EuroScan International Network

Prostatic artery embolisation to treat benign prostatic hyperplasia

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Technology, Company and Licensing

Technology name	Embosphere microspheres,Embozene microspheres, •Polyvinyl alcohol particles
Technology - Description	Prostatic artery embolisation (PAE) was first introduced in the 1970s as a technique to control major bleeding associated with prostatectomy and prostate biopsies.(1-3) The therapeutic benefits of this technique on benign prostatic hyperplasia (BPH) were later realised (4) and animal studies later ensued.(5, 6) PAE was first investigated as an alternative treatment for benign prostatic hyperplasia in 2010.(7) The aim of prostatic artery embolisation for the treatment of BPH is to starve the prostate gland of its blood supply and nutrients leading to ischaemic necrosis of part of the gland.(8) As a result, the prostate gland shrinks in size thereby improving benign prostatic hyperplasia and its associated symptoms of lower urinary tract symptoms (LUTS). PAE is a non-invasive technique performed by interventional radiologists, in consultation with urologists, under local anaesthesia and sedation. The procedure is performed using a left or right femoral artery approach. Fine microcatheters are guided through the internal iliac and vesical arteries allowing the super-selective catheterisation of the small prostatic arteries.(9) Embolisation involves releasing microparticles into the prostatic arteries to block the vessels that feed the prostate gland.(9) Several types of embolisation agents have been reported in published prostatic artery embolisation trials which include: •Tris-acryl gelatin microspheres7, 10 •Non-spherical polyvinyl alcohol (PVA) particles (11-14) •Spherical embolic agents: hydrogel microspheres with a proprietary coating (15) Various sized embolising particles have been used. One study has compared different polyvinyl alcohol particle sizes on the outcome for PAE.(16) Embolising particle sizes used in published prostatic artery embolisation trials which include: •300–500 µm microspheres,(10, 17) •80–180 µm or 180–300 µm nonspherical polyvinyl alcohol (PVA) particles,(11-13, 16, 18, 19) •100–400 µm spherical embolic agents.(15) A pelvic angiography using non-ionic contrast medium is often used to make an initial assessment of the anatomy of the iliac and prostatic arteries. The blood supply of the prostate is then assessed using a selective angiography. Contrast medium is injected manually to ensure the correct positioning of the tip of the micro-catheter. The embolising agent is delivered in a solution of contrast medium and saline under the guidance of a fluoroscopy. The National Institute for Health and Care Excellence (NICE) in the UK has published an interventional procedures programme20 and a procedure guidance (9) of prostatic artery embolisation for benign prostatic hyperplasia. These guidelines recommend that the procedure should only be performed in the context of research and that consideration of the patient should be undertaken by a multidisciplinary team (including an interventional radiologist and urologist).

Company or developer	CeloNova Biosciences, Cook Medical, Merit Medical
Reason for database entry	Prostatic artery embolisation is a treatment of LUTS due to benign prostate hyperplasia and is a less invasive alternative to a transurethral resection of prostate (TURP) operation.
Technology - stage in early warning process	Assessment complete
Technology - stage of development	Other
Licensing, reimbursement and other approval	The embolising agents approved for use in Australia TGA are: •Embospheres (Endotherapeutics Pty Ltd) ARTG 144426 This device is currently only indicated for arterial embolisation to provide controlled vascular occlusion to selected regions of the neurovasculature and peripheral vascular circulation. In Europe, the embosphere microspheres (Merit Medical Systems, South Jordan, UT) has recently received the CE mark to allow the device to be used in Europe to relieve the symptoms caused by benign prostatic hyperplasia. •Polyvinyl Alcohol Foam Embolisation Particles (William A Cook Australia Pty Ltd) ARTG 216797 This device is intended for embolisation of the blood supply to hypervascular tumours, symptomatic uterine fibroids and arteriovenous malformations, including use in intracranial embolisation. •Embozene TANDEM Microspheres (N Stenning & Co Pty Ltd) ARTG 217807 and Embozene Color-Advanced Microspheres (N Stenning & Co Pty Ltd) ARTG 216397. These devices are indicated for embolisation for the following conditions: hypervascular tumours; arteriovenous malformations; uterine fibroids; hepatocellular carcinoma; tumours of head, neck, torso, and skeletal system; bleeding and trauma; pre-operative reduction of bleeding other than in the central nervous system.
Type(s)	Procedure
Use(s)	Therapeutic

Patient Indication and Setting

Patient indications	Patients with acute urinary retention due to benign prostatic hyperplasia
Disease description and associated mortality and morbidity	BPH is characterised by non-malignant enlargement of the prostate gland caused by hyperplasia (increase in number) or hypertrophy (increase in size) of prostatic stromal and epithelial cells.(9) The enlarged prostate compresses the urethra giving rise to LUTS including voiding symptoms (weak stream, hesitancy, intermittency, straining and incomplete bladder emptying) and/or storage symptoms (frequency, urgency, nocturia and urinary incontinence).(21) In severe cases, BPH can lead to renal insufficiency and failure, urinary tract infection, and bladder stones and acute urinary retention.(22) Acute urinary retention, a sudden inability to pass urine, requires emergency treatment to empty the bladder using a urinary catheter. Benign prostatic hyperplasia and lower urinary tract symptoms are associated with serious morbidities.(23) The presence of severe LUTS has been demonstrated in one study to significantly increase the risk of falls by 63 per cent compared to men without symptoms.(24) Benign prostatic hyperplasia, and its related symptoms, significantly interfere with normal daily activities and sleeping patterns and are associated with depression and diminished health-related quality of life.(25, 26)

Number of patients	Benign prostatic hyperplasia is a common age-related condition affecting males.9 The Urologic Diseases in America study of BPH showed an increase in the prevalence of moderate-to-severe LUTS with age, affecting a quarter of males in their 50s, a third of males in their 60s and nearly a half of males over 80 years.(27, 28) The study also showed an overall incidence of acute urinary retention of 6.8 episodes per 1000 patient-years of follow-up rising to 34.7 episodes per 1000 patient-years in males over 70 years with moderate-to-severe lower urinary tract symptoms.(27, 29) Based on the latest hospital separation data from the Australian Institute of Health and Welfare National Hospital Morbidity Database,30 a total of 19,407 TURP operations were performed in 2011-12 across public and private hospitals in Australia. An additional 11,928 prostatectomy (open and closed) operations were performed during this period; however these procedures are primarily performed for prostate cancer with a small proportion for benign prostatic hyperplasia. In Australia during 2009-1031, there were a total of 7,686 public hospital admissions for transurethral prostectomy (L05A and L05B). The number of public hospital admissions for benign prostatic hyperplasia (M61Z) was 1,674.
Technology - specialties	Renal disease & urology, Mens Health & Sexual Health
Technology - Setting(s)	Specialist hospital
Setting - further information	

Impact

Alternative and/or complementary technology	Additive or complementary technology
Current technology	For males with moderate-to-severe lower uterine tract symptoms, TURP is considered the gold standard surgical intervention for management of benign prostatic hyperplasia. The morbidity of TURP is low (<1%) and has an associated mortality rate of 0–0.25%.(32) The morbidities associated with TURP surgery can be serious and common postoperative complications include serious bleeding, clot retention, storage urinary symptoms and urinary tract infections.(32) Bleeding can be markedly increased in patients with urinary retention.(32) In the long-term, major adverse events include permanent ejaculatory dysfunction (53%–75%), urethral strictures (2.2–9.8%) and bladder neck contractures (0.3–9.2%) with a retreatment range of 3–14.5% after five years.(32)
Health impact	
Diffusion	Prostatic artery embolisation is not performed in Australia for the management of BPH. The Urological Society of Australia and New Zealand recommends that PAE should be considered experimental and as such, should only be offered within the context of an approved clinical trial.(33) The technique of arterial embolisation is, however, a widely diffused technique for a range of other clinical indications such as controlling bleeding and the blood supply to hypervascular tumours, symptomatic uterine fibroids and arteriovenous malformations.

Cost, infrastructure and economic consequences	Costs associated with PAE to treat benign prostatic hyperplasia largely depend upon the procedural costs and prostheses (i.e. embolising agent). The procedure, as described in trial publications, involves the following steps: 1.The iliac and prostatic vessels are initially assessed using a pelvic angiography. 2.The blood supply of the prostatic arteries is further assessed using a catheter under a selective arteriography. 3.A micro-catheter is used for super-selective catheterisation of the bilateral inferior vesicle arteries. 4.An angiography is performed using contrast medium to ensure that the correct positioning of the micro-catheter. 5.Under the guidance of a fluoroscopy, embolisation is conducted using an embolising agent (diluted in a solution of contrast medium and saline). The estimated cost to government for prostatic artery embolisation procedure are presented in Table 1. The costs presented in this table are Medicare costs only using MBS item numbers and do not include out-of-pocket costs associated with the procedure. The estimated total cost of the prostatic artery embolisation is $4,489. These costs are similar to the reported fee of €4,712 (AUD$6,620) per patient for a prostatic artery embolisation procedure in a clinic in Portugal.(37) In addition to the procedural and prostheses costs for PAE, additional out-of-pocket costs including associated pharmaceuticals, hospitalisation required associated with complications, equipment, training, and annual service contracts should be considered.
Ethical, social, legal political and cultural impact	Prostatic artery embolisation is a minimally invasive procedure that may be a favourable option for men with symptomatic benign prostatic hyperplasia who may wish to minimise the risks of sexual dysfunction and reduced fertility.

Evidence and Policy

Clinical evidence and safety	For full results/tables please access the full report using the website link provided Safety and effectiveness Most of the studies on prostatic artery embolisation for benign prostatic hyperplasia are of low quality due to their case series design. As such, these studies are unable to provide evidence regarding the effectiveness of prostatic artery embolisation as an intervention, however, they can inform on the safety of the procedure. Comparative studies are necessary in order to adequately assess the effectiveness of an intervention. There is only one published randomised controlled trial (RCT) comparing the effectiveness of prostatic artery embolisation with the "gold standard" transurethral resection of the prostate (TURP) in patients with lower urinary tract symptoms due to benign prostatic hyperplasia.(38) To date, no high-quality multi-centre RCTs have been published on the short- or long-term safety, effectiveness and cost-effectiveness of prostatic artery embolisation for management of benign prostatic hyperplasia. A recent systematic review (39) on PAE in patients with BPH identified eight cohort studies (10-13, 15, 17-19) and one RCT (compared two different sized embolising particles).(16) All of the nine studies involved patients benign prostatic hyperplasia and moderate-to-severe lower urinary tract symptoms and were conducted by three research groups and, therefore, the total sample reported (n=706 patients) involves considerable overlap in patients.(14) All patients had benign prostatic hyperplasia and moderate-to-severe lower urinary tract symptoms. One study excluded patients with acute urinary retention (15) whilst one study included only patients with acute urinary retention (n=11).(10) Only one study was identified for inclusion in this Brief: the prospective RCT comparing the effectiveness of PAE with TURP by Gao et al. (2014) in patients with lower urinary tract symptoms related to BPH.(38) The RCT comparing PAE versus the reference standard TURP surgical treatment was conducted in China by Gao et al. (2014).(38) The study enrolled 114 male patients who had BPH with moderate-to-severe lower urinary tract symptoms refractory to medical treatment. Patients were randomised to receive PAE (intervention arm, n=57) or TURP (n=57). The description of this RCT trial is summarised in Table 2. There was no blinding of participants. Patients with an International Prostate Symptoms Score (IPSS) greater than 7, prostate volume of 20 – 100 ml and a peak urinary flow less than 15 ml/sec were included in the study. The proportion of patients with acute urinary retention was not recorded. The prostatic artery embolisation was performed with polyvinyl alcohol microspheres (355–500 µm). The mean length of follow-up was 22.5 months (follow ups at 1, 3, 6, 12, and 24 months). Primary outcomes included International Prostate Symptom Score (IPSS), quality of life, peak urinary flow, post voiding residual urine volume, prostate volume and prostate specific antigen (PSA) level. No differences in baseline characteristics were found between the two groups (Table 3). At baseline, the mean IPSS for both groups was approximately 23; this is in the severe range for urinary symptoms. Participants had a mean peak urine flow of between 7.3 to 7.8 ml/sec and a mean post-void residual urine volume for PAE and TURP of 115.4 +/- 69.1 and 126.9 +/- 68.8, respectively. Results of the relevant pre-operative and post-operative outcomes comparing PAE and TURP are presented in Table 4. All efficacy variables showed similar improvements at 12- and 24- month follow-up in both groups. The functional measures showed greater improved in the TURP group at 1- and 3- month follow-up compared to PAE group. This finding reflects the different mechanisms of action between the two interventions as PAE requires several months for the change in blood supply to take effect on the prostate gland.(12, 13) Prostate volume showed a significantly greater reduction in the TURP group at all time-points. Quality of life was assessed using a single item question rating scale from 0 (delighted) to 6 (terrible) and showed similar improvements between groups at 12- and 24-month follow-up. There is a paucity of high quality, peer-reviewed data for longer than 24 months of follow-up for patients with PAE. A cohort study by Pisco et al (2013)13 of

patients with LUTS due to BPH (n=255) presented data up to 36 months and showed deterioration in IPSS, peak urinary flow (Qmax) and Post-void residual volume after 3 and 6 months for some patients following an initial improvement. This data was however, only based on a small proportion (<4%) of patients at 36 month follow-up. A case series study by Carnevale et al (2013)10 (n=11) followed up patients from 19 months to 4 years (mean 28.6 months), however, only two patients had a follow-up at 4 years.

The long term outcomes following PAE remain fairly unclear, with limited data beyond 24 months. From the data presented, PAE appears to offer inferior short-term improvements, yet similar medium-term (6 to 24 months) symptom control, urinary flow and post-void residual compared to TURP.

Safety

Four studies were identified as relevant for inclusion in evaluating the safety of PAE: one RCT38 comparing the PAE to TURP and three cohort studies.(10, 13, 15) Five cohort studies (11, 12, 17-19) were not included in the safety analysis due to the significant overlap in patients with the included studies. These studies are summarised in Table 5.

Intraoperative outcomes

The intraoperative outcomes, adverse events and complications for the four included studies (10, 13, 15, 38) are summarised in Table 6. In the study by Gao et al. (2014), the mean procedure time for PAE (89.7 +/- 17.1 minutes) was not significantly different to TURP (83.5 +/- 17.5 minutes). The procedure time for PAE was fairly consistent between most of the studies ranging from 72.0 to 89.7 minutes (13, 15, 38), however, one study reported a longer mean procedure time for PAE of 197.5 minutes. This is potentially due to a learning curve for the procedure.

Intra-operative (radiation exposure)

The PAE procedure required interventional fluoroscopy which involves a radiation beam directed over a small surface area of skin for a considerable amount of time. PAE is a complicated procedure involving complex anatomical structures of the prostatic arteries. This complexity leads to an increased radiation dose to patients and health care providers. Older males are less sensitive to the stochastic effects of radiation, however, fluoroscopy time also influences the radiation dose.(40) Lengthy fluoroscopy times during PAE can occur regularly.(41) The mean fluoroscopy time across the four studies ranged from 18 to 86 minutes which is longer than uterine artery embolisation, a relatively similar vascular embolisation procedure.(42) It is possible the longer fluoroscopy time for PAE may be due to the complex nature of the prostatic arteries. Alternatively, PAE is a novel procedure and the fluoroscopy time may reduce as interventional radiologists gain more experience performing the technique.

The highest radiation dose is targeted on the patient's skin. Acute radiation doses of >2 Gy can lead to radiation-induced skin damage such as skin burn, hair loss and in severe cases, skin necrosis.(43) Long-term effects of interventional fluoroscopy include the potential risk of cancer.(44) The radiation dose was reported in only two15, 38 of the four studies with a mean radiation dose of 11,305.1 cGy/cm2 reported by Goa and colleagues38 and average dose-area product of 55,923 µGy.cm2 reported by Bagla and colleagues.(15) None of the studies reported any serious skin injuries or complications related to radiation exposure, however, more long term research is required to determine the effects of radiation exposure from PAE with fluoroscopy imaging.

Chronic radiation exposure also poses a risk of radiation to health care personnel with increased reported of skin changes on the hands and damage to the lens of the eye (45) and radiation-induced cancers. In order to minimise the risk of radiation to both the patient and the health care providers, the fluoroscopic procedures should be performed with the lowest acceptable exposure for the shortest length of time. The TURP operation does not involve fluoroscopy imaging and therefore, has no risks associated with radiation.

Intra-operative (minor and major complications)

The most common minor complications during PAE included patients experiencing a burning sensation and/or pain in the pelvic areas (10, 13) whilst the main intraoperative complication for TURP was the need for blood

	transfusion.(38) Technical failures were the most commonly reported major adverse event occurring during the PAE procedure (Table 6). Technical failure, when defined as a failure to embolise either prostatic side, occurs in two to five per cent of patients. Depending on the definition used in the trial, embolisation of only one prostatic side (unilateral embolisation) may also be classified as technical failure and occurs in 5 to 25 per cent of patients. Technical failures were often a result of tortuosity and atherosclerotic changes of the iliac arteries. The high rates of technical failure found in these studies may be due to the complexity and variation of the structure of prostatic arteries, tortuosity and atherosclerotic changes in the iliac arteries and the differing levels of experience of the interventional radiologists. PAE is an endovascular procedure, rather than a transurethral method, and therefore, many of the serious adverse events associated with TURP are avoided. During TURP surgery, major adverse events of serious bleeding and transurethral resection syndrome were reported.(38) PAE was associated with significantly fewer hospitalisations (48% vs 100%) and a shorter mean hospital stay duration (2.9 ± 1.6 days vs 4.8 ± 1.8 days) compared to TURP.(38) Postoperative and follow-up The postoperative and follow-up complications and adverse events for PAE and TURP are presented in Table 7. Within one month postoperatively, common minor complications associated with PAE included post-embolisation syndrome, pain, acute urinary retention and haematuria. Acute urinary retention may be caused by compression of the urethra related to ischaemic oedema and generally resolves within 72 hours postoperatively.38 Other minor complications following PAE including urinary tract infections, focal hypo-perfusion in the bladder area and inferior vesical artery dissection, haematospermia, rectal bleeding (rectorrhagia), diarrhoea and haematoma (at puncture site) were recorded. Major adverse events for PAE include clinical failures and ischaemia of the bladder wall. Minor complications associated with TURP include acute urinary retention, haematuria, clot retention, urinary tract infections and urethral stricture. Major adverse events for TURP include clinical failures and bladder neck stenosis. Sexual dysfunction is typically associated with TURP, however, no sexual dysfunction or retrograde ejaculation has been reported in these studies for either TURP or PAE. The definition of a clinical failure varied between studies and was defined as limited improvement in quality of life measures and urinary symptoms according to the International Prostate Symptom Score (IPSS)(13, 38) or American Urological Association symptom score (AUA)(15), failure to void spontaneously,(10) and/or limited increase in peak urinary flow.(38) In the RCT,(38) PAE was shown to be associated with higher clinical failures (9.4%) compared to TURP (3.9%). Clinical failures rates are higher if only unilateral embolisation is achieved.(19) The benefits of PAE must be balanced with the risk of technical failure and/or clinical failure, requiring further treatment.

Economic evaluation	No cost-effectiveness studies of PAE were identified in the literature search. The cost of the PAE procedure is estimated in this report to be at least $4,489 per patient, plus out-of-pocket expenses, based on the available evidence. The incremental costs required for the PAE procedure include: •Urologist and Interventional Radiologist consultations •angiography •selective arteriography •arterial embolisation •fluoroscopy and contrast medium •prostheses (embolising agent) •outpatient hospitalisation to perform embolisation procedure •additional adverse events associated with embolisation. A recent study by Griffith University's Health Institute, in conjunction with Queensland Health, estimated the mean procedural cost of the comparator treatment, TURP, (including the cost of the disposable loop) at $8240 per patient.(46) Currently, there is no robust evidence on the improvement in quality of life of PAE compared to TURP. It is not possible to estimate the long term costs associated with PAE as there is insufficient long term data on the safety, efficacy and costs of PAE as a treatment for BPH.
Ongoing research	Searches of ClinicalTrials.gov registry and the ANZCTR (Australian New Zealand Clinical Trials Registry) found twelve studies on PAE in progress. Details of these studies are outlined in Table 8. Of the twelve studies underway, five randomised controlled trials plan to recruit a total of 499 participants (range 60 - 186 participants). These RCTs aim to evaluate the effectiveness of PAE compared to: TURP (NCT01789840, NCT02054013, NCT01963312); placebo sham procedure (NCT02074644); and GL-PVP (NCT02006303) with follow ups to 12 months. No RCTs include control groups. Four of the twelve trails are yet to begin recruiting participants. A single group study of 50 participants in the USA (NCT02026908) will aim to evaluate the safety and the adverse events of PAE over a 5 year follow-up period. This trial, estimated to be completed in 2020, may provide long term follow up data on the safety and efficacy of the PAE procedure.
Ongoing or planned HTA	Although evidence described significantly fewer hospitalisations associated with prostatic artery embolisation compared to TURP as well as low morbidity and mortality, concerns remain over potential safety issues including migration of particle, necrosis of surrounding tissues and exposure of patients to radiation from fluoroscopy. In addition, no cost-effectiveness evidence around this technology has been published. Consideration also needs to be given to the high degree of expertise required to perform this procedure and that it should only be performed in centres of excellence. Therefore HealthPACT determined that at this point no further research on their behalf is warranted at this time and that when evidence base for this technology matures it would be identified via normal horizon scanning activities.
Web link	http://www.health.qld.gov.au/healthpact/docs/briefs/WP204.pdf

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