106. Risk Classification to Differentiate Autoimmune from Viral Encephalitis

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Background. Autoimmune encephalitis is an urgent treatable etiology that needs to be differentiated from viral encephalitis. Prompt recognition and therapy is of utmost importance.

Methods. We performed a retrospective cohort of encephalitis cases in 16 hospitals in Houston, Texas, between January 2005 and December 2019. A total of 1,310 adult patients (age ≥ 18 years) inpatient hospital admissions were identified by the presence of an encephalitis-related discharge diagnosis per the International Classification of Disease 9th edition codes. Of these, only 279 cases met the 2013 International Encephalitis Consortium criteria for probable encephalitis. A laboratory confirmed diagnosis of autoimmune encephalitis or viral encephalitis was identified in 36 (12.9%) and 88 (31.5%) cases, respectively. There were 155 cases (55.5%) that had no identifiable cause and were considered idiopathic.

As compared to viral encephalitis, patients with autoimmune encephalitis were more likely to be younger (< 60 years old), have a subacute (6-30 days) or chronic (> 30 days) presentation, have seizures, and have psychiatric and/or memory complaints (P < 0.001). Furthermore, patients with autoimmune encephalitis were less likely to be febrile and to lack inflammatory cerebrospinal fluid (CSF) (defined as white blood cells < 50 per microliter or protein < 50 milligrams per deciliter) [See Table 1]. In the multivariable logistic regression model, subacute/chronic presentation, psychiatric and/or memory complaints, and lack of inflammatory CSF were significantly associated with autoimmune encephalitis. Using these 3 variables, patients were classified into 3 risk categories for autoimmune encephalitis: low risk (0-1 variables); intermediate risk (2 variables); and high risk (3 variables); 83% (P value < 0.001).

Table 1. Risk Classification to Differentiate Autoimmune from Viral Encephalitis

| Autoimmune (%) | Viral (%) | OR (95% CI) | P value |
|----------------|-----------|-------------|---------|
| Low (0-1 variables) | 76.0 | 32.0 | 2.3 (1.3-4.3) | 0.005* |
| Intermediate (2 variables) | 16%; and high risk (3 variables); 83% (P value < 0.001). |

Conclusion. Adults with encephalitis can be accurately stratified for the risk of having autoimmune encephalitis using clinical variables available upon presentation.

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107. A Phase 3, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Oteseconazole (VT-1161) Oral Capsules versus Fluconazole and Placebo in the Treatment of Acute Vulvovaginal Candidiasis Episodes in Subjects with Recurrent Vulvovaginal Candidiasis (ultraViolet)

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Background. Recurrent vulvovaginal candidiasis (RVVC) affects nearly 138 million women globally each year. Currently there are no FDA approved treatments. The study was conducted to evaluate the efficacy of oral oteseconazole (VT-1161) in the prevention of culture-verified acute VVC episodes through Week 50 and compare the efficacy of oteseconazole and fluconazole in treatment of an acute VVC episode in RVVC subjects.

Methods. 219 subjects with history of RVVC (≥ 3 acute episodes within prior 12 months) were enrolled at 51 US sites. The study consisted of two phases. Induction Phase: Subjects who presented with a vulvovaginal signs and symptoms score of ≥ 3 and positive KOH test identifying Candida were randomized to either: • 600 mg oteseconazole on Day 1, 450 mg oteseconazole on Day 2 and matching placebo capsules; OR • 3 sequential 150 mg doses (every 72 hours) of over-encapsulated fluconazole together with matching placebo capsules

Maintenance Phase: 185 subjects with resolved acute VVC infections (clinical signs and symptoms score of < 3) on Day 14 received: • 150 mg oteseconazole or placebo weekly for 11 weeks • then 3-week Follow-up period

Results. Study achieved primary and secondary efficacy endpoints. Oteseconazole was superior to fluconazole/placebo in the proportion of subjects with ≥ 1 culture-verified acute VVC episode through Week 50 in the intent-to-treat (P < 0.001). The average percentage of subjects with ≥ 1 culture-verified acute VVC episode through Week 50 was lower in the oteseconazole group (5,1%) compared to the fluconazole/placebo group (42,2%). Oteseconazole was noninferior to fluconazole in the proportion of subjects with resolved acute VVC infections at Day 14; 93.2% oteseconazole group versus 85.8% fluconazole/placebo group. The percentage of subjects who had ≥ 1 treatment-emergent adverse event (TEAE) that was similar; oteseconazole (54%), fluconazole/placebo (64%). Most TEAEs experienced were mild or moderate severity in both groups and no drug-related SAEs or adverse effects on liver function or QT intervals.