Assessing Effects of Treatment With Lisdexamfetamine Dimesylate for Pediatric ADHD Using a Parental Survey

Donna Antonucci, MD, Craig Kunins, MD, Michael Manos, PhD, Frank A. López, MD, and Donna L. Kerney, PhD

ABSTRACT

Introduction: Lisdexamfetamine dimesylate (LDX) is a prodrug stimulant approved for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults and children 6–12 years of age. Parent surveys provide valuable information regarding the impact of ADHD treatments.

Methods: Parents of children with ADHD beginning treatment with LDX voluntarily completed surveys through an automated telephone system or the Internet before and 6 weeks after LDX treatment initiation. Prescribing physicians received individual reports of the responses for each survey completed by their patients' parents. All patients whose parents completed both baseline and 6 week surveys were included in the analyses. Subgroup analyses were conducted for those previously treated with medications to treat ADHD, including mixed amphetamine salts-extended release.

Results: LDX treatment was associated with a significant decrease in ADHD symptom interference with school activities, family interactions, homework, and social interactions ($P<.01$; N=11,576). Parents rated satisfaction with LDX

FOCUS POINTS

- Lisdexamfetamine dimesylate (LDX) is the first long-acting prodrug stimulant indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children 6–12 years of age and in adults.
- After 6 weeks of treatment with LDX, parents reported significant improvement in ADHD symptomatology and the impact of their child's ADHD symptoms on daily activities.
- Parent-rated satisfaction with LDX was significantly higher than with their child's previous treatment. Global improvement, tolerability, convenience, and satisfaction with LDX were all highly rated.

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Faculty Disclosures: Dr. Antonucci is a consultant to and on the speakers' bureau of Shire. Dr. Kunins is on the speakers' bureau of Shire. Dr. Manos is a consultant to Cephalon, Eli Lilly, and Shire; is on the speaker's bureau of Shire; and has received grant/research support from McNeil, Noven, Shire, and Sigma Tau. Dr. Lopez is on the speakers' bureau of Cephalon, Eli Lilly, Novartis, Noven, and Shire; and has received grant/research support from Bristol-Myers Squibb, Cephalon, Eli Lilly, GlaxoSmithKline, New River Pharma, Novartis, Noven, Shire, and Wyeth. Dr. Kerney reports no affiliation with or financial interest in any organization that may pose a conflict of interest.

Funding/Support: Funding was provided by Shire US, Inc., Wayne, Pennsylvania.

Acknowledgment: Editorial assistance was provided by Kira Belkin, William Perlman, and Rosa Real, Excerpta Medica, Bridgewater, New Jersey.

Submitted for publication: May 20, 2009; Accepted for publication: March 5, 2010.

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https://doi.org/10.1017/S1092852900000080 Published online by Cambridge University Press

as significantly higher than with their child's previous treatment ($P<.01$). On average, global improvement, tolerability, convenience, and satisfaction with LDX were all highly rated.

Conclusion: Patients treated with LDX showed significant symptom improvement and parents reported significantly greater satisfaction than with prior treatment.

CNS Spectr. 2010;15(4):248-256.

INTRODUCTION

Attention-deficit/hyperactivity disorder (ADHD), one of the most common psychiatric disorders in childhood, affects 8% to 12% of children worldwide.[1] ADHD can negatively affect children's school performance and social interactions. For ADHD, available data on treatment impact and satisfaction in typical care settings are limited. Randomized controlled trials (RCTs) have become routine in all fields of medicine and are the gold standard for assessing treatment efficacy. Although data from RCTs can provide the clinician with invaluable information, especially when combined with data from long-term tolerability and effectiveness studies, RCTs are designed to collect data on objectively measurable or quantifiable clinical outcomes. These studies purposely exclude subjects with comorbid conditions or illnesses that might affect outcomes on clinical or safety measures, or that might place human subjects at increased risk of adverse events. They may select standardized outcomes measures that are not the ones used by community physicians managing ADHD patients. The standardized rating scales used in studies also may not be expressed in the same terms or language that patients or parents use to describe their perceived impact of ADHD. As a result, they may not capture other measures of the condition or treatment impact that can be meaningful to patients and their families.

There is a need for specific information that has direct bearing on treatment adherence as well as patient and parent satisfaction. Though surveys are not typically validated and are not designed to capture information with the specificity of validated quality-of-life instruments used in controlled clinical trials, they can nevertheless include more participants and are able to define qualitative parameters often unavailable in endpoint data from clinical trials. This can inform physicians and parents alike. The perspectives of patients and/or family members regarding the impact of a medical or mental health condition and its treatment may be valuable for selection of optimal therapy and treatment titration, as well as the facilitation of patient-clinician communication in real world settings.

Despite a wealth of data regarding the quality of trained rater information in the context of clinical trials, there remains a dearth of information regarding assessments from parents and families. The perspectives of parent/guardian observers deserve further analysis, including the identification and rating of symptoms combined with their impact on daily activities. These observations may vary from those of the treating clinician. In an effort to add this perspective to the literature, a survey was designed for parents whose children were initiating pharmacological treatment for ADHD.

The primary objective of the survey was to assess parents' perceptions regarding the impact of ADHD and pharmacological treatment with once-daily lisdexamfetamine dimesylate (LDX; Vyvanse) on their children in a naturalistic real world environment. LDX, the first long-acting prodrug stimulant, is indicated for the treatment of ADHD in children 6–12 years of age and adults.[2] LDX is a therapeutically inactive molecule, which is converted to l-lysine and active d-amphetamine after oral ingestion; d-amphetamine is responsible for the therapeutic effect.[3] One of the properties attributed to LDX is a consistent delivery of d-amphetamine from patient to patient, as shown in a clinical trial of pediatric subjects with ADHD.[3] In addition, a pharmacokinetic study of healthy adults demonstrated low intrapatient variability in pharmacokinetic parameters when measured over all doses within individual subjects.[4]

In a forced-dose titration RCT in children with ADHD, parent ratings obtained after a median dosing time between 7:30 and 8:00 AM indicated that a morning dose of LDX was effective throughout the day, up to 6 PM.[5] In this pivotal study, LDX was generally well tolerated with a safety profile consistent with long-acting stimulant use. The Conners' Parent Rating Scale–Revised: Short Form was used by parents to assess symptom

severity throughout the day, both at survey baseline and following LDX treatment.[5] Parents of patients in each LDX dose group (30, 50, or 70 mg) reported significantly greater symptom control in the morning, afternoon, and evening compared with controls ($P<.01$).[5]

The safety and efficacy of LDX were studied in 129 children 6–12 years of age with ADHD. The study found medication effectiveness for up to 13 hours.[6] A secondary endpoint of this randomized, double-blind, placebo-controlled, crossover, analog classroom study was parent satisfaction with their child's treatment as assessed by the Medication Satisfaction Questionnaire.[6] This questionnaire was completed by the same parent at the end of the 4 week, open-label, dose-optimization phase. Most parents (76%) were very satisfied with LDX. Adverse events were consistent with other pediatric studies of LDX and were similar to other stimulants.[7]

In a prospective, open-label, multicenter, dose-optimization study to assess the efficacy and safety of LDX in children 6–12 years of age with ADHD, a secondary endpoint was the global impression of ADHD severity and improvement with treatment, as measured by the Parental Global Assessment.[8] Most parents (85%) rated their children as either "much improved" or "very much improved" while receiving LDX.

These studies not only collected information from parents regarding symptom severity throughout the day but also parent satisfaction with medication. In the present survey, in an attempt to further broaden the scope of a parent survey beyond symptom severity and satisfaction, parent feedback was solicited on additional topics, including most bothersome symptom, most bothersome time of day, level of symptom interference with family interactions, school activities, social interactions, and homework, and the impact of treatment on these variables. Observed and reported results were gathered from parents of children with ADHD before and after 6 weeks of treatment with LDX. Parents were asked if their child had taken any prescription ADHD medication prior to LDX, and if so to indicate the type (ie, brand) used most recently. These medications included mixed amphetamine salts-extended release (MAS-XR), extended-release oral methylphenidate hydrochloride, extended-release transdermal methylphenidate hydrochloride, extended-release dexmethylphenidate hydrochloride, and atomoxetine. Any medication other than those listed was referred to as "other medication." This paper reports results gathered from a subset of children who switched to LDX from MAS-XR (Adderall XR).

METHODS

Vyvanse New Start Program

The Vyvanse New Start Program is a patient-feedback system designed to engage patients and, in this case, their parents, in providing treatment feedback to their children's treating physician. The objective of the Vyvanse New Start Program was to conduct a survey of parents of children being treated with Vyvanse to rate their perceptions of its impact on their child's symptoms and their overall medication satisfaction. This survey was not designed to establish comparative clinical efficacy. Data from the Vyvanse New Start Program were obtained from prospective surveys conducted nationwide and completed by parents/guardians of children 6–12 years of age, for whom LDX is indicated,[2] who were initiating treatment with LDX. Parents opted into the Vyvanse New Start Program via Shire's Shine program—an Internet-based patient-support program that helps parents become active in the child's treatment by providing free practical tools and tips on how to help the child improve focus and organization, how to work with the child's teachers, and how to track progress and success. There were no preconditions on parent participation based on prior treatments or reasons for initiating LDX.

Data presented here were analyzed following collection from surveys conducted between July 2007 and September 2008, and completed either via telephone using interactive voice-response technology or through a secure Internet site. Parents completed three clinician-designed surveys: a baseline survey prior to LDX initiation, a follow-up survey ~3 weeks after initiation of LDX, and a follow-up survey~6 weeks after initiation of LDX (Baseline and 6 week follow-up surveys available online at www.cnsspectrums.com). Collection of data from the Vyvanse New Start Program remained ongoing after the September 2008 cutoff for the data analysis presented here.

The first follow-up was completed 16–27 days following LDX treatment initiation. If <16 days

https://doi.org/10.1017/S1092852900000080 Published online by Cambridge University Press

had passed, parents trying to access the survey were instructed that they were responding too early and to return 3 weeks after the baseline survey date. If ≥28 days had passed since the baseline survey was completed, parents completed the 6 week follow-up, regardless of whether the first follow-up had been completed. Parents could take the 6 week follow-up at any time after at least 28 days had passed since baseline, with no maximum time interval. Parents were considered to have "completed" the program as long as the baseline and 6 week follow-up surveys were answered. For purposes of this article, data from only the baseline and 6 week follow-up surveys are presented, as not all parents who "completed" the program responded to the 3 week survey.

Physicians received a summary of the responses for each survey completed by their patients' parents. Physicians could receive up to three reports for each patient participating in the program. After completing the final survey, parents received a progress report summarizing their responses for all completed surveys and a $25 coupon toward their child's next prescription of LDX.

Survey Content

Survey questions were designed in consultation with three independent, clinically practicing physicians who are experts in the treatment of ADHD. Topics in the baseline survey included duration of time since ADHD diagnosis, use of prescription medication for ADHD prior to LDX, satisfaction with prior medication, most bothersome symptom, most bothersome time of day, and level of symptom interference with activities. Topics in the follow-up surveys included change in most bothersome time of day, level of symptom interference with activities, change in most bothersome symptom, global assessment, satisfaction with LDX, convenience of LDX, tolerability of LDX, and intent for the child to continue treatment with LDX.

Statistical Analyses

Survey responses were summarized and reported as means or frequency distributions, as appropriate. Analyses were conducted on all who completed the baseline and 6 week follow-up surveys. Additional subgroup analyses were conducted on all who completed the baseline and 6 week follow-up surveys, and reported use of MAS-XR prior to LDX. All analyses were conducted using SPSS v. 16.0.2. The statistical comparisons were generated as a post hoc analysis. The Wilcoxon signed rank test was used to evaluate differences in the level of interference of ADHD symptoms with family interactions, social interactions, homework, and school activities. Ratings at baseline were compared with those at follow-up for each measure. The Wilcoxon signed rank test was used to assess the statistical significance of the difference in satisfaction with prior prescription and LDX.

RESULTS

Baseline Demographics

In this ongoing program, a total of 39,209 participants had completed the baseline survey at the time of analysis. Of these, 11,576 completed the baseline and 6 week follow-up surveys. The average time from baseline survey to 6 week follow-up was 46 days. Nearly one out of four reported no prior use of prescription ADHD medication. Most patients (63%) previously received stimulant medication (31% MAS-XR, 16% extended-release oral methylphenidate hydrochloride, 11% extended-release dexmethylphenidate hydrochloride, 5% extended-release transdermal methylphenidate hydrochloride), while 5% previously received a nonstimulant (atomoxetine) and 10% had received an unspecified other medication. Thirty-five percent had an ADHD diagnosis for <1 year, 56% for 1–5 years, 9% for >5 years, and 1% of parents were unsure of the length of time since their child was diagnosed (Figure 1A). In the subgroup of patients who previously received MAS-XR (n=3,558), the average time between baseline survey and the 6 week follow-up was 47 days. In the MAS-XR subgroup, 20% of patients had an ADHD diagnosis for <1 year, 68% for 1–5 years, 11% for >5 years, and <1% of parents were unsure of the length of time since their child was diagnosed (Figure 1B).

The majority (60%) of parents considered attention or focus difficulties the most bothersome symptom, while 24% and 16% considered impulsiveness and hyperactivity, respectively, to be the most bothersome (Figure 2A). The most bothersome time of day for their child was school time (45%), followed by homework time (23%), and the time during after-school activities (15%; Figure 3A). These baseline results were similar to those in the MAS-XR subgroup. Among patients previously prescribed MAS-XR, the majority (57%) of

https://doi.org/10.1017/S1092852900000080 Published online by Cambridge University Press

parents considered attention or focus difficulties the most bothersome ADHD symptom, while 26% and 17% considered impulsiveness and hyperactivity, respectively, to be most bothersome (Figure 2B). The most bothersome time of day for children in this subgroup was school time (35%), followed by homework time (28%), and time during after-school activities (18%; Figure 3B).

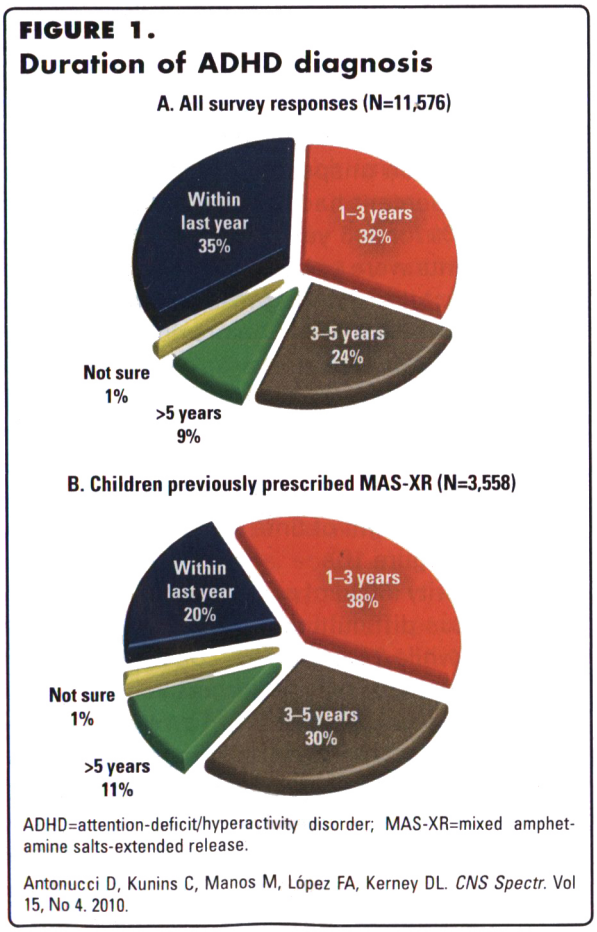
Results of 6 Week Survey

Based on case-by-case clinician decisions, the LDX regimen consisted of either daily (7 day) dosing (85%; n=9,890) or school days only (5 day) dosing (15%; n=1,686). Compliance with the prescribed regimen was high; 87% of parents in each dosing group reported their children took their medication in accordance with their treatment regimen.

LDX treatment was associated with a significant decrease in the level of interference of ADHD symptoms with school activities, family interactions, homework, and social interactions ($P<.01$; Figure 4A). Eighty-four percent of parents reported that treatment with LDX resulted in improvement in ADHD symptoms during their child's most bothersome time of day (Figure 5A). Improvement was seen regardless of which time of day was most bothersome. Similarly, 84% of parents reported that treatment with LDX resulted in improvement in their child's most bothersome symptom (Figure 6A), regardless of which symptom was most bothersome.

Using 9 point scales, parents indicated that LDX treatment resulted in substantial global improvement on average (6.2; 1=no improvement, 9=very much improved), good tolerability (7.2; 1=not at all well tolerated, 9=very well tolerated), high convenience (8.0; 1=not at all convenient, 9=very convenient), and high satisfaction (7.0; 1=not at all satisfied, 9=very satisfied). Among patients who had previously been prescribed a different ADHD medication (n=8,956), parents reported a higher satisfaction level with LDX treatment than with the previous treatment (mean 6.9 vs 5.1 on 9 point scale; $P<.01$). Seventy percent of parents reported satisfaction ratings of 7–9 with LDX

FIGURE 1.
Duration of ADHD diagnosis



ADHD=attention-deficit/hyperactivity disorder; MAS-XR=mixed amphetamine salts-extended release.

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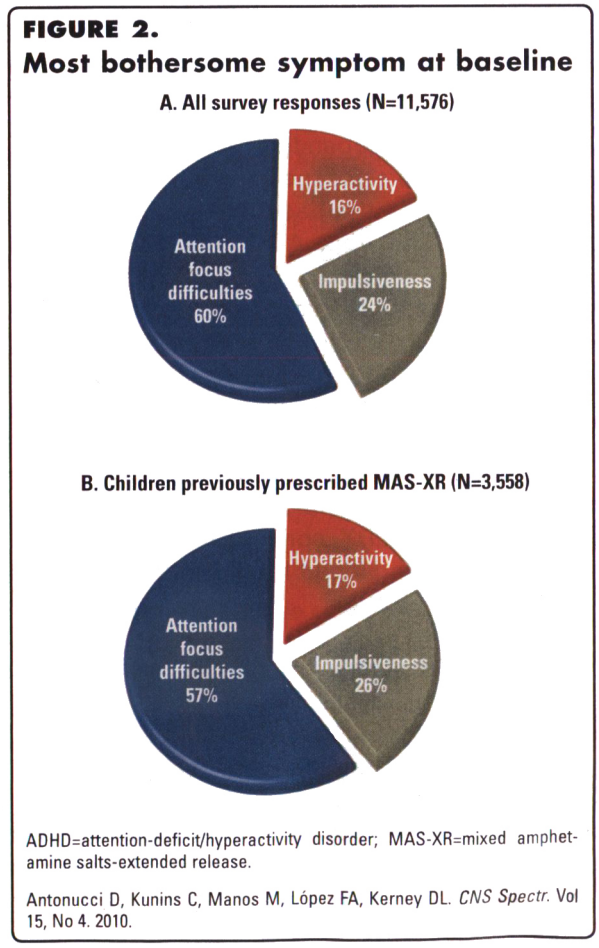
FIGURE 2.
Most bothersome symptom at baseline



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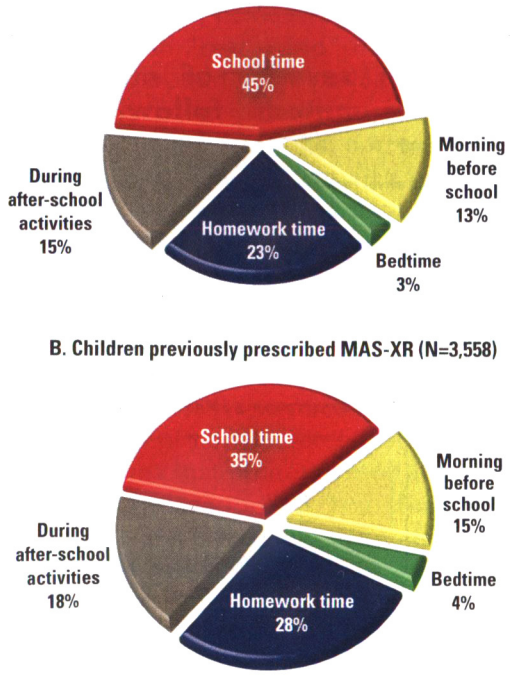
https://doi.org/10.1017/S1092852900000080 Published online by Cambridge University Press

treatment versus only 29% with prior treatment. When asked about intent to continue treatment with LDX, 84% responded yes, 13% maybe, and 3% did not intend to continue.

In the subgroup of patients previously prescribed MAS-XR, 87% (n=3,099) were prescribed 7 day dosing and 13% (n=459) were prescribed 5 day dosing, for school days only. The dosing regimen was determined on a case-by-case basis by the prescribing physician. Compliance was high, with 88% of parents in the 7 day group and 90% of parents in the 5 day group reporting that their children adhered to the dosing regimen.

In the subgroup of participants previously treated with MAS-XR, LDX treatment was associated with a significant decrease in the level of interference of ADHD symptoms on school activities, family interactions, homework, and social interactions ($P<.01$; Figure 4B). In this subgroup, 79% of parents reported that treatment with LDX resulted in improvement in ADHD symptoms during their child's most bothersome time of day (Figure 5B). Similarly, 80% of parents reported that treatment with LDX resulted in improvement in their child's most bothersome symptom (Figure 6B). Using 9 point scales, parents in the MAS-XR subgroup indicated that, on average, LDX treatment resulted in substantial global improvement (5.8; 1=no improvement, 9=very much improved), good tolerability (7.3; 1=not at all well tolerated, 9=very well tolerated), high convenience (8.0; 1=not at all convenient, 9=very convenient), and high satisfaction (6.9; 1=not at all satisfied, 9=very satisfied). The parents reported significantly greater satisfaction with LDX (average rating 6.9) than with MAS-XR (average rating 5.5; $P<.01$). In the subgroup analysis, 69% of parents reported satisfaction ratings of 7–9 for LDX treatment, versus only 35% for MAS-XR. When asked about intention to continue treatment with LDX, 83% responded yes, 14% maybe, and 3% no.

FIGURE 3.
Time of day that ADHD symptoms are most bothersome, at baseline



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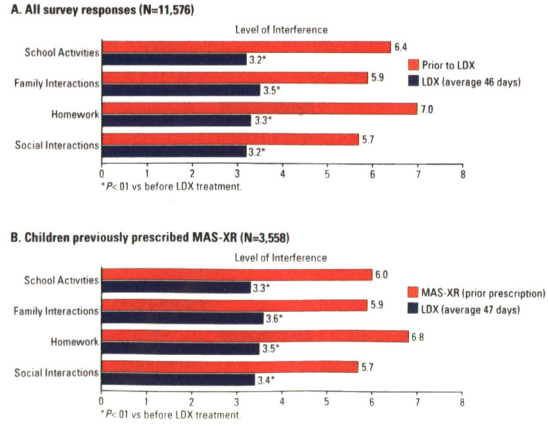
DISCUSSION

The Vyvanse New Start Program was based on the need to provide parent feedback to physicians about the perceived impact of treatment on children with ADHD. This feedback included information about improvement in daily functioning and not symptom reduction alone. Parents of children receiving 6 weeks of treat-

FIGURE 4.
Interference of ADHD with activities, before and after LDX treatment



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https://doi.org/10.1017/S1092852900000080 Published online by Cambridge University Press

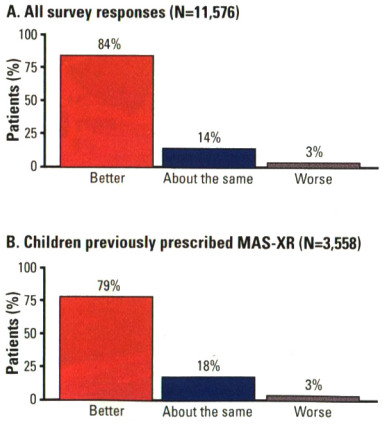
ment with LDX reported significant improvement in broadly defined ADHD symptomatology and in the impact or interference of their child's ADHD symptoms on daily activities. This was found to be so regardless of what they perceived to be the most bothersome symptom or the most bothersome time of day. Parents of children receiving LDX treatment reported significant improvements in symptoms that caused substantial interference with school activities, family interactions, homework, and social interactions. Eighty-four percent of parents noted improvements in their child's symptoms during the most bothersome time of day. For >40% of parents, the most bothersome time was after school and during evening hours, when they are most likely to observe their children. A recent clinical trial demonstrated that LDX efficacy extends for up to 13 hours, lasting into the afternoon and evening.[6]

Parents of children taking LDX reported a greater level of satisfaction with the effects of LDX compared with their level of satisfaction with the previous medication. They observed improvement of symptom control after treatment with LDX, and reported good tolerability and convenience of once-daily dosing. This was true for the overall group, as well as for the subgroup of patients who had switched from a different amphetamine treatment, MAS-XR.

Parents have proven to be observant and reliable raters of ADHD symptoms in clinical trials of stimulant[9-11] and nonstimulant[12] treatments for pediatric ADHD. Because of their familiarity with and proximity to their children, they may be even more conservative in their ratings of improvement, and more focused on symptoms in the home and school settings or in social situations that may not be readily apparent to a clinician rater. Pediatric ADHD studies comparing parent assessments with those of teachers or physicians have used validated clinical scales, such as the ADHD Rating Scale-IV-Parent Version,[12] Conners Global Index,[10] or the Swanson, Nolan, and Pelham questionnaire.[11] These validated instruments are useful for obtaining quantifiable data in RCTs. Parent preference and satisfaction questionnaires have also been used to assess treatment satisfaction and preference in clinical trials of MAS-XR following a switch from immediate-release MAS, immediate-release methylphenidate, and extended-release methylphenidate.[13]

The use of surveys similar to those employed

FIGURE 5.
Change in ADHD symptom severity at most bothersome time of day following LDX treatment



A. Average treatment duration for survey respondents was 46 days.

B. Average treatment duration for patients previously prescribed MAS-XR was 47 days.

ADHD=attention-deficit/hyperactivity disorder; LDX=lisdexamfetamine dimesylate; MAS-XR=mixed amphetamine salts-extended release.

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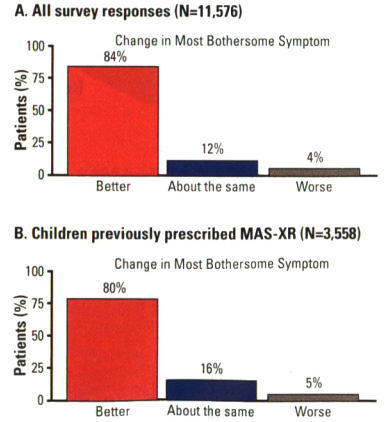
FIGURE 6.
Change in severity of most bothersome symptom following LDX treatment



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https://doi.org/10.1017/S1092852900000080 Published online by Cambridge University Press

in our study has limitations. The symptomatology of ADHD was broadly classified into only three categories: attention or focus, hyperactivity, and impulsiveness. The times of day and the affected activities were similarly defined only in general terms. Therefore, these survey instruments lack the specificity of formally validated quality-of-life questionnaires. The surveys were also provided through the anonymity of the Internet or interactive telephone, and were not subject to immediate assessment and opportunity for clarification provided by questionnaires administered in a physician's office or in a clinical trial, though physicians and parents received a report that could be used at subsequent clinic visits. Further limitations include a lack of placebo or active comparator, potential effect of financial incentive on participants' responses, and nonrandom sampling with a potential bias toward parents who were dissatisfied with their child's current medication or children whose symptoms are not representative of the overall population. No data were collected on reasons for non-completion of the follow-up survey. We therefore cannot exclude the possibility that some patients who did not complete the survey were dissatisfied with the LDX therapy provided and ended therapy without providing further feedback.

The surveys do, however, provide an opportunity to obtain "real world" information that is difficult to obtain from clinical trials, which often have stringent inclusion/exclusion criteria, a lack of real world settings, narrowly defined endpoints, and relatively small sample sizes. This survey included >11,000 patients in a real world setting. The large number of participants is a strength of the survey method compared with the much smaller enrollments characteristic of RCTs. Additionally, more patient treatment exposures and experiences can be described with this approach. However, the limitations presented by use of nonvalidated instruments and sampling plans that do not control for potential bias cannot be overlooked. Therefore, surveys provide a useful complement to clinical trials for gathering data on treatment effectiveness as well as valuable practical information for prescribing clinicians concerning parental perceptions of their child's treatment. Parental surveys can be an important clinical tool for evaluating the impact of treatment on children with ADHD in the real world setting.

Few studies have examined the relationship between patient satisfaction with medication, subsequent compliance or adherence to a treatment regimen, and real world outcomes. Two of these studies employed surveys similar to those used in our study to examine patient-reported perceptions of medications and report information to prescribing physicians. One of these studies assessed the association between patient-reported compliance with topical cyclosporine 0.05% emulsion therapy and the onset of increased tear production in patients with dry eye.[14] The results of the study suggested a relationship between patient-reported compliance with the medication regimen and more rapid onset of the effects of increased tear production, as those who complied with cyclosporine treatment reported that the effects of increased tear production occurred significantly sooner compared with those who were noncompliant ($P<.01$). A relationship was also found between patient-reported compliance with the medication regimen and patient-reported satisfaction with cyclosporine. Compliant patients reported significantly higher satisfaction with cyclosporine than noncompliant patients ($P<.01$).[14]

Another survey study examined patient-reported perceptions of insulin detemir as treatment for diabetes.[15] Patients were prescribed insulin detemir as part of the normal course of patient care, with each patient's physician directing the prescribing regimen. Therefore, compliance was not assessed, as there was no specified treatment protocol for patients to follow. Patient-reported satisfaction with insulin detemir was significantly higher than satisfaction with their prior treatment ($P<.05$), likely due in part to high levels of patient confidence in avoiding symptoms, and the relative ease of controlling and judging blood sugar levels.[15] Results from both survey-driven studies of real world outcomes suggest that survey data provided valuable feedback to treating physicians that they might not typically have had.

CONCLUSION

Parents reported significant improvements in ADHD symptoms with LDX treatment and high levels of satisfaction, tolerability, and convenience. Parents whose children switched from MAS-XR reported improvements over previous treatment similar to those reported by the population treated with LDX as a whole. Surveys are effective tools for soliciting information regard-

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ing treatment effectiveness that may be difficult to obtain in clinical trials. ***CNS***

REFERENCES

1. Biederman J, Faraone SV. Attention-deficit hyperactivity disorder. *Lancet.* 2005;366:237-248.
2. Vyvanse® [package insert]. Wayne, PA: Shire US Inc; 2008.
3. Biederman J, Boellner SW, Childress A, López FA, Krishnan S, Zhang Y. Lisdexamfetamine dimesylate and mixed amphetamine salts extended-release in children with ADHD: a double-blind, placebo-controlled, crossover analog classroom study. *Biol Psychiatry.* 2007;62:970-976.
4. Ermer J, Homolka R, Martin P, Buckwalter M, Purkayastha J, Roesch BG. Linear dose proportionality, low inter- and intrasubject variability, and safety of lisdexamfetamine dimesylate in an open-label single-dose pharmacokinetic study in healthy adult volunteers. *Poster presented at: U.S. Psychiatric and Mental Health Congress; October* 30-November 2, 2008; San Diego, CA.
5. Biederman J, Krishnan S, Zhang Y, McGough JJ, Findling RL. Efficacy and tolerability of lisdexamfetamine dimesylate (NRP-104) in children with attention-deficit/hyperactivity disorder: a phase III, multicenter, randomized, double-blind, forced-dose, parallel-group study. *Clin Ther.* 2007;29:450-463.
6. Wigal SB, Kollins SH, Squires LA, Childress AC. Lisdexamfetamine dimesylate demonstrated efficacy throughout the day up to 13 hours in an analog classroom study in children with attention-deficit/hyperactivity disorder. Poster presented at: American Academy of Child & Adolescent Psychiatry Annual Meeting; Oct 28-Nov 2, 2008; Chicago, IL.
7. López FA. ADHD: new pharmacological treatments on the horizon. *J Dev Behav Pediatr.* 2006;27:410-416.
8. Findling R, Jain R, Gao J, Richards C, Ginsberg L. A dose-optimization study of the efficacy, safety, and tolerability of lisdexamfetamine dimesylate in children aged 6 to 12 years with attention-deficit/hyperactivity disorder. Poster presented at: American Academy of Child & Adolescent Psychiatry Annual Meeting; Oct 28-Nov 2, 2008; Chicago, IL.
9. Schachter HM, Pham B, King J, Langford S, Moher D. How efficacious and safe is short-acting methylphenidate for the treatment of attention-deficit disorder in children and adolescents? A meta-analysis. *CMAJ.* 2001;165:1475-1488.
10. Faraone SV, Biederman J, Roe C. Comparative efficacy of Adderall and methylphenidate in attention-deficit/hyperactivity disorder: a meta-analysis. *J Clin Psychopharmacol.* 2002;22:468-473.
11. Biederman J, Faraone SV, Monuteaux MC, Grossbard JR. How informative are parent reports of attention-deficit/hyperactivity disorder symptoms for assessing outcome in clinical trials of long-acting treatments? A pooled analysis of parents' and teachers' reports. *Pediatrics.* 2004;113:1667-1671.
12. Biederman J, Gao H, Rogers AK, Spencer TJ. Comparison of parent and teacher reports of attention-deficit/hyperactivity disorder symptoms from two placebo-controlled studies of atomoxetine in children. *Biol Psychiatry.* 2006;60:1106-1110.
13. Sallee FR, Ambrosini PJ, López FA, Shi L, Michaels MA; LADD.CAT Study Group. Health-related quality of life and treatment satisfaction and preference in a community assessment study of extended-release mixed amphetamine salts for children with attention-deficit/hyperactivity disorder. *J Outcomes Res.* 2004;8:27-49.
14. Trattler W, Katsev D, Kerney D. Self-reported compliance with topical cyclosporine emulsion 0.05% and onset of the effects of increased tear production as assessed through patient surveys. *Clin Ther.* 2006;28:1848-1856.
15. Kerney DL, Paradis D, Brunton S. Patient perceptions of insulin detemir as reported through patient telephone surveys. *Curr Med Res Opin.* 2007;23:2043-2049.

https://doi.org/10.1017/S1092852900000080 Published online by Cambridge University Press

https://doi.org/10.1017/S1092852900000080