USE OF CALCIUM CARBONATE EMULSION FOR THE TREATMENT OF HYPERPHOSPHATEMIA ON CHRONIC HEMODIALYSIS PATIENTS REDUCES TOTAL ELEMENTAL CALCIUM DOSE

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OBJECTIVES

Hyperphosphatemia is directly related to mortality in hemodialysis patients. Calcium carbonate is the captor of phosphorus frontline, nevertheless hypercalcemia and related vascular calcifications limit their use. We compared the efficacy of calcium carbonate emulsion (CCE) (Pluscal®) vs calcium carbonate tablets (CCT) in the control of hyperphosphatemia using a total dose of elemental calcium lower than that used in CCT in the case of CCE.

METHODS

We conducted a longitudinal, phase IV, prospective, controlled, randomized, crossover, open label, multicentric study. Patients with at least 90 days on hemodialysis and hyperphosphatemia (defined as Pi> 5 mg/dl) were included.

After signing informed consent, subjects were randomized into two groups. In the 1st stage of Group 1 patients received intervention A (CCT) and Group 2 intervention B (CCE). In the 2nd stage, patients in Group 1 received intervention B and Group 2 intervention A. Monthly laboratory controls were performed. Product doses were adjusted as outlined in the table. Efficacy was measured by assessing the ability to lower blood phosphorus levels.

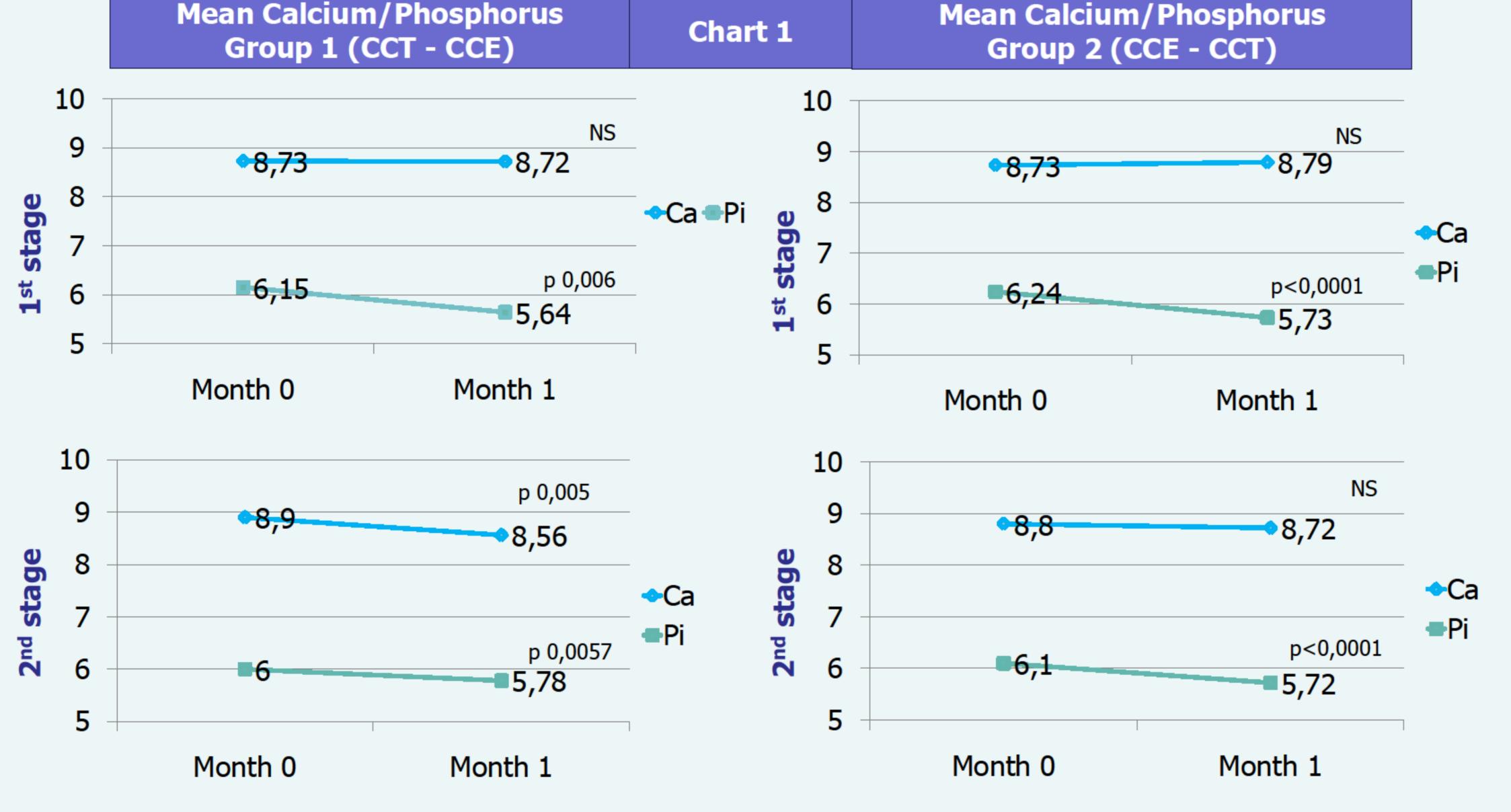
Phosphorus level	Intervention A (CCTablets)	Total elemental calcium dose	Intervention B (CCEmulsion)	Total elemental calcium dose
3,5 a 4 mg/dl	0 tablets / day	0 mg	0 doses / day	0 mg
>4 a 4,5 mg/dl	2 tablets / day	1000 mg	1 doses / day	500 mg
>4,5 a 5 mg/dl	3 tablets / day	1500 mg	2 doses / day	1000 mg
>5 mg/dl	4 tablets / day	2000 mg	3 doses / day	1500 mg

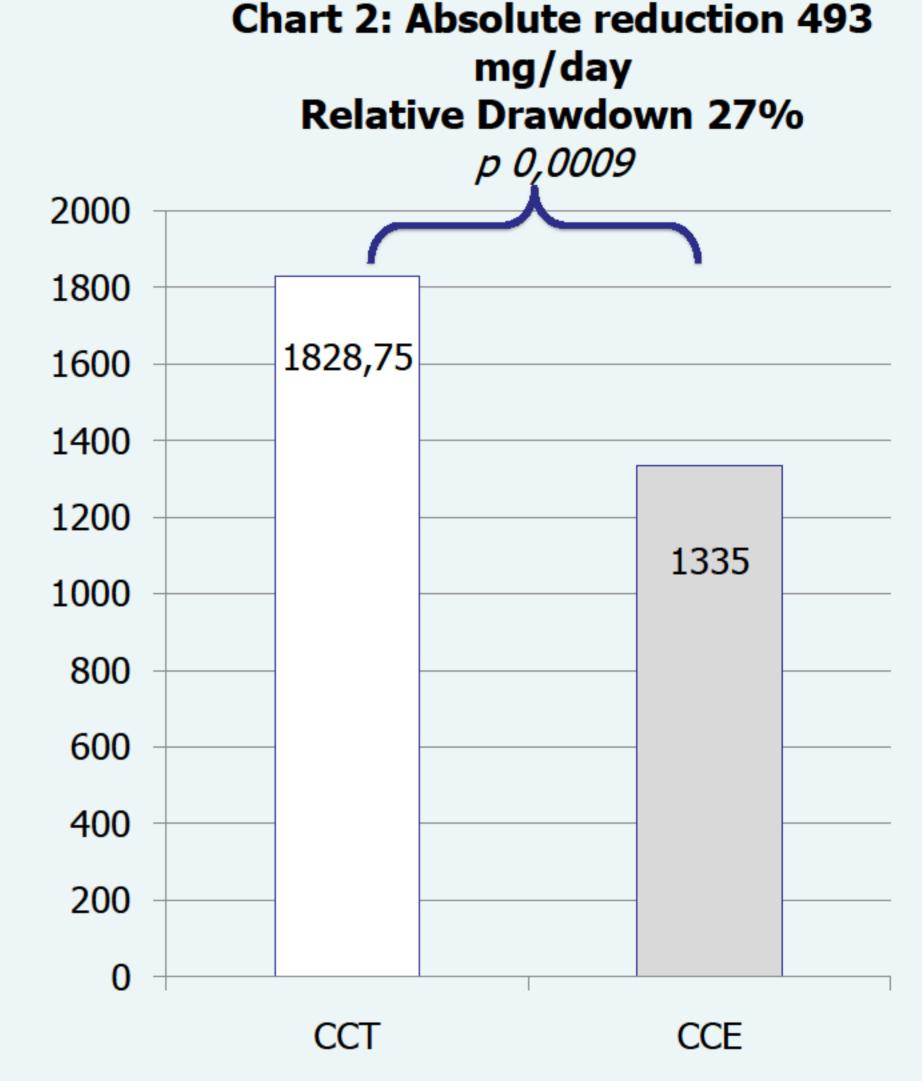
RESULTS

From 416 eligible patients, 102 met the inclusion criteria. Sixtyfive patients completed the trial. Phosphorus and calcium levels are shown in chart 1. Reduction in phosphorus levels were statistically significant comparing Month 0 vs Month 1 in both stages and in both groups. Reduction in calcium levels were statistically significant comparing Month 0 vs Month 1 only in 2nd stages Group 1 (CCE). No statistically significant difference was found between Groups 1 and 2 for the values of phosphorus in every stage. The mean total dose of elemental calcium was significantly lower in patients receiving CCE (1829mg/day vs CCT 1335mg/day CCE) (see chart 2).



Average dose of elemental calcium (mg)





CONCLUSIONS

- 1. CCE and CCT reduce phosphorus significantly.
- 2. Efficacy of CCE showed no inferiority to CCT to reduce phosphorus level.
- 3. CCE requires less total calcium dose (-27%) to maintain similar efficacy.

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