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Effect of Oral Sodium Bicarbonate in Maintaining Acid Base Balance and Qol in Chronic Kidney Disease and Long-Term Acidosis 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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Original Research Article

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ABSTRACT

AIM: Aim of the study is to determine the effect of oral sodium bicarbonate in maintaining acid base balance and quality of life in chronic kidney disease and long-term acidosis patients.
Study Design: A prospective observational study.
Study Population: Approximately 174 people who came to nephrology department, Selected based upon inclusion and exclusion criteria.
Study Criteria / Patient Enrollment: Patients are enrolled in study based on inclusion and exclusion criteria.
Inclusion Criteria: The patients who are diagnosed with CKD and receiving oral sodium bicarbonate as part of treatment
Exclusion Criteria: the patients who are having other comorbidities, hypertension, diabetes, and other cardiovascular problems who are not given with oral sodium bicarbonate.
Study Duration : 6 months (December 2021- May 2022).

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Methodology: A prospective observational study on effect of oral sodium bicarbonate in maintaining acid base balance and quality of life in chronic kidney disease and long term acidosis patient's which was carried out in the Department of nephrology.
Results: Most of the patients are in between the age of 70-80 years, married, with good nutritional status, with minimum 5 months of CKD, approximately 50%of the patients are suffering from HTN along with CKD followed by diabetes. Patients are using OSB for a minimum of 5 months with 500mg dose given thrice a day, along with Calcium channel blockers and pantoprazole. OSB is given as a oral tablet.
Conclusion: Oral bicarbonate is widely used to correct acidosis in advanced CKD, this is not underpinned by trial evidence, and real uncertainty exists regarding the balance of benefit and risk for this intervention. That we concluded that most of the patients using OSB was analyzed from nephrology department in QOL, in maintaining acid-base balance was observed in CKD patients.

Keywords: Chronic kidney disease; metabolic disease; oral sodium bicarbonate; quality of life.

ABBREVATIONS

OSB : Oral Sodium Bicarbonate
QOL : Quality of life
CKD : Chronic Kidney Disease
GFR : Glomerular Filtration Rate
AKI : Acute Renal Failure
CHF : Congestive Heart Failure
GIF : Gastro Intestinal Tract
BUN : Blood Urea Nitrogen
ACE : Angiotensin Converting Enzyme
PT : Prothrombin Time
FDA : Food and Drug Administration
ESRD : End Stage Renal Disease
WHO : World Health organization
VA : Alveolar Ventilation
COPD : Chronic Obstructive Pulmonary Disease
ABG : Arterial Blood Gas
CO : Carbon monoxide
OHS : Obesity Hypoventilation Syndrome
DCMP : Dilated cardiomyopathy

1. INTRODUCTION

Chronic kidney disease (CKD) is the progressive, irreversible decreasing of renal function. Which is resulting from long standing disease, CKD sometimes derives from AKI that does not respond to treatment. [1,2] In a clinical study in patients suffering with CKD (circle 15-30ml/min/1.73(2)), sodium bicarbonate 600mg orally 3 times a day were administered to preserve renal function. Serum bicarbonate was adjusted as needed to maintain serum bicarbonate levels of at least 23mmol per liter Decreased pH due to HCO3 – reduction is known as metabolic acidosis [3,4].

Bicarbonate deficit – blood concentration of bicarbonate decreases from 22mEq/L. Oral sodium bicarbonate is used in treating metabolic acidosis in patients suffering with CKD [5].

2. ORAL SODIUM BICARBONATE [5]

2.1 Dose

2.1.1 General dosing information

178mg of sodium per tablet effervescent contains 770mg of sodium per capful Neonates and children younger than 2 years, limit rate of administration because rapid injection (10ml/min) may produce hypernatremia.

2.1.2 Metabolic acidosis chronic

Initial,600mg orally 3times daily, increase to maintain serum bicarbonate level at 23mmol/liter or greater.

2.1.3 Uses

Diarrhea severe
Indigestion
Metabolic acidosis chronic
Toxicity of drug
Cardiac arrest due to hyperkalemia
Injection site pain -rocuronium adverse reaction

2.2 Dosing Adjustments

2.2.1 Oral route

2.2.1.1 Metabolic acidosis (chronic)

In a clinical study in patients suffering with CKD (circle 15-30ml/min/1.73(2)), sodium bicarbonate 600mg orally 3 times a day were administered to preserve renal function. Serum bicarbonate was adjusted as needed to maintain serum bicarbonate levels of at least 23mmol per liter.

2.2.2 Sodium content

The sodium bicarbonate tablet contains 178 mg of sodium per tablet.

2.2.3 Administration

If the dosage is in the form of powder, then dissolve in one half glass of cool water, take while effervescing.

2.2.4 Contraindications

- Chloride loss, by vomiting or from continuous gastrointestinal suction.
- Concomitant use with diuretics that produce hypochloremia alkalosis.

2.2.5 Precautions

- Elderly, dose adjustment recommended.
- Metabolic acidosis associated shock monitoring recommended.
- Potassium depletion increased risk of metabolic alkalosis.
- Renal impairment, sodium retention may occur.
- Sodium restricted diet, use not recommended unless advised by physician.
- Anuria or oliguria, increased risk for excessive sodium retention.

2.2.6 Adverse effects

2.2.6.1 Cardiovascular effects

- Decreased cardiac output
- Hypotension
- Injury of vein

2.2.6.2 Dermatological effects

- Cellulitis
- Injection site extravasation
- Skin ulcer
- Tissue necrosis
- Vascular calcification

2.2.6.3 Endocrine metabolic effects

Metabolic alkalosis

2.2.7 Drug interactions

- Acalabrutinib
- Amphetamine
- Aspirin
- Atazanavir
- Benzenediamine
- Bosutinib
- Cabotegravir
- Cefpodoximeproxetil
- Chloroquine
- Chlorpropamide
- Coltronics acid
- Cysteamine • Masitinib
- Deflazacort
- Dextroamphetamine
- Digoxin
- Erdafitinib
- Erlotinib
- Flecainide
- Gefitinib
- Hydroxychloroquine
- Iron
- Itraconazole
- Ketoconazole
- Ledipasvir
- Lisdexamfetamine
- Lithium
- Mecamylamine
- Mefenamic acid Memantine
- Mepenzolate
- Methamphetamine
- Neratinib
- Octreotide
- Pazopanib
- Ponatinib
- Pseudoephedrine
- Rifampin
- Sotorasib
- Selpercatinib
- Sulpiride
- Tetracycline
- Velpatasvir

2.3 Pregnancy and Lactation

2.3.1 Teratogenicity/effects in pregnancy

Crosses placenta –unknown

Frequent use of this drug as an antacid may result in metabolic alkalosis and fluid overload in both mother and fetus injection or infusion of sodium bicarbonate has been used to treat fetal hypoxic stress [6-9], fetal acidosis to prevent metabolic acidosis [10-13] during labor and to improve acid base balance in normal full-term infants.

2.3.2 Breast feeding

World health organization: compatible with breast feeding.

Infant risk is minimal. Except consensus suggests this rug poses minimal risk to the infant

when used during breast feeding.

The WHO considers sodium bicarbonate to be compatible with breast feeding:

No reports describing the use of sodium bicarbonate during human lactation or measuring the amount, if any of the drug excreted into milk have been located.

2.4 Monitoring Effects of Sodium Bicarbonate A. Therapeutic

2.4.1 Laboratory parameters

- Blood ph.
- Arterial blood gases
- Total co2
- Urinary Ph
- CLINICAL:
- Correction of acidosis
- Increase in renal clearance of acidic drugs /chemicals
- Bowel evacuation

2.4.2 Toxic parameters

2.4.2.1 Laboratory parameters

- Blood pH
- Arterial blood pH
- Total co2
- Serum electrolytes
- Serum osmolality
- Blood glucose
- Renal function
- Urinary chloride
- EKG
- CLINICAL:
- Nausea, vomiting, weakness
- Blood pressure.

2.5 Mechanism of Action Systemic Alkaliser

Increase the plasma bicarbonate, buffers excess hydrogen ion concentration, and raises blood ph. thereby reversing the clinical manifestations of acidosis:

- Alkalizer
- Urinary

Increases the excretion of free bicarbonate ions in urine, thus effectively raising the urinary ph. by maintaining an alkaline urine, the actual dissolution of uric acid stones may be accomplished

3. MATERIALS AND METHODS

Sodium Bicarbonate In Maintaining Acid Base Balance And Quality Of Life In Chronic Kidney Disease And Long Term Acidosis Patient's which was carried out in the Department of nephrology.

3.1 Study Design

A prospective observational study.

3.2 Place of Study

A prospective observational study on Effect Of Oral Sodium Bicarbonate In Maintaining Acid Base Balance And Quality Of Life In Chronic Kidney Disease And Long Term Acidosis Patient's which was carried out in the Department of nephrology.

3.3 Study Population

Approximately 174 people who came to nephrology department.

3.4 Study Criteria / Patient Enrollment

Patients are enrolled in study based on inclusion and exclusion criteria.

3.4.1 Inclusion criteria

The patients who are diagnosed with CKD and receiving oral sodium bicarbonate as part of treatment.

3.4.2 Exclusion criteria

The patients who are having other comorbidities, hypertension, diabetes, and other cardiovascular problems who are not given with oral sodium bicarbonate.

3.5 Study Materials

A. Patient informed consent form
B. A specially designed patient data collection proforma.

3.6 Study Method

This study will be initiated after obtaining the permission from the institutional review board. the patients will be enrolled in study after taking informed consent from them, the enrolment of patient will be done on basis of inclusion and exclusion criteria.

The data for the present will be collected by graph pad prism, which is well-suited to identify all necessary baseline information, which includes

Patient demographics like

3.7 Study Procedure

- Age
- Socio economic status
- Educational status
- High risk factors
- Past and present history
- Laboratory data
- Radiographic data
- Physiscian medication order form
- NURSE'S medication administration record (drug chart) and any other verbal communication data

1.Analytical epidemiologic studies are most useful for testing a hypothesized association between human exposure and health effects. Analytic study design includes prospective studies.

A prospective observational study was conducted for six months of duration in the Nephrology Department.

Based on inclusion and exclusion criteria the CKD patients receiving oral sodium bicarbonate were recruited in the study.

The data was collected from graph pad prism and personal (patient representative /and patient). Interviews, by using a well – structured.

Patient data collection proforma and followed up.

All the necessary and relevant baseline information was collected on patient data collection proforma which includes:

- Patient demographic details such as age, gender, personal history, habits, and employment status.
- Past medication history.
- Past medical history.
- Present medication.
- Risk factors (modifiable and non-modifiable).

The collected and documented data was analyzed based on following parameters.

1. Patient distribution based on demographic data:
    - Patient distribution based on age
    - Patient distribution based on gender
    - Patient distribution based on personal history and social habits.
2. Patient distribution based on risk factors
3. Patient distribution based on drug regimen.
4. Patient distribution based on stage of CKD.

3.8 Statistical Analysis

The Percentage method was used to analyses the patient distribution based on various parameters.
T-test will be performed to calculate p-value for the purpose of comparison of results.

The main data was collected from the patients using the questionnaire which was specially designed based on WHO and other health care organizations regulations. Demographics of patient

Details:-

NAME:	AGE:-	SEX:-	IP.NO:-	WEIGHT:-
BLOOD GROUP:-	OCCUPATION:-		DIAGNOSIS:-	
Present illness: -		Personal history: -		
Smoking(Y/N) :-		Personal history: -		
Comorbid conditions: -		Hypertension(Y/N):-		
Diabetes mellitus:(Y/N) :-		Others:		

Vitals:-

BP:-	Temperature:-	Pulse:-	Respiratory rate:-

Labaratory Reports:-

Kidney function tests	
Test	**Value**
Serum urea	
Serum albumin	
creatinine	
Serum uric acid	
Serum Electrolytes	
Sodium	
calcium	
potassium	
chlorides	
phosphate	
Complete Hemogram	
Hemoglobin	
Rbc total	
ESR	
MCH	
MCV	
PCV	
MCHC	
RDW	
Routine Urine Examination	
Physical appearance	
colour	
Specific gravity	
Analytes	
Protein	
glucose	
ketones	
bilirubin	
urobilinogen	
Microscopy	
RBC	
Pus cells	
Epithelial cells	
ACR	
casts	
24 Hour UreaProtein	

Assessment parameters of metabolic acidosis

Arterial blood gas	
PaCo2	
PaO2	
bicarbonate	
Anion gap	
Sodium Bicarbonate	
Dose per day:	
Dosage form:	
Number of doses/days:	
Frequency :	
Duration of therapy:	
Any ADRS Observed:	
Any interactions found:	
Dialysis Information	
No of times in a week:	
Duration of each dialysis :	
Type of dialysis performed:	
Drugs used during session:	

Drug	Brand	Dose	ROA	Frequency

Measurement of Qol of Patients: The QOL of the patients was measured or estimated based on the following factors

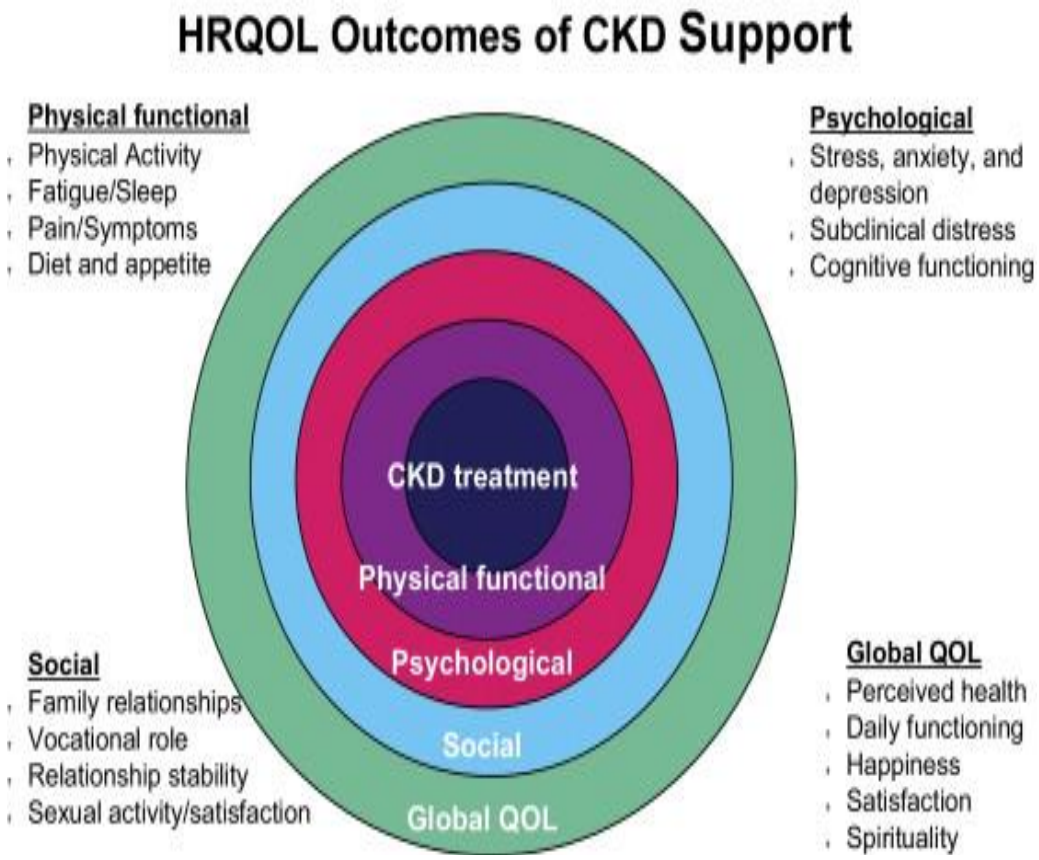

Fig. 1

3.9 Treatment Regimen

3.9.1 Chronic kidney disease patient questionnaire

You have most likely been referred to this clinic by a health care professional or yourself to address concerns about impaired kidney function. This is a short questionnaire designed to help your doctor fully evaluate and manage your kidney health.

Section I: Kidney Disease

1. Have you ever been told you have kidney disease? Y / N (If no, skip to next section)
2. How long has it been since you were first diagnosed? (Circle one) < 1 year / 1-3 years / 3-5 years / 5-10 years / > 10 years
3. How was this diagnosed? (Check those that apply)Blood test (elevated creatinine)

   Protein in the urine

   Other: _____

4. Have you been told what caused your kidney disease (e.g. diabetes, high blood pressure, glomerulonephritis, kidney stones, medication, related to surgery or severemedical illness)

Have you ever had any of the following (Checkifyes):

Kidney problems at birth or in childhood?Hospitalization due to kidney failure?
Kidney failure while hospitalized for another reason?Kidney stones?

Bladder or kidney infections? Difficulty emptying your bladder? Bladder or other urologic surgery? Radiation to the abdomen or pelvis?Chemotherapy for cancer?
Family history of kidney disease?Blood in the urine?
Foamyurine?

If you answered yes to any of the above, please enter more details here:

Section II: Medications

1. Do you use regularly pain or antiinflammatory medicines or NSAIDS (i.e. Aleve, naproxen, ibuprofen, Motrin)? Y / N
    a. If yes, how often? at least daily / 3 times per week / once a week / once amonth

2. Do you use herbal supplements? Y / N
    a. If yes, list them here please:

Section III: High blood pressure

1. Do you have high blood pressure or take medicine for high blood pressure? Y / N (If no, skip to next section).
2. How long ago were you first diagnosed? < 1 year / 1-3 years / 3-5 years / 5-10 years / > 10 years
3. Do you check your blood pressure at home? Y / N
4. If yes, how often? Daily / several times per week / once per week / once per month)
5. How often is your blood pressure greater then 140/90? Most of the time / occasionally /never
6. Do you add salt to your food? No / occasionally / often / with each meal
7. Do you eat canned or processed food? No / occasionally / few times a week / every day
8. If you exercise, how often? at least daily / 3 times per week / once a week /once a month
9. Do you snore? Y / N
10. If yes, are you sleepy during the daytime or take frequent naps? Y / N
11. Have you ever been hospitalized for high blood pressure? Y / N
12. Have you had a stroke? Y / N
13. Do you have heart failure? Y / N
14. Have you had a heart attack? Y / N
15. Have you had a surgery for arteries supplying the legs? Y / N

Section IV: Diabetes

1. Have you ever been told you have diabetes or prediabetes? Y / N (If no, skip to nextsection)
2. How long ago were you first diagnosed? < 1 year / 1-3 years / 3-5 years / 5-10 years /> 10 years
3. Do you take or have you ever taken pills for diabetes? Y / N
    -If yes, how many years did you take it? < 1 / 1-5 / 5-10 / > 10
    -If you have stopped taking, how long ago did you stop (yrs)? < 1 / 1-5 / 5-10 / > 10

4. Do you take or have you ever taken insulin? Y / N
    -If yes, how many years did you take it? < 1 / 1-5 / 5-10 / > 10
    - If you have stopped taking, how long ago did you stop (yrs)? < 1 / 1-5 / 5-10 / > 10

5. How well have you blood sugars been controlled? Usually < 100 / 100-150 / 150-200 / > 200 / I don't check them
6. Do you have eye disease from diabetes? Y / N
7. Have you had laser treatment for your eyes? Y / N
8. Do you have numb feet? Y / N

Section V: Anemia

1. Have you ever been told you were anemic, had a low blood or hemoglobin count? Y / N (If no, skip to next section).
2. How long ago were you first diagnosed? < 1 year / 1-3 years / 3-5 years / 5-10 years / > 10 years
3. Have you had to take medication to prevent anemia? Y / N If yes what type:Folate or folic acid Y / N

Dose:_____

Iron (pills or injections) Y / N

Dose:_____

Vitamin B12 Y / N
Dose:_____
Epogen or Aranesp Y / N

Dose:_____

4. Do you have any black stools? Y / N
5. Do you have any bright red blood in your stool? Y / N
6. Do you have any blood in your urine? Y / N
7. If female, do you still menstruate? Y / N
   If yes, how often:_____
8. Do you have a family history of anemia? Y /NIf yes, please explain below:

_____

_____

9. Have you ever been diagnosed with the following:

Lymphoma	Y / N
Leukemia	Y / N
Vomiting blood	Y / N
Stomach ulcers	Y / N
Recurrent nosebleeds	Y / N

Any other cance

4. RESULTS

Most of the patients are in between the age of 70-80 years, married, with good nutritional status, with minimum 5 months of CKD ,approximately 50%of the patients are suffering from HTN along with CKD followed by diabetes. Patients are using OSB for a minimum of 5 months with 500mg dose given thrice a day, along with Calcium channel blockers and pantoprazole [14,15]. OSB is given as a oral tablet. In our study we have gathered the data of the patients who are using oral sodium bicarbonate are considered based on inclusion and exclusion criteria [16-20]. The main reason for admission in the nephrology ward and reasons for using oral sodium bicarbonate are evaluated and estimated in the CKD patients [21,22,23-25] .The comorbid conditions of the patients and duration of treatment its effects are also analyzed .Mostly the information regarding oral sodium bicarbonate is analyzed and documented [26-29]. The quality of life of the patient before and after oral sodium bicarbonate usage and treatment outcomes changes in lifestyle was also discussed [30-34]. The following tables are used to obtain results.

Table 1. Showing age, marital status, nutritional status and education of patients

Age	No. of patients	Percentage (%)
10-20	2	1.14
20-30	6	3.44
30-40	19	10.91
50-60	36	20.68
60-70	38	21.83
70-80	51	29.31
80-90	22	12.643
90-100	00	00
Marital status		
Married	166	95.4
Unmarried	8	4.5
Education		
Primary education	2	1.1
Secondary education	120	68.9
Higher education	4	2.2
Uneducated	48	27.5
Nutritional status		
Excellent	13	7.47
Good	97	55.7
Poor	64	36.7

Table 2. Showing duration of chronic kidney disease

Duration of CKD	No. of patients	Percentage (%)
12	32	18.39
5	74	42.52
1	13	7.47
3	34	19.54
6	3	1.72
8	18	10.34

Table 3. Showing reasons for patient admission

Reason for admission	No. of patients	Percentage (%)
CKD with HTN	86	49.42
DCMP WITH LV	22	12.6
Dysfunction		
DM with CKD	38	21.38
Urosepsis	12	6.8
Anemia	8	4.59
UTI	8	4.59

Table 4. Showing treatment outcomes

Treatment outcomes	No. of patients	Percentage(%)
Recovered	124	71.26
Not recovered	47	27.0
No change	00	00
Shifted to higher centres	00	00
Left against to medical advice	00	00
Economic burden	3	1.724

Table 5. Showing duration of oral sodium bicarbonate

Sodium bicarbonate duration (months)	No. of patients	Percentage (%)
1	13	7.47
3	34	19.54
5	106	60.91
6	3	1.72
8	18	10.34

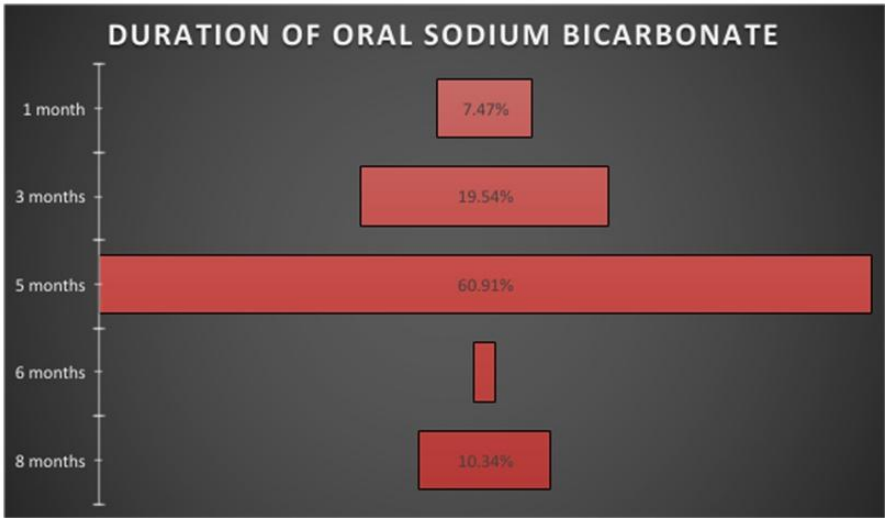

Fig. 2. Duration of oral sodium bicarbonate

Table 6. Showing routes of oral sodium bicarbonate

Sodium bicarbonate route	No. of patients	Percentage (%)
Oral	174	100
Other routes	0	0

Table 7. Showing treatment for metabolic acidosis

Treatment for acid base balance	No. of patients	Percentage (%)
Sodax	116	66.66
Sobonix	1	0.57
Sobosis	57	32.75

Table 8. Showing doses of oral sodium bicarbonate

Dose of oral sodium bicarbonate	No. of patients	Percentage (%)
1 gm ,OD	35	20.11%
500mg , TID	139	79.88%

Table 9. Showing different class of drugs used in CKD

Class of drug	No. of patients	Percentage (%)
Calcium channel blockers	97	55.74%
Aminoglycosides antibiotics	53	30.45%
Cephalosporin antibiotics	72	41.37%
Nutritional supplements	159	91.37%
Antacids	162	93.1%
Ca supplements	45	25.8%
Alkalising agent	174	100%

Table 10. Showing mostly used drugs with oral sodium bicarbonate

Drug	No. of patients	Percentage (%)
Tab.Nicardia	97	55.74%
Tab.Lasix	72	41.37%
Tab.Azithromycin	53	30.45%
Tab.Cefglobe	72	41.37%
Tab.Pantoprazole	162	93.1%
Tab.Shelcal	45	25.8%
Tab.Meropenem	46	26.43%

Table 11. Showing quality of life of patients

Quality of life	No. of patients	Percentage (%)
Excellent	44	25.28
Good	69	39.65
Poor	61	35.05

5. DISCUSSION

In our study we have gathered the data of the patients who are using oral sodium bicarbonate are considered based on inclusion and exclusion criteria the patients who are willing to provide the information are gathered and tabulated in the results like demographics which include age ,marital status, education and nutritional status [35-38]. The main reason for admission in the nephrology ward and reasons for using oral sodium bicarbonate are evaluated and estimated in the CKD patients [39-42].The comorbid conditions of the patients and duration of treatment its effects are also analyzed .Mostly the information regarding oral sodium bicarbonate is analyzed and documented [43-46]. Different categories of drugs used for this complications and mechanism and effect of drug on this health was observed .We also estimated the most frequent used drugs in CKD was reported in our study .The quality of life of the patient before and after oral sodium bicarbonate usage and treatment outcomes changes in lifestyle was also estimated and evaluated our study also explains about the acid base balance regulation by using different class of drugs for this conditions which are also regulated and discuss [47-50]. The main data was collected from the patients using the questionnaire which was specially designed based on WHO and other health care organizations regulation.

6. CONCLUSION

Oral bicarbonate is widely used to correct acidosis in advanced CKD, this is not underpinned by trial evidence, and real uncertainty exists regarding the balance of benefit and risk for this intervention. As most patients with CKD are old, and many are frail, it is critical that trials testing such interventions enroll typical patients and use outcome measures that are relevant to older people. Few older people with even advanced CKD will progress to end-stage renal disease; the risk of death from cardiovascular disease or infection often supervenes long before the need for renal replacement therapy. The range of outcomes selected for this study will allow an estimation of overall net benefit or harm across a range of disease outcomes including renal, and also maintaining acid base balance, as well as focusing on outcomes that are important to patients. So that we concluded that most of the patients using OSB was analyzed from nephrology department in QOL, in maintaining acid-base balance was observed in CKD patients .OSB supplements produce a dose dependent increase in serum bicarbonate was observed. Clinicians and clinical pharmacists have updated knowledge for treating the condition by using OSB. Future studies should determine improvement.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

ACKNOWLEDGEMENTS

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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