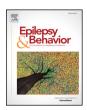
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Optimizing parents' performance in anticonvulsant rescue medication administration



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ABSTRACT

Objective: Parents of children with epilepsy are at risk of committing high-risk handling errors with a high potential to harm the patient when administering anticonvulsant rescue medication. We developed a training concept addressing identified high-risk handling errors and investigated its effects on parents' skills.

Study design: In a controlled prospective intervention study, parents of children with epilepsy were asked to demonstrate their administration of rescue medication by using dummy dolls. A clinical pharmacist monitored rectal or buccal administration and addressed errors in the intervention group with training and information sheets. Three to 6 weeks later, intervention's sustainability was assessed at a home visit.

Results: One hundred sixty-one parents completed full study assessment: 92 in the intervention group and 69 in the control group. The number of processes with at least one handling error was reduced from 96.4% to 56.7% in rectal tube administration and from 66.7% to 13.5% in buccal administration (both p < 0.001).

Conclusion: A one-time intervention for parents significantly and sustainably reduced high-risk handling errors. Dummy dolls and information sheet were adequate for an effective and feasible training to support the correct administration of anticonvulsant rescue medication.

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1. Introduction

Especially outside the hospital, benzodiazepines such as rectal diazepam and buccal midazolam are used for seizure termination in pediatric patients with epilepsy [1–3]. Administration of those drugs as emergency measure is recommended when the seizure has lasted 5 min [4]. Frequently, these applications are prone to error with an estimated high risk for the patient [5]. In the outpatient setting, the person administering the rescue medication is usually a medical nonprofessional such as a parent who is the main caregiver. The administration procedure contains several steps of patient and drug handling. Additionally, it has to be completed quickly and successfully at every possible situation, in which a seizure occurs. To ensure effectiveness, a correct administration is necessary [4–6]. The use of long-term medication can be monitored and trained in the daily routine [7–10], whereas

the administration of on-demand medication, such as anticonvulsant rescue medication for seizure termination, is hard to predict and difficult to observe. Therefore, effective measures have recently been established using a doll for the rectal administration and an artificial mouth reproduction for the buccal administration to identify parents' handling errors in the administration of anticonvulsant rescue medication outside an actual emergency [5]. This use of dummy dolls revealed the high frequency of high-risk handling errors that were independent of a previous use of the rescue medication. We developed an individual and prioritized teaching and training concept for parents and caregivers based on the administration of rescue anticonvulsants (most frequently prescribed dosage forms in Germany: rectal diazepam and buccal midazolam) to dummy dolls. We further investigated its sustained effects on parents' practical skills in home visits by clinical pharmacists 3-6 weeks after discharge from hospital or after outpatient visit in a hospital.

2. Materials and methods

2.1. Participants and setting

After ethical approval for the study protocol from the local ethics committee and written informed consent from the parents concerned, we enrolled parents to participate in this study after their child's

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hospital discharge or outpatient visit in our neuropediatric department. All parents of children with seizures including febrile seizures and living no more than 50 km from the hospital were invited to take part in this study, if diazepam via rectal tube and/or buccal midazolam was prescribed as rescue medication. Parents who did not understand the given task were not enrolled in the study. Also, parents of patients who were fostered in a nursing home or by a nursing service or patients that had an official guardian were not enrolled.

2.2. Study protocol

In this controlled prospective intervention study, we performed a consecutive enrollment in two periods (Fig. 1). First, we recruited participants and assessed full data for the control group (CG), and after that, the procedure was repeated for the intervention group (IG). This subsequent procedure was necessary to avoid bias such as information exchange on intervention procedures between the parents of the IG and CG, which was to be expected if data assessment for both groups had happened at the same time. After informed consent, participating parents were asked to complete a questionnaire about the name and dosage form of their child's rescue medication to ensure their awareness of the actual prescribed rescue medication. Furthermore, they were asked if they had already used the rescue medication. Additionally, participants in the IG were asked to demonstrate the administration of the rescue medication prescribed to their child by using dummy dolls and a placebo device, either a rectal tube or an oral syringe for buccal administration as reported in Kaune et al. [5]. For this purpose, we used a prepared doll for the rectal administrations and an artificial mouth reproduction for the buccal administrations. In this manner, all drug handling steps performed by parents administering the respective rescue medication as placebo device could be monitored. The monitoring was performed by two trained clinical pharmacists. Each administration process performed by parents was monitored by one of those two pharmacists using standardized checklists for rectal tube or oral syringe with all necessary drug handling steps. Deviations in the processes from these checklists were, as published in Kaune et al. [5], considered as handling errors (Table 1). According to a standardized expert rating of the clinical risk (1 lowest to 6 highest risk), all possible handling errors were defined as high-risk (risk score: 4-6) for the patient [5]. Handling errors identified in the IG were addressed to the participating parent after the dummy demonstration as described in Section 2.4. This intervention took place at discharge from hospital or following an outpatient visit in our neuropediatric department. Parents in the CG did not receive an intervention at this time (Fig. 1). The intervention strategy was also standardized to avoid personal bias.

To assess the sustainability of the pharmaceutical intervention, we carried out an assessment at the patients' and their parents' homes in both groups, 3–6 weeks after discharge from hospital or outpatient visit (home visit by a trained clinical pharmacist). Parents from both groups were asked to perform rescue medication administration using the dummy dolls. The success of the intervention was quantified by the reduction of processes with at least one handling error performed by parents in the IG compared with that by parents in the CG while administering placebo devices (rectal tube or an oral syringe for buccal administration) to the dummy dolls at home visit. For ethical reasons, parents in the CG received a one-to-one intervention addressing identified handling errors at home after data collection was completed.

2.3. Prioritizing handling errors with high clinical risk for practical intervention

Based on an expert definition and classification of the handling errors with respect to their clinical risk to harm the patient as described in Kaune et al. [5] (Table 1), identified handling errors in the monitored process were prioritized for the individual intervention of the participant. The interventions for errors with a higher clinical risk had the top priority. For this purpose, the trained clinical pharmacists showed the correct administration by using the respective dummy doll and placebo device in a one-on-one training to the participating parent. The clinical pharmacists were obliged to point out a maximum of three of the highest-priority errors identified in the process.

2.4. Intervention strategy

The individual intervention offered to each parent addressed actual handling errors that were carried out and that were prioritized based on their clinical risk (as described in Section 2.3). In the CG, only routine counseling by physicians and nurses was offered (Fig. 1). There are no other detailed guidelines for the practical training of drug administration besides the information in the drug label. Therefore, the routine counseling usually contains nonstandardized theoretical information on name, administration route and main administration steps without any practical demonstration of the drug handling. The intervention

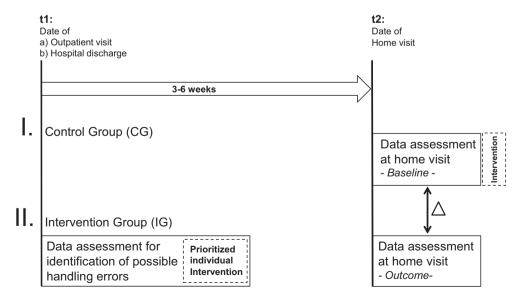


Fig. 1. Overview of subsequent data assessment in the CG and IG. Data from home visits in both groups were compared. Intervention performed in IG was carried out on the day of hospital discharge or of outpatient visit.

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