ABSTRACT

Background: Somatostatin analogs are the most widely used medical treatment in acromegaly. Available long-acting formulations are given subcutaneously (intramuscular or deep subcutaneous injections). Results of a multicenter, baseline-controlled, 3-month study showed that a new investigational oral analog was well tolerated and safe in acromegaly. The Treatment Satisfaction Questionnaire for Medication (TSQM), assessed in the phase 3 study as an exploratory endpoint, compared Patient Reported Outcomes (PRO) in responders to injections versus responders to octreotide capsules.

Methods: TSQM, a validated PRO measure, consists of 14 multiple-choice items encompassing 4 domains: Effectiveness, Side Effects, Convenience, and Overall Satisfaction. Additional supplemental items were developed specifically for this study and relate to the occurrence of symptoms and direct comparison of the overall satisfaction with octreotide capsules versus injections. The results herein include a cohort of 155 patients (of 160 enrolled) who were treated on oral and continued treatment with octreotide capsules for up to 3 months.

Results: A higher percentage of patients taking octreotide capsules reported improved satisfaction compared to deterioration in Effectiveness, Side Effects, Convenience, and Overall Satisfaction (improvement in 41, 36, 48, and 39, respectively, vs deterioration in 28, 13, 39, and 29%) while others maintained their scores. The improved Effectiveness score supported the improvement in acromegaly symptoms (AIS score), reported in the phase 3 study. Mean satisfaction with octreotide capsules was higher than with injections, based on the response to the statement, “I am satisfied with this medication as compared to others” (5.2 score on a scale of 0-7). This was consistent with 86% of core study completers electing voluntarily to continue into the extension phase.

Conclusions: Patients treated with octreotide capsules compared with injections. Improvements were noted for oral acromegaly in all TSQM scale scores, especially for Effectiveness and Side Effects.

INTRODUCTION

Acromegaly is a rare and debilitating disorder characterized by excessive growth hormone (GH) secretion, usually due to a benign pituitary adenoma.

Somatostatin receptor ligands (SRLs) (octreotide [Sandostatin®] and lanreotide [Somatuline®]), the most widely used medical treatments for acromegaly, are currently available as long-acting formulations that must be administered parenterally by intramuscular or deep subcutaneous injections.

In a multicenter, single-arm, baseline-controlled phase 3 study in acromegaly patients (n=155) previously treated with injectable SRLs, the efficacy of octreotide capsules in controlling and maintaining GH and insulin-like growth factor 1 levels was demonstrated in 66% of modified-intent-to-treat patients for up to 7 months and in 62% of patients for up to 13 months.

• Treatment with octreotide capsules was associated with a significant reduction in the incidence and severity of acromegaly symptoms as measured by the Acromegaly Index of Severity (AIS) score compared with SRL therapy.

• The Treatment Satisfaction Questionnaire for Medication (TSQM), a validated Patient Reported Outcomes measure, was an exploratory endpoint in the phase 3 study.

OBJECTIVE

To evaluate treatment satisfaction among patients participating in the phase 3 trial, using the TSQM and supplemental items developed specifically for the study.

METHODS

Study Design

• Patients with acromegaly who were responsive to and receiving a stable dose of a parenteral SRL therapy for at least 3 months prior to screening switched to octreotide capsules. 3

• The octreotide capsules treatment period lasted 213 months and 24% of patients (of 160 enrolled) who were treated on oral and continued treatment with octreotide capsules for up to 3 months followed by a fixed-dose phase (6-11 months). Patients completing 7 months of treatment could voluntarily choose to enter a 6-month extension phase.

• In the TSQM modified E-ITT Population, more patients reported improvement (41.2%) in the Effectiveness domain than a deterioration (28.2%). More patients reported an improvement (37.8%) in the Control of symptoms than a deterioration (12.9%), and more patients reported an improvement (48.2%) in Convenience than a deterioration (38.8%) (Figure 1).

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• Conclusions: Patients receiving octreotide capsules for acromegaly were more satisfied with their treatment compared with SRL injections.

• Improvements were reported in all TSQM scale scores, especially in the Effectiveness and Side Effects domains.

• Octreotide capsules improved overall satisfaction with a reduction in the incidence of breakthrough symptoms.

• These findings are consistent with those of the phase 3 study in which 66% of patients completing the fixed-dose phase of the study voluntarily chose to enroll in the extension phase and receive octreotide capsules for an additional 6 months.

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