TECHBRIEF

HORIZON SCANNING REPORT

WEARABLE DIALYSIS DEVICE

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WEARABLE DIALYSIS DEVICE

INTRODUCTION

Chronic kidney disease is a situation where the glomerular filtration rate (GFR) is below than 60 ml/min per 1.73 m^2 for three months or longer with or without kidney damage; or the kidney is damaged by structural or functional abnormalities for more than three months with or without decrease of GFR.[1]

In year 1990 to 2010, the global prevalence of end stage renal disease (ESRD) exceeded two million individuals while the global incidence substantially increased from 44 per million population (pmp) in 1990 to 93 pmp in 2010.[2-3]

In Malaysia, there is an upward trend in the prevalence of ESRD where the figure increased from 325 pmp (2001) to 762 pmp (2009) and the incidence surged from 88 pmp (2001) to 170 pmp (2009).[4]

The best treatment of ESRD is kidney transplant. However, the kidney transplant rate is low in Malaysia where only 63 kidney transplantations were done in year 2014. According to 22nd Report of the Malaysia Dialysis and Transplant Register 2014, about 32,767 patients received dialysis in year 2014 which was a tremendous increase from 13,356 patients in 2005 while the number of new dialysis patients doubled in 2014 (7,055 patients) when compared to year 2005 (3,167patients).[5]

Haemodialysis required patients to have thrice sessions a week with about six hours each session. As long hours of dialysis may limit patients freedom and restrict them from their dietary choices, the idea to develop wearable haemodialysis device was brought up by Kolff and team since early 1970s to improve the device and patients' circumstances. Besides, advances in technology and miniaturisation has motivated scientists to invent wearable and portable device for dialysis to revolutionise the treatment and quality of life for patients with ESRD.[6-7]

THE TECHNOLOGY

There are few concepts of wearable dialysis device being studied and researched by scientists for both haemodialysis (HD) and peritoneal dialysis. All these studies aimed to make wearable dialysis machine a reality to help patients improve their quality of life by allowing them to pursue any activities of their interest rather than sitting tethered to the dialysis machine. The available wearable dialysis devices which are still under research stage includes wearable haemodialysis system (Wearable Artificial Kidney or WAK), and wearable peritoneal dialysis system (Vicenza Wearable Artificial Kidney for Peritoneal Dialysis or ViWAK

PD, Automated Wearable Artificial Kidney or AWAK, and Mobilysis) (Table 1 at Appendix 1).[8-10]

WEARABLE HAEMODIALYSIS DEVICE

a) Wearable Artificial Kidney (WAK):

Wearable artificial kidney is a new, portable and wearable dialysis machine developed by Victor Gura, a scientist from David Geffen School of Medicine, University of California, Los Angeles. In April 2012, WAK was awarded a special fast-track to market status through USFDA Innovation Pathway Program. The USFDA has also approved the start of the first human clinical trials in the US for WAK in February 2014. It has received the first FDA-approved proof-of-concept trial in November 2015 and also passed proof of concept studies in Italy and England. [11-12]

Wearable artificial kidney is a miniaturised, wearable, HD machine based on dialysate regenerating sorbent technology. It is designed to be worn like a belt and used by patients for up to 24 hours per day as a slow and gentle dialysis. This is considered as the best way to mimic the natural kidney and its functions to constantly cleansing the toxins in blood (Figure 1). Continuous dialysis also may keep blood pressure within normal range, eliminate the need for phosphate binders, and reduce the need for anaemia drugs. The weight of the first WAK prototype is about 10-pound (~5 kg) and powered by 9-volt batteries (Figure 2).

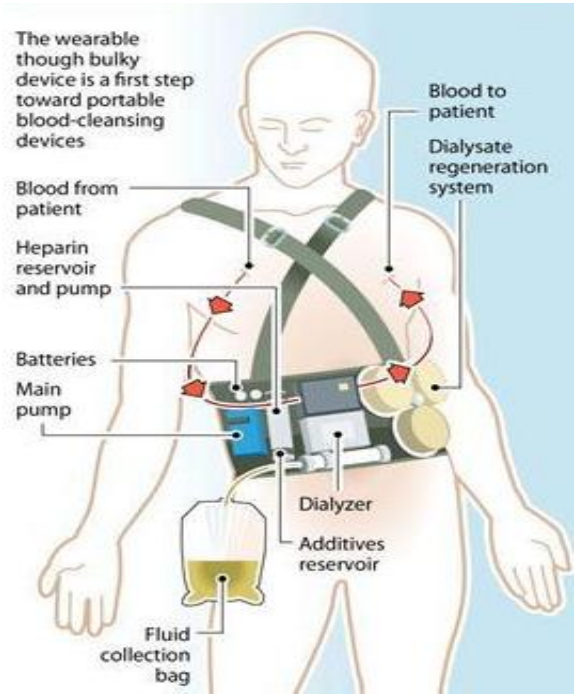

Figure 1: Structure of wearable artificial kidney
Source: (*http://www.reuters.com/article/us-kidney-artificial-idUSL1243564120071214*)

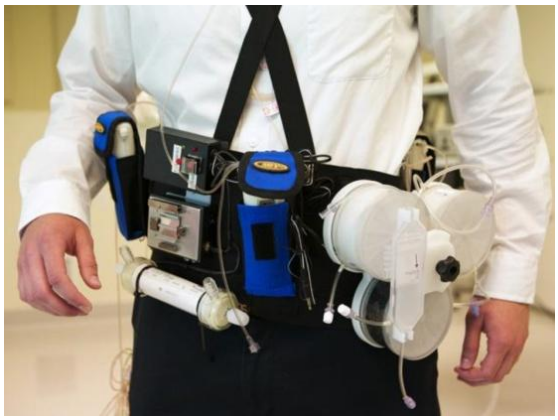

Figure 2: Prototype of wearable artificial kidney

According to the researchers the current WAK prototype will become smaller, lighter and easier to wear in the future. The comparison of WAK and current haemodialysis machine is shown in Table 2 (Appendix 1).[12-14]

Figure 3 (Appendix 2) showed how WAK works. The patient's blood is drawn and flow through a double lumen catheter (red) and circulate through the blood channel of the WAK pump (grey) into the dialyser. The reservoir (white) containing heparin, is used to anticoagulate the blood in the catheter by using battery-operated micro pump. The blood then, returns to the venous side of the double lumen catheter (blue) to the patient. During the process, the clean dialysate (green) enters the dialyser. The dialysate is infused with a solution containing potassium, calcium, and magnesium from another reservoir (black) by using a pump. The dialysate in the dialyser flow countercurrently to the blood and exits (yellow) into the dialysate channel. After that, another pump removes a predetermined amount of the spent dialysate (yellow) into a collection bag. Next, the rest of the dialysate flow through a series of sorbent (yellow) which consists of canisters that contained urease, zirconium phosphate, hydrous zirconium oxide, and activated carbon. At the same time, a solution containing sodium bicarbonate from a reservoir (purple) is pumped and infused into the dialysate. Lastly, the clean dialysate then returns back to the dialyser (green) for the next process.[15]

For safety reason, the WAK is equipped with three sensors. Blood flow will automatically stop once the sensor detected bubbles in the blood circuit. Another sensor is to stop the ultrafiltration pump if the patients' blood flow stopped for any reason. Special wetness sensors were applied to both the arterial and venous access connections to detect any leakage in the system. The pulsatile blood pump also had a self-limited capacity to generate negative pressure for suction from the arterial side of the vascular access which may results in termination of the blood pump if any disconnection on the arterial side occurred. The blood pump also stops if any venous resistance exist.[16-17]

WEARABLE PERITONEAL DIALYSIS DEVICE

a) Vicenza Wearable Artificial Kidney for Peritoneal Dialysis (ViWAK PD):

Vicenza Wearable Artificial Kidney for Peritoneal Dialysis developed by AWAK Technologies is a miniaturised system for continuos-flow PD with capacity to regenerate spent dialysate. It weight just about two pounds (~1 kg), small in size, battery-operated and able to provide effective recirculation of PD solution at a rate of 20 ml/min for more than 12 hours. This system is meant to be an alternative for continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis (APD) to reduce the time consumption, the steps of procedure and amount of solution required to perform PD. The system is based on a combination of a long overnight dwell exchange and a continuos-flow PD during the day performed with a special catheter and a special minicycler which utilised a

mixture of sorbents to regenerate the PD solution.[8,18,19]

The ViWAK PD system consists of:[8,18]

- A double lumen peritoneal catheter
- A dialysate outflow line
- A miniaturised rotary pump
- A circuit for dialysate regeneration featuring a waterproof container with four cartridges in parallel with a mixture of activated carbon and polystyrenic resins
- A filter for deaeration and microbiological safety
- A dialysate inflow line
- A handheld computer as a remote control

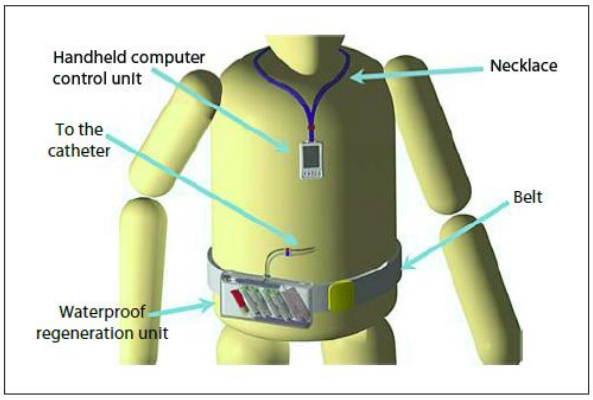

Figure 4: Schematic representation of ViWAK PD

The ViWAK PD required minimal handling only in the morning and in the evening. In the morning, two litres of fresh PD solution is loaded into the peritoneal cavity. The recirculation is activated for 10 hours at a rate of 20ml/min after 2 hours of the first step when 50% dialysate/plasma equilibration has been achieved. Then, recirculation stops after a complete equilibration is obtained in the remaining indwelling solution. Glucose is optionally added to the peritoneal cavity to achieve ultrafiltration if needed through a line connected to a small reservoir which is located on the belt. Patient may activate this function via handheld computer. After 2 hours, the fluid is drained and 2 litre of icodextrin exchange is performed overnight to achieve further ultrafiltration. The clearance is further increased by the 2 litre exchange and the overnight exchange.

The system operates 24 hr/day and provides creatinine and β_2 microglobulin clearance in the range of 15-16 litres/day, corresponding to a weekly clearance of 100-110 litres. The number of exchanges reduced when compared to CAPD and uses less fluid than in APD. Figure 5 showed the schematic diagram of the ViWAK.[18]

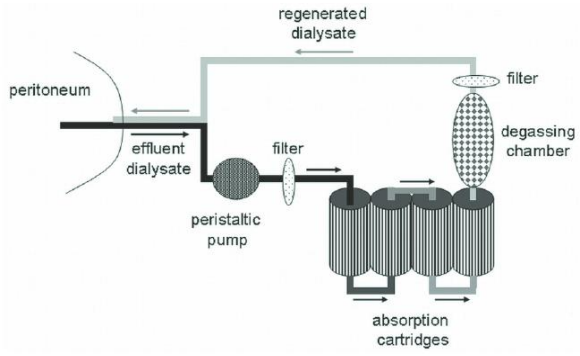

Figure 5: Schematic circuit diagram of the ViWAK.[19]

b) Automated Wearable Artificial kidney (AWAK):[20,21]

The concept of AWAK is to functionally imitate natural kidneys by operating on a 24/7 basis. It has the potential to remove middle molecules and protein-bound solutes including small molecular-weight solutes, and works automatically to provide dialysis-on-the-go. This device is a wearable, automated, powered by rechargeable batteries (estimated life is about 18 hours), bloodless as no extracorporeal circulation is required, and waterless dialysis as it is designed to continuously regenerate and reuse the spent dialysate for long hours. The feature of continuous regenerate and recycle use of the spent dialysate make the AWAK differs from the ViWAK as it can be either daily or monthly disposable and ease for replacement.

The AWAK use a catheter for the dialysate to flow in and out of the patient's peritoneal cavity. A small fraction of the spent dialysate is stored in a bladder reservoir while the bulk of the spent dialysate flows through a sorbent assembly which consist of a fibrin that functions as a debris trap, and a carbon filter. The sorbents are designed and engineered to regenerate both the ultrafiltrate and the proteins of the spent dialysate, in order to produce a fresh protein-containing dialysate. The enrichment motif infused potassium, calcium, magnesium and glucose to the regenerated dialysate. After that, the replenished fresh dialysate will pass through a sterilising filter and a gas removal module before being recycled back into the peritoneal cavity (Figure 6).

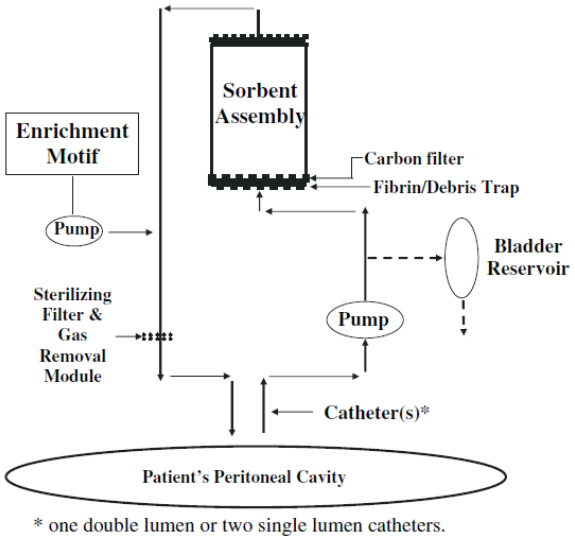

Figure 6: Basic component of AWAK.[20]

c) Mobilysis:

Mobilysis consists of one flexible belt that is separated into membrane compartments filled with dialysis fluid with a hard shell front. Dialysing liquid is pumped from the containing belt into the abdominal cavity in multiple cycles, where it cleans the blood through peritoneum. The catheter connection are integrated with infrared cleansing unit and Mobilysis can be controlled using a smartphone application with comprehensive and intuitive possibilities where user may use the buttons to perform necessary functions located on the device itself. After each peritoneal dialysis cycle, the dialysis fluid is cleansed in the technical section and then ready for the next cycle.[22]

Figure 7: Mobilysis

PATIENT GROUP AND INDICATION

The wearable dialysis device is meant for patients who suffer from chronic kidney disease requiring dialysis treatment.

CURRENT PRACTICE

The treatment of chronic renal failure depends on the degree of kidney function which may include:[5]

- Dialysis
  - The current haemodialysis (HD) machine allows removal of large amount of fluid in relatively short periods which may lead to adverse haemodynamic changes. Patients need to undergo dialysis process for at least three times weekly and attached to the machine.[6,17]
  - Peritoneal dialysis (PD) is another way to remove waste products from blood in patients with CKD. There are two main way of PD namely continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis (APD). CAPD is a continuous, machine free and done by holding up plastic bag and cleansing fluid to patients. Unfortunately, peritonitis remains the major complication of the PD technique in spite of antibiotics creams applied at the exit site. Furthermore, patients have to spend time performing their exchange three to four exchanges per day with CAPD or connect themselves to an automated overnight cycler or APD (automated peritoneal dialysis) which although transportable, still requires a mains electrical supply and fresh dialysate, and they are certainly not wearable.[6,19]
- Medications (to help with growth, prevent bone density loss, and/or to treat anaemia)
- Diuretic therapy or medications (to increase urine output)
- Specific diet restrictions or modifications
- Kidney transplantation

EFFICACY & SAFETY

We identified two studies that have been conducted to prove the efficacy and safety of WAK. There is a proof of concepts test for AWAK while for ViWAK PD, there was no retrievable evidence.

EFFICACY

a) WAK:

A prospective, non-randomised, and exploratory clinical trial (NCT02280005) approved by FDA was conducted by Gura V et al. involving seven subjects where only five of them completed the 24-hours treatment period.[24]

The results showed the mean weighted-average concentrations of blood urea nitrogen (BUN) during the 24 hours WAK treatment (17±5 mg/dL) were significantly lower compared to 48 hours period before the WAK session where patients underwent conventional haemodialysis treatment (39±18 mg/dL). The mean β_2-microglobulin concentrations was also significantly lower during the WAK treatment (17±8 mg/l) when compared to periods of conventional haemodialysis (22±11 mg/l). Conversely, the mean serum potassium (3.8±0.5 meq/l) and serum phosphate (3.1±0.5 mg/dl) concentration were increased after 24 hours WAK treatment (3.9±0.4 meq/l and 3.9±0.8 mg/dl respectively). The acid-base and electrolyte homeostasis was found to be maintained during the study without patients' dietary restriction and phosphorus-binding medications intake. Mean BUN, creatinine, phosphorus, and β_2-microglobulin clearance during the trial were 17±10, 16±8, 15±9 and 5±4 ml/min which were close concordance of blood-based and dialysate-based measurements of solute clearance.[24]

From the study, no patient was observed to experience systolic blood pressure lower than 100 mmHg but one patient had systolic blood pressure lower than 120 mmHg. Individual Renal Treatment Satisfaction Questionnaire (RTSQ) was used to assess the WAK treatment experience satisfaction compared to conventional haemodialysis treatment among the patients and the results showed that satisfaction with WAK treatment was significantly higher ($p<0.001$) compared to the conventional haemodialysis including satisfaction with treatment-related side effects, convenience and flexibility of treatment, discomfort or pain involved with treatment, and also satisfaction with freedom during dialysis treatment.[24]

A pilot study was conducted by Armignacco P et al. in 2007 to analyse the performance of WAK. The study which was approved by the UK Medicines Health Regulation Authority (MHRA) involved eight patients with CKD who were treated with regular haemodialysis three times a week. Since the efficacy of WAK had not been established, the MHRA requested that the treatment using WAK should not replace patients' standard intermittent haemodialysis treatment. Thereby, fluid removal to achieve target postdialysis weight was not set as the objective of this study.[7,16]

Patients' blood oxygen saturation and the cardiac cycle were monitored continuously. Patients' weight before and after treatment was recorded and biochemical test was also done. [7,16]

The MHRA has determined that between two and four patients, the WAK treatment should be performed up to four hours only. The treatment were allowed to be extended up to eight hours after the first phase completed and no major adverse events observed. The mean blood flow and dialysate flow during the treatment was 58.6 (11.7) ml/min and 47.1 (7.8) ml/min respectively and the results showed that the device performed well in removing fluid with no cardiovascular adverse event, no changes in ECG as well as serum electrolytes and acid-base balance. During the study, patients had no difficulty to sleep and no time taken to recover after completing the treatment. [7,16]

b) ViWAK PD

A conceptual proposals for ViWAK PD was put up but no clinical trials have been conducted.[18,25]

c) AWAK

A proof of concept test was done where ninety successful PD session ranging from 4 to 24 hours each were conducted in 20 male patients using a single-lumen catheter either by conventional in-and-out or a tidal PD dialysate flow pattern. One patient was maintained on this sorbent regeneration system for two months.[20]

SAFETY

a) WAK:

The non-randomised study conducted by Gura et al. portrayed that the device performed well with no serious complication as there were no evidence of saturation with uraemic solute but the trial was stopped after the seventh subject due to device-related technical problems such as excessive carbon dioxide bubbles in the dialysate circuit. Two subjects needed lithium ion battery replacement before the 24 hours treatment completed and three subjects required gas bubbles removal from the circuit.[24]

One subject was discontinued treatment after four hours due to clotting of the blood circuit. Another subject was discontinued treatment after 10 hours due to pink discolouration of dialysate.[24]

There was no serious adverse events reported such as significant changes in serum haptoglobin, lactate dehydrogenase or haematocrit which may indicate significant haemolysis. The tolerability was good except two subjects experienced mild muscle cramping, one subject experienced a brief episode of nausea, one had an episode of diarrhea on the day following treatment and one subject encountered moderate malaise after discontinuation of the treatment. However, all seven subjects were able to ambulate while receiving WAK treatment.[24]

In the pilot study by Armignacco P et al, two patients experienced clotting and the treatment was discontinued after

seven hours and four hours respectively as both patients were not receiving adequate anticoagulants at that time. One patient encountered fistula needles dislodgement and the built-in safety mechanism had stopped the blood pump during the incident. Patient was temporarily disconnected but the needle was quickly reinserted and the treatment was continued smoothly. [7,16,17,26]

b) AWAK

A sorbent-based assembly in AWAK device which regenerates both the aqueous and the protein components (AqC and PrC) of the spent dialysate is considered as a novel, autologous protein-containing dialysate. The AWAK has capacity to regenerate AqC which have similar composition with commercially available peritoneal dialysate, but contains bicarbonate instead of lactate and has slightly higher pH value (pH: 6.5-7.0) compared to commercial dialysate (pH:5.0-5.5). For regenerated PrC, it is recycled back into the peritoneal cavity to rehabilitate or eliminate protein loss (Table 6).[20,21]

The regenerated dialysate that is sterilised through the filter-sterilisation before being infused into patients has been tested and the results were negative in culture and pyrogen free.[20]

ESTIMATED COST

The actual cost implication of wearable dialysis device is not known yet. However, it was postulated this new device will reduce the overall cost.[20]

According to a study conducted by Mushi L et al the cost of dialysis in Malaysia was estimated as RM 79.61 to RM 475.79 per HD treatment (mean cost: RM169/HD) and RM 1,400 to RM 3,200/patient/month for CAPD treatment (mean cost: RM 2186/patient/month).[27]

ORGANIZATIONAL ISSUES

Training on managing wearable dialysis device should be provided to the healthcare provider that will be involved in this device-based intervention as they may need to advise and guide patients in performing their own dialysis at home or work place.

AWAK needs no purchase, construction and maintenance of physical facilities and equipment and also expected to minimise professional personnel involvement as patients may perform dialysis process themselves.[20]

POTENTIAL IMPACT

WAK is an innovative device that allow patients to have dialysis treatment anywhere 24 hours per day. Since the function mimics the natural kidney, this new device may have potential in providing patients with freedom to work and perform their daily activities while dialysing.[6,17]

Improvement in size and weight of WAK prototype in the future will make this device more convenient for patients to wear it consistently. In terms of safety, there was no serious adverse events during the treatment reported in the published studies.

A PD system using concept of recycles dialysate, and less frequency of exchanges, connections/ disconnections of catheter, and a continuous closed PD system could potentially reduce the risk of peritonitis. In combination with a nighttime 7.5% icodextrin exchange, this system may provide patients daytime freedom from exchanges while ensuring adequate ultrafiltration and the maintenance of electrolyte and acid-base balance.[6,19,20,25]

The ViWAK PD and AWAK also may have potential to reduce the cost of dialysis fluid by fluid regeneration to remove toxic products, and offer the major prospect of increasing the efficiency of PD. However, the devices are still in early development stage and not much been studied.[18,20]

In general, these wearable dialysis devices may possibly reduce the needs for dialysis centre as well as minimise the healthcare professional involvement as patients may perform the dialysis on their own. Besides, these devices also relatively require less storage space for supplies. Moreover, not as kidney transplantation, patients do not need anti-rejection treatment and medications to improve the side effects. All these potentials are likely to benefit patients and society, however, further study and clinical trial need to be conducted to prove the effectiveness and safety of the devices comprehensively.[18,20]

REFERENCES

1. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. 2002. Available from: https://www.kidney.org/sites/default/files/docs/ckd_evaluation_classification_stratification.pdf. Accessed on 9 November 2016.

2. Gura V, Rivara MB, Bieber S et al. A wearable artificial kidney for patients with end-stage renal disease. JCI Insight. 2016:1(8).

3. Thomas B, Wulf S, Bikbov B et al. Maintenance dialysis throughout the world in years 1990 and 2010. Journal of the American Society of Nephrology. 2015:ASN-2014101017

4. Clinical Practice Guidelines: Management of Chronic Kidney Disease in Adults. Ministry of Health, Malaysia. June 2011. Available from http://www.moh.gov.my/attachments/CPG%202014/Kidney01.pdf

5. BL Goh, LM Ong and YN Lim (Eds). 22nd Report of the Malaysian Dialysis and Transplant Registry 2014. The National Renal Registry, Malaysia Society of Nephrology. Kuala Lumpur, 2015. Available from: http://www.msn.org.my. Accessed on 9 November 2016.

6. Davenport A. Portable and wearable dialysis devices for the treatment of patients with end-stage kidney failure: Wishful thinking or just over the horizon?. Pediatric Nephrology. 2015;30(12):2053-2060.

7. Armignacco P, Lorenzin A, Neri M et al. Wearable devices for blood purification: Principles, miniaturization, and technical challenges. In Seminars in dialysis 2015; 28(2):125-130.

8. Shin SJ. Current status of bioartificial kidney. Journal of Biomedical Science and Engineering. 2014;2014.

9. Armignacco P, Garzotto F, Neri M et al. WAK engineering evolution. Blood purification. 2015;39(1-3):110-114.

10. Ronco C, Davenport A, Gura V. The future of the artificial kidney: moving towards wearable and miniaturized devices. Nefrología (Madrid). 2011;31:9-16.

11. FDA approves trial for wearable artificial kidney. Available from http://www.nephrologynews.com/fda-approves-trial-for-wearable-artificial-kidney/. Accessed on: 22 July 2016

12. FAQ: Seattle Wearable Artificial Kidney safety trial. Answers to common questions about the WAK and its initial testing. Available from http://hsnewsbeat.uw.edu/story/faq-seattle-wearable-artificial-kidney-safety-trial. Accessed on: 22 July 2016

13. Miniature Portable Dialysis Machine on Fast Track for FDA Approval. Available from http://www.industrytap.com/miniature-portable-dialysis-machine-fast-track-fda-approval/23979. Accessed on 11 July 2016

14. Nephrology nursing and the wearable artificial kidney. Available from http://www.nephrologynews.com/nephrology-nursing-and-the-wearable-artificial-kidney/. Accessed on 9 September 2016

15. Gura V, Macy AS, Beizai M et al. Technical breakthroughs in the wearable artificial kidney (WAK). Clinical Journal of the American Society of Nephrology. 2009;4(9):1441-1448.

16. Davenport A, Gura V, Ronco C et al. A wearable haemodialysis device for patients with end-stage renal failure: a pilot study. The Lancet. 2007;370(9604):2005-2010.

17. Gura V, Ronco C, Nalesso F et al. A wearable hemofilter for continuous ambulatory ultrafiltration. Kidney international. 2008;73(4):497-502.

18. Ronco C, Fecondini L. The Vicenza wearable artificial kidney for peritoneal dialysis (ViWAK PD). Blood purification. 2007;25(4):383-388.

19. Davenport A. Portable or wearable peritoneal devices–the next step forward for peritoneal dialysis. Adv Perit Dial. 2012;28:97-101.

20. Lee DB, Roberts M. A peritoneal-based automated wearable artificial kidney. Clinical and experimental nephrology. 2008;12(3):171-180.

21. Fissell WH, Roy S, Davenport A. Achieving more frequent and longer dialysis for the majority: wearable dialysis and implantable artificial

kidney devices. Kidney international. 2013;84(2):256-264.

22. Mobilysis. Available from http://www.tuvie.com/mobilysis-portable-dialysis-system-allows-patients-to-have-active-and-productive-lives/. Accessed on 11 July 2016

23. End-stage Renal Disease. Available from http://www.hopkinsmedicine.org/healthlibrary/conditions/kidney_and_urinary_system_disorders/end_stage_renal_disease_esrd_85,P01474/. Accessed on 13 July 2016

24. Gura V, Rivara MB, Bieber S et al. A wearable artificial kidney for patients with end-stage renal disease. JCI Insight. 2016:1(8).

25. Kooman JP, Joles JA, Gerritsen KGF. Creating a wearable artificial kidney: Where are we now? Expert Rev. Med. Devices. 2015;12(4):373-376

26. Gura V, Ronco C, Davenport A. The wearable artificial kidney, why and how: from holy grail to reality. In Seminars in dialysis 2009 Jan 1 (Vol. 22, No. 1, pp. 13-17). Blackwell Publishing Ltd.

27. Mushi L, Marschall P, Fleßa S. The cost of dialysis in low and middle-income countries: a systematic review. BMC health services research. 2015;15(1):1.

Table 1: Comparison of various devices for wearable artificial kidney.[8]

Technology	Therapeutic category	Technology breakthrough	Advantages	Disadvantages	Current status
WAK	Haemodialysis	Pulsatile pump dialysate regeneration	Low power light weight small dialysate volume	Variation of dialysate composition and pH	Clinical trial
ViWAK	Peritoneal dialysis	Remote control double lumen PD catheter	Less dialysate volume less protein loss	Variation of dialysate composition and pH glucose infusion lack of small molecule removal	Prototype
AWAK	Peritoneal dialysis	Dialysate regeneration protein regeneration	Less dialysate volume less protein loss	Variation of dialysate composition and pH glucose infusion	Before clinical trial

Table 2: The differences of WAK and current available haemodialysis machine

WAK	Current Available Dialysis Machine
Smaller size	Bigger size
Haemodialysis	Haemodialysis
Operates on batteries	Electric power
Work continuously and slow to remove fluids from the body at the same pace as healthy kidneys do naturally	Equipment runs intermittently only about a few hours each time
Require about a pint of water daily (~0.48 L)	Require about 40 gallons fresh water per treatment (~151 L)

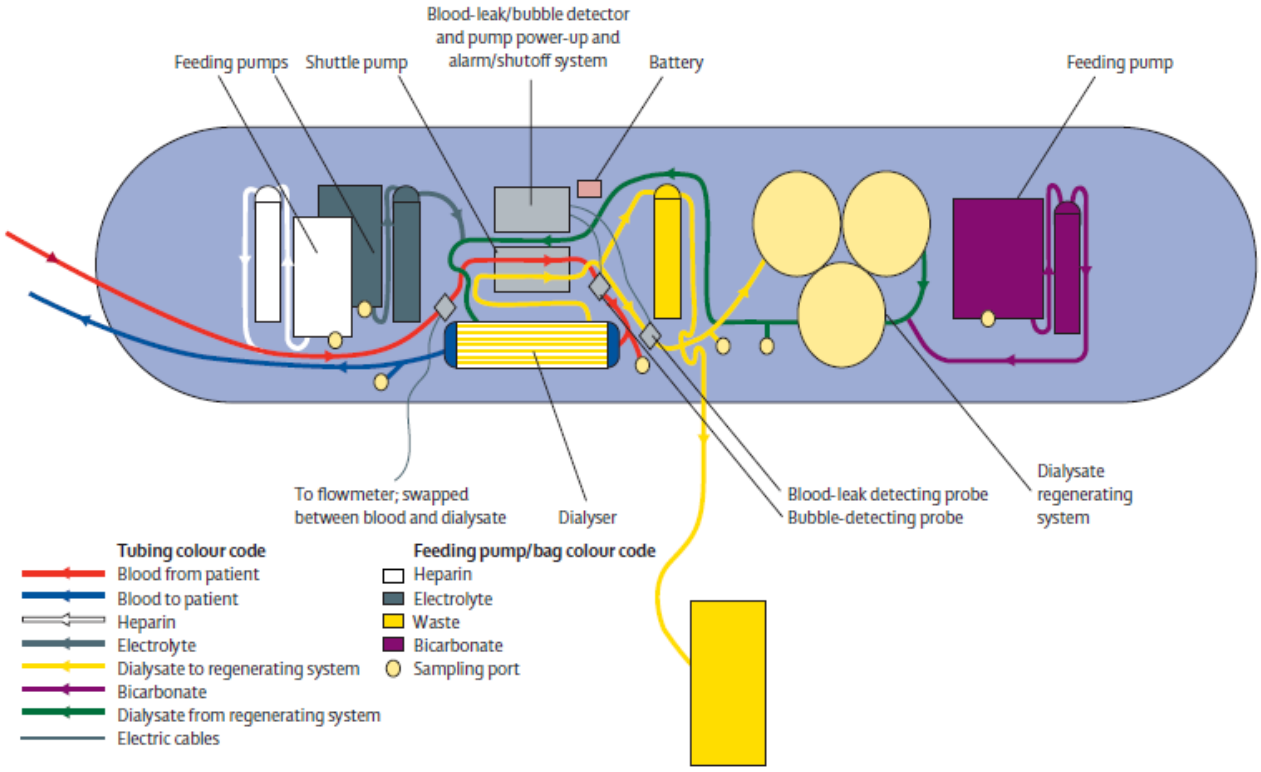

Figure 3: Schematics of the wearable artificial kidney.[16]

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