1151:Retrospective Analysis of Vaccinated and Unvaccinated Monoclonal Antibody Patients and their Emergent Needs (RAVEN) and Hospital Utilization

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BACKGROUND

- In response to the COVID-19 pandemic, in fall 2020 the US Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for Monoclonal Antibody (MAB) and COVID vaccines.
- While vaccines aim to prevent patients from getting infected or developing symptoms, MAB aims to prevent patients with mild to moderate symptoms from progressing to severe disease.
- As COVID vaccination became widespread, breakthrough cases of COVID began to emerge. Unexpectedly, the administration of MAB was distributed in nearly equal proportion to vaccinated and unvaccinated patients.
- We evaluated MAB treatment outcome in vaccinated and unvaccinated patients.

METHODS

- Retrospective chart review of patients treated with MAB at a single quaternary care center in West Michigan between March 1, 2021, and November 30, 2021.
- Patients who completed 2 doses of Pfizer or Moderna or one dose of J&J vaccine were considered vaccinated.
- Outcomes were defined as:
  - number of ED visits within 14 days from MAB infusion
  - number of hospitalizations within 14 days of MAB infusion
  - severe disease development defined as ICU admission within 14 days or death within 30 days from MAB infusion
- All COVID positive patients with known vaccination history who were at least 18 years old at the time of treatment and who met EUA criteria for MAB treatment were included in the study
- Collected data included basic demographics, comorbidities, timing and location of MAB administration, vaccination status, number of ED visits, hospitalizations and ICU admissions within 14 days, and number of deaths within 30 days from MAB infusion
- Statistical analysis:
  - Data collected from unvaccinated MAB recipients and vaccinated MAB recipients were used to create models of adjusted relative risk for ED visits and hospitalizations 14 days after MAB therapy. Outcomes by adjusted relative risk were assessed with a confidence interval of 95% and a statistical significance at $p < 0.05$.

RESULTS

Characteristic	n = 3,898	
	Vaccinated n = 1,889	Unvaccinated n = 2,009
Age (Years), mean ± SD	580 ± 18.8	52.4 ± 16.4
Sex, n (%)		
Female	1,059 (56)	1,147 (57)
Male	830 (44)	862 (43)
Race, n (%)		
Caucasians	1,742 (92)	1,783 (89)
Other	110 (6)	174 (9)
Unknown	37 (2.0)	52 (3)
Disease Stage (Days from symptom onset when infused), n (%)		
Typical (1-7)	1534 (91)	1540 (77)
Late (8-10)	355 (19)	469 (23)
Location of Infusion		
Infusion Clinic	1,612 (85)	1,264 (63)
Emergency Department	151 (8)	590 (29)
Mobile Unit	126 (7)	155 (7)

Table 1: MAB Recipient Demographics, Vaccinated vs Unvaccinated. Non-Hispanic Caucasians made up majority in vaccinated and unvaccinated groups. Unvaccinated patient were treated more frequently in the ER and in the later stage of the disease

Comorbidity	Incidence, n (%)	
	Vaccinated n = 1,889	Unvaccinated n = 2,009
Elevated BMI	1,446 (76.5)	1,441 (71.7)
Hypertension	775 (41.0)	527 (26.2)
Smoker	550 (29.1)	547 (27.2)
Lung Disease	402 (21.3)	336 (16.7)
Cardiovascular Ds	380 (20.1)	243 (12.1)
Diabetes	324 (17.2)	222 (11.1)
Cancer	200 (13.8)	118 (5.9)
Immunosuppression	147 (7.8)	114 (7.2)
Chronic Kidney Ds	119 (6.3)	70 (3.5)
Neurological Condition	79 (4.2)	67 (3.3)
Pregnancy	13 (0.7)	33 (1.6)
Transplant Patient	27 (1.4)	9 (0.4)
Others	45(2.4)	34 (1.7)
Number of Comorbidities per Patient		
Zero or One	560 (37.3)	940 (62.7)
Two	566 (49.9)	569 (50.1)
Three	404 (57.5)	298 (42.5)
Four or More	359 (64)	202 (36)

Used to develop RR models;
Patients may have multiple comorbidities

Table 2: MAB Recipient Comorbidities, Vaccinated vs Unvaccinated. All comorbidities expect pregnancy were predominant in vaccinated cohort

RESULTS (continued)

Outcomes	Number of events n (%)
Deaths	12 (0.31%)
Severe Disease (ICU admission and deaths)	25 (0.64%)
Hospital Admissions	154 (3.95%)
ED Visits	296 (7.59%)

Table 3: Outcomes Following MAB Therapy. Overall Morbidity and mortality were low in MAB Recipients

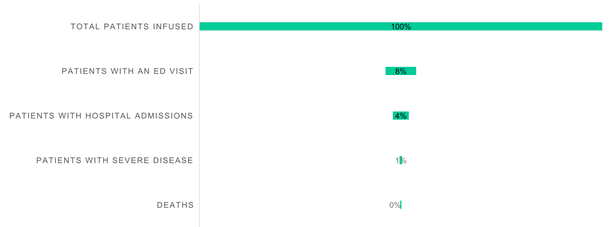
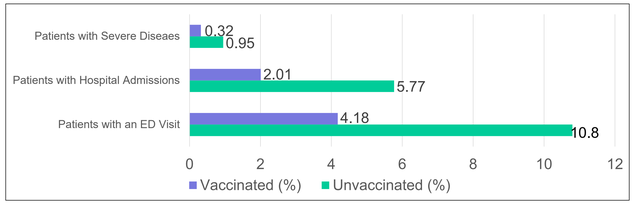


Figure 1: Outcomes Following MAB Therapy. Overall Morbidity and mortality were low in MAB Recipients

Outcomes	Vaccinated n (%)	Unvaccinated n (%)
Severe Disease	6 (0.32%)	19 (0.95%)
Hospital Admissions	38 (2.01%)	116 (5.77%)
ED Visits	79 (4.18%)	217 (10.80%)

Table 4: Outcomes following MAB therapy by Vaccination Status. Unvaccinated patients had more ER visits, hospitalizations and ICU admissions/ deaths comparing with vaccinated.



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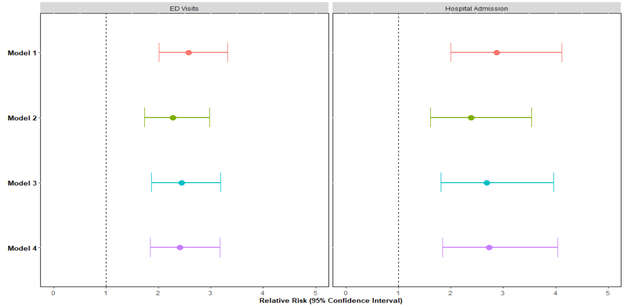

Figure 3: Relative Risk by Vaccination Status. Risk is higher in all models for ED visits and hospital admissions in unvaccinated individuals

Figure 2 Legend
- Model 1 – Unadjusted
- Model 2 – Adjusted for demographics, infusion location and stage of the disease (table 1)
- Model 3 – Model 2 Variables + Comorbidity Count
- Model 4 – Model 2 + Comorbidities

ED Visit within 14 Days	2.41 (1.84, 3.17)
Hospital Admission within 14 Days	2.73 (1.84, 4.04)

Table 5: Outcomes by Adjusted Relative Risk, 95% CI (Model 4). Compared with vaccinated patients, unvaccinated patients had a 2.41 higher risk of seeking help in the ED and a 2.73 higher risk of getting hospitalized.

DISCUSSION

- Overall, the vaccinated group had lower baseline level of health as evidenced by number of comorbidities. Despite this, the vaccinated group had a lower rate of ER visits, hospitalizations and progression to severe disease. On the other hand, unvaccinated patients were treated more frequently in the later stages of the disease and in the ER, which may suggest that they were sicker at the time of treatment.
- Study limitations include retrospective nature, data collection from a single site, limited comorbidity data to conditions determined by the EUA guidelines and lack of data on clinical presentation.

CONCLUSION

- Vaccinated patients utilized hospital resources and progressed to severe disease less frequently than unvaccinated patients suggesting that there may be a synergistic effect between MAB and vaccination.