Psycho-Oncology
Psycho-Oncology **25:** 421–427 (2016)
Published online 12 May 2015 in Wiley Online Library (wileyonlinelibrary.com). **DOI**: 10.1002/pon.3849

Cost-effectiveness of a behavioral intervention for persistent urinary incontinence in prostate cancer patients

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Trial Registration: clinicaltrials.gov Identifier: NCT01365182

Abstract

***Objective*: The aim of this study was to evaluate the cost-effectiveness of a behavioral intervention for urinary incontinence of prostate cancer patients. Study subjects were either participating in or eligible but declined (i.e., nonparticipating) the active intervention study.**

***Methods*: The intervention-participating subjects were randomized into three groups, including two intervention groups (support and telephone groups) and a usual care reference group. Intervention-nonparticipating subjects were concurrently enrolled. Intervention effectiveness was assessed on the EQ-5D measure. The costs included direct healthcare cost from medical billing data, patient out-of-pocket expense, caregiver expense, patient loss-of-work cost, and intervention cost. We calculated incremental cost-effectiveness ratios (ICERs) from societal, provider, and patient perspectives.**

***Results*: Two hundred and sixty-seven intervention-participating and 69 intervention-nonparticipating post-cancer treatment patients were included. The support and telephone groups, but not the usual care group, had significantly higher EQ-5D index scores (0.054, $p = 0.033$, and 0.057, $p = 0.026$, respectively) than the intervention-nonparticipating group at month 6. Within 6 months, intervention cost per subject was $252 and $484, respectively, for providers, and $564 and $203, respectively, for the support and phone group subjects. The final ICERs were $16,759 per quality-adjusted life year (QALY) and $12,561/QALY for support and telephone groups, compared with those of the intervention-nonparticipating group. These ICERs are much smaller than $50,000/QALY, the consensus threshold to determine cost-effectiveness for society.**

***Conclusions*: The study interventions are cost-effective in consideration of eligible patients who declined the interventions. The interventions can provide meaningful outcome improvement on urinary continence at a low cost. This evidence provides critical information for future health policy decision-making of healthcare providers and payers.**

Received: 5 September 2014
Revised: 26 March 2015
Accepted: 14 April 2015

Background

Economic analysis of prostate cancer treatment has mainly focused on the patient's decision-making about medical treatment [1], with some comparison of the cost-effectiveness of different medical treatments [2]. Despite an increase of psychosocial/behavioral treatments for cancer patients and survivors, analysis of economic impacts of such treatments is still lacking. A major behavioral treatment for prostate cancer patients is the intervention of pelvic floor muscle exercises (PFME, i.e., Kegel exercises) for urinary incontinence [3]. Urinary incontinence places a significant burden on US society, with an annual cost of billions of dollars [4]. It affects over 30% of prostate cancer patients 12 months after surgery [5,6] and is the most distressing symptom for this patient population [7]. Although the PFME effect on persistent incontinence remains inconclusive because of considerable variations in study methods and subject selection [3], we found in a randomized, controlled, and longitudinal study that PFME practice and symptom management together significantly improved urinary function and quality of life in prostate cancer patients with long-term urinary incontinence (reported elsewhere). This finding along with rising utilization of PFME underscores the need for an economic evaluation of this behavioral approach.

The literature shows that poverty and lack of resources adversely affect continence status [8] and that incontinence severity is associated with significantly greater utilization of healthcare resources [9], labor cost [10], and loss of productivity [11]. A substantial amount of cost for urinary incontinence stems from out-of-pocket expenses for personal medical and home care [8], and this expense can play a significant role in a patient's consideration of seeking treatment for incontinence. Inconsistency in the current research findings about PFME effectiveness has raised doubts about the application of PFME to men [3]. A lack of economic analysis has further left US society in vacillation about the actual value of this treatment. Without an evidence-based economic analysis, patients, providers, policy makers, and the general public cannot make a sound decision on a potentially viable treatment for the significant health problem of urinary incontinence.

Further, the enrollment of eligible patients into clinical trials including behavioral interventions has been a small fraction of the patient community [12]. Information on the conditions of the unavailable, nonparticipating patient population is limited. We reported previously that there was a greater economic (e.g., loss of wages and transportation costs) and healthcare (e.g., care for family member and comorbidity) burden for the nonparticipants [13]. By not taking part in a behavioral intervention study out of economic concerns, these patients may in fact endure higher costs and lower quality of life in the long term because of preexisting conditions and/or worsening urinary incontinence. Inclusion of the nonparticipants in an economic analysis is important, because it adds a real-world context and better representation of the incontinent prostate cancer population, producing a more realistic and informative estimation of the cost and benefits. This information is particularly useful to prostate cancer patients living under socioeconomically disadvantageous conditions that impede their access to available treatments.

We therefore collected cost and effectiveness information from both participants and nonparticipants of our randomized, controlled longitudinal clinical trial that tested a behavioral intervention to urinary incontinence, combining both PFME and symptom self-management. The intervention was delivered over 3 months through either the support group or individual-based telephone contact. Subjects from these two intervention groups and a usual care control group, as well as a group of intervention-nonparticipating subjects—all had completed cancer treatment—were assessed over a period of 6 months. Cost-effective analysis was performed to address whether the intervention groups were more cost-effective than the usual care control group and the intervention-nonparticipating (INP) groups, respectively. The goal of the present study is to elucidate the costs and benefits of PFME and symptom self-management for society, healthcare providers, and patients to aid the decision-making process on whether it is beneficial to integrate this behavioral intervention into routine standard care.

Methods

Study design

The data reported in this study were collected from a randomized, controlled longitudinal clinical trial, Improving Urinary Continence and Quality of Life in Prostate Cancer Patients (R01CA127493), which was conducted at a major medical center in Northeast Ohio between 2009 and 2013 after obtaining approvals from local institutional review boards. Subject eligibility included a diagnosis of early stage prostate cancer, completion of cancer treatment at least 6 months prior, and presence of incontinence symptoms. The exclusion criteria included receiving hormonal treatment during the past 6 months, having urinary tract infection or retention, and exhibiting cognitive impairment. Eligible and consenting intervention participants were randomized at 1:1:1 ratio by the minimization method [14] to three study groups. Strata used for randomization included treatment type (surgery ± radiotherapy versus radiotherapy alone), surgery types (open versus laparoscopic) within the surgery ± radiotherapy strata, radiotherapy types (brachytherapy versus external beam) within the radiotherapy-alone strata, hospital site, and race.

The three randomized study groups included (1) biofeedback PFME plus a support group (BF + group), (2) biofeedback PFME plus telephone (BF + phone), and (3) usual care (UC). Additionally, eligible patients who declined the intervention study but agreed to provide feedback were recruited consecutively as an INP group. The BF + group and BF + phone participants learned PFME in a session of biofeedback training and symptom management skills by attending six group meetings or six telephone sessions of the problem-solving therapy, biweekly over 3 months. Each support group consisted of three to five participants and met for an hour each session. The telephone sessions entailed a one-on-one contact between a therapist and a patient for 45 min. Both the UC and INP groups continued receiving usual care without receiving any training session.

A certified biofeedback technician conducted the biofeedback-PFME session. Using an intervention manual, three licensed professionals (two health psychologists and a nurse specialist) served as therapists and delivered the problem-solving therapy individually to teach symptom management skills. Print materials unrelated to the study interventions were mailed periodically to the UC and INP subjects to minimize a potential attention bias. Research assistants who collected data were kept blind to each participant's treatment group assignment. Subjects from all four study groups were assessed three times, at baseline (T_1), 3 months (T_2), and 6 months (T_3) at their homes or a hospital office. Data relevant to this cost-effectiveness analysis were collected from using measures of costs (healthcare utilization cost, out-of-pocket expense, cost of intervention, and loss of productivity) and effectiveness (quality-adjusted life years [QALYs]).

Cost-effectiveness data

Effectiveness

This is measured in QALYs, which is the multiplication of duration of life (6-month follow-up time for this study) with utility. Utilities or utility score, measured on a scale from 0 (death) to 1 (full health), was used to assess the general health-related quality of life for given health states, using the EQ-5D index [15]. EQ-5D is a measure of valuation for health status (i.e., health outcome) and has been widely used internationally for calculating

DOI: 10.1002/pon

QALYs in cost-effectiveness analysis. We used the US preference-based scoring algorithm to calculate the utility score in this study [16].

Cost of healthcare utilizations and out-of-pocket expense

We collected the cost of healthcare utilizations using administrative data that detail the utilization of inpatient and outpatient services with its charged amount and are then adjusted using the cost-to-charge ratio [17]. We used questions from the National Overactive Bladder Evaluation study [10,18] to identify out-of-pocket expenses for urinary incontinence, including the use of incontinence-related routine care items such as undergarments and laundry products. Information on out-of-pocket co-payments for inpatient and outpatient services and medication use was queried at T_1, T_2, and T_3.

Cost of interventions

Biofeedback + group and BF + phone costs were assessed using micro-cost methods for personnel and patient costs. We excluded research-related costs (e.g., costs of data collection and entry) that would not be incurred if this intervention was used in clinical practice. From the healthcare provider's perspective, intervention costs included the expense of biofeedback and time required of interventionists/therapists. From the patient's perspective, intervention costs included the intervention time, travel time, and gasoline expense that study participants needed to spend. We used a log to track the time spent (in minutes) by interventionists/therapists and the time spent in training and/or quality improvement efforts. We combined personnel time with wage rates (including benefits), using national average wages from the Bureau of Labor Statistics [19]. Further, we used the log to track the time that participants spent in the BF + group, including their transportation to and from the group meetings. Travel distance was estimated by measuring the distance between the center of the zip codes of a participant's home and the provider's facility, as captured on study forms. The cost of travel was estimated by multiplying the distance by the standard Internal Revenue Service mileage reimbursement rate. We further estimated cost of the participant's travel time (time multiplied by age-adjusted national average wage rate) [19].

Cost of employment and productivity

Questions from the Health and Retirement Survey [20], modified by RAND corporation for clinical trials [21], were used to measure employment status, working hours, level of productivity (hours in a week), and sick leave from work because of the study interventions and diseases. From the societal perspective, such costs are associated with both patients and their caregivers. At T_1, T_2, and T_3, loss of workday hours were collected, including the time of nonintervention-related medical visits and transportation to/from the clinic due to these visits. The loss of productivity and time-related costs were calculated as a product of days (measured in hours) lost multiplied by the national average wage.

Power analysis

In the parent intervention study, a sample size of 78 subjects per group has 99% power to detect a difference in one-way analysis of variance with 0.017 (alpha) one-sided significance level for three group comparisons according to an observed effect size (0.71) from a pilot study. Thus, we planned to enroll an additional INP group of the equal size (i.e., 78 subjects) for the study reported herein.

Statistical analysis

The cost-effectiveness analysis was conducted from the perspectives of the society, healthcare providers, and patients. A summary of healthcare utilization cost and provider intervention cost is used to calculate the cost from the healthcare provider's perspective. A summary of patient out-of-pocket expense and patient intervention cost is used to calculate the cost from the patient's perspective. We then summarized all aforementioned costs and the productivity cost to calculate the cost from the societal perspective. The analysis was performed for a 6-month period as the changes in cost-effectiveness take time to become observable.

The incremental cost-effectiveness ratio (ICER) was calculated as the incremental cost divided by the incremental effectiveness between comparison groups. The cost-effectiveness threshold used was \$50,000/QALY, which has been established and widely accepted in US society [22,23]. We calculated the incremental effectiveness by multiplying 0.5 years (6 months of the intervention) with the group difference of EQ-5D index scores. A linear mixed model was used to analyze the EQ-5D group differences while accounting for individuals' repeated measures. The effect of each intervention (BF + group and BF + phone) compared with the reference group (UC or INP) at month 6 was estimated controlling for baseline sociodemographic and clinical characteristics. We used the generalized linear model with logarithmic link and gamma variable distribution to analyze the cost differences between groups (incremental cost), adjusting for the same baseline sociodemographic and clinical characteristics [24,25]. All analyses were carried out using SAS (version 9.3; SAS Institute Inc., Cary, NC). All p-values were two-sided, and p-values <0.05 were considered statistically significant.

Results

A total of 336 participants were included in this study, including 267 from the parent clinical trial (BF + group,

DOI: 10.1002/pon

BF + phone, and UC) that provided cost-effectiveness data, and 69 participants enrolled in the INP group. Patient baseline sociodemographic and clinical characteristics are listed in Table 1. The study sample had a mean (±SD) age of 65 (±7.6) years. A majority of the patients had stage II prostate cancer. There are no statistically significant differences with regard to baseline sociodemographic and clinical characteristics among the four groups (Table 1).

Table 1. Patient characteristics at baseline (mean or percentage)

	BF + group	BF + phone	Usual care	Intervention nonparticipating
n	88	86	93	69
Sociodemographics				
Age	65.8	63.9	64.6	64.9
Race				
White	61.1%	66.7%	63.2%	72.4%
Black	38.9%	30.0%	35.8%	26.3%
Other race	0%	3.3%	1.0%	1.3%
Education				
8th grade or less	3.3%	3.3%	2.1%	2.6%
Some high school	6.6%	5.5%	6.2%	5.3%
High school graduate/GED	25.3%	17.6%	33.0%	44.7%
Some college/associate's degree	31.9%	30.0%	26.8%	25.0%
College graduate	13.2%	20.9%	18.6%	14.5%
Graduate or professional school	19.8%	23.1%	13.4%	7.9%
Household income				
Under $15,000	16.7%	11.5%	13.9%	11.4%
$15,000–$24,999	22.2%	16.7%	17.7%	22.9%
$25,000–$49,999	26.4%	24.4%	31.7%	24.3%
$50,000–$100,000	25.0%	23.1%	24.1%	25.7%
Over $100,000	9.7%	24.4%	12.7%	15.7%
Marital status				
Married	65.9%	65.9%	62.9%	61.8%
Single	11.0%	12.1%	14.4%	15.8%
Widowed	1.1%	5.5%	5.2%	1.3%
Separated	5.5%	2.2%	1.0%	5.3%
Divorced	16.5%	14.3%	16.5%	15.8%
Religion				
Christian	78.0%	84.6%	89.5%	86.8%
Jewish	5.5%	0%	1.1%	2.6%
Others	9.9%	4.4%	7.4%	6.6%
None	6.6%	11.0%	2.1%	4.0%
Employment				
Full-time employed	20.9%	34.1%	36.1%	21.1%
Part-time employed	14.3%	16.5%	9.3%	15.8%
Unemployed	5.5%	3.3%	2.1%	6.6%
Retired	47.3%	29.7%	36.1%	46.1%
Cannot work – with disabilities	11.0%	16.5%	12.4%	9.2%
Other	1.1%	0%	4.1%	1.3%
Clinical characteristics				
BMI	28.8	28.9	29.2	28.6
Cancer stage				
Stage 1	23.1%	28.6%	30.2%	39.5%
Stage 2	71.4%	67.0%	64.6%	56.6%
Stage 3	5.5%	4.4%	5.2%	4.0%
Surgery (Y/N)	52.8%	55.0%	60.4%	71.1%
Radiation (Y/N)	55.0%	49.5%	45.8%	42.1%
Chemotherapy (Y/N)	0%	0%	1.1%	1.3%
Prostate-specific antigen (PSA) score	0.73	0.81	0.58	0.28
Gleason score	6.57	6.76	6.93	6.96
Charlson comorbidity score	0.69	0.71	0.93	0.84
Effectiveness outcome				
EQ-5D index score	0.813	0.778	0.795	0.826

Table 2 presents the linear mixed model results for EQ-5D index scores. Both BF + group and BF + phone intervention groups demonstrated statistically significant higher EQ-5D index scores (0.054, 95% CI: 0.004–0.103, $p = 0.033$, and 0.057, 95% CI: 0.007–0.106, $p = 0.026$, respectively) than the INP group in changes from baseline to month 6. No statistically significant differences were identified when UC was the reference group. Similarly, no significant difference was identified between BF + group and BF + phone (−0.011, 95% CI: −0.059–0.038, $p = 0.67$; data not shown in the table). The trend line of EQ-5D index scores from baseline to month 6 by groups is illustrated in Figure 1. It shows that the EQ-5D index score went downward for the INP group, but upward for all three other groups.

Average incremental costs between BF + group versus INP group and BF + phone versus INP group are presented in Table 3. Provider intervention cost is more expensive for the BF + phone ($484) than that for the BF + group ($252) per patient in 6 months, whereas the patient intervention cost is more expensive for the BF + group ($564) than that for the BF + phone ($203) per patient in 6 months. We did not identify any statistically significant differences between groups on healthcare utilization cost, patient out-of-pocket expense, and productivity cost. However, the numerical differences on cost numbers were applied to final ICER calculations. Compared with INP, BF + group and BF + phone have ICERs of $17,276/QALY and $11,612/QALY from the societal perspective, respectively. These numbers are much smaller than the $50,000/QALY cost-effectiveness threshold, indicating that both interventions are cost-effective relative to the INP group. No ICER calculations were conducted when UC is the reference group or for the comparison between

Table 2. Linear mixed models for change of EQ-5D index score from baseline to month 6 between groups

	Adj. mean diff.	95% CI	*p*
Model with UC as the reference			
BF + group versus UC	0.008	−0.041, 0.058	0.74
BF + phone versus UC	0.016	−0.033, 0.065	0.53
Model with INP as the reference			
BF + group versus INP	0.054	0.004, 0.103	0.033*
BF + phone versus INP	0.057	0.007, 0.106	0.026*
UC versus INP	0.037	−0.012, 0.086	0.14

Note: Linear mixed models control for baseline age, race, household income, marital status, education, employment, religion, BMI, cancer stage, PSA, Gleason, and Charlson comorbidity scores.

BF, biofeedback; UC, usual care; INP, intervention nonparticipating; CI, confidence interval.

*$p < 0.05$.

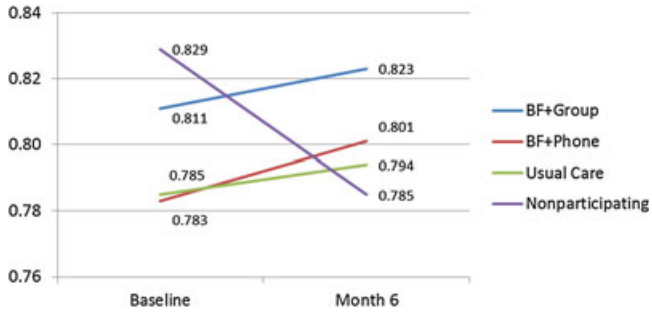

Figure 1. EQ-5D index score from baseline to month 6 by study groups

Table 3. Summary of incremental cost-effectiveness

	BF + group versus INP	BF + phone versus INP
Cost outcomes in 6 months ($)		
Cost categories		
Provider intervention cost	252.0	484.0
Patient intervention cost	564.0	203.0
Healthcare utilization cost	158.4	79.2
Patient out-of-pocket cost	−69.4	−49.9
Productivity cost	19.0	−54.4
Total cost (societal)	923.9	661.9
Total cost (provider)	410.4	563.2
Total cost (patient)	494.6	153.1
EQ-5D index in 6 months	0.054	0.057
Cost-effectiveness ($/QALY)		
ICER (societal)	17,276	11,612
ICER (provider)	7600	9881
ICER (patient)	9159	2686

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; BF, biofeedback; INP, intervention nonparticipating.

BF + group and BF + phone, because neither cost nor effectiveness (EQ-5D) had any statistically significant differences.

Conclusions

Our study identified that the interventions of BF + group or BF + phone were cost-effective compared with those of patients who were eligible but declined participation (INP group) over 6 months. This study is the first of its kind to elucidate the cost and benefit information on a behavioral intervention for prostate cancer survivors with urinary incontinence. We showed that both intervention arms of this program produce health outcome improvement at a low cost in a real-world situation.

It is worth noting that the observed cost-effectiveness of interventions relative to the INP group is primarily attributable to their effectiveness outcome, that is, the EQ-5D index score. EQ-5D index has been widely used throughout the world in both clinical investigations and health policy determinations [26,27]. Previous research has claimed minimally clinically important differences for the EQ-5D index score, which is approximately 0.03 [28,29]. Therefore, our identified EQ-5D differences in 6 months are not only statistically significant but also reflecting a meaningful change in the general health-related quality of life.

We observed different quality-of-life trajectories on EQ-5D as shown in Figure 1. Quality of life of the INP group decreased over time, but quality of life of all other three groups increased slightly. This is likely due to the declining urinary function in the INP group over time. Our sub-analysis confirmed that from baseline to month 6, men from the three groups of the parent clinical trial (BF + group, BF + phone, and UC) had improved urinary function measured by the urinary function subscale on the University of California-Los Angeles Prostate Cancer Index (UCLA-PCI) [30], while men in the INP group had continuous decline of urinary function. The UCLA-PCI is a disease-specific quality-of-life measure and thus more sensitive to a change of urinary function than EQ-5D. The different trajectories of urinary function from the UC and INP groups can be explained in part by the intervention participation that can incur a placebo effect or some improvement. The data suggest that the study interventions are worth adoption into clinical practice because the INP patients' health-related quality of life, either general or disease-specific, can worsen over time without the interventions.

We did not identify any statistically or clinically meaningful differences between BF + group or BF + phone and the UC group in cost-effectiveness. EQ-5D measures general health-related quality of life rather than disease-specific quality of life. It is likely that the intervention effect on urinary function would not be readily translated to EQ-5D unless the intervention effect size is sufficiently large. A relatively small sample size of the clinical trial might also set a limit to identifying this group difference on EQ-5D. Nevertheless, the observed upward movement of quality of life among all clinical trial participants supports the importance of the provision of the behavioral intervention.

We did not identify statistically significant differences for several important cost outcomes, including healthcare utilization cost, patient out-of-pocket expense, and productivity cost among all groups. The findings indicate that the study intervention did not reduce nonintervention-related healthcare cost within 6 months, but its long-term impact on cost reduction of caring for these patients remains to be seen, as we expect that improved quality of life would manifest in overall health improvement and lesser need for health care. The sample size could be another reason for the insignificant results. However, if such findings remain true with a larger population, it could imply that society does not have to allocate significantly more healthcare resources for these particular

DOI: 10.1002/pon

nonintervention components if BF + group and BF + phone interventions are the ones in use.

The two intervention groups did not differ significantly in cost-effectiveness, but incurred the intervention cost differently. The per-person intervention cost from the patient's perspective is more expensive in the BF + group arm of the study than the BF + phone arm. The extra cost of the BF + group arm is due primarily to the time for travel and gas mileage, which could be an important factor for patients. By contrast, the intervention cost from the healthcare provider's perspective is more expensive per patient in the BF + phone arm of the study than the BF + group arm. This is because a therapist in the BF + phone arm had to talk with each patient individually over the phone, whereas a therapist in the BF + group arm can meet with a group of patients (typically five/group) simultaneously. These cost findings provide informative data for future health policy decision-making on the choice of intervention modalities.

This study has several strengths. First, our analysis was conducted from three different perspectives, including society, healthcare providers, and patients, which is more informative and specific to the interest of each party. Second, the cost estimation informs society of the intervention's benefits in a real-world context that encompasses nonparticipating eligible patients. The findings highlight that existing standard care that does not provide behavioral interventions for urinary continence is unable to prevent worsening health conditions in many prostate cancer patients. Third, our estimate of cost-effectiveness informs healthcare providers on the possibility of integrating the study interventions into routine standard care. Fourth, the analysis of out-of-pocket expense informs the patients, especially the INP patients, on the financial value of the study interventions, which may disabuse them of their belief that study participation is too costly.

However, our findings are subject to limitations. The major limitation is the relatively small sample size of the clinical trial, which yielded a limited statistical power to discern differences in the cost-effectiveness among the three clinical trial groups, particularly when comparing the intervention groups with the UC control group. Cost-effectiveness analyses are conducted usually with a sample size of thousands of subjects to provide data and evidence at the population level. Moreover, our intervention was conducted within four hospitals of the local Cleveland metropolitan area in Ohio. Results may not be representative of the entire USA. Future multisite randomized trials across various geographical locations would address such limitations.

In summary, the study interventions are cost-effective in consideration of eligible but intervention-declined patients in a real-world situation. Without interventions for persistent urinary incontinence, incontinent prostate cancer patients could experience worsening quality of life over time. The findings of this study provide the first evidence of the economic expense and value of behavioral interventions for prostate cancer patients' urinary function, filling a gap in the current literature. They call for a change of standard care in providing behavioral treatments of incontinent prostate cancer patients at a low cost following cancer treatment. The findings also provide critical information for policy makers, healthcare providers, and payers. They warrant that intervention elements be adapted, as a result of research or practice, to be more suitable for delivery in various clinical settings, particularly for patients who are hard to reach because of social, economic, and other reasons. Changes toward this direction in research and clinical practice will make existing health services more cost-effective in improving the quality of life of this patient population and will offer the potential to incur cost saving in the long run.

Acknowledgements

The study was supported by the National Institutes of Health/National Cancer Institute (R01CA127493; PI: Zhang). Cleveland Clinic, University Hospitals of Cleveland, Louis Stokes Cleveland Veterans Affairs Medical Center, and the MetroHealth System, which are all affiliated with Case Western Reserve University, provided support for patient access.

There are no financial disclosures from the authors.

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