EVALUATION OF TOXICITY OF STANDARDIZED TRIPLE INTRATHECAL CHEMOTHERAPY

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Background

- Intrathecal administration of methotrexate, cytarabine and hydrocortisone (i.e., triple intrathecal therapy) is commonly used to treat and prevent central nervous system (CNS) involvement in leukemias and lymphomas. The dose, volume and method of preparation and administration of intrathecal chemotherapy are highly variable in clinical practice.
- Thus, the standardization of the preparation of the triple intrathecal therapy (TIT) is recommended.

Objective

- Describe the incidence and severity of adverse events (AEs) due to a standardized TIT in adult patients.

Methods

- Prospective observational study performed from January 2013 to June 2014 of adult patients treated with standard TIT: Methotrexate 12mg, cytarabine 30mg and hydrocortisone 20mg, in a final volume of 8ml and pH and osmolarity values 7 – 7.5 and 280 – 310 mOsm/kg, respectively.
- The severity of AEs was classified according to Common Terminology Criteria for Adverse Events (CTCAE) grade.

Results

- N = 25 patients (15 male).
- Age (median) = 50 years.
- Median monitoring time = 8.5 months [1,5 – 19].
- TIT administered = 56 → 2.8 TIT/patient:
  - Via lumbar puncture = 25 patients.
  - CNS involvement prophylaxis = 19 patients.

- Adverse events:
  - 7 patients (36%) showed any AE.
  - 30% of administrations:
    - 23.2% headache
    - 17.9% vomiting
    - 5.4% dizziness
    - 3.6% back pain
    - 1.8% paresthesias
    - 1.8% orthostatic hypotension
  - All AEs were acute:
    - Median time of onset: 26 [1 – 72] hours
  - Every toxicity was resolved.

- The incidence of mild and moderate AEs associated with TIT is relatively frequent, being headache the most common AE such as described in the literature.
- No long-term toxicities were observed. Therefore, the TIT shows an acceptable toxicity profile.

Conclusions

- The incidence of mild and moderate AEs associated with TIT is relatively frequent, being headache the most common AE such as described in the literature.
- No long-term toxicities were observed. Therefore, the TIT shows an acceptable toxicity profile.