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Real-world Experience with Advanced Long-term Prophylaxis Agents to Treat Hereditary Angioedema in Canada

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Introduction

Hereditary angioedema (HAE) is a rare genetic disorder caused by a deficiency or dysfunction in the serine protease inhibitor of C1, which results in an accumulation of the vasodilator bradykinin. Angioedema is a type of temporary swelling that can be histaminergic (mast cell-mediated) or non-histaminergic (bradykinin-mediated), of which HAE is an example.[1]
The prevalence of HAE is approximately 1:50,000 individuals, and no major differences in prevalence between ethnicities or sex have been reported for the most common subtypes I and II.[2,3] There are three categories of HAE; type I is the most prevalent and is characterized by low C1-inhibitor (C1-INH) levels, type II is characterized by normal levels but low activity of C1-INH (dysfunctional C1-INH), and patients with the nC1-INH subtype have normal C1-inhibitor levels and function.[2,4] This last subtype has an unknown prevalence, but is less commonly observed than type I and II.

The dysfunction or deficit in C1-INH results in accumulation of the vasodilator bradykinin. C1-INH is involved in inhibiting proteins in the bradykinin pathway, such as factor XIIa and kallikrein.[5] Due to the overproduction of bradykinin, vascular permeability increases, resulting in recurrent episodes of potentially severe angioedema in various body parts (HAE attacks).[6] HAE management includes acute attack management, and potentially short-term and/or long-term prophylaxis (LTP). This article will discuss disease burden, patient unmet needs, challenges with conventional treatments, and clinical trial and real-world experience with the newer LTP agents lanadelumab, berotralstat, and garadacimab, with a particular emphasis on Canadian experience with these newer drugs.

Burden of Disease

HAE attacks occur randomly and vary in intensity, location, and duration, and frequency does not correlate with severity.[7] Before diagnosis, 42% of patients reported weekly HAE attacks, with the most affected areas being the abdomen (89%), larynx (66%), feet (66%), hands (63%), and face (63%). Most of these attacks were severe (66%) or moderate (31%).[4] Abdominal attacks can be severely debilitating due to extreme cramps/colicky pain, and laryngeal attacks can be fatal due to the risk of asphyxiation.[8]

HAE attacks often lead to emergency department visits and hospitalization. The variable frequency, unpredictability, and severity of the attacks may lead to anxiety and depression in patients and induce a significant burden on their personal and professional lives, contributing to a lowered quality of life, in particular with respect to the domains of general health, bodily pain, and vitality.[4,9]

Patients may experience significant delays in getting appropriate treatment. A Québec survey showed that patients generally have a median 10-year delay between their first symptoms and an established diagnosis of HAE, and 69% of patients had received unnecessary treatments and procedures.[4] The majority of patients were diagnosed by an immunologist or allergist (74%).[4] Furthermore, patients often have to wait for medical attention during attacks, with 46% waiting over an hour in the emergency department to see

a physician. Preventing attacks and increased awareness and education among Canadian physicians is warranted to address this issue.

Historically, prophylactic treatment options have included oral attenuated androgens and antifibrinolytics. The latter are not effective, and androgens are associated with many anabolic and androgenic adverse events (AEs).[10] In the past 10 years, targeted therapies have been developed. These LTP agents include C1-INH replacement therapy, which requires frequent intravenous (IV) or subcutaneous administration. A new class of LTP agents available in Canada are inhibitors of kallikrein, including the monoclonal antibody lanadelumab, which is a subcutaneously injected plasma kallikrein inhibitor, and the oral plasma kallikrein inhibitor berotralstat.[8,10] Additionally, garadacimab is a monoclonal antibody which is subcutaneously injected and targets activated factor XII, thereby inhibiting bradykinin formation.[11,12]

In a 2024 report, before the new class of LTP agents was available, the most common treatments in Québec, between May 2019 to February 2020, were reported to be tranexamic acid (18%), subcutaneous plasma-derived C1-INH (pdC1-INH) (53%), and IV pdC1-INH (41%).[4] Most patients (91%) self-administered these treatments, and 44% reported AEs. Treatment decreased attack frequency and attack duration. Most of the survey respondents in Québec received long-term prophylaxis (LTP) (89%), which seemed to reduce the number of emergency department visits.[4]

Before the introduction of newer classes of LTP agents, there was an unmet need among patients and providers for improved therapies that addressed the challenges of conventional HAE treatments specifically around efficacy and safety.[13,14] Agents with various modes of administration, and improved efficacy and safety profiles were developed to address these unmet needs also with the potential to impact patient compliance, adherence, and to reduce the overall burden of treatment.

Evaluation of Clinical Evidence of Modern LTP Agents Lanadelumab and Berotralstat

Lanadelumab

Lanadelumab is approved as LTP for HAE in Canada and other countries based on results of the HELP study.[15] Following this trial and approval, real-world effectiveness and long-term efficacy and safety have been evaluated in follow-up studies.

Ad hoc analyses from the HELP study showed that treatment has a rapid onset of action within the first two weeks of starting treatment, and the effects are sustained over longer periods of time (days 70-182 of treatment – steady state). The study also compared AEs during early treatment (days 0-69) and during steady state (days 70-182) and found a comparable safety profile.[6]

The HELP OLE study was a Phase 3 open-label extension of the HELP study, in which lanadelumab (300 mg/2 weeks) was evaluated over a long follow-up time.[8] The study included 212 patients, and the mean follow-up time was 29.6 months.

Efficacy analysis showed:

- The mean attack rate was reduced by 87.4% during treatment,
- Patients had a lower need for acute treatment,
- There was a reduction in moderate/severe attacks,
- The attack proportion reduced ≥50% for 96.6% of patients and ≥90% in 75.5% of patients, resulting in patients remaining attack-free for a mean of 97.7% of days during treatment.

In terms of safety, 97.2% of patients reported at least one treatment-emergent adverse event (TEAE), of which most were mild or moderate in severity. The most commonly reported TEAEs were injection site pain, viral upper respiratory tract infection, upper respiratory tract infection, and headache. Treatment-related TEAE were reported by 54.7% of patients and were most commonly injection site reactions. No serious treatment-related TEAE were reported. AEs of special interest related to lanadelumab (hypercoagulability and bleeding events) were reported by 3.3% of patients. The long-term safety profile in this study was similar to findings in the initial HELP study, suggesting no new treatment-related TEAEs in the long-term study.[8]

In another follow-up of the HELP OLE international study, the long-term impact of lanadelumab on patient-reported outcomes were measured using various surveys.[16] Compared to baseline (before treatment start), 48.9% of rollover patients (who completed the initial HELP study) had a clinically important improvement in health-related quality of life. Non-rollovers (patients newly enrolled in this study) had an even larger

Endpoints	Lanadelumab[8,16]	Berotralstat[10,18]
Efficacy	• 87.4% reduction in mean attack rate • Lower need for acute treatment • Reduction in moderate/severe attacks • Attack proportion reduced ≥50% in 96.6% of patients, and ≥90% in 75.5% of patients • Attack-free for mean of 97.7% of days during treatment • Improved quality of life • Improved anxiety • High treatment satisfaction • Increased work productivity/activity	• 30.0-44.2% reduction in attack rate • Lower need for acute treatment • 76% of attack were mild or moderate • Reduction in attack frequency • Improved angioedema quality of life scores
Adverse events	• Mild/moderate • No drug-related serious TEAE • Injection site pain, viral upper respiratory tract infection, headache • 3.3% hypercoagulability/bleeding events	• Mild/moderate • Drug-related serious TEAE (1.3%) • Upper respiratory infection, abdominal pain, vomiting, headache, diarrhea, back pain

Table 1. Long-term clinical studies assessing LTP agents for HAE[8,10,16,18]

Abbreviations: AEs: adverse events; **HAE:** hereditary angioedema; **LTP:** long-term prophylaxis.

change in scores. Furthermore, both patients (78.7%) and investigators (82.4%) reported excellent treatment responses. The study also revealed improvements in anxiety, a high level of treatment satisfaction, and increased work productivity or activity.[16]

A German study provided data from a 4-year follow-up for the first 34 patients treated with lanadelumab.[17] Of the 34 patients, 32 were still using the treatment after 4 years. The yearly attack rate was low, and over 70% of patients reported being attack-free since the start of their injection interval, suggesting well-controlled disease, with 21 patients having complete control. Compared to an earlier report, the quality of life improved further over the 4-year period, particularly regarding fear and shame, and patients reported very high levels of treatment satisfaction.[17]

Berotralstat

Berotralstat is another plasma kallikrein inhibitor, which is taken orally once a day.[10] APeX-S was a Phase 2 open-label study in 22 countries, in which patients received 150 mg or 110 mg once daily. For patients followed up for at least 48 weeks, the median attacks reduced after month 1 and remained at low levels through 12 months. Angioedema quality of life scores improved on treatment, suggesting treatment was well tolerated and that effectiveness was durable. TEAEs were reported for 91% of patients, with the most commonly reported being upper respiratory tract infection, abdominal pain, headache, and diarrhea, most of which were mild-to-moderate in severity. Treatment-related AEs occurred in 50% of patients, and 8% had to discontinue treatment due to these AEs. Further, 1.3% had a drug-related serious TEAE.[10]

Following this initial trial, APeX-2 was a double-blind, parallel-group study performed in 11 countries, including 121 patients receiving 110 mg or 150 mg of berotralstat, or placebo.[16] This study also showed a significant reduction in attack frequency over the 24-week study period for both doses, with effects starting in the first month of treatment and sustaining over the treatment period. The most common TEAEs were abdominal pain, vomiting, diarrhea, and back pain. The study determined that a dose of 150 mg daily had the best benefit-to-risk profile.[18]

Real-world experience with berotralstat in France was presented at the European Academy of Allergy and Clinical Immunology conference

in 2022.[19] Eighteen patients were treated, and treatment was effective in most patients, and efficacy was found to be correlated to compliance. Most of the gastrointestinal AEs were transient (resolved within 3 months) in most patients and could be controlled by taking berotralstat after a meal.

Garadacimab

More recently, data on a third LTP, garadacimab, have been published. In the VANGUARD phase 3 study with open label extension, results showed that treatment reduced the mean HAE attack rate by 95%, 60% of patients remained attack-free, and 93% of patients rated their response as good or excellent.[12] The most common TEAEs were injection site reactions, and most TEAEs were mild or moderate.

Utilization of Advanced LTP Agents in Canadian Routine Clinical Practice

Lanadelumab was authorized by Health Canada in 2018 for patients aged ≥12 years with HAE based on data from the Phase 3 HELP study.[15] Following its approval and availability, clinicians have started to gain experience with lanadelumab in clinical practice.

A chart review study of patients treated at academic centres in Ontario, BC, and Nova Scotia, included 12 patients who had received lanadelumab for at least 6 months.[5] Patients had 72% mean reductions in attack rate, with three patients having a complete remission from attacks after the start of the treatment. The case series also showed a significant improvement and impact on patients' social life.[5]

A case report from Alberta assessed the use of lanadelumab in a patient with HAE with normal C1-INH levels and negative genetic testing, who was diagnosed with HAE-nC1.[20] The patient had a high frequency of attacks (3 times per week), with a significant impact on quality of life. After initiating the use of 300 mg of lanadelumab subcutaneously every two weeks, within two months, the attack frequency was reduced to 2 per month, and the attacks become more mild, requiring limited use of acute medication.[20]

The EMPOWER study is a multicentre study in Canada and the US assessing the real-world effectiveness and safety of lanadelumab, including long-term usage. The results of the final data analysis were presented at the Canadian Society of Allergy and Clinical Immunology (CSACI) Scientific Meeting in 2024.[21] The study enrolled 13 patients from Canada. This included 7 patients who were de novo lanadelumab users (followed-up for a mean of 315 days) and 6 who were established users of lanadelumab. In the newly treated patients, the attack rate decreased by 80%. Patients had low rates of attacks throughout the study period, and TEAEs were non-serious and unrelated to the treatment. Therefore, effectiveness and safety in Canadian patients were similar to that found in international studies.

Berotralstat was approved by Health Canada more recently in 2022, and a retrospective real-world evidence study performed by researchers in Alberta assessed the effectiveness and AEs of the drug.[22] Eight patients were included in the study, and effectiveness data were available for seven who had used berotralstat 150 mg/daily for at least 3 months. The frequency of attacks reduced by 52% in this patient population, resulting in a higher angioedema control test score. Five patients experienced gastrointestinal AEs, which led to treatment discontinuation in one patient, while for the other patients, they were mostly mild and transient. Average treatment satisfaction was between 'satisfied' and 'very satisfied'.

Garadacimab has not received Health Canada approval yet, and clinical experience in Canada is therefore limited.

Healthcare System Challenges Related to HAE Treatment

The cost of these therapies along with patient access continue to remain a challenge for the Canadian healthcare system. Estimates from studies in other jurisdictions suggest high healthcare system-wide costs associated with these therapies.[23] While these agents may come with high costs, there is also a high financial burden of not managing HAE for the healthcare system. A Canadian real-world survey of 113 adult patients living with HAE showed high healthcare resource utilization associated with HAE management relative to the general population. Hospital and ER visits are uncommon for the general public in any given year but amongst patients with HAE surveyed, 53% had at least one ER visit and 77% had a hospital visit, indicating a greater health care burden. These findings suggest that having HAE leads to substantial healthcare costs. Costs would be even higher were it not for the high proportion of patients who receive treatment at home.[24] An additional issue is that access to these newer drugs is not uniform

in Canada, with differences in terms of public and private plans and interprovincial differences in coverage and reimbursement.

Patient counselling and education for the management of HAE in Canada continues to center on shared decision-making between the clinician and the patient. As patients are able to access more and more information about the disease and interact with other patients and families, it is important that clinicians work towards a dialogue that predominantly focuses on the patient's desires for an optimal quality of life. Additionally, clinicians may play an important role in directing patients to trustworthy sources of information and encouraging them to reach out to advocacy groups like HAE Canada and Angio-oedème Héréditaire du Québec (AOHQ).

A Canadian Clinician's Perspective

Below, a Canadian clinician provides their perspective and experience with treating patients living with HAE with advanced LTP agents. As with any case presentation, the results should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition. Any off-label mention or use of products in this article is at the clinical discretion of the treating physician.

"In my clinical practice, I have had the opportunity to follow several patients with HAE who were treated with LTP. This experience has allowed me to thoroughly evaluate its efficacy, safety, and impact on patients' quality of life. I have observed a marked reduction in the frequency of HAE attacks among my patients since the introduction of lanadelumab and berotralstat, although I have had more experience with lanadelumab due to its availability and approval prior to berotralstat. It is worth noting that the improvement under lanadelumab was also observed in patients with normal C1-INH HAE, although this improvement was not as clinically meaningful as observed with types I and II. Improving patients' quality of life has been one of the most rewarding aspects of this experience. Patients reported a noticeable reduction in anxiety related to unpredictable attacks and greater freedom in their daily and professional activities. Several noted that they felt more confident travelling and participating in social activities, which were often limited before the treatment"
– Dr. Boursiquot

Experience with Lanadelumab in Canadian Practice

A young patient aged 3.5 years was diagnosed with type I HAE, based on a family history of type HAE (mother) and confirmation by genetic testing. The early clinical presentation was surprising to us, but we decided to treat her with lanadelumab despite the fact that this was off label, which reduced the frequency of attacks and hospital visits. This has reduced the family anxiety caused by the child's medical condition.

A 40-year-old patient suffering from type III angioedema experienced abdominal pain and HAE was preventing her from working. Treatment with lanadelumab resulted in a decrease in the frequency and severity of her attacks. She still experiences intermittent abdominal pain, but its duration is shorter (a few hours instead of a few days). She has been able to return to work gradually and is very happy to have access to this treatment. Despite the considerable improvement with lanadelumab, it was decided to continue the therapy every 2 weeks rather than every 4 weeks.

A 35-year-old patient with type I HAE experienced peripheral angioedema attacks 2-3 times per month, forcing her to take frequent leave from work. Since she started lanadelumab, her attacks have been reduced to one per quarter, allowing her to resume a stable and productive professional life. While she was initially hesitant about bi-weekly injections, she quickly adhered to her new treatment after seeing clinically meaningful improvements in her clinical condition.

A fourth patient (50-year-old) we treated had HAE with normal C1-INH levels. Before her diagnosis, she frequently visited the hospital for recurrent abdominal pain. She consulted specialists from various disciplines (internal medicine, gastroenterology, surgery, psychiatry, etc.) and was desperate to get her symptoms resolved. When the diagnosis of HAE was made, it brought her some hope. However, the initial treatments (i.e. danazol, tranexamic acid, progestogens) were either ineffective and/or caused many side effects. Intravenous C1-INH was initiated, but the IV administration frequency of 2-3 times per week was complicated due to difficult venous access. Subcutaneous (SC) C1-INH was an interesting option, but the twice-weekly injections were becoming difficult for the patient. After this treatment, she was switched to bi-weekly lanadelumab, which improved her

clinical symptoms and greatly enhanced her quality of life.

Experience with Berotralstat in Canadian Practice

A 34-year-old female healthcare professional has been diagnosed with normal C1-INH hereditary angioedema (nC1-INH HAE). Her attacks were mainly recurring abdominal pain. Her family history is notable in that her mother, who experienced recurrent hand swelling and abdominal pain, never received a clear diagnosis. The patient was started on berotralstat. Following several months of berotralstat treatment, the patient has experienced a meaningful reduction in abdominal pain episodes. Prior to treatment, she had multiple attacks per week, but now these episodes occur only once or twice a month and are less severe. Though not completely symptom-free, the patient has seen a notable improvement in managing her condition. The decrease in HAE-related attacks has allowed her to resume professional duties, while the remaining symptoms are more manageable.

Due to the shorter time of availability of berotralstat in Canada compared with lanadelumab, there is limited clinical experience with this therapy and fewer cases are highlighted in this supplement. In the near-term future, further therapeutic developments for HAE treatment are expected to enhance patient care, including treatment options such as garadacimab and donidalorsen (an investigational antisense oligonucleotide that selectively binds prekallikrein mRNA to reduce the production of prekallikrein protein)[25], as well as new developments in apps, digital quality of life monitoring, attack and risk prediction, as well as in testing, diagnosis, and long-term management at home.

Conclusion

The past decade has brought major changes to the treatment landscape of HAE with the introduction of advanced LTP agents targeting the kallikrein pathway. Among others, lanadelumab and berotralstat have both been shown to markedly improve the quality of life of patients by reducing the frequency of HAE attacks. Studies have found that effects are noticeable within the first weeks of treatment, and long-term follow-up studies show no evidence of patient intolerance. Access to treatment, patient preferences, and AEs will need to be considered when choosing the right therapy for each patient. Future research efforts may examine the potential for head-to-head studies of these advanced LTP agents. Based on international and Canadian experience, increased adoption of these LTP agents as standard of care is warranted for this patient population in Canada.

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