

ABSTRACT

Candidate: Lenka Polláková¹

Supervisor: prof. RNDr. Jiří Vlček, CSc.¹

Consultant: doc. MUDr. Tomáš Soukup, Ph.D.²

¹ Department of Social and Clinical Pharmacy, Faculty of Pharmacy in Hradec Králové, Charles University

² 2nd Department of Internal Gastroenterology, University Hospital in Hradec Králové

Title of the master thesis: Analysis of non-cardiac adverse event of glucocorticoid pulse therapy

Intravenous glucocorticoid pulse therapy (PT GC) is effective in life threatening flares of rheumatic diseases. However, due to GC's pleiotropic effect, higher doses and additive nongenomic mechanism in pulse regimen, it is not free of complications (1).

The aim of theoretical part was to describe from literature research the relevance of PT GC, its non-cardiac adverse events (AE) in rheumatic patients and their influencing factors. The aim of experimental part of the study was to analyze the occurrence of non-cardiac AE in real-life setting, analyze risk factors of potential adverse drug reactions (ADR) and its complications and analyze the risk minimalization management in real-life setting.

Patients were administered 1000 mg methylprednisolone in 3 to 5 doses on alternating days. Analysis includes 277 rheumatic patients with 325 pulse therapy courses. Data were collected retrospectively from their medical records and analyzed using Excel and IBM SPSS Statistics software.

Median age was 55 years and 67 % of patients were women. Patients mostly suffered from connective tissue diseases (n=191, 59 %) and systemic vasculitis (n=120, 37 %). Non-cardiac AE occurred in 13 % (n=42) of courses and AE in 4 % (n=13) lead to termination of the therapy. Common non-cardiac AE were significant increase of blood pressure (4,6 %, n=15), steroid diabetes (4,3 %, n=14), infection (2,2 %, n=7), abnormal serum amylase and diarrhea, each appearing in 1,2 % (n=4) of PT GC. Occurrence of another non-cardiac AE was uncommon (<1 %). Risk minimalization management was observed as monitoring in 100 % and pharmacotherapy revision in form of gastroprotection in 93 % and kalium supplementation in 52 % of courses, leading to uncommon incidence of expected hypokalemia (0,3 %, n=1) and gastrototoxicity (0,3 %, n=1).

Limitations are based on retrospective character. Occurrence of non-cardiac AE was very common (13 %), but not all expected ADR of GC were present, thanks to use of practical risk minimalization utilities. Our study presents PT GC as relatively safe, if precise risk minimalization strategy is met.

Key words: pulse glucocorticoid therapy, adverse event, adverse drug reaction, risk minimalization