Outcomes of an Education and Exercise Program for Adults with Type 2 Diabetes, and Comorbidities that Limit their Mobility: A Preliminary Project Report

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Cardiopulmonary Physical Therapy Journal

Volume 21 ❖ Number 2 ❖ June 2010

Official Journal of the Cardiovascular & Pulmonary Section
American Physical Therapy Association

APTA
American Physical Therapy Association
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Cardiopulmonary Physical Therapy Journal

Official Journal of the Cardiovascular & Pulmonary Section
American Physical Therapy Association

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Publication Title:
Cardiopulmonary Physical Therapy Journal
Statement of Frequency:
Quarterly: March, June, September, & December
Authorized organization's name and address:
Orthopaedic Section, APTA, Inc.
For the Cardiopulmonary Section
2920 East Avenue South, Suite 200
La Crosse, WI 54601-7202

Editorial

Practice-Based Evidence

In December of 2009, I was invited to participate in an innovative conference co-sponsored by the Research and Practice Departments of the APTA. It was entitled "Vitalizing Practice through Research and Research through Practice" and brought together some of the greatest PT (and non-PT) minds on the forefront of research and practice. It was at this conference that I was exposed to the concept of "Practice-Based Evidence." Now, most of us have become very familiar with "evidence-based practice" as the key to utilizing the best research to inform practice. However, this term is often misconstrued as "if it isn't proven via an RCT (randomized controlled trial), it should never be done." This misconception stems from the historical concept of the scientific method, which infers that we can understand our world in a cause and effect way. However, to quote Albert Einstein, surely one of the greatest scientific minds in history: "*Not everything that can be counted counts and not everything that counts can be counted*."

In the concept of Practice-Based Evidence, the real, messy, complicated world is not controlled. Instead, real world practice is documented and measured, just as it occurs, "warts" and all. It is the process of measurement and tracking that matters, not controlling how practice is delivered. This allows us to answer a different, but no less important, question than "does X cause Y?" This question is "how does adding X PT intervention alter the complex personalized system of patient Y before me?" Julie Fritz and her colleagues in Utah are one group that has used this method to explore physical therapy processes for persons with low back pain.[1] Their findings regarding the best interventions and processes for physical therapy for REAL patients is truly the best type of translational research that can be done. Patients are not controlled as research subjects, who must meet certain inclusion/exclusion criteria. Rather they are grouped together by factors they share. This type of research respects that people are complex, and don't readily fit the "cause and effect" model of science.

Recently, the Cardiovascular and Pulmonary Section has been approached to develop clinical guidelines in our content areas. Here we can learn from our orthopedic physical therapy colleagues. They have systematically collected real world data and synthesized them into guidelines for practice, such as clinical prediction rules for diagnosis. Clinical practice guidelines provide the practitioner with a valuable starting place when faced with a patient scenario. These are extremely important and helpful. Some practitioners have viewed these guidelines as restrictive to practice or a "cookbook" approach that removes clinical reasoning and decision-making. However, I argue that these protocols in themselves do not fully address the issue of the patient in front of you—with his or her own unique physical, psychological, emotional, environmental, and cultural perspective. The skilled practitioner must take these guidelines and make decisions regarding the appropriateness for the individual patient. However, this is not an excuse to throw out the guidelines entirely and utilize a "guru" approach. As practitioners, it is our responsibility to measure what we do and the outcomes for all patients to create an even richer database of clinical scenarios to improve the guidelines.

Thus, we return to practice informing research, and research informing practice. They are an inseparable team and neither element is complete on its own. We need the full range of researcher, from the cellular studies, to the systematic reviews, to RCTs, to ethnographic qualitative research. However, we also need the thoughtful practitioner who carefully describes each unique patient, and measures the results of every clinical decision made. A wonderful illustration of this concept was found in the January 2010 issue of *Physical Therapy*, where Bill Boissonnault and colleagues carefully describe the process of obtaining direct access practice status in a large, academic health system as an administrative case study.[2] I believe there are similar partnerships that can be forged within cardiovascular and pulmonary physical therapy as well. We need to develop clinical prediction rules and guidelines through systematic reviews, consensus processes, and documentation of practice such as case series. Both researchers and clinicians have an obligation to work together toward the goal of best practice for all patients we encounter. Then we truly will achieve Evidence-Based Practice AND Practice-Based Evidence. Let's roll up our sleeves and get to work!

Anne K. Swisher PT, PhD, CCS
Editor-in –Chief

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Outcomes of an Education and Exercise Program for Adults with Type 2 Diabetes, and Comorbidities that Limit their Mobility: A Preliminary Project Report

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ABSTRACT

Purpose: Some adults with type 2 diabetes mellitus (T2DM) have comorbidities and mobility impairments that limit their exercise capacity. In consideration of this, we developed and piloted a program called *Active Steps for Diabetes* for people with T2DM, comorbidities, and mobility impairments. The purpose of this paper was to report outcomes for the pilot program. **Methods:** *Active Steps for Diabetes*, an 8-week program, included instruction on diabetes self-care and group and home exercise programs. Twenty-two females (62.7 $\pm$ 6.1yrs) with T2DM and self-reported mobility impairments completed the program. Six participants used a walking aid. Outcome measures included two risk factors for coronary artery disease [daily physical activity and body mass index (BMI)], cardiovascular fitness (6-minute walk distance), and knowledge of diabetes-specific exercise guidelines. A two-way repeated measures ANOVA was used to compare outcomes before and after the program and between participants who did and did not use a walking aid. **Results:** *Active Steps for Diabetes* was effective in increasing daily physical activity in both groups of subjects (walking aid group: 2.6 days/week [95% confidence interval (CI) = 2.1 to 3.3]; no walking aid group: 1.9 days/week [95% CI=1.2 to 2.5]). This was accompanied by increases in 6-minute walk distances (walking aid group: 54.0 m [95% CI = 36.4 to 71.6]; no walking aid group: 62.6 m [95% CI=55.7 to 69.4]). Changes in BMI were not significant (walking aid group: -0.4 [95% CI = -1.2 to 0.4]; no walking aid group: -.24[95% CI = -.91 to .44]). Increases in knowledge of diabetes-specific exercise guidelines were observed in both groups (walking aid group: 18.8% [95% CI = 11.3 to 26.4]; no walking aid group: 19.3% [95% CI = 16.1 to 22.5]). **Discussion:** Physical inactivity and low cardiovascular fitness are predictors of CAD morbidity and mortality in adults with T2DM. This pilot program suggests that a model for diabetes education, incorporating exercise programs developed by a physical therapist, may increase physical activity, improve endurance, and thereby potentially reduce CAD risk in people with T2DM and mobility impairments from comorbidities.

Key Words: type 2 diabetes, physical activity

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INTRODUCTION AND PURPOSE

The American Diabetes Association (ADA) recommends that adults with type 2 diabetes (T2DM) accumulate at least 150 minutes of moderate intensity aerobic exercise and 3 sessions of resistance exercise per week.[1] The recommendation is based on substantial evidence that moderately intense physical activity (PA) improves glycemic control and coronary artery disease (CAD) risk. Moderately intense PA improves hemoglobin A1c (HbA1c), triglycerides, and adiposity in adults with T2DM.[1] Conversely, physical inactivity and low cardiovascular fitness are predictors of CAD morbidity and mortality in adults with T2DM.[2-5] Physical inactivity also contributes to the high prevalence of impaired mobility in adults with T2DM.[6-8] While there is substantial evidence supporting the ADA recommendation, the ability to generalize it is limited since it is based primarily on studies involving subjects with normal mobility and moderate or vigorous intensity exercise interventions.[1,9] This is an important limitation to address because many people with T2DM have co-existing chronic conditions that affect their mobility and, in turn, limit their exercise capacity. In the United States over 80% of people with T2DM are overweight or obese, 75% have high blood pressure, 30% have impaired pedal sensation due to diabetic neuropathy, and over 50% have osteoarthritis.[10] Older adults with diabetes are 2 to 3 times more likely than those without diabetes to report that they have a mobility impairment.[11] Over 70% of older adults with impaired mobility report that they do not achieve recommended amounts of PA.[7,12]

Research is needed to determine strategies for increasing PA, improving glycemic control, and reducing CAD risk factors for people who have T2DM and mobility impairment. Typical exercise interventions, involving 30 minutes of continuous moderately-intense aerobic exercise may be too demanding for this population. Aerobic exercise training began at a low intensity and gradually increased to a moderate intensity for $\geq$ 30 minutes has been shown to improve glycemic control, fitness, and blood pressure in adults

with T2DM.[13-16] Resistance training has also been shown to enhance glucose control.[17-19] Combined training, including both aerobic and resistance exercise, has been shown to improve blood glucose control at least as much as aerobic training only.[20-24] Recently, interval training with alternating, short bouts of moderately-intense aerobic and resistance exercises has been advocated.[25,26] Interval training produces a lower cardiorespiratory challenge than aerobic-only training. Therefore, people with T2DM and a low tolerance for exercise may be able to perform interval training for longer periods of time allowing for a greater amount of total work performed compared to continuous aerobic training. This type of training (using short-duration bouts of stationary cycling followed by resistance exercises) was reported to be effective in improving glycemic control, body composition, blood pressure, and muscle strength in 11 patients with insulin-treated T2DM and a high CAD risk profile.[26]

While diabetes education programs uniformly include information on ADA diabetes-specific exercise guidelines, few modify the recommendations to address patients' impaired mobility and limited exercise capacity.[27] Furthermore, few diabetes education programs include supervised exercise. Physical therapists possess the knowledge and expertise needed to provide individualized physical activity recommendations for people with impaired mobility and complex medical conditions. In consideration of this, we developed *Active Steps for Diabetes*, a program for adults with T2DM and mobility impairment. *Active Steps for Diabetes* includes instruction on diabetes self-care behaviors provided by a certified diabetes educator, plus group and home exercise programs provided by a physical therapist. The premise of *Active Steps for Diabetes* is that while people with T2DM and mobility impairments may not be able to achieve the optimal amount of PA for glycemic control on their own, they can (through PA programs developed by physical therapists) gradually increase their exercise capacity, improve their glycemic control, and reduce their risks for CAD.

The primary purpose of this pilot project was to examine the effects of *Active Steps for Diabetes*, a specially designed education and exercise program for adults with T2DM and self-reported mobility impairment on 3 types of variables; namely two risk factors for CAD [level of PA and body mass index (BMI)], an index of exercise tolerance [six-minute walk distance (6MWD)], and knowledge of diabetes-specific exercise guidelines. Outcomes were compared before and after the program and between participants who did and did not use a walking aid. The secondary purpose was to identify the limitations of this pilot project and recommend methods for subsequent studies.

METHODS

Subjects

Participants for *Active Steps for Diabetes* were recruited from outpatient clinics at a local hospital that provides health care for a predominately low-income and ethnically diverse population. Health care providers recruited participants by distributing flyers to individuals eligible for the program. Eligible participants included adults who had: (1) a diagnosis of T2DM from their primary care physician, and (2) used a walking aid or had self-reported mobility impairment. Mobility impairment was defined, per the National Health Interview Survey (NHIS), as use of a walking aid or self-reported inability to do one or more of the following tasks without stopping to rest: walk ¼ mile; walk up 10 steps; stand for 2 hours; or do work involving stooping, bending, or kneeling for 30 minutes.[11] Participants also were medically cleared for exercise by their physician in the form of a written clearance form. Individuals interested in participating in *Active Steps for Diabetes* contacted the primary investigator to enroll in the program. Individuals with medical conditions for which aerobic or resistance exercise is contraindicated as defined by the American College of Sports Medicine[28] and the ADA[1] [conditions such as severe retinopathy, uncontrolled cardiovascular problems including uncontrolled hypertension [resting blood pressure >160/90], and renal failure requiring dialysis] were excluded from participation.

Active Steps for Diabetes consisted of two classes per week for 8 weeks. The program was offered 4 different times. Thirty females enrolled and 22 (73%) completed the program. Completion was defined as missing no more than 4 of the 16 classes (ie, attending 75%). Reasons for not completing the program included illness (n=2 participants), lack of reliable transportation (n=3 participants), and family/work commitments (n=3 participants). All participants signed a consent form approved by the Institutional Review Board of Bellarmine University.

Demographics for participants who completed the program are shown in Table 1. The mean age of the participants was 62.7 ± 6.1 years. Seventy-three percent of the participants were African American and 27% were Caucasian. Six participants who completed the program used a walking aid (ie, 27%); 5 used a cane and one used a rolling walker. The

Table 1. Participant Demographics

Demographics	Walking Aid (n=6)	No Walking Aid (n=16)	Total (n=22)
Age (yrs) $\overline{X}$ **(SD)**	64.5 (3.4)	62.3 (3.5)	62.7 (6.1)
Diabetes Duration (yr) $\overline{X}$ **(SD)**	12.2 (7.6)	10.7 (7.8)	11.3 (8)
Ethnicity:			
• **Caucasian**	3 (50%)	4 (25%)	7 (27%)
• **African American**	3 (50%)	12 (75%)	15 (73%)
Risk Factors for CHD			
• **Hypertension**	6 (100%)	15 (94%)	21 (95%)
• **Hyperlipidemia**	6 (100%)	15 (94%)	21 (95%)
• **Obesity**	6 (100%)	13 (81%)	19 (86%)
• **Smoking**	2 (33%)	3 (19%)	5 (23%)
• **Sedentary**	6 (100%)	12 (75%)	18 (82%)
Other Comorbidities			
• **Osteoarthritis**	6 (100%)	13 (81%)	19 (86%)
• **PN**	6 (100%)	1 (.06%)	5 (23%)
• **COPD**	3 (50%)	1 (.06%)	4 (18%)
• **CHF**	3 (50%)	1 (.06%)	4 (18%)

Hypertension (resting BP ≥ 140/90 or use of antihypertensive medications); Hyperlipidemia (use of cholesterol medications); Obesity (BMI≥ 30kg/m^2); Smoking (during ≤ previous six months); Sedentary (engaged in moderately intense PA < 3 days/week); PN=peripheral neuropathy; CHF= coronary heart failure; COPD=chronic obstructive pulmonary disease

primary reasons for use of a walking aid were joint pain and peripheral neuropathy. All 5 participants who used a cane reported knee and back pain due to osteoarthritis; 3 had peripheral neuropathy (PN). The participant who used a rolling walker had knee and back pain due to osteoarthritis, a thoracic kyphosis due to osteoporosis, and PN. The prevalence of cardiovascular disease and cardiovascular disease risk factors was high (Table 1). Ninety-five percent of participants had hypertension and hyperlipidemia. Eighty-six percent were obese. Eighty-two percent were sedentary. Five participants (23%) smoked. Four participants (18%) reported that they had both congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) (Table 1).

Intervention

The biweekly *Active Steps for Diabetes* program classes consisted of 45 minutes of group exercise followed by 30 minutes of diabetes education. Prior to each class, each participant's blood glucose, resting blood pressure (BP), and resting heart rate (HR) were measured and recorded on an exercise log. Pre-exercise BP of < 160/90 mmHg and blood glucose levels between 100-300 mg/dl were required to proceed with exercise. If participants arrived with a blood glucose level between 70-100mg/dl or > 300 mg/dl, the guidelines for exercise and blood glucose levels outlined in an American Physical Therapy Association document on physical fitness for special populations were followed.[29]

Group exercise classes were led by the primary investigator and a qualified assistant (a student in physical therapy, or a nurse/diabetes educator). The primary mode of exercise was seated aerobic and resistance training. However, several exercises were also demonstrated in the standing position. Participants progressed from performing exercises in sitting to standing based on their abilities. Each session consisted of a warm-up phase (5 min), a balance and posture exercise phase (5 min), an aerobic and resistance training phase (30 min) and a cool-down phase (5 min). The warm-up and cool-down phases consisted of breathing exercises and flexibility exercises for the trunk and extremities. The posture and balance exercise phase consisted of static and dynamic balance activities plus instruction and practice in body mechanics for transition movements from sitting and standing. The aerobic/resistance phase consisted of interval training involving intermittent bouts of low to moderate intensity cardiovascular endurance and muscle strengthening exercises. The Borg perceived exertion scale was used to monitor exercise intensity.[28] Participants were instructed to exercise at a rating of perceived exertion (RPE) between 11/20 (light) and 13/20 (somewhat hard). At the beginning of *Active Steps for Diabetes* the bouts of low to moderate intensity aerobic exercise (such as seated marching with or without simultaneous arm raises) were limited to 2 to 3 minutes and were followed by 2 to 3 minutes of resistance exercises. The duration of the aerobic exercise bouts was gradually increased so that by the end of the 8-week program participants were performing 20 minutes of continuous light to moderately intense aerobic exercise. Muscle strengthening exercises were performed with elastic bands or tubing and principles of progressive resistance training were employed. The resistance training volume for each exercise was 3 sets of 8 to 12 repetitions. Over the duration of the program, participants used elastic bands/tubing that provided progressively greater resistance. While these exercise classes were group-based, the physical therapist/instructor tailored the exercises to each participant's needs.

In addition to the twice weekly group exercise classes, participants were instructed to accumulate 30 minutes of low to moderate intensity exercise on at least one other day of the week. Exercise bouts lasting ≥ 10 minutes were included in their total exercise times. Participants selected a variety of exercise modes; most selected walking or chair aerobics. Participants electing to do chair aerobics followed a video or a television program called Sit and Be Fit™ (SIT AND BE FIT, Spokane, WA). Participants recorded their exercise time on a log.

In addition to group-based and home-based exercise, participants were given a pedometer (Omron HJ-112) to use as a tool for motivating and monitoring their PA. The accuracy of the pedometer given to the participants was deemed acceptable for clinical purposes.[30] Participants were instructed in proper placement and use of their pedometers. They were encouraged to wear them each day during waking hours and to record their steps taken each day on their exercise logs. Participants were given weekly step goals. Their average number of steps/day, determined prior to the program, was used to establish their initial step goal (baseline step count plus ≥ 100 additional steps.). Exercise logs were used to establish subsequent step goals (generally 100 steps above their daily average).

Outcome Measures

Participants were assessed within the week prior to and again during the week following completion of the *Active Steps for Diabetes* program. Outcome measures included: two indicators of daily PA (steps/day and exercise logs), cardiovascular endurance (6MWD), BMI ($kg \cdot m^2$), and knowledge of exercise and diabetes-specific exercise guidelines.

Participants used a 7-day exercise log sheet that had spaces for recording exercise episodes of ≥ 10 minutes (such as walking for exercise). Occupational activities and household chores were not included in the exercise log. The number of days per week participants accumulated ≥ 30 minutes of exercise was recorded. To assess PA (defined as mean number of steps/day), each subject wore a research-grade pedometer (New Lifestyles NL-2000 piezo-electric pedometer) over 7 consecutive days during their waking hours. Participants were instructed in proper placement of the pedometer and asked to keep its cover closed so that they could not view their step count. Steps per day, stored in the pedometer, were summed and divided by 7 days of wear. The pedometers are valid for assessing PA in obese individuals and healthy older adults.[31,32] However, their accuracy is affected by slow walking speeds. At speeds ≤ 0.7 m/s the pedometers may underestimate actual steps taken by 25%.[32] Devices that more accurately record steps taken at slow gait speeds

are significantly more expensive and were cost prohibitive when this pilot project was performed.

Cardiovascular endurance was measured using the six-minute walk test (6MWT).[33] The 6MWT is a valid measure of responses to exercise training in patients with cardiopulmonary disease.[34] The test-retest reliability of the 6MWT has been reported to range from ICC = .92 to .99 in healthy and frail older adults.[34] The test was administered by one investigator whose role in the project was limited to testing. This investigator was not involved in the delivery of the intervention. Instructions given to participants were standardized. Participants walked on a 25.9 meter circular path. Encouragement, which was also standardized, was given after 1 minute, 3 minutes, and 5 minutes. Body mass index was determined from measurements of the subject's height and weight obtained using a standard medical scale.

Knowledge of exercise and diabetes-specific exercise guidelines was measured using an 18-question multiple choice test developed by the investigators. The test included questions about benefits of exercise, exercise prescription, and exercise precautions. Test questions were derived from diabetes exercise guidelines published by ACSM[28] and ADA.[1] Consistent with public health diabetes education materials, the multiple-choice test questions were written in lay language and presumed to be appropriate for people with a 6th to 8th grade English reading level. A pilot study was undertaken to examine the clarity of the test questions. The test was administered to 17 volunteers enrolled in a diabetes self-management class offered by a local department of public health. The demographics for these volunteers and the participants in this project were similar. Upon review, 4 frequently missed questions were rewritten to improve the clarity of the distracters.

Data Analysis

Data were analyzed using SPSS version 16.0. Data were analyzed for the 22 participants who completed the program. Descriptive statistics were calculated for participant characteristics and dependent measures. Characteristics of participants who did (n=6) and did not use a walking aid (n=16) were compared using *t* tests for independent samples. Parametric *t* tests were used to compare age, number of years with T2DM, and BMI and 6MWD at baseline. A Mann Whitney U, was used to compare PA because the number of days/week a participant acquired ≥ 30 minutes was ordinal data.

To determine the effects of *Active Steps for Diabetes* on 4 of the 5 dependent measures (steps/day, 6MWD, BMI, and exercise knowledge), separate 2 X 2 repeated measures analyses of variance were done. Time was the within-subject factor with two levels (pre-test and post-test). Group was the between-subject variable with two levels (those who did and those who did not use a walking aid). When an interaction effect between group and time was found, the mean between group difference and the 95% CI were reported. To further analyze the responses of the groups, the mean within-group difference and the 95% CIs were calculated for all dependent variables. Wilcoxon's Signed-Rank Test, was used to compare pre- and postintervention means for the number of times per week participants exercised at least 30 minutes. The level of statistical significance was set at $p < .05$.

RESULTS

Participants who did and did not use a walking aid were similar in age and BMI at baseline (Table 2). Both groups were sedentary. The group that used a walking aid was less active and had a lower 6MWD at baseline than the group that did not use a walking aid (Table 2).

There was a significant main effect for time ($p < .001$) for number of days per week participants accumulated ≥ 30 minutes of moderately intense exercise. The mean within group change was 2.7 days (95% CI = 2.1 to 3.3) for the group that used a walking aid and 1.9 days (95% CI = 1.2 to 2.5) for the group that did not use a walking aid (Table 3). Furthermore, there was a significant interaction ($p = .027$) between group and time with respect to change in number of days per week participants exercised 30 minutes or more. Greater increases were observed in the group that used a walking aid [mean between group difference = .98 days (95% CI = 0.12 to 1.8)]. Prior to Active Steps for Diabetes all 6 participants who used a walking aid reported they did not exercise; afterwards 5 were exercising 3 times per week (two times in Active Steps and one time on their own). Among the 16 participants who did not use a walking aid, 7 reported no exercise prior to the program and only 4 participants (25%) were engaged in 30 minutes of exercise 3 or more days/week. Afterwards the number who exercised 3 or more times per week had increased to 14 participants (88%).

There was a significant main effect for time ($p < .001$) for steps/day (Table 3). In addition, there was a significant interaction ($p = .012$) between group and time with respect to change in steps/day, with greater increases experienced by the group that did not use a walking aid [mean between group difference = 1393.0 steps/day (95%CI = 345.6 to 2440.5)]. Pedometer-determined PA increased about 65% from the baseline mean for both groups. During Active Steps for Diabetes participants were encouraged to increase their daily step count by at least 100 steps above baseline each week (ie, ≥ 800 steps at the conclusion of the program). This goal was achieved by all but 3 participants. These 3 participants, all of whom used a walking aid and had multiple comorbidities, did increase their total step count; increases ranged from 500 to 608 steps/day

There was a significant main effect for time ($p < .001$) for 6MWD (Table 3). In addition, there was a significant interaction ($p = .029$) between group and time with respect to changes in 6MWD, with greater improvements exhibited by the group that did not use a walking aid [mean between group difference = 46.8m (95% CI = 5.2 to 88.3)]. For the 6MWT, the minimal clinically important difference (MCID) is estimated to be 54-80 meters for participants with cardiopulmonary disease.[35] Mean gains in 6MWD, 54m for the group that used a walking aid and 62.6m for the group did not use a walking aid, were within the MCID range. The main effect, time, was not significant for BMI ($p = .265$; Table 3). Furthermore, there was no significant interaction between group and time with respect to changes in BMI ($p = .268$). There was a significant main effect for time ($p < .001$)

Table 2. Baseline Characteristics for Participants Who Did and Did Not Use a Walking Aid

Variable	Walking Aid (n = 6)	No Walking Aid (n = 16)	*p*
Age (yr) $\overline{X}$ (SD)	64.5 (3.4)	62.3 (3.5)	.09
BMI (kg/m²) $\overline{X}$ (SD)	38.7 (3.8)	37.3 (3.4)	.21
6MWD (m) $\overline{X}$ (SD)	471.3 (32.0)	513.8 (45.9)	.048
Steps/day $\overline{X}$ (SD)	1383.8 (204.5)	2607.4 (977.8)	.003
# Days/wk (≥ 30 min PA) $\overline{X}$ (SD)	0.0	1.4 (1.5)	.04
Knowledge (%) $\overline{X}$ (SD)	74.8 (7.9)	79.1 (5.9)	.19

Table 3. Outcomes for Participants Who Did and Did Not Use a Walking Aid

	No Walking Aid Group (n=6)			Walking Aid Group (n=16)		
Variable	Pretest $\overline{X}$ (SD)	Posttest $\overline{X}$ (SD)	Within Group Difference (95% CI)	Pretest $\overline{X}$ (SD)	Posttest $\overline{X}$ (SD)	Within Group Difference (95% CI)
# Days/week (≥ 30 min PA)	1.4 (1.5)	3.3 (.68)	1.9 (1.2 to 2.5)[a,b]	0.0 (0.0)	2.7 (.52)	2.7 (2.1 to 3.3) [a,b]
Steps/day	2607 (978)	3834 (1438)	1226.8 (896.3 to 1557.3) [a,b]	1384 (204)	2271(594)	887.8 (458.4 to 1317.2) [a,b]
6MWD (m)	513.8(45.9)	576.4 (39.8)	62.6 (55.7 to 69.4) [a,b]	471.3 (32.0)	525.3(46.4)	54.0 (36.4 to 71.6) [a,b]
Knowledge (%)	79.0 (5.9)	98.4 (2.0)	19.3 (16.1 to 22.5) [a,b]	74.8 (8.0)	93.7 (7.0)	18.8 (11.3 to 26.4) [a,b]
BMI (kg/m²)	37.3 (1.3)	37.1 (1.8)	-.24 (-.91 to .44)	38.7 (3.5)	38.3 (4.4)	-0.4 (-1.2 to 0.4)

[a] = significant time effect ($p < .05$)
[b] = significant interaction (group x time)

for knowledge of diabetes-specific exercise guidelines (Table 3). In addition, there was a significant interaction ($p = .043$) between group and time with respect to changes in knowledge test scores. The group that did not use a walking aid exhibited slightly greater improvements in knowledge [mean between group difference = 4.67% (95% CI = .15 to 8.8)].

DISCUSSION

The pilot *Active Steps for Diabetes* program was found to be a safe and effective way to improve health outcomes in people with T2DM and mobility impairment. All outcome measures improved except body mass index (Table 3). Taking into consideration the emphases and the duration of the program, improvement in BMI was not anticipated. Primary emphases included: self monitoring of blood glucose levels, increased physical activity, and healthy food choices and portion control (as opposed to reducing calories). Several examples of healthy meal plans were shared; however, these plans were not aimed at weight reduction. The minimal dose of PA recommended for weight loss is consistent with the dose recommended by the ADA to promote blood glucose control and cardiovascular health (30 minutes of moderate to vigorously intense PA most days of the week) and some individuals may need to do 60 to 90 minutes of daily exercise to lose weight.[28] While participants significantly increased their PA due to their mobility limitations and health co-morbities, they were not able to achieve the amount of exercise needed for weight loss within the 8 week study duration.

There were several compelling reasons for choosing 8 weeks as opposed to a shorter or longer duration intervention. Intensive programs, having more than 10 contact times and focusing on behavior-related tasks and feedback, are more effective in improving diabetes care than shorter-term didactic programs focusing on diabetes knowledge.[36] With a total of 16 1.25 hour classes and a hands-on approach to teaching and learning, *Active Steps for Diabetes* is a time and labor intensive program. Eight weeks was sufficient to complete all diabetes education modules and to initiate lifestyle changes.

The 73% completion rate was excellent, especially since the participants had numerous barriers to participation, including mobility impairments and reliance upon public transportation. Weekly incentives for attendance may have facilitated attendance. Items donated to the program such as glucometers, nutrition posters, carbohydrate counters, diabetes skin care product samples, and elastic resistance bands were used as incentives.

Prior to *Active Steps for Diabetes,* 60% of the participants reported no weekly exercise and only 18% accumulated 30 minutes of exercise on ≥ 3 days/week. These results are consistent with previous reports. In a survey of older adults with diabetes, 55% reported no weekly activity.[37] In two large population studies, less than 40% of adults with

diabetes reported engaging in regular PA, and adults with mobility impairments reported the least amount of PA.[38,39]

Physical inactivity has been correlated with several subject demographic characteristics in this pilot study. It is more common in women, African Americans, and individuals with physical limitations.[36,40] Individuals with physical limitations are least active.[40] Promotion of PA in this at-risk population is a primary focus of *Active Steps for Diabetes*. Therefore, the program includes attributes (social support, frequent feedback, and a task-oriented focus) that have been shown to help individuals successfully adopt an exercise program.[36] These attributes probably contributed to the observed significant increases in PA. At the conclusion of *Active Steps for Diabetes* the mean days per week participants accumulated 30 minutes of exercise increased from approximately 1 to 3 days per week (or 30 minutes to 90 minutes of exercise/week) bringing them closer to the amount recommended by the ADA.

The pre- and the postintervention means for steps/day found in this study were largely below means reported for people with T2DM. Previously reported means ranged from 4352 to 9049 steps (average = 7123 steps), whereas our participants only averaged 3408 steps/day at the conclusion of the program.[41,42] There are two factors that may account for the discrepancy. The first is differences in subject inclusion/exclusion criteria. Previous studies, with the largest step counts, included younger individuals and excluded individuals taking insulin as well as those with mobility impairments.[42-44] Consistent with this, the step counts for participants in *Active Steps for Diabetes* were similar to the counts reported in the literature for individuals with osteoarthritis and physical limitations.[41] The second factor pertains to accuracy of the pedometer. It is possible that the pedometer step counts for the participants underestimated the actual number of steps they took, particularly for those using a walking aid due to their slow walking speed.

Pedometer focused PA programs have been shown to elicit large increases in daily walking in participants with T2DM free from secondary complications. Araiza and colleagues[43] reported a 69% increase in daily walking in 6 weeks; Tudor-Locke and colleagues[42] reported an increase of over 100% in 16 weeks. Consistent with this, participants in *Active Steps for Diabetes* increased their steps/day by approximately 65% over baseline. The small weekly step goals, and logs for tracking steps were well received by *Active Steps for Diabetes* participants, including participants who used an assistive device for ambulation. Thus pedometers may serve as a useful tool for initiating increases in PA in people who have T2DM and a low capacity for sustained aerobic activity.

The mean preintervention 6MWD for participants in *Active Steps for Diabetes* was well below mean distances reported for healthy older adults[45] and similar to mean distances reported for participants with T2DM and comorbidities.[46] Sixty-four percent of the participants had a clinically significant difference between pre- and postintervention distances. The mean increase in distance walked (60.2 $\pm$ 20.4m) was somewhat higher than increases reported in two studies involving individuals with T2DM.[24,47] In a 12-week weight loss program for obese patients with diabetes (n=60 subjects), the mean 6MWD increased 46.9 $\pm$ 31.1m.[48] The exercise intervention in this program consisted of aerobic and resistance training at a moderate intensity and participants progressed from 20 to 60 minutes of exercise 6 days/week. In a 16-week intervention (n=7 subjects) involving moderate-intensity aerobic and eccentric resistance training 3 times per week, 6MWD improved 45.5m (95% CI: 7.5m to 83.6m).[24] Two possibilities that could explain the higher observed gain in distance in this report are: (1) the participants' lack of familiarity with the test and (2) their initial level of conditioning. While the 6MWD is reproducible, prior studies have shown a learning effect in subjects with pulmonary disease, with the majority of the increase in distance walked over 3 or more trials occurring between the first and second trials.[48] A practice test was not employed in this pilot study and therefore, preintervention scores may not have reflected participants' best efforts. It has also been suggested that individuals who are more deconditioned may gain more distance than sedentary but otherwise healthy individuals. Participants' in *Active Steps for Diabetes* were more deconditioned than the subjects in the two studies described above; thus they had more room for improvement.

Participant knowledge of exercise and diabetes specific exercise guidelines improved. To achieve this outcome oral and written instruction on exercise was repeated numerous times throughout the program and participants practiced implementing the exercise guidelines as well. Prior to each class participants measured their own blood glucose and were encouraged to determine whether or not they should proceed with exercise. Knowledge of exercise benefits and guidelines is considered a prerequisite for behavior change.[49] While some investigators have shown a relationship between knowledge and initiation and maintenance of exercise others have not. It is important that people with T2DM and diabetic complications are familiar with exercise guidelines for their safety and to allay fears they may have about safety.

STUDY LIMITATIONS AND SUGGESTIONS FOR SIMILAR PROGRAMS

This report is an examination of preliminary outcomes for *Active Steps for Diabetes*, a unique education and exercise program developed to serve the needs of individuals with T2DM and mobility impairments. The program's "real" clinical service context may be considered a strength of the study. However, by nature of this context, the study has fewer controls than those carried out in laboratory settings. The study sample was not a random sample. Instead it consisted of people who voluntarily registered for *Active Steps for Diabetes*; therefore they may have been more motivated than people who did not register for the program. In laboratory-based studies, exercise equipment is used to precisely control and accurately measure exercise intensity and duration. Group exercise programs often use less than exact methods of measuring exercise intensity (eg, rating of perceived exertion); consequently, it may be difficult to relate group program outcomes to exercise dosing.

While this preliminary report suggests that *Active Steps for Diabetes* can improve PA and endurance in people with T2DM and impaired mobility, a longer duration follow-up study is needed to determine if the program has lasting effects on these measures. A comparison between the effects of *Active Steps for Diabetes* and the effects of standard diabetes education programs on PA and other health outcomes is needed. Additional recommended outcome measures include assessments of participant's waist circumference, mobility, and blood glucose levels. While BMI is unequivocally associated with health risk, waist circumference provides specific information about a person's fat deposition pattern and it is also an important index of cardiovascular disease risk. A test of mobility such as the Modified Physical Performance Test[50] is recommended to better describe the severity of mobility impairments exhibited by study participants. To best discern the benefits (if any) of the labor intensive supervised exercise sessions in *Active Steps for Diabetes*, participants in the control standard diabetes self-management training should receive a pedometer, exercise video, exercise logs, and recommendations for a specific home exercise program over the study duration.

CONCLUSIONS

People with T2DM often demonstrate mobility impairments and low exercise tolerance. This frequently leads to decreased PA and increased risk factors for CVD. Exercise can clearly mitigate these detrimental changes. However, this population must overcome numerous barriers to PA and as a consequence they typically do not engage in any form of physical exercise. Based on the results of this pilot study, the authors suggest that the proposed model for diabetes education, incorporating exercise programs developed by a physical therapist, may effectively increase PA and ultimately improve health in this vulnerable population. Physical therapists possess the expertise in exercise prescription for individuals with physical limitations and multiple health comorbidities, and thus are essential in caring for this population.

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Total Artificial Heart and Physical Therapy Management

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ABSTRACT

Purpose: To describe the total artificial heart (TAH) device as a bridge to heart transplantation (BTT), and related physical therapy management, while comparisons to left ventricular assist devices (LVAD) are made. **Summary**: The SynCardia CardioWest Temporary TAH System is the only TAH approved by the Food and Drug Administration (FDA), Health Canada and Consultants Europe (CE) for BTT. CardioWest implantation involves cardiectomy thus avoiding pulmonary hypertension, right heart failure, inotropic or anti-arrhythmic agents, myocardial and valve related problems. CardioWest has a fixed beat rate and cardiac output is dependent upon venous return and preload. Both TAH and LVADs are adaptive with exercise, increasing cardiac output during activities, allowing for conditioning to occur peripherally. Left ventricular assist devices have portable drivers permitting discharge home, while the CardioWest's large driver console necessitates inpatient therapy. Exercise progression, positioning, and monitoring of exercise intolerance are similar with LVAD and TAH. Ventricular fill volumes in TAH dictate cardiac output and require close attention. Cardiectomy in TAH prevents electrocardiography, telemetry, and native pulse rate monitoring. **Conclusion:** While mechanical differences exist between TAH and LVAD, physical therapists can provide evidence-based treatment for patients with TAH using previously established guidelines for patients with heart failure and mechanical circulatory support.

Key Words: artificial heart, heart failure, physical therapy

INTRODUCTION AND PURPOSE

The purpose of this paper is to describe the total artificial heart (TAH) device as a bridge to heart transplantation, and related physical therapy (PT) management, while comparisons to left ventricular assist devices (LVAD) are made.

BACKGROUND

Heart transplantation remains the primary intervention for patients with end-stage heart disease, severe heart failure, and life-expectancy less than one year. As of January 1, 2006, even in the most urgent cases, the percentage of transplant candidates who received a heart at the end of 30, 60, and 90 days was 37%, 54%, and 58% respectively.[1]

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The Organ Procurement and Transplant Network (OPTN) classifies these candidates as "Status 1A." Patients who are Status IA are typically managed with any of the following: mechanical circulatory support, mechanical ventilation, intra-aortic balloon pump, or continuous infusion of intravenous (IV) inotropes in the intensive care setting. Additionally, Status 1A patients are classified as having a life expectancy of less than 7 days without heart transplantation if they are unable to be managed with the aforementioned devices or medications. The next most urgent category of listed patients is Status 1B. These patients have implanted ventricular assist devices for more than 30 days or receive continuous IV inotropes in a nonintensive care setting. For Status 1B candidates, 12% to 34% received transplants between 30 and 90 days, respectively, of being actively listed as a transplant candidate.[1] The remaining patients (21.9%), who are actively listed, will wait at least two years for a donor heart.[2]

While the supply of donor hearts decreases, the demand is increasing. As of 2005, the OPTN has shifted the selection of patients more towards urgency and survival benefit rather than waiting time alone. Patients using LVAD or TAH as a bridge to transplant have improved survival to and after heart transplantation, improving utilization of donor hearts.[3-5] Literature currently exists on physical therapy management for patients with LVADs, with regards to the safety and effectiveness of exercise for this population during bridging to transplant.[6-8] However, there is no specific literature regarding physical therapy management in patients who have been implanted with TAH.

Following is an overview of LVAD and TAH device design and PT management considerations. In order to highlight these considerations, as well as the hemodynamic properties of the TAH during PT intervention, a brief case description is included for one patient's hospital course during his bridge to transplant phase with a CardioWest TAH. Descriptive comparisons between the LVAD and TAH will also be made throughout the paper. The goal of this paper is to begin providing a resource for physical therapists for this new TAH device and technology. Posttransplant PT management will not be addressed in this paper.

THE DEVICES

Appendix 1 provides a comparison of the HeartMate XVE LVAS, the HeartMate II LVAS, and the CardioWest TAH. Please note that specific to the Thoratec Corporation, their preference is to label their devices "left ventricular assist systems," however for ease of terminology in this paper, these devices will continue to be referred to in the category of LVAD. The two LVADs are chosen for comparison be-

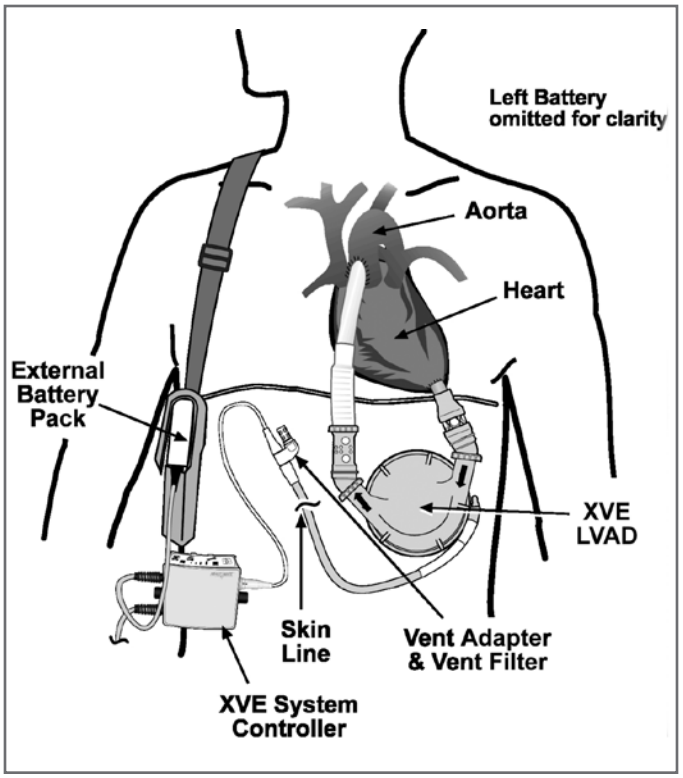

Figure 1. HeartMate XVE LVAS. Reprinted with permission from Thoratec Corporation.

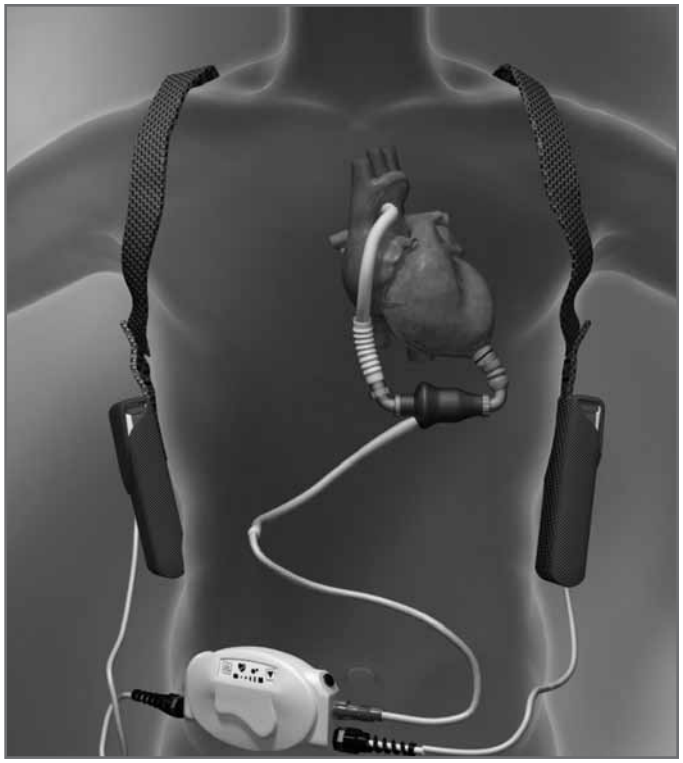

Figure 2. HeartMate II LVAS. Reprinted with permission from Thoratec Corporation.

cause they are commonly used devices[9] and are ones that are used at the author's clinical setting. Figures 1 and 2 illustrate the two LVADs respectively and Figure 3 illustrates the TAH. Because there is less information available for the TAH, a more detailed description of this device follows.

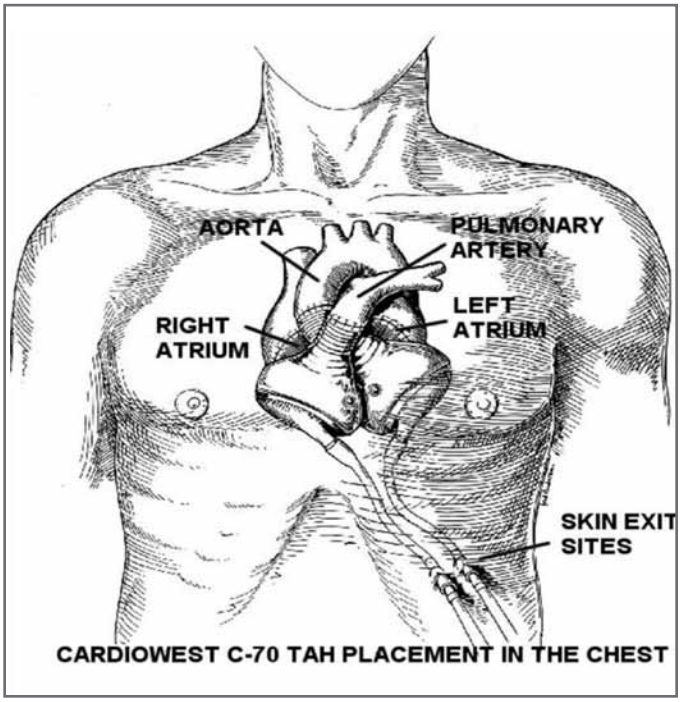

Figure 3. CardioWest TAH-t System. Courtesy of SynCardia.com.

CardioWest TAH

The SynCardia CardioWest Temporary Total Artificial Heart System is the only TAH approved by the Food and Drug Administration (FDA), Health Canada and Consultants Europe (CE) Mark for bridge to transplantation. As of May 5, 2008, Centers for Medicare and Medicaid Services (CMS) has approved coverage of TAHs, including the Cardio West. The device is being implemented in 12 certified centers nationwide, including the Cleveland Clinic.[10] When implanted, the CardioWest replaces the native ventricles and valves. Patients with a TAH do not require inotropic or antiarrhythmic agents and avoid pulmonary hypertension, right heart failure, and myocardial and valve related problems. The CardioWest is indicated for patients with biventricular failure, cardiogenic shock, multiple organ failure, and/or those at risk for LVAD implantation. It occupies the space of the removed heart and valves, making a surgical pocket unnecessary.

The CardioWest weighs 160 grams and occupies 400 cm^3 of space. The lower limit of body surface area necessary for proper fit is considered to be 1.7 m^2, suitable for most adults and some larger adolescents; although similar results have been reported for patients with body surface area as low as 1.5 m^2.[11] The two independent polycarbonate ventricles of the CardioWest have a total volume of 750 ml with unidirectional inflow and outflow valves. It is pulsatile and pneumatic. Polyurethane diaphragms separate blood from air pressure pulses controlled by an external driver. A driver delivers pneumatic pulses through drive lines into the air chambers of the ventricles, distending the diaphragms and ejecting blood. Seven foot pneumatic drive lines exiting the body are Dacron velour covered to allow tissue ingrowth and avoid spread of infection along

the lines.[12] The driver console contains two compressed air tanks and a backup power supply (battery) for mobility; the battery is automatically activated in any instance where the hospital's air and power supply are interrupted. A laptop computer on the console calculates and provides noninvasive monitoring information. The computer screen displays the device rate, stroke volume, cardiac output, drive pressure and flow waveforms, cardiac output trends, and patient related alarms. The large size of the console prevents patients from being discharged from the hospital (Figure 4). A portable and wearable driver allowing hospital discharge is currently being used in Europe.[13]

The CardioWest has the shortest blood flow path of any device, reducing the risk of thromboembolism.[14] It also has the largest inflow conduit area allowing for high cardiac output, with flows up to 9.5 L/min. The large inflow diameter and short blood flow distance through the device reduces central venous pressure, while high cardiac output increases systemic pressure, improving end organ perfusion and function.[14] The device has a range of 100 to 130 beats per minute and a 70 mL ventricle. It is typically set to partial fill and runs at a fixed percentage of systole and a fixed beat rate of 120 to130 beats per minute with a stroke volume of 50 – 60 mL. The beat rate remains at the preset value and does not fluctuate until the value is reset on the device. The 70 mL ventricle is not fully filled to accommodate increases in venous return. With exercise or volume loading, cardiac output automatically increases as in a normal heart (Appendix 1).

Studies have been favorable for the CardioWest TAH. It has been shown to reduce the occurrence of stroke and transient ischemic attack during bridging to transplant in comparison to LVAD or BiVentricular Assist Devices (BIVAD) devices, with competitive rates of bleeding and infection.[14] The CardioWest currently has the highest survival to transplant rate of any device.[4] In 2004, Copeland and colleagues[4] reported 79% of patients using the CardioWest bridged to transplant versus 46% of controls not receiving mechanical circulatory support. Survival at one and 5 years after transplant was 86% and 64% for study patients versus 69% and 34% of controls. Overall one year survival among implanted patients was 70% as compared to 31% of controls. The study also reported that 75% of patients were out of bed within one week of implantation of the CardioWest, and that patients bridging to transplant with the CardioWest experienced improvements in quality of life and mobility (defined as walking greater than 100 feet within two weeks).

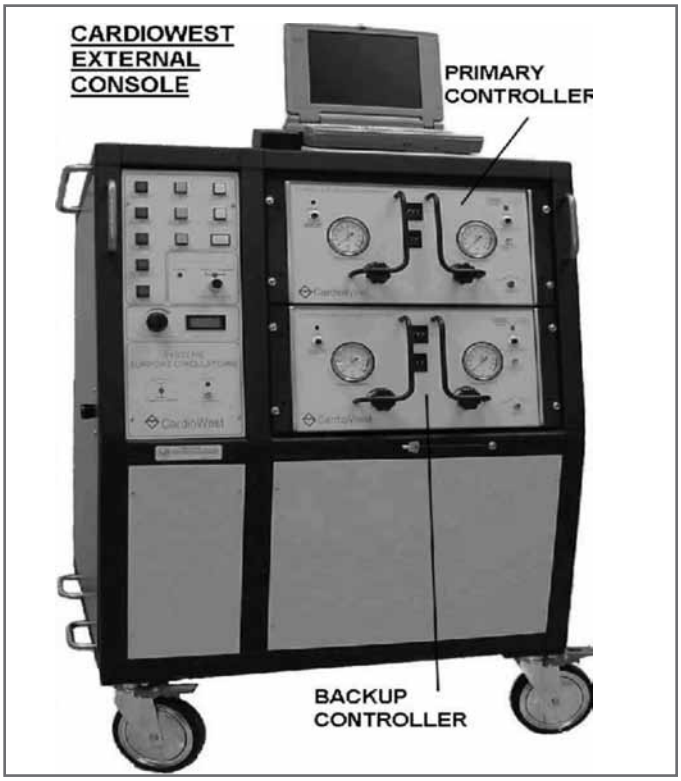

Figure 4. "Big Blue." Courtesy of SynCardia.com.

Comparison between LVAD and TAH

A primary difference between LVAD and TAH is that currently, the only approved use for TAH is for bridge to transplant therapy whereas the Heartmate XVE can be used for either bridge (temporary) or destination (permanent) therapy (Appendix 1). Functionally the TAH console is larger and somewhat more cumbersome to mobilize a patient with and may require more technical support. All devices are adaptive with exercise and have the ability to increase flow or cardiac output during activities that allow for conditioning to occur peripherally.[8,15,16]

Monitoring the patient is similar for TAH and LVAD with the following exceptions: Since a patient with a TAH has undergone a cardiectomy, there is no native heart rate or monitoring via telemetry. If necessary or in the ICU setting, native heart rates and rhythms in patients with LVADs may be monitored via telemetry. Blood pressure for patients with TAH or LVAD can be taken manually, although for the HeartMate II, a mean arterial pressure (MAP) may be taken via doppler ultrasound in the event that peripheral pulses become diminished. The continuous motor and flow of blood through the Heart Mate II device may diminish peripheral pulses particularly in cases where left ventricular contribution to flow is compromised such as when the ventricle is flaccid or in fibrillation.

In all patients with either TAH or LVAD, device rate, flow and volume, blood pressure, oxygen saturation, and symptoms of orthostasis and exercise intolerance [rating of perceived exertion (RPE)] should be monitored throughout each treatment session.[17] Physical therapy should be withheld or terminated and the medical team notified when: the patient is short of breath or reports exercise intolerance, systolic blood pressure is less than 80 mmHg or decreases by more than 20 mmHg, flow is less than 3 L/min, reduced volumes, the device alarms, and if the therapist notices neurological changes or bleeding. In LVAD recipients, other causes for concern and course of action are chest pain and palpitations, which are not considerations in a patient with TAH as the native heart has been removed. With the HeartMate XVE, care needs to be taken not to occlude the vent filter. The filter protects the motor from any contamination that could be introduced through the vent adapter located on the drive line. Occlusion of the filter can impair the pneumatic drive lines

and ultimately LVAD function. Nursing needs to be notified immediately if fluid enters the filter.

Infection, especially along the drivelines exiting the body, is a major issue[9] for patients with LVAD or TAH. Good hand washing on the part of the clinician is essential, along with patient education regarding wearing of an abdominal binder and avoiding disturbance of the drivelines. Patients should avoid sleeping, turning to and lying on the side of the body where the drive lines exit, and prone positioning.

The CardioWest, HeartMate XVE and II devices each have audio and visual alert for alarms. HeartMate devices alarm when issues are detected related to low flows or device rates, low voltage of batteries, and disruptions of the system controller, driver or power cables. Therapists working with patients implanted with the HeartMate II should also monitor the pump power and pulsatility index (PI), both found on the system monitor. Pump power is a direct measurement of the work of the pump. Pulsatility index is an average of the magnitude of pump flow pulses over 15 second intervals; it represents LV filling and native cardiac pulsatility. Higher PI values indicate greater ventricular filling and pulsatility (the pump is providing less support) and lower values indicate less ventricular filling and pulsatility (the pump is providing greater support to the ventricle) (Appendix 1). Pulsatility index should not vary considerably during rest. Significant increases in PI (gradual or abrupt) may indicate the presence of a thrombus in the pump. Significant drops in PI may indicate a decrease in native heart function or circulating blood volume and need to be evaluated. The CardioWest will alarm with disturbances of driveline pressure, low or left/right imbalances of cardiac output, activation of reserve air tanks or low air tank pressure, and faults related to the monitoring computer.

There are other safety concerns as patients with either LVAD or TAH become increasingly mobile with progression of ambulation in PT. Therapists ambulating patients outside of their rooms need to ensure that batteries and air tanks (where applicable) are charged and full (Appendix 1). The proper back up or emergency equipment such as an extra controller, hand pump, or power base unit (where applicable) need to travel with the patient (Appendix 1). Generally, patients have been educated in and are aware of the proper procedures required for mobility. Physical therapists can enhance safety and empower patients, who are becoming increasingly independent as they bridge to transplant or prepare for discharge home, by reinforcing patient education each treatment session regarding mobility and exercise safety.

CLINICAL APPLICATION

At the time of this writing, two patients at the author's facility have undergone TAH implantation with one of those patients successfully receiving orthotopic heart transplantation and being discharged home. Provided below is a brief synopsis of his clinical course highlighting specific PT management considerations in relation to the TAH with a focus on hemodynamic monitoring and exercise response. Prior to reviewing the medical record and documenting pertinent aspects for this paper, informed consent was obtained from the patient.

The patient is a 61-year-old previously independent and active white male with a past medical history of ischemic cardiomyopathy, coronary artery disease, congestive heart failure (CHF), mitral valve disorder, myocardial infarction, atrial fibrillation, and ejection fraction of 10% and a surgical history of coronary artery bypass grafting (1992), percutaneous transluminal coronary angioplasty, and automated implantable cardioverter-defibrillator. He was admitted to an outside hospital via the emergency department with shortness of breath. After admission, the patient experienced respiratory failure and full cardiac arrest. He was intubated and administered inotropic therapy of levophed and dopamine. Once extubated, and weaned off of levophed and dopamine, dobutamine was initiated. The patient was then transferred to the Cleveland Clinic with a diagnosis of cardiogenic shock and as a potential heart transplantation candidate. Six days after admission he underwent implantation of the CardioWest TAH.

Beginning at postoperative day (POD) 7, when PT was consulted and the initial PT examination was completed, the patient received PT services through the majority of his bridge to heart transplantation. Table 1 outlines the results of the initial examination that was completed at bedside in the ICU. Therapists working with the patient had completed a training course by the SynCardia Company regarding the device, its operation, and patient safety. However because of the recent initiation and clinical implementation of this device at the Cleveland Clinic, no specific PT guidelines for patients with TAH had been established. Therefore the rehabilitation team decided to use the pre-existing guidelines, referenced in the literature, that are implemented for patients with cardiac dysfunction, including those receiving LVAD placement.[6-8,17-22]

Department guidelines were followed such as the observance of activity orders and sternal precautions along with careful progression of activity and monitoring for symptoms of exercise intolerance. Activity orders from the physician were "out of bed to chair as tolerated." Medications that the patient was initially prescribed included Hydralazine (Apresoline), a direct peripheral vasodilator and Amlodipine (Norvasc), a calcium channel blocker used for vasodilation.[23] Over time, the patient was transitioned to Hydralazine and Lisinopril (Zestril or Prinivil), an angiotensin converting enzyme (ACE) inhibitor, used to minimize fluid retention and vasoconstriction.[23] He also took Propoxyphene (Darvon) as needed for pain. Documentation regarding the medication adjustment was not clear; however for purposes of comparison, as a result of the cardiectomy and TAH implantation, medications need to be directed peripherally as opposed to patients who receive LVAD may still receive centrally acting cardiovascular agents such as positive inotropes.

During the examination, at rest and with activity, the therapist assessed for signs of orthostasis, monitoring left and right fill volumes, cardiac output, heart rate, and blood pressure.[6,7,18] Monitoring fill volumes are unique to patients with TAH as these volumes will help dictate cardiac output. Cardiac output, heart rate, and fill volumes are displayed on the computer screen, while blood pressure was moni-

Table 1. Physical Therapy Examination Results

Examination	Results
Cognition/Orientation	Alert and oriented to person, place, date/time and situation
Safety Awareness/Judgment	Pt's judgment and awareness of safety issues and precautions is WFL
Command Following	Able to follow commands
Pain (visual analog scale)	Pt reported headache and incisional pain, but did not give a pain level
Range of Motion	WFL
Strength (manual muscle test)	Formal manual muscle testing not assessed, pt's strength is decreased since prior to admission (per patient report)
Sensation	Light and deep touch and proprioception are within normal limits
Functional Mobility	▪ Rolling: Moderate assist ▪ Supine – Sit: Moderate assist ▪ Sit – Supine: Not tested ▪ Sit – Stand: Minimal assist ▪ Bed – Chair: Minimal assist
Balance	▪ Sitting o Static: Supervision o Dymamic: Contact guard assist ▪ Standing o Static: Contact guard assist o Dynamic: Minimal assist with a walker
Gait	Pt was ambulated 2 feet from bed to chair with a wheeled walker and minimal assistance. Pt exhibited decreased cadence and step length.
Vital Signs	Pre-mobility ▪ HR: 130, BP: 124/58 ▪ LCO: 5.3, RCO 5.5, L Fill: 41, R Fill: 47 During mobility (standing/sitting/transfer) ▪ BP: 98/68 Post-mobility (after reclining in bedside chair) ▪ HR: 130, BP: 126/64 ▪ LCO: 4.8, RCO 5.1, L Fill: 36, R Fill: 41 Oxygen requirement: 2 liters via nasal cannula

Pt: patient WFL: within functional limits HR: heart rate (beats per minute) BP: blood pressure (mmHg)
TAH Parameters:
- LCO: left cardiac output (liters per minute)
- RCO: right cardiac output (liters per minute)
- L Fill: left fill volume (milliliters)
- R Fill: right fill volume (milliliters)

Table 2. Total Artificial Heart Parameters at Rest ("Pre") and During ("Peak") Exercise

	HR	BP* Pre	BP Peak	LCO Pre	LCO Peak	Activity
Initial examination	130	124/58	98/68	5.3	4.8	Bed to chair
Week 3	120	150/50	170/80	5.6	5.3	Supine and seated AROM. Ambulation 150 feet.
Week 5	120	130/72	132/82	6.9	6.5	Ambulation 960 feet
Week 7	120	134/82	138/62	7.1	7.1	Treadmill ambulation** 16 min, 0.9 mph
Week 9	120	136/72	138/76	6.8	6.8	Treadmill ambulation 32 min, 1.2 mph
Week 11	120	116/74	124/72	6.8	6.8	Treadmill ambulation 46 min, 1.4 mph

AROM: active range of motion
BP: blood pressure
LCO: left cardiac output (liters/min)
HR: heart rate (beats/minute) set by TAH
Min: minutes
Mph: miles per hour
*BP taken from arterial line reading for initial evaluation, and via cuff measurements other sessions.
**Treadmill ambulation data were recorded during Cardiac Rehabilitation

tored by arterial line readings (Table 2). Once the patient was transferred out of the ICU, subsequent blood pressure measurements were taken manually with a cuff. Care was taken not to disturb the abdominal location of the exiting drive lines, which the patient reported were painful. Patient education focused on sternal precautions, symptom awareness, and mobility safety with drive lines including the use of an abdominal binder and positioning to avoid kinking of drive lines or trauma to the surgical site.

Evaluation findings associated with the initial examination were impairments of gait, balance, activity tolerance, pain, and knowledge deficit. Despite the TAH implantation, the evaluation findings are consistent with those reported in the literature for patients with LVAD placement.[8,19] The consulting therapist's initial plan of care included a treatment frequency of 6 days per week to address these impairments and functional limitations. Goals were to prevent the deleterious effects of immobility, improve his functional limitations with bed mobility, transfers, ambulation, pain management and safety awareness, and ultimately maximize his strength and endurance in preparation for heart transplantation. Since this was a novel experience for the consulting therapist, the decision making and plan of care for this patient was based on literature for patients with LVADs.[8,17,19]

The first 3 weeks of PT consisted of active and active-assisted range of motion (ROM) exercises, bed mobility progression, sitting and standing activities to increase tolerance to upright, progressive ambulation, and instruction for gentle active ROM exercises that the patient could perform on his own as tolerated in supine and sitting.[8,18] During week 3 after implantation of the CardioWest, the patient progressed to being able to perform standing therapeutic exercises and ambulating 150 feet with a wheeled walker and contact guard assist from the PT. An additional health care worker was needed to push the console while the patient performed gait training. Hemodynamic measurements and responses are noted in Table 2. Thorough warm-ups consisting of seated and standing exercises preceded each episode of ambulation in PT. Though the patient was never symptomatic, it was noted that at times, if the patient sat down in a slumped position immediately after ambulation without any cool down activity, his left cardiac output would drop to or just below 4.0 liters per minute. From week 3, onwards cardiac output prior to and during gait training averaged from 5 to 7 liters (Table 2). More gradual cool downs and postural awareness were incorporated into treatment sessions. Cool downs consisted of a shorter, lower intensity walk after endurance training and/or gentle seated lower extremity exercises prior to termination of activity or exercise. Postural awareness addressed the patient's tendency to "slump" while seated, or improve thoracic positioning while seated. These measures reduced incidences of post-activity drops in left cardiac output during PT.

By postoperative week 6, the patient progressed to ambulation at supervision level without an assistive device and to a distance greater than 1,000 feet with the hemodynamic response shown in Table 2. Hemodynamically, between weeks 3 and 7, the patients resting blood pressure went from 150/50 to 134/82, while his peak blood pressure went from 170/80 to 138/72. The therapist referred the patient to Phase I Cardiac Rehabilitation (Cardiac Rehab); a supervised and monitored exercise program for ambulatory inpatients that require endurance progression, which is provided by a team of exercise physiologists at the Cleveland Clinic. The patient began daily treadmill training with Cardiac Rehab on POD 42, and the PT plan of care was reduced in frequency to 3 days per week. Treadmill training continued throughout the remainder of the patient's bridge to transplant phase. Over the course of 5 weeks, he progressed in level treadmill walking from a speed of 0.8 mph for 10 minutes to walking at 1.5 to 2.0 mph for 65 minutes. During these Cardiac Rehab sessions, despite the increases in exercise intensity and frequency, his peak blood pressure remained steady in the 130s (systolic) and 60 to 70s (diastolic). While the patient underwent endurance training with Cardiac Rehab, his PT sessions focused on gait and balance training via walking and standing exercises, and strength training via seated and standing exercises with the addition of one pound ankle weights.[20]

After 10 weeks in PT, the patient was ambulating and safely performing strengthening exercises independently, and had transitioned to progressive treadmill training with Cardiac Rehab. Physical therapy essentially "signed off," and followed the patient at a distance should any issues arise. After 83 days of bridging with the CardioWest, and 27 days actively listed as Status 1A, the patient underwent successful heart transplantation.

DISCUSSION

Because of the recent initiation and clinical implementation of this device at this author's facility, no PT guidelines had been established for patients with TAH. The patient's presentation however was similar to those referenced in the literature for patients with heart failure and circulatory assist devices.[8,19] Therefore, the early mobilization of our patient was appropriate for the sequence suggested by Humphrey and colleagues for patients with LVAD.[7] This sequence consisted of careful monitoring of device flows and fill volumes, signs of orthostasis, and avoidance of positioning or activity causing stress to drive line insertion site.[6,7,18] Ongoing assessment and treatment of the patient was carried out with monitoring of hemodynamics and symptoms of exercise intolerance. Because the patient's functional limitations were consistent with most cardiac patients seen at this facility, the majority of this discussion will focus on the hemodynamic response in relation to the TAH device. Comparison of blood pressure responses from the initial examination to week 3 onwards cannot be made because of the different measurements conducted (ie, arterial line to cuff measurements).

With reference to the specific features of the TAH, the heart rate is fixed with increased cardiac output occurring as a result of increasing preload. As stated earlier in the paper, the 70 ml ventricle is not fully filled at rest in order to accommodate more venous return during exercise, thus being able to adapt to a certain amount of workload. This is demonstrated in Table 2 with regards to the heart rate, beginning in week 3, remaining fixed at 120 beats per min-

ute throughout the course of rehabilitation while the peak cardiac output increases from 5.6 liters/min. to 6.8 liters/min (weeks 3-11). Interestingly enough, in weeks 3 through 5, the increased cardiac output, both at rest and with activity, did not result in a concurrent increase in systolic blood pressure at rest and during activity. In weeks 5 through 9, there appeared to be a plateau in both blood pressure and cardiac output at rest and during activity despite an increase in endurance as noted both by the treadmill parameters and duration of activity.

Interpretations of these hemodynamic responses are limited in this single retrospective case review. However, it appears that the TAH mechanism, such as a fixed heart rate and maximal stroke volume, maybe responsible for some of the cardiovascular responses measured during exercise with this patient. Additionally as result of early mobilization, initiation of progressive ambulation and exercise training with physical therapy; peripheral skeletal muscle adaptation and associated vasodilation may have occurred, possibly accounting for the relative plateau in blood pressure and cardiac output from weeks 5-9.[18,22,24] Vascular response may also be influenced pharmacologically by the vasodilators that the patient was receiving as part of his medical management.

The patient's achievements in exercise performance at 9 weeks was somewhat consistent with findings by Morrone and colleagues[8] for patients with LVAD, where after 6 to 8 weeks of conditioning, only minimal improvements in exercise tolerance and functional capacity occurred. Since this patient's response to exercise is consistent with literature for patients with LVAD, it appears that following these established parameters in the literature is appropriate for patients with TAH. However, given the limitation of a single case report and the mechanical differences between LVAD and TAH, further study on these physiological aspects is warranted in the future to fully determine management guidelines.

The incidences of low left cardiac output during PT appeared to be related to improper cool down (ie, sitting abruptly) after endurance training, or positioning. Poor thoracic posture while seated may have stressed the drive lines exiting the body, compromising TAH function. Improper cool down, coupled with being managed with vasodilators, could have led to pooling of the blood in the lower extremities, and a sudden decrease in venous return to the TAH. Since the TAH relies on venous return to increase cardiac output, then these drops in cardiac output appear to be both reasonable and preventable as long as the clinician keeps the mechanical aspects of the device in mind.

Ventilatory limitation was not a likely factor in his training as oxygen desaturation was not an issue with the patient. However ventilatory adaptations may have played a role in this patients exercise reponse.[25] No formal measurements of pre-rehabilitation and post-rehabilitation ventilatory function were conducted and would be a beneficial factor for future study particularly based on recent literature review by Arena et al[26] describing the diagnostic benefits of examining ventilatory parameters during exercise in patients with heart failure. Central cardiac adaptations would not have occurred due to the mechanical device replacing the native heart.

Standardized tests and scales were not used. Literature regarding the rehabilitation of patients with CHF or with LVAD suggests using the Borg RPE ratings to assess exercise tolerance and the Six Minute Walk Test to safely progress exercise in this population.[7,19,21] In the future, therapists at this facility should implement these suggestions, with patients who have these diagnoses, to further promote evidence-based practice. Additionally more thorough documentation of vital sign response during specific activities with physical therapy, such as seated exercises or balance activities, need to occur to further investigate and understand the physiological responses that are associated with this device.

Given these limitations and the lack of PT literature regarding TAH and the recent initiation and implementation of the TAH in this facility, examination and intervention for this patient with TAH relied on similar parameters to that of patients with LVAD. Surgical precautions for patients who are status post median sternotomy applied in this patient situation, as did the exercise safety guidelines for the treatment of patients with CHF[21,25] or denervated heart.[18]

CONCLUSION

The CardioWest TAH is proving to be an effective and increasingly prevalent mechanical bridge to heart transplantation. While mechanical differences exist between TAH and LVAD, physical therapists can provide evidence-based treatment to this population using previously established guidelines[6-8,18-22] for patients with heart failure and mechanical circulatory support. As more and more patients receive TAH implantation, further evidence supporting physical therapy management of bridge to heart transplantation with TAH should continue to be gathered and documented.

ACKNOWLEDGEMENTS

The authors wish to thank Dean Jeris, PT, and Stephanie Liebert, MPT, Clinical Team Leader, both at the Cleveland Clinic Neurological Institute, for their assistance in managing this patient during his course of therapy and providing clinical consult for this manuscript.

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Appendix 1. Comparison between Left Ventricular Assist Devices (LVAD) and Total Artificial Heart (TAH)

	HeartMate XVE LVAS[a]	HeartMate II LVAS[b]	CardioWest TAH[c]
Indications	▪ FDA approved for BTT and DT ▪ BSA >1.5m^2 ▪ Irreversible LV failure ▪ Pt with NYHA Class IV end-stage LV failure s/p optimal medical therapy for at least 60 of the last 90 days and a life expectancy of less than 2 years, and not a candidate for cardiac transplantation ▪ For use in and out of hospital	▪ FDA approved for BTT ▪ Irreversible LV failure ▪ Used in and out of hospital ▪ Limited data supporting implantation in patients with BSA < 1.5m^2	▪ FDA approved for BTT ▪ Irreversible biventricular failure, multiple organ failure, cardiogenic shock, larger pt needing higher CO, failed transplant ▪ BSA >1.7m^2 ▪ Inpatient use in U.S.
Pump Drive	Vented-electric	Electric	Pneumatic
Flow	Pulsatile	Continuous	Pulsatile
Characteristics	▪ Textured blood-contacting surfaces (including polyurethane diaphragms) forms cellular lining and reduces thromboembolism ▪ No anticoagulation required (aspirin only) ▪ Porcine valves ▪ LV, pump and aortic pressure differentials open/close valves ▪ Tendency of diaphragm to recoil to "full" position creates negative pressure in pump which allows filling even if LV is flaccid ▪ Drive line is vented to motor chamber and must accommodate a volume of air equal to volume of blood pumped ▪ Belt mounted system controller and holsters for portable batteries	▪ Polished titanium surface with textured inflow and outflow conduits ▪ Requires anti-coagulation ▪ LV contraction is amplified as a flow pulse delivered to aorta; systemic flow is pulsatile unless heart flaccid or in fibrillation ▪ Belt mounted system controller and holsters for portable batteries	▪ Polycarbonate ventricles, polyurethane diaphragms, artificial valves ▪ No surgical pocket required ▪ No EKG monitoring ▪ Blood path <20cm inflow to outflow ▪ Requires anticoagulation ▪ Large console contains battery; wearable driver only available in Europe
Size	1150 g	375 g	160 g
SV, Flow / CO	83 mL, 10 L/min	124 mL, 10 L/min	70 mL, 9.5 L/min CO
Operating Modes	▪ Fixed Rate ▪ Auto Rate	Fixed Speed	Fixed beat rate, % systole and left and right driving pressures
Exercise Response	▪ Can produce flows approximating 10 L/min at a MAP of 120 mmHg, a fill pressure of 20 mmHg, and a pump rate of 120 bpm ▪ Responds to increasing pulmonary return by increasing the pump beat rate and pump output ▪ Auto Rate mode varies rate of blood pump filling by increasing or decreasing beat rate to maintain SV at 90-95% of pump capacity ▪ Rates between 50 – 120 bpm ▪ Postural hypotension will result in reduced pump flows	▪ Flow is determined by the speed of rotation of the rotor and the differential pressure across the pump ▪ The rotary pump auto-regulates its flow to match the volume delivered by the right heart ▪ LV pressure fluctuation at pump inflow changes pump differential pressure which alters flow accordingly ▪ Postural hypotension will result in reduced pump flows	▪ Run at 120-130 bpm ▪ Heart rate and % systole are fixed for ventricular filling of 50-60 mL ▪ CO automatically increases with increased venous return up to 70 mL
Vitals and Parameters to Monitor	Pump Rate, Flow, SV, Mode, Native HR if on telemetry, BP, SpO_2, RPE	Pump Flow, Speed, Power, Pulsatiliy Index, Native HR if on telemetry, BP or MAP, SpO_2, RPE	Left Fill, Right Fill, Left CO, Right CO, HR, BP, SpO_2, RPE
PT Considerations and Patient Safety	▪ Treat in Auto Rate mode ▪ Do not position pt on right side or stomach ▪ Pt to wear abdominal binder and take care not to disturb lead exit site ▪ When mobile, place pt on batteries and bring 2 spares ▪ Battery life 3-5 hrs for 2 batteries ▪ Bring extra controller and emergency hand pump ▪ Bring PBU if pt being transported and needs monitored once at location ▪ Know how to interpret alarms ▪ Do not allow controller to hang off bed ▪ Notify nurse immediately if fluid enters vent filter; do not occlude filter ▪ Showering permitted only when clinician approves lead exit site readiness	▪ Measure BP manually or via doppler (MAP) if pulse diminished ▪ Do not position pt on right side or stomach ▪ Pt to wear abdominal binder and take care not to disturb lead exit site ▪ When mobile, place pt on batteries and bring 2 spares ▪ Battery life 3-5 hrs for 2 batteries ▪ Bring extra controller (No hand pump) ▪ Bring PBU if pt being transported and needs monitored once at location ▪ Know how to interpret alarms ▪ Do not allow controller to hang off bed ▪ Showering permitted only when clinician approves lead exit site readiness	▪ Large console must be transported with pt; may need tech support ▪ Do not position pt on left side or stomach to avoid drive line occlusion. ▪ Pt to wear abdominal binder and take care not to disturb lead exit site ▪ Portable for 45 min (limited by air tanks) ▪ Check air tank pressure and power before ambulating pt ▪ Console contains primary and backup controller; facility must have extra console available ▪ No hand pump ▪ Know how to interpret alarms

SV=stroke volume, CO=cardiac output, BTT=bridge to transplant, DT=destination therapy, BSA=body surface area, Pt=patient, LV=left ventricular, MAP=mean arterial pressure, HR=heart rate, BP=blood pressure, SpO_2=saturation of peripheral oxygen, RPE=rate of perceived exertion, PBU=power base unit

[a] HeartMate XVE LVAS Operating Manual, Thoratec Corporation, www.thoratec.com

[b] HeartMate II LVAS Operating Manual, Thoratec Corporation, www.thoratec.com

[c] CardioWest TAH Directions for Use, SynCardia Systems Inc., http://www.fda.gov/OHRMS/DOCKETS/ac/04/briefing/4029b1_FINAL.pdf

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THE LINDA CRANE MEMORIAL LECTURE

Thursday February 18, 2010

APTA's CSM San Diego, CA

Striving For Excellence

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ABSTRACT

Historically, invited lecturers have often challenged us to define excellence in physical therapy practice, or in our academic programs. While some have addressed different characteristics of excellence, our profession has not really come together to address 2 very important questions: what does "quality" mean in physical therapist education? And how do we measure it? Using 3 elements of Friendship, Leadership, and Mentoring, and Defining Excellence and juxtaposing these with Linda Crane and her life, a vision of excellence in physical therapy educational programs was explored in this invited lecture. The text of that lecture ensues.

Good afternoon everyone. I would first like to thank Dr. Frese, and the Awards Committee of the Cardiovascular and Pulmonary Section for selecting me for this great honor. I would also like to thank Drs. Meryl Cohen and Carol Davis (both previous Linda Crane Lecturers) for nominating me, making me the third person from the University of Miami, on the 10th anniversary of this Lecture.

I would also like to assure the cardiopulmonary physical therapists in the audience that while I teach neuroanatomy, I am really an acute care person at heart. I learned a lot from two very notable cardiopulmonary people—(1) The first person was while at Columbia Presbyterian Medical Center in New York City as a new graduate in 1970. We could work overtime on weekends doing chest physical therapy, but we all had to be trained first by the superb pulmonary physical therapist, Micah Rie; and (2) later at Hartford Hospital (in CT) in 1977, where I first met Linda Crane. Thus, I feel I have probably learned from two of the very *best*.

I also have something to share with this audience. We are all familiar with the bumper stickers that say "I Love NY," or something similar, with the red heart in the middle. The University of Miami is often called simply "the U." Well, one of my students came to class with this t-shirt (see Figure 1). Linda would have loved it!

When trying to decide what to speak about today, I tossed around many ideas. But I realized that I knew Linda most as a ***teacher***. I found this poem that really captured so much of Linda as a teacher:

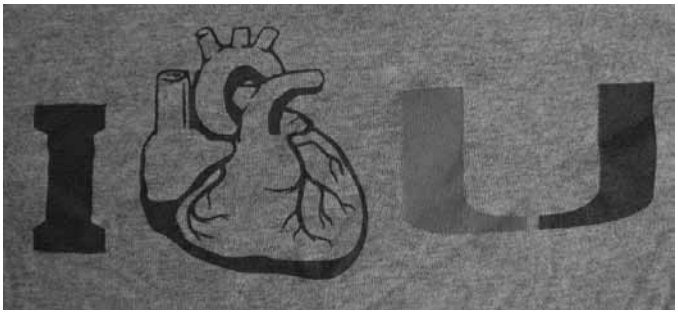

Figure 1. "I Heart *U(M)*."

Teaching is a Lifelong Journey - Donna Bulgur[1]

To teach is to touch the lives of many
and to help us learn life's lessons.
But to teach **well** is to make a difference
in all the lives you touch.

To teach is to be a parent, nurse, friend,
and confidant;
to be a supporter, a leader, and a motivator.
But to teach **well**
is to be all of these things,
yet not lose sight of who you are.
You share a part of yourself
with all whose lives
you have touched.

To teach is to be tender,
loving, strong, and giving,
to all who rely upon you;
to encourage and praise.
But to teach **well**
is to believe in what
and whom you teach.

A teacher comes to master
these many jobs
throughout the years.
But those who teach **well**
recognize that there
will always be more
to learn in life's journey,
and they never hesitate
to strive to learn it.

"Friend, Supporter, Leader, Motivator; Believe in what and whom you teach; Always more to learn." Linda was all of these things. She was one of those inspiring teachers who always *strived for excellence*. I was Linda's Chair for 11 years. We've all heard of Linda's good qualities, especially in this forum. Somehow, however, this quote seemed perfect:

> **"***Most great men and women are not perfectly rounded in their personalities, but are instead people whose one driving enthusiasm is so great it makes their faults seem insignificant.***"** *(Charles A. Cerami)*

As her Chair, I can tell you that Linda had a *few* faults. She was stubborn, impatient, demanding, and a perfectionist; but she was also dedicated, extremely loyal, caring, and fun-loving. She was a good friend. She was *my friend*. I felt that if Linda were here today, there are a few things she would expect me to say. I am going to focus on excellence; specifically, **leadership and excellence in physical therapy education**.

I have chosen 3 main themes: (1) educators love to use stories, so I have a little story about friendship and my history with Linda to share with you; (2) the importance of leadership (and mentoring) in our profession; and (3) excellence in physical therapist professional programs --where we are now, and where we need to be. For me, all 3 are intertwined and inseparable, as you will soon see.

In short, my goal is to enlighten and entertain, as well as to challenge you.

1. **A story and a friendship**.

At the University of Miami, Linda was famous for her cardiopulmonary practical examinations and simulations. She often had other faculty participate, and be the "actors" for some of these cases. Sometimes it was random selection; sometimes she had a particular reason for putting specific faculty into one of the roles.

Well, my "perpetual" case was "a middle aged woman, PMH of hypertension, a previous myocardial infarction (MI), overweight, and--a smoker. The patient is in the hospital now for an open reduction-internal fixation (ORIF) - fracture of the R ankle; physical therapy prescription = teach her gait training, nonweight bearing (NWB), with a walker, prior to discharge tomorrow."

Now – our students would often be annoyed, complaining "why is there an ortho case? This is a CP course??!!" Of course, as you all know, the reason was that this was serious cardiac and pulmonary work for someone not really physically fit; or to use a familiar admonition, especially with *this* audience – *ALL patients have hearts and lungs, and are therefore C-P patients!* Linda had me act all of this out–coaching me when to feel dizzy, c/o shortness of breath, etc., in order to emphasize the need for doing continuous vital sign checks.

Well, except for the heart attack, I actually became that case on July 31, 2009 – and I can tell you – it wasn't fun. Lisa Sanders, MD, says it well[2]: It really is "like waking up in a foreign country; life, as you formerly knew it, is on hold." Like all physical therapists, I was used to being on the *other* side of the rehab equation.

So, after the first surgery, I was really *screwed* (1 plate, 9 screws!). I came home from the hospital, NWB with a walker--in a very modern house with 3 levels (very modern, very chic, which I always loved *before* my accident!). I also had two bad shoulders from previous arthroscopic surgeries, so NWB with a walker was scary. And crutches? They were just plain dangerous! I became quite adept with one of those scooters they have now, which was a life-saver for me. I became the perfect example of all the bad things that happen when you are NWB for 10 weeks; I have learned a new appreciation for ankles, along with a new vocabulary (tri-malleolar fracture; "stress risers" – who knew?), and I'm still in therapy. At some point, I remembered, and thought – **OMG!** (texting term) I have become Linda's case! But my ultimate tribute to Linda is even better, since I finally kicked that nasty habit of mine.

During the process, I have to thank my husband, Tom (who *really* had the major caretaking challenge), as well as my faculty and staff (and especially Meryl Cohen, who was much nicer to me in her admonitions than Linda would have been!). I think Linda is watching and smiling, right now, and saying, *"finally!"*

So, Linda and I met in 1977 at Hartford Hospital. Our paths crisscrossed for a number of years, despite very different lives, but we would always catch up at national conferences. I taught at the University of Connecticut and in 1985, I moved to Miami, to the University of Miami (UM), with my husband and 3 children. Linda taught at the University of Connecticut, then moved to the University of Alabama-Birmingham, and then to the University of New England. In 1985, she became one of the first three ABPTS-certified Cardiopulmonary Clinical Specialists ever. While in Maine, she was doing some clinical site visits in Ft. Lauderdale, she called me, and came to stay at our house. I started trying to recruit her – and she joined us at the University of Miami in 1988.

The same year, Dr. Steven Rose also came to UM. I highlight these two individuals for a reason. Linda was Interim Chair at University of New England, and Steve was Chair at Washington University in St. Louis, as well as Editor of *Physical Therapy*. Also on the faculty at the time were Dr. Ira Fiebert, former Chair at UM, and Dr. Carol Davis, former Interim and Co-Chair at Boston University. In 1988, counting myself, there were **5** Interim or former Chairs on our faculty of 8 people. The phrase "*herding cats*" comes to mind. Daunting? Yes. Intimidating? Yes. But also, quite amazing. We were quite a unique and experienced group in the early days, building something special, together.

So to summarize the theme about *Friendship*, Linda and I knew each other for a long time. We stayed close despite distances and circumstances. We were different, but had a few things in common (Dutch and German heritage, stubborn, perfectionists, strong-willed, feisty). We went on day cruises (gambling), to holiday parties, birthday parties, and to UM football games during the "glory years." There were the annual pool parties for the students at my house, X-Files parties, and Marquette Challenge Galas.

Finally, in October of 1998, we went to Las Vegas together. I went to do some clinical site visits, Linda came

just to keep me company--and because we all knew she loved Vegas. I think we *both* knew it was her last trip there, and we made the most of it. We did the tourist things, we gambled, we "did the shows," we gambled, we caught up with alumni, we had a blast. It was a very special trip together, for two friends.

2. Leadership

"A leader takes people where they want to go. A great leader takes people where they don't necessarily want to go, but ought to be." *Rosalynn Carter*

It has been nearly 25 years since I was named Interim Chair at the University of Miami, and I am still there. Back in 1985-86, times were different, when most of us only had our MS degrees, even as Chairs. And there I was – along with many here today. But we were fortunate, because we learned from people like Steve Rose, Marilyn Gossman, Mary Lou Barnes, Helen Hislop, Beverly Schmoll, Bob Bartlett, Geneva Johnson, and others.

We learned from those senior people, who mentored us. Some of them may have even "picked us up and dusted us off" when we needed it. Granted, there were only 90-something PT programs back then; but the senior people eagerly shared advice, and we novices eagerly learned.

The recent discussions regarding the new American Council of Academic Physical Therapy, or "The Council," are important for the future of physical therapy education. Frankly, I see a little history repeating itself, with many of the objectives proposed, as well as the initial rationale for beginning the discussions, being similar to what some of us recalled, and honestly have missed, from 25 years ago. For example, when I read the proposed bylaws,[3] some of the objectives of this "new entity" sounded very familiar. For example:

- "providing mechanisms to develop, assess new models for curricula, mentoring, and leadership;
- define the dimensions and metrics of quality and excellence within academic physical therapy to enhance programs;
- provide resources, mentorship, and leadership to those seeking change and improvement in academic programs"[3(p. 1)]

While there are certainly some exceptions, as a whole, we (current leaders and Chairs) have not sat with new Program Directors or Chairs and gotten to know them, or mentored them, as we were ourselves. The need for expertise, mentorship, and some friendly advice remains, and perhaps is even more acute with so many more programs. And the need for defining quality metrics to describe, compare, and enhance our programs is definitely more critical.

I am thrilled to see these objectives, and hope that the Council, while not yet a reality, becomes one, and rapidly attends to implementing them. So, here are two pearls of wisdom that I've learned from my mentors, and from trial-and-error experience, for both academic and clinical faculty:

1. Building a TEAM is hard work--in organizational terms, it involves both tasks and maintenance activities. Unfortunately, most of us spend too much time on tasks (those numerous reports, budgets, Accreditation Reports, memos, and *meetings*). In short, the things that have to get done for the organization, but that we don't necessarily enjoy. And we spend little time on maintenance activities, the enjoyable things that a group or team actually enjoys doing, like going to lunch, throwing a baby shower, or celebrating birthdays. In short, *having fun together*. I believe having fun together is the key to a successful team.
2. Mentor! Build a formal mentoring program, identify your rising stars, and begin mentoring them for leadership positions in your department, your school, or the profession. On a more global scale, we need to develop a national workshop similar to that of ELAM® (Executive Leadership in Academic Medicine, for women in academic medicine, "aimed at preparing senior women faculty at schools of medicine, dentistry and public health for institutional leadership positions where they can effect positive change.")[4] According to the Web site, "ELAM's year-long program develops the professional and personal skills required to lead and manage in today's complex health care environment."[4] What I believe is needed in physical therapy is just such an immersion experience, for a limited number of people, with an application process, vetting, and selection. There should be several workshops over the course of a year, with homework, electronic conversations, and mentoring in-between, culminating in a final project of some magnitude and with significant value to the respective institutions. *Even the very brightest people need some direction at times, to realize their potential*. This format has been highly successful for many years for the ELAM program.

How can you build a strong team? One thing I would strongly urge is to have an Annual Retreat--and preferably, go away somewhere. If you can't go away in this economy, then pretend that you do, even if you only go bowling for some fun diversion. Retreats are for many things: for renewal, friendly competition, or for concentrated efforts when needed (like self studies or developing new curricula). Retreats help to revitalize the collective spirit of a team, with a commitment to a shared mission, goals, and to each other. So, don't just do tasks--have some fun!

At the University of Miami between 1988 and 1999, we had highs, and we had lows. We had two devastating and untimely deaths--Steve Rose in 1989, and Linda Crane in 1999. We had Hurricane Andrew; and we had 9 faculty members complete PhDs. We had personal tragedies, individual triumphs, family milestones, and group celebrations. When Linda was ill, as both Scot Irwin and Meryl Cohen noted in their Linda Crane lectures, we brought in a roster of specialists from all over the country to teach "Linda's course." I am not entirely sure that the students in those classes (1997-1999) recognized that all those guest lecturers read like a virtual "who's who" of the Cardiovascular and Pulmonary Section!

And when Linda and her Mom needed support, we quickly had a schedule, with all of us —faculty and staff—

signing up to bring dinners, sit with her, and stay overnight. We made sure someone was with Linda 24/7. And the important thing was that we did it all together. This wasn't a new behavior--it evolved from years of *friendship*, and from attending to those *maintenance* aspects of the Team.

So, where do we go from here? Linda was a leader--and *Leadership* is a vital component of *Excellence*. I recommend that the Council, or some other group, take us to new heights in *educational excellence*. We need a structured and intensive **Leadership Academy**, perhaps something along the model of the ELAM program, where we can start to build a cadre of people ready to take charge for the next generation.

Just as we are responsible for teaching the next generation of practitioners, it is also incumbent on us to *mentor the leaders* of tomorrow.

3. **Excellence**. – How to define it in Physical Therapy Education.

I am reminded of Supreme Court Justice Potter Stewart, when asked how he would define "pornography." Now famous, he said "I can't define it, but I know it when I see it." I think the same analogy can be made about excellence in physical therapy programs.

In the United States, we seem to take great delight in rankings of all kinds: Consumer Reports (cars, cookware), Fortune (richest), People (most beautiful), Associated Press (college sports teams), and *U.S. News & World Report* (colleges, majors, graduate and professional programs).[5] The use of ratings for the sake of appearing successful is an indicator commonly used by universities, in newsletters or Web sites targeting alumni, new faculty, and new students. When favorable, they provide fodder for bragging rights; when less than favorable, people usually downplay their importance.[5]

There is a great story about rankings that was in the newspaper recently that is particularly germane for us today. The story goes that there is a university president who apparently kept copies of his past ratings of the other universities in the same state (where - apparently he rated *his* school a 5, or "the highest score," and all others a 1 or 2). His obvious bias didn't sit well with his other presidential colleagues when, of course, those old copies somehow surfaced.

About this story, a wise university president said to me: the lesson shouldn't be "don't keep copies." It should be: "*be honest in your assessment as a peer*, base your opinion on quality indicators, like the accomplishments and reputation of the faculty, the competitiveness of the students, with GPA or SAT indicators. There *are objective measures* of quality that can be used."

And thus, I believe we need to look at what is being done in other professions and perhaps consider what criteria we could use to compare our programs. Because students and their parents are doing this--using whatever information they can find. *U.S. News & World Report* (USN&WR) is but *one piece* of this information, and we should make the information better and more complete.

First – I want to begin with Law School rankings, but think that first we need to look at the kinds of criteria that are used in these kinds of educational rankings. There are *quality assessments* done by peers. There are also *input criteria* (GPA, LSAT, MCAT, class ranks, etc), and *output criteria* (retention or graduation rates, pass rates on boards, etc.). As we see in Table 1, peer rankings are weighted the highest (done the same as those in Physical Therapy, by Deans or Chairs, rated 1-5, low to high). In the case of law, also included are the opinions of lawyers who might employ the graduates, and judges who might see them before the bench. This latter ranking is done differently, in that the lawyers and judges are asked to "list the top 20 law schools," and not to give all schools numerical ranks of 1-5. All scores are standardized about their means, scores are weighted, totaled, and rescaled so that the top school receives 100; other schools are then a % of the top score.

Table 1. Criteria Used for Ranking of Law Schools – *USN&WR*[6]

Quality Assessment	**.40**
Peer assessment (Chairs, Senior Faculty)	.25
Assessment by lawyers/judges	.15
Objective Criteria:	
Selectivity	**.25**
Median LSAT	
Median UG GPA	
Acceptance rate	
Placement success	**.20**
Employment rates at Graduation	
Employment rate 9 month after	
Bar passage rate	
Faculty resources	**.15**
Expenditures / student	
Student / Faculty ratio	
Library resources	

The law criteria are *not* without problems, especially with some recent changes in some of the criteria, and are the subject of many articles.

Second, we need to look at rankings for Medical Schools, as depicted in Table 2. As a means of comparison, there are 126 schools of medicine (compared to 220+ for Physical Therapy). There are some differences in weightings, based upon whether the Medical School is strongly research oriented or more oriented to the preparation of primary care practitioners. The ranking categories are similar to those used for Law Schools, with the Peer assessments (rankings of 1-5, low to high) from the Deans/Senior Faculty. There are then opinions of Directors of Residency Programs (a category similar to the judges and other lawyers, where the Residency Directors are asked to "list the top 20 medical schools.") The scores are standardized about their means, weighted, totaled, and rescaled so that the top school receives 100, and remaining schools are a % of the top score.

Medical school rankings are probably the most comparable to physical therapy, in terms of characteristics, but are also not without controversy. In fact, there are numerous

Table 2. Criteria Used for Ranking of Medical Schools – *USN&WR*[7]

Quality assessment	**.40**
Peer assessment score	.20 research school
	.25 primary care school
Assessment by Residency director	.20 research school
	.15 primary care school
Objective criteria:	
Research activity	.**30** in research med school only
Total research activity	($ NIH, 2 year average)
Aver research faculty member	(2 yr average)
Primary care rate (% entering primary care)	.**30** in primary med school only
Student selectivity	**.20**
Mean MCAT score	
Mean UG GPA	
Acceptance rate	
Faculty resources	**.10**

articles criticizing these rankings, with some authors offering additional potential criteria they considered to be more important:

1. impact factors of journals – although advocated by some, these can be problematic, according to Epstein;[8] (some question the usefulness of impact factors due to the "*Publish or Perish*" ethos in academia today);
2. accreditation – Kasselbaum[9] discusses accreditation criteria, but recognizes that all schools must meet the same criteria, thus this is not a good way to differentiate among schools; *how* criteria are met or exceeded might be a better means of differentiation, but at present, there is no way to determine this;
3. prestige of the institution as a whole - definitely there are "halo effects" and different "perceived" market values of a degree based upon the prestige of the institution itself.[5]

Nevertheless, all authors conclude that rankings such as *USN&WR* are readily available on the Internet, and are here to stay.

There has been a lot of discussion on our education list serve over the years about the ratings in *USN&WR* for physical therapy programs. Problems were cited about the flawed methodology, because they are merely based on peer assessment and not on anything objective. This is *true*; and when *USN&WR* agreed to add objective criteria along with the peer ratings (as they do for other professional graduate programs, such as law and medicine) we (physical therapy) realized something--we didn't really have any specific, *agreed upon, or consensus-based criteria*, for measures of quality in physical therapy programs.

Historically, physical therapy was first included in the rankings in 1995. At first, it was exciting to be included among all the other fields–it was *recognition!* But when some people took particular notice of the rankings, or some people took offense at *not* being included, the controversy began. Because what happened, I believe, was that some protested, and some were silent (and as I recall, the silent ones were the ones ranked in the "top tier"). Perhaps, some people felt that by being in such an enviable position (ie, ranked), it would not have been politically correct to comment at all. In the words of John Maxwell,

> *"The pessimist complains about the wind. The optimist expects it to change. The leader adjusts the sails."*

I believe we are perfectly capable of *adjusting our own sails*. One thing I have noted in physical therapy over the years is that we are a bit timid to criticize ourselves, even constructively, and certainly not publicly. If I were to try to define some categories for physical therapy, not reinventing the wheel but trying to use what could apply to PT programs, here might be a place to begin (See Table 3):

Table 3. Criteria (Proposed) for Ranking of Physical Therapy Professional Programs (Modeled after McGaghie)[10]

Quality assessment	**.40**
Both Chairs/Deans (1-5 scale)	.25
Professionals who hire new graduates*	.15
**could be tricky, but Medical schools use Residency Program Directors, we could too; and not to rank 1-5, but to "name the top 20 Programs"*	
Objective Criteria	
Student Selectivity:	**.20**
Graduation rate	
GRE scores	
Acceptance rate (Applicant/Accepted)	
Student Outcomes:	**.10**
NPTE performance	- first time pass rate
NPTE performance	- ultimate pass rate
Research Activity: (Research Schools only)	**.25**
# peer reviewed publications (2 year average)	
$ NIH and NIH-type grants (2 year average) – (this could be only for research-extensive institutions)	
Faculty Credentials: (non-Research Schools)	**.25**
For non-Research oriented Schools only - % FT faculty with post-professional doctoral degrees/clinical specialization	
Faculty Resources:	**.05**
Student to faculty ratio	

As with Medical Schools and Law Schools, besides the numerical ranking of schools, the entire scores (for all criteria) would be shown in an open table, so that prospective students could determine what kinds of criteria mattered, or were important to them, such as research activity,

faculty/student ratio, or small classes. It is also true that the highest ranked school might not rank the highest in every category. There could be other criteria, suggested by some authors, like "*commitment to public service*."[11] This may seem difficult to measure, although one could note the number of community service programs offered, the percentage of student participation, to gain a measure, for example. *Racial and ethnic diversity* of the faculty and student body could be a useful item, and important to some applicants.[12] These kinds of criteria can also be used by Chairs for benchmarking.

Nonetheless, it is important to note, with respect to peer assessments something that Hendrix[13] said: that *professional opinions* (ie, peer rankings**)** are vital in a ranking process because they are the *opinions of experts in the field*. Furthermore, since response rates < 50% are not scientifically acceptable, I believe it is our professional responsibility then, to (1) assume this mantle of responsibility; (2) to develop some meaningful criteria to use; (3) to participate in (and not boycott) these peer assessments when asked, and (4) to answer *honestly*.

So, what do we need? Some years ago, some of us talked about the need to establish some "benchmarks of quality" in PT education. Unfortunately, this concept vanished from our collective consciousness until recently revived in the Council's proposed Objectives.[3] This is unfortunate, because benchmarks are really helpful for academic chairs. Chairs need to be able to see how they are doing compared to either their "comparable peers," or their "aspirational peers."

To illustrate what "comparable and aspirational peers" means, in *research institutions* there are rankings that really matter to top administration (like Presidents and Provosts), such as the AAU[14] (Association of American Universities) ranking of institutions (essentially the top 62 institutions, public and private). The AAU is truly an "*exclusive club*," by invitation only, that *everyone wants to be in*, essentially because they are considered "*the top 62 institutions*."

Even within the AAU, there are multiple comparisons and rankings, in terms of SAT scores (25th and 75th percentile), comparisons by public or private school only, the number of faculty members in the Institute of Medicine or National Academy of Science, salary and benefits comparisons, etc. There are also rankings of NIH funding within Medical Schools by the Blue Ridge Institute for Medical Research,[15] but this does not include physical therapy programs.

I believe that it is important for us to understand that there is a drive by higher administration (and sometimes Boards of Trustees), to rise higher in the rankings--*any* rankings--especially for those "not in the top 20," or "not in the AAU." And for <u>nonresearch</u> institutions, there are still rankings, just *different* kinds, like "top tier," or "top quartile," or the "most selective" institutions. For <u>all</u> of us then, no matter the kind of institution, it helps to have a barometer about which to judge our own performance--the amount of grant funding, salaries, percentage of faculty with tenure, faculty/student ratio, etc.

In summary, my point is this: We *should be able* to define QUALITY in our educational programs. Rankings are here to stay. They will not go away because we find them unfair, or because we can't quantify quality. We do have some criteria that are usable and comparable; and some criteria that we may question. We need to face the fact that there *are* differences among us, perhaps because of the type of institution, perhaps because of a specific history, and that may be OK. Some of us are better at some things than others. What matters then is that we recognize our strengths and our weaknesses, and that we celebrate our differences.

We are what we repeatedly do. Excellence, then, is not an act, but a habit.

--- Aristotle

Figure 2. Linda Crane and Meryl Cohen, on a Faculty Retreat Sail.

You don't get to choose how you're going to die. Or when. But you can decide how you're going to live now.

-- Joan Baez

Some elements of an educational program are *intrinsic*; things like caring, integrity, passion, cooperation, and can't be measured. Several of these elements have been themes in previous Linda Crane Lectures. But the <u>products</u> of these intrinsic qualities can be measured by the accomplishments and achievements of the faculty and the graduates of a program.

I believe that Linda would want us to take a chance, and to do something about how to measure quality in our educational programs. She was a cardiopulmonary clinical specialist, but she was, in her heart and soul, a **Teacher;** one who always strived for Excellence.

I like the quote by Mark Twain (see Figure 3). I think it's perfect; but I also like one that Linda had on her bulletin board by her office door: "When my ship finally came in, I was at the airport."

In the 10 years since Linda's death, there have been explosions in medical breakthroughs, and an increased respect for physical therapy services: (1) the advances in human genomics and how they impact our clinical practice; (2) the advances in the use of stem cells for the treatment of cancer patients, especially breast cancer, and for patients with heart attacks; (3) the development of the first residency program in Cardiovascular & Pulmonary Physical Therapy;

Figure 3. ***Twenty years from now you will be more disappointed by the things that you didn't do than by the ones you did do. So throw off the bowlines. Sail away from the safe harbor. -- Mark Twain***

and (4) the recent humanitarian aid to the people of Haiti, and the selfless dedication shown by our faculty, alumni, and colleagues. Linda would have been thrilled and excited to be a part of **all** of these. *She wouldn't want to miss the boat…..*

Finally—to come full circle, and to paraphrase Apter & Josselson[16] – "*Every time we get overly busy with work and family, the first thing we do is let go of our friendships….This is a mistake, because friends are such sources of strength to each other.*" I have been blessed over these many years by having many colleagues who are also great friends; by having mentors in my life like Steve Rose and Helen Hislop, who helped me to grow and mature professionally. And, I have been blessed by my students—past and present—that I cherish and from whom I continue to learn. I have always said that "I am the luckiest Chair of all," and I mean it. And by "lucky," I don't mean that things just happened to me without hard work, but that I feel fortunate to be surrounded by such fantastic people, who are leaders, always striving for excellence, and who are my friends.

So you see, I do think these 3 themes are intertwined and inseparable. We are a great profession. I think it is time that we define ourselves. Let's be proactive and really target programs for developing the leaders of tomorrow. And let's be proactive in identifying benchmarks to use, so that we can identify our different strengths, and improve rankings like *U. S. News & World Report*, or even to develop our own.

Let's focus on leadership and excellence. We owe it to our profession, and to the future leaders of our profession – our students.

Thank you.

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In order for a manuscript to be considered for review, it must fit into one of the following categories:

Research Report includes any original research study with an experimental, quasi-experimental, or non-experimental design. Pilot studies that add to the current body of knowledge in cardiovascular or pulmonary physical therapy will be considered as well.

Case Report focuses on a patient or group of patients and describes an element of cardiovascular or pulmonary physical therapy practice, which has not been previously documented in the literature.

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