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A Prospective Study On Tolerability And Efficacy Of SucroferricOxyhydroxide (Dynulta) In Reduction Of Phosphate Levels In End Stage Renal Disease (Esrd) Patients On Maintenance Hemodialysis (Mhd)

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Abstract:
Background: *End stage renal disease (ESRD) is a permanent stage of chronic kidney disease, where kidneys can no longer function on their own. The increase in phosphate levels leads to bone disease, risk of calcification and hyperphosphatemia, which can be treated with Sucroferricoxyhydroxide (Dynulta). It is a non-calcium, iron-based phosphate binder used to control the serum phosphate levels in adults with CKD on peritoneal dialysis and hemodialysis. Therefore, this study attempts to assess the tolerability and efficacy of Sucroferricoxyhydroxide in reduction of phosphate levels in end stage renal disease (ESRD) patients and improving clinical outcomes.*
Methods: *A prospective and observational study was conducted to determine tolerability and efficacy of Sucroferricoxyhydroxide (Group A) by comparing it with other phosphate binder (Group B) in reduction of serum phosphate levels in ESRD patients on maintenance haemodialysis.*
Results:*According to the collected data Sucroferricoxyhydroxide therapy shows effective results when compared to other phosphate binder. Patients receiving Sucroferricoxyhydroxide (Group A) therapy shows mean reduction of serum phosphate levels i.e., 1.44, whereas patients receiving other phosphate binder (Group B) therapy shows mean reduction of serum phosphate levels i.e., 1.005. Overall serum phosphate levels saw significant reduction in patients receiving Sucroferricoxyhydroxide. Patients receiving other phosphate binder did not show significant reduction in serum phosphate levels. This results states that our prospective study was successful in determining effective phosphate binder to treat hyperphosphatemia.*
Conclusion:*During the study follow up with Sucroferricoxyhydroxide, serum phosphate levels were controlled effectively, when compared with other phosphate binder. Sucroferricoxyhydroxide (Dynulta) is an effective option for the treatment of hyperphosphatemia in patients with ESRD on maintenance haemodialysis. Adverse effects occurred can be easily monitored.*
Key Word: *Tolerability, Sucroferricoxyhydroxide, Phosphate binder, Hyperphosphatemia, Haemodialysis.*

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I.INTRODUCTION

The last and most severe stage of chronic kidney disease, end-stage renal disease (ESRD),occurs when the kidneys ability to function on their own has been completely lost. Dialysis or a kidney transplant are required for an ESRD patient to live. GFR less than 15 ml/min is used to characterise end stage renal disease. [1]

The signs and symptoms of end-stage renal disease might be complex. Among these are metabolic abnormalities such as hyperkalaemia, hyponatremia, metabolic acidosis, hypo/hypercalcemia, and hyperphosphatemia as well as volume overload resistant to diuretics, unresponsive hypertension to medication,

anaemia, mineral and bone diseases, and hyperphosphatemia. [2] Haemodialysis (HD) is a process of purifying the blood of a person whose kidneys are not working properly. This type of dialysis achieves the extracorporeal removal of waste products such as creatinine, urea, and free water from the blood when the kidneys are in a state of kidney failure. Haemodialysis is one of the renal replacement therapies (the other two are peritoneal dialysis and kidney transplantation). Haemodialysis can be an outpatient or inpatient therapy. [3]
Patients with chronic renal disease who depends on dialysis frequently develop hyperphosphatemia. [4]

Secondary hyperparathyroidism is largely caused by elevated serum phosphorus, which is also linked to vascular calcification, an increase in cardiovascular events, and higher mortality in dialysis patients.[5]

To decrease gastrointestinal (GI) absorption of phosphate and achieve serum phosphorus control, the majority of dialysis patients need to be treated with oral phosphate binders (PBs). [6]

Sucroferricoxyhydroxide is a prescription drug which is sold under brand name of Dynulta, it is a non-calcium iron-based phosphate binder which is used to treat the condition hyperphosphatemia (elevation of serum phosphorus levels) in adults with chronic kidney disease (CKD) on hemodialysis or peritoneal dialysis. This drug is used in form of chewable tablet. [7]

Starting dose of SO is 3 tablets (1500 mg) per day i.e., 500 mg 3 times daily with meals. The maximum daily dose of SO 6 tablets per day (3000 mg). [8]

ADR's of Sucroferricoxyhydroxide include diarrhea, discoloredfeces, nausea, skin rash, change in taste and tooth discoloration. [9]

Other phosphate binders used for reduction of phosphate levels are Sevelamer hydrochloride, calcium acetate, magnesium carbonate. [10]

II.Material and Methods

Study Aim &**Objectives**

Study Aim - To study tolerability and efficacy of Sucroferricoxyhydroxide (Dynulta) in reduction of phosphate levels in end stage renal disease [ESRD] patients.

Objectives - To analyze the tolerability and efficacy of Sucroferricoxyhydroxide (Dynulta) in reduction of phosphate levels in end stage renal disease [ESRD] patients in both Group A and Group B.

Study Methodology:

Study design: Prospective and Observational

Proposed sample size: 50

Study duration: 6 months

Study Criteria:

Inclusion Criteria:
1. Patients > 18 years of age.
2. All outpatients who are diagnosed with end stage renal disease undergoing maintenance hemodialysis.
3. Patients having phosphate levels > 5.5 mmol/L (hyperphosphatemia).
4. Patients receiving Sucroferricoxyhydroxide therapy. 1. Patients < 18 years
2. Pregnant women and lactating women.
3. Other immune compromised patients like SLE.

Exclusion Criteria:

Sources of data: Patient demographic details along with appropriate subjective and objective data will be collected from patient medical records and from hemodialysis unit.

Study procedure: A prospective and observational study was conducted to determine the tolerability and efficacy of Sucroferricoxyhydroxide (Dynulta) in both Group A and Group B in reduction of phosphate level in end stage renal disease [ESRD] patients, after obtaining approval from research and ethics department.

After obtaining the patient's consent, the relevant data from the patient profile chart along with physician recommendations, who are diagnosed with end stage renal disease (ESRD) with hyperphosphatemia the data was collected in a data collection form, which included all the required parameters.

The study was conducted for both

GROUP A: Patients receiving Sucroferricoxyhydroxide therapy.
GROUP B: Patients receiving other phosphate binders (Sevelamer) for reduction of phosphate levels.

III.RESULTS

Our study titled "A Prospective study on tolerability and efficacy of SucroferricOxyhydroxide (Dynulta) in reduction of phosphate levels in end stage renal disease (ESRD) patients on maintenance Haemodialysis (MHD)" was conducted on a total number of 50 patients. Out of 50 patients (60%) were Male, and (40%) were Female.

In our study, the age group of 50-60 years with 42% of the patients, followed by the age group of 60-70 years with 16% of the patients, 14% of the patients were in the age group of 40-50 years, the age group of 30-40 years had 12% of thepatients, and the age group of 20-30 years and 70-80 years had 8% of the patients in each group.

Patients were classified based on their weights, 36% of patients has a weight of 61-70kgs, 30% of the patients has a weight of 71-80kgs, 20% of the patients with 51-60kgs, followed by the weight of 40-50kgs and 81-90kgs with 6% of patients in each group, and 2% of patients with 91-100kgs.

In our study, 60% of patients had one comorbidity, 26% of patients showed two comorbidities, and 14% of patients had more than two comorbid conditions.

The most common comorbidity among all the 50 patients is hypertension, followed by diabetes mellitus type 2, coronary artery disease and thyroid disease.

Patients were also categorized based on the no. of side effects of Sucroferricoxyhydroxide, out of which 25% of patients had two side effects, 55% of patients had three side effects, and 20% of patients had more than three side effects.

TABLE 1: Distribution Of Patients Based On Tolerability Of SucroferricOxyhydroxide

Tolerability	***No.of patients***
Diarrhoea	*07*
Discoloured Feaces	*10*
Nausea	*15*
Skin Rash	*05*
Difficulty Breathing	*00*
Tooth Discolouration	*07*
Swelling Of Face, Tongue and Throat	*15*

Tolerability OfSucroferricOxyhydroxide:

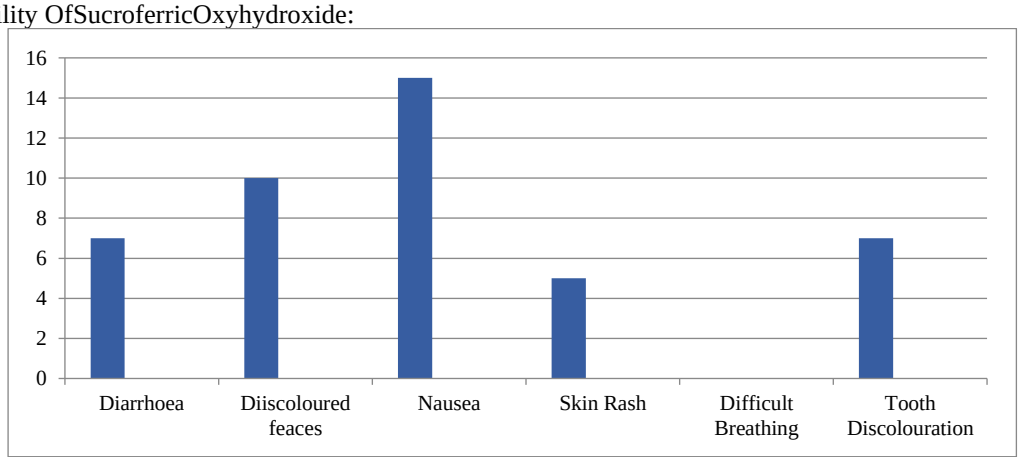

FIGURE 1:14% of patients had diarrhoea, 20% of patient had discoloured faeces, 30% of patients had nausea, 10% of patients had skin rashes, another 14% of patients had tooth discoloration and 30% of patients had swelling of face, tongue and throat.

TABLE 2: Reduction Of Serum Phosphorus Levels In Group A (SucroferricOxyhydroxide)

Group A	**Mean ± SD**
Baseline	6.885± 1.163
Follow Up	5.445± 0.540

SucroferricOxyhroxide:

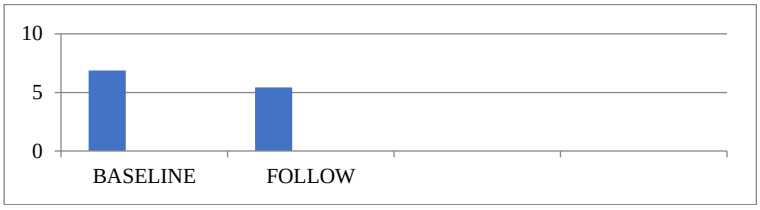

FIGURE 2:Shows the baseline phosphorus levels of 6.88 and after the administration of Sucroferricoxyhydroxide, the phosphorus levels got reduced to 5.44.

TABLE 3: Reduction Of Serum Phosphorus Levels In Group B (Other Phosphate Binder)

Group B	Mean ± SD
Baseline	6.51 ± 0.761
Follow up	5.5 ± 0.979

Other Phosphate Binder:

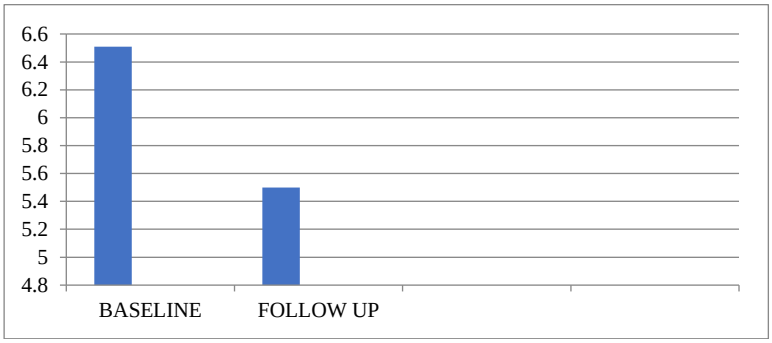

FIGURE 3:Shows the baseline phosphorus levels of 6.51 and after the administration of the other phosphate binders, the phosphorus got reduced to 5.5.

TABLE 4: REDUCTION OF SERUM PHOSPHORUS LEVELS IN GROUP A AND GROUP B

Group A & Group B	Mean Reduction
Sucroferricoxyhydroxide	1.44
Other phosphate binder	1.005

SucroferricOxyhydroxide V/S Other Phosphate Binder

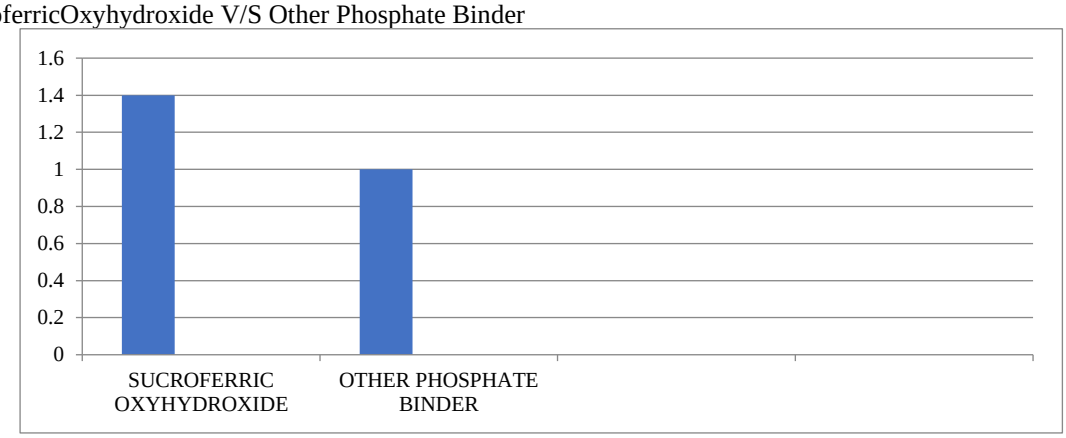

FIGURE 4:Shows the mean reduction of phosphorus levels of 1.4 for Sucroferricoxyhydroxide and 1.00 for other phosphate binders.

IV.DISCUSSION

A Study was conducted on tolerability and efficacy of Sucroferricoxyhydroxide (Dynulta) in reduction of phosphate levels in end stage renal disease (ESRD) patients on maintenance hemodialysis (MHD)",SucroferricOxyhydroxide is a non-calcium, iron-based phosphate binder used for the control of serum phosphorus levels in adults with chronic kidney disease.

Other phosphate binders include Sevelamer, Revelamer are used for the prevention of high serum phosphorus levels in patients with chronic kidney disease.

We have enrolled 50 patients out of which two-third of them were females, the maximum number of patients fall between the age group of 50-60years. Out of 50 patients, many of them had comorbidities such as Hypertension, Diabetes Mellitus type2.

Study was conducted to determine the tolerability and efficacy of SucroferricOxyhydroxide in both group A and group B in reduction of phosphate level in end stage renal disease patients.

After the treatment with SucroferricOxyhydroxide in Group A significantly resulted in lower levels of serum phosphorus than Group B receiving other phosphate binders.

Among all patients, other adverse effects were mild but 55% of population showed 3 side effects i.e., Nausea, swelling of face, tongue, throat and Discoloredfeces.

After administration of Sucroferricoxyhydroxide, the mean score was (1.44) > other phosphate binder (1.005) i.e., SucroferricOxyhydroxide was more efficacious than other phosphate binders in reducing the high phosphorus level.

V.CONCLUSION

From this prospective study, we concluded that SucroferricOxyhydroxide is an effective option for the reducing the high serum phosphorous levels (hyperphosphatemia) than other phosphate binder in end stage renal disease patients on maintenance hemodialysis.

Although, symptoms like nausea, swelling of face, tongue, throat and discoloredfeces were observed which can be monitored.

The required daily pill burden was lower with SucroferricOxyhydroxide than other phosphate binder.

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