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Lose Weight to Donate: Development of a Program to Optimize Potential Donors With Hepatic Steatosis or Obesity for Living Liver Donation

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Background. Living donor liver transplantation offers an attractive option to reduce the waitlist mortality. However, in recent years, the rising prevalence of obesity and nonalcoholic fatty liver disease has posed a serious threat to the donor pool while simultaneously increasing demand for liver transplant. To our knowledge, there have been no major published studies in the United States documenting a diet and exercise intervention to expand the living donor pool. Hereby, we established a pilot program called "Lose Weight to Donate" and present our initial experience. **Methods.** Our center instituted a remotely monitored diet and exercise pilot program to increase eligibility for living liver donation. Potential donors with any of the following were included: body mass index >30 kg/m², hepatic steatosis >5% on screening MRI, or isolated hypertension. **Results.** Over 19 mo, 7 individuals enrolled in the program of remote monitoring for at least 6–8 wk. Initial and follow-up abdominal MRI was performed in 5 of these individuals to assess steatosis, anatomy, and volume. Initial steatosis was highly variable (fat signal fraction range, 8%–26%). Follow-up MRI fat signal fraction values and hepatic volume all decreased to varying degrees. Ultimately, 2 of 7 individuals donated, whereas a third was approved, but the intended recipient was transplanted in the interim. **Conclusions.** These results indicate the feasibility of a remotely monitored program to expand donation in light of the rising incidence of hepatic steatosis and obesity.

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INTRODUCTION

There has been a progressive increase in the number of candidates newly added to the liver transplantation (LT) waiting list each year. However, out of this, 95% of the LT performed

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J.T.R. participated in conception and design of the article; writing of the article; collection, assembly, analysis, and interpretation of data; statistical analysis; and drafting of the article. P.V. participated in writing of the article, drafting the work, critical revision of the article for important intellectual content, and approval of the final version of the article. T.S. participated in acquisition and generation of data, analysis and interpretation of data, and writing and drafting of the article. A.J.P. participated in generation, collection, assembly, analysis, and interpretation of in 2017 were performed with deceased donor grafts and only 5% with a living donor graft.¹

Living donor LT offers an attractive option to reduce the waitlist mortality. In addition, it has been shown to offer a survival advantage over deceased donor LT when analyzing

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from an intention-to-treat basis.²⁻⁴ However, in recent years, the rising prevalence of obesity and nonalcoholic fatty liver disease has posed a serious threat to the donor pool while simultaneously increasing demand for LT.⁵ A logical solution to addressing potential donor steatosis is undertaking lifestyle modification through intensive programs, overseen by transplant centers with appropriate ancillary expertise. Several studies, primarily in Asian countries, have demonstrated the success of diet and exercise in significantly reducing hepatic steatosis in potential living liver donors.⁶⁻¹⁰

Despite this, to our knowledge, there have been no major published studies in the United States documenting a diet and exercise intervention to expand the living donor pool, especially in light of the obesity epidemic experienced not only in North America but also around the world. To expand the living donor pool, we instituted a pilot program "Lose Weight to Donate" (LWTD) in the hope of including motivated potential living donors who were initially ineligible for the above reasons while simultaneously improving their functional and nutritional status to maximize wellness and become living liver donors.

MATERIALS AND METHODS

Program Overview

The LWTD program aims to increase eligibility for living liver donation by conversion of ineligible candidates into acceptable potential living liver donors. Our program allows a defined pathway for people who are incidentally found to have steatosis on MRI (despite not being obese in some cases). People with incidental steatosis, especially older individuals, may only need a small degree of weight loss and could benefit from a pragmatic and flexible program.

The program is both highly individualized and simultaneously relatively low maintenance and pragmatic based on a self-directed food-based diet (no prescribed nutrition shakes) with input of nutrition counseling, implementation of an exercise plan supervised through an electronic device, and with broad inclusion criteria.

The coordination of the program is performed by the living donor nurse coordinator, who works in conjunction with a nutritionist. In addition, the medical and surgical directors of the living donor program help with the management of these potential donors.

Inclusion Criteria for LWTD Program

Candidates were required to be aged 18–60 y at the time of program enrollment and a willing liver donor to a specific recipient. Candidates were eligible for the program if they had a body mass index (BMI) >30 kg/m², the need for health optimization due to uncontrolled essential hypertension, or if hepatic steatosis was seen on routine screening MRI independent of their BMI. For candidates with BMI >35 kg/m², LWTD program participation was allowed, but in general, neither screening imaging nor evaluation by a transplant physician was performed until a BMI of 35 kg/m² or less had been achieved.

Living Donor and LWTD Enrollment

At our center, all potential living donor candidates, following an initial screening, are subject to an abdominal computed tomography angiography and MRI for anatomic, volumetric, and qualitative fat content assessments. In conjunction with general living donor LT criteria, our center requires living donors to have a BMI <35 kg/m², no significant steatosis on the routine screening MRI (ie, <5%), and well-controlled blood pressure with up to 1 prescribed antihypertensive medication. Our threshold of fat content by MRI, to be included in the program, is rather conservative. This is done to counteract the high variability seen when MRI fat content is >5%, which may not reflect the real histological fat percentage.¹¹ In contrast, when MRI steatosis percentage is <5%, the variability is very low and more accurately corresponds to the histological steatosis. However, to proceed with donation, up to 10% macrosteatosis is acceptable histologically.

Contact information of any interested potential living donor is presented to the transplant coordinator for intake. In our pilot, candidates were sent intake paperwork, regardless of BMI and before being informed about LWTD. This was to prevent candidates simply joining to be part of a "free weight loss program" with no intent of organ donation. Then, potential donors return paperwork and document their acknowledgment of understanding along with the risks of donation. Candidates who meet all BMI and health status criteria by phone proceed with our standard living donor evaluation including an MRI abdomen with organ volumetrics, computed tomography angiography abdomen, and evaluation by a transplant multidisciplinary team (ie, surgeon, hepatologist, living donor coordinator, living donor nurse practitioner, living donor advocate, nutritionist, etc).

If a potential donor candidate does not meet these criteria, then the transplant coordinator determines if any other potential donors are available. When no other potential donors are available, the transplant coordinator discusses the LWTD program with the candidate. Then, if the candidate wants to participate in the LWTD program, he/she is subsequently fully introduced to the program and is offered the opportunity to participate.

LWTD participants were required to have a signed release form by their primary care provider (PCP) and a recent hemoglobin A1c result documented before official enrollment. If there was no visit to a PCP within 1 y, then they needed to see a PCP to get clearance to participate in the program. This was done at their own expense.

Once records are received, a registered nurse schedules the candidate to come to the clinic for the LWTD program. Official LWTD program enrollment required an initial clinic visit with the LWTD coordinator and a registered dietician, at which point the candidate signed an agreement for the program, received further program description, and completed the activity-tracker device setup.

An alternative pathway to the LWTD program existed for candidates who were not obese but had steatosis on initial imaging or the need for health optimization (ie, inadequately controlled hypertension).

Diet and Exercise Protocol

Individualized nutrition and physical activity goals were set upon official enrollment. Exercise goals consisted of at least 7500 steps a day, with a minimum goal of 30 min of exercise 3–4 d per week averaged over the duration of the program. Recommended nutrition regimens varied but largely ranged from 17 to 25 kcal/kg/d of adjusted body weight. The nurse coordinator performed weekly or biweekly assessments by phone to evaluate and document the progress and adherence to the program. During the course of the program, activity-tracker device monitoring was introduced for several candidates and the nurse coordinator monitored their activity. Potential donors were loaned a FitBit smartwatch, an activity-tracker device worn on the wrist, which provided an accurate, consistent, and timely record of what exercise activity was actually performed by keeping track of calories consumed, calories burned, and steps taken in a day. The potential donors were also given a prepaid envelope to return it upon discontinuation of the program.

Candidates were instructed to weigh themselves at home and report their weight and dietary patterns. No weight loss supplements were recommended by the LWTD team.

Program Duration

For candidates who met the criteria to be imaged (ie, initial BMI <35 kg/m²) and were compliant and meeting all goals (weight or exercise and dietary patterns), follow-up imaging was scheduled after at least 6–8 wk to determine if there was resolution of the initial steatosis. Maximum program duration was not defined. However, individuals were reviewed on a monthly basis to determine candidacy to continue in the program. If the candidate was adherent and meeting the individual goals, program duration could be extended in the setting of slower progress than expected. If necessary, participants were removed from the program based on an individualized assessment of nonadherence and the needs of their intended recipient. Similarly, if another donor became definitely available for an intended recipient, an individual would be discharged from the program.

Program Evaluation: Calculation of Fat Fraction and Liver Volumes

Liver volume estimation and fat signal fraction (FSF) analysis were all performed on a 3-Tesla MR system (Magnetom Skyra, Siemens, Munich, Germany). Liver volumes were measured on a postcontrast 3D T1-weighted spoiled gradient echo breath-hold sequence (volumetric interpolated breath-hold examination) with a slice thickness of 3.00 mm. Planimetric measurements of the liver were performed by the same radiologist by manually tracing the hepatic boundaries on each individual axial slice. The sum of the cross-sectional area of each slice was then multiplied by the slice thickness to estimate the total liver volume.

Hepatic FSF estimation was performed utilizing the different precession frequencies of fat and water within a magnetic field. These tissue characteristics result in signal loss on outof-phase imaging, compared with in-phase imaging in which both fat and water are present within the same voxel. The fraction of fat infiltration can thereby be estimated by comparing the signal intensity of the liver on out-of-phase imaging to inphase imaging based on the following formula in accordance with the previously published equation (1).¹² Reproducibility of this technique has been described elsewhere.^{13,14}

$$FSF = \frac{(In phase signal intensity - Out of phase signal intensity)}{(2 \times In phase signal intensity)} (1)$$

Initial and Follow-up BMI Calculations

To minimize variability in individual scales and to maximize imaging-body mass correlation, weights taken in a clinic in closest temporal proximity to MRI dates were used for initial and follow-up BMI calculations in this program evaluation whenever available.

The collection and analysis of Personal Health Information here presented were to evaluate the implementation of our program. It was determined by the University of Virginia IRB-HSR to not represent human subject research and therefore no further submission was required.

RESULTS

Over a 19-mo period, 7 participants (I–VII) ultimately enrolled in the program. The timeline is shown in Figure 1. Duration of the program was highly variable. Our data include time from true first contact with the living donor office and entail the often real-world delays of MRI scheduling, financial authorization, and travel coordination to make appointments around the work schedules of potential donors. True program length and active monitoring time can be significantly shorter. For instance, candidate VII met the physical goal to be reimaged, but an additional 5 wk elapsed afterward due to delays on the recipient's end regarding social issues.

Participant characteristics are shown in Table 1. The majority of participants were not obese. One participant had isolated uncontrolled hypertension without obesity or steatosis on the initial MRI. Another participant had both steatosis and the need for optimization of hypertension.

Six of 7 participants had initial transaminases obtained within 8 wk before program initiation. These were within normal limits for all individuals with the exception of 1 individual who had an elevated preprogram alanine aminotransferase of 74.

Imaging and Weight Parameters

For the 5 participants with both initial and follow-up MRI, calculated initial FSF ranged from 7.6% to 25.4%. Official weights used for initial BMI calculations were obtained within a day of the initial MRI for all but 1 individual (Figure 1). Follow-up weight and MRI were subsequently performed. Although the interval between imaging was 10-26 wk depending on the candidate, actual official program duration was shorter for some of these participants. All 5 had reduction in liver volume and FSF (Table 1). Notably, following initial contact with the health system and a passive recommendation to lose weight, 3 candidates were able to attain a significant fraction of their total measured weight loss in the weeks before meeting with the nutritionist. For instance, candidates I and VI lost 5 pounds, a significant amount of total weight loss, between first contact with our living donor candidate and true intervention (first visit with nutritionist). Candidate VI did not have a weight loss goal but simply needed blood pressure control.

Other candidates noted for completeness include candidate VII, who had minor, nonsignificant weight loss before meeting with the nutritionist, losing 3 pounds out of 11.8 total pounds. In addition, candidate IV had minor, nonsignificant weight loss (*after* meeting with the nutritionist but before officially being accepted into the program), losing only 9% of the total weight loss. In contrast, another individual (candidate III) was asked to lose 8 pounds on preliminary phone conversations with the living donor office. However, by the time of evaluation by the nutritionist 3 mo later, the individual had



FIGURE 1. Timeline and disposition of program participants. This figure demonstrates the total time from the first documented phone contact with the transplant center nurse coordinator until disposition for the 7 program participants. The arrows represent initial and follow-up MRI. Color dots represent the timing of initial and follow-up weights used to calculate initial and final BMIs. Candidate III was formally approved as a donor by our committee after the program, but the intended recipient was transplanted in the interim with a deceased donor graft. BMI, body mass index.

gained 2 pounds. Approximate self-reported weight trajectories are depicted in Figure 2.

Program Adherence and Disposition

Smartwatch data were used to assess adherence in a total of 4 candidates. The MyFitnessPal App was initially used but later discontinued because of difficulty with tracking candidate activity. Despite doing well for calorie counting, it did not capture or verify daily exercise amounts. Thus, we decided to discontinue the use of this app and replace it with FitBit. Although a FitBit does not necessarily improve adherence, it certainly allowed for rapid assessment of compliance. Focus on reliable exercise reports and self-reported weight would eliminate the risk of expending resources and time on unacceptably slow progress or on verification of dietary intake.

Across the candidates, there was significant variation in adherence and communication. Particular limitations were present for candidates II and V, who were either not making adequate rates of progress or had significantly limited communication with the coordinator. Thus, in the future, more objective criteria could be set for acceptable progress (eg, set a particular weight loss goal per week according to the baseline nutritional status of the candidate and their nutritional requirements). In contrast, Figure 3 demonstrates rapid weight loss and reduction in steatosis for one of the most highly motivated participants.

Diet and Exercise Protocol

Intake was monitored mainly on self-registered food choices entered into the FitBit app, using calories as a guide. Therefore, the FitBit would tip us off to a patient making the wrong choices, such as drinking most of their calories (eg, 4 glasses of milk per day). A limitation to the FitBit App was that it required candidates to manually enter food intake,

TABLE 1.

Initial and follow-up BMI, FSF, and MRI estimated liver volume for program participants

• • •						
Candidate	BMI		Percent MRI FSF		Whole liver volume (mL ³)	
	Initial	Final (% change)	Initial	Final	Initial	Final (% change)
I	28.6	27.5 (-4%)	13.3	-3.3	1849	1685 (-8.9%)
	25.4	25.7 (+1%)	12.2	6.4	1639	1367 (-17%)
III	30.0	28.3 (-6%)	15.4	8.8	1581	1400 (-11%)
IV	32.5	28.0 (-14%)	25.8	6.1	2703	2045 (-24%)
VII	28.3	27.0 (-5%)	7.6	4	1836	1578 (-14%)
Participants without full ima	aging					
V	36.8	35.0 (-5%)	2.2	_	1740	_
VI	27.6	25.4 (-8%)	-	-	-	-

This table depicts the change in BMI, FSF, and estimated liver volume for candidates between the initial and follow-up MRI scans. Candidates I and VII ultimately donated. Two candidates without full imaging are included with data restricted to change in BMI. BM, body mass index; FSF, fat signal fraction.

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FIGURE 2. The approximate weight change for the 5 imaged candidates between initial and follow-up imaging. These are self-reported weights from phone calls and FitBit entries. Only candidates III and IV had a program prescribed weight loss goal. Candidate II had significantly limited adherence. The arrow denotes the time of the first nutritionist consult for each candidate. BMI, body mass index.



FIGURE 3. Program trajectory for candidate IV. This figure depicts weight change trajectory for candidate IV with an overlay of before and after transverse MRI depicting average intensity of the ROI: 275 before vs 133 after regular exercise, reduced caloric intake, alcohol cessation, and 14% loss of BMI. This individual was one of the most highly motivated individuals. Candidate IV still would have required more time in the program to eradicate remaining steatosis, however, was removed from the program because of an incidental intracranial finding during predonation evaluation. BMI, body mass index; FSF, fat signal fraction; ROI, region of interest.

making actual calorie count variable. Adherence was based on meeting an average of 120 min per week of exercise and reaching step goals most days as assessed by FitBit.

Ultimately, 2 of the 7 participants completed donation after the program. Another participant completed the program and was approved as a donor; however, the intended recipient was transplanted in the interim. Two other participants did not have complete imaging. Reasons for nondonation are shown in Figure 1.

Candidate I was one of the 2 successful donors. The initial MRI demonstrated approximately 13% FSF despite being within BMI criteria (Table 1). During the program, candidate I limited alcohol intake, fried food, and fast food consumption along with averaging 10000+ daily steps via the smartwatch report. Reimaging occurred after a 10-wk interval (figure 1).

DISCUSSION

Following a personalized diet and exercise program designed to increase eligibility for living donation, 2 of 7 program participants donated and 3 others reduced hepatic FSF and estimated volume. The impetus for this program stems from the shortage of liver grafts and the growing impact of hepatic steatosis on living donor availability.⁵ Indeed, a study on living donation found that nearly 1 out of 6 living donors was excluded because of >10% macrovesicular steatosis evident on liver biopsy.¹⁵

Larger prior studies in Japan, Korea, India, and Canada have durations ranging from 2 wk to 6 mo and report successful donation rates of 70%–100%.^{6-10,16} Our pilot program's conversion rate of 2 out of 7 participants moving to donation is lower. The weight change in our program was generally less than other programs, which have average weight losses of 6%–14%. Additionally, the degree of reduction in steatosis was smaller than in previous series.^{6-10,16} In other reports, relative reduction in biopsy-evident steatosis ranges from 60% to 85%.^{6,16} A critical caveat is that direct comparison of fat content between the aforementioned studies and our report is not possible.

Although our program is in its early stages, it is a potential way to expand the donor pool. This initial experience would help others to implement similar programs with the capacity to convert initially ineligible donors into acceptable candidates. Nevertheless, a more structured intervention may be necessary to increase the conversion rate and further optimize donors. Our lower rate could be attributed to candidate-specific or program-specific reasons. For instance, despite the limitation of manually entering foods into the accompanying FitBit app, the advantages of a single source product (eg, smartwatch) that accurately records exercise activity seem to outweigh the disadvantages encountered at the beginning of our program when using an additional app like MyFitnessPal. This is supported by the fact that dietary activity could be monitored by proxy through more objective serial weight reports.

Future changes from a program perspective could include mandatory smartwatches for all candidates, allowing for universal assessment of adherence. Having a more regimented dietary guideline could also be beneficial, as was done in a study from Toronto using Optifast nutrition shakes rather than general nutrition guidelines.⁶

This may also address the dramatic variability in candidate weight loss. Outpatient (ie, weekly) monitoring of blood pressure was not done in the present program but would add an important aspect given that 3 pilot candidates had elevated blood pressure at various points. Finally, more stringent end dates for the program and increased frequency of required remote check-ins could prevent resource diversion in the case of unacceptably slow progress. The latter is especially true in the case of the significantly limited progress or communication seen in 2 of our candidates. Despite the program's modest conversion rate, a strength is its personalized approach and proof of concept in the United States. The outpatient program required minimal office visits because of phone monitoring and relied on noninvasive assessments of steatosis. It also used smartwatch technology in several candidates to provide objective remote monitoring data. Our program included individuals in their sixth decade at the time of enrollment, which although reported elsewhere has not been reported in the Western Hemisphere in the context of weight loss programs for living donation.9,16

This pilot program evaluation also has limitations. First, we acknowledge the limitation of chemical shift MRI in assessing fat content, particularly at high iron content, low true fat

content, fat content >50%, and in the absence of adjustment for confounding factors like T2* decay.¹⁷ Indeed, our center has since implemented the 6 echo multi-Dixon technique that has been shown to have good sensitivity (85%) for detection of histologic steatosis >10%.11 Second, regarding volume calculations, a limitation is postcontrast respiratory motion artifact in candidate I, history of prior cholecystectomy in candidate II, which may lead to artifact, and potentially variable eating patterns near the time of imaging. In addition, the initial and follow-up MRI contrast brand used differed in 3 individuals of the 5. Nonetheless, all volumes decreased by >10% with the exception of candidate I (8.9%), giving sizable differences. We acknowledge time constraints as another limitation to our study. Upstream delays can definitely affect the outcome-in this case, time to achieve donation-and should be taken into account. Following optimal scheduling policies has proven to be effective in reducing service wait times by using existing resources in a more efficient way.¹⁸ By having shorter periods in the donor evaluation phase, donor-related delays (ie, work schedule changes, insurance approval, etc) would be potentially avoided and recipients transplanted in a more timely manner.

Finally, our program included 2 individuals who reported routine alcohol use before program initiation. Alcohol is a well-established cause of liver disease and steatosis.¹⁹ We cannot exclude the likely benefit achieved from the significant alcohol reduction in these candidates. Both of these candidates subsequently normalized or stopped their alcohol use demonstrating determination to pursue the program. Neither had evidence of significant transaminitis immediately before program initiation aside from an isolated alanine aminotransferase elevation in 1 candidate.

In conclusion, our pilot program demonstrates the feasibility of an outpatient remote monitoring regimen to expand living donation in the United States across a wide age range of participants while also indicating the need for a more structured program for a higher conversion rate to a successful donation.

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