Impact of Hemocontrol on Hypertension, Nursing Interventions, and Quality of Life: A Randomized, Controlled Trial

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Background: Volume overload contributes to the pathogenesis of hypertension in hemodialysis (HD) patients. Design, setting, participants, and measurements: The Hemocontrol (HC) system (Gambro), which automatically adjusts ultrafiltration rate and dialysate conductivity during dialysis, has been suggested to improve hemodynamic tolerance and thereby facilitate fluid removal. A 6-mo randomized, controlled trial was performed to test the hypothesis that the addition of the HC system to a systematic BP management protocol may lower home BP in comparison with standard HD as primary end point. Secondary end points were the number of nursing interventions during dialysis and health-related quality of life.

Results: Complete BP data were available for 36 of the 44 patients who completed the trial. There was a statistically significant overall decrease in systolic BP during the study period (P = 0.005). However, the difference between the HC group and the standard HD group was NS (HC: from 147.8 ± 21.7 to 139.8 ± 16.2 mmHg; standard HD: from 141.9 ± 19.2 to 135.2 ± 9.9 mmHg). The number of HD sessions that required nursing interventions decreased in the HC group, whereas it increased in the standard HD group (HC: 42.9% reduction; standard HD: 35.7% increase; P = 0.04). There was also a significant improvement in health-related quality of life in the HC group but not in the standard HD group.

Conclusions: These results suggest that the addition of the HC system to a systematic BP management protocol provides no additional benefit with regard to BP reduction. However, the HC system may improve the patient tolerability to dialysis.


Hypertension is a common problem in patients who undergo long-term maintenance hemodialysis (HD), with a reported prevalence of 50 to 90% (1). As a major risk factor for cardiovascular disease, hypertension contributes to the high rate of morbidity and mortality in patients with ESRD (2,3). For a majority of dialysis patients, volume overload (VO) plays a major role in the pathogenesis of hypertension (4–6), and removing excess volume can often normalize BP (4). Unfortunately, correcting VO frequently proves to be difficult because of hemodynamic instability during HD sessions. As much as 20 to 50% of dialysis patients present with symptoms of intradialytic hypotension (IDH) (7). IDH increases nursing work load and negatively affects the efficacy of dialysis and the quality of life of HD patients. Various measures are used to avoid IDH, such as limitation of salt and water intake, avoidance of antihypertensive medication before dialysis, use of low-temperature dialysate, and modeling of ultrafiltration (UF) and/or dialysate conductivity. However, these measures often generate mixed results.

The Hemocontrol (HC) biofeedback system (Gambro AB, Stockholm, Sweden) has been reported to reduce hemodynamic instability and hypotensive episodes during HD (7–13). The HC system consists in a fully integrated biofeedback system that monitors and regulates blood volume contraction during HD through software-driven adjustments of UF rate and dialysate conductivity. By improving hemodynamic tolerance during dialysis, the use of the HC system has been suggested to facilitate fluid removal and correction of VO.

This randomized, controlled trial was conducted to test the hypothesis that the addition of the HC system to a systematic BP management protocol would help to control hypertension through a better achievement of dry weight. The primary end point of the study was the change in home BP with the HC system in comparison with standard HD. Secondary end points were a variation in the percentage of HD sessions that required nursing interventions and a change in the health-related quality of life of HD patients.

Materials and Methods

Study Design
We designed a prospective, randomized, controlled study to compare the use of the HC system with standard HD. Patients were recruited from one dialysis unit of a university-affiliated teaching institution (Montreal, Canada). All patients were studied in the trial from January to July 2003, preceded by a 4-wk run-in period. Patients, investigators, and dialysis staff were not blinded to treatment assignment. Randomization was performed with a computer-generated randomization list using a block randomization method and stratification for hypotension-prone patients. The study protocol was accepted by the
local ethics committee and was undertaken in accordance with the Declaration of Helsinki. All patients gave written, informed consent.

Study Population
On November 15, 2002, among the 135 prevalent HD patients who were treated in our center, 80 patients satisfied eligibility criteria. Eligible individuals included patients who were ≥18 yr of age, on maintenance HD for 3 mo or more, on thrice-weekly HD with treatment time of at least 9 h per week, and willing to participate in the study and to measure their home BP at least three times a day for the entire study duration. Of the 80 eligible patients, 57 were randomly assigned and 23 were excluded because of anticipated change in renal replacement modality (transfer to nocturnal HD or peritoneal dialysis), planned transplantation, expected transfer (temporary or definitive) to another center, enrollment in another clinical trial, subsequent refusal to participate in the trial, or death.

Definitions
**Hypotension-Prone Patient.** A patient was defined as being hypotension prone when any of the following was present in >30% of HD sessions during the 4-wk run-in period that preceded randomization: Hypotensive episode(s), symptoms compatible with IDH that required interventions by nurses, and/or regular use of midodrine (Amatine) before and/or during HD.

**Nursing Interventions.** The following actions were considered IDH-related nursing interventions: Prompt reclining of dialysis chair (Trendelenburg position), manual reduction of UF rate and/or blood flow, and infusion of saline.

**Technical Considerations**
All treatments were performed using Integra generators (Gambro AB), including blood volume sensors and automatic blood volume control software (HC) A complete description of the HC system has been previously published (10,14). Briefly, the HC system consists of (1) an optic reader that permits online measurement of the hemoglobin concentration to determine the variation of circulating blood volume and (2) software that automatically adjusts both UF rate and dialysate conductivity throughout the HD session. An automatic BP monitor (model HEM-757; Ommron Healthcare, Kyoto, Japan), validated by the Association for the Advancement of Medical Instrumentation, was provided to every patient in our study for home BP measurements.

**Interventions**

**Run-In Period.** During a 4-wk period that preceded randomization, HD prescriptions were standardized and optimized for all patients who were enrolled in the trial. An attempt to adjust dry weight more precisely was done, using usual clinical criteria (shortness of breath or orthopnea; peripheral edema; pre-, intra-, and interdialytic BP; and cramping during or after dialysis). All patients were reminded of general recommendations, such as avoidance of antihypertensive medication before dialysis and diet counseling. Dialyzer type and surface, blood flow, dialysate flow, electrolyte concentration, vascular access, and the duration of the HD sessions were not changed during the run-in period and the randomized study period, unless clinically indicated.

**Study Period.** Patients were randomly assigned to either the HC system or standard HD. For patients who were randomly assigned to HC, we used 12 consecutive HD sessions during the run-in period to determine the blood volume reduction ratio normalized for UF (ΔBV/UF) required for HC prescription. The equivalent dialysate conductivity with HC was set to 140 mmol/L sodium concentration, and the software was set to operate within limits that ranged from 135 to 150 mmol/L. In the standard HD group, patients continued their routine dialysis treatments, and no changes were made initially to the HD prescriptions. When ramped sodium modeling and/or low dialysate temperature (<37°C) was used before the inclusion in the study, it was continued during the trial.

Patients from both groups were evaluated by interview and examination at least twice a month by one of the investigators. Dialysis charts and home BP measurements were analyzed. For both HC and standard HD patients, a systematic BP management protocol that was based on an intervention algorithm (Figure 1) and guided patients’

![Figure 1. Decision algorithm for BP management for patients in the Hemocontrol (HC) and standard hemodialysis (HD) groups.](image-url)

*Increase hypotensive medication if dry weight reduction is impossible because of adverse effects or patient reluctance.*
treatment was used. Clinical hypervolemia was determined with clinical criteria previously mentioned.

Data Collection

The following data were collected at baseline: Age, gender, race, dialysis vintage, HD prescriptions, presence of diabetes, hypertension, hypotension during HD, heart failure, left ventricular hypertrophy, and ischemic heart disease. Antihypertensive medications were reviewed carefully, with a confirmation from a pharmacist as necessary. All drugs were recorded, with their dosage, frequency of administration, and indications. Quality of life was assessed using the Kidney Disease and Quality of Life–Short Form (KDQOL-SF) questionnaire (French Version 1.2 and English Version 1.3). KDQOL-SF questionnaires were completed by patients, with help from relatives or staff as needed.

During the study, the following data were recorded: Any changes to the HD prescription or the patient medication, selected laboratory data (hemoglobin, hematocrit, albumin, and single-pool Kt/V), body weight before and after every HD session, and percentage of sessions that required nursing interventions. All patients were trained to measure their BP at home thrice daily using the automatic BP monitor. Patients were advised to take one measurement at rest after sitting for at least 5 min and to record their BP readings on a provided data sheet. The memory feature of the home BP monitor was not used during the study. In addition, sodium removal during dialysis (15) was measured at baseline and at the end of the study and was computed according to the formula \[ \text{VD} = \frac{(\text{final body weight} \times \text{VD}) + \text{total UF}}{\text{initial plasma sodium}} - \frac{(\text{final body weight} \times \text{VD}) \times \text{final plasma sodium}}{\text{initial plasma sodium}} \]

Outcome Measures

The primary end point measure was the variation from baseline to the end of the study in systolic BP (SBP), diastolic BP (DBP), and mean BP in both study groups. BP measurements were averaged over the first 2 wk and the last 2 wk of the trial for each patient. Secondary outcome measures were the variation from baseline to the end of the study in the number of HD sessions that required nursing interventions for IDH over the first 2 wk and the last 2 wk of the trial for each patient and the quality-of-life scores.

Sample Size

For the primary end point, a priori power analysis revealed that 20 patients in each group would provide 80% power to detect a difference of 8 mmHg on the average BP from baseline to the end of the study. A preliminary analysis concluded that among 80 eligible patients, 60 patients could presumably be included in our study. Regarding secondary end points, a priori power analysis revealed that the sample size would possibly not generate a power >80%, but the results would potentially disclose tendencies and allow conception of new hypotheses.

Statistical Analysis

All end points were analyzed when sufficient data permitted analysis. Two-way repeated measures ANOVA was used to analyze mean variations in BP values between baseline and end of study in each treatment group. Post hoc test was applied in case of significant main effect differences. The change from baseline to end of study in the number of dialysis sessions that required IDH-related nursing interventions for each patient was compared between the HC group and the standard HD group using the Mann-Whitney U test. For the KDQOL-SF questionnaires, a score (on 100) was assessed for every domain, higher scores indicating a better quality of life. The mean score variation from baseline to end of study was compared between the two treatment groups using t test or Wilcoxon test, when appropriate. A Bonferroni correction was performed to adjust for multiple comparisons. In addition, multivariate analysis (linear regression) was performed to adjust the results for the following confounding factors: Age, gender, ethnicity, hypotension, number of nursing interventions during dialysis, and number of pills per day. Two-way ANOVA was used to analyze mean variations in antihypertensive treatment (mean number of drugs and number of pills per day) and variations in dry body weight.

Continuous variables are reported as means ± SD. Mathematical transformation was performed for non-normally distributed variables. Dichotomous and categorical variables are reported as percentages. All P values are two tailed, and P < 0.05 was considered statistically significant. All analyses were performed using SAS (SAS Institute, Cary, NC).

Results

Baseline Characteristics

From 80 eligible patients who were screened during November 2002, 57 patients were randomly assigned on January 13, 2003 (Figure 2). Overall, 13 patients did not complete the trial because of death (n = 6), transfer to other centers (n = 3), renal transplantation (n = 2), and change in dialysis modality (n = 2) and therefore were not included in the analysis. Forty-four patients completed the study, 22 in each group. Complete home BP measurements were available for 36 patients (19 in standard HD group and 17 in HC group). Patients with >5% of BP readings missing were excluded from the primary end point analysis.

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**Figure 2.** Study population. *Excluded because of anticipated change in renal replacement therapy modality (transfer to nocturnal HD or to peritoneal dialysis), planned renal transplantation, expected transfer (temporary or permanent) to another center, enrollment in another clinical trial, subsequent refusal to participate to the trial, or death.
The study groups were similar in terms of demographic characteristics and presence of hypertension, heart failure, diabetes, and ischemic heart disease (Table 1). SBP and DBP and antihypertensive drug use were also similar. There were no significant differences in the percentage of hypotension-prone patients, use of UF or sodium profiling before the enrollment, dialysate temperature, or dialysate conductivity. The percentage of sessions that required nursing interventions was higher at baseline in the HC group, although this difference was not statistically significant.

**Primary End Point: Control of BP**

Figure 3 shows the mean variations in BP values between baseline and end of study in each treatment group. There was a statistically significant overall decrease in SBP during the study period (two-way ANOVA \( P = 0.005 \)). However, the difference between the HC group and the standard HD group was NS (\( P = 0.27 \)). The interaction effect between time and groups was also NS (\( P = 0.85 \)). Assessment of individual differences showed that BP was significantly lower at the end of the study compared with baseline in the HC group (from 147.8 ± 21.7 to 139.8 ± 16.2 mmHg; \( P = 0.036 \)) but not in the standard HD group (from 141.9 ± 19.2 to 135.2 ± 9.9 mmHg; \( P > 0.05 \)). There was also a statistically significant overall decrease in DBP during the study period (two-way ANOVA \( P = 0.037 \)), but there was no significant difference between the groups. An exploratory analysis of the subpopulation of hypertensive patients (\( n = 23 \)) revealed a significant reduction in SBP over time for both standard HD and HC regimens. Mean SBP in the standard HD group decreased from 150.6 mmHg at baseline to 138.0 mmHg at 6 mo (\( P = 0.003 \). A similar finding was observed in the HC group, with a reduction from 162.5 to 147.6 mmHg (\( P = 0.002 \)).

Antihypertensive medications did not change significantly from baseline to end of study, especially in terms of number of drugs used (HC: from 1.2 ± 0.9 to 1.2 ± 0.9; standard HD: 1.9 ± 1.4 to 1.8 ± 1.4; NS) or number of pills per day (HC: 2.1 ± 1.9 to 2.2 ± 2.0; standard HD: 3.2 ± 2.2 to 3.2 ± 2.6; NS). The correlation between SBP variation and dry weight variation was studied for both groups (\( n = 36 \)) and in the subgroup of hypertensive patients (\( n = 23 \)). However, no significant correlations were observed.

Sodium removal during dialysis in the HC group was 323 ± 170 mmol/L at baseline and 362 ± 127 mmol/L at 6 mo (\( P = 0.22 \)). In the standard HD group, it was 305 ± 168 mmol/L at baseline and 370 ± 193 mmol/L at 6 mo (\( P = 0.06 \)).

### Table 1. Baseline characteristics of the study population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Standard HD</th>
<th>HC</th>
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<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Complete BP Data</td>
</tr>
<tr>
<td><strong>n</strong></td>
<td>22</td>
<td>19</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>65 ± 14.9</td>
<td>65.8 ± 15.6</td>
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<tr>
<td>Gender (M/F)</td>
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<td>8/11</td>
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<tr>
<td>Race (white %)</td>
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<tr>
<td>Body weight (kg)</td>
<td>64.0 ± 14.4</td>
<td>63.5 ± 15.3</td>
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<tr>
<td>HD duration (mo)</td>
<td>54</td>
<td></td>
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<tr>
<td>Diabetes (%)</td>
<td>6 (27)</td>
<td>5 (26)</td>
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<tr>
<td>Hypertension (%)</td>
<td>15 (50)</td>
<td>13 (68)</td>
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<td>Antihypertensives agents (no. of classes)</td>
<td>1.9 ± 1.3</td>
<td>1.9 ± 1.4</td>
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<td>Antihypertensive pills (n/d)</td>
<td>3.3 ± 2.2</td>
<td>3.2 ± 2.2</td>
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<tr>
<td>Heart failure (%)</td>
<td>6 (27)</td>
<td>5 (26)</td>
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<tr>
<td>LVH (%)b</td>
<td>5 (23)</td>
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<tr>
<td>Ischemic heart disease (%)</td>
<td>15 (68)</td>
<td>12 (63)</td>
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<tr>
<td>Mean SBP (mmHg)</td>
<td>141.5 ± 18.1</td>
<td>141.9 ± 19.2</td>
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<td>Mean DBP (mmHg)</td>
<td>80.4 ± 12.4</td>
<td>80.4 ± 12.3</td>
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<td>Hypotension-prone (%)</td>
<td>11 (50)</td>
<td>9 (47)</td>
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<td>Mean interdialytic weight gain (kg)</td>
<td>2.9 ± 1.0</td>
<td>2.8 ± 1.0</td>
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<td>UF modulation (%)</td>
<td>14 (64)</td>
<td>11 (58)</td>
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<tr>
<td>Na⁺ modulation (%)</td>
<td>7 (32)</td>
<td>7 (37)</td>
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<tr>
<td>Dialysate Na⁺ concentration (mmol/L)</td>
<td>140.1 ± 1.9</td>
<td>139.8 ± 1.6</td>
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<tr>
<td>Dialysate temperature (°C)</td>
<td>36.4 ± 0.5</td>
<td>36.2 ± 0.5</td>
</tr>
<tr>
<td>Nursing interventions for IDH (% of HD sessions)</td>
<td>24.6 ± 26.8</td>
<td>22.8 ± 25.6</td>
</tr>
</tbody>
</table>

Data are means ± SD or n (%). DBP, diastolic BP; HC, Hemocontrol; HD, hemodialysis; IDH, intradialytic hypotension; LVH, left ventricular hypertrophy; Na⁺, sodium; SBP, systolic BP; UF, ultrafiltration. All \( P > 0.05 \) for differences between standard HD and HC groups.

bAvailable in 18 patients in the standard HD group and 16 in the HC group.
Secondary End Points

Percentage of Sessions with Nursing Interventions. Figure 4 shows the number of dialysis sessions per patient for which IDH-related nursing interventions were required during the first 2 wk and the last 2 wk of the trial in both the HC and standard HD groups. The percentages (in parentheses) represent the proportions of sessions per patient for which nursing interventions were required over the total number of dialysis sessions during each period of observation (2 wk). *P value for the comparison in the baseline to end of study change in the number of dialysis sessions between the HC group and the standard HD group (using Mann-Whitney U test).

Quality of Life. With the use of the KDQOL-SF questionnaire, quality of life was assessed at 0 and 6 mo (Table 2). A score (on 100) was assessed for every subquestion, higher scores indicating a better quality of life. There was a significant improvement in the burden of kidney disease score in the HC group (from 40.1 ± 30.0 to 45.3 ± 29.4), while there was a deterioration in the standard HD group (from 36.9 ± 27.7 to 30.7 ± 24.3; P = 0.004. for comparing the mean score variation between the two study groups). This difference remained statistically significant after correction for multiple comparisons using a Bonferroni procedure. In addition, after further adjustment for age, gender, ethnicity, percentage of nursing interventions, and pill number, the difference remained statistically significant. There was no other significant variation in quality-of-life items during the study period (Table 2).

Discussion

By improving hemodynamic tolerance during dialysis, the use of the HC system has been suggested to facilitate fluid removal and correction of VO. This randomized, controlled trial was conducted to test the hypothesis that the use of the HC system can improve home BP control in comparison with standard HD as a primary end point.

During the study period, significant improvement in BP control was observed in both study groups. There was an 8-mmHg reduction in SBP in the HC group (from 147.8 ± 21.7 to 139.8 ± 16.2 mmHg) and a 6-mmHg reduction in SBP in the standard HD group (from 141.9 ± 19.2 to 135.2 ± 9.9 mmHg). The difference between the study groups, however, was NS. Several reasons may have contributed to these findings: First, both groups benefited from strict BP management based on an al-
...variables in our study. Several reasons may have contributed to variation with HC. Similarly, in a crossover study of eight patients, Santoro et al. (13) demonstrated an improvement in the predialysis to postdialysis SBP variation with HC. In addition, in a randomized, controlled trial of 36 hypotension-prone patients, Santoro et al. (12) demonstrated an improvement in the predialysis to postdialysis SBP variation with HC. Similarly, in a crossover study of seven patients during 3 mo, Bégin et al. (9) showed an increase in mean postdialysis SBP with HC. In addition, in a randomized, controlled trial of 36 hypotension-prone patients, 30% reduction in IDH events was observed in patients who were treated with HC. However, Wolkotte et al. (13) and Pastore et al. (22) showed no difference between pre- and postdialytic BP. In this study, we used home BP measurements alone, because measurements in HD units have been shown to be systematically unreliable (23-25). In addition, home BP measurements have been shown to be highly correlated to ambulatory BP measurements (26,27).

This randomized, controlled trial clearly demonstrates that BP may be lowered in long-term HD patients when strict attention is given to BP management. The mean overall reduction in SBP during the study period was 7 mmHg. The benefits of such a reduction in BP are important. SBP has been shown to be strongly related to cardiovascular risks in large cohorts of nondialysis patients (18-20). In addition, adequate BP control has been shown to be associated with lower rates of cardiovascular complications in cohorts of HD patients (21).

Several studies on the effects of HC on BP control have been reported (9,12,13,22). However, all were done using BP measured in HD units, and none used ambulatory or home BP measurements, as recommended by several authors (1,23). In a crossover study of eight patients, Santoro et al. (12) demonstrated an improvement in the predialysis to postdialysis SBP variation with HC. Similarly, in a crossover study of seven patients during 3 mo, Bégin et al. (9) showed an increase in mean postdialysis SBP with HC. In addition, in a randomized, controlled trial of 36 hypotension-prone patients, a 30% reduction in IDH events was observed in patients who were treated with HC. However, Wolkotte et al. (13) and Pastore et al. (22) showed no difference between pre- and postdialytic BP. In this study, we used home BP measurements alone, because measurements in HD units have been shown to be systematically unreliable (23-25). In addition, home BP measurements have been shown to be highly correlated to ambulatory BP measurements (26,27).

As previously mentioned, variation in BP did not correlate with body weight variation during the study period. We initially expected to observe a correlation between these two variables in our study. Several reasons may have contributed to this finding: (1) Lack of a consistent definition of dry body weight, (2) lack of a reliable diagnostic tool for dry body weight (variations in lean body mass may have been missed in some patients), (3) temporal lag between body weight change and the BP variation (reported to be as long as several weeks by some
authors) (28), and (4) other factors than volume’s contributing to BP response (e.g., changes in venous refilling pressures, cardiac output, peripheral resistance) (6). However, our study was no different from previous studies with regard to the absence of correlation between dry weight and BP variations. Santoro et al. (12), Bégan et al. (9), and Pastore et al. (22) found no significant correlation between BP and dry weight variations.

The number of HD sessions that required IDH-related nursing interventions significantly decreased in the HC group, showing a 42.9% relative reduction, compared with a 35.7% relative rise in the standard HD group. These findings are consistent with the results of previous studies that have reported a reduction in the use of saline infusion or nursing interventions with HC (9–12). However, none of the previous studies was a randomized, controlled trial, and all included a higher proportion of hypotension-prone patients. Santoro et al. (12) demonstrated in five hypotension-prone patients a lower use of isotonic or hypertonic saline and later confirmed this result in a crossover trial of eight patients. Ronco et al. (10) similarly observed a reduction in hypotensive episodes and saline infusion requirement in 12 hypotension-prone patients in a crossover study.

There was a significant improvement in the quality of life in the HC group during the course of this study. This improvement in the KDQOL-SF burden of disease score was observed in the HC group, whereas there was deterioration in the standard HD group. This result remained significant despite adjustment for age, gender, ethnicity, hypotension, treatment group, nursing intervention numbers, and pill numbers. Such an improvement in quality in life is consistent with results that were obtained from other studies with HC that were concerned about HD symptoms. Santoro et al. (12) reported a significant reduction in overall incidence of complaints in the HC group, especially for muscular cramps. Basile et al. (29) showed, in a self-evaluation of HD symptoms, a statistically significant difference in post-HD asthenia with HC. However, neither study used standardized validated questionnaires as was the case in this trial.

Our results were not explained by variations in the number or dosage of antihypertensive drugs, variations in erythropoietin dosage, or differences in dialysate composition and temperature. Throughout the study, there were no significant differences between the two arms of the trial with regard to these factors. However, seasonal variation in BP may have contributed to our findings. Higher temperatures and low humidity are linked with better BP control in patients who are on HD (30). In Montreal, January presents the lowest temperatures and July present the highest, so part of the reduction in BP during the trial may be related to seasonal variations. However, a recent study on this topic found an absence of seasonal variation in BP in a Canadian cohort of dialysis patients (31), although that report was based on predialysis BP rather than home BP measurements.

Some limitations of our data merit consideration. First, the small sample size and the short study duration may have prevented the study from detecting a significant difference between the HC group and the standard HD group with regard to BP control. A priori, the study was sufficiently powered to detect an 8-mmHg difference in BP; therefore, smaller differences in BP may have been missed. Second, neither the staff nor the patients were blinded to the study interventions. Blinding was technically impossible to perform because the HC monitors look relatively different compared with standard HD monitors. The absence of double-blind evaluation could have influenced our assessment of intradialytic symptoms, requirement for nursing interventions, and quality of life. However, the impact on BP measurement was probably minimal. Third, our primary end point was based on BP measurements that were obtained from patients who recorded their home BP results; we relied on data that were collected by study participants rather than by research nurses. However, all patients were provided with a calibrated automatic BP monitor and received standardized training. In addition, in a recent study, home BP measurements were found to be reliable to estimate systolic hypertension when compared with ambulatory BP measurements (27). Finally, dry weight assessment was done by study physicians on the basis of clinical evaluation. An objective technique, such as bioimpedance, could have yielded more objective results, but such techniques are not used routinely in clinical practice.

Conclusion

The addition of the HC system to a systematic BP management protocol provides no additional benefit over that of standard HD with regard to BP reduction. However, it does improve the tolerability to dialysis by reducing nursing interventions during HD and improving the burden of kidney disease for dialysis patients. This randomized, controlled trial clearly demonstrates that improved control of BP is possible in long-term HD patients with systematic BP management.

Acknowledgments

We thank Gambro Canada for providing financial support for this study. F.M. is a scholar of the Fonds de la recherche en santé du Québec.

Preliminary results of this work were presented at the annual meeting of the American Society of Nephrology; October 29 through November 1, 2004; St. Louis, MO; and have been published in abstract form (J Am Soc Nephrol 15: 47A, 594A, 2004).

We thank Aurélie Valleeau and Melanie Kerangueuen for the analysis of statistical data.

Disclosures

None.

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