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Patient reported quality of life (QoL) for docetaxel (Doc) vs lutetium177-617-PSMA (LuP) for metastatic castration-resistant prostate cancer (mCRPC): Results from the Canadian cancer trials group (CCTG) PR21 trial

D. Khalaf¹, K.N. Chi², F. Saad³, F. Benard⁴, M. Soleimani², B.J. Eigl⁵, M.P. Kolinsky⁶, M. Azizi⁷, P. Fallah⁸, A.A.N. Rose⁹, C. Ferrario¹⁰, C. Maurice-Dror¹¹, J-F. Castilloux¹², V. Castonguay¹³, S. Sridhar¹⁴, K.R. Potvin¹⁵, M. Smoragiewicz¹⁶, M.D. Brundage¹⁷, K.U. Ding¹⁸, W.R. Parulekar¹⁸

¹ Department of Medical Oncology, Odette Cancer Centre - Sunnybrook Health Sciences Centre, Toronto, Canada, ² Department of Medical Oncology, BC Cancer - Vancouver, Vancouver, Canada, ³ Urology Department, Centre Hospitalier de Université to Montréal (CHUM), Montreal, Canada, ⁴ Department of Molecular Imaging and Therapeutics, BC Cancer - Vancouver, Vancouver, Canada, ⁵ Medical Oncology Department, BC Cancer - Vancouver, Vancouver, Canada, ⁶ Medical Oncology, Cross Cancer Institute, Edmonton, Canada, ⁷ Department of Urology, CHUM - Centre Hospitalier de l'Université de Montréal, Montreal, Canada, ⁸ Medical Oncology Dept., Jewish General Hospital McGill University, Montreal, Canada, ⁹ Medical Oncology Department, Jewish General Hospital McGill University, Montreal, Canada, ¹⁰ Department of Oncology, Jewish General Hospital McGill University, Montreal, Canada, ¹¹ Oncology Department, Faculty of Medicine, University of British Columbia - Vancouver General Hospital, Vancouver, Canada, ¹² Medical Oncology Department, Sherbrooke University CHU - Hôpital Fleurimont, Sherbrooke, Canada, ¹³ Hematology-Oncology Department, CHU de Québec - Hotel Dieu de Québec et CRCEO, Quebec City, Canada, ¹⁴ Medical Oncology Department, UHN - Princess Margaret Cancer Centre, Toronto, Canada, ¹⁵ Department of Medical Oncology, London Health Science Centre, London, Canada, ¹⁶ Department of Oncology, Kingston Health Sciences Centre, Kingston, Canada, ¹⁷ Department of Cancer Centre Southeastern Ontario, Queens University School of Medicine, Kingston, Canada ¹⁸ Sinclair Cancer Research Institute, Canadian Cancer Trials Group, Kingston, Canada

Background

CCTG PR21 is a phase II randomized clinical trial of Doc vs LuP for patients (pts) with mCRPC who have received prior androgen receptor pathway inhibitor. There was no significant difference in the primary endpoint of radiographic progression-free survival (rFPS). In this analysis, we present the comparison of QOL outcomes between treatment arms.

Methods

Inclusion required completion of baseline and minimum of one questionnaire on treatment. FACT-P questionnaire schedule was every 6 weeks (wks) on therapy and every 12 wks prior to cross-over. The FACT-P Trials Outcome Index (TOI) was a pre-specified outcome. For all FACT-P domains, we calculated the mean change from baseline at each timepoint during the 36-wk treatment period. A linear mixed model, with visit (wks from randomization), treatment arm, and treatment-by-visit interaction as the fixed effects, was utilized to compare the change in QOL domains over time. Pts' scores on the GP5 item ("I am bothered by side effects of treatment") were described by the distribution of high scores (3 or 4) by arm.

Results

189 of 199 randomized patients started treatment (n=94 LuP; n=95 Doc). Questionnaire completion rates were 96% at baseline and exceeded 70% for most time-points. Baseline scores were similar between arms. Mean change for TOI was worse for Doc vs LuP at wk 24 (-4.1 vs +0.5, p=0.041) and wk 30 (-7.1 vs +2.8, p<0.001) and for total FACT-P at wk 24 (-4.8 vs +1.2, p=0.024), wk 30 (-8.3 vs +4.7, p<0.001) and wk 36 (-8.9 vs +1.5, p=0.027). The mixed model showed a significant interaction between treatment arm and visit, with worsening over time for Doc and stability for LuP for most domains including TOI, FACT-P, and FACT-G (each p<0.01). The proportion of pts reporting high GP5 score at any time was 40.7% vs 15.4% for Doc vs LuP.

Conclusions

Doc has a greater detrimental impact on QOL than does LuP as determined by the FACT-P TOI, total FACT-P and most domain scores. Pts also reported more perceived side-effects with Doc, consistent with the global impact of treatment on QOL. Taken together, the PR21 trial findings suggest that LuP is better tolerated without demonstrable difference in rPFS compared to Doc.

Clinical trial identification

NCT04663997.

Legal entity responsible for the study

Canadian Cancer Trials Group (CCTG).

Funding

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Disclosure

K.N. Chi: Financial Interests, Personal, Invited Speaker: Astellas, AstraZeneca, Janssen, Novartis; Financial Interests, Personal, Advisory Board: Astellas, AstraZeneca, AstraZeneca, BMS, Janssen, Merck, Novartis, Pfizer, Roche, Amgen, Abcellera, Bayer, Chugai Pharmaceutical, Curium Pharma, GSK; Financial Interests, Institutional, Steering Committee Member: AstraZeneca, Janssen, Novartis, Roche; Financial Interests, Institutional, Trial Chair: AstraZeneca, Janssen, Novartis, BMS; Financial Interests, Institutional, Steering Committee Member, Contract for trial conduct: Amgen. F. Saad: Financial Interests, Personal, Advisory Board: Astellas, Bayer, BMS, Janssen, Pfizer, Novartis, AstraZeneca, Merck, AbbVie, Tolmar; Financial Interests, Institutional, Local PI: Novartis, Astellas, Bayer, Janssen, Sanofi, BMS, Pfizer, Merck; Financial Interests, Institutional, Coordinating PI: AstraZeneca, AbbVie; Non-Financial Interests, Principal Investigator: Bayer, AstraZeneca, Novartis, AbbVie. All other authors have declared no conflicts of interest.

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