Shockwave lithotripsy compared with ureteroscopic stone treatment for adults with ureteric stones: the TISU non-inferiority RCT

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and the Percutaneous nephrolithotomy, flexible Ureterorenoscopy and Extracorporeal shockwave lithotripsy for lower pole kidney stones (PUrE) randomised controlled trial, he was co-applicant on both and principal investigator at the site. James N'Dow was a member of the HTA General Board (2016–March 2019). Francis X Keeley is a member of the Boston Scientific (Marlborough, MA, USA) Advisory Committee and is assisting with the development of a new ureteroscope (Olympus Medical, Hamburg, Germany). Kath Starr reports grants from the NIHR HTA programme during the conduct of the study.

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Plain English summary

The TISU trial

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Plain English summary

Approximately 1 in 20 people suffers from kidney stones that pass down the urine drainage tube (ureter) into the urinary bladder and cause episodes of severe pain (ureteric colic). People with ureteric colic attend hospital for pain relief and diagnosis. Although most stones smaller than 10 mm eventually reach the bladder and are passed during urination, some get stuck and have to be removed using telescopic surgery (called ureteroscopic stone treatment) or shockwave therapy (called shockwave lithotripsy).

Ureteroscopic stone treatment involves passing a telescope-containing instrument through the bladder and into the ureter to fragment and/or remove the stone. This is usually carried out under general anaesthetic as a day case. For shockwave lithotripsy, the patient lies flat on a couch and the apparatus underneath them generates shockwaves that pass through the skin to the ureter and break the stones into smaller fragments, which can be passed naturally in the urine. This involves using X-ray or ultrasound to locate the stone, but can be carried out on an outpatient basis and without general anaesthetic. Telescopic surgery is known to be more successful at removing stones after just one treatment, but it requires more time in hospital and has a higher risk of complications than shockwave lithotripsy (however, shockwave lithotripsy may require more than one session of treatment).

Our study, the Therapeutic Interventions for Stones of the Ureter trial, was designed to establish if treatment for ureteric colic should start with telescopic surgery or shockwave therapy. Over 600 NHS patients took part and they were split into two groups. Each patient had an equal chance of their treatment starting with either telescopic surgery or shockwave lithotripsy, which was decided by a computer program (via random allocation). We counted how many patients in each group had further procedures to remove their stone. We found that telescopic surgery was 11% more effective overall, with an associated slightly better quality of life (10 more healthy days over the 6-month period), but was more expensive in an NHS setting. The finding of a lack of any significant additional clinical benefit leads to the conclusion that the more cost-effective treatment pathway is shockwave lithotripsy with telescopic surgery used only in those patients in whom shockwave lithotripsy is unsuccessful.

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This report

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