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Böttger-Apotheke | Markt 5/6 | 07970 Schleiz | DEUTSCHLAND/GERMANY

Optimization of analgesic drug therapy using software-assisted pharmacokinetical simulation

Kristin Lippoldt and Dr. Jörg Wittig | Böttger-Apotheke | Markt 5/6 | 07970 Schleiz | GERMANY – apotheke-schleiz.de – find us on facebook

Abstract: In Germany about 4.5 million people suffer from chronic pain diseases.[1] According to the number of approximately 830 thousand outpatient-clinics[2], which are specialized in pain relief therapy, most of the pain patients might be under a general practitioner's care. Due to the high patients throughput practitioners in average invest about 3 minutes per patient[3] which stands in extreme conflict to the sophisticated pain-therapy including time consuming dose-titration of analgesics as required in actual guidelines.[4;5]

However the Schleizer-Schmerzmittel-Studie (SSS) project examines whether well-trained public pharmacists might assist general practitioners to shorten the mentioned dose-titration by giving them dosing suggestions.

The first project phase investigates the correlation of software simulated blood levels of administered painkillers with circadian pain description collected in pharmacist-patient consultation.

Using the simulated analgesics-blood-level in a second project-phase the ongoing pain therapy was optimized and results were verified by validated questionnaires as there are the numeric rating scale (NRS), SF36 and SES respectively.

material and methods:

Randomized controlled pilot-study (n=6)

Software Pharkin 3.0[6] using patients data (weight, height, sex, renal or liver status respectivley) and pharmakokinetical drug data (absorbtion, elimination, cmax, tmax, t1/2, etc.)

Validated questionaires (SF36 and SES) and numeric rating scale (NRS)

PHASE I — Correlation of software simulated blood levels with patients circadian pain description.

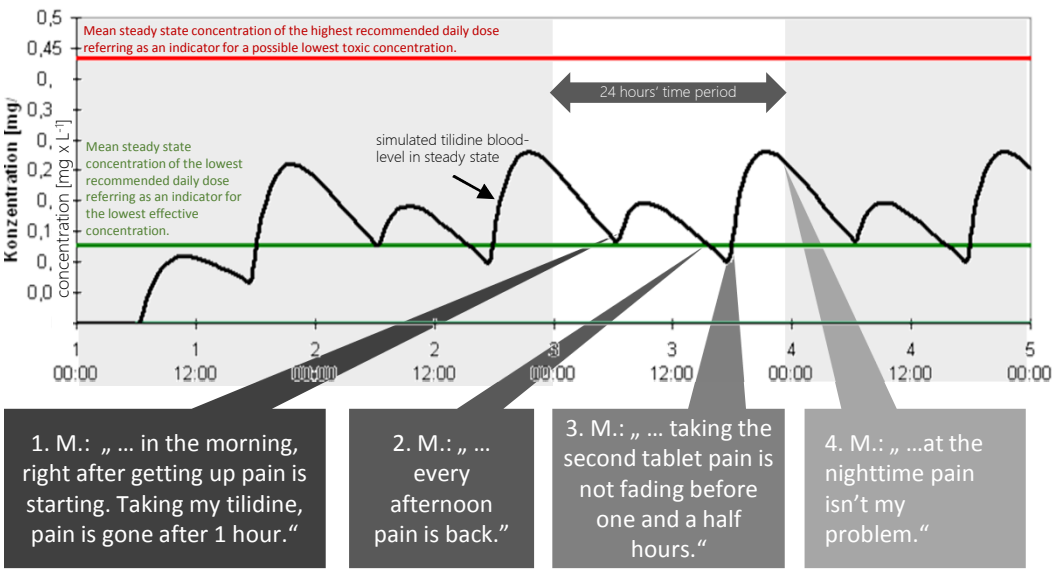
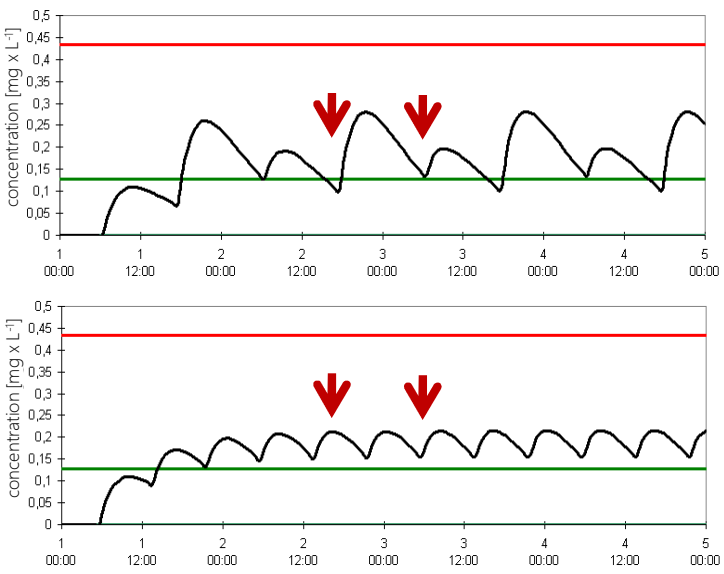


Figure 1: software assisted blood level simulation of an analgesic medication consisting of tilidin retard 50mg at 6:30 am and tilidine retard 100mg at 6:00 pm. Pain discription collected from a pharmasist-patient-consultation are translated from German.

PHASE II — Optimization of painkiller therapy using simulated analgesics-blood-levels.



tilidine retard tablet		
medication plan before intervention		
6.30 am	2.00 pm	6:00 pm
50 mg	-	100 mg
medication plan after intervention		
6.00 am	2:00 pm	10.00 pm
50 mg	50 mg	50 mg

Figure 2: software assisted blood level simulation of tilidine from the medication plan before (see figure 2 above) and after (see figure 2 below) intervention.

RESULTS & DISCUSSION

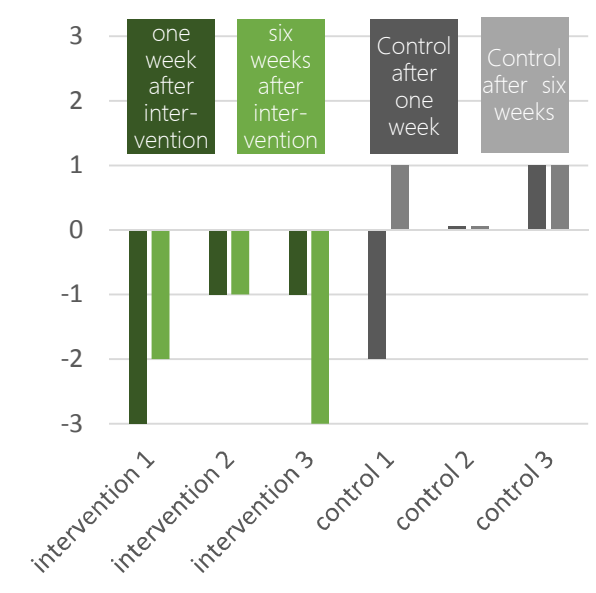


Figure 3: change of the pain status after intervention from baseline before intervention detected by NRS (lower values imply lower pain levels).

Discussion: Software assisted blood-level simulation of analgesics seem to allow an accurate prognosis of the patient's pain situation. Focussing the time elapsed from painkiller-intake to pain improvement at the simulation-function an individual minimal effective concentration can be estimated and used for dosage optimization respectively.

Facing the NRS results, which scale the physical aspect of pain, optimization of ongoing pain therapy is effective one and six weeks after intervention. NRS-Control showed no pain improvement after six weeks as there was performed a pharmacist-patient consultation and no intervention. However, results of validated questionnaires, which focus on the psychological aspect of pain (SF36 and SES), showed no significant difference between intervention and control. It suggests that the pharmacist-patient relationship leads into better quality of life by itself, but not into physical pain relief.

In routine care annual costs of analgesic therapy could be reduced by software assisted dose titration. However further research is needed.

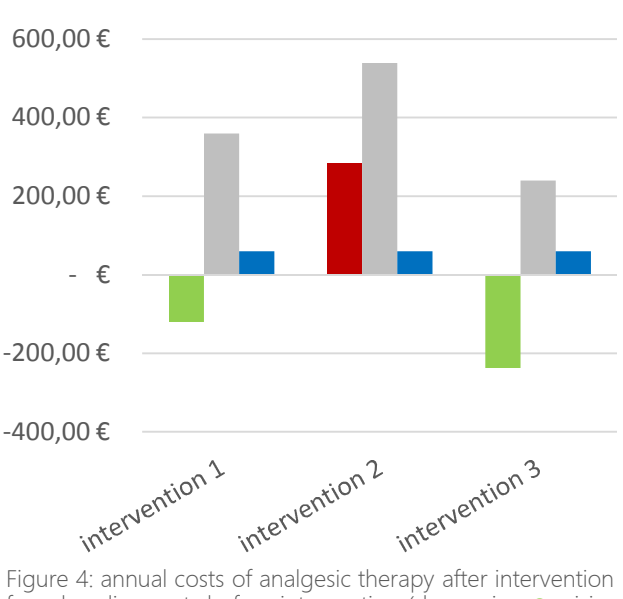


Figure 4: annual costs of analgesic therapy after intervention from baseline costs before intervention (decreasing ● ; rising ●) compared to costs of intervention itself within the pilot-study ● and routine care ●. (Attendance fees are taken from the ARMIN project in Thuringia and Saxony – 1min = 1€.)

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3) http://www.detect-studie.de/medien/mainpost.pdf (22. Dezember 2014, 07:04 Uhr)
4) Häuser W, Bock F, Engeser P, Tölle T, Willweber-Strumpf A, Petzke F: Clinical practice guideline: Long-term opioid use in non-cancer pain. Dtsch Arztebl Int 2014; 111: 732–40. DOI: 10.3238/arztebl.2014.0732
5) Annette Becker, Michal Becker, Peter Engeser S1-Leitlinie Chronischer Schmerz – Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin | AWMF-Registernr. 053/036
6) Probst W, Frey O, http://www.kliniken-heidenheim.de/klinik/Zentrale_Einrichtungen/Klinikapotheke/Therapeutisches_Drug_Monitoring/ (10. März 2015, 15:23 Uhr)