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Minimally invasive percutaneous nephrolitholapaxy medium (MIP-M) for removing kidney stones

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is minimally invasive percutaneous nephrolitholapaxy medium (MIP-M). It is used to remove kidney stones.
- The **innovative aspects** are the reduced size of the instruments, which is designed to reduce procedure time and complications, and the novel way in which stone fragments are removed.
- The intended **place in therapy** would be as an alternative to standard lithotripsy, ureteroscopy or nephrolithotomy procedures in people with kidney stones.

- The **main points from the evidence** summarised in this briefing are from 3 retrospective observational studies in 200 patients showing high rates of technical success. There was 1 retrospective observational study in 482 patients that included comparative data on complications and length of stay in hospital.
- **Key uncertainties** around the evidence or technology are that none of the studies were done in the UK and they are all retrospective. Future prospective comparative studies are needed to compare MIP-M with current standard procedures. These should consider the size and complexity of the kidney stone treated because these are important factors that influence procedure success. The comparative study used a retrospective design and patients were not randomly assigned to a treatment group which may have biased results.
- The **cost** per procedure using MIP-M is £4,400. The **resource impact** would be less than standard care for removing kidney stones larger than 20 mm. Using MIP-M may also lead to savings if its use reduces operation time, length of stay in hospital or rates of complications.

The technology

MIP-M (Karl Storz, Germany) is a device used to remove kidney stones. MIP-M is a miniaturised version of percutaneous nephrolithotomy (PCNL) and is suitable for people with kidney stones 12 to 24 mm in diameter in any renal calyx or in the renal pelvis. This device can be used on larger stones but this could increase the operative time and chances of complications. The MIP-M device comprises a 12 Fr nephroscope, a 16.5/17.5 Fr operating nephrostomy or Amplatz sheath, a single-step dilator and grasping forceps.

The procedure is done by making a small incision, usually in the patient's back, and a needle is inserted into the renal pelvis. The position of the needle is confirmed by X-ray or ultrasound. A guide wire is placed through the needle into the renal pelvis. It is then withdrawn, leaving the guide wire in place. A single-step dilator is passed over the guide wire to widen the access channel and a 16.5/17.5 Fr sheath is introduced. A miniaturised 12 Fr nephroscope is then passed inside the sheath; it allows the surgeon to see the kidney stones. The nephroscope has a channel through which grasping forceps are introduced to remove small stones. Bigger stones may have to be broken up using ballistic lithotripsy or laser treatments before removal. Ultrasound and laser instruments are also passed through the nephroscope channel.

Irrigation fluid is circulated under controlled pressure to remove stone fragments. This and the design of the sheath help to prevent fluid overload. When removing the instruments under a continuous flow of irrigation fluid, a vortex develops in the lumen of the sheath causing a vacuum effect. This flushes out stone fragments without the need for a stone retrieval basket.

The stone fragmentation equipment must be available and checked to make sure it is compatible with the MIP-M device before use. MIP-M may be used with lithotripsy devices as small as 5 Fr in size and ballistic lithotripsy probes up to 2 mm in diameter. The size of the laser fibre used ranges between 200 µm and 600 µm.

Innovations

The instruments in the MIP-M system are smaller than standard PNCL devices. This aims to reduce procedural morbidity and complications, including blood loss and infection, in order to reduce the length of hospital stay.

MIP-M instruments are designed to allow control (inflow and outflow) of irrigation fluid. This can avoid introducing grasping instruments to remove the stone, which in turn can reduce the procedure length.

Current NHS pathway or current care pathway

Small stones may pass out of the kidney into the urine without any treatment. Larger stones and those that cause symptoms may need to be broken up or removed. This is usually done with extracorporeal shock wave lithotripsy (ESWL), flexible ureteroscopy (also known as retrograde intrarenal surgery; RIRS) or PCNL.

- ESWL is used for stones (up to 20 mm in diameter) that cannot be passed in urine. X-ray or ultrasound are used to find the stone, which is then broken up using lithotripsy.
- Flexible ureteroscopy or RIRS is used if the stone is up to 15 to 20 mm in diameter and has moved into the ureter. This is done by inserting a telescope into the urethra, through the bladder and into the ureter. The surgeon can remove the stone using another instrument or try to break it up using a laser so that they can be passed in the urine.

- PCNL is commonly used for larger stones (larger than 20 mm in diameter). This is done by making a small incision in the patient's back and using a 24 to 30 Fr dilator to open a tract. A 24 to 30 Fr operating sheath is placed over this to allow access for the 18 Fr nephroscope. The stone is either pulled out or broken up using a laser or ultrasound lithotripsy. These fragments are then passed in the urine.

The MIP-M device would be used as an alternative to standard care for people with kidney stones measuring up to 30 mm in diameter.

Population, setting and intended user

The MIP-M device would be used in an inpatient surgical setting when patients are under general anaesthetic. The device would most likely be used by urological surgeons. Additional training would be needed for surgeons with no previous experience of doing PCNL surgery. The training is provided by the manufacturer and is included in the cost of the device.

Costs

Technology costs

The costs of MIP-M are outlined in table 1.

Table 1 Cost of MIP-M

Description	Cost	Additional information
Standard MIP-M set	£9,322.00	Per reusable set, which includes a nephroscope, dilator and sheath, all of which are autoclavable
Foley catheter	£6.19	Consumable and single use
2 guide wires	£35.34	Consumable and single use
Ureteric catheter	£6.01	Consumable and single use

Based on information received from 2 specialist commentators that provided input for this briefing, the estimated cost per procedure is £4,439. This estimate includes costs for staffing, device, consumables, theatre time and an assumed 2-day stay in hospital. These estimates have not been validated in NHS trusts using MIP-M.

Costs of standard care

The average procedure cost of percutaneous nephrolithotomy is between £4,982 and £5,516 depending on the severity of illness. The average procedure cost of ESWL is £948 and RIRS is between £2,500 and £3,320 depending on severity of illness (NHS reference costs 2015/16). A recent study on the effectiveness of ESWL in removing small renal and ureteric stones in 225 patients found that over 75% of stones were removed after just 1 ESWL session, with a mean of 1.3 sessions needed per patient for complete removal (Al-Marhoon et al. 2013).

Resource consequences

According to clinical experts the estimated cost per procedure of MIP-M is £4,400 and can be used to remove kidney stones measuring up to 30 mm in diameter. The costs of comparator treatments are estimated at around £1,200 to remove kidney stones measuring up to 20 mm in diameter, based on an average of 1.3 sessions needed per person. Costs of removing kidney stones measuring between 15 mm and 20 mm in diameter are estimated at around £2,900 and the costs of removing kidney stones larger than 20 mm in diameter are estimated to be around £5,200 (NHS reference costs 2016/17). The costs are outlined in table 2.

Table 2 Cost of MIP-M compared to comparator treatments

NHS reference costs 2016-17	Comparator treatments	Cost of comparator (£)	Cost of MIP-M (£)	Difference in cost per procedure compared to comparator (£)
LB36Z	ESWL used to remove kidney stones up to 20 mm	1,200	4,400	3,200

LB65C, D E	RIRS used to remove kidney stones between 15 mm and 20 mm	2,900	4,400	1,500
LB75A, B	Standard PCNL used to remove kidney stones larger than 20 mm	5,200	4,400	−800

Using MIP-M rather than PCNL to remove kidney stones larger than 20 mm in diameter would lead to cost savings. However, savings may also result from using smaller size instruments with MIP-M procedures compared to those used with comparator treatment options. Using smaller instruments may reduce procedural morbidity and complications including blood loss and infection which may also reduce the length of stay in hospital.

Any training that may be needed for MIP-M will be included in the cost of the device.

Changes to current care pathway and infrastructure should be minimal as MIP-M is a smaller version of a current system. At the time of preparing this briefing, there were 17 NHS trusts using this device.

Regulatory information

The components of the MIP-M device were CE marked as follows:

- nephroscope – class IIa
- dilator – class I
- operating sheath – class IIa
- operating sheath for supine position – class IIa
- grasping forceps – class I.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Kidney stones are more common in men than in women. Onset tends to be between the ages of 40 to 60 years. The average age of onset is 10 years older in men than in women. Sex and age are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Four studies are summarised in this briefing with a total of 682 patients. All studies used a retrospective case series or observational design and 1 was an abstract. Primary post-procedure stone-free rates ranged from 78% to 97%. About 20% of patients treated with MIP-M experienced non-serious complications (Clavien–Dindo grades I to II), while about 5 to 6% of patients had more serious complications (Clavien–Dindo grade III or more).

In comparison to current standard procedures (RIRS and ESWL), using MIP-M led to higher stone-free rates particularly for patients with larger stones (10 mm or more). However MIP-M patients needed more postoperative care and were found to have a longer stay in hospital.

Table 3 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The size of kidney stones in the studies were different (both smaller and larger) than the ideal size for which MIP-M is indicated. The stones varied in complexity, which may affect post-procedure stone-free rates and volume of blood loss. Patient characteristics such as age and sex that are associated with the presence of kidney stones were not always reported and all of the studies used a retrospective design, which may lead to biased patient selection. Prospective comparative studies or randomised controlled trials would be valuable to show the effectiveness of MIP-M compared with standard care.

None of the studies included were done in the UK, but the outcomes reported are relevant to the NHS. It would be beneficial to have evidence directly comparing MIP-M with NHS treatment options and patient selection criteria.

Table 3 Summary of selected studies

Abdelhafez et al. (2012)	
Study size, design and location	73 patients with renal stones >20 mm; mean stone size was 36.7 mm). Retrospective case series. Germany.
Intervention and comparator(s)	Intervention was MIP-M. No comparator.

Key outcomes	51 (61.4%) stones were classed as complex stones and 32 (38.6%) were classed as simple stones. Stone size not reported. Mean surgical time was 99.2 (SD=48.3) minutes. This did not significantly differ between complex and simple stones. Post-procedure, primary stone-free rate was 78.3% with 16.9% of patients needing an auxiliary procedure to become stone free, resulting in an overall stone-free rate of 95.2%. There was a significant difference in primary stone-free rates between simple stones (96.9%) and complex stones (66.7%). There were complications in 26.5% of patients; 20.5% of complications were Clavien–Dindo grades I or II and 6.0% were grade IIIb. Grade I complications were significantly more likely to happen with simple stones (33.3%) than with complex stones (5.8%). The grade IIIb complications were more likely to occur with complex stones, but this was not significant. No complications were grade IV or V. Haemoglobin-level decrease was not significantly different between simple and complex stone groups. One patient (who had complex stones) needed a blood transfusion.
Strengths and limitations	No comparator device. Retrospective study design.
Abdelhafez et al. (2013)	
Study size, design and location	98 patients with renal stones <20 mm and 93 with renal stones >20 mm. Retrospective observational study. Germany.
Intervention and comparator(s)	Intervention was MIP-M. No comparator.

Key outcomes	There were 74 complex renal stones (58 large, 16 small) and 117 were simple (35 large, 82 small). Mean overall surgical time was 82.9 (±44.4) minutes. This was significantly longer in large stones compared with small stones (97.4 versus 69.2 minutes). Mean overall decrease in haemoglobin was 1.5 g/dl. This was significantly different between groups (large, 1.7 and small, 1.3). One participant (with a large complex stone) needed a blood transfusion. Primary stone-free rate was 83.8%. Some 13.1% of patients needed an auxiliary procedure to become stone free, resulting in an overall stone-free rate of 96.9%. There was a significant difference in primary stone-free rates between large stones (76.7%) and small stones (90.8%). The overall complication rate was 23%, with 17.8% of these Clavien–Dindo grade I or II, 5.3% grade IIIb and none grade IV or V. There was no significant difference in the complication rate between large and small stones. Mean hospital stay was 3.9±1.4 days. This was significantly longer for those with large stones compared with small (4.3 versus 3.7 days respectively).
Strengths and limitations	No comparator device. Assessed consecutive MIP-M procedures from a single site.
Kruck et al. (2013)	
Study size, design and location	482 patients having their first renal stone removal: 202 ESWL; 108 RIRS; and 172 MIP-M procedure. Retrospective comparative observational study. Germany.
Intervention and comparator(s)	Intervention was MIP-M. Comparators were shock wave lithrotripsy and retrograde intrarenal surgery.

Key outcomes	The mean stone size was significantly larger in the MIP-M group compared with the comparator groups. Primary stone-free rates were significantly higher in the MIP-M group compared with the RIRS and ESWL groups (79.7%, 77.8% and 58.4% respectively). There was a higher stone-free rate for patients with stones >10 mm when using MIP-M compared with ESWL. RIRS and MIP-M patients needed significantly more postoperative care compared with ESWL. Length of hospital stay was significantly higher in the MIP-M group compared with RIRS and ESWL (4.5, 2.3 and 2.2 days respectively). Complication rates (Clavien–Dindo grades I to III), were higher in the RIRS and MIP-M groups. For lower pole stones, MIP-M showed significantly prolonged stone-free survival compared with RIRS and ESWL.
Strengths and limitations	Moderate sample sizes. Comparator devices. Retrospective design.
Schilling et al. (2009)	
Study size, design and location	29 patients with renal stones between 8 mm and 15 mm in diameter. Retrospective chart review. Germany.
Intervention and comparator(s)	Intervention was MIP-M. No comparator.
Key outcomes	96.5% were post-operatively stone free; 1 patient had further ureteroscopy to become stone free. No Clavien–Dindo grade VI or V complications were reported. No patients needed a blood transfusion.
Strengths and limitations	No comparator. Abstract only. Small sample size.

Abbreviations: MIP-M, minimally invasive percutaneous nephrolitholapaxy medium; ESWL, extracorporeal shock wave lithrotripsy; RIRS, retrograde intrarenal surgery.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialists commentator comments

Comments on this technology were invited from clinical experts working in the field. The comments received are individual opinions and do not represent NICE's view.

All 4 experts who provided responses were familiar with, or had used, this technology.

Level of innovation

Three experts thought that MIP-M was only a variation of an existing technology but 1 felt it was a completely novel design because its miniaturised nephroscope and sheath and low-pressure uncoupled system result in a new way of removing renal stones. All experts said they were aware of other miniaturised systems which have a similar function as MIP-M and 1 noted that the role of miniaturised PCNL is evolving so the exact size of the kidney stone for which it is appropriate is still unclear.

Potential patient impact

All experts thought that because the incision needed would be smaller with the MIP-M there would be improved patient outcomes for both adults and children. The benefits listed included reduced bleeding that may result in less need for nephrostomy tube and stent insertion, less postoperative pain and subsequent treatment with analgesia, quicker recovery and shorter length of stay in hospitals. All experts said that people with smaller stones – particularly those ranging in size between 10 mm and 30 mm – would benefit from this device. There were also other groups of people that at least 1 or more expert said could benefit. These included people with recurrent stones who need multiple surgeries, those with stones that are not accessible by flexible ureteroscopy and children.

Potential system impact

None of the experts thought that using MIP-M would change the care pathway or need additional or altered infrastructure. It was noted that stone fragmentation equipment must be available on-site and small enough to be compatible with MIP-M and 1 expert claimed that surgeons may need to be trained in using the device. All experts agreed MIP-M may be beneficial to the NHS if it leads to shorter stays in hospital, the ability to offer an alternative treatment to the more invasive standard PCNL treatments and potential reductions in consumable costs. However, 1 expert stated that the initial expense could deter some trusts from purchasing MIP-M.

General comments

All experts agreed this device may benefit a large number of people who need PCNL treatment. But a full randomised controlled trial comparing MIP-M to RIRS or PCNL in a large sample in the NHS is needed.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Matthew Bultitude, consultant urologist, Guy's and St Thomas' NHS Foundation Trust. The following conflicts of interest were declared:
  - Boston Scientific – acted as a consultant for the purpose of Twitter chats on stone-related topics (2 honoraria of £600 each)
  - Karl Storz – demonstrated the MIP-M technique at the European Association of Urology conference in London 2017 with live surgery from the operating theatres. The company paid a contribution of £500 towards registration fee
  - Olympus Medical – received £1,000 for speaking at a symposium at a conference (British Association of Urological Surgeons [BAUS] 2016).
- Mr Stuart Irving, consultant endourological surgeon, Norfolk and Norwich University Hospital NHS Trust. No conflicts of interest declared.
- Mr Shalom Srirangam, consultant urological surgeon, East Lancashire Hospitals NHS Trust. No conflicts of interest declared.

- Ms Sharon Scriven, consultant endourologist, Nottingham University Hospitals NHS Trust. No conflicts of interest declared.

Development of this briefing

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