Short-term Effects of Intravenous Dexketoprofen Trometamol and Tramadol on Perfusion-Related Physiological Parameters in Renal Colic

Short-term Perfusion Effects: Dexketoprofen/Tramadol

METHODS

Study design and setting

This single-centre, prospective, randomised study was conducted in the emergency department of Atatürk University Research and Training Hospital between November 2024 and April 2025. Adult patients aged 18–55 years presenting with flank pain and diagnosed with renal colic based on clinical evaluation and appropriate imaging were screened for eligibility.

Participants

Patients who met the inclusion criteria were required to have a Glasgow Coma Scale score of 15, spontaneous respiration, and the capacity to provide informed consent. Exclusion criteria encompassed pregnancy or breastfeeding, chronic kidney disease, known allergy to study medications, chronic respiratory disease, hemodynamic instability, acute intoxication, uncontrolled epilepsy, or recent monoamine oxidase inhibitor use.

Randomisation and interventions

Participants were randomly assigned to one of three groups in a 1:1:1 ratio, receiving intravenous dexketoprofen trometamol (50 mg), tramadol (100 mg), or a combination of dexketoprofen trometamol (50 mg) and tramadol (50 mg). All medications were diluted in 100 mL of normal saline and administered intravenously. The administration of rescue analgesia in the form of intravenous morphine (5 mg) was permitted at the discretion of the treating physician.

Data collection and monitoring

Physiological variables, including blood pressure, heart rate, oxygen saturation, respiratory rate, and EtCO2, were recorded at baseline (T0), 30 minutes (T30), and 60 minutes (T60). Arterial blood-gas analysis was performed at T0 and T60. The primary outcome of the study was a change in $EtCO_2$ over time, while secondary outcomes included changes in vital signs and blood-gas parameters.

The primary outcome was the change in $EtCO_2$ over time (T0, T30, T60) and the comparison of these changes between the three analgesic groups as a surrogate marker of global tissue perfusion. Secondary outcomes encompassed the trajectories of heart rate, blood pressure and SpO_2 over time; changes in arterial blood gas parameters (pH, bicarbonate, $PaCO_2$, lactate and

base deficit) between T0 and T60; and comparison of these physiological responses across treatment groups.

Sample size and statistical analysis

Sample size was calculated in G*Power using previously published data on $EtCO_2$ changes after tramadol or oxycodone administration (16). With $\alpha = 0.05$ and 80% power, 34 patients per group (102 in total) were required.

The analysis of the data was conducted utilising the SPSS version 25.0 software. The assessment of normality was conducted through histogram inspection and the implementation of the Shapiro–Wilk test. Continuous variables are presented as mean ± standard deviation or change over time, and categorical variables as counts and percentages. The alterations in vital signs and blood-gas variables occurring within and between the groups were subjected to analysis using repeated-measures ANOVA. For the purpose of comparing the between-group alterations, one-way ANOVA with Tukey post hoc tests were employed. Paired t tests were utilised for within-group comparisons between T0 and T60, and χ^2 tests were used for the analysis of categorical variables. Statistically speaking, a p value of less than 0.05 was deemed to be significant.

Ethics Approval

The study was approved by the Erzincan Binali Yıldırım University Clinical Research Ethics Committee (Decision No. 2024-16/01, 07 Nov 2024) and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent.

CRediT authorship contribution statement

G. D.: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Software.
M. G.: Conceptualization, Formal analysis, Investigation, Methodology, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no competing financial interests or personal relationships that could have influenced the work reported in this paper.

Data availability statement

The data that support the findings of this study are not publicly available due to privacy and ethical restrictions, as they contain identifiable patient information.

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