Do We Really Need Steroids? Real-World Safety of Steroid-Free Ocrelizumab and Ublituximab Infusions

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Background

Ocrelizumab (OCR) and ublituximab (UBL) are anti-CD20 treatments for multiple sclerosis (MS) that result in the rapid depletion of B-cells[1]. Infusion-related reactions (IRRs) are thought to result from cytokines and chemokines released from lysed B-cells. The prescribing information for both therapies recommends premedication with intravenous (IV) methylprednisolone or equivalent and an oral or IV antihistamine to reduce frequency and severity of IRRs[2,3]. Continued use of premedication with corticosteroids may be unnecessary since the incidence and severity of IRRs decrease with repeated treatment[4,5]. Forgoing corticosteroid pretreatment would shorten treatment time, reduce immunosuppression and could eliminate steroid-related side effects.

Objectives

To demonstrate the safety and tolerability of administering OCR or UBL without steroid premedication in a series of patients with MS.

Methods

A medical record review was conducted to identify patients who completed OCR 600mg or UBL 450mg infusions without steroid premedication. Information about the number of OCR or UBL infusions with and without steroid premedication, reason for withholding steroid premedication, and presence or absence of IRRs and/or other adverse events during or after infusions was obtained through patient interview and medical records.

Results

- A total of 26 patients were identified.
- The median number of infusions with steroids premedication prior to withholding steroids was 7.5 (Q1=4.25, Q3=13).
- The median number of infusions without steroid premedication was 2 (Q1=1, Q3=4).
- Reasons for excluding steroids from the premedication regimen included insomnia, hyperglycemia, tachycardia, hypertension, anxiety, flushing, allergy, facial swelling, and dyspepsia.
- 20 out of 26 patients had no infusion related symptoms after eliminating steroid premedication.
- Six patients experienced mild infusion related symptoms. Two patients were given rescue doses of antihistamine (one patient at one infusion, another at two infusions), and both had previously tolerated infusions without steroids.
- Only one patient chose to resume steroids at their subsequent infusion.

Table 1: Demographics

Age, mean (SD)	46 (9)
Sex	
F, n (%)	20 (77%)
M, n (%)	6 (23%)
No. of infusions prior to withholding steroids, median (Q1, Q3)	7.5 (4.25, 13)
No. of infusions without steroids (patients)	
OCR	55 (20)
UBL	13 (8)
CD19 at first infusion without steroid, median (Q1, Q3)	0 (0,0)

Table 2: Reasons for Withholding Steroids

Reason for withholding steroid	No. of patients
Insomnia	12
Mood changes/Irritability/Anxiety	6
Hyperglycemia	4
Arthralgias/Myalgias	2
Facial swelling/Allergy	2
Concern about long term side effects	2
Hypertension	1
Malaise	1
Tachycardia	1
Flushing	1
Dyspepsia	1
Candida	1

Conclusions

- In this case series, most patients were able to safely eliminate corticosteroid premedication without an increase in clinically significant IRRs.
- Elimination of corticosteroid premedication may be a feasible option for carefully selected patients receiving anti-CD20 therapy.

References:
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