Initial Dosing of Paricalcitol Based on PTH Levels in Hemodialysis Patients With Secondary Hyperparathyroidism

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• **Background:** Adjustment of the initial dose of paricalcitol in hemodialysis patients with secondary hyperparathyroidism (SHPT) on the basis of severity of SHPT generally is preferred in current practice. Whether the proposed dose, based on the formula baseline intact parathyroid hormone (iPTH [picograms per milliliter]) divided by 80, is the most appropriate has not been assessed adequately. **Methods:** A double-blind randomized trial comparing iPTH/80 dose with the immediately lower iPTH/120 dose was undertaken. Forty-three hemodialysis patients with iPTH levels between 300 and 900 pg/mL (300 and 900 ng/L) were followed up for 12 weeks. The primary outcome was control of iPTH levels within a target range between 150 and 300 pg/mL (150 and 300 ng/L). **Results:** No difference between the 2 dose groups was noted in time to achieve target iPTH levels of 150 to 300 pg/mL (150 to 300 ng/L). More episodes of excessive decrease in iPTH levels occurred in the iPTH/80 group compared with the iPTH/120 group (P = 0.003). Nine patients in the iPTH/80 group (45%) versus 2 patients in the iPTH/120 group (10%) had iPTH levels less than 150 pg/mL (<150 ng/L) in at least half the measurements performed during the second half of the study (P = 0.034). Increases in calcium levels were greater in the iPTH/80 group at all times during the study (P < 0.05 at weeks 4 and 10). The number of required dose reductions was significantly greater in the iPTH/80 group compared with the iPTH/120 group (P = 0.008). **Conclusion:** In hemodialysis patients with SHPT, a lower initial dose of iPTH/120 shows efficacy similar to that of the already widely used iPTH/80 scheme in reaching target iPTH levels (150 to 300 pg/mL [150 to 300 ng/L]), with less required dose adjustments, lower increase in calcium levels, and lower cost. In addition, the initial dose of paricalcitol based on the iPTH/80 formula leads significantly more patients to excessive suppression of iPTH (<150 pg/mL [<150 ng/L]) than the iPTH/120 dose. **Am J Kidney Dis** 48:114-121.

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INDEX WORDS: Hemodialysis (HD); secondary hyperparathyroidism; hypercalcemia; hyperphosphatemia; vitamin D.

SECONDARY HYPERPARATHYROIDISM (SHPT) is a frequent manifestation of renal osteodystrophy and is characterized mainly by increased parathyroid hormone concentration and calcium, phosphorus, and vitamin D level alterations. Its prevalence in hemodialysis patients is estimated to reach 50%. Calcitriol and vitamin D analogues are the mainstay of treatment for patients with SHPT, although they increase the risk for hypercalcemia, hyperphosphatemia, and increased calcium-phosphorus (Ca \( \times \) P) product. Furthermore, excessive suppression of parathyroid hormone by vitamin D compounds was implicated in the development of adynamic bone disease. Such side effects can lead to the development of vascular calcifications, which, in turn, can contribute to increases in cardiovascular morbidity and mortality. For this, administration of calcitriol or vitamin D analogues to patients with end-stage renal disease (ESRD) and SHPT should be done with caution. Maintenance of intact parathyroid hormone (iPTH) levels between 150 and 300 pg/mL (150 and 300 ng/L), at the same time avoiding substantial increases in calcium, phosphorus, and Ca \( \times \) P product levels, generally are accepted principles for the treatment of SHPT in patients with ESRD.

Both laboratory and clinical studies showed that paricalcitol, a new vitamin D analogue, is effective in decreasing iPTH levels without causing severe hypercalcemia or hyperphosphatemia. There are studies in which it was shown to be superior to calcitriol in these terms. Although the proposed initial dose of paricalcitol according to the Food and Drug Administration is 0.04 to 0.1 \( \mu \)g/kg of body weight, a more commonly used scheme takes into account the severity of the underlying SHPT, as in determining the initial dose of calcitriol. The first and probably only study that examined...
the efficacy and safety of determining the initial dose of paricalcitol on the basis of severity of SHPT is by Martin et al.12 which showed that patients administered an initial paricalcitol dose determined by baseline iPTH level divided by 80 (a formula proposed by the drug manufacturer, Abbott Laboratories, Abbott Park, IL) achieved a more rapid decrease in serum iPTH levels of 30% or greater than those for whom the initial dose was calculated by using the formula 0.004 × body weight (in kilograms), with no differences in incidence of hypercalcemia (defined as serum calcium level > 11.5 mg/dL [>2.87 mmol/L]) or elevated (>75) Ca × P product. However, it was not examined whether this rapid decrease in iPTH levels eventually will lead to the desired iPTH levels (150 to 300 pg/mL [150 to 300 ng/L]) or to iPTH oversuppression (<150 pg/mL [<150 ng/L]), given that the manufacturer’s instructions regarding dose adjustments and the National Kidney Foundation–Kidney Disease Outcomes Quality Initiative guidelines regarding the frequency of iPTH, calcium, and phosphorus measurements are followed.

The purpose of this study is to compare 2 different initial dosing schemes for the administration of paricalcitol to patients with ESRD with SHPT (baseline iPTH level, 300 to 900 pg/mL [300 to 900 ng/L]): the iPTH/80 scheme already in use and an iPTH/120 scheme, which corresponds to the immediately lower dose, based on current instructions for paricalcitol dose adjustment. We chose to administer a lower initial dose based on the clinical observation that with the iPTH/80 scheme, we often had to decrease the dose to reach target iPTH levels. Conversely, in the scheme based on the “body weight × 0.04” formula, paricalcitol dose gradually increases.6,12 The primary outcome was reaching iPTH levels within a desired target range (150 to 300 pg/mL [150 to 300 ng/L]). As a secondary outcome, we assessed the frequency of iPTH oversuppression (<150 pg/mL [<150 ng/L]) in the 2 groups (iPTH/80 and iPTH/120). In addition, we assessed total paricalcitol dose and required dose adjustments during the 12 weeks of our study, as well as changes in calcium, phosphorus, and Ca × P product values.

**METHODS**

A double-blind randomized trial was undertaken to compare the 2 initial dosing schemes. The study protocol was approved by the Institutional Scientific Board of Papageorgiou General Hospital, Thessaloniki, Greece. The first scheme, iPTH/80, is the one proposed by the drug manufacturer, Abbott Laboratories, and the second, iPTH/120, involves the lower paricalcitol dose, by 30%, that is the immediately lower dose level according to the standard paricalcitol dose-adjusting protocol. Using the standard scheme, mean initial dose for a group of patients with SHPT (iPTH level, 300 to 900 pg/mL [300 to 900 ng/L]) and a mean iPTH level of 600 pg/mL (600 ng/L) would be 7.5 μg (600/80 = 7.5) per session. If a dose decrease is required, this should be of the order of 2 to 3 μg (mean, 2.5 μg), and the immediately lower dose level therefore would be 5 μg, which is the dose determined by the iPTH/120 formula (600/120 = 5).

Patients on maintenance hemodialysis therapy (3 sessions/wk) for at least 3 months with SHPT (iPTH level, 300 to 900 pg/mL [300 to 900 ng/L]) were recruited if they satisfied the following criteria: older than 18 years, normal serum calcium concentration (8.1 to 10.4 mg/dL [2.02 to 2.59 mmol/L]), Ca × P product less than 70, off any vitamin D metabolite replacement therapy for at least 1 month before enrollment, and aluminum levels less than 60 μg/L (<2.23 μmol/L). Exclusion criteria were administration of calcitriol, bisphosphonates, or corticosteroids; presence of a clinically serious medical condition; and previous parathyroidectomy or active malignancy. Informed consent was obtained from all patients before entering into the study. Patients were dialyzed using a calcium dialysate concentration of 6.64 mg/dL (1.66 mmol/L). During the study period, the dialysis regimen remained unchanged.

Enrolled patients were randomized into 1 of the 2 paricalcitol initial dosing schemes, either baseline iPTH/80 or baseline iPTH/120. Paricalcitol dose would be decreased by 2 μg every 2 weeks if iPTH levels decreased to less than 150 pg/mL (<150 ng/L), iPTH level decreased by more than 60% during the last 2 weeks, or serum calcium level increased to greater than 11.5 mg/dL (≥2.87 mmol/L) or Ca × P product increased to greater than 75. In the case in which iPTH levels decreased to less than 150 pg/mL (<150 ng/L) and, at the same time, serum calcium level increased to greater than 11.5 mg/dL (≥2.87 mmol/L) or Ca × P product increased to greater than 75, paricalcitol therapy was discontinued and then restarted at a dose decreased by 2 μg when serum calcium level decreased to less than 10.4 mg/dL (<2.59 mmol/L) and/or Ca × P product decreased to less than 65. Paricalcitol dose was increased by 2 μg every 4 weeks given that the iPTH level decrease was less than 30% for the last 4 weeks and, at the same time, iPTH level was greater than 300 pg/mL (<300 ng/L), serum calcium level was less than 11.5 mg/dL (<2.87 mmol/L), and Ca × P product was less than 70. Paricalcitol dose was kept constant in any other case. Only intravenous administration of paricalcitol was used because the oral format was not available in Europe. All patients included were advised to follow a diet containing phosphorus content of 800 to 1,000 mg/dL. During the course of the study, all patients were administered.
sevelamer hydrochloride as phosphate binder and calcium carbonate or aluminum hydroxide in case sevelamer did not suffice. Study duration was 12 weeks. Laboratory measurements were performed every 2 weeks, except for cases in which paricalcitol therapy was discontinued, for which calcium and phosphorus measurements were performed every hemodialysis session until paricalcitol readministration. Measurements of serum phosphorus, calcium, magnesium, and alkaline phosphatase were performed on an Olympus AU-800 clinical chemistry analyzer (Olympus, Hamburg, Germany). Measured serum calcium concentration was corrected for the presence of hypoalbuminemia by using the following equation: Corrected (serum calcium) = measured total (serum calcium) / (0.8 – [serum albumin]). Serum iPTH was measured by using the solid-phase 2-site chemiluminescent enzyme-labeled immunometric method in the immulite analyzer, using reagents of DPC Diagnostic Products (DPC, Los Angeles, CA).

Statistical Analysis

Results are expressed as mean ± SD. Groups were compared by means of 2-tailed Student t-test and Fisher exact test. The Kaplan-Meier method was used to assess time to first occurrence of 2 consecutive iPTH values within the target range (150 to 300 pg/mL [150 to 300 ng/L]). Log-rank test was used to compare survival curves from different groups. P less than 0.05 is considered statistically significant.

RESULTS

Forty-three patients fulfilled entry criteria and were randomly assigned to receive either 1 of the 2 paricalcitol initial dosing schemes, eg, either baseline iPTH/80 (n = 22) or baseline iPTH/120 (n = 21). Total duration of the study was 12 weeks, and all except 2 patients completed it. Of these 2 patients, 1 patient died of cardiac arrest in week 9, and paricalcitol therapy was discontinued in the other patient in the same week because of a mild allergic reaction. Both patients were part of the iPTH/80 group and were included in the analysis (intention to treat). Demographic features of the 2 groups of patients are listed in Table 1. No significant differences between the 2 groups in regard to age, sex, body weight, primary renal disease, use of phosphate binders, and prior use of vitamin D compounds were present. Of 43 patients, 21 patients never were administered vitamin D and 22 patients were being administered alfacalcidol. Of these, 10 patients with a mean alfacalcidol dose of 3.9 ± 1.4 μg/wk for 16 ± 16 months were included in the iPTH/80 group, and 12 patients with a mean alfalcacidol dose of 4.2 ± 1.7 μg/wk for 19 ± 14 months were included in the iPTH/120 group. Alfacalcidol therapy was discontinued for all patients at least 1 month before their enrollment in the study protocol. Baseline values for iPTH, calcium, phosphorus, and alkaline phosphatase were not significantly different for the 2 groups (Table 1).

Table 1. Demographic Features and Baseline Laboratory Values

<table>
<thead>
<tr>
<th></th>
<th>iPTH/80 (n = 22)</th>
<th>iPTH/120 (n = 21)</th>
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<tbody>
<tr>
<td>Men</td>
<td>16 (73)</td>
<td>14 (67)</td>
</tr>
<tr>
<td>Age (y)</td>
<td>61.5 ± 13.6</td>
<td>60.8 ± 11.2</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>70.5 ± 14.1</td>
<td>73.0 ± 13.0</td>
</tr>
<tr>
<td>Hemodialysis duration (y)</td>
<td>4.8 ± 3.3</td>
<td>3.5 ± 1.6</td>
</tr>
<tr>
<td>Primary renal disease</td>
<td></td>
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<tr>
<td>Diabetes mellitus</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Glomerulonephritis</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Hypertension</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Interstitial nephritis</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Baseline iPTH levels (pg/mL)</td>
<td>516 ± 148 (322-827)</td>
<td>532 ± 169 (319-831)</td>
</tr>
<tr>
<td>Baseline calcium levels (mg/dL)</td>
<td>9.02 ± 0.47</td>
<td>8.95 ± 0.58</td>
</tr>
<tr>
<td>Baseline phosphorus levels (mg/dL)</td>
<td>5.09 ± 1.05</td>
<td>5.19 ± 1.03</td>
</tr>
<tr>
<td>Baseline alkaline phosphatase levels (U/L)</td>
<td>81 ± 38</td>
<td>91 ± 43</td>
</tr>
</tbody>
</table>

NOTE. Values expressed as mean ± SD (range), number of patients, or number (percent) unless noted otherwise. To convert iPTH in pg/mL to ng/L, multiply by 1.0; serum calcium in mg/dL to mmol/L, multiply by 0.2495; phosphorous in mg/dL to mmol/L, multiply by 0.3229.
Decreases in iPTH levels were greater in the iPTH/80 group at all times throughout the study, albeit without reaching significant levels (Fig 1). Time to first occurrence of 2 consecutive iPTH values within the target range (150 to 300 pg/mL [150 to 300 ng/L]) did not differ between the 2 groups. At the same time (by week 6), 50% of patients in both groups had at least the first of 2 consecutive iPTH values within the target range. By the end of the study, 78% of patients in the iPTH/80 group had at least 2 consecutive iPTH values within the target range versus 71% for the iPTH/120 group (Fig 2; log-rank test, $P = 0.597$). Likewise, time to achieve the first of 2 consecutive 30% or greater decreases from baseline iPTH levels did not differ significantly between the 2 groups (3.82 weeks for the iPTH/80 and 4.76 weeks for the iPTH/120 group; $P = 0.295$).
During the course of the study, 15 patients in the iPTH/80 group experienced at least 1 episode of iPTH oversuppression (<150 pg/mL [<150 ng/L]), with 23 episodes in total, versus 8 patients and 13 episodes in the iPTH/120 group (P = 0.003 for number of episodes, P = 0.069 for number of patients). The percentage of patients with iPTH levels less than 150 pg/mL (<150 ng/L) during the course of the study is shown in Fig 3, separately for the 2 groups. Throughout the course of the study, this percentage was greater in the iPTH/80 group, reaching a value as high as 50% for week 8. Despite frequent (every 2 weeks) dose adjustments, this percentage in the iPTH/80 group remained high at the end of the 12-week period (30% versus 5% for the iPTH/120 group; P = 0.045). Oversuppression of iPTH during the second half of the study (weeks 6 through 12) was more frequent in patients in the iPTH/80 group: 9 patients (45%) from the iPTH/80 group had at least 2 consecutive iPTH values less than 150 pg/mL (<150 ng/L) during this period versus only 2 patients (10%) in the iPTH/120 group (P = 0.034).

Mean initial paricalcitol doses were 6.41 μg/session for the iPTH/80 group and 4.38 μg/session for the iPTH/120 group. Mean paricalcitol dose had to be decreased gradually in the iPTH/80 group, whereas it remained literally constant throughout the study period in the iPTH/120 group (Fig 4). Thirty-three dose adjustments in total were needed in the iPTH/80 group versus...
21 in the iPTH/120 group ($P = 0.083$). Dose decreases were significantly more frequent in the iPTH/80 group (28 versus 12; $P = 0.008$), whereas dose increases did not differ between the 2 groups (5 versus 9). Mean paricalcitol doses per session throughout the study were 5.46 $\pm$ 1.80 $\mu$g in the iPTH/80 group and 4.38 $\pm$ 1.78 $\mu$g (ie, 20% lower) in the iPTH/120 group. In the iPTH/80 group, phosphate-binder dose remained constant throughout the study period in 16 patients (73%) and increased in 6 patients, whereas the same figures for the iPTH/120 group were 18 patients (86%) and 3 patients ($P = 0.457$).

Baseline calcium and phosphorus concentrations did not differ between the 2 groups (9.0 $\pm$ 0.5 mg/dL [2.25 $\pm$ 0.12 mmol/L] and 5.1 $\pm$ 1.1 mg/dL [1.65 $\pm$ 0.36 mmol/L] for the iPTH/80 group and 8.9 $\pm$ 0.6 mg/dL [2.22 $\pm$ 0.15 mmol/L] and 5.2 $\pm$ 1.0 mg/dL [1.68 $\pm$ 0.32 mmol/L] for the iPTH/120 group). The increase in calcium levels was more pronounced in the iPTH/80 group throughout the entire study period, reaching statistical significance at weeks 4 ($P = 0.015$) and 10 ($P = 0.049$; Fig 1). During the course of the study, 8 patients from the iPTH/80 group versus only 2 patients from the iPTH/120 group experienced at least 1 episode of hypercalcemia (serum calcium $> 10.4$ mg/dL [2.27 mmol/L]; $P = 0.689$). Changes in values for phosphorus, as well as Ca $\times$ P product, were similar for both groups; there were more episodes of Ca $\times$ P product increases to greater than 65 in the iPTH/80 than iPTH/120 group (11 patients and 26 episodes versus 7 patients and 16 episodes, respectively), although the difference did not reach statistical significance.

Baseline alkaline phosphatase levels, as well as their changes throughout the study period, did not differ between the 2 groups. Mean decreases in alkaline phosphatase levels at week 12 were 15.8 U/L for the iPTH/80 group and 7.7 U/L for the iPTH/120 group ($P = 0.546$). Finally, no differences between the 2 groups were noted regarding other laboratory parameters or the frequency of other side effects during the course of the study.

**DISCUSSION**

Intravenous administration of paricalcitol has proven efficacy in the treatment of patients with ESRD-related SHPT. Patients administered paricalcitol had fewer prolonged periods of hypercalcemia and elevated Ca $\times$ P product than patients administered calcitriol. Furthermore, patients showing resistance to treatment with calcitriol showed a significant decrease in iPTH values when they were switched to paricalcitol therapy, without significant changes in calcium or phosphorus levels.

The Food and Drug Administration–approved initial dose for paricalcitol is 0.004 to 0.1 $\mu$g/kg of body weight. Whether the main factor for calculating the initial dose should be dry weight or severity of SHPT, as with calcitriol, is controversial. In many centers, initial paricalcitol dose is being calculated based on baseline iPTH levels. The report by Martin et al$^{12}$ was the only study that compared the efficacy and safety of an initial dosing scheme based on body weight (dose $= 0.04 \times$ body weight [kg]) with one based on severity of SHPT (dose $= iPTH/80$). Patients in the iPTH/80 group achieved a more rapid decrease in serum iPTH levels by greater than 30% without an increase in incidence of hypercalcemia (serum calcium $> 11.5$ mg/dL [2.87 mmol/L]) or elevated Ca $\times$ P product ($> 75$). However, the extent to which these dosing schemes can lead to oversuppression of iPTH ($< 150$ pg/mL [< 150 ng/L]) or their success rate in maintaining target iPTH levels (150 to 300 pg/mL [150 to 300 ng/L]) was not examined.

In our study, we compared 2 different initial paricalcitol dosing schemes, the standard scheme (iPTH/80) with the immediately lower dose scheme (iPTH/120), in their ability to control iPTH values within a desired target range (150 to 300 pg/mL [150 to 300 ng/L]). The 2 initial dosing schemes were equivalent in bringing iPTH levels within the target range. By the end of 12 weeks, the percentage of patients with at least 2 consecutive iPTH measurements within the range of 150 to 300 pg/mL (150 to 300 ng/L) was similar for the 2 schemes (78% for the iPTH/80 versus 71% for the iPTH/120 group). Median time to the first of these 2 consecutive measurements was 6 weeks for both groups ($P = 0.597$). Consequently, the lower dosing scheme does not lack efficacy in leading to the desired iPTH levels. As shown in Fig 1, the percentage of change in iPTH levels was greater (although not significantly) in the iPTH/80 group. However, a greater percentage of change does not necessar-
ily imply more patients reaching target levels because, as shown in our study, this might lead to iPTH oversuppression.

The present study uncovers for the first time a significant percentage of patients who, by using the iPTH/80 initial dosing scheme, experienced sustained oversuppression of iPTH. In particular, our findings suggest that with use of the iPTH/80 scheme, iPTH oversuppression at levels less than 150 pg/mL (<150 ng/L) occurs in almost 50% of patients. The immediately lower paricalcitol dose (iPTH/120) has the same efficacy in decreasing iPTH levels within the target range as the recommended dose, but with a significantly lower rate of iPTH oversuppression (Fig 3). This finding is strengthened further by taking a closer look at the final 4 iPTH measurements (weeks 6 to 12), when a chance for 2 dose adjustments already had been given. During this period, 9 patients from the iPTH/80 group had at least half the iPTH measurements (2 of 4) at levels less than 150 pg/mL (<150 ng/L) versus only 2 patients from the iPTH/120 group (P = 0.034). This suggests that the dose calculated by using the iPTH/80 scheme probably is too high for the recommended dose adjustment scheme that fails to prevent oversuppression of parathyroid hormone. However, this is hardly desirable because it was speculated that excessive suppression of parathyroid hormone constitutes a principle factor in the development of adynamic bone disease.¹³,¹⁴

The increase in calcium levels tended to be greater in the iPTH/80 group throughout the study, being significantly greater at weeks 4 and 10. This finding might also bear some importance, especially in light of recent reports correlating elevated calcium levels (>8.0 mg/dL [>2.00 mmol/L]) to increased risk for death in hemodialysis patients.¹⁵ Sustained elevated calcium and depressed parathyroid hormone levels in these patients might predispose to the development of vascular calcifications and, consequently, increased morbidity and mortality.⁴,⁵

In the iPTH/80 group, mean paricalcitol dose decreased significantly from 6.41 µg/session at the beginning of the study to 4.12 µg/session at week 12 (mean decrease of 36%; P = 0.003). Conversely, it remained relatively constant in the iPTH/120 group, from 4.38 to 4.10 µg/session (mean decrease of 6%; P = 0.452). Throughout the study period, mean paricalcitol dose in the iPTH/120 group was lower by 20% in comparison to the iPTH/80 group; accordingly, cost of treatment also would be significantly lower in the iPTH/120 group. In addition, patients in the iPTH/80 group would need more dose adjustments compared with those in the iPTH/120 group, mainly because of the significantly more required dose decreases (28 versus 12, respectively; P = 0.008). Therefore, the iPTH/120 scheme bears 2 additional advantages. First, patient follow-up is easier because iPTH levels reach the target range by using fewer dose adjustments, and second, this is achieved at a significantly lower cost.

One of the limitations of our study is the relatively small number of recruited patients because it was a single-center study. However, this is the first study that approaches the effect of paricalcitol on parathyroid hormone levels, focusing not only on the percentage of change, but also on achievement of the desired iPTH level, as well as on the incidence of iPTH oversuppression (iPTH < 150 pg/mL [<150 ng/L]). Baseline iPTH, calcium, and phosphorus values all followed normal distributions. This and the fact that baseline iPTH levels, as well as mean iPTH level decreases, in patients administered the iPTH/80 dosing scheme were similar in our study and the study by Martin et al¹² (baseline iPTH of 516 pg/mL [516 ng/L] and mean iPTH decrease of 52% at week 6 of treatment versus baseline iPTH of 550 pg/mL [550 ng/L] and mean iPTH decrease of 47% after 47 days of treatment, respectively), suggest that our study population is representative. That vitamin D levels were not measured at the beginning of the study is one more limitation of our study. Alfacalcidol therapy was discontinued in all patients at least 1 month before their enrollment in the study protocol, and a similar strategy was followed in other studies.¹²,¹⁶ In addition, the number of patients administered alfacalcidol before the study was not significantly different between the 2 groups. In addition, our study recruited only patients with baseline iPTH values between 300 and 900 pg/mL (300 and 900 ng/L). However, such patients constitute the majority of those that need to begin treatment with vitamin D compounds.
That this is a single-center study bears some advantages, as well. Most importantly, using data from a single center provides stability and homogeneity in implementation of the clinical protocol in particular and in treating patients in general. The possibility of confounding factors therefore is smaller.

In conclusion, an initial paricalcitol dose calculated by using the formula baseline iPTH/80 results in excessive suppression of parathyroid hormone to levels less than 150 pg/mL (<150 ng/L) in a considerably larger number of hemodialysis patients compared with a dose based on the baseline iPTH/120 formula. Initial dosing based on an iPTH/120 scheme requires fewer dose adjustments, has lower cost, and achieves similar efficacy in decreasing iPTH levels within the target range (150 to 300 pg/mL, [150 to 300 ng/L]) to the recommended iPTH/80 scheme. At the same time, it produces a smaller increase in calcium levels. Trials that are larger and more extended in time are needed for full justification of the superiority of a less aggressive paricalcitol dosing scheme.

REFERENCES