

National Institute for Health and Care Excellence

IP 1008/2 / Prostate artery embolisation for lower urinary tract symptoms caused by benign prostatic hyperplasia

IPAC date: 8 February 2018

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
				Please respond to all comments
1	Consultee 8 British Association of Urological Surgeons	Title	Regarding the title, Prostate Artery Embolisation for Benign Prostatic Hyperplasia, we would like to remind NICE that BPH is a histological diagnosis and clinical BPH was invented by drug companies and that as we advised in the NICE LUTS guidance that the title should be "Prostate Artery Embolisation for Lower urinary tract symptoms (LUTS) presumed secondary to Benign Prostatic Hyperplasia (BPH)"	Thank you for your comment. The title has been changed.
2	Consultee 6 Behalf of BSIR	1.2	For consultation document: 1.2 – Possibly include anaesthetics	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
3	Consultee 8 British Association of Urological Surgeons	1.2	We welcome the fact that it is stated that patient selection should be done by a urologist and an interventional radiologist, but note that it is unlikely that patients would get directly referred to a radiologist without a urologist being involved, (except perhaps inappropriately in private practice)	Thank you for your comment.
4	Consultee 8 British Association of Urological Surgeons	1.3	"Only interventional radiologists who have been fully mentored should perform these procedures, and they should be working closely with their local urologists."	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
5	Consultee 6 Behalf of BSIR	2.2	2.2 – Potential complications of surgical procedures to include % for each one	Thank you for your comment.

				This section of the guidance is intended to be a brief summary of alternative treatments. The IP programme does not assess the efficacy and safety of comparator interventions.
6	Consultee 5 Behalf of BSIR	2.3	Paragraph 2.3 Super-selective catheterisation of the small prostatic arteries is <u>performed by manipulating</u> fine microcatheters through the pelvic arteries. Embolisation involves the introduction of microparticles to completely block the prostatic vessels. Embolisation agents include polyvinyl alcohol (PVA) and other newer synthetic biocompatible materials.	Thank you for your comment. Section 2.3 of the guidance has been changed.
7	Consultee 5 Behalf of BSIR	2.4	Paragraph 2.4 The aim of prostate artery embolisation is to reduce the prostate's blood supply, causing some of it to undergo necrosis and shrink. It is common for patients to experience <u>mild</u> pelvic pain during and after the procedure, this does not usually last more than 1 to 3 days. The potential benefits of prostate artery embolisation compared with surgery include fewer complications, avoiding a general anaesthetic <u>and, being a day case procedure, a shorter hospital stay.</u>	Thank you for your comment. Section 2.4 of the guidance has been changed.
8	Consultee 8 British Association of Urological Surgeons	3.2	Key outcome measures are improvement in symptoms and quality of life and no loss of sexual function with secondary improvements of flow rate and residual volume improvements.	Thank you for your comment. 'No loss of sexual function' has been added to the key safety outcomes in section 3.3 of the guidance.
9	Consultee 6 Behalf of BSIR	3.5	3.5 – should include the Quality of life score change from baseline for studies.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.

10	Consultee 5 Behalf of BSIR	Lay box	<p>Consultation document</p> <p>First paragraph</p> <p>Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement of the prostate. It can block or narrow the tube that urine passes through to leave the body, <u>causing difficulty in passing urine.</u> In this procedure, using X-ray guidance, a thin tube called a catheter is inserted into an artery in the groin. It is guided into the blood vessels that supply the prostate. Small particles are then injected into these vessels. This reduces the prostate's blood supply,</p>	<p>Thank you for your comment.</p> <p>The lay description in the overview has been changed.</p>
11	Consultee 5 Behalf of BSIR	Overview	<p>PAE</p> <p>Comments from ██████, ██████ Hospital</p> <p>My edits should you wish to use them are in red</p> <p>Project Information</p> <p>Description</p> <p>Prostate artery embolisation for benign prostate hyperplasia is usually <u>performed</u> using local anaesthesia <u>as a day case procedure.</u> Under x-ray guidance, the prostate is approached through the left or right femoral arteries <u>and sometimes the radial artery in the wrist</u> . Super-selective catheterisation of the small prostatic arteries is done using fine microcatheters through the <u>arteries that supply the pelvis into the prostate.</u> Embolisation involves the introduction of <u>tiny</u> particles to completely block the prostatic vessels. Embolisation agents include polyvinyl alcohol (PVA) and other newer synthetic biocompatible materials. The aim of prostate artery embolisation is to reduce the prostate's blood supply, causing some of it to undergo necrosis and shrink. It is common for patients to experience <u>mild</u> pelvic pain during and after the procedure, <u>this</u> does not usually last more than 1 to 3 days. The potential benefits of prostate artery embolisation compared with surgery include fewer complications, avoiding a general anaesthetic <u>and, being a day case procedure, a shorter hospital stay.</u></p>	<p>Thank you for your comments.</p> <p>The procedure description in the overview has been changed.</p>

12	Consultee 8 British Association of Urological Surgeons	safety	<p>The side effects do not appear outwith what we might have expected for a minimally invasive prostate procedure.</p> <p>The greatest potential complication is inadvertent embolisation of other sites. There is one case of bladder necrosis in the world literature and the UK study had 2 patients with small areas of penile necrosis but both settled spontaneously.</p>	<p>Thank you for your comment.</p> <p>Bladder wall ischaemia and small penile ulcers are included in the safety summary of the overview. Inadvertent embolisation of other sites is included in the key safety outcomes listed in section 3.3 of the guidance.</p>
13	Consultee 8 British Association of Urological Surgeons	safety	<p>It involves a long radiology imaging time and more detailed measurement of radiological exposure would be sensible.</p>	<p>Thank you for your comment.</p> <p>The Committee considered this comment but decided not to change the guidance.</p> <p>A committee comment in section 3.7 of the guidance notes that the procedure involves extensive imaging, which may result in significant radiation exposure.</p>
14	Consultee 1 Patient	safety	<p>As a potential patient and long term suffer, PAE is a very attractive concept as it is less invasive than the alternatives and a General Anesthetic becomes more dangerous with advancing years but ; There is only one Hospital (██████) performing the procedure and if something goes, will the local NHS undertake corrective surgery . I think NICE should consider not only the embolisation but how the patient copes if the wrong artery is blocked.</p>	<p>Thank you for your comment.</p> <p>The Committee considered this comment but decided not to change the guidance.</p>

15	Consultee 8 British Association of Urological Surgeons	General	<p>"The BAUS response has been prepared by ██████, Consultant Urological Surgeon, ██████ Hospital, ██████.</p> <p>The procedure is clearly very relevant to the speciality of urology. ██████ hasn't actually done any of these as they are done by radiologists but he regularly refers patients for consideration for PAE. ██████ has studied the literature fairly extensively and the UK ROPE study, of which he is one of the authors, is under review for publication in the BJUI."</p> <p>"BAUS was involved in setting up the ROPE registry study, that is referred to particularly in the larger consultation document, jointly with BSIR (Br. Soc interventional radiologists) and NICE. It was run by the Academic Cedar unit in Cardiff university under the instructions from NICE.</p> <p>This resulted in 17 UK centres identifying trained radiologist working with local urologists and 218 patients underwent PAE and were compared with a cohort of patients having TURP in the same centre. They were not randomized. These results were broadly in line with the world literature and all the studies are listed in detail in the 48-page NICE consultation document. The UK results showed a 10-point improvement in LUTS (cf 15 in TURP) and a statistically significant improvement of flow rate but half the benefit of TURP.</p> <p>It is predominantly a day case procedure. Approx 7% of patients get post-op retention and therefore need catheterisation which may require overnight stay or a second appointment for a trial without catheter.</p> <p>It is important to state that whilst the technique of PAE is not a new technique and therefore "established" its use in LUTS/BPH is still a relatively new indication and still only accepted in a limited number of countries.</p> <p>However, if accepted it is likely that it would be provided in all regions and probably most DGHs.</p>	<p>Thank you for your comment.</p> <p>Safety data from the ROPE registry study are included in the overview (study 7). No efficacy data were extracted from the unpublished ROPE registry report as it is not yet available as a peer-reviewed journal paper.</p>
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16	Consultee 8 British Association of Urological Surgeons	General	A cost effectiveness analysis is still needed. It appears to have a fairly high re-intervention rate of 5% in the first year and up to 15% in subsequent years and these costs should be borne in mind	Thank you for your comment. Cost-effectiveness is not part of the remit of the Interventional Procedures Programme.
17	Consultee 4 patient	General	I am not in favour of surgery for benign prostatic hyperplasia due to the possibility of side effects, particularly sexual dysfunction. Embolisation would appear to be a less aggressive and less invasive procedure with the likelihood of fewer side effects. I appreciate that radiological equipment is expensive and incurs running costs, but compared with surgical options there would be a saving on the cost of general anaesthesia and the side effects of surgery.	Thank you for your comment. Cost-effectiveness is not part of the remit of the Interventional Procedures Programme.
18	Consultee 8 British Association of Urological Surgeons	General	Conclusion is that it is not as "good" as a TURP achieving about half the outcome benefits and is probably more comparable to the Urolift procedure but will be popular with patients as it is day-case and local anaesthetic and has no significant negative impact on sexual function	Thank you for your comment.

19	Consultee 2 Patient	General	<p>Dear Sir or Madam</p> <p>With reference to your inquiry re: the above, I should say that I had this procedure carried out at [REDACTED] hospital toward the end of 2012 [September I think]. Before presentation I had great difficulty in passing water & had been hospitalized a couple of times following bouts of retention; in the year prior, I was self-catheterizing on a regular basis, not ideal!!!! I was offered TURPS but my father had this procedure, in 1992, by a very competent surgeon & yet it was never entirely satisfactory: far worse, he lost all sexual function. After much research I came to the conclusion that this procedure carried too much risk. My PSA on presentation was around 20 [I think] reflecting a very over-sized prostate & this came down to around 6 [I think] following the procedure. The last time it had been that low was following a course of Avodart, in 2004, which, unfortunately, had the undesirable effect of increasing breast tissue, among other things! It would appear that the blood supply to my prostate has now resumed & my last PSA was around 10 or 11, however, I have no further problems in emptying my bladder [albeit flow is not fantastic, but then, I can't remember the last time it was]; I have reasonable control, which means I can defer without consequence & have no fear of retention. Sexual function is perfect; if this state of affairs continues I will be more than happy - it is a staggering result!</p> <p>Trust this is helpful to your inquiry</p> <p>Yours faithfully [REDACTED]</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have had this procedure and considered your experience and views in their deliberations.</p>
20	Consultee 2 Patient	General	<p>one further thing I didn't mention was the impact on sleep; prior to the PAE I was getting up around six or seven times a night to use the bathroom; since I have not been troubled with more than one, occasionally two visits; mainly my sleep is uninterrupted. You might like to add this to my earlier note</p> <p>Thankyou [REDACTED]</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have had this procedure and considered your experience and views in their deliberations.</p>

21	Consultee 3 patient	General	<p>First of all I should like to point out that I am not one for going to my doctors and prior to cracking up with complete water retention I had not been to the practice for over thirteen years. Apart from the medical professionals who will promoting the procedure I consider that is essential that the panel is made fully aware of my journey from the initial beginning of BHP and eventually extremely poor care at a local supposedly centre of urology excellence to my total salvation in having PAE.</p> <p>I eventually in November 2011 woke up one morning being totally unable to urinate. My BHP had been gradually increasing problems with passing urine from going from initially to suddenly all the time rushing to use a toilet to having trouble to pass even pass minute amounts of urine. Like most men, you ignore medical things that you are suffering with and hope that the problem will just vanish of its own accord. On the day in question I around dinner time went to see the GP who stated the obvious that I had acute urine retention and choose a local hospital for me to go to as it was a matter of urgency for my extended bladder to be drained. I was catheterised in A and E and kept in overnight on the assessment ward where I saw a female doctor who checked me over and also carried out a DRE of my prostate and her conclusion was that it was moderately large. Transferred in the middle of the night onto the urology ward. In the morning all the other patients saw the consultants / doctors they were under and I saw nobody. Late that afternoon I asked a nurse why had I not seen anyone and it transpired they had lost my notes. A female registrar thence came to see me and did another DRE examination and her conclusion once again was that I had a moderately large prostate. The decision was for me to be discharged with arrangements to be made for a kidney scan and also a trial without catheter in two weeks time. I had the kidney scan which showed small stone in the right kidney. Thence came the trial without catheter and this was an a total mess up. Turned up as required and the catheter in situ was removed by a mature female nurse and I spent the next few hours drinking water in order to fill up my bladder and in due course urinate. After over three hours I was unable to urinate so had ask the same nurse to insert a new catheter as I was in</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have had this procedure and considered your experience and views in their deliberations.</p> <p>Section 1.1 of the guidance states that this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit.</p>
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		<p>loss to be seen with in a two weeks as there could be a possibility of cancer. The first thing they did was to carry out a flexible cystoscopy and the results were that I had been left with a very vascular prostatic bed and it was rather lumpy. Then had CT urogram which was essentially normal. Then saw in out patients a registrar who put me Avodart to stop the bleeding and also to reduce the size of my prostate. Experienced bad side effects so it was decided to change to Finasteride. The bleeding did cease whilst I was on the medication but once I stopped taking the tablets it returned. From what I went through I consider both these drugs to be highly toxic and in taking them it has been one of the worst decisions I have ever made. I had to cease taking them due terrible side effects some of which I am still suffering from. The worst by far was dental decline resulting in numerous extractions. It will cost nine thousand pounds to get back to an acceptable teeth volume / implants. I did subsequently see a very nice urology consultant who admitted that I had been very unlucky. He offered to do a definitive Turps himself but for obvious reasons I declined this offer.</p> <p>I have related the above for the reason to show what in the case of Turps which is deemed to be the Gold Standard of BHP resolution is very flawed in the respect that it might cure the urinary flow rate you could end up with serious conditions that you never had previously as was my case. Finasteride and it's version for hair loss (Propecia) are highly toxic with terrible life changing side effects. There is a lot of litigation over these products in the USA. And from my personal aspect by relating my story I consider I can now have closure.</p> <p>-----</p> <p>Let's now continue to what happened after the above leading up to total resolution of haematuria / reoccurring urine infections / trips to the toilet etc by having PAE at [REDACTED] Hospital. This procedure has given me my life back.</p> <p>-----</p>	
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		<p>As I was totally against having anything to do with the previous mentioned I just carried on with unpredictable haematuria etc. I had numerous e-coli bladder infections. I was resigned to leading the rest of my life having to put up the prior mentioned lifestyle restrictive problems. I slowly but surely became depressed as there seemed no procedure out there to give me back normality. I became rather reclusive my children and grand children became fed up with me I cried off going to family outings / holidays / party's etc for fear of urine leakage / unpredictable haematuria. In August 2016 I was talked into going with the whole family to Crete and I really enjoyed the holiday and being with the family but what spoilt it was that each night going to bed I was petrified of staining the bed if bleeding would occur. To try and ease my concerns I purchased from a pound shop a few packs of disposal baby changing plastic sheets. The hotel the clients with unlimited dark blue pool towels and so each night I would position the prior mentioned baby sheets on the bed on top of them I laid out the hotels pool towels and that's how I slept. That's how I carried on living keep looking for any new procedure which could cure my problems without being left with new ones. I tend to read the Daily Mail. On a Tuesday they include new medical procedures and this how I came across Dr [REDACTED] and PAE. Sometimes in life you come across something that is so right it hits you like a thunderbolt. Reading the article I soon realised that this would be my salvation and this proved to be the case. PAE is the only procedure which thinks outside the box apart Urolift (not applicable for myself) which I consider to be just not a cure but a delaying tactic. All the other procedures are just a better version of Turps procedure using laser or heated water vapour. Any organ has to have a blood supply to thrive. The concept of PAE is to block off so many of the arteries supplying the prostate gland and thus achieving a thirty per cent reduction in size. I applied to Dr [REDACTED] at [REDACTED] Hospital as they were carrying out PAE under UK ROPE trial. I was overjoyed after stringent tests that I met the criteria to have the procedure. This was carried out in May 2015. What should be taken into account was that I was damaged goods. Only the left lobe was fully</p>	
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treated and I still had the prior mentioned problems. It was proposed to carry out another PAE on the still large right lobe but as can happen funding ran out. Subsequently it was started again but one had to live in the Hampshire catchment area which of course i did not. Then out of the blue in the autumn of last year I was contacted by them and informed I could have it redone. Of course I had to be reassessed for suitability which I was. I had the procedure redone on the [REDACTED] of November of last year. Dr [REDACTED] carried out the procedure and Dr [REDACTED] was in the room and they consulting all the time with each other. The procedure has been beneficially enhanced (improved beads). The consultants were very happy with the results as distribution of the beads were excellent through out the whole prostatic gland. I was having haematuria during travelling down to [REDACTED] / left home at just prior to 2am to be at the hospital for 7am. I am sorry that I have rambled on a bit.

SUMMARISE THE REASON FOR THIS E-MAIL

SINCE THE [REDACTED] NOVEMBER OF LAST YEAR I AT LAST FREE OF THE FOLLOWING CONDITIONS WHICH I HAD SUFFERED FROM FOR THE PREVIOUS FOUR AND A HALF YEARS.

- a. NO HAEMATURIA AT ALL
- b. No URINE INFECTIONS.
- c. VASTLY IMPROVED URINE FLOW RATE.
- d. BETTER SLEEP.
- e. EMPTYING THE BLADDER FINE.
- f. NO PROBLEMS WITH DRIBLING.
- g. ON CHRISTMAS EVE I WAS IN A LARGE HOTEL IN BLACKPOOL AND 1 NEEDED TO URINATE AND WENT TO THE GENTS TOILETS AND INSTEAD OF DOING WHAT I HAD BEEN DOING FOR THE LAST FOUR AND A HALF

		<p>YEARS AND USING A CUBICLE HAD THE CONFIDENCE TO USE A URINAL. THIS MIGHT SEEM TO A VERY MINOR POINT BUT IS A MAJOR ONE FOR MYSELF.</p> <p>-----</p> <p>FROM THE PATIENTS ASPECT.</p> <ul style="list-style-type: none">a. A DAY CASE PROCEDURE.b. NO DETRIMENTAL SIDE EFFECTS.c. AWAKE DURING THE PROCEDURE.d. ONLY SLIGHT DISCOMFORT THE FIRST WEEK AFTER THE PAE.e. THE MAIN THING THAT IT WORKS. <p>FROM THE NHS POINT OF VIEW.</p> <ul style="list-style-type: none">a. VERY COST EFFECTIVE,b. FAR BETTER FOR THE PATIENT.c. NOT HAVING TO SPEND MONIES TRYING TO PUT RIGHT FAILED PROCEDURES. <p>I HOPE WHAT I HAVE WRITTEN IS OF HELP TO THE PANEL. I HAVE BEEN GIVEN NOW TO LEAD A BETTER LIFE WITH THE VERY DRAINING WEIGHT LIFTED OFF MY SHOULDERS AND I URGE YOU TO AUTHORISE PROSTATE ARTERY EMBOLISATION TO GIVE OTHER MEN WHO FIND THEMSELVES IN THE STATE I WAS IN TO BE LIKE I AM NOW.</p>	
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22	Consultee 7 Patient	General	<p>The chronology for my condition BPH started in 2008 when I experienced a haematuria. My G P arranged to see a Consultant. He recommended a thorough examination of my renal system from the results it was evident that my prostate was significantly enlarged and it was likely the cause of the haematuria. It was decided to keep a watching brief on the condition with regular PSA testing and my reporting if the haematuria became more frequent.</p> <p>Between 2008 and 2015 there were a few minor incidences of blood in the urine. In 2015 I experienced frequent incidence of haematuria usually associated with my keep fit exercises, mainly running. A further visit to the Consultant and further imaging [CT & MRI] and a cystoscopy was performed which all revealed a grossly enlarged prostate of 193 cc. My symptoms were bearable however the frequency of requiring urination coupled with mild incontinence began to make life somewhat problematic. Because of my reluctance to undergo surgery I agreed with the consultant that we should continue to wait and see.</p> <p>The situation reached a crisis in April 2017 when I experienced a serious retention which required a visit to the A&E in order to relieve bladder pressure I was catheterised and went to see my Consultant the following day. He suggested that we leave the catheter in place for a few days to see if the condition improved he was not hopeful and this was borne out when he removed it later that week and the blockage returned.</p> <p>My Consultant informed me that the only option was surgery. He recommended a specialist who was very experienced in this field and that he would reduce or possibly remove the prostate. Since the possibility of neurological damage was the main reason why I had decline to proceed with these procedures in the past and my experience with colleagues and anecdotal evidence from others it was clear that in a percentage of cases impotence and incontinence were real side effects.</p>	<p>Thank you for your comment.</p> <p>The Committee very much welcomes hearing from patients who have had this procedure and considered your experience and views in their deliberations.</p>
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		<p>I have access to nature journals and I can across a procedure that appear in Portugal in 2008 Coincidentally the same year my troubles began. A web search revealed your guidelines on a procedure called PAE that was under trial in the UK under your direction I communicated with [REDACTED] hospital and [REDACTED] NHS trust but I was unable to speak to anyone who was involved in this trial. I then contacted the other centre in the SE at the university hospital in [REDACTED] and I arranged to see Mr [REDACTED] a consultant urologist and Dr [REDACTED] an interventional radiologist who had performed a number of PAE procedures in the last few years.</p> <p>My meeting with Mr [REDACTED] went extremely well and he was surprise that no one had recommended a visit to [REDACTED] and that t I had to do the research myself. I told him of my concerns for the regular surgical procedures. He was sympathetic but explained that these procedures were very safe but that side effects could occur. I asked if I could be considered for the PAE procedure. He immediately took me to see Dr [REDACTED] who arrange for a CT scan to access the prostate situation and determine the vascular configuration. On studying the results he felt that I was a good candidate for the procedure and arranged for me to have the procedure a week later I was at this time still catheterised and I believe this was one of a few occasions where PAE had been performed on a catheterised patient. The procedure went extremely well with little inconvenience or discomfort and lasted about 90 mins. I was on my way back home early evening.</p> <p>I returned the clinic about 3 weeks later for a ultra sound scan and to have the catheter removed this was achieved successfully with the ultra sound showing a mark reduction in prostate volume in the area of embolization. I remained at the centre for the rest of the day to check renal function i.e. fluid in and fluid out and by early evening I was on my way home catheter free.</p> <p>I made a final visit to the clinic for a follow up MRI the results of which showed significant reduction in volume of the prostate.</p>	
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		<p>Which now had a volume of around 130 cc. Dr [REDACTED] was very pleased with result and set up a follow up visit in a year's time. Mr [REDACTED] checked my urine vol/min which was very good with little or no retained volume in the bladder.</p> <p>In conclusion let me say, that having come from a situation where the location of the next toilet was vital to the completion of the journey as intervals between urination became shorter, the number of nocturnal visits had reach two and sometimes three and with urgency on the increase and incontinence being threatened. My quality of life had decreased somewhat. But after PAE I now have good control of my renal system I no longer go to the toilet during the night and long journeys have lost their dread.</p> <p>I hope your consultation process goes well and you are able to recommend that this greatly effective but minimalistic interventional procedure is offer widely.</p> <p>Should you require further information please ask.</p> <p>Yours Sincerely [REDACTED]</p>	
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