



The Use of Immune Globulin Intravenous, Human-slra 10% Therapy in Lung Transplant Recipients

Susan Bauer, BSN, RN, CRNI, VABC¹ • Miranda Anaya, PharmD² • Marie-Chantale Simard, PhD² • Michael Fadeyi, PharmD, MS, IgCP¹
¹AOM Infusion, ²ADMA Biologics



BACKGROUND

- Lung transplant is a surgical procedure in which one or both lungs are replaced with a donor's lungs due to end-stage lung diseases such as chronic obstructive pulmonary disease (COPD), interstitial lung disease, and cystic fibrosis.¹
- Complications of lung transplant include allograft rejection and infection.²
- Immune globulins are used to manage various immunodeficiency and inflammatory conditions and can be used for hypogammaglobulinemia in lung transplant to prevent infections.³
- Immune globulin intravenous (IVIG), human-slra 10% is FDA-approved for the treatment of primary humoral immunodeficiency⁴
- IVIG, human-slra is manufactured using a blend of normal source plasma and plasma from donors with high antibody titers to respiratory syncytial virus (RSV).⁵

PURPOSE

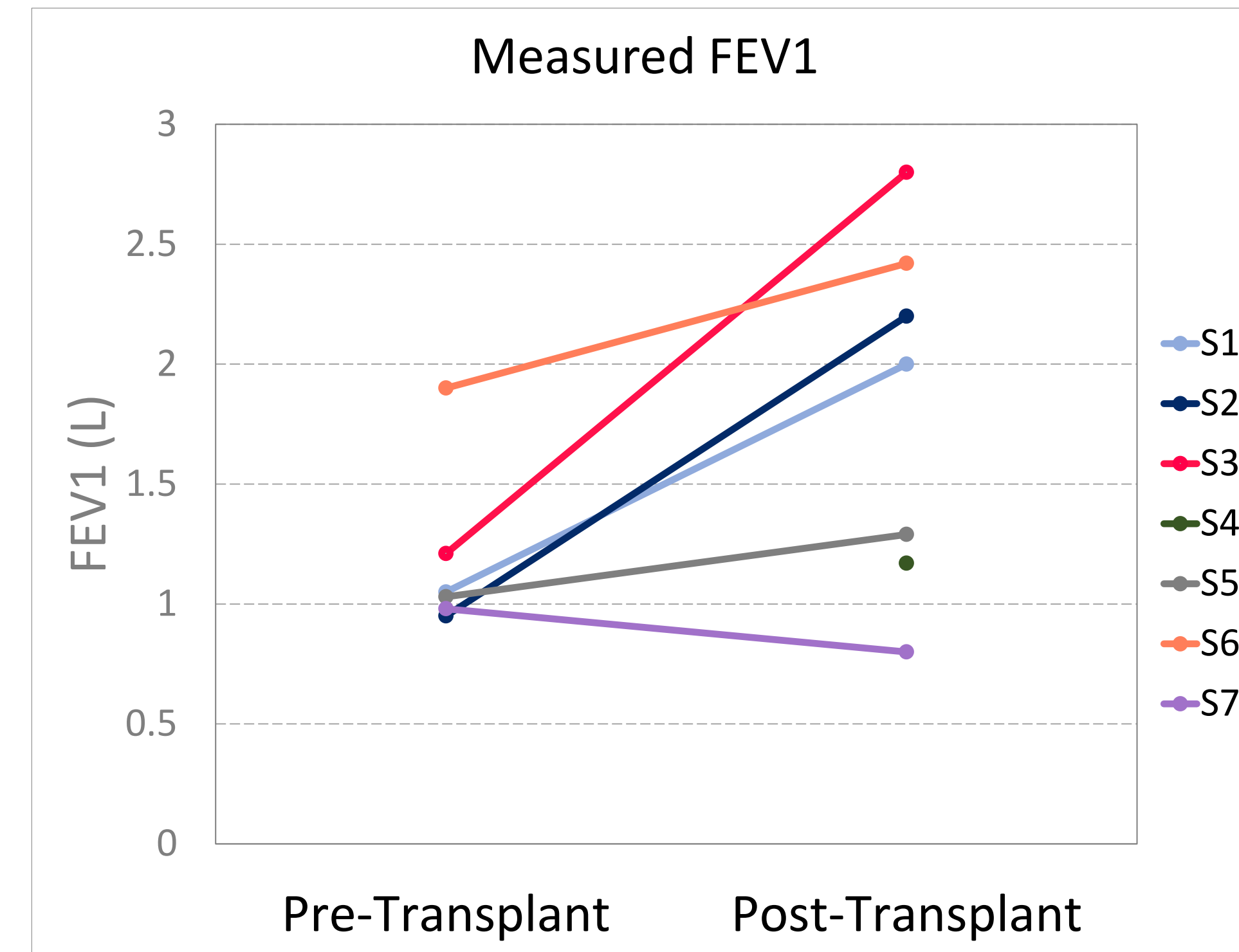
- The purpose of this study is to evaluate the use of IVIG, human-slra 10% in patients post-lung transplant.

METHODS

- This study is a retrospective chart review of 7 patients receiving a lung transplant who received IVIG, human-slra (ASCENIV™) infusions through this home infusion organization post-transplant in the United States.
- All patients received immunosuppressive agents, prophylactic antibiotics and antivirals as standard of care.

Demographics	
Total Patients, n (%)	7 (100%)
Age (median, years)	51
Single lung transplant, n (%)	6 (85.7%)
Double lung transplant, n (%)	1 (14.3%)
Diagnosis	
ILD, n (%)	4 (57%)
CLAD, n (%)	1 (14%)
Sarcoidosis, n (%)	1 (14%)
NSIP/Scleroderma, n (%)	1 (14%)

CLAD=chronic lung allograft dysfunction; ILD=interstitial lung disease; NSIP=nonspecific interstitial pneumonia.

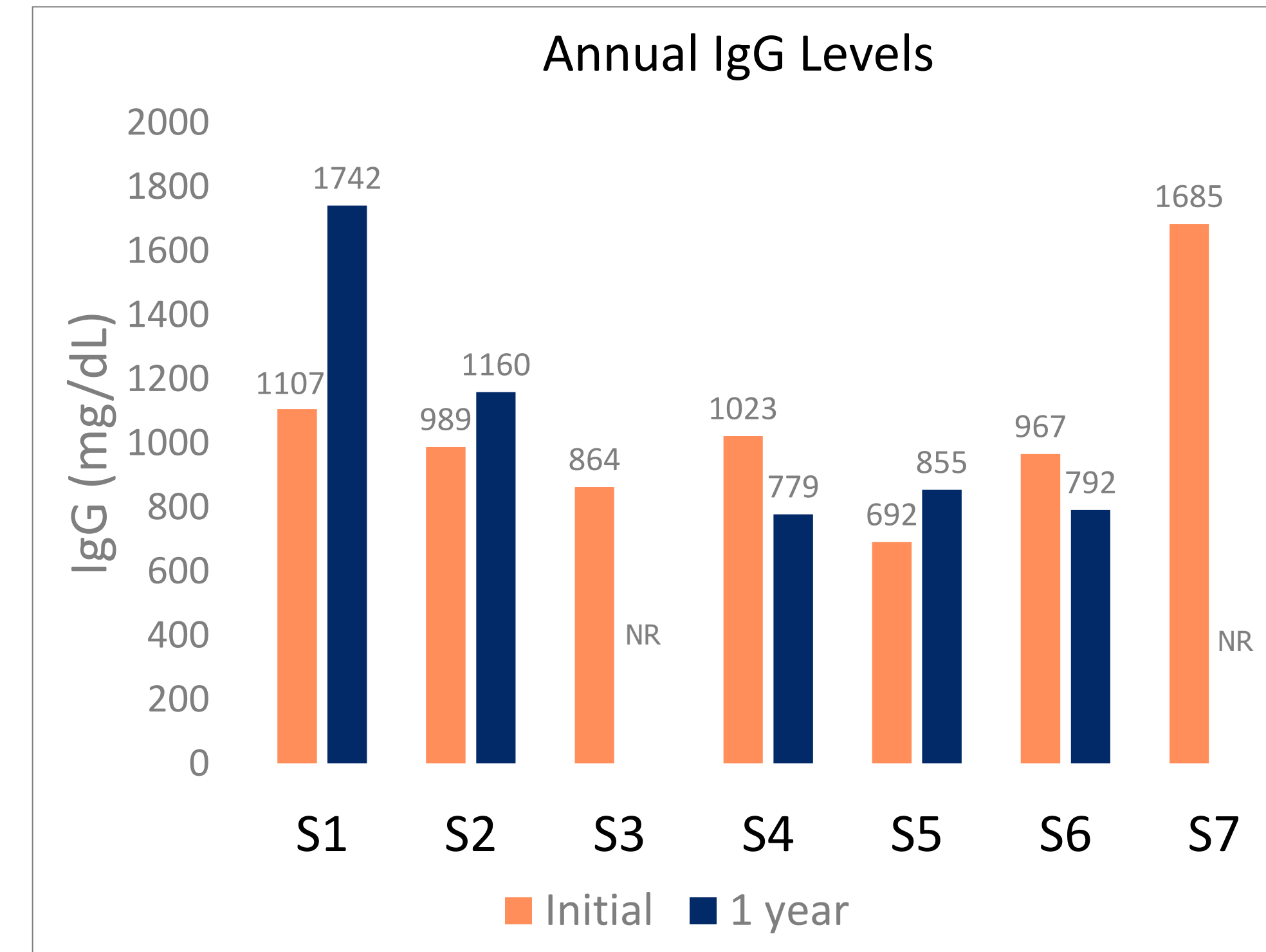


FEV1=forced expiratory volume in 1 second; L=liter; NR=not recorded; S=subject.

RESULTS

- 5 of the 7 patients were alive upon analysis, with the two deceased patients having compromised post-operative lung status.
- Three patients acquired COVID-19 post-operatively, and one required hospitalization during their course of illness. No patients had documented RSV.
- One patient had 5 hospitalizations following transplant, all unrelated to lung status.
- FEV 1/FVC showed improvement in 3 of 5 surviving patients.
- All surviving patients were able to regain the ability to exercise in varying degree with 4 of the 5 able to walk significantly outdoors or climb stairs.
- 5 of the 7 patients were on IVIG, human-slra for 1 year, while 2 were on IVIG, human-slra for 6 months. All patients tolerated IVIG, human-slra with no reported adverse events.

80% of surviving subjects presented as eupneic with normal lung sounds



dL=deciliter; IgG=immune globulin G; mg=milligram; NR=not recorded; S=subject.

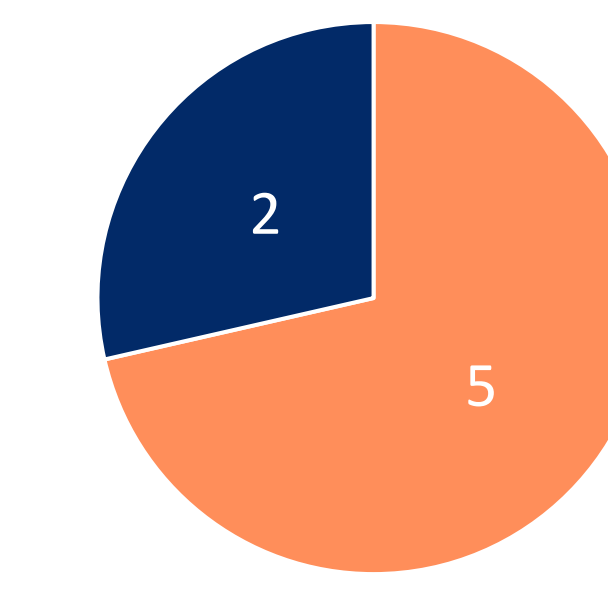
DISCUSSION

- IVIG, human-slra was used successfully in the study patients in conjunction with immunosuppressive agents and prophylactic antibiotics and antivirals.
- Restoration of lung function due to respiratory stability was present in 80% of the surviving patients evaluated.

Subject	Yrs since TX	Survived*	ISx	Infxn Px	IVIG-slra (mg/kg)
Subject 1	1.9	Yes	TAC	Vanc; VGCV	473
Subject 2	1.4	Yes	TAC	CEX; VCV	528
Subject 3	3.8	Yes	TAC	TMP-SMX; VGCV	483
Subject 4	5 [#]	No	CsA	TMP-SMX; VGCV	347
Subject 5	3.4	Yes	TAC	AZM; VGCV	308
Subject 6	0.7	Yes	TAC	TMP-SMX; VGCV	458
Subject 7	1.8 [#]	No	TAC	TMP-SMX; VGCV	606

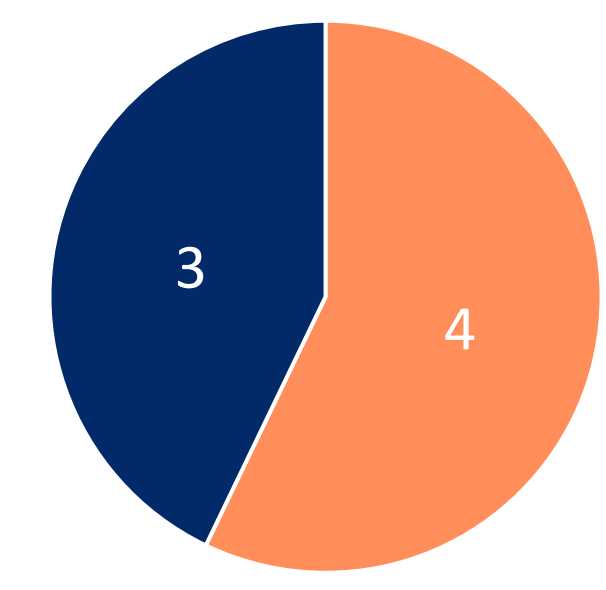
*Patients who were alive at time of analysis; #years from transplant to date of death; AZM=azithromycin; CEX=cephalexin; CsA=cyclosporine; Infxn=infection; ISx=immunosuppressant; IVIG-slra=immune globulin intravenous, human-slra; kg=kilogram; mg=milligram; Px=prophylaxis; TAC=tacrolimus; TMP-SMX=trimethoprim-sulfamethoxazole; TX=transplant; Vanc=vancomycin; VCV=valaciclovir; VGCV=valganciclovir; yrs=years.

Survival at Analysis



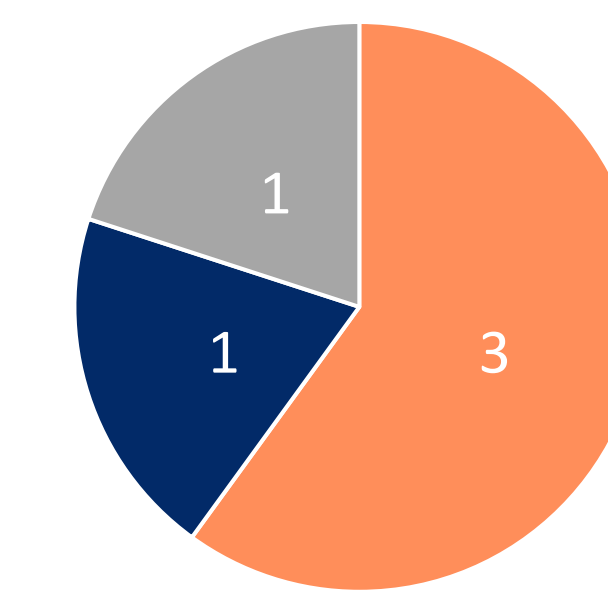
Survived* Expired

Reported Hospitalizations



Yes No

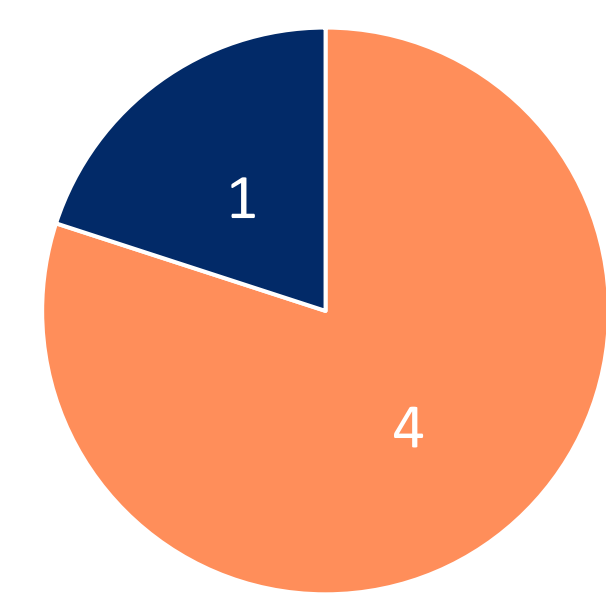
Exercise Frequency of Survivors*



Daily x4-5/wk x3/wk WNL SOB, Cough, Wheezing

*Patients who were alive at time of analysis; SOB=shortness of breath; wk=week; WNL=within normal limits.

Lung Sounds of Survivors*



CONCLUSION

- IVIG, human-slra's unique antibody composition may have a role in the effective management of patients' post-lung transplant.
- Improvement in overall lung function was noted with 80% of the surviving study patients presenting as eupneic with clear lungs and all surviving patients regaining the ability to exercise in varying degrees.

DISCLOSURES

Susan Bauer and Michael Fadeyi are paid employees of AOM Infusion who financially supported this presentation. Marie-Chantale Simard and Miranda Anaya are paid employees of ADMA Biologics.

REFERENCES

- Hachem R, et al. UpToDate. Lung transplantation: General guidelines for recipient selection. Updated Aug 30, 2024. Accessed Sep 30, 2024.
- Hachem R, et al. UpToDate. Lung transplantation: An overview. Updated May 23, 2024. Accessed Sep 30, 2024.
- Otani IM, et al. *J Allergy Clin Immunol.* 2022;149(5):1525-1560. doi:10.1016/j.jaci.2022.01.025
- ASCENIV [Immune globulin intravenous, human-slra 10%]. Prescribing information. Boca Raton, FL: ADMA Biologics. Revised March 2024.
- Orange JS, et al. *Front Immunol.* 2015;6:431. Published 2015 Aug 28. doi:10.3389/fimmu.2015.00431