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Defining the Value Framework for Prostate Brachytherapy using Patient-Centered Outcome Metrics and Time-Driven Activity-Based Costing

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Abstract

PURPOSE—Value, defined as outcomes over costs, has been proposed as a measure to evaluate prostate cancer (PCa) treatments. We analyzed standardized outcomes and time-driven activity-based costing (TDABC) for prostate brachytherapy (PBT) to define a value framework.

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Conflict of interest:

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METHODS AND MATERIALS—Patients with low-risk PCa treated with low-dose rate PBT between 1998 and 2009 were included. Outcomes were recorded according to the International Consortium for Health Outcomes Measurement (ICHOM) standard set, which includes acute toxicity, patient-reported outcomes, and recurrence and survival outcomes. Patient-level costs to one year after PBT were collected using TDABC. Process mapping and radar chart analyses were conducted to visualize this value framework.

RESULTS—A total of 238 men were eligible for analysis. Median age was 64 (range, 46–81). Median follow-up was 5 years (0.5–12.1). There were no acute grade 3–5 complications. EPIC-50 scores were favorable, with no clinically significant changes from baseline to last follow-up at 48 months for urinary incontinence/bother, bowel bother, sexual function, and vitality. Ten-year outcomes were favorable, including biochemical failure-free survival of 84.1%, metastasis-free survival 99.6%, PCa-specific survival 100%, and overall survival 88.6%. TDABC analysis demonstrated low resource utilization for PBT, with 41% and 10% of costs occurring in the operating room and with the MRI scan, respectively. The radar chart allowed direct visualization of outcomes and costs.

CONCLUSIONS—We successfully created a visual framework to define the value of PBT using the ICHOM standard set and TDABC costs. PBT is associated with excellent outcomes and low costs. Widespread adoption of this methodology will enable value comparisons across providers, institutions, and treatment modalities.

Keywords

Value; Prostate; Brachytherapy; outcomes; time-driven activity-based costing; TDABC

INTRODUCTION

Direct medical costs of cancer care, including costs for localized prostate cancer (PCa) [1], have risen dramatically [2, 3] and have nearly doubled between 1987 and 2005, approaching nearly \$125 billion annually. PCa can be treated with a variety of treatment modalities, including active surveillance, brachytherapy (PBT), intensity-modulated radiation therapy (IMRT), proton therapy, or radical prostatectomy. Despite the steep rise in cost, there has been little evidence of a rise in clinical outcomes [4–6]. In reality, recent studies have shown that reimbursement incentives under the current fee-for-service (FFS) system have, in part, led to the decreased utilization of cost-effective modalities, such as PBT [6, 7], and simultaneous increase in use of more expensive alternatives, such as IMRT [8]. Increasingly, payment for cancer care will be moving away from FFS and towards value-based payment [9], defined by better outcomes achieved at lower financial cost.

At the core of sub-optimal outcomes and higher costs is a measurement gap, where validated and accepted outcome and costing metrics are not systematically collected or reported for patients treated for PCa over the full cycle of care. Porter and colleagues have advocated that treatments for medical conditions be evaluated by the value they create for patients [10, 11]. Providers have been unable to implement the value framework because of inconsistent collection and reporting of outcome metrics by medical condition, particularly patient-reported outcomes (PROs). Providers also do not collect accurate cost data by medical

condition across a patient's care cycle. As a result, providers cannot compare outcomes and costs across institution to identify and implement best practices that could increase the value of care delivery.

This paucity of valid value-based measurements, however, is changing. The International Consortium for Health Outcomes Measurement (ICHOM) [12] has recently defined a standardized set of rigorous and multi-dimensional outcome metrics that potentially sets a modern standard for all men with localized prostate cancer and holds promise for clinical comparisons across the healthcare system.

Historically, studies assessing the cost of various treatment modalities have focused on reimbursed costs rather than actual resource utilization throughout the entire cycle of patient care. The current FFS system has led to a focus on volume over value [13], cross-subsidization of under-valued services, and fragmentation of healthcare services with little incentive to improve coordination between provider groups [14–16]. Time-driven activity-based costing (TDABC) has been introduced to health care to remedy these problems [17, 18]. TDABC is a bottom-up costing tool that measures resource utilization over the full cycle of patient care to determine the true cost of delivering care to the provider [19–21]. This methodology has been successfully utilized by several industries [17, 18], and more recently, TDABC has been used to measure costs and drive process improvements in a variety of medical settings [22, 23].

This study is the first to apply the value framework for prostate cancer treatment. We implement the ICHOM standard set and TDABC in order to define the standardized value framework for low-risk PCa, using PBT as a model example.

MATERIALS AND METHODS

Patient Selection Criteria

Patients with low-risk PCa treated with ^{125}I (98%) or ^{103}Pd (2%) prostate brachytherapy monotherapy between May 1998 and November 2009 were eligible for this institutional review board-approved analysis. Criteria for low-risk included: 1) pre-treatment prostate-specific antigen (PSA) ≤ 10 ng/mL; 2) Gleason Score ≤ 6 ; and 3) American Joint Committee on Cancer (AJCC 7th edition) Stage \leq T2a. Information on tumor stage and grade, initial serum PSA level, race, age, medical comorbidities, medications, survival, recurrence, and toxicity data were prospectively inputted into an outcome database. PROs were also prospectively collected but inputted into a separate outcome database. All patients were treated definitively with monotherapeutic PBT and mostly prescribed doses of 144–145 Gy using a standard transrectal ultrasound-guided, transperineal technique with preloaded brachytherapy needles, as described previously [24, 25]. No patient in this study received supplemental external beam radiation therapy or androgen deprivation therapy.

Measurement of patient-centered outcomes

The ICHOM standard set of patient-centered outcomes for localized prostate cancer [12] was utilized to measure and report outcomes. These data were prospectively collected by the clinical and research staff. Major radiation complications were recorded via the Common

Terminology Criteria for Adverse Events (CTCAE), version 4.0 [26] at 6 months after PBT, as defined by the ICHOM standard set. Patient-reported health status was recorded via the Expanded Prostate Cancer Index Composite (EPIC)-50 questionnaire [27, 28] given before initiation of PBT (i.e. baseline) and at regular follow-up intervals of 1, 4, 8, and 12 months after brachytherapy and for every 6 months thereafter, as described previously [29]. EPIC endpoints for urinary continence, urinary bother, bowel bother, sexual function, and hormonal function (vitality) were used at last follow-up to track PRO, as suggested by ICHOM. EPIC scores were tabulated according to EPIC instrument guidelines scaled from 0 to 100, with higher scores representing better outcomes [28]. Biochemical failure (bFFS) based upon the Phoenix Consensus Conference PSA elevation definition [30], metastasis-free survival (MFS), prostate cancer-specific survival (PCSS), and overall survival (OS) were recorded for survival and disease control outcome dimensions, as described previously [29, 31]. Outcome metrics were obtained from all three outcome tiers, as previously described [10, 32].

Statistical Analysis

The Kaplan-Meier product-limit estimator was used to estimate OS and bFFS of patients from the date of PBT implant. Cumulative incidence of late grade 2 and 3+ genitourinary (GU) toxicity, rectal toxicity, and incidence of biochemical failure were calculated. Death was considered a competing event for these estimates. We defined a clinically significant change from baseline for an EPIC domain score as 0.5 times the baseline standard deviation for that domain, as described previously [33]. Student *t*-test was utilized to assess if change from baseline was significantly different from zero or greater than a clinically significant change from baseline. Changes from baseline were also confirmed utilizing a second published methodology for determining the minimally important difference for EPIC scores [34], but not reported in this manuscript. All statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC), S-PLUS[®] 7.0 for Windows (Insightful Corp., Seattle, Washington), and STATA[™] 11.0 for Windows (StataCorp LP, College Station, Texas).

TDABC Measurement

Process Mapping—Process maps were created for the full cycle of PBT from initial consultation (Figure 1A) and treatment planning (Figure 1B) to one year after implantation and for all ancillary clinical services rendered during the course of RT. All process maps were created in 2012. A one year time-point was chosen for costing analysis to capture the costs of resource utilization after implantation, but to also limit the analysis to a finite period of time that would provide information pertinent to potential future alternative payment models. Each step in the process map was associated with a specific personnel resource and the time required by that person to perform that activity step [35]. Activity times for each activity were documented by content experts, by frontline clinical staff, by direct observation of personnel, and from the institutional scheduling system. Decision and chance nodes were embedded throughout the process maps, with percentage value at each node to indicate the probability that each patient would pass through that specific clinical pathway. A chance node occurs when at least two possible outcomes can occur where a degree of uncertainty exists. A decision node occurs when a decision between at least two possible alternatives could be made.

Cost Calculation—TDABC analyses were conducted as previously described [35, 36]. Briefly, each activity was associated with a personnel resource. Adjusted average hourly rates (AHR) were calculated for each personnel resource based upon the particular job code. Compensation data based on job codes were obtained from the institutional PeopleSoft (Oracle Inc., Redwood Shores, CA) payroll application. Fully allocated costs included employment costs, such as salary and benefits, direct costs associated with treatment, and indirect costs. The total salary and benefit expense for a particular job group was divided by the annual number of work hours in a year, and adjusted for non-productive and indirect work time. The AHR was divided by 60 minutes to calculate the dollar per minute capacity cost rate (CCR). The cost of performing each activity could then be calculated by multiplying the time elapsed during the activity in minutes by the CCR for the personnel resource performing the activity. Costs associated with depreciation of radiation therapy and diagnostic imaging equipment were also embedded into the cost analysis using a simple depreciation model based upon institutional and manufacturer's recommendations. The total TDABC cost for the full cycle of brachytherapy was calculated as the sum of the cost of all patient activities from initial consultation to one year after the PBT implant. All costs are based upon data from the 2012 fiscal year.

Radar Chart Analysis

We used the radar chart tool in Microsoft Excel (Microsoft Corporation, Redmond, WA) to visually display the cost and all outcome metrics in a single diagram [37]. Outcome data points for each treatment modality were graphed on separate axes, with all axes being scaled equally from 0–100.

RESULTS

Patient demographic and clinical characteristics for all 238 eligible men with low-risk PCa are summarized in Table 1. Median age was 64 (range, 46–81) and median follow-up for patient centered outcomes was 5 years (range, 0.5–12.1) and TDABC cost was measured up to one year after PBT implant.

Acute complications of PBT

There were no CTCAE grade 3, 4, or 5 complications within 6 months of PBT (Table 2). The cumulative incidence of grade 2 GU toxicity at 2, 5, and 10 years was 9.2%, 20.7%, and 23.0%, respectively (**Supplemental Figure 1A**). However, grade 2 toxicity was reached when the patient required an alpha-blocker medication (*e.g.* tamsulosin) for urinary symptoms, regardless of the length of time on the medication. The cumulative incidence of late grade 3+ GU toxicity at 2, 5, and 10 years was 1.3%, 1.7%, and 4.9%, respectively (**Supplemental Figure 1B**). The cumulative incidence of grade 2 rectal toxicity at 2, 5, and 10 years was 2.1%, 3.0%, and 3.0%, respectively (**Supplemental Figure 2A**). The cumulative incidence of late grade 3+ GI toxicity at 2, 5, and 10 years was 0.8% (**Supplemental Figure 2B**).

Patient-reported health status

Forty-eight month EPIC-50 follow-up data were available for PRO analysis (Table 2). There were statistically significant changes from baseline at one and four months for both bowel bother ($p = 0.018$) and urinary bother ($p < 0.001$) (Figure 2). However, there were no changes from baseline for any PRO at any other time point, including the most recent 48-month follow-up.

Survival and disease control

Ten-year outcome data were used to report survival and disease control outcomes. At last follow-up, 5 patients (2%) were alive with disease, 14 (6%) patients were dead without evidence of disease, and at least 214 patients (90%) were alive with no evidence of disease. PCSS at 10-years was 100%, with all five patients with biochemical failure and one patient with metastasis remaining alive at last follow-up. bFFS (based upon an elevated PSA after PBT) was 97.5%, 94.2%, and 84.1% at 2, 5, and 10 years, respectively. Survival free from PCa metastasis at 10-years was 99.6%. Overall survival was 97.9%, 95.2%, and 88.6% at 2, 5, and 10 years, respectively (Table 2).

TDABC and Radar Chart analyses

TDABC costs were aggregated over the full cycle of PBT from the time of initial pre-registration and consultation through 12 months of follow-up after implantation. The overall cost to the provider for delivering PBT and one year of follow-up was low. Forty-one percent of the total TDABC cost was accrued in the operating room alone, while the single pre-operative planning MRI, consultation, and treatment planning were 10%, 7.7%, and 7.8% of costs, respectively (Figure 3). Each of the outcome metrics and TDABC costing data were plotted on a single radar chart diagram (Figure 4).

DISCUSSION

In this study, we successfully applied a standardized outcome metric set developed by ICHOM and analyzed costing data with TDABC to develop a framework for communicating the value of PCa treatments, using PBT as a model example. Our analysis confirms that PBT delivers excellent short-term, patient-reported, and long-term outcomes at low costs to the provider.

Value-based healthcare delivery holds promise for aligning the interests of all healthcare stakeholders by improving outcomes and decreasing healthcare delivery costs. However, outcome measures have traditionally been non-standardized and costing measures have rarely been utilized, making meaningful treatment modality comparisons challenging for patients. PCa, in particular, can be treated with several highly effective treatment options. However, the absence of comparative clinical data and reimbursement incentives under the current FFS system have, in part, lead to the decreased utilization of cost-effective modalities, such as PBT [7], and the concomitant increase in use of IMRT [6] and urology-owned IMRT facilities [8]. The lack of randomized and standardized evidence comparing PROs between PBT and other options for low-risk PCa also make it difficult for patients and providers to make informed treatment decisions [38]. A standard set of outcome-based

(included PRO) and costing metrics would help focus the discussion on comparative clinical and cost effectiveness of various interventions.

Historically, prospective payment system-exempt cancer centers have been exempt from many payment reform and public reporting efforts due to the complexity of cancer care [39]. However, Section 3005 of the Patient Protection and Affordable Care Act of 2010 (PPACA) specifically establishes a quality-reporting system for these cancer hospitals [40]. Although dozens of possible measures have been suggested by various groups, only three cancer-specific process measures, including the timing of adjuvant chemotherapy in patients with AJCC Stage III colon cancer, have been implemented in the program's first year [41, 42]. In order to transition towards a healthcare system that rewards high-value care, focus will need to turn to streamlining outcome metric collection to enable comparative outcome and cost measurement across a wide range of providers that are customized and specific to the type of medical condition being treated. In the case of PCa, functional outcomes, such as incontinence and sexual function, are vital measures of the quality of care delivered and are important to patient decision-making [14]. Indeed, increased funding for patient-centered outcomes research, through the federally-funded Patient-Centered Outcomes Research Institute, has placed an emphasis on functional and PROs [43]. The ICHOM standard set used in this study is a particularly promising set of outcome metrics that can allow for meaningful comparisons across a global network of providers in order to better identify best practices and optimize the patient decision-making process [12]. This standard set is a product of a cross-disciplinary effort that has focused on literature-derived outcome metrics, including PRO.

In addition to outcome measures, the measurement of provider cost is equally important when communicating the value of healthcare delivery. A singular focus on improving outcomes, even when modest gains are realized, could raise costs inordinately. Conversely, in the absence of valid outcome metrics, cost reduction initiatives, even when based on valid costing data, could ultimately reduce the quality of care and result in worse outcomes. Furthermore, focus on improving a single outcome or cost metric can also lead to inadvertent worsening of other, non-measured outcome metrics, highlighting the need for collection of a wide-range of metrics. Both outcome and costing measures, therefore, need to be simultaneously measured and managed at the individual patient-level (rather than simply from a population-level) to ensure that recommended changes will increase, rather than decrease, value.

Our current and previous work suggests that TDABC is an innovative costing methodology that can be utilized to measure the true cost of care delivery [17, 18, 44, 45]. Traditionally, measurement of "costs" in healthcare has relied on summation of reimbursements, which are not directly related to the intensity of healthcare resources that are needed to deliver care. Reimbursements and coverage of healthcare services, instead, are a result of current and historical political, economic, and social pressures [46]. TDABC is uniquely positioned to identify the true cost drivers of healthcare delivery and can, therefore, provide insight into how to improve the efficiency and quality of healthcare delivery. In our analysis, we demonstrate the major cost drivers of PBT over the complete care cycle. The realization that the combined cost of the operating room and the MRI scan is more than half of the full care

cycle has focused our quality improvement initiatives to improving the efficiency of operating room time and making more judicious use of pre-operative MRI scans for low-risk PCa patients. These findings have led to eliminating non-value-added steps, driving process improvements, sharing best practices across institutions, and even conceptualizing potential reimbursement rates in future bundled payment environments. Similar studies for other treatment modalities for prostate cancer will lead to an opportunity to improve the efficiency and lower the cost of delivering those modalities, enable value comparison across multiple modalities, and would inform selection and reimbursement for the alternative modalities. However, our TDABC costs in this study reflect the PBT technique utilized at our institution, and costs and resource utilization will likely differ between institutions. These costs will also change if another isotope, such as ^{131}Cs or ^{103}Pd , are utilized instead of ^{125}I . Finally, limiting cost accounting to the first 12 months after PBT may not capture the costs associated with managing late toxicities and recurrence. As we continue to accrue more longitudinal costing data for PBT and other competing modalities of treatment, we will be able to further define the acute and long-term costs associated with each modality and its toxicity or recurrence profiles.

Despite the proof-of-principle nature of this study, there are several limitations to expanded adoption of this approach. First, the ICHOM standard set includes a wide-range of outcome metrics including PROs that may be difficult for some provider organizations to adopt. In our institution, we have utilized the expanded EPIC survey over the past 10 years, whereas other organizations have historically implemented different surveys, or even no PRO measures at all [12]. Given the evolving nature of PRO assessment in healthcare, limited cross-walks exist between PRO tools [43, 47], which can create additional barriers for comparative analyses. Certain PRO endpoints also have limited usefulness for patients. For instance, the ICHOM sexual function metric is currently scored based on the aggregated EPIC survey score, but a more meaningful analysis may be to identify the proportion of patients who can maintain erections firm enough for sexual activity [48] at follow-up. Similarly, cumulative grade 2 GU toxicities are recorded when patients utilize an alpha-blocker medication for even a transient period of time – an endpoint that may not be meaningful to patients' long-term outcomes. Although the ICHOM set includes a wide-range of outcomes, it does not include other meaningful metrics, such as time to recovery, access to care, emergency room and hospital visits, and others. The standard set also intends for mean or median EPIC values as endpoints, rather than proportion of patients experiencing a minimally important difference, which would potentially be more informative and consistent with other reported parameters. Furthermore, our analysis incorporated outcomes from patients treated over an 11 year period, while a more recent time period was utilized to generate the TDABC cost. Additionally, although other modalities, such as active surveillance, may become preferred choices for management for the low risk prostate cancer patient group, the principles and methodology utilized in this manuscript can readily be applied to other treatments, other risk groups, and even other disease sites in the future. Given these limitations, this value framework necessarily utilizes a snapshot of several outcome and costing metrics, but we anticipate that this framework will need to continually evolve and be updated as new data on metrics become available.

Furthermore, as healthcare organizations move towards value measurement, providers will need to increasingly utilize health information technology to seamlessly gather and report outcome and cost data. Unfortunately, most electronic medical records (EMR) do not uniformly capture the three tiers of outcomes described in this study, which places additional pressure on provider staff to manually maintain and abstract data from research databases or EMRs. In this study of PBT alone, our research staff needed to manually abstract data from two prospectively-maintained databases to collect the full range of outcome metrics. TDABC costing analyses also required manual calculation as well as time-intensive collaboration with financial teams. These TDABC analyses are also specific to each institution, and data collection, therefore, require substantial time and resources from each provider. Current efforts are underway in our institution to compare PBT with other treatment modalities, but such large-scale comparisons have required an even larger manual effort to abstract data, as described previously [49].

CONCLUSION

Measuring and publicly reporting a standard set of clinical outcomes and costs will provide a more rigorous approach to understanding the value of treatments and will galvanize value-based competition among provider organizations. In this study, we demonstrate successful implementation of a novel value framework using PBT as a model. Efforts are currently underway to utilize these measurement tools to compare the value of PCa care among providers within a single institution, among providers across regional care centers, among providers in different institutions, and among various treatment modalities. Future payment reform will tie reimbursement to the demonstrable value of care, and we will therefore need to develop a focused infrastructure to collect, analyze, and report outcome and costing metrics to assign value accurately.

List of abbreviations

PCa	prostate cancer
TDABC	time-driven activity-based costing
PBT	prostate brachytherapy
ICHOM	International Consortium for Health Outcomes Measurement
EPIC	Expanded Prostate Cancer Index Composite
MRI	magnetic resonance imaging
FFS	fee-for-service
IMRT	intensity-modulated radiation therapy
PROs	patient-reported outcomes
PSA	prostate-specific antigen
CTCAE	Common Terminology Criteria for Adverse Events

bFFS	Biochemical failure free survival
MFS	metastasis-free survival
PCSS	prostate cancer-specific survival
OS	overall survival
GU	genitourinary
AHR	Adjusted average hourly rates
CCR	capacity cost rate

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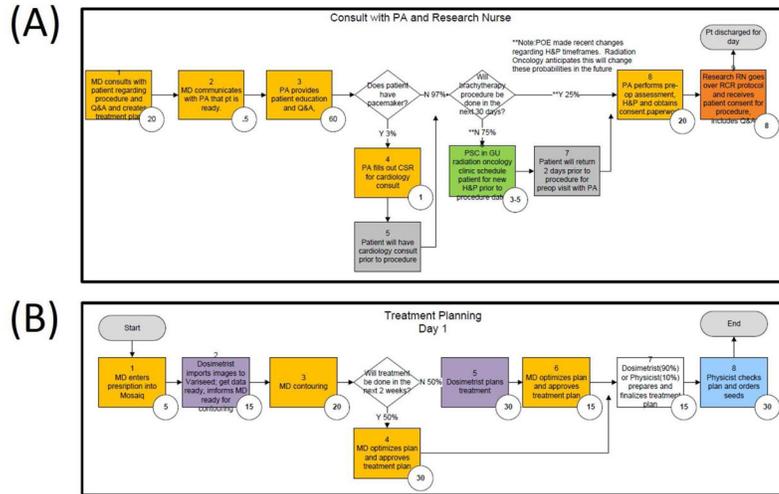


Figure 1. Example process maps for brachytherapy. (A) Consultation; (B) Treatment planning. Each box represents a step or activity through which a patient passes in the process. The number at top of each box represents the number in sequence of step/activity. Colors in each box represent the resource that completes the step/activity in the process. Numbers circled at bottom right corner of step/activity box are used to represent the estimated number of minutes needed to complete each activity described in the box. In this example, the minutes are simply used as examples and do not reflect true process times. Percentages are the probability that patients pass through each step in the process, Y = yes, N = no. MD, radiation oncology physician.

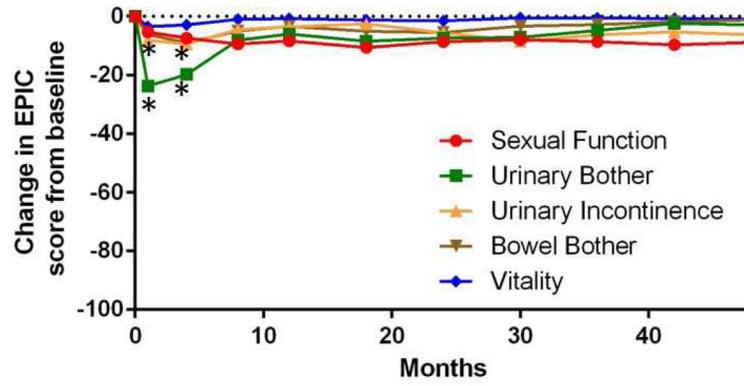


Figure 2. EPIC score change from baseline. There were statistically significant changes from baseline at 1 and 4 months for both bowel bother and urinary bother. However, there were no changes from baseline for any PRO at any other time point, including the most recent 48-month score

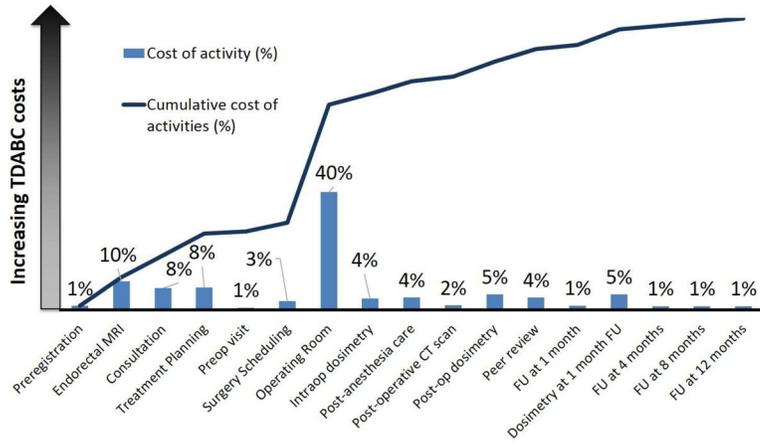


Figure 3. Time-driven activity-based costing (TDABC) of PBT from initial preregistration and consultation through one-year follow-up after PBT implantation.

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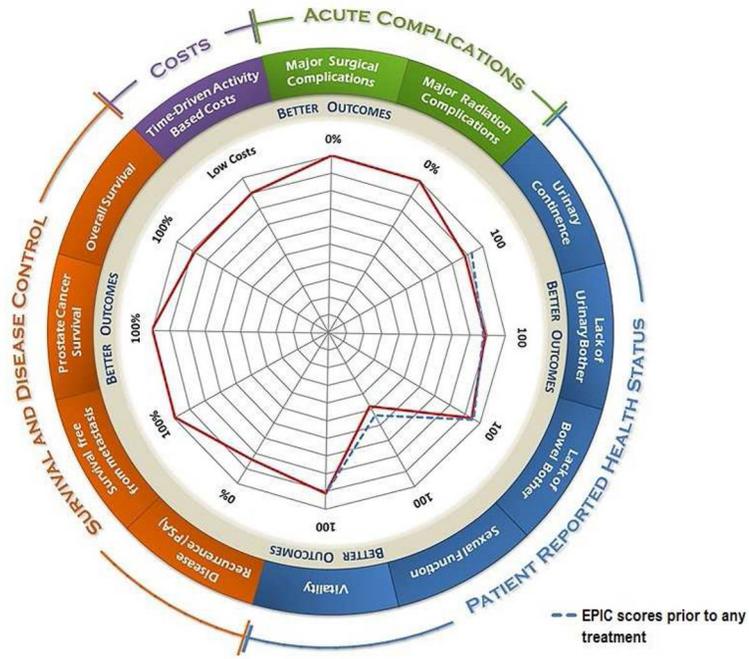


Figure 4. Radar Chart representing the value framework for PBT. The radar chart tool can be used to visualize multiple outcome and costing metrics simultaneously. The chart allows direct visualization of the 6-month complications, 4-year patient reported outcomes, 10-year survival, and TDABC provider costs at one year after implantation. The red line visually connects each numerical outcome or cost value on each axis. The blue dotted line represents the baseline EPIC scores prior to PBT treatment.

Table 1

Patient demographics and treatment characteristics. ANED, alive without evidence of disease. AWD, alive with disease. DNED, dead without evidence of disease. NED, without evidence of disease.

Characteristic	Value
Total number of patients	238
Median follow-up (range)	5 (0.5–12.1) yrs
Median age (range)	64 (46–81) yrs
Race (%)	
White	211 (89)
Black	17 (7)
Hispanic	6 (3)
Asian	3 (1)
Other	1 (0)
AJCC Stage (%)	
T1c	192 (81)
T2a	46 (19)
Gleason Score (%)	
5	1 (1)
6	237 (99)
Mean PSA (range)	5.1 (0.6–9.8) ng/mL
Implant Type (%)	
I-125	236 (99)
Pd-103	2 (1)
Implant Dose (Gy) (%)	
145	208 (87)
144	28 (12)
125	2 (1)
Hypertension (%)	
No	124 (52)
Yes	111 (47)
Unknown	3 (1)
Diabetes (%)	
No	212 (89)
Yes	22 (9)
Unknown	4 (2)
Vascular Disease (%)	
No	195 (82)
Yes	40 (17)
Unknown	3 (1)
Prior Rectal Surgery (%)	

Characteristic	Value
No	227 (95)
Yes	2 (1)
Unknown	9 (4)
History of Hemorrhoids (%)	
No	181 (76)
Yes	47 (20)
Unknown	10 (4)
Anticoagulant Use (%)	
No	170 (71)
Yes	65 (27)
Unknown	3 (1)

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Table 2

Standardized PBT outcomes.

Acute Complications	6 months (CTCAE grade 3 or 4)		
Major surgical complications	0%		
Major radiation complications	0%		
Patient-reported outcomes	4-year EPIC Outcomes		
	Baseline	Outcome	P-value
Urinary Continence	92.7	88.3	NS
Urinary Bother	87.4	88.7	NS
Bowel Bother	96	94.5	NS
Sexual Function	53.9	48	NS
Vitality	91.2	91.1	NS
Survival and disease control	10-year outcomes		
Biochemical failure-free survival	84.1%		
Metastasis-free survival	99.6%		
Prostate cancer-specific survival	100%		
Overall survival	88.6%		