Medtronic

Medtronic will be offering simulation workshops on EVAR (including HeliFX) or TEVAR for physicians interested in learning more about the endovascular treatment options for patients with pathologies of the aorta. In these practical and interactive workshops, participants will be working in small groups on a Simbionix 3D Systems simulator with the facilitator introducing participants to Medtronic's products in EVAR (Endurant and HeliFX) and TEVAR (Valiant captivia). Pre-registration is required to sign up, visit the Training Village welcome desk.

Sunday, September 11
09:00-10:30 | 11:00-12:30
13:30-15:00 | 15:30-17:00

Monday, September 12
09:00-10:30 | 11:00-12:30
13:30-15:00 | 15:30-17:00

Philips Volcano

Philips Volcano will be offering opportunities to get hands-on experience with both their Phoenix Atherectomy System for PAD and their Digital IVUS Technology for EVAR and TEVAR throughout Sunday, Monday and Tuesday. To participate, visit the Philips Volcano booth. During the IVUS-guided EVAR/TEVAR procedures, delegates will navigate the procedural steps, get hands-on experience on a flow model while learning how IVUS guidance can reduce contrast and radiation exposure, and improve their technical and procedural expertise.

Sunday, September 11
12:00-13:00 | 16:00-17:00

Monday, September 12
11:00-12:00 | 12:00-13:00 | 13:00-14:00

Tuesday, September 13
11:00-12:00 | 13:00-14:00

We hope that you will all enjoy exploring the first-ever IDEAS Training Village and take advantage of this great opportunity to get free hands-on experience with a number of thoracic and abdominal aortic devices!

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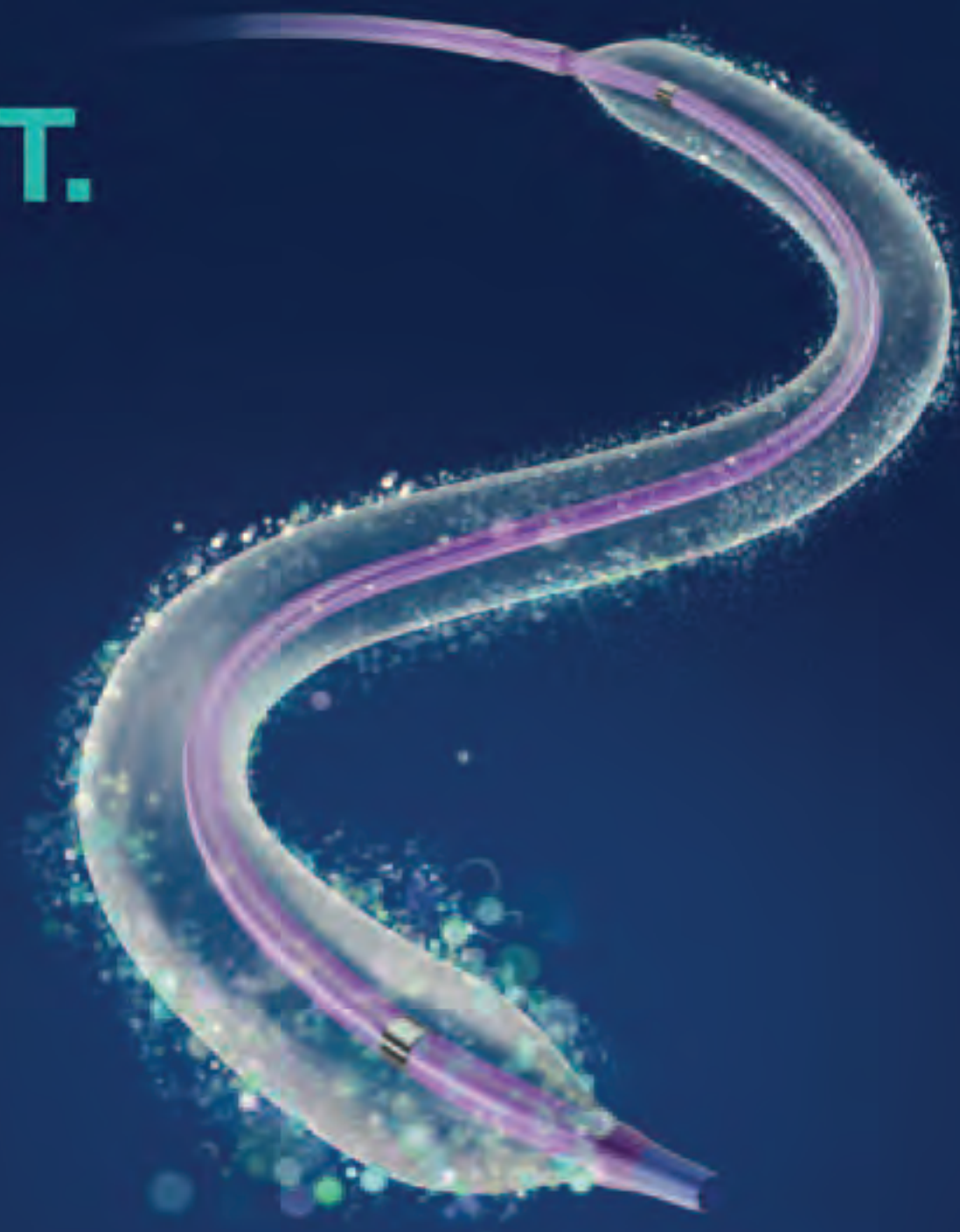

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FROM BENCH TO BEDSIDE: TECHNOLOGY, EVIDENCE AND TREATMENT ALGORITHMS IN PERIPHERAL ARTERIAL DISEASE

Sunday, September 11 at 13.00, Auditorium 2

Medtronic
Further, Together

Don't miss it !
Controversies in new fields of embolisation
Special Session
Sunday, September 11, 08:30-09:30
Auditorium 1

Haemorrhoid embolisation – Con

Petr Vávra

Petr Vávra
University Hospital Ostrava
Ostrava, Czech Republic

Prof. Vávra received his medical degree from Palacky University in Olomouc, Czech Republic in 1991 and earned his Ph.D. in 2003 from Comenius University in Bratislava, Slovakia. Prof. Vávra currently works as the Team Leader in Hepatic Surgery at the Surgical Clinic of the University Hospital Ostrava. Since 2014, he has also been the Head of the Department of Surgery at the University of Ostrava. He has performed a number of studies as the principal investigator or co-investigator and is credited for over 200 publications, including a textbook, two patents, and three book chapters.

Symptomatic patients with haemorrhoids are some of the most frequent visitors of the out-patient 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 plexus 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 haemorrhoid treatment may include oedema, rebleeding, necrosis of the rectum, pseudoaneurysm, 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 pain is lower in the most frequent types of treatment. With open surgery, the complication rate is 8-10% for urinary retention, 4-15% for bleeding and up to 5% for continence disorders [4]. Post-operative pain is common, however, it usually 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 (0.3-22%) or rectal bleeding (4-17%) [6]. The Doppler-guided ligation 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 out-patient 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 haemorrhoid 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 haemorrhoid tissue. The range of possible complications is extended by a set of catheterisation-specific complications, i.e. an infection of the catheterisation site or pseudoaneurysms 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 haemorrhoid 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 ligation requires 20-30 minutes to perform, while open surgery is usually completed in about 40 minutes. The "emborrhoid" technique is reported to be 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.

References:
1. Ho, Yik-Hong, Margaret TAN a Francis Seow-Choen. Micronized purified flavonidic fraction compared favorably with rubber band ligation and fiber alone in the management of bleeding hemorrhoids. Diseases of the Colon & Rectum [online] 2000; 43(1), 66-69 [cit. 2016-07-11]. DOI: 10.1007/BF02237246. ISSN 0012-3706
2. Vidal, V., M. Sapoval, Y. Sielezneff, V. De Parades, F. Tradi, G. Louis, J. M. Bartoli a O. Pellerin. Emborrhoid: A New Concept for the Treatment of Hemorrhoids with Arterial Embolization. CardioVascular and Interventional Radiology [online] 2015; 38(1), 72-78 [cit. 2016-07-11]. DOI: 10.1007/s00270-014-1017-8. ISSN 0174-1551
3. Madoff, Robert D. a James W. Fleshman. American gastroenterological association technical review on the diagnosis and treatment of hemorrhoids. Gastroenterology [online] 2004; 126(5), 1463-1473 [cit. 2016-07-11]. DOI: 10.1053/j.gastro.2004.03.008. ISSN 00165085
4. Higuero, T., L. Abramowitz, A. Castinel, et al. Guidelines for the treatment of hemorrhoids (short report). Journal of Visceral Surgery [online] 2016; 153(3), 213-218 [cit. 2016-07-08]. DOI: 10.1016/j.jviscsurg.2016.03.004. ISSN 18787886
5. Jayaraman, S, PHD Colquhoun, RA Malthaner a Shiva Jayaraman. Circular stapled anopexy versus excisional hemorrhoidectomy for hemorrhoidal disease. Cochrane Database of Systematic Reviews [online], Chichester, UK: John Wiley & Sons, Ltd, 1996 [cit. 2016-07-11]. DOI: 10.1002/14651858.CD005393
6. Bleday, Ronald, Juan P. Pena, David A. Rothenberger, Stanley M. Goldberg a John G. Buls. Symptomatic hemorrhoids. Diseases of the Colon & Rectum [online] 1992; 35(5), 477-481 [cit. 2016-07-11]. DOI: 10.1007/BF02049406. ISSN 0012-3706
7. Pucher, P. H., M. H. Sodergren, A. C. Lord, A. Darzi a P. Ziprin. Clinical outcome following Doppler-guided haemorrhoidal artery ligation: a systematic review. Colorectal Disease [online] 2013; 15(6), e284-e294 [cit. 2016-07-11]. DOI: 10.1111/codi.12205. ISSN 14628910
8. Vidal, V., M. Sapoval, Y. Sielezneff, V. De Parades, F. Tradi, G. Louis, J. M. Bartoli a O. Pellerin. Emborrhoid: A New Concept for the Treatment of Hemorrhoids with Arterial Embolization. CardioVascular and Interventional Radiology [online] 2015; 38(1), 72-78 [cit. 2016-07-11]. DOI: 10.1007/s00270-014-1017-8. ISSN 0174-1551
9. Longo, A. Treatment of haemorrhoidal disease by reduction of mucosa and haemorrhoidal prolapse with a circular stapling device: A new procedure. 6th world congress of Endoscopy Surgery, Naples: Mundozzi Editore; 1998. pp. 777–84
10. Tarazov, Pavel G. Arterial Embolization of Hemorrhoids. CardioVascular and Interventional Radiology [online] 2015; 38(4), 1055-1055 [cit. 2016-07-11]. DOI: 10.1007/s00270-015-1148-6. ISSN 0174-1551

To find out who will win this, and other exciting embolisation debates, join us in Auditorium 1 at 08:30!

Haemorrhoid embolisation – Pro

Vincent Vidal

Don't miss it !
Controversies in new fields of embolisation
Special Session
Sunday, September 11, 08:30-09:30
Auditorium 1

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, phlebotonics and/or non-surgical outpatient treatment, such as infrared photocoagulation 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 expansion 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 arteries.

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 haemorrhoid 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.

Vincent Vidal
University Hospital Timone
Marseille, France

Prof. Vidal is an Academic Professor of IR at the Aix-Marseille University and has served for nine years as Director of the Experimental Interventional Imaging Laboratory in the European Center for Research in Medical Imaging (CERIMED). He is also responsible for the interventional radiology section in the Department of Medical Imaging at the University Hospital Timone in Marseille, France.

References:
1. Aigner F, Bodner G, Conrad F, Mbaka G, Kreczy A, Fritsch H. The superior rectal artery and its branching pattern with regard to its clinical influence on ligation techniques for internal hemorrhoids. Am J Surg 2004; 187:102–108
2. Moussa N, Sielezneff I, Sapoval M, Tradi F, et al. Embolization of the superior rectal arteries for chronic bleeding due to hemorrhoidal disease. Colorectal Dis 2016; Jun 24 doi: 10.1111/codi.13430
3. Infantino A, Altomare DF, Bottini C et al. Prospective randomized multicentre study comparing stapler haemorrhoidopexy with Doppler-guided transanal haemorrhoid dearterialization for third-degree haemorrhoids. Colorectal Dis 2012; 14:205–211
4. Vidal V, Louis G, Bartoli JM, Sielezneff Y. Embolization of the hemorrhoidal arteries (the emborrhoid technique): a new concept and challenge for interventional radiology. Diagn Interv Imaging 2014; 95:307–315
5. Vidal V, Sapoval M, Sielezneff Y, De Parades V, Tradi F, Louis G, Bartoli JM, Pellerin O. Emborrhoid: a new concept for the treatment of hemorrhoids with arterial embolization: the first 14 cases. Cardiovasc Intervent Radiol 2015; 38:72–8
6. Bilhim T, Pereira JA, Rio Tinto H, et al. Middle rectal artery: myth or reality? Retrospective study with CT angiography and digital subtraction angiography. Surg Radiol Anat 2013; 35:517–522

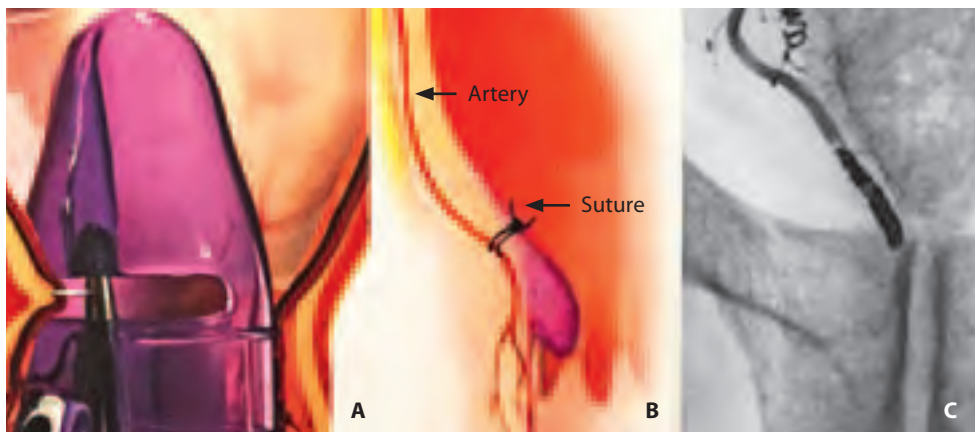
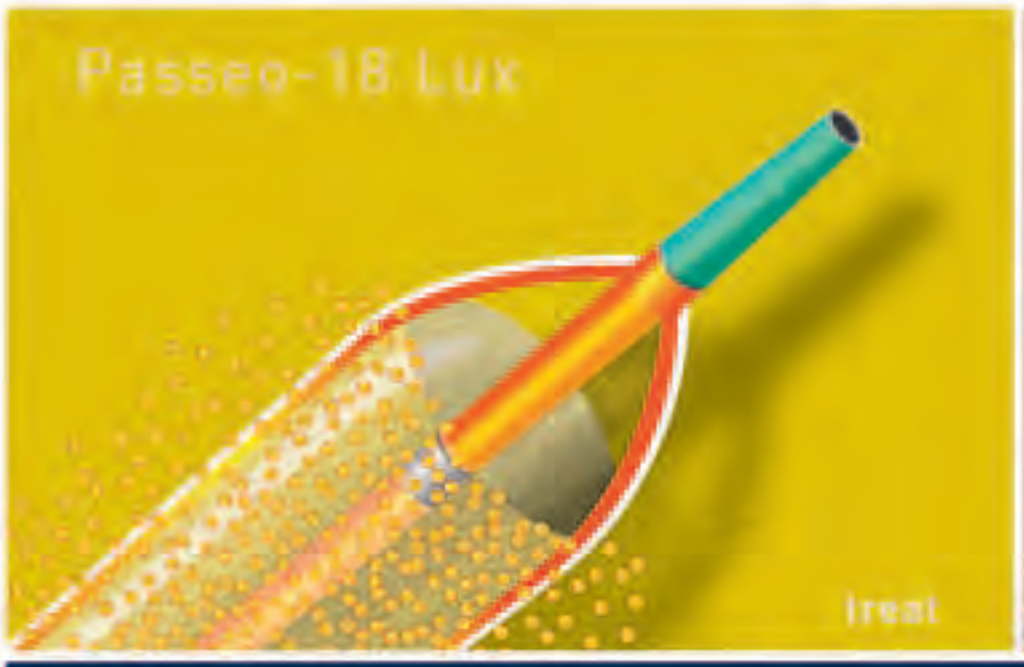
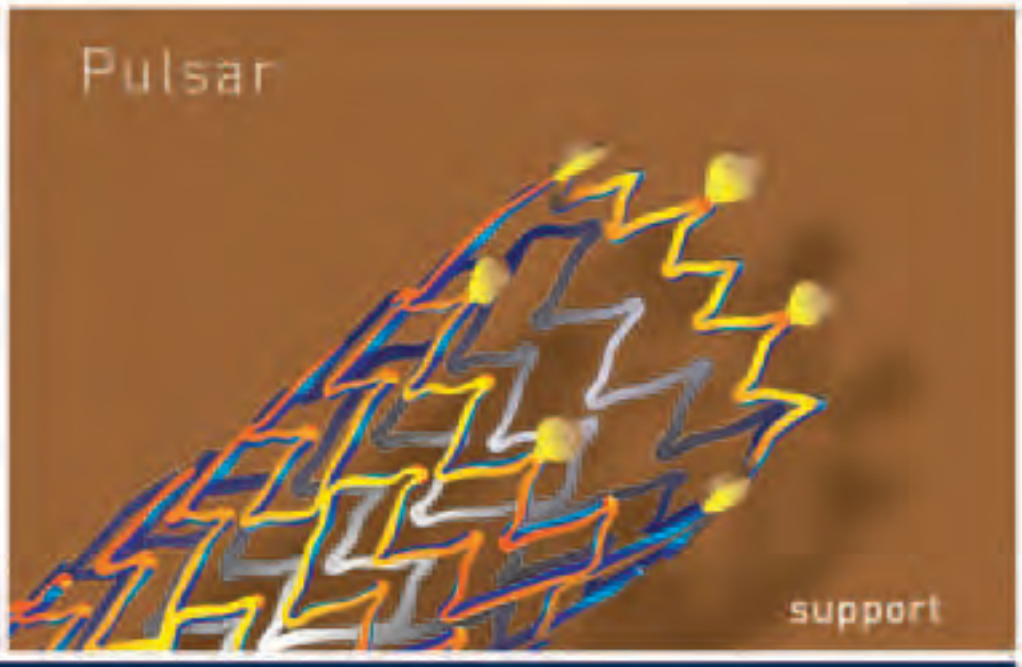


Fig. 1: DG-HAL procedure with arterial suture (A & B) and the corresponding occlusion with coils "Emborrhoid technique" (C).

Controversies in new fields of embolisation:
• Bariatric embolisation • Haemorrhoid embolisation • Transradial approach to visceral interventions





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

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-III 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

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Lithoplasty: last frontier in calcium modulation

Andrew Holden

Don't miss it !
Calcium burden and treatment solutions in modern endovascular practice
Special Session
Sunday, September 11, 08:30-09:30
Room 117

Andrew Holden
Auckland City Hospital
Auckland, New Zealand

Dr. 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 IRSA (Interventional Society of Australasia) and ARGANZ (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.

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 lithotripsy 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. 1). 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 core 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) imaging pre- and post-treatment (Fig. 3).

In the 95-patient combined DISRUPT PAD trials, the mean lesion length, percent stenosis, and total occlusions were 7.3 ± 3.7 cm, 77 ± 13%, 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.

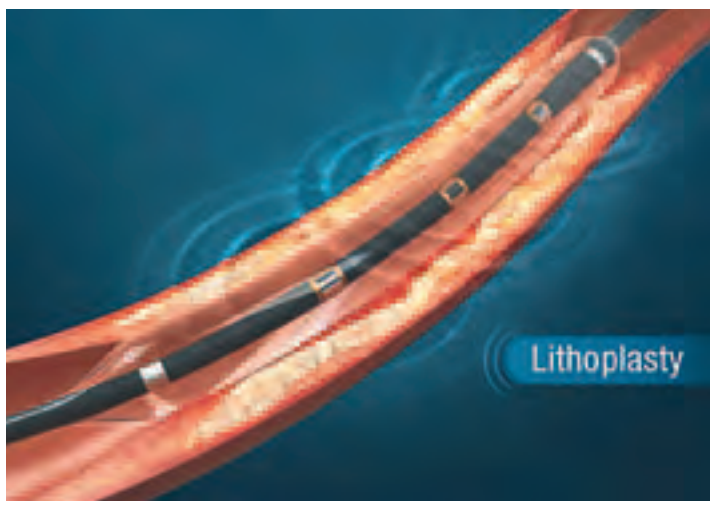

Fig. 1: The Shockwave Peripheral Lithoplasty Catheter System.

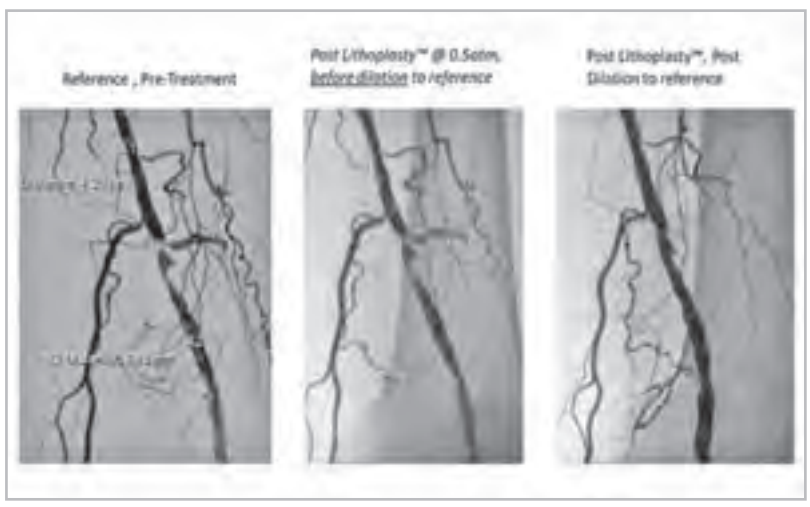

Fig. 2: "First-in-man" case with Shockwave Lithoplasty.
Fig. 2a: Procedural images.

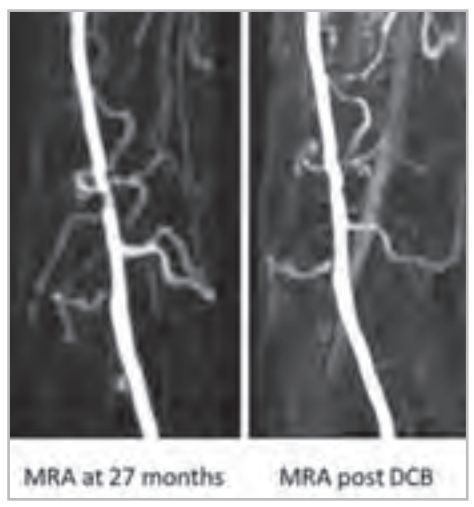

Fig. 2b: Post-procedural MRA images before and after target lesion revascularisation with drug-coated balloon angioplasty.

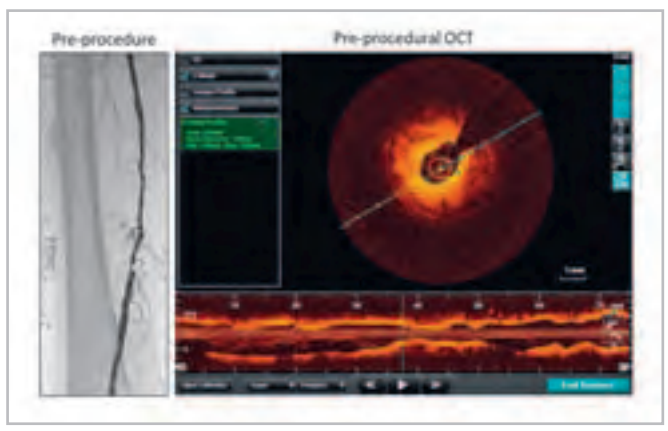

Fig. 3: Lithoplasty and OCT imaging.
Fig. 3a: Angiography and OCT pre-treatment.

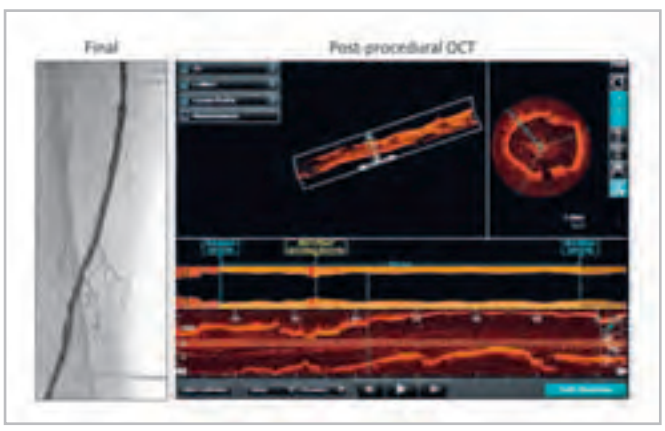

Fig. 3b: Angiography and OCT post-lithoplasty.

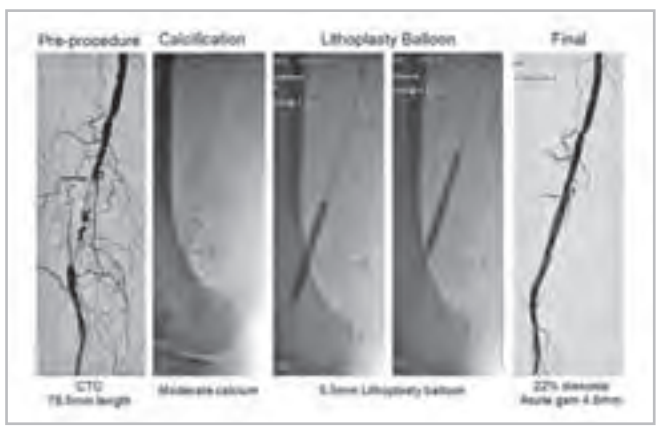

Fig. 4: Challenging, calcified near complete occlusion with an excellent result after Shockwave lithoplasty.

Congratulations to this year's CVIR award winners!

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 Cited Article in 2015* – Giovanni Mauri et al., "Real-Time US-CT/MRI Image Fusion for Guidance of Thermal Ablation of Liver Tumors Undetectable with US: Results in 295 Cases"
- 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 not 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 *Anaesthesia 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 anaesthesia providers (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 general anaesthesia versus sedation for the most common hepatobiliary procedures.

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 NAAP (non-anesthesiologists-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 debate 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 (somehow) predictable differences between countries and national regulations, showing how significantly many "local" factors (type and size of centres, the 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 (use 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-containment benefits of IR at 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 IRs 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.

Don't miss it !
Anaesthesia and interventional radiology: time to face reality?
Special Session
Sunday, September 11, 11:30-12:30
Room 116

Alessandra Vari
University of Rome, La Sapienza
Rome, Italy

Prof. Alessandra Vari is a senior consultant in anaesthesiology and perioperative medicine at the Policlinico Umberto I Hospital, of the Sapienza University of Rome (Italy), where she graduated in medicine in 1992. She is also an aggregate professor in emergency medicine at Sapienza's Postgraduate School of Orthoptics and Opthalmic Nursing. She is part of the faculty of the Master in Minimally Invasive Image-Guided Interventional Techniques that is held by the University of Zaragoza, and acts as a consultant to several NGOs in Africa and Central America, including Orbis International and Doctors without Borders. Prof. Alessandra Vari has been a member of CIRSE since 2013.

Survey results to be published soon in CVIR!

Today's Featured Papers

will be presented in the Free Paper sessions, taking place from 16:15-17:15 and from 17:30-18:30

16:15-17:15

FP 1407 Non-vascular IR: biopsies and drainages
Room 133
Free-hand vs. instrument-guided needle puncture using CT imaging and optical navigation in vitro
J. Kettenbach[1], G. Toporek[2], L. Kara[3], S. Weber[2];
[1]St. Pölten/AT, [2]Bern/CH, [3]Zurich/CH

FP 1408 Peripheral 1
Room 116
Lithoplasty for the treatment of calcified SFA lesions: the DISRUPT PAD study program
T.J. Brinton[1], U. Illindala[2], M. Brodmann[3], M. Werner[4], G. Tepe[5], A. Holden[6], D. Scheinert[7], G. Torsello[8], F. Wolf[4], T. Zeller[9];
[1]Stanford, CA/US, [2]Fremont, CA/US, [3]Graz/AT, [4]Vienna/AT, [5]Rosenheim/DE, [6]Auckland/NZ, [7]Leipzig/DE, [8]Münster/DE, [9]Bad Krozingen/DE

17:30-18:30

FP 1506 Bone and spine
Room 133
Percutaneous internal fixation to prevent impeding pathological hip fractures: a 1-year follow-up study
F. Deschamps[1], T. Carteret[2], L. Tselikas[1], B. Lapuyade[2], T. de Baère[1], F. Cornelis[2];
[1]Villejuif/FR, [2]Bordeaux/FR

FP 1507 Dialysis: what's new
Room 114
Pilot randomized trial of conventional balloon angioplasty vs. drug coated balloon angioplasty for the treatment of dysfunctioning autologous dialysis fistulae
W. Vander Mijnsbrugge[1], N. Verbeeck[2], D. Henroteaux[3], A. Laenen[1], S. Cornelissen[1], S. Heye[1], G. Maleux[1];
[1]Leuven/BE, [2]Luxembourg/LU, [3]Liège/BE

FP 1508 Oncology: liver
Room 113
New drug-eluting beads for sorafenib delivery in HCC embolization
L. Bédouet[1], L. Moine[2], E. Servais[1], A. Beilvert[1], F. Pascale[1], D. Labarre[2], A. Laurent[3];
[1]Jouy-en-Josas/FR, [2]Châtenay-Malabry/FR, [3]Paris/FR

FP 1509 TIPS, portal vein intervention and BRTO
Room 134
Three-dimensional image fusion guidance for transjugular intrahepatic portosystemic shunt in cirrhotic patients
H. Derbel, V. Tacher, A. Petit, M. Chiaradia, F. Ridouani, D. Azoulay, C. Duvoux, H. Kobeiter; Créteil/FR

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- Syringe presentation

■ **SYMPOSIUM**
Sunday 11th September 2016
13:00 – 14:00 | Room 117
Generating Clinical Evidence in Interventional Oncology
Moderator: Prof. K. Malagari
Speakers: Prof. T. De Baere, Dr. F.V. Gomes, Prof. P.L. Pereira, Prof. M.G.E.H. Lam

- **From bench top to clinical results: LifePearl in HCC**
- **Loco-regional 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**

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[1] Data on file. Ref. LPMCV-004. Microvention, Inc.
[2] Data on file. Ref. LPMCV-004. Microvention, Inc. Comparison with Terumo's previously commercialized product.
[3] Data on file. Ref. LPBTG-002, LPMCV-003, LPMCV-004. Microvention, Inc. Comparison with Terumo's previously commercialized product.
[4] Pereira PL, et al. An in-vitro evaluation of three types of drug-eluting microspheres loaded with Irinotecan. Anticancer Drugs. 2016 Jul 12.
[5] De Baere T, et al. An in vitro evaluation of four types of drug-eluting microspheres loaded with Doxorubicin. J Vasc Interv Radiol. 2016 Jul 8.
[6] Alberti C, et al. Hepatic arterial infusion of polyethylene glycol drug-eluting beads for primary and metastatic liver cancer therapy. Anticancer Res. 2016 Jul; 36(7):3515-21.

Meet CIREL – the CIRSE Registry for LifePearl Microspheres

Birgit Tkalec-Bekina, CIRSE Office

In its continuous efforts to push innovation and boost scientific understanding of medical procedures, CIRSE is proud to announce that it is about to launch the second observational study to be exclusively sponsored by the society. The CIRSE Registry for LifePearl Microspheres (CIREL) will prospectively observe, throughout Europe, the administration of irinotecan-eluting microspheres, a newly CE-approved transarterial chemoembolisation (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 adenocarcinoma 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, intensification and end-stage treatment. Secondary objectives of CIREL will be to assess the observed 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). CIRSE is proud to reveal the list of leading experts from the fields of interventional 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 treated with this device.

The Steering Committee agrees that this registry 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 continuously strives to support its evidence-based approach in every possible way.

CIRSE 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.

Members of the CIREL Steering Committee:

- Philippe L. Pereira *(Co-Chairperson, Interventional Radiology, Heilbronn/DE)*
- Julien Taieb *(Co-Chairperson, Oncology, Paris/FR)*
- Dirk Arnold *(Oncology, Lisboa/PT)*
- Patrick Chevallier *(Interventional Radiology, Nice/FR)*
- Thierry De Baère *(Interventional Radiology, Paris/FR)*
- Raúl García Marcos *(Interventional Radiology, Valencia/ES)*
- Fernando Gomez Muñoz *(Interventional Radiology, Barcelona/ES)*
- Thomas Helmberger *(Interventional Radiology, Munich/DE)*
- Geert Maleux *(Interventional Radiology, Leuven/BE)*
- Hassan Malik *(Surgery, Liverpool/UK)*
- José Martinez *(Interventional Radiology, Valencia/ES)*
- Olivier Pellerin *(Interventional Radiology, Paris/FR)*
- Simon Pernot *(Oncology, Paris/FR)*
- Hans Prenen *(Oncology, Leuven/BE)*
- Bruno Sangro *(Hepatology, Pamplona/ES)*
- Vladimir Borovicanin *(Non-voting member from Terumo Europe)*

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 IO?

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 showing additional treatment benefits 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 important 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 communication and collaboration between different disciplines a practical necessity in daily clinical practice. The importance of this good collaboration is also reflected in the composition of the CIREL 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.

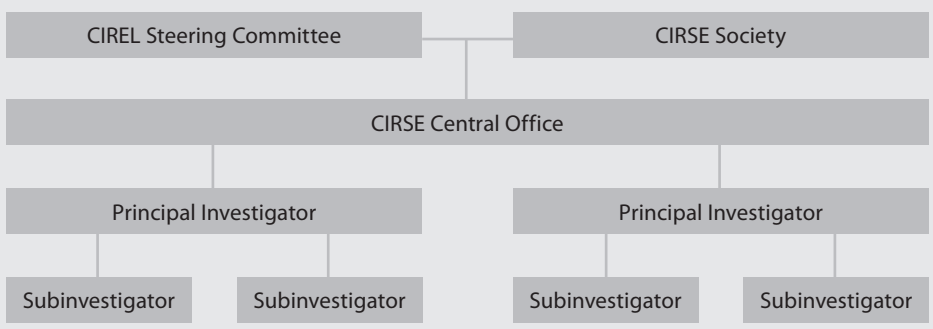
As a co-chair of the CIREL Steering Committee, but also as an active member of the OAS and the CIRSE Research Committee, why do you think the research agenda CIRSE is currently pursuing is so important for the society?

Prof. Philippe Pereira: I believe it is a great achievement that CIRSE can provide a platform that brings together these diverse medical specialties involved in interventional oncology 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.

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**

CIREL CIRSE Registry for LifePearl Microspheres

CIREL Governance Structure



IDEAS 2016

Stroke: the big enemy

Michael P. Jenkins

Don't miss it !
Arch and ascending thoracic aorta
Lecture Session
Sunday, September 11, 16:15-17:15
Auditorium 2

Michael P. Jenkins
Imperial College Healthcare NHS Trust, St Mary's Hospital London, UK

Mr. Michael Jenkins has been a Consultant Vascular Surgeon at St. Mary's Hospital since 2002 and is currently the Director of AAA screening in NW London and Director of the Major Trauma Centre at St. Mary's. He serves as President of the British Society of Endovascular Therapy and as a Council Member for the Vascular Society of Great Britain and Ireland. His interests include thoracic and aortic aneurysm, aortic dissection and endovascular surgery.

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 echo classification [1] is often cited as a more objective grading (from i, with normal or mild intimal thickening, to v, 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 4-12% [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 but 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 and PAU patients in addition to atherosclerotic aneurysms [8]. Numerous series have shown that the more proximal the intervention, the higher the stroke risk.

More recently, a number of industry partners have developed branched endovascular devices for use within the aortic arch. The experience is not sufficiently mature to comment on durability and, thus far, case selection and learning curve constraints have meant that the comparison with open and hybrid surgery is probably not fair [9].

What is clear is that, whether the arch is compressed with a surgical clamp or instrumented with a stiff wire, an embolic risk is inevitable and no amount of statin medication can eradicate that risk. From an endovascular embolic perspective, the two main risk periods have already been established: contrast injection and stent deployment, as seen in Fig 1. From a hypoperfusion perspective, some lessons are already clear from more distal TEVAR use, including that revascularisation of the left subclavian artery reduces the risk of both stroke and paralysis in patients at risk. Strategies to protect the brain from the inevitable potential insult are therefore necessary. Diffusion-weighted MRI technology has allowed the burden of "silent" microembolisation to be visualised, which has led to the belief that full-blown clinical strokes probably represent the tip of the iceberg of the cerebral insult. Neuroimaging studies are demonstrating a concerning rate of silent cerebral infarction associated with TEVAR, with reported rates ranging from 63-68% [10] and corroborated in our own unit data. Embolic "showers" and large volume lesions have been demonstrated in patients undergoing TEVAR (Fig. 2), with a sustained neurocognitive decline observed in those with cerebral injury. These "silent lesions" are, in fact, not so silent; they are proven predictors of a two- to four-fold [11] increased risk of future stroke and are associated with dementia [12], depression and neurocognitive decline [13].

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 thoracic stenting 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 benefit [14, 15].

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.

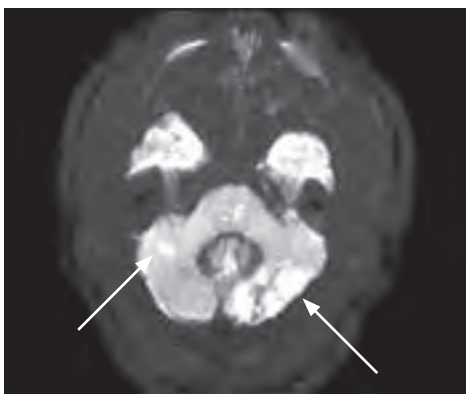


Fig. 2: Silent cerebral infarction. Post-operative MRI patient with TEVAR and no clinical stroke.

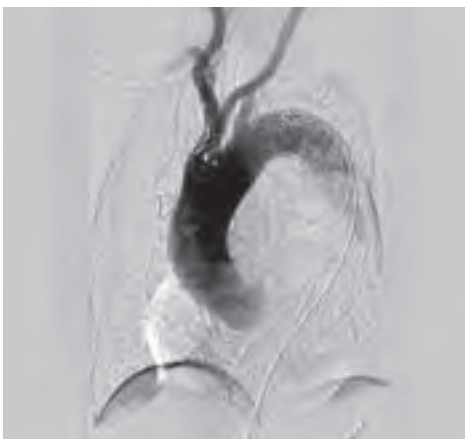


Fig. 4: Proximal and distal filters in-situ brachiocephalic and left common carotid. TEVAR deployed distal to the left subclavian artery.

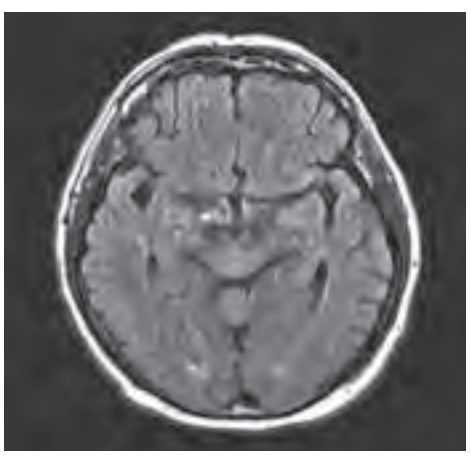


Fig. 5: Post-operative DW MRI in patient undergoing TEVAR with cerebral embolic protection.

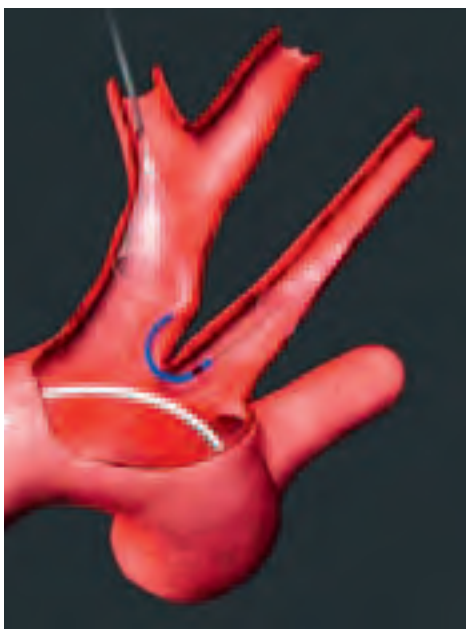


Fig. 3: Sentinel Cerebral Protection System. Claret Medical. Embolic protection filters deployed at origin of innominate and left common carotid.

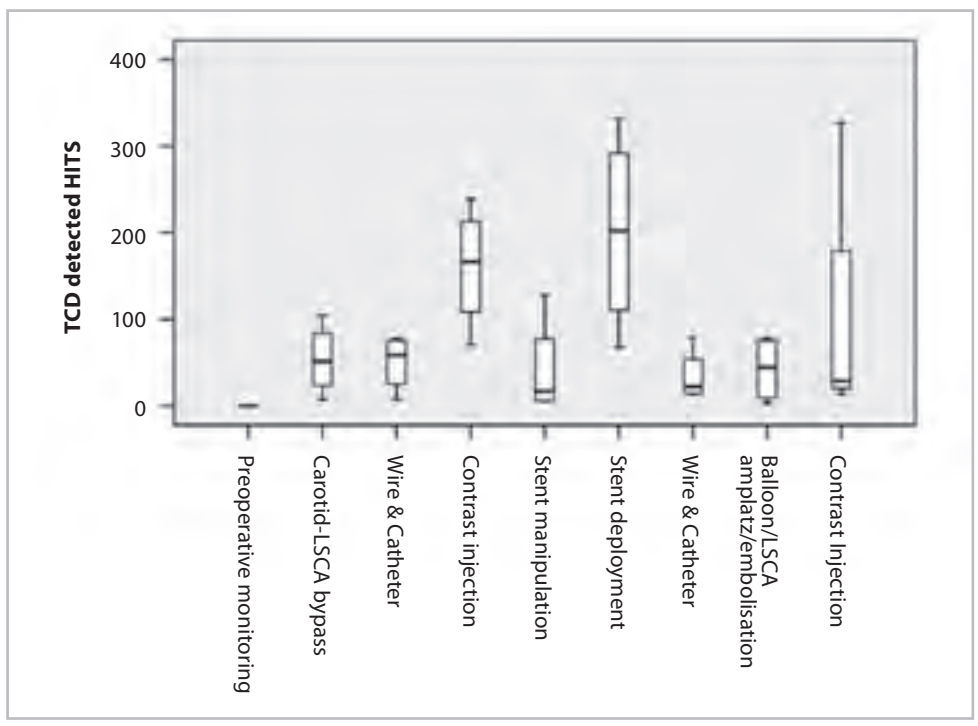


Fig. 1: TCD hits during phases of TEVAR.

References:
1. Montgomery DH, Ververis J, McGorisk G, Frohwein S, Martin RP, Taylor WR. Natural history of severe atheromatous disease of the thoracic aorta: A transesophageal echocardiographic study. J Am Coll Cardiol 1996; 27: 95-101
2. Sundt TM 3rd, Orszulak TA, Cook DJ, Schaff HV. Improving results of open arch replacement. Ann Thoracic Surg 2008; 88: 787-796; discussion 787-796
3. Tian DH, Wan B, Di Eusanio M, Yan TD. A systematic review and meta-analysis on the safety and efficacy of the frozen elephant trunk technique in aortic arch surgery. Ann Cardiothorac Surg 2013; 2: 581-591
4. Minakawa M, Fukuda I, Yamauchi S et al. Early and long-term outcome of total arch replacement using selective cerebral perfusion. Ann Thorac Surg 2010; 90: 72-77
5. Okada T, Shimamoto M, Yamazaki F et al. Insights of stroke in aortic arch surgery: Identification of significant risk factors and surgical implication. Gen Thorac Cardiovasc Surg 2012; 60: 268-274
6. Antoniou GA, Mireskandari M, Bicknell CD et al. Hybrid repair of the aortic arch in patients with extensive aortic disease. Eur J Vasc Endovasc Surg 2010; 40: 715-721
7. Moulakakis KG, Mylonas SN, Markatis F et al. A systematic review and meta-analysis of hybrid aortic arch replacement. Ann Cardiothoracic Surg 2013; 2: 247-260
8. Bosiers MJ, Donas KP, Mangialardi N, Torsello G, Riambau V, Criado FJ, Veith FJ, Ronchey S, Fazzini S, Lachat M. European Multicenter Registry for the Performance of the Chimney/Snorkel Technique in the treatment of Aortic Arch Pathologic Conditions. Ann Thorac Surg 2016, Jan 12 pii: S0003-4975(15)01838-X doi: 10 1016/j.athoracsur 2015 10 112
9. Haulon S, Greenberg RK, Spear R et al. Global experience with an inner branched arch endograft. J Thorac Cardiovasc Surg 2014; 148: 1709-1716
10. Kalhert P, Eggebrecht H, Janosi RA et al. Silent cerebral ischaemia after thoracic endovascular aortic repair: a neuroimaging study. Ann Thorac Surg 2014 Jul; 98(1): 53-8
11. Kobayashi S, Okada K, Koide H, Bokura H, Yamaguchi S. Subcortical silent brain infarction as a risk factor for clinical stroke. Stroke 1997; 28: 1932–1939
12. Vermeer SE, Prins ND, Den Heijer T et al. Silent brain infarcts and the risk of dementia and cognitive decline. N Engl J Med 2003; 348: 1215–1222
13. Schmidt WP, Roesler A, Kretzschmark K et al. Functional and cognitive consequences of silent stroke discovered using brain magnetic resonance imaging in the elderly population. J Am Geriatr Soc 2004 Jul; 52(7): 1045-50.
14. MISTRAL–C. Randomised clinical trial. Clinical trials govt. identifier NTR4236, Netherlands; MD van N. Meigham
15. CLEAN-TAVI. Claret Embolic Protection and TAVI. Clinical trials govt. identifier NCT01833052, University of Leipzig; Prof A Linke

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IDEAS 2016

Acute TEVAR for ruptured aneurysm and dissection

Ajay Chavan

Don't miss it !
Aortic emergencies
Hot Topic Symposium
Sunday, September 11, 15:00-16:00
Auditorium 1

Ajay Chavan
Klinikum Oldenburg
Oldenburg, Germany

After completing his medical degree and radiology training in India, Prof. Ajay Chavan migrated to Germany and commenced his advanced training in radiology at the Hannover Medical School in 1991, where he was later made Professor in 2008. He has done extensive clinical and research work in the fields of chemoembolisation of hepatic tumours, renal angioplasty, interventional treatment of vascular malformations as well as the minimal invasive therapy of aortic aneurysms and aortic dissections. He has been Director of the Institute for Diagnostic and Interventional Radiology at Klinikum Oldenburg, European Medical School since 2004.

Ruptured aneurysms and dissections involving the ascending aorta or the aortic arch are still the domain of open surgery [1-3]. 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. Clinically, rupture is characterised 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-bronchial 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 quick and 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 admission and death was 10.5 hours in the report by Lloyd and colleagues [11], it appears 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 and 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 aneurysm 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 early institution of CSF-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 adequate 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 vigilance 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 rTAA, 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 opposed to this, in ruptured type B dissections, the primary aim of entry closure is to cut off direct blood flow to the ruptured false lumen and thus achieve haemodynamic stability, ultimately preventing mortality and major cardiac, cerebral, visceral and renal complications. Trimarchi and colleagues consider rTEVAR to be a suitable bridging procedure to elective open repair at a later stage [17]. This however is a topic of debate in the "PETTICOAT era" with proximal entry closure being followed by bare metal stenting of the distal true lumen to initiate complete aortic remodelling [18, 19]. In aortic dissection, certain procedural details are of the essence. Care should be taken to identify the true lumen correctly and ensure that the endograft is placed over its entire length in the true lumen. Excessive 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 endoluminal repair of rTAA appeared in the mid-nineties [4], TEVAR has been used not only for elective repair, but also for emergency repair of rTAA [5, 20].

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, 21]. 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 carotid-subclavian or celiac artery 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 1-5% [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 conversion to open surgical repair may become necessary either in the acute or in the chronic phase. Furthermore, persistent thoraco-abdominal malperfusion may require further measures downstream to optimise outcome [10].

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 appropriate catheters, guidewires, percutaneous suture 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 interventionists, surgeons, anaesthetists, radiology technicians as well as OR staff [17, 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.

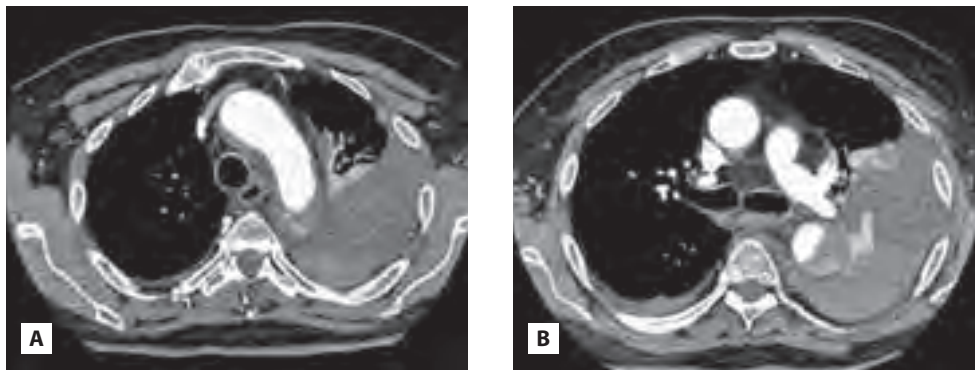

Fig. 1: Acute type B dissection with rupture. Note the haemorrhagic pleural effusion as denoted by the hyperdense areas in the dependent part of the pleural fluid.

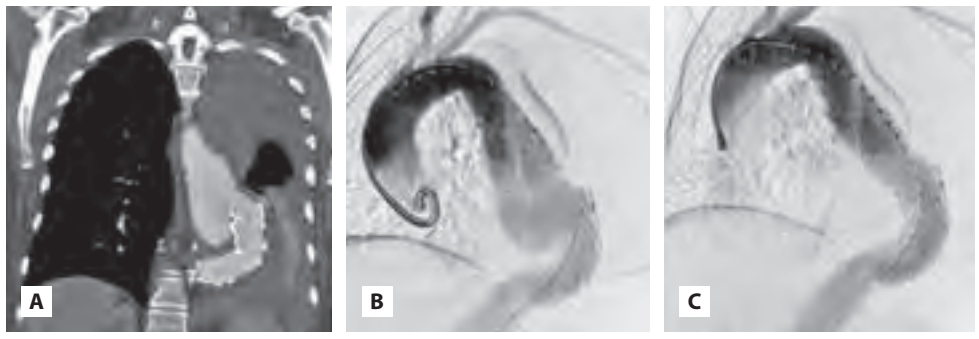

Fig. 2: Ruptured TAA proximal to stent graft implanted 5 years ago; associated haemothorax. (a) Coronal CT reconstruction; note the haemorrhagic pleural effusion. (b) DSA prior to endoluminal treatment. (c) Control DSA after implanting a stent graft proximally and fixing the lower end of the old endograft distally with the help of a bare metal stent which covers the origin of the celiac trunk.

References:
1. Borst HG, Heinemann MK, Stone CD (eds.) (1996). Surgical treatment of aortic dissection. Churchill Livingstone, New York
2. Karck M, Chavan A, Hagl C, Friedrich H, Galanski M, Haverich A. The 'Frozen Elephant Trunk Technique': A New Treatment for Thoracic Aortic Aneurysms. J Thorac Cardiovasc Surg 2003; 125: 1550-3
3. Chavan A, Karck M, Hagl C, Winterhalter M, Baus S, Galanski M, Haverich A. Hybrid Endograft for One-Step Treatment of Multisegment Disease of the Thoracic Aorta. J Vasc Interv Radiol 2005; 16(6): 823-829
4. Semba CP , Kato N, Kee ST, Lee GK, Mitchell RS, Miller DC, Dake MD. Acute rupture of the descending thoracic aorta: repair with use of endovascular stent-grafts. J Vasc Interv Radiol 1997; May-Jun; 8(3): 337-42
5. Patel HJ, Williams Dm, Upchurch GR, Dasika NL, Deeb GM. A comparative analysis of open and endovascular repair for the descending thoracic aorta, J Vasc Surg 2009; 50: 1265-1270
6. Dake MD, Noriyuki Kato, Mitchell RS, et al. Endovascular Stent-Graft Placement for the Treatment of Acute Aortic Dissection. N Engl J Med 1999; 340: 1546-52
7. Morgan R, Loosemore T, Belli AM. Endovascular Repair of Contained Rupture of the Thoracic Aorta. Cardiovasc Intervent Radiol 2002; 25: 291-294
8. Hausegger KA, Tiesenhausen K, Schedelbauer P et al. Treatment of acute aortic type B dissection with stent grafts. Cardiovasc Intervent Radiol 2001; 24: 306-312
9. Jonker FH, Verhagen HJ, Lin PH, Heijmen RH, Trimarchi S, Lee WA, Moll FL, Atamneh H, Rampoldi V, Muhs BE. Open surgery versus endovascular repair of ruptured thoracic aortic aneurysms. J Vasc Surg 2011 May; 53(5):1210-6
10. Chavan A. (Ed.) (2016): Vaskuläre Interventionen, Georg Thieme Verlag, Stuttgart, New York.
11. Lloyd GM, Brown MJ, Norwood MGA. Feasibility of preoperative computed tomography in patients with ruptured AAA: a time to death study in patients without operation. J Vasc Surg 2004; 39:788-791
12. Jonker FHW, Verhagen HJM, Lin PH, Heijmen RH, Trimarchi S, Lee WA, Moll FL, Athamneh H, Muhs BE. Outcomes of endovascular repair of ruptured descending thoracic aortic aneurysms. Circulation. 2010; 121: 2718–2723.
13. van der Vliet JA, van Aalst DL, Schultze Kool LJ, Wever JJ, Blankensteijn JD. Hypotensive hemostasis (permissive hypotension) for ruptured abdominal aortic aneurysm: are we really in control? Vascular 2007 Jul-Aug; 15 (4): 197-200
14. Veith FJ, Ohki T. Endovascular approaches to ruptured infrarenal aorto-iliac aneurysms. J Cardiovasc Surg (Torino) 2002 Jun; 43(3): 369-78
15. Alsac JM, Desgranges P, Kobeiter H, Becquemin JP. Emergency endovascular repair for ruptured abdominal aortic aneurysms: feasibility and compariso of early results with conventional open repair. Eur J Vasc Endovasc Surg 2005 Dec; 30(6): 632-9
16. Quiroga E, Tran NM, Hatsukami T, Starnes BW. Hypothermia is associated with increased mortality in patients undergoing repair of ruptured abdominal aortic aneurysm. J Endovasc Ther 2010; 17: 434-438
17. Santi Trimarchi, Sara Segreti, Viviana Grassi, Chiara Lomazzi, Carlo de Vincentiis, Vincenzo Rampoldi. Emergent treatment of aortic rupture in acute type B dissection. Ann Cardiothorac Surg 2014; 3(3): 319-324
18. Nienaber CA, Kische S, Zeller T et al. Provisional Extension to Induce Complete Attachment After Stent-Graft Placement in Type B Aortic Dissection: The PETTICOAT Concept. J Endovasc Ther 2006; 13: 738-746
19. Melissano G, Bertoglio L, Rinaldi E et al. Volume changes in aortic true and false lumen after the "PETTICOAT" procedure for type B aortic dissection. J Vasc Surg 2012; 55: 641-51
20. Jonker FHW, Giacovelli JK, Muhs BE, Sosa JA, Indes JE. Trends and outcomes of endovascular and open treatment for traumatic aortic injury. J Vasc Surg 2010; 51:565-571
21. Jonker FH, Trimarchi S, Verhagen HJ, Moll FL, Sumpio BE, Muhs BE. Meta-analysis of open versus endovascular repair for ruptured descending thoracic aortic aneurysm. J Vasc Surg 2010; 51: 1026–1032; 1032.e1–1032.e2
22. Coselli JS, Gopaldas RR. Ruptured Thoracic Aneurysms. To Stent or Not to Stent? Circulation 2010; 121: 2705-2707
23. Willigendael EM, Cuypers PW, Teijink JAW, van Sambeek MRHM. Systematic approach to ruptured abdominal aortic aneurysm in the endovascular era: Intention-to-treat eEVAR protocol. J Cardiovasc Surg 2012; 53: 77-82

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F.G. Irani (Singapore/SG)
A. Krajina (Hradec Králové/CZ)
P. Minko (Homburg/DE)
O. Pellerin (Paris/FR)
P. Reimer (Karlsruhe/DE)
M. Szczerbo-Trojanowska (Lublin/PL)
S.O. Trerotola (Philadelphia, PA/US)

Women conquering IR – Spain shows how it's done

Petra Mann, CIRSE Office

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 through the media, mainly the internet. Nevertheless 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 interdisciplinary 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 is not limited to Spain – it 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 IR units. 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 relatively 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 into 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 Spain undoubtedly started in Barcelona where, thanks to enthusiastic physicians like Dr. Rius and Dr. Montañà, 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. I personally 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 OR 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 effective 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 non-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 technology 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?

Dr. Elena Escalante (back row, 4th from left) with her team nurses, from Bellvitge hospital, H. de Llobregat

Dr. Mercedes Perez (middle) with Dr. Iratxe Diez and Dr. Carla Gonzalez at the Hospital Vall d'Hebron, Barcelona

Dr. Marta Burrel and Dr. Marta Barrufet with their colleagues Dr. Patrícia Bermudez and Dr. Maria Isabel Real from the Hospital Clínic Barcelona

Robotic interventions for the visceral artery?

Dimitrij Kuhelj

Don't miss it !
Robotic interventions: which patients; is it worth it?
Special Session
Monday, September 12, 08:30-09:30
Room 116

Dimitrij Kuhelj
Clinical Radiology Institute, UMC Ljubljana, Slovenia

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 fractured bare Cheatham-Platinum stent following stenting for aortic coarctation, which was featured in Cardiology in the Young.

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 and the rate of peri-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 manoeuverability 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 dilatations and stenting, grafting, embolisation, chemoembolisation and coiling to chimneys, snorkels, 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 angiosuite [4].

Catheter stabilisation with an RCS offers obvious advantages in difficult anatomies. 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 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 healthy specimens, and the results 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 83% [6]. RCSs offer centerline navigation, producing minimal impact to the vessel wall and reducing the possibility of vessel damage, distal embolisation, 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 route 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, trans-femoral 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 could possibly reduce the learning time 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 angiosuite. 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 delivery 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 aneurysm. 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 including 15 patients and 37 vessel cannulations, during branched and fenestrated stent graft implantations, not 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 offers no 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-tissue measurements, 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, 6 Fr. is 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 disposable 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 angiosuites. 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, 6]. 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 disposable catheters.

References:
1. Bargar WL, Bauer A, Borner M.. Primary and revision total hip replacement using the Robodoc system. Clin Orthop Relat Res 1998; (354): 82-91
2. Marohn MR, Hanly EJ.. Twenty-first century surgery using twenty-first century technology: surgical robotics. Curr Surg 2004; 61: 466-73
3. Rockall TA. The da Vinci telerobotic surgical system. In: Ballantyne GH, Marescaux J, Giulianotti PC. eds. Primer of robotic & telerobotic surgery. Philadelphia: Lippincott Williams & Wilkins, 2004: 57-60
4. Cochennec F, Kobeiter H, Gohel M, et al. Feasibility and safety of renal and visceral target vessel cannulation using robotically steerable catheters during complex endovascular aortic procedures. J Endovasc Ther 2015; 22: 187-93
5. Duran C, Lumsden AB, Bismuth J. A randomized control animal trial demonstrating feasibility and safety of the Magellan endovascular robotic system. Ann Vasc Surg 2014; 28; 470-8
6. Riga CV, Bicknell CD, Hamady M, et al. Tortuous iliac systems--a significant burden to conventional cannulation in the visceral segment: is there a role for robotic catheter technology? J Vasc Interv Radiol 2012; 23: 1369-75
7. Riga CV, Bicknell CD, Hamady MS, et al. Robotically-steerable catheters and their role in the visceral artery segment. J Cardiovasc Surg 2011; 52: 352-62
8. Raghu C, Louvard Y. Transradial approach for percutaneous transluminal angioplasty and stenting in the treatment of chronic mesenteric ischemia. Catheter Cardiovasc Interv 2004; 61: 450-4
9. Kuhelj D, Zdešar U, Jevtič V, et al. The risk for deterministic effects in patients during endovascular aortic stentgraft implantation. Br J Radiol 2010; 83: 958-63
10. de Ruiter QMB, Moll FL, van Herwaarden JA. Current state in tracking and robotic navigation. J Vasc Surg 2015; 61: 256-64
11. Bismuth J, Duran C, Stankovic M, et al. A first-in-man study of the role of the flexible robotics in overcoming navigation challenges in the ileofemoral arteries. J Vasc Surg 2013 Feb; 57(2 suppl): 14S-19S
12. Antoniu GA, Riga CV, Mayer EK, et al. Clinical applications of robotic technology in vascular and endovascular surgery. J Vasc Surg 2011; 53: 493-9

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10 Reasons for IESIR in Italy

Franco Orsi, Fabrizio Fanelli and Francesco Florio, IESIR

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.

We are proud to belong to such a strong network of clinical experts!

IESIR members celebrate at CIRSE 2015

Posters on Stage

Selected posters and their presenting authors will take centre stage in these sessions. The posters will be displayed and navigated on terminals which are specifically designed for poster discussions in small groups. Come and meet authors of top-rated posters in an informal and open setting, join in lively debates and ask questions!

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Posters on Stage – Embolisation

Moderators: C.A. Binkert (Winterthur/CH), F. Wolf (Vienna/AT)

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P-456 Endovenous radiofrequency-powered thermal ablation of the marginal venous system
W. Uller (Regensburg/DE)

P-93 The role of pre-operative bilateral internal iliac artery balloon occlusion in patients with abnormally invasive placenta (accreta, increta, percreta)
I.S. Al Salmi (Muscat/OM)

P-308 First human experience with directly imageable iodinated embolization microbeads
E. Levy (Bethesda, MD/US)

P-300 Preoperative devascularization of juvenile nasopharyngeal angiofibromas: direct percutaneous tumoral injection with cyanoacrylate glue in conjunction with particulate endovascular embolization
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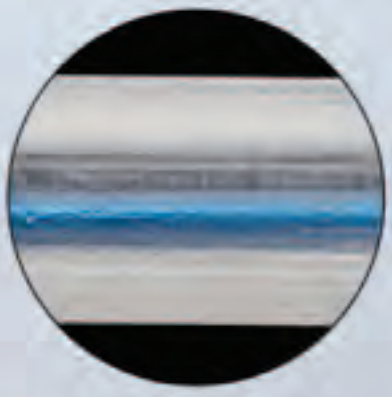

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Visit the Radiation Protection Pavilion

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

11:00 – 11:15	**There is more than meets the eye** (MDT)	*D. Janssen (Hilvarenbeek/NL)*
11:15 – 11:30	**Last Image Hold (LIH) to reduce patient and occupational exposure: control of interventional procedures without radiographs or DSA series**	*R.W. Loose (Nuremberg/DE)*
12:30 – 12:45	**Improving patient follow-up in interventional radiology** (GE HEALTHCARE)	*F. Gardavaud (Paris/FR)*
12:45 – 13:00	**DICOM tools help to manage patient radiation exposure** (Mini refresher course series)	*A. Trianni (Udine/IT)*
13:00 – 13:15	**Through the looking glass: Improving radiation safety in the interventional suite through room design, workflow and protection verification** (AMRAY)	*P. Gilligan (Dublin/IE)*
14:00 – 14:15	**Managing radiation metrics with Radimetrics** (BAYER)	*H. Haubenreisser (Mannheim/DE)*
14:15 – 14:30	**Pre-procedural patient-specific simulation of endovascular interventions reduces patient and personnel radiation exposure** (3D SYSTEMS)	*G. Bartal (Kfar Saba/IL)*
16:00 – 16:15	**Radiation-related illnesses in the cath lab** (RADPAD)	*E. Radtke (Kansas City, KS/US)*

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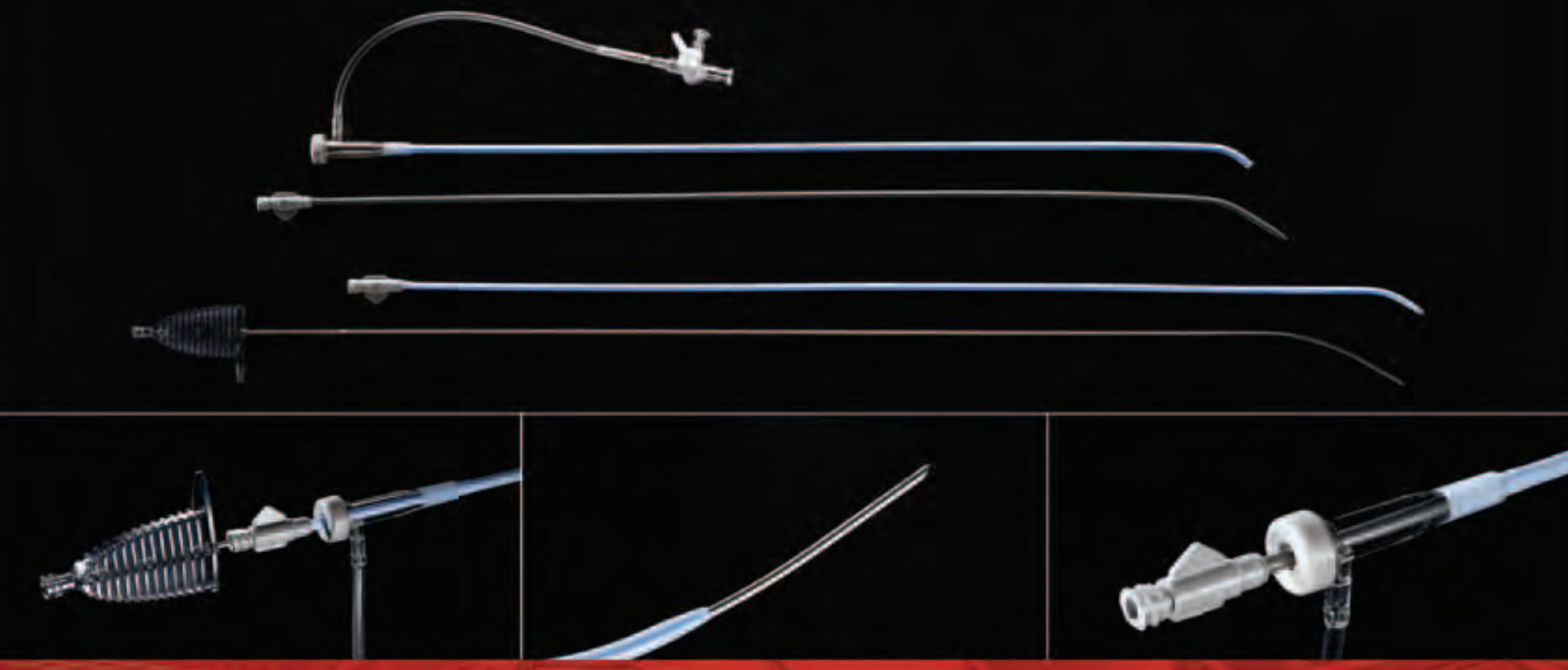

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TIPS Breakfast Symposium

Monday, September 12, 2016, 7:40–8:20 am
Room 114, CIRSE 2016, Barcelona

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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.
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