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A new approach in prevention and correction of intradialytic hypotension in patients on maintenance hemodialysis

I.Yu. Drachev[1,2], V.Yu. Shilo[3,4], G.S. Dzhulay[1]

[1] Tver State Medical University,

4 Sovetskaya St., Tver 170100 Russia;

[2] LLC "B.Braun Avitum Moscow" (LLC "Medical Center of High Technologies polyclinic № 1"),

3 Bldg. 1 Rodionovskaya St., Moscow 125466 Russia;

[3] A.I. Yevdokimov Moscow State University of Medicine and Dentistry,

20 Bldg. 1 Delegatskaya St., Moscow 127473 Russia

[4] LLC "B.Braun Avitum Russland"
29 lit. Z 18th Ln. of Vasilyevsky Island, St. Petersburg 199178 Russia

Correspondence to: Ivan Yu. Drachev, Postgraduate of the Department of Internal Diseases at Tver State Medical University, Nephrologist in the Dialysis Center of LLC "B.Braun Avitum Moscow" (LLC "Medical Center of High Technologies Polyclinic № 1"), e-mail: ivan-dr@mail.ru

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The aim *of the study was to evaluate the efficacy of various approaches to correcting and preventing hypotension episodes in patients on maintenance hemodialysis (HD)*

Material and methods. *The study included 35 patients on maintenance hemodialysis in the Dialysis Center of* "*MCHTP No.1*"*, which is a part of "B.Braun Avitum" network centers in the Russian Federation.*

All patients underwent an automatic blood pressure (BP) measurement using a machine-inbuilt option device for noninvasive blood pressure measurement. Prior to the study, all patients underwent a clinical test with a "dry weight" assessment and a bio-impedance analysis. The study had a cross-over design: first, all patients were treated using the standard methods for correcting hypotension episodes (at 4 initial procedures). Then, in the following 4 procedures, in addition to standard methods, a computer algorithm was used to automatically regulate the ultrafiltration (UF) rate: the automatic pressure monitoring system (biologic rr Comfort) with continuous monitoring of blood pressure throughout the procedure; BP was recorded before and after the HD procedure, as well as at least once every 5 minutes during 3 initial procedures; and starting from the 4th procedure, the intervals were determined by the algorithm automatically. The average blood pressure values were analyzed during the dialysis procedures for the entire observation period. The duration of the study was 3 weeks for each patient.

***Results**. The average predialysis blood pressures in the group with the standard approach to hemodynamic correction were 124.6 ± 27.7 and 74.5 ± 21.1 mm Hg, the postdialysis blood pressures were 114.4 ± 24.4 and 71.3 ± 16.3 mm Hg. With the use of automatic pressure monitoring system, the predialysis and postdialysis blood pressures were significantly higher than those with the standard approach: 133.2 ± 21.3 and 79.3 ± 15.8 mm Hg ($p < 0.001$ and $p = 0.009$), vs. 125.7 ± 23.9 and 75.9 ± 18.3 mm Hg ($p < 0.001$ and $p < 0.001$), respectively. Upon closer examination of the intradialysis pressure variations, the intradialytic blood pressures were 110.2 ± 17.3 and 68.3 ± 13.9 mm Hg when measured by using the standard approach, and significantly higher: 124 ± 20.5 and 75.9 ± 14.2 mm Hg when the automatic*

pressure monitoring system was used ($p = 0.03$; $p = 0.02$). Also, higher mean arterial pressures were noted: 82.5 ± 13.9 with the standard approach vs. 91.5 ± 15.6 mm Hg. ($p = 0.01$) with the automatic pressure monitoring system. Studying UF rates, we found that the UF rate was slightly higher without using the automatic pressure monitoring system (8.0 ml/kg/h vs. 7.9 ml/kg/h). Thus, the new approach used in addition to the standard methods of correcting hypotension was effective and safe. No significant differences were seen in Kt/V values. However, when automatic pressure monitoring system was used in patients, the target phosphate levels were achieved: the inorganic phosphorus values were 1.5 mmol/L when using the UF control algorithm vs. 1.8 mmol/L with a standard dialysis program. However, these data did not reach the statistical significance ($p = 0.07$).

***Conclusion**. Intradialytic hypotension and high UF rates remain frequent and potentially dangerous complications of HD procedure, which worsen the long-term prognosis of patients on HD, mainly due to the increase in cardiovascular morbidity and mortality. The new approach to the prevention and correction of hypotension by using the automatic pressure monitoring system allows one to reduce the UF rate in a timely manner, preventing the development of hypotension episodes, reducing their rates, and improving the achievement of target blood pressure values, both pre- and postdialysis, as well as intradialytic blood pressure variations.*

Keywords: chronic kidney disease 5D, complications of hemodialysis, intradialytic hypotension, hemodialysis, clinical outcomes, blood pressure monitoring, arterial pressure, ultrafiltration rates, dialysis adequacy, cardiovascular complications

APMS, automatic pressure monitoring system

BP, blood pressure

CKD 5D, chronic kidney disease 5D stage

DBP, diastolic blood pressure

HD, hemodialysis

IDH, intradialytic hypotension

Kt/V, quantitative measure of hemodialysis adequacy

SBP, systolic blood pressure

UF, ultrafiltration

The study objective was to evaluate the efficacy of various approaches to the correction and prevention of hypotension episodes in patients on maintenance hemodialysis.

The study tasks were to compare the frequency of hypotension episodes occurred when using a computer-assisted method of managing ultrafiltration vs. without using it.

Introduction

In patients with chronic kidney disease (CKD 5D) receiving treatment with maintenance hemodialysis (HD), the intradialytic hypotension (IDH) is the most common complication of dialysis procedures. IDH is considered an actual clinical problem not only because it occurs in up to 20–30% of all HD procedures [1], but also because approximately 17.8% of symptomatic IDH require a medical intervention [2]. The IDH problem is crucial as it may cause ischemia episodes in vital organs, including the heart and brain, which are often asymptomatic during the HD procedure. Severe intradialytic (synonym of syndialytic) hypotension causes local impairments of myocardial contractility and its “stunning”, frequently recurrent such episodes may lead to fibrosis, systolic dysfunction, and increased cardiovascular mortality [3, 4]. So, Burton et al. in their study said about correlation between severe IDH and a local myocardial contractility impairment [5]. IDH causes arrhythmias. The tolerance of HD procedures becomes worse, which often leads to shortened dialysis time. Equally important are the increased risk of thrombosis and the vascular access failure when IDH occurs [6]. The most severe episodes of IDH occur in people with a low predialysis systolic blood pressure (BP) and increased vascular stiffness, which leads to even greater ischemia [7]. The IDH symptoms are dizziness, nausea, vomiting, and sweating. The most dangerous symptoms include angina pectoris, arrhythmias, a loss of consciousness, convulsions, and cardiac arrest. There are various definitions of IDH, including those based on the hypotension episodes with systolic blood pressure (SBP) decreasing to 90 mm Hg and below, or a fall in intradialytic SBP by 20–30 mm Hg accompanied by clinical symptoms (weakness, sweating, nausea, vomiting, flickering “flies” before the eyes, or the loss of consciousness as a severe case). Such definitions are the most useful in clinical practice, since in this case, the strongest association with the increase in mortality was revealed. The causes and risk factors for the development of hypotension during the HD procedure are varied (low predialysis BP, "patient overheating" at inadequate dialysis solution temperature, acetate dialysis, incorrect assessment of the "dry weight", abundant food intake during the dialysis procedure, taking antihypertensive drugs immediately before the procedure, diastolic myocardial dysfunction, severe anemia, age 65 years and older, diabetes mellitus, protein and energy deficiency, hypoalbuminemia). However, the most common cause of IDH is a high ultrafiltration (UF) rate that occurs when free fluid is removed too quickly from the vascular bed, large interdialytic fluid increases, and short dialysis. According to a number of studies, there is a relationship between a too rapid fluid elimination during the dialysis and a deterioration of patient's condition during the dialysis, and also increased mortality [8]. Intensive UF leads to hypovolemia, since the UF rate exceeds the rate of fluid transition from the interstitial space into the vascular bed, causing an IDH episode. Data presented by Yuetal suggest that IDH does not develop without UF [9]. There are different approaches to prevent IDH: the avoidance of abundant food intake during hemodialysis, an individual-based choice of dialysis solution temperature (0.5ºC below the body temperature), the unrecognized dehydration control, the use of bicarbonate dialysis rather than the acetate one, the discontinuation of antihypertensive therapy. At the same time, the most effective prevention methods include the reduction of fluid elimination rate during the dialysis procedure, or the UF rate: an increase in dialysis time, control of interdialytic fluid gain (limiting the dietary salt intake), administration of additional procedures. Nowadays, new approaches to the IDH prevention are increasingly being used, such as software and hardware complexes for controlling the UF rate. This approach is based on continuous monitoring of patient's BP. Hemodynamics readings of the patient are stored in his personal medical record, which ensures an individual-based approach to each patient. The use of a computer-assisted self-educating algorithm allows assessing the hemodynamics condition during several initial procedures, and further, reacting to its changes, keeping the blood pressure within the target values, controlling the UF rate. If a tendency to the IDH occurrence is recorded, the algorithm either reduces the UF rate or stops it for a short period of time sufficient for the intravascular volume replacement from the interstitial space and for the hemodynamics stabilization. As soon as the target BP values have been reached, the UF rate is restored automatically, possibly, reaching the target UF. The advantages of this approach include the continuous on-line monitoring of blood pressure and an immediate response to a tendency for IDH, i.e. the emphasis is placed on preventing the episodes of symptomatic syndialytic hypotension. Meantime, the use of a computer-assisted algorithm does not allow exceeding a preset UF limit rate, avoiding the high UF rates (above 12.4 ml/kg/h) that could lead to an increase in mortality, both according to literature, and our own data [10]. However, the literature data on the use of a computerized UF control algorithm is very scarce. In order to fill in the gap and test the presented hypothesis in real practice, this study was conducted.

Material and methods

The material for the study included the data of a comprehensive examination of patients in Moscow and the Moscow Region. In total, the study analysis included 35 patients who were on HD during the study period in the Dialysis Center of MCHTP No.1" that is a part of B.Braun Avitum network centers in the Russian Federation. The mean age of the patients (16 women, and 19 men) was 52 years old. The provided dialysis dose was 1.89±0.3 (spKt/V is a quantitative assessment of the hemodialysis adequacy, where "K" is the urea clearance during hemodialysis, "t" is the hemodialysis duration, "V" is the urea distribution volume approximately equal to the total patient body water). The mean UF rate was 8.03 ± 3.6 ml/kg/h. Blood pressure before the HD session made 124.6 ± 27.7 mm Hg and 71.3 ± 16.3 mm Hg. The effective HD time was 255.6 ± 18.2 minutes. The mean UF volume was 2351.2 ± 1125.6 ml, the blood flow rate was 325.4 ± 46 ml/min. Different approaches were used to prevent IDH n patients: 1) the standard approach when during the initial 4 HD sessions in the dialysis center, the predialytic blood pressure was measured before the patient's connection to the device; further the blood pressure was measured regularly during the dialysis session once per hour in the hemodynamically stable patients with blood pressure within targeted value range, once per half an hour or more often in the unstable patients with blood pressure outside the target value range; 2) the approach with using a computer-assisted unit for the UF control by the automatic pressure monitoring system (APMS) (the biologic RR Comfort option) embedded in the "Artificial Kidney" machine ("B. Braun Dialog + Evolution") that analyzed the curves of blood pressure changes and, using an intelligent approach system in subsequent dialysis sessions, automatically set up the ranges of blood pressure for each individual patient, which made it possible to make an idea about the blood pressure data forming the measurement intervals. When SBP reached the lower limit of the range, the system partially or completely limited the UF rate, notifying of it the staff; that allowed the staff to respond to IDH episodes immediately (Fig. 1).

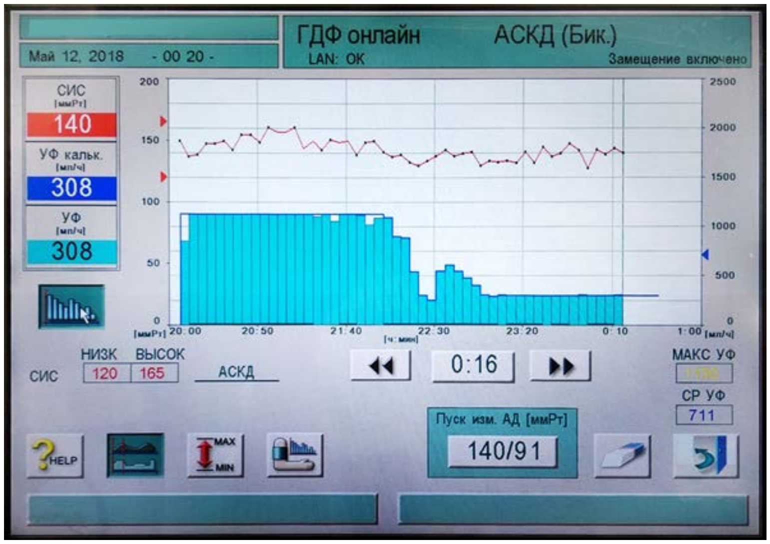

Fig. 1. An example of the automatic pressure monitoring system. The upper curve represents the systolic blood pressure level, the lower curve shows the ultrafiltration rate. There was a tendency to an intradialytic hypotension episode development in the middle of the procedure. The automatic pressure monitoring system reduced the ultrafiltration rate, thereby preventing an episode of intradialytic hypotension. On restoring the level of systolic blood pressure, the use of the algorithm allowed establishing a lower ultrafiltration rate, continuing the procedure, and finally achieving the target ultrafiltration values

When using the UF control unit, the blood pressure was measured once per every 5 minutes for initial 3 procedures (that was necessary for statistical data collection to make the blood pressure curves and predict IDH episodes); starting from the 4th procedure, the intervals for measuring blood pressure were automatically set up with using the algorithm. The last measurement was made after disconnecting the patient from the device (a postdialysis blood pressure). The mean post-dialysis weight was 67.9 ± 11.4 kg, the dry weight, according to bioimpedance analysis, was 67.4 ± 11.2 kg.

The mean postdialysis weight exceeded the measured dry weight by 0.52 kg, which is a generally accepted value (the dry weight + 0.5 kg = the postdialysis weight).

The study used the averaged blood pressure data measured before, during and after HD for the entire study period. Averaged measurement values for the entire study period were used as variables. The measurements were made using a non-invasive blood pressure measurement unit built-in in the “Artificial Kidney” machine (“B.Braun Dialog +”). The statistical analysis was performed using the STATISTICA 6.0. statistical software. Standard methods of descriptive and variation statistics were used: the calculation of means, an interquartile range and a standard deviation in a normal distribution of values or the median determination. The variables with a normal distribution were compared using the Student's t-test. When comparing the data with the distribution other than normal, the Wilcoxon test was used. Differences were considered statistically significant at $p<0.05$. The hypotension episodes were defined as the SBP decrease to 90 mm Hg and below, the SBP drop by 20 mm Hg or more during the procedure with the manifestation of typical clinical symptoms. The SBP value below 100 mm Hg A was considered a low predialysis SBP level qualified as the risk factor for the IDH development while on hemodialysis. The study protocol was approved by the Ethical Committee of Tver State Medical University in 2018.

Results

In this study, we compared the predialysis, postdialysis values of the SBP, diastolic blood pressure (DBP), and mean blood pressure, as well as intradialysis variations in blood pressure of the patients in whom different approaches to the hypotension correction were used. The comparison demonstrated that the averaged predialysis SBP and DBP were statistically significantly lower with the standard approach than with the use of APMS: 124.6 ± 27.74 and 74.45 ± 21.13 mm Hg vs. 133.2 ± 25.8 and 79.3 ± 20.5 mm Hg, respectively ($p < 0.001$ and $p = 0.009$). The postdialysis blood pressure data differed: the blood pressure was higher when using APMS than with the standard therapy: 125.7 ± 24 and 75.9 ± 18.3 mm Hg vs. 114.3 ± 24.4 and 71.2 ± 16.3 mm Hg, respectively ($p<0.001$ and $p<0.001$). The data of intradialysis variations showed statistically significant differences: the blood pressures were higher with the use of APMS compared to those with the standard approach 124 ± 20.5 and 75.9 ± 14.2 vs. 110.2 ± 17.3 and 68.3 ± 17.9 mm Hg, respectively ($p=0.03$; $p=0.02$) (Fig. 2).

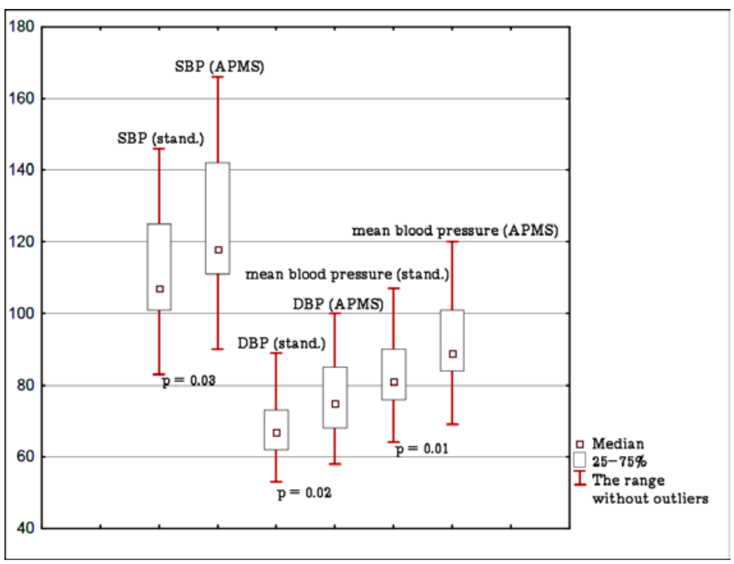

Fig. 2. Comparison of intradialysis variations of the systolic, diastolic, and mean arterial pressures when using the standard approach to the correction of intradialytic hypotension versus using the ultrafiltration rate control algorithm of the automatic pressure monitoring system (explained in the text)

The data of mean BP obtained when studying the intradialysis variations had a similar result: 82.5 ± 13.9 and 91.5 ± 15.6 mm Hg (p=0.01). Thus, the use of the UF control system led to the increase in the intradialytic SBP by 14 mm Hg, DBP by 8 mm Hg, and mean blood pressure by 10 mm Hg. The IDH occurrence during the procedures was 26.2% with a standard approach versus 8.3% with the use of an automatic UF rate control unit (Fig. 3).

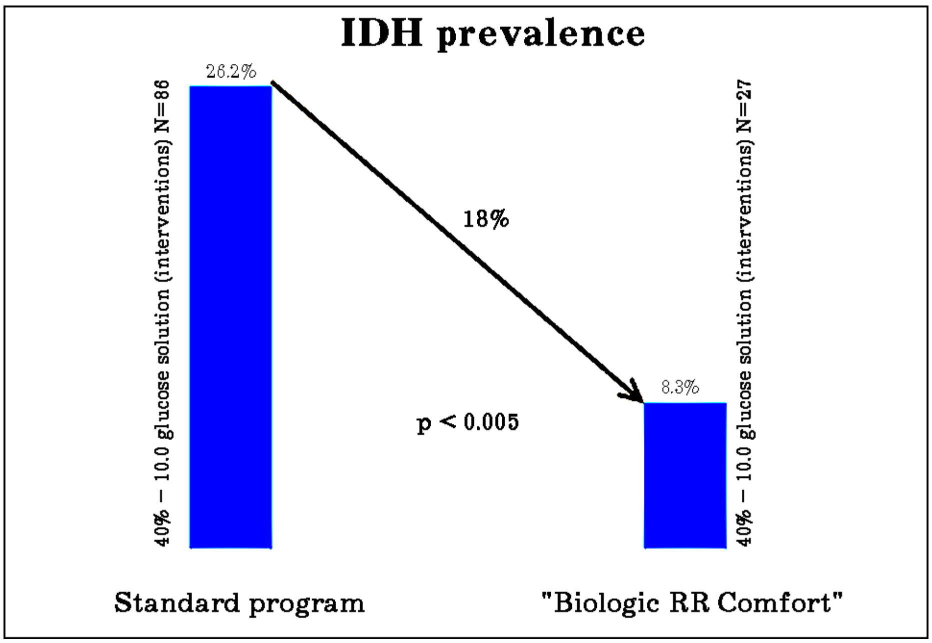

Fig. 3. Reduction of intradialytic hypotension incidence. The compared ratios of the intradialytic hypotension occurrences and their clinical manifestations to the total number of blood pressure measurements between the treatment options throughout the observation period. When using an automatic pressure monitoring system, the intradialytic hypotension incidence reduced by 18%; the number of 40%-10.0 glucose solution interventions decreased from 86 to 27.

The averaged UF rate did not show significant differences in values and made 8.2 ml/kg/h with the standard approach versus 7.9 ml/kg/h when using the biologic RR Comfort algorithm. The mean duration of the procedure when using the UF rate control algorithm increased slightly by 3 minutes which did not entail an increase in the Kt/V. Meanwhile, the phosphate levels improved in the patients when the UF rate control algorithm was used: blood phosphorus decreased and entered the reference range of values: 1.8 mmol/L versus 1.5 mmol/L, but the difference did not reach the statistical significance (p=0.07). The number of hyperosmolar glucose solution interventions was respectively decreased: 86 vs. 27.

Discussion

The clinical significance of IDH during an HD procedure is a pressing problem nowadays, being the subject of many reports in literature. The available data suggest that large variations in blood pressure during a HD session have a negative impact on clinical outcomes [11]. At the same time, the occurrence of hypotension episodes, especially repeated, with a severe course (with SBP decreased to 30 mm Hg or below) during the dialysis session, is a no less formidable complication and not only worsens the tolerability of HD, but also requires the medical staff attendance (for turning off the UF, making the interventions of hyperosmolar glucose solution, saline infusion, interrupting the procedure), which often affects the treatment quality in general [12] and may also increase the incidence of cardiovascular events, including death [13]. IDH is associated with repeated episodes of ischemia and impaired local myocardial contractility, resulting in myocardial fibrosis and the development of heart failure [14]. That leads to an increase in blood pressure variations, widening the range of blood pressure extreme values in patients with a high UF rate, thus causing complications [15]. This fact caused difficulties, because in their attempts of attaining a “dry weight” to normalize the blood pressure, the practitioners aggressively reduced the BP pressure to target values, which could lead to an increased mortality. The present study is devoted to investigating the distribution, prevention, and correction of IDH. We analyzed two groups of patients included in the study, using the individual data on their blood pressure, which were recorded during the HD procedures and registered in the Nexadia medical information system for the entire observation period. We made a comparison between the standard approach to the IDH prevention and correction, the automatic UF rate control system, and the dry weight correction method to achieve the target blood pressure values. In our work, we managed to demonstrate the advantage of APMS in the IDH prevention by directly regulating the UF rate: one of side effects of reducing the IDH prevalence was a decrease in the number of hyperosmolar glucose solution interventions to correct an IDH episode, which reduced a medical staff workload. Unlike our expectations, the Kt/V did not differ significantly between the study groups. At the same time, the mean blood level of phosphorus was within the reference range in the patients receiving the treatment with the algorithm, unlike to the patients receiving the procedure without it. That might be due to the increase in effective dialysis time. The results of our work in this part correspond to data presented in literature. For example, in the review by C.Chazot et G.Jean, the dialysis duration was directly related to a decrease in phosphate levels [16]. It is noteworthy that the UF rate in the investigated group did not differ significantly in the patients when being treated either with or without the use of the algorithm. At the same time, the IDH prevalence was clearly lower in the patients while the APMS was used. The SBP, DBP, and mean arterial pressure levels were, on average, also higher with the use of the automatic UF rate control system. This might be explained by the specific features of Biologic RR Comfort functioning, since, thanks to the existing algorithm, the blood pressure is continuously monitored, and there is a possibility of an immediate response to the slightest tendency to hypotension by correlating the UF rate for a short period of time, which does not significantly affect the overall averaged data but allows the prevention of IDH episodes. The SPRINT study [17] investigated the effect of BP close monitoring in over 9000 American patients for 3.26 years and showed that a significantly lower incidence of cardiovascular events and overall mortality can be achieved in high-risk patients of cardiovascular diseases when reducing the SBP to a level of 120 mm Hg and below. In the group with BP equal to 120 mmHg, with a close monitoring of blood pressure, there was observed a 27% decrease in total mortality and a 43% lower risk of cardiovascular death. However, a higher incidence of adverse events, such as hypotension, syncope, acute kidney injury, or renal failure, was observed in this group. The data we obtained (post-dialysis SBP of 125.8 mm Hg while using the "Biologic RR Comfort") were close to the target results of this study. This suggests a reduction in a cardiovascular risk for these patients, which is relevant for the dialysis population. In our study, the patients treated using a standard approach to the IDH correction and prevention had the postdialysis SBP of 115.7 mm Hg that may provoke an increased cardiovascular mortality, increased risk of hypotension, which also corresponded to the SPRINT data. Having achieved a 18% decrease in the IDH prevalence when using the Biologic RR Comfort, we can speak of a good clinical outcome. Our data are comparable with the results of a large study involving 15 dialysis centers in Italy [18], where the IDH prevalence was reduced by 25%. We believe that the strong sides of our work included studying the issue in conditions of a real clinical practice and no patient selection when included in the study (except for the predisposition to hypotension).

Summary

The IDH occurring against a high UF rate remains a frequent and potentially dangerous complication of an HD procedure; its development worsens the long-term prognosis of patients on HD, mainly due to the increase in cardiovascular morbidity and mortality. As a result of the conducted study, we obtained the data on reducing the IDH occurrence from 26% to 8%. The correlation between the APMS use and the reduction in the number of hypertonic glucose interventions was noted.

Conclusion

A new method for the prevention and correction of intradialytic hypotension during a dialysis procedure using an automatic pressure monitoring system allows for timely reduction of the ultrafiltration rate, preventing the development of intradialytic hypotension and improving the achievement of target blood pressure values (both pre- and post-dialysis), as well as preventing the large intradialytic variations of blood pressure.

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Conflict of interest. The work was performed in the Dialysis Center of B.Braun Avitum Moscow LLC (LLC High-tech Medical Center Polyclinic No. 1).

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Information about authors

Ivan Yu. Drachev, Postgraduate of the Department of Internal Diseases at Tver State Medical University, Nephrologist in the Dialysis Center of LLC "B.Braun Avitum Moscow" (LLC "Medical Center of High Technologies Polyclinic № 1"), ORCID: 0000-0001-9911-3889

Valeriy Yu. Shilo, Cand. Med. Sci., Associate Professor, Department of Nephrology, Epidemiological and Clinical Department, A.I. Yevdokimov Moscow State University of Medicine and Dentistry, Medical Director of the network of dialysis clinics of LLC "B.Braun Avitum Russland" in Russia, ORCID: 0000-0001-9025-8061

Galina S. Dzhulay, Dr. Med. Sci., Head of the Department of Faculty Therapy at Tver State Medical University.