



## **Effect of Blood Volume Monitoring on Reducing Hypotensive Episodes in Hemodialysis Patients**

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### **Authors' contributions**

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

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### **ABSTRACT**

**Objective:** To compare the frequency of intradialytic hypotensive episodes in haemodialysis (HD) patients by using conventional hemodialysis versus assessment with Crite-Line.

**Study Design:** Cross-sectional survey.

**Place and Duration of Study:** The study was conducted at Hemodialysis unit of Sheikh Zayed Federal Postgraduate Medical Institute Lahore from 1<sup>st</sup> August 2009 to 31 January 2010.

**Methodology:** Fifty patients were included in the study according to inclusion criteria and the study was divided into two phases. In the first phase, all 50 patients underwent two sessions of haemodialysis by conventional haemodialysis machine. In the second phase same 50 patients underwent two sessions of haemodialysis by blood volume monitor by Crit-line. The intradialytic hypotensive episode was recorded in both phases when there was a decrease in systolic blood pressure by  $\geq 20$  mm Hg and a decrease in MAP by 10 mm Hg. All this information was collected through proforma. Statistical analyses were conducted by SPSS version 16.

**Results:** Total 200 hemodialysis sessions were included, there were 62 (62%) sessions of intradialytic hypotension in conventional hemodialysis (phase 1) and 43 (43%) sessions of intradialytic hypotension in Crit-line (phase II). The mean age was  $47.02 \pm 14.63$  in both phases of the study. Male to female ratio was 1:1.4.

**Conclusions:** It is concluded that the closed-loop system for automatic profiling of ultrafiltration by Crit-line provides reliable blood pressure stabilization in patients during all phases of HD treatment. The Crit-line method of hemodialysis is better in reducing hypotensive episode during hemodialysis than the other methods of conventional hemodialysis.

*Keywords: Intradialytic hypotension; dialysis sessions; Crit-line; end-stage renal.*

## 1. INTRODUCTION

Chronic kidney disease (CKD) is defined as structural or functional abnormalities of the kidney, with or without decreased GFR and kidney damage for three or more months, manifested by pathologic abnormalities or markers of kidney damage, including abnormalities in the composition of blood, urine or abnormalities in imaging tests [1]. CKD can also be defined as GFR of  $< 60$  ml per minute per  $1.73 \text{ m}^2$  for three months or more, with or without kidney damage [2,3]. The median prevalence of CKD is 7.2% in persons aged 30-63 years and up to 35.8% in persons aged 64 years or above [4]. CKD is characterized by progressive destruction of renal mass with irreversible sclerosis and loss of nephrons [5].

End-stage renal disease (ESRD) is the point in this progression when kidneys no longer function well enough to support life and at this stage, the patient needs renal replacement therapy either as haemodialysis (HD), peritoneal dialysis (PD) or renal transplantation [6].

HD refers to the process by which a solute passively diffuses down its concentration gradient from blood to dialysate [7]. During haemodialysis, urea, creatinine, and potassium move from blood to dialysate, while other solutes, such as calcium and bicarbonate, move from dialysate to blood [8].

Intradialytic hypotension (IDH) remains a relatively common morbid complication during haemodialysis despite increasing technological sophistication of dialysis hardware and application of techniques to maintain intravascular volume [9]. IDH is defined as a decrease in systolic blood pressure by  $\geq 20$  mm Hg or decrease in mean arterial pressure (MAP: Diastolic blood pressure + one-third of pulse pressure) by 10 mmHg [10]. Previous studies showed that the intradialytic hypotension in dialysis was 70.8% through conventional hemodialysis machine and 49.2% through the use of Crite-line [11].

The causes of dialysis induced hypotension are multifactorial. Hypovolemia mainly caused by improper ultrafiltration is considered to be a leading factor [12]. Change in osmolality of serum results in fluid shifts between intra and extravascular spaces. About hypovolemia, a certain success in preventing hypotensive episode can be achieved by hematocrit-based intradialytic monitoring. These devices achieve fluid removal along a predefined trajectory by varying the dialysate sodium concentration and automating ultrafiltration rate to follow well-defined haemoconcentration profile [13].

This study aims to compare the frequency of intradialytic hypotensive episodes in haemodialysis patients by using conventional hemodialysis versus assessment with Crite-Lin. If there is comparatively marked reduction in the intradialytic hypotensive episode by Crite-line then it can be used more frequently in dialysis patient to reduce morbidity and mortality.

## 2. METHODOLOGY

Fifty patients from Haemodialysis unit, Sheikh Zayed Hospital Lahore from 1<sup>st</sup> August 2009 to 31 January 2010, who were on regular HD twice weekly for more than three months and target hematocrit between 33% and 36%, were enrolled in this study after taking verbal and written consent. The procedure of the study and complications during the dialysis were discussed with the patients and appropriate steps were taken to treat the complication that occurred during HD.

A brief history was taken regarding duration on regular dialysis in months, and then clinical examination was done to see hemodynamic stability like blood pressure and volume status.

Dialyzer type, treatment time and blood flow ( $Q_b$ ) were kept constant during the study. Haemodialysis was started after applying blood tubing set with the external optical sensor on Fresenius Medical Care 4008H dialysis machine having F8 polysulphone dialyzer.

50 Patients were included in the study according to inclusion criteria and the study was divided into two phases. In the first phase, all 50 patients underwent two sessions of HD by conventional HD machine. In the second phase same the 50 patients underwent two sessions of haemodialysis by blood volume monitor by Crit-line. Both phases were completed in 6 months.

The intradialytic hypotensive episode was recorded in both phases when there is a decrease in systolic blood pressure by  $\geq 20$  mm Hg and a decrease in MAP by 10 mm Hg. All this information was collected through proforma attached.

Statistical analyses were conducted by SPSS version 16. The age was expressed as the mean  $\pm$  standard deviation (SD) and sex was expressed as a percentage. Presence and absence of hypotensive episode were presented by frequency and percentages and compared between two groups by applying the chi-square test. P-value of less than 0.05 was considered statistically significant.

### 3. RESULTS

In the study total, 50 patients were included who were on maintenance HD twice weekly. The study was divided into two phases. In the first phase, all 50 patients underwent two sessions of HD by conventional HD machine. In the second phase, the same 50 patients underwent two sessions of HD by blood volume monitor by Crit-line.

The patients shown in Table 1 were divided into three age groups. The first group had patients aged 18 to 40 years (n = 17; 34%), in second group, patients aged 41-60 years (n = 22; 44%) and in the third group, patients aged 61-80 years (n = 11; 22%). The mean ages of all the study subjects were  $47.14 \pm 14.76$  years of group A and

$47.52 \pm 13.67$  years of group B. Statistically the difference was not significant ( $P > 0.05$ ).

There were 42 hemodialysis sessions in males (42%) and 58 hemodialysis sessions in females (58%) in group A while in group B, there were 42 hemodialysis sessions in males (42%) and 58 hemodialysis sessions in females (58%). The male to female ratios of group A was 1:1.40 and group B was 1:1.40 (Table 2).

There were 200 dialysis sessions, which were divided into two groups, conventional method and Crit-line method. There was a statically significant association regards intradialytic hypotension episodes between conventional method (62%) and Crit-line method (43%) [ $P < 0.007$ ] (Table 3).

Table 4 showed the hypotensive hemodialysis sessions by sex. There were 33 females (53.2%) and 29 males (46.7%) hypotensive in the conventional method, whereas in Crit-line method there were 30 females (69.7%) and 13 males (30.2%).

In normotensive hemodialysis sessions, there were 20 females (52.6%) and 18 males (47.4%) in the conventional method, whereas, by Crit-line method, there were 28 females (49.2%) and 29 males (51.8%) (Table 5).

### 4. DISCUSSION

Intradialytic hypotension is one of the most common complications observed during HD, occurring in 70.8% with the use of conventional hemodialysis machine [5]. Intradialytic hypotension is defined as lowering of mean blood pressure up to 20 mmHg or more during HD associated with symptoms [2].

It is well known that most of the complications that occur during HD, especially hypotensive episodes, are of multifactorial aetiology and caused by different mechanisms [14].

**Table 1. Distribution of patients by age (n = 100)**

Age (Years)	Conventional method (n = 50)		Crit-line method (n = 50)	
	No.	%	No.	%
18 – 40	17	34.0	17	34.0
41 – 60	22	44.0	22	44.0
61 – 80	11	22.0	11	22.0
Mean $\pm$ SD	47.02 $\pm$ 14.63		47.02 $\pm$ 14.63	
P value	>0.05			

**Table 2. Hemodialysis sessions (n = 200) by sex distribution**

Sex	Conventional method (n = 100)		Crit-line method (n = 100)	
	No.	%	No.	%
Males	42	42.0	42	42.0
Females	58	58.0	58	58.0
Male to female ratio	1:1.4		1:1.4	

**Table 3. Distribution of hemodialysis sessions (n = 200) by the method of intradialytic hypotension**

Intradialytic hypotension	Conventional method (n = 100)		Crit-line method (n = 100)	
	No.	%	No.	%
Yes	62	62.0	43	43.0
No	38	38.0	57	57.0

$$\chi^2 = 7.23; df = 1; P = 0.007$$

**Table 4. Hypotensive hemodialysis sessions by sex distribution in Crit-line method and conventional method**

Sex	Crit-line method (n=43)		Conventional method (n = 62)	
	No.	%	No.	%
Females	30	69.7	33	53.2
Males	13	30.2	29	46.7

**Table 5. Normotensive hemodialysis sessions by sex distribution in Crit-line method and conventional method**

Sex	Crit-line method (n = 57)		Conventional method (n = 38)	
	No.	%	No.	%
Females	28	49.2	20	52.6
Males	29	51.8	18	47.4

Volume substitution, injection of osmotic substances, an increase of dialysate conductivity, decrease of ultrafiltration to zero, reduction of speed of the blood pump and administration of vasoactive drugs are methods proven in clinical practice to treat acute hypotension during HD. To prevent hypotensive episodes, open-loop systems with pre-programmed ultrafiltration and sodium-profiles have been developed [15].

However, clinical experience shows that the methods mentioned above are of limited therapeutic effect in treating patients with vascular instability during HD since actual changes in blood pressure behaviour are not considered continuously. Reliable prevention of dialysis-induced hypotension is achievable only from biofeedback has driven closed-loop systems and external or internal optical sensor guided by frequent blood pressure measurements [16].

Blood pressure guided ultrafiltration profiling has proven its superiority in all studies done yet. In

our study, the frequency of hypotensive episodes remains higher in conventional therapy than Crit-line therapy of HD. In the first phase of this study, the frequency of hypotensive episodes was 62% with conventional method and in second phase the frequency of hypotensive episodes was 43% with Crit-line method (Table 3), results that are comparable with the study conducted by Begin et al. [17] in 2002, which shows the hypotensive episodes were 70.8% with conventional method and 49.2% with Crit-line. During the second phase of treatment by Crit-line method show decrease frequency of hypotensive episodes in contrary to the increasing trend during conventional therapy. Thus, the closed-loop system for automatic profiling of ultrafiltration provides reliable blood pressure stabilization in patients during all phases of HD treatment.

There was a significant improvement in the number of event-free sessions with blood volume regulation compared with standard dialysis (50.8% of sessions vs. 29.2%). Percentages of event-free sessions and mean

post-dialysis systolic blood pressure improved progressively throughout the study, indicating improved hemodynamic stability over the study period. Therefore, the use of a biofeedback system to monitor and regulate blood volume during dialysis helped restore cardiovascular stability in hemodialysis patients [18].

Several studies have clearly shown that the Crit-line method of hemodialysis HD is better in reducing hypotensive episode during hemodialysis than the other methods of conventional HD. The study conducted by Santoro et al. [19] showed a 30% reduction in IDH events was observed in blood volume treatment as compared with conventional hemodialysis (23.5% vs. 33.5%). The more IDH episodes in conventional hemodialysis, and the better the response in blood volume treatment.

The study performed by Schmidt et al. [20] reported that only 32.4% of conventional treatments were hypotensive free, which is almost equal to hypotensive free episodes in our study. It was concluded that the conventional type of HD has more frequent episodes of IDH.

In a study conducted by Reddan et al. [21] patients had a mean age of 59.2 yr, and 51% were males, whereas in the present study the mean age was 47.02 years, and 42% were males (Tables 1-2). In the study of Schroeder et al patients had a mean age of 50 years which is comparable to our study. We found that females developed more episodes of intradialytic hypotension as compared to males. In our study, 53.2% of females and 46.7% of males were hypotensive in the conventional method, whereas in Crit-line method 69.7% of females and 30.2% of males were hypotensive.

This study was designed to evaluate the accuracy and safety of Crit-line method of hemodialysis in reducing hypotensive episode during hemodialysis than the other methods of conventional hemodialysis.

In our society where most people are living with low socioeconomic status, the financial constraint is the major factor for dialysis with blood volume monitor like Crit line. Apart from economic reasons, most of the hemodialysis centres do not have the facility of blood volume monitor like Crit line, thus it should be available in all hemodialysis centres to reduce the morbidity of hemodialysis patients.

## 5. CONCLUSION

Intradialytic hypotension remains the most prevalent side effect of hemodialysis although its incidence has diminished with the advent of more advanced dialysis technology. We observed that in hemodialysis outpatients, the availability of biofeedback driven closed-loop systems with external or internal optical sensor guided by frequent blood pressure measurements like IBVM with Crit-Line was associated with a significantly lower incidence in hypotensive episodes and a reduction in the frequency of symptoms during the inter-dialytic period than in patients who received conventional monitoring.

Randomized trials of dialysis interventions are desperately needed in our society. It remains difficult to perform, because of the financial constraint of patients and availability of machine in hemodialysis.

## CONSENT AND ETHICAL APPROVAL

As per international standard, patients' consent and ethical approval have been collected and preserved by the authors.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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