

Acceptability of the reusable SurePal™ self-injection device for Omnitrope® among pediatric patients: results from a questionnaire-based, cross-sectional, multicenter observational study

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Background: SurePal™ is a reusable self-injection system that has been developed to support daily administration of Omnitrope® (Sandoz, Kundl, Austria). A questionnaire-based cross-sectional survey was conducted to evaluate acceptability of, and preference for, SurePal™ in pediatric patients who were prescribed treatment with Omnitrope® within routine clinical care.

Methods: This multicenter, observational study was incorporated into the ongoing non-interventional PATRO (PATients TReated with Omnitrope®) Children study. Patients (or caregivers) were provided with a questionnaire that included five main topics; attractiveness of the device, training received, using SurePal™, the low drug wastage system, and experience versus other devices used previously (where applicable). Questions were scored on a 5-point scale, with -2 being the worst possible outcome (eg, very hard/very poor) and 2 being the best possible outcome (eg, very easy/excellent).

Results: A total of 186 patients were included in this study (Germany, n=154; UK, n=32). The attractiveness of SurePal™ was rated as excellent/good by 87.1% of patients. Overall, 86.5% of patients found that using their SurePal™ was very easy/easy. Almost all patients (96.2%) found that preparing their SurePal™ for injection was very easy/easy, and 89.2% found that injecting with SurePal™ was very easy/easy. 85.5% of patients recorded that the dose memory function was helpful, and 87.6% that taking their SurePal™ apart after an injection was very easy/easy. Of the 88 patients who recorded that they had used the low drug waste feature, 89.8% found the feature to be helpful. Among pre-treated patients (n=42), 81% recorded that SurePal™ was much better/better than their previously used device.

Conclusion: This questionnaire-based cross-sectional survey in pediatric patients confirms the ease of use and patient preference for SurePal™, a reusable self-injection system that has been developed to support daily administration of Omnitrope®.

Keywords: PATRO children, Omnitrope, SurePal, self-injection, growth hormone, intervention adherence

Introduction

Recombinant human growth hormone (rhGH) is used to treat a variety of growth disorders in childhood/adolescence. Adherence to pediatric rhGH therapy is suboptimal; poor adherence is associated with reduced clinical effectiveness and possible increased economic costs.¹ Factors affecting adherence to GH therapy include the patients' preference for the delivery device, its simplicity and convenience, as well as appropriate education and technique training.^{2,3} Improving patient adherence to long-term

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GH treatment through enhanced self-administration devices may be important to ensure patients reach their final target height.^{3,4}

GH injection devices continue to evolve and improve; conventional syringes and needles have been replaced by more sophisticated and user-friendly devices designed to better meet the needs of patients. Reliability, ease of use, lack of pain, safety during use/storage, and the number of steps involved in the injection process have been identified as important factors in the design of a GH injection device intended for long-term use.^{2,5-8} SurePal™ is a reusable self-injection system that has been developed to support daily administration of Omnitrope® (Sandoz, Kundl, Austria). Injections are given subcutaneously and the injection site varied to prevent lipoatrophy. Approved needle sizes are BD 29G ×12.7 mm, BD 31G ×5 mm, and BD 31G ×8 mm. SurePal™ has been specifically designed to be easy and convenient to use, and to minimize drug wastage.⁹ Key features include ready-to-use cartridges (no reconstitution necessary), auto priming, and a sliding button that requires minimal injection force. In addition, safety features include: an optional needle hider; pre-assembled cartridges to ensure only the correct dose can be used with each device; a dose memory function that enables the correct dose to be pre-set and locked into the device which reduces the risk of incorrect dosing; and a rotating dose knob that provides certainty that a full dose has been delivered.⁹

A study to validate the usability and assess the ease of use of SurePal™ has been conducted in both adults and children/adolescents (n=106), in Germany and in the USA.⁹ Overall, 92% of participants rated the injection procedure (into an injection pad) as very easy or easy. In addition, 99% were able to disassemble the pen device successfully. In this paper we report data from a questionnaire-based cross-sectional survey to evaluate acceptability of, and preference for, SurePal™ in pediatric patients who were prescribed treatment with Omnitrope® within routine clinical care.

Patients and methods

A questionnaire-based, cross-sectional, multicenter (Germany and the UK), observational survey study was conducted, which was incorporated into the ongoing non-interventional PATRO (PATients TReated with Omnitrope®) Children study.¹⁰ Patients eligible for inclusion into PATRO Children are infants, children, and adolescents (either male or female) who are receiving treatment with Omnitrope® and who have provided informed consent. Patients who have been treated with another rhGH product before starting Omnitrope® are

also eligible for inclusion. The study was approved by the relevant ethics committees in Germany and the UK.

Patients (or their caregivers) who had provided additional written informed consent were provided with a folder containing the questionnaire, an explanation of the survey and procedures, and timelines for returning the completed questionnaire via a pre-paid and pre-addressed envelope (completed questionnaires were to be returned ≥1 month after start of use of SurePal™, and no later than 7 months after start of use). All patients (or their caregivers) received training on the use of SurePal™ before the start of the survey.

The questionnaire included questions on five main topics; attractiveness of the device, training received, using SurePal™, the low drug wastage system, and experience compared with other devices used previously (where applicable). Questions were scored on a 5-point scale, with -2 being the worst possible outcome (eg, very hard or very poor) and 2 being the best possible outcome (eg, very easy or excellent). Most questions also included an option to respond 'I don't know'.

All completed questionnaires were sent to the same data collection center, where they were anonymized before data entry and analysis. Participants received a gift voucher on receipt of their completed questionnaire. Analyses were conducted for the overall study population and by pre-treatment (with rhGH) status.

Results

A total of 186 patients were included in this study, 154 from Germany and 32 from the UK. These numbers reflect response rates of 68.4% in Germany and 62.5% in the UK. Twenty-seven per cent of children completed the questionnaire by themselves, and 73% had help from a family member or another person.

Key characteristics of study participants are shown in Table 1. The majority of participants were male (55%), and the mean age of all participants was 10.1±3.5 years. Almost three-quarters of participants (73%) were GH treatment-naïve. The largest group by diagnosis were patients with GH deficiency (n=91, 48.9%), followed by children born small for gestational age (n=55, 29.6%), those with Turner syndrome (n=17, 9.1%), those with Prader-Willi syndrome (n=5, 2.7%) and children with chronic renal insufficiency (n=1, 0.5%). These proportions are generally consistent with those for the overall PATRO Children population.

At the time of completing the questionnaire, the mean duration of SurePal™ use was 75.9 days for the overall study population, 85.5 days for GH treatment-naïve patients and 44.3 days for pre-treated patients. Almost half (49.5%) of

Table 1 Key characteristics of study participants

| Characteristic | Treatment-naïve (n=136) | Pre-treated (n=42) | Total (N=186) |
|---|-------------------------|----------------------|-------------------------|
| Country, n (%) | | | |
| Germany | 112 (82.4) | 38 (90.5) | 154 (82.8) ^a |
| UK | 24 (17.6) | 4 (9.5) | 32 (17.2) ^a |
| Sex, n (%) | | | |
| Male | 76 (55.9) | 26 (61.9) | 102 (54.8) ^a |
| Female | 60 (44.1) | 16 (38.1) | 76 (40.9) ^a |
| Mean age (SD, range), years ^b | 9.6 (3.3, 2.6–17.0) | 11.8 (3.4, 4.6–18.8) | 10.1 (3.5, 2.6, 18.8) |
| Diagnosis, n (%) ^a | | | |
| GHD | 75 (55.1) | 16 (38.1) | 91 (48.9) |
| SGA | 36 (26.5) | 19 (45.2) | 55 (29.6) |
| TS | 13 (9.6) | 4 (9.5) | 17 (9.1) |
| PWS | 4 (2.9) | 1 (2.4) | 5 (2.7) |
| CRI | 1 (0.7) | 0 (0.0) | 1 (0.5) |
| Other | 7 (5.1) | 2 (4.8) | 9 (4.8) |
| Mean duration of SurePal™ use, days (SD) ^c | 85.5 (155.9) | 44.3 (32.9) | 75.9 (135.9) |
| Previous rhGH use, n (%) ^d | | | |
| Omnitrope® | N/A | 2 (1.1) | 2 (1.1) |
| Other rhGH ^e | N/A | 40 (21.5) | 40 (21.5) |

Notes: ^aUnknown pre-treatment status, sex, and diagnosis for eight patients (four patients from Germany and four patients from the UK); ^b177 patients analyzed, missing data for one patient in the treatment-naïve group and eight patients in the unknown pre-treatment status group; ^c162 patients analyzed, missing data for 18 patients in the treatment-naïve group, five patients in the pretreated group and one patient in the unknown pre-treatment status group; ^done patient had started and stopped Genotropin® three times and one patient had previously received Genotropin® then Saizen®; ^eGenotropin®, Norditropin®, Saizen®, Nutropin AQ®, or Zomacton®.

Abbreviations: CRI, chronic renal insufficiency; GHD, Growth Hormone Deficiency; N/A, not applicable; PWS, Prader–Willi syndrome; rhGH, recombinant human growth hormone; SD, standard deviation; SGA, children born small for gestational age; TS, Turner syndrome.

children prepared their SurePal™ for injection themselves, 48.4% had a family member prepare the device, and 1.1% had a nurse do the preparation (data missing for 1.1%). Injections were performed by 43.5% of children themselves, by a family member in 52.2% of subjects, and 1.6% had a nurse do the injections (data missing for 2.7%).

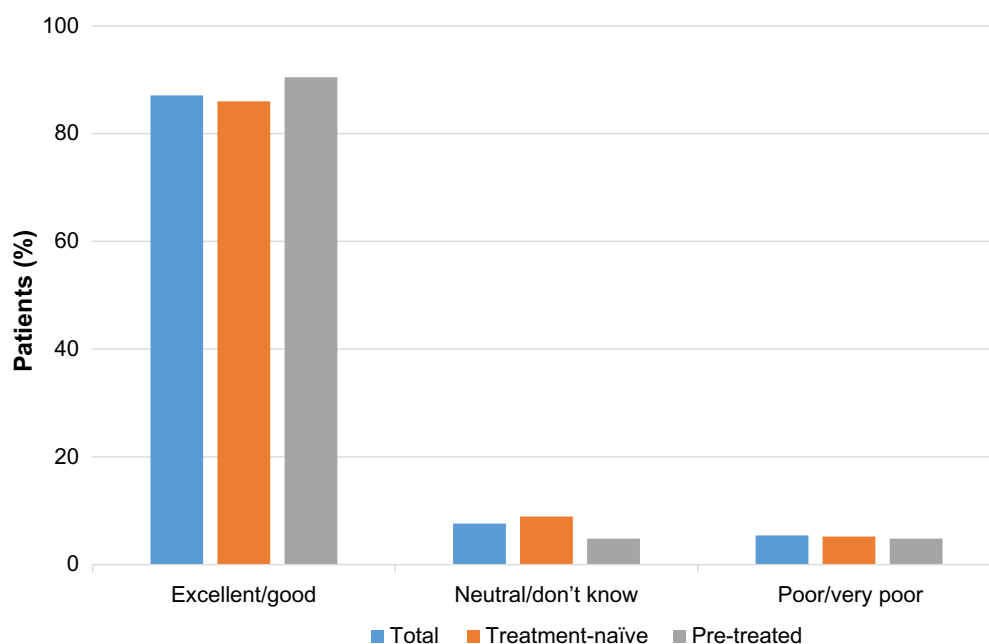
Training

Most patients received training on the use of SurePal™ from their doctor or doctor's assistant (31.7%); training was received from a hospital nurse by 29%, and from a homecare nurse by 16.1%; 22% received their training from another person (data missing for 1.1%). Overall, 86% of patients found that learning to use SurePal™ was very easy or easy; this proportion was slightly higher (95.3%) among pre-treated patients than among treatment-naïve patients (83.1%).

Attractiveness and use of SurePal™

The attractiveness of SurePal™ was rated as excellent or good by 87.1% of patients (86% among treatment-naïve patients and 90.5% among pre-treated patients) (Figure 1). Overall, 86.5% of patients found that using their SurePal™ was very easy or easy (Figure 2). The proportion was slightly higher among pre-treated patients (92.9%) than among treatment-naïve patients (84.6%).

Almost all patients (96.2%) found that preparing their SurePal™ for injection was very easy or easy, and 89.2%

**Figure 1** Patients' rating of attractiveness of SurePal™.

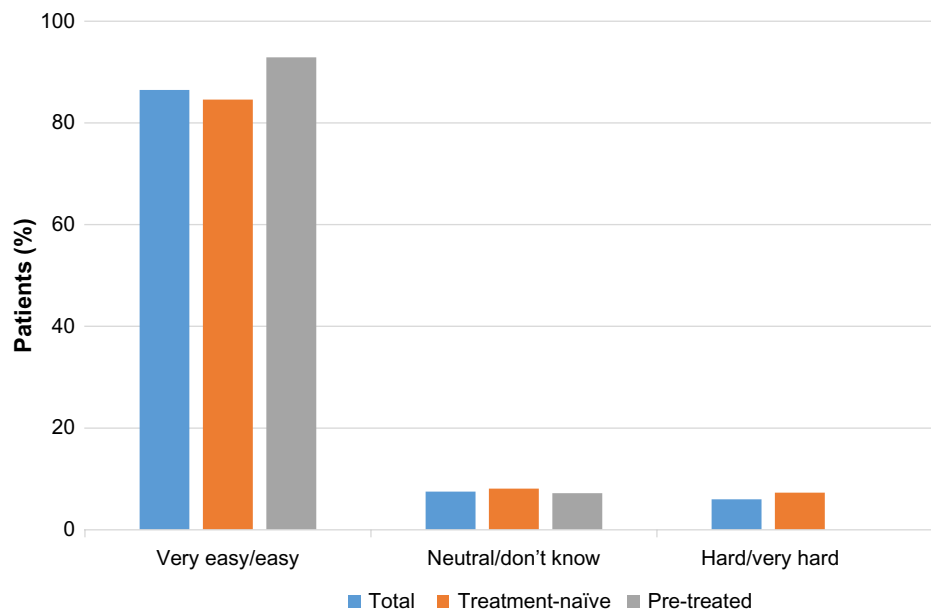


Figure 2 Patients' rating of overall ease of use of SurePal™.

found that injecting with SurePal™ was very easy or easy. Again, the proportions were higher among pre-treated patients (100% and 95.3%, respectively) than among treatment-naïve patients (94.8% and 87.5%, respectively). 85.5% of patients recorded that the dose memory function was helpful, and 87.6% thought that taking their SurePal™ apart after an injection was very easy or easy. Of the 88 patients who recorded that they had used the low drug waste feature, 89.8% found the feature to be helpful.

Experience compared with previous devices used

Among the pre-treated patients (n=42), 81% recorded that SurePal™ was much better/better than their old device (Figure 3). Among this same group, 61.9% felt that SurePal™ made their GH treatment plan easier to follow, as compared with their previously used device.

Discussion

Adherence to rhGH therapy among children is sub-optimal.¹ Several device-related factors have been identified that may impact adherence, including simplicity and ease of use, convenience, and patient preference.^{2,3} SurePal™ is a reusable self-injection system that has been developed to support daily administration of Omnitrope®. In the present study, patients overall had a good impression of the device, with 87% rating its attractiveness as excellent/good. The vast majority of patients also found SurePal™ easy to use (overall, to prepare for injection and to carry out an injection). Several features

of SurePal™ may have contributed to patients rating the device as easy to use. These include the auto priming feature; cartridges that are pre-assembled and ready-to-use; a sliding injection button that requires minimum force to perform an injection; and a dose memory function that enables the correct dose to be pre-set and locked into the device.

SurePal™ has also been specifically designed to minimize drug wastage; if a cartridge in the device does not contain sufficient amount of drug to inject, the device automatically administers the correct amount of additional drug once a new

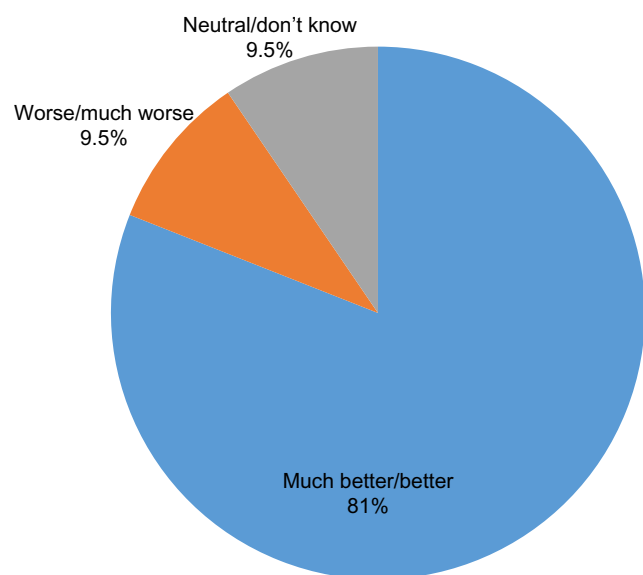


Figure 3 Patients' rating of SurePal™ compared with their previous device (pre-treated patients only).

cartridge is inserted (with no need for priming or adjusting of the dose setting). The automated nature of this feature makes it easier to administer a second injection compared with some other GH injection devices, which require the user to calculate the amount of additional dose required and reset their device accordingly.⁹ Eighty to 90% of participants reported that this feature (and others, such as the dose memory function), were helpful.

All study findings were generally consistent across treatment-naïve and pre-treated patients. The proportion of patients who found SurePal™ easy to learn to use, easy to use overall, easy to prepare for use, and easy to carry out an injection was slightly higher in the pre-treatment group; this possibly reflects these patients' greater experience of using a device to administer GH treatment. Among patients who had experience with other GH injection devices, >80% preferred SurePal™ to their previous device and almost two-thirds felt that SurePal™ would make it easier to follow their GH treatment plan.

The open-label and uncontrolled nature of the study represented potential limitations. Nevertheless, the findings are consistent with those of an earlier report on the usability and ease of use of SurePal™, in which the vast majority of patients rated a variety of handling tasks as easy.⁹ An important distinction is that the earlier study required participants to perform an injection into an injection pad, whereas the present study involved the use of SurePal™ in a real-world clinical practice setting.

Conclusion

In summary, this questionnaire-based cross-sectional survey in pediatric patients confirms the ease of use and patient preference for SurePal™, a reusable self-injection system that has been developed to support daily administration of Omnitrope®. The continued improvement of GH injection devices may support improved adherence by patients to their long-term treatment.

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Disclosure

CJP is a member of the German PATRO Children board, and has received lecture fees from Sandoz/Hexal. DS is a member of the German Omnitrope® advisory board. SE and HJ are investigators in the PATRO Children study. WK is an advisor to Sandoz, Ipsen and Novo Nordisk. MZ is an employee of Sandoz.

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