

# Psychosocial factors and medication adherence among recipients of vascularized composite allografts

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## Abstract

**Objectives:** Psychosocial factors are important predictors of medication adherence, and subsequently graft survival, in solid organ transplantation. Early experiences suggest this may also be the case in vascularized composite allotransplantation.

**Methods:** Using validated tools, we surveyed upper extremity transplant recipients at two centers to assess depression (Patient Health Questionnaire-9), personality (Ten-Item Personality Inventory), anxiety (Generalized Anxiety Disorder 7-Item Scale), post-traumatic stress disorder (Primary Care Post-Traumatic Stress Disorder Screen for *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition), and social support (Multidimensional Scale of Perceived Social Support). Medication adherence among vascularized composite allotransplantation recipients at two centers was assessed by a member of the clinical research team using the recipients' medical records.

**Results:** Medication adherence was reported for 12 vascularized composite allotransplantation recipients, and 9 vascularized composite allotransplantation recipients completed psychosocial assessments. Most recipients were believed to be adherent to their immunosuppression, however, three recipients were believed to be non-adherent and a member of the clinical team had discussed non-adherence at least once with five recipients. Results from the psychosocial assessment (n=9) indicated that eight participants had high levels of social support, and eight demonstrated high levels of conscientiousness which have been associated with better medication adherence in solid organ transplantation. However, three participants demonstrated mild anxiety, two demonstrated minimal symptoms of depression, and one demonstrated post-traumatic stress disorder which have been associated with worse medication adherence in solid organ transplantation.

**Conclusion:** These findings lay the groundwork for future assessments of the role psychosocial factors play in facilitating medication adherence and broader transplant outcomes.

## Keywords

Psychosocial, medication adherence, vascularized composite allotransplantation

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## Introduction

In 1998, a French team completed the first hand transplant with advances in microsurgery and immunosuppression medication. Though the operation was initially successful, the transplanted graft was removed just 29 months after the original surgery due to medication non-adherence.<sup>1</sup> As vascularized composite allotransplantation (VCA) continues to emerge as an alternative to prostheses or traditional reconstructive surgery, the same concerns from the 1998 case (medication adherence and the more general psychosocial impact) have risen in parallel with the growth of VCA.

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Given early experiences with non-adherence and graft loss among VCA recipients, there is interest in identifying measurable psychosocial factors that predict non-adherence.<sup>2-4</sup> Like solid organ transplantation (SOT), VCA outcomes depend on immunological, surgical, and psychosocial factors. Due to the novelty of VCA, researchers have used SOT as a comparative model for understanding VCA outcomes. In SOT, social support, conscientiousness scores, and mental health factors were observed to be associated with post-transplant medication adherence.<sup>5-7</sup> These and other psychosocial factors may be of greater concern among VCA recipients, as many have faced psychological traumas or stigmatization prior to their transplant.<sup>8-11</sup>

Nevertheless, prior research focuses on the functional and sensory outcomes of VCA, while psychosocial outcomes and their relationship to immunosuppression adherence remain understudied.<sup>3,10</sup> An improved understanding of the interplay between psychosocial factors and outcomes following VCA could guide clinicians in assessing risk in VCA candidates and recipients. This study aims to characterize recipient psychological factors, social support, and medication adherence following VCA.

## Methods

### Study population and design

VCA recipients at two centers were referred to the study by a care provider. Recipients of any VCA organ at any time were eligible. De-identified transplant and medication adherence information was provided by a member of the transplant team for all eligible participants. Recipients were then recruited by phone to complete the psychosocial assessment; transplant and medication adherence information was identified and linked to psychosocial assessments for those participants who consented to the study. This study was approved by the Johns Hopkins Medicine Institutional Review board (IRB00126651).

### Psychosocial assessment

Psychosocial factors were measured using validated tools administered by phone (Appendix 1). Tools were selected based on their use in SOT and/or VCA, and with the intention of minimizing participant burden. The Patient Health Questionnaire (PHQ-9)<sup>8,12</sup> was used to assess depression, the Ten-Item Personality Inventory<sup>13</sup> was used to assess personality traits, the Generalized Anxiety Disorder 7-Item Scale<sup>14</sup> was used to assess anxiety, the primary post-traumatic stress disorder (PTSD) screen for *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5)<sup>15</sup> was used to assess post-traumatic stress, and the Multidimensional Scale of Perceived Social Support<sup>12,16</sup> was used to assess social support.

### Medication adherence assessment

Medication adherence was reported by a member of the clinical research team using the patient's medical record. The clinical research team member completed a form for each participant (Appendix 2) that described the patient's demographic information, transplant background (including year, organ type, graft loss, and number of rejection episodes), immunosuppressive information (including patient's insurance status and single- vs multi-drug regimen), comorbidities (using the Charlson Comorbidity Index) and a medication adherence assessment. Adherence was assessed by asking the clinical research team member to review the patient's medical record and report any indications that the patient is not adhering to their immunosuppressive medication regimen (including erratic immunosuppression levels, frequent rashes, resistance to having labs drawn, and rejection episodes unresponsive to steroids), and whether or not a member of the clinical team has discussed non-adherence with the patient. Clinical research team members were also asked to rate each patient's overall medication adherence on a Likert-type scale from not at all adherent to completely adherent.

### Statistical analysis

Descriptive analyses were performed using Stata 14.0/MP for Linux (College Station, Texas, USA).

## Results

### Study population

Medication adherence and demographic information was reported for 14 participants, and psychosocial assessments were completed by nine participants. All VCA recipients were Caucasian (n=14), and most were male (n=13, 93%).

### Transplant background

Median (interquartile range (IQR)) years since transplant was 8.5 (5–11), and most received upper extremity transplants (n=13, 93%). Median (IQR) number of rejection episodes was 5 (2–10), but few participants had lost their VCA graft (n=2, 14.3%). Most recipients were covered by private insurance (n=10, 71%), and most were on a multi-drug immunosuppressive regimen (n=10, 71%).

### Medication adherence

Most recipients were believed to be adherent to their immunosuppressive medication (n=11, 79%), but three were believed to be non-adherent (21%). Providers reported

frequent rashes and resistance to having labs drawn in one recipient and episodes of confusion leading to non-adherence in a second recipient. Non-adherence was suspected in the third patient based on communication from their spouse. All participants suspected of being non-adherent were on multi-drug regimens, but no statistically significant difference in adherence was detected when comparing multi- and single-drug regimens ( $p=0.5$ ).

Providers had discussed non-adherence with five recipients, and providers rated all participants as either completely adherent ( $n=9$ , 64%) or mostly adherent ( $n=5$ , 36%).

### **Psychosocial factors**

A majority of participants ( $n=6$ , 67%) exhibited no symptoms of depression. However, two participants (22%) exhibited minimal symptoms and one participant (11%) exhibited minor depression/mild major depression. Likewise, a majority of participants ( $n=5$ , 56%) were observed to have no anxiety, while four participants (44%) exhibited mild anxiety. One participant screened positive for PTSD (11%).

Most participants ( $n=8$ , 89%) reported high levels of social support, whereas one participant (11%) reported only moderate social support. High levels of conscientiousness were observed in eight participants (89%), high levels of emotional stability and openness to experiences were observed in six participants (67%), high levels of extraversion and agreeableness were observed in five participants (56%).

### **Discussion**

In this study of the psychosocial factors affecting VCA recipients, 21% were believed to be non-adherent to their immunosuppression medication. At least minimal symptoms of depression were observed in 33% of participants, 44% exhibited mild anxiety, and one screened positive for PTSD. We found that most participants in this study (89%) had high levels of social support and high levels of conscientiousness (89%).

The high levels of social support and conscientiousness among VCA recipients in this study are promising, as prior studies have found social support and conscientiousness to be important factors in predicting medication adherence. A prospective study of 141 lung, heart, and liver transplant recipients in Belgium found that lower levels of conscientiousness and social support pre-transplant were associated with worse medication adherence post-transplant.<sup>5</sup> Likewise, a systematic review of 37 articles regarding adherence in kidney transplant recipients

found that low social support was significantly associated with non-adherence.<sup>6</sup>

By contrast, the higher prevalence of depression and anxiety may be of some concern. A single-center study of 51 heart transplant recipients found that patients with pre-transplant depression were 3.5 times more likely to be non-adherent post-transplant.<sup>7</sup> Likewise, the systematic review of kidney transplant recipients found depression and anxiety to predict medication adherence; severity of depression was also positively correlated with non-adherence.<sup>6</sup> While at least some symptoms of depression were reported in 33% of participants in our study, no participants exhibited major depression.

Current evaluation of VCA candidates includes rigorous psychosocial screening. Whereas some VCA candidates are recommended for exclusion on the basis of mental health conditions such as personality disorders, psychosis, or a history of suicide, other potential participants with history of mood disorder, anxiety, or bereavement have no reason to be excluded.<sup>8</sup> Determining which factors should be considered in VCA evaluation requires an understanding of, first, the prevalence of psychosocial factors in VCA candidates and recipients, and second, the relationships between those factors and transplant outcomes.

This study has several limitations. First, the small sample size limited our ability to test associations between the psychosocial factors, adherence, and transplant outcomes. However, only approximately 80 VCA transplants had been reported in the United States at the time these surveys were performed.<sup>17</sup> Second, data were collected retrospectively post-transplant, whereas candidate eligibility should assess psychosocial factors pre-transplant. Future work should prospectively assess psychosocial factors and medication adherence throughout the VCA evaluation, transplantation, and recovery process. Finally, the psychosocial evaluation undergone by VCA candidates is more rigorous than that of SOT candidates;<sup>18</sup> therefore, the overall levels of psychosocial concerns may be lower in this population, and comparisons with solid organ recipients may be biased.

In conclusion, this study characterized psychosocial factors and medication adherence among VCA recipients at two transplant centers. While VCA recipients in this study had high levels of social support and conscientiousness, depression and anxiety may yet be of concern in this population. These findings lay the groundwork for future assessments of the role psychosocial factors play in facilitating medication adherence and broader transplant outcomes. Such an understanding may inform VCA candidate evaluation, as well as interventions to improve psychosocial well-being and medication adherence, potentially reducing cost of care and improving graft life for VCA recipients (Table 1).

**Table 1.** Characteristics of the study population.

Participant demographics (n = 14)	
Caucasian	14 (100%)
Male	13 (93%)
≥1 comorbidity	9 (64%)
Transplant and adherence background (n = 14)	
Years since transplant (median (IQR))	8.5 (5–11)
Lost VCA graft	2 (14.3%)
Episodes of rejection (median (IQR))	5 (2–10)
Private insurance	10 (71%)
Indications of non-adherence	3 (21%)
Providers have discussed non-adherence	5 (36%)
Extent of adherence	
Completely	9 (64%)
Mostly	5 (36%)
Multi-drug immunosuppressive regimen	10 (71%)
Psychosocial factors (n = 9)	
Depression	
No symptoms	6 (67%)
Minimal symptoms	2 (22%)
Minor depression/major depression, mild	1 (11%)
Major depression, moderately severe	0
Major depression, severe	0
Anxiety	
No anxiety	5 (56%)
Mild anxiety	4 (44%)
Moderate anxiety	0
Severe anxiety	0
Personality traits (high levels)	
Emotional stability	6 (67%)
Extraversion	5 (56%)
Openness to experiences	6 (67%)
Agreeableness	5 (56%)
Conscientiousness	8 (89%)
Social support	
Moderate support	1 (11%)
High support	8 (89%)
Post-traumatic stress disorder	1 (11%)

IQR: interquartile range; VCA: vascular composite allotransplantation.

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The analyses described here are the responsibility of the authors alone and do not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products or organizations imply endorsement by the US government.

### Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr M.L.H. is a member of the Board of Directors of the Organ Procurement and Transplantation Network, and the United Network for Organ Sharing. The authors of this manuscript have no other conflicts of interest to disclose as described by the journal *Vascularized Composite Allotransplantation*.

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## Appendix I

### Psychosocial assessment

#### Demographics

1. Please indicate the highest level of education you have completed:
  - a. Less than high school
  - b. High school or GED
  - c. Associate's degree
  - d. Bachelor's degree
  - e. Graduate degree
2. Are you currently employed?
  - a. Yes, part time
  - b. Yes, full time
  - c. No
  - d. No, on disability
  - e. Retired
3. What is your combined annual household income?
  - a. \$0–19,999
  - b. \$20,000–39,999
  - c. \$40,000–59,000
  - d. \$60,000–79,999
  - e. \$80,000–99,999
  - f. \$100,000–119,999
  - g. \$120,000–139,999
  - h. \$140,000–159,999
  - i. >\$160,000
4. Is all or part of this from disability?
  - a. Yes
  - b. No
5. What is your marital status?
  - a. Single
  - b. Married
  - c. Co-habiting
  - d. Divorced

#### Generalized Anxiety Disorder 7-Item Scale

Over the last 2 weeks, how often had you been bothered by the following problems?

1. Feeling nervous, anxious or on edge
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
2. Not being able to stop or control worrying
  0. Not at all
  1. Several days

2. More than half the days
3. Nearly every day
3. Worrying too much about different things
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
4. Trouble relaxing
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
5. Being so restless that it is hard to sit still
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
6. Becoming easily annoyed or irritable
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
7. Feeling afraid as if something awful might happen
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day

#### Patient Health Questionnaire-9

Over the last 2 weeks, how often have you been bothered by any of the following problems?

1. Little interest or pleasure in doing things
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
2. Feeling down, depressed or hopeless
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
3. Trouble falling or staying asleep, or sleeping too much
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day

4. Feeling tired or having little energy
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
5. Poor appetite or overeating
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
7. Trouble concentrating on things, such as reading the newspaper or watching television
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
8. Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
9. Thoughts that you would be better off dead or hurting yourself in some way
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day

#### Ten-Item Personality Inventory

Here are a number of personality traits that may or may not apply to you. Please write a number next to each statement to indicate the extent to which you agree or disagree with that statement. You should rate the extent to which the pair of traits applies to you, even if one characteristic applies more strongly than the other

- 1=Disagree strongly
- 2=Disagree moderately
- 3=Disagree a little
- 4=Neither agree nor disagree
- 5=Agree a little
- 6=Agree moderately
- 7=Agree strongly

I see myself as:

1. \_\_\_\_\_ Extraverted, enthusiastic.
2. \_\_\_\_\_ Critical, quarrelsome.
3. \_\_\_\_\_ Dependable, self-disciplined.
4. \_\_\_\_\_ Anxious, easily upset.
5. \_\_\_\_\_ Open to new experiences, complex.
6. \_\_\_\_\_ Reserved, quiet.
7. \_\_\_\_\_ Sympathetic, warm.
8. \_\_\_\_\_ Disorganized, careless.
9. \_\_\_\_\_ Calm, emotionally stable.
10. \_\_\_\_\_ Conventional, uncreative.

#### Primary Care PTSD Screen for DSM-5

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you:

1. Have had nightmares about it or thought about it when you did not want to?

YES/NO

2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?

YES/NO

3. Were constantly on guard, watchful, or easily startled?

YES/NO

4. Felt numb or detached from others, activities, or your surroundings?

YES/NO

*Current research suggests that the results of the PC-PTSD should be considered “positive” if a patient answers “yes” to any three items.*

#### Multidimensional Scale of Perceived Social Support

Instructions: We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement.

- 1=Very Strongly Disagree
- 2=Strongly Disagree
- 3=Mildly Disagree
- 4=Neutral
- 5=Mildly Agree

6=Strongly Agree

7=Very Strongly Agree

1. \_\_\_\_\_ There is a special person who is around when I am in need.
2. \_\_\_\_\_ There is a special person with whom I can share joys and sorrows.
3. \_\_\_\_\_ My family really tried to help me.
4. \_\_\_\_\_ I get the emotional help & support I need from my family.
5. \_\_\_\_\_ I have a special person who is a real source of comfort to me.
6. \_\_\_\_\_ My friends really try to help me.
7. \_\_\_\_\_ I can count on my friends when things go wrong
8. \_\_\_\_\_ I can talk about my problems with my family
9. \_\_\_\_\_ I have friends with whom I can share my joys and sorrows.
10. \_\_\_\_\_ There is a special person in my life who cares about my feelings.
11. \_\_\_\_\_ My family is willing to help me make decisions
12. \_\_\_\_\_ I can talk about my problems with my friends.

## Appendix 2

### *Medication adherence and transplant outcomes abstraction form*

#### *Provider information*

1. What is your role on the transplant team?
  - Surgeon
  - Coordinator
  - Nurse
  - Research
  - Other: Please describe

#### *Patient background and transplant information*

2. Patient Race/Ethnicity: Click or tap here to enter text.
3. Transplant type (organ): Click or tap here to enter text.
4. Year of transplant: yyyy
5. Sex: Click or tap here to enter text.
6. Has the patient experienced loss of the transplanted VCA graft? Choose an item.
  - No
  - Yes
7. Number of episodes of rejection of the transplanted VCA graft  
(If no episodes, please enter "0"): Enter number here

- a. How many of those episodes were:
  - i. Mild: Enter number here
  - ii. Acute: Enter number here
  - iii. Biopsy Proven: Enter number here

#### *Immunosuppressive medication and adherence information*

8. What is the patient's insurance status?
  - Public insurance
  - Private insurance
  - Uninsured
9. Who pays for this patient's immunosuppressive medication?
  - The patient's insurance
  - The transplant center
  - The patient
  - A research grant
10. Are there any indications that this patient is not adhering to their immunosuppressive medication regimen?
  - No
  - Yes
11. Do you suspect that the patient is not adhering to their immunosuppressive medication regimen?
  - No
  - Yes
12. If yes to numbers 10 and/or 11, please describe the indications that this patient is not adhering to their immunosuppressive medication regimen.  
Click or tap here to enter text. Textbox will expand if you have a long response.
13. If yes to numbers 10 and/or 11, have you noticed any of the following in this patient? Please mark all that apply.
  - Erratic immunosuppression levels
  - Low immunosuppression levels
  - High immunosuppression levels
  - Frequent rashes
  - Patient resistant to having labs drawn
  - Rejection episode that is unresponsive to steroids (e.g. IV prednisone)
14. Have you or a member of your clinical team ever discussed being non-adherent to immunosuppressive medications with this patient?
  - Yes
  - No
15. If yes, approximately how many times have you discussed being non-adherent to immunosuppressive medications with this patient? Enter number here.
16. Overall, how would you rate the patient's medication adherence?
  - Completely adherent
  - Mostly adherent
  - Somewhat adherent
  - Not at all adherent

17. Is this patient on a single- or multi-drug immunosuppression regimen?
- Single-drug
  - Multi-drug
18. Is there anything else you'd like us to know about immunosuppressive adherence in this patient?  
Click or tap here to enter text. Text box will expand if you have a long response.

#### *Charlson Comorbidity Index*

Please indicate if the patient has been diagnosed with any of these conditions.

1. Myocardial infarction or heart attack Choose an item.
2. Peripheral vascular disease such as intermittent claudication, acute arterial insufficiency, or thoracic or abdominal aneurysm Choose an item.
3. Cerebral vascular disease such as stroke or transient ischemic attack (mini stroke) Choose an item.
4. Dementia Choose an item.
5. Chronic lung disease Choose an item.
6. Rheumatological disease, such as lupus, connective tissue disease, or rheumatoid arthritis Choose an item.
7. Peptic ulcer disease Choose an item.
8. Diabetes Choose an item.
9. Diabetes with complications, such as retinopathy, neuropathy or nephropathy Choose an item.
10. Moderate or severe liver disease, such as cirrhosis, portal hypertension, or variceal bleeding Choose an item.
11. Metastatic cancer Choose an item.
12. Leukemia Choose an item.
13. Lymphoma Choose an item.
14. HIV Choose an item.
15. Disability Choose an item.
  - a. Visual impairment Choose an item.
  - b. Hearing impairment Choose an item.
  - c. Walking disability Choose an item.
  - d. Other disability Choose an item.
    - i. 1st other disability Click or tap here to enter text.
    - ii. 2nd other disability Click or tap here to enter text.
    - iii. 3rd other disability Click or tap here to enter text.
    - iv. 4th other disability Click or tap here to enter text.
    - v. 5th other disability Click or tap here to enter text.
16. Traumatic Brain Injury Choose an item.
17. Substance Abuse (alcohol, prescription drugs, or illicit drugs) Choose an item.
18. Anger management issues Choose an item.