Oklahoma State University Center for Health Sciences

Assessing the Uptake of Core Outcome Sets in Randomized Controlled Trials for Localized Prostate Cancer

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Background

Prostate cancer is the fifth leading cause of cancer deaths worldwide and the most commonly diagnosed cancer in men. A lack of standardized outcomes in localized prostate cancer (LPC) makes comparing clinical trial treatment results difficult and hinders patient outcomes. To mitigate potential difficulties in comparing clinical trial results, a core outcome set (COS) was developed by institutes such as the COMET Initiative. A set of standardized outcomes for LPC was published by BJUI International in 2017.

Methods

In this cross-sectional study, we identified the original localized prostate cancer (LPC) core outcome set (COS) from the COMET Initiative. On June 29, 2023, we conducted a search of LPC clinical trial registries from databases on ClinicalTrials.gov and ICTRP via who.int. We then screened the clinical trials from our search in a masked, duplicate fashion. We extracted trial characteristics and specific COS outcomes for survival, bodily functions, quality of life, and treatment-specific outcomes also in a masked, duplicate fashion. Our results were then analyzed using an interrupted time series analysis to assess COS uptake in LPC clinical trials from 2013 to 2023.

Results

- Our initial search of ClinicalTrials.gov and ICTRP yielded 13,909 trials. After exclusions, we extracted data from 82 clinical trials.
- Disease Progression" (76/82; 92.68%) was the most commonly measured outcome while "Need for Salvage Therapy" (27/82; 32.93%) was the least. Hormonal drugs (30/82; 36.60%) was the most common intervention type and surgery (3/82; 3.70%) was the least.
- Prior to COS publication, a non-significant decrease is seen in COS adherence among LPC clinical trials. After COS publication a non-significant increase is seen in COS adherence.

Domain	Outcome Set Item	N = 82
Cancer/Survival (Universal)	Death from Prostate Cancer, n (%)	
	Yes	55 (67.1)
	No	27 (32.9)
	Death Attributed to Another Cause, n (%)	
	Yes	48 (58.5)
	No	34 (41.5)
	Local Disease Recurrence, n (%)	
	Yes	54 (65.9)
	No	28 (34.1)
	Distant Disease Recurrence/Metastases, n (%)	
	Yes	52 (63.4)
	No	30 (36.6)
	Disease Progression, n (%)	
	Yes	76 (92.7)
	No	6 (7.3)
	Need for Salvage Therapy, n (%)	
	Yes	27 (32.9)
	No	55 (67.1)
Bowel Function (Universal)	Fecal Incontinence, n (%)	
	Yes	34 (41.5)
	No	48 (58.5)
	Bowel Function, n (%)	
	No	45 (54.9)
	Yes	37 (45.1)
Urinary Function (Universal)	Urinary Incontinence, n (%)	
	Yes	37 (45.1)
	No	45 (54.9)
	Urinary Function, n (%)	
	Yes	39 (47.6)
	No	43 (52.4)
Sexual Function (Universal)	Sexual Function, n (%)	
	Yes	36 (43.9)
	No	46 (56.1)
Quality of life (Universal)	Overall Quality of Life, n (%)	
	Yes	43 (52.4)
	No	39 (47.6)
Cancer/Survival (Surgery)	Positive Surgical Margin, n (%)	
	No	4 (100.0)
	Not Applicable	78
Adverse Events (Surgery)	Perioperative Deaths, n (%)	
	Yes	2 (50.0)
	No	2 (50.0)
	Not Applicable	78
	Thromboembolic Disease, n (%)	
	Yes	1 (25.0)
	No	3 (75.0)
	Not Applicable	78
	Bothersome or Symptomatic Urethral or Anastomotic Stricture, n (%)	
	Yes	1 (25.0)
	No	3 (75.0)
	Not Applicable	78
Cancer/Survival (Ablative Therapy)	Treatment Failure, n (%)	
	Yes	31 (93.9)
	No	2 (6.1)
	Not Applicable	49
Cancer/Survival (Active Surveillance)	Need for Curative Treatment, n (%)	
	Yes	2 (18.2)
	No	9 (81.8)
	Not Applicable	71
Adverse Events (Hormone Therapy)	Side-effects of Hormonal Therapy, n (%)	
	Yes	30 (61.2)
	No	19 (38.8)
	Not Applicable	33

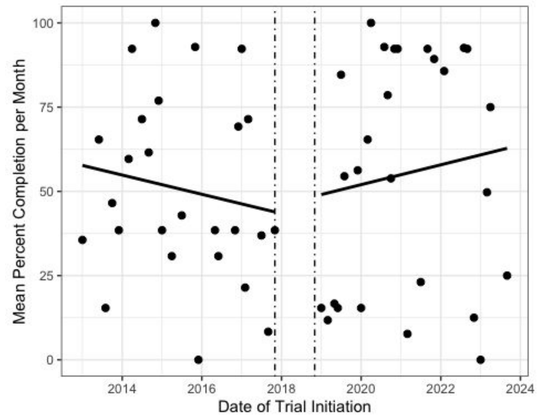

Figure 1: Interrupted Time Series Analysis

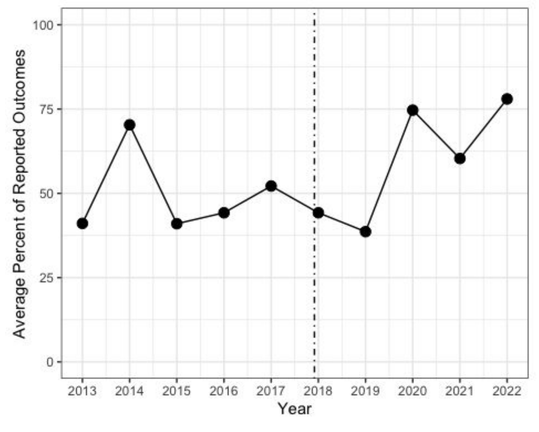

Figure 2: Avg. Reported Outcomes Per Year

Discussion

Our study found a non-significant decrease in COS adherence prior to the publication of a COS for LPC in 2017, then a subsequent non-significant increase in COS adherence after. We recommend LPC clinical trialists adhere to the COS outlined in our study and that further uptake studies be done to assess future LPC COS adherence.

References

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