Effectiveness of the Diabetic StepAhead Program in Improving Patient Care Among Diabetic ESRD Patients

DaVita Clinical Research

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Introduction

Diabetes mellitus (DM) is a leading cause of mortality and morbidity in end-stage renal disease (ESRD). StepAhead is an integrated DM care management program aimed at enhancing patient outcomes via physician-driven DM-management, regular eye exams and foot checks, and patient education on DM self-management. The objective of this comprehensive DM care pilot is to improve patient quality of life through delayed disease progression and loss of function and to reduce the likelihood of unnecessary complications from diabetes, such as lower limb amputations.

Objective

The following interim analysis assessed the program's effectiveness after 12 months of implementation.

Methods

- **Data Source:** Data were obtained from diabetic ESRD patients at a large dialysis organization (LDO). Electronic medical records were used to determine patient characteristics, including age, sex, race, dialysis vintage, insurance, catheter use, Charlson Comorbidity index, ESRD etiology, presence of heart failure and heart disease, and laboratory test results.
- **Study Design:** Demographic information, as well as information on amputations, mortality, and foot checks were obtained from the electronic medical record at baseline, 6 months, and 12 months. Information regarding physician-managed care, blood glucose education, glucometer own/use, and eye examinations were obtained through patient interviews by clinic staff.
- **Study Cohort:** A total of 447 patients were enrolled in the StepAhead pilot at 11 participating clinics ("enrollees"). Of the 447, 271 remained in the program through the 12-month follow up and are termed "completers." A 1:1 propensity matched control population was chosen from clinics not participating in the pilot program.
- **Study Period:** Patients were enrolled in StepAhead between 01 January 2012 and 10 February 2012 and were followed for 12 months. Patients who enrolled after 10 February 2012 were excluded from this analysis due to the need for 12 months of follow-up data.
- **Study Outputs:** Outcome metrics included physician-managed DM, glucose education, and verification of eye exams, glucometer use, and foot checks. The study also looked at amputation rates, program persistence, and mortality rates.

Results

- StepAhead enrollees and propensity-score matched controls were well balanced (Table 1). Among StepAhead enrollees the mean age was 63 years, 45% were female, 45% were black, 43% were Hispanic, 80% had Medicare as a primary insurer, mean body mass index was 27.9 kg/m^2, and mean Charlson Comorbidity Index was 6.1.
- Of the 271 completers at the end of the follow-up period (Table 2, Figure 1):
  - Physician-managed DM: 56.8% (n = 154) at baseline vs 94.8% (n = 257) at end of follow up.
  - Eye examinations: 56.8% (n = 154) at baseline vs 93.0% (n = 252) at end of follow up.
  - Glucometer: 58.3% (n = 158) at baseline vs 94.8% (n = 257) at end of follow up.
  - Glucose education: Baseline data not available; 95.2% (n = 258) had glucose education at follow up.
  - Foot checks: 7.8% (n = 21) had 0-5 foot checks, 63.8% (n = 173) had 6-11, and 28.4% (n = 77) had 12+ during follow-up; 92.0% (n = 249) had at least 6 foot checks at end of follow up (Figure 2).
  - 7 participants underwent lower limb amputations (1.9 amputations per 100 patient-years); due to lack of retroactive data regarding amputations, amputation rate for control patient population is not available. One 1994 study found an amputation rate among diabetic ESRD patients on dialysis of 13.8 per 100 patient-years,[1] while another study found an amputation rate of 4.6 amputations per 100 patient-years among hemodialysis patients with diabetes.[2]

Table 1. Baseline Comparisons of StepAhead Enrollees and Control Patients[a]

	PSM Diabetic ESRD Controls (N = 447)	StepAhead (N = 447)	p-Value
Age, years	62.4 ± 12.7	62.9 ± 12.3	0.49
Female	209 (46.8%)	201 (45.0%)	0.59
Race			0.50
White	29 (6.5%)	34 (7.6%)	
Black	212 (47.4%)	203 (45.4%)	
Hispanic	179 (40.0%)	191 (42.7%)	
Other	27 (6.0%)	19 (4.3%)	
Vintage, months			0.87
< 12	105 (23.5%)	108 (24.2%)	
12-23	98 (21.9%)	86 (19.2%)	
24-47	123 (27.5%)	124 (27.7%)	
> 48	113 (25.3%)	122 (27.3%)	
missing	8 (1.8%)	7 (1.6%)	
Primary Insurance			0.94
Medicare	350 (78.3%)	358 (80.1%)	
Other[b]	97 (21.7%)	89 (19.9%)	
Dual eligibility	198 (44.3%)	193 (43.2%)	0.74
Catheter use	101 (22.6%)	102 (22.8%)	0.94
Charlson Comorbidity Index			0.88
3	11 (2.5%)	10 (2.2%)	
4	54 (12.1%)	56 (12.5%)	
5	127 (28.4%)	111 (24.8%)	
6	89 (19.9%)	98 (21.9%)	
7	93 (20.8%)	94 (21.0%)	
8+	73 (16.3%)	78 (17.5%)	
Cause ESRD			0.61
Diabetes	308 (68.9%)	316 (70.7%)	
Other or unknown	139 (31.1%)	131 (26.6%)	

Abbreviations: ESRD, end-staged renal disease; PSM, propensity-score matched; VA, Veterans Administration.
[a] Values reported as mean ± standard deviation or n (%). The number of observations equals the column N except where otherwise noted. P-values by t-test for continuous variables, chi-square test for categorical variables.
[b] Other category includes Medicaid, no insurance, VA, and other insurances
Note: Other parameters measured but not shown include presence of heart failure and/or ischemic heart disease, and laboratory values for hemoglobin, albumin, and phosphorus. There were no significant differences in these values between PSM diabetic ESRD controls and StepAhead participants.

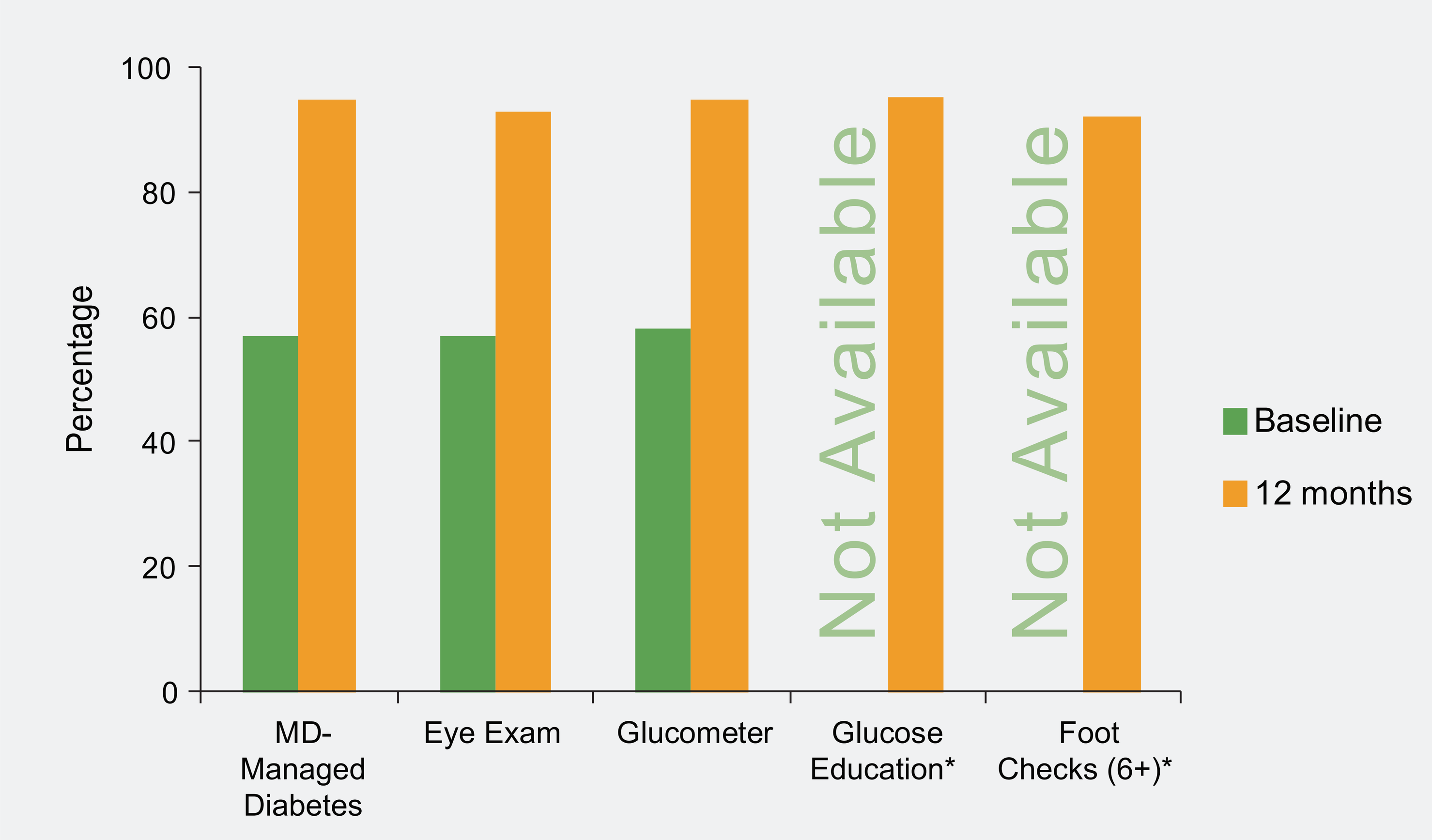
Table 2. Outcome Metrics Among StepAhead Participants[a]

	Enrollees (N = 447)	Completers (N = 271)
MD-Managed Diabetes		
• Baseline	214 (47.9%)	154 (56.8%)
• By end of follow up	373 (83.4%)	257 (94.8%)
Eye Exam Verification		
• Baseline	228 (51.0%)	154 (56.8%)
• By end of follow up	369 (82.5%)	252 (93.0%)
Glucometer		
• Baseline	223 (49.9%)	158 (58.3%)
• By end of follow up	389 (87.0%)	257 (94.8%)
Glucose Education		
• Baseline	NA	NA
• By end of follow up	385 (86.1%)	258 (95.2%)
Foot Checks		
• 0-5 during follow up	140 (31.3%)	21 (7.8%)
• 6-11 during follow up	230 (51.5%)	173 (63.8%)
• 12+ during follow up[b]	77 (17.2%)	77 (28.4%)

Abbreviations: MD, medical doctor; NA, not applicable.
[a] Values reported as mean ± standard deviation or n (%).
[b] Reported as 12+ because some patients had 13 foot checks; one each month February 2012 through February 2013

- When censored for death, transfer of care, or discontinuation of dialysis, the 447 enrollees contributed 364 patient-years during which 78 patients disenrolled from StepAhead.
- Crude mortality was not different between enrollees (14.1 deaths/100 patient-years) and controls (13.6 deaths/100 patient-years) (log-rank p = 0.86) (Figure 2). According to the United States Renal Data System (USRDS), the unadjusted 2010 mortality rate for all Medicare dialysis patients was 28.3 deaths for 100 patient-years at risk.[3]

Figure 1. Outcomes for StepAhead Completers



* Glucose education and foot checks were unique to StepAhead, so baseline information is not available.

Figure 2. Foot Checks Among Completers Over the 12-Month Follow-up Period

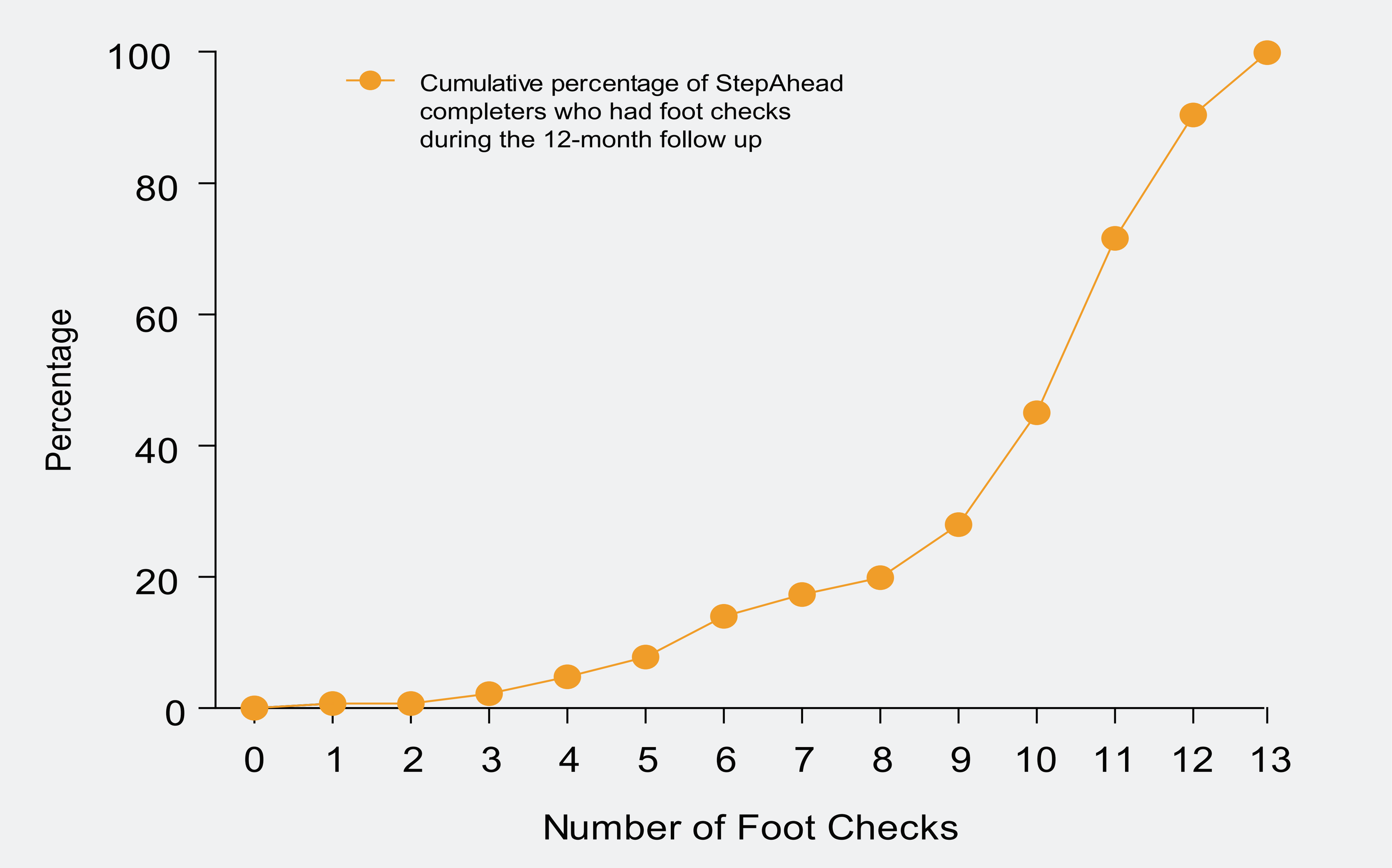


Figure 3. Cumulative Incidence of Death During StepAhead Participation

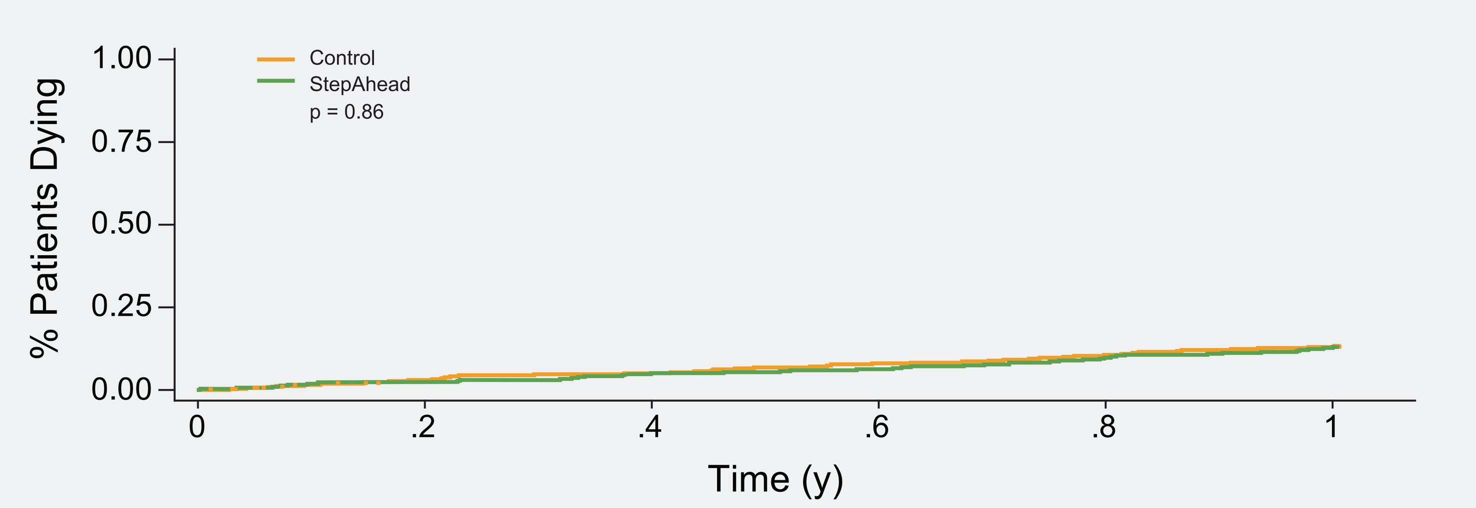


Figure 3 shows the Kaplan-Meier cumulative incidence curve for death during StepAhead participants and controls. Patients were considered at risk beginning at the time of enrollment and continuing until death was observed or until patients were censored for StepAhead disenrollment, transfer of care away from the LDO, or discontinuation of dialysis. The 447 enrollees contributed a total of 364 patient-years at-risk during which 46 deaths were observed (rate 12.6 deaths/100 patient-years).

Conclusions

- StepAhead was successful in enhancing physician-driven diabetes management (94.8% of study completers), eye exams (93% of completers), glucometer possession (94.8% of completers), glucose education (95.2% of completers), and foot checks (92.0% of completers had at least 6 foot checks) across 12 months.
- Rates of program retention were high, particularly when considering only disenrollment events and not patient attrition due to transfer of care away from DaVita, discontinuation of dialysis, or death (time to 25% patient loss from the program was 0.6 years).
- Amputation rates among StepAhead participants were favorable (1.9 per 100 patient-years) compared to published normative data (range 4.6 to 13.8 per 100 patient-years).
- The mortality rate was 12.6 deaths/100 patient-years during program participation. Mortality rates among StepAhead enrollees and propensity-matched control patients were not significantly different. Both groups compared favorably to normative mortality data for diabetic dialysis patients.[3]

References

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