Background

Carcinoid heart disease (CaHD) is a rare condition that occurs in patients with carcinoid syndrome (CS) whose tumor burden has increased and whose cardiovascular system is increasingly affected. CaHD is associated with an increased risk of mortality and morbidity.

Methods

The efficacy of telotristat ethyl (TEL) was evaluated in two randomized, double-blind, placebo-controlled trials (TELESTAR and TELECAST) in patients with CS and CaHD. In TELESTAR, patients were randomly assigned to receive placebo, telotristat ethyl 250 mg tid, or telotristat ethyl 500 mg tid. In TELECAST, patients were randomly assigned to telotristat ethyl 250 mg tid or telotristat ethyl 500 mg tid. The primary efficacy endpoint was the percentage of patients with ≥50% reduction in average daily stool frequency compared with baseline.

Results

In TELESTAR, the primary endpoint was met in the telotristat ethyl 500 mg tid group (15/19 patients [78.9%], p=0.002) but not in the telotristat ethyl 250 mg tid group (4/14 patients [28.6%]). In TELECAST, the primary endpoint was met in both the telotristat ethyl 250 mg tid (10/17 patients [58.8%], p=0.03) and telotristat ethyl 500 mg tid (12/17 patients [70.6%], p=0.007) groups. The most commonly reported adverse events were gastrointestinal disorders, including nausea, diarrhea, and constipation.

Conclusions

Telotristat ethyl was effective in reducing the frequency of bowel movements in patients with carcinoïd heart disease, with a safety profile consistent with previous studies. Further research is needed to determine the long-term effects of telotristat ethyl on patient outcomes.

References

2. Zacks JS. Poster at NANETS 2017 Annual Symposium; October 19–21, 2017; Philadelphia, PA, USA.
3. Overall combined safety analysis in patients with CaHD and the overall safety population. Poster 212.
4. The incidence of new cardiac events was low in both the DBT and DBT + OLE groups.
5. The most common TEs in the CaHD subgroup were gastrointestinal disorders.
6. The incidence of new cardiac events was lower in the DBT + OLE group compared with the overall study population.