“Drugs Don’t Work in Patients Who Don’t Take Them”

Medication Adherence in Adolescents with Mental Illness

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Abstract: The more recent term “adherence” is now taking the place of the earlier notion of “compliance,” as it emphasizes the physician-patient partnership. To date, however, it has not been clearly defined. There are many limitations to measuring adherence, and presently no standard methods have been established. Even in clinical trials throughout medicine, the reported rates for adherence range only between 43 % and 78 %. Particularly medication adherence is highly relevant to the treatment of mentally ill adolescents, as they make up a population especially vulnerable to nonadherence – and high rates thereof have been reported. Factors influencing adherence are poorly understood and researched, especially in adolescents with mental illness. Physicians can currently rely only on concepts from other populations and expert recommendations. Concepts for children or adults should not directly be transferred to adolescent patients. Results from the current “SEMA” study should contribute to guiding future research in the development of interventions to improve medication adherence, in particular for this juvenile population.

Keywords: medication adherence, measuring adherence, factors impacting adherence, mentally ill adolescents, “SEMA” study

“Medikamente wirken nicht bei Patienten, die sie nicht nehmen” – Medikamenten-Adhärenz bei Jugendlichen mit psychischen Erkrankungen

Zusammenfassung: Der aktuelle Begriff “Adhärenz” ersetzt den bisher gebräuchlichen der “Compliance” und steht für eine partnerschaftliche Arzt-Patienten-Beziehung; bisher gibt es jedoch keine eindeutige Definition des Begriffs. Beim Messen von Adhärenz bestehen diverse Einschränkungen, und es haben sich keine einheitlichen Standardmethoden etabliert. Selbst in klinischen Studien aus verschiedenen medizinischen Fachbereichen, wurden lediglich Adhärenzraten zwischen 43 % und 78 % erhoben. Medikamenten-Adhärenz ist von hoher Relevanz in der Behandlung von psychisch kranken Jugendlichen, da diese Population für Non-Adhärenz besonders gefährdet ist. Dies zeigen entsprechend hohe Raten von Non-Adhärenz, welche bisher veröffentlicht wurden. Faktoren, die Adhärenz beeinflussen, sind bisher nur unzureichend verstanden und erforscht, insbesondere bei psychisch kranken Jugendlichen. Behandler können daher derzeit nur auf Behandlungskonzepte für andere Populationen und Empfehlungen von Experten zurückgreifen. Konzepte für Kinder oder Erwachsene sollten jedoch nicht einfach auf Jugendliche übertragen werden. Die Ergebnisse der derzeit durchgeführten “SEMA” Studie werden die Entwicklung und Erforschung zukünftiger Interventionen zur Verbesserung von Medikamenten-Adhärenz, speziell bei Jugendlichen, unterstützen.

Schlüsselwörter: Medikamenten-Adhärenz, Messen/Erfassen von Adhärenz, Adhärenz-beeinflussende Faktoren, Psychisch kranke Jugendliche, “SEMA” Studie

Over the last decades, clinical treatment in child and adolescent psychiatry has seen the development of various pharmacological agents – in clinical practice, in regulatory trials, and in somatic and psychiatric patients. One important clinical topic that accompanied routine medication treatment is “medication (non)adherence” – which may be summed up simply by the following quote by the former Surgeon General of the United States, Charles Everett Koop MD (Osterberg & Blaschke, 2005): “*Drugs don’t work in patients who don’t take them.*”

The Definition of Adherence

Recently, the term “adherence” has become more and more widely used as a synonym for “compliance.” While the latter describes a more hierarchical relationship between an order-giving physician and a subordinate patient, adherence was coined to represent equal partners sharing information and making shared decisions (De las Cuevas, 2011). Yet both pictures seem too extreme, and it may rightly be questioned just how relevant the diffe-

rence in terminology actually is, especially from a clinical point of view.

Like compliance, adherence is not really clearly defined. Conceptually, it can be understood both in a dichotomous (adherent vs. nonadherent) as well as in a dynamic and continuous fashion (partial adherence). In most clinical trial settings, a participant is regarded as “medication adherent” if a so-called pill count performed by the study team suggests that at least 80 % of the prescribed pills have been taken (Smitch & Shuchman, 2005).

Why Is Adherence an Important Aspect in Mentally Ill Adolescents?

Even in clinical trials throughout medicine, reported rates for adherence range only between 43 % and 78 % (Osterberg & Blaschke, 2005). Bearing in mind that such trials regularly offer a significantly more structured and more intensive clinical care than treatment-as-usual, such rates seem astonishingly low.

In general, nonadherence may lead to reduced effectiveness of the prescribed medication, increasing severity or the number of symptoms as well as the presence of or increase in adverse events (“side effects”), higher rates of relapse and/or rehospitalization, reduced quality of life, higher mortality, and higher societal/healthcare costs (Gearing et al., 2014; Hack & Chow, 2001; Osterberg & Blaschke, 2005). In the United States, overall costs stemming from a lack of adherence have been estimated to be as high as \$100 billion per year (Hack & Chow, 2001). While such calculations and the resulting figures must be interpreted with great caution, a high socioeconomic impact is clearly evident.

This is no new insight. In 2003, the World Health Organization, in its “Evidence for Action,” stated that “poor adherence to treatment of chronic diseases is a worldwide problem of striking magnitude,” “the impact of poor adherence grows as the burden of chronic disease grows worldwide,” and “the consequences of poor adherence to long-term therapies are poor health outcomes and increased health care costs” (WHO 2003).

Moreover, rising prescription rates for psychotropic medications in children and adolescents have been noted worldwide over the last decades, especially for ADHD medication (Abbas et al., 2016; Bachmann et al., 2017; Wong et al., 2004).

The transition period of adolescence is characterized by difficulties in self-reflection, decision-making, planning and organization as well as in higher emotional lability, sensibility for immediate reinforcement, weak self-regulation, and striving for autonomy (Buitelaar et al., 2017). The group of adolescents has also been identified

as one of several social groups that are particularly sensitive to and influenced by stigma (Clement et al., 2015). Because most psychiatric disorders, such as psychotic disorders, begin in adolescence, they have a major impact on the lives of patients. Consequently, the first years of treatment of these disorders (especially psychotic disorders) are of utmost importance regarding long-term clinical outcome, while even intermittent treatment may lead to negative or no positive effects.

All these factors seem to accumulate in adolescents who are mentally ill and are prescribed psychotropic medications. Thus, they need to be considered a subgroup especially vulnerable to nonadherence.

How to Measure Adherence

Similar to the difficulties in defining adherence, there are also no established standards for measuring it. Today, many different methods exist, all of which have advantages as well as disadvantages and vary in costs, practicability, and validity. For an overview see Table 1. Direct methods, such as measuring the blood level of a medication, can be distinguished from indirect methods, such as patient diaries (Osterberg & Blaschke, 2005). An important factor is found in the effect of the measuring approach itself and in the resulting difficulties of assessing “true,” real-life adherence. Research in children with asthma suggests that patient self-reporting in pediatric populations is unreliable and prone to overestimating adherence to treatment (Burkhart et al., 2001; Engelkes et al., 2015; Morton et al., 2017). Modern technologies are also utilized to measure adherence, including pill boxes that log the time they were opened or tablets with an embedded and ingestible sensor that transmits signals to a wearable skin patch. The latter was just recently approved by the FDA for the substance aripiprazole (Profit et al., 2016).

What Has Been Measured So Far?

For adults, rates of medication adherence for both somatic and psychiatric disorders are reported to lie between 24 % and 90 %, and for children/adolescents between 25 % and 94 % (Cramer & Rosenheck, 1998; Häge et al., 2018). In general, in the literature adolescents are regarded as less adherent than children, and patients with a psychiatric disorder are less adherent than patients with a somatic disorder (Cramer & Rosenheck, 1998; Dimatteo 2004; Hack & Chow, 2001; Julius et al., 2009).

For example, in a subsample of the MTA study (highly structured, in children), medication adherence was assessed in 254 participants (7 to 9 years old at study start)

Table 1. Methods of assessing medication adherence and their positive and negative aspects (adapted from Osterberg & Blaschke, 2005)

Method	Positive	Negative
Direct observation of medication administration	Accurate	Impractical; interferes with normal adherent behavior; patients can still hide pills
Measuring blood level of compound	Objective	Requires drawing blood; expensive; difficult to interpret
Questionnaires/self-report/patient diaries	Simple and cost-effective	Reflect patient's subjective opinion and intention
Pill count	Objective, simple, and cost-effective	Patient can actively influence result
Prescription data	Objective, simple, and cost-effective	Prescription does not reflect actual intake of medication
Measuring clinical response	Generally simple to measure	Not medication specific; many potential confounders
Electronic medication monitors	Precise and complete data	Expensive; requires technical equipment, expertise, and adherence of patient to instructions of use; may interfere with normal adherent behavior

by measuring methylphenidate levels at four timepoints. The results indicated “nonadherence” in 24.5% of all blood samples; only 53.5% of participants showed levels indicative of adherence at all four timepoints, and 24.8% showed levels indicative of nonadherence at two or more timepoints (Pappadopulos et al., 2009).

Investigating adolescents with mental illness, systematic reviews found considerable differences across studies in how adherence was defined and measured. Consequently, more specific analyses of factors potentially influencing adherence were not possible, for example, disorder, substance, or sex (Frank et al., 2015; Gajria et al., 2014; Häge et al., 2018). It was unanimously concluded that rates for mentally ill adolescents were relatively high. Most frequent reasons for stopping medication among adolescents were adverse events/side effects, lack of clinical effectiveness, complex dosing regimens, stigma, negative attitude toward medication, or the feeling that the medication was no longer needed (Frank et al., 2015; Gajria et al., 2014; Häge et al., 2018).

Which Factors Influence Adherence?

The WHO presented five dimensions that influence adherence: the healthcare system as well as social and economic, condition-related, therapy-related, and patient-related factors (WHO 2003).

Older research from pediatrics suggested that self-concept was a predictor of healthy behaviors, and that higher self-esteem was significantly associated with higher adherence (Ferrand & Cox, 1993; Ricker et al., 1998). Also, nonadherence appeared to be associated with anxiety and depressive symptoms in children with end-stage kidney disease (Brownbridge & Fielding 1994).

In child and adolescent psychiatry, other sources suggested further relevant factors related to medication adherence: effectiveness and tolerability of medication, dosing regimen, therapeutic alliance, health beliefs, perceptions about the disorder, attitudes toward prescribed medication of the patient and the surrounding social system (families and friends) as well as subjective illness theories and experiences (Charach & Fernandez 2013; Ferrin et al., 2012; Gajria et al., 2014; Velligan et al., 2017). Yet, research investigating these factors in mentally ill adolescents is scarce. Hence, no more specific statements based on high-quality evidence regarding those factors can be made at this point.

Improving Adherence

To date, there is no evidence specific to (child and) adolescent psychiatry regarding interventions to improve/enhance adherence. Physicians in clinical practice and in research settings can currently rely only on concepts from other populations and expert recommendations (Gajria et al., 2014). For example, these may suggest focusing on psychoeducation, strengthening the therapeutic alliance, obtaining help from family and friends, openly discussing adherence, plus simplifying instructions and dosing regimens (e.g., one dose of extended-release methylphenidate versus two single doses per day). Authors also note that concepts for children or adults should not be simply transferred to adolescent patients in a “copy-and-paste” fashion (Julius et al., 2009; Osterberg & Blaschke 2005).

After careful review and informed consent, long-acting injectable (“depot”) antipsychotic medications might represent a beneficial treatment option in a very selective group of patients, for example, those with severe schizophrenia. To our knowledge, this approach has not been

systemically assessed in adolescent psychiatric population, thus calling for future studies.

Motivational interviewing has shown first positive results as a further approach to improving adherence in adolescents with mental illnesses (Hamrin & Iennaco, 2017). Smartphone apps and other technological methods that function as reminders to take medication are available, but their effectivity has not been scientifically assessed in this population yet.

A total of 93 interventional approaches to improve adherence in adults with somatic or psychiatric disorders were evaluated by a Cochrane review in 2008. Unfortunately, almost all of them were deemed to be complex and expensive, while none was considered very effective (Haynes et al., 2008).

The SEMA Study

This evident gap in medication adherence research in adolescents led the Mannheim research group for Pediatric Psychopharmacology to conduct the “SEMA” study (Head: R. W. Dittmann), which investigates “Subjective illness Experience and Medication Adherence” in adolescents with psychiatric disorders. Its goal is to identify factors that influence medication adherence in this specific population. Adolescent patients 12 to 18 years of age receiving psychopharmacological treatment were included at the Central Institute of Mental Health in Mannheim, the AWO Psychiatriezentrum in Königslutter, and the Klinikum am Weissenhof in Weinsberg, all in Germany.

For data collection, we selected an array of instruments in order to both quantitatively and qualitatively assess adherence, subjective experiences, and perceptions. The Questionnaire on Attitudes Toward Treatment (QATT, Ferrin et al., 2012) was adapted for this study. In addition to the Medication Adherence Rating Scale (MARS, Thompson et al., 2000), we assessed the extent of medication adherence using self-report and ratings by parents and treating physicians. A semistructured interview with 72 questions regarding illness, treatment, patient-physician relationship, family situation, social environment, and (medication) adherence gave adolescents room to reflect on their individual cognitions, health beliefs, thoughts, concerns, etc., which were then subjected to qualitative (text/content) analysis. Data collection was successfully completed in $n > 70$ adolescents suffering from a number of psychiatric disorders and being treated with various psychotropic compounds. Qualitative and quantitative analyses are currently ongoing. First results will be published soon (submitted). Ideally, these results will enable translation into psychoeducational statements, strategies to enhance (medication) adherence,

and into feasible interventions that can be adopted in clinical practice, possibly matching current concepts of personalized/individualized medicine.

Conclusions

The term “adherence” (incl. medication adherence) is the modern term that is replacing “compliance,” emphasizing the physician-patient partnership. Yet, to date it has not clearly been defined. There are many limitations to measuring adherence, and there are no established standard methods. Medication adherence is of high relevance in the treatment of mentally ill adolescents, as they comprise a population especially vulnerable to nonadherence, and high rates thereof have been reported. Factors that influence adherence are poorly understood and researched, especially in adolescents with mental illness. Results from the current “SEMA” study will contribute to guiding future research for the development of interventions to improve medication adherence, in particular for this juvenile population.

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Conflicts of interests

KM served as subinvestigator in clinical trials conducted by Lundbeck, Shire, Sunovion, and Teva, plus in EU FP7 and the Horizon 2020 program funded projects.

AH served as subinvestigator in clinical trials conducted by Janssen-Cilag, Otsuka, Shire, Sunovion, plus in EU FP7 and the Horizon 2020 program funded projects. He has received conference travel support and compensation for serving as consultant or speaker by E. Lilly and Shire.

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CME-Fragen

1. Question: Which answer is correct? In contrast to 'compliance', 'adherence' describes ...

- a. The hierarchical relationship between an order-giving physician and a subordinate patient
- b. An equal partnership between physician and patient with shared information and shared decision-making
- c. A partnership between physician and patient with the patient informing himself about treatment possibilities and the physician prescribing the medication as chosen by the patient
- d. The hierarchical relationship between the parents and the adolescent patient
- e. An equal partnership between physician and the parents of the adolescent patient with shared information and shared decision-making

2. Question: Which answer is false? Nonadherence to medication may typically lead to ...

- a. Reduced effectiveness of the prescribed medication
- b. Increased severity or number of symptoms
- c. Presence or increase in adverse events
- d. Higher rates of relapse and/or rehospitalization
- e. Improved quality of life

3. Question: Which of the following is not an established method to measure medication adherence?

- a. Direct observation of medication administration
- b. Measuring the blood level of medical compound
- c. Positron emission tomography
- d. Patient diary
- e. Pill count

4. Question: Which answer is false? The most frequent reasons for stopping medication among adolescents as found in several systematic reviews were ...

- a. Adverse events/side effects
- b. Lack of clinical effectiveness
- c. Complex dosing regimens
- d. Price of medication
- e. Stigma

5. Question: Which answer is false? Based on the available evidence, which strategies may improve medication adherence in adolescents?

- a. Strengthening the therapeutic alliance
- b. Animal-assisted therapy
- c. Obtaining help from family and friends
- d. Openly discussing adherence
- e. Simplifying dosing regimens

To receive your CME certificate (at least three correct answers), please send the completed questionnaire with a stamped self-addressed envelope to the adjacent address by 3 January 2020. Answers received later and those without or with unstamped envelopes can no longer be considered.

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„Medication Adherence in Adolescents with
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Die Antworten bitte deutlich ankreuzen!

	1	2	3	4	5
a	☐	☐	☐	☐	☐
b	☐	☐	☐	☐	☐
c	☐	☐	☐	☐	☐
d	☐	☐	☐	☐	☐
e	☐	☐	☐	☐	☐

Ich versichere, alle Fragen ohne fremde Hilfe
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