In Vitro Stability of Low-Concentration Ziconotide Alone or in Admixtures in Intrathecal Pumps

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Résumé en anglais	ObjectivesZiconotide is often administered in combination with other analgesics via an intrathecal pump. Studies have established that ziconotide is stable when delivered alone in high concentrations. No stability data are available, however, for ziconotide given in low concentrations and/or with other analgesics as usually occurs in clinical oncology practice. The objective of this study was to assess the in vitro stability of ziconotide alone and combined with other analgesics in intrathecal pumps at 37°C, as well as in syringes at 5°C, to evaluate conditions for storing and transporting preparations. Materials and Methods Various ziconotide concentrations (0.1, 0.25, 0.5, and 0.75 µg/mL) were combined with an admixture of ropivacaine (7.5 mg/mL), morphine (7.5 mg/mL), and clonidine (15 µg/mL) in 20-mL intrathecal pumps at 37°C and in syringes at 5°C. Solutions of ziconotide alone in concentrations of 0.25, 0.5, 0.75, and 1 µg/mL were introduced into pumps at 37°C and syringes at 5°C. Assays were performed using ultra high pressure liquid chromatography. Results In admixtures, mean ziconotide concentrations decreased linearly to 53.4% (±3.33%) of baseline after 35 days. When ziconotide was introduced alone in pumps at 37°C, the residual concentration on day 31 was 35.54% (±0.04%) with 0.25 µg/mL, 39.37% (±0.15%) with 0.5 µg/mL, and 44.49% (±0.18%) with 1 µg/mL. Ziconotide alone or combined with the other analgesics was stable in syringes stored at 5°C. The preparations complied with the prescriptions, with a mean error of less than 10%, except with the lowest ziconotide concentration (0.1 µg/mL). Conclusions At the low ziconotide concentrations studied, the degradation of ziconotide admixed with other drugs was linear and only weakly influenced by the baseline concentration. Linear regression with intrapolation to 30 days showed that the degradation of ziconotide admixed with other drugs was consistent with previously published data.
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