

## Andreas Gruentzig Lecture

CIRSE's Andreas Gruentzig Lecture has been given by some of Interventional Radiology's most outstanding personalities. This year's lecture will be given by Riccardo Lencioni who will speak about Interventional Oncology.

We invite all of you to attend the Lecture today after the CIRSE meets Brazil Session at 14:15 in Auditorium 1.



**Riccardo Lencioni**  
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Department of Liver Transplantation, Hepatology, and Infectious Diseases  
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## Interventional Oncology

During the past four years, the use of image-guided interventions in cancer treatment has experienced unparalleled growth. Several innovative techniques and devices for direct tumour ablation and transarterial therapy have been introduced, sophisticated imaging methods improving tumour targeting and treatment monitoring have been devised and a number of trials have been successfully completed in different clinical settings. Interventional oncology procedures are increasingly used as an alternate or complementary treatment for a variety of solid cancers under the common denominator of effective local tumour control without the morbidity of open surgery or the toxicity of chemotherapy and radiation.

Image-guided percutaneous ablation is currently accepted as the best therapeutic choice for nonsurgical patients with early-stage hepatocellular carcinoma (HCC) (1-3). Over the past two decades, several methods for chemical ablation or thermal tumour destruction through localised heating or freezing have been developed and clinically validated in HCC treatment. Transarterial chemoembolization has become the accepted standard of care for patients with multinodular disease confined to the liver (4). The recent introduction of drug-eluting beads has been instrumental in improving response rate and tolerability of the procedure and has opened new prospects for combination strategies including chemoembolization and image-guided ablation or chemoembolization and molecular targeted therapies (5,6).

The use of radiofrequency ablation to treat unresectable or medically inoperable patients with liver-dominant hepatic metastatic disease, especially from colorectal cancer, was proposed 10 years ago (7). Since then, several investigators have refined techniques and approaches, and 8 cohort studies have reported long-term survival outcomes of RFA-treated patients (8). Recently, the interim results of a randomised controlled trial comparing chemotherapy vs. chemotherapy plus radiofrequency ablation

CIRSE 2009 - Lisbon  
Sunday, September 20, 2009

have been presented at the annual meeting of the American Society of Clinical Oncology, providing unquestionable evidence of clinical benefit (9).

Treatment of kidney cancer has become one of the most effective indications for percutaneous ablation. The technique has been optimised and reported results seem to compare very well with those of surgical management, both in term of clinical outcomes and treatment-related costs (10,11). The reported clinical outcomes of lung ablation have exceeded even the best expectations, resulting in impressive rates of complete cure and offering a viable treatment option for the many patients who cannot have standard surgery due to reduced pulmonary function or co-morbidities (12). Interventional techniques are gaining increasing acceptance in the management of painful bone metastases. The impact on quality of life of percutaneous procedures has been well documented, and technical refinements have allowed even critical locations to be treated successfully (13).

Much has still to be done, however. A comprehensive, multi-pronged approach to the discipline of interventional oncology with a robust portfolio of clinical, basic and translational research is required to achieve significant discovery and clinical implementation of novel and effective therapeutic approaches to benefit patients with cancer (14). A central conviction underpinning the research strategy is that the core approaches to cancer treatment, namely systemic drug administration and surgery, can and will be supplemented by minimally-invasive treatments for locally-dominant disease to increase response, achieve better side-effect profile, reduce cost and potentially improve survival.

An integrated, multidisciplinary approach is instrumental for interventional oncology to be accepted by referring physicians, governing bodies and patients as another defined arena

similar and coequal to radiation oncology, surgical oncology and medical oncology in the field of clinical cancer care. Such an approach will eventually enable interventional oncology to have a pivotal role in the therapeutic management of cancer. The incorporation of interventional radiology procedures into clinical practice has always resulted in an important change in patient care. Many procedures initially developed as "therapeutic alternatives" have now become first choice treatments (15). Interventional radiology societies should take a leadership position in organising a basic and clinical research agenda for interventional oncology and in implementing a structured educational programme to meet the needs of interventionalists who wish to acquire knowledge and skills in this emerging field. CIRSE is highly committed to interventional oncology supporting clinical trials and research development and carrying out registries and studies in collaboration with other professional societies or on its own.

The CIRSE Foundation is a permanent source of funds in order to provide training programmes in the field of minimally invasive, image guided procedures. It has also recently started a very successful continuing educational programme with a focus on oncology, including a number of local courses within the framework of the European School of Interventional Radiology and the first European Conference on Interventional Oncology held in spring 2008. Interventional oncology will become the fourth pillar of cancer care, along with medical oncology, surgical oncology and radiation oncology. However, the more oncologic interventions will be recognised, the more they will become a subject of turf issues. As other specialties continue to move toward minimally invasive approaches, a very competitive environment has already formed. Total patient care with direct referral will be the key to the long-term survival of oncologic interventions inside Interventional Radiology and within the house of Radiology (15).

### Don't miss it!

**Interventional Oncology**  
**Andreas Gruentzig Lecture**  
Sunday, September 20, 14:15-16:00  
Auditorium 1

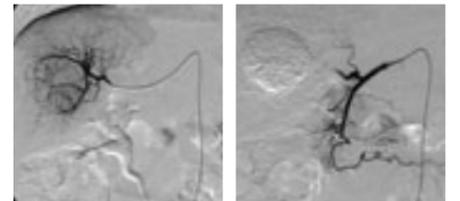


Fig. 1: Hepatocellular carcinoma before (a) and after transarterial chemoembolization (b).

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Cryotherapy achieves tumour ablation with lethal freezing temperatures ranging from -20 to -40°C. Although this technique has been known for decades, its indications in urologic oncology remained limited. Indeed, the first generation of cryodevices was using large nitrogen-driven probes which limited their use to a surgical approach. Since the development of new generation gas-driven cryosystems, miniaturisation of the cryoprobes was possible, thus allowing their percutaneous use in CT and MR tunnels. In urologic oncology, cryoablation allows treatment of kidney, adrenal and prostate cancers for poor surgical candidates.

#### Mechanism

Gas driven cryomachines rely on the physical relationship between temperature and pressure (Joule-Thomson effect): at atmospheric pressure, most gases are cooled by expansion. Only small gases such as helium are warmed by expansion due to reduced collisions (negative Joule-Thompson effect).

Based on this phenomenon, high pressure argon is used for freezing and helium is used for active thawing. Active thawing accelerates the treatment process, allows for repositioning of the probe and provides additional safety by enabling rapid stopping of the ice ball formation. Tumour destruction is achieved by combining two major mechanisms: immediate cellular death caused by intracellular ice crystals that break cell membranes and delayed ischemia as intravascular ice crystals stop the blood flow in small vessel (less than 3-4 mm diameter).

During the first freezing cycle ice crystals are mainly extra-cellular. During slow thawing water re-crystallises and diffuses into the intracellular compartment due to the osmotic effect. After a second freezing cycle, intracellular crystal formation achieves membrane rupture and cell death. For this reason, a complete freeze-thaw-freeze cycle is needed to achieve certain cell death. Compared to radiofrequency which does not discriminate the ablated tissues, cryoablation offers a relative protection of the poorly hydrated tissues such as collagen.

#### Equipment

Last generation gas-driven cryoprobes are 17 gauge mini-invasive needles that can be used in CT and MR tunnels. These two imaging modalities allow a precise monitoring of the ice ball with multiplanar control to achieve optimal tumoural covering. Up to 25 cryoprobes can be activated simultaneously. Thus several probes can be combined to treat a large single tumour or to treat multiple small tumours simultaneously. Different cryoprobes are available, producing different sizes and shapes of ice balls.

## New perspectives in urologic cryoablation

To prevent thermal damage to adjacent structures, thermal protection techniques are often used; dedicated thermo-sensors can be connected to the cryomachine to continuously monitor the temperature of the vulnerable organ. Also, organ displacement and insulation can be achieved with targeted CO2 dissection between the tumour and the vulnerable structure. Hydrodissection, which is a commonly used thermal protection technique in radiofrequency ablation, is not suitable with cryoablation.

#### Indications and Technique

In urologic oncology, cryoablation has been used to treat kidney, adrenal and prostate tumours. The indications and the planning of renal cryoablation procedures are very similar to those of radiofrequency ablation. This technique is a curative alternative for tumours <4 cm in poor or non-surgical candidates. Best indications include risky partial nephrectomy, contraindication of general anaesthesia, renal dysfunction, solitary kidney, bilateral tumours, Von Hippel Lindau disease.

Absolute contra-indications include acute infection and uncontrollable hemostasis problems. Tumours >4 cm or close contact with vulnerable structures are relative contra-indications. However, most of these cases can be solved with good knowledge of thermal protection techniques.

Compared to radiofrequency ablation, renal cryoablation offers several advantages. The precise visual control of the ice ball with CT and MRI allows optimal tumoural covering and better control of adjacent vulnerable structures. Peri- and post-procedural pain is reduced. The risk of thermal injury to the pyelic structures is reduced, as collagen tissue underlying the urothelium is less vulnerable to cold temperatures. This last point is a major advantage for the treatment of renal tumours in central location.

Adrenal cryoablation can be considered as an alternative technique in poor surgical candidates suffering either from benign hormonally active tumours or adrenal metastases of slow growing cancers. In those cases, cryoablation is performed with a curative intent. Less often, adrenal cryoablation can be considered in a palliative intent for patients suffering from painful adrenal metastases.

The precise visual control of the ice ball allows optimal tumoural covering and reduces the risk of thermal damage to adjacent vulnerable organs (particularly bowel and pancreas). Similar to adrenal radiofrequency ablation, cryoablation of adrenal tumours is associated with a significant risk of hypertensive crisis due to sudden release of active hormones. For this reason, most adrenal cryoablation procedures are performed under general anaesthesia with a well trained anaesthesiology team.

Cryoablation of prostate cancer is still under evaluation as an alternative treatment for non-surgical local prostate cancers. Cryoablation is generally performed by urologists under endorectal ultrasound guidance. However, the visualisation of the tumour is poor and control of the ice ball incomplete. The development of MR compatible cryomachines offers new perspectives in the treatment of prostate cancer. Better visualisation of the tumour with MR combined with multiplanar monitoring of the ice ball could improve the treatment and the safety of prostate cryoablation and maybe pave the way for focal prostate cancer therapy in selected cases.

#### Conclusion

In the field of urologic oncology, cryoablation is becoming a major alternative technique for poor surgical candidates suffering from renal, adrenal or prostate cancers. Renal cryoablation is a very promising curative technique for tumours up to 4 cm. Compared to radiofrequency ablation, the major advantages of cryoablation are the precise visual monitoring of the ice ball extension allowing better control of the tumoural covering and decreased risk of thermal injury to adjacent organs. Moreover, the better preservation of collagen tissue with cold temperatures reduces the risk of thermal damage to the pyelic structures when ablating central tumours. However, the cost of cryoablation is significantly higher and radiofrequency ablation is still used for many indications.

Adrenal cryoablation is also a promising technique in poor surgical patients suffering from slow growing or painful adrenal tumours. Cryoablation of prostate cancer performed under ultrasound guidance is still under evaluation. The development of MR compatible cryo-devices offers new opportunities. MR-guidance may improve the potential of prostate cryoablation, as it combines visualisation of the tumour and multiplanar control of the ice ball. A good understanding of the cryobiology principles, respect of clinical indications and perfect knowledge of the techniques (particularly thermal protection techniques) are the keys for successful treatment.

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### Don't miss it!

Kidney radiofrequency- and cryoablation  
Special Session  
Sunday, September 20, 10:00-11:00  
Auditorium 2



The authors wearing ear protection for interventional MR. From left to right: Buy, Gangi and Lang

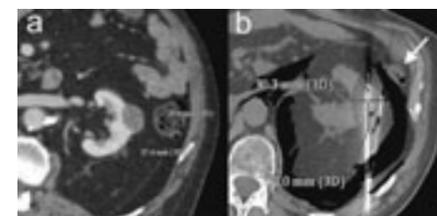


Fig.1: Left renal cancer close to the colon (a). Cryoprobes are inserted into the tumour via a posterior approach and pararenal CO2 insufflation is performed to achieve thermal protection of the colon (b, arrow). Note the sharp visible margins of the ice ball covering the tumour.

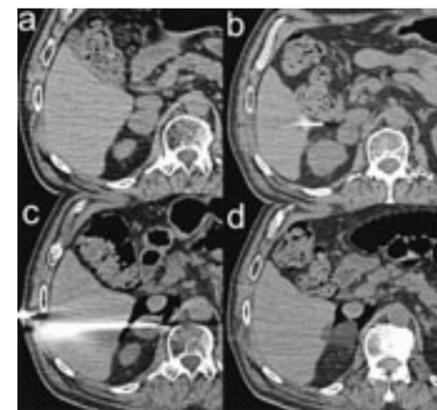


Fig.2: Right slow growing adrenal metastasis in contact with the vena cava (a). Cryoprobes are inserted into the tumour via a lateral transhepatic approach and retroperitoneal CO2 dissection is performed to protect the vena cava and reduce the "cold sink effect" (b and c). Complete tumoural covering by the ice ball with slight extension to the adjacent liver parenchyma (d).

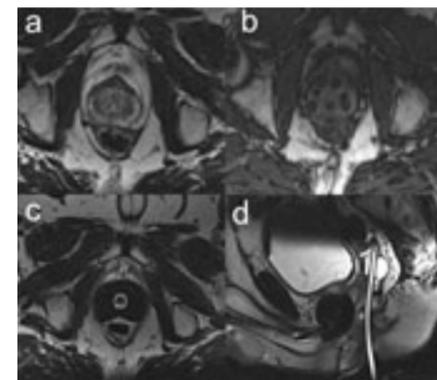


Fig.3: MR-guided cryoablation of prostate cancer in a patient contraindicated for surgery and radiotherapy due to prior history of rectal cancer (a). Six cryoprobes and a pararectal thermosensor are inserted via a perineal approach (b). Complete covering of the prostate by the ice ball (c and d); note the warming catheters to protect the ureter and the rectum.

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School of Medicine  
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Robert Morgan  
Consultant Vascular and Interventional Radiologist  
St. George's Hospital  
London, UK

With more experience of the technique, it is becoming increasingly evident that more and more patients with pathology of the thoracic aorta can be treated by endovascular techniques. The published evidence for many indications shows that thoracic aortic endografting has clear advantages in terms of reduced mortality and morbidity and shorter hospital stay compared with open surgery.

These favourable outcomes have inspired interventionalists to try these endovascular methods in patients with more complex pathology, such as lesions involving the aortic arch and the thoracoabdominal segment. The indications for thoracic endografting have been expanded in the last few years (Fig.1). The following account briefly describes the management approach for patients with descending thoracic aneurysms, aortic arch aneurysms, thoracoabdominal aneurysms, complicated aortic dissection and traumatic aortic injury.

#### THORACIC ANEURYSMS

##### Descending thoracic aneurysms

Inclusion criteria for endografting are suitable landing zones of normal aorta (42mm diameter or less, at least 20mm long) proximal and distal to the aneurysm, and adequate access arteries (iliac and femoral arteries) of at least 7mm in diameter. Endografts can be inserted under regional, local or general anaesthesia, so that patients who are not fit for general anaesthesia should not be excluded from treatment.

For patients with standard aneurysms of the descending aorta, the procedure is usually straightforward and quick. Technical success approaches 100% and the main complications are paraplegia which is around 2%, and groin complications related to the arteriotomy. In many cases patients are discharged a few days after the procedure. Follow-up should be by periodic CT scans. Late complications include type 3 endoleaks, graft strut disruption and migration, which are all low.

##### Aortic arch aneurysms

Patients with aneurysms very close to or involving the supraaortic vessels can be treated by surgical bypass of one, two or all three supraaortic vessels followed by the insertion of endografts. This is known as hybrid treatment. The aim of surgical bypass is to create a proximal landing zone for the aortic endografts. Left subclavian to left common carotid bypass, and right to left common carotid bypass are relatively straightforward procedures in experienced hands, with low morbidity. Aneurysms involving the proximal arch require bypass of all three supraaortic vessels which is achieved by taking grafts from the lower ascending aorta. This involves a sternotomy, and aortic side-clamping avoids the need for cardiopulmonary bypass. Although this sounds rather drastic, complications are very low and are substantially lower than the open surgical alternative involving replacement of the entire aortic arch.

Insertion of the aortic endografts to exclude the lesion is usually performed as a separate procedure a few weeks later. Using this hybrid technique, many patients who were previously refused conventional open surgery can now be treated. The main complications of arch hybrid procedures are stroke (7%) and paraplegia (2%) and are mainly related to endograft insertion rather than the surgical bypass procedure.

## Endovascular treatment of thoracic aortic aneurysm and dissection: Expanding indications

In order to avoid the need for surgical bypass, the device manufacturers are making great efforts to develop branched devices for use in the aortic arch. Although several prototype devices have been used in selected patients, a widely available device is not yet available. It is likely that the first branched devices for use in the arch will contain a single branch. Devices with two or even three branches are a much more distant prospect.

##### Thoracoabdominal aneurysms

Similar to arch aneurysms, thoracoabdominal aneurysms can be treated by less invasive techniques compared with open surgery. Treatment options include hybrid procedures, totally endovascular procedures using branched and fenestrated endografts, and combinations of hybrid and branched and/or fenestrated devices. The worldwide experience of the use of branched devices for thoracoabdominal aneurysms is limited, but is increasing on an annual basis.

On the basis of the limited available data, this most attractive treatment option seems to be effective and safe. The main inclusion criteria are an aortic arch of favourable morphology to enable cannulation and stent-grafting of the visceral vessels from the left arm, adequate iliac arteries for access, the ability for the patient to wait 4-6 months for manufacture and delivery of the endograft, and the financial ability of the patient or institution to pay for the devices. It should be stressed that the relatively high costs of the devices are balanced substantially by the cost savings incurred by the lower complications and hospital stays experienced by patients treated with this technology.

Hybrid procedures are a reasonable alternative to branched grafts for thoracoabdominal aneurysms, especially in patients with unfavourable aortic arch morphology. The main inclusion criterion is fitness to undergo visceral artery bypass. Up to all four visceral arteries (coeliac artery, superior mesenteric artery and the renal arteries) can be bypassed using grafts inserted in the common iliac artery or to the distal aorta. Clearly, any procedure involving visceral artery bypass will have a higher complication rate compared with a totally endovascular alternative. However, for patients with low comorbidity the results for elective procedures are acceptable and better than surgical replacement of the thoracoabdominal aorta.

##### THORACIC DISSECTION AND ACUTE AORTIC SYNDROME.

Management of uncomplicated acute type B intramural haematoma (IMH), penetrating aortic ulcer (PAU) and dissection remains conservative with intervention reserved for complications. Patients with acute IMH and PAU should undergo serial CT scans every few days to assess for changes in the aortic morphology. If there is persistent pain, an increase in the size of the lesion, the development of dissection or evidence of rupture, the lesions should be treated by the insertion of one or more endografts.

Patients with established acute type B dissection should be treated by endografts if they develop signs of rupture, malperfusion syndrome involving the visceral or lower extremity arteries, or if there is dilatation of the aorta either at presentation or on successive CT scans. A cross-sectional diameter of 22 mm of the false lumen is used by many as a threshold for endografting. The aim of endografting in acute dissection is to cover the main communication(s) in the thorax.

Regarding chronic dissection (>2 weeks after presentation), the main indications for endografting are aneurysm formation (>5.5cm aortic diameter) and rupture. Because the flap becomes fibrotic and immobile with time, there is evidence that endografts should extend to the diaphragm to achieve as little residual false lumen perfusion as possible after endografting.

The 30-day outcomes of endografting for complicated acute and chronic dissections remain better than open surgical alternatives. Most series report mortality rates below 10% with paraplegia rates of less than 3%. The long term outcomes for acute dissection are good. In the vast majority of cases late aneurysm formation involving the thoracic aorta seems to be uncommon, although long term data are limited. A small cohort of patients goes on to develop aneurysms of the abdominal aorta which may require treatment.

In the case of chronic dissection, there is a subset of patients who, despite endografting, continue to perfuse the thoracic false lumen and increase the thoracic aortic diameter. This is the most challenging situation faced by specialists in aortic intervention. An option being increasingly used is to close all of the communications between the true and the false lumen by extension of endograft coverage as far distally as is necessary after bypass of the visceral vessels. Clearly, such procedures are very complex. However, early results confirm that these patients do have a workable treatment option and should not be denied treatment.

##### TRAUMATIC AORTIC INJURY

Due to its low complication rate TEVR has in many centres superseded surgery for TAI in the last decade. The procedural time is short and the operation confers very little in terms of additional morbidity to these severely ill patients. Due to the focal nature of the injury, only a short length of aorta requires covering with an endograft. The published data are limited, although the procedural mortality is in most cases less than 5% and the paraplegia rate is negligible. The main area of research involves the development of endografts which better conform to the angulated aortic arch in younger patients who present with TAI. At least one manufacturer plans to release one such device iteration very soon.

##### SUMMARY

Endografting for lesions of the descending aorta seems to be here to stay. Moreover, using Hybrid procedures, branched devices, or a combination of these methods, the indications for endografting can be expanded to include lesions involving the aortic arch and the thoracoabdominal segment. It behooves us to consider these methods for our patients presenting with challenging pathology of the aorta so that they are offered the best option for survival.

Therefore, to offer the optimal care to our patients, each patient with a thoracic aortic lesion should be assessed for suitability for endovascular repair. If there is insufficient experience locally, patients should be referred to other centres with recognised expertise in thoracic aortic endografting for an opinion regarding suitability for endovascular treatment. In 2009, it is suboptimal management to regard the majority of patients with thoracic aneurysms or complicated dissection as being unsuitable for any treatment, because they are not fit to undergo open surgery.

### Don't miss it!

Thoracic aneurysm and dissection  
Special Session  
Sunday, September 20, 10:00-11:00  
Auditorium 6

Fig.1: Aortic lesions that can be treated with thoracic endografts:



Fig.1a: Aneurysm of the aortic arch.



Fig.1b: Thoracoabdominal aneurysm.



Fig.1c: Acute dissection with malperfusion (left renal artery and SMA).



Fig.1d: Aneurysmal chronic dissection.

##### References:

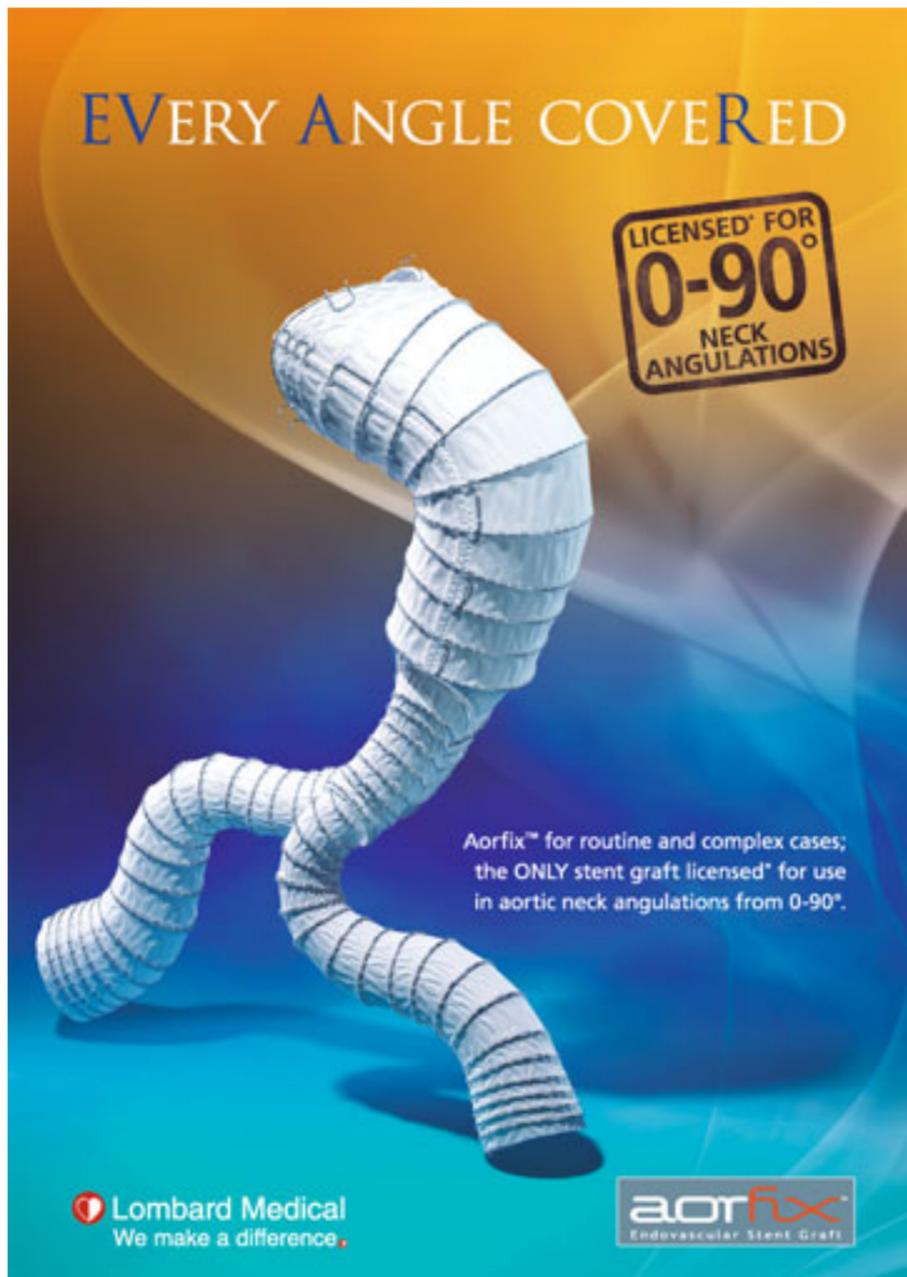
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**EVERY ANGLE COVERED**

LICENSED\* FOR  
**0-90°**  
NECK  
ANGULATIONS

Aorfix™ for routine and complex cases;  
the ONLY stent graft licensed\* for use  
in aortic neck angulations from 0-90°.

 **Lombard Medical**  
We make a difference.

 **AORFIX™**  
Endovascular Stent Graft

**Q: Brian, Aorfix™ and Lombard have come a long way in the last year. Can you give us an update?**

**Brian Howlett:** We have made significant progress focusing our resources on building the long-term success of Aorfix™. It is now the only product approved in Europe for the treatment of AAAs with peri-renal neck angulations from 0–90 degrees\*. We are also making solid progress towards completing our trials and filing for approvals in the important US market. Our unique label claim extension will enable us to increase sales in our target markets and greatly assist us as we come closer to realising the full potential of Aorfix™ in the global AAA market, which is forecast to be worth over \$1 billion by the end of 2010<sup>1</sup>.

On the funding side during 2008 and at the beginning of this year, we raised additional funds of £14.4 million net of expenses which has enabled the Company to advance its core commercial objectives.

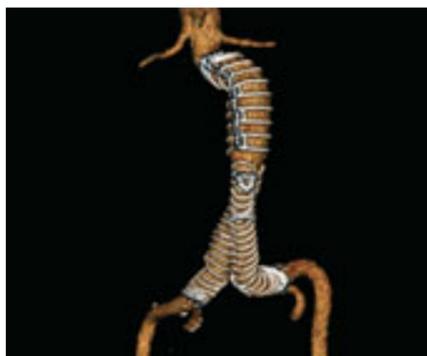
**Q: Tell me more about the unique label claim that Lombard has achieved and how you got it when others have been limited to much lower angulations and a smaller range of patients?**

**Brian Howlett:** Our 0–90 degree indication\* that we gained in June 2009 extends the use of endovascular treatment to patients with challenging anatomy who are often at risk in open surgical procedures due to their age or co-morbidities. Furthermore, it demonstrates to clinicians the unrivalled versatility of Aorfix™ in treating a broad spectrum of patients and achieving good clinical outcomes, regardless of the tortuosity of the vascular anatomy. The approval follows submission of clinical data from a study to assess Aorfix™ in the treatment of AAAs with high-angled infra renal neck angulations of between 60 and 90 degrees.

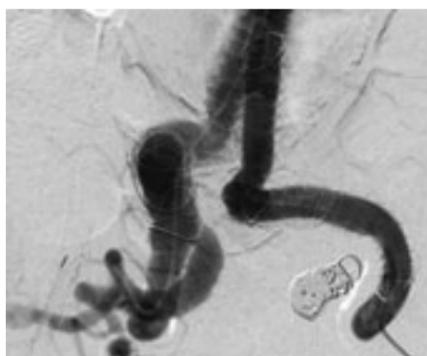
For patients in the study who had 30-day and 6 month follow-ups, there were no reports of device rupture, migration, stent fracture, loss of patency, vessel perforation, significant obstruction or conversion to open repair. Furthermore, all patients reviewed at six months were found to have a stable or shrinking aneurysm sac, indicating that the aneurysm was under control. The study reported that Aorfix™ was safe and effective in treating this group of challenging patients with difficult vascular morphology.

**Q: What other studies are ongoing?**

**Brian Howlett:** Data from this study (ARBITER 2) complements that from Lombard Medical's Retrospective Aorfix™ Data Retrieval (RADAR) open, voluntary registry. This has been presented at major medical conferences during the spring and summer and an update will be given at CIRSE this year. The results are derived from a wide spectrum of over 600 patients from 16 countries. In those patients with 12 month follow-up, it is clear that Aorfix™ has the ability to treat successfully both standard and severely-angled AAAs with equally good results as can be seen in these scans:



High Angle Neck Aneurysm<sup>2</sup>



Tortuous Iliac Arteries<sup>3</sup>

The results also compare favourably with other commercially available stent grafts for which the neck angle is restricted to below 60 degrees.

Clinical adoption of Aorfix™ has also been supported by a number of positive clinical presentations by leading vascular surgeons in peer-reviewed medical publications. Our team at CIRSE will have these available for review. In addition the pivotal USA study PYTHAGORAS continues to make progress. The Company has completed full enrolment into the open surgical control group of 75 patients and has sufficient patients 46, in the low-angle (below 60 degrees of aneurysm neck angulation) endovascular arm of the study for 12 month follow-up.

Recruitment into the high-angle group currently stands at 100 patients out of a total of 120 required to start the 12 month follow-up necessary for clinical submission to the FDA. This milestone is most likely to be met early in Q4, allowing for the clinical submission to be made to the FDA in Q4 2010 and an approval to be received in Q1 2011.

The Company's Principal Investigator, Dr Mark Fillinger, Dartmouth Hitchcock-Medical Centre, Lebanon, USA, one of the US's most eminent physicians in the field of endovascular aortic repair ("EVAR"), stated that: "The Aorfix™ stent graft has treated the most challenging anatomy ever attempted in a US clinical trial and has produced similar results to approved devices used in straightforward cases."

**Q: What is the company's growth looking like?**

**Brian Howlett:** Sales of Aorfix™ are growing rapidly in our target markets. Over 18 months since full commercial launch, Aorfix™ has already gained 6% market share in the UK, in early 2009 an estimated 12% in the Czech Republic, 5% in Greece and 5% in Poland. Interestingly the RADAR registry data shows that the majority of Aorfix™ implants (>85%) are in patients with normal vascular anatomy indicating that clinicians are not just using Aorfix™ in a niche segment of difficult to treat patients, but are primarily recognising its superior clinical performance and using the product in preference to longer established stent grafts. The number of Aorfix™ implants worldwide is now approaching 1000, with good clinical outcomes in follow-up extending to five years. Sales of Aorfix™, outside of the US, have grown by 72% in the first half of the year.

**Q: Looking ahead, what new products are in the pipeline?**

**Brian Howlett:** The EndoRefix™ endostapling device and Thoracic Aorfix™ products are valuable assets which could help drive the future value of the Company.

In the case of EndoRefix™, the Company is collecting data from the 58 patients that were enrolled in our study. Once available this data will determine our future development and commercial strategy for this device.

The thoracic version of Aorfix™ also continues to be a valuable asset because of the limitations of the devices currently available commercially. The Company is planning the further development of this device.

**Mike Karim: Thanks for the chance to discuss Lombard and Aorfix™; its sounds like there is great progress.**

**Brian Howlett:** Thanks Mike.

**For those who would like to know more about our progress and registry results with Aorfix™ we have a breakfast time symposium on MONDAY 21 SEPTEMBER AT ROOM 3B, 08h00 – 08h20.**

\*Refer to current IFU for indications of use.  
MLIT/002/AUG2009 Issue 1

<sup>1</sup> Medtech Ventures Report 2008

Courtesy of Mr A. D. McLain, Consultant

<sup>2</sup> Vascular Surgeon, Royal Gwent Hospital, UK.  
Courtesy of Mr D. Morrow, Consultant Vascular

<sup>3</sup> Surgeon, Norfolk & Norwich Hospital, UK.



Thierry de Baère  
Department of Interventional Radiology  
Institut de Cancérologie Gustave Roussy  
Villejuif, France

Radiofrequency ablation (RFA) has achieved impressive results in the treatment of unresectable primary and metastatic liver cancer. Today RFA of primary and metastatic lung tumours is increasingly used and seems to provide equally impressive results.

#### Local efficacy

Rates of 70 - 90% of complete ablation are reported after RFA of small size lung tumours. The rate of complete ablation at 2 years for tumours less than 2 cm is 80 to 90% in most reports. While several studies report a statistically significant lower success rate of ablation with tumours more than 2 to 3 cm in diameter, the overall rate of incomplete local treatment is approximately equivalent to incomplete surgical resection (12% as reported by Pastorino et al.). However, head to head comparison between surgery and RFA series is impossible, as patient selection criteria differ between studies.

The rate of complete ablation is highly dependent on the volume of ablation relative to the tumour volume and, consequently, on ablation margins. Indeed, in our experience when the ratio between the area of post-RFA ground glass opacity and the tumour area before treatment was at least 4, the rate of complete ablation was 96% -- significantly higher ( $p=0.02$ ) than when this ratio was below 4, averaging 81% complete ablation. Gillams et al. report that in 85% of incompletely ablated tumours there was no ground glass opacity margin on post RFA CT. The ROC analysis constructed from recurrence according to ground glass opacity minimal width after ablation confirmed the usefulness of the ablation zone as a predictor of recurrence, with an estimated cut-off of 4.5mm for a specificity of 100%, i.e. no local recurrence. Hiraki et al. reported an 83% success rate of ablation at one year when the ratio of ablation volume to tumour volume was 3 or higher, while the success rate was 61% when this ratio was lower than 3. These results from three different centres clearly emphasise that there is a need for over-sizing ablation zone when compared to the tumour. Moreover because RFA tools provide volume of ablation with the shortest diameter being around 4 to 5 cm, selection of tumour below 3 cm will provide better complete ablation rate.

## Lung tumour radiofrequency ablation: Where do we stand?

Contact with a large vessel (>3 mm) has been reported by Hiraki et al. and Gillams et al. as a negative predictive factor of complete tumour ablation in lung tumours, in the same manner it has been reported in liver tumours. The so-called heat sink effect which is convection cooling by the vessel of the ablated zone is probably responsible for this increased failure rate. We have performed technically and clinically successful, but mildly tolerated balloon occlusion of the pulmonary artery branch during lung RFA. As reported in lung animal study and in clinical studies in the liver, PBO allows an increase in the volume of ablation and renders a more spherical zone of ablation. The use of new energy such as microwave, which has a better thermal profile by working at higher temperature and is consequently less subject to convection cooling, could be a valid answer to these difficulties in ablation for tumour close to large vessels, although this theoretical superiority has not been demonstrated in clinical practice.

#### Survival

There is no comparative study of RFA and surgery either for small size (stage I) NSCLC or lung metastases. Even if early reports of survival after RFA seem close to rates after surgery, the data is preliminary. Ideally randomised control trials are needed.

In 75 primary NSCLC (75% stage IA and 25% stage IB) Dupuy et al. demonstrated median survival of 29 months (IC95% : 20-30 months) with 30 months for stage IA and 25 months for stage IB. Overall survival was 78%, 36%, and 27% at 1, 3, and 5 years. Better survival was reported for tumours 3cm or smaller with a survival rate close to 50% at 5 years.

Grieco et al. combined radiation therapy and RFA in 41 patients with NSCLC (Stage IA : 21; Stage IB: 17, Stage IIB: 3). The 27 patients with the largest tumours received external beam radiation (66Gy) while 27 and the 14 patients with tumours less than 3cm received brachytherapy through the puncture tract used for RFA. Combination treatment seems to improve results in NSCLC with 57% survival at 3 years. The median survival was  $34.6 \pm 7$  months for tumours larger than 3 cm and  $44.4 \pm 5.4$  months for tumours 3 cm or smaller.

Very similar overall survival has been reported by 4 different teams (de Baere, Simon, Yamajado, Yan) in colorectal cancer lung metastases with an overall survival of 64 to 78% at 2 years.

#### Imaging

CT is currently the best imaging guidance modality for lung RFA. Real time CT with foot pedal control renders needle placement faster than other technologies and the procedure more comfortable for the operator. In our practice, multiplanar reconstruction is mandatory to assess adequate needle positioning; imaging of the differences in density makes it easy to differentiate clearly between normal lung tissue, tumour and needle tines.

CT images immediately following RFA show the lung tumour surrounded by ground glass opacity which enlarges the diameter of the hyperattenuating tumour to a maximum size seen 24 and 48 hours post-treatment. Then an ablation volume which does not increase in size on subsequent imaging is considered complete ablation. This method of evaluation has some drawbacks; specifically, delayed discovery of incomplete treatment which occurred between 4 and 12 months (mean $\pm$ SD =  $7.66 \pm 2.77$ ) in our experience.

In order to avoid late discovery of incomplete ablation, PET-CT appears promising to provide early evaluation of treatment response. Sensitivity and specificity of PET has been reported superior to CT in early detection of incomplete ablation, but numerous pitfalls such as G6PD uptake in mediastinal lymph nodes or at the puncture site have occurred. Okuma et al. demonstrated in a pre-clinical study that timing of PET after ablation is a key factor, as G6PD uptake is highly increased 1 to 3 weeks after ablation with an SUV ratio of 5 and higher between RF ablation zone to muscle. Consequently it is wise to avoid PET imaging between 1 and 4 weeks before ablation in order not to misinterpret a post-RFA inflammatory reaction for active tumour.

#### Tolerance

Tolerance of the technique is reported to be excellent, with no changes in post-ablation respiratory test as reevaluated prospectively at one month by de Baere, et al., and confirmed at 12 months by Lencioni et al. Consequently we were able to treat patients with FEV1 as low as 0.8 liters/second without clinical modification of the respiratory function in the mid and long term. Obviously, some compromised patients will have temporary worsening of respiratory function with the need of oxygen therapy from 1 day to 3 weeks. In our experience, no patients required long term or permanent oxygen therapy.

### Don't miss it!

Lung RF Ablation  
Special Session  
Sunday, September 20, 08:30-09:30  
Auditorium 2

as a result of RFA. Consequently, it is difficult today to place a clear lower threshold of respiratory function for lung RFA. A major benefit of lung RFA to treatment of NSCLC is that the excellent tolerance of the treatment allows curative treatment in non-surgical early NSCLC. Moreover, this excellent tolerance allows safe treatment of single lung patients as reported in the oncologic intervention session 1207 (Sunday 20<sup>th</sup> September, 16:15-17:15, Auditorium 4).

#### Conclusion

RFA is a promising treatment, with high success rates of complete ablation in small primary and metastatic lung tumours. It is already adopted as a potentially curative treatment in non-surgical candidates. RFA can be compared with sophisticated external beam radiation, such as tomotherapy and gamaknife for primary NSCLC. RFA warrant evaluation versus surgery both in metastases and primary NSCLC. However, a randomised trial would be difficult to conduct. A combination of RFA with other anti-cancer treatment (radiation therapy, chemotherapy, etc.) should be evaluated further.

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# ECIO 2010

## Second European Conference on Interventional Oncology

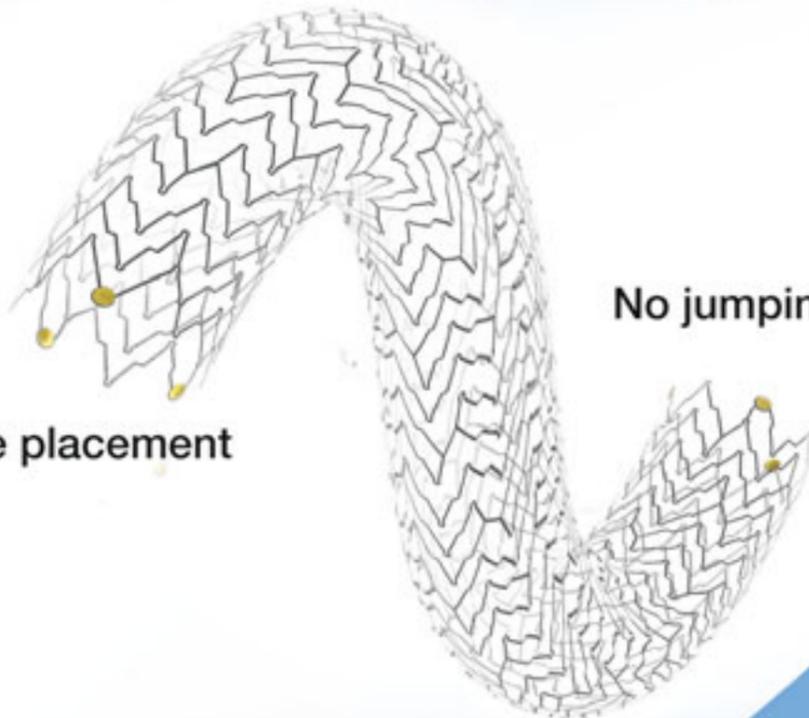
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Francisco Cesar Carnevale  
SoBRICE President

Gustavo Andrade  
SoBRICE Board of Directors

At the end of the 80ies there were still very few interventionists in Brazil. Trying to disseminate and improve the new techniques, they created an informal meeting for case discussions. The meeting rapidly grew in size and became a regular feature in Brazil's radiological year. One of the meeting's founders, Dr. Renan Uflacker dubbed it "Clube dos Angiografistas" or "Angiografer's Club". The Brazilian Society of Interventional Radiology and Endovascular Surgery – SoBRICE – was founded at the 1997 Clube dos Angiografistas. Since then SoBRICE has been carrying out its activities in cooperation with the Brazilian College of Radiology (CBR), representing interventionist and angiologists on a national level.

With the growth of the specialty in our country and the consolidation of our society, SoBRICE started to do its first steps; an annual SoBRICE meeting was created. Always aiming for a high scientific level, it soon became one of the most important IR events in Latin America. Despite the SoBRICE meeting the Clube dos Angiografistas has continued to take place until today for the sake of tradition.

Interventional Radiology quickly grew in Brazil; starting out as an association of 10 to 15 active participants it became a respectable national society within only a few years' time, the annual meeting adding hundreds of interested physicians. In 2001 the third annual SoBRICE meeting took place together with the Brazilian Congress of Radiology and in 2003 it was co-organized with the third SIDI Congress (Latin American Society of Interventionism). Thanks to its invited speakers, directors and collaborators, but most of all thanks to the active members of the society the SoBRICE meeting kept developing and in 2005 it was officially named the annual SoBRICE Congress.

SoBRICE's 2008 congress took place at the wonderful beach town of Costa do Sauípe in Bahia, Northeastern Brazil. Again, we had the pleasure of organizing the meeting in cooperation with the Latin American Society of Interventionism (SIDI) as well as the Brazilian Therapeutic and Diagnostic Neuroradiologic Society (SBNRDT). As there are so many meetings all over the world, companies and physicians are quite happy with the association of neurological and peripheral interventional societies. A highlight of this event was the participation of twenty foreign professors, including CIRSE members

## Interventional Radiology in Brazil

Dierk Vorwerk, Anna-Maria Belli, Jean Pierre Pelage and Tobias Jakobs. This year's faculty also comprised eleven professors from the United States including our society's founding father Dr. Renan Uflacker. More than 600 participants made SoBRICE 2008 the biggest annual congress of Interventional Radiology in South America.

During the mornings and afternoons the sessions took place in parallel in two rooms. Additionally there were 12 courses and 12 round table discussions offering formal lessons and informal interactive discussions on specific issues. 90 selected scientific posters were showed, two of which were awarded.

SoBRICE 2008 comprised a comprehensive technical exhibition supported by 19 companies with a special participation of ev3. We are very grateful for the participation and support of almost all international IR companies. The meeting provided wonderful moments for the participants who enjoyed a vast and high quality programme.

Costa do Sauípe with its beautiful landscape, sunny beaches and numerous parties was the perfect backdrop for the scientific meeting, livening it up with Latin music and tropical drinks. In the official dinner Wilfrido Castañeda-Zuñiga received a well-deserved distinction from our society. With the start of the New Year we are already organizing the 2009 congress which will be held in São Paulo.

Brazil is a country of continental dimensions, being the fifth biggest in the world regarding population and size. The Brazilian market makes up more than 50% of the consumption of specific materials in South America. Nevertheless the health system presents many difficulties. Up until five years ago IR procedures were almost only offered by private healthcare clinics. Thanks to changes in healthcare legislation the government was finally obliged to include them in the public system, causing an exponential growth of the specialty.

In the last five years many new groups appeared working with Interventional Radiology and the number of physicians looking for a residence or fellowship in the area increased substantially, exceeding the capacity of the established training centres. Currently there are about three hundred interventionists

adequately certified for our population of more than 180 million inhabitants. Unfortunately the hospitals offering IR procedures are still not homogeneously distributed, making it almost impossible to gain access to the procedures in some regions. Therefore some IR procedures are offered by colleagues from other specialties. This reality is one of our greatest challenges.

The skill level in Brazil is quite good, some of our colleagues being internationally renowned experts in their fields. This of course creates a favourable environment for trials. Unfortunately academic research is barely stimulated in Brazil. Nevertheless these conditions are slowly changing and we are starting to see Brazilian papers in international scientific journals. Three books dealing exclusively with Interventional Radiology and Endovascular Surgery have been published in Brazil, one of which will be translated into English shortly.

SoBRICE is working to develop diagnostic and therapeutical procedure guidelines that will provide better results and a more homogeneous reality in our country, also helping to control the work of professionals, services and healthcare companies. Credential training centres will assist in the training and further education of current and future interventionists. It is in this field that SoBRICE is hoping to cooperate strongly with CIRSE in the future. In this context we would like to thank CIRSE for its great work in this field.

Being almost 12 years old now SoBRICE continues to grow. It has been headed by five presidents who all made their particular contributions. The new Executive Committee recently elected for 2009/2010 is planning many exciting projects. The new challenge is to let the society mature and stimulate its members to actively contribute to the development of our specialty. In addition to The Angiographers' Club and the Annual SoBRICE Congress, regional meetings have been created to disseminate our specialty in regions far from the major cities.

We have many plans for the future of our society. Most importantly we will continue to implement quality programs at our meetings and offer continuous updates and advantages to our members. Tight cooperation with bigger and more mature societies such as CIRSE will hopefully greatly help in these endeavours.

### Don't miss it!

CIRSE meets Brazil  
Sunday, September 20, 14:15-16:00  
Auditorium 1



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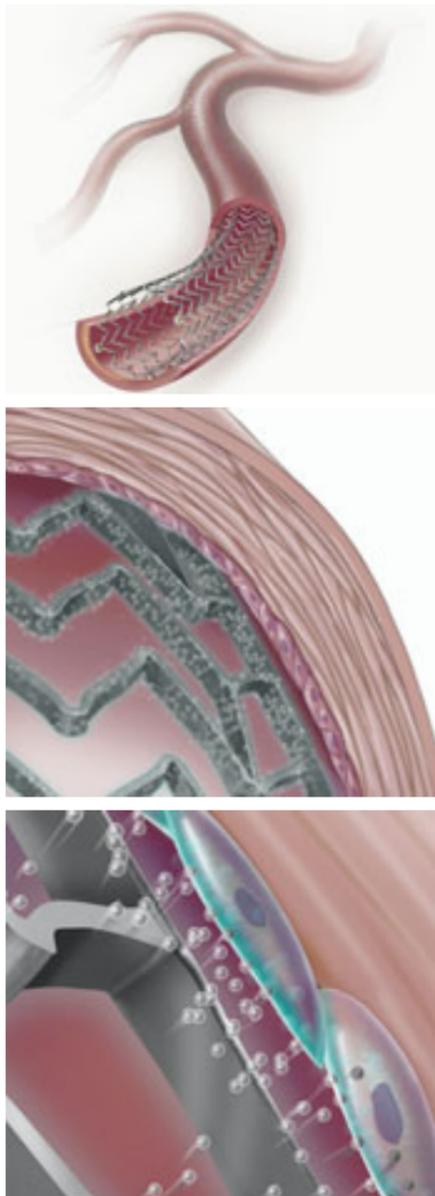
Advertorial

## Zilver PTX Stent from Cook Medical Gains CE Mark Breakthrough Drug-Eluting Stent to Treat Peripheral Artery Disease Now Available in Europe

### ABOUT COOK MEDICAL

Cook Medical was one of the first companies to help popularise interventional medicine, pioneering many of the devices now commonly used worldwide to perform minimally invasive medical procedures. Today, the company integrates device design, biopharma, gene and cell therapy, and biotech to enhance patient safety and improve clinical outcomes in the fields of aortic intervention; interventional cardiology; critical care medicine; gastroenterology; radiology, peripheral vascular, bone access and oncology; surgery and soft-tissue repair; urology; and assisted reproductive technology, gynaecology and high-risk obstetrics. Cook is a past winner of the prestigious Medical Device Manufacturer of the Year Award from Medical Device & Diagnostic Industry magazine.

For more information, visit [www.cookmedical.com](http://www.cookmedical.com).



In a breakthrough development offering a truly modern, highly effective medical treatment for peripheral artery disease (PAD), physicians across Europe have completed patient implants of the first CE Mark approved drug-eluting stent designed specifically to treat severe blockages in the challenging and largest artery in the leg.

Approval of the polymer-free Zilver® PTX® Drug-Eluting Peripheral Stent from Cook Medical, a world leader in minimally invasive diagnostic and interventional devices, represents a global landmark in effective peripheral intervention for treating PAD, a chronic disease affecting tens of millions of patients worldwide that is a leading cause of leg amputation and shortened lifespans.

Cook's Zilver PTX is specifically designed and approved to treat PAD affecting the main blood vessel in the thigh, the superficial femoral artery (SFA). It is a self-expanding stent made of nitinol, a space-age 'shape memory' metal that offers unique mechanical advantages for a stent in the SFA.

By eliminating the need for a polymer or plasticising agent to hold the drug to the stent body, Cook has created a medical breakthrough that solves two key problems. First, it allows targeted delivery of a drug (paclitaxel) proven to reduce the re-narrowing (restenosis) of arteries opened using balloon angioplasty. Second, by eliminating the need for a polymer, which was left behind on the body of earlier drug-eluting stents after the drug dissolved into the surrounding tissues, Zilver PTX avoids the potential patient risks posed by leaving a permanent foreign, plastic substance in the body. In addition, the Zilver stent was proven during its clinical trial to be the most durable peripheral stent available, suggesting even greater patient safety, according to the clinical trial data.

The CE Mark follows the world's largest-ever clinical trial for a peripheral stent, led by Dr. Michael Dake, professor in the Department of Cardiothoracic Surgery at Stanford University Medical School and medical director of the Cath/Angio Laboratories at Stanford University Medical Center, Palo Alto, California. The data collected in the Zilver PTX registry involved 791 patients from Europe, Russia, Canada, and Korea and demonstrated highly positive results. Only 8 per cent of patients with de novo (new) lesions needed a reintervention to reopen the artery in the first 12 months – a rate significantly surpassing existing treatments for PAD in the SFA, such as balloon angioplasty and bare metal (non-drug-eluting) stents.

Also, specific patient groups that are often very hard to treat, such as diabetics and patients with in-stent restenosis (those treated previously with a noncoated stent), were shown in the trial to benefit from the Zilver PTX. As the trial data indicate, the superior results achieved in the first year have been largely maintained throughout 24 months, an important clinical milestone. In comparisons with other trials published, the Zilver PTX stent showed a reduction in re-intervention of between 50 per cent and 75 per cent, an important patient benefit.

*"The awarding of the CE Mark is set to herald a revolution in the treatment of peripheral arterial disease,"* comments **Dr. Michael Dake**. *"This global study proves that the Zilver PTX has the integrity, safety, and durability needed to successfully address many of the well-known limitations of current treatments for the management of PAD."*

**Rob Lyles**, global leader and vice president of Cook Medical's Peripheral Intervention division states, *"We've specifically designed the Zilver PTX to be safer and more effective for PAD patients by engineering this device for the unique demands of treating this disease in the SFA. It's polymer free, it's fracture resistant, and through the largest trial of its nature in history, it's been clinically proven to be significantly more effective in treating peripheral arterial disease in the SFA than other treatment modalities."*

*"Our unique ability to adhere the drug to the stent without using a polymer is a major clinical advantage. It eliminates the risk some patients may face due to reactions and other potentially poor outcomes that are associated with polymer coatings used on current generations of drug-eluting stents. It's a truly exciting time for Cook Medical and our partners, as well as for physicians and patients alike. With the European launch of this first-of-its-kind 21<sup>st</sup> century medical technology, we are truly at the vanguard of a revolution in peripheral intervention."*

PAD is one of the fastest-growing and most pervasive diseases of our time, and it is estimated to affect 27 million individuals in Europe and North America<sup>1,2,3</sup>. Yet, approximately only a quarter of these people have any symptoms at all. The 'silent' nature of this condition can result in a number of patients being diagnosed only when their condition has progressed to the severe stage. In many countries, untreated PAD is the leading cause of leg amputation, and previous treatments such as bypass surgery and the use of angioplasty are much more invasive and/or only have shown only limited long-term success rates.



Following more than 1,200 patients treated worldwide during its clinical evaluation and CE Mark approval on 24 July 2009, the first commercial implantations of the Zilver PTX stent were conducted yesterday in a coordinated effort by physicians in the United Kingdom, Germany, France, Holland, Belgium, Sweden, Switzerland and Spain. In the United States, the Zilver PTX drug-eluting stent is an investigational device not available for sale.

In the UK Dr. Nick Chalmers from the Manchester Royal Infirmary participated in the first commercial use.

Cook licenses the rights to use paclitaxel on peripheral stents and other noncoronary medical devices from Angiotech Pharmaceuticals, Inc., of Vancouver, British Columbia, Canada ([www.angiotech.com](http://www.angiotech.com), NASDAQ: ANPI, TSX: ANP).

*"Cook is to be congratulated for succeeding where many others have failed in making drug-eluting stent technology a reality for patients with peripheral vascular disease,"* said **Bill Hunter, Ph.D.**, president and CEO of Angiotech. *"The Zilver stent platform has shown tremendous durability and performance in clinical trials, and when combined with the proven benefits of paclitaxel in the prevention of restenosis, the Zilver PTX is poised to become the first choice for interventionalists in the management of this common medical condition."*

<sup>1</sup> Belch JJ, Topol EJ, Agnelli G, et al. Critical Issues in peripheral arterial disease detection and management: a call to action. *Arch Intern Med.* 2003;163(8):884-892.

<sup>2</sup> Golomb BA, Dang TT, Criqui MH, et al. Peripheral arterial disease: morbidity and mortality implications. *Circulation.* 2006;114(7):688-699.

<sup>3</sup> Hirsch AT, Haskal ZJ, Hertzler NR, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic). *J Am Coll Cardiol.* 2006;47(6):1239-1312.

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## Biliary Drainage: How we do it and how we deal with arterial haemobilia

**Technique (Fig. 1) :** Percutaneous transhepatic biliary drainage (PTBD) consists in lodging a catheter inside the biliary duct proximal to the obstruction, which enables drainage of bile to the exterior. Generally, it is an elective procedure for obstructions resulting from neoplasias, and in pre-surgery. Urgent procedures include acute severe cholangitis and in cases of breakdown of endoscopic biliary drainage. Patient preparation needs to include coagulation assessment, prophylactic antibiotics, as well as careful evaluation of the clinical history and available imaging tests.

In our opinion, the safest technique (and, as such the standard in our centre) is that of double puncture. The first puncture is with a fine needle (21-23G) to establish percutaneous transhepatic cholangiography (PTC) which will serve to select and to guide the access to an ideal bile duct in which to place the drainage catheter.

Usually, the PTC is performed via a lateral access, the selected puncture point being between the lines of the median and posterior axilla, under fluoroscopic control (avoiding the interposition of the costophrenic sinus and the hepatic angle of the colon). Under certain circumstances there may be the need to access the left hepatic lobe (LHL) from an anterior route (anterior abdominal wall, below the rib cage or the sternum).

After achieving PTC, and to perform the PTBD correctly, we need to access a peripheral bile duct at a minimum distance from the skin puncture and with a favourable angle (>90°). Once the duct is selected and to prepare for the second puncture, we place the intra-operative fluoroscopy (C-arm) in the lateral position with the intensifier alongside and we mark the point of puncture on the skin. The needle can be progressed in the lateral position with the help of a covering to avoid radiating the hand. The distance covered by the second needle into the liver should not exceed 3-5 cm.

Having crossed the selected bile duct we place the C-arm in the A-P position and, if needed, we withdraw the fine needle until its point remains within the interior of the lumen of the duct. We then pass the 0.018" guidewire as distally as possible up to the principal bile duct (PBD). Subsequently, we introduce the single-puncture system onto the 0.018" guidewire, up to the entrance of the bile duct and with only its plastic components proceeding beyond this point.

A preformed catheter and a hydrophilic guidewire may be needed to reach the bile duct where the drainage is to be located. To proceed, we exchange the hydrophilic guidewire for a rigid guide and we slide the drainage catheter over it (while keeping the retention systems at the puncture at all times). Once the drainage catheter is correctly placed, we aspirate the greatest quantity of bile possible and withdraw the needle from the first puncture.

The drainage catheter needs to have an appropriate sized bore (generally we use 8.5F) and the longest possible distance from the interior of the bile duct to ensure greater stability.

### Discussion

PTBD is the quickest, safest, most efficient and economical method for the drainage of bile that is frequently infected in patients with biliary route obstruction. It can be a one-off procedure (for example, acute cholangitis with poor response to conservative medical treatment) or the first intervention enabling subsequent interventional procedures in cases of choledocholithiasis or biliary-pancreatic neoplasias.

Having PTBD available around the clock is of special importance in cases of severe acute cholangitis with inadequate response to antibiotic treatment. For these patients, PTBD may be the only therapeutic option and, if the procedure is delayed, can be fatal.

### Arterial Haemobilia: How to deal with it

**Technique (Fig.2):** If there is a suspicion of haemobilia of arterial origin (intense sharp pain that may be accompanied by haemodynamic instability, immediate outflow of any contrast medium introduced into the biliary tract, pulsating blood flow from skin puncture), the angiographic diagnosis needs to be performed as soon as possible so that the first therapeutic option (i.e. embolisation) can be performed, if possible, at the same time as the diagnostic arteriography. The single branch involvement of the hepatic artery in the arteriographic assessment may be identified as: 1) pseudoaneurysm; 2) segmental arterial stenosis (pseudospasm); 3) extravasation of contrast medium. These lesions are associated with hepatic haematomas and, frequently, with flow of blood into the intestine (haematemesis/melena).

Once the lesion has been identified, the embolisation is performed as selectively as possible by accessing the lesioned vessel with a microcatheter. The most frequently used materials for embolisation are the PVA microspheres and microcoils.

If a venous vascular lesion is suspected, the diagnostic procedure is different. The drainage catheter is substituted by an 8 or 9F introducer via two guidewires (a safety guidewire of 0.018" and a working guidewire of 0.035"). We introduce a catheter across the working guide and which, while being withdrawn, has contrast medium injected; the intention being to assess the trajectory of the damage. Once identified, the tract proximal to the site of lesion is embolised with microcoils (if the venous structure is a portal branch we can introduce part of a coil into its interior). The safety guidewire will be changed and will serve for the placement of a new bile drainage catheter.

### Discussion

The most stressful complications of PTBD are haemorrhagias, the most severe being those of arterial origin. If the techniques and access to the biliary tract are appropriate, most haemorrhagias will have their origin in the manipulation of the guidewires and catheters or in lesions in small veins and, as such, will be self-limiting and of low clinical significance.

The haemobilia caused by vascular lesions are of greater severity, especially those of arterial origin which can put the life of the patient in danger. The probability of producing severe haemobilia by vascular lesion is related directly to the biliary tract access. The more peripheral the access, the lower the probability of producing a vascular lesion, which if produced will be less severe.

Biliary access, as a function of risk of vascular lesion, can be classified as:

#### Right Hepatic Lobe

- Ideal: Sub-segmented ducts. Considered minimum risk
- Acceptable: Segmented ducts
- Dangerous: Central ducts (anterior or posterior segments)
- Prohibited: Common hepatic duct. It is not justified to place a drainage catheter under any circumstances

#### Left Hepatic Lobe

- Ideal: Peripheral segment III duct (anterior-lateral)
- Acceptable: Posterior-lateral segmented duct II
- Dangerous: Left principal duct
- Prohibited: Common hepatic duct

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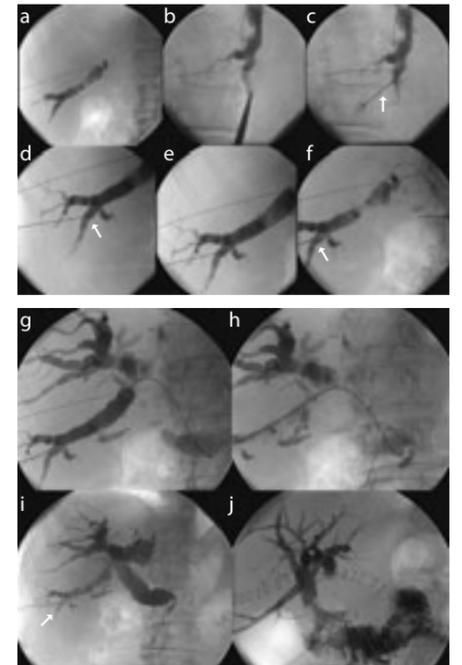


Fig.1: Percutaneous transhepatic biliary drainage. a) Fine needle transhepatic cholangiography, A-P projection; b) Selection of access point for the 2nd puncture; c) 2nd puncture performed in lateral projection with fine needle (arrow); d) Position of the needle point in the interior of the biliary canaliculus (arrow), A-P projection; e) Passage of the 0.018" guidewire; f) Advance of the single-puncture system, retaining the metal component in the access point of the biliary canaliculus (arrow).

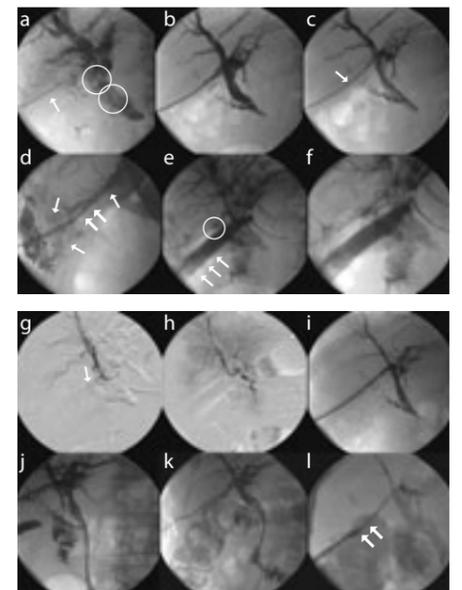


Fig.2: Haemobilia of arterial origin: a) External biliary drainage (arrow), filling defects corresponding to haemobilia at the end of the procedure (circles); b) Cholangiography at 48h; c) Rapid and massive outflow of contrast medium from the biliary tract on withdrawal of the drainage 0.035" guidewire (the start of the point is marked by the arrow); d) Substitution of the drainage by the vascular introducer, and injection of contrast medium through the hepatic tract (broad arrow), darkening arterial branches of the right hepatic duct (narrow arrows); e) Hepatic arteriography in which a pseudoaneurysm (circle) is identified adjacent to the access to the intra-hepatic biliary tract. Sub-hepatic haematoma (arrow); f) Selective catheterisation of the right hepatic artery and of the lesioned branch

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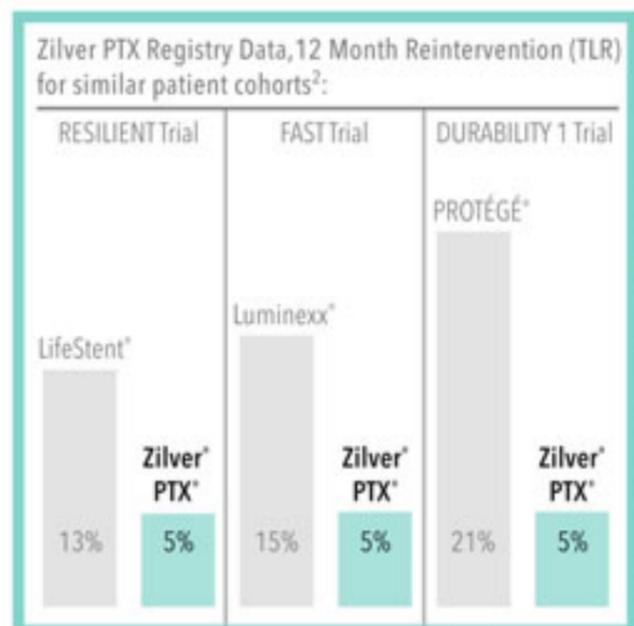
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References:  
1. Target lesion revascularization (TLR): clinically driven reintervention for  $\geq 50\%$  DS within treated segment (included  $\pm 5$  mm); surgical bypass of target vessel. 2. Dake M. Interim analysis of two-year results for the Zilver PTX drug-eluting peripheral stent. Presented at: 2009 Vascular Annual Meeting, June 11-14, 2009, Denver, CO. LifeStent and Luminex are registered trademarks of C.R. Bard, Inc. PROTÉGÉ is a registered trademark of EV3 Peripheral, Inc.



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## Covered Metallic Stents for Palliation of Biliary Malignancies

Despite the gigantic achievements of the oncology oriented specialties in medicine, biliary and pancreatic malignancies are still not detected early enough to be resectable. Surgical palliation is linked to high morbidity and mortality and therefore endoscopic or percutaneous metallic stent placement is likely to be the best option, particularly when jaundice occurs. Metallic stent technology is an exciting research area of medicine. In the case of palliation of malignant jaundice, covered metallic stents have been developed in the effort to prevent stent re-occlusion from tumour ingrowth. The successful placement of a covered stent depends on the appropriate stent and patient selection.

### STENT SELECTION

#### 1. Type of covering material

The main goal of the covering material is to prevent tumour ingrowth. Several materials have been tested throughout the years and several theories have been developed. Initially covered stents were "home made" by fixing a coverage membrane on the available bare stents. In 1994 Saito et al. used biliary Gianturco-Rosch Z-stents covered with a Gore-Tex membrane (1) and reported satisfactory medium- to long-term results in a study of six patients.

In 1996 Thurnher et al. reported their experience with the first type of covered Wallstent (2). The coverage was a 0.015mm thick polyurethane membrane that was also used by Rossi et al. in 1997 (3) and Hausegger et al. in 1998 (4). Both reported that the 0.015mm polyurethane membrane was eroded by tumour and gastric juice. Similar results were also presented by Kanasaki et al. in 2000. In this case nitinol Strecker stents were used with the same coverage (5). A 0.035mm polyurethane membrane was used in homemade covered Gianturco-Rosch Z-stents and spiral Z-stents from Miyayama et al. in 1997 with better results (6).

Han et al. reported a 71% patency at 20 weeks using a 0.030mm thick polyurethane membrane in covered Niti-S stents (7). Using 0.040-0.050mm thick polyurethane-covered Wallstents Isayama et al. did not report tumour ingrowth (8) and presented even improved results with a 0.050-0.060mm polyurethane membrane in covered Diamond stents (9).

In 2002 Bezzi et al. (10) described the results of the use of a nitinol covered stent with ePTFE/FEP coverage. The microporous material was contrasting the tendency that the thicker membrane would be more effective in preventing from tumour ingrowth. In 2007 in the study of Hatzidakis et al. (11) ePTFE/FEP has shown to be effective in preventing from tumour ingrowth and may actually be considered as the most suitable stent coverage material in the palliation of malignant jaundice.

#### 2. Migration rate

Migration has always been a problem with covered stents. In the study of Saito et al. (1994) with Gore-Tex covered Gianturco-Roesch Z-stents, stent migration was observed in two out of six patients (1), while Thurnher et al. reported migration in 20% of the cases (2). Fully covered Wallstents were also prone to migrate, but newer versions with uncovered portions have been developed which were less likely to do so. The presence of anchoring fins in the Viabil stent has limited migration cases only to those in which the endoprosthesis may slip before getting fully deployed.

#### 3. Flexibility and radial force

Flexibility permits appropriate stent placement without kinking or fracture problems, whereas radial force permits better expansion and less sludge formation, both offering longer stent patency. Covered stents have been evolved together with uncovered ones regarding flexibility and radial force. The stainless-steel alloy covered Wallstent has shown to be relatively flexible, but with lower radial force than the recently developed covered nitinol stents. Nitinol covered stents, like the uncovered ones, gain their final diameter 24 hours after placement and do not get shortened thereafter. It is therefore suggested that the proximal and distal margins should have a 2cm distance from the tumour's proximal end in order to avoid tumour overgrowth.

### PATIENT SELECTION

#### 1. Anatomical considerations

Covered stents are not suitable for all patients with malignant jaundice. Anatomical considerations include stricture location, location and patency of the intrahepatic, cystic and pancreatic ducts. Usually only Bismuth type I strictures are suitable for covered stent placement (Fig. 1), whereas specific covered stents may be placed in some cases of type II. The covered portion should not be advanced in the intrahepatic ducts in order to avoid cholangitis.

The same principal should be followed for the cystic duct, but less for the pancreatic duct, since pancreatitis may less frequently occur and the location of the pancreatic duct is not a true limit in stent placement. For this purpose covered stents with side holes have been developed. The holed region does not prevent from tumour ingrowth and it is also not extending proximally enough to prevent from tumour overgrowth as a bare stent would. Nevertheless, side holes permit placement in anatomically complicated cases avoiding cholangitis or cholecystitis.

#### 2. Tumour type and staging

In a recent randomised study conducted by our group it was shown that the Viabil stents may offer better clinical results in terms of re-intervention and patency rates than bare Wallstents (12) (Fig. 2). The study was performed only for cases of extrahepatic cholangiocarcinoma. This is the only study in the literature offering a comparison between covered and uncovered stents for a particular type of malignancy. In addition only patients with a performance status higher than three according to the Eastern Cooperative Oncology Group Scale were included.

We believe that similar results may be obtained for cases of pancreatic tumours in patients with expected survival above six months, whereas we do not consider appropriate covered stent placement in strictures from lymphnodes or when patient survival is estimated less than six months.

In summary, covered stents seem to offer a valid option for palliation of malignant jaundice. Careful stent and patient selection are necessary in order to avoid complications and maintain the procedure cost effective.

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Fig. 1a: Percutaneous Transhepatic Cholangiography shows dilatation of the biliary tree due to a Bismuth type I stricture. Note that the cystic duct is infiltrated.



Fig. 1b: Drainage catheter followed by



Fig. 1c: Placement of a 10X60mm Viabil covered stent without side holes

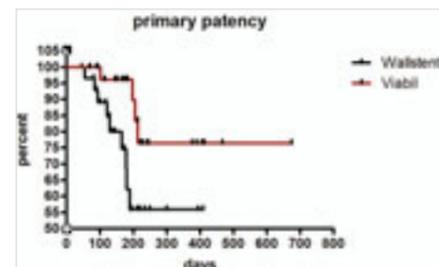


Fig. 2: Kaplan-Meier analysis of patency in days for Viabil stents compared with Wallstents in cases of extrahepatic cholangiocarcinoma (p=0.046).



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## Trauma – The time is right for Interventional Radiology to shine

Interventional Radiology provides patients with treatments that avoid some of the invasive problems associated with open surgery. However, it is not immune from complications and over the years techniques have been developed to manage many of these problems.

A number of situations may arise which require treatment of the trauma inflicted by these procedures, so-called iatrogenic trauma. These include bleeding from biopsy sites, pseudoaneurysms associated with arterial access, arterial and venous disruption and reopening of vascular beds. The techniques developed are not only applicable to treatment of complications of Interventional Radiology procedures, but also extend to interventions performed at open surgery (or other places within hospitals) and to trauma sustained in the community, such as road accidents.

Whilst these techniques are very familiar to Interventional Radiologists and are indeed used regularly to maintain the high degree of safety associated with Interventional Radiology procedures, other clinicians are often unaware of the opportunities that exist to manage problems generated both from within the hospital and from outside. In addition the advent of arterial closure devices, which provide mechanical closure of the remote arterial access site used to deliver these treatments, means that minor degrees of clotting abnormality are of relatively little consequence. This is of great use when considering the management of patients who have undergone major trauma, and may have disorders of clotting as a result of the blood loss and replacement. Such advantages make IR approaches even more useful, as in these circumstances open surgery is often contraindicated.

Endovascular approaches to treatment of trauma have been described in many circumstances, including hepatic and splenic injuries (1-3), renal trauma (4-5), pelvic and limb injuries (6) and many less common sites of traumatic bleeding (7). IR's have a duty to patients to make other clinical groups aware of what can be offered and to ensure that the circumstances (rotas) are such that these life saving interventions can be offered when they are needed (24 hours a day). This may require IR's to work in groups, teams and networks and it certainly will require that IR's take a more direct role in the clinical management of patients and raise their profile within institutions.

At present many doctors treating patients who have undergone trauma give little thought to considering IR treatments for their patients (8). The consequences for those patients may be prolonged bleeding, unnecessary transfusion of blood products and the cardiovascular consequences of major blood loss.

Whilst trauma can be conveniently considered as either that resulting from medical procedures (iatrogenic) or from outside, the IR treatment options are usually based around

- embolisation
- stent-grafts
- stents

### Embolisation for Trauma

Embolisation is the process whereby a blood vessel is blocked, thereby interrupting the flow in that vessel, with the purpose of either stopping bleeding or reducing the blood flow to a tumour. In the context of trauma, it is usually the former that is intended. Embolisation may be achieved by the delivery of particles, liquids, or devices which are designed to block the blood flow. In the earliest descriptions patient's own blood was removed, allowed to clot, and this was then reintroduced via a catheter placed as closely as possible to the bleeding site. In some ways this was a most elegant method of embolisation, as the material used was not a foreign body, there was no risk of an allergic reaction and there was no risk of external infection. However, in the field of trauma the application was limited, as the clotted blood was of unpredictable dimensions and effected a very temporary occlusion, as the patient's endogenous lytic agents caused it to dissolve and allowed blood flow to re-establish.

Since then a variety of embolic agents have been developed which may be temporary or permanent and are available in a variety of sizes. In this way if an artery that is bleeding can be identified, the segment of the vessel that has a defect can be identified and the blood flow to it stopped. At the time of traumatic bleeding the supply to the bleeding vessel may be a part of an end organ supply, in which case interrupting the in-flow to that region will effectively treat the bleeding (Fig. 1).

This may be the intention so long as the vascular bed embolised is not critical to the patient's survival. In such circumstances a non-permanent embolisation is ideal, giving the patient time to heal the defect, and allow revascularisation at some time in the future. A non-permanent agent such as gelfoam is well suited to such circumstances allowing for healing and repair prior to the agent dissolving away (Fig. 2).

One of the limitations of gelfoam is that it has to be cut by hand prior to use and the sizes of particles are generally both relatively large and variable. In addition its use with micro-catheters is significantly limited which means that it has to be delivered from relatively large arteries. This almost inevitably means that it is relatively distant from the bleeding point. More

recently particles with a greater degree of size reliability have become available, however these tend to be more permanent, which must be taken into account when choosing the embolic agent. However, they are suitable for use with micro-catheters, allowing for a much more sub-selective delivery of the agents.

One of the safety mechanisms developed by many parts of the body is the collateral circulation which protects against the loss of an artery. This allows for blood to flow in a reversed direction from an alternative arterial source and therefore to maintain tissue perfusion. This is potentially problematic from the perspective of embolisation. If a traumatic event occurs which causes an artery wall to lacerate, blood can potentially reach this site from the normal antegrade approach. However, if this is occluded by embolisation, bleeding can continue via the collateral supply. Therefore, for embolisation to be effective both, the collateral ("back door") supply and the antegrade ("front door") supply must be blocked.

It is usual for a bleeding point to be approached along the line of the normal flow, therefore it is important that the delivery catheter be passed such that it is possible to embolise (usually with coils) the collateral supply (known as embolising the back door) first, the catheter can then be withdrawn to allow embolisation of the "front door" (Fig. 3). Should the "front door" be closed first, it is usually very difficult or impossible to achieve access to the "back door". If this were to occur, then effective embolisation would not be achieved. Indeed it is always worth remembering that coil embolisation is often a very effective procedure. However, once an artery has been coiled, it will no longer be possible to access that artery distal to the coils.

### Stent Grafts

One of the problems of embolisation for trauma is that arteries and veins are deliberately occluded, often in a permanent fashion. This has the potential to be harmful for a patient. The recent development of stent-grafts (covered stents) has offered an alternative method for sealing a hole/laceration produced in an artery as a result of trauma. Covered stents were originally developed to treat aneurysmal disease. However, the fact that they are a metal frame upon which a covering is mounted or incorporated means that they are well suited to sealing arterial tears whilst maintaining an arterial lumen and therefore perfusion to the arterial bed distally. In general terms stent-grafts are more bulky to deliver than their uncovered equivalents and are less flexible. As a result it may be difficult to place stent-grafts into the necessary place to effect treatment, and this is particularly so as arteries become smaller and

### Don't miss it!

Trauma  
Foundation Course  
Sunday, September 20, 08:30-09:30  
Auditorium 1

more difficult to access. Therefore stent-grafts are very well suited to treatment of larger vessels such as the aorta (Fig. 4), but may be less applicable to smaller arteries where access is more difficult.

### Uncovered Stents

Not all of the endovascular treatment for trauma centres on the cessation of bleeding. In some circumstances trauma results in disruption of the arterial wall and this in turn leads to an intimal tear, which causes the lumen to be occluded. In some situations this results in end organ ischemia which needs to be relieved. In these situations it is often possible to pass a guidewire in either an antegrade or retrograde approach to cross the occluded segment and join the two patent regions. Once this has been achieved, the intimal disruption can be pushed back into position by the placement of an open mesh stent. In this way antegrade (normal direction) blood flow can be re-established (Fig. 5).

### Conclusions

As indicated above, Interventional Radiology has a great deal to offer in the field of trauma, both in the cessation of life-threatening bleeding and the re-establishment of tissue perfusion. There remain two very significant hurdles to widespread use of these techniques in routine trauma practice. Firstly is the appreciation by trauma surgeons and specialists that IR has much to offer in this area of patient care. The second hurdle is the availability (and willingness) of suitably trained individuals and teams of IR's to provide this facility. Unfortunately it is a fact of life that trauma occurs at unsocial hours and presents clinical teams with stressful and difficult clinical scenarios. It is the responsibility of IR's to make ourselves available, through sustainable and organised rotas, in order to provide the trauma care that patients need and deserve.

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7. Successful angiographic embolisation of bleeding into the chest wall after chest drain insertion. Khalil MW, Cleveland TJ, Sarkar PK, Rao J. *Interactive Cardiovascular & Thoracic Surgery*. 8(1):166-7, 2009 Jan.
8. Damage Control Resuscitation for Patients with Major Trauma. Jansen J O, Thomas R, Loudon MA, Brooks A. *BMJ*, 338: 1436-1440



Fig.1a: Active bleeding seen from a splenic artery branch (arrow) following a road accident

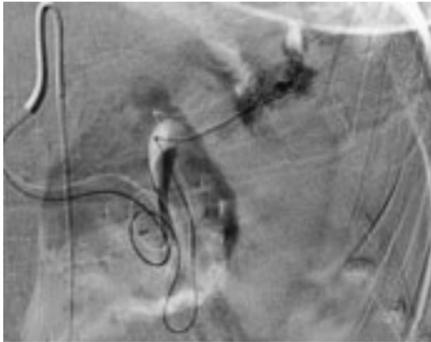


Fig.1b: A microcatheter has been passed to the bleeding site

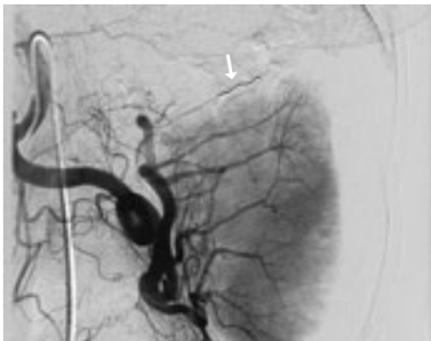


Fig.1c: A coil has been placed to stop the bleeding (arrow)

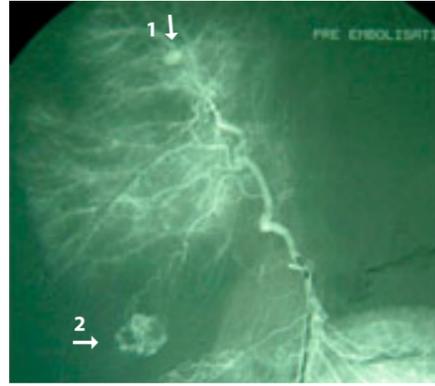


Fig.2a: Right hepatic artery angiogram in a patient who has sustained a liver laceration which was not controlled by a laparotomy. There is active bleeding into the gall bladder (arrow 1) and a pseudoaneurysm deep in the liver (arrow 2).



Fig.2b: Following gelfoam embolisation of the hepatic artery, both bleeding sources have been excluded

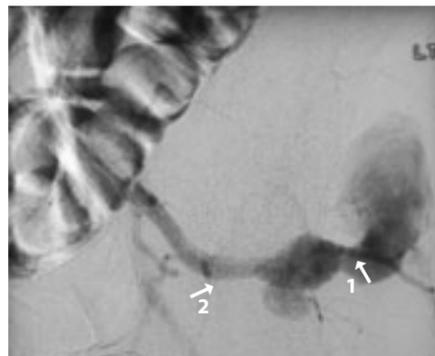


Fig.3: A laceration of the superior gluteal artery as a result of a knife wound. Embolisation required closure of both the "back door" (arrow 1) and the "front door" (arrow 2)



Fig.4a: Aortogram of an 18 year old back seat passenger in a road accident, showing a thoracic aortic transection

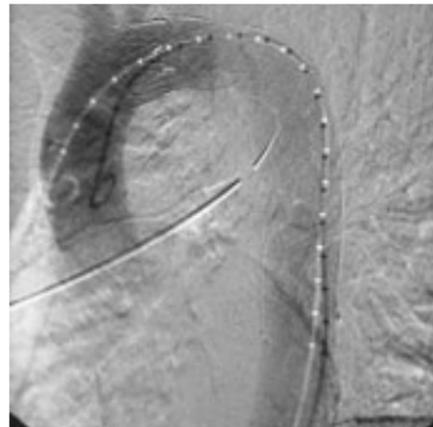


Fig.4b: Aortogram following placement of a stent-graft

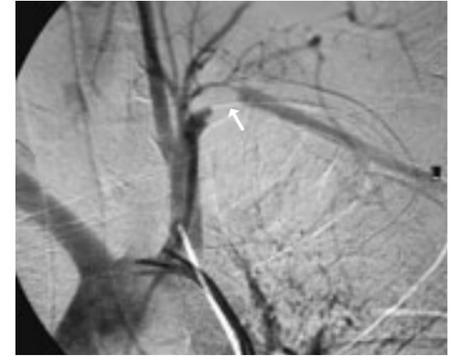


Fig.5a: Left subclavian angiogram showing an occlusion of the subclavian artery (arrow) due to a traumatic dissection after a motor cycle injury.

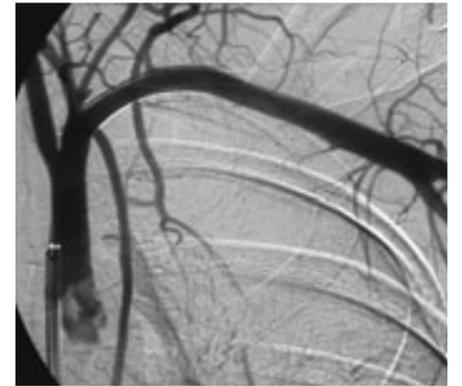


Fig.5b: The occluded segment has been treated with a stent

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**Not yet a member? Don't wait any longer!**  
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**CIRSE** Cardiovascular and Interventional Radiological Society of Europe  
Society

Advertorial

## Innova 3D clinical benefits for vascular interventions



Dr O. François  
Head of Department Interventional Radiology  
General Hospital ASZ Aalst, Belgium

### Background

The General Hospital ASZ in Aalst, Belgium is equipped with the Innova 3100IQ digital flat panel angiography system. The Innova 3100IQ system, installed by GE Healthcare has a 30cmx30cm digital detector designed to perform interventional procedures in radiology, neuroradiology, cardiology, gastro-enterology and anaesthesiology. Digital subtraction angiography (DSA), 3D Angiography and 3D CT imaging modalities were used to fully understand the following case study.

### Patient History

A 45-y-old man suffered from severe right sided headache since a few days. No other neurological abnormalities were found with clinical examination by a staff neurologist. A CT-scan of the brain was performed to exclude an intracranial haemorrhage. There was no intracranial bleeding, but the contrast enhanced CT scan (CECT) revealed a dissection of the right internal carotid artery (RICA).

### Procedure and discussion

The initial CECT, performed on 64-slice CT, was imported on the multi-modality Advantage Workstation™ Volume Share 2 and post-processed (Fig.1 and Fig.2). On the axial and

curved planar reconstructions of the RICA, it was not possible to see whether the lumen was partially or completely occluded by the dissection. A DSA acquisition was performed to evaluate the patency of the RICA, the extent of the dissection and the direction of the intracranial flow. Using a right femoral approach, a 4F Berenstein catheter (Angiodynamics, Queensbury, NY) was selectively placed in the right common carotid artery. The acquisition was performed (Fig. 3) with 10 cc of contrast media (300 mg I/ml) at 5 cc/s.

After sub selective placement of the catheter at the origin of the RICA, an Innova 3D acquisition is launched at 40°/s, using 16 cc of contrast media (300 mg I/ml) at 4 cc/s and an X-ray delay of 1 second.

On the AW, the 3D images were processed with 3D Volume Rendering (3DVR) (Fig.4 and Fig.6) and Maximal Intensity Projection (MIP) (Fig.5), through the dissection of the RICA and 3D CT images in axial plane (Fig.7)

The origin of the dissection is seen in the distal segment of the cervical, extracranial internal carotid artery. The false lumen, created by the dissection of the vessel wall has a re-entry in the true lumen of the RICA in the carotid channel of the petrosal bone.

This re-entry point is clearly depicted on the axial thin MIP reconstruction images.

### Conclusion

In this case the high quality of the 3DVR and axial cross-section images acquired with the Innova 3D acquisition gives an accurate and precise anatomical and diagnostic information on the dissection and vessel wall (re-entry) in planning an eventual endovascular treatment. The Innova 3D acquisition with intra-arterial contrast injection in the RICA provides more

and (extra)luminal information in comparison with a intravenous 64-slice CECT scan in eligible patients for interventional neurovascular procedures.

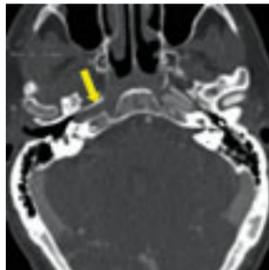


Fig.1: 64-slice-CT axial view at carotid channel level. It shows the absence of luminal contrast in the RICA.

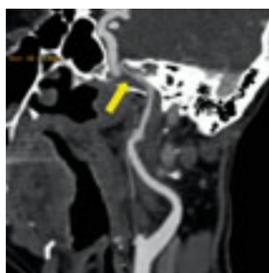


Fig.2: Curved planar reconstruction is highly suggestive for complete occlusion of the petrosal part of the RICA.



Fig.3: DSA, showing the lateral view of the RICA.



Fig.4: Innova 3D VR showing the RICA.



Fig.5: Innova 3D MIP Showing the dissection

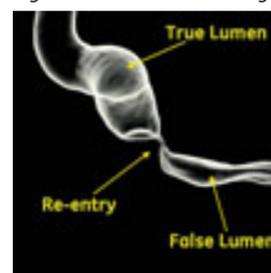


Fig.6: Innova 3D VR Showing the re-entry point

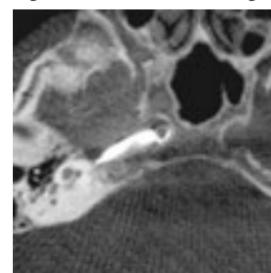


Fig.7: Axial view: True lumen (in black) and rim of contrast on the false lumen

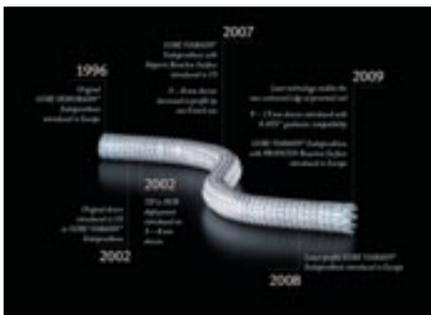
Advertorial

## GORE VIABAHN® Endoprosthesis: The Continuous Evolution of Performance



Gore's ongoing commitment to delivering innovative devices has allowed the rapid evolution of the GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface to address a broad range of physician and patient needs for sustained clinical performance.

Interventionalists treating patients suffering from Peripheral Vascular Disease (PVD) consistently look to the Medical Products Division of W. L. Gore & Associates, Inc. for innovative therapeutic solutions required to ensure patient safety and satisfaction.



GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

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The GORE VIABAHN® Endoprosthesis is the only stentgraft approved by the US Food and Drug Administration (FDA) for the treatment of patients suffering from PVD in superficial femoral artery (SFA) lesions and iliac artery lesions. The device is constructed with a durable, reinforced, biocompatible, expanded polytetrafluoroethylene (ePTFE) liner attached to an external nitinol stent structure. The flexibility of the GORE VIABAHN® Endoprosthesis enables it to traverse tortuous vasculature and to conform closely to the complex anatomy of the artery.

### Introduced in 1996

Gore has recently made a series of modifications to the product, demonstrating the company's commitment to its customers with innovative, nextgeneration devices. Since the introduction of the original GORE HEMOBAHN® Endoprosthesis in Europe in 1996, Gore has been committed to advancing manufacturing processes and implementing design enhancements.



### A History of Innovation

In 2002 Gore introduced TIP to HUB deployment on 5 – 8 mm devices. In 2008, Gore reduced delivery profile and, in 2009, added the PROPATEN Bioactive Surface. Also in 2009, manufacturing process were implemented that provided a contoured edge at the end of the endoprosthesis which may improve flow dynamics under conditions of oversizing\*.

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### Next Generation Now Available for Large Diameters

The most recent design for device diameters 9 – 13 mm is now also approved, enabling the same streamlined TIP to HUB deployment direction over an 0.035" guidewire as the 5 – 8 mm sizes. This latest change transitions all GORE HEMOBAHN® Devices into the GORE VIABAHN® Device family\*\*.

\* Data on file

\*\* Pending CE approval

## CIRSE African Grant - A Report

Ato Quansah

At last I was in Amsterdam! After many e-mails and letters and a two hour delay at Frankfurt airport I had arrived in the Netherlands and finally got to meet Professors Reekers and Lameris. After a quick introduction to my instructors it was time to go to bed after a long and tiring trip, but it was only an hour later that I could find my apartment on that cold winter night, so the first day of my educational stay was quite exhausting.

Wow! - that was my initial impression of the interventional radiology suites at the AMC which undoubtedly must be one of the best hospitals in Europe; twelve weeks of living within the pages of a text book had begun.

With countless opportunities to assist in various kinds of procedures, I got to attempt a few myself. The most common procedures included ultrasound guided biopsies mainly of intra abdominal tumours and lymph nodes. The luxury of having a cytologist right there, in the IR suite, meant that we could almost instantly be sure whether we had a good sample or not. I had never experienced that.

The Rotex screw needles were my personal favourite. (Ursus should give me free samples for this free publicity, ha ha!). I was also exposed to the use of several other biopsy guns including stereotactic biopsy as well as CT guided biopsy for breast and other lesions. On my first weekend I had the opportunity to watch a fluoroscopy guided bone biopsy from the 12th thoracic vertebra via the pedicle performed right before my eyes. This was to be followed by one of the most fascinating procedures I ever imagined; a transjugular hepatic biopsy which I again had the privilege to assist. I had a go at a percutaneous gastrostomy as well.

I greatly enjoyed working with my Dutch colleagues and soon we had special nick names for each other. The times I spent in the vascular suite were even more exciting, as I had the opportunity to assist in cases of thrombosuction and the deployment of vena caval filters. The dream to see a UAE and other arterial embolizations became a reality. Assisting in many angiographic procedures performed by Prof. Reekers at different times was a great learning experience which I will cherish forever. Training the recanalization of stenosed AV shunts for patients on dialysis was of immense value considering the fact that we have a growing number of patients on dialysis in Ghana as well.

A quick tour through the IR store, however, reminded me of the reality, of how hard it would be to transfer such sophistication to the ordinary person in Africa. A microcatheter priced at € 800 for one procedure is obviously beyond the reach of an ordinary middle income worker in Africa. Then I remembered Prof. Lameris saying "I am always thankful I do not have to think whether the patient can afford it or not. I just use it when I need it". His patients are lucky enough to be entirely covered by a good health care system. Back home I have to rely on a few donated packs and procure a few more catheters from the US via a relative who resides there to make IR possible in Ghana and Kumasi where I am based. At \$ 35 or more per set, one procedure costs the patient close to \$ 60. As IR procedures become more popular, hopefully the newly established health insurance schemes in my country will accept to run with these costs on behalf of their patients. Donations will also be gladly accepted. Hopefully some day I will be able to say what Prof. Lameris said for my patients as well.

Back home I have been busy with introducing and promoting IR with great acceptance especially from the departments of surgery, child health and internal medicine, in that order. It is my hope that adjuvant IR procedures will be introduced for patients with prolonged small bowel perforation resulting from typhoid fever, which is quite prevalent.

The first PTC was to be attempted in a 30 year old woman with what I suspect could be retroperitoneal fibrosis presented with such severe obstructive jaundice. This was not to be, as her clotting profiles were so delayed by the laboratory that she died before I could attempt this procedure.

I had assisted and been coached during three of such procedures at the AMC and given three sets biliary drainage sets. Of course it was a great disappointment when nevertheless this young patient passed away. However with the skills I was able to acquire and my new knowledge in catheter and stent placement a successful procedure is surely beckoning. I hope to share my success story with you soon.

The second non palpable breast carcinoma was successfully operated after effectively and single-handedly placing a wire under ultrasound guidance.

My newly acquired knowledge in drainage of hydatid cysts allowed me to successfully drain and sclerose three intra-abdominal simple cystic lesions of tremendous volumes, the last one being 1600 mls. All patients are up and about again.

I have been able to drain large and longstanding intra abdominal abscesses achieving great outcomes. The abscess patients usually come from the hinterland where they are not diag-

nosed until late. The most recent reported case was a two week old baby with a volume of 1500 mls of frank pus. The satisfaction of achieving instant relief with clinical improvement has simply been amazing.

I have recently done a US guided biopsy of an intra abdominal mass. Sadly I have not had the possibility to attempt any vascular IR procedures. Using the facilities in one of our newly built theatres for IR procedures may avail me the opportunity of trying something simple soon, such as vena cava filter placement for lower limb DVT and some venograms.

I wish to thank CIRSE and everybody at the AMC most sincerely for sponsoring this three month fellowship in Interventional Radiology and for the opportunity to see, experience and interact with a "higher form" of Radiology than what I was used to.

I feel it is my duty to disseminate these invaluable skills to colleagues in other cities and regions of Ghana with the assistance of all those interested in spreading this "gospel" to help the poor and needy who suffer so much at the hands of quacks. My greatest appreciation goes to Prof. Dr. Jim Reekers for this initiative to have me trained, to Prof. Dr. J.S. Lameris for opening his department to me and allowing me to avail myself of this immense knowledge. My sincere thanks also go to the staff of the IR unit in AMC, Drs Van Liedden, Otto Van Delden, Mark Meier and Elham Ghazi. Thank you so much for your time and willingness to share your knowledge! Thank you also to Kenneth (I hope you read this) and the CIRSE staff in Vienna. And of course I would like to thank Dr. Elizabeth Joekes and Dr. Harmien Zonderland from the bottom of my heart; you started it all.



Assisting a thrombosuction in the angiosuite



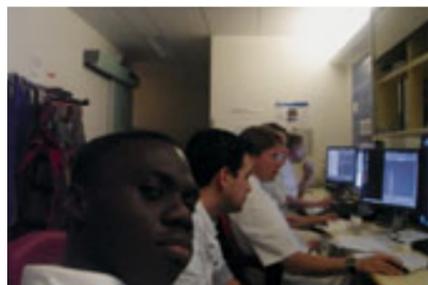
Back home in Ghana: success at draining a percutaneous intra-abdominal abscess



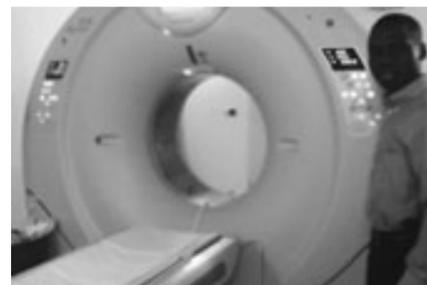
This 9 year old with an omental cyst could finally be diagnosed and the cyst drained.



Learning through discussions



At work in the emergency unit at the AMC



Dr Quansah admiring the CT scanner at Lieden Medical Center



Learning to introduce a guide wire properly



One of Dr. Quansah's patients in Ghana

## Review article from Cardiac & Vascular Update

Professor Jim Reekers,  
Chair of the Diabetic Leg Program Committee



# The Diabetic Leg Today symposium report

### Introduction

This year was the fifth installment of the annual Cordis Cardiac and Vascular Institute (CCVI) Endovascular Symposium on Peripheral Vascular Disease (PVD). As in previous years, the Symposium was held at the European Surgical Institute (ESI) in Hamburg, Germany. Even though the first Symposium was dedicated to carotid disease, the last four have been dedicated to lower limb PVD. The topic for this year was 'The Diabetic Leg Today'. This was in acknowledgement of the current and future impact of the growing diabetes pandemic on PVD and its treatment. Cordis, a division of Johnson & Johnson, is uniquely positioned to address diabetes and PVD in a holistic fashion through partnership with other Johnson & Johnson divisions such as Lifescan and the Johnson & Johnson Diabetes Institute.

Diabetes and diabetes-related medical problems are a fast growing global health problem. The number of patients with known type 2 diabetes in the Western world is increasing every year and exceeding all predictions. It is estimated that about 30% of all these patients will develop vascular problems. Of this group, 4-5% will eventually undergo an amputation. Most patients who undergo amputation have a history of a non-healing ischemic ulcer. A crucial point in preventing amputation is early ulcer healing. It has become more evident recently that early intervention for revascularisation plays an important role in preventing amputations. It is also clear that treatment of ischemic diabetic ulcers needs a multidisciplinary approach.

Treating diabetic vascular disease is more than treating local vascular lesions. Of course, the interventional techniques and skills are important and were discussed at the meeting. Endovascular intervention, employing minimally invasive, catheter-based technologies, is becoming the treatment of



choice for diabetic leg disease. The development of new technologies and clinical studies are contributing to the shift to less invasive treatment. Through a series of expert presentations and question-and-answer sessions, the distinguished faculty examined the evolution in PVD, diabetes and therapeutic choices available to practicing physicians treating leg PVD. Interventionalists also need to have more background in diabetic vascular disease to be able to fully participate in their local diabetic foot team. Interventionalists have the unique possibility to really make a difference in this patient group by offering them good minimally invasive care. However, only interventionalists who will take the holistic patient-centred approach will be successful in the future.

This year, there were a few firsts for the Symposium. It was the first time ever that we published a book of abstracts on any CCVI Endovascular event. It was also the first

time we had a 'chaise longue' setup for the interactive sessions, which worked extremely well and gave a relaxed interactive feel to the discussions. We also added interesting presentations on new topics such as plastic surgery reconstruction of the diabetic foot and the health economic considerations in the treatment of diabetic foot ulcers.

Finally, there was a fun run on the second morning. Even though it was raining, the winning time was under 8 minutes on the beautiful track between the trees and the golf course. No mean feat! It may have been labelled a 'fun run' but there was a serious side to this event with Jim Reekers presenting a cheque for €1,000 to Karel Bakker, Chair, Consultative Section on the Diabetic Foot, International Diabetes Federation. Thanking Cordis and those who had part in the fun run, Dr Bakker informed attendees that the donation would go to the 'Step by Step, improving diabetic foot care in the developing world' project, currently executed in the Caribbean Region.

The feedback on these changes from the more than 175 attendees was positive across the board, and the plan is to add more surprises for the Leg Symposium in 2010. Hope to see you there!

To read or download a copy of the abstract book for the symposium 'The Diabetic Leg Today' please go to [www.ccv-online.com](http://www.ccv-online.com)



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## CIRSE Supports Major European Campaign for Interventional Radiology



*"Doing business without advertising is like winking at a girl in the dark. You know what you are doing, but nobody else does."*

Steuart Henderson Britt

... And Interventional Radiology fares no differently.

Interventional radiologists everywhere should be bursting with pride at the thought of the discipline's progress since its beginnings in the late 1950s. Its superiority in terms of preserving the integrity of the body as well as its limitless scope have made it a most inspiring area to be a part of in any capacity.

CIRSE has always provided substantial backing for appropriate projects which aim to raise awareness of Interventional Radiology and this is one of the most significant to date.

The brand new magazine *Interventional Quarter* places minimally invasive medicine under the floodlights, making it visible not only to radiologists and referring physicians but also hospital administrators, healthcare politicians, the medical insurance industry and healthcare providers. It provides accurate, independent, unbiased coverage of all aspects of minimally invasive medicine ensuring all voices are heard loudly and clearly.

The launch edition of *Interventional Quarter* addresses the role of minimally invasive techniques in diabetes care. The reality of diabetic life, the available treatments, what role interventional medicine can play, and the political and economic issues surrounding this condition are all discussed.

**Interventional Quarter will have a circulation of around 35,000, comprising medical professionals, hospital management and some of the most influential decision-makers in healthcare today.**

If you think any of your colleagues, be they referring physicians, hospital administrators, or local healthcare politicians, etc. could benefit from receiving *Interventional Quarter*, please visit [www.intervention-iq.org](http://www.intervention-iq.org) to add their details to the mailing list.

**Interventional Quarter:  
expanding the reach of the discipline**

**A copy of *Interventional Quarter* can be found in all congress bags as well as at the Interventional Quarter booth (78)**

## Film Interpretation Panel

Join us for this year's  
Film Interpretation Panel and see  
how much fun an educational  
session can be!

Together with junior panellists  
senior IRs will diagnose several  
tricky cases.

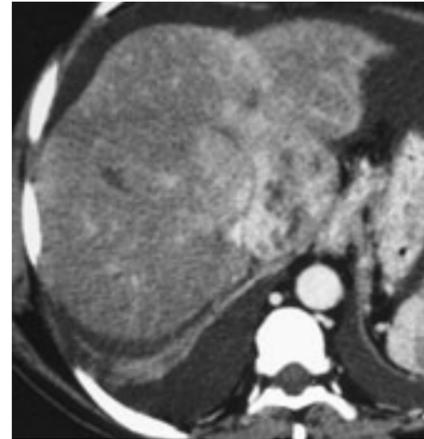
To give you a head start, we are  
showing you the cases in advance.



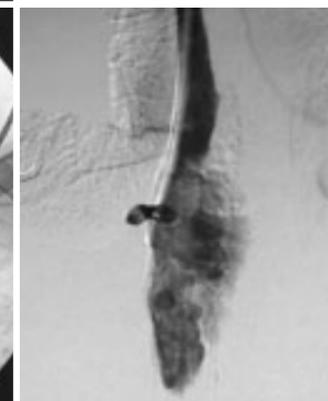
### Case A

Male, 44 y.o.

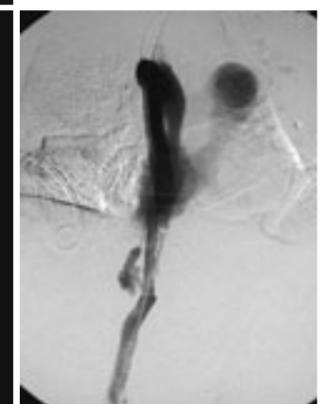
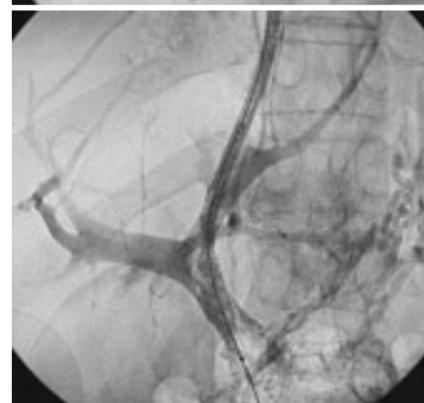
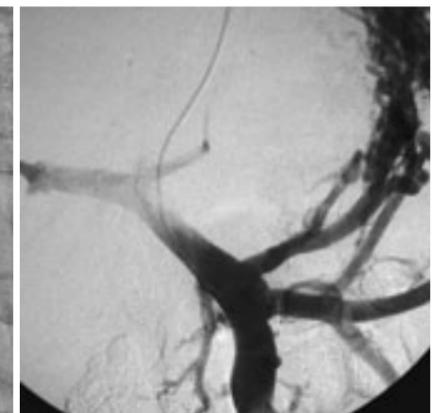
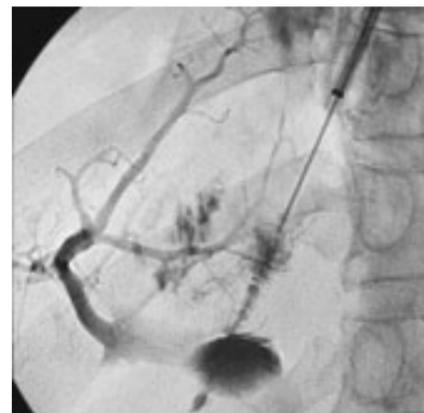
- HCV + cirrhosis, drug abuse
- Suspected hypercoagulable disorder
  - Progressive liver insufficiency
  - Diagnosis of Budd-Chiari syndrome
    - Hepatorenal syndrome, anuria, stage IV hepatic encephalopathy
    - Bilateral pleural effusion and ascites
    - TIPS was proposed



Rt jugular vein thrombosis



Lt jugular vein thrombosis



**What is your diagnosis?**

**Don't miss it!**

**Film Interpretation Panel**

Monday, September 21, 15:00-16:00

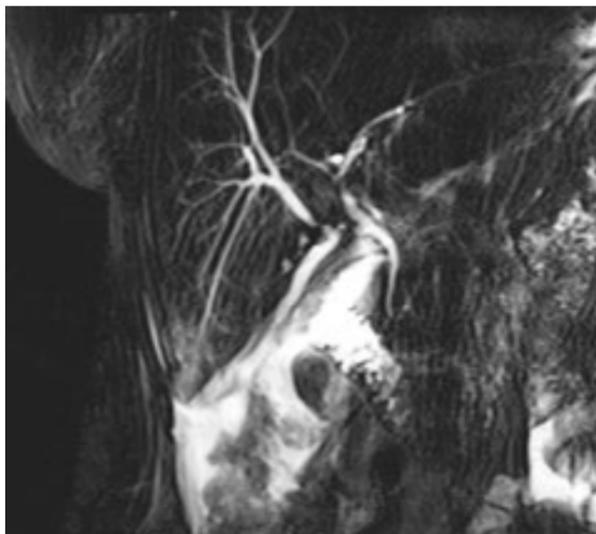
Auditorium 1



## Case B

Female, 32 y.o.

- Laparoscopic cholecystectomy for gallstones
- Leak from subhepatic drain after 12-24 hrs.
- ERCP done after 3 days.
  - Little sludge, no stones, no leak, normal biliary tree.
  - Endoscopic sphincterotomy performed.
- No improvement after other 2 days.
  - Leak persists. Fever (37.8°C)
- MRCP



**What is your diagnosis?**

## Case C

Female, 27 y.o.

- Routine chest X-ray taken as part of pre-employment exams
  - no symptoms, no history of trauma



**What is your diagnosis?**

As a special service to its members, CIRSE is offering a CIRSE Members Lounge at CIRSE 2009

# Members' Lounge

Cardiovascular and Interventional Radiological Society of Europe

Located in the foyer on the first floor it provides all CIRSE members wishing to relax between sessions in a comfortable atmosphere and around

the clock catering. For those who wish to use their breaks to catch up on some work or check their e-mails, W-LAN is available.

## Exhibition on the Pioneers of Angiography



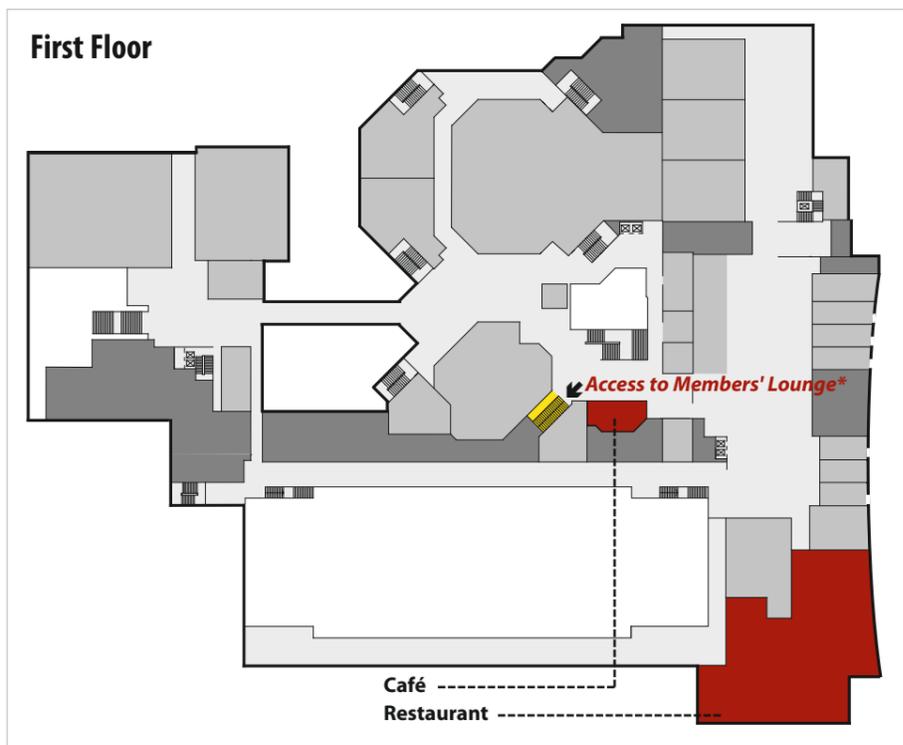
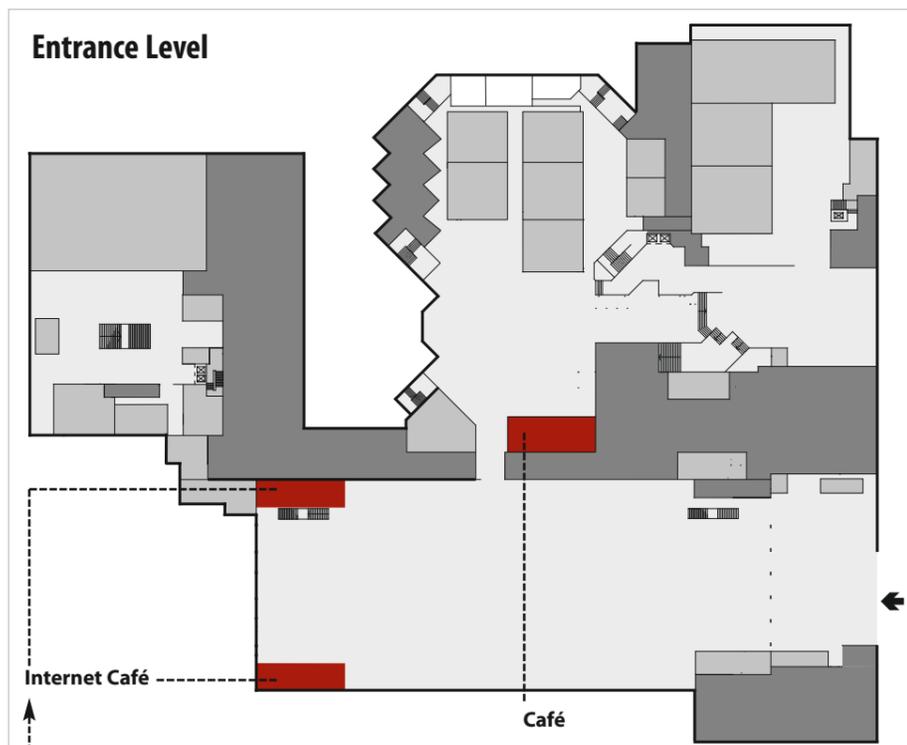
On the occasion of CIRSE 2009 CIRSE is celebrating the achievements of Nobel Prize Laureate Egas Moniz and the Portuguese School of Angiography with an exhibition about the discoveries of this remarkable group of physicians.

We warmly invite you to visit the exhibition including the table first used in cerebral angiography by Egas Moniz, located in front of Auditorium 6.

## Don't go hungry! Catering at CIRSE 2009

### Opening Hours

Restaurant (first floor)	12:30-15:30
Café Bar (ground floor)	08:00-18:00
Café Bar (first floor)	08:00-18:00



Complementary coffee will be served here at the following times:

Saturday, September 19	11:00-11:30	15:30-16:00
Sunday, September 20	11:00-11:30	16:00-16:30
Monday, September 21	11:00-11:30	16:00-16:30
Tuesday, September 22	11:00-11:30	14:45-15:15
Wednesday, September 23	11:00-11:30	

\* Around the clock catering will be offered here for all CIRSE members

## The Age of Discovery – A slice of Africa anyone?

Petra Mann  
CIRSE Office

The Age of Discovery was the time at which Europeans, mainly the Portuguese, Spanish and English, explored the world oceans searching for trading partners and exotic goods, such as spices and cheap knock-off watches. Portugal's colonial ambitions began when Portuguese navigators started exploring the coast of Africa as early as 1419, helped by recent developments in navigation, cartography and maritime technology. According to history text books the Age of Discovery lasted until the 17<sup>th</sup> century. If you ask me, it hasn't ended yet, as a decent tasting diet coke or a comfortable plane seat have yet to be found.

Another important factor for the onset of the Age of Discovery was the development of the caravel, a small, highly manoeuvrable two or three mast ship with lateen sails. Commissioned by Henry the Navigator, it was based on the so-called qarib used by Muslim Andalusian explorers in the 13<sup>th</sup> century, obviously a time before copyright.

Since seafaring in the 15<sup>th</sup> and 16<sup>th</sup> centuries was not exactly a walk in the park, explorers were often hard-pressed to find anyone who would be willing to stay locked up on a ship for months with the only entertainment being bird-poop dodging. The chances of survival for the average sailor, which were sometimes as bad as three to one, did not exactly make a great selling point either. This is why some of the more assertive employers resorted to "shanghaiing" to persuade the unknowing pub-drunk of the advantages of a career at sea. It would consist in, let's say, "over-serving" the targeted individual in a tavern. Later his unconscious body would be provided with shelter on a boat which just so happened to embark on a very long and treacherous journey.

Now imagine waking up with the hang-over of a lifetime and discovering that

- you live in a time before aspirin,
- the place where you are headed is uncharted territory marked "Good luck!" on the map,
- you have just been volunteered for a month if not year long trip, possibly ending in scurvy, the loss of a couple of limbs or quite possibly death,
- you are pretty sure you left your iron plugged in.

### THE WHO-IS-WHO OF PORTUGUESE SEAFARING

#### Henry the Navigator

Henry the Navigator, who ruled Portugal in the early 15<sup>th</sup> century, is considered the founding father of the Portuguese Empire, having a great passion for seafaring and the necessary cash to go along with it. He first started exploring the coast of Africa in the pursuit to stop the pirates coming from there to capture Portuguese as their slaves. Henry then figured that while he was already there, he might as well keep going down the coast and dip into the gold trade, as a king can never have too much bling.

As a result of Henry's ambitions Portuguese explorers discovered the Madeira Islands which are still part of Portugal. Technically speaking the islands were discovered by accident when two of Henry's captains were stranded there in a storm. Later they returned to claim the islands for Portugal by sticking a flag in it, not unlike claiming a doughnut by licking it. Shortly after, the Azores were discovered, surely destroying Madeira's real estate market.

#### Vasco da Gama

Vasco da Gama was the commander of the first ships to sail directly from Europe to India in 1497/98, a time when Christopher Columbus was still wondering why the people he called Indians could not cook up a decent curry.

Vasco da Gama has two alternating birth dates, depending on the different historic reports, quite similarly to most women past 50. What is certain though is that da Gama set out from Lisbon for his famed voyage to India in July of 1497. He left port with four ships and 170 men out of which only 54 returned (really makes you wonder what his job advertisements must have looked like).

Once he had reached the East African coast, da Gama realised that before crossing Muslim controlled waters he better make some friends, which is why he met with the Sultan of Mozambique. Having nothing to offer but some left over pickles and 6 months worth of toe-nail clippings, it didn't take long until the explorer and his men were chased out of the sultanate. Their response? Firing their canons back at the city, because you just don't mess with a bunch of men who haven't seen a female or at least a decent drink in half a year! Since they were already at it, da Gama's men also looted several Arab merchant ships, a rather inglorious detail often forgotten in history books.

The fleet arrived in Calicut on May 20, 1498, only 10 months and 12 days after departing from Lisbon, a feat most charter airlines have yet to achieve.

#### Pedro Álvarez Cabral

Knowing that Pedro Álvarez Cabral had received excellent nautical training, King Manuel I. commissioned him to continue Vasco da Gama's work. The king also wanted Cabral to introduce Christianity wherever he went "using force of arms if necessary", because nothing says love thy neighbour like a head on a fence post, plus I'm pretty sure this would make the trips tax deductible.

In 1500 Cabral set out to re-trace Vasco da Gama's route, but trying to avoid the calm waters of the Gulf of Guinea drifted off just a notch, making him the first European to land on the coasts of Brazil. Like most explorers of the time (and men in general) Cabral had no clue where his short cut had landed him and named the newly found land Vera Cruz. At first, Portugal had very little interest in Brazil, as it could not contribute to the lucrative spice trade and Samba hat not yet been invented.

#### Ferdinand Magellan

Ferdinand Magellan was born around 1480. Originally stemming from Portugal he later adopted the Spanish nationality to sail for the Spanish court, which his why both countries like to claim him for themselves. Despite his many other voyages, Magellan is of course most famous for being the first person to circumnavigate the earth. What is less commonly known is that he died halfway through the trip in a battle in the Philippines, but doing the rest of the trip as a corpse apparently counts, too.

Only a few months after having set out on his journey, Magellan had to fight off a mutiny, executing one of its instigators and marooning two other, i.e. leaving them behind on a deserted island without provisions or suntan lotion. Magellan and his crew then became the first Europeans to enter the Pacific, rounding the tip of South America and giving the strait between Chile and Tierra del Fuego the name Strait of Magellan.



Out of the 237 men who had set out to circumnavigate the earth only 52 returned, destroying Magellan's chances to become employer of the year.



Life on board was not for the squeamish, harsh punishments being imposed for mutiny, stealing provisions and asking "Are we there yet?"

IR Congress News is published as an additional source of information for all CIRSE 2009 participants. The articles and advertorials in this newspaper reflect the authors' opinion. CIRSE does not accept any responsibility regarding their content. If you have any questions about this publication, please contact us at [mann@cirse.org](mailto:mann@cirse.org).

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# It's a matter of millimetres.

**KYPHON® Express™ System** gives you access to smaller, higher thoracic vertebrae. Maybe it's time for you to hear about the difference? We look forward to seeing you at the Medtronic Satellite Symposium at CIRSE 2009.

Sunday, September 20, 2009 | 18.40 - 19.40 | Auditorium 3



## Latest KYPHON® Balloon Kyphoplasty Innovations: Do they change the great debate about Vertebroplasty versus Kyphoplasty?

**Programme:**

**18.40 - 19.00:**

KYPHON® Balloon Kyphoplasty Innovations:  
What is changing, what is not changing?

**19.00 - 19.20:**

KYPHON® Balloon Kyphoplasty:  
The benefit of smaller tools

**19.20 - 19.40:**

The great debate: Vertebroplasty versus  
Kyphoplasty: What is the way forward?

**Faculty:**

Dr. Gerrit Bonacker,  
Praxisklinik Mittelhessen, Germany

Dr. Hendrik Fransen,  
AZ St. Lucas Gent, Belgium