3PC-014 METAMORPHINE INSTEAD OF POLYSUBSTANCE USE?

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Background and Importance Opioid therapy is still not optimal. As PCA pumps with combinations of opioids and NSAR are produced in many hospital pharmacies to minimise the dose and the side effects of opioids, this polysubstance use is accompanied by incompatibility problems. Several admixtures with opioids and metamizole change their composition during administration time. In case of admixtures with morphine and metamizole, we could define and isolate the main reaction product 'metamorphine'. Dependent on morphine concentration, storage temperature and storage time, PCA-pumps with admixtures of metamizol and morphine can contain 100% metamorphine instead of morphine.

Aim and Objectives As the stability problems did not result in a change of the prescribing routine, the pharmacology of this new substance was interested, especially because the PCA pumps still had their analgesic potency and new adverse effects were never reported.

Material and Methods After permission of the Ethics Committee and informed consent, morphine and metamorphine were determined in serum samples of patients with regular morphine/metamizole PCA therapy.

Results Up to now, we have determined the morphine and metamorphine concentrations in serum of four patients treated with admixtures of morphine/metamizole. In three of them we could identify or quantify metamorphine beside morphine. In one patient's serum we found 0,75 µg/mL metamorphine beside a morphine concentration of 0,16µg/mL. No loss of the analgesic effect and no change of adverse effects during PCA therapy of these patients was found.

Conclusion and Relevance Incompatibilities of polysubstance use in PCA pumps can also lead to other active substances than prescribed. Since patients do not notice a loss of the analgesic potency or change of side effects and the serum level of morphine decreased significantly, it is very likely that metamorphine has analgesic and/or spasmolytic potency and compared to morphine alone its effects to µ-, κ- and δ-opioid receptors may be different. The study is relevant to understand a successful, well-established therapy and leads possibly to a new optimised opioid therapy in future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-015 IN-USE STABILITY OF COMIRNATY AND SPIKEVAX CLINICAL SOLUTIONS: PFIZER-BIONTECH AND MODERNA COVID-19 VACCINES: A COMPARATIVE STUDY FROM A HOSPITAL PHARMACY PERSPECTIVE

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Background and Importance COVID-19 emerged as a novel infectious disease by late 2019, spreading very rapidly and being categorised as a pandemic by March 2020 by the WHO. Several vaccines have been authorised and administered worldwide, demonstrating efficacy and safety, being Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) the mostly administered globally. Although having demonstrated efficacy and safety, one of the major issues has been their stability, from which hardly any stability data is available in the public domain. Analysing the *in-use* stability of these novel vaccines is paramount for ensuring rationale use in hospitals.

Aim and Objectives This study is aimed at assessing and comparing the *in-use* stability of Comirnaty and Spikevax clinical solutions by characterising the particulate profile using Dynamic Light Scattering (DLS).

Material and Methods Expired and non-expired clinical solutions of the vaccines were subjected to different stress conditions: visible light and mechanical stresses. The Z average and the polydispersity index (PDI) of the vaccines clinical solutions were evaluated by DLS, using a Zetasizer Nano ZS-90 (Malvern, UK). For statistical analysis, a simple ANOVA followed by Dunnett's post-hoc test, using GraphPad Prism 8 Software was used. Stressed samples were compared to control (non-stressed samples). Furthermore, differences were considered significant at a p-value < 0.05. The study was conducted in triplicate.

Results Comirnaty DLS parameters were mainly affected by mechanical agitation and vortex stresses. In this case, the Z-average and PDI increased significantly, even in the expired samples. On the other hand, the DLS parameters were maintained in Spikevax clinical samples regardless of the stress and the expiration date.

Conclusion and Relevance This study highlights the necessity of a careful preparation of these vaccines, given their demonstrated fragility upon gentle stress. However, Comirnaty has proven to be more fragile than Spikevax in their handling in real-use conditions. Previous literature commented on the stability of Comirnaty, having presented similar results. Nonetheless, no stability data were available on the in-use stability of Spikevax. Therefore, this data will be of interest to hospital pharmacists towards following vaccination campaigns.

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