patients > 65 years, including those with preserved systolic function and at higher serum digoxin concentration, digoxin reduces HF hospitalization but has no effect on mortality or all-cause hospitalizations [16].

Due to the fact that during routine TDM we focus prioritally on a safety (avoiding overdose, revealing non-compliance), the one-compartment (pharmacokinetic) model, used by MwPharm, is thus sufficient for these purposes, even though pharmacokinetics of digoxin is better described by the two-compartment (PK/PD) model [5, 17].

In the context of our finding, a major limitation of this study should be acknowledged. A small sample size in a subgroup of infants and pregnant women (one infant or pregnant woman) which is a common problem of studies in diseases with low incidence. Although there is a PK/PD target for digoxin, a comparison of two different versions of the same software package is still lacking [18]. This makes it difficult to analyze the results with respect to efficacy. Diversion of data (especially, difference in the PK of digoxin and its high concentrations in children and pregnant women) taken into account by a model is necessary.

Conclusions

The digoxin model in the Windows version of the MwPharm software suite was validated. Based on available evidence and our study results, we conclude that there is no significant difference between quality of prediction of plasma levels of digoxin by both TDM software packages, their %PE were comparable. DOS and WIN versions of the s/w suite can be used for TDM of digoxin interchangeably.

In general, variations in results occurred with the same immunoassay processed on different analysers, as well as using different TDM software packages. In case when blood samples from the same patient are every time analyzed in different laboratories, it may increase an amount of the possible laboratory-based errors. These apparent and marked differences in SDC may have significant implications for patient care. Clearly, there is considerable potential for confusion or dosing error. Accurate TDM remains essential to ensure appropriate concentrations are maintained.

Consequently, it should be considered if routinely using updated versions of the same TDM software always brings benefits to patients – not only in case of MwPharm, but also other packages. As a result, future research is needed to gain a better understanding of this thema.

Author contributions

TP: manuscript writing and literature search; BK: manuscript writing and literature search; MG: study design; IK: study design

Conflict od interest statement

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