NICE advice

RenalSense Clarity RMS for acute kidney injury

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is RenalSense Clarity RMS. It is used for people in critical care and high dependency care settings who are at risk of developing acute kidney injury (AKI).
- The **innovative aspects** are that it automates a step in the care pathway.
- The intended **place in therapy** would be as an alternative to an urometer in people with catheters, particularly those at risk of developing AKI or who already have AKI.
- The **main points from the evidence** summarised in this briefing are from 1 study (observational) including a total of 63 patients in a general intensive care unit. It shows that RenalSense Clarity RMS is more effective in identifying AKI than using serum creatinine.
- **Key uncertainties** around the evidence are that the evidence came from 1 non-comparative observational study done in Israel, which was only a conference abstract.

- The **cost** of RenalSense Clarity RMS is £3,810 per unit (excluding VAT), and the sensors cost £65 per person. Standard care, which is a urometer test, costs between £8 and £10.

The technology

Clarity RMS (RenalSense) is a critical care monitoring system that continuously measures urine flow and automatically sends data and alerts of fluctuations to medical staff in real-time. This is done on a '24 hours a day, 7 days a week' basis. Information on changes in renal function provides an early indication of acute kidney injury (AKI) risk and allows rapid intervention. It also helps monitor treatment efficacy and manage fluid balance.

RenalSense Clarity RMS consists of 3 components:

- Clarity RMS electric sensor: connects to a Foley catheter and continuously measures critical fluctuations in urine flow. When a temperature-sensing Foley catheter is used, the sensors can also measure real-time core body temperature.
- Clarity RMS console: the embedded technology in this battery-powered bedside monitor continuously calculates and sends real-time data from the sensor directly to all hospital information systems.
- Clarity RMS intelligent notification system: notifies the medical team when the patient's urine flow is below the threshold set by the user for urine output (ml/kg/hour), based on the risk, injury, failure, loss and end-stage kidney disease (RIFLE), AKI network (AKIN) and kidney disease: improving global outcomes (KDIGO) criteria.

Innovations

The company claims that the automated system replaces a step in the current patient pathway (urometer) by measuring the urine flow in real time, displaying this data on the console and sending it to hospital information systems. The company claims that this limits the need for manual intervention and that Clarity RMS is more consistent, reliable and accurate than nursing records.

Current care pathway

Those at risk of AKI should be monitored and can be diagnosed based on an acutely rising serum creatinine or reduction in urine output.

AKI is present if 1 or more of the following criteria is met:

- a rise in serum creatinine of at least 0.3 mg/100 ml within 48 hours
- a rise in serum creatinine to more than 1.5 times baseline, which is known or presumed to have happened in the past 7 days (in practice, you can use the lowest value from the past 3 months as the baseline for the patient) **or**
- urine volume of less than 0.5 ml/kg/hour for at least 6 hours.

Urine output is measured manually using a urometer that is attached to a urinary catheter and placed within the sealed catheter bag. Measurements are done hourly or for a set time. Expert advice noted that the AKI criteria above only apply after any dehydration has been corrected.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on AKI: prevention, detection and management
- NICE's COVID-19 rapid guideline: managing COVID-19
- NICE's diagnostics guidance on tests to help assess risk of AKI for people being considered for critical care admission (ARCHITECT and Alinity i Urine NGAL assays, BioPorto NGAL test and NephroCheck test).

Population, setting and intended user

RenalSense Clarity RMS is intended to automatically monitor urine output for people weighing more than 50 kg, who have an indwelling Foley catheter. It can be used for people with catheters who are on an intensive care unit (ICU) or ward, who are at risk of developing AKI. It can also be used for people who have AKI.

AKI is seen in 10% to 20% of people admitted to hospital as emergencies, with an inpatient mortality over 20%. The overall incidence of AKI in the ICU is higher at 20% to 50% and it is

associated with mortality over 50% (BMJ best practice: AKI).

The technology can be used in both secondary and tertiary care by consultant nephrologists, consultant intensivists, ICU nurses, high dependency unit nurses and ward nurses, who care for people with catheters.

The company states that the console is simple to use and needs minimal training. The training is included in the cost of the device for free, lasts 30 to 40 minutes and is done either face-to-face or via Microsoft Teams.

Costs

Technology costs

- Clarity RMS console: £3,810.
- Disposable sensor kit: £65 per person.

The company states that the lifespan of the console is between 5 and 10 years.

Costs of standard care

- Urometer: £8 to £10 per person.

Resource consequences

The company states that the technology is currently not used in the NHS. However, they are in discussion with 2 pilot sites to adopt and evaluate the technology in 2021.

The company claims that the automation of measuring urine flow replaces manual intervention by healthcare assistants and therefore could use less staff resource. The company also claims that Clarity RMS allows earlier or more accurate diagnosis, which may reduce the length of hospital stay or allow earlier discharge.

The company states that for the hospital to realise the full benefit of the technology, the system needs to be integrated into the hospital information system. Clarity RMS currently needs an ethernet connection at the patient's bedside; however, the company states that

wireless connectivity is under development and will be available in 2021.

Regulatory information

RenalSense Clarity RMS is a CE-marked class 2a medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Older people and people with chronic kidney disease or other long-term diseases (such as heart disease, liver failure or diabetes) are at risk of developing acute kidney injury. Age and disability 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 for medtech innovation briefings. 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

There is 1 study summarised in this briefing, including 63 people.

This non-comparative prospective observational study was reported in abstract form only.

The clinical evidence and its strengths and limitations is summarised in the section on overall assessment of the evidence.

Overall assessment of the evidence

The evidence is of low methodological quality and has small patient numbers. No comparative studies were identified, and none were done in the UK. The study shows that measuring urine output using RenalSense Clarity RMS can identify acute kidney injury (AKI) sooner than by using serum creatinine. The evidence came from 1 conference abstract so more high-quality research is needed comparing RenalSense Clarity RMS with standard care, in more patients. There is a further study measuring urine output accuracy compared with standard care but this is not for patients at risk of AKI, so is not included here.

Goldman et al. (2017)

Study size, design and location

Prospective observational study in 63 hospitalised people with an indwelling urinary catheter in Israel.

Intervention and comparator

RenalSense Clarity RMS with urometer.

Key outcomes

The patients were split into 3 groups based on the kidney disease: improving global outcomes (KDIGO) criteria: serum creatinine only, urine output only and serum creatinine plus urine output. Results were reported for patients with AKI compared with patients without AKI. Length of stay in the intensive care unit (ICU) in the serum creatinine only ($p \leq 0.0023$), urine output only ($p \leq 0.0074$) and serum creatinine plus urine output groups ($p \leq 0.0018$) was statistically significantly longer for people with AKI than people without AKI. There were 13 people in the AKI serum creatinine plus urine output group (12 with AKI urine output stage 2, and 1 with stage 1). AKI was identified as much as 120 hours earlier by urine output than by serum creatinine. In all 3 methods, AKI patients had significantly more fluid in the first 24 hours of urine output monitoring than those without AKI.

Strengths and limitations

The authors conclude that monitoring urine output in real time will provide valuable

information to identify AKI earlier, intervene earlier, and set protocol goals such as decisions for timely fluid and diuretic administration as well as evaluating response. The accuracy of the sensor was validated using a scientific scale and then the validated RenalSense Clarity RMS was used to measure urine flow. The urometer was incorporated into the RenalSense Clarity RMS sensor kit so that nurses could record urine output as per standard practice. The staff were blinded to both Clarity RMS and scale measurements. However, comparative results were not presented. This study is reported in conference abstract form only and is limited in detail. All apart from 1 study author are employees of RenalSense.

Sustainability

The sensors are for single patient use and are disposed of in clinical waste as per similar products.

Recent and ongoing studies

- Automated urine flow detection to reduce errors and nursing workload (AiDe-RN). ClinicalTrials.gov Identifier: NCT03636113. Status: active, not recruiting. Indication: AKI; kidney injury. Devices: Clarity RMS electronic sensor versus standard method of urine output monitoring. Country: US.

The company is aware of 2 additional studies that are yet to be published.

Expert comments

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

All 3 experts were familiar with but had not used this technology before.

Level of innovation

All 3 experts said that the technology is novel but of uncertain safety and efficacy. One expert said that the ability to measure flow rate is innovative. The experts agreed that

there are no other similar technologies currently available to the NHS.

Potential patient impact

Two experts said that RenalSense Clarity RMS may improve accurate measurement and documentation of urine output. One expert also said that it can lead to early detection of not only acute kidney injury but also dehydration or underlying causes of AKI such as haemorrhage or sepsis. One expert felt unable to comment based on the limited evidence available.

Two experts suggested patient groups that would particularly benefit from using this technology. These included people who are critically ill, people at risk of having fluid overload, people with electrolyte disorders, people with drug toxicity and people who are elderly.

One expert said that the technology can be used on any patient in the intensive care unit (ICU). Another expert noted that this includes many thousands of patients, including most patients admitted to the ICU, high dependency unit, renal units or after major surgery.

Potential system impact

Two experts said that this technology has the potential to change the current pathway and may lead to improved outcomes through earlier detection of AKI and dehydration. However, 1 expert noted that there is little evidence to support this. One expert said that it may impact on time spent by nursing staff monitoring urine output. Furthermore, 1 expert said that urine output documentation is generally poor, it is often incomplete and prone to error.

All experts agreed that RenalSense Clarity RMS costs more than standard care. However, 1 expert said that if the technology would reduce the incidence of severe AKI, the need for renal replacement therapy and length of hospital stay, then there could be overall cost savings.

Experts said that relatively few changes are needed to the clinical facilities to use the technology. One expert noted that the technology needs to be compatible with the NHS trusts' information technology systems and have specific areas for charging batteries.

Two experts said that training is needed to use the technology safely and effectively. One expert said that poor training can lead to potential harm.

General comments

Two experts said that the technology has the potential to replace current standard care. However, the technology costs more than standard care so 1 expert said that it may only be used in specific settings and with complex and high-risk patients. Another expert said because of the high cost, this would be in addition to standard care.

One expert raised issues with the usability stating that a wireless connection would be expected and may lead to the potential for more remote monitoring.

The experts expressed some concerns about the cost, efficacy and safety of the technology. One expert is unsure if it is better than standard care and will improve hard clinical outcomes. Another expert is concerned about the technology not being used appropriately and that there should be clear guidelines about which patients it may be suitable for and why. This expert also said that the technology is expensive and needs to show cost versus benefit.

Two experts agreed that further research is needed including a large clinical trial comparing RenalSense Clarity RMS to a urometer in the ICU focusing on relevant clinical outcomes. One expert said the setting should include trauma surgical wards or acute medical wards because this is where people with AKI are.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Edward Sharples, consultant in renal medicine, Oxford University Hospitals NHS Trust. Did not declare any interests.
- Ms Charlotte Trumper, clinical governance lead/acute kidney injury network chair (independent), Milton Keynes University Hospital. Did not declare any interests.

- Dr Mark Devonald, consultant nephrologist, Liverpool University Hospitals NHS Foundation Trust. Has publications in acute kidney injury (AKI) including methods of urine output and is a co-inventor of AKI urinary biomarkers with a US patent awarded (other territories pending).

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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