

Big strides in evidence backing prostatic artery embolization

New evidence supporting prostatic artery embolization created a buzz at the Cardiovascular and Interventional Radiological Society of Europe annual meeting (CIRSE; 16–20 September, Copenhagen, Denmark). Six-month results from a randomised trial from Spain found embolization a genuine alternative to resection of the prostate and the first presentation from the UK-ROPE registry showed that embolization is highly effective in reducing lower urinary tract symptoms (LUTS) in men with benign prostatic obstruction, and that it really wins on patients' length of stay in hospital.

Randomised trial finds prostatic artery embolization “a real treatment alternative” to resection

Six-month results from a prospective, randomised, non-inferiority study presented at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE; 16–20 September, Copenhagen, Denmark) reveal that prostatic artery embolization is safe and effective in the treatment of benign prostatic hyperplasia (BPH) and that it results in symptomatic improvement for patients based on achieving a decrease in prostate volume.

Ana Sáez de Ocáriz García, Complejo Hospitalario de Navarra, Pamplona, Spain, who reported the results, said: “This clinical trial shows that prostatic artery embolization is a real alternative that is not inferior to transurethral resection. Further, the results show that there are no severe complications related to prostatic artery embolization. We would like to emphasise the importance of teamwork between urology and interventional radiology in furthering this treatment.”

BPH can result in lower urinary tract symptoms (LUTS) which are usually treated with medication at first instance. However, medical treatment often fails in the medium to long term. At this point, the “gold standard” treatment offered to patients is transurethral resection of the prostate (TURP), but there are many alternatives that are being explored such as microwave treatment, laser ablation, and high-intensity focused ultrasound. Superselective transarterial embolization



Ana Sáez de Ocáriz García

of the prostate is one such treatment alternative and interventionists hope that it will have the same effectiveness, but with fewer side-effects.

The randomised trial set out to compare clinical and urodynamic results of prostatic artery embolization and TURP in the treatment of LUTS in patients with BPH. The trialists also set out to evaluate early complications related to sexual function and compare the gain in quality of life between the two treatments.

“In our study, we enrolled 80 patients. Twenty one were excluded and then 60 patients were randomised in a 1:1 ratio. We assigned 30 to the embolization group and 30 to the TURP group (however, one patient declined the surgical procedure). There was no substitution mechanism and the treatment allocation was not masked. We collected data on maximum urinary flow rate (Qmax), international prostate symptom score (IPSS), quality of life (QoL), international index erectile function (IIEF), prostate specific antigen, prostatic volume, and post void residual volume in the follow-up

visits scheduled for one, three, six and 12-months after treatment. Here, we present the six-month results,” Sáez de Ocáriz García said.

Patients had to be older than 60 years of age, diagnosed with BPH and have moderate or severe obstructive LUTS that was refractory to six months of medical therapy in order to be eligible. They also needed to have a Qmax of less than 10mL/s, and to be able to provide written informed consent. Baseline characteristics between the two groups were comparable.

Patients were excluded if they had severe atherosclerosis and tortuosity of the iliac arteries; unidentifiable prostatic arteries by CT angiography; allergy to iodinated contrast; urethral stenosis; neurogenic bladder; malignant tumour; glomerular filtration rate of less than 30mL/minute; and any other important and uncontrolled disease that interferes with participating in a trial.

The improvement in maximum urinary flow rate (Qmax) was the main effectiveness endpoint. Secondary endpoints included improvement in IPSS score. Reduction in prostatic volume, no worsening or improvement of erectile function; reduction of PSA and post-void residual volume; and patient satisfaction with the intervention performed.

“One of the most important things is CT angiography that helps to select patients and obtain the imaging needed to perform the procedure. While the origin of the prostatic arteries is very variable, the most important arteries are the internal pudendal, gluteal pudendal, obturator artery and

Continued on page 2



John Kaufman:
IVC filters

Page 22



Andrew Holden:
Profile

Page 26

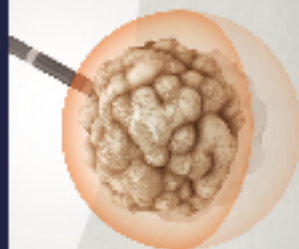
Randomised data reveal theoretical benefit with microwave ablation “does not translate into clinical benefit” for hepatocellular carcinoma patients

A prospective randomised controlled study that compared outcomes between hepatocellular carcinoma patients who were treated either by microwave ablation with those who were treated by radiofrequency ablation, did not find a benefit for microwave over radiofrequency. For local tumour progression and survival at two-year follow-up, “the theoretical benefit of microwave does not translate into clinical benefit for hepatocellular patients with lesions smaller than 4cm. This was a negative trial as microwave failed to demonstrate superiority over radiofrequency,” said Alban Denys, Radiology, Lausanne University Hospital, Lausanne, Switzerland, who presented the results at CIRSE 2017.

Denys reported that this was the first prospective, randomised, multicentre study to compare the efficacy of radiofrequency ablation with microwave ablation. The theoretical advantages of microwave include

Continued on page 6

MINIMALLY
INVASIVE.
MAXIMUM
PREDICTABILITY.



EMPRINT™
ABLATION SYSTEM
POWERED BY
THERMOSPHERE™
TECHNOLOGY

2016
TOP 100
GLOBAL
INNOVATORS
Clarivate
Analytics

Big strides in evidence backing prostatic artery embolization

Continued from page 1

vesical-prostatic artery," she noted.

Results

The investigators achieved technical success in 100% of patients with both techniques. At 24-hours, patient satisfaction with embolization was nearly 84%; whereas it was 77% with TURP. Those who underwent embolization reported a mean pain score of 0.5, compared to those who underwent TURP (mean VAS = 2.9). On average, embolization was a longer procedure than TURP. On average, those who underwent embolization stayed in hospital for a day, when compared to nearly two days for those who underwent TURP. There were no complications with either procedure.

At six months, there was significant improvement in the Qmax of both groups with the gains being very similar. There was also improvement in the IPSS score in both groups, with TURP appearing to confer a greater benefit. "Most of the quality of life improvement was seen in the first three months after the procedure with some subsequent stability. While post-void residual volume reduction was similar in both groups, the reduction of prostate volume was greater with TURP than embolization," Sáez de Ocáriz García explained.

Minor complications after embolization included haematuria (two patients); haemospermia (two patients); intermittent claudication (one patient) and radiodermatitis (one patient). There was also one major complication—a rectal ischaemic plaque.

Minor complications after TURP included urinary incontinence (one patient); stenosis of the urethral meatus (one patient); testicular pain (one patient) and urinary urgency (one patient). There was also one major complication of urethral stenosis in one patient.

"The results after six months of embolization were a decrease of 25 points in IPSS, an increase of three points on IIEF, and a decrease of 37.2% in prostate volume. All patients with acute urinary retention could remove the bladder catheter, three weeks after," the authors reported.

Multicentre UK registry results highlight embolization strengths and importance of physician experience

The first results from the UK- ROPE multicentre registry reveal that prostatic artery embolization is highly effective in reducing lower urinary tract symptoms (LUTS) in men with benign prostatic obstruction (BPO).

When compared directly with a matched cohort of men undergoing Transurethral Resection of Prostate (TURP) it was almost as effective as resection. Patients who underwent minimally invasive embolization stayed significantly fewer days in hospital compared to those who underwent TURP.

Nigel Hacking, a consultant interventional radiologist at University Hospital Southampton NHS Foundation Trust, Southampton, UK, presenting the results at the CIRSE annual meeting, said: "We have showed that prostatic artery embolization is safe and efficacious and we really win out on length of stay. The median length of stay after embolization is zero days compared with a median of two days with TURP. "So for men who would rather avoid surgery, embolization is an excellent first option with likely economic benefits due to the day case nature of the procedure," Hacking said

UK ROPE (Registry of prostate embolization) is the first multidisciplinary registry of the prostatic embolization. It aimed to compare two cohorts of patients who underwent different treatments for lower urinary tract symptoms following benign prostatic hyperplasia: prostatic artery embolization and resection. The embolization arm had 216 patients; the resection arm included TURP (n=89) and holmium laser prostatectomy (HoLEP; n=13). The registry was designed as a non-inferiority study, ie, one that compares a novel treatment to an active treatment with a view to show that it is not clinically less effective with regards to a specified endpoint. The UK registry was jointly funded by the National Institute of Health and Care Excellence (NICE), the British Society of Interventional Radiology (BSIR), the British Association of Urological Surgeons (BAUS) and Cook Medical.



Nigel Hacking

Investigators began recruiting in July 2014 and closed in January 2016. They enrolled 318 patients. The primary endpoint was the International Prostate Symptom Score (IPSS) score at 12 months. There were multiple secondary endpoints including length of stay; complication rates; re-intervention rates; prostate volumes; flow studies; and erectile function after the procedures, diagnosed using the International Index of Erectile Function (IIEF-5).

The UK ROPE registry results show a significant improvement in 12 months for both groups. Embolization is clinically effective, producing a median 10-point improvement in IPSS score. There was greater IPSS improvement in TURP cases, with a median 15-point IPSS improvement. "Propensity score analysis on 65 closely matched embolization/TURP patient-pairs support these findings. Embolization had "slightly worse" outcomes than TURP, but was still very effective," said Hacking.

Similarly, the IPSS quality of life score showed that there was significant improvements in both groups at 12 months. There was greater quality of life improvement in TURP cases, "but the urologists and scientists have been very impressed with these results for embolization," Hacking explained.

Results from the registry

- Erectile function as measured by the IIEF-

5 (that has a maximum score of 25), went up from a baseline of about 14.5 in both groups to 16.3 after embolization, and 14.8 in the TURP group at one year.

- Urinary flow (Qmax) improved from baseline in both groups, but more in the TURP group. At baseline, the median score for embolization was 8.8 and at 12 months, it was 14.1. For TURP, baseline median Qmax was 10.4 and at 12 months, it was 22.3.
- Residual volume in the embolization group was 161 at baseline and 129 at 12 months. Baseline values in the TURP group were 263 and at 12-months, they were 80.
- There was a reduction in prostate size in both groups, with an average reduction of nearly 30% in the embolization group.
- Embolization scored over TURP when it came to the time that patients took to return to normal; on average, this was about five days after embolization, as against 14 days after TURP.

National Institute for Health and Care Excellence (NICE), which provides national guidance in the UK and advice to improve health and social care, is currently reviewing the data and investigators anticipate that there will be new guidelines issued in Spring 2018.

Complications and reoperations

There was one blood transfusion, four haematomas, and one case of sepsis in the group that underwent embolization. This compared with no blood transfusions, or haematomas, but two cases of sepsis in the TURP group.

The reoperation rate for the embolization group was 5% within 12 months and 11.6% when planned operations after the 12-month period are taken into account. In the TURP group, within the 12-month period, the reoperation rate is 3.4% and just 1.1% after the 12-month period. The reoperation rate in the embolization group was slightly higher than reported in some other series. Prostatic artery embolization failures are mainly due to unilateral embolization, median lobe obstruction, or patient dissatisfaction despite

Continued on page 4

InterventionalNews

Editors-in-chief:
Professor Andy Adam
Dr Brian Stainken

Publisher:
Stephen Greenhalgh

Director of Publishing and Communications:
Marcio Brito

Editor:
Urmila Kerslake
urmila@bibamedical.com

Editorial contribution:
Amanda Nieves
David Brennan

Design
David Reekie and Naomi Amorra

Layout:
Naomi Amorra

Advertising:
Shilpa Suthar
shilpa@bibamedical.com

Subscriptions:
Susan Couch
susan@bibamedical.com

Please contact the *Interventional News* team with news or advertising queries
Tel: +44 (0)20 7736 8788
Published by:

BIBA Medical,
526 Fulham Road
London, UK
SW6 5NR
Tel: +44 (0) 20 7736 8788
Fax: +44 (0) 20 7736 8283

Printed by:
Buxton Press

Reprint requests and all correspondence regarding the newspaper should be addressed to the editor at the above address.

© BIBA Medical Ltd, 2017
All rights reserved.

Write to us!

If you have comments on this issue or suggestions for upcoming editions write to urmila@bibamedical.com



Make sure you get your copy of

InterventionalNews

Next issue **February 2018**

New guidelines on radiation exposure to significantly reduce annual eye dose limits

ELISEO VANO
GABRIEL BARTAL



COMMENT & ANALYSIS

The new European Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation will come into effect on 6 February 2018. The most relevant change for interventionists in the occupational exposure section is the new annual limit for the lens of the eyes (20 mSv/year, instead of 150 mSv/year), write Eliseo Vano (Madrid, Spain) and Gabriel Bartal (Kfar Saba, Israel).

With these new radiation safety legislation coming into effect soon, the Radiation Protection Pavilion at the Cardiovascular and Interventional Radiological Society of Europe's annual meeting in Denmark was a timely and interactive awareness campaign for radiation protection and dose management.

The new European Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation is expected to have a relevant impact on European diagnostic and interventional radiology. The Directive was adopted by the Council of the European Union (EU) on 5 December 2013. Member States of the European Union are required to complete the transposition

of the Directive into national legislation by 6 February 2018. After the transposition, the implementation of the new requirements will represent a serious challenge for the interventional practices in Europe, but is expected to substantially improve the radiation safety for patients, as well as personnel.

The most relevant changes in the new Directive (with impact on interventional practices) in comparison to the existing ones may be summarised as follows: Use and regular review of diagnostic reference levels (DRLs) including interventional procedures; Education and training (not included in the chapter on medical exposures); Responsibilities (involvement of several professionals in optimisation); Role of medical physics experts in

diagnostic and interventional procedures; New requirements for equipment; Procedures: optimisation process, clinical protocols and clinical audit; Registry and analysis of accidental or unintended exposures of the patients. The most relevant change in the occupational exposures is the new annual limit for the lens of the eyes (20 mSv/year instead of 150 mSv/year).

The use and regular review of diagnostic reference levels is a new requirement. Appropriate local reviews are needed whenever diagnostic reference levels are consistently exceeded and require corresponding corrective action without undue delay. The impact of complexity factors when setting diagnostic reference levels in interventional procedures will be a challenge

and implemented gradually with the transition to new angiography equipment.

Member States shall ensure that practitioners and the individuals involved in the practical aspects of medical radiological procedures have relevant competence in radiation protection. Appropriate curricula need to be established and corresponding diplomas, certificates or formal qualifications, recognised. Continuing education and training after qualification need to be provided and especially when new techniques are introduced.

With regards to responsibilities, it is stressed that any medical exposure takes place under the clinical responsibility of a practitioner and that the practitioner, the medical physics expert and those entitled to carry out practical aspects of the procedures shall be involved in the optimisation process.

The Directive contains new requirements for equipment: Any equipment used for interventional radiology shall have a device or a feature informing on the quantity of radiation produced by the equipment during the procedure and shall have the capacity to transfer the dosimetric information to the record of the examination (equipment installed prior

to 6 February 2018 may be exempted from this requirement). Member States shall ensure that "Information relating to patient exposure forms part of the report of the medical radiological procedure".

It is also required to give information to the referrer, the practitioner, and the patient or their representative, about clinically significant unintended or accidental exposures and the results of the analysis and to declare them as soon as possible to the competent authority.

References

1. European Council Directive 2013/59/Euratom on basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. OJ of the EU. L13; 57: 1-73 (2014).
2. European Society of Radiology (ESR). Summary of the European Directive 2013/59/Euratom: essentials for health professionals in radiology. Insights Imaging. 2015 Aug; 6(4): 411-417.
3. CIRSE 2017. Copenhagen. Hot Topic Symposium. Radiation Protection: Burning Issue. Radiation Protection: Are you prepared for the new legislation in 2018? E. Vano.

Eliseo Vano is with the Department of Medical Physics Service, San Carlos University Hospital, Instituto de Investigación Sanitaria del Hospital Clínico San Carlos, Madrid, Spain. Gabriel Bartal is director, Department of Medical Imaging and Interventional Radiology at Meir Medical Center, Kfar Saba, Israel. The authors have reported no disclosures pertaining to the article

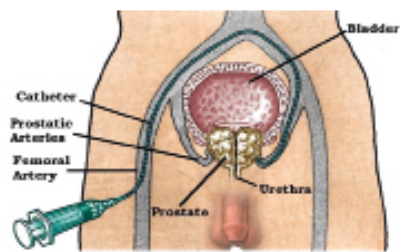
Big strides in evidence backing prostatic artery embolization

Continued from page 2

IPSS improvement, Hacking said.

Patient reported complications included haematuria, haematospermia, and retrograde ejaculation (24% in the embolization group and 47% in the TURP group). These figures are likely to be inaccurate, due to the nature of a 'questionnaire-based study' as on direct questioning many of the men reporting retrograde ejaculation after embolization admitted that this symptom started after oral medication, months or years, before the prostatic artery embolization.

Commenting on the strengths of the data, he noted: "This was the first multicentre study, funded by multiple stakeholders, with an independent medical assessment unit. There was a free choice of embolic, and catheter/microcatheter. Still, this is non-randomised data, and the results would have been influenced by the learning curve for all but two participating centres who were being trained to perform prostatic



Prostatic artery embolization

artery embolization, even as they recruited to the registry as this is a difficult procedure with a clear learning curve. Also, the study had a 12-month endpoint, meaning that outcomes outside of this defined window will not form part of the analysis. We also used the original rather than the PerFecTED technique."

New EURO-ROPE registry on the cards

Hacking also said that another multidisciplinary, multinational, multicentre registry of prostatic artery embolization,

EURO-ROPE, is on the cards, potentially scheduled to begin recruiting in 2018. EURO-ROPE will have support from CIRSE and advice from key members of the European Association of Urology (EAU). It will be industry-sponsored and designed to rapidly collect data from 1,000 patients who will undergo embolization and then be followed for two years. "Participant centres are being trained and proctored in 2017, so that experienced teams of interventional radiologists and urologists will be involved in the data collection," Hacking concluded.

Other presentations at the CIRSE annual meeting demonstrated that prostatic artery embolization is a very useful technique for controlling the quite debilitating condition of haematuria in patients with normal upper urinary tracts. Charles Tapping, Oxford, UK, who presented the study, also reported embolization has shown

promise in controlling haematospermia "which is a notoriously difficult condition for urologists to treat", he said. The results of the Oxford study showed that controlling haematuria in patients with inoperable cancer and benign prostatic hyperplasia allows an improved quality of life. "Further studies on prostatic artery embolization and prostatic cancer are warranted," Tapping noted.

Another study, also from Southampton, reported that prostatic artery embolization improves both voiding and storage symptom "which suggests that neural denervation plays a considerable role in symptomatic improvement," D Maclean, presenting, said. He also explained that if benign prostatic obstruction is confirmed with formal urodynamic studies, severe storage symptoms are the best predictors of a good symptomatic improvement.