Treatment of COVID-19 infected pregnant women with Sotrovimab

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Introduction

- Prior to the wide uptake of vaccination, pregnant women infected with SARS-COV-2 virus were identified a as risk group for severe disease. A 1.5-3x higher risk of ICU admissions was reported, in particular those with pre-existing comorbidities such as obesity.
- Of the new treatments that had emerged at the time of the delta outbreak, Passive immunization with monoclonal antibodies (mAbs) such as Sotrovimab (GlaxoSmithKline Australia Pty Ltd, a FC-modified human IgG mAB which can neutralize the SARS-CoV-2 virus and its variants in vitro, emerged at the time of the delta outbreak and appeared to show promise.

Methods

Between 1st September 2021 to 10th November 2021 65 COVID-19 positive pregnant women residing in the Nepean Blue Mountains Local Health District were admitted to the Hospital in the Home COVID-19 (HiTH-COVID) program, if well enough to be managed at home, or in-patient COVID-19 wards, if requiring hospitalisation.

Patients suitable for Sotrovimab treatment were identified through the HiTH-COVID program, Maternity COVID team review, Emergency Department presentations, and in-patient ward admissions.

All pregnant women not yet fully vaccinated (two COVID-19 vaccine doses at least 14 days prior to presentation) were regarded as being at increased risk of severe disease and suitable for Sotrovimab if within 7 days of disease onset or positive test.

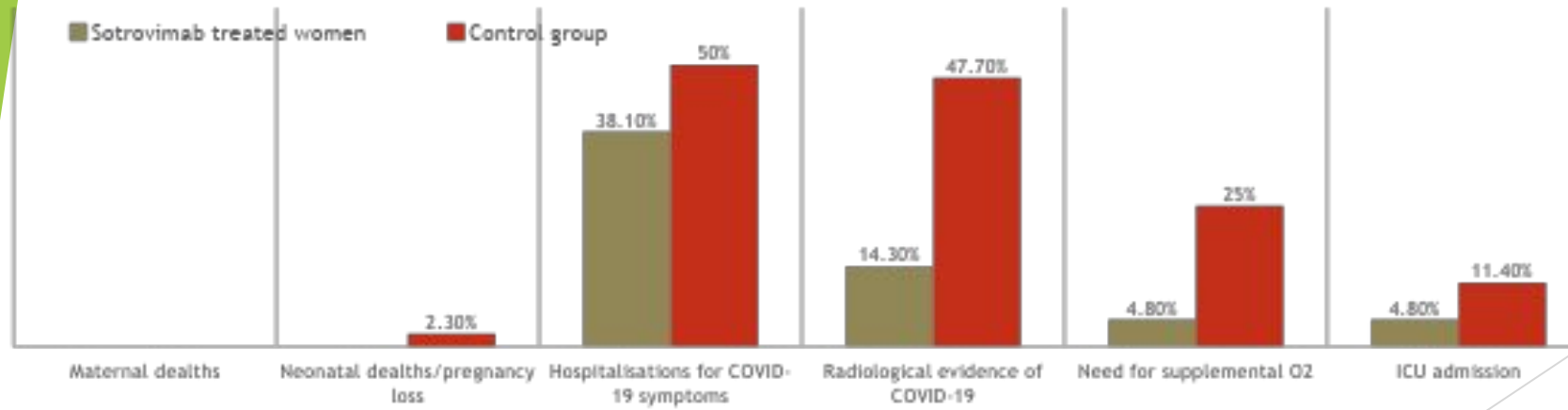
Results

- Sotrovimab was administered to 21/65 women with a GA ranging from 9-39 weeks gestation (in this period 44 women were not offered or declined Sotrovimab and acted as the control cohort).
- 14/21 (66.7%) of women had at least 1 risk factor for COVID-19 progression beyond their pregnancy
- No adverse effects were observed that could be associated with the administration of Sotrovimab.
- Two lost to follow-up
- No deaths or pregnancy losses were reported in any of the women treated with Sotrovimab
- Following administration of Sotrovimab, 8 (38%) women were still admitted hospital.
- Considerable differences were noted in the COVID-19 vaccination status of women in the untreated group compared to the Sotrovimab treatment group and this remains a confounder in the data. This was largely due to the parallel acceleration in vaccination in the community and clinician caution with the use of an unknown agent in pregnancy. 93.2% (41/44) of women not receiving Sotrovimab had not received at least a single dose of an approved COVID-19 vaccine at the time of presentation for COVID-19 compared to 57.1% (12/21) in the Sotrovimab-treatment cohort who had incomplete vaccination (all but one patient having received one dose only).
- After presentation, 22/44 patients who received Sotrovimab were hospitalized for COVID-19 symptoms and 21/44 were found to have detectable radiological evidence of COVID-19. 11 women required supplemental O2 with 5/44 women requiring hospital ICU admission.

Conclusion

The COVID-19 disease course amongst this group appeared to be milder with fewer appearing to progress to serious COVID-19 disease. This was despite over half of the women in this cohort having a BMI ≥ 30, a key risk factor for poor COVID-19 prognosis. This observation is consistent with the results of the initial Sotrovimab clinical trial and subsequent real-world experiences of using Sotrovimab in Australia and elsewhere, reporting reductions in rates of hospitalisation amongst at-risk COVID-19 patients treated with this mAB.

Rates of hospitalisation and death have fallen dramatically in pregnant women with the rapid uptake of vaccination and importantly the activity of mAbs appears highly variant specific. Poor activity against the subsequent omicron variants has led to mAbs playing only a very modest role in most COVID therapeutic protocols. Despite these limitations, we nevertheless note that the favorable clinical outcomes described in these women are consistent with the results of larger case-controlled studies and would suggest that mAbs should not be forgotten as potential beneficial treatment options as future variants evolve for clinicians faced with the clinical care of this difficult group.



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