

Relationship Between Patient-Perceived Treatment Burden and Health-Related Quality of Life in Heart Transplant Recipients

Kimberly M. Deininger, MPH¹, Jan D. Hirsch, BSPHarm, PhD², Sarah A. Graveline, BS², Ashley A. Feist, PharmD², Steven M. Smith, PharmD, MPH³, Jennifer A. Reich, PhD¹, Joanne LaFleur, PharmD, MSPH⁴, Amrut V. Ambardekar, MD¹, JoAnn Lindenfeld, MD⁵, Christina L Aquilante, PharmD¹

¹University of Colorado Schools of Pharmacy and Medicine, Aurora, Colorado; ²University of California San Diego School of Pharmacy, La Jolla, California.; ³University of Florida College of Pharmacy, Gainesville, Florida; ⁴University of Utah College of Pharmacy, Salt Lake City, Utah; ⁵Vanderbilt Heart and Vascular Institute, Vanderbilt University, Nashville, Tennessee.

INTRODUCTION

- Patient-perceived treatment burden is a patient’s overall estimation of the burden their chronic disease treatment regimen imposes on them and their family [1].
— Often referred to as the “work of being a patient” [2,3].
- Treatment burden is influenced by patient and treatment characteristics, disease conditions, support systems, and the healthcare system [1-5].
— Influences health-related decisions, treatment adherence, resource utilization, and personal relationships [1].
- Health-related quality of life (HrQOL) is a patient's perceptions of their mental and physical health and correlates (e.g., health risks and conditions, functional status, social support, and socioeconomic status) [6].
— Improves from pre- to post-heart transplant (HTx), but decreases over time [7].
— Poor HrQOL is associated with depression in HTx patients [8].
- Few studies have comprehensively evaluated treatment burden and its relationship to HrQOL in transplant recipients.

OBJECTIVE

To evaluate the relationship between patient-perceived treatment burden and self-reported HrQOL in adult heart transplant recipients.

METHODS

- **Study design:** Cross-sectional multi-center study.
- **Study sites:** University of Colorado and University of California San Diego.
- **Study population:**
 - Inclusion criteria: Heart transplant recipients 18-90 years of age; 18 years of age or older at the time of transplant.
 - Exclusion criteria: Combined organ transplant (e.g., heart and kidney); re-transplantation.
- **Data collection:** Single study visit during which patients were administered the following two questionnaires in random order.

Treatment Burden Questionnaire (TBQ)

- Validated 15-item questionnaire published by Tran et al. in 2012 [9].
- Developed in patients with chronic diseases (e.g., diabetes, hypertension).
- Measures degree of burden regarding:
 - Medications;
 - Medical follow-up;
 - Administrative burden;
 - Financial burden; and
 - Lifestyle changes.
- Each question is scored on a scale of 0 (not a problem) to 10 (big problem).
 - Total possible score is 150.

2. Regarding your medical follow-up, how would you rate the constraints related to:

A. Lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated nuisances or inconveniences

Does not apply

Not a problem

0

1

2

3

4

5

6

7

8

9

10

Big problem

B. Self-monitoring (sugar): frequency

Does not apply

Not a

0

1

2

3

4

5

6

7

8

9

10

Big problem

C. Doctor visits as difficulties find

Does not apply

Not a

0

1

2

3

4

5

6

7

8

9

10

Big problem

D. The difficulties (for example: if)

Does not apply

Not a

0

1

2

3

4

5

6

7

8

9

10

Big problem

E. Arranging med

Does not apply

Not a

0

1

2

3

4

5

6

7

8

9

10

Big problem

F. The necessary precautions when taking your medication (for example: taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down...)

Does not apply

Not a problem

0

1

2

3

4

5

6

7

8

9

10

Big problem

Short Form-12v2 Health Survey (SF-12v2)

- Validated 12-item questionnaire published by Ware et al. in 2002 [10].
- Measures functional health and well-being in eight domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health.
- Questions answered in rating scales which are transformed to mental component summary (MCS) and physical component summary (PCS) scores.
 - Scored on a scale of 1-100, higher scores represent greater HrQOL.

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

All of the time

Most of the time

Some of the time

A little of the time

None of the time

Accomplished less than you would like

Were limited in the kind of work or other activities you could do

Accomplished less than you would like

Did work or other activities less carefully than usual

5. During the past 4 weeks (including both work and non-work activities), how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your emotional health?

All of the time

Most of the time

Some of the time

A little of the time

None of the time

Accomplished less than you would like

Were limited in the kind of work or other activities you could do

Accomplished less than you would like

Did work or other activities less carefully than usual

Accomplished less than you would like

Were limited in the kind of work or other activities you could do

Accomplished less than you would like

Did work or other activities less carefully than usual

- **Statistical analysis:**
 - Correlation analysis was used to determine relationships between TBQ score, SF-12v2 MCS and PCS, and patient characteristics.

RESULTS

Table 1: Description of study cohort

Characteristic	n=102
Study site	
• University of Colorado	82 (80.4%)
• University of California	20 (19.6%)
Caucasian race	74 (72.6%)
Men	78 (76.5%)
Age on day of study consent, years	56 ± 13 (21-84)
Age at transplant, years	49 ± 13 (19-70)
Time post-transplant on day of consent, years	7.2 ± 7.0 (0.1-27)
Transplant Medications	
• Tacrolimus	66 (64.7%)
• Cyclosporine	34 (33.3%)
• Mycophenolate	85 (83.3%)
• Azathioprine	9 (8.8%)
• Prednisone	40 (39.2%)
• mTOR Inhibitor	18 (17.6%)
Total medication count	16 ± 5 (7-30)
Employed	41 (40.2%)
Married/living with partner	71 (69.6%)

Data are presented as n (%) or mean ± SD (range).

Table 2: Description of treatment burden and HrQOL characteristics

Questionnaire	Measurement	Score
TBQ	Treatment Burden	24.3 ± 21.1 (0-108)
SF-12v2	Quality of Life-Mental Component	53.2 ± 8.8 (28.4-68.1)
	Quality of Life-Physical Component	44.7 ± 10.3 (16.7-62.0)

Data are presented as mean ± SD (range). TBQ, Treatment Burden Questionnaire; SF-12v2, Short-Form 12v2 Health Survey.

Table 3: Patient factors correlated with treatment burden or HrQOL

Questionnaire	Patient Characteristic	Spearman’s Rho	P Value
TBQ Score	Age on day of study consent	-0.30 ^a	0.002
SF-12v2 MCS	Age on day of study consent	0.27 ^b	0.006
SF-12v2 PCS	Employment status (i.e., employed vs not)	0.31 ^c	0.001

TBQ, Treatment Burden Questionnaire; SF-12v2, Short-Form 12v2 Health Survey; MCS, mental component summary; PCS, physical component summary. ^aOlder age correlated with lower treatment burden; ^bOlder age correlated with higher mental quality of life; ^cBeing employed correlated with higher physical quality of life compared to not being employed.

Table 4: Relationship between treatment burden and HrQOL

Correlation with TBQ Score	Adjusted Spearman’s Rho	Adjusted P Value
SF-12v2-MCS	-0.39 ^a	<0.0001
SF-12v2-PCS	-0.20 ^b	0.049

TBQ, Treatment Burden Questionnaire; SF-12v2, Short-Form 12v2 Health Survey; MCS, mental component summary; PCS, physical component summary. ^aAdjusted for age on day of study consent; ^bAdjusted for age on day of study consent and employment status (i.e., employed vs not).

CONCLUSIONS

- Greater treatment burden was associated with lower patient-reported mental HrQOL after adjusting for age on day of study consent.
- Greater treatment burden was modestly associated with physical HrQOL after adjusting for age on day of study consent and employment status (i.e., employed vs not).
- Assessment of patient-perceived treatment burden may be helpful in identifying patients who are in need of intensified mental health interventions following HTx.

REFERENCES

1. Sav et al. Health Expect. 2015;18(3):312-324.

2. May et al. BMJ. 2009;339:b2803.

3. Eton et al. Patient Relat Outcome Meas. 2012;3:39-49.

4. Eton et al. Patient Relat Outcome Meas. 2015;6:117-126.

5. Gallacher et al. PLoS Med. 2013;10(6):e1001473.

6. Yin et al. PHM. 2016;14:22.

7. Czyżewski et al. Ann Transplant. 2014;19:288-294.

8. Fusar-Poli et al. JHLT. 2005;24(12):2269-2778.

9. Tran et al. BMC Medicine. 2014;12:109.

10. Ware et al. Lincoln, RI: Quality Metric Inc. 2002.

RELEVANT FINANCIAL RELATIONSHIP DISCLOSURES

I will not discuss off label use and/or investigational use of **any** drugs/devices. The following relevant financial relationships exist related to this presentation: KMD, JDH, SAG, AAF, SMS, JAR, JL, AVA, JL: No relationships to disclose. CLA: Principal Investigator of ALSAM Foundation Skaggs Scholars Program Grant, which funded the study.

ACKNOWLEDGEMENTS

Study funded by The ALSAM Foundation Skaggs Scholars Program grant at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences. Email for correspondence: christina.aquilante@ucdenver.edu.