

Intervention

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**IR Becomes Official
UEMS Division**

**Non-Dedicated Staff:
may cause serious
side-effects**

The Early Days of IR

Diabetes

An Interventional Response

**The Crippling
Cost of Diabetes**

**Type I Diabetes:
closer to a cure**

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Discuss ...

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A Welcome from the Editor



Dear Readers,

First of all, a warm welcome to the launch issue of Interventional Quarter: the independent, non-commercial magazine taking you on a journey through the world of minimally invasive therapy under image guidance.

The procedures, the profession, as well as health economics and politics will all be addressed in an open and unbiased fashion, targeting all levels of healthcare, thereby expanding the current reach of the discipline.

Furthermore, every issue offers an all-encompassing report on a specific condition or disease area - in this case, the extensive scope of diabetes - including the benefits as well as drawbacks of employing specific interventional radiology methods in the diagnosis, treatment and cure of a condition, with an emphasis on optimal patient service and care.

Interventional Quarter will be published four times a year; for guaranteed access to some of the latest and most effective treatments in medicine today, make sure your address is included in our mailing list; please see details on page 2.

We are especially enthusiastic about the presence of Interventional Quarter online as it opens the doors to collaboration with other esteemed publications dealing with minimally invasive image-guided therapy. The product of this friendly teamwork can be witnessed at www.intervention-iq.org, your "one-stop" daily resource for clear, relevant, up-to-date news, reports and highlights from the realms of the discipline.

We place much importance on freedom of speech and open discussion; please feel free to contact us at info@intervention-iq.org with your feedback on any of the issues discussed in either the online or printed editions of Interventional Quarter.

As you may already be aware, interventional radiology has undergone rapid development in the last 40 years, evolving into a viable alternative for a number of open-surgery procedures and it is also one of the fastest growing sub-divisions of radiology. Interventional Quarter presents the discipline with a unique opportunity to directly communicate and interact with its peers to strengthen the situation of advanced healthcare for all.

We very much hope you enjoy the launch issue of Interventional Quarter.

A handwritten signature in black ink, appearing to read 'Jim Reekers', written in a cursive style.

Professor Jim A. Reekers
Editor-in-Chief

General Information

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An invitation to our readers

IQ is your magazine, and we would welcome your views and your news. Readers who wish to comment on any of the issues raised (or who would like to raise any of their own) are most welcome to submit letters to the Editor. Likewise, if you have any promotions, awards, honorary lectures or other tit-bits you'd like to share with the interventional community, please send them to us by post or by email.

We look forward to hearing from you!
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Diabetes:

an Interventional Response

In the Middle Ages, they used to taste urine to test for diabetes; 90 years ago, experiments on dogs paved the way for insulin treatment - how far has medicine come in diabetes treatment, and how much do we actually know about it? Diabetes is predicted to reach pandemic levels within 15 years, but what are we doing to prevent its spread? IQ investigates the increasing role interventional radiology is playing to reduce its impact.

What is diabetes?

Diabetes is a metabolic disorder affecting the body's ability to control blood sugar levels.

This is down to either a lack of or insensitivity to a hormone called insulin.

Insulin is produced by the pancreas, and is used to regulate when we store excess glucose (sugar), and when we release stored glucose.

There are several different types of diabetes, the most common being diabetes mellitus Type 1 and Type 2.



www.worlddiabetesday.org
www.eatlas.idf.org
www.worlddiabetesfoundation.org
www.diabetes.org
www.diabetes.org.uk
www.euphix.org
www.tcoyd.org

Diabetes mellitus Type 1

Type 1 diabetes used to be known varyingly as “child-hood onset” or “insulin-dependant” diabetes, as it most frequently occurs in children, and requires life-long management using both insulin injections and strict diet. It occurs when the pancreas stops producing enough insulin, usually as a result of the body’s immune system attacking the Islets of Langerhans, a cluster of cells that house the insulin producing cells of the pancreas. Without sufficient insulin, the blood sugar levels are not regulated, and can reach dramatic lows (hypoglycaemia) or dangerous highs (hyperglycaemia), both of which can cause severe damage, immediate and long-term. Onset is usually sudden and quite dramatic, and symptoms include extreme thirst, frequent urination, insatiable hunger, weight loss and blurry vision. Without insulin, Type 1 diabetes leads to fatal results.

Diabetes mellitus Type 2

Type 2 diabetes was formerly referred to as “adult-onset diabetes”; as it most commonly occurs after the age of 40. However, it is affecting people at an ever younger age, and there are currently a worrying number of reports of children presenting with Type 2 diabetes. Type 2 diabetes is caused by the body becoming resistant to its own insulin levels, and having a relative insulin deficiency. It can remain asymptomatic and undetected for years. It is often associated with obesity, poor diet and inactivity - in other words, what is known as a “western” lifestyle, and is becoming ever more prevalent around the globe. Depending on its severity, it can often be managed with strict diet, improved exercise and weight loss, but some Type 2 sufferers can also become insulin dependent. Type 2 accounts for 85-95% of diabetes worldwide¹.

Symptoms

- Excessive thirst
- Frequent urination
- Constant hunger
- Weight loss
- Blurred vision
- Extreme sudden tiredness
- Irritability

Managing diabetes correctly is essential to maintaining good health

Management

Blood glucose

For all categories of diabetics, blood glucose monitoring is essential to controlling the disorder. Generally, patients will feel the effects of very high blood sugar, and get all the classic symptoms (thirst, fatigue, etc.), but the most effective way of monitoring accurately is using a blood glucose meter (a small computerised machine with a small screen like a calculator). This meter reads glucose strips, onto which the patient has put a drop of blood, usually taken from a finger using a special needle called a lancet. These tests may need to be done after fasting, or before or after meals. An HbA1c test is a profile average built up over several weeks, and gives a more accurate, reliable overall indication of your glucose levels. Urine glucose can also be measured using a lower-priced but less accurate test. The disadvantage of this type of testing is that it only returns a positive result for high glucose levels - it does not differentiate between normal and low blood sugar.

Oral medication

Based on the outcome of these glucose tests, diabetic patients may need to use the right amount of medication to balance their blood sugar. For patients with Type 2 diabetes, this is generally done using oral medication, such as OHAs, sulphonylureas or biguanides. These medications work by either stimulating the pancreas to produce more insulin or improve the effectiveness of existing insulin secretions. These are only effective for patients that are still producing some amount of insulin independently.

Insulin

Type 1 patients do not produce any of their own insulin, and so it must be delivered into the body artificially. Some Type 2 patients also require it. As insulin is a protein, it cannot be given orally, as stomach acid would dissolve it. It must be administered through the skin, either by injection or insulin pump. An insulin patch has also been devised, but is not ready for commercial sale, due to ineffectiveness and erratic absorption rates. However, an insulin inhaler is predicted to be ready for the market within a few years. Insulin cannot be substituted by regulatory tablets, and though it may seem expensive, a daily dose of insulin costs less than 3-4 cups of tea or coffee.

Ketone testing

Those with diabetes should also check their urine for ketones every so often using special testing strips. If present, they indicate that the body is burning fat for energy because there is insufficient insulin for glucose usage, or insufficient sugar in the body. When too many ketones are present in the body, it can lead to diabetic ketoacidosis, a life-threatening condition. The risk of developing this is higher during a period of illness.

Lifestyle choices

Supplementary to this, though no less important, are the lifestyle choices that can manage the condition better. Following a diet that carefully regulates intake of sugars and fats helps the body’s glucose levels to stabilise, and particularly for Type 2 patients, weight loss could help reduce the severity of their condition. Alongside dietary management, exercise can help weight loss and general health, as well as aiding stress relief. Stress can change the body’s hormones, and make it harder for insulin to do its job properly.

Complications

Controlling diabetes is essential to prevent immediate reactions such as ketoacidosis and diabetic coma, which can be swift and fatal. However, one of the most alarming and underestimated consequences of diabetes mellitus is the long-term damage that can result. High blood glucose levels (hyperglycaemia), which are symptomatic of diabetes, are harmful to the body's nerves and blood vessels. If left untreated, the damage to these nerves and blood vessels can lead to devastating complications, such as the total loss of sensation in the limbs, impotence, blindness, kidney failure, the need for amputation and serious cardiovascular diseases such as heart failure and stroke. Those with diabetes also face increased risk of bacterial or fungal skin conditions, oral infections, gastroparesis and depression.

Controlling diabetes is essential to prevent immediate reactions

Retinopathy

Damage of the retina (eye)

Symptoms

- blurred vision (macular edema - swelling of retina)
- blood leaks forming spots or clouds in vision
- blindness

Diabetic nephropathy

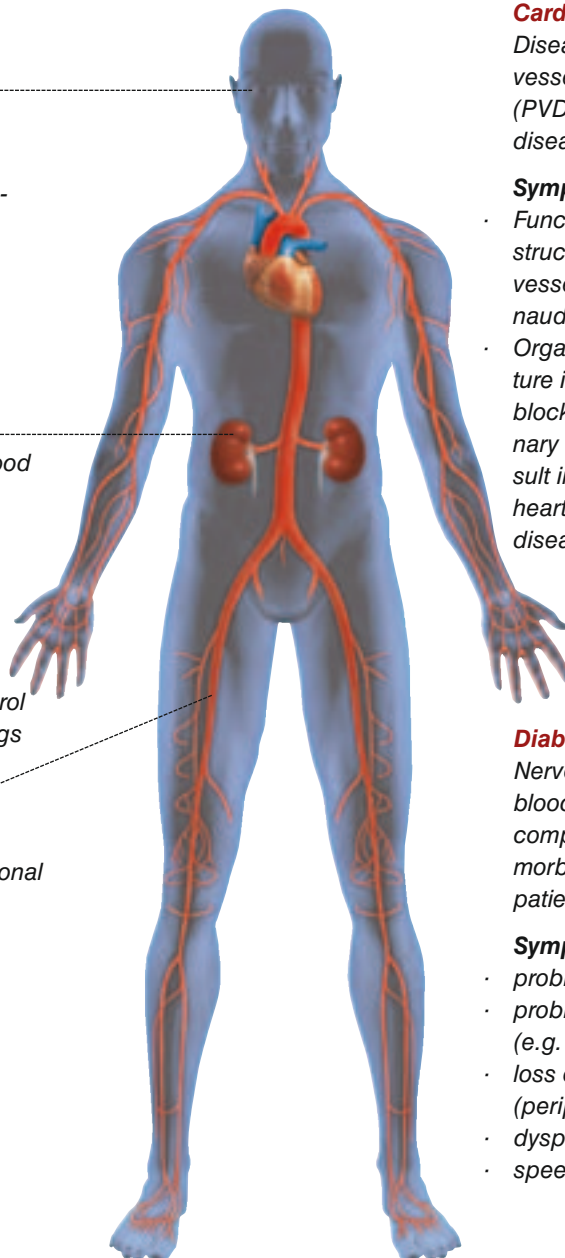
Kidney damage due to high blood glucose levels

Symptoms

- usually asymptomatic
- micro- or macroalbuminuria (protein leaking into the urine)
- build up of toxins in body
- higher blood pressure/cholesterol
- swelling (edema) in feet and legs (progressed)

Femoral Artery

Port of entry for many interventional procedures



Cardiovascular diseases (CVDs)

Diseases of the heart and blood vessels. Peripheral vascular disease (PVD) is a form of cardiovascular disease.

Symptoms

- Functional PVDs (do not involve structural malformations of blood vessels) - examples include: Raynaud's disease
- Organic PVDs (blood vessel structure is changed, for example, by a blockage) examples include: coronary artery disease, which can result in angina pectoralis. Strokes, heart attacks and peripheral arterial disease*

Diabetic neuropathy

Nerve damage as a result of high blood glucose levels. Most common complication and greatest source of morbidity and mortality in diabetes patients.

Symptoms

- problems urinating, impotence
- problems with various bodily organs (e.g. heart, stomach)
- loss of sensation in limbs (peripheral neuropathy)
- dysphagia (swallowing difficulty)
- speech or vision impairment

***Case Study: Peripheral arterial disease (PAD)**

Caused by a partial or total blockage of the peripheral arteries, it results in a decrease of blood flow in the limbs. In diabetes, this arterial blockage is typically located in the vessels below the knee. Due to the decreased peripheral blood flow, ulcers may appear, most commonly on the toes and heels, and may even become infected and gangrenous. These ulcers are usually painful, except in patients with peripheral neuropathy who have lost all sensation in the area. In the severe cases of PAD, the restriction of blood to the limbs can lead to their amputation.

Causes

In general, atherosclerotic PAD is different from diabetic induced PAD as this is more often located in the vessels above the knee. The most common cause of PAD is atherosclerosis - the gradual build up of cholesterol and scar tissue in the arteries. This restricts blood flow, limiting the supply of nutrients and oxygen to the various parts of the body. The arteries also become rigid and less able to respond to changes in blood flow and are thus often referred to as "hardened". Lifestyle choices such as smoking, poor diet and lack of exercise are also among the main causes of atherosclerosis and Type 2 diabetes.

Diagnosis

The Ankle-Brachial Blood Pressure Index (ABPI) is most commonly used for PAD screening and diagnosis. Here, the ratio of blood pressure in the lower legs is measured in relation to the blood pressure in the arms - lower pressure in the legs is an indication of atherosclerosis, which is symptomatic of PAD. Following the ABPI, further tests may be needed such as an angiograph, CT or MRI, which is a necessity if surgery is to be carried out. In some cases, the blood supply to the ankle is so weak that a Doppler probe or a Doppler ultrasonography may be necessary in order to locate the pulse.

PAD is one of the most common diabetes-induced cardiovascular complications

PAD in diabetes is often under-recognised as many patients may not experience symptoms



Increasing degree of atherosclerotic artery damage

Images supplied courtesy of Cordis Europe, a division of Johnson & Johnson Medical NV

Available treatments

Patients with diabetic foot and PAD should be closely monitored and daily foot inspections are paramount

For most patients with atherosclerotic PAD, quality of life can be improved with specific lifestyle changes, such as giving up smoking, blood pressure and diabetes control, making dietary changes and increasing their amount of exercise. In some cases, anti-platelet drugs or simple, common-or-garden aspirin can help those at risk of heart disease. Patients with diabetic foot and PAD should be closely monitored and daily foot inspections for injuries are also paramount to preventing severe infections. The recommendations of the WHO, International Diabetes Federation and World Bank follow the old adage of prevention being better than cure, and often simple, cost-effective treatments yield the greatest results. While lifestyle changes and medication may be effective in alleviating or preventing symptoms from worsening, some patients may need more advanced medical treatment. As diabetic complications are a result of damage to and blockages in the blood vessels, medicine's best option to prevent and reverse this damage is to find ways of increasing blood flow to those areas affected wherever possible. Luckily, many advances are being made, and a number of options are available to patients and doctors.

Interventional Radiological Procedure	What it involves	Further considerations
Percutaneous Transluminal Angioplasty (PTA)	A balloon-tipped catheter is inserted into the narrowed artery through a small nick in the patient's skin. The balloon is inflated to expand the blocked artery and then removed. A stent may be inserted to hold the artery open if needed.	Suitable for large and small arteries (see <i>illustrations opposite</i>).
Subintimal Angioplasty	Using the loop-wire technique, a new passage is created as opposed to re-opening an existing blocked passage.	Effective in treating large and small blood vessels, longer occlusions and calcified blockages.
Percutaneous Endarterectomy	Uses specially designed catheters to re-open occluded vessels by removing atheroma.	Can be used in larger vessels, but not in small vessels.
Cryoplasty	Balloon-tipped catheter filled with liquid nitrous oxide dilates and cools occlusions. No need for stents.	Suitable in peripheral arteries.
Laser Recanalisation	Laser irradiation of blockage - catheter accompanied by microlens-tipped optical fibre.	Only suitable for larger peripheral arteries.

Surgical Procedure	What it involves	Further considerations
Thromboendarterectomy	Surgical removal of blockage.	Only suitable for short lesions.
Bypass Grafting (revascularisation)	Relocates healthy veins to carry blood supply past damaged area. Relieves claudication and helps prevent the need for amputation.	Patients need to have good veins available to create the bypass.
Amputation	Removal of the affected limb.	Effect on quality of life and cost of follow-up care.

Minimally invasive methods to re-open occluded (blocked) or narrowed arteries include Percutaneous Transluminal Angioplasty (PTA), subintimal angioplasty, percutaneous endarterectomy, cryoplasty and laser recanalisation. Concerning PTA and subintimal angioplasty, numerous studies such as the BASIL trialⁱⁱ have confirmed their safety and benefits, which include lower risk of infection and surgical complications, and shorter hospitalisation and recovery times. This is not just a major advantage for the patient, but also saves on the costs of hospitalisation and follow-up costs, which can account for a huge portion of the associated costs of such procedures. An Italian studyⁱⁱⁱ on diabetic patients with severe PAD concluded that PTA should be regarded as a feasible treatment, especially for patients with severe foot ulcers.

Nevertheless, angioplasty is not always the treatment of choice for all patients and the importance of carrying out a thorough assessment of the extent of the occlusion before patient referral must be stressed. Surgical options should be reserved for patients for whom the less invasive option of PTA is not possible. However, recent advances in below the knee PTA technique with smaller wires and balloons have certainly increased the indications for below the knee PTA. PTA should therefore be the first choice treatment option. Occasionally PTA may be unsuccessful and an occlusion may reappear in the blood vessel. In such cases, surgery may be considered.

Angioplasty



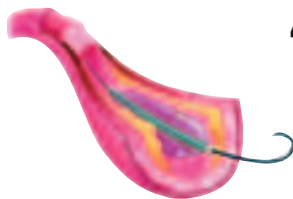
- 1** An artery obstructed by plaque. Poor blood circulation accounts for related symptoms.



- 2** First of all, a guidewire is inserted up to the lesion site.



- 3** An angioplasty balloon is pushed over the guidewire.



- 4** The balloon is inflated so as to widen the artery walls and compress the plaques (build up of cholesterol and fatty deposits on the artery walls).



- 5** In some cases, a stent (small metal mesh tube supporting the inside of the artery) is implanted. This can either be placed on the balloon or is, by nature, self-expandable.



- 6** The stent is positioned at the level of the lesion, the balloon is deflated and the guidewire removed - only the stent remains in place.



- 7** The artery walls are now widened, and blood circulation is back to normal.

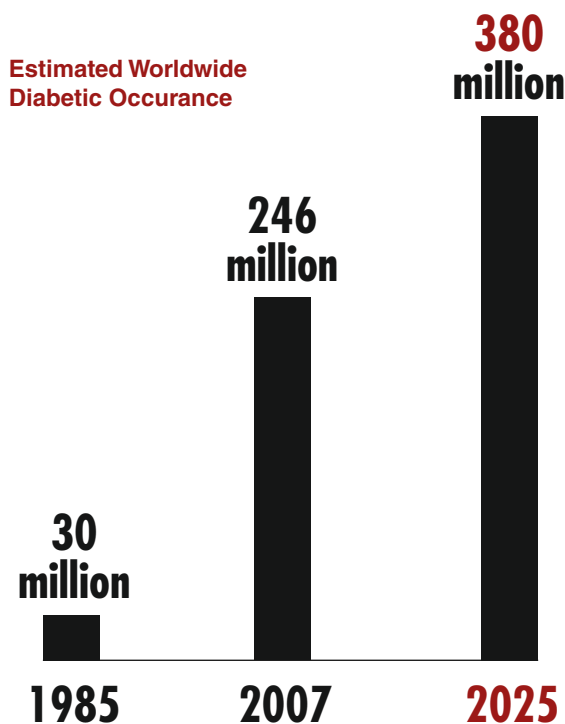
Images supplied courtesy of CIRSE

Concerning PTA and subintimal angioplasty, numerous studies have confirmed their safety and benefits

Diabetes causes as many deaths each year as HIV/AIDS

Diabetes is often known as a “silent killer”, as Type 2 can remain undetected for many years, and is often only detected when irreparable damage has already occurred, for example to the kidneys or eyes. It is also one of the most underestimated diseases in the world - far from being a disease of the rich and elderly, as it is often portrayed, it is one of the most common non-communicable diseases worldwide, and is on the rise. It is currently ranked as the fourth or fifth leading cause of death in the developed world, and as most diabetes deaths are officially put down to heart disease, stroke or renal failure (common complications of diabetes), the true toll could be even higher^{iv}.

The World Health Organization estimates that diabetes causes as many deaths each year as HIV/AIDS, but it receives far less attention or funding, as it is non-contagious. However, international bodies such as the United Nations, the WHO and the World Bank are starting to warn of the dangers of ignoring the growing incidence of diabetes.



Why IR is gaining ground

Interventional radiology can play an important role in reversing the effects of diabetic complications

So far, minimally invasive solutions have been found for a number of complications, and have proved to be highly effective. Of course, improved management of diabetes is the best solution, and will help reduce the incidence of complications, but even the most rigid blood sugar regimens can be insufficient to hold back the tide of devastation that this condition can wreak.

It is in these cases that interventional radiology can help. In many cases, it provides a better alternative to traditional surgical methods. For patients in a weakened condition, open surgery can be physically traumatic and dangerous, and may not be an option. Recovery can take longer, a negative consequence for both the patient and the health board's budget (see page 13). Bypass grafting, while producing similar outcomes, requires that the patient has sufficient healthy veins from which to make a graft vessel - and most often, this is not the case. In particular, for diabetic foot conditions, interventional radiology can help salvage a limb, which should always be the first choice outcome. Indeed, data collected on PAD treatment in New Hampshire^v (1996-2006) has shown that over the course of a decade, interventional procedures have increased more than threefold, while simultaneously, a 42% reduction in amputations occurred - a clear indicator of the growing preference for interventional procedures over traditional surgery amongst those who are aware of the option.

Given that most diabetic complications stem from the same cause (high glucose levels damaging blood vessels), it is reasonable to assume that in the future, interventional radiology may adapt its current techniques to treat other diabetic complications as well. More than that, interventionists have already pioneered a new treatment that could spell the end of artificial insulin dependence - using minimally invasive techniques, doctors have successfully transplanted donor islets into diabetic patients (see page 20). Interventional radiology has always been a discipline of innovation, and it will be interesting to see what else the future holds.

Politics

If interventional radiology holds so many clinical and economic benefits, why is it not more commonly performed? The main obstacle to access to interventional treatment lies in the current medical structures.

For myriad reasons, a situation has come about where interventional radiologists in Europe have no direct patient contact. This has been a recurrent theme among interventional societies, with the presidents of many of these societies warning interventionists that without positive action to change this, they will continue to work in obscurity, and will not succeed in establishing themselves or their techniques. Intervention is a very technically innovative field, but it seems that the medical system has not developed as fast as interventional radiology. Somewhere along the way, interventionists were left in the lab to develop the procedures that have been adapted by other fields with a better aptitude for marketing. Angioplasty is one example - this image-guided technique is now commonly being performed by vascular surgeons. The disadvantage of this state of affairs is that trained radiologists are often better skilled at interpreting medical images and their skills are to some extent going to waste. Diagnostic radiology is, of course, invaluable to modern medicine, but interventional radiology also has its role to play in patient care.

Without proper clinical facilities, interventionists are losing out on many patients - and patients are missing out on many opportunities. Most interventionists in Europe have no admission facilities, no beds, and no patients of their own. The current referral structures do little to improve access to interventional techniques, as patients are rarely directly referred to an interventional radiologist. A general practitioner diagnosing obstructive artery disease will most likely refer this patient to a vascular surgeon - many doctors remain unaware of the availability of less invasive options. Many patients who do opt for interventional radiology cite the internet as their primary source of information. This raises serious legal questions about informed consent, and this gap in knowledge needs to be closed.

Better collaboration between different medical fields is needed, if patients are to be offered the best possible care. The most effective diabetic care clinics are those that are multidisciplinary. Diabetologists, podiatrists, interventionists and surgeons all have something to offer a patient, and in working together can better improve their own outcomes. Many patients treated with surgery would have faster recovery rates if treated with interventional methods - similarly, not all patients are suitable candidates for such treatments, and should be referred to the surgery department. What is most important is to make sure that each patient receives the best possible treatment available to them.

Conclusion

The most effective diabetic care clinics are those that are multidisciplinary

The incidence of diabetes is set to reach pandemic levels by 2025 if our current lifestyle and healthcare structures are left unchecked. In many cases, Type 2 diabetes can be prevented, or at least delayed by healthy lifestyle choices. For those that do develop diabetes, it can be controlled with conscientious blood glucose management and regular health checks. Unfortunately, it seems likely that the dire warnings of the WHO, UN and World Bank will come to pass unless these recommendations are implemented.

What is certain is that ways of reducing and treating its complications will remain an important aspect of diabetes care, as will the ongoing search for a cure. As outlined, interventional radiology is already playing an important role in both of these projects, and can be expected to continue to do so. While open surgery has saved many lives and limbs, and remains the only option for some patients, the arrival of new interventional radiology techniques has given patients and clinicians the option of treatment that is less invasive, less risky, more economical and can help preserve the integrity of the body. Rather than removing or relocating body parts to override malfunctions, interventional radiology aims primarily to heal these malfunctions at the source. As it is minimally invasive, patients experience shorter recovery times and fewer negative side-effects, and it is important that these benefits are recognised, made available to patients and developed further.

Please refer to www.intervention-iq.org for further reading suggestions.

ⁱ www.idf.org/diabetes-prevalence


ⁱⁱ Adam D.J., et al, Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicare, randomised and controlled trial. *Lancet* 2005; 366:1925-34

ⁱⁱⁱ Faglia E., et al, Extensive use of peripheral angioplasty, particularly infrapopliteal, in the treatment of ischaemic diabetic foot ulcers: clinical results of a multicentric study of 221 consecutive diabetic subjects. *Journal of Internal Medicine* 2002; 252:225-232

^{iv} www.eatlas.idf.org

^v Schwarze M.L., et al, Age-related trends in utilization and outcome of open and endovascular repair for abdominal aortic aneurysm in the United States 2001-2006. *The Journal of Vascular Surgery* 29 June 2009; 10.1016/j.jvs.2009.05.010

IR gets more involved in diabetes management



Universal Symbol of Diabetes
International Diabetes Federation

CIRSE



EASD

Leading forces in the area of diabetes awareness and management are the International Diabetes Federation (IDF), the European Association for the Study of Diabetes (EASD) and the Danish-based World Diabetes Foundation (WDF).

These groups do much to further awareness and research of diabetes and its complications, and through close work with other medical societies or industry partners, look set to increase the scope of their influence.

One example of interest to readers of IQ is this year's collaboration between the EASD and CIRSE (Cardiovascular and Interventional Radiological Society of Europe). The two groups are working together to promote both awareness of medical solutions to diabetic complications and research into further treatment options. In this framework, representatives of EASD have been invited to speak at the Annual Scientific Congress of CIRSE in a dedicated session on the Diabetic Foot.

Collaboration between CIRSE and the IDF Working Group on the Diabetic Foot is also underway with the purpose of revising the existing guidelines for the treatment of the condition, as well as launching an educational programme which will deal with such issues as how to set up a diabetic foot clinic.

The decision to form such a joint venture was taken on the grounds that vascular disease is the major cause of death in people with diabetes, and is an area in which interventional radiology is making incredible progress.

The mutual efforts of the major diabetes associations aim to raise awareness of the benefits of multidisciplinary care clinics, and encourage individual hospitals, diabetologists and interventional radiologists to establish such institutions.

For more information on the associations, please refer to their respective websites:

www.cirse.org
www.idf.org
www.easd.org



The Crippling Cost of Diabetes

Diabetes can affect more than a patient's well-being - it can also take its toll on the patient's finances, and those of the relevant healthcare provider. These costs are even higher than might be expected, and with diabetes set to become pandemic, may place an unbearable strain on economies. The results of many health economic studies indicate that the most affordable solution to the overwhelming costs of diabetic complications is to invest sufficient time, money and attention in basic primary care, and failing that, opt for minimally invasive treatment options.

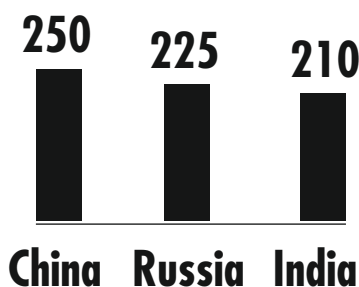
The Individual

The economic effects of diabetes and its complications are manifold. For individuals, diabetes can mean pain, disability or death, as well as horrendous expenses and reduction of quality of life. Diabetic complications can often cost people their livelihoods, as blindness and disability can make performing certain professional tasks impossible. It can also cost people their independence, and in many cases, family members are required to become temporary or permanent carers. For these families and local communities, diabetes can mean poverty and loss of time that would otherwise be used for study, work or leisure. In Latin America, families pay 40-60% of care costs, while in India, families with a diabetic member spend on average 25% of their income on private careⁱ. Even in the affluent West, many patients in the US are finding it hard to afford medical care in the face of the economic crisisⁱⁱ (see page 16).

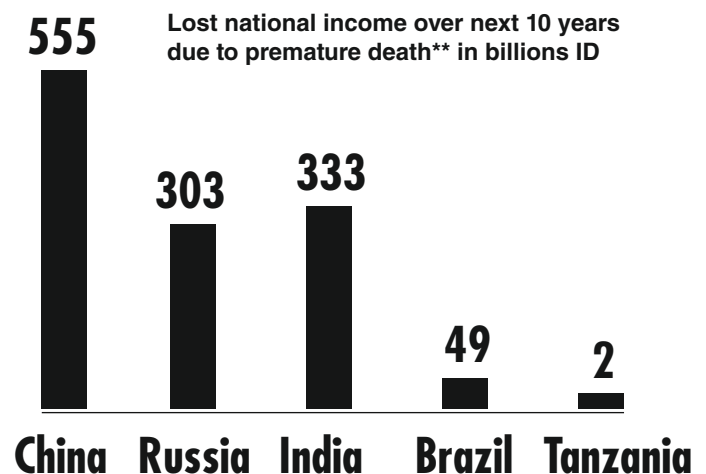
The Government, Private Insurer and Employer

For governments, private insurers and employers diabetes is no less costly, and these costs are not determined solely by medical bills - individuals also contribute to the economy, and sick leave, disability or premature death can reduce the overall financial health of a country.

WHO estimates the following costs per annum based on mortality from diabetes, heart disease and stroke* in billions ID (International Dollar):



Even from a budget perspective, prevention is far better than cure. Early intervention and proper treatment is key, and offers good value for money.



This covers only lost earnings - factoring in social and medical costs, disability payments and pensions would drive the cost up further still.

* heart disease and stroke are often diabetes-linked - diabetes not usually given as primary cause of death

** taking disability into account might double or triple estimates

Benefits of Proper Care

Numerous health economic studies and computer simulation models have indicated the economic benefits of providing proper diabetes care. Often treatment can be cost-saving, when therapy stops complications developing, thus saving on total care costs.

- Control of blood pressure, blood sugar and lipids reduce the need for open-heart surgery, dialysis and other expensive procedures, thereby saving money. Off-patent pills (especially combined polypills) are an inexpensive way of doing this.
- Foot care for those at risk of ulcers.
- The IDF estimates that low-dose aspirin treatment for those with elevated risk of cardiovascular disease reduces the risk by 25-30%.

The World Bank's assessment returned the verdict that although certain measures are cost-effective only in stronger economies, some were universally beneficial, and recommended glycaemic control in people with HbA1c higher than 9%, blood pressure control in people with pressure higher than 160/95 mmHg, and foot care for people with a risk of ulcers for all countries.

Cost Comparisons

The cost of 16 amputations is more than the cost of managing 120 active ulcer cases or 834 preventative casesⁱⁱⁱ.

The direct costs of 8 below-knee amputations is equal to the combined annual salary of a medical team of 3 doctors, 5 nurses, 1 dietician, 1 secretary and 3 auxiliary staff^{iv}.

Clearly, even from a budget perspective, prevention is far better than cure. Early intervention and proper treatment is key, and offers good value for money.

In 2002 alone, the US economy lost \$39.8 billion (\$3,290 per person with diabetes) due to lost work days, restricted activity days, mortality and permanent disability caused by diabetes, according to estimates of the American Diabetes Association.

A great proportion of costs are attributable to prolonged hospitalisation and amputation. Over 10 million Type 2 diabetes patients in Europe produce €29 billion of associated costs (of which the highest percentage, 32.7%, is attributed to hospitalisation and only 2.7% to oral anti-diabetics)^v.

Difficulty of Establishing Data

More detailed health economics studies examine the economic outcomes of treating the complications. It must be pointed out that this is a difficult task to undertake, as different clinics in different regions collect different data, and that local variations such as reimbursement schemes and cost-sharing arrangements can lead to vastly different evaluations of cost. More specifically, in nearly all countries, reports tend to examine only procedural costs, and can omit to mention the costs of follow-up care or consequences for the individual. These costs can be substantial, and should certainly be taken into account when devising healthcare budgets.

These costs (indicated below) include far more than the cost of a single procedure, as a patient is far more complex than that, in economic as well as personal terms. These costs can amount to a sum that is substantially more than the estimates that are currently being made for medical procedures.

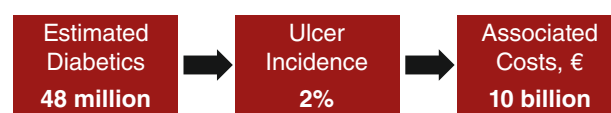
Medical Costs

- Homecare nursing
- Transportation to and from a clinic
- Follow-up procedures
- Recurrence of a condition

Non-medical Economic Impact

- Loss of earnings due to hospitalisation, recovery or disability
- Disability pensions
- Social-service support
- Impact on the family (further loss of earnings/study time)
- Potential reduced purchasing power of the individual or family due to altered economic circumstances

Europe in 2003

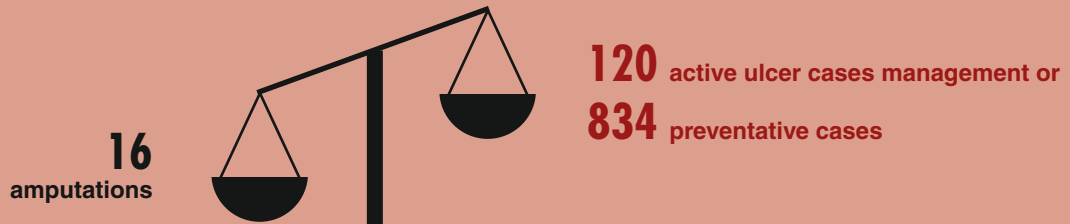


In 2003, there were an estimated 48 million diabetics in Europe, with an ulcer incidence of 2% per year, for which the associated costs were as high as €10 billion annually.

The annual salary of:

$$\begin{array}{|c|} \hline 3 \\ \hline \text{doctors} \\ \hline \end{array} + \begin{array}{|c|} \hline 5 \\ \hline \text{nurses} \\ \hline \end{array} + \begin{array}{|c|} \hline 1 \\ \hline \text{dietician} \\ \hline \end{array} + \begin{array}{|c|} \hline 1 \\ \hline \text{secretary} \\ \hline \end{array} + \begin{array}{|c|} \hline 3 \\ \hline \text{auxiliary} \\ \text{staff} \\ \hline \end{array} = \begin{array}{|c|} \hline 8 \\ \hline \text{BELOW-KNEE} \\ \text{AMPUTATIONS} \\ \hline \end{array}$$

There is strong evidence that a multidisciplinary approach can reduce amputation rates by a sizable percentage.



Reimbursement

Reimbursement also plays a crucial role in reducing amputations. Currently, cost sharing structures tend not to encourage patients to seek early intervention, as they usually pay a higher proportion of preventative care than they do for curative care, and often patients at risk of PAD and foot ulcers are not in a position to self-diagnose, meaning that treatment is only sought when conditions are already advanced, and thus causing pain and great expense. In Belgium, for example, curative care is 6 times as expensive as preventative care, but proportionally, patients pay 10% of curative fees, and 14% of preventative^{vi}. Reimbursement schemes can also function as financial incentive for clinicians, with some health economists recommending that reimbursement should be adapted to encourage fewer amputations by awarding higher remuneration for revascularisation, rather than the current “per time investment” structure.

This data is a strong indicator of the advantages of not just limb-salvage over amputation, but also of the benefits of minimally invasive medicine in general - shorter hospital stays, shorter recovery times and less chance of sustaining disability or deformity. These are very important considerations, not just for the individual, but also for the health authority and the state, and minimally invasive treatment should be given serious consideration for any patients who are suitable candidates.

“Unfortunately, the most dangerous enemy for the diabetic foot can be the reimbursement system” -
Apelqvist

- ⁱ www.idf.org/human-social-and-economic-impact-diabetes
- ⁱⁱ Associated Press, *Diabetics skimp on lifesaving care in recession. Diabetes Today*, 12.04.2009
- ⁱⁱⁱ Assal J.P., 1995 in Van Acker K., *The Diabetic Foot. Antwerp 2001*, p.93
- ^{iv} Apelqvist J., et al, *The global burden of diabetic foot disease. Lancet 2005*; 366:1719-24
- ^v Van Acker K., *The Diabetic Foot. Antwerp 2001*, p.9-10
- ^{vi} Van Acker K., *The Diabetic Foot. Antwerp 2001*, p.66

www.worldbank.org
www.diabetesvoice.org
www.pubmed.gov
www.diabetes.co.uk
www.intervention-iq.org



Recession leads to decline in healthcare

The Associated Press has discovered a worrying trend in economising in the US - many diabetics are cutting back on or discontinuing medication and doctor visits in an attempt to save money. Many Americans who lost their jobs as a result of the recession have also lost their job-linked healthcare plans.

Many diabetics are thus reducing their medication or switching to cheaper (often less effective) brands. Subsidised clinics are seeing such an increase in demand for their services that they, too, are being forced to ration resources.

Ms. Eileen Collins cut back her medication following her husband being laid off, and attempted to counter it with a strict diet. Shortly afterwards, she was rushed to hospital, vomiting blood with sky-high blood sugar levels. She, like many diabetics in a similar situation, simply didn't realise the consequences of not managing diabetes carefully. Unmanaged diabetes can lead to costly hospital stays, disability or even death. Many clinics seeing a downturn in patient attendance are asking patients to make their financial difficulties known to the clinic, rather than not seeking treatment.

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Health Springs Eternal

Iceland has the lowest incidence of diabetes in Europe, a mere 2%. Scientists have long wondered why, and have tried everything from genetic surveys to investigating environmental factors. The higher incidence of diabetes in neighbouring Sweden and Finland seems to rule out latitude as a factor.

They have swabbed cheeks, poured over church records, looked into the shielding properties of omega 3 oil and tested the milk of their cattle, which have been reared in isolation for hundreds of years. A link between larger birth weight and lower diabetes risk was established, but seems to be a local anomaly. An extensive genetic survey seemed to reveal a mutant gene that is responsible for diabetes, but a lot more research is needed before this can be established as a primary cause of the disease.

Worldview

RAPIA - Rapid Assessment Protocol for Insulin Access

Insulin is classified by the WHO as an essential drug, yet many diabetics have limited or no access to it. The International Insulin Foundation's RAPIA programme (Rapid Assessment Protocol for Insulin Access) was recently implemented in Zambia, Mali and Mozambique.

The World Bank classifies all three as Highly Indebted Poor Countries (HIPC), i.e. countries whose income is outweighed by their debt. The results of the RAPIA reveal interesting findings on healthcare management.

Although all countries have similar economic situations, different policies have led to drastically different outcomes. For various reasons, treatment is calculated to be 5-10 times better in Zambia than in Mozambique. The life expectancy for a child presenting with diabetes stands at 11 years in Zambia, 30 months in Mali, and just 12 months in Mozambique. By examining the flaws in the health policy, governments can improve their tackling of the disease and management of resources.

www.access2insulin.org/html/rapia.html

Diabetic Foot Clinic

4.4 million of the world's 246 million diabetics live in Egypt, ranking it as one of the Top 10 countries for diabetes incidence. Unfortunately, projections for 2025 estimate that this number will rise as high as 7.6 million.

Accordingly, the International Diabetes Federation's BRIDGES programme has given 2 year funding to the Faculty of Medicine in Alexandria, Egypt and the Alexandria Western Club of Rotary International to open a diabetes foot care centre, aiming to provide care and education to diabetics in and around Alexandria. The outcome of assessments, routine care, footwear counselling and workshops to train local healthcare providers will be measured by the reduction rate in amputations. The goal is to reduce amputations by at least 25% within 2 years. www.idfbridges.org

Olympian Determination

Sir Steve Redgrave is considered Britain's greatest Olympian, being one of only four people to have won gold at five consecutive Olympic Games.

It's hard to believe that the fifth was won after he was diagnosed with insulin-dependent diabetes, but his healthy attitude towards managing this serious condition allows him to achieve his goals. He retired from rowing in 2000, but remains very active, having completed 3 London Marathons, raising a record £1,800,000 for charity in 2006 alone - a clear indication that with the right approach, diabetes doesn't control you: you control it.

TAF and HHF

In 1992, Singapore's government launched the "Trim and Fit" programme to combat childhood obesity and its consequences, such as Type 2 diabetes. Children over 9 deemed overweight by BMI and fitness tests had to take at least 1.5 hours supplementary exercise.

Ration vouchers restricted the holder to a certain maximum of calories in the school canteen. TAF reduced childhood obesity from 14% in 1992 to 9.8% by 2002, but was criticised for promoting physical health over psychological health. Some schools even implemented a segregation system in canteens, separating overweight children from their slimmer peers. Overweight children were stigmatised and eating disorders increased, according to a 2005 study by the National University of Singapore. In 2007, the Holistic Health Framework replaced TAF, aiming to promote physical, mental and social health in all school children, not just overweight ones.

Tropical Cures

The University of Ulster and the United Arab Emirates University are currently jointly researching an interesting phenomenon found in some tropical flora and fauna - the skin of a certain Amazonian frog was found to secrete a substance that could be used to boost insulin production in Type 2 diabetics.

At the same time, another University of Ulster team is researching the bark of a Himalayan plant, chirette. Compounds found in this bark contain similar properties to those of the frog, stimulating production and effectiveness of insulin. Research into both is reported to be at an exciting stage, and more potent synthetic versions have the potential for development into a treatment for Type 2 diabetes.

A Terrible Shame

For many Asian families, the social implications of diabetes can often be as difficult as the medical implications. Doctors in Hong Kong have reported that many parents see it as shameful, and many children face bullying or ostracisation from their peers.

Other families worry that their children will not find marriage partners, and sometimes try to hide the disease from the public eye. In one tragic case in Chennai, a young bride had kept her condition secret from her fiancé, and didn't take her insulin during her honeymoon. As a result, she slipped into a coma and died. One wonders if the young widower wouldn't have been happier to have a diabetic young bride, rather than a dead one.

The Sugarman

Sadly, native populations seem to be at higher risk of developing diabetes than their non-indigenous neighbours. South Australia fares no differently, where the diabetes rate among the non-indigenous population stands at 9% - however, in most Aboriginal towns, this figure increases to over 50%.

Registered nurse and diabetes educator, Michael Porter, devised an unconventional but effective workshop to educate communities about diabetes, based on Aboriginal story-telling tradition, christened "The Sugarman."

The Sugarman is a large canvas outline of a body on which participants play games to learn about diabetes. For example, participants (representing insulin) try to shoot balls (sugar) through a basketball hoop (muscles), acting out metabolism. Michael Porter (diabetes) tries to block these balls, much as diabetes prevents sugar getting to the muscles in a real body. Communities have been very positive about the Sugarman helping children understand their bodies, saying that giving the disease a face and a name has made it easier to deal with.

The Diabetic Foot Clinic

From Roman times to the present day, people have come from all over the Italian territories to the town of Abano Terme. The hot springs and mud baths of the north-western town have long been considered therapeutic, but these days, there is something else which attracts those in search of health. We spoke to Dr. Marco Manzi, Director of the Interventional Radiology Unit of Abano Policlinic's Foot and Ankle Clinic to find out more ...

Diabetic feet in the best hands

An exemplary approach to patient care

Multidisciplinary diabetic foot clinics are widely recognised to be, both clinically and economically, the most effective way of treating diabetic foot disorders, which of all diabetic complications are the most costly and have the greatest toll. Worldwide, 70% of lower limb amputations are the result of diabetes - 1 every 30 seconds. Despite this, specialised clinics are not always widely available.

In 2003, the inspired hospital management of Abano Policlinic realised that this was precisely what the region needed, and provided a modern catheter lab, dedicated operating rooms and personnel, heralding the birth of the Foot and Ankle Clinic. In fact, demand is so high that another catheter lab is to be opened next December.

"The future will be less and less invasive, and Interventional Radiology must be there"

The spice of life

Dr. Manzi explains the advantages of having a mixed bag of medics under one roof - on the one hand, the team is small enough that communication and discussion of clinical problems can be carried out quite easily, and on the other hand, with so many different specialists available, a solution can always be found, whatever the problem. This affords patients at the clinic the best standards of care.

The clinic recognises the value of bringing together both interventional radiologists and vascular surgeons - both specialists have expertise to offer the patient, and both play an important role within the clinic.



Foot and Ankle Clinic

Specialists & Staff

7 Podologists
5 Diabetologists
3 Orthopaedics
2 Vascular Surgeons
1 Interventional Radiology team

Dedicated Beds

30

The Interventional Radiology Team

1 Interventional Radiologist (Dr. M. Manzi)
1 Interventional Cardiologist
1 Technician
5 dedicated Nurses

No. of Patients

1,000 treated annually

Left to right: M. Marangotto (Head of Nursing), J. Alec (Radiographer), G. Erente (Interventional Cardiologist), E. Sultato (Nurse), M. Manzi (Interventional Radiologist), C. Brigato (Nurse)

In terms of treatment, the first choice is minimally invasive techniques: treating the complication from within the blood vessel, minimising ancillary damage. With new patients, Dr. Manzi and one of the clinic's diabetologists decide the most suitable strategy and the surgical indications, which he puts at about 10% of presenting cases. The clinic evaluates its clinical and operative success on the basis of strict follow-up examinations.

Dr. Manzi believes that the natural progression of medicine will favour less invasive procedures, and so interventional radiology will take a more prominent role. As such, it is important that trained interventionists be available, and he sees the career opportunities for young doctors training in this field as favourable: "there will always be a career opportunity for young IRs, especially in vascular, oncological and gynaecological treatments." He firmly believes that IR will develop further techniques for dealing with other diabetic complications, and cites treatment of ischemic hand syndrome and management of atherosclerotic fistulas in diabetic-dialysed patients as likelihoods.

He also believes that the revision of TASC II guidelines (recommendations on best practice treatment of peripheral artery disease) is long overdue - their recommendation that interventional techniques be used for patients with TcPO₂ of <30mmHg could also be applied to patients with 30-40mmHg, as they are also at risk of amputation, and are thus valid candidates.

Cost-effective medicine

The Foot and Ankle Clinic offers more than just clinical benefits: it has impressive economic ones as well. Dr. Manzi calculates that the average cost per patient of materials used in revascularisation (limb salvage) is €1,170, whereas in the US, an elective amputation alone costs \$6,000 (around €4,300), and one following a by-pass failure will cost \$28,000 (around €20,000), without taking into account any health or socioeconomic costs.

Communication

With most interventional units, one of the major stumbling blocks is the lack of direct referrals. The Foot and Ankle Clinic has a solution for this too: they have established both a website (www.policlinicoabano.it) and good GP relations. Meetings are organised with small groups of GPs to involve them in prevention and early detection of clinic signs. They are also kept up-to-date with interventional and diagnostic procedures for diabetic foot and CLI. Using this "grass-roots" network, the clinic manages to promote both interventional radiology and better diabetic foot care in the wider community.

"For us, ambulation function salvage is most important"

Using such approaches, Dr. Manzi's colleagues seek to give each patient the best possible outcome. Unlike general medical literature, which defines limb salvage as time free of amputation, the Foot and Ankle Clinic sees it as salvaging or restoring ambulation in a patient - it is not their aim to simply spare the limb, but also to return it to full health and function. Interventional radiology has a very important role to play in this, providing as it does a minimally invasive option of re-opening the blocked vessels that cause so many diabetic foot problems.

www.policlinicoabano.it

The Vitals

Dr. Manzi qualified as a radiologist in 1990, but developed an interest in interventional procedures, and investigated Ultrasound-guided PEIT (Percutaneous Ethanol Injection Therapy) of thyroid and liver tumours. For him, the main advantage of the interventional approach was the therapeutic role, which is not part of diagnostic radiology. This convinced him to specialise as an interventionist, and he pursued his chosen field at various centres in Italy and France. In 1996, he became responsible for the IR unit of the Radiology Department of Vicenza Regional Hospital, where he devoted himself to establishing an effective IR Unit and instilling a passion for IR in young radiologists. As far as current treatments are concerned, Dr. Manzi has published papers on the Pedal-Plantar Loop technique, a new approach to recanalise below-the-knee occlusions that do not respond to commonly-practiced revascularisation techniques. One such study published in the June 2009 issue of the Journal of Cardiovascular Surgery demonstrates the effectiveness of this technique - of the 1,331 CLI patients, 135 were treated with the pedal-plantar foot loop and acute success was achieved in 115 (85%), demonstrating the safety and effectiveness of this new technique.

Results published with kind permission of the Journal of Cardiovascular Surgery and Minerva Medica.

Type 1 Diabetes: Closer to a Cure?

Finding a cure for Type 1 diabetes has long eluded scientists as its cause still remains unclear. However, modern medical advances are enabling the development of several curative procedures all of which hold the promise of a cure. Such a cure would not only free diabetics from their dependence on insulin but also decrease their risk of serious diabetes-related complications. The two main curative procedures currently being used are pancreatic islet transplantations and pancreas transplantations.

Pancreatic Islet Transplantations

In 1972, Dr. Paul E. Lacy embarked on a well-planned experiment that would help bring the ideas of many scientists before him to fruition. He successfully transplanted pancreatic islets into a laboratory rat with Type 1 diabetes, curing it. These pancreatic islets, or islets of Langerhans, contain the body's insulin producing beta cells. Type 1 diabetes results from an autoimmune reaction in which the pancreatic islets are destroyed. Further experiments followed and in 1989, Lacey and his team successfully carried out the first pancreatic islet transplantation on a human being.

How is this interventional procedure carried out?

Step 1

Pancreatic islets are extracted from the pancreas of a recently deceased donor and isolated using specialised enzymes. They are fragile and must be transplanted soon after their removal.

Step 2

The patient receives a local anaesthetic and a sedative and the whole procedure is carried out through a tiny nick in the skin. An interventional radiologist uses x-rays and ultrasound to guide a catheter through the patient's upper abdomen into the portal vein of the liver.

Step 3

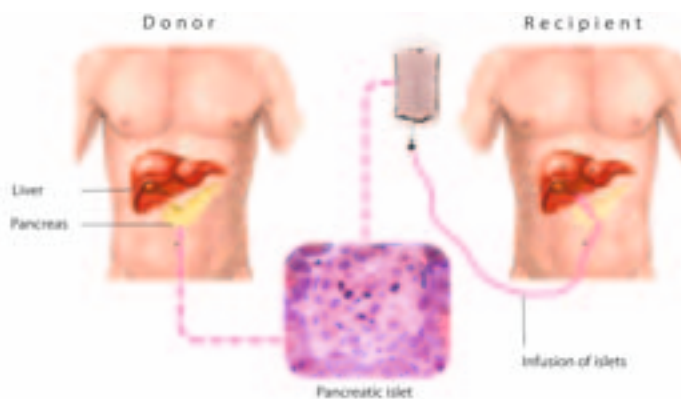
The islets are then infused into the patient's liver where they soon secrete insulin. The patient may need to undergo more than one transplant in order to achieve full insulin independence.

What are the advantages?

- Patients become free from the need for daily insulin injections, and potentially dangerous hypoglycaemic episodes are prevented.
- By helping to control blood sugar, the transplanted islets also aid in reducing the risk of diabetes-related complications.
- The minimally invasive technique shortens the patient's recovery time in comparison to those who undergo surgical transplants and operations costs are less.

What are the disadvantages?

- There is a shortage of islets with which to carry out the transplantation as they make up only 2% of pancreatic tissue. Patients normally need islets from more than 1 pancreas to achieve insulin independence.
- As with all transplantations, there is a risk of organ rejection. Rejection occurs when the body's immune system recognises a newly transplanted organ as "foreign," and in turn attempts to destroy it. This autoimmune reaction was what triggered the destruction of the patient's own pancreatic islets to begin with.
- Expensive immunosuppressive drugs are prescribed to prevent rejection and must be taken for life or as long as the islets function. The long term effects of such drugs are unclear but they can cause serious side effects such as decreased kidney function and increased susceptibility to viral and bacterial infections. However, research carried out in the University of Edmonton showed that the adverse effects of immunosuppressive drugs can be lessened.



Edmonton Protocol

Working to find a solution to the problem of immunosuppressive drugs, researchers of the University of Edmonton prescribed a novel combination of immunosuppressant drugs to patients following successful pancreatic islet transplantations. Their findings were dubbed the Edmonton Protocol and showed how patients could attain a state of insulin independence when sufficient numbers of pancreatic islets were transplanted and how the side effects of immunosuppressive drugs could be reduced. The success of the Edmonton protocol has provided researchers with new hope for improving the pancreatic islet transplantation process.

Pancreas Transplantation

In pancreas transplantations, the whole organ is transplanted, not just the insulin producing pancreatic islets. Following the first successful combined pancreas and kidney transplant by Dr. Richard Lillehei in 1966, the patient remained independent from insulin for a few months until her body rejected the new organ. Dr. Lillehei carried out further transplantations and in 1968, he led a team which carried out the first pancreas-only transplant. There are 3 types of pancreas transplants; simultaneous pancreas-kidney transplantation (SPK), pancreas after kidney transplantations (PAK) and pancreas-only transplantations. Pancreas-only transplantations are only carried out on patients who have numerous life threatening hypoglycaemic episodes.

How is this surgical procedure carried out?

Step 1

A pancreas is extracted from a recently deceased donor. In rare cases, a part of the pancreas of a living donor can be used.

Step 2

The donor pancreas is grafted to the small intestine and to blood vessels in the lower abdomen of the patient. The patient's own pancreas is not removed so that it can continue its function in aiding digestion. Depending on the type of operation, the kidney may also be transplanted.

What are the advantages?

- Usually, the newly transplanted pancreas starts functioning immediately as do the new kidneys. Occasionally, this can take up to a few weeks to start.
- By helping to control blood sugar, the transplanted pancreas also aids in reducing the risk of diabetes-related complications.
- Successful pancreas transplants free the patient from the need for daily insulin injections.

What are the disadvantages?

- Shortage of donors.
- Risk of organ rejection means strong immunosuppressant drugs must be prescribed.
- Complications associated with open surgery such as excessive bleeding and infection can occur, unlike with the minimally invasive procedure of pancreatic islet transplantation.
- General anaesthesia can be dangerous for certain patients, increasing the chances of heart attack and breathing problems during the operation.
- Some patients risk thrombosis and pancreatitis, an inflammation of the pancreas as a result of pancreas transplantations.

Conclusion

The discovery of insulin and the insulin producing beta cells of the pancreatic islets has proved to be an essential step in the search for a cure. As research into possible cures is being carried out in various fields of medicine, doctors could be on the brink of finding a definitive cure. The minimally invasive treatment of pancreatic islet transplantations offers patients an effective alternative to open surgery with the added benefits of being less painful and more cost-effective. With advances such as the Edmonton Protocol being made into decreasing the risk of immunosuppressant drugs, pancreatic islet transplantations could well be a key future diabetic cure.

Other Treatments on the Horizon

Treatment	What is it?
Stem cell-based treatment	<p>Stem cells, differentiated into insulin producing beta cells are administered to the patient via intravenous injection. Stem cells can be extracted in various ways including from 5-day-old human embryos, or from the patient's own bone marrow.</p> <p><i>Risks unclear due to lack of research.</i></p>
Nano-medical techniques	<p>A new medical specialty based on engineering and production on the scale of a nanometre (a billionth of a metre and 20 times wider than the diameter of a hydrogen atom). One procedure involves transplanting beta cells contained in silicon boxes with holes large enough for insulin and glucose to pass through but too small for the body's immune system molecules to enter and attack the beta cells.</p> <p><i>Risks unclear due to lack of research.</i></p>

<http://diabetes.niddk.nih.gov>
www.intervention-iq.org





Diabetes Trials

Coronary CT Angiography in Asymptomatic Diabetes Mellitus

Contact person

Prof. David A. Halon,
Lady Davis Carmel Medical Center, Israel

Date opened

August, 2007

Status of trial

Recruiting finished, data to follow

Source

www.clinicaltrials.gov

Description

In this study readily available patient medical data relating to diabetes and its complications/risk factors will be collected and patients will be referred for exercise, stress testing and eye examinations. The coronary CT angiogram will be examined for early signs of coronary artery disease and the outcomes will be examined after 2 years or later using computerised databases.

Islet Transplantation for Type 1 Diabetes Mellitus

Contact person

Deborah L. Dicke-Henslin
Mayo Clinic Rochester, Minnesota, US

Date opened

July, 2006

Status of trial

Recruiting

Source

www.clinicaltrials.gov

Description

This study evaluates the safety and efficiency of islet transplantation in five patients with Type 1 diabetes, satisfying extensive inclusion and exclusion criteria under IND, approved recently by the FDA.

Percutaneous Transluminal Balloon Angioplasty (PTA) and Drug Eluting Stents for Infrapopliteal Lesions in Critical Limb Ischemia (PADI)

Contact person

Dr. Hans Van Overhagen
Netherlands Society for Interventional Radiology, Netherlands

Date opened

August, 2007

Status of trial

Recruiting

Source

www.clinicaltrials.gov

Description

This study aims to investigate the performance of paclitaxel-coated balloon expandable stainless steel coronary stent for the treatment of infrapopliteal stenoses and occlusions in patients with critical limb ischemia compared to percutaneous transluminal balloon angioplasty (PTA).

Trial: a study carried out with the purpose of testing a new medical treatment on a defined group of people. The results are compared with a group that are treated using another method and/or a control group.

Solitary Islet Transplantation for Type 1 Diabetes Mellitus Using Steroid Sparing Immunosuppression

Contact person

Dr. David M. Harlan
National Institute of Diabetes and Digestive & Kidney Diseases, US

Date opened

November, 2000

Status of trial

Recruiting finished, data to follow

Source

www.clinicaltrials.gov

Description

This study will test whether a new islet transplant procedure using the findings of the Edmonton Protocol can enable patients with Type 1 diabetes mellitus to stop insulin therapy. Radiation and lower-dose chemotherapy will not be used.

Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY)

Contact person

Kathryn Hirst
George Washington University Biostatistics Center, US

Date opened

May, 2004

Status of trial

Recruiting finished, data to follow

Source

www.todaystudy.org

Description

The TODAY trial aims to compare the efficacy of metformin alone, metformin plus rosiglitazone, and metformin plus on the length of time to treatment failure based on glycaemic control.

Please note that this does not constitute an exhaustive overview of Diabetes trials. If you are aware of a Diabetes trial or registry, which may be of interest to our readers, please feel free to contact us at info@intervention-iq.org.

IQ takes no responsibility for the content of the individual trials; please refer to their Source for further information.

www.clinicaltrials.gov
www.who.int/trialsearch/default.aspx
<http://clinicaltrials.mayo.edu>



Interventional Radiology becomes Official UEMS Division

At the Czech Radiological Congress in 1962, an astounded group of physicians listened attentively as Charles Dotter described how angiography could be used for treatment and not merely for diagnosis. His pivotal speech sparked the bright beginning of interventional radiology's journey. A few decades later, this journey continues and has seen numerous milestones, which have helped IR develop into the multifaceted and valuable discipline it is today.

Another milestone came on 25th April 2009 as members of the European Union of Medical Specialists (UEMS) voted to establish a division for IR under the auspices of their Radiology Section. The new division will be instrumental in complementing ongoing efforts to establish and promote IR in Europe, while at the same time opening up new avenues for IR's further development.

What does the new division mean for IR?

More acknowledgement of the benefits of IR procedures

IR offers patients an invaluable alternative to open surgery. The new division will reinforce actions being taken to raise awareness of the benefits of IR to patients and other specialists as well as to referring physicians and hospital management.

Increased involvement in health politics

IR's international backing by the UEMS will help strengthen its position in negotiations with national health politicians particularly in the areas of greater media coverage, improved patient access to IR treatment and meeting public health objectives.

The promotion of IR research

Cutting edge technology is central to IR's minimally invasive procedures, and official recognition from the UEMS will reinforce the vital research behind it. This will in turn lead to safer more effective treatments and improved quality of life for patients.

Synchronisation of European IR training and certification

The compilation of existing IR training curricula into a single European training curriculum and the establishment of a European IR Skill Certificate would be an important step towards synchronising IR training and to providing IRs with recognised Europe-wide certification of their IR training and skill.

Common guidelines for IR clinical practice in Europe

Efficient clinical practice has become crucial for IR and the relationship between physicians and patients helps forge a bond of trust. This bond is not only important for successful post-procedural care but also for giving physicians a greater understanding of the patient's needs, enabling them to tailor treatment accordingly. A set of common guidelines can improve and unify clinical practice across Europe.

Greater reach for IR training institutions

Institutions for IR training, like the European School of Interventional Radiology (ESIR), have come a long way over the past years, constantly updating the training they provide to adhere to the latest training standards. IR training institutions strive to expand training to countries in which IR has yet to be established and recognition by the UEMS will reinforce their efforts.

Greater interdisciplinary cooperation

Interdisciplinary cooperation is fundamental to offering patients high quality medical care. Having an Interventional Radiology Division in the UEMS will encourage such cooperation between IR and the other specialties represented.

How did the division come to be?

Efforts made in advance of the meeting in April were key to the establishment of the division as delegates were clearly informed on IR and the significance of having an Interventional Radiology Division in the UEMS. The cooperation between CIRSE President Jim A. Reekers, European Society of Radiology (ESR) President Christian Herold and UEMS Radiology Section Chairman Peter Pattynama was central to the success of the efforts made.

www.uems.net
www.uemsradiology.eu
www.cirse.org



THE EUROPEAN UNION OF MEDICAL SPECIALISTS (UEMS)

Established in 1958, the UEMS represents medical associations of the European Union and other associated countries on a non-profit basis. It is credited with the creation of the influential European Accreditation Council of Continuing Medical Education (EACCME).

The current president is Dr. Zlatko Fras.

UEMS main objectives:

- Studying and promoting various medical specialties
- Harmonising medical specialist training in the European Union
- Assuring a high level of professional autonomy for medical specialists
- Preserving the right of all European citizens to quality medical care

5 minutes with ...

Dr. Christoph Binkert

We speak to Dr. Christoph Binkert about America, Switzerland and the importance of good working relations.

An Ideal Relationship ... with your vascular surgeon

Many European doctors choose to gain professional experience in America. Why did you decide to go there?

"Well even now, there is no structured IR training programme in Europe, so the 2-year fellowship offered at the Dotter Institute was very attractive for me. Hospitals in the US have more consistent case loads, which is an advantage for trainees. There were also the personal reasons - I, like many others, wanted to spend some time abroad, and the US is a very interesting place to do that, as well as being justifiable career wise."

What opportunities did it provide? What impact did it have on your career?

"Often in Europe IR training is autodidactic, but in the US it's very methodical. Also, any time spent in a different environment can be eye-opening, and shows you a different approach to both work and life. Overall, I would recommend going away to any young doctor, because when you come back you appreciate more what your country has to offer, and you're more open-minded to many things, in personal life but also in the hospital. You can see that things are done differently and I think, beside the excellent education I got in the US and my experiences in the medical field, this was the most valuable thing that I learned."

It's been two years since you returned to Switzerland. What have the main challenges been coming back to Europe? What ideas did you bring home with you?

"I was actually surprised when I returned how easy it was to adapt, and how little had changed in the 7 years I was gone. The biggest change I had to get used to was my new professional position, but returning to my home country wasn't the shock one might expect."

"I think it was my clinical involvement which allowed me to achieve a good working relationship"

What was the situation in Winterthur when you came back?

"In general, many things were similar to the situation in the US. Diagnostic radiology was structured the same way, but the interventional radiology situation was a bit different, as IR isn't so well established in Europe yet. The Kantonsspital Winterthur was quite advanced in this field by European standards. My predecessor, also an interventionist, had already done a lot of work, which gave me a good starting position."

Promoting IR is a main consideration for interventional radiologists, especially in the areas of patient information and patient referral. How is this dealt with in Winterthur? How does it compare with your experiences in the US?

"The hospital itself doesn't have any specific patient information programmes promoting IR, but our management is very open-minded, and was very supportive of the various changes I tried to make, for example, the collaboration between interventional radiology, vascular surgery and angiology or the start of a vertebroplasty programme. Surprisingly, it was quite easy, as I have very forward-thinking clinical colleagues, but essentially, I had to take the initiative to implement them myself."

What, in your opinion, constitutes an ideal relationship between an IR and a vascular surgeon and how would one be established?

"I think personality is important - it's not something that can be enforced by outside regulation, you've got to negotiate the best working set-up yourself. I was lucky because I work with a very open-minded vascular surgeon who was really interested in a good collaboration. As team members, both sides have to play fair - this applies to the interventional radiologists just as much as to the vascular surgeons. For me, the main issue is that you discuss things on an equal footing, you can both make suggestions, you can approach your patients the way you want to, and the surgeon can do it his way. I think you have to deserve this position by being clinically active, by actually seeing patients and emergency cases, making judgements yourself and also doing follow-ups on these patients. I think it was my clinical involvement which allowed me to achieve a good working relationship."

What is it that IRs need to do?

"Again, I have to say I was already in a very good starting position in terms of the existing structures and my open-minded colleagues here at Winterthur. But if that hadn't been the case, I definitely would have tried to do more on my own. Interventionists cannot use the excuse, "I'm not lucky, it's just not working for me." I think most interventionists want to have it easy; they would rather not be



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Director of the Institute of Radiology, and Chairman
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Winterthur Kantonspital, Switzerland*



clinically-involved and simply have the vascular surgeon prepare the patient for the procedure, where they can then step in to do a procedure and then send the patient right back to the surgeon. This is a model that doesn't really work well and I can understand that surgeons don't really like that.

But if you as an interventionist take care of your patients from work-up and consent, informing the patient to talking to the family, you usually earn respect. I think the other important thing you have to make sure is that you have visibility, for example that you're on the letterhead so people understand that you're part of this team."

So do surgeons prefer IRs to take responsibility?

"I think at the beginning they may not. When I first took the initiative to see patients and get my own referrals, they were a little bit anxious about what was happening. Once the Head of Vascular Surgery understood that I play fair and inform him about the cases and keep him in the loop, he realised that it's a great arrangement, that I bring additional patients into the vascular institute and the vascular system and everyone benefits. That was crucial to establishing a good working relationship. In general, I don't think it's a question of whether they like it or not, I think it's absolutely mandatory that interventionists see their patients - that's the only way for the future."

"It's absolutely mandatory that interventionists see their patients - that's the only way for the future"

Do you have any words of wisdom for your younger colleagues?

"Teamwork and the interdisciplinary approach are crucial - not just when working with vascular surgeons, but generally. That's what I'd recommend to everybody.

Interventional radiologists should have enough self-confidence to see their own patients, make their own plans, ensure that they are allowed to do their jobs properly and are seen as clinical colleagues. This is something I learned from the States. The lack of referrals hit them hard over there and as a result, they quickly adapted new strategies. I think in Europe this would be a great time to do this, because we still are involved in PVD work, but I don't think we can keep that going if we're not adapting a

more clinical work style. This is a message I'd really like to give to my younger colleagues, because I think it is key."

"Teamwork and the interdisciplinary approach are crucial - not just when working with vascular surgeons, but generally"

We know that you have an MBA in hospital management from the American Intercontinental University. How important are management skills for interventional radiologists?

"In advancing my career, I knew the next step would involve more administrative duties. I think in standard medical education, we learn a lot about medicine, but not so much about how to lead and structure a department, and for me it was helpful to learn how to do that and to understand a little bit more about how things are done, what costs are involved, how a hospital is structured, how to decide when expensive equipment is justified, how you can set up a contract. For me, this information was more valuable from the point of view of head of a department, than as an interventionist. Nevertheless, I think it's important for interventionists to be aware of the costs, so we know when we are expensive, and when we are less expensive compared with other specialties."

Moving to different environments must have influenced your leisure time. What does Dr. Binkert do when he is not in office?

"I'm an outdoor person, and I have 3 boys, and it was great for them in the States: the sports activities and other things available to them in their spare time were unbelievably good, so that is something we miss a little bit back in Switzerland. I am an enthusiastic skier, and am naturally doing more of it being back in Switzerland. What I brought home with me was a new sport: kite-surfing. I started kiting on the Pacific Coast when the kids were little, but only with a training kite. Although I'm still not very good at this point, practice makes perfect. There are opportunities to do it in Switzerland too, but the mountains with very cold lakes aren't ideal, especially for someone like me who's still most of the time in and not out of the water."

Non-Dedicated Staff: may cause serious side effects*

A huge number of clichés exist about the value of a harmonious and well-structured team: “a chain is only as strong as its weakest link,” “the strength of the team is each individual member - the strength of each member is the team,” and so on. While such clichés are... well, clichéd, their existence nonetheless reveals a basic truth - that in all walks of life, more can be achieved by a specialised group than by an individual.

This is not only true for football teams, Formula 1 teams and factory workers; it is also true for medical departments. It seems not only an obvious, but also an obsolete statement, as most medical departments already consist of a well-regimented team of doctors, nurses, technicians, secretarial staff, and any other personnel they need for their purposes. It seems laughable that a highly-trained surgeon should have to bother with ordering medical supplies, or that a technician would have no background experience of the specialist department he finds himself working in. Yet, for interventional radiology departments, this is very often the case.

"Cannot imagine working in an IR suite without dedicated staff"

The recent recognition by the UEMS of interventional radiology as an official division within radiology was a huge coup for interventionists everywhere, but it is only the tip of the iceberg. Up till now, it was very often seen as a sort of sideline to diagnostic radiology - something akin to Dads having a passion for tinkering around in the shed at the end of the garden after their real working day was over. However, this attitude is not at all justified, as interventional radiology has proven its mettle time and again over the last 4 decades. Indeed, many of their procedures are being adapted and used by other specialists.

A quick look through history shows us that the deriding of new ideas is more often than not a last-ditch attempt to counter a perceived threat - usually only seen as such because of a lack of understanding. But as it turns out,

the world is not flat, women are capable of voting, and interventional radiology procedures have been proven to be safe and effective. Being such a multidisciplinary branch, treating as it does cardiovascular and vertebral complaints, oncology, gynaecology and the rest, it is often perceived as being competition by many other hospital departments. For the patient, interventional radiology can be a lifeline; for the non-interventional specialist, it can seem like an intruder.

As such, interventional radiology tends to find itself without allies within the hospital system. Whether due to a lack of knowledge of its potential or a fear that it could undermine the existing status quo, there is a tendency to treat it like a bothersome younger sibling: someone to be shunted elsewhere, mocked and ignored. Usually there is no independent interventional radiology department in the hospital. If they are lucky, they are hosted by the Radiology Department, some of which are supportive of interventional radiology, and some of which are fully committed to diagnostic radiology, having a limited view of the needs of an interventionist. One thing that is certain is that there are no existing legal guidelines as to what constitutes an interventional radiology department, and thus, no framework for resource allocation.

One of the most important resources of any medical department is its staff. For optimal care to be provided, each member of the team must be able to perform their duties correctly and efficiently. However, in a large number of hospitals, interventional radiologists do not have dedicated staff, and share nurses and radiographers with other departments. The problem with this is that with constantly rotating staff, there is nobody available to ensure that medical supplies are maintained and correctly stored and kept track of. Another problem is that nurses and radiographers who are required to assist with a wide variety of procedures have less opportunity to familiarise themselves with their roles within these procedures, or to build up a working rapport with the performing clinician.

While no legislation exists about allocating dedicated staff to interventional radiology departments, a number of interventionists have nonetheless reported that their hospital managers are very supportive of their work, and that they have the resources they need to perform their jobs optimally. These doctors can testify to the advantages of having dedicated staff - Professor Jan Peregrin of the Czech Republic stated that he “cannot imagine working



"Dedicated personnel are not always available ... a major reason for failure, complications, redoing and postponing the intervention"

in an IR suite without dedicated staff." Professor Dierk Vorwerk describes his designated technician as "an absolute must to prevent friction and frustration." St. George's Vascular Institute in the UK also allocates adequate staff to its interventional radiology department: interventionist Dr. Robert Morgan said, "I cannot see how any IR department can work unless there are constant personnel who have the task of ordering catheters, balloons, etc. and monitoring the stock to make sure that it does not run out."

Other doctors are not so fortunate. Professor José Ignacio Bilbao, while more than content with his own staffing arrangements, tells us that "in Spain, we do not have an independent section of IR, apart from the radiology department in even the largest hospitals. A nurse can be in CT one week, then in MR, and later in IR." Professor Marc Sapoval tells of a similar situation in France: "...the situation is very different from one place to another and dedicated personnel are not always available. This is a major reason for failure, complications, redoing and postponing the intervention." Professor Elias Brountzos of Greece, while blessed with dedicated nurses, tells us "we don't have dedicated technicians, and I believe this is a problem in difficult and complicated cases."

There is debate as to whether legislation is the answer to this problem. Dr. Tomasz Jargiello says that in Poland, despite there being no specific regulations on the subject, every department has staff members responsible for supplies. In his opinion, legislation is not needed, as it is an issue for local hospital administration. Indeed, it does just seem common sense that all departments should be

given the resources they need, but unfortunately, not all hospital directors think the same way. As Professor Bilbao puts it, "our work is fully dependent on the sensibility of our chiefs and directors."

Professor Michael J. Lee of Beaumont Hospital, Dublin has another suggestion for circumnavigating the lack of legislation, and points out that these issues could be deemed to fall under the category of risk management. Indeed, the issue at hand is one of basic patient safety. Having irregular staff and fluctuations in availability of medical supplies is not simply inconvenient for the interventionist (although, understandably, it is); it also increases the risk of mistakes being made. Lack of equipment can mean certain conditions cannot be treated, and staff unfamiliar with the equipment increases the likelihood of errors. And errors in a medical setting can have more serious consequences than mere inconvenience.

The issue at hand is one of basic patient safety

As such, many interventionists feel that legislation is needed to make sure that these errors are avoided. It is the general opinion of interventional experts in Europe that having an international charter on interventional radiology would be beneficial, and some are already taking steps towards drawing one up. Should such a document be published, it seems certain that allocation of resources and staff will be a priority issue. Department directors and hospital managers need to be aware of the support needed by interventionists if they are to ensure state-of-the-art care for the patient, particularly the support provided by skilled and dedicated staff. A chain, after all, is only as strong as its weakest link.

** please note, the hard work carried out by supporting staff is not brought into question, rather the difficult working situation they and their colleagues are faced with.*

Mother Nature Knows Best

The natural world often has ingenious solutions to solve the most complicated of problems, and scientists can harness this for our use.

The snake has always been an object of fear for mankind, and rightly so: prey has very little defence against the venom or constrictions of a hungry snake. Its venom is either haemotoxic (attacking circulatory and muscle tissue, causing scarring, gangrene and loss of motor skills), neurotoxic (attacking the central nervous system and resulting in heart failure or breathing difficulties), or a combination of the two.

This use of chemicals to manipulate biological responses is central to medicine, and scientists have already found ways to isolate and use the venom elements that can, for example, prevent blood clotting or destroy blood vessels (feeding tumours). When these elements are isolated as a treatment, they can have better results than completely synthetic compounds, as natural toxins have evolved to target very specific cell types, which avoids many of the side effects caused by their synthetic counterparts (such as chemotherapy drugs).

So far, the venom compounds have been used for research into treatment for cancer, Alzheimer's and Parkinson's diseases, blood clots in strokes and thinning the blood. For interventional radiology, the work into drugs to regulate cardiovascular disorders is of particular significance. Anti-platelet and anti-coagulant drugs (to thin the blood and prevent clots) can help patients who are at risk of restenosis following angioplasty. The most commonly prescribed are aspirin and warfarin.

A study on Exanta, an anti-coagulant drug derived from cobra venom, has been presented as a more effective alternative to warfarin. Warfarin is hard to monitor, as it acts differently in different patients, and can be influenced by minor dietary changes. Patients taking this substance must have their blood checked every month to ensure that their blood is not becoming too thin, which can cause internal bleeding or haemorrhage following an accident. Exanta, on the other hand, seems to be more stable and, after the initial routine blood tests, patients would be spared the need for frequent check-ups. The drug has been submitted to the FDA for approval.

The potential of using natural venoms to reduce the risk of restenosis further is very exciting, and may make angioplasty an even more effective technique that is suitable for a wider range of patients. Whether these venom-based drugs could be used as post-operative control tablets or even incorporated into drug-eluting stents remains to be seen, but initial results are certainly very encouraging, and are a step on the ladder to winning the game.

Snake venom compounds have been used for research into treatment for cancer, Alzheimer's and Parkinson's diseases, blood clots in strokes and thinning the blood



<http://news.nationalgeographic.com>
www.annieappleseedproject.org

ACST-2

(Asymptomatic Carotid Surgery Trial)

ACST-2, a large simple international randomised controlled trial, is comparing carotid stenting (CAS) and carotid endarterectomy (CEA) in patients having intervention for asymptomatic carotid stenosis. Independently funded (£1.8m, UK NIHR & BUPA Foundation), the recruitment target is 5,000 patients.

Stroke is associated with a very impaired quality of life and high mortality. Patients consider major stroke a worse fate than many cancers. On a scale of 0 (death) to 1 (perfect health), major stroke scores a quality of life weighting of around 0.36 (0.2-0.7) compared to 0.6-0.7 for many cancers. We plan to evaluate the effect of CAS and CEA on patients' quality of life. This will involve procedural and stroke related healthcare costs and EuroQol-based quality of life assessments in a subset of patients.

The influence of ACST on the medical community

The five year results from the first ACST trial (comparing immediate CEA with deferred endarterectomy in patients on best medical therapy) were published in the Lancet in 2004. In asymptomatic patients ≤ 75 years of age with a $\geq 70\%$ stenosis (many of whom were on aspirin, antihypertensive, and, in recent years, statin therapy), immediate endarterectomy halved the net 5-year stroke risk from about 12% to about 6% (including the 3% perioperative hazard). Half of this 5-year benefit involved disabling or fatal strokes.

Since publication of these data, the (traditionally conservative) Northern European countries have increased their rates of carotid intervention in younger asymptomatic patients. Audit of UK carotid interventions shows an increase in CEA for asymptomatic patients (8% in 2002, 16% 2006-8 and around 20-25% currently).

Current status of ACST-2

Randomisation in ACST-2 began in 2008. The randomisation process is simple (a 2-minute phone call to the centre [open 24/7]), with one post-procedure clinical follow-up. The trial design ensures that collaborator work is minimised. Patients from centres in nine countries have already been entered and there is worldwide interest; over 180 interventionist from 96 centres have submitted track record forms and have joined or are doing so. Carotid interventionists regardless of specialty, working with stroke physicians/neurologists are invited to participate in ACST-2.

www.asct.org.uk



Report kindly submitted by Prof. Alison Halliday and Dr. Sumaira Macdonald.

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Please see overleaf for a selection of other relevant trials and registries...



Trials and Registries

Trial: a study carried out with the purpose of testing a new medical treatment on a defined group of people. The results are compared with a group that are treated using another method and/or a control group.

Registry: a (retrospective) collection of data about a certain treatment/illness. Using the compiled data, conclusions can be drawn about effectiveness of a particular treatment method.

Angioplasty

ICSS (International Carotid Stenting Study)

Contact person

Prof. Martin M. Brown, UCL Institute of Neurology, UK

Date opened

2005

Status of trial

Recruiting finished, data to follow

Source

www.cavatas.com

Description

A follow-on study to the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS), ICSS is an international, multicentre, randomised, controlled, open, prospective clinical trial evaluating primary stenting of carotid artery stenosis in patients with symptomatic disease in comparison to endarterectomy.

CORAL Study Cardiovascular Outcomes in Renal Atherosclerotic Lesions

Contact person

Dr. Lance D. Dworkin

Date opened

2005

Status of trial

Recruiting finished, data to follow

Source

www.coralclinicaltrial.org

Description

The purpose of the CORAL study is to determine the best treatment for patients who have high blood pressure and blockage of the renal artery that supplies blood to the kidney. As a patient in the study there are 2 courses of treatment. One group will receive blood pressure medication only. The second group will receive blood pressure medication plus a surgically placed stent, which is used to open the blockage.

www.clinicaltrials.gov

www.who.int/trialsearch/default.aspx

<http://clinicaltrials.mayo.edu>

CREST (Carotid Revascularization Endarterectomy vs. Stenting Trial)

Contact person

Dr. Thomas G. Brott, Mayo Clinic and University of Medicine and Dentistry, New Jersey, US

Date opened

February, 2000

Status of trial

Recruiting finished, data to follow

Source

www.umdj.edu/crestweb

Description

The purpose of this trial is to compare stent-assisted carotid angioplasty (CAS) with carotid endarterectomy (CEA) for the treatment of carotid artery stenosis to prevent recurrent strokes in those patients who have had a TIA (transient ischemic attack) or a mild stroke within the past 6 months (symptomatic) and in those patients who have not had any symptoms within the past 6 months (asymptomatic).

ASTRAL (Angioplasty and STent for Renal Artery Lesions)

Contact person

Dr. Jan Harding

Date opened

April, 2007

Status of trial

Recruiting finished, data to follow

Source

www.astral.bham.ac.uk

Description

ASTRAL is designed to address the issue of whether renal arterial revascularisation with balloon angioplasty and/or endovascular stenting can safely prevent progressive renal failure amongst a wide range of patients with ARVD.

Trans-Catheter Arterial Embolization and Surgery in Patients with Peptic Ulcer Bleeding Uncontrolled by Endoscopic Therapy (TAE)

Contact person

Dr. James Y.W. Law, Kim W.L. Au, Hong Kong University

Date opened

October, 2008

Status of trial

Recruiting

Source

www.clinicaltrials.gov

Description

The aim of the study is to examine the hypothesis that trans-catheter arterial embolisation (TAE) is safer than and probably as effective as surgery in the control of bleeding from ulcers after failed endoscopic therapy.



Angio-Seal Vascular Closure Device Registry**Contact person**

Prof. Jim A. Reekers, CIRSE

Date opened

January, 2009

Status of registry

Recruiting finished, data to follow

Sourcewww.e-dendrite.com/databases.php**Description**

Closure devices have enabled the benefits of early sheath removal and mobilisation resulting in early patient discharge. In some cases, a reduction in complications at the access site has also been reported. However, there is still limited data regarding the use of closure devices after non-coronary procedures. This registry has been initiated as a new research initiative to determine the experience of the device in interventional radiology patients. The registry has been designed to collect data from up to 100 sites by members of CIRSE and intends to recruit 1,000 patients. The data collected will include deployment success, time to haemostasis, time to mobilisation and time to discharge. A record of all in-hospital access site complications will also be made. Also, patients returning with late closure device problems can be included in this registry.

Embolisation

Pilot Study of MRI-Guided High Intensity Focused Ultrasound Ablation of Uterine Fibroids**Contact person**

Sarah Baxter

Date opened

February, 2009

Status of trial

Recruiting

Sourcewww.clinicaltrials.gov**Description**

To study the use of magnetic resonance imaging (MRI) in enhancing the safety of the FDA approved technique to treat fibroids called High Intensity Focused Ultrasound (HIFU). In this pilot study, women with symptomatic fibroids will undergo MRI guided HIFU and then have a hysterectomy. This will allow us to confirm studies done in animals which show that it is possible to destroy specific tissue without harming normal tissue surrounding the targeted area.

For more trials and registries, please visit www.intervention-iq.org. Please note that this does not constitute an exhaustive overview of trials and registries. If you are aware of a trial or registry which may be of interest to our readers, please feel free to contact us at info@intervention-iq.org.

Vertebroplasty/Back/Pain Management

A Safety and Efficacy Study for Treatment of Painful Vertebral Compression Fractures Caused by Osteoporosis**Contact person**

Dr. Maarten Persenaire, Chief Medical Officer, Orthovita, US

Date opened

February, 2006

Status of trial

Recruiting finished, data to follow

Sourcewww.clinicaltrials.gov**Description**

To describe the methods for the clinical evaluation of Cor-toss for vertebroplasty in patients with painful osteoporotic compression fractures.

Restoration of Disc Height Reduces Chronic Low Back Pain**Contact person**

Dr. Joseph V. Pergolizzi Jr., NEMA Research, Inc., US

Date opened

January, 2009

Status of trial

Completed

Sourcewww.clinicaltrials.gov**Description**

The investigators hypothesised that a 6-week treatment of non-invasive spinal decompression reduces discogenic low back pain (LBP), increases lumbar disk height, and that an increase in lumbar disc height is associated with decreased LBP.

Pain Quantification and Pain Management in Interventional Radiology**Contact person**

Dr. Ravi Murthy, Associate Professor, U.T.M.D. Anderson Cancer Center, US

Date opened

July, 2007

Status of trial

Recruiting finished, data to follow

Sourcewww.clinicaltrials.gov**Description**

This trial aims to measure and record patients' pain levels before, during, and after standard procedures performed in IR. Different procedures will also be compared in terms of respective pain levels and patient satisfaction (as determined by questionnaire).

IQ takes no responsibility for the content of the individual trials and registries; please refer to their Source for further information.



The Early Days of IR

It's amazing where accidents can lead. While many advances are the work of knowledge, inspiration and hard graft, countless others are just happy coincidences. Examples include such revolutionary innovations as penicillin, the microwave, Viagra, and the mighty, monumentally important potato chip.

Another such happy accident was the original inspiration behind interventional radiology. In November 1963, Dr. Charles Dotter was performing an everyday abdominal aortogram in a patient with renal artery stenosis. While passing a percutaneously introduced catheter retrogradely through the occlusion, he accidentally re-canalised an occluded right iliac artery. This led him to realise that, similar to plumbers using augers and drain rods to unblock pipes, catheters could be used to remove or dislodge blockages in the blood vessels. These theories were reported at the Czechoslovak Radiological Congress in June that year.

However, this was still all very theoretical - surgery was an effective discipline, and what did radiologists know about fixing patients? Finding someone to try this out on was going to prove difficult.

As luck would once again have it, the Oregon Health Sciences University soon admitted just such a candidate. 82-year-old Laura Shaw presented with a painful left foot, which was found to be due to a non-healing ulcer and gangrenous toes. All doctors she had consulted recommended that the foot be amputated, but the strong-willed lady refused. Her surgeon, Dr. William Krippaehne, had a good working relationship with Dotter, and figured if she was refusing surgery, Dotter might as well have a look at her. The reason for the injury was established to be an ideal lesion on which to perform this new therapy, and she agreed to try it. Within minutes of the procedure, her foot was warm, blood flowed easily, her pain disappeared within a week, and the ulcer soon healed. She died 3 years later of an unrelated heart complaint, with both feet still intact.



"Do not fix" case notes, from 1964
Images reproduced by kind permission of the Dotter Interventional Institute, Oregon Health and Science University

Charles Dotter 1920 - 1985
"the Father of Interventional Radiology"

- Youngest person ever to chair a radiology department in a major American medical school (Department of Diagnostic Radiology at Oregon Health Sciences University) - 1952-1985
- Goal: use of catheters for diagnosis and treatment in an attempt to replace the scalpel
- Gold medals from the American College of Radiology, the Radiological Society of North America, the Chicago Medical Society and the Chicago Radiological Society
- In 1978, nominated for Nobel Prize in Medicine
- Interventional Institute opened in his honour at Oregon Health & Science University in 1990

Surprisingly (given the positive outcome), many surgeons were not best pleased. Perhaps they genuinely felt that such experimental therapy was irresponsible and against the best interests of the patients, or perhaps they felt their specialty to be threatened - we can't be sure. But the relationship between the early interventionists and their surgical colleagues was certainly strained.

One surgeon, when sending a patient to have a left superficial femoral artery imaged, even wrote "visualize, but do not try to fix!!!" on the case notes. Dotter did what was asked, but with one slight difference: the diagnostic angiogram revealed that there were not one, but two occlusions in the leg - the deep femoral artery also showed signs of stenosis.

So Dotter fixed the one not mentioned in the case notes. He later took great delight in highlighting the fact that while the open superior femoral arterioplasty (surgical) procedure failed, his dilated stenosis remained open for 5 years.

Despite his interventional procedure having, in this case and in many others, a better outcome than surgically-treated occlusion, many still felt disinclined to consider these procedures as a valid treatment. Some even attempted to have his medical licence revoked. In trying to get the results of his work published, he met with difficulty - the surgical journals were not interested in this new quackery, and the radiology journals (diagnostic as they were) did not understand his papers. In the end, the first clinical results of angioplasty were published in, of all places, a gynaecology magazine. Funny how things go.

www.sirweb.org
www.cirse.org
www.pubmedcentral.nih.gov



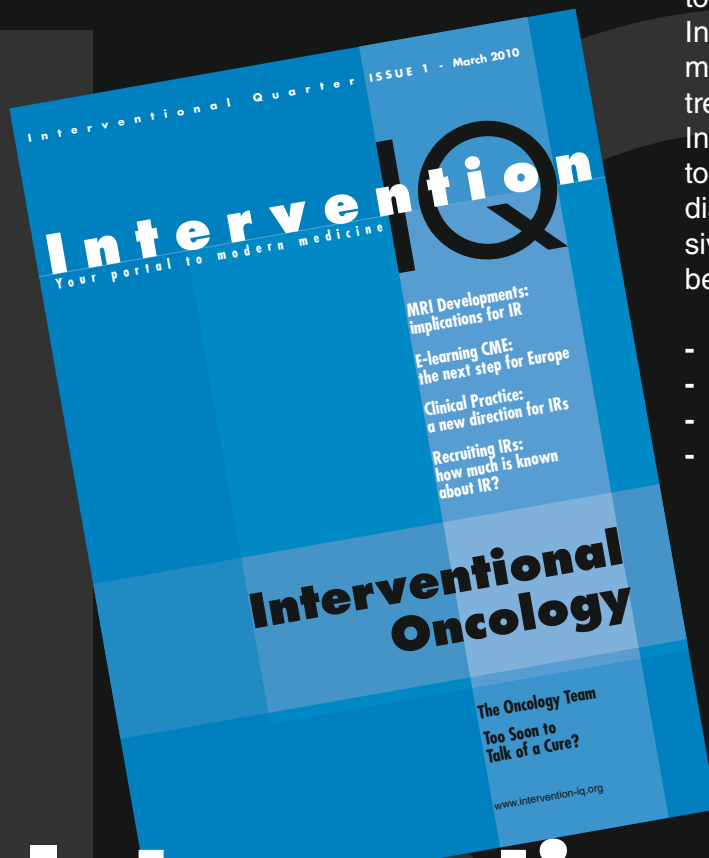
What's in store

Coming up in Issue 1, March 2010

Taking a closer look at the increasing role interventional oncology is playing in the fight against cancer

Interventional oncology is working alongside the more traditional treatment fields of medical oncology, surgical oncology and radiation oncology to treat this highly-prevalent disease. Interventional breakthroughs have been made in many types of cancer, with the most commonly treated being lung, liver and prostate cancer. Interventional oncology techniques can be used to target the tumour directly, to relieve pain or to diagnose cancer without the need for more invasive surgical biopsy. Interventional oncology has become well established in the following areas:

- Chemoembolisation
- Tumour ablation
- Relief of obstructions
- Tumour biopsy



Interventional Oncology

... Quarterly Focus

If you are interested in contributing to IQ, please contact info@intervention-iq.org

Also featured:

- MRI Developments: implications for IR
- E-learning CME: the next step for Europe
- Clinical Practice: a new direction for IRs
- Recruiting IRs: how much is known about the profession?

