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A study to evaluate the efficacy of RBV device (relative volume of blood) in hemodialysis patients and to determine the correlation between RBVand hypotensionin these patients (as in vivo)

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KEYWORDS

Blood concentration, dialysis, hemodialysis, hypotension, relative volume of blood

A B S T R A C T

During dialysis process, excess water in the dialysis patient's body shifts firstly from intracellular to extracellular, and then passes into blood stream. Finally, it is removed from the body by dialysis. During this process, if the amount of water taken from the blood by dialysis be more than the amount of water transferred in to the blood from extracellular, the dialysis patient would suffer from a decreased blood volume followed by hypotension. Due to the hypotension occurred during dialysis, the blood pressure of dialysis patients should be monitored continuously during the dialysis process. Since, the continuous and direct monitoring of blood pressure is difficult and the devices in this regard are very expensive, in order to achieve this goal, the parameters associated with the blood pressure should be used. One of the associated parameters is the relative volume of blood (relative changes in blood concentrations RBV), because it involves both an easier measurement and also a good ability to demonstrate the hemodynamic status. To investigate the RBV and to calculate the blood pressure, a device provided during are search project in the Army Medical University was applied. In this project, the efficiency of RBV device was examined in hemodialysis patients, then, a scientific correlation between the parameter and hypotension of dialysis patients were found and evaluate during the clinical testing of the device on a group of dialysis patients and recording the data, including RBV measured by the device and the blood pressure rate. Based on the RBV definition, the changes in this factor and the blood pressure of hemodialysis patients during the hemodialysis process are inversely to each other. The results obtained using the device were pursuant to the definition with an acceptable accuracy more than80%. According to the accuracy of data obtained from the device, it can be concluded that this device can be used as a non invasive method with a good accuracy to detect the hypotension in this group of patients in order to prevent the occurrence of subsequent complications. However, firstly the accuracy, and secondly the manner of correlation between these two parameters differs depending onthe selected model of the correlation between RBV and hypotension.

Introduction

Hemodialysis is the most common method used to treat renal failure, and in comparison to other methods causes rapid changes in the plasma levels of soluble substances and the rapid removal of excess water accumulated in the body. In order to obtain the excess water from the body via the bloodstream, hemodialysis device accesses only to the plasma, which is non-cellular part or indeed a fluid in the blood. The plasma fluidis associated with fluids in all the body parts through the vascular system and regulates the body fluid volume.

The control of blood volume during the hemodialysis process is performed by controlling the plasma volume and hydration rate and has a direct impact on the health of the patient's cardiovascular and cerebro vascular systems[1, 2]. The lack of attention to this issue would be followed by the excessive reduction of plasma volume and then the blood volume decrease which leads to a sudden drop in blood pressure[1, 3, 4].The remarkable point is that this phenomenon occurs in about20 to30% of dialysis processes [1, 3].As a result, the prevention of hypotension is one of the most important problems of nurses in the dialysis unit[1].Several solutions have been proposed while some of them are actualized and used to solve this problem and to control optimally the dialysis process, in order to perform the dialysis in an appropriate duration and without occurring problem for the patient[3]. To control the dialysis process, the patient's blood pressure ought to be acquired during the dialysis process in synchronized with the time, continuously and non-invasively[5]. Since it is difficult in practice, therefore, a parameter named Relative blood volume (RBV)is specified[6-8]. RBV Device(relative volume of blood) in hemodialysis patients was manufactured in another research project of AJA University of Medical Sciences [9]. To determine the accuracy of the performance of innovated and designed system, the device ought to be tested practically and in vivo system, and then, the correlation between the measured RBV and hypotension should be determined in hemodialysis patients[10]. Therefore, a Method can be found to avoid hypotension in patients during dialysis non-invasively.

Materials and Methods

Various parameters were recorded in tests conducted in patients. The parameters include time, RBV device output and patients" blood pressure, simultaneously. The parameters and tools applied to record them are specified in Table 1.

Table.1 the reference devices used in clinical test

Output displayed on the screen of manufactured device	RBV
By Analogpressure gaugeand NIBP device	Blood pressure

Since the made RBV device includes a part to convert the analog signal to digital and an LCD screen, thus, no lateral instrument was needed to record the values measured by the dedicated circuit of device, and the digital part calculated the desired values and displayed the final value of RBV at 1 minute intervals on the display. The values were also saved at 5-minute intervals in the internal memory which could be transported to a computer by a USB connection after completing the experiment to perform analysis on it.

Recording the in vivo clinical test results

For clinical testing, the coordination with the dialysis unitofImam Reza Hospital was done, and the authorities agreed to test the device. For this test, 14 cases (14patients) were examined, and the patients were selected randomly among all patients in the mentioned unit in different times in order to create a more diverse target population. All tests were carried out with the consent of patient. In this measurement, due to the nature of device, RBV was recordedevery5minand the blood pressure was performedevery15 to 30 minutes to not cause inconvenience for the person under test.

Table.2 Patient characteristics

Time of dialysis	History of Dialysis (Month)	Age	Gender	Test number
Morning	6	56	Female	1
Noon	12	80		2
Morning	9	56	Female	3
Noon	36	65	Male	4
Morning	18	78	Male	5
Noon	1	68	Male	6
Evening	36	65	Male	7
Morning	4	58	Male	8
Noon	18	60	Male	9
Morning	30	72	Male	10
Noon	3	65	Male	11
Noon	1	68	Male	12
Evening	9	44	Female	13
Evening	9	70	Female	14

First, the mean arterial pressure was applied as reference pressure to consider the effect of both systolic and diastolic pressures. Mean arterial pressure (MAP) is an average blood pressure in an individual that can be used in medicine. This parameter is the mean of arterial pressure in cardiac cycle and can be approximated by the following formula.

$$MAP \cong \frac{(2 \times DP) + SP}{3}$$

SP is systolic pressure and DP is diastolic pressure. In all cases the valueswere measured and recorded.

Result and Discussion

First, a logical correlation between RBV changes and hypotension must be shown in hemodialysis patients. For this purpose, we compared and evaluated by four different methods; qualitative and theoretical study, RBV graphs based on the patient's blood pressure, the study of the differential changes of RBV and blood pressure, the study of 10% reduction in blood pressure (hypotension) due to changes in RBV.

Qualitative and theoretical study

One of the simple and primary methods to compare the two phenomena is to study intuitive and visual similarities. Using this method can not be accepted as a scientific method to prove the phenomenon, but since in the first review, this method is able to show the visual similarities of two data sets, therefore, in this section the graphs related to the RBV obtained from the device and also the measured blood pressure were compared.

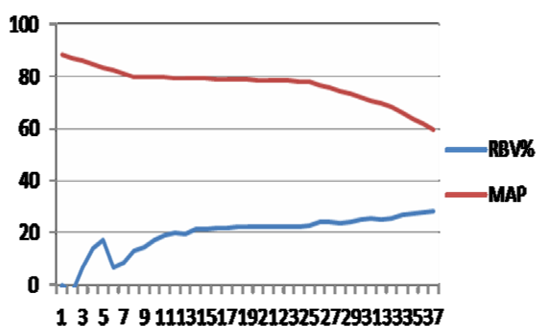

Figure 1: A sample of graphs obtained from the conducted tests (RBV, Blood pressure).

In this study, the accuracy of the performance of system was 85.71%

RBV changes based on Blood pressure

According to the RBV definition, the RBV and the blood pressure changes of hemodialysis patients during the dialysis process are inversely to each other, meaning that an increase in the RBV lead to a decrease in blood pressure[11].It is also clear that based on RBV definition, this parameter is always a positive value, like blood pressure. The simplest method and formula for the correlation between these two parameters is to model it as $y = \frac{1}{x}$which has a diagram similar to the graph inFigure2.

Figure 2: The diagram of y=1/x

Thus using this method, the correlation between these two parameters can be studied as intuitive –visual and finding an interpolation from the RBV graph compared to blood pressure. Since in the conducted tests, the RBV sampling rate(output device)differed from the blood pressure sampling rate, the first parameterwassampledevery5minutes and the blood pressure very 30minutes, due to the Coordination with the patient's clinical condition, therefore, using the linear interpolation of two points from blood pressure, the valuesbetween them were calculated and their sampling rate increased to be suitable for comparison with RBV samples. In the following, the RBV graph based on the blood pressure of one of the patients as an example, and as an points cattering and also an interpolation as a line is drawn(Figure 3).

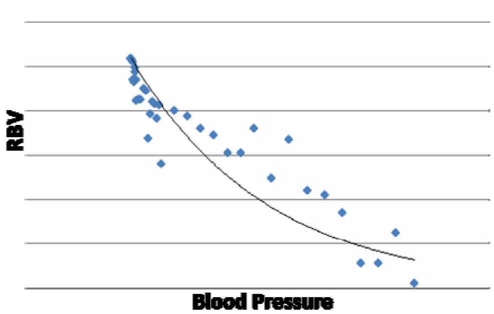

Figure 3: The patients' recorded data, RBV in terms of Blood pressure

In this study, the accuracy of the performance of system was 85.71%

Momentarily changes in RBV and blood pressure

This method was also operated according to the RBV definition, the RBV and the blood pressure changes during the dialysis process are inversely to each other, meaning that an increase in RBV lead to a decrease in blood pressure. Therefore, the momentarily changes in RBV and blood pressure were studied in this method. Two new parameters were defined as follows:

$$\Delta RBV = RBV_t - RBV_{t-1}$$
$$\Delta P = P_t - P_{t-1}$$

According to the above description, in the moments that RBV increases, a reduction in the blood pressure is anticipated and in the moments that RBV decreases, an increase in the blood pressure is anticipated. In other words, two above parameters must have different signs. With this assumption, the values of above parameters as well as the accuracy were calculated and studied for each patient. The accuracy of the performance of above study for all patients are shown in Table 3.

Hypotension, 10% reduction in primarily blood pressure

Accordingtomedicalissues,10% reduction in the blood pressure is considered to be equivalent to Hypotension[12], so in this study, two graphs of the RBV and the blood pressure obtained from each patient were compared and showed that with a decrease in the blood pressure more than10% of patient's primarily blood pressure, the RBV also crossed a constant imaginary line and would be more than a specified amount. The value of this imaginary line is calculated for each patient. Figure.4 is an example of the test performed.

4	3	2	1	The patient's number
70.000	83.33	66.67	51.28	The accuracy (%)
8	7	6	5	The patient's number
71.43	69.23	68.18	70.59	The accuracy (%)
12	11	10	9	The patient's number
56.41	72.73	80.56	73.53	The accuracy (%)
		14	13	The patient's number
		68.24	75.00	The accuracy (%)

Table 3: The accuracy of the study of momentarily changes in blood pressure and RBV According to the above table, the mean of accuracy in this methodis 69.81%

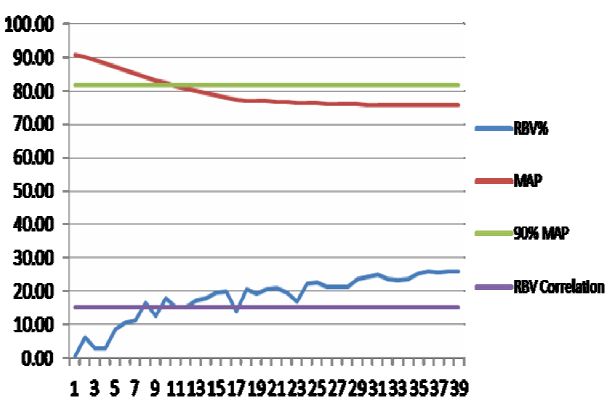

Figure 4: the sample diagram of patients' recorded data with 10% reduction in blood pressure

It was clear that in case of a decrease in the blood pressure more than10% of patient's primarily blood pressure, the RBV crosses a constant imaginary line and will be more than a specified amount. We can say that for each distinct patient with its own conditions, there is a defined amount of RBV, that the hypotension is expected during the dialysis process in case of an increase in RBV over this limitation,(with a reduction over 10% in primarily blood pressure).

The hypotension of hemodialysis patients during hemodialysis process is of the major problemswhich20% to 30%ofdialysis patients are faced with. The main reason is the imbalance of hemodynamic system due to different reasons, the main reasonis cardiovascular system failurei n these patient stores tore blood plasma[4].

To prevent the occurrence of this incident, the patient's blood pressure should be continuously evaluated during hemodialysis [13, 14]. Since the constant blood pressure monitoring along with time in direct and non-invasive manner is very expensive using current devices, therefore, this method is generally not used and cuff method is used instead at specified intervals(depending on condition).

This problem caused extensive studies to be performed in the field of parameters relating to the blood pressure of dialysis patients that in addition to the ease of access, be cheaper than continuous blood pressure monitoring[15].

The results lead to the manufacture of a device that measures the patient's relative blood volume (RBV) during dialysis, momentarily and non-invasively.

The data obtained by the device was studied and analyzed using four different methods.

According to the data obtained in each study, which its method was independent of each other, it was found that an acceptable amount of RBV recorded by device, more than 80%, was in correlation with the blood pressure reduction and hypotension during hemodialysis, and the device can be used as a non invasive method with good accuracy to detect the hypotension in this group of patients and to prevent further complications

However, based on the above conducted studies, it should be noted that depending on the model chosen for the correlation between the hypotension and the RBV, firstly, the accuracy and secondly the manner of correlation between these two parameters differs. In the above modeling approach, it was expressed that a single formula can be used for this correlation which is actually an easier method, but its accuracy is lower than other methods. Dedicated methods can also be applied for each patient in term of its particular clinical conditions, and the model parameters can be calculated for each patient specifically. As it was observed it involves a higher accuracy but requires some initial tests and the determination of specific parameters for each patient[16].

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