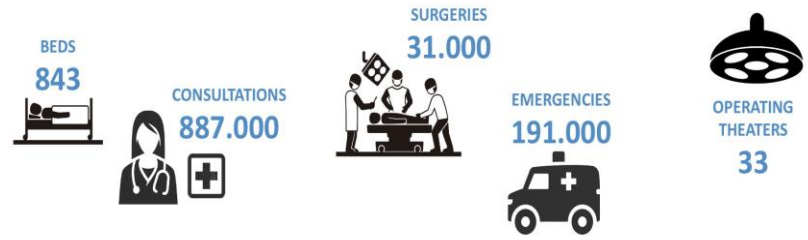
USE OF VALUE-BASED-HEALTHCARE METHODOLOGY TO EVALUATE A NOVEL TREATMENT PROTOCOL FOR LOCALIZED PROSTATE CANCER.

Alfonso Gomez-Iturriaga, David Buscher, Borja Santos, Raquel Gonzalez, Eunate Arana, Ines Gallego, Francisco Casquero. Hospital Universitario Cruces, Biocruces Bizkaia Health Research Institute
. Innovation and Quality Deputy Direction, Cruces University Hospital, Barakaldo, Spain; 3. Biocruces Bizkaia Health Research Institute, Barakaldo, Bizkaia

CONTEXT & BACKGROUND

Cruces University Hospital/IHO Ezkerraldea Enkarterri Cruces Osakidetza is the reference centre for specific medical conditions in the Basque Country.



Prostate cancer

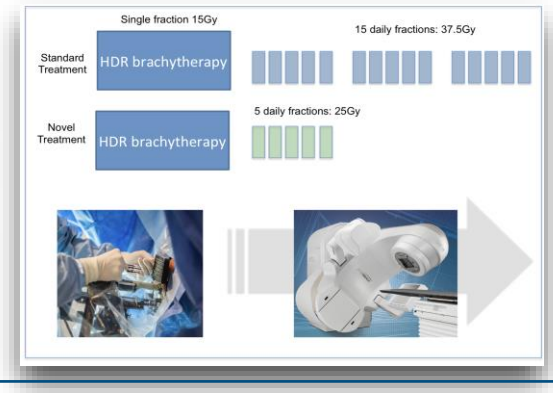
Prostate cancer is an enormous health issue, being the second most frequent cancer diagnosis made in men and the fifth leading cause of death worldwide. Based on GLOBOCAN 2018 estimates, 1,276,106 new cases of prostate cancer were reported worldwide in 2018, with higher prevalence in the developed countries. Radiotherapy is one of the most frequently used treatments for prostate cancer.

Introduction

In 2017 the ICHOM methodology was implemented in our institution for all patients undergoing definitive treatment for prostate cancer. This methodology allows us to evaluate and compare different treatment modalities assessing prospectively outcome measures that really matter to patients (PROMS) and clinical outcomes

Methods

Our current standard of care for intermediate and high-risk disease prostate cancer is the combination of high-dose- rate Brachytherapy (HDR) and moderate hypofractionated external beam radiotherapy to a dose of 37.5Gy in 15 fractions.
In June 2019, a prospective phase II clinical trial investigating a novel radiation schedule for patients with intermediate and high-risk prostate cancer was set up in our radiation oncology department. This novel approach, consisting of the combination of HDR and Stereotactic Ablative Radiotherapy (SABR), shortens the overall treatment time to 6 days.
The objective of this study is to demonstrate the feasibility, safety and effectiveness of this novel treatment, as well as to compare PROMS, outcomes and costs between both treatment modalities based on VBHC-ICHOM methodology.



Results

Fifty-one patients had completed treatment at the time of the current analysis with a median follow-up of 10 months, 34.6% had favorable Intermediate Risk (IR), 17.3 unfavorable IR, 34.6% High Risk and 13.5% Very High Risk.

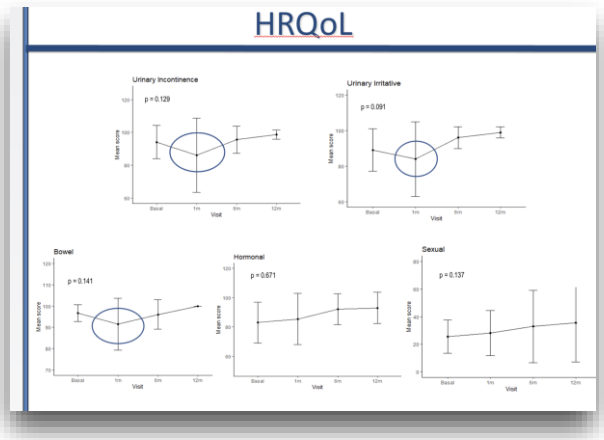
Median age was 75 years and median baseline IPSS was 4.

Short-term androgen deprivation therapy (ADT) was administered to 21.2% of patients, 42% received long-term ADT, the rest of the patients did not receive hormonal therapy.

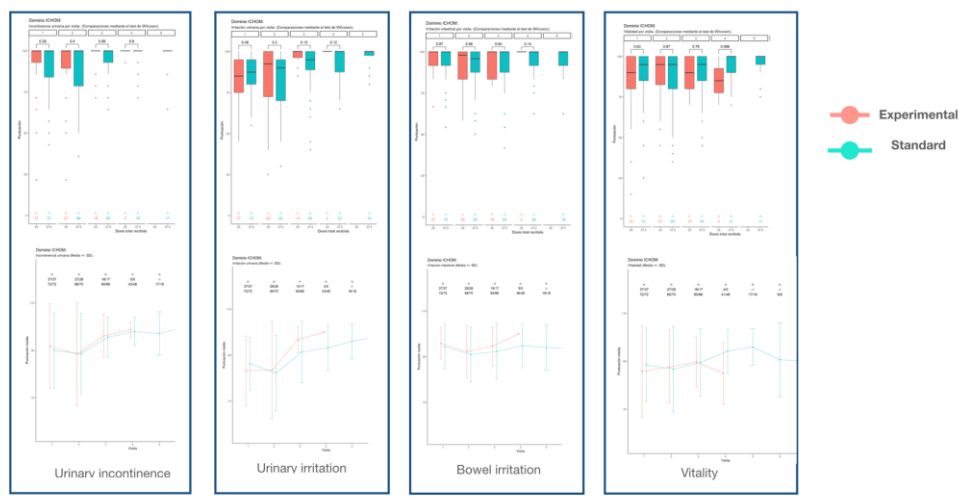
No severe (i.e. G3-4) acute or late events were recorded. The accumulated incidence of acute G2 GU and GI events were 17.3% and 3.8% respectively. The most common acute GU symptom was dysuria whereas the most common acute GI event was proctitis. Thirty-seven patients reached a follow-up > 6 months and were eligible for chronic toxicity analysis. Among these, accumulated incidence of late G2 GU events was 10.8%, no G2 late GI event was observed. The most common late GU symptom was nocturia.

No significant decline in patient QoL (0.5 x standard deviation) between the standard and the experimental treatment was observed in any domain (Urinary incontinence, urinary irritation, bowel, vitality and sexual domains) after evaluation using ICHOM methodology

There was not impact on HRQoL over time after treatments



No differences were found between both treatment modalities, based on ICHOM criteria



Conclusions

The combination of 15Gy HDR prostate brachytherapy and prostate SBRT (25 Gy in 5 daily fractions) is a well-tolerated scheme without severe adverse events observed in our prospective phase II trial. Moreover, the majority of patients did not suffer from any adverse event. The evaluation of PROMs using ICHOM methodology confirm these results, we could not find any significant decline in any domain from baseline values. Also, when comparing with the standard schedule, no significant differences were found between both treatment modalities.

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