Comparison of prostatic artery embolisation (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomised, open label, non-inferiority trial

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Cite this as: *BMJ* 2018;361:k2338
http://dx.doi.org/10.1136/bmj.k2338

RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Abt D, 2018	RCT	?? ?	+	+	?	+

Characteristics of studies

Abt D, 2018

Population	1. Exclusion criteria were severe atherosclerosis, aneurysmatic changes or severe tortuosity in the aortic bifurcation or internal iliac arteries, acontractile detrusor,

	neurogenic lower urinary tract dysfunction, urethral stenosis, bladder diverticulum, bladder stone, allergy to intravenous contrast media, contraindication for magnetic resonance imaging, pre-interventionally proven carcinoma of the prostate, and renal failure (glomerular filtration rate <60 mL/min). 2. Inclusion criteria were men aged at least 40 years, TURP indicated, refractory to medical treatment or not willing to undergo or continue medical treatment, with a prostate size 25-80 mL as measured by transabdominal ultrasound, with an international prostate symptoms score (IPSS) of at least 8, with an IPSS related quality of life of at least 3 points, with a maximum urinary flow rate of less than 12 mL/s or urinary retention, and who provided written informed consent. 3. The incidence of benign prostatic hyperplasia in men aged 50-60 years is 50% and rises with increasing age. 1 Treatment for the disease incurs a substantial economic burden, with estimated annual costs of WhAt Is AlreAdy knoWn on thIs topIc Prostatic artery embolisation (PAE) for the treatment of benign prostatic hyperplasia has been introduced into clinical practice without high level evidence, and is now increasingly performed worldwide Available PAE data point to promising outcomes, including a favourable safety profile Only three trials so far have included a control group receiving established surgical treatments for benign prostatic hyperplasia; all studies performed so far have been criticised for methodological drawbacks and have shown highly contradictory results
Interventio n	1. All patients received perioperative antibiotic prophylaxis, which was discontinued after removal of the bladder catheter or after three days at the latest (ciprofloxacin 500 mg twice daily). 2. An antiinflammatory (diclofenac 75 mg twice daily) and acid suppressant (pantoprazole 40 mg once daily) were administered for one week.
Outcomes	1. Main outcomes and measures Primary outcome was change in international prostate symptoms score (IPSS) from baseline to 12 weeks after surgery; a difference of less than 3 points between treatments was defined as non-inferiority for PAE and tested with a one sided t test. 2. Free uroflowmetry @BULLET Postvoid residual urine assessed by transabdominal ultrasound @BULLET Quality of life related to lower urinary tract symptoms (ranging from 0 (" delighted ") to 6 (" terrible ")) @BULLET Questionnaire chronic prostatitis symptoms index (CPSI) that assesses pain, voiding, and quality of life (score ranging from 0 (best) to 43 (worst)) @BULLET International index of erectile function short form 5 (IIEF) (score ranging from 0 (worst) to 25 (best)) 3. Secondary outcomes included further questionnaires, functional measures, magnetic resonance imaging findings, and adverse events; changes from baseline to 12 weeks were compared between treatments with two sided tests for superiority.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Randomisation We performed randomisation using the data management software SecuTrial, stratifying for patient age (<70 or ,â•70 years) and prostate volume (<50 or ,â•50 mL) through minimisation. 2. SecuTrial was programmed by the clinical trials unit's data manager, and automatic doi: 10.1136/bmj.k2338 | BMJ 2018;361:k2338 | the bmj treatment allocation by SecuTrial was determined for individual patients without a predefined sequence after inclusion and entry of baseline characteristics by the investigators. 3. Two patients allocated to PAE and one allocated to TURP refused to undergo surgery after randomisation and were excluded from the study.
Allocation concealment	low	1. SecuTrial was programmed by the clinical trials unit's data manager, and automatic doi: 10.1136/bmj.k2338 | BMJ 2018;361:k2338 | the

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Blinding of participants and personnel	high/unclear	1. PAE was not possible due to vascular disorders in one patient, who underwent laser vapourisation of the prostate subsequently and was also excluded from the analysis. 2. No patients were involved in setting the research question, trial design, outcome measures, or recruitment of the study. 3. Interventions PAE was performed by an experienced interventional radiologist (LH) who was familiar with the procedure.
Blinding of outcome assessment	low	1. SecuTrial was programmed by the clinical trials unit's data manager, and automatic doi: 10.1136/bmj.k2338 | BMJ 2018;361:k2338 | the bmj treatment allocation by SecuTrial was determined for individual patients without a predefined sequence after inclusion and entry of baseline characteristics by the investigators. 2. The trial was designed by the lead investigators and supported by biostatisticians from the hospital's clinical trials unit. 3. Technical conduct of TURP adhered to generally accepted standards described elsewhere, 24 and was performed step by step for the middle lobe, lateral lobes, ventral part, and apical residual tissue with the surgical capsule of the prostate serving as a landmark.

References

1. Abt D et al. Comparison of prostatic artery embolisation (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomised, open label, non-inferiority trial Zhonghua Nan Ke Xue 2018. 361(5); 435-9 PMID: 21837955