Research Article
Volume 7:6, 2022

Journal of Pediatric Neurology and Medicine

ISSN: 2472-100X

Open Access

Parents' Recognition of Side Effects Experienced by Children Taking Intuniv® and Information Sharing with Teachers: A Retrospective Cohort Study

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Abstract

Attention deficit hyperactivity disorder (ADHD) is a developmental disorder characterized by a lack of attention, hyperactivity, and impulsivity. Intuniv® was used to treat ADHD. The side effects of Intuniv®, including hypotension and sedation (sleepiness and drowsiness), have a significant impact on children's daily lives. This study aimed to evaluate parents' perceptions of the side effects of Intuniv® at home, nursery schools, kindergartens, and schools. It also aimed to clarify the current state of information sharing between parents and school teachers. We distributed a self-administered survey form to all parents who visited Ito Pharmacy and had a child administered Intuniv®. We investigated the patients' background, whether the schoolteachers were informed by the parents about Intuniv® intake by their children, and the occurrence of side effects of Intuniv® administration. We also examined the means of sharing information between parents and school teachers when side effects occurred. The results revealed that most children experienced serious side effects. Approximately 92.5% of the parents informed the schoolteachers about Intuniv® intake by their children. Parents of children who experienced side effects at school used more frequent means of contact with teachers than those who did not experience side effects at school. Some parents who used frequent means of contact were aware that their children experienced hypotension. Frequent sharing of information with school teachers enables parents to be aware of the occurrence of side effects experienced by their children at school.

Keywords: ADHD • Intuniv® • Information sharing • School children • Side effect

Abbreviations: Attention Deficit Hyperactivity Disorder (ADHD)

Introduction

The 4th edition of the attention deficit hyperactivity disorder (ADHD)–Diagnosis and Treatment Guideline states that "the association between the parents of children with ADHD and schools is crucial from the perspective of improving the environment for these children and their treatment and support. However, the kind of available information sharing among parents, healthcare professionals, nursery teachers, kindergarten teachers, and school teachers needs to be clear to enable children to offer ADHD therapy while efficiently supporting their daily lives [1].

One therapeutic agent for ADHD is guanfacine hydrochloride extended-release tablets (Intuniv®). The typical side effects include hypotension and somnolence. These side effects can have a significant impact on children's lives. To date, the occurrence of side effects in children is not completely understood. This study aimed to evaluate parents' perceptions of the side effects of Intuniv® at home, nursery schools, kindergartens, and schools. It also aimed to clarify the current state of information sharing between parents and school teachers.

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Received: 01 November 2022, Manuscript No. JPNM-22- 84371; **Editor assigned:** 03 November 2022, Pre QC No. P- 84371; **Reviewed:** 17 November 2022, QC No. Q- 84371; **Revised:** 22 November 2022, Manuscript No. R- 84371; **Published:** 29 November 2022, DOI: 10.37421/2472-100X.2022.7.206

Methods

All parents of children taking Intuniv® who visited Ito Pharmacy between November 28, 2018, and February 4, 2019, were considered eligible for participation in this study. The participants were asked to complete a self-administered survey. The form contained seven items: children's age, sex, number of days of the administration, whether their parents informed their teachers about Intuniv® dosing, side effects experienced by children, sharing information when a side effect occurred, and frequency of contact between parents and teachers. The survey items were compared by dividing the participants into two groups: side effect experienced and side effect inexperienced groups. In addition, focusing on the location of the side effects, we compared the two groups according to the presence of side effects at school. The Mann–Whitney U test and Student's *t*-test were used to compare the two groups. The dependent variables in the study were age, sex, days of administration of Intuniv®, and sharing of information about Intuniv® dosing. Simultaneously, we focused on where the side effects of Intuniv® occurred and divided the participants into two groups: A group that experienced side effects in school and a group that did not experience side effects in school. The effect size was calculated as Cohen's *d* for continuous variables and the φ coefficient for categorical variables. The statistical significance level was set at 5%. The statistical software IBM SPSS Statistics (Version 27) was used for statistical analyses.

The rate of parents' recognition of side effects in their children was defined as the number of people who recognized side effects out of the total number of respondents. This rate was compared with the incidence of adverse drug reactions in a domestic clinical study (combined domestic placebo-controlled study (A3122) and continuous long-term study (A3131)). The study was approved by the Aichi Pharmaceutical Association Ethics Review Committee (approval number: 2018-6).

Results

Participants

The questionnaire was distributed to 66 participants and collected from 40 participants (response rate: 60.6%). All respondents were mothers of children with ADHD. Approximately 90.0% of the children were male, and 10.0% were female. Approximately 5.0% of the children attended nursery schools, 65.0% attended elementary schools, and 27.5% attended junior high schools. The median number of days of Intuniv® administration was 180 (Table 1).

Occurrence of side effects

Approximately 72.5% of participating children experienced adverse effects. Their mean age was 9.8 ± 2.5 years (6–14 years old), while the mean age of participants who did not experience any side effects was 10.8 ± 2.8 years (7–15 years old). No statistically significant difference in the age of the two groups (Mann–Whitney U test) was found.

In contrast, children who did not experience any side effects received Intuniv® for 192.7 ± 127.9 days (30–478 days), while children who did not experience any side effects received Intuniv® for 230 ± 156.5 days (30–525 days; Student's *t*-test; P = 0.473). Moreover, there was no significant difference in information-sharing between the two groups of children receiving Intuniv® (Table 2).

A combined domestic clinical study compared the rate of parents' recognition of the side effects experienced by their children and the incidence of adverse drug reactions (A3122 and A3131). Sedation (sleepiness and drowsiness) was the side effect most recognized by the respondents in this study, and the frequency of its occurrence in their children was higher than that reported in a domestic clinical study (Figure 1). Some children experienced hypotension and bradycardia.

Side effects in schools

Approximately 65.5% of the children experienced side effects in schools (mean age, 9.6 ± 2.5 years; range, 6–14 years old), while the children who did not experience side effects in schools were aged 10.0 ± 2.6 years (6–15 years old; P = 0.717).

Children who experienced side effects were administered Intuniv® for 172.1 ± 128.7 days (30–465 days), and those who did not experience any side effect were administered Intuniv® for 232.0 ± 123.1 days (30–487 days; P = 0.237).

Contact frequency with teachers was considered a surrogate marker for the strength of sharing information about Intuniv® intake between parents and teachers. Parents of children who had experienced side effects in schools had a higher tendency to use frequent contact means, such as contact books and telephone calls (Table 3).

Discussion

The guidelines for the treatment of ADHD by the UK National Institute for Health and Clinical Excellence provide schoolteachers and parents with the following information [2]: (1) the diagnosis of ADHD varies widely, (2) symptoms can easily affect school life, (3) complications, such as learning disabilities, require different environmental adjustments than ADHD, and (4) information received from schools is highly valuable. These guidelines are consistent with the findings of the present study. In this survey, we investigated the provision of information on the use of Intuniv® tablets. The overwhelming majority of respondents informed their schoolteachers about drug use. It was implied that the mothers of the affected children expected the schoolteachers to provide them with information regarding changes in the physical condition of their children.

The incidence of adverse drug reactions (sedation) was higher in this study than that in a domestic clinical trial. This could be explained by the fact that the parents were the only observers of the children in the domestic clinical study, while in the present study, schoolteachers and parents observed side effects in the affected children. In contrast, the awareness of parents and schoolteachers about serious side effects, such as hypotension and bradycardia, was lower in this study than in the domestic clinical trial. This could be attributed to the measurement of blood pressure and pulse rate on a daily basis for safety evaluation in a domestic clinical study but not in this study.

However, the American Academy of Pediatrics guidelines for ADHD treatment list daily report cards and a point system as methods of intervention for the affected children at school; however, they do not indicate the means of communication between the school and family [3]. The Japanese ADHD treatment guidelines also do not specify the means of communication between the school and family to share the condition of the affected children at school. In the current study, parents used visits and contact books as a means of

Table1: Demographic characteristics of children with ADHD.

		N	%
Sex	male	32	88.9
	female	4	11.1
Grade	Nursery schools	2	5.6
	Kindergarden	0	
	Primary school	24	66.7
	Junior high school	9	25.0
	High school	0	
	Other	1	2.8
Median of the number of days of Intuniv® administraion [first quartile-third quartile]		180 [60-187.5]	

Table2: Demographic characteristics in the sample.

	Group of children who experienced side effects (N = 29)		Group of children who did not experienced side effects (N = 11)		p
	N	%	N	%	
Age	9.8 ± 2.5*		10.8 ± 2.8*		0.663
Sex (male)	26	86.7	10	90.9	0.906
Day of administration of Intuniv®	192.7 ± 127.9*		230.6 ± 156.5*		0.327
Sharing information about dosind with Intuniv®	27	93.1	10	90.9	0.815

*mean ± S.D (standard deviation)

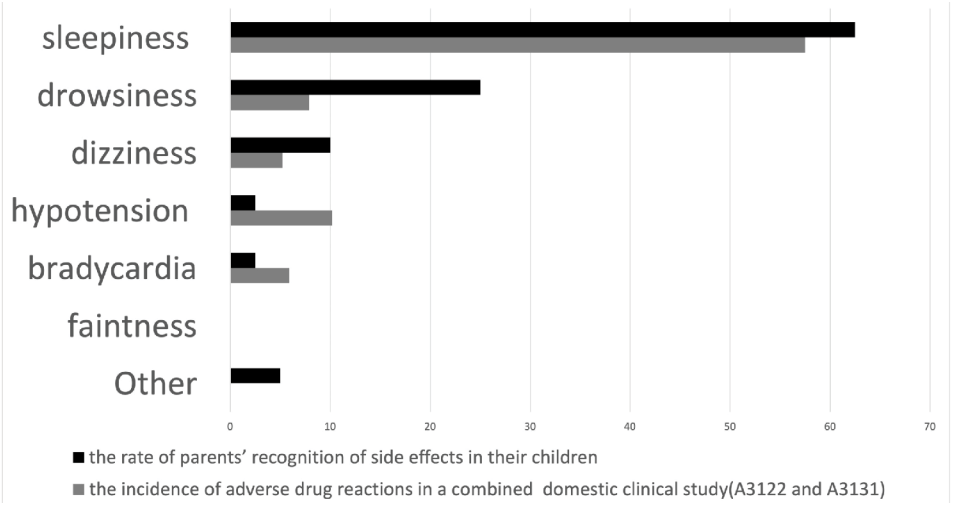

Figure 1: Percentage of the rate of parents' recognition of side effects in their children and the incidence of adverse drug reactions in a combined domestic clinical study (A3122 and A3131).

Table3: Demographic characteristics of children in school in the sample.

	Group of children who experienced side effects in schools(N=19)		Group of children who did not experience any side effects in schools(N=19)		p	Effect size
	N	%	N	%		
Age	9.6 ± 2.5*		10.0 ± 2.6*		0.717	0.143
Sex (male)	18		8	80	0.267	0.23
Day of administration of Intuniv®	172.1 ± 128.7*		232.0 ± 123.1*		0.237	0.473
Sharing information about dosind with Intuniv®†	18	94.7	9	90	0.357	0.253
Use of frequent contact means††	9	47.4	(1)	(10.0)	0.011	0.5

*mean ± S.D (standard deviation)
†1 defect in side effect group at school ††1 defect in each group

communication between the school and family. Accordingly, parents are more likely to recognize the occurrence of adverse effects at school and other places when information sharing among parents, schoolteachers, and other involved people is efficient. This can be further augmented by using smartphone applications for the management of mental illnesses. Based on these findings, it is necessary to promote information sharing between school teachers and parents and develop tools that enable real-time sharing of observations about side effects and situations in the future.

Conclusion

Sharing information about children with ADHD by teachers is valuable for evaluating the occurrence of side effects of Intuniv® and their impact on the daily lives of children.

Acknowledgments

None.

Conflict of Interest

The authors have no conflicts of interest to declare.

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How to cite this article: Ito, Rie and Fumiko Ohtsu. "Parents' Recognition of Side Effects Experienced by Children Taking Intuniv® and Information Sharing with Teachers: A Retrospective Cohort Study." *J Pediatr Neurol Med* 7 (2022): 206.