LETTER TO THE EDITOR

Renal cell carcinoma: incidence and cost estimation in the era of targeted therapy

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To the Editor: We have read with great interest the article of Bosetti *et al.* about the estimates of the incidence and prevalence of renal cell carcinoma (RCC) in Italy¹.

The medical management of metastatic RCC has changed considerably over the past several years and this tumor represents the best example of the introduction of targeted therapy into clinical practice, surpassing the traditional and less efficacious traditional therapies such as cytokine and chemotherapy.

Although the incidence data might have general significance, the interest of medical oncologists regarding RCC is based particularly on the numbers and types of patients that could benefit from a particular type of treatment. RCC has been the subject of increasing attention not only of physicians and producers but also payers because of the costs and rapid adoption of new agents and technologies².

Bosetti *et al.* define their approach as being based on epidemiological knowledge and reasonable assumptions and for this reason it is readily questionable and lacks clinical confirmation. Nevertheless, the data can be indirectly confirmed by the 2007 National Report of the Italian Drugs Agency (AIFA) on cancer drugs subject to surveillance³. To ensure the correct use of cancer drugs, AIFA requires completion of a web page for each patient receiving particular cancer drugs including the biological agents sunitinib and sorafenib.

Considering that the number of patients estimated by Bosetti *et al.* in 2007 with a diagnosis of RCC is 7350 and that stage IV at diagnosis is reported as 22% of new diagnoses annually⁴, the number of patients with stage IV disease can be expected to be approximately 1617. This number corresponds to the number of patients who could receive treatment for advanced or metastatic disease. If the estimate of Bosetti *et al.* is correct, the number of patients registered at AIFA should be close to the calculated value.

From 21 December 2006 to 30 September 2007, 662 and 797 patients were registered to receive treatment with sorafenib or sunitinib either because their disease had progressed after first-line treatment with interferon (IFN) or interleukin-2 (IL-2), or because they showed intolerance to these agents. To avoid patients receiving both target therapies, patients who had received treatment other than IFN or IL-2 (43.1% and 44.0% of those treated with sorafenib and sunitinib, respectively) were excluded. If 823 patients were registered in 9 months (91.4 patients per month), we can estimate the number of patients treated in 1 year to be 1097.

The number of patients registered at AIFA accounts for only 67.8% of Bosetti's estimate. What about the remaining 32.2%? Are these patients undertreated? The difference might be explained if we consider that not all patients with a diagnosis of metastatic disease are eligible for targeted therapy. AIFA formally includes only patients who receive second-line therapy with target agents and the AIFA register does not include patients enrolled in clinical trials. We may therefore conclude that the presented estimate can be regarded as sufficiently reliable and useful, considering the possibility to calculate the number of new patients per year eligible for active therapy. In the light of the increasing number of new molecules registered in recent years for the treatment of RCC, these data are extremely important to estimate the increasing cost of cancer care, and consequently to choose the best therapeutic strategies, particularly in countries with a national health system.

References

- 1. Bosetti C, Bianchi C, Negri E, La Vecchia C: Estimates of the incidence and prevalence of renal cell carcinoma in Italy in 2002 and projections for the years 2007 and 2012. Tumori, 95: 142-145, 2009.
- Meropol NJ, Schrag D, Smith TJ, Mulvey TM, Langdon RM Jr, Blum D, Ubel PA, Schnipper LE; American Society of Clinical Oncology: American Society of Clinical Oncology guidance statement: the cost of cancer care. J Clin Oncol, 27: 3868-3874, 2009.
- Agenzia Italiana del Farmaco AIFA: Registro farmaci oncologici sottoposti a monitoraggio. Rapporto Nazionale 2007. Available at http://antineoplastici.agenziafarmaco.it/rapporto_RFOM_2007.htm
- 4. Ries LAG, Eisner MP, Kosary CL, Hankey BF, Miller BA, Clegg L, Mariotto A, Feuer EJ, Edwards BK (Eds): SEER Cancer Statistics Review, 1975-2002, National Cancer Institute, Bethesda, MD, http://seer.cancer.gov/csr/1975_2002/ (accessed April 2010) based on November 2004 SEER data submission, posted to the SEER web site 2005.