Evaluation of the JuniorSTAR® Half-unit Insulin Pen in Young People with Type 1 Diabetes – User Perspectives

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Abstract

This paper discusses the results of a survey on the usability of a new half-unit insulin pen, JuniorSTAR® (CE mark pending, under the responsibility of Haselmeier), in children with type 1 diabetes. Insulin pen devices have advantages over the traditional vial-and-syringe method of insulin delivery, including improved patient satisfaction and adherence, greater ease of use and superior accuracy, especially when delivering small doses of insulin. The accuracy and design of insulin pens is particularly important in the paediatric population. Young children often require half-unit adjustments. As the incidence of type 1 diabetes is expected to increase in the coming years in children less than 5 years old, a higher use of half-unit dosing pens may be anticipated. A survey with JuniorSTAR half-unit insulin pen has shown that it is easy to use, read, carry and dial back. This was confirmed by patients and also by nurses. In conclusion, the JuniorSTAR half-unit pen is well suited to the lifestyle of young people with type 1 diabetes and could help them to gain autonomy to self-inject.

Keywords

Adolescents, children, insulin pen, type 1 diabetes

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Type 1 diabetes is the most common metabolic disorder in children. Worldwide, there are approximately 490,000 children with type 1 diabetes, and 78,000 new cases are diagnosed each year.[1] As of today, the incidence of type 1 diabetes in children younger than 15 years old is increasing. If this trend continues, new cases in European children less than 5 years are predicted to double between 2005 and 2020.[2] Type 1 diabetes is a lifelong condition with short- and long-term implications. Recommendations by the American Diabetes Association (ADA) support the use of an intensive insulin regimen that involves a 'basal/bolus' pattern of insulin administration to maintain blood glucose levels as close to normal as possible, with a target glycated haemoglobin (HbA_{1C}) of 7.5 % to 8.5 % in children aged younger than 6 years, less than 8 % in children aged 6–13 years and less than 7.5 % in those aged 13–18 years.[3] The recommendation of the International Diabetes Federation (IDF) and the International Society for Paediatric and Adolescent Diabetes (ISPAD) is to reach a target of less than 7.5 % in all age groups (children and adolescent).[4] These targets can be achieved by intensive management of the condition, involving multiple insulin injections, blood glucose monitoring, nutrition planning and detection and treatment of hypoglycaemia.[5]

The medical benefits of insulin regimes in type 1 diabetes are well established.[6–8] However, there is a danger that metabolic targets may be attained at the expense of the psychological wellbeing of children and their families. Children and adolescents with diabetes are still developing cognitively and emotionally, therefore self-management is challenging,[9] particularly when acknowledging or adapting to the disease conflicts with their lifestyles.[5,10] In adolescence, these challenges may result in conscious behaviours (e.g. choosing not to inject at a social event) that may be mistaken for simple non-compliance.[10] With increasing age, autonomy in relation to disease management becomes important.[11] Self-management presents different challenges to younger patients: children frequently make mistakes in self-administering insulin but increasing age is associated with improved insulin administration skills.[12] There is therefore a need to make the process of insulin administration as simple and convenient as possible to avoid errors, particularly in relation to adjusting doses of insulin.

Insulin pens, comprising an insulin cartridge, a dial button to set the dose and disposable needles, have facilitated insulin delivery for young people.[13] Compared with syringes, pen devices lead to better compliance, because a pen is easier to carry around, are quicker to inject, give more accurate dosing and are more cost-effective.[14] To cope with the needs of an increasingly young user base, pens have become more sophisticated with higher technology, easier to use and are able to dose in smaller increments. Half-unit dose increment insulin pens

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Table 1: Responses to Questionnaire

	Nurses (n = 109)		Patients/Parents (n = 58)		All (n = 167)	
	% Overall Positive*	Mean Response (SD)	% Overall Positive*	Mean Response (SD)	% Overall Positive*	Mean Response (SD)
Convenience/Weight						
How would you rate this pen in terms of weight?	71	3.8 (0.9)	67	3.8 (0.8)	69	3.8 (1.0)
To what extent do you agree that it is easy to carry this pen on a daily basis?	86	4.1 (0.8)	81	4.2 (0.9)	84	4.1 (0.8)
Robustness						
How would you rate this pen in terms of its robustness?	89	4.3 (0.7)	90	4.4 (0.8)	89	4.3 (0.7)
Dose Display						
How would you rate this pen in terms of how easy it is to read the dose?	94	4.7 (0.6)	98	4.8 (0.5)	96	4.7 (0.6)
Dose Dialling						
Thinking about the audibility and tactility (volume of the sound and feeling) of the dial, how would you rate this pen in terms of how easy it is to dial the dose?	87	4.3 (0.8)	66	3.8 (1.0)	80	4.2 (0.9)
How would you rate this pen in terms of how easy it is to dial back?	92	4.6 (0.7)	78	4.2 (1.0)	87	4.4 (0.8)
Thinking about when you dial back, to what extent do you agree or disagree that the mechanism of dialling back gives flexibility in dialling the correct dose?	94	4.6 (0.6)	95	4.6 (0.7)	94	4.6 (0.6)
To what extent do you agree or disagree that a mechanism that does not leak insulin makes dialling back easy?	89	4.5 (0.9)	91	4.6 (0.8)	90	4.5 (0.9)
To what extent do you agree or disagree that the ease with which you can read a dose, the ease of dialling a dose and the ease of dialling back, help achieve a high level of accuracy when dialling a dose?	100	4.6 (0.5)	93	4.5 (0.7)	98	4.6 (0.6)
Injection						
How would you rate this pen in terms of how easy it is to inject young people with type 1 diabetes (from 2–18 years old)?	87	4.4 (0.8)	97	4.7 (0.7)	90	4.5 (0.7)
To what extent do you agree or disagree that the injection force is suitable for young people with type 1 diabetes (from 2–18 years old)?	84	4.3 (0.9)	93	4.6 (0.8)	87	4.4 (0.9)
To what extent do you agree or disagree that the injection force would help your child gain the autonomy to self-inject?	83	4.3 (0.9)	84	4.4 (0.9)	83	4.3 (0.9)
Cartridge Replacement						
How would you rate this pen in terms of the ease with which the cartridge can be changed?	65	3.8 (0.9)	83	4.1 (0.9)	71	3.9 (0.9)
To what extent do you agree or disagree that the process of changing the cartridge would help your child gain the autonomy to self-inject?	61	3.7 (1.1)	66	3.8 (1.0)	62	3.7 (1.1)
Overall Use						
To what extent do you agree or disagree that the following statements are true for this pen?						
This pen is easy to use.	94	4.3 (0.6)	93	4.4 (0.6)	93	4.4 (0.6)
This pen would help my child gain the autonomy to self-inject.	86	4.2 (0.8)	78	4.1 (1.0)	83	4.2 (0.9)
This pen would be convenient for everyday use.	92	4.5 (0.7)	88	4.4 (0.9)	90	4.4 (0.8)
This pen suits the lifestyle of a young person with type 1 diabetes.	88	4.4 (0.8)	84	4.3 (0.9)	87	4.3 (0.8)

SD = standard deviation.

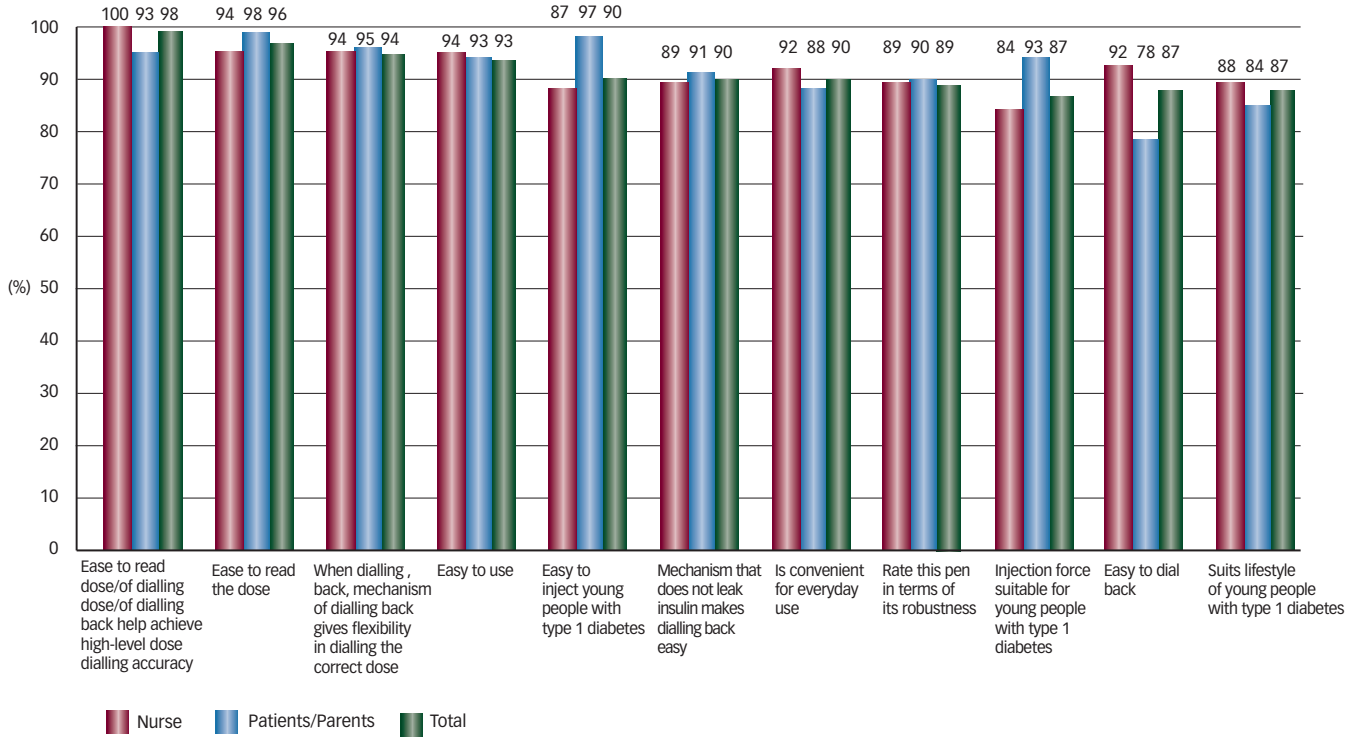
Ratings were made on a five-point scale.

When asked to rate the product: 1 = very poor; 2 = somewhat poor; 3 = neither poor nor good; 4 = somewhat good; 5 = very good.

When asked to agree/disagree with a statement: 1 = completely disagree; 2 = somewhat disagree; 3 = not sure; 4 = somewhat agree; 5 = completely agree.

** Overall positive percentages are based on the sum of those giving a score of 4 or 5 as a percentage of the total sample.*

Figure 1: Key Strengths of JuniorSTAR®



have been shown to be more accurate than syringes for the delivery of low insulin doses.[15] This provides greater flexibility to achieve target insulin doses for younger children and adolescents with type 1 diabetes. Half-unit dose accuracy is particularly important in this patient population because studies have shown a positive correlation between the percentage of hypoglycaemic events in children and the errors in the accuracy of a regular insulin dose.[13] JuniorSTAR® (Sanofi) is a reusable, half-unit pen weighing ~34 g ± 10 % (with outer body made of aluminium material) existing in three colours (blue, red and silver) to allow differentiation between insulins and allowing dialling by half-unit increment, up to 30 units per injection. It was developed for young people with diabetes. The JuniorSTAR is pending CE mark (under the responsibility of Haselmeier) and is planned to be used with insulin glargine (Lantus™), insulin glulisine (Apidra™) and human insulin (Insuman™). This article describes a survey whose objective was to assess the major features and usability of JuniorSTAR pen through individual, parent and diabetes specialist nurse ratings.

Materials and Methods

The survey was a non-comparative assessment of JuniorSTAR in insulin pen users from five European countries (France, UK, Germany, Italy and Spain). Performance was assessed through individual, parent and diabetes specialist nurse ratings of the attributes of this pen, given as responses to a questionnaire. Participants were interviewed on a face-to-face basis. The study enrolled: 1) nurses who were working with children with type 1 diabetes (n=109); 2) parents of children with type 1 diabetes aged less than 5 years (n=16); 3) children aged 6–12 years (n=8); 4) parents of children aged 6-12 (n=12); and 5) adolescents with type 1 diabetes aged 13–18 years (n=22). Only diabetes specialist nurses who teach at least five children a week on how to use a reusable pen were enrolled. All participants signed a consent form. All patients were already using an insulin pen: either disposable (18.3 %), reusable (57.3 %), a combination of both reusable and disposable (23.2 %) or type of pen was not recorded (1.2 %).

JuniorSTAR was rated on a five-point scale on 3 scales as follows: when asked to rate the product, 1 = very poor; 2 = somewhat poor; 3 = neither poor nor good; 4 = somewhat good; 5 = very good or 1 = very difficult; 2 = somewhat difficult; 3 = neither easy nor difficult; 4 = somewhat easy; 5 = very easy. When asked to agree/disagree with a statement, 1 = completely disagree; 2 = somewhat disagree; 3 = not sure; 4 = somewhat agree; 5 = completely agree. We defined a positive response as the percentage of the total respondents (answers of parents and children were pooled) who responded with either a 4 or a 5 score.

Results

The responses of all 167 participants, as total study population and patients/parents and nurse subgroups, are presented in *Table 1*. Participants rated JuniorSTAR highly (min–max standard deviation [SD]: score: 3.7 (1.1)–4.7 (0.6)) across all attributes tested.

In terms of practicality, JuniorSTAR was found to be easy to carry in daily life by 84 % of all participants (81 % of patients/parents; 86 % of nurses) with a weight rated good or very good by 69 % of participants and sufficiently robust to withstand the daily demands of children by 89 % of participants.

In terms of usability, 96 % agreed that the dose display was easy to read (by children 98 %; by nurses, 94 %). When assessing the dose dialling, 80 % agreed that the audibility and tactility of the clicks made dialling a dose easy (66 % of children; 87 % of nurses). Furthermore, 87 % agreed that the pen is easy to dial back in case of accidentally dialling a dose larger than required (78 % of children/parents; 92 % of nurses), and 94 % found that the dial-back mechanism of JuniorSTAR permitted flexibility in dialling the correct dose. Of the participants, 90 % considered that the dial back mechanism, which does not leak insulin, increases the ease of dial back. Given the ease

of reading, dialling and dialling back the dose, 98 % of all participants found that JuniorSTAR helped patients achieve a high level of dose dialling accuracy (with 93 % in children/parents and 100 % in the nurses' population).

Regarding suitability for young patients, 90 % of all participants reported that the JuniorSTAR is easy to inject for young patients (with 97 % in children/parents; 87 % in nurses), and 87 % found the injection force to be suited to the ability of young patients with type 1 diabetes (93 % in children/parents; 84 % in nurses). Regarding the ease of changing the cartridge, 71 % of the total population (83 % of patients; 65 % in nurses) found it easy to change the cartridge.

Overall, 93 % of participants found JuniorSTAR half-unit pen to be easy to use, 90 % considered JuniorSTAR convenient for everyday use (88 % by children/parents; 92 % by nurses). JuniorSTAR half-unit pen was considered as suitable to the lifestyle of a young patient with type 1 diabetes by 87 % of the total population (84 % by children/parents; 88 % by nurses), with 83 % of all participants considering that JuniorSTAR would help a child gain the autonomy to self-inject (78 % by children/parents; 86 % by nurses). The profile of responders and their concerns differed, and this was reflected in the difference in responses between nurses and children/parents. In some cases, the question was more related to the patient's personal preference (e.g. injection force) but other questions were of more concern to nurses (e.g. changing cartridges).

When the scores were below 4 (non-positive responses to the questions), the answers were mostly scored as 3 (neutral responses). Complete disagreement (which was a score of 1) was never reported by more than 2 % of respondents for any question. When asked the question, "can you give me one word that best describes how you feel about this pen", the most common replies were practical, easy and simple.

In summary the key strengths of the half-unit insulin pen, JuniorSTAR, found in at least 84 % of the total population, are its practicality, its ease of carrying (84 %), ease of reading the dose (96 %), ease of dialling back (87 %) and a suitable injection force for young people (87 %).

This ease of use should make it easier to teach patients how to perform dose adjustments, particularly in terms of accurate dose dialling at half-unit increments and dialling back. In the qualitative overall assessment, only a minority have identified some points that could be improved such as the dial is too stiff and not sufficiently smooth and the cap is too stiff to remove. The adolescents would prefer a quieter dial to assure discretion.

Conclusions

Children and adolescents are faced with many challenges in managing their condition. It is important for them to have access to insulin delivery technology that can permit adjustment of their insulin doses to be as easy and accurate as possible. In our survey, the JuniorSTAR half-unit insulin pen was well received by patients with type 1 diabetes and their caregivers. JuniorSTAR was found to be easy to carry, easy to read for accurate dose dialling and easy to dial back so mistakes could be corrected without any insulin penalty, with an injection force suited to the ability of young patients with type 1 diabetes. Considering these advantages, the JuniorSTAR half-unit insulin pen is likely to be easy to handle and suitable for the lifestyle of the young type 1 diabetes population. ■

1. IDF, International Diabetes Federation Diabetes Atlas, 5th edition http://www.idf.org/diabetesatlas/5e/the-global-burden, 2011; date last accessed 22 July 2013.
2. Patterson CC, Dahlquist GG, Gyurus E, et al., Incidence trends for childhood type 1 diabetes in Europe during 1989–2003 and predicted new cases 2005-20: a multicentre prospective registration study, *Lancet*, 2009;373:2027–33.
3. American Diabetes Association, Standards of medical care in diabetes–2013, *Diabetes Care*, 2013;36(Suppl. 1):S11–S66.
4. ISPAD/IDF, Global IDF/ISPAD guideline for diabetes in childhood and adolescence; http://www.idf.org/sites/default/files/Diabetes-in-Childhood-and-Adolescence-Guidelines.pdf, 2011; accessed: 22 July 2013.
5. Strawhacker MT, Multidisciplinary teaming to promote effective management of type 1 diabetes for adolescents, *J Sch Health*, 2001;71:213–7.
6. Chih AH, Jan CF, Shu SG, et al., Self-efficacy affects blood sugar control among adolescents with type I diabetes mellitus, *J Formos Med Assoc*, 2010;109:503–10.
7. Hood KK, Peterson CM, Rohan JM, et al., Association between adherence and glycemic control in pediatric type 1 diabetes: a meta-analysis, *Pediatrics*, 2009;124:e1171–9.
8. Levine BS, Anderson BJ, Butler DA, et al., Predictors of glycemic control and short-term adverse outcomes in youth with type 1 diabetes, *J Pediatr*, 2001;139:197–203.
9. Coffen RD, Dahlquist LM, Magnitude of type 1 diabetes self-management in youth: health care needs diabetes educators, *Diabetes Educ*, 2009;35:302–8.
10. Davidson M, Penney ED, Muller B, et al., Stressors and self-care challenges faced by adolescents living with type 1 diabetes, *Appl Nurs Res*, 2004;17:72–80.
11. Comeaux SJ, Jaser SS, Autonomy and insulin in adolescents with type 1 diabetes, *Pediatr Diabetes*, 2010;11:498–504.
12. Ekim A, Pek H, Insulin administration skills of children with type 1 diabetes, *Journal of Diabetes Nursing*, 2010;14:70–4.
13. Lteif AN, Schwenk WF, Accuracy of pen injectors versus insulin syringes in children with type 1 diabetes, *Diabetes Care*, 1999;22:137–40.
14. Asamoah E, Insulin pen-the "iPod" for insulin delivery (why pen wins over syringe), *J Diabetes Sci Technol*, 2008;2:292–6.
15. Gnanalingham MG, Newland P, Smith CP, Accuracy and reproducibility of low dose insulin administration using pen-injectors and syringes, *Arch Dis Child*, 1998;79:59–62.