

- d. Representation on hospital wide clinical committees
 - e. Research activities
 - f. Implementing new policies/procedures
 - g. Evaluating new policies/procedures
3. The process of utilizing CDEs
- A CDEs involvement in:
 - a. Community activities
 - b. Patient clubs
 - c. Regulatory affairs
 - d. Nursing education
 - e. Physician education
 - f. Medical resident/physician education in-servicing
 - g. Preceptorship of nurses

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Mentorship Program for Regional Endocrine Nurses

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British Columbia is a vast province consisting of a population that spans five regional health authorities and one provincial health authority. General care can be accessed within these health authorities; however, pediatric subspecialty care is mainly provided at our hospital located in Vancouver. This requires many families to travel long distances to receive subspecialty care.

The limited local access to subspecialty care and the burden of making visits to Vancouver impact the health outcomes of children living with chronic conditions outside of metropolitan Vancouver. Families face financial strain because of the cost of time off work, transportation, accommodations, child care, and food. From a safety standpoint, families also risk traveling in poor weather in the winter to maintain regular follow-up. This may cause families to postpone travel or decrease the number of visits to our hospital. A number of studies (Vierhout et al., 1995; Tyrer, 1990; Williams, 1989, as cited in Gruen et al., 2009) show that clinical outcomes are poorer when patients are not seen in follow-up regularly.

Current literature suggests that outreach clinics are beneficial in improving access to specialty care (Gruen et al., 2006), reducing costs of accessing care (O'Brien et al., 2001), and improving the proportion of patients living in rural or remote communities receiving guideline consistent care (Howe et al., 1992).

It is obviously challenging within a regional system of care to provide specialty level services, but with capacity building and increased support from our hospital within these communities, I believe that children and families throughout BC can receive standardized nursing care and experience improved health outcomes such as prevention of severe illness episodes and stability of condition.

At our hospital, we have developed a mentorship program to enhance the capacity of regional clinic nurses working with pediatric endocrine patients and families. In addition, we have made efforts to improve accessibility of hospital resources, standardize care by creating an online guide, and increase support to nurses in regional clinics by providing telehealth and in person in-services and telephone or telehealth consultations.

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A Multicenter, Observational Study of Girls with Central Precocious Puberty Treated With Histrelin Subcutaneous Implant

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Background: Gonadotropin-releasing hormone agonists (GnRHa) are the standard of care for treating patients with central precocious puberty (CPP). However, there is a paucity of long-term, posttreatment follow-up data for patients previously treated with GnRHa.

Aims: The aim of this study was to provide long-term data documenting the reactivation of the hypothalamic–pituitary–ovarian (HPO) axis in girls with CPP who have been treated with histrelin subcutaneous implants (Supprelin LA).

Methods: This is an ongoing multicenter, observational patient registry. Girls diagnosed with CPP by 8 years of age, who started histrelin implant therapy by 8.5 years of age, and who are either currently on or have completed histrelin implant therapy are eligible. For this registry, CPP diagnostic criteria include breasts at Tanner stage 2 or higher and at least one of the following: random luteinizing hormone (LH) ≥ 0.3 IU/L and estradiol ≥ 20 pg/mL; GnRHa-stimulated LH ≥ 4 IU/L; or GnRHa-stimulated estradiol ≥ 20 pg/mL. Patients are treated by the investigators according to locally accepted clinical practices. Height and data related to puberty including Tanner stages, menarche or resumption of menses, puberty hormone levels (including LH, follicle-stimulating hormone, and estradiol), and bone age are extracted from charts or recorded during routine visits. Predicted adult height is calculated using the Bailey–Pinneau method. Primary end point is time to menarche or resumption of menses after discontinuing histrelin therapy. Patients will be followed for up to 3 years from the time of last implant removal.

Results: Up to 150 girls are expected to be included in the registry. To date, 17 sites are participating, and 2 patients (age 7 and 9 years) have been enrolled. At baseline, both patients had a normal body mass index, and a Tanner staging breast score of 3. On-therapy data from the first set of patients in the registry will be presented. Any adverse drug reactions will also be discussed.

Conclusions: This is the first patient registry to assess the recovery of the HPO axis after discontinuing histrelin for the treatment of girls with CPP.

Clinical Implications: Data from this ongoing registry will help determine the effect of long-term continuous gonadotropin suppression in girls with CPP in regard to the timing of HPO axis recovery.

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Long-Term Efficacy of Growth Hormone in Short Japanese Children Born Small for Gestational Age

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Background: Approximately 5% of all newborns are born small for gestational age (SGA), below 2 standard deviation scores (SDS) for height and/or weight. Beneficial effects of long-term

growth hormone (GH) treatment on height have not been studied in short Japanese SGA children.

Aim: The aim of this study was to investigate the long-term efficacy and safety of two doses of GH in short Japanese children born SGA.

Methods: This was a multicenter, double-blind, randomized trial comparing two doses of GH for the treatment of short stature in prepubertal (Tanner Stage 1) Japanese children born SGA with no catch-up growth. Initial GH treatment was 0.033 mg/kg per day ($n = 39$), 0.067 mg/kg per day ($n = 38$), or no treatment ($n = 21$) for 52 weeks. During a 208-week extension period, patients in the treated groups continued treatment at the same dose, and those in the no treatment group were randomized to receive either 0.033 ($n = 10$) or 0.067 mg/kg per day ($n = 10$) GH. The primary end point was the change in height standard deviation score (HSDS) for chronological age (CA). Secondary end points included change from baseline in height velocity (HV) SDS, bone age (BA), ratio of BA/CA, and metabolic parameters.

Results: A dose-dependent increase in mean HSDS for CA was seen in the two treated groups. After 260 weeks (5 years) of treatment, the mean HSDS for CA increased from -3.00 to -1.78 in the 0.033 mg/kg per day group and from -2.83 to -0.82 in the 0.067 mg/kg per day group. The initial no-treatment group showed a similar dose-dependent increase in HSDS after 4 years of treatment in the extension period. Bone age increased during GH treatment with the mean (standard deviation) change in bone age after 260 weeks being 5.79 (1.05) and 7.15 (1.05) years in the low- and high-dose groups, respectively. Both doses of GH were well tolerated with few treatment-related adverse events.

Conclusions: Long-term treatment with GH improved HSDS in a dose-dependent manner in short, prepubertal Japanese children born SGA and was well tolerated in this patient population.

Clinical Implications: Long-term GH treatment improves the height outcome of SGA children and is well tolerated.

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Comparison of Device Preference and Use Errors for a New Growth Hormone Injection Device Versus Comparator Devices

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Background: Recombinant growth hormone (GH) is used to treat short stature in children with GH deficiency and other conditions. Treatment adherence, which may be poor because of the need for daily injections and treatment length, may be improved with easy-to-use injection devices.

Aim: The aim of this study was to compare patient preference and use errors of a new GH injection pen (Norditropin FlexPro; Novo Nordisk A/S, Denmark) relative to four other pens: easypod (Serono, Switzerland), Genotropin pen (Pfizer, USA), Nutropin AQ NuSpin pen (Genentech, USA), and Omnitrope pen (Sandoz, Germany).

Methods: In two noninterventional, randomized, crossover studies, children (10–17 years) treated with GH (≥ 6 months) were randomly assigned to intuitiveness ($n = 30$, $n = 32$) or instruction ($n = 26$, $n = 32$) groups. All subjects performed a usability test involving needle attachment, dose setting, and

injection into an Eppendorf tube. Intuitiveness groups had brief verbal instructions on device use. Instructed groups were instructed in full according to the user guide. Patient preference for devices was assessed by a 13-item questionnaire. The number and type of use errors were recorded.

Results: FlexPro was rated as the most preferred device in the majority of items in intuitiveness (9/13, 11/13) and instructed groups (10/13, 11/13) and was the most preferred device in both groups (intuitiveness: 15/30, 19/32; instruction: 19/26, 23/32). FlexPro scored highest for ease of use, easypod for best delivery feedback, Genotropin and NuSpin pens for appearance and quality. Technical errors were less with FlexPro (1 to 2 errors) than with comparator devices (9 to 39 errors) in intuitiveness groups, and fewer errors were recorded in instruction groups (1 to 2 errors for each device).

Conclusions: Both instructed and uninstructed patients preferred Norditropin FlexPro to comparator devices. The numbers of errors in the intuitiveness group reflect the problems/errors patients or caregivers face when they have not received training or do not understand it. Overall, use of FlexPro was associated with fewer errors than the comparator devices.

Clinical Implications: An easy and less error-prone device may help improve treatment adherence. Training can reduce error rate.

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Treatment of Children With Central Precocious Puberty: 3 Years of Continuous Suppression With Histrelin Subdermal Implants

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Background: Central precocious puberty (CPP) is defined as the reactivation of the hypothalamic–pituitary–gonadal (HPG) axis before age 8 in girls and age 9 in boys. Gonadotropin-releasing hormone analog (GnRHa) therapy is the standard of care for patients with CPP. In a Phase 3 open-label study, a 12-month histrelin subcutaneous implant (Supprelin LA) suppressed peak luteinizing hormone (LH) and sex steroid levels for 1 year; a subsequent implant suppressed the HPG axis through a second year. Herein reports on Year 3 of histrelin therapy.

Aims: The aim of this study was to report on the prospective extended-access phase of the open-label study involving a third 12-month histrelin implant.

Methods: Patients who completed the initial extension (second implant) portion of the study and for whom the decision was made to continue GnRHa therapy were offered the option for a third implant.

Results: Thirteen children (12 females [8 treatment-naive, 4 with prior treatment] and 1 male with prior treatment; at baseline, mean age = 6.6 years [range = 4.5–9.1]) received a third implant. LH suppression, assessed by GnRHa stimulation, was maintained in all patients throughout the third year of therapy ($M = 0.36$ vs. 13.71 mIU/mL at baseline; $p = .0132$). Mean estradiol levels in the girls remained suppressed (<4.73 pg/mL). Mean bone age to chronological age ratio after 36 months of therapy was significantly lower compared with baseline (1.21 vs. 1.41; $p < .002$). Consequently, Bailey–Pinneau predicted that adult height (PAH) after 36 months of therapy was significantly higher compared with baseline (156.87 vs. 150.05 cm; $p < .015$). During 3 years, 9 (69%) patients experienced implant site reactions (mild pain, itch, and discomfort)