**Evaluation of cabazitaxel in metastatic castration-resistant prostate cancer with real-life use, effectiveness, safety, and quality of life in the FUJI cohort**


**Abstract**

Background: Cabazitaxel (CAB) was marketed in March 2012 in France. The FUJI trial compared CAB vs best supportive care (BSC) in patients with metastatic castration-resistant prostate cancer (mCRPC). The TROPIC trial (11.9 months), and the subsequent TROPIC extension, showed that adding CAB to docetaxel (DX) achieved longer progression-free survival (PFS) and overall survival of 15.1 months (60.7 vs 49.6 months for DX+BSC) and 25.6 months, respectively. However, the real-life use of CAB is not well described.

Methods: FUJI is a multicentre (n=212) cohort study in mCRPC CAB initiators in real-life, included from Sept 2013 to Aug 2015 in a prospective cohort (follow-up FUJI), and a retrospective cohort (FUJI cohorts) to analyze the outcomes of 401 patients (median age 70) with CAB in 2L (18%), 3L (39%), 4L (23%), or >4L (20%). CAB discontinuation, and other related data were collected through medical files, coded using NCI-CTCAE v4.0 and MedDRA. Treatment-related death was associated with death. Quality of life (QoL) changes were assessed using the EORTC QLQ-C30-CR and BPI-SF questionnaires. A multivariate Cox regression analysis on death was carried out.

**Objectives**

- To evaluate the overall survival (OS) and PSA response in mCRPC patients treated by CAB.
- To evaluate the real-life safety of CAB treatment.
- To evaluate the quality of life (QoL) and pain during CAB treatment.
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**Results**

- After at least 3-month of CAB use, a PSA decrease ≥50% from baseline concerned 39.9% of 258 patients evaluable for main cohort and 32.6% of 43 evaluable patients in QoL cohort (Figure 3).
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**Conclusion**

- Real-life median OS at 18-month in the FUJI cohort was slightly lower than what was reported in the TROPIC trial (11.9 vs 15.1 months). However, at baseline TROPIC patients were younger than FUJI patients, had a better baseline performance status, and received fewer hormones before CAB. A validated endpoint is needed to measure cabazitaxel efficacy in real-life.

- Safety profile in FUJI cohort was similar to that reported for TROPIC trial (AE grade ≥3: 54.4% vs 57.4%)

- Cabazitaxel was marketed in March 2012 in France, based on an overall survival (OS) benefit in mCRPC in 2nd-line post-docetaxel. little data on CAB use in real-life practice are available.

- The 16-month OS rate was 32.4% [95% CI, 27.8-37.1] and median OS was 11.9 months [95% CI, 10.1-12.9] for main cohort (Figure 2). Factors associated with the risk of death are presented in Table 2.

- Pain: 44 patients were evaluable for pain. At CAB initiation, 63.2% of patients had a mild pain, 27.3% a moderate pain and 4.5% a severe pain. QoL changes from baseline during CAB use are presented in Figure 4.

- QoL: 49 patients were evaluable for QoL. At CAB initiation, total FACT-P score was 93.3 on a scale of 0 to 150. QoL changes from baseline during CAB use are presented in Figure 4.

- Discontinuation of CAB use was 10.5% at 12 months and 20% after 24 months. Discontinuation was associated with death.

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