## SUBLINGUAL DESMOPRESSIN IS EFFICIENT AND SAFE IN THE THERAPY OF LITHIASIC RENAL COLIC



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- The only two medications currently used for the therapy of acute renal colic are nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids
- Intranasal Desmopressin was proposed as an adjuvant for NSAIDs in the therapy of acute renal colic
- The sublingual administration form of Desmopressin was not used for treating acute renal colic in monotherapy or combined with NSAIDs

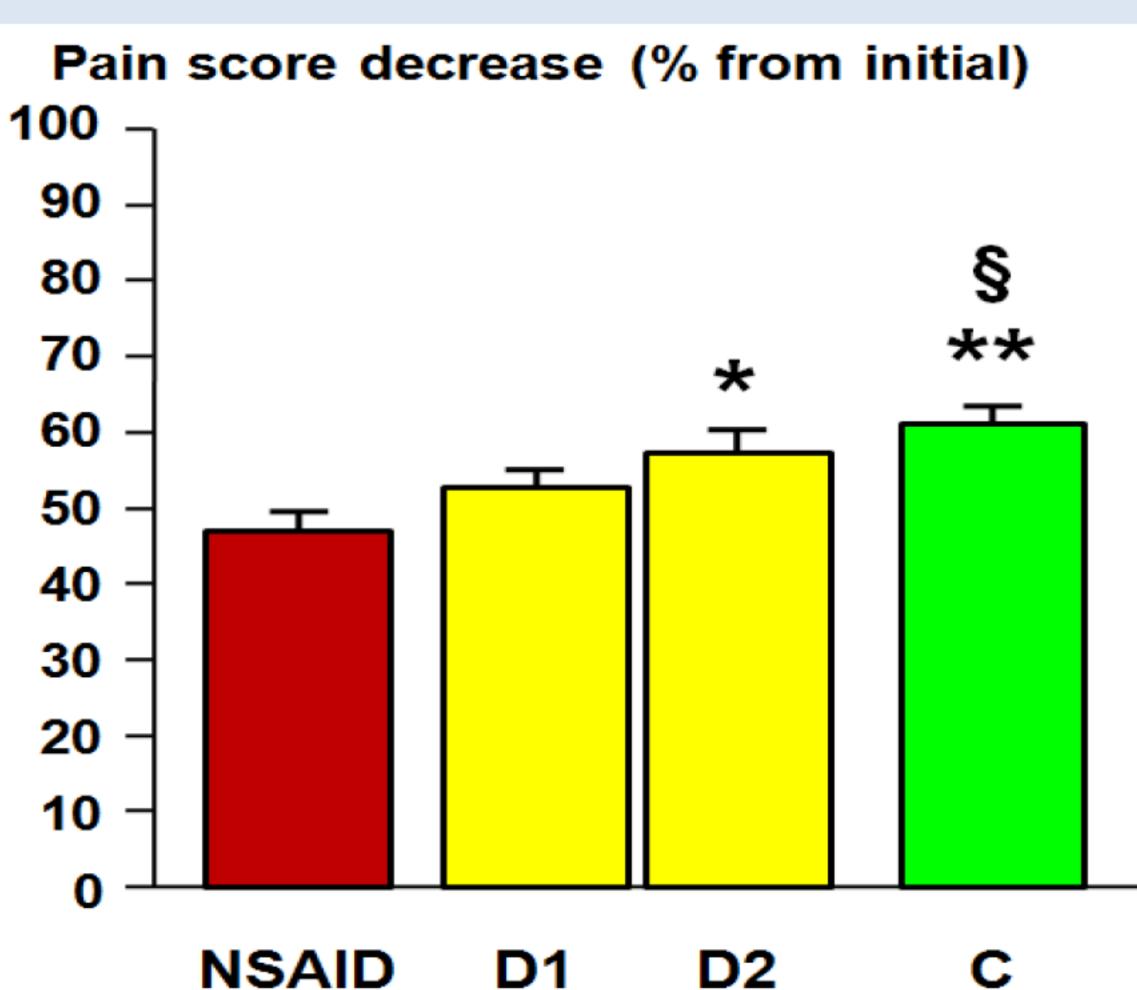


- To evaluate the therapeutic efficacy and safety of recent onset renal colic with sublingual Desmopressin
- To compare the efficacy of sublingual Desmopressin compared to a classical NSAID (Ketorolac) in the therapy of acute renal colic
- To evaluate the therapeutic efficacy of a combination between sublingual Desmopressin and Ketorolac in the therapy of acute renal colic
- Single-blind randomized prospective multicentric study, enrolling 249 patients (167 males and 82 females) with recent onset renal colic of lithiasic etiology in the emergency units of two Romanian University hospitals (laşi and Târgu Mureş) during a period of 2 years.
- Study groups
  - NSAID (71 patients)D1 (57 patients)
- Ketorolac 50 mg im and sublingual placebo (vitamin C)
- Desmopressin 60 μg sl - Desmopressin 120 μg sl
- D2 (62 patients)C (59 patients)
- Desmopressin 60 μg sl + Ketorolac 50 mg im

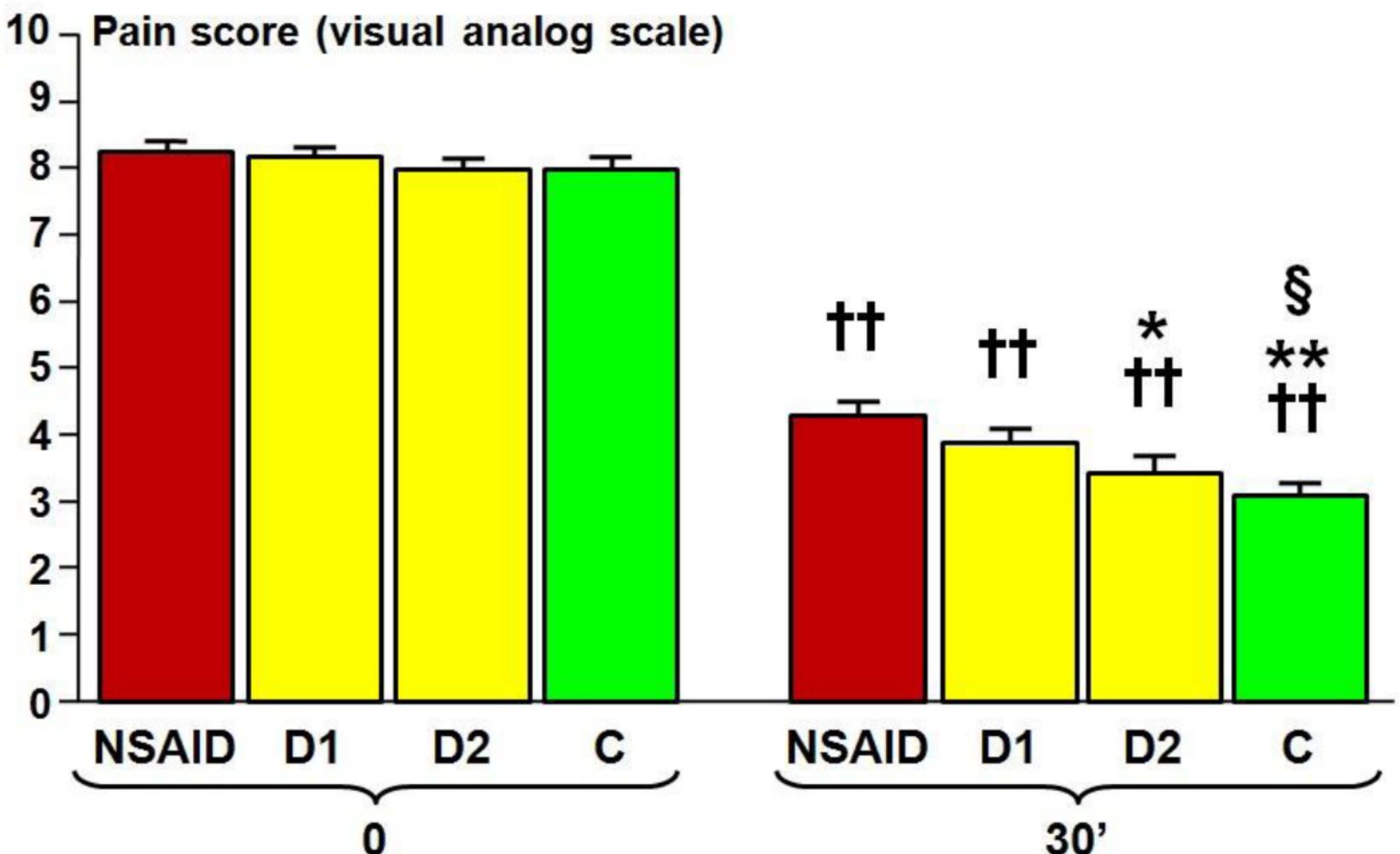
- Endpoints
  - Number of dropouts (patients experiencing no pain relief or pain aggravation, submitted to rescue therapy opioids or surgery)
  - ▶ Mean decrease of pain intensity evaluated by a visual analogue scale 30 minutes after therapy administration
  - **▶** Evaluation of side effects (blood pressure, serum natrium and serum creatinine before and 30 minutes after therapy)



Number of drop outs due to pain aggravation. Red bars - number of drop outs, green bars - number of patients responsive to therapy kept in the study. \*p < 0.01, \*\*p < 0.001 compared to the NSAID group (Chi-square test)



Mean pain score decrease  $\pm$  SEM (% from initial pain score evaluated by the visual analogue scale) in patients treated with Ketorolac 30 mg im and placebo sI (group NSAID, red bar), Minirin Melt 60 and 120  $\mu$ g sI (groups D1 and D2, yellow bars) and the combination of Minirin Melt 60  $\mu$ g sI with ketorolac 30 mg im (group C, green bar). \*p < 0.05 compared to mean pain score decrease of the NSAID group. \*rp < 0.001 compared to mean pain score decrease of the NSAID group. § p < 0.05 compared to mean pain score decrease of the D1 group (Student's t test)



Mean pain score  $\pm$  SEM (visual analogue scale) at admission (left) and 30 min after therapy (right) in patients treated with Ketorolac 30 mg im and placebo sl (group NSAID, red bars), Minirin Melt 60  $\mu$ g and 120  $\mu$ g sl (groups D1 and D2, yellow bars) and a combination of Minirin Melt 60  $\mu$ g sl with Ketorolac 30 mg im (group C, green bars). †† p < 0.001 compared to mean pain score at admission; \*p < 0.05 and \*\*p < 0.001 compared to mean pain score of the NSAID group at 30 min. § p < 0.05 compared to mean pain score of the D1 group at 30 min (Mann–Whitney U test and Student's t test)

Biological parameters before and 30 minutes after therapy

Serum Na

Blood pressure



(mm Hg) (mEq/L) (mg/dL) Systolic Diastolic Group 30' 30' NSAID 130±17 126±18 77±12 75±12 127±16 74±12 140±2.1 1±0.12 D1 129±19 79±11 139.6±2.7  $0.99 \pm 0.1$ D2 0.98±0.09 76±13 140.2±2.3 139.8±2.4 1.01±0.11 73±13 139.9±2.2 139.5±2.5 1±0.11 ΑII 131±18 126±16 78±9 74±10

All volunteers enrolled in the study and receiving sublingual desmopressin had normal blood pressure, serum sodium and creatinine 30 min after drug administration, irrespective of their age or sex, with unmodified mean values.



- Sublingual Desmopressin is efficient and safe in treating acute crisis of lithiasic renal colic.
- Sublingual Desmopressin is easy to be administered and seems devoid of toxic side effects.
- Sublingual Desmopressin was at least as efficient as classical NSAIDs in treating lithiasis crisis.
- An association between sublingual Desmopressin and NSAIDs conferred mild but significant additive analgesic effects in lithiasic renal colic.
- Sublingual Desmopressin may find immediate application as first-line therapy for lithiasic renal colic, alone or in combination with NSAIDs.











Serum creatinine