Impact of parathyroid hormone product recall on severe hypoparathyroidism patient management: understanding transitions in care

ABSTRACT NUMBER: IR023
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Background

Hypoparathyroidism is an orphan condition impacting an estimated 70,000 Americans. High-dose calcium and active vitamin D supplements, thiazide diuretics, and/or parathyroid hormone (PTH) replacement are used to prevent symptomatic hypocalcemia and related complications.[1] Guidelines reserve PTH replacement for severe patients unable to achieve laboratory and symptomatic control on conventional therapy. In September 2019, the only FDA-approved PTH replacement was recalled. A post-recall consensus statement jointly issued the same month by the Endocrine Society and American Society for Bone and Mineral Research (ASBMR) recommended management with active vitamin D3 and calcium, at potentially higher than pre-PTH replacement requirements, or off-label teriparatide, a PTH analog.[2] The purpose of this case study is to describe prescribing patterns and drug utilization in severe hypoparathyroid patients after the market recall of parathyroid hormone (PTH) for injection.

Methods

A large commercial claims database was used to conduct a pre-/post-cohort analysis in continuously eligible patients on PTH replacement during the six months prior to the recall. PTH dosage levels (low, 25 mcg; medium, 50 mcg; high, 75–100 mcg) at time of the recall were assessed. The index date of September 19, 2019, was used as the start of the study period to measure prescription drug utilization during the 12 months after the PTH recall. Utilization of vitamin D3, calcium, thiazide diuretics and/or teriparatide after the index date was assessed. Age of the patient was determined at the index date.

Results

Claims data were used to identify 255 eligible patients prescribed PTH replacement therapy (for demographics, see Figure 1). At the time of recall, 55% of patients required high-dose PTH replacement, 36% required medium and 9% required low (Figure 2). Most prescriptions were managed post-recall by internists (71.9%). Prescriber sub-specialty could not be validated in our dataset. Disruptions in care were evident, as 21.0% (n = 56) of prior PTH users had no post-recall prescription claims. Within 12 months of recall, vitamin D3 analog claims were present for 78% (n = 198) and teriparatide for only 10% (n = 26; Figure 3). Calcium utilization was likely over the counter, and those managed on calcium alone or who received PTH therapy outside their benefit, such as compounded, compassionate use program or cash pay, could not be accounted for in claims data.

Eighty-three percent of vitamin D claims post-recall initiated within 30 days; however, a late spike (≥120 days) after the last PTH replacement claim was seen in 9% of prescription vitamin D users. Delays in initiation of off-label teriparatide were also evident. Only 19% of teriparatide claims initiated early (≤30 days from last PTH claim), and 27% started more than 120 days after the last PTH claim. Teriparatide utilization did not differ widely by prior PTH dose, with 14%, 8% and 11% of low-, medium- and high-dose patients initiating teriparatide, respectively.

Figure 1: Demographics

Population	N = 255
Percentage female	85.9
Average age (years)	50.1 (+/-13.8)

Figure 2: Pre-recall PTH replacement dose

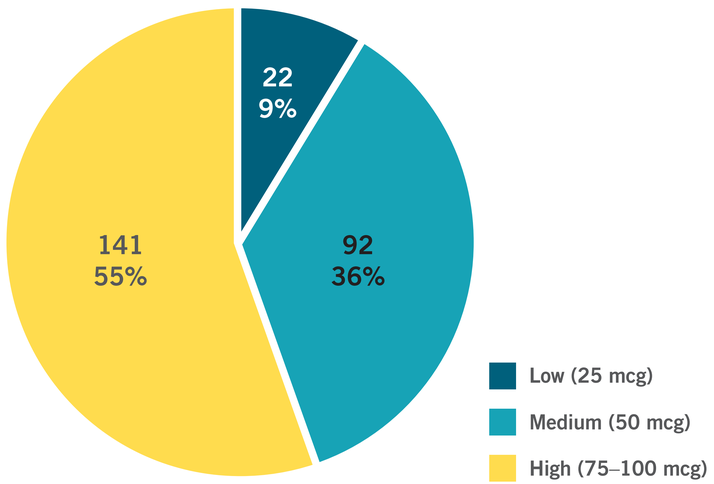
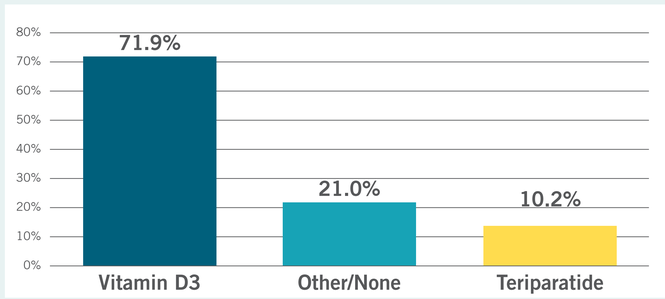


Figure 3: Post-recall hypoparathyroid treatment



Conclusions

Care disruptions and treatment delays were evident for severely hypoparathyroid patients after PTH recall. Since all patients needed PTH replacement pre-recall, lower-than-expected utilization of active vitamin D and teriparatide was seen post-recall, despite rapid endorsement by practice guidelines as recommended treatment alternatives. One likely factor in therapeutic decision-making and patient acceptance was the two-to-three-times-daily injections needed when using teriparatide formulations for hypoparathyroidism, compared with once daily injection pre-recall with PTH replacement. The predominance of vitamin D or over-the-counter supplement monotherapy may also be attributable to lack of payer authorization requirements for these agents, compared with PTH analogs, such as teriparatide. Although published rapidly, guideline updates were distributed by specialty medical societies, so it is also possible that nonspecialist prescribers may not have had the same level of awareness as the societies' member base. Late therapy initiation implies sub-optimal early patient management and may represent challenges with timely navigation of patient, payer and prescriber dynamics in the face of rapidly evolving clinical guidance. Advocacy opportunities exist for broader prescriber, payer and patient education and support regarding hypoparathyroidism management. While our study was specific to the PTH recall scenario, these results may serve as an illustration of the susceptibility of fragile, orphan-condition patients to market disruptions.

[1] Abate, Ejigayehu G., and Bart L. Clarke. (2017) "Review of Hypoparathyroidism." *Frontiers in Endocrinology*; 7: 172.8"
[2] ASBMR. n.d. "Joint American Society for Bone and Mineral Research (ASBMR) – Endocrine Society Guidance on Transitioning Hypoparathyroidism Patients from NATPARA®" Accessed September 26, 2023. https://www.asbmr.org/about/statement-detail/joint-american-society-bone-mineral-research-asbmr.