Development of Dialysis and Leakage Detection on Different Technology

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Dialysis is the treatment for chronic kidney disease (CKD) patients, including acute or end-stage renal disease (ESRD), by performing the filtration of toxic or waste substances from the patient's body. Haemodialysis (HD) and peritoneal dialysis (PD) are common treatments for dialysis patients with the use of extracorporeal dialysis machines such as haemodialysis machines or automated peritoneal dialysis (APD) for HD and PD, respectively. For HD, is required a dialyser act as a single-use consumable during the treatment of the patient. However, the major concern on the haemodialysis machine might be the issue on false sense during the treatment. The leakage detector of the dialysis machine is important to detect and sense the parameters when that is a leakage event, such as blood leakage at the dialyser or arteriovenous fistula (AVF) dysfunction. Thus, this study provides a review of leakage detection that has been developed with different methodologies of the sensing unit on a haemodialysis machine.

Keywords: haemodialysis (HD); peritoneal dialysis (PD); venous needle dislodgement (VND); arteriovenous fistula (AV) access; health system; health risk

I. INTRODUCTION

Dialysis is a selection of treatment for patients who are suffering acute or chronic kidney failure, or named as chronic kidney disease (CKD), and for permanent kidney failure, it is an end-stage renal disease (ESRD). Purpose of the this is to perform the filtration of the toxic or waste substances (urea, uric acid, creatinine) from the patient's body and to balance the electrolytes with an unused dialysate solution (Mehmood *et al.*, 2019). For the method of dialysis, haemodialysis (HD) and peritoneal dialysis (PD) are the usual dialysis treatment, where they perform the filtration through the patient's blood or peritoneal cavity, respectively. According to clinical practice guidelines 2018, 'Management of Chronic Kidney Disease in adults (2nd edition)' published by the Ministry of Health Malaysia (MOH), that is several criteria in defining of a patient with CKD (MaHTA, 2018) the patient is experiencing,

- Heavy proteinuria it indicates the ratio of urine protein and creatinine, uPCR ≥ 100 mg/mmol.
- Loss of estimated glomerular filtration rate (eGFR) >5 ml/min/1.73 m2 in one year or >10 ml/min/1.73 m2 within 5 years.
- Urine protein ≥ 0.5 g/day or uPCR ≥ 50 mg/mmol that has the sign of haematuria with proteinuria.
- Suspected in renal artery stenosis or hereditary kidney disease.
- Persistent abnormalities level of serum potassium.

According to the presented data, the expenditure on HD and CAPD is on the average of RM 39, 790.58 ± 4696.28 and RM 37,576.03 ± 4369.59, respectively, for ESRD patients annually in Malaysia. Costs on staffing and dialysis consumables are the two highest costs with the weightage of 37.6% and 10.2 % (staff), 29.3 % and 70.5% (consumable) in HD and PD, respectively, due to the treatment procedure required by the healthcare professional in setting up the

treatment with the preparation of a single use dialyser and different concentration of dialysate for HD and CAPD patients respectively (Surendra, 2018), Table 1.

Table 1. Average cost on the patients for the treatment of HD and CAPD in annually (Surendra, 2018).

Cost Components	HD		CAPD	
Outpatient Clinic Care	Mean, SD (RM)	%	Mean, SD (RM)	%
Medications (including EPO)	3647.09 (2226.17)	9.1	2868.99 (2228.88)	7.6
Laboratory	972.47 (74.01)	2.4	1018.33 (100.06)	2.7
Radiology	249.16 (38.81)	0.6	209.12 (10.98)	0.6
Clinic visits and referrals	447.69 (118.10)	1.1	386.17 (98.66)	1.0
Access surgeries	1209.24 (894.67)	3.0	477.26 (218.70)	1.3
Building and Land	783.95 (782.99)	2.0	68.57 (32.46)	0.2
Equipment	3299.05 (785.98)	8.3	417.73 (245.10)	1.1
Staff	14818.36 (2063.42)	37.6	3815.55 (609.81)	10.2
Overheads	1775.30 (856.72)	4.4	223.72 (160.77)	0.6
Dialysis Consumables	11700.99 (679.13)	29.3	26486.05 (568.85)	70.5
Hospitalisation	887.28 (2619.22)	2.2	1604.55 (3377.27)	4.3
Total	39,790.58 (4696.28)	100	37,576.03 (4369.59)	100

II. DEVELOPMENT OF DIALYSIS

A. Design of Circuitry on Haemodialysis Machine

An example of a modern haemodialysis machine consists of two different circuitries that circulate the patient's blood and dialysate by separating them with a dialyser. Dialyser, known as the artificial kidney of patients, is made of semipermeable membrane, in order to perform the function in exchange of essential substances and filtering the excess and harmful substances. Thus, the circuitry of the blood circulatory, the incoming blood flows to the circuit is from the arterial vessel and returns to the venous vessel with 'filtered' blood back to the blood mainstream of the patient. In between this circuitry, its components include a blood pump, which is to drive the patient's blood to the haemodialysis machine, and a Heparin pump, to prevent the formation of blood clots during the dialysis treatment. Moreover, an air detector is used to detect the volume of air bubbles if that is an excessive amount of air bubbles detected and back into the patient's bloodstream, it might endanger the patient's life, causing cardiac arrest or ventricular fibrillation during the dialysis treatment.

At the other end of the circuitry, a dialysate circuit consists of an ultrafiltration (UF) control system, heater, blood leakage detector, dialysate pump, and a mixture of dialysate solution. The formation of dialysate solution includes the composition of acid concentrate, bicarbonate (sodium bicarbonate) and purified water with a ratio that is required by the patient. Moreover, the heater is used for getting the optimal temperature of the dialysate, and it has been integrated with a temperature monitoring system to monitor its temperature to prevent the overheating of the solution during the treatment. After the ultrafiltration process, the return of the dialysate solution would pass through the blood leak detector. If that is a blood leakage event occurs, the dialysate would reflect a low transmission of light that indicates the interruption of the light transmission between the photocell and the light source. With this occurrence, it would trigger the alarm unit or a buzzer and stop the blood pump immediately pumping the blood from the patient at the blood circulatory circuit. Figure 1 shows the example circuitry of a haemodialysis machine with different electrical components.

B. Haemodialysis

Before the start of the haemodialysis treatment for the patient, a physical examination (PE) is required from the doctor by performing the examination on vascular access to examine the blood vessel of the patient and whether it can withstand the high volume of strong blood flow during the haemodialysis treatment. Meanwhile, it is also to prevent the incidents of dysfunction and immaturity of the arteriovenous fistula (AVF) and arteriovenous graft (AVG) if the patient is not suitable for the treatment of haemodialysis (Abreo, 2018). For AVF, it is a procedure of connecting the radial artery and cephalic vein together, whereas, for AVG, it requires the use of a synthetic graft to connect the median cubital vein and radial artery. After the establishment of AVF or AVG, a haemodialysis catheter is cannulated on the vein and artery and further connected to the extracorporeal circuit of the haemodialysis machine. The circulation of the blood flows from the vascular access to the dialyser in performing the filtration with the dialysate, and yet the filtered blood is returned to the bloodstream of the patient. In common, the dialyser is designed in the structure of a hollow fibre membrane, as a single-use consumable for one patient only after performing a haemodialysis treatment.
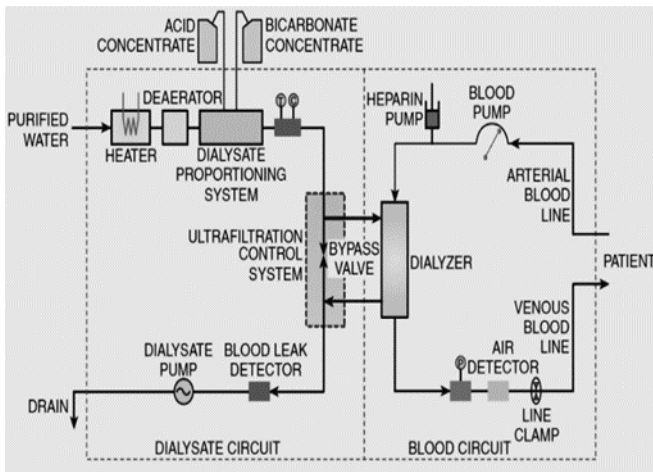

Figure 1. Example of a circuitry of haemodialysis machine.

C. Peritoneal Dialysis

For the PD treatment, the implant of a Tenckhoff catheter in the abdominal wall is required in order to allow the bidirectional flow in and drain out the dialysis solution during the treatment (Mehmood *et al.*, 2019; Tee, 2018; Leong, 2014b). The catheter penetrates the layers of skin, subcutaneous tissue and muscle and reaches the abdominal cavity, and the end of the catheter is further inserted ideally at the peritoneal cavity of the abdomen. The concept of PD is liaised on the working principles of osmosis and diffusion, followed by the low-to-high or high-to-low concentration gradient, respectively, that the infusion process occurs at the peritoneal membrane as the semipermeable membrane for the exchanging of the materials such as water, electrolytes and waste products (Astle, 2015). Hence, the dialysis solution will start to infuse into the peritoneal cavity of the patient's body via gravity, known as the instillation phase. After the completion of instillation, the used dialysate and wastes required to be drained out from the patient's body via gravity from the peritoneal cavity to an empty drain bag. The dialysate will remain inside the patient's peritoneal cavity to allow the processes of osmosis and diffusion to occur. The entire process could be taken up 4 times in a day, with time intervals of 4 to 8 hours for continuous ambulatory peritoneal dialysis (CAPD) or performed 3 to 6 times by an automated cycle while the patient falls asleep during the nighttime as the treatment of automated peritoneal dialysis (APD) (Andreoli, 2020; Leong, 2019).

III. RESULT AND DISCUSSION

From the existing dialysis machine, the development of the haemodialysis machine and automated cycler have been widely used for the treatment of haemodialysis and peritoneal dialysis, respectively. These extracorporeal systems integrate the functionality of detection on blood or the dialysate that is placed inside of the dialysis circuitry. The purpose of the importance of detection is to alert the healthcare personnel and action required if a leakage event happens on a patient during the treatment. Improper handling on the dialysate temperature will cause the incidence of thermal injury as hyperthermic haemolysis when that is a use of an overheated dialysate to the patient (Saha, 2017). It is important that the dialysis machines need to be capable of monitoring the dialysate temperature, patients' body condition and other parameters such as flow rate, time driven on and off of the valves or sensing unit by

respecting the response with the processing mechanism of the dialysis machine. Hence, the display of the error and warning message play an important role to the personnel for them, in getting the information of the procedure at every dialysis treatment. In this review, it is more emphasises the leakage detection on the haemodialysis machine that was designed at the dialysis circuitry or the access site of arteriovenous (AV) fistula that was implemented with different methodologies in recent years.
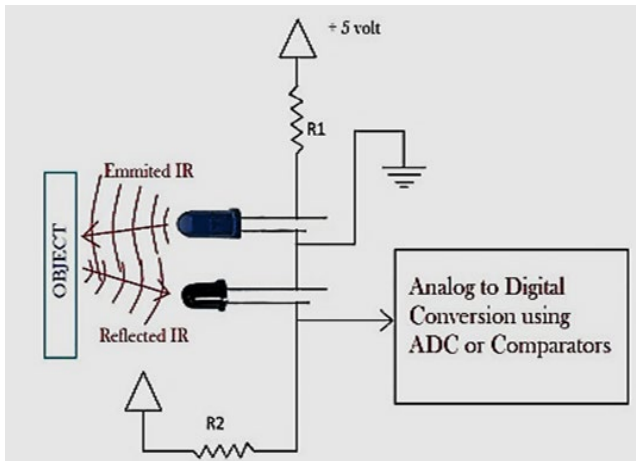

Figure 2. Example 8-bit output flexible impedance-based sensor (Lin, 2016).

A. Limitation on Methods of Leakage Detection

Venous needle dislodgement (VND) is one of the causes that leads to the complications of the haemodialysis because the placement of the venous needle might be poorly connected at the AV site, access tubing is improper taping or not visible at the access site. If that is a VND event happens without attention by the personnel, the patient might become unconscious in a few minutes and lose his or her blood due to the haemodialysis machine draining out approximately 500 ml/min of blood for filtration from the patient body in every minute (Saha, 2017; Yedke, 2018). Therefore, the preventative way for this scenario is the treatment would be immediately stopped by the haemodialysis machine and triggering the alarm unit to alert the healthcare personnel with the shorter response time on the indication of the error message. The problem with the VND is usually the needle is loosely cannulated and lies beneath the skin due to the AV site is not clearly visible by our naked eye. Thus, it is important to have an effective way of detecting on the connection of the needle or catheter at the AV access site and prevent the blood loss or leakage events from the VND.

Next, the following focus issue is the design and development of the sensing unit on the blood leakage detector that is placed over the dialysate circuitry of the haemodialysis machine. In common, the leakage detector is an optical-based sensor with a photocell and light source for detecting and monitoring the reflectivity on the surface of the dialysate that circulates in the dialysate circuitry. A high-sensitivity leakage detector is needed for the detection of blood leakage events and to increase the safety level of the patients. However, the limitation of the leakage detector has a conformity issue on the sensing unit because of the false sense that the leakage events might happen during the treatment (Saha, 2017; Leong, 2008). The cause of this occurrence could be the malfunction or faulty on the sensors, causing the detector not to sense the leakage events. Hence, it will be difficult for those healthcare personnel to be attentive if there is no safety measurement on the faulty indication prompted out at the interface of the haemodialysis machine.

B. Conceptualise and Implementation on Existing Leakage Detection

1) Impedance Based Blood Leakage Detection

The methodology of the impedance-based leakage detector uses the concept of the voltage divider rule in calculating the nodal voltage on each branch of the designed sensing unit. In common, the input voltage level of the sensing unit is about 3.3 VDC – 5 VDC. The changes on the nodal voltage have to identify the states of the events, either with or without the leakage event happening. The leakage event could happen when the sensing nodal voltage is less than 70% of input voltage or it is dropped over the threshold of input voltage that was implemented in the previous research. All the analogue input voltages will convert to digital output as logic '0' and logic '1' that is used for the prediction of the possibility of leakage events, in the form of a matrix and computed with the algorithm. Figure 2 shows the example of the proposed circuit configuration of the impedance detector

as the sensing unit. Thus, the voltage divider rule can be expressed as:

$$V_2 = (I_s \times V_s)(\frac{R_{ref2}}{R_{ref1}+R_{ref2}}) \qquad (1)$$

2) Optical-based blood leakage detection

The working principle of the current blood leakage detector applies the concept of the optical waveguide in reflection for the detection of blood leakage inside the dialysate circuit. This optical sensing unit depends on the light intensity and reflectivity of the light transmission between the photocell and the light source. The changes in light intensity will cause the low transmission of light if that is an absorbent material that absorbs the light and it causes that there is no transmission of light over the dialysate circuitry and will trigger the alarm unit. For example, the use of an optical Infrared (IR) sensor, with the features of IR diode and photodetector as emitting and detecting the infrared radiation, respectively. The IR diode will emit a beam of IR through the used dialysate and detect the light by the photodetector (Leong, 2008; 2006a; 2006b).
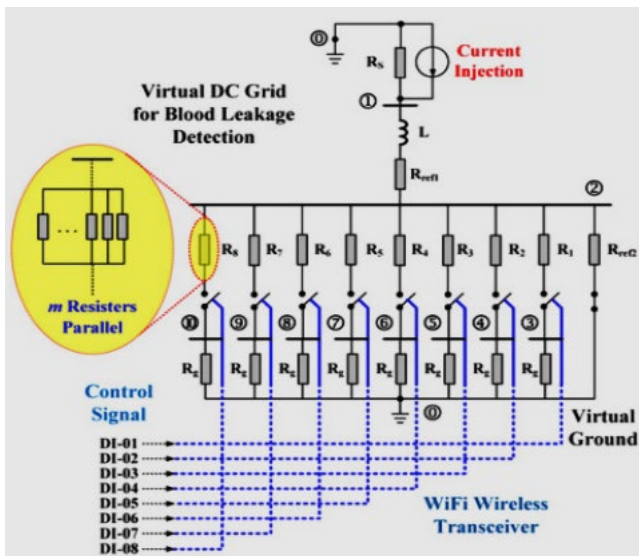

Figure 3. Proposed configuration of IR optical leakage detection (Sathiya, 2016).

Hence, high sensitivity and specificity of the photodetector is required for the detection that detects the specific range of IR radiation. Figure 3 shows an example of the proposed circuit configuration with the use of IR LEDs and a photodetector for the detection of leakage (Sathiya, 2016). For the response coefficient of the photodiode, R_λ expressed

as the ratio of the output photocurrent, I_p, and the input optical power, P_{out}:

$$R_\lambda = \frac{I_P}{P_{out}} \qquad (2)$$

Meanwhile, the attenuation of the light can be expressed by the coefficient of effective light attenuation, μ_{eff} with the coefficient of the light propagation of scattering (Liou, 2021).

$$\mu_{eff} = \frac{(0+ \sqrt{(3\,\mu a\,(\mu a+ \mu's)))}}{1} \qquad (3)$$

where $\mu's = \mu s\,(1-g)$, anisotropy of the tissue, $a = 0.9$

1) Pulse radar detection on AV fistula access site

Pulse radar sensor consists of the use of two antennas, named as transmit and receive antenna, in order to transmit a damped sinusoidal pulse to detect the blood flow on the AV fistula vessel wall. This damped sinusoidal pulse was generated by a pulse generator with 4 ns of pulse duration at 250 kHz frequency and connected to a square wave generator before the transmission to the blood vessel wall (Yedke, 2018).
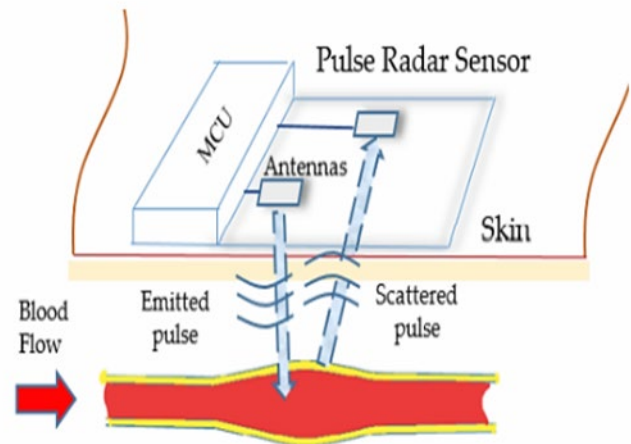

Figure 4. Implementation of the proposed pulse radar sensor at AV fistula detection (Chen, 2021).

Figure 4 shows the proposed pulse sensor on the AVF site in transmitting the pulse signals to the blood vessel wall. The pulse radar sensor was placed to the AVF access site of the patient's arm and it is near to the outcoming blood flow of the venous. Thus, the changes on the scattered pulse that received from the receive antenna will indicate the flow motion of the vascular wall as a VWM waveform whether is normal or abnormal baseband signals on the AVF flows

activities in the patient's arm. All the VWM data has been converted into the frequency spectrum data by using Fast Fourier Transform (FFT) to get the data in the frequency domain and further analysed by the support vector machines (SVM) machine learning algorithm for the prediction of the AVF's status. The datapoint of the SVM reflects the decision function that might be a low or more confident decision that lies on the right or left sides of the hyperplane (y-axis) (Chen, 2021). If all the data points have a positive prediction value, the accuracy of the performance is 100 % in the prediction. Hence, the algorithm of the FFT spectrum is given as:

$$X_k = \sum_{n=0}^{\frac{N}{2}-1} x_{2n}\, e^{-\frac{i2\pi kn}{\frac{N}{2}}} + e^{-\frac{i2\pi k}{N}} \sum_{n=0}^{\frac{N}{2}-1} x_{2n+1}\, e^{-\frac{i2\pi kn}{\frac{N}{2}}} \qquad (4)$$

where k = 0, 1, ..., N-1.

For the emitting a settling pulse waveform to the target area, $X(t)$ and receiving the feedback signal, $Y(t)$, are expressed by respecting the time,

$$X(t) = A\sin(2\pi ft) \qquad (5)$$

$$Y(t) = X\left(t - \frac{2 \times R(t)}{c/\sqrt{\in}}\right) \qquad (6)$$

f = Settling frequency of pulse radar signal
c = Speed of the light
$\in$ = Effective permittivity of skin and subcutaneous tissue

C. Gap Analysis on Methodology from Previous Research

Table 2 shows that various methods had been implemented in different detection on the blood leakage at the circuitry of the haemodialysis machine and over the AVF access site in these five years recently. The common methods are mainly depending on the sensing units in performing the leakage detection and integrated with the alarm units or a monitoring system that transmitting the faulty and alerting message to the healthcare personnel, through the wireless communication such as the Bluetooth or WiFi transceiver communication channel (Kumar, 2023). Moreover, the feature of the sensing units promotes the advantages of increasing the safety level to the patient by integrating the alarm and monitoring system. From the findings on Table 1, the performance of the sensing units usually is having short response time in detecting the leakage event, probably can be less than a second with high sensitivity and specificity on detection (Wang, 2009; Leong, 2005). The merits on

smaller size, easy installation and low voltage for operation when that is used on impedance and optical leakage detector (Mohankumar, 2016a; Xu, 2023). Unfortunately, these sensing leakage units are not presented to the actual haemodialysis machines and its performance on response time, sensitivity or effectiveness required to be justified once that is an actual implementation with the consideration of costs as well (Mohankumar, 2016b; 2017; Lim, 2012).
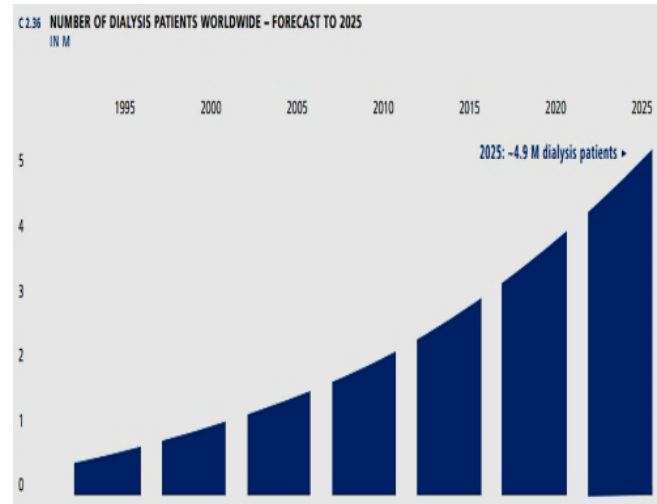

Figure 5. Estimation on number of dialysis patients in worldwide in Year 2025 (Fresenius Medical Care, 2019).

From the research on the AVF detection, the methodologies included the infrared with fast imaging technique and pulse radar detection on VWM with the SVM classifier prediction in getting the leakage information on the AV site from the reflectivity of the transmitted and receiving light wave or pulse wave respectively (Leong, 2014a; Wang, 2010). The advantage from both findings, it shows the accuracy of AVF detection can be fulfilled and achieved by using the high resolution lens as vein detection and preventing the damage on the fistula that can increase lifespan of the fistula (Liou, 2021) by implementing the prediction method in algorithm for early detection of dysfunction (Chen, 2021) and further prevent the occurrence of thrombosis. From the advantage of AVF leakage detection, it can be implemented as the first inspection procedure if a leakage event happens during the haemodialysis treatment by using those developed techniques. Furthermore, the techniques also provide the merit of shorter reaction time for the detection of blood

leakage (Mohankumar, 2014; Leong, 2022a; 2020; 2012; 2022b; 2005; 2023a; Han, 2012; Mehrotra, 2009).

IV. CHALLENGE ON FUTURE HAEMODIALYSIS TREATMENT

Figure 5 shows the estimated number of 4.9 million dialysis patients worldwide in the Year 2025, by comparing the prediction of 3.7 million patients in the Year 2020 (Fresenius Medical Care, 2019). The difference between them is 1.2 million and will increase by 32.4 % in percentage in the next 5 years. This is because of the increasing ageing population with the prediction of increasing directly on the incidence of CKD and kidney failure patients. Thus, one of the innovative and alternative solutions is the development of the miniature dialysis machine that can reduce the use of the needle and smaller size of the dialyser for replacement in order to be affordable for everyone (Leong, 2023b). Moreover, dialysis treatment can be fully sponsored or undergoing the business modal of private-public partnership (PPP) that gets the attention from the government and public with the funds in order to cover the ESRD patients that reduces the burden of suffering from morbidity and mortality that leads to serious related complications.

V. CONCLUSION

Dialysis technology has undergone remarkable transformations, transitioning from traditional haemodialysis to more sophisticated methods such as peritoneal dialysis and continuous renal replacement therapy (CRRT). These advancements have enabled improved patient outcomes, increased treatment efficiency, and greater flexibility in accommodating different patient needs. Furthermore, the integration of automation and real-time monitoring has facilitated precise control of dialysis parameters, optimising therapy delivery.

Leakage detection technology has become an integral component of dialysis systems, safeguarding against potential hazards. Traditional methods relied on visual inspection, which posed limitations in identifying subtle leaks. However, the advent of sensor-based and pressure-monitoring systems has revolutionised leakage detection. These technologies offer continuous and accurate monitoring, promptly alerting healthcare providers to any deviations from normal pressure levels, thereby mitigating the risk of fluid leakage and minimising patient discomfort.

Moreover, advancements in materials science have led to the development of improved dialysis membranes and tubing that are more resistant to leaks and biofouling. These innovations contribute to longer-lasting and more reliable dialysis systems.

In the context of renal replacement therapy, wearable and portable dialysis devices have emerged as groundbreaking solutions, granting patients greater mobility and freedom. These devices incorporate sophisticated leakage detection mechanisms alongside efficient dialysis functions, underscoring a holistic approach to patient care.

However, challenges persist in the development and integration of these technologies. Ensuring compatibility, addressing potential errors in monitoring systems, and optimising user-friendliness remain areas of active research and innovation.

In conclusion, the development of dialysis and leakage detection technologies has witnessed remarkable progress, revolutionising the landscape of renal therapy. As these advancements continue to unfold, they hold the promise of enhancing patient quality of life, minimising complications, and shaping the future of dialysis treatment.

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Table 2. Gap analysis on the implementation of detection with its merit on different methodologies.

Previous research	(Liou, 2021)	(Lin, 2016)	(Wu, 2017)	(Chen, 2021)	(Sathiya, 2016)
Dialysis type	Haemodialysis Arteriovenous fistula	Haemodialysis	Haemodialysis	Haemodialysis Arteriovenous fistula	Haemodialysis
Methodology	Infrared thermography on illuminate blood vessel and vein: • Far infrared radiation for tissue repair therapy. • Near infrared radiation for vein detection.	Flexible sensor in sensing the blood flow and getting to trigger the alarm unit if a blood leakage event occurs.	Array photocell sensor by using fog computing and hetero-associative memory model (HAM).	Pulse radar sensor serves for the vascular wall motion (VWM) with the monitoring on the AVF flow with the prediction on machine learning classifier.	IR sensor used for the blood flow detection with sensing the colour of the blood.
Detection implemented	• Vein detection. • Capture the near infrared images. • Irradiate the fistula with far infrared rays.	Blood leakage detection: • A virtual DC grid, 8 branches with m resistors in parallel. 2 additional branches connected a reference resistor, one of the branches is connected an injection current source. • Change on the nodal voltage and adherent resistance can identify the blood leakage event.	Blood leakage detection: • The corresponding binary output patterns, R represented as the risk level of 1, 2 and 3. Indicated green, yellow and red LEDs when an output signal of '1' detected respectively. • HAM model was used in detecting the blood leakage by performing the associative memory and getting the weight, W associative matrix, A.	Vein detection on AVF flow dysfunction: • VMW data has converted into FFT spectrum data with SVM classifier. • Output of SVM lies along the hyperplane, close to hyperplane means a low confidence decision, whereas it is a more confidence decision.	Blood leakage detection: • Control unit is the MCU of ATMEGA 16 that controls the signal of the IR sensor, with a fixed 5V voltage supply to the circuit. • A buzzer used as the alarming unit with an alert signal and with the blood leak monitor if that is a trigger on blood leakage event.

Merit	• Promote the observation on leaking of needle and blood seepage during the haemodialysis treatment. • Recognition of vein is easy to distinguish. • Fast imaging speed and high-resolution during monitoring.	• Signal can be transmitted through the Wi-Fi wireless transceivers. • Reduce the number of electrical units. • VAU is being virtualised and implemented into embedded and mobile devices.	• Duration of computing time, < 0.15 ms. • Reaction time on detection of blood leakage, < 1s. • Recalling process is in iteration computation ≤ 2. • Low power consumption, low cost and implemented easily.	• Performance of SVM classifier has high sensitivity, specificity and accuracy on the detection threshold.	• Non-invasive and easy installation on blood detection to the existing dialysis machine. • Alert signal sent to a monitoring computer with the user interface software via Bluetooth wireless transmission.