

Oncological Outcome of Docetaxel-Based Chemotherapy for Men with Metastatic Castration-Resistant Prostate Cancer

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Objective: To retrospectively review the oncological outcome of docetaxel-based chemotherapy in men with metastatic castration-resistant prostate cancer (mCRPC).

Material and Method: The present study included 68 patients with mCRPC who were treated with 3-weekly docetaxel (75 mg/m²) plus prednisone between 2010 and 2014. The prognostic significance of several clinicopathologic factors in these patients were analyzed. The endpoints of oncological outcome were overall survival (OS). The effect of clinical variables on OS was statistically analyzed by a log-rank test or Cox regression with hazard ratios. All analyses were performed using a 0.05 level of significance.

Results: In these 68 patients, the median age and serum value of prostate-specific antigen (PSA) prior to docetaxel-based chemotherapy were 69 years and 173 ng/ml, respectively. Of these patients, PSA decline $\geq 50\%$ was observed in 46 patients (67.6%). The OS and progression-free survival were 25.4 and 11.7 months, respectively. Of several factors examined, univariate analysis identified PSA at diagnosis mCRPC, PSA at diagnosis of mCRPC, PSA at first cycle of CMT ≥ 150 ng/mL, number of CMT response ≤ 2 cycle as significant predictors of OS, of which only PSA at first cycle of CMT ≥ 150 ng/mL appeared to be independently related to poor OS on multivariate analysis.

Conclusion: Oncologic outcomes in mCRPC patients receiving docetaxel-based chemotherapy is generally favorable and only PSA at first cycle of CMT more than 150 ng/mL appeared to be independently related to poor OS on multivariate analysis.

Keywords: Castration-resistant prostate cancer; Docetaxel, Overall survival

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Prostate cancer is the second most commonly diagnosed malignancy in men worldwide⁽¹⁾. Thailand has a low rate of prostate cancer incidence (ASR = 5.0 per 100,000 individuals in the years between 1998 and 2002) and the prostate cancer mortality rate in Thailand is extremely low, at 0.3 per 100,000 individuals⁽²⁾. Despite the lower incidence of PCa in Thailand, the incidence has been increasing in recent years. Prostate cancer is typically hormone-responsive, however, once castration resistance sets in, median overall survival (OS) is generally less than two years⁽³⁾. Based on the results of two landmark studies, Southwest Oncology Group (SWOG) 9916 and TAX-327, docetaxel-based chemotherapy is currently widely administered for patients with metastatic castration-resistant prostate cancer (mCRPC) worldwide^(4,5). TAX 327 studies showed

a 2- and 3-month improvement in OS for docetaxel-based chemotherapy as compared with mitoxantrone and prednisolone (MP) (19.2 vs. 16.3 months, HR 0.79, 95% CI 0.67 to 0.93, $p = 0.004$). A SWOG 99-16 phase III comparative trial of docetaxel plus estramustine (EM) vs. mitoxantrone plus prednisone found a survival benefit in favor of the docetaxel-based arm. Patients with castration-resistant prostate cancer (CRPC) are candidates for chemotherapy with the goals of prolonging survival and improve the quality of life (QOL).

In Thailand, since the approval of this agent in 2007, docetaxel-based chemotherapy is used primarily for treating lung cancer and breast cancer. It also has been widely applied to men with mCRPC. A few studies have reported the clinical outcomes of this therapy. The present retrospective study investigated the oncological outcomes of 68 Thai patients who were diagnosed as having mCRPC and treated with docetaxel-based chemotherapy and assessed the clinical parameters resulted our treatment and focused

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on a recommended cut-off prostate-specific antigen (PSA) value for the first docetaxel administration.

Material and Method

The present retrospective study included 68 consecutive Thai patients with mCRPC that received docetaxel-based chemotherapy between 2010 and 2014 at Songklanagarind Hospital. All study participants had histologically proven adenocarcinoma of the prostate with metastatic disease and had progressed despite the castration level of testosterone achieved after bilateral orchiectomy (serum testosterone below 50 ng/dL) and no previous history of treatment with chemotherapeutic agent. Clinicopathologic, treatment and response data were extracted from a retrospective review of hospital charts and medical records.

Treatment and data collection

Pretreatment evaluation included a complete medical history-taking, a physical examination, complete blood cell count (CBC), serum chemistry profile, serum PSA, bone scan, CT of the pelvis and abdomen, and chest X-ray. Patients were treated with 75 mg/m² intravenous docetaxel every three weeks on the schedule reported by Tannock et al⁽⁴⁾ and 5 mg of prednisone twice daily, following premedication with 8 mg of dexamethasone. Patients underwent physical examination, CBC count, liver function test, and renal function test before docetaxel administration. Patients were followed-up by 3-weekly PSA determinations before docetaxel administration. Chemotherapy (CMT) was continued until disease progression or unacceptable adverse events occurred. All patients received docetaxel treatment as an in-patient each cycle.

End points and statistical analysis

All patients were evaluated for PSA response, objective measurable disease response, time to progression, and survival. A PSA response was defined as a reduction of at least 50% from the baseline maintained for next cycle. PSA progression was defined as a 25% increase in the serum PSA level (to at least 5 ng/ml) over the nadir and/or the appearance of a new lesion or the progression of one or more known lesions classified according to the Response Evaluation Criteria in Solid Tumors (RECIST) in the case of patients with measurable disease⁽⁶⁾. Treatment with docetaxel was continued until disease progression, unacceptable adverse events, or patient refusal occurred.

The progression-free survival (PFS) and OS were defined as the time between first docetaxel

administration and events. Then, they were determined by the Kaplan-Meier method. For univariate and multivariate analyses, Cox proportional hazards regression model was used. The R program was used for statistical analysis with 2-sided $p < 0.05$ were considered significant. The exclusion criteria included previous radiotherapy and major cardiovascular, liver, renal diseases, and/or comorbid conditions limiting survival. Patients with a previous malignant disease who had been disease-free for 5 years could be eligible. Performance status (PS) was determined according to the criterion of the Eastern Cooperative Oncology Group (ECOG). The study design was approved by the Research Ethics Committee of Faculty of Medicine, Prince of Songkla University. All statistical analyses were performed using R program.

Results

Patient characteristics

Sixty-eight patients who finished their docetaxel-treatment and were evaluated for best response were available for analysis. Their characteristics were summarized in Table 1. The mean age and PSA before first cycle of docetaxel plus prednisolone treatment were 69.4 years (52 to 85 years) and 172.9 ng/ml respectively.

Efficacy

Biological response

In the overall population, median PSA value at baseline was 172.9 ng/ml. PSA response (PSA decrease 50% from the baseline) was observed in 46 of the 68 patients (67.6%), following treatment with docetaxel-based chemotherapy.

Overall survival

The median PFS and OS from the beginning of CMT were 11.7 and 25.4 months (95% CI 23.2 to 27.0 months), respectively. The OS and progression-free survival curve are presented in Fig. 1A and B. The OS rates at 12 and 24 months were 81.6%, and 50.6%, respectively.

To identify parameters associated with OS in patients treated with docetaxel-based chemotherapy, univariate, and multivariate analyses were performed using the Cox proportional hazard regression model was shown in Table 2.

The OS was significantly associated with the PSA at diagnosis mCRPC, PSA at first cycle of CMT at cut-off 150 ng/mL, and number of cycle of CMT response at cut-off 2 cycle with $p < 0.001$ on univariate

Table 1. Patient characteristics at diagnosis and result of treatment in 64 mCRPC patients treated with docetaxel

| Parameter | Number (%) |
|--|------------|
| Age (year) | |
| ≤70 | 35 (51.5) |
| >70 | 33 (48.5) |
| ECOG | |
| 0 | 6 (8.8) |
| 1 | 61 (89.7) |
| 2 | 1 (1.5) |
| Gleason | |
| 6 | 6 (8.8) |
| 7 | 17 (25.0) |
| 8 to 10 | 45 (66.2) |
| Prior treatment before CMT | |
| Hormonal treatment followed by bilateral orchiectomy | 27 (39.7) |
| Bilateral orchiectomy | 41 (60.3) |
| PSA at diagnosis of mCRPC (ng/mL) | |
| ≤150 | 32 (47.1) |
| >150 | 36 (52.9) |
| PSA at first cycle of CMT (ng/mL) | |
| ≤150 | 25 (36.8) |
| >150 | 43 (63.2) |
| Number of cycle of CMT (cycle) | |
| ≤6 | 57 (83.8) |
| >6 | 11 (16.2) |
| Biochemical response | |
| No response | 22 (32.4) |
| Response | 46 (67.6) |
| Cycle of CMT responsive (cycle) | |
| <2 | 25 (36.8) |
| ≥2 | 21 (30.9) |
| Non response | 22 (32.4) |

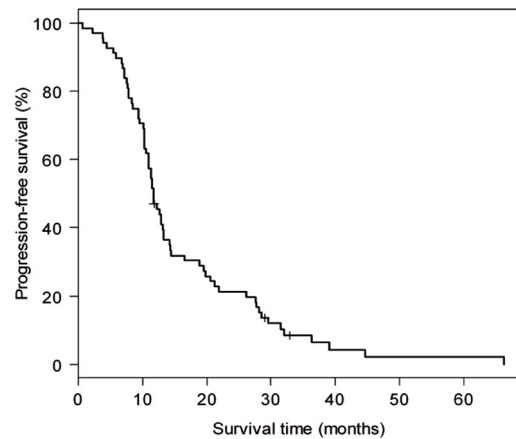
ECOG = Eastern Cooperative Oncology Group; CMT = chemotherapy; PSA = prostate-specific antigen; mCRPC = metastatic castration-resistant prostate cancer

analysis in (Fig. 2A-C). Of several factors examined, initial PSA cut-off 100 at diagnosis mCRPC, Gleason score, PSA at first cycle of CMT cut-off 150, and number of cycle of CMT response were identified as significant factors associated with OS on univariate analysis. Of these factors, PSA at first cycle of CMT cut-off 150 ng/mL appeared to be independent predictors of OS on multivariate analysis.

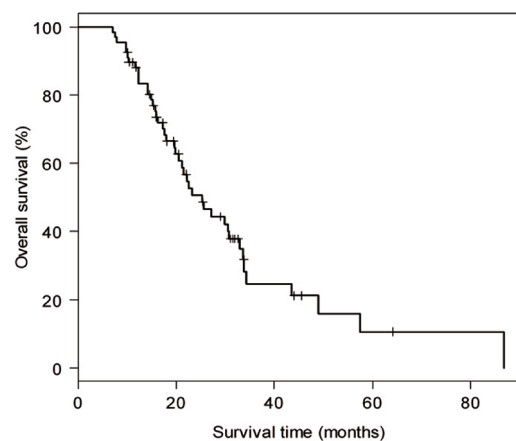
Discussion

To the best of our knowledge, this is the largest study of mCRPC patients receiving docetaxel chemotherapy and the first to provide data concerning the clinical outcomes of CMT in Thai patients.

Docetaxel has been strongly advocated as a standard treatment for metastatic CRPC. In Thailand, docetaxel-based chemotherapy has been widely applied to mCRPC patients. For docetaxel, treatment is often continued until the appearance of unacceptable toxicity, disease progression, or until a few cycles beyond the best response⁽⁷⁾. However, in our clinical practice, we have limitations of reimbursement involving the number of CMT administration. The present study was conducted to explore the oncological outcomes of treatment with 3-weekly administration of docetaxel in combination with daily prednisolone, and to demonstrate the efficacy of this regimen in Thai



(A) Progression-free survival (months)



(B) Overall survival (months)

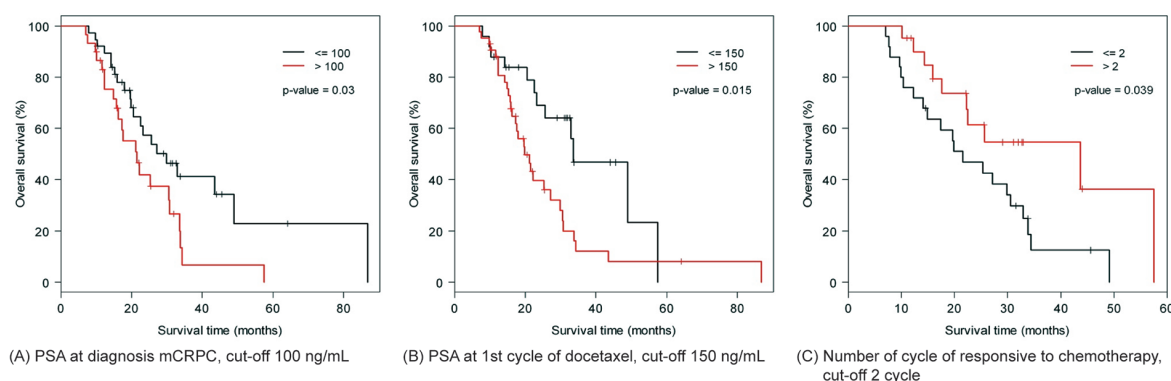
Fig. 1 (A) Progression-free survival of 68 patients with metastasis castration-resistant prostate cancer who received docetaxel plus prednisolone chemotherapy. (B) Overall survival of 68 patients with mCRPC who received docetaxel plus prednisolone chemotherapy.

Table 2. Univariate and multivariate analysis of association between parameters and overall survival

| Parameter | Univariate analysis | | Multivariate analysis | |
|---|---------------------|-----------------|-----------------------|-----------------|
| | HR (95% CI) | <i>p</i> -value | HR (95% CI) | <i>p</i> -value |
| Age: >70 vs. ≤70 | 1.12 (0.61, 2.06) | 0.720 | | |
| Performance status: 1 or 2 vs. 0 | 0.71 (0.28, 1.82) | 0.478 | | |
| PSA at diagnosis: >100 vs. ≤100 | 1.92 (1.04, 3.53) | 0.037** | | |
| Gleason: 6 | | 0.079 | | 0.059 |
| 7 | 0.58 (0.12, 2.82) | 0.500 | 0.39 (0.08, 1.98) | |
| 8 to 10 | 1.36 (0.32, 5.71) | 0.679 | 0.99 (0.23, 4.29) | |
| Prior treatment: bilateral orchiectomy vs. hormonal treatment | 0.92 (0.49, 1.73) | 0.805 | | |
| Cycle of CMT: >6 vs. ≤6 | 0.71 (0.32, 1.54) | 0.384 | | |
| PSA at first cycle of CMT: >150 vs. ≤150 | 2.28 (1.16, 4.51) | 0.017** | 2.08 (1.03, 4.20) | 0.042** |
| Initial PSA diagnosis mCRPC: >150 vs. ≤150 | 1.20 (0.64, 2.25) | 0.562 | | |
| Number of cycle of CMT response: >2 vs. ≤2 | 0.45 (0.21, 0.98) | 0.045** | | |
| CMT response | | 0.144 | | 0.133 |
| >2 | 0.49 (0.23, 1.04) | 0.062 | 0.47 (0.22, 1.04) | |
| Non response | 0.65 (0.31, 1.37) | 0.254 | 0.60 (0.28, 1.30) | |

HR = hazard ratio

** 95% confidential interval

**Fig. 2** (A-C) Overall survival of 68 patients with metastasis castration resistant prostate cancer who received docetaxel plus prednisolone chemotherapy according to (A) PSA at diagnosis mCRPC, cut-off 100, (B) PSA at 1st cycle of docetaxel, cut-off 150, and (C) number of cycle of chemotherapy responsive, cut-off 2 cycle.

patients with mCRPC. The PSA response rate in the present study was 67.5%, which was similar or superior to those found in the previous studies performed in Western countries^(4,5,12,13). For example, Tannock et al reported that the rates of PSA response were 45% in the group given docetaxel every three weeks and 48% in the group given weekly docetaxel in the TAX 327 trial⁽⁴⁾, while Petrylak et al showed the achievement of a PSA response in approximately 50% of patients treated with docetaxel and EM in the SWOG 99-16 trial⁽⁵⁾.

In the overall population of the present study, the median PFS and OS were 11.7 and 25.4 months,

respectively. For Thai men with mCRPC also resulted in the achievement of oncologic outcomes comparable with or even superior to those carried out in Western countries. In TAX 327 and SWOG 99-16 trials, the median durations of OS in the groups assigned to docetaxel-based chemotherapy were less than 20 months^(4,5). Some reports in the English literature have addressed the efficacy and safety of docetaxel-based chemotherapy in patients with Asian ethnicity⁽⁸⁻¹¹⁾. Additionally, they showed similar oncological outcomes such as the Japanese retrospective study showing long median OS of 25.4 months in patients receiving docetaxel-based chemotherapy⁽¹⁰⁾.

Identification of factors predicting the prognosis of men with mCRPC treated with docetaxel-based chemotherapy is important. Subgroup univariate analyses identified PSA at diagnosis of mCRPC, PSA at first cycle of CMT cut-off 150 ng/mL and number of CMT response cut-off 2 cycle as significant predictors of OS. Finally, only PSA at first cycle of CMT cut-off 150 ng/mL appeared to be independently related to OS on multivariate analysis. No previous study reported the PSA value cut-off for first cycle of CMT administration resulting in survival outcomes. Consequently, these results will be useful for clinical application of docetaxel administration. For the prognostic factor resulting from TAX 327 trials, PS was identified by multivariate analysis as an independent prognostic factor⁽¹⁴⁾. However, the authors showed PS was not associated with OS significantly.

Collectively, these findings suggest that application of docetaxel-based chemotherapy to Thai patients with mCRPC might result in oncologic outcomes comparable with those in Western mCRPC patients. It would be of interest to identify factors predicting the prognosis of men with mCRPC who were treated with docetaxel-based chemotherapy.

The authors would like to emphasize the limitations of the present study. First, this was a retrospective study. Second, a small sample size of 68 patients of mCRPC was small. Third, the response criterion of PSA used in this series was different from the widely cited consensus document⁽¹⁵⁾, resulting in the possible overestimation of response frequency compared with that evaluated by the criterion of PSA response defined as a reduction of 50% from the baseline that was maintained for at least 12 weeks. The fourth limitation was the lack of examination of the validity of molecular markers in predicting disease prognosis in addition to conventional clinicopathologic parameters, since mCRPC is characterized by unique biological features as well as heterogeneous genetic backgrounds^(16,17).

Conclusion

These findings suggest that docetaxel-based chemotherapy for Thai men with mCRPC resulted in the achievement of oncologic outcomes comparable with or even superior to those carried out in Western and other Asian countries. The serum PSA at first cycle of CMT less than 150 ng/dL was identified as independent predictor of OS in Thai men with mCRPC following docetaxel based CMT that can significantly prolong survival in Thai men with mCRPC.

What is already known on this topic?

Docetaxel has been proved to be first line treatment of metastatic castration resistant prostate cancer. Many study showed the oncological outcomes based on the results of two landmark studies, SWOG 9916 and TAX-327. Docetaxel-based chemotherapy is currently widely administered for patients with mCRPC worldwide^(4,5). The TAX 327 studies showed a 2- and 3-month improvement in OS for docetaxel-based chemotherapy as compared with MP (19.2 vs. 16.3 months, HR 0.79, 95% CI 0.67 to 0.93, $p = 0.004$) while a SWOG 99-16 phase III comparative trial of EM vs. mitoxantrone plus prednisone found a survival benefit in favor of the docetaxel-based arm. Patients with CRPC are candidates for CMT with the goals of prolonging survival and improve the QOL but no previous study in Thai mCRPC patient. In addition, prognostic factor from TAX-327, PS was identified by multivariate analysis as an independent prognostic factor.

What this study adds?

Oncologic outcomes in Thai mCRPC patients receiving docetaxel-based chemotherapy is generally favorable. The median PFS and OS from the beginning of CMT were 11.7 and 25.4 months (95% CI 23.2 to 27.0 months), respectively. The median OS rates at 12 and 24 months were 81.6%, and 50.6%, respectively. Identification of factors predicting the prognosis of men with mCRPC treated with docetaxel-based chemotherapy was done. Subgroup analyses of several factors examined identified initial PSA cut-off 100 at diagnosis mCRPC, PSA at first cycle of CMT cut-off 150, and number of cycle of CMT response with a cut-off of 2 cycle as significant predictors of OS. For the significant factor is PSA at first cycle of CMT cut-off 150 ng/mL appeared to be an independent predictors of OS on multivariate analysis. This would help us treat mCRPC patient with docetaxel-based chemotherapy. Consequently, these results will be useful for clinical application of docetaxel administration.

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Potential conflicts of interest

None.

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ผลการรักษาผู้ป่วยมะเร็งต่อมลูกหมากระยะแพร่กระจายที่ได้ออกฤทธิ์รักษาด้วยฮอร์โมนที่รักษาด้วยยา docetaxel

ธัญญ์ เพชรานนท์, ชุศักดิ์ พัฒนานนท์, มณฑิรา ตัณฑนุช, วาทีต กาญจนวิชกุล

วัตถุประสงค์: ศึกษาแบบย้อนหลังเพื่อประเมินผลการรักษาผู้ป่วยมะเร็งต่อมลูกหมากระยะแพร่กระจายที่ได้ออกฤทธิ์รักษาด้วยฮอร์โมน
วัสดุและวิธีการ: ผู้ป่วยมะเร็งต่อมลูกหมากระยะแพร่กระจายที่ได้ออกฤทธิ์รักษาด้วยฮอร์โมน จำนวน 68 รายที่ได้ยา docetaxel ขนาด 75 มิลลิกรัมต่อตารางเมตร ร่วมกับยาเพรดนิโซโลนขนาด 10 มิลลิกรัมต่อวัน ทุก 3 สัปดาห์ ในช่วงระหว่าง พ.ศ. 2553 จนถึง พ.ศ. 2557 และวิเคราะห์ปัจจัยที่ส่งผลกระทบต่อการอยู่รอดของผู้ป่วย โดยใช้เครื่องมือวิเคราะห์ log-rank หรือ Cox regression และ hazard ratios โดยทุกการวิเคราะห์จะใช้นัยสำคัญที่ 0.05

ผลการศึกษา: จากผู้ป่วย 68 ราย พบว่าอายุเฉลี่ย 69 ปี ค่าเฉลี่ยมะเร็งต่อมลูกหมาก (PSA) ก่อนให้ยาเคมีบำบัด 173 นาโนกรัมต่อมิลลิลิตร พบว่าผลการตอบสนองของการรักษาโดยประเมินจากค่ามะเร็งต่อมลูกหมากที่ลดลงมากกว่าร้อยละ 50 คือ 46 ราย คิดเป็นร้อยละ 67.6 ระยะเวลาการอยู่รอดโดยเฉลี่ย คือ 25.4 เดือน และระยะเวลาที่โรคไม่เพิ่มขึ้น คือ 11.7 เดือน ปัจจัยที่ส่งผลกระทบต่อแบบตัวแปรเดียวต่อการอยู่รอดอย่างมีนัยสำคัญ ได้แก่ ค่ามะเร็งต่อมลูกหมากตอนที่วินิจฉัย mCRPC ค่ามะเร็งต่อมลูกหมากตอนที่เริ่มให้ยาเคมีบำบัดครั้งแรกโดยใช้จุดตัดที่ 150 นาโนกรัมต่อมิลลิลิตร จำนวนรอบของเคมีบำบัดที่ตอบสนองดีต่อการให้ยาเคมีบำบัดใช้จุดตัดที่ 2 รอบ โดยการวิเคราะห์แบบหลายปัจจัยร่วม พบว่าค่ามะเร็งต่อมลูกหมากตอนที่เริ่มให้ยาเคมีบำบัดครั้งแรกโดยใช้จุดตัดที่ 150 นาโนกรัมต่อมิลลิลิตร เป็นปัจจัยเดียวที่ส่งผลกระทบต่ออัตราการอยู่รอดจากการรักษาด้วยยาเคมีบำบัด

สรุป: การรักษาผู้ป่วยมะเร็งต่อมลูกหมากระยะแพร่กระจายที่ได้ออกฤทธิ์รักษาด้วยฮอร์โมนที่รักษาด้วยยา docetaxel มีผลการรักษาที่ดี ช่วยเพิ่มอัตราการอยู่รอดของผู้ป่วย
