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Using intrathecal rituximab in two pediatric patients with PTLD

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Background and Aims: Rituximab, the first FDA-approved monoclonal antibody is licensed for various therapeutic indications. Aseptic preparation of rituximab is essential for intrathecal administration with limited data and information explaining the full method of preparation. The delivery of this monoclonal antibody as a therapeutic agent to the central nervous system has posed a hurdle because of the blood-brain barrier (BBB). At Central Manchester University Hospital NHS Foundation Trust, rituximab was prepared and used in two pediatric patients with post-transplant lymphoproliferative disorder (PTLD) following hematopoietic stem cell transplant (HSCT) and its successful short-term outcome.
Methods: Rituximab 100mg/10ml (Roche) and sodium chloride 0.9% 10ml (Braun) vials were used to prepare one syringe (polypropylene syringe (BD)) containing 2.5ml of rituximab and another syringe (polypropylene syringe (BD)) containing 2.5ml sodium chloride 0.9%, the contents of both syringes were then transferred into a final syringe (polypropylene syringe (BD)) without the use of 0.2micron filter to the total volume of 5ml.
Results: The prepared rituximabs were used in the management of two cases of post HSCT patients who developed the Epstein-Barr virus (EBV) associated isolated CNS PTLD in the early post transplant period. The maximum trial dose was determined to be 25mg in 5ml with the expiry date of 24 hours when prepared in strict aseptic conditions, stored in a fridge and away from light.
Conclusions: A new preparation method has been developed based on very little existing literature and mostly on pharmaceutical and clinical judgments. The intrathecal rituximab with the final concentration of 5mg/ml and total volume of 5ml can be used in pediatric patients diagnosed with PTLD. To our knowledge, these were the first cases of patients who successfully used intrathecal rituximab when prepared as described. The use of such protocols in preparing rituximab for patients with similar presentations is proposed.

Keywords: Intrathecal; Post-transplant lymphoproliferative disorder; Rituximab