ORIGINAL ARTICLE

EFFECT OF SODIUM BICARBONATE SUPPLEMENTATION ON IMPROVING NUTRITIONAL STATUS AMONGST PATIENTS ON MAINTENANCE HAEMODIALYSIS

Muhammad Iqbal✉, Abdul Rehman Arshad, Nauman Karim, Muttahar Abbas, Muhammad Sulman, Sohail Sabir

Pak Emirates Military Hospital Rawalpindi-Pakistan

Background: Patients undergoing maintenance haemodialysis for end stage renal disease are frequently frail and malnourished due to various metabolic and uremic insults. This study was conducted to determine effect of sodium bicarbonate supplementation on nutritional status of patients on maintenance haemodialysis. **Methods:** This clinical trial was carried out at dialysis unit of Pak Emirates Military Hospital Rawalpindi on adult haemodialysis patients with serum bicarbonate <23 mmol/L. Patients with active infections, haemodialysis for less than 6 months, limb amputation, and those on sodium bicarbonate therapy were excluded. They were randomized to receive sodium bicarbonate 600 mg three times a day in addition to usual care, or usual care alone. Anthropometric data including weight, hand grip strength, mid-arm circumference, triceps skin fold thickness, and laboratory parameters were compared amongst the two groups at baseline and after 3 months. Changes in these parameters were also compared amongst the two groups. **Results:** There were 32 patients, mean age of 51.38±16.37 years. There was significant increase in dry weight (1.76±1.59 vs -0.31±1.81 kg), hand grip strength (2.37±2.80 kg vs -0.97±3.39 kg), mid arm circumference (1.14±1.26 vs -1.12±1.05 cm), haemoglobin (1.02±1.57 vs -0.16±1.38 g/dL), serum albumin (3.37±2.75 vs -2.00±1.50 g/L) and bicarbonate (7.98±3.38 vs -1.44±2.46 mmol/L) in the intervention arm as compared with the control group, respectively. Triceps skinfold thickness fell in both arms, and to a greater extent in the intervention arm (-1.20±1.10 vs -0.19±1.58 mm). A greater proportion of patients who received bicarbonate therapy had elevation in blood pressure as compared to the control group (68.75% vs 25.00%). **Conclusion:** Sodium bicarbonate supplementation significantly improved the nutritional status of patients on maintenance haemodialysis.

Keywords: Biomarkers; End stage renal disease; Metabolic acidosis; Nutritional status; Pakistan; Renal dialysis

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INTRODUCTION

Chronic kidney disease (CKD) is on a rising trend in Pakistani population, with a prevalence of 21.2% reported in recent literature.[1] End stage renal disease (ESRD) is associated with a few inherent metabolic complications including, but not limited to, metabolic acidosis (MetA) and malnutrition. MetA is characterized by bicarbonate levels <22 mmol/L along with pH less than 7.35.[2] It impacts the nutritional status of patients with ESRD. There is an alteration in ubiquitin – proteasome pathway leading to inhibition of muscle growth, increased insulin resistance and downregulation of albumin synthesis.[3] It also decreases skeletal muscle mass by inducing proteolysis, decrease in appetite, inflammation and electrolyte imbalance.[4] Correction of MetA has been studied to bring an improvement in health as correction of MetA not only downregulates proteolysis but also decreases all-cause mortality and improves nutritional status of the patients.[5]

Patients undergoing maintenance HD for ESRD are frequently frail and malnourished. Previously published local data shows that two out of three such patients have frailty, and one in four have malnutrition.[6,7] The link between malnutrition and poor outcomes in HD is well established as decline in nutritional status is linked to an increased morbidity and mortality as well as impaired health related quality of life.[8] Assessment and management of nutritional status is thus an important component of care for such patients. In addition to MetA, the uremic milieu, poor appetite, dietary restrictions imposed by physicians, recurrent infections, and protein loss during HD play a contributory role.

Correction of high anion gap metabolic acidosis provides an excellent opportunity to uplift the nutritional status in ESRD. Serum bicarbonate levels <22 mmol/L and >26 mmol/L are also associated with increased morbidity and mortality, thus providing a very narrow therapeutic window.[9] Yenchek, *et al* have previously shown that even after accounting for the existence of CKD, individuals with a baseline serum bicarbonate

concentration <23 mmol/l were 1.6 times more likely to experience a functional limitation than those with a value of at least 26 mmol/l.[10] During a HD session, serum bicarbonate levels are replenished as bicarbonate diffuses from the dialysate into the blood compartment, but during the intradialytic period, MetA ensues and brings into action the associated deleterious effects on muscle mass. There is inconsistent data about the effect of MetA on muscular strength as few researchers have seen benefits, while others have not.[11,12]

A meta-analysis by Cheng *et al* incorporating data on 1853 patients showed that sodium bicarbonate supplementation did not improve anthropometric nutritional parameters.[13] On the contrary, another meta-analysis by Visser, *et al* including 1995 patients showed that sodium bicarbonate supplementation improves muscle mass in ESRD.[14] Taking into account the inconsistency in available literature, we planned this study to evaluate the effect of sodium bicarbonate supplementation on clinical and laboratory markers of nutritional status in patients undergoing maintenance haemodialysis. The results of this study will help us provide better nutritional care to such patients.

MATERIAL AND METHODS

This open label randomized clinical trial was conducted at Haemodialysis Unit of Pak Emirates Military Hospital Rawalpindi after approval of Institutional Ethical Board vide certificate no. A/28/ERC/624/23. The trial protocol was registered with the Iranian Registry of Clinical Trials (IRCT registration number IRCT20240208060941N2). Sample size calculation was based on assumption that the mean increase in serum albumin would be 40.11±2.85 g/L in patients given sodium bicarbonate and 36.96±3.52 g/L in the control arm respectively, as reported by Lamsal.[15] The sample size was calculated to be 34 i.e. 17 in each arm. For this purpose, we used the Epitools sample size calculator with a two-tailed test, power set at 80% and a significance level of 5%. Patients were enrolled from the HD unit using convenience sampling after assessing for inclusion and exclusion criteria. Individuals of either gender having >18 years of age, on maintenance haemodialysis for more than 6 months, able to comply with study instructions and having serum bicarbonate levels <23 mmol/L were included in the study. Individuals having active infection, unstable heart disease, congestive heart failure, poorly controlled blood pressure, limb amputation, dementia, cerebrovascular disease, and hepatic impairment were excluded from the study. Moreover, patients on bisphosphonate therapy, calcium or sodium bicarbonate replacement therapy, and conditions like malignancies that could impair sodium bicarbonate metabolism were also excluded.

All patients provided written consent. Using online computer-generated sequences, patients were randomly allocated to intervention and control groups in a 1:1 ratio. Clinical data including age, gender, known comorbid conditions, cause of ESRD and haemodialysis prescription details were noted. Baseline biochemical profile including haemoglobin, serum creatinine and urea, electrolytes and albumin were recorded. Blood gas analysis was also done on venous blood samples to check for pH and bicarbonate levels. Patients in the intervention arm were given oral sodium bicarbonate 600mg three times a day in addition to their usual/ routine medications, whereas those in the control arm received just the routine medications and care. Biochemical analysis done at baseline was repeated at the end of 3 months. Apart from serum albumin levels, we also used anthropometric parameters as marker of nutritional status. Baseline body weight was recorded as first post-dialysis weight. During the first dialysis session, best of three readings of hand grip strength as measured by a dynamometer (Camry digital hand dynamometer, EH101, USA) was noted. Triceps skinfold thickness (TSFT) and mid arm circumference (MAC) were measured at mid of distance between olecranon of ulna and acromion of shoulder girdle respectively using triceps skinfold thickness calliper (XTDGN Skinfold Body Fat Calliper, China) and non-stretchable measuring tape. All these measurements were repeated at the end of study period as well. Throughout the study period, patients' blood pressure was monitored before the start of dialysis sessions to note any rise above usual values. Side effects to sodium bicarbonate (including headache, bloating, abdominal pain) were enquired from the patients on a weekly basis. Need for urgent extra haemodialysis sessions because of fluid overload was also monitored.

Statistical analysis was done using Statistical Package for Social Sciences version 25.0. Continuous variables were described as mean± standard deviation, and they were compared amongst two groups using independent samples t-test. Frequencies/ percentages were used for categorical variables and they were compared amongst two groups using Chi square test/ Fisher's exact test. The *p*-value ≤0.05 was taken as significant

RESULTS

Thirty-two patients, with a mean age of 51.38±16.37 years, were included in the study. The flow of participant through various stages of this study, as per CONSORT statement, is shown in Figure-1. Baseline characteristics are reflected in Table-1. The two groups were comparable with respect to age, gender, cause of end-stage renal disease, dialysis frequency and height. Baseline dry weight was, however, significantly lower in the sodium bicarbonate group than in the control group (56.00±7.46 vs 66.37±10.89 kg; p=0.004; Table-2), and this imbalance should be borne in mind when interpreting the subsequent change in dry weight.

There was no significant difference in the blood pressure changes over the three-month period amongst the two groups (p=0.188 and p=0.376). However, the clinical and laboratory parameters reflecting nutritional status improved to a greater extent amongst patients who received sodium bicarbonate replacement therapy. Details are shown in Table-2.

A greater proportion of patients in the intervention group had a rise in blood pressure significant enough to require up titration of antihypertensive medications (68.75% vs 25.00%; p=0.033). There was no difference in the incidence of fluid overload or other side effects amongst the two groups, as shown in Table-3. None of the patients died during this study period.

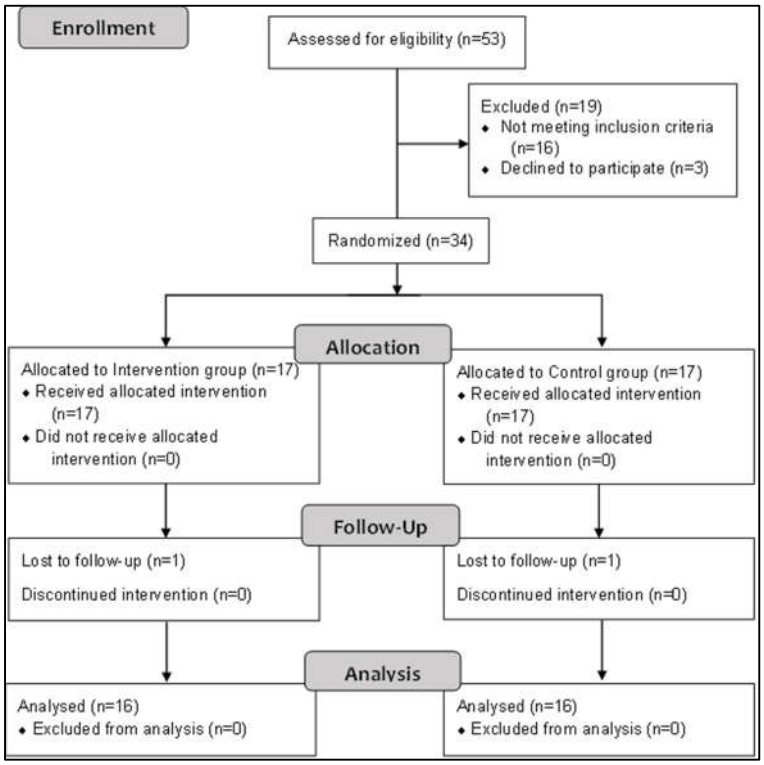

Figure-1: Flow of participants (CONSORT Statement)

Table-1: Baseline characteristics

Variable	**Total** (n=32)	**Sodium bicarbonate group** (n=16)	**Control group** (n=16)	**p**
Age (years)	51.38± 16.37	46.06±15.96	56.69±15.47	0.065
Gender				1.000
• Male	21 (65.63%)	11(68.75%)	10(62.50%)	
• Female	11 (34.37%)	5(31.25%)	6(37.50%)	
Cause of ESRD				0.334
• HTN	5 (15.63%)	2(12.50%)	3 (18.75%)	
• DM	16 (50.0%)	6(37.50%)	10(62.50%)	
• GN	4 (12.50%)	2(12.50%)	2(12.50%)	
• Nephrolithiasis	3 (9.38%)	3(18.75%)	-	
• Others	4 (12.50%)	3(18.75%)	1(6.25%)	
ESRD Frequency (sessions/ week)				0.156
• Twice weekly dialysis	17 (53.13%)	6 (37.50%)	11(68.75%)	
• Thrice weekly dialysis	15 (46.9%)	10(62.50%)	5(31.25%)	
Height (inches)	67.63±2.51	67.69±2.60	67.56±2.50	0.886
ESRD Duration (months)	51.69 (12.0-74.75)	57.44 (14.00-69.25)	45.94 (12.0-82.0)	0.560*

HTN: hypertension, DM: Diabetes Mellitus, GN: Glomerulonephritis, ESRD: End Stage Renal Disease. Continuous variables compared using the independent samples t-test; categorical variables using Fisher's exact test, as expected cell counts were below five throughout. *ESRD duration is summarised as median (interquartile range) and was compared using the Mann-Whitney U test.

Table-2: Details of clinical and anthropometric measures in participants

Variable	Timeline	Sodium bicarbonate group	Control group	*p*
Dry Weight (kg)	Baseline	56.00±7.46	66.37±10.89	0.004
	12 weeks	57.76±7.36	66.06±10.28	0.014
	Change	1.76±1.59	-0.31±1.81	0.002
Mid arm circumference (cm)	Baseline	22.61±2.85	25.06±3.98	0.055
	12 weeks	23.75±2.91	23.94±3.52	0.867
	Change	1.14±1.26	-1.12±1.05	<0.001
Hand grip strength (kg)	Baseline	25.39±9.83	20.81±4.81	0.105
	12 weeks	27.76±9.75	19.84±6.53	0.012
	Change	2.37±2.80	-0.97±3.39	0.005
Triceps skinfold thickness (mm)	Baseline	43.481±5.36	44.45±4.35	0.579
	12 weeks	42.28±5.26	44.26±5.09	0.288
	Change	-1.20±1.1	-0.19±1.58	0.046
Systolic blood pressure (mmHg)	Baseline	139.69±23.19	137.19±15.16	0.721
	12 weeks	152.19±17.03	140.94±23.32	0.131
	Change	12.50±15.60	3.75±20.69	0.188
Diastolic blood pressure (mmHg)	Baseline	80.0±10.0	78.75±11.90	0.750
	12 weeks	89.38±10.46	84.38±11.09	0.200
	Change	9.37±11.81	5.62±11.81	0.376
Haemoglobin (g/dL)	Baseline	10.03±1.75	9.76±1.45	0.656
	12 weeks	11.04±1.19	9.61±1.27	0.003
	Change	1.02±1.57	-0.16±1.38	0.032
Serum albumin (g/L)	Baseline	31.25±4.40	32.69±3.36	0.308
	12 weeks	34.63±2.68	30.69±2.80	<0.001
	Change	3.37±2.75	-2.00±1.50	<0.001
Serum bicarbonate (mmol/L)	Baseline	18.00±3.08	19.79±2.14	0.068
	12 weeks	25.99±1.42	18.36±2.17	<0.001
	Change	7.98±3.38	-1.44±2.46	<0.001

Table-3: Adverse events

Variable	Sodium bicarbonate group	Control group	*p*
Rise in blood pressure	11 (68.75%)	4 (25.00%)	0.033
Headache	5 (31.25%)	3 (18.75%)	0.685
Abdominal pain	7 (43.75%)	3 (18.75%)	0.252
Bloating	6 (37.50%)	2 (12.50%)	0.220
Extra dialysis session for fluid overload	4 (25.00%)	4 (25.00%)	1.000

DISCUSSION

This study has shown that sodium bicarbonate replacement improves the nutritional status in ESRD. Our patients had an increase in dry weight, mid arm circumference and hand grip strength; triceps skinfold thickness declined in both arms. Similarly, biochemical markers including haemoglobin and serum albumin showed augmentation in the intervention group while same was not observed in control group. These advantages came at the cost of an increase in blood pressure, as a greater proportion of patients in the intervention arm required adjustment of antihypertensive medicines (68.75% vs 25.00; p=0.033). However, no surge in the incidence of fluid retention leading to overload was noted.

Data published by Melamed *et al* and Szczecińska *et al* didn't find any significant change in blood pressure after sodium bicarbonate supplementation, contrary to our findings.[2,16] A high sodium intake has long been associated with the development of hypertension, principally through sodium retention and expansion of the extracellular fluid volume, and this is the basis for restricting salt intake in hypertensive patients. Though at the end of study period, the change in mean blood pressure was the same in both groups, prescription adjustment was required in a greater proportion of patients requiring sodium bicarbonate supplements. The statistically insignificant results in the end just reflect good timely management of blood pressure in affected patients.

In our study, there was a significant change in dry body weight amongst the two groups, with patients receiving sodium bicarbonate gaining weight, and those receiving standard treatment alone actually losing a little bit. In a study by Jeong *et al* from Korea, alkali therapy given for a period of 12 months improved nutritional status and body weight amongst patients with CKD- 5, similar to what our study has demonstrated.[17] However, this effect was not seen in patients with CKD-4. Despite gaining weight, fluid overload and the need for urgent HD was not greater in these patients, reflecting the slow increase in muscle mass and thus the body weight. In contrast, a meta-analysis of 17 studies involving 2203 patients revealed that sodium bicarbonate supplementation did not have any effect on body weight.[11]

Amongst patients receiving sodium bicarbonate, serum albumin levels increased over the study period, in contrast to those getting routine treatment only. Various studies published previously found an improvement in serum albumin levels after correction of acidosis and sodium bicarbonate supplementation, while others did not.[2,12,17–19] Serum albumin has been widely studied marker of nutritional assessment and levels tend to change in inflammation and chronic disease, i.e., CKD and chronic liver disease. Moreover, MetA in CKD also has detrimental and catabolic effects on protein synthesis and metabolism. This variation among the studies might be due to difference in baseline health status (BMI), patients' characteristics, duration of ESRD, use of different dialyzer flux, and length of study.

In our study, haemoglobin levels gradually increased amongst the patients in sodium bicarbonate group, a phenomenon not seen in patients receiving standard care alone. This is in conformity with a study done by Szczecińska *et al*.[2] Amongst 18 patients from Poland, having CKD 3-5, sodium bicarbonate replacement increased haemoglobin levels from 10.2±2.0 to 11.00±1.7 g/dL over a 3-month period. The rise in haemoglobin can be attributed to correction of underlying MetA, as it increases the serum levels of total proteins and albumin. Moreover, it was found that acidosis and hyperphosphatemia are associated with increased erythropoietin stimulating agent requirements. It can be inferred that correcting acidosis might result in improved outcomes with respect to haemoglobin levels. Contrasting results have been reported by Ori *et al*.[20] Amongst 13 patients with CKD 4-5 receiving sodium bicarbonate for one month, haemoglobin levels did not change. The authors have not provided an explanation for this. However, the relation between malnutrition and acidosis is well established. The acidosis has been found to be associated with increased protein catabolism, reduced assimilation, endocrine abnormalities and inflammation.[21] The cumulative effect of these factors contributes to decreased protein synthesis and ultimately malnutrition.

Previously conducted research has given variable results regarding the effect of correction of metabolic acidosis on muscle bulk. In a systematic review comprising 14 studies with 1398 patients, Navaneethan *et al* showed low to moderate degree of evidence for an improvement in muscle strength, though at the cost of greater requirement of antihypertensive medications.[22] In a study done by Kittiskulnam *et al* on 42 patients, higher serum bicarbonate levels were associated with a greater improvement in whole body muscle mass and appendicular lean balance.[23] On the other hand, Casarin *et al* showed that bicarbonate replacement improves muscle strength but not the lean muscle mass or mid-arm circumference.[24] The effective correction of MetA leads to improvement in muscle strength and anthropometric measures. Moreover, the pre-dialysis low serum bicarbonate levels (as in MetA) were found to be associated with decreased muscle strength and higher mortality.

This study has several limitations. Despite randomisation, baseline dry weight was significantly lower in the intervention arm, and with only sixteen patients per group such imbalance is not unexpected; the gain in dry weight in that arm may therefore partly reflect regression towards the mean rather than treatment effect alone. Being a single-centre study, the results generated during the follow-up of participants cannot be generalized and extrapolated to other setups. In addition, we did not have any placebo formulations to be used in the control arm. Thus, bias due to absence of masking cannot be completely excluded. Urinary sodium was not measured, so an assessment of dietary compliance and a picture of sodium balance in the body was not possible. The question addressed in this study has been under-investigated in regional healthcare setups, and we would suggest further multi-centre trials with titration and different sodium bicarbonate dosage regimens based on periodic evaluation of serum bicarbonate levels.

CONCLUSION

Sodium bicarbonate supplementation markedly improved both anthropometric and biochemical parameters reflecting nutritional status.

AUTHORS' CONTRIBUTION

MI: Conception and design of the work; acquisition of data; Drafting the work and revising it critically. AR: Design of the work; the analysis of data; revising it. NK: Design of the work; data analysis; revising it critically. MA: design of the work; data analysis revising it critically for important intellectual content. MS: Study design; the acquisition and interpretation of data; manuscript drafting. SS: conception and design of the work; acquisition of data; draft and critical review.

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Address for Correspondence:

Dr. Muhammad Iqbal, Pak Emirates Military Hospital Rawalpindi-Pakistan
Cell: +92 342 700 7463
Email: iqbalkharal2934@gmail.com