Partial Nephrectomy Improves Survival in Early Kidney Cancer

For patients with small, early-stage kidney cancers, overall survival is better with partial nephrectomy than with radical nephrectomy, reports a study in the *Journal of the American Medical Association*. The study included 7138 Medicare fee-for-service patients who had surgery for clinical stage T1a kidney cancer between 1992 and 2007: radical nephrectomy in 73 percent of patients and partial nephrectomy in 27 percent. Patients undergoing partial nephrectomy were younger: about one-third were less than 70 years old, compared with one-fourth in the radical nephrectomy group. They were also more likely to be men, about 58 percent versus 54 percent, and to have a higher income and more years of education. The median follow-up time was 62 months.

Overall mortality was significantly lower in the partial nephrectomy group: 25.3 percent versus 41.5 percent for those who underwent radical nephrectomy, adjusted hazard ratio 0.54. There was no significant difference in kidney cancer-specific mortality: 1.9 percent versus 4.3 percent, respectively.

The percentage-point difference in survival with partial nephrectomy increased over time: from 5.6 at 2 years to 15.5 at 8 years. The data suggested that for every seven patients undergoing partial rather than radical nephrectomy, one additional life could be saved.

Previous reports have suggested that partial nephrectomy achieves similar oncologic control of early-stage kidney cancer, with better preservation of renal function, compared with radical nephrectomy. This large retrospective study found substantially better overall survival after partial nephrectomy in older adults with early kidney cancers. "[O]ur findings support partial nephrectomy as the preferred treatment option for the ever-expanding pool of patients with kidney tumors measuring 4 cm or smaller," the researchers wrote. [Tian H], et al. Long-term survival following partial vs radical nephrectomy among older patients with early-stage kidney cancer. *JAMA* 2012; 307:1629–1635.

No Increased Cancer Risk with ARBs vs ACEIs

Angiotensin-receptor blockers (ARBs) are not associated with an increased overall cancer risk, according to a study in the *British Medical Journal*. The researchers analyzed British general practice data on nearly 378,000 patients with at least 1 year of initial treatment with ARBs or angiotensin-converting enzyme inhibitors (ACEIs). Overall and specific cancer risks were compared for the two types of antihypertensive drugs, considering the effects of cumulative treatment time. About 20,000 cancers were diagnosed during a median follow-up time of 4.6 years.

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<tr>
<th>Time Period of Trial</th>
<th>NHS</th>
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<td>2004 to 2009</td>
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Patients with Chronic Kidney Disease Not on Dialysis

OMONTYS is contraindicated in patients with: • Uncontrolled hypertension [see Warnings and Precautions].

**INDICATIONS AND USAGE**

OMONTYS is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis.

**Limitations of Use**

OMONTYS is not indicated and is not recommended for use: • in patients with CKD not on dialysis because of safety concerns in this population [see Warnings and Precautions].

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- in patients with CKD not on dialysis because of safety concerns in this population [see Warnings and Precautions].
- in patients receiving treatment for cancer and whose anemia is not due to CKD, because ESAs have shown harm in some settings and the benefit-risk factors for OMONTYS in this setting have not been evaluated [see Warnings and Precautions].
- as a substitute for RBC transfusions in patients who require immediate correction of anemia.
- OMONTYS has not been shown to improve symptoms, physical functioning, or health-related quality of life.

**CONTRAINDICATIONS**

OMONTYS is contraindicated in patients with:

- Uncontrolled hypertension [see Warnings and Precautions].

**WARNINGS AND PRECAUTIONS**

**Increased Mortality, Myocardial Infarction, Stroke, and Thromboembolism**

- In controlled clinical trials of other ESAs in patients with CKD, including hemo-oxygen (treatment of patients with cancer due to cancer therapy showed decreased (control group) mass, progression-free survival and/or decreased overall survival. The findings were observed in clinical trials of other ESAs administered to patients with: breast cancer receiving chemotherapy, advanced head and neck cancer receiving radiation therapy, lymphoid malignancy, cervical cancer, non-small cell lung cancer, and with various malignancies who were not receiving chemotherapy or radiotherapy.

**Hypertension**

OMONTYS is contraindicated in patients with uncontrolled hypertension. Appropriately control hypertension prior to initiation of and during treatment with OMONTYS. Reduce or withdraw OMONTYS if blood pressure becomes difficult to control. Advise patients of the importance of compliance with antihypertensive therapy and dietary restrictions.

**Lack or Loss of Response to OMONTYS**

For lack or loss of hemoglobin response to OMONTYS, initiate a search for the causative factor (e.g., iron deficiency, infection, inflammation, bleeding). If typical causes of lack or loss of hemoglobin response are excluded, evaluate the patient for the presence of anti-peginesatide antibodies. If antibodies to peginesatide, follow dosing recommendations for management of patients with an insufficient hemoglobin response to OMONTYS. Contact Amgen, Inc. (1-855-486-6688) to perform assays for binding and neutralizing antibodies.

**Diarylaziness**

Potential for errors in their dialysis prescriptions post initiation of OMONTYS. Patients receiving OMONTYS may require increased anticoagulation with heparin to prevent clotting of the extracorporeal circuit during hemodialysis. Laboratory Monitoring Evaluate transferrin saturation and serum ferritin prior to and during OMONTYS treatment. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/l, or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of treatment.