

EVALUATING THE EFFICACY OF CALCIUM CARBONATE EMULSION (CCE) FOR THE TREATMENT OF HYPERPHOSPHATEMIA IN PATIENTS ON CHRONIC HEMODIALYSIS

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OBJECTIVES

Hyperphosphatemia is directly related to mortality in hemodialysis patients. The difference in the effectiveness of various phosphorus binders is controversial. Calcium carbonate produces digestive intolerance often leading to poor adherence to treatment.

Several commercial presentations achieve greater or lesser tolerance and adherence. We evaluated the efficacy of calcium carbonate emulsion (Pluscal®) in the control of hyperphosphatemia as compared to calcium carbonate tablets (CCT).

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 (Calcium Carbonate Tablets) and Group 2 intervention B (Calcium Carbonate Emulsion - Pluscal®). 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 Table 1.

Efficacy was measured by assessing the ability to lower blood phosphorus levels and to maintain the KDIGO target phosphorus level in range.

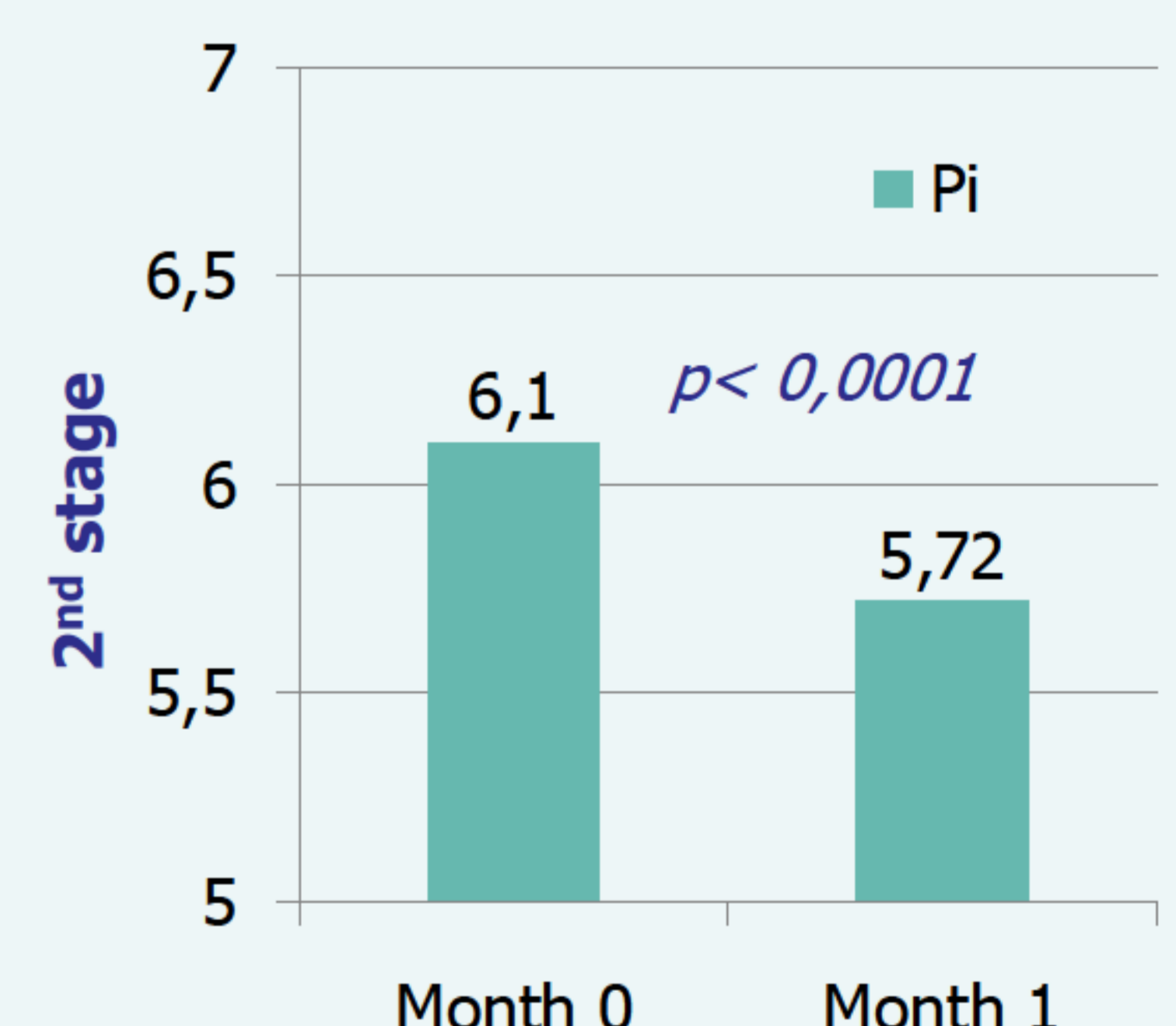
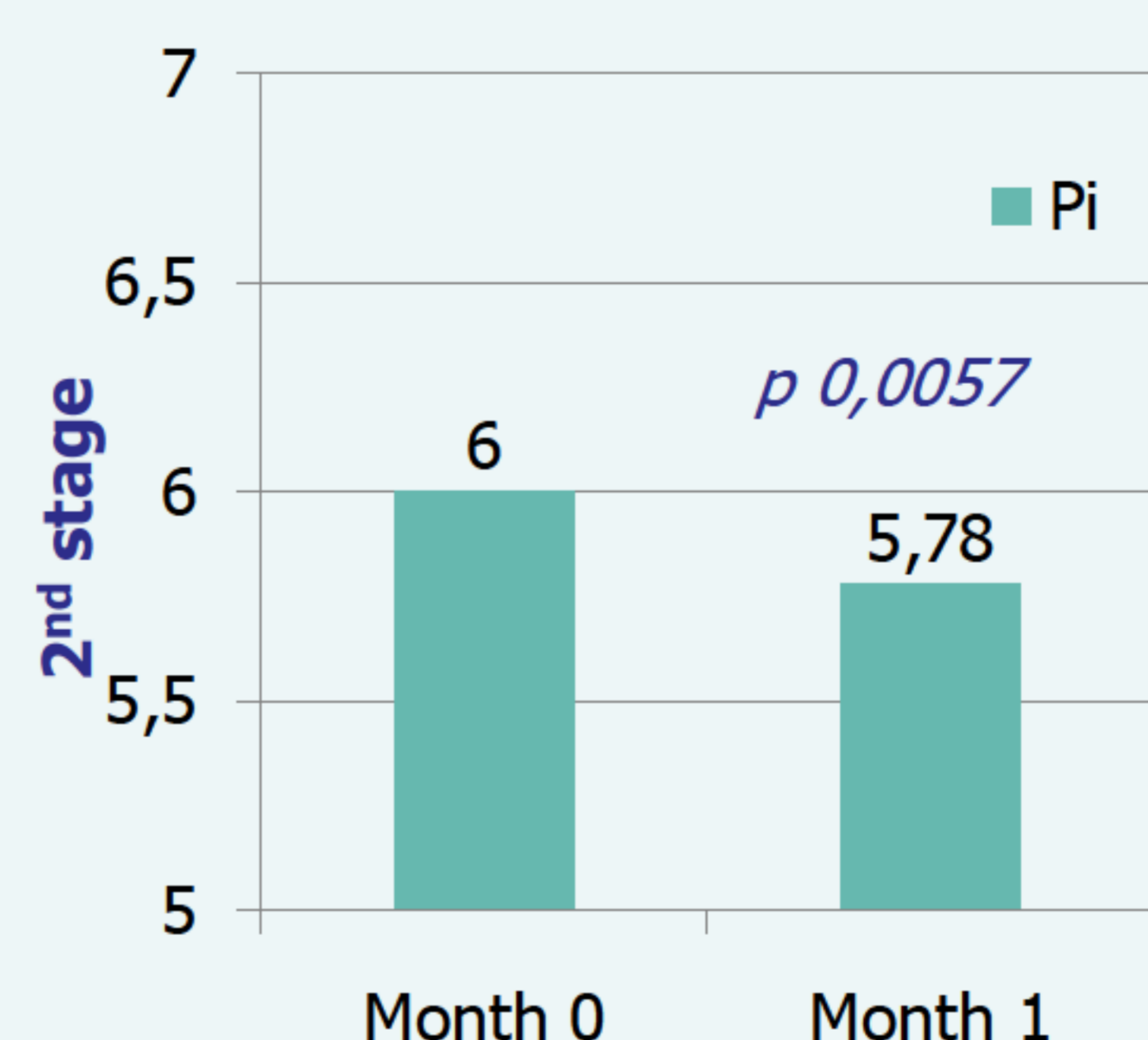
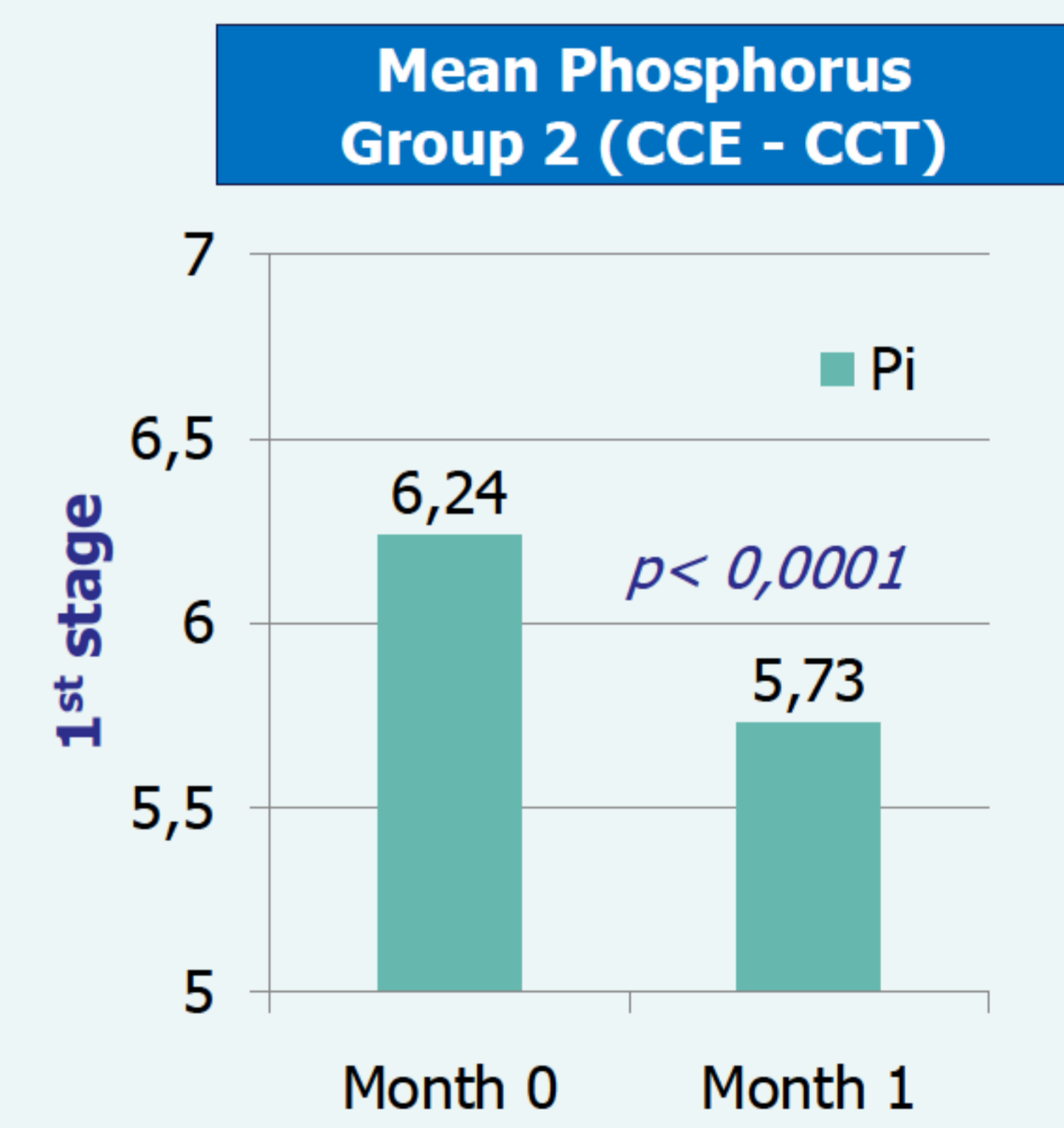
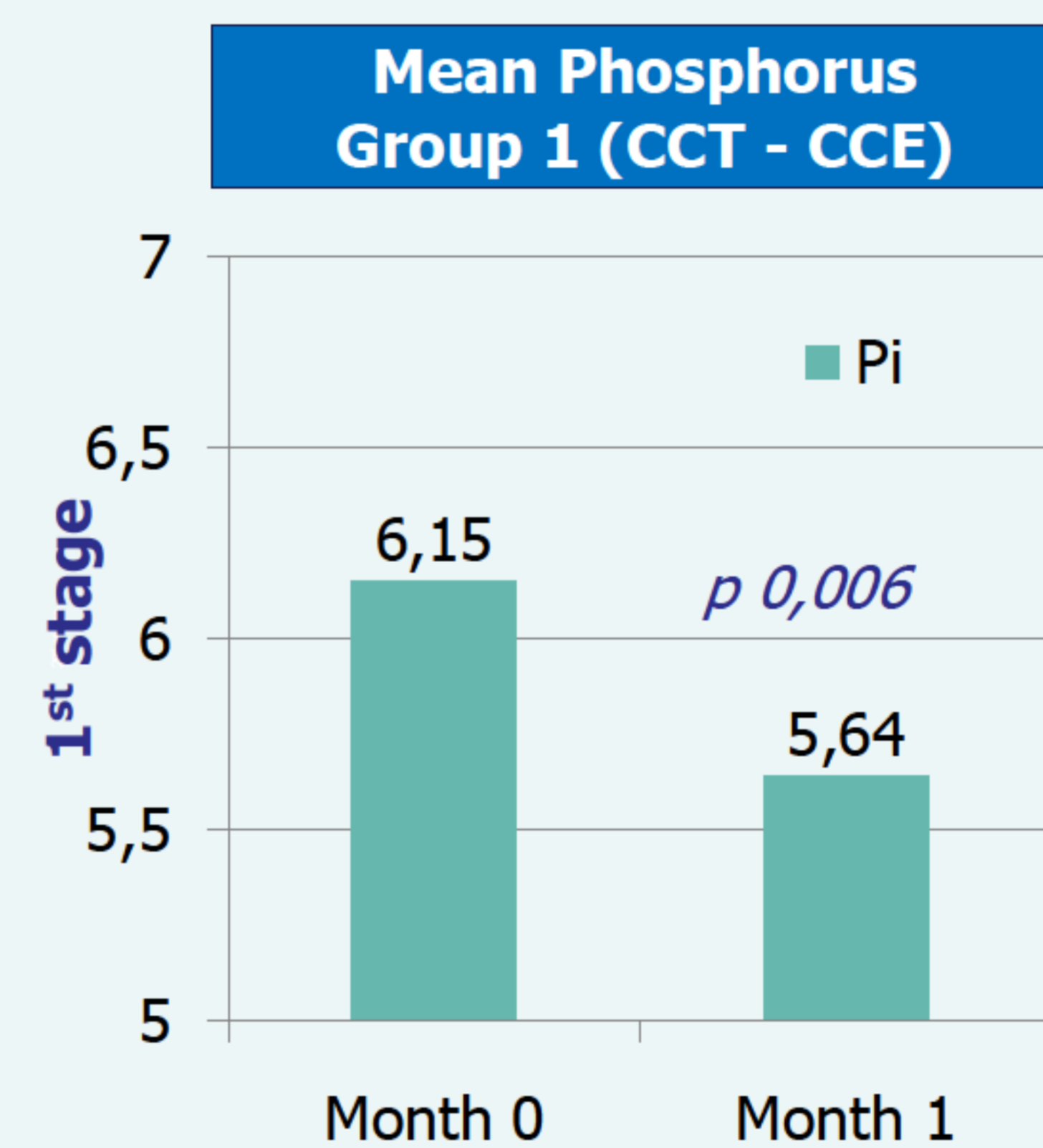
RESULTS

From 416 eligible patients, 102 met the inclusion criteria. Sixtyfive patients completed the trial. Phosphorus level and KDIGO targets achievement are shown in table 2. Reduction in phosphorus levels and increase in phosphorus target achievement for KDIGO were statistically significant comparing Month 0 vs Month 1 in both stages and in both groups. No statistically significant difference was found between Groups 1 and 2 for the values of phosphorus and objective compliance rates in every stage.

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

| Group 1 | Product | CCT | CCT | CCE | CCE |
|---------|---------------------------|---------|---------|---------|---------|
| | Month | Month 0 | Month 1 | Month 0 | Month 1 |
| | Phosphatemia (mg/dl) | 6,15 | 5,64 | 6 | 5,78 |
| | K-DIGO target achievement | 12,50% | 34,00% | 12,80% | 21,90% |

| Group 2 | Product | CCE | CCE | CCT | CCT |
|---------|---------------------------|---------|---------|---------|---------|
| | Month | Month 0 | Month 1 | Month 0 | Month 1 |
| | Phosphatemia (mg/dl) | 6,24 | 5,73 | 6,1 | 5,72 |
| | K-DIGO target achievement | 10,60% | 33,30% | 15,60% | 21,90% |



CONCLUSIONS

1. Carbonate Calcium Emulsion and Carbonate Calcium Tablets reduce phosphorus and increase KDIGO phosphorus target significantly.
2. Nevertheless phosphorus level and KDIGO target achievement were not different between Group 1 (CCT – CCE) and Group 2 (CCE – CCT).
3. Efficacy of Carbonate Calcium Emulsion showed no inferiority to Carbonate Calcium Tablets to reduce phosphorus level and to accomplish KDIGO phosphorus target.
4. Carbonate Calcium Emulsion requires less total calcium dose to maintain similar efficacy.

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