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ORIGINAL RESEARCH

Validation of a mobile app for reducing errors of administration of medications in an emergency

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Abstract

Medication errors occur frequently and are a risk to patient safety. To reduce mistakes in the medication process in emergencies, a mobile app has been developed supporting the calculation of doses and administration of drugs. A simulation study was performed to validate the app as a tool to reduce medication errors. This was a randomised crossover study conducted in the Academic Hospital. The participants included were residents and attendings in anaesthesiology. 74 Participants performed four simulation scenarios in which they had to calculate and administer drugs for emergencies. Two scenarios were performed with the app ("app scenarios") and the other two scenarios were performed without the use of the app ("control scenarios"). The order of drugs, simulation patients and usage of aid were randomized. The accuracy of administered drug doses were measured. Medications were categorised as either "accurate" (±20% of target dosage) or "wrong" (less than 50% or more than 200% of target dosage). The dosage calculated and the dosage administered were documented separately to differentiate between calculation and handling errors. During app scenarios, there were no "wrong" dosages, whereas 6.8 (95% CI 2.7–10.8%) of dosages in control scenarios were evaluated as "wrong". The probability of giving an "accurate" dosage was increased from 77.7 (70.9–84.5%) in control scenarios to 93.9 (90–97.8%) in app scenarios. Calculation errors were the main cause for wrong dosing. The app is an appropriate and feasible tool to reduce calculation and handling errors and may increase patient safety.

Keywords Medication errors · Medication aid · Patient safety · Calculation errors · Dosage errors · Mobile app · Drug errors

1 Introduction

Errors occur everywhere in daily live. Errors in drug administration are a risk to patient safety and are responsible for increased costs in health care systems [1]. Fortunately, many of them are without harm to the patient. Still they are medication errors "regardless of whether an injury occurred or the potential for injury was present" [2]. Many of the medication errors are due to inaccurate dosing [3–5]. An underdosage might be associated with a reduced effect of the drug whilst an overdosage increases the risk of side effects and adverse drug events [6]. Other causes of dosing errors are calculation errors [7, 8].

In 1999 Kohn et al. drew attention towards medication errors by describing the high rate of deaths caused by those errors [9]. Little is known about medication errors in emergency medicine as this topic cannot be easily studied in prospective studies [10] and they are underreported as many of those errors are not realized by the emergency staff. There is a low rate of errors reported to Critical Incident Reporting Systems (CIRSs) [11, 12].

In emergencies, many drug dosages must be calculated according to the patient's body weight. Distracting factors and stressors reduce the likelihood that the right dose is given [13, 14]. Results from CIRS [15] and surveys [16] confirm that medication errors are an important topic for patient safety in emergency cases.

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There are many tools to support the medication process. For some of them, it has been reported that they reduce medication errors [12, 17, 18]. For other tools, no reduction of medication errors could be shown [19]. Mobile apps are used with an increasing frequency, especially in paediatric settings, to support the medication process in emergencies [14]. But so far, there is little evidence that they reduce medication errors. Furthermore, they have to be licensed and they have to be updated with information the user can rely on [7, 20]. Because of the good availability of mobile phones and the possibility to combine databases and calculating support in one aid, mobile apps have a high potential to improve patient safety in emergency cases. However, few of them have been validated in scientific investigations.

Therefore, this simulation study investigated whether a proprietary mobile app reduces calculating and handling errors in emergency situations and whether it is feasible to use.

2 Methods

This study was performed in the Department of Anesthesiology of the University Medical Center Hamburg–Eppendorf (UKE), Germany from 15 November 2016 to 15 January 2017. All anaesthesiologists were invited to participate in this simulation study. Due to the Declaration of Helsinki (Article 6), this non-human study did not require ethical approval.

2.1 Study design

For this simulation study, a mobile app supporting calculation and administration of intravenous drugs in emergency cases had been developed by the authors. The main goal of the app is to combine the advantages of a reference tool to find dosage information and a calculation aid. The database contained drugs and their dosage information according to their professional information. The user needs to enter the patients age and weight, choose the drug and then select the correct dosage. The app will then present all the important information for drug administration in an overview.

In four simulation scenarios the participants had to calculate and administer a given drug at a target dosage into an intravenous cannula of a mannequin. Each participant completed two scenarios without the app and two scenarios supported by the app. The order of the app usage was randomized (either to the first two scenarios or last two) (study design is depicted in Fig. 1). The simulation cases were presented to the participant with a tablet-computer. The information of the cases included weight and age of the patient, a clinical description of an emergency situation, a drug that

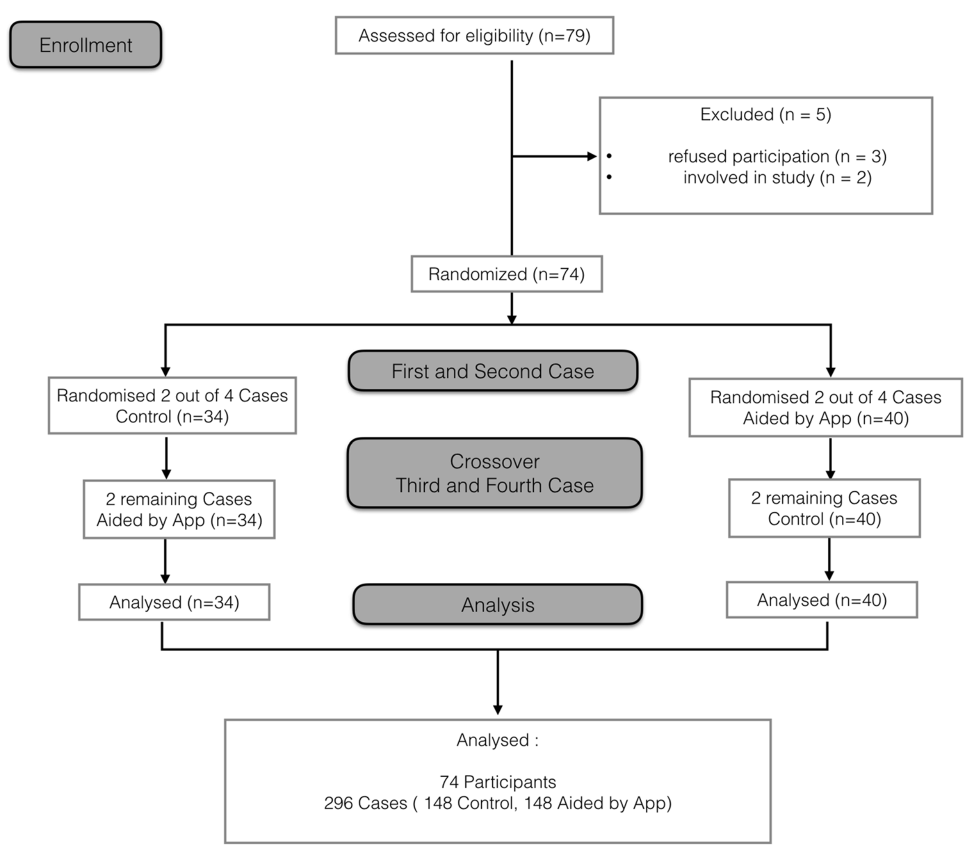


Fig. 1 CONSORT Flowchart. 79 participants have been assessed for eligibility, 3 of which declined to participate and 2 were involved in the study. Finally, 74 participants were randomized to perform two scenarios with app and two scenarios without app in a crossover design. 40 Participants (54%) started with the aid of the app. In total 296 scenarios (148 control and 148 aided) were performed and analyzed

was to be administered and the target dosage. The exact dosage had to be given in mg per kg body weight. The participants were supposed to calculate and administer the drug within 90 s, shown as countdown on the tablet-computer.

The four scenarios contained four different drugs (amiodarone, esketamine, clemastine and rocuronium). For each drug the tablet-computer randomized one out of three possible patients differing in age and body weight (further details of the patients and frequencies are given in the Appendix).

2.2 Outcome

For each scenario the participant was asked to communicate the results of the amount and volume clearly for documentation. The time was measured from the presentation of the scenario until injection of the fluid into the mannequin. After the injection, the participants rated their own self confidence by using a visual analog scale between 1 and 10, where 1 was very unconfident and 10 was very confident.

The actual given volume was measured by weighing the mannequin with a precision balance (mean value of three measurements). To calculate volume from weight, all drug ampoules were filled with distilled water with a known weight density. As primary endpoint a variable to describe the accuracy of the given dosage was calculated as follows:

$$Accuracy\_of\_administered\_dosage = \frac{volume\_administered}{target\_volume} \quad (1)$$

To distinguish the reasons for errors, a variable to describe the calculation accuracy (secondary endpoint) was determined as follows:

$$Accuracy\_of\_calculation = \frac{volume\_communicated}{target\_volume} \quad (2)$$

Further handling deviation was assessed as a counter-part to calculation errors. Handling errors were defined as the difference between given and communicated volume (secondary endpoint). Therefore the handling errors included all errors except calculation errors. The deviation of the handling was calculated as follows:

$$Deviation\_of\_handling = \frac{volume\_administered}{volume\_communicated} \quad (3)$$

The given dosages were classified into three groups. Dosages within a 20% range of the target dosage were rated as “accurate”. This corresponds to a very safe medication administration without calculation or handling errors.

The professional information from the used drugs described limits for unsafe use, mostly less than 50% or more than 200% of the target dose. Therefore, it was decided to rate doses lower than 50% or greater than 200% as “wrong”. Wrong dosages were considered to be a risk to patient safety.

All dosages between the “accurate” and “wrong” dosages were rated as “deviant”, as they were considered not to be tolerable for safe medication use, but also not to have a high potential of morbidity for the patient.

One week after participation in the study the participants were asked to fill out a short questionnaire to give feedback on the usage of the app. Most importantly, they were asked to judge the feasibility of the app with a “yes” and “no” answer.

2.3 Statistical methods

The statistical analysis was performed using SPSS (IBM Corp. Released 2015. IBM SPSS Statistics for Macintosh, Version 23.0. Armonk, NY: IBM Corp.).

All variables were tested for normality with Kolmogorov–Smirnov–Lilliefors and Shapiro–Wilk. As most of the data did not follow normal distribution, no parametric tests were performed and data is presented as medians (with the 25th–75th percentiles). Only for the difference in frequencies and therefore the probability of an “accurate” or “wrong” dosage a paired t-test was performed and the 95% CI calculated.

The distribution of accuracy of administered dosages is illustrated with an histogram. The relation between calculation deviation and administered accuracy is illustrated with a scatterplot.

Correlation between variables was calculated with Pearsons correlation coefficient. A p-value < 0.05 was considered to be statistically significant.

Significance of difference of means of non-parametric data was calculated with one-way ANOVA. A p-value < 0.05 was considered to be statistically significant.

3 Results

3.1 Demographic data

74 Anaesthesiologists (34 male and 40 female) performed a total of 296 simulated scenarios (148 control and 148 with app). The participants had a median age of 31–35 years and a median working experience of 3–5 years (Table 1).

3.2 Accuracy and occurrence of errors

Given dosages were more frequently in the “accurate” dosing range when administration was supported by the app. The administered dosages ranged from 73 to 135% of the

Table 1 Demographic data

	Number (%)
Gender	
Male	34 (46)
Female	40 (54)
Age	
21–25	2 (3)
26–30	22 (30)
31–35	26 (35)
36–40	14 (19)
40+	12 (16)
Level	
Resident	54 (73)
Attending	20 (27)
Working experience in anaesthesiology (years)	
0–2	22 (30)
3–5	25 (34)
6–10	15 (20)
10+	12 (16)

34 (46%) male and 40 (54%) female anaesthesiologists participated in this simulation study. 65% of the participants were between the age of 26 and 35 reflecting the high rate of residents (73% residents, 27% attendings)

target dosage in the app scenarios and from 12 to 521% in the control scenarios.

The probability of an "accurate" rated dosage was 77.7 (70.9–84.5%) in the control scenarios and 94 (90–97.8%) in the app scenarios.

There were no "wrong" dosages in the app scenarios. Therefore the probability of a "wrong" rated dosage with a risk to patient safety could only be calculated for control scenarios 6.8 (2.7–10.8%).

Distribution of the accuracy of administered dosages is shown in Fig. 2 and the probabilities of "accurate" and "wrong" dosages are presented in Fig. 3.

3.3 Calculation errors

Calculation errors resulting in medication errors could be avoided with the app.

Calculated volumes were closer to the target volume when calculations were supported by the app. Calculated dosages were between 7 and 513% in the control scenarios and between 81 and 128% in the app scenarios.

The influence of calculation errors on inaccurate dosing was higher in the control group. The correlation between calculated and administered dosage was 0.779 ($p < 0.01$) for the control scenarios and 0.48 ($p < 0.01$) for the app scenarios. The higher correlation combined with the wider spread around the target dosage shows that calculation errors are an important reason in this simulation study for the occurrence of medication errors in the control group. For the app scenarios, deviation of administered dosages might not be adequately explained by calculation errors.

Figure 4 shows a scatterplot of the accuracy of calculation and the accuracy of administered dosage.

3.4 Handling errors

Handling errors were the reason for some medication errors in the control scenarios whilst they were the main cause for deviations in the app supported scenarios. Still, these deviations did not lead to dosages in the "wrong" dosing range.

The range of handling errors was 22–1000% in control scenarios and 74–132% in app scenarios. The largest deviation of 1000% was a combination of a calculation and a handling error. The correlation between the handling errors and the given dose was higher in the aided group (Pearsons r 0.847 $p < 0.01$) than in the control group (Pearsons r 0.299 $p < 0.01$).

Handling errors are depicted in Fig. 4.

3.5 Time and confidence of participants

There was no significant difference with respect to time to drug administration. The time until administration was 80 (67–100) s in the control scenarios and 80 (67–98) s in the app scenarios.

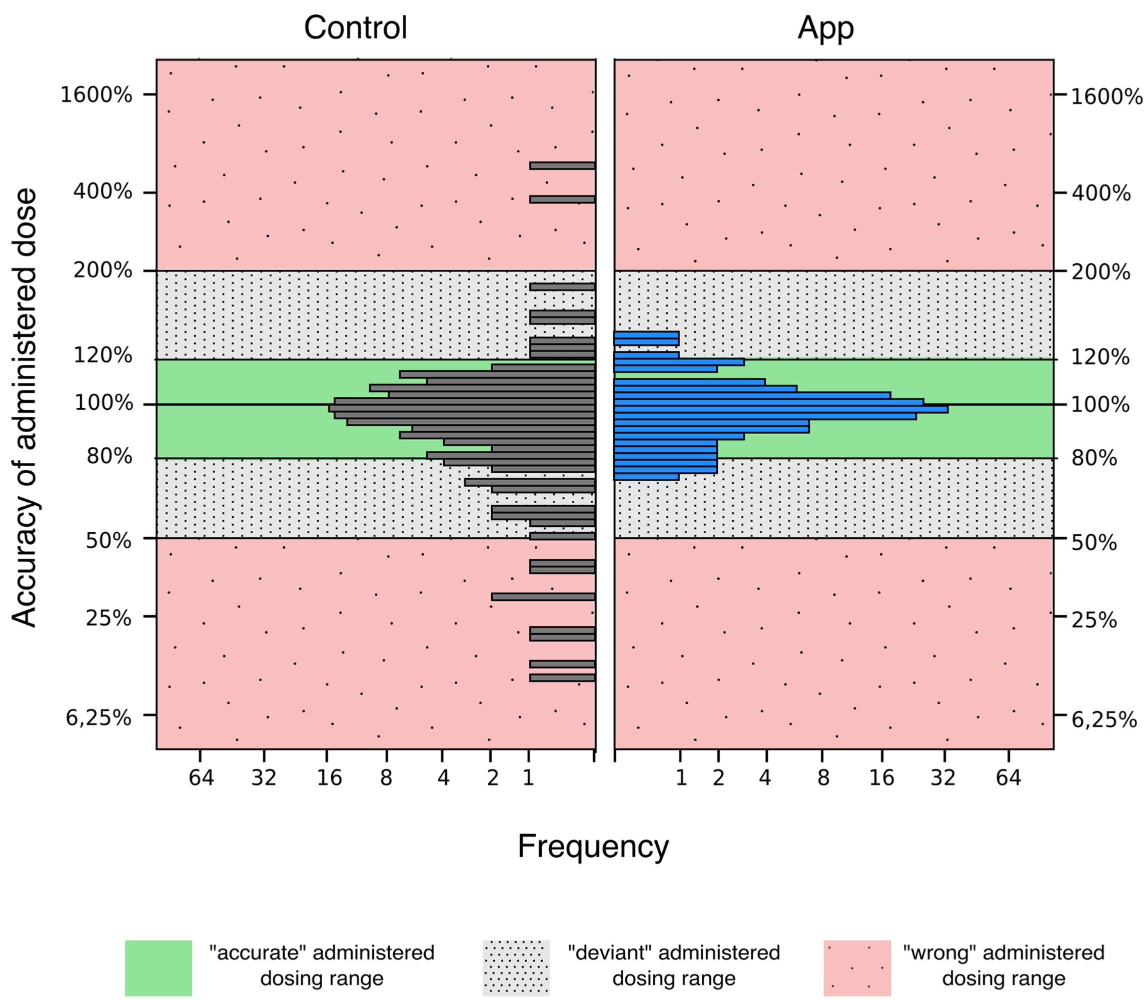
The self confidence in correct dosing was significantly higher in the scenarios with app usage ($p < 0.01$). Confidence was rated as 7 (5–8) in the control scenarios and 9 (7–10) in the app scenarios.

3.6 Patient age and working experience

Patient age and working experience had an influence on dosing accuracy.

The probability of an accurate dosage in paediatric emergencies was 67 (56.5–77.7%) in control scenarios and 88.6 (80.9–96.2%) in app scenarios. The probability of an accurate dosage for adult patients was 89.8 (82.5–97.2%) in control scenarios and 98.7 (96.2–101.3%) in app scenarios. Using the app increased the probability of accurate dosing in both groups. Children had a lower probability of receiving the correct dosage compared to adults. Still, the probability of a wrong dosage did not differ significantly between children and adults.

Participants within their first 5 years in anaesthesia had the probability of an "accurate" dosage of 79.8 (71.5-88%) in control scenarios and 92.5 (87.1–98%) in app scenarios. Participants with experience in anaesthesia of more than 5 years had the probability of an "accurate" dosage of 74.1 (62–86.1%) in control scenarios and 96.3 (91.1–101.5%)

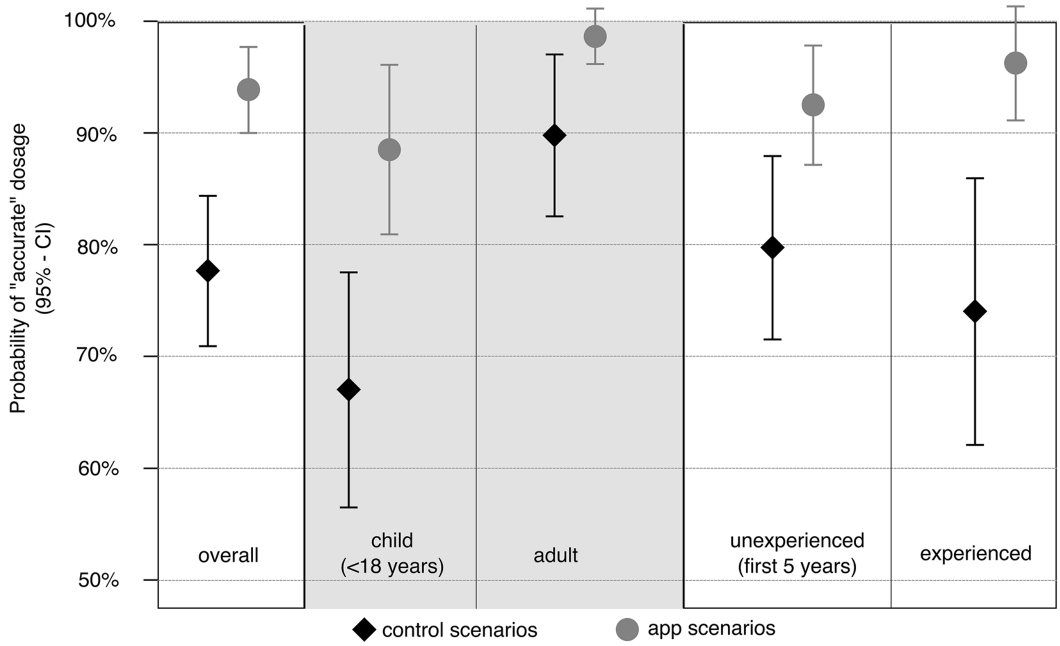


	Control	App
accurate	115 (77.7%)	139 (93.9 %)
deviant	23 (15.5 %)	9 (6.1 %)
wrong	10 (6.8 %)	-

Fig. 2 Accuracy of administered dosage for control and app scenarios. The accuracy of the administered dosage is presented as the percentage deviation from target dosage for app (right side) and control scenarios (left side). The Y-axis shows the variable accuracy_of_administered_dosage, after $\log_2$ transformation (for equal distribution). The X-axis presents the frequency of dosage deviations on a logarithmic scale. Deviations less than ±20% are labeled "accurate" (green area), deviations between 50 and 80 or 120 and 200% are labeled "deviant" (gray area) and deviations less than 50% or more than 200% are labeled "wrong" (red area)

in app scenarios. Still, the probability of a wrong dosage did not differ significantly between both groups of working experience.

Differences in probabilities of "accurate" and "wrong" dosages divided by patient age and working experience are shown in Fig. 3.



Probability of "wrong" dosage (95% - CI):

control scenarios ◆	6.8% (2.7% - 10.8%)	7.6% (1.6% - 13.6%)	5.8% (0.14%-11.45)	5.3% (0,7% - 9,9%)	9.2% (1.3% - 17.2%)
app scenarios ●	-	-	-	-	-

Fig. 3 Probabilities of accurate and wrong doses. Probabilities of an "accurate" and "wrong" dosage with their 95% CI are shown for app and control scenarios. Since "wrong" dosages were not calculable for the app scenarios, only the probabilities for "accurate" dosages are presented graphically. The probabilities are shown for different groups: (1) all scenarios, (2) children (age < 18 years), (3) adults (age ≥ 18 years), (4) inexperienced practitioner (working experience ≤ 5 years) and (5) experienced practitioner (working experience > 5 years)

3.7 Survey results

According to the questionnaire, 82.6% of the participants considered the app to be a feasible tool for safe drug administration and would like to use it for their work.

4 Discussion

This simulation study suggests that medication errors in emergency medicine can be effectively reduced with a mobile app supporting drug administration. In the simulation scenarios, the app was able to eliminate the occurrence of calculation errors and severe medication errors which are a high risk to the patient safety.

A safe medication process is important to ensure patient safety. There are different reasons for medication errors, which might occur alone or in combination. Firstly errors occur during the prescription of drugs, for example the choice of a drug that is not indicated or not tolerated. Furthermore, the dosage might be wrong when the correct dosing is unknown or when patients' characteristics are not considered. Once the drug is prescribed correctly, there might be calculation or handling errors, on which this study has focused. Calculation and handling errors are a frequent cause for medication errors [7, 8] and are responsible for increased costs in health care systems [1].

In this study, the issue of medication errors was addressed with a simulation since medication errors are underreported [11, 12] and often not documented which limits retrospective analysis. Simulation seems appropriate to prospectively investigate the administered dosages on accuracy, frequency of medication errors and the influence of calculation errors. In the present study, there was a good comparability of the scenarios used.

The dosages in the "accurate" dosing range are interpreted as a very safe drug usage. Using the app, the frequency of this safe drug usage could be significantly increased. A safe

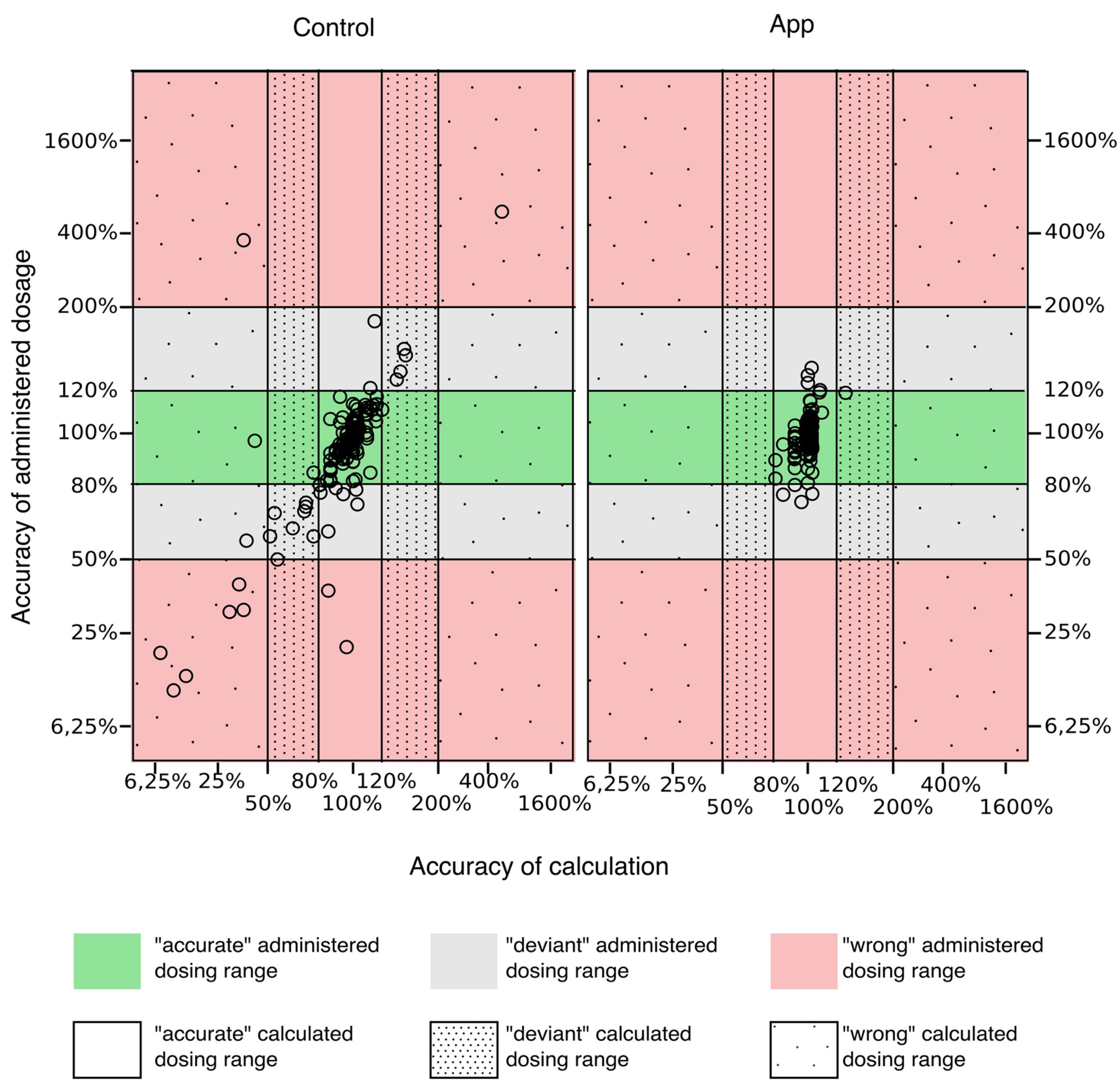


Fig. 4 Accuracy of calculation and accuracy of administered dosage. The accuracy of calculation is plotted against the accuracy of administered dosage. The control scenarios are shown on the left side and the app scenarios are shown on the right side. The X-axis shows the accuracy_of_calculation. The Y-axis shows the administered dosage. Both axis are expressed in percent of the target dosage. Deviations are categorized as follows (first: for administration, second: for calculation): deviations less than ±20% are labeled "accurate" (green area, no fill), deviations between 50 and 80 or 120 and 200% are labeled "deviant" (gray area, many dots) and deviations less than 50% or more than 200% are labeled "wrong" (red area, less dots)

drug usage was considered as a deviation of less than ±20% from target dosage in accordance with previous studies [19, 21].

In contrast, deviations of more than 200% or less than 50% were labeled "wrong" as they might be considered to cause harm to the patient. While the frequency of wrong dosages in control scenarios was similar to those in previous studies [2, 19, 22], no "wrong" dosage was administered in the app scenarios. All dosing deviations between 20–80 and 120–200% might be of harm to the patient depending on the patient, drug and clinical situation. Using the app the large majority of dosages were accurate (94%) and only 6% were in this grey zone of unsafe drug administration.

To our knowledge this is the first validation of a mobile app demonstrating that it actually increases the likelihood of safe drug usage and vice versa reduces the likelihood of unsafe drug usage.

In this study, mainly calculation errors were responsible for severe medication errors. It is likely that these errors can be avoided with the app. Usually, a calculation error results in wrong drug administration.

Handling errors are the main cause of inaccuracies in the app scenarios. Still, the deviation around the target dosage was less compared to the control scenarios. Handling errors in app scenarios only lead to "deviant" but not "wrong" dosages. Therefore, the visualization of drug administration with a syringe seems to be an important tool of the app. This tool is something that most medication aiding tools do not provide. However, this visualization has to be adapted to the clinical standards of each department before use.

The app had no influence on the time the participants needed to administer the drug. The time needed to handle the app seems to be saved in the calculation process. So the app seems feasible. Furthermore, it increases the self-confidence of the user.

Correct dosing was significantly more frequent in adult patients than paediatric patients. This is in accordance with previous reports [8, 23]. Dosing errors increase the risk of harm to the patient, especially in very young and very old patients. The app was able to avoid wrong dosing for both adults and children. According to our results it is useful both for physicians with little clinical experience and those that have been in patient care for many years.

The app presented in this study provides drug information and is both a calculation and handling aid. Its use resulted in a decrease in wrong drug administrations as mentioned above. Aids that only provide drug information cannot prevent calculation and handling errors. Further tools such as pocket calculators are needed [14]. The combination of an information, calculation and handling aid seems advantageous and should be further evaluated in clinical use.

4.1 Limitations

A simulated scenario always differs from real emergency situations, as external distractions and stressors are lacking. These might reduce the willingness to use the app or disturb the correct handling of the app.

To focus on calculation and handling errors, a target dosage was given for all scenarios. Thus, no conclusions can be drawn as to whether the app has a further advantage by providing dosage information.

The lack of knowledge of correct dosage is an important source of medication errors, which we couldn't assess with this study design. Further special handling situations, e.g., dilution of drugs were nor necessary.

The classification of "accurate", "deviant" and "wrong" dosages was made to separate between dosages without risk ("accurate") and dosages with a high risk ("wrong"). Since there is always a zone of uncertainty (grey-zone) in real life, it has been decided to focus on definitely accurate (green-zone) and definitely wrong (red-zone) dosages. The ±20% range around the target dosage for "accurate" dosing was chosen in accordance with two previous studies [19, 21]. Other studies suggested that deviations of ±5% [4] or ±10% [24] would be tolerable.

5 Conclusion

According to this simulation study, a mobile app can be an appropriate and feasible tool to reduce simple calculation and handling errors in drug administration. With a mobile app, a standard smartphone may contribute to an increase in patient safety. Mobile apps combining medical information, calculation and handling support should be further investigated in clinical studies.

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Compliance with ethical standards

Conflicts of interest The mobile app was developed by D. Baumann with the help of W. Reip, J.C. Kubitz and N. Dibbern. For the remaining authors none were declared.

Appendix

See Table 2.

Table 2 Overview of cases and frequency during the study

Drugs	Target doses (mg/kg)	Possible patients [age (years), weight (kg)]	Number of cases (control, app)
Amiodarone	5	19, 65	9, 13
		45, 53	12, 15
		88, 78	11, 14
Clemastine	0.03	2, 13	15, 11
		4, 18	14, 12
		11, 37	9, 13
Esketamine	0.25	3, 14	13, 10
		21, 69	15, 13
		61, 83	12, 11
Rocuronium	0.6	7, 23	14, 12
		12, 31	14, 12
		56, 67	10, 12

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