assessment Of HeALth Literacy on Medication AdheRence and graft outcomes in Kidney transplant recipients (HALLMARK)

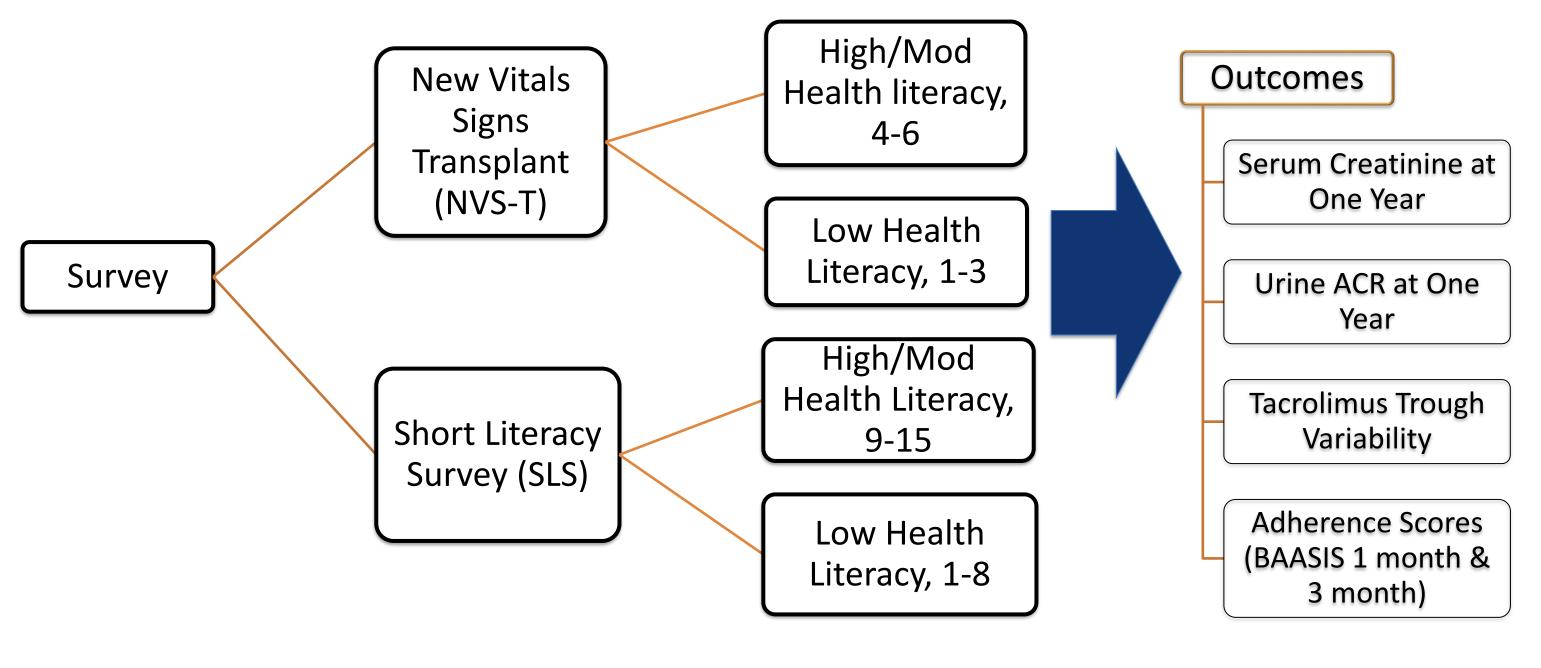
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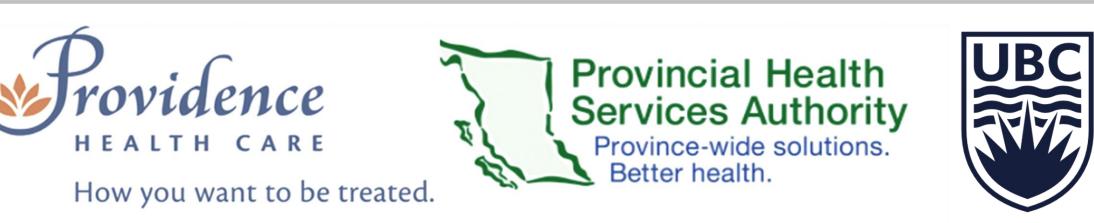
Purpose

- Our study investigated if targeted medication adherence interventions based on the health literacy level of kidney transplant recipients could improve medication adherence and graft outcomes.
- Upon successful kidney transplantation, many patients have difficulty adhering to their medication regimens.
- Previous studies have established low health literacy to be independently associated with lower immunosuppressant adherence and adverse outcomes in kidney transplant recipients.

Methods

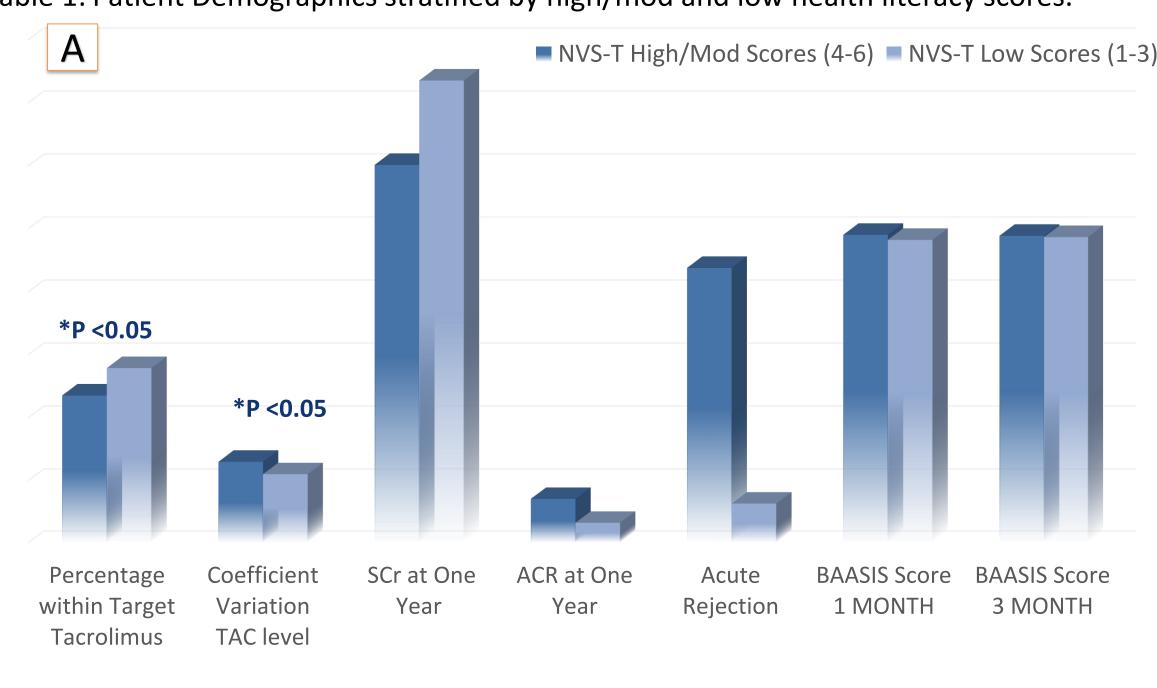
- A prospective, open label, interventional design trial in living and deceased kidney transplant recipients at a tertiary transplant center.
- ▶ Patients under the age of 18, with limited English language abilities or patients unable to complete health literacy surveys were excluded.
- Once consented, patients were administered validated health literacy tests: New Vital Signs-Transplant (NVS-T) & Short Literacy Survey (SLS).
- Tacrolimus trough level variability (coefficient variation and percentage within target), graft function (serum creatinine, urine ACR), # acute rejections and target adherence scores were collected.
- Targeted interventions were provided to low health literacy groups based on needs, e.g. adherence device, daily dispense, caregiver support, simplified materials and/or enhanced counselling
- Adherence rates and clinical outcomes were compared with high/moderate and low health literacy groups.





Results

Baseline Characteristics	NVS		SLS		
	High/mod (4-6)	Low (<4)	High/Mod (9-15)	Low (1-8)	
Age	53 ± 14	57 ± 11	52 ± 14	63 ± 9	
Sex					
Female	25	2	26	1	
Male	70	9	75	4	
Race					
Black	2	0	2	0	
White	60	4	60	3	
Asian Oriental	11	3	12	2	
Middle Eastern/Arabian	5	0	5	0	
Filipino	6	2	8	0	
Asian Indian	8	1	9	0	
North American Indian	3	1	4	0	
Comorbidities					
Transient Ischemic Attack (TIA)	1	0	1	0	
Cerebrovascular Accident (CVA)	5	0	5	0	
Diabetes	29	4	31	2	
Seizures	2	0	2	0	
Depression	9	2	10	1	



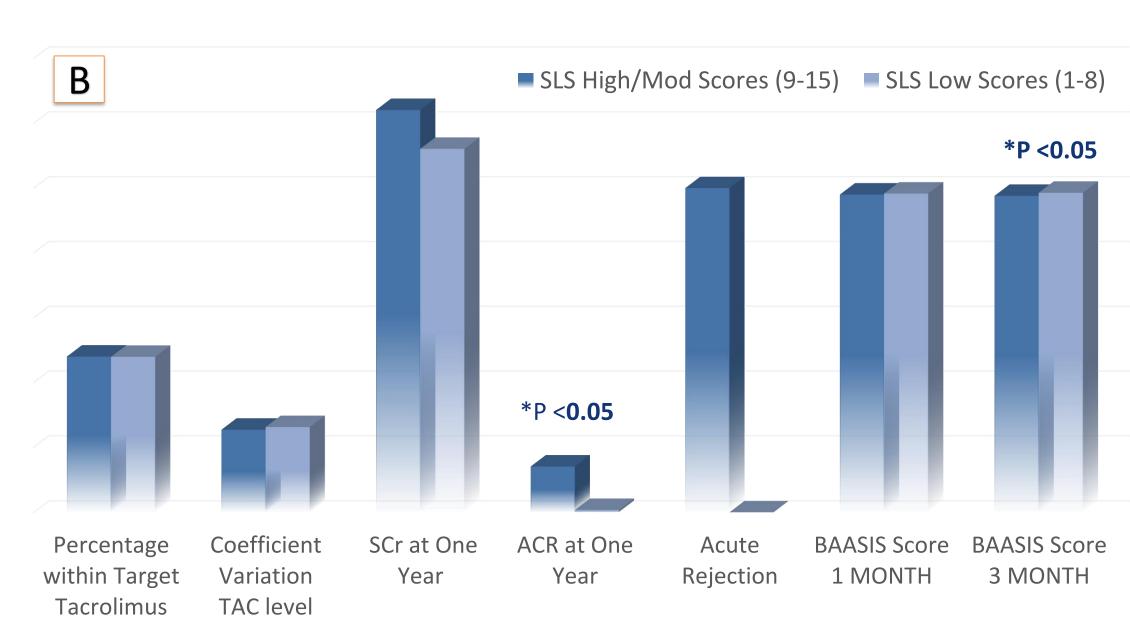


Figure 1: Outcomes between high and low health literacy scores. Figure 1A: NVS-T Score; Figure 1B: SLS scores

* t-test; BASSIS = The Basel Assessment of Adherence to Immunosuppressive Medication Scale

- One hundred and six patients were included for analysis (75.4% men, 24.5% women).
- Patients were stratified by high/mod or low literacy based on NVS and SLS scores (Table 2).
- Higher % within target tacrolimus levels and lower tacrolimus variation in low NVS score group.
- No statistically significant difference was found in terms of tacrolimus level variability between SLS groups. Higher BAASIS scores and lower urine ACR was found in low SLS score group.

	High NVS Scores, 4-6 (n=93)	Low NVS Score, 1-3 (n= 13)	p-value	High SLS Scores, 10- 15 (n=98)	Low SLS, 1-9 (n=8)	p-value
% within Target Tacrolimus [†]		59.1%	0.032	47.5%	54.44%	0.379
Tacrolimus Level Coefficient Variations*	25.9	20.0	0.0476	25.3	24.0	0.842
SCr at 1 Year (µmol/L)	119 ± 32	149 ± 43	0.0526	123 ± 37	112 ± 34	0.422
ACR at 1 Year (mg/mmol)	14 ± 41	7.1 ± 7	0.223	14 ± 40	0.72 ± 0.4	0.004
# Acute Rejection	7 (87.5%)	1 (12.5%)		8 (100%)	0 (0%)	
BAASIS Adherence Score 1 Month Post-Transplant**	98.2%	96.1%	0.188	98.0%	97.5%	0.843
BAASIS Adherence Score 3 Month Post-Transplant*‡	97.8%	97.0%	0.728	97.5%	99.96%	3.63E-05

Table 2: Outcomes between high and low health literacy scores (data presented in averages). *n= 104 for BAASIS 1- month. n= 87 for BAASIS 3- month; n=104 for tacrolimus level coefficient variation & % within target tacrolimus level. [†] Target tacrolimus level was defined as 5-7µg/L. for 6-12 months post-transplant

Limitations

- Small sample size enrolled in the low health literacy category, NVS-T (n=11) and SLS (n=5).
- Participation was optional Patients with low or marginal health literacy scores may not have been inclined to participate.
- Targeted interventions in the low health literacy group were provided at the discretion of the post-transplant team and not clearly captured.

Conclusion

- Some clinical outcomes appeared to be better in kidney transplant recipients with low health literacy scores after targeted interventions; however, the small sample size and discordant results between NVS-T and SLS low health literacy groups limit interpretation of the study results.
- We hope this study will encourage further studies to establish the role of health literacy in both adherence and ultimately kidney graft function