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Research Article

Evaluating the Ease-of-Use of Genotropin Go Quick Disposable Injection Pen for Treatment of Short Stature in Paediatrics

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Abstract

Objective: To evaluate the patient perception of the ease of use associated with Genotropin Go Quick disposable injection pen for the treatment of pediatric short stature and growth hormone deficiency.

Methods: This is a descriptive study including patients between 2-18 years of age undergoing GH treatment using Genotropin Go Quick for a minimum of 6 months. Data were collected through a personal interview in pediatric endocrinology clinics and questions were answered by those primarily administering the medication. Subjects were asked to grade the difficulty of each of the 9 steps involved in setting up Genotropin Go Quick pen at the start of treatment, 3 months, and 6 months after on a scale of very easy, somewhat easy, neutral, challenging, or difficult.

Results: A total of 310 patients were included of whom 48.4% were female. At the start of treatment, 28.8% found its use easy whereas 71.6% found it difficult. After 3 and 6 months, 81.9% and 86.8% found its use to be easy whereas 14.8% and 12.3% still found it difficult, respectively. The hardest steps identified were premixing of Genotropin solution and removal of trapped air, whereas the easiest steps were disposal of the pen or its associated parts, attaching the needle guard, and injecting the dose. 99% found storing Genotropin Go Quick and 97% found transporting it while traveling to be very easy.

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Conclusion: Ease of use of an injection device is essential to ensure optimal treatment outcome and duration, minimal metabolic consequences, and avoid unnecessary high treatment costs. The majority perceived Genotropin Go Quick as difficult to use at the start of treatment yet easy after 3 months. The two most challenging steps were identified as premixing the solution and removing trapped air. Genotropin Go Quick almost unanimously was considered easy to store and transport when traveling.

Keywords: Growth hormone; Genotropin; Go quick; Short stature; Ease-of-use.

Introduction

Genotropin is a synthetic form of somatotropin that is manufactured via recombinant DNA technology in Escherichia coli [1]. Somatotropin is the natural human growth hormone (hGH) that is produced by somatotrophs in the anterior pituitary gland of the brain. Genotropin, a recombinant GH (rGH), has an identical amino acid sequence to the natural 191-amino acid hGH and therefore exerts a similar physiological action to that of endogenous somatotropin by promoting both linear and tissue growth via anabolism, increasing circulating levels of insulin growth factor (IGF-1), and playing a significant role in lipid, protein, carbohydrate, mineral and bone marker metabolism [2]. The prevalence of short stature in Saudi in 2007 was estimated around 24.8% among a population constituting of over 19,000 children and adolescents [3]. In many children, the cause of short stature is unknown and therefore diagnosed as Idiopathic Short Stature (ISS). There are many causes of short stature but the following list is exhaustive of the indications rGH has been internationally licensed for use in treatment of short stature, including growth hormone deficiency (GHD), ISS, children born small for gestational age (SGA) with subsequent growth failure, chronic renal failure, and certain syndromic disorders such as Turner syndrome, Noonan syndrome, Prader-Willi syndrome (PWS), Russel-Silver syndrome (RSS), and SHOX gene mutations [4]. Contraindications include closed growth plates or fused epiphyses on bone age scans, evidence of papilloedema or proliferative retinopathy on fundoscopy, pre-existing intracranial hypertension, severe or uncontrolled diabetes mellitus, active malignancy, severe secondary hyperparathyroidism, patients with PWS who are severely obese and at risk of obstructive sleep apnea, or patients with known hypersensitivity to the active substance or excipients [5].

Doses differ according to the specific aetiology and are calculated based on body weight or body surface area; they are similarly accordingly adjusted by the overseeing physician while taking into consideration the patient's treatment response during follow up. Doses may range between 25-50µg/kg/day or 0.7-1.4mg/m^2/day and are formulated for daily injection in the subcutaneous tissue [5]. Considering that compliance to treatment, particularly in pediatric patients, is significantly affected by practicality and convenience in delivering medications, and the importance in using injection pen devices that are easy to use and navigate [6], our aim was to evaluate our patient population's

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overview on using the Genotropin Go Quick pen as growth hormone treatment for short stature.

Methodology

This is a descriptive study covering patients who were already undergoing growth hormone treatment using the Genotropin Go Quick from April 2021 to September 2021 in Jeddah, Saudi Arabia. An ethical approval was obtained from the Research Ethical Committee at King AbdulAziz University prior to the commencement of this study. Considering the involvement of human subjects, we declare this study to be following the Helsinki declaration.

Literature search for similar studies was done through typing relative MeSH terminology in the PubMed search engine while filtering search results according to publication date, narrowing the results to articles that were published within the past 5 years in order to obtain recent references.

Sample Selection

All children between the ages of 2-18 years undergoing GH treatment using Genotropin Go Quick injection pen for a minimum duration of 6 months to manage short stature were included in the study. Patients were excluded if they did not complete a minimum of 6 months of GH treatment. All children on treatment with Genotropin Go Quick were ensured to have been appropriately treated having fulfilled the indications for treatment and not exhibiting any of its contraindications.

Data collection

Data was collected through a personal interview with patients attending pediatric endocrinology clinics for short stature who were at that time already undergoing treatment with Genotropin Go Quick. Individual patient consent to participate in this study was verbally obtained prior to the start of the interview.

The questions were answered mainly by those primarily administering the medication, whether it was the parents exclusively as children were too young to self-inject, both the parents and the patients if they were self-injecting under parental observation, or the patients on their own when age appropriate. Subjects were asked to grade their perceived difficulty of each of the 9 steps involved in setting up the Genotropin Go Quick pen as best as they can recall at time of treatment, 3 months into treatment, and after completing 6 months of treatment. The difficulty scale was through very easy, somewhat easy, neutral, challenging or difficult. There are 9 steps to using the Genotropin Go Quick pen for the first time: attaching the needle, mixing the Genotropin, removing trapped air, attaching the needle guard (this step is optional), priming the pen, setting the dose, drawing up the dose, giving the injection, and disposal of the needle and cap.

Difficulty with using the injection pen experienced at each of these 9 steps were assessed individually as perceived by the child or parent at the time of treatment, 3 months into the treatment, and after completing 6 months of the treatment. Additional variables

assessed included difficulty experienced with storage and transportation of the Genotropin Go Quick pen.

Data Analysis

All variables in this study were categorical and therefore were presented as frequencies and percentages. Missing data management was not required because all the necessary data was collected appropriately.

Results

The sample size who fulfilled all criteria were 310, with an approximately even gender distribution (48.4% were females). The majority were between the ages of 10-15 years (76.5%) whereas 15.5% were between 6-9 years of age. All of the population were of middle-eastern ethnicity with 94.1% being Saudi Arabian. Where appropriate, the older child answered the questions with the help of a parent (12%) whereas some adolescents were able to answer them independently (10%). Of the 310 patients and their families, 99.4% felt they received adequate instructions before starting treatment over how to use the Genotropin Go Quick pen, of whom 39% were instructed by pharmacists, 29.7% by physicians, 25.2% by health educators, and 6.1% via supplemental videos. Three quarters (76.1%) of patients have previously used a different brand to Genotropin Go Quick.

Nearly half the patients (44.5%) felt that there were easier brands to use than Genotropin Go Quick and nearly one third (28.7%) of patients felt that the difficulty associated with the use of Genotropin Go Quick would lead them to prefer the use of another brand. Three quarters (75.5%) found an odor to Genotropin Go Quick but only 2.6% thought it repulsive.

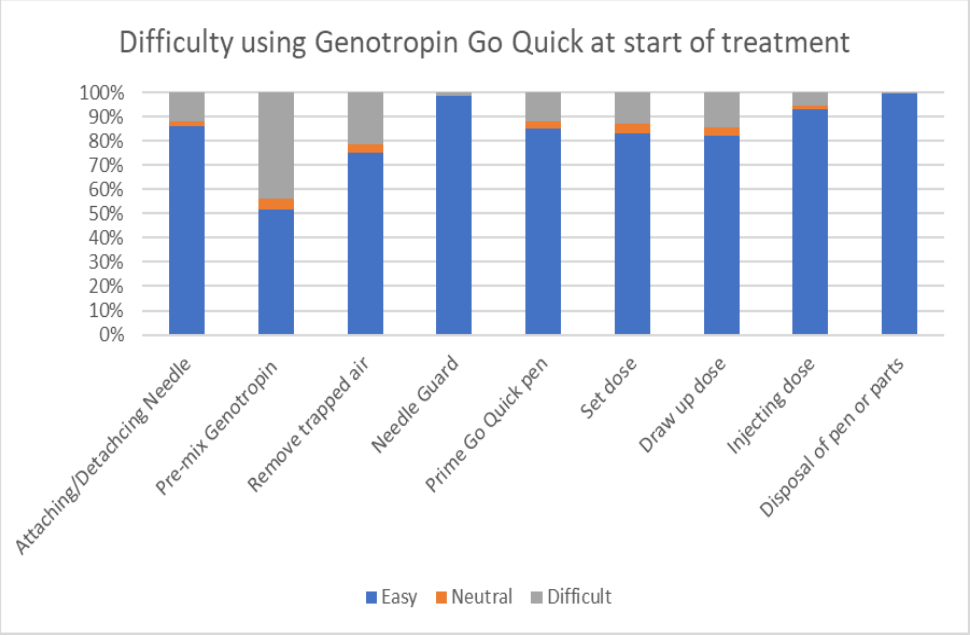

Figure 1: Ease of use surrounding the use of Genotropin Go Quick at the initiation of treatment.

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Results regarding ease of use and difficulty over each of the 9 steps in setting up the

Genotropin Go Quick for the first time at the start of treatment, 3 months post treatment

initiation and after 6 completed months of treatment are displayed in Table 1. Comparative bar graphs are displayed in Figure 1 at initiation of treatment and Figure 2 after 6 months of completed treatment. Overall, at the start of treatment 28.8% found its use to be easy whereas 71.6% found it to be difficult. After 3 and 6 months of treatment, 81.9% and 86.8% relatively found its use to be easy whereas 14.8% and 12.3% still found it to be difficult.

The hardest steps involved in using Genotropin Go Quick at initiation of treatment were identified as the premixing of Genotropin solution (43.6%) followed by removal of trapped air (21.3%). After 6 months of treatment, the majority of the difficulty experienced in using Genotropin Go Quick was still found to involve premixing of the solution (12.5%), followed by the removal of trapped air (11.3%).

The easiest steps involved in using Genotropin Go Quick at initiation of treatment were identified as disposal of the pen or its associated parts (99.6%), followed by attaching the needle guard (98.7%) and injecting the dose (93%). In terms of storage and transport, majority of patients found storing Genotropin Go Quick (99%) and transporting it while travelling (97%) to be very easy all throughout the duration of treatment.

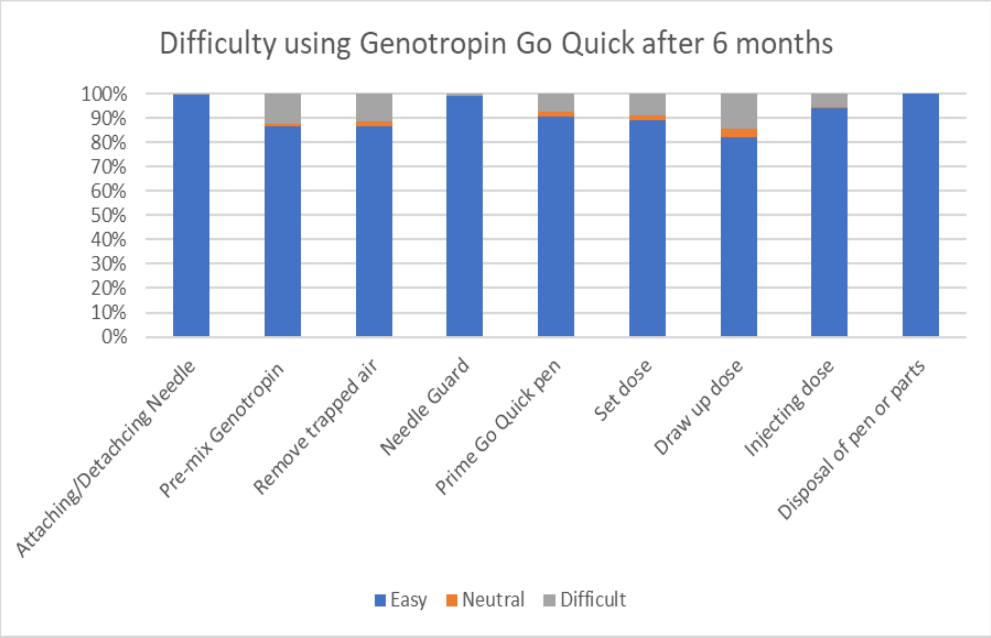

Figure 2: Ease of use surrounding Genotropin Go Quick after 6 months of completed treatment.

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Steps in setting up Genotropin Go Quick:	**Step 1**			**Step 2**			**Step 3**			**Step 4**			**Step 5**			**Step 6**			**Step 7**			**Step 8**			**Step 9**		
Duration of treatment:	**0**	**3**	**6**	**0**	**3**	**6**	**0**	**3**	**6**	**0**	**3**	**6**	**0**	**3**	**6**	**0**	**3**	**6**	**0**	**3**	**6**	**0**	**3**	**6**	**0**	**3**	**6**
Very easy	245	299	301	129	236	243	192	243	246	300	303	305	238	258	255	214	240	250	220	243	248	278	282	283	308	308	310
Somewhat easy	22	6	7	31	25	25	41	23	23	6	4	1	26	22	26	43	29	26	35	27	24	10	8	8	1	2	0
Neutral	7	2	0	15	5	3	11	8	6	0	0	1	10	6	6	13	7	7	10	8	5	5	4	2	0	0	0
Challenging	24	1	0	76	35	32	53	32	30	3	2	2	30	22	20	32	30	25	35	29	29	12	11	12	1	0	0
Difficult	12	2	2	59	9	7	13	4	5	1	1	1	6	2	3	8	4	2	10	3	4	5	5	5	0	0	0
Total number of responses	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310	310

Table 1: Results of patient impression on the ease of use of each of the 9 steps of preparing Genotropin Go Quick throughout the duration of treatment: 0= at the start of treatment, 3= three months into treatment, and 6= after completing six months of treatment. Step 1 (attaching the needle), Step 2 (mixing the Genotropin), Step 3 (removing trapped air), Step 4 (attaching the needle guard), Step 5 (priming the pen), Step 6 (setting the dose), Step 7 (drawing up the dose), Step 8 (giving the injection), and Step 9 (disposal of the needle and cap).

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Discussion

GH treatment is mainly used for the treatment of short stature with the aim of normalizing final adult height and in cases of GH deficiency, to replace the deficient hormone and offset the metabolic and cardiovascular consequences that are usually more apparent in adult life [7,8]. Short stature is defined either by a height that is less than 2 standard deviations below the average mean or a height that is below the 3rd centile for age and gender on an appropriate chart. Growth failure is defined by a height velocity that is less than the 25th centile for age and gender.

Compliance to treatment is essential for ensuring optimal treatment response in terms of physical and psychological improvements and avoiding an unnecessary prolonged treatment duration, further avoidable treatment costs, and later-onset cardiovascular and metabolic adverse events [6-9].

As the GH must be injected subcutaneously every night prior to bedtime to mimic the natural physiology of GH secretion as closely as possible, the acceptability and usability of the device is paramount to ensuring optimal compliance. This is because the frequent daily administration regimen as a factor on its own can lead to poorer compliance due to avoidance and has been linked to an overall suboptimal treatment response [10-12].

Poor compliance to treatment may be as high as 50-75% of the time and is attributable in many cases to difficulty experienced in preparing and administering medication particularly in the setting of daily dosing [13-16]. A western survey conducted in 2006 amongst patients and health care professionals revealed that the most pertinent features of an injection device to ensure adequate adherence is ease of use, reliability, and lesser pain [17].

A survey done including 239 caregivers and 61 patients using GH treatment revealed that the main reason for poor compliance and missing doses was because patients were either away from home or travelling, with over one third considering that overall storage of the GH injection pen is significantly troubling and inconvenient [18]. Available literature supports that GH injection pens that are easier to store are significantly associated with better compliance ($p<0.05$) when compared to injection pens requiring refrigeration for storage [19].

The Genotropin Go Quick pen may be stored at a room temperature<25 Celsius degree for up to one month prior to constitution of the medication and refrigerated after constitution at a temperature between 2-8 Celsius degree with acceptable use for up to 4 weeks [20]. Prolonged treatment duration due to suboptimal results from poor compliance may further reduce adherence to treatment, with up 52% of children generally able to finish treatment at an earlier stage than anticipated with proper compliance [21,22].

Desirable compliance is defined by a timely administration of 80-95% of the prescribed dose [23]. Ensuring optimal compliance greatly determines the outcome more than any treatment itself [22]. A study done in New Zealand over pediatric patients receiving GH

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treatment over a 4-month period in 2007 showed that 66% experienced reduction in linear growth due to suboptimal compliance at a rate of missing as little as one or more of their injections per week [24]. Many formulations of Genotropin have been manufactured, but the Genotropin Go Quick pre-filled pen is available in two presentations of 5.3mg and 12mg and can be used to deliver multiple doses over the course of 4 weeks [25]. A study done over 39 pediatric patients using Genotropin for GH treatment revealed that 95% prefer the multidose feature in an injection pen [26]. Another study done to evaluate the convenience, functionality and usability of a GH injection device revealed that the environmental benefits associated with a reusable pen are greatly valued and might compensate for the advantages featured by other single-use pens [27].

Conclusion

The ease of use of an injection device in terms of growth hormone treatment is of essential significance to ensure an optimal treatment outcome and duration, minimal metabolic consequences, and avoid unnecessary high treatment costs. The majority of our sample population perceived Genotropin Go Quick injection as difficult to use at the start of treatment but became easy after 3 months of treatment. The two most challenging steps in using the pen identified persistently at the start of treatment, 3 and 6 months into treatment were steps 2 and 3, which were to premix the solution and remove the trapped air. Genotropin Go Quick almost unanimously was identified as easy to store and transport when travelling.

Conflict of interest

Nothing to declare.

Source of Funding

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