

National Retrospective Metastatic Renal Cell Carcinoma (MRCC) Treatment Study: Key Findings

Thomas Orsagh, Ph.D.
Clarity Pharma Research

Jack R. Gallagher, Ed.D.
Clarity Pharma Research

December 13, 2003

Abstract

A nationally representative sample of 65 oncologists extracted detailed medical history and treatment information from the records of 123 randomly selected patients with stage IV renal cell carcinoma. Study data were transmitted to researchers by fax or mail. Three out of five patients were at stage IV at time of initial renal cell carcinoma diagnosis. Of the other two-fifths of patients, almost all (94%) had received pre-stage IV treatment. Biologic/immune therapy was the most frequent type of treatment for MRCC. Biologic/immune therapy was administered to almost three-fourths of the stage IV RCC patients (73%). Only 45% of the MRCC patients were treated surgically, whereas, prior to stage IV, 98% of the patients in this cohort received surgery. Only 9% of MRCC patients experienced “no response” from stage IV treatment, compared with seven out of ten patients who experienced “complete response” (8%), “partial response” (32%), or “stable response” (30%).

Background and Objectives of Study

Renal cell carcinoma is the most common type of kidney cancer. An estimated 30,000 patients in the United States were diagnosed with renal cancers in 1999, with an estimated 17,800 deaths (S.H. Landis, T. Murray, S. Bolden, and P.A. Wingo. “Cancer statistics” 1999 *CA Cancer J Clin* 1999. 49: 8-31). The arrival incidence of primary renal cell carcinoma appears to have increased slowly over the past 20 years by 2 to 4% per year (W.H. Chow, S.S. Devesa, J.L. Warren, and J.F. Fraumeni Jr. “Rising incidence of renal cell cancer in the United States” *JAMA* 1999. 281: 17 1628-1631).

The current study was conducted to foster a better understanding of the treatment of renal cell carcinoma in patients who had progressed to stage IV (metastatic renal cell carcinoma - MRCC).

Methodology

Detailed medical histories and treatment information were provided on a nationally representative sample of 123 patient records by a nationally representative sample of 65 oncologists who were currently treating MRCC patients. Detailed information was extracted from the records of up to the last four MRCC patients who were treated by a physician study participant. Study data were transmitted to researchers by fax or mail. Statistical adjustments were made to ensure that each patient represented the exact corresponding number of patients in the universe of total MRCC patients.

Key Findings of Study

- Three out of five patients were at stage IV at time of initial renal cell carcinoma diagnosis.
- More than nine out of ten MRCC patients who were diagnosed before stage IV (94%) received pre-stage IV treatment.
- Areas to which cancer metastasized were distributed as follows:
 - Lungs - 40%
 - Bones - 18%
 - Liver - 11%
 - Lymph nodes - 8%
 - Brain - 5%
 - Abdomen - 5%
 - Bladder cancer - < 1%
 - Other - 12%
- ECOG performance at initiation of stage IV therapy was as follows:
 - Fully active, able to carry on all pre-disease performance (ECOG 0) - 30%
 - Restricted in physically strenuous activity, but ambulatory (ECOG 1) - 43%
 - Ambulatory and capable of self-care, but unable to work (ECOG 2) - 16%
 - Limited self-care, confined to bed or chair >50% of waking hours (ECOG 3) - 6%

- Completely disabled. Cannot self-care.
Totally confined (ECOG 5) - 5%
- More than four out of five MRCC patients (83%) had normal organ function at the date stage IV treatment was initiated.
- ECOG levels were significantly related to higher rates of normal organ function:
 - 88% of patients with ECOG values of 0 or 1 had normal organ function;
 - Only 74% of patients with ECOG values of 2, 3, 4, or 5 had normal organ function

Type of Treatment Prior to Stage IV

- 37% of MRCC patients had no treatment prior to stage IV.
- For MRCC patients who were treated prior to stage IV, percentages of major types of therapy or treatment received were as follows:
 - Surgery - 98% of patients
 - Biologic/immune therapy - 16% of patients
 - Chemotherapy - 11% of patients
 - Radiation therapy - 11% of patients
- Distribution of MRCC treatments prior to stage IV by major type of therapy or treatment was as follows:
 - Surgery - 64% of treatments
 - Biologic/immune therapy - 14% of treatments
 - Chemotherapy - 11% of patients
 - Radiation therapy - 10% of treatments

Type of Treatment During Stage IV

- Percentages of MRCC patients treated during stage IV by major type of therapy or treatment were as follows (multiple treatments for some patients):
 - Biologic/immune therapy - 73% of patients
 - Chemotherapy - 47% of patients
 - Surgery - 45% of patients
 - Radiation therapy - 28% of patients
 - Hormone therapy - 2% of patients
 - Other therapy - 4% of patients
- Distribution of MRCC treatments during stage IV by major type of therapy or treatment was as follows:
 - Biologic/immune therapy - 40% of treatments
 - Chemotherapy - 30% of treatments
 - Surgery - 18% of treatments
 - Radiation therapy - 10% of treatments
 - Hormone therapy - 1% of treatments
 - Other therapy - 1% of treatments
- **Results of MRCC Treatments as Reported by Treating Oncologist**
 - Partial response - 32% of patients
 - Stable response - 30% of patients
 - Cancer progressing - 14% of patients
 - No response - 9% of patients
 - Complete response - 8% of patients
 - Death - 6% of patients
 - Too soon to evaluate - 1% of patients

About the Authors

Thomas Orsagh, Ph.D., is an internationally recognized economist who has made numerous scientific contributions during and after his distinguished academic career. Dr. Orsagh attended the Wharton School and obtained a Ph.D. from the University of Pennsylvania. Dr. Orsagh has served on the faculties of the University of Pennsylvania, Lehigh University, the University of Karlsruhe in Germany, and the University of North Carolina in Chapel Hill. He is a Fulbright Research Scholar, a former editor of the **Southern Economics Journal**, and a former member of a national Presidential Task Force.

Jack R. Gallagher, Ed.D., is a behavioral modeling scientist with more than 25 years of experience in medical and systems research. He is a former member of the University of Virginia School of Medicine faculty and was director of a five-university research consortium. Dr. Gallagher has published many scientific papers, presented at numerous national and international conferences, and has served on the editorial review boards of two national journals. Dr. Gallagher also is author of the book **Changing Behavior: How and Why**.