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Measurement accuracy of total cell volume by automated dialyzer reprocessing: A prospective cohort study

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HIGHLIGHTS

- Over the past decade, dialyzer reprocessing machines have replaced human labor and time spent in preparing re-usable dialyzers.
- It also made the process of total cell volume (TCV) measurement become faster.
- Volumetric evaluation was considered as the standard to compare with the TCV values from the reprocessing machine.
- Nevertheless, there has been a lack of data on efficacy of weight evaluation on TCV by machine compared to volume evaluation by the conventional method.
- The aim of study was to evaluate the efficacy of TCV measurement performed by the reprocessing machine compared to that of the conventional method.

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ABSTRACT

Introduction: Dialyzer reprocessing machines have replaced human labor in preparing re-usable dialyzers. It also made the process of total cell volume (TCV) measurement become faster. Nevertheless, there has been a lack of data on efficacy of weight evaluation on TCV by machine compared to volume evaluation by the conventional method. The aim of this study was to evaluate the efficacy of TCV measurement performed by Kidney-Kleen® reprocessing machine, produced by MEDITOP Company in Thailand, compared to that of the conventional method.

Methods: This prospective cohort study was performed during September 2014 to December 2015.The low-flux ($N = 101$) and high-flux dialyzers ($N = 100$) were included for TCV evaluation. Reused times were up to 5 in the low-flux and 20 in the high-flux dialyzers. The Bland Altman analysis was used to evaluate value measured by different methods.

Results: The values measured by weight evaluation (by machine) were higher than those obtained by volumetric evaluation of the conventional method in the low-flux (0.81 ± 0.20%) and high-flux (1.32 ± 0.39%) dialyzers. The correlation of TCV values of the two methods were $r = 0.98$, $p < 0.001$ and $r = 0.71$, $p < 0.001$ for the low- and high-flux dialyzers. Moreover, there was robust association and agreement between the two methods, confirmed by the Bland-Altman Analysis, which suggested that the values acquired by machine were within the limits of agreement, indicating acceptable accuracy of equipment.

Conclusion: The approach of measurement differed from that of the conventional method (weight evaluation was used instead of volumetric evaluation), the reprocessing machine could offer accurate results.

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1. Introduction

A hemodialyzer is an instrument that has been used universally to purify fluid and waste metabolites from the blood of renal failure patients. Different types of dialysis membrane (flux) were categorized by the clearance of β2 microglobulin across membrane during hemodialysis. The dialyzers with β2 microglobulin clearance less than 20 ml/min are called 'low-flux dialyzer', usually used for small uremic toxin removal in acute kidney injury. Meanwhile, the dialyzers with β2 microglobulin clearance more than 20 ml/min are called 'high-flux dialyzer', usually used for middle molecular size removal such as in setting of chronic hemodialysis for end-stage renal disease patients.

Reprocessing dialyzer machines have been used worldwide for economic advantage [1–4], improvement in blood-dialyzer membrane biocompatibility, and benefits of preventing the first-use syndrome which is an anaphylactoid reaction to the dialysis membrane causing wide-range of symptoms including cardiac arrest [5–7]. The machines have helped shorten the period of cleaning, leak testing, and sterilant filling. However, there have been still some concerns about the use of machines such as infection. The Centers of Disease Control and Prevention (CDC) have recommendations against dialyzer reuse in patients with active bacterial and hepatitis B infection [8–11]. Decline in dialyzer performance after reuse has also been of concern. Performance indices can be measured by two approaches, namely total cell volume (TCV) measurement and urea clearance evaluation. The KDOQI guidelines [1] have suggested that a dialyzer is suitable for reuse only when a TCV value is at least at 80% of the baseline or the urea clearance of the dialyzer is at least at 90% of the original value [12–15].

TCV, one of the parameters indicating dialyzer performance mentioned above, refers to the volume of the blood compartment of a dialyzer. A TCV value is determined by measurement of volume of water being filled in a blood compartment of a dialyzer either with the conventional method or with automated reprocessing machines. With the conventional approach, a dialysis nurse fills reverse-osmosis (RO) water into the blood compartment of dialyzer and later measures the volume of water flowing out of the compartment equipped with an air pump. With the development of the reprocessing machines, several hemodialysis centers have replaced the conventional TCV evaluation with an automated method in addition to the cleaning of dialyzer. Evaluation of TCV relies on the principle of fluid mechanics by volumetric evaluation. There has been an attempt to discover the best indirect approach to measure TCV in order to substitute volumetric evaluation performed by human such as weight measurement, hydrostatic pressure measurement, and ultrasonic detection [16–20].

Kidney-Kleen® employs weight measurement, one of the most popular techniques, to determine TCV. Weight measurement is an indirect approach to measure and translate weight into volume, based on an assumption that 1 mg of water is equal to 1 mL of water. However, several factors may have affected on the weight measurement of TCV by the reprocessing machine such as space-occupying air bubbles, weight of debris particles in patient's blood, incomplete collection of fluid from dialyzers' membrane. By using the automated approach, the reprocessing and the TCV measurement are done simultaneously, and the healthcare provider may benefit from reduced human workload and shortening of overall process time. Nevertheless, the efficacy of TCV measurement by weight has not been widely studied since the main purpose of the reprocessing machines was to clean the dialyzer, not to measure the TCV. Therefore, this study is the first to compare the efficacy of conventional measurement and automated approach. Our hypothesis is that TCV measurement from volumetric measurement (manual method) can be cost-beneficially replaced by the weight measurement (automated machine).

2. Materials and methods

2.1. Clinical data collection

This prospective cohort study was performed at the hemodialysis unit within HRH Princess Maha Chakri Sirindhorn Medical Center, Srinakharinwirot University, Thailand. Our study was conducted during September of 2014 to December of 2015. All dialysis patients receiving either high or low flux dialysis during this period were informed of study, and all gave full consent to participation.

In this study, the low-flux dialyzer, was equipped with synthetic polysulfone membrane with 1.5 m^2 effective surface area and 90 mL of TCV (Diacap Polysulfone® LO PS 15 Dialyzer) and the high-flux dialyzer was synthetic polynephron membrane dialyzer with effective surface area of 1.9 m^2 and 115 mL of TCV (Elisio-190HR®). The protocol and patient's participation were approved by the Human Research Ethics Board of Srinakharinwirot University (Issue #SWUEC-X-037/2557).

The reused times were up to 5 times in the low-flux and 20 times in the high-flux with acute kidney injury (AKI) and end stage kidney disease (ESRD), respectively. Patients with HIV, hepatitis B, hepatitis C infection and suspected sepsis or bacteremia were excluded. All patients were dialyzed for 4 h per a dialysis session which was maintained by an initial loading of intravenous heparin 3000 IU, followed by hourly bolus of heparin 1000 IU intravenously. Each dialyzer was reprocessed with formaldehyde 4% and reused again for the same patient only when TCV was $\geq$80% of the original value.

2.2. TCV evaluation

All the dialyzers were cleaned by the reprocessing machine (Kidney-Kleen®) before the measurement of TCV was performed. TCV was measured for the evaluation of quality of each dialyzer values were calculated as a percentage ratio compared to the baseline value.

2.3. The conventional TCV evaluation

After the cleaning process by machine, a TCV was first measured by machine. A dialyzer was then removed and underwent 2 separate TCV conventional evaluations by 2 blinded dialysis nurses who have at least 5-year experience on cleaning processes of dialyzer. Both the dialysis nurses were blinded to the patient's clinical presentation, any value from the machine, and the value of TCV obtained from each other. The blood and dialysate compartment of the machine were filled with reverse osmosis (RO) water, and TCV was subsequently measured by evacuating water from the blood compartment with an air pump. Two manual TCV values from the same dialyzer were averaged and used as its reference value for quality evaluation and onward comparison with the value obtained from the machine. Any dialyzer with referenced TCV of less than 80% of its original value was discarded (<72 mL and <92 mL for low-flux and high-flux machines, respectively).

2.4. The reprocessing machine TCV evaluation

Similar to the conventional TCV measurement, RO water was filled into the blood compartment vertically from bottom to top of the dialyzer. Later, water was evacuated from the blood compartment into a measure tank and the weight of water was measured by a load cell sensor as shown in Fig. 1.