

PB-PG-0909-20214 – NIHR Research for Patient Benefit Programme – Final report

Project title: Pilot investigation on the effect of the Memokath® 028 prostatic stent on Quality of Life in patients with urethral obstruction – a comparison with long term catheter

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Plain language summary: Men suffering with urine retention are unable to void urine in the normal way. This is usually caused by an enlargement of the prostate gland, resulting in compression of the tube carrying urine from the bladder to the penis (called the urethra).

There are several options for treating urine retention, the most commonly used treatment being a long-term catheter (LTC). This is a plastic tube inserted into the penis, through the urethra to the bladder. It collects urine in a plastic bag attached to the leg. These work well in most people, but do need changing every few weeks. They can be inserted, usually at home, by a community nurse and an operation is not needed.

Another option, which is not very widely used in the UK at present, is for the man to have a prostatic stent. A prostatic stent is a metal coil, like a biro spring, which is inserted into the urethra where it passes through the prostate. Once in position, it prevents the prostate from squeezing the urethra shut. The stent is fitted in the operating theatre in a 10-15 minute procedure using a flexible telescope, under a local anaesthetic. About 4 out of 5 men who have this done can pass urine normally afterwards.

The research team aimed to conduct a randomised controlled trial investigating the quality of life of men having these two treatments, to see if one treatment is preferable over the other. In order to run such a trial, it was necessary to first conduct this 'pilot' trial, so as to inform the design and feasibility of the future trial.

Men suffering with urine retention treated with a long term catheter were invited to participate, and were allocated either to continue with their LTC or to have a stent fitted. Allocation was determined by a computer according to a randomisation schedule, so that neither patients nor their doctor could choose which treatment they received. Participants were to take part for 6 months, answering questions about their treatment and quality of life at the beginning of the study, and then after 3 months and again after 6 months.

The researchers had expected to recruit 60 patients over an 11-month period. However, only 6 patients were recruited despite efforts to widen the recruitment catchment area. The researchers conclude that a full trial conducted in the same way as this pilot would not be a feasible venture.

Keywords: Pilot; Feasibility; Urine retention; Prostatic stent; BPH;

Summary of research findings:

Background:

Benign prostatic enlargement (BPE) is an increase in size of the prostate. As the prostate enlarges, the layer of tissue surrounding it stops it from expanding, causing the gland to squeeze the urethra, usually resulting in Lower Urinary Tract Symptoms (LUTS). The bladder wall becomes thicker and irritable, contracting even when it contains small amounts of urine causing more frequent voiding. Eventually, the bladder weakens and loses the ability to empty itself, so some of the urine is retained in the bladder. Urinary retention and strain on the bladder can lead to urinary tract infections, bladder or kidney damage, bladder stones, and incontinence. As many as 90% of men in their seventies and eighties have histological evidence of disease and some symptoms of BPE, and 3.4% of these will develop retention of urine. There are a number of treatments for BPE, including life-style measures, drug therapy, transurethral microwave procedures and transurethral needle ablation. Surgical treatments such as transurethral resection of the prostate (TURP) – where pieces of tissue are shaved off using an instrument pushed into the urethra - are sometimes not suitable for older men who may be too sick or frail to cope with them. Long term catheterisation is usually recommended in men considered to be at high risk for surgery, but this treatment is frequently associated with complications such as recurrent urine infection and catheter blockages which reduce quality of life. Prostatic stents have been in use since 1980 but early designs had a number of problems (migration, encrustation and epithelial in-growth) and so were extremely difficult to remove and deterred urologists from using them. The Memokath 028 stent® (PnnMedical, Denmark) overcomes many of these problems by being relatively easy to place and remove under local anaesthetic. It is composed of nickel-titanium alloy which has a 'memory'; the deformed stent can be positioned when cold and expanded to its original shape using saline at 50°C, locking it in position. Previous studies summarised in a systematic review together with audit in our own department have shown the Memokath prostatic stent to be a good functional alternative to a long term catheter. Quality of life data have not previously been collected. A randomised controlled trial comparing quality of life in men treated with the prostatic stent and long term catheter would provide an evidence base on which to determine whether stents should be more widely used.

Aims and objectives:

This pilot trial set out to test the feasibility of running such a trial. Some of the specific aims and objectives were: to evaluate the processes for identification and recruitment of patients, assess recruitment rate and identify reasons for non-recruitment, record attrition from the trial, in particular estimating the rate of successfully obtaining outcome data up to 6 months after randomisation, test the data collection methods, suitability of patient questionnaires and record distribution of outcome data to determine the sample size for the future, definitive study.

Methods:

Recruitment: Patients were identified for recruitment via two main pathways. Firstly, hospital records of all male inpatients and outpatients under the care of the urologist were pre-screened for eligibility by the designated study research nurse. This included patients being seen in the Royal Devon and Exeter hospital (RD&E) and in outlying clinics run by the Trust through other local outlets. Patients presenting to the Emergency Department with

urinary retention were also brought to the attention of the RN, and urology consultants at other local hospitals agreed to refer anyone who appeared to fulfil the eligibility criteria to the Chief Investigator. Anyone identified by these means as being potentially eligible was approached during their inpatient stay or appointment by the research nurse and was provided with a patient information sheet (PIS). The research nurse then followed up these patients to determine whether or not they were interested in participating.

Secondly, 10 GP practices local to Exeter and with experience of research were identified via the Primary Care Research Network. The aim of this was to identify men with urine retention being treated in the community rather than in a hospital setting. These practices searched their database using search terms based on the eligibility criteria and prescriptions relating to catheters. Everyone who fulfilled these criteria was sent a copy of the PIS with a covering letter with instructions on how to contact the research nurse if they were interested in taking part, along with a stamped addressed envelope to return a reply slip if they wished.

Randomisation: Patients expressing a willingness to participate were invited to an appointment with the research nurse at which eligibility was confirmed and written informed consent obtained. Baseline health-related quality of life data (SF36, ICIQ-MLUTS, ICIQ-LUTSqol) was collected at this visit.

After completing the baseline assessments, participants were randomised using computer generated randomisation codes prepared by an independent statistician. Minimisation was used to ensure the groups were balanced by age (<80 years vs ≥80 years) and by bladder urine residual volume at the time of initial catheterisation (<500ml vs ≥500ml). Patients for whom no bladder residual urine was documented at the time of initial catheterisation were allocated to the <500ml group on the assumption that a residual volume of >500ml was likely to have been recorded at the time of catheterisation as a clinically significant finding.

Participants were randomised in a 1:1 ratio to either receive a Memokath™ 028 Prostate stent or to continue with LTC treatment.

Intervention: Letters sent by the research nurse to the participants' General Practitioners (GPs) explained the trial and to which treatment group the patient had been allocated to. Participants randomised to the LTC (standard care) were advised to continue with their catheter as normal. Trial participation cards given to LTC participants requested that the GP or community nurse should contact the RN in the event of LTC removal, so the condition of the catheter could be recorded. It was emphasised to the LTC cohort that they should make their GP and community nurse aware of their involvement in the trial in the event of any contact with those persons.

Participants randomised to receive the Stent were given an appointment for the stent to be fitted, within 2 weeks following randomisation. Standard procedures and manufacturer's instructions were followed for the pre-operative preparation, stent insertion, and post-operative follow up care. Data was collected at the time of insertion regarding the ease of the procedure and any problems encountered.

Follow Up: All participants were contacted by telephone after two weeks (post randomisation for LTC participants; post-stent insertion for stent participants) by the RN, who conducted a structured telephone interview. The structured interview asked questions about general wellbeing, whether the participant was experiencing any specific problems with their allocated treatment, and the number of visits which had been made to or by other medical professionals.

At 3 and 6 months after baseline, all participants attended an outpatient appointment and completed the same questionnaires as were completed at baseline, and answered the same structured questions as were asked at the 2-week timepoint.

At the 6 month follow up visit participants also completed a questionnaire designed to record how participants felt about their involvement in the study and the acceptability of the questionnaires used.

At the end of the 6 months participation period, all participants were given the option to continue treatment with their allocated intervention, or to switch to the alternative method.

Results:

Recruitment to the study closed on 30th September 2012, as originally planned, with a total of 6 participants randomised. A total of 441 secondary care patients were pre-screened for eligibility by the research nurse as described. Of these, 23 were found to be potentially eligible, 16 of which received a copy of the Participant Information Sheet (PIS). Of these, only 4 consented and were subsequently randomised to the trial. A total of 77056 primary care patients were pre-screened by participating GP practices, resulting in the 120 potentially eligible people. Of these, 53 patients contacted the research nurse in response to the invitation but only 2 were ultimately willing and eligible to participate. Both were recruited into the study taking the total number randomised to 6.

10 patients elected not to take part in the trial despite being eligible. 1 decided to have a TURP; 1 had been diagnosed with prostate cancer and did not want to be in a trial; 3 felt they were happy with their catheter and did not want to risk being randomised to receive a stent; 5 felt certain that the stent would provide better treatment and were not willing to risk being randomised to the LTC group (stent-fitting was available to such patients without entering the trial).

Follow up was scheduled to continue until April 2013 but in light of the disappointing recruitment figures, and in acknowledgement of the fact that no meaningful information about trial feasibility would be gained from keeping the trial open, the trial was terminated with effect from January 31st 2013. Of the 6 patients who took part in the trial, 1 died before the 3-month follow up visit (unrelated to trial intervention) and 3 participants did not reach the 6-month follow-up assessment before trial termination. 2 participants in the stent group completed the 6-month follow up assessment.

The researchers conclude that a full trial conducted in the same way as this pilot would not be a feasible venture.

Patient and public involvement:

Maintaining a consistent source of service user input for the duration of the research proved difficult in this project. Chief Investigator Mr Crundwell had good engagement with one of the original patient representatives (who had helped develop the original application) throughout the trial, but that patient was unable or unwilling to attend meetings. He was quite certain that the stent was preferable and found it difficult to understand why a trial was necessary, reflecting his business background. This was an opinion that had been acknowledged by the research team and is the reason why participants were advised that they could choose their preferred treatment at the end of the trial. In retrospect however, such strong opinion may

have led to the withdrawal of the stent as a standard treatment option throughout the trial which may have helped recruitment.

Whilst the patient representative maintained contact with Mr Crundwell throughout, the project may have benefitted from having access to further input. A number of groups in the Peninsula region have been developed recently meaning that any future research projects have access to panels of lay reviewers and registers of patients interested in taking part in research development.

Data sharing statement

See link

[\[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253\]](https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253) for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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This project was carried out between November 2011 and January 2013 . This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.