



ORIGINAL ARTICLE

Learning curve for the management of tyrosine kinase inhibitors as the first line of treatment for patients with metastatic renal cancer[☆]

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KEYWORDS

Renal cancer;
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Learning curve;
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Abstract

Objectives: To analyze the learning curve for the management of tyrosine kinase inhibitors as the first line of treatment for patients with metastatic renal cancer.

Material and methods: We evaluated 32 consecutive patients treated in our department for metastatic renal cancer with tyrosine kinase inhibitors (pazopanib or sunitinib) as first-line treatment between September 2012 and November 2015. We retrospectively analyzed this sample. We measured the time to the withdrawal of the first-line treatment, the time to progression and overall survival using Kaplan–Meier curves. The learning curve was analyzed with the cumulative sum (CUSUM) methodology.

Results: In our series, the median time to the withdrawal of the first-line treatment was 11 months (95% CI 4.9–17.1). The mean time to progression was 30.4 months (95% CI 22.7–38.1), and the mean overall survival was 34.9 months (95% CI 27.8–42). By applying the CUSUM methodology, we obtained a graph for the CUSUM value of the time to withdrawal of the first-line treatment (CUSUM TW), observing 3 well-differentiated phases: phase 1 or initial learning phase (1–15), phase 2 (16–26) in which the management of the drug progressively improved and phase 3 (27–32) of maximum experience or mastery of the management of these drugs. The number of treated patients needed to achieve the proper management of these patients was estimated at 15.

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PALABRAS CLAVE

Cáncer renal;
Tratamiento;
Curva aprendizaje;
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quinasa;
Metástasis

Conclusions: Despite the limitations of the sample size and follow-up time, we estimated (in 15 patients) the number needed to reach the necessary experience in the management of these patients with tyrosine kinase inhibitors. We observed no relationship between the time to the withdrawal of the first-line treatment for any cause and progression.

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Curva de aprendizaje en el manejo de los inhibidores de tirosina quinasa como primera línea de tratamiento en pacientes con cáncer renal metastásico

Resumen

Objetivos: Analizar la curva de aprendizaje en el manejo de los inhibidores de la tirosina quinasa como primera línea en el tratamiento de los paciente con cáncer renal metastásico.

Material y métodos: Evaluamos 32 pacientes consecutivos tratados en nuestro servicio de cáncer renal metastásico con inhibidores de la tirosina quinasa (pazopanib o sunitinib) en primera línea entre septiembre de 2012 y noviembre de 2015. Analizamos retrospectivamente dicha muestra. Medimos tiempo hasta retirada de primera línea, tiempo hasta progresión y supervivencia global mediante curvas de Kaplan Meier. La curva de aprendizaje fue analizada con «cumulative sum (CUSUM) methodology».

Resultados: En nuestra serie la mediana hasta la retirada de primera línea fue de 11 meses (IC 95% 4,9-17,1). El tiempo medio hasta progresión 30,4 meses (IC 95% 22,7-38,1) y la media de la supervivencia global 34,9 meses (IC 95% 27,8-42). Al aplicar la metodología CUSUM obtenemos una gráfica para el valor CUSUM tiempo hasta retirada de la primera línea (CUSUM TR) observando 3 fases bien diferenciadas: fase 1 o fase de aprendizaje inicial (1-15), fase 2 (16-26) en el que se mejora progresivamente el manejo del fármaco y una tercera fase (27-32) de máxima experiencia o maestría en el manejo de estos fármacos. Estimamos en 15 el número necesario de pacientes tratados para conseguir el manejo adecuado de estos pacientes.

Conclusiones: Pese a la limitación del tamaño muestral y el tiempo de seguimiento estimamos en 15 pacientes el número necesario para alcanzar el nivel de experiencia óptimo de madurez en el manejo con inhibidores de la tirosina quinasa de estos pacientes. No observamos relación entre el tiempo hasta retirada de primera línea por cualquier causa y la progresión.

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Introduction

The inhibitors of the enzyme tyrosine kinase (TKI) have been the first-line treatment of advanced renal tumors since 2007.^{1,2} Their management requires learning to minimize side effects and thus reduce suspensions or reductions of doses as much as possible.³ The treatment time at full doses seems to be related to the overall survival of the patient.⁴ In some articles, less experience in the employment has been proposed as a possible confounding factor to compare the efficacy of these drugs, compared to the series with treatments prior to the appearance of TKIs.⁵ The impact of the learning curve on the results of the surgical techniques is well known,^{6,7} but no data are available in the literature on the medical management of these patients. The overall objective is to analyze our series to determine the learning curve in the use of TKIs within an Urology Department. Since the appearance of the new molecules, we have started the treatment of these patients in these phases of the disease, launching advanced urooncology consultations, so this analysis is included within a strategy of continuous evaluation of results. As a specific objective, we consider the analysis of the use as a quality criterion of time until the withdrawal of the first line. We took the CUSUM methodology as a

measurement tool that has as its origin the monitoring of industrial processes and that has been incorporated later into the sanitary field and the assessment of techniques, especially in anesthesia and surgery.⁸

Material and methods

We retrospectively analyzed a cohort of 32 consecutive patients treated in our department with TKI (pazopanib or sunitinib) in the first line since September 2012, the start date of the use of these drugs by our group until November 2015, without restriction by Charlson or risk group. The data was analyzed as of November 2016 without any loss in this period. Follow-up was carried out according to the protocol of the department depending on the molecule used, taking into account the technical sheet of each one, as well as the SOGUG recommendations and renal cancer treatment guideline of the Grupo Cooperativo Andaluz.^{9,10} All the patients were followed in a specific clinic of advanced urology, open 2 times a week (Fig. 1), by five urologists specialized in urooncology. These urologists are included in a continuing education program (courses, congresses, external rotations) as well as involved in the generation of evidence and organization of specific training courses

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