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Is cinacalcet a cost-effective treatment in severe secondary hyperparathyroidism in patients on hemodialysis?

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SUMMARY

Background: A previous study using cinacalcet, as compared to vitamin D alone, showed a better reduction response of PTH levels and a significant diminution of secondary effects. The objective of present study was to evaluate the additional cost of adding cinacalcet to the standard treatment of patients with severe secondary hyperparathyroidism (SHPT) taking into account the treatment goals achieved.

Methods: 12 month prospective study of 23 patients with severe SHPT. Two treatment regimens were considered: standard treatment (m 0) and standard treatment plus cinacalcet (m 12). Four consequences of inadequate control of SHPT were registered: parathiroid hormone (PTH), Calcium (Ca), Phosphorus (P) and the Ca x P product serum levels. Treatment effectiveness was measured as percentage of patients who achieved treatment goal according to each indicator: PTH < 800 pg/mL, PTH between 150 and 300 pg/mL, Calcium < 9.5 mg/dL, Phosphorus < 5.5 mg/dL, and Ca x P product < 55. Annual and monthly costs were calculated for both treatment regimens using Spanish 2007 tariffs, and taking into account the dose reduction in some other treatments. Results are presented as incremental costs and cost per patient who achieved treatment goal.

Results: At 12 month it was observed a higher percentage of patients who achieved simultaneously the 4 therapeutic goals with respect to basal moment, from 0% to 52.1%. Cinacalcet allowed to save costs in concomitant drugs, achieving a total saving of 149 € per patient and month. At 12 month, Cinacalcet achieved a reduction of percentage of patients with PTH > 800 pgr/mL with half of costs than standard treatment (651.35 \in vs 1,363.68 €). It was not possible to calculate the cost for PTH indicator since at the study onset, there was no patient who achieved a level between 150 and 300 pg/mL. Cinacalcet allowed reaching treatment goals in Calcium, Phosphorus and Ca x P product in a more cost-effective way (2,164.2 \in vs 2,684.8 \in). Conclusions: Although Cinacalcet is expensive, patients treated with Cinacalcet showed a minor cost per patient who achieved treatment goal than patients without Cinacalcet. The ability of cinacalcet to reduce PTH secretion, along with the reductions in the serum Ca, P, and Ca x P product, provides an alternative to

Correspondence: María Dolores Arenas Jiménez Hospital Perpetuo Socorro Plaza Dr. Gómez Ulla, 15 03013 Alicante. España Iola@demiswebs.com the traditional treatment paradigm, and should be a welcomed addition in the management of SHPT.

Key words: Hyperparathiroidism. Cinacalcet. Vitamin D. Cost effectiveness anaylisis. Efficiency.

RESUMEN

Introducción: Un estudio previo mostró que la adición de cinacalcet a la vitamina D conseguía una mejor respuesta del Hiperparatiroidismo secundario (HPTS) en pacientes en hemodiálisis. El objetivo del presente estudio fue conocer el coste adicional que supone la adición de cinacalcet al tratamiento estándar en pacientes con HPTS severo teniendo en cuenta los objetivos terapéuticos obtenidos.

Métodos: Estudio prospectivo durante 12 meses en 23 pacientes con HPTS severo, en los que no se podía mantener un tratamiento continuado con vitamina D por presentar hipercalcemia y/o hiperfosforemia. Se analizaron 2 regímenes de tratamiento: tratamiento estándar (m 0) y tratamiento estándar asociado a cinacalcet (m 12). Se analizaron las siguientes variables: iPTH, calcio, fósforo, producto CaxP, dosis de vitamina D, dosis de captores del fósforo y % de cumplimiento de indicadores. Los resultados del análisis se expresan en términos de coste-incremental y costeconsecuencia por paciente que consigue el objetivo terapéutico en base a 5 marcadores: PTH < 800 pg/ml, PTH entre 150 y 300 pg/ml, Calcio < 9,5 mg/dl, Fósforo < 5,5 mg/dl y Ca x P < 55.

Resultados: A los 12 meses de tratamiento con cinacalcet, la proporción de pacientes que alcanzaron los 4 objetivos simultáneamente pasó de 0% a 52,1%. Cinacalcet permitió un ahorro en medicación concomitante (sevelamer, vitamina D e hidróxido de aluminio), que minimizó su coste adicional, suponiendo un incremento global de 149 €/mes. En términos de costes y consecuencias, cinacalcet conseguía una reducción del porcentaje de pacientes con PTH > 800 pg/ml a la mitad de coste que el tratamiento estándar. (651,35 € vs 1.363,68 €). La falta de pacientes con PTH entre 150 y 300 pg/ml en el m0 (sin cinacalcet) no permitió la comparación entre el momento basal y el final del estudio. Cinacalcet permitía una consecución de los objetivos de calcio, fósforo y producto calcio-fósforo en su conjunto más coste-efectiva (2.164,2 € vs 2.684,8 €).

Conclusiones: Los pacientes tratados con cinacalcet presentan un coste por éxito terapéutico menor que los pa-

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cientes sin cinacalcet (pre-tratamiento), a pesar del mayor coste de adquisición de cinacalcet. La capacidad de cinacalcet de reducir la secreción de PTH, junto a la reducción en el Ca, P, y producto Ca x P, proporciona una alternativa al tratamiento tradicional y debe ser tenida en cuenta en el HPTS severo.

Palabras clave: VIH. Hiperparatirodismo. Cinacalcet. Vitamina D. Análisis de coste efectividad.

INTRODUCTION

Impaired bone and mineral metabolism is common in patients on chronic hemodialysis and is associated to a significant mortality risk. Almost 50% of patients on hemodialysis die from cardiovascular (CV) events.¹ Classical cardiovascular risk factors do not explain by themselves this increased cardiovascular mortality, and changes in mineral metabolism have emerged as a significant predictor of morbidity and mortality, both general and cardiovascular, in these patients.^{2,3} SHPT, hyperphosphatemia, and total body calcium overload have been associated to an increased morbidity and mortality in the dialysis population.⁴

New treatments providing a certain improvement have been launched in recent years,⁵ but such improvements do not appear to be sufficient to achieve an acceptable control of this condition. Recent studies have shown the difficulty for achieving objectives with the standard treatment.^{6,7} In addition, some authors think that generalized compliance of the recommendations given by the K/DOQI guidelines for bone and mineral metabolism would require use of increasingly expensive new drugs and involve significant costs, and suggest that publication of data showing significant improvements in patient prognosis should be waited.⁸

Vitamin D replacement is a significant therapeutic option for SHPT management, but has the disadvantage of a narrow therapeutic window, and easily induces hypercalcemia and elevation of plasma phosphorus levels. Vitamin D start and maintenance has to be based not only on plasma PTH levels, but also on serum levels of calcium and phosphorus.9 Calcimimetics are new agents that increase sensitivity of calcium receptors in parathyroid glands. Calcimimetics therefore allow for simultaneously reducing PTH and extracellular calcium concentrations, in contrast to the available vitamin D treatments.¹⁰ Cinacalcet was approved by the FDA in March 2004 (Sensipar[®])¹¹ and by the EMEA in October 2004,¹² and was approved by the Spanish Medicines Agency for marketing in Spain in June 2005 (Mimpara®). Recent studies have shown that patients treated with cinacalcet were more likely to achieve the goals recommended by the NFK-K/DOQI guidelines for Ca x P (65%) and for both Ca x P and PTH simultaneously (41%),^{13,14,15} and appeared to decrease the risk of parathyroidectomy as compared to placebo.16

A previous study conducted at our hemodialysis units supported the efficacy of cinacalcet in patients with severe SHPT at 9 months. Cinacalcet achieved a better response in PTH reduction than vitamin D alone, as well as a significant improvement in side effects such as hypercalcemia and hyperphosphoremia.⁹

The aim of this cost-effectiveness analysis was to assess the additional costs involved in adding cinacalcet to standard treatment in patients with severe secondary hyperparathyroidism in terms of incremental cost and cost-consequence per patient achieving the therapeutic goal.

METHODS

Patients

All 23 patients with severe SHPT on hemodialysis at our unit who had hypercalcemia (> 10.2 mg/dL) and/or hyperphosphatemia (> 5.5 mg/dL) with use of vitamin D were enrolled into the study and treated with calcimimetic drugs for one year. No parathyroidectomies were performed at any time during the study. Serum calcium levels < 8.4 mg/dL were considered an exclusion criterion for starting treatment. This sample of 23 patients was analyzed at two time points during follow-up, while they were being treated with phosphate binders and vitamin D (m0) and 12 months after the start of cinacalcet added to standard treatment (m12).

All patients underwent hemodialysis sessions 3.5-4 hours in duration three times weekly, using mid- and high-permeability polysulphone dialyzers of 1.8-2.1 m². No changes were made in the treatment scheme during the study. The NFK-K/DOQI recommendations were implemented in our hemodialysis units as of October 2005.

Methodology

Treatment was started with cinacalcet (Mimpara[®]) at an oral dose of 30 mg once daily, added to the standard treatment taken by the patient, consisting of the vitamin D metabolite, alphacalcidol (Etalpha[®]) at the doses previously used. Calcium concentration was also initially changed from 2.5 to 3 mEq/L to prevent hypocalcemia associated to cinacalcet administration. In order to achieve the target phosphorus levels, each patient was given a combination of phosphate binders consisting of calcium acetate (Royen[®]) -without exceeding 1,500 mg/day of elemental calcium-, sevelamer (Renagel[®]), and aluminium hydroxide (Pepsamar®), that were individualized according to patient requirements and preferences.

This treatment scheme was kept unchanged when cinacalcet was started. Doses were adjusted during the study period depending on the response of each patient. Criteria for adjusting doses of vitamin D metabolites and/or cinacalcet were based on the K/DOQI guidelines.¹⁷ At study completion, a dialysate with a calcium content of 2.5 mEq/L was used again in 7 patients. PTH, Ca, and P were routinely measured every month. An institutional review board approved the study, and informed consent was obtained from every patient.

Direct costs of medication were estimated at both time points (m0 and m12) based on official costs published in Spain in 2007.¹⁸ Costs are given in Euros. Indirect costs and costs related to clinical monitoring and follow-up of patients were not considered in cost analysis, as they were assumed to be similar in both treatment groups.

The cost involved in adding cinacalcet to standard treatment was evaluated in two ways: 1) An analysis of incremen-

Table I. Mean PTH, calcium, phosphorus, and calcium-phosphorus product values before (month 0) and after (month 12) cinacalcet treatment, and percent achievement of objectives recommended in the NFK-K/DOQI guidelines

	Before cinacalcet (month 0)	After cinacalcet (month 12)	Р
Number of patients	23	23	
Serum PTH (pg/mL)	712.09 ± 279.2	310.5 ± 259.4	< 0.001
Serum calcium (mg/dL)	9.7 ± 0.6	8.7 ± 0.8	< 0.001
Serum phosphorus (mg/dL)	4.7 ± 1.4	4.4 ± 1.3	0.48
Calcium-phosphorus product (mg²/dL²)	46.1 ± 14.8	39.1 ± 12.9	0.10
% of patients with PTH < 800 pg/mL	8/23 (34.7%)	22/23 (95.6%)	< 0.001
% of patients with PTH ranging from 150-300 pg/mL	0/23 (0)	15/23 (65.2)	< 0.001
% of patients with calcium < 9.5 mg/dL	8/23 (34.7)	18/23 (78.2)	< 0.001
% of patients with phosphorus < 5.5 mg/dL	17/23 (73.9)	20/23 (86.9)	< 0.05
% of patients with Ca x P < 55 mg ² /dL ²	16/23 (69.5)	22/23 (95.6)	< 0.05
% of patients simultaneously achieving Ca, P, and PTH objectives	0/23 (0)	12/23 (52.1)	< 0.001

tal drug cost, in which benefit is measured in monetary units, and 2) a cost-consequence analysis, in which benefit is measured in monetary units by consequence, in this case the proportion of patients meeting the goals of the K/DOQI guidelines.

The analysis of incremental drug cost took into account the additional cost involved in adding cinacalcet to the standard treatment, regardless of the results of treatment. For this cost assessment, costs of other drugs such as phosphate binders and vitamin D were also considered. Incremental cost was calculated by subtraction of the two total costs: m12 cost-m0 cost.

The cost-consequence analysis evaluated the additional cost per patient achieving the therapeutic objective by dividing the treatment costs of the whole population by the proportion of patients who met the goal established by the K/DOQI guidelines for each indicator: PTH ranging from 150-300 pg/mL, serum calcium levels > 9.5 mg/dL, serum phosphorus levels < 5.5 mg/dL, and Ca x P product < 55 mg²/mL², at each time point, m0 and m12.

Statistical analysis

Statistical analysis was performed using SPSS 12.1 software. A Student's *t* test was used to compare the means of Ca, P, Ca x P, and PTH measurements in each patient and in the two periods. Percentages were compared using a McNemar's test. A value of p<0.05 was considered statistically significant.

RESULTS

Mean age of the patient sample at study start was 53.1 ± 14.8 years. Median time of patients on hemodialysis was 126.9 months (range, 52-358.6). Thirteen patients (56.5%) were male, and 10 patients (43.4%) were female. No significant differences were seen between the mean Kt/V and hemoglobin values at m0 (1.46 \pm 0.54 and 12.4 \pm 0.5g/dL, respectively) and m12 (1.47 \pm 0.54 and 12.3 \pm 0.4 g/dL, respectively).

Table I shows the percentages of compliance with the objectives recommended by the NFK-K/DOQI guidelines and the mean serum levels of the four markers considered in the study (PTH, calcium, phosphorus, and calcium-phosphorus product) at cinacalcet start (m0) and at the end of the 12-month treatment period with this drug (m12). All markers measured improved after addition of cinacalcet to standard treatment (p < 0.05).

Table II shows the mean PTH, calcium, phosphorus, and calcium-phosphorus values in patients who met or did not meet the objectives at one year of treatment.

Analysis of incremental drug cost

Table III shows the differences in incremental drug cost of several components of SHPT before and one year after cinacalcet was added to standard treatment. Although cinacalcet costs represented an additional monthly cost of $371.8 \in$ at one year of treatment, the difference in total cost between patients using and not using cinacalcet was $149.5 \in$ per month. This was due to reduction of the required doses of sevelamer, aluminium hydroxide, and vitamin D, particularly sevelamer doses, which represented cost savings of $205 \in$. Calcium ace-

Table II.	Mean serum levels of PTH, calcium, and
	phosphorus 12 months after cinacalcet star in patients achieving and not achieving K/DOQI objectives

	Achieving objectives	Not achieving objectives	Р
Serum PTH (pg/mL)	190.6 ± 62.7	535.3 ± 259.4	p < 0.001
Serum calcium (mg/dL)	8.4 ± 0.6	9.9 ± 0.3	p < 0.001
Serum phosphorus (mg/dL)	4.0 ± 0.8	6.9 ± 1.4	p < 0.001
Calcium x Phosphorus (mg ² /dL ²)	37.4 ± 10.2	76.5 ± 0	p < 0.001
Man cinacalcet dose (mg/day)	42.0 ± 22.1	60 ± 21.2	p < 0.01

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Table III. Incremental cost analysis: calculation of diferences in monthly cost of SHPT treatment when cinacalcet is added to standard treatment

	Unit cost	Units per month	Mean patient dose (m 0)	Cost/month (m 0)	Mean patient dose (m 12)	Cost/month (m 12)	Mean patient dose	Cost/month
			Month 0 (withou	t cinacalcet)	Month 12 (with	cinacalcet)	Diffe	rence
Alphacalcidol IV	3.56€	4.33	3.3 mcg/week (*)	50.86€	2.2 mcg/week (*)	33.91€	-1.1	-16.95€
Calcium acetate	0.10€	30.33	2.53 tab/day	7.67 €	3 tab/day	9.09€	0.47	1.42 €
Sevelamer	1.19€	30.33	11.4 tab/day	411.4€	5.7 tab/day	205.7 €	-5.7	-205.7 €
Cinacalcet	0.20€	30.33	0 mg/day (*)	0€	61.3 mg/day (*)	371.8€	61.3	371.8€
Aluminium hydroxide	0.04€	30.33	2.7 tab/day	3.27€	1.87 tab/day	2.2€	-0.83	-1.07€
				473.2€		622.7 €		149.5€

Time units: 1 month = 4.33 weeks; 1 month = 30.33 days.

(*) Measurement units are given as daily tablets, except for vitamin D (mcg/week) and cinacalcet (mg/day). Vitamin D is given as mcg/week because it is administered during dialysis sessions (1, 2, or 3 times weekly). Cinacalcet cost is given per mg/day rather than per daily tablets because a single daily tablet of different strengths (30, 60, 90, 120, and 180 mg) is used.

Monthly costs of each drug are obtained by multiplying the mean dose used in each period by units used in the month and by the cost of each drug unit.

Total monthly cost is estimated by adding the costs of each of the drugs at m 0 and m 12.

Incremental cost analysis is obtained by subtracting the two total costs: m 12 cost-m 0 cost.

tate dosage was increased, but impact of such increase on total costs was minimal $(1.42 \in)$. Cinacalcet allowed for savings in concomitant medication, which minimized its additional cost.

Cost-consequence analysis

If, in addition to considering drug costs, the cost in relation to the ability to achieve the established objectives is also taken into account (table IV), addition of cinacalcet to standard treatment achieved, after 12 months of follow-up, an increase in the proportion of patients who reached such therapeutic objectives. When cost-consequence was analyzed by objectives, cinacalcet addition was seen to allow for achieving the calcium objective (796.29 \in vs 1,363.68 \in) (p < 0.01) and control of Ca x P product < 55 mg²/dL² (651.36 \in vs 506.9 \in) (p > 0.05) at a lower cost as compared to without cinacalcet, and for achieving phosphorus levels < 5.5 mg/dL at a slightly higher cost (716.57 \in vs 640.32 \in) (p > 0.05). Cinacalcet allowed for more cost-effective overall achievement of the calcium, phosphorus, and calcium-phosphorus product targets $(2,164.2 \in vs \ 2,684.8 \in)$. The lack of patients on the apeutic target (150-300 pg/mL) for PTH at m0 (without cinacalcet) prevented comparison between the study baseline and end, as cost-consequence cannot be calculated because it is a value divided by 0, which would tend to infinity. When the costconsequence of achieving PTH values < 800 pg/mL was assessed, cinacalcet treatment allowed for an increase from 34.7% to 95.6%. Cinacalcet therefore allowed for reaching this objective at half the cost as compared to standard treatment (651.35 \in *vs* 1,363.68 \in).

DISCUSSION

SHPT and mineral metabolism changes play an essential role in cardiovascular disease and in morbidity and mortality of patients with chronic kidney disease. Mineral metabolism status was described for a representative sample of patients, and units from seven countries participated in the DOPPS study (Dialysis Outcomes and Practice Patterns Study).¹⁹ This study showed that almost 20% of this population did not meet any of the markers of the K/DOQI guidelines for mineral metabolism, and only 5% of patients were able to simultaneously meet all four recommendations in the guidelines. The risks of cardiovascular and all-cause mortality were directly and independently associated to each of the four indicators.³

The benefit of vitamin D for treating high PTH levels has been adequately established. Several studies have shown improvements in bone metabolism and density with treatment with active vitamin D.20 However, in addition to this beneficial effect, vitamin D stimulates intestinal absorption of calcium and phosphorus, and is therefore able to cause hyperphosphatemia, raise the Ca x P product, and increase total calcium load. Effective implementation of therapeutic strategies based on compounds containing vitamin D is therefore difficult, because these agents are associated to substantial and often dose-limiting calcemic and phosphatemic actions that make calcium and phosphorus objectives difficult to achieve.²¹ In a previous study conducted by our group, discontinuation or dose reduction of vitamin D metabolites was required in 37.1% of patients due to serum calcium levels > 10.2 mg/dL or serum phosphorus levels > 5.5 g/dL. Patients requiring discontinuation of vitamin D metabolites were those having more severe secondary hyperparathyroidism,¹⁹ which suggested that these patients required an alternative treatment to standard therapy with vitamin D and were the patients who could benefit most from cinacalcet treatment.

Our group recently reported⁹ the results obtained after adding cinacalcet to standard treatment with low-dose vitamin D in patients with severe SHPT on chronic hemodialysis who could not be controlled with vitamin D due to inadequate elevations of serum calcium and phosphorus levels according to

Table IV. Cost-consequence analysis: calculation or differences in monthly cost of SHPT treatment when cinacalcet is added to standard treatment as compared to the ability to achieve the established objectives

	% patients achieving objective (m 0)	% patients achieving objective (m 12)	Cost per patient achieving objective (m 0)	Cost per patient achieving objective (m 12)
% of patients with PTH < 800 pg/mL	34.7%	95.6%	1,363.68 €	651.35€
% of patients with PTH < 600 pg/mL	43.4%	91.3%	1,090.32 €	682.03 €
% of patients with PTH < 300 pg/mL	0.00%	71.40%	N/E €	872.13€
% of patients with PTH ranging from 150-300 pg/mL	0.00%	65.2%	N/E €	955.06 €
% of patients with calcium < 9.5 mg/dL	34.7%	78.2%	1,363.68 €	796.29 €
% of patients with phosphorus < 5.5 mg/dL	73.9%	86.9%	640.32 €	716.57 €
% of patients with Ca x P < 55 mg/dL ²	69.5%	95.6%	680.86 €	651.36 €
% of patients simultaneously achieving Ca, P and PTH objectives	0.00%	52.1%	N/E	1,195.20 €

Cost-consequence analysis is obtained by dividing mean treatment cost per patient (m 0: 473.2 \in ; m 12: 622.7 \in) by the proportion of patients who met the objective established by the K/DOQI guidelines for each indicator.

Cost-consequence at m 0 = monthly cost at m 0 (473.2 €) divided by % patients achieving the objective at m 0 x 100.

Cost-consequence at m 12 = monthly cost at m 12 ($622.7 \in$) divided by % patients achieving the objective at m 12 x 100.

N/E: Not evaluable. The total absence of patients on the therapeutic objective at time m 0 before cinacalcet prevented quantification of cost, that would tend to infinity.

the new K/DOQI criteria. Combined use of cinacalcet and vitamin D metabolites improved achievement of the K/DOQI objectives in these patients with no adverse effects and lower doses of phosphate binders. In fact, 52.1% of patients simultaneously achieved the Ca, P, Ca x P, and PTH objectives at 12 months. Using conventional vitamin D treatment, only a small fraction (6%)⁴ of the patients reached all four K/DOQI objectives.

In this study, use of cinacalcet significantly increased treatment cost in these patients, but less than expected, since significant savings were made in concomitant medication (vitamin D, sevelamer, and aluminium-based binders). The hypothetical additional monthly cost of $371.8 \in$ derived from cinacalcet use was reduced to $149.5 \in$ /month because decreased use of sevelamer resulted in significant savings of up to $205 \in$ per month.

Use of cinacalcet allowed achievement of objectives in up to 62.5% of patients who did not reach them previously. Although the cost of reaching the goal of PTH levels ranging from 150 and 300 pg/mL was 955.06 \in , the cost of not achieving the goal in any patient without cinacalcet is incalculable. Since not calculable parameters impair understanding of results, the cost-consequence for the objective of PTH levels < 800 pg/mL was analyzed. Cinacalcet treatment allowed for increasing from 34.7% to 95.6% the proportion of patients meeting this objective, therefore permitting this objective to be reached at half the cost as compared to standard treatment (651.35 \in vs 1363.68 \in). Cinacalcet was thus shown to be highly cost-effective for the control of severe SHPT.

The group of patients responding with a PTH decrease to cinacalcet treatment received a lower dose than the non-responding group (table II). Among the 8 patients who did not reach the objective of PTH levels < 300 pg/mL, 5 patients had PTH levels below 400 pg/mL, 2 patients levels ranging from 500 and 700 pg/mL, and parathyroidectomy was only indicated in one patient with PTH levels > 1,000 pg/mL on long-

term hemodialysis who had an ectopic gland in mediastinum and a high surgical risk (patient was receiving 180 mg/day of cinacalcet).

Since the risk of cardiovascular and all-cause mortality is directly and independently associated to each of the four indicators,³ achievement of these objectives could make possible a significant improvement in morbidity and mortality in these patients.

Ruth Garside et al²² recently published an article in which they concluded that cinacalcet is unlikely to be considered cost-effective for SHPT treatment based on the fact that its long-term clinical implications are not sufficiently clear yet. In their article, they developed a Markov model to estimate the incremental cost-utility of cinacalcet. As compared to standard treatment, cinacalcet involved an additional lifetime cost of 21,167 \in per person and an additional 0.34 qualityadjusted life years (QALY), which resulted in an incremental cost-effectiveness ratio of 61,890 \in (approximately 89,000 \in) per QALY.

Our approach to the problem differs from that of Garside, as we only focused on a patient subgroup with special characteristics: patients with severe SHPT who could not be controlled with vitamin D metabolites due to inadequate serum calcium and/or phosphorus elevations, and centered our analysis on the cost per objective achieved. Our results showed that while cinacalcet increased the overall costs, it allowed for simultaneous control of objective parameters in treatment of SHPT, and considering compliance with guidelines represents a better use of healthcare resources when compared to standard treatment.

The ability of cinacalcet to reduce PTH secretion allows for decreasing calcium, phosphorus, and calcium-phosphorus product, providing an alternative to standard treatment in a group of patients in whom the only possible alternative was parathyroidectomy. Cinacalcet should therefore be a welcome addition to our standard strategy for SHPT treatment. Use of

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cinacalcet in patients on hemodialysis with severe SHPT resistant to vitamin D or in patients with significant adverse reactions such as hypercalcemia and/or hyperphosphatemia should be considered as a cost-effective option.

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